

DISTRICT OF COLUMBIA
DEPARTMENT OF HEALTH
STATE HEALTH PLANNING AND DEVELOPMENT AGENCY
899 North Capitol Street, NE
WASHINGTON, DC 20002

APPLICATION FOR CERTIFICATE OF NEED

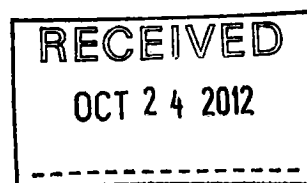
Registration No. 12-3-9

Establishment of a Proton Therapy Service at
MedStar Georgetown University Hospital (MGUH) /
Lombardi Comprehensive Cancer Center (LCCC)



EXHIBIT NOTEBOOK

October 24, 2012



Establishment of a Proton Therapy Service at MedStar Georgetown University Hospital
(MGUH) / Lombardi Comprehensive Cancer Center (LCCC)

**APPLICATION FOR CERTIFICATE OF NEED
Registration No.12-3-9**

EXHIBIT LIST

- Exhibit 1: MGUH Incorporation documents
- Exhibit 2: Service Area Map
- Exhibit 3: MGUH Magnet Certification by the American Nurses Credentialing Center
- Exhibit 4: Mentoring Program
- Exhibit 5: Georgetown Excellence in Nursing Science and Practice Scholarship
- Exhibit 6: 2013 Benefits Guide
- Exhibit 7: Mevion System Build Agreement
- Exhibit 8: Architectural Drawings of Proposed Facility
- Exhibit 9: Patient Rights and Responsibilities
- Exhibit 10: MGUH Policy on Patient Rights and Responsibilities
- Exhibit 11: MGUH Community Health Assessment
- Exhibit 12: Americans with Disabilities Act ("ADA") Policy
- Exhibit 13: MGUH Financial Statement on Charitable Care
- Exhibit 14: MGUH Certificate of Accreditation by The Joint Commission
- Exhibit 15: MGUH D.C. Department of Health License
- Exhibit 16: MGUH Rules and Regulations of the Professional Staff
- Exhibit 17: MGUH Policy on the Documentation of Licensure, Certification, and Registration of Professional Staff
- Exhibit 18: MGUH Quality and Patient Safety Improvement Plan for Fiscal Year 2013 with Methodology (p.10)
- Exhibit 19: Overview of Center for Patient Safety
- Exhibit 20: MGUH Patient Handbook – Patient Rights and Advocacy Information
- Exhibit 21: MedStar Health Code of Conduct – Treatment of People and Patient Care
- Exhibit 22: MGUH Policy on Communication Between Caregivers

Establishment of a Proton Therapy Service at MedStar Georgetown University Hospital
(MGUH) / Lombardi Comprehensive Cancer Center (LCCC)

**APPLICATION FOR CERTIFICATE OF NEED
Registration No.12-3-9**

EXHIBIT LIST (continued)

- Exhibit 23: MGUH Policy on Patient Complaint and Grievance Procedures
- Exhibit 24: MGUH Policy on Confidential Patient Information and Patient Privacy
- Exhibit 25: MGUH Confidentiality Statement
- Exhibit 26: MGUH Confidentiality Statement for Students and Visitors
- Exhibit 27: Advisory Neighborhood Commission 2E Letter of Support
- Exhibit 28: MGUH Division of Nursing, Standard of Care Policy on Transfer of Nursing Care
- Exhibit 29: MGUH Policy and Procedure for the Admission, Transfer, and Discharge of a Patient.
- Exhibit 30: MGUH Policy on Nurse-to-Physician Communication
- Exhibit 31: MGUH Policy on Patient Referral and Transfer to Other Facilities or Agencies
- Exhibit 32: MGUH Policy on Patient and Family Education
- Exhibit 33: MGUH Policy on Discharge Planning
- Exhibit 34: MGUH Discharge of Patient Procedures
- Exhibit 35: MGUH Discharge Orders for Adult Homecare form
- Exhibit 36: MedStar Health Audited Financial Statement
- Exhibit 37: Anatoly Dritschilo, M.D. Curriculum Vitae
- Exhibit 38: Curriculum Vitae for Pediatric Oncologists
- Exhibit 39: Curriculum Vitae for Radiation Therapy Clinicians
- Exhibit 40: Siteman Cancer Center Newspaper Articles
- Exhibit 41: Mevion Premarket Notification (501(k)) Summary

Exhibit 21

Code *of* Conduct



MedStar Health



MedStar Health

To All MedStar Health Associates:

The foundation of MedStar Health is to consider our patients' needs first in providing comprehensive, quality care. As the largest healthcare provider in the region, we have a responsibility to the community to operate with the highest principles and standards as we strive to ensure a compassionate and ethical approach in healthcare delivery.

This Code of Conduct provides a clear statement of MedStar Health's purpose in conjunction with the MedStar Health vision, mission and values. This Code of Conduct was developed to help associates apply legal and ethical practices to their everyday work. All patient encounters, supplier interactions and business decisions must be grounded in compliance with applicable laws and the highest standards of honesty and fairness.

As associates in the MedStar Health system, we must always be aware of how our individual actions affect the integrity and credibility of the hospitals or business units in which we work, the system as a whole, and the overall healthcare industry. To that end, we encourage you to work with your fellow associates and use this Code of Conduct as a reference throughout your tenure with MedStar Health.

Thank you for taking the time to review this important manual.

Sincerely,

Kenneth A. Samet, FACHE
President and Chief Executive Officer



**MedStar Health's Office of Corporate Business Integrity
General Information**

410.772.6606

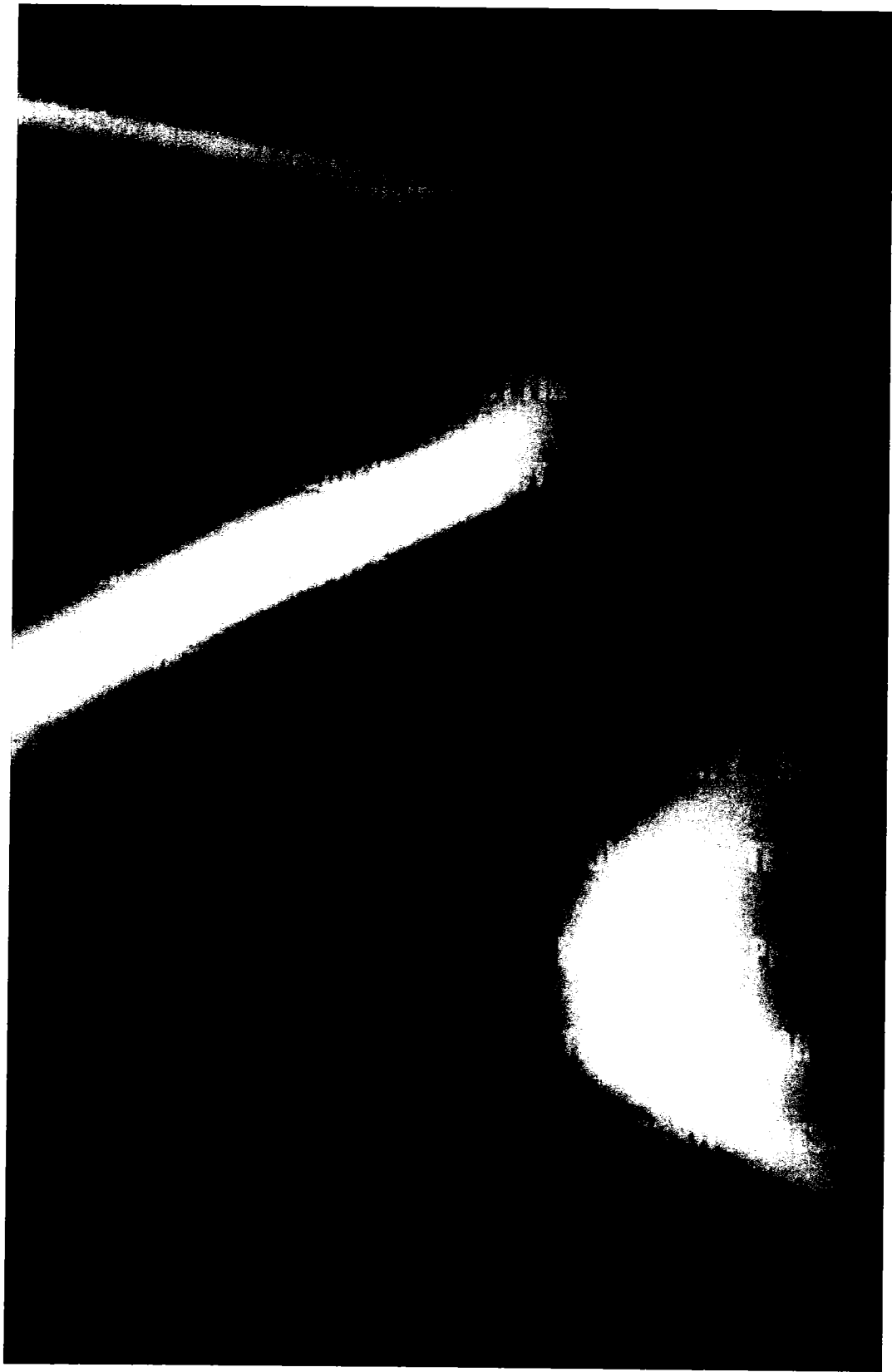
Table of Contents

■ Purpose of Our Code of Conduct	1
■ Vision, Mission & SPIRIT Values	2
■ Treatment of People	3-4
■ Patient Care	4-7
■ Confidential Information	7-11
■ MedStar Health's Reputation and Branding	11-12
■ Accuracy, Retention and Disposal of Documents and Records	12
■ Employment Practices	13
■ Environmental Concerns	13-14



MedStar Health

■ Associate Rights and Responsibilities	14-15
■ Business Practices	16-17
■ Accepting or Giving Personal Gifts	17-18
■ Accepting and Extending Invitations	18-20
■ Additional Legal Considerations	20-21
■ Fraud, Abuse and Waste	21-23
■ Compliance with Federal and State False Claims Acts	23-24
■ Notice to Associates	25
■ MedStar Health's Corporate Compliance Program	26
■ Code of Conduct Attestation	27





MedStar Health

of our

Our Code of Conduct provides guidance to all MedStar Health associates, contractors, volunteers, students, and all other agents to assist us in carrying out our daily activities within appropriate ethical and legal standards and in accordance with the SPIRIT Values and MedStar Mission.

While no single document can address every issue, you may face a situation where the right course of action is unclear. Use this Code of Conduct and other MedStar Health policies as guidelines along with your own good judgment. If you are unsure about how to handle a situation, ask yourself the following four questions:

1. Is it inconsistent with MedStar Health's values and policies?
2. Is it illegal or unethical?
3. Is it unfair or inappropriate, or does it appear unfair or inappropriate?
4. Would MedStar Health (or you) be compromised or embarrassed if it became public knowledge?

If the answer to any of the above questions is yes, then you should refrain from engaging in the conduct.

If you are still unsure, or if you are unclear about anything in this Code of Conduct, please talk to your supervisor. You may also contact your facility's compliance director or Human Resources. As appropriate, you may contact MedStar Health's Privacy Officer, MedStar Health's Compliance Officer, the MedStar Health Office of Corporate Business Integrity (OCBI), or the MedStar Health Integrity Hotline at 1-877-811-3411.

MedStar Health associates are expected to fully comply with this Code of Conduct, MedStar Health and affiliated entity policies, and applicable laws and regulations. Associates are also expected to exhibit the highest professional ethics to maintain the reputation of MedStar Health. MedStar Health expects that any associate who reasonably concludes that a matter violates this Code of Conduct, a MedStar Health Policy, or any applicable laws or regulations, should report it immediately through the appropriate channels.

Vision, Mission and SPIRIT Values

Vision

To be the trusted leader in caring for people and advancing health.

Mission

The mission of MedStar Health is to serve our patients, those who care for them, and our communities.

SPIRIT Values

Service

We strive to anticipate and meet the needs of our patients, physicians and co-workers.

Patient First

We strive to deliver the best to every patient every day. The patient is the first priority in everything we do.

Integrity

We communicate openly and honestly, build trust and conduct ourselves according to the highest ethical standards.

Respect

We treat each individual, those we serve and those with whom we work, with the highest professionalism and dignity.

Innovation

We embrace change and work to improve all we do in a fiscally responsible manner.

Teamwork

System effectiveness is built on the collective strength and cultural diversity of everyone, working with open communication and mutual respect.

Treatment of People

Open Communication

As the area's largest health system, we make every effort to work openly across the system to promote the value of teamwork, collectively building effectiveness through the strength and cultural diversity of everyone.

Open communication must be practiced when we are serving our patients, dealing with outside vendors or other business contacts, and working with our fellow associates. We must always remember that our patients come first. Our patients look to their MedStar Health providers for their medical care, treatment and healing, as well as for kind words of support. MedStar Health associates are expected to deal with patients, outside vendors, other business contacts, and co-workers with the utmost courtesy and professionalism.

MedStar Health values the contributions of every associate and believes that the free exchange of information promotes and enhances performance, teamwork and innovation. We communicate frequently and honestly, listening to each other regardless of level or position. The open exchange of knowledge, opinions and expressions of concern among associates and supervisors is always encouraged, and associates should never be discouraged or penalized for voicing their concerns or opinions in an appropriate manner.

Keep in mind, disagreements are bound to arise in the workplace. Constructive conflict can lead to healthy learning and understanding between associates and need not result in disruptive arguments. Under no circumstances should disagreements lead to unprofessional conduct. Being rude or abusive to a patient, visitor, co-worker, manager, supervisor, or others is never acceptable.

Professional Responsibility

MedStar Health embraces a patient first philosophy that combines care, compassion and clinical excellence with an emphasis on customer service. We value our associates and recognize their contributions and their right to prosper and obtain personal and professional goals in a clean and safe environment. We value our physician partners and seek to maintain strong and respectful relationships with them and with other healthcare professionals. We value diversity of ideas and cultures and encourage open, two-way communication based on trust.

The stress of patient care situations can sometimes generate tense interactions among healthcare givers, family members and other individuals. Associates, consultants, vendors, volunteers, contractors, and healthcare providers are expected to treat others with respect, courtesy, and dignity, and to conduct themselves in a professional and cooperative manner.

Conduct that is disruptive to the safe operations of MedStar Health will not be

tolerated. Disruptive behavior includes verbal and/or physical conduct or behavior on the part of an associate, consultant, vendor, volunteer, contractor, or healthcare provider that tends to:

- Cause stress among other staff and affect overall morale within the work environment;
- Impede the ability to work harmoniously with others;
- Undermine productivity;
- Contribute to high staff turnover; or
- Adversely affect the quality and safety of patient care.

Patient Care

Patient Rights

MedStar Health will serve the needs of our patients, those who care for them, and our communities. Among other rights, patients have the right to be treated with courtesy and respect, and to receive the highest quality of appropriate medical care.

We will make every effort to ensure patient satisfaction in all aspects of care, and we are committed to treating patients in a manner that preserves their dignity, autonomy, self-esteem, civil rights, and involvement in their own care. MedStar Health is committed to the following for the patients we serve:

- Patients shall have equal access to MedStar Health facilities and services in accordance with federal and state legal requirements. MedStar Health does not tolerate discrimination of any kind against its patients.
- Patients have the right to receive care in a safe setting.
- Patients have the right to be free from all forms of abuse or harassment.
- Patients have the right to participate in the development and implementation of a plan of care and to make informed decisions regarding their care unless they lack capacity to make healthcare decisions.
- Patients have the right to accept or refuse care and should be informed of the medical consequences of such decisions.
- Patients have the right to formulate advance directives and have medical staff comply with those directives to the extent permitted by law and hospital or business unit policy.
- Each patient or patient representative has the right to be provided with a clear explanation of the proposed care including diagnosis and treatment plan.
- Patients should provide their informed consent for treatment only after receiving an appropriate explanation of the medically reasonable risks, benefits and alternatives to proposed treatments in a manner that is understandable to them.
- Patients have a right to be free of physical or chemical restraints

that are not medically necessary or are used as a means of coercion, discipline, convenience, or retaliation by staff.

- Patients have a right to privacy, safety, and the security of their health information and should have confidence that MedStar Health is committed to protecting patient privacy.
- Patients have the right to review their records and have questions about their care answered as well as certain other rights relating to access and control over their health information.
- Patients should be offered continuity of care, where appropriate, and should be given a reasonable amount of time to find a qualified replacement if a physician-patient relationship must be terminated.
- Patients being discharged from a hospital should be presented with a discharge plan, including realistic care options when hospital care is no longer appropriate.

If a patient or patient representative needs assistance resolving an ethical dilemma or conflict, he or she should be advised of the availability of ethics consultation services.

Patient Responsibilities

The effectiveness of care and patient satisfaction with the treatment depends, in part, on the patient or the patient's legal representative, fulfilling certain responsibilities including:

- Providing the healthcare team with complete and correct information including health history and any necessary information for insurance claims or other information necessary to make payment arrangements;
- Asking for additional information or explanation about their health status or treatment when they do not fully understand information and instructions;
- Ensuring that the healthcare team has a copy of their written advance directive if they have one;
- Allowing the healthcare team to follow all policies, including those for infection control, administration of medications, dietary plans, as well as all other policies;
- Notifying the healthcare team of changes in the patient's condition;
- Communicating and collaborating with the healthcare team to establish a schedule of care based on realistic expectations;
- Following the plan of care established in collaboration with the healthcare team;
- Acting in a considerate and respectful manner toward other patients, staff and facility property (including not using derogatory language or exhibiting threatening behavior);
- Allowing staff to provide effective and efficient services;
- Maintaining a safe environment; and
- Taking personal responsibility for lifestyle choices.

Emergency Treatment

At MedStar Health, we are required to follow the guidelines mandated by the Emergency Medical Treatment and Active Labor Act (EMTALA) in providing emergency medical treatment to all patients regardless of their ability to pay. Every person who comes to a MedStar Health hospital and requests medical treatment will be given a medical screening exam. Anyone with an emergency medical condition will be treated based on medical need or stabilized and transferred, consistent with EMTALA requirements. In an emergency situation, financial and demographic information will be obtained only after the immediate needs of the patient are met and the patient has been screened and stabilized. A patient who has not been stabilized will only be transferred to another facility if either: 1) the patient or the patient's legal healthcare representative, after being informed of the risks, requests the transfer in writing; or (2) a determination is made by a physician that the benefits of treatment at another facility outweigh the risks of transfer. In either case, the receiving facility must be able to provide appropriate care and must have agreed to accept the patient prior to transfer.

Research

We follow high ethical standards at MedStar Health for all research conducted in our facilities by physicians and professional staff. Research is a privilege at MedStar Health and is subject to oversight by internal and external departments. We do not tolerate violations of the internal or external policies or regulations, or laws governing research or the unethical conduct of research.

To assure the accuracy, reliability and integrity of research conducted at MedStar Health, research misconduct is strictly forbidden. Research misconduct includes, but is not limited to:

- Making up or changing results (fabrication);
- Omitting or suppressing results (falsification);
- Copying results from other studies without performing the research (plagiarism);
- Failing to adhere to standards governing the use of human beings as research participants (including but not limited to failing to obtain Institutional Review Board approval prior to conducting such research); or
- Failing to adhere to appropriate research practices applicable to the area of research.

In addition, MedStar Health is committed to maintaining high standards of objectivity and integrity in research and requires all potential conflicts of interest to be disclosed and properly resolved before engaging in research activities.

All patients asked to participate in research projects must be given a full explanation of alternative services that might prove beneficial to them. They also must be fully informed of potential risks and expected benefits. The patients shall be given a full explanation of the procedures to be followed, especially those that are experimental in nature. Refusal by patients to participate in research studies will not compromise their access to healthcare services provided by MedStar Health. All persons applying for or performing research of any type at a MedStar Health

facility are responsible for maintaining the highest ethical standards regarding research projects. Compliance is required with all policies, conditions of approval and directives of internal oversight departments and administrators (including the MedStar Health Research Institute (MHRI), MHRI Office of Research Integrity policies/procedures, the MHRI Institutional Review Board's directives, and MedStar research compliance personnel). As in all record keeping, our policy is to maintain accurate study files, data and financial statements and to submit only true, accurate and appropriate costs related to each research project.

Confidential Information

Patient Privacy and Confidentiality

At MedStar Health, patient information including medical condition, history, medication, and family illnesses is obtained in order to provide the best possible care. This information is highly sensitive and MedStar Health is committed to maintaining its confidentiality. The Health Information Portability and Accountability Act of 1996 (HIPAA) as well as other state and federal laws, protect the privacy and confidentiality of patient information, and grant certain privacy rights to all of our patients. The MedStar Health Notice of Privacy Practices explains our legal obligations under these laws as well as patient privacy rights. It is our promise to our patients that we will only access, use and disclose their health information as described in the Notice of Privacy Practices, and that we will seek their written authorization for any other use or disclosure.

Protecting patient privacy is an essential part of gaining and maintaining the trust of our patients. MedStar Health's associates are obligated to protect patient information (including during patient examination, case discussion or consultation) and must never access, use or disclose any information that violates the law, our policies, or the privacy rights of our patients. No MedStar Health associate, affiliated physician or other healthcare partner has a right to access, use or disclose any information unless it is necessary to perform his or her job.

As a MedStar Health associate or affiliate, you may have access to MedStar Health systems to perform your job duties. If you also are a MedStar Health patient, you are not permitted to explore your own health records (or the records of friends or family). This would not be a permitted use of the information since you probably do not need the information to perform your job.

For more information about the privacy of patient information, patient privacy rights or the Notice of Privacy Practices, visit StarPort or contact your facility's privacy liaison, the Corporate Privacy Officer, the MedStar Health Privacy Office or the MedStar Health Integrity Hotline at 1-877-811-3411.

Associate Privacy and Confidentiality

MedStar Health recognizes that privacy is important to every one of us. For that reason, MedStar Health retains only those associate records required for business, legal or contractual reasons. Access to, and knowledge and disclosure of those

records is limited to people who need the information for legitimate business or legal purposes.

If you have access to personal information regarding co-workers, you are required to take every precaution to ensure it is not improperly accessed, used or disclosed. In addition, associates are expected to be aware of and to observe all applicable laws, the Notice of Privacy Practices, and MedStar Health policies regarding associate information, which includes limiting the use or disclosure of personal data.


Identity Theft Prevention Program

Identity theft and medical identity theft are growing problems worldwide. In order to be *the trusted leader in caring for people and advancing health*, we must protect the credit, finances and medical history of our patients, as well as the interests of our staff by regularly looking out for signs that personal information has been compromised or is being misused.

Although the deterrence and detection of identity theft and medical identity theft have long been critical elements of MedStar Health's privacy and information security efforts, the Federal Trade Commission (FTC) has issued new regulations that require certain steps to detect, deter and respond to potential identity theft incidents.

MedStar Health has formalized a systemwide identity theft prevention program aimed at detecting, deterring and mitigating the harmful effects of known or suspected identity theft incidents. Identity theft or medical identity theft incidents could involve the compromise of our own patient or associate information, or they could occur externally and be detected through our program efforts.

MedStar Health's Identity Theft Prevention Program includes:

- 
- The adoption of new corporate policies;
 - A set of guidelines and best practices (which may be amended from time to time) to which facility policies must be aligned; and
 - Training and education about potential identity theft or medical identity theft.

Computer Equipment, Information Security and Use of MedStar Health Electronic Resources

The Health Information Portability and Accountability Act of 1996 (HIPAA) Security Regulations require that we "ensure the confidentiality, integrity and availability of all electronic protected health information (ePHI)" that we "create, receive, maintain, or transmit." MedStar Health has stringent policies regarding computer use and the security of ePHI. All computers and laptops must be encrypted in accordance with MedStar security policy. Furthermore, appropriate measures should be taken at all times to physically secure any MedStar Health computer, laptop or other equipment when it is taken off site. Any associate who experiences loss or theft of MedStar Health equipment must report it immediately to his or her supervisor.

Examples of information security violations include, but are not limited to:

- Logging on using someone else's ID;
- Allowing yours or someone else's ID and password to be used by anyone else; or
- Attempting to circumvent the security system to perform functions or access data for which a user has not been granted access.

All communication systems, electronic mail, Intranet, Internet access, telephone, pagers, and voice mail, or other information systems that are the property of MedStar Health are to be used for business purposes only. Corporate policy currently allows limited "personal" use. Associates may not use internal communication channels or access the Internet at work to post, store, transmit, download, distribute, or view any material that is threatening, knowingly reckless, maliciously false, obscene, or sexually harassing. Additionally, these channels of communication may not be used to send or receive chain letters or personal broadcast messages, for illegal downloading of any type, or to conduct job searches or open misaddressed mail. MedStar Health data centers monitor Internet use, and inappropriate use of the Internet using MedStar information systems may be grounds for dismissal.

For more information regarding computer use and security, please contact the MedStar Health Information Security Office.

Confidential Business Information

MedStar Health creates and receives confidential information on a regular basis, and just as we protect the privacy of our patient information, it is important that we also maintain the confidentiality of our fellow associates, our business information, as well as the information of vendors and suppliers who support the services we provide.

MedStar Health will not share or disclose confidential information given to us by a supplier with anyone outside of MedStar unless authorized in writing to do so by the supplier. We will not disclose contract pricing and information to outside parties. Contracts involving potential sharing of confidential information must include a contractual commitment from contractors that neither they nor their associates will disclose such information without the consent of MedStar Health.

Proprietary Information

Confidential information concerning MedStar Health's business strategies and operations is a valuable asset. Protection of this proprietary information is important to our organization's continued growth. Proprietary information must not be disclosed to others, except as required by law, or when permitted by company policy. When there is a legitimate business need to disclose proprietary information outside of MedStar Health, a nondisclosure agreement may be needed. In such situations, associates must contact the MedStar Health Legal Department.

Proprietary information includes, but is not limited to:

- Personnel data maintained by the organization;
- Associate lists including associate home addresses, telephone numbers, or other personal contact information;
- Patient lists, records and clinical information;
- MedStar Health research and development, such as inventions and patent applications;
- Pricing and cost data;
- Information pertaining to acquisitions, divestitures, affiliations, and mergers;
- Financial data;
- Research data;
- Strategic plans and marketing strategies; and
- Technology component/IT System information.

It is essential to maintain the confidentiality of, and not improperly access, use, publish, or disclose, any private or proprietary information acquired, learned, or created while employed with MedStar Health. Always store such proprietary information in a safe place and follow security procedures for the computer systems in use. In addition, use common sense to help prevent accidental disclosure of confidential information. Remember that conversations can be overheard in public places such as elevators, hallways, cafeterias, and restaurants, and when using portable communication devices. In addition, do not discuss MedStar Health proprietary information with family or friends, as they may not understand its significance or its confidential nature. Associates could be held responsible for the inadvertent disclosure of such information by a family member, friend or acquaintance.

Innovation and Intellectual Property

MedStar Health values the creativity and innovation of its associates and has established processes for covering the costs associated with protecting our patent interests. We encourage individual creativity that will lead to scientific discoveries, new methods, processes, or products that benefit the patients we serve. Intellectual property includes, but is not limited to, any invention, discovery, improvement, idea, computer software, scientific or technological development, or other form of expression of an idea (whether patentable, copyrightable, or subject to other forms of protection).

With certain limits, all intellectual property created by professional and management associates of MedStar Health during the course of performing duties for MedStar Health is the property of MedStar Health. However, MedStar Health has adopted policies which fairly encourage our associates to develop intellectual property and permit our associates to share in the rewards resulting from the inventions discovered in the course of their employment. All intellectual property discovered or created must be disclosed to the MedStar Health Legal Department.

Patent Protections

A patent is an intellectual property right granted by the Government of the United States of America to an inventor "to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States" for a limited time in exchange for public disclosure of the invention when the patent is granted. There are three types of patents:

- (1) Utility Patents – granted to anyone who invents or discovers any new and useful process, machine, article of manufacture, or composition of matter, or any new and useful improvement of such discoveries;
- (2) Design patents – granted to anyone who invents a new, original and ornamental design for an article of manufacture; and
- (3) Plant patents – granted to anyone who invents or discovers and asexually reproduces any distinct and new variety of plant.

Copyright Protections

Copyright laws protect the original expression in, among other things, written materials, computer software, works of art, and music, and prohibit their unauthorized duplication, distribution, display, and performance. As a result, materials including software, spreadsheets, and even form documents created by MedStar associates are protected and may not be used or distributed without prior approvals.

In addition, we generally may not reproduce, distribute, or alter copyrighted materials from books, trade journals, computer software, or magazines without permission of the copyright owner or its authorized agent(s). Remember that computer software must be used only in accordance with appropriate licensing. Unlicensed software could constitute copyright infringement.

Trademarks and Service Marks

MedStar Health vigorously protects its brand and the brands of its subsidiaries by registering its trade and service marks with the U.S. Patent and Trademark Office and by opposing confusing registrations. Trademarks can include any word, phrase, symbol or design, or a combination of words, phrases, symbols or designs, that identifies and distinguishes the source of the goods of one party from those of others. Service marks are the same as trademarks, except that they identify and distinguish the source of a service rather than a product. Any request to register any trade or service mark must be sent to the MedStar Health Legal Department.

MedStar Health's Reputation and Branding

Marketing and Reputation

Patients trust MedStar Health because they are aware of our excellent reputation and they know we stand behind our patient-first commitment. The way we market and advertise our services is an important element of maintaining that trust and our good reputation. MedStar's internal and external publications and marketing

materials avoid offensive, deceptive or unfair marketing practices. These ethical values enhance the trust of our patients and the communities we serve.

Advertising Standards

MedStar's advertising can help establish a person's positive impression of MedStar Health and inform them of the services we offer. It can give patients confidence in the healthcare services we provide. To maintain our patients' hard-won trust, our advertisements and other communications must always be accurate, fairly describe our services, and follow MedStar's advertising and branding standards. Anything less would be a disservice to our patients and could damage MedStar Health's reputation.

Accuracy, Retention and Disposal of Documents and Records

Accuracy of Records

Every MedStar Health associate is responsible for the integrity and accuracy of our documents and records in any media. All records, whether medical, operational, or financial, should be maintained in accordance with applicable laws, accreditation standards, and policy. No one may alter or falsify information on any record or document. In addition, associates must be accurate in completing or providing information for such records as time reports, leave of absence records, expense reports, or other employment-related documents.

Record Retention

Medical and business documents and records must be maintained in accordance with procedures and timeframes established by applicable laws, accreditation standards, and MedStar Health's Record Retention and Destruction Policy, whichever period is longer. Medical and business documents include paper documents such as letters and memoranda; computer-based information, such as e-mail or computer files on disk or tape; and any other medium that contains information about MedStar Health or its business activities.

Destruction of Records

Records should be promptly destroyed once they have served their useful business life and have been retained as required by applicable laws and MedStar Health policy. However, at MedStar Health, we will not tamper with records, nor remove or destroy them before the time period specified in the MedStar Health Document Retention and Destruction Schedule, and we will not destroy any records we know relate to pending litigation or government investigation.

Employment Practices

Workplace Health and Safety

Workplace Health

It is the policy of MedStar Health to comply with all government regulations, policies and guidelines, and to develop and enforce company policies that promote the protection of workplace health and safety.

Workplace Safety

MedStar Health is committed to making the work environment safe and healthy for its associates, patients and others. Accordingly, MedStar Health prohibits dangerous activities including threatening or violent behavior, or even the suggestion of such behavior; possession of firearms, explosives, or other weapons on company property while conducting company business; and willful destruction of company property or the property of others.

Substance Abuse

To protect the interests of our associates and patients, MedStar Health is committed to an alcohol, tobacco and drug free work environment. All associates must report to work free of the influence of alcohol and illegal drugs. Reporting to work under the influence of any illegal substance, or using, possessing, distributing, or selling illegal drugs while on MedStar Health work time or property, may result in immediate termination. MedStar Health associates can be subject to substance abuse testing in accordance with federal, state and local laws and regulations, and with collective bargaining agreements. MedStar Health's Associate Assistance Program is available to all associates who request assistance with a substance abuse problem.

Environmental Concerns

Environmental Laws and Regulations

It is the policy of MedStar Health to comply with all environmental laws and regulations as they relate to our operations. We operate our facilities with all necessary permits, approvals and controls. At MedStar Health, we strive to manage and conduct our business in a manner that respects the environment and preserves natural resources.

Hazardous Materials and Medical Waste

We make every effort to ensure all MedStar Health associates and agents follow proper procedures with respect to the handling and disposal of hazardous materials and medical waste. In accordance with applicable laws and policies, associates should be informed about the nature of the chemical hazards to which they may be exposed and the appropriate procedures for handling them. Hazardous materials in the workplace are to be properly marked and stored in designated locations only.

Cooperating with Environmental Agencies

MedStar Health will report environmental issues to relevant agencies within the time limits imposed by the agencies. Furthermore, we will work cooperatively with the appropriate authorities to remedy any environmental contamination or improper disposal. MedStar entities will ensure that appropriate processes and associate education are in place to meet this requirement.

Associate Rights and Responsibilities

Equal Employment Opportunity

At MedStar Health, we treat each other with respect and dignity, valuing individual and cultural differences. MedStar Health is committed to equal employment opportunity without regard to race, color, religion, national origin, gender, sexual orientation, age, disability, marital status, or veteran status, pertaining to associates, students, volunteers, and business partners. We comply with legal requirements applicable to human rights and equal employment legislation. Just as MedStar Health does not allow discrimination in hiring practices or against patients, we do not tolerate discrimination on the job. Nondiscrimination policies apply to all employment practices including, but not limited to: hiring, recruiting, compensation, benefits, disciplinary actions, educational assistance, promotions, and terminations.

Harassment

MedStar Health prohibits any kind of harassment in the workplace, particularly but not limited to, harassment based on race, color, religion, sex, national origin, age, marital status, sexual orientation, physical or mental disability, or any other basis prohibited by law. Harassment prohibited by this Code of Conduct will not be tolerated, whether it is committed by, or committed against: supervisory or non-supervisory personnel, physicians, consultants, contract associates, vendors, patients, or visitors of MedStar Health.

Any form of sexual harassment is strictly prohibited. This prohibition includes, but is not limited to, unwelcome sexual advances or requests for sexual favors in conjunction with employment decisions. Moreover, verbal or physical conduct of a sexual nature that interferes with an associate's work performance or creates an intimidating, hostile or offensive work environment has no place at MedStar Health.

You should familiarize yourself with the sexual harassment policy applicable at your entity. If you have any questions, or if you believe you have been subjected to any form of harassment or discrimination, you should follow your entity's complaint procedures or immediately inform Human Resources. If those options are not effective, associates may also call the MedStar Health Integrity Hotline. Associates will not be subject to any form of retaliation for filing what they believe to be a legitimate complaint.

How to Report a Concern

Every MedStar Health associate has an affirmative obligation to report any

situation that you believe to be unethical and/or illegal whether involving another associate or anyone acting on behalf of MedStar Health. Any potential issue should be reported to your supervisor through the normal chain of command. If you believe your concern is not being handled appropriately, and/or your concern relates to the confidentiality of patient information, a patient privacy issue, or any other compliance issues, you can contact your entity's compliance director or privacy liaison, contact the Office of Corporate Business Integrity or make an anonymous report via the toll-free MedStar Health Integrity Hotline at 1-877-811-3411.

Associate Discipline

Associates may be disciplined for failure to adhere to compliance requirements or any provision of this Code of Conduct. Disciplinary measures may also be taken against those who intentionally make a false accusation against an associate. This means that violations of this Code of Conduct, even when committed for the first time, may lead to disciplinary action, up to and including dismissal. Additionally, certain incidents may be subject to criminal investigation and prosecution as provided by law.

Non-Retaliation

Retaliation is any adverse employment action taken in response to an associate's good faith reporting or participation in a protected activity, such as a government investigation or filing a grievance. MedStar Health will not tolerate retaliation in any form by management or non-management staff against an associate who reports in good faith, an actual or potential Code of Conduct, or any other type of legal, regulatory, compliance, quality, safety, or MedStar Health policy violation. Similarly, retaliation against an associate for cooperating in a government, compliance, legal, or human resources investigation is equally prohibited. Associates who engage in such retaliation may be subject to disciplinary action, up to and including dismissal.

Retaliation does not include disciplinary actions taken in response to an associate's job performance or failure to meet job requirements.

Associates who believe that they may be the subject of retaliation as described above should immediately report such conduct to their supervisors, or to their facility compliance directors or Human Resources departments. If those avenues for reporting do not work for some reason, associates may also call the MedStar Health Integrity Hotline.

Excluded (Sanctioned) Individuals or Entities

Each MedStar Health entity/facility will perform a check of potential new associates, physicians or contracted business partners/vendors to ensure they do not appear on the U.S. Department of Health and Human Services' Office of Inspector General's List of Excluded Individuals/Entities or the General Services Administration's (GSA) Excluded Parties List System. MedStar Health will not knowingly employ or contract with any individuals or entities who appear on either of these lists. The Office of Corporate Business Integrity will review current associates against these lists on an annual basis.

Business Practices

Conflict of Interest

As associates of MedStar Health, we owe our first working allegiance to our employer. A conflict of interest may occur if outside activities or personal interests influence, or appear to influence, our ability to make objective decisions or otherwise to perform our work responsibilities. Some conflict of interest situations may also implicate violations of the False Claims Act, Anti-Kickback Statute, Stark and other laws and regulations. Examples of conflicts of interest include, but are not limited to:

- Owning, or having a financial interest in an outside organization that does business with MedStar Health, unless the business arrangement has been undertaken in accordance with the MedStar Health contracting and conflict of interest policies. (This prohibition does not apply to ownership of stock held by an associate in a publicly held corporation, where the value of the associate's stock does not exceed three (3%) percent of the value of the company.)
- Conducting business for personal gain with a vendor, supplier, contractor, or agency that does business with MedStar Health, or with any officer or associate of such an organization, outside the vendor's usual business practices.
- Influencing either directly or indirectly, MedStar Health's dealings with any vendor or supplier with whom you have a personal or financial relationship.
- Representing MedStar Health in a transaction in which you and/or immediate family member(s) have a substantial personal or financial interest. Immediate family members means the spouse or domestic partner, household members and dependents of an individual with an actual or potential conflict of interest, including step-children and children by adoption.
- Disclosing or using MedStar Health's private or patient information for your and/or your family's personal gain or advantage.
- Competing with MedStar Health, directly or indirectly, in the purchase, sale, or ownership of property or property rights, or in business investment opportunities.
- Using MedStar Health's name, information, property, time, and/or other resources to perform outside activities such as a second job, or to volunteer for community activities not specifically sponsored or approved by MedStar Health or a MedStar Health entity.
- Outside employment arrangements that may compete with MedStar interests.

MedStar Health and each of its subsidiaries will require annual disclosures of any board member, senior level associate, employed and contracted physicians, or any other person with contracting, hiring or purchasing decision making responsibilities. Individuals who do have a conflict of interest will be asked to

work with their leadership to establish a way to remediate the conflict. For questions regarding the Conflict of Interest Policy and/or the management of potential conflicts of interest, contact the MedStar Health Legal Department or the Office of Corporate Business Integrity.

Contracting

It is the responsibility of those contracting on behalf of MedStar Health to secure contracts that will be in the best interest of the organization. We strive to build good working relationships with our suppliers because they help us achieve the highest standards of quality. Moreover, we manage our contractor and supplier relationships in a fair, ethical, and reasonable manner, consistent with all applicable laws and good business practices.

Vendor Selection

At MedStar Health, we employ high ethical standards in vendor selection, negotiation, determination of contract awards, and the administration of all contracting activities. Contracting decisions are based on the supplier's ability to meet MedStar Health's needs and not on personal relationships, friendships or self-interests. Contracts are awarded in a fair manner with no discrimination or bias toward or against any bidders. MedStar associates with a business or personal interest in a vendor, or an appearance of such interest, will remove themselves from the vendor selection process if that vendor is involved, or, if that is not possible, will ensure that processes are in place to create an objective and unbiased selection process which includes final approval by someone other than the conflicted individual.

Accepting or Giving Personal Gifts

Cash or Cash Equivalents

Gifts are usually given to create good will. However, sometimes accepting or giving a gift may create a conflict of interest or the appearance of a conflict of interest. Accepting gifts can also pose concerns under the federal and state Anti-Kickback Statutes. In general, all cash, cash equivalents (i.e., gift cards), and non-cash gifts including but not limited to, personal gifts (such as branded materials, artwork, music, sporting event tickets, or other entertainment) that are not part of a bona-fide and permitted business function as further described below, are prohibited.

Non-Branded Non-Cash Gifts

Unsolicited, non-branded, and general use gifts which have an educational value and are for the benefit of patient care or medical education, including books, anatomic models, illustrations, clinical diagrams, etc. are permitted so long as they are of nominal value (not to exceed \$100) and are not solely for the benefit of a specific individual.

Meals (including Perishable Gifts)

Meals (including perishable or consumable gifts), whether provided to individuals or departments, have the potential to unduly influence purchasing or vendor

selection and are generally not acceptable. Meals or individual gifts from Industry (i.e., pharmaceutical and device manufacturers) are specifically prohibited by MedStar Policy. However, associates may accept meals as a customary courtesy that is extended to further develop business relationships, provided that the meal is: (1) modest; (2) not being offered to inappropriately influence business decisions; and (3) offered only in conjunction with a legitimate business event. Unsolicited perishable gifts (such as a holiday gift basket) that are provided to a department or entity and not to an individual, are acceptable.

Soliciting Gifts

It is never appropriate to solicit for gifts of any kind, whether directly or indirectly, from anyone doing business, or seeking to do business, with MedStar Health. It is also not appropriate to solicit charitable donations or contributions from a vendor unless that is part of your specific job responsibilities (such as associates of MedStar's foundation or development departments). Purchasing decisions should always be made separate from fund-raising solicitation activities and purchases may not be conditioned upon any promises of donations.

Accepting and Extending Invitations

Complimentary education/invitations to sales, promotional, or educational events, complimentary training/education and/or reimbursement by vendors for reasonable and necessary expenses associated with modest travel, meals, and lodging may be acceptable, so long as:

- You receive prior approval from your department's vice president;
- The event is a bona-fide purchasing, sales, training, or education session; and
- If the event is sponsored by an Industry company (i.e., pharmaceutical and device manufacturer):
 - i. The primary purpose of the event must be to provide education or training on how to properly and safely use medical devices, equipment, and other technologies, or compliance with legal, regulatory or accreditation requirements; and
 - ii. The payment is pursuant to the terms of a written agreement with the sponsoring company or is related to the review of capital equipment MedStar Health is considering purchasing or acquiring, which cannot be transported to the MedStar facility.

Accepting Invitations for Charitable Events or Entertainment

MedStar Health representatives may accept invitations from vendors to charitable events or events which include entertainment that benefit MedStar Health or MedStar Health's business relationships, so long as the individuals involved either remove themselves from a vendor selection process involving that vendor, or ensure that objective vendor selection criteria are in place to prevent inappropriate influence. Associates may not accept invitations to outside events that have no direct relationship to MedStar Health's business and charitable purposes, such as sporting

events or golf outings, unless those events meet the above criteria.

For entertainment meeting those criteria, the value of such an event shall not exceed \$250 per person and must be infrequent (not more than once every six months) with respect to any one individual/vendor.

Extending Business Courtesies/Invitations to Potential Referral Services

MedStar Health does not buy referrals. Physicians send their patients to MedStar providers because of our clinical expertise, our community-based facilities and our patient-first philosophy. Associates must never offer money, favors, gifts, or promises of gifts, or anything else of value to influence, direct, obtain, or retain business and/or patient referrals. It is critical to avoid the appearance of impropriety when giving gifts to individuals who do business or are seeking to do business with MedStar Health. At MedStar Health, we will never use gifts or other incentives to improperly influence relationships or business outcomes.

Extending Business Courtesies/Invitations to Non-Referral Sources

There may be times when you may wish to extend an invitation to attend a social event in order to develop your business relationship with a current or potential business associate. The purpose of the entertainment must never be to inappropriately induce any favorable business action. These social events must not include any long distance travel or overnight lodging. During these events, topics of a business nature must be discussed, and you must be present. The cost of such an event shall not exceed \$250 per person and must be infrequent (not more than once every six months) with respect to any one individual. Any exception must be pre-approved by your department's vice president.


Memberships and Sponsorships

MedStar Health has established guidelines and criteria for the purposes of determining whether a membership or sponsorship is appropriate. Associates should reference the MedStar Health Memberships and Sponsorships Policy for more information and should contact the MedStar Health Chief of Staff with any questions.

Your Responsibilities

It is every MedStar associate's responsibility to know what types of gifts or invitations may be acceptable and under which conditions. Also, in addition to the guidance outlined in this Code of Conduct, MedStar associates should refrain from any conduct that could have an appearance of impropriety if viewed objectively. If there is any question, you should decline it and explain MedStar Health's position to the gift giver as follows:

- MedStar Health's associates may not accept or give gifts or other incentives that improperly influence, or give the appearance of improperly influencing relationships or business outcomes.

- 
- Associates may not accept cash or cash equivalents, such as gift certificates, from anyone doing business, or seeking to do business (including patients), with MedStar Health.

Additional Legal Considerations

Tax Exempt Status

MedStar Health and many of its affiliated entities are organized and operate primarily for scientific, educational, or charitable purposes and therefore are organized as tax-exempt companies. In exchange, every year MedStar provides millions of dollars of charity care to the communities we serve and we promote health within our communities through the operation of our public Emergency Room; by permitting qualified community physicians to practice at our facilities; by providing educational opportunities for residents; by treating patients using public programs; and by using excess funds to improve patient care, expand hospital facilities, and advance medical training, education and research.

To fulfill our legal obligations and commitment to our communities, it is important that no part of our organization's net earnings is distributed for the benefit of any private individual. In addition, it is important that individuals in a position to exercise substantial influence over our organizations such as managers, directors, physicians, executives, and board members do not receive any benefits in excess of the value of services they provide to our organizations.

Political Contributions and Activities

MedStar Health supports associate participation in the political process. However, MedStar Health is prohibited from participating in political activities. MedStar Health's funds or resources are not to be used to contribute to or support candidates or their political campaigns, or for gifts or payments to any political parties or any of their affiliated organizations.

It is important to separate personal and corporate political activities in order to comply with the appropriate rules and regulations relating to lobbying or attempting to influence government officials. You may not use your position at MedStar Health or use MedStar Health equipment and supplies to support a personal philosophy or belief without approval of senior management. Of course, associates may participate in the political process on their own time and at their own expense. Associates cannot seek to be reimbursed by MedStar Health for any personal contributions for such purposes.

At times, MedStar Health may ask associates to advocate on its behalf by writing letters that present our position on specific healthcare issues to various government agencies and elected officials. It is your choice whether to participate in these efforts. Additionally, some MedStar Health associates interface with government officials on a regular basis. If you are involved in these communications on behalf of MedStar Health, be certain that you are familiar with applicable regulatory constraints and observe them.

Antitrust

Antitrust laws are designed to benefit consumers by promoting competition. These laws primarily prohibit activities that reduce or eliminate competition. Our competitors are other healthcare systems and facilities in markets where we operate. Antitrust laws could be violated by discussing with a competitor certain aspects of MedStar Health's business such as how our prices are set, current wage rates, strategic and marketing plans, or the terms of key contracts.

An agreement with a competitor that establishes pricing levels for services is unlawful. Discussions about pricing arrangements should be viewed as highly sensitive and should be reviewed by MedStar Health's Legal Department. Additionally, the antitrust laws are violated when two competitors agree not to compete against each other with respect to a geographical area or particular services or when they agree to boycott certain vendors or service providers. Discussions with competitors about services and strategic planning may raise concerns under the antitrust laws and require the close scrutiny of MedStar Health's Legal Department.

Fraud, Abuse and Waste


Fraud, Abuse, and Waste

MedStar Health is committed to complying with all applicable laws and requirements of participation in the federal healthcare programs. This includes providing care and billing for services that are medically necessary, billing only for services which are actually provided, and not otherwise wasting our valuable resources in exchange for payments. It also requires each MedStar Health associate to diligently identify and report any activities that appear to be deceptive, misrepresentations of fact, or otherwise of potential concern. In the event you have a concern of this nature, you should report it to your supervisor, your entity's Human Resources Department, compliance director, the Office of Corporate Business Integrity, the Legal Department, or Internal Audit. Anonymous reports may also be made to the MedStar Health Integrity Hotline.

Examples of Inappropriate Conduct

Although it is not an exhaustive list, MedStar Health and its associates will specifically refrain from engaging in the following practices:

- Billing for services or supplies not rendered
- Billing for services that are not documented
- Billing for services that are not "medically necessary"
- Double billing (billing twice for the same service)
- Upcoding (changing a procedure code to one that is reimbursed at a higher rate)
- Misrepresenting a diagnosis in order to obtain payment
- Accepting or paying a kickback for patient referrals
- Providing leased space to physicians for less than fair market value
- Brand-name billing for generic drugs

- 
- Falsifying any type of records including payroll or time records, medical records, scientific research records, etc.
 - Giving unlawful patient inducements (free gifts or services to patients)
 - Providing "charity care" without following and documenting appropriate processes
 - Maintaining cost reports, or filing cost reports without adequate supporting documentation

Claims Submission

At MedStar Health, we are committed to ensuring that all claims to government and private insurance payers are accurate and truthful. Claims include not only individual claims for patient services but also cost reports. All claims must conform to all applicable federal, state, and local laws and regulations. Claims should be submitted only for services that were appropriately provided and documented. MedStar Health prohibits any of its associates or agents from knowingly presenting, or causing to be presented, claims for payment or approval that are false, fictitious or fraudulent. No false or misleading entries shall be made or submitted on any bills or claim forms, and no associate shall participate in any arrangement that results in such prohibited acts. Making a false statement in a medical record or any document that is used to support billing of medical services may be considered criminal fraud. Providing and billing for a service that results from a kickback arrangement may also be considered a false claim and must not be submitted.

Overpayments

There are times when, through various means, we may discover that we've been overpaid due to a billing error. MedStar Health is committed to providing repayment of any money appropriately identified as an overpayment by government payors or private payors whose contract terms mirror those of the government payors. All MedStar Health associates who know of a potential error in reimbursement that may require the return of any prior payments must immediately provide all information related to the potential error to the appropriate department head. In the event a systematic error is discovered, the entity's compliance director and the department and/or facility leadership will work with Office of Corporate Business Integrity and the Legal Department, if necessary, to identify appropriate processes for mitigation.

Interactions with Physicians and Allied Health Professionals

MedStar Health strongly values its relationships with the exceptional and professional physicians and Allied Health professionals who provide services within our facilities. MedStar Health prohibits kickbacks and bribes to physicians and Allied Health professionals because they may taint the integrity of these relationships and patient care. It is important that all physician and Allied Health professional relationships are structured and documented appropriately to comply with all applicable laws and regulations. In general, any compensation provided to physicians in exchange for services should be consistent with fair market value and such compensation should not take into account the value or volume of any referrals. Please contact the Legal Department with any questions regarding structuring these relationships.

Responding to Government Audits/Investigations

Any MedStar Health associate or agent receiving notice of a government audit or investigation shall immediately refer the issue to their compliance director, the MedStar Health Compliance Officer, or the MedStar Health Legal Department, who will respond in accordance with established protocols. If you are contacted by a government representative, it is important that you obtain and forward a copy of any documents presented to you as well as the name and contact information of the government representative.

Compliance with Federal and State False Claims Acts

Requirements Pertaining to False Claims and Statements

The Office of Corporate Business Integrity provides all MedStar Health facilities with compliance support, billing integrity support, occurrence reporting and resolution, and training and education. MedStar Health's Internal Audit department conducts routine independent audits of business practices, and all financial managers are required to attend training on the Financial Manager's Code of Ethics and reporting obligations. Under the Code of Conduct, every associate has an obligation to report any situation reasonably believed to be fraudulent or illegal. Associates are encouraged to report privacy, financial reporting, human resources, and other compliance concerns to their supervisors or local compliance directors, or to make an anonymous and confidential report to the MedStar Health Integrity Hotline. The confidential hotline is available 24 hours a day. Associates can also e-mail the MedStar Health Compliance Officer at complianceofficer@medstar.net. Retaliation against an associate for reporting in good faith or cooperating in a compliance, legal, or human resources investigation, is expressly prohibited.

Federal False Claims Act and Civil Monetary Penalties

The Federal False Claims Act, 31 U.S.C. §§3729-3733, makes it illegal for persons or entities to knowingly and willfully submit, cause to be submitted, or conspire to submit a false or fraudulent claim, or use a false record or statement in support of a claim for payment from a federally-funded program. The phrase "knowingly and willfully" means that the person or entity had actual knowledge of the falsity of the claim, or acted with deliberate ignorance or reckless disregard of the truth or falsity of the claim. Any person who violates the Federal False Claims Act may be liable to the federal government for civil penalties and damages.

Under the Federal False Claims Act, any private party may bring a civil action in the government's name against the person or entity that allegedly submitted a false claim, subject to certain jurisdictional bars and statutes of limitations. These are known as the False Claims Act's "*qui tam*" or whistle blower provisions. Depending on the outcome of the case, a whistle blower may be entitled to a portion of any judgment or settlement in favor of the

government. The Federal False Claims Act provides legal protection to whistle blowers that are retaliated against by his/her employer for investigating, filing or participating in a False Claims Act lawsuit. In addition, other civil monetary penalties and damages may be imposed against persons or entities that knowingly and willfully present or cause to be presented a claim that the person knows or should know is a false or fraudulent claim, is a claim that the person knows or should know was not provided as claimed, or is for a pattern of medical items or services that a person knows or should know are not medically necessary (42 U.S.C. § 1320a-7a).

State False Claims Acts

A number of jurisdictions have enacted false claims acts in an attempt to prevent the filing of fraudulent claims to state funded programs. The District of Columbia has established such an act under Title 2, Chapter 3 of the District of Columbia Code. The District of Columbia law provides that "any person who knowingly presents, or causes to be presented, a false claim, record or statement for payment by the District, or conspires to defraud the District by getting a false claim paid can be liable to the District for penalties and damages." District of Columbia law allows whistle blowers to bring claims under certain circumstances, and protects whistle blowers from retaliation by employers.

Maryland also has its own False Claims Act that prohibits certain actions constituting false claims against a Maryland health plan or a Maryland health program. Any person that knowingly presents or causes to be presented a false or fraudulent claim for payment or approval, or knowingly makes, uses, or causes to be made or used a false record of statement material to a false or fraudulent claim, may be held liable for penalties and damages under the law. Like the District of Columbia False Claims Act, Maryland permits whistle blowers to file suits on behalf of the state, but limits recovery under the law if the Maryland Attorney General's Office declines to intervene in the lawsuit. Maryland's False Claims Act protects whistle blowers from retaliatory action by employers.

Virginia has a similar law known as the Taxpayers Against Fraud Act established under Chapter 3 of Title 8.01 of the Virginia Code. Virginia's law also permits whistle blowers to bring actions in the name of the Commonwealth of Virginia and protects whistle blowers from discrimination by employers.

Attestation

MedStar Health requires all associates to sign an attestation document confirming they have received, read, understood, and will abide by this Code of Conduct. New associates will be required to confirm their receipt and understanding of the Code of Conduct and sign an attestation as a condition of employment. Adherence to and support of MedStar Health's Code of Conduct, and participation in related activities and training, may be considered in decisions regarding hiring, promotion and compensation for all candidates and associates.

Notice to Associates

This code provides information about standards of integrity and conduct that MedStar Health and its subsidiary associates are expected to follow. It does not address every situation or set forth every rule. In fact, additional rules can be found in each associate's work site personnel and operational policies. It is the responsibility of each MedStar entity to ensure that its associates are complying with the policies stated herein. In addition, this Code is not a contract of employment and does not create any contractual rights of any kind between MedStar Health or its subsidiaries and their associates. Under an at-will employment relationship (i.e., where the associate is not covered by a contract or collective bargaining agreement), there is no fixed duration to the employment relationship. Therefore, associates can terminate their employment whenever they wish and for whatever reason they may have, just as the employer may terminate an associate's employment at any time and for any reason.

It is important to understand what makes up the MedStar Health system. Specifically, the system is composed of MedStar Health as the parent company, located in Columbia, Maryland. In addition, the system is made up of a number of wholly-owned subsidiaries that are located throughout Maryland and the Washington, D.C., region including Franklin Square Hospital, St. Mary's Hospital, Montgomery General Hospital, Georgetown University Hospital, Good Samaritan Hospital, Harbor Hospital, MedStar Enterprises, MedStar Physician Partners, MedStar Health Research Institute, National Rehabilitation Hospital, Union Memorial Hospital, Visting Nurse Association (VNA), and Washington Hospital Center. While these facilities operate independently of one another and as separate employers, they also work toward the common vision, mission and values with the ultimate goal to be the healthcare provider of choice in Maryland and the Washington, D.C., region. In working to achieve this goal, it is the responsibility of each subsidiary to enforce the policies contained in this Code of Conduct and to issue appropriate disciplinary or other actions for associate violations. Please note that for the purposes of this Code of Conduct, the MedStar Health parent company and all of its subsidiaries and other facilities will be referred to collectively as "MedStar Health."

MedStar Health's Corporate Compliance Program

Our Commitment

MedStar Health is committed to adhering to all applicable laws and to our own ethical standards in carrying out our mission of providing quality healthcare services to the community. Associates are expected to support these goals and incorporate them into their job responsibilities.

Program Structure

MedStar Health has instituted a comprehensive Corporate Compliance Program and has directed all operating subsidiaries to develop companion Compliance Programs to address issues specific to their operations. The Audit & Compliance Committee of the MedStar Health Board of Directors has oversight responsibility for these compliance initiatives. The Compliance Officer is responsible for implementing and overseeing the operation of a Compliance Plan, and responding to reports of alleged wrongdoing. Each of our major operating subsidiaries also has its own compliance director.

Education

MedStar Health associates receive periodic training on legal and ethical compliance standards. Associates are expected to incorporate this education and training into their daily functions.

Monitoring

MedStar Health has implemented monitoring and review systems to ensure adherence to all legal and ethical standards. The organization also routinely seeks other means of ensuring and demonstrating compliance with laws, regulations and MedStar Health policies. For example, MedStar Health has checked to ensure that no associate appears on the Department of Health and Human Services' Office of Inspector General's List of Excluded Individuals/Entities or the General Services Administration's Excluded Parties List System.

Investigations

Once a concern is reported to Compliance, it will be logged in, investigated and documented. Individuals with knowledge about the issue at hand will participate in the investigation. Corrective action and discipline will depend upon the findings of the investigation. Investigators will make a reasonable effort to protect the confidentiality of the individuals involved.



Code of Conduct Attestation

By signing below, I acknowledge that I have received, read, understood, and will abide by MedStar Health's Code of Conduct. I understand that adherence to the Code of Conduct is a requirement and failure to adhere to it can result in disciplinary action up to and including termination of employment and/or affiliation.

Print Name (Legal Name): _____
(write legibly or you will not be given credit)

Signature: _____

Date: ____/____/____

Facility: _____

Department: _____

Upon completion, return this page to:
**your local compliance director,
Human Resources Department
or
MedStar Health's
Office of Corporate Business Integrity:
5565 Sterrett Place
Columbia, MD 21044**

Please keep a copy for your records.



MedStar Health

MedStar Health
5565 Sterrett Place • Columbia, MD 21044
410.772.6606 • Fax 410.772.6611

© 2011 MedStar Health

Exhibit 22



Georgetown
University
Hospital 

MedStar Health

Title: COMMUNICATION BETWEEN CAREGIVERS	Policy Number: 412
Issued: October 24, 2006	Page: 1 of 3
Last Reviewed: July 28, 2009	Attachment: A , B , C and D
Last Revised: July 28, 2009	

POLICY:

It is the policy of Georgetown University Hospital that information about patient care is communicated in a consistent manner which ensures the continuity and safety of the patient's care. Breakdowns in communication between health care providers are a primary reason in episodes of avoidable patient harm.

DEFINITIONS:

Hand Off Communications:

Hand off communications refers to the contemporaneous process of passing accurate, relevant, patient specific information from one caregiver to another or from one health care team to another thereby ensuring the continuity and safety of the care provided. These include, but are not limited to, physicians transferring complete responsibility for a patient, physicians transferring on-call responsibility, nursing shift changes, temporary responsibility for staff leaving the unit for short periods of time, transfer of patients from the emergency department to the inpatient units and the transfer of patients to other hospitals, nursing homes and home health care providers.

Effective hand offs have the following qualities:

- A. Information to be communicated includes up-to-date information about the patient's care, treatment and services, condition and any recent or anticipated changes.
- B. Interruptions are limited to preclude/minimize the possibility that important information is not omitted.
- C. There is a process for verification of the received information such as repeat-back or read-back.
- D. Print or electronic information media is available when appropriate.
- E. There is an opportunity for the receiver of the hand off information to review relevant patient historical data to include previous care, treatment and services.
- F. There is an opportunity for interactive communications which allows for questioning between the giver and receiver of patient information.
- G. Handoff communications are standardized in that the same process/format is used in "like" handoffs.

Structured Communication Techniques

Since the efforts of the multidisciplinary health care team often involve urgent interactions between human beings with varying styles of communication, a standardized approach to information sharing is needed to ensure patient information is accurate and relevant. The techniques provide a focused, standardized way to set expectations for “what” is to be communicated and “how” among clinicians – nurse-to-nurse, physician-to-physician, nurse-to-physician, respiratory therapist-to-physician, etc. The use of structured communication techniques is especially useful during critical points in patient care such as shift handoffs and transfers.

PROCEDURE:

I. Physician Hand Offs

Physician hand off communication may include, but is not limited to such items of information as:

- A. Patient’s name
- B. Code Status
- C. Patient’s diagnosis and current condition
- D. Chronic problems
- E. Drug allergies, medications and IV fluids
- F. Central lines, catheters and drains
- G. Course of treatment to date
- H. Current or anticipated changes in condition or treatment
- I. What to watch for in the next interval of care

II. Nursing Hand Offs

A. Nursing hand offs for change-of-shift reports, breaks, lunch, meetings, transfer from unit to special procedure, OR, Dialysis, Radiology, and/or unit to unit transfers may include:

- 1. Patient’s name
- 2. Code status
- 3. Medical/surgical history
- 4. Patient’s vital signs and systems review
- 5. Orders/labs/tests

6. Drug allergies, medications and IV fluids
 7. Current or anticipated changes.
 8. What to watch for in the next interval of care
There should be an opportunity between shifts to ask and respond to questions regarding the patient's care.
- B. For transfers to pre-operative holding a report may be completed via the fax report for pre-operative procedures if applicable. (*Attachment A*) A verbal report may be given to the holding room nurse when a fax report is not possible. Regardless of the report format, there is an opportunity to ask and respond to questions regarding the patient's care.
- C. When transferring patients from the PACU or ED to the unit, a fax report sheet may be completed and faxed to the unit. Verbal confirmation is made with the receiving unit via telephone allowing for the opportunity to ask and respond to questions regarding the patient's care. (*Attachment B*)
- D. When transferring adult patients from unit to unit, a fax report will be completed and faxed to the receiving unit. (*Attachment B*) Verbal confirmation is made with the receiving unit via telephone or a face to face report is conducted to allow for the opportunity to ask and respond to questions regarding the patient's care.
- E. When using an "intermediary" such as a transporter who is not the recipient of the patient for "care" services and are often not capable of providing actual "assumption" of care, the report should be to the person that will actually be caring for the patient during this change of care site, such as radiology, dialysis, etc.

III. Procedural Area Hand Offs

Hand off communications from procedural areas may be done using a variety of methods to include fax, electronic or telephone. Regardless of the method, there is an opportunity for the receiver of the report to ask clarifying questions and to receive answers. In addition to the standard information other key information such as tests completed, results, the patient's response to the test or procedure and any problems experienced and similar information should be included in the report as applicable.

- A. Documents that should remain with the patient or should be available electronically per MedConnect scope during a handoff include the MAR, current medical record, flow sheets and interdisciplinary education records as appropriate. These are key communication tools and may decrease the amount of verbal or written information that must be given and will allow the interim care givers to document their activities.
- B. Care must be taken to identify areas where handoff communications may be overlooked. Some examples include relief of staff during a procedure in the OR or other areas; psychiatric patients leaving the area for therapies; a child going to a play room if the area is not "readily accessible" to the care provider; or when a patient has more than one procedure in the OR and OR teams change.

IV. Structured Communication Techniques

Members of the health care team may use structured communication techniques to improve information sharing so that patient information is consistently and accurately shared between members of health care team. An example is provided at *Attachment C*. The technique outlined at Attachment A has been modified to reflect its use as a report to a physician about a critical situation. This illustrative use of the format is contained as *Attachment D*.

Richard L. Goldberg, M.D.
President

Exhibit 23



**Georgetown
University
Hospital**

MedStar Health

Title: PATIENT COMPLAINT AND GRIEVANCE PROCEDURE	Policy Number: 10
Issued: April 20, 1990	Page: 1 of 4
Last Reviewed: July 28, 2009	Attachment: A
Last Revised: July 28, 2009	

POLICY:

It is the policy of Georgetown University Hospital to provide individuals the opportunity to express concerns about issues or questions, (including those related to privacy or confidentiality), that may arise during their hospitalization or treatment and to assure that current or future access to care is not compromised by this expression.

DEFINITIONS:

Patient Grievance

A written or verbal complaint (when the verbal complaint about patient care is not resolved at the time of the complaint by staff present) by a patient or patient representative regarding the patient's care, abuse or neglect, issues related to the Hospital's compliance with Center for Medicare Medicaid Services Conditions of Participation or a Medicare beneficiary billing complaint.

PROCEDURE:

I. PATIENT CARE LINE

- A. The Patient Care Line shall be available to all patients and their families. Information about this service shall be posted in patient rooms, exam rooms and waiting rooms, and shall be made available in the Patient Admission Handbook. Patient and Physician Advocacy staff shall handle calls received during normal business hours. Clinical Administrators shall handle calls received after hours and during weekends.
- B. The Patient and Physician Advocacy staff shall personally address all patient concerns or shall refer the patient to the appropriate member of Hospital Administration, the Medical Staff, Nursing Administration, Hospital Privacy Liaison, or to the Department Head/Manager.
- C. The Hospital Privacy Liaison must be informed of any patient complaint alleging a breach of privacy or confidentiality. When appropriate, the Hospital Privacy Liaison will inform the MedStar Privacy Officer of the complaint and will take follow-up action under Hospital Policy # 457 Patient Privacy Rights.
- D. The Patient Handbook contains information about lodging a complaint with Joint Commission and/or the D.C. Department of Health

II. VERBAL COMPLAINT

When a Hospital staff member receives a verbal complaint from a patient or a member of a patient's family, the staff member shall attempt to resolve the complaint or advise the patient of the appropriate individual to contact.

- A. If the complaint relates to care being provided by physicians, the individual should be advised to discuss the matter with the attending physician. If the individual has already done so and continues to be dissatisfied, he/she may express concerns to either the chief of service, department chair, and if necessary, the Vice President, Medical Affairs.
- B. If the complaint relates to the nursing care being provided, the individual should be advised to discuss the matter with the Nursing Coordinator or designee. If the individual has already done so and continues to be dissatisfied, he/she may express concerns to either the Clinical Administrator or the Senior Vice President and Chief Nursing Officer,
- C. If the complaint involves any allegation of privacy or confidentiality breaches, the staff should inform the Hospital Privacy Liaison.
- D. If the complaint involves several departments or issues, the patient/family should be advised to discuss the matter with Patient and Physician Advocacy.
- E. Staff members are encouraged to inform individuals about the Patient Care Line if they are unable to resolve a patient's concerns to the patient's satisfaction.

III. WRITTEN COMPLAINT

When a Hospital staff member receives a written complaint other than about an alleged breach of confidentiality or privacy from a patient or a member of a patient's family (see Policy #457 Patient Privacy Rights), the complaint shall be acknowledged within a reasonable timeframe either through verbal or written communication.

- A. The appropriate Department Head/Manager shall acknowledge written complaints either through verbal or written communication. The appropriate Department Head/Manager shall investigate, follow up with the patient/family member in writing, personal meeting, or via telephone and document response.
- B. Written complaints involving multiple departments shall be referred to the Vice President responsible for the person/department to whom the complaint was addressed. The appropriate Vice President will coordinate the investigation and second response.
- C. The Department Head/Manager will forward a copy of the original complaint letter and documentation of acknowledgement and final contact to their AVP/VP for review.
- D. The GPG Administrators will maintain a database of complaint correspondence and responses other than for complaints alleging privacy/confidentiality violations. All information gathered during an investigation is confidential and only information required to satisfy regulatory and quality reporting requirements will be available on a need to know basis.

- E. Any written complaints relating to the Hospital's privacy policies, procedures, or practices will be handled by the Hospital Privacy Liaison as indicated in Policy #457 Patient Privacy Rights. The Privacy Liaison will :
 - 1. Notify the MedStar Privacy Officer.
 - 2. Track the process
 - 3. Retain all correspondence for six years
- F. The Chair of each Department receives a monthly update from the Administrator and uses the information in evaluating provider performance.

IV. GRIEVANCE PROCEDURE

A patient or patient's family member may request in writing an additional level of review by the President of Georgetown University Hospital if the patient/family believe the issue has not been completely addressed at the patient complaint level.

- A. Upon receipt of a written grievance outlining the details of the issue, the President, Senior Vice President, or VP for Medical Affairs, or their designees will contact appropriate managers and/or employees to collect further information.
- B. If the Executive Officer/designee is satisfied that the collected information, in concert with the patient/family written account, contains sufficient information for an informed decision, he/she will contact the patient with a response within ten working days of the receipt of the written grievance. Occasionally a grievance will require additional investigation and the patient will be informed in writing of the need for additional time.
- C. If the Executive Officer/designee determines that the process could benefit from additional information by a meeting of the involved parties (including the patient/family), all efforts will be made in good faith to convene the meeting within 15 working days of the receipt of the letter. The Executive Officer's discretion will be used to determine the participants. The patient will be contacted within ten working days of the meeting.
- D. All information obtained during the grievance process is confidential and only information required to satisfy regulatory and quality reporting requirements will be available on a need to know basis.

V. COMPLIMENTS/POSITIVE FEEDBACK

GUH welcomes positive feedback from patients, visitors and families.

- A. The Department Manager/Head will acknowledge the complimentary letter with a response. (See Attachment A Standard Format for Responses to Patient Compliments)
- B. The Department Manager/Head shall forward a copy of the complimentary letter and the acknowledgement to :
 - 1. the employee
 - 2. Director of Internal Communications
 - 3. Appropriate Vice President

VI. TRENDING OF DATA

Patient complaint and compliment data are categorized by type and reported quarterly to the Quality and Safety Executive Council. Documentation of correspondence to and from the Hospital President is maintained in the Quality Improvement Office.

Richard L. Goldberg, M.D.
President

Related Policy: #457 Patient Privacy Rights

Exhibit 24



MedStar Georgetown University Hospital

Title:	Policy Number:
CONFIDENTIAL PATIENT INFORMATION AND PATIENT PRIVACY	456
Issued:	Page:
August 1, 1980	1 of 8
Last Reviewed:	
February 22, 2011	
Last Revised:	Attachment:
September 25, 2012	A and B

POLICY:

It is the policy of MedStar Georgetown University Hospital to respect the right of the patient, within the limits of law, to personal privacy and confidentiality of information. The medical record is the property of MGUH and shall be maintained to serve the patient, the healthcare providers, and the institution in accordance with legal, accrediting, and regulatory agencies. Access to the medical record is governed by the procedures outlined below.

DEFINITIONS:

Access

The ability to view, obtain, edit or delete information in an electronic resource.

Authorization

Process of giving individuals access to system features and capabilities based upon their identity.

Confidential Information

Any or all Protected Health Information

Medical Record

A compendium of information in paper, microfilm, and electronic media about an individual patient during the course of his/her treatment at MedStar Georgetown University Hospital. This policy applies to all medical information regardless of medium as well as *Hospital Policy # 410 General Use and Disclosure of Protected Health Information*

Mental Health Record

Any information about a patient receiving psychiatric treatment. This information may only be released upon written authorization from the patient, or as otherwise permitted by law.

Protected Health Information (PHI)

Information created or received by MGUH that relates to past, present or future physical or mental health or condition of the individual; the provision of healthcare to an individual or the past, present or future payment for the provision of health care to an individual that identifies or could identify an individual. Any one of the following items about a patient, patients' relatives, employers or household members is defined as a direct identifier:

- Names
- Postal address information other than town, city, state and zip code
- Social Security Numbers
- Medical Record Numbers
- Account Numbers
- Certificate/license numbers
- Telephone numbers
- Fax numbers
- E-mail addresses
- Device identifiers and serial numbers
- Vehicle identifiers and serial numbers including license plate numbers
- Biometric identifiers such as finger prints or voice prints
- Full face photographic images or comparable images
- URLs (Web Universal Resource Locators)
- IP addresses
- Health Plan beneficiary numbers

Purpose Based Access

Means access and use that is permitted only because the nature of the intended access or use. Therefore even though an individual may have access to a system due to their role, they may not access a system; unless they also have a permitted purpose for accessing the system.

Role-Based Access

Access and use that is permitted based on one's roles or responsibilities with the organization.

Secondary Records

Records such as indices and all other individually identifiable patient health information maintained at MedStar Georgetown University Hospital are subject to this policy.

Substance Abuse Record

Any information about a patient receiving treatment for substance abuse. This information may only be released upon written authorization from the patient.

User

Any Hospital employee, privileged provider, student, volunteer or contractor authorized to access patient related information in an electronic information system

PROCEDURE:

I. Confidentiality Compliance

- A. All individuals engaged in the collection, handling or dissemination of patient health information shall be specifically informed of their responsibility to protect patient data and of the penalty for violation of this trust. Violation of confidentiality of patient information shall be cause for immediate termination of access to further data, and/or immediate termination of employment and/or privileges at MedStar Georgetown University Hospital. In addition, the individual may be subject to sanctions and criminal fines under Federal regulations. (see Section VIII)

- B. Employees are not to access, use, or disclose their own medical records or the medical records of any other employee, family member, neighbor, friend, acquaintance, VIP or celebrity, etc for **personal purposes**. Violation shall be cause for immediate termination of access to further data, and/or disciplinary action up to and including immediate termination of employment and/or privileges at MedStar Georgetown University Hospital. In addition, the individual may be subject to sanctions and criminal fines under Federal regulations. (see Section VIII). Employees , like all patients, must use the same procedure that patients use to access their own medical records as outlined in ***Policy #410 General Use and Disclosure of Protected Health Information***. Employees, like all patients, may access approved patient portals for personal care related information
- C. Employees will take appropriate administrative, technical and physical safeguards to protect the privacy of Protected Health Information to include:
1. Never leaving PHI unattended in public areas
 2. Locking patient record rooms or cabinets containing patient records
 3. Use of paper shredders to dispose of PHI
 4. Never removing PHI from MGUH without permission of the Director of Health Information Management or Clinic Administrator
 5. Limiting public access to fax and copy machines
 6. Not discussing patient information in elevators or hallways
 7. Keeping voices low when discussing patient information
 8. Being aware of surroundings when using cellular phones
 9. Limiting public traffic near areas where medical records are kept
 10. Turning charts towards the wall so that patient identifiable information is not visible
 11. Not leaving x-rays unattended on a light board
 12. Using minimal information on patient whiteboards
- D. Employees may have role-based access to PHI but need to be clear about having permitted access to PHI.
- E. This policy shall be made known to all employees at the time of employment. Each employee shall indicate understanding of this policy through a signed statement as part of his/her departmental orientation (***Attachment A***). The signed statement will be maintained in the employee's departmental personnel record. For purposes of this policy, employees include faculty, residents, staff, volunteers, and Georgetown University employees who require access for patient care purposes. Students shall sign the Confidentiality Statement for Students (***Attachment B***).

II. Confidentiality of Mental Health Records

Release of mental health information from patient records will be allowed only in accordance with the requirements of the District of Columbia Mental Health Information Act of 1978.

III. Access to Medical Records by Authorized Individuals

- A. Medical records shall be available for use within the facility for direct patient care by all staff involved in the care and treatment of the patient.
- B. Direct access to patient medical records for routine administrative functions, including billing, is only permitted when in strict accordance with the work assignment and when the employees have signed the confidentiality statement.
- C. Direct access to patient medical records after discharge for patient care-related functions, such as quality improvement and utilization management is only permitted when in strict accordance with the work assignment.
- D. Medical records shall be made available for research to individuals who have obtained approval for their research projects from the Institutional Review Board and the Vice President, Medical Affairs of the Hospital. Research projects that involve use of medical records shall be conducted in accordance with institutional policies on use of medical records for research. (See Policy #130 Patients involved in Biomedical Research)
- E. Access to areas housing medical records shall be limited to Medical Records personnel. The sole exception to this policy shall be the individual designated by the Director of Medical Records for access at times when the Department is not staffed. Medical records must be available and accessible at all times for patient care.
- F. If photocopies or facsimiles of the medical record or portions thereof are provided to authorized internal users, the same policies/procedures and controls regarding access and confidentiality of the original document apply. Wherever possible, internal users will be encouraged to use the original medical record rather than to obtain a facsimile or photocopy.

IV. Requests for Information Contained in the Medical Record

See Policy 410 "General Use and Disclosure of Protected Health Information"

V. Mitigation and Sanctions

- A. MGUH must mitigate any known harmful effect of a use or disclosure of PHI in violation of its policies and procedures made by any MGUH staff or its business associates.
- B. MGUH will sanction members of its workforce who fail to comply with privacy policies up to and including termination.
 - 1. Sanctions do not apply to whistleblowers or to staff who are crime victims (See Section VI)

2. The MGUH Privacy Liaison will document any sanction applied and retain the documentation for six years
 3. The MGUH Privacy Liaison must report any applied sanction for a privacy violation to the MedStar Privacy Officer
- C. The following must be reported to the MGUH Privacy Liaison who will report to the MedStar Privacy Officer:
1. All breaches of privacy and confidentiality.
 2. Any known harmful effects of a use or disclosure of PHI
 3. Any mitigation done or required regarding privacy violations
 4. All violations of privacy policies and procedures

VI. Whistleblowers and Workforce Member Crime Victims

- A. If a workforce member or a business associate believes in good faith that MGUH has engaged in conduct that is unlawful or otherwise violates clinical standards, or that the care, services or conditions provided by MGUH potentially endangers one or more patients, workers, or the public, the workforce member or business associate may disclose relevant patient PHI to:
1. A health oversight agency or public health authority authorized by law to investigate the conduct or conditions;
 2. An appropriate health care accreditation organization for the purpose of reporting the allegation of failure to meet the professional standards or misconduct;
 3. An attorney retained by or on behalf of the workforce member or business associate for the purpose of determining legal options;
- B. If a workforce member is the victim of a criminal act, he/she may disclose relevant patient identifiable information to a law enforcement official, provided that:
1. The patient identifiable information is about a suspected perpetrator of the criminal act;
 2. The patient identifiable information is limited to:
 - a. Name
 - b. Address
 - c. ABO blood type and Rh factor
 - d. Type of injury
 - e. Date and time of treatment
 - f. Date and time of death (if applicable)
 - g. Description of distinguishing physical characteristics

VII. Refraining from Retaliatory Acts or Intimidation

MGUH may not intimidate, threaten, coerce, discriminate against, or take other retaliatory action against individuals:

- A. For filing a complaint with the Secretary of the Department of Health and Human Services;
- B. Testifying, assisting, or participating in an investigation, compliance review, hearing or proceeding about an alleged violation of the HIPAA Privacy Rule;
- C. Opposing any act or practice that is in violation of the HIPAA Privacy Rule

VIII. Compliance Reviews and Investigations

- A. Privacy Compliance Review by the MedStar Privacy Officer
The MedStar Privacy Officer will conduct periodic privacy compliance reviews at GUH.
- B. Investigation and/or Privacy Compliance Review by the Department of Health and Human Services (DHHS)
 - 1. The MGUH representative should immediately contact the Privacy Liaison, MedStar Privacy Officer and Legal Services upon notification of a compliance review or an investigation by the DHHS.
 - 2. MGUH must cooperate and provide records and compliance reports as requested by DHHS.
 - 3. MGUH may only permit the DHHS to access information:
 - a. During normal business hours to its facilities, books, records, accounts, and other sources of information;
 - b. At any time and without notice if the DHHS determines that exigent circumstances exist.
 - 4. MGUH must certify and document efforts made to obtain information required by the DHHS that are in the possession of any other agency, institution or person and they fail to produce the information.
 - 5. Any individually identifiable PHI disclosed to the DHHS during a review or investigation will not be re-disclosed by the DHHS, except in necessary for determining or enforcing compliance or as required by law.
 - 6. The DHHS will notify MGUH when an investigation or a compliance review results in a failure of compliance. In cases where the investigation or compliance review arose from an individual complaint, the DHHS will inform the individual in writing.
 - 7. If MGUH is found not to be in compliance and the matter can not be resolved by informal means, the DHHS may issue written findings documenting the non-compliance to both MGUH and to the individual making the complaint.

8. If the DHHS determines that further action is not warranted after a review or investigation, it will inform MGUH and the person making the complaint.

IX. Civil and Criminal Penalties

The responsibility for enforcing the HIPAA statute rests with the Department of Health and Human Services, Office of Civil Rights (OCR). OCR will not conduct criminal prosecutions, but will alert the government prosecutors at the Department of Justice. The HITECH Act (2009) creates a tiered approach to civil monetary penalties for violations of HIPAA and the HITECH Act. The new tiers are as follows:

1. If the person did not know (and by exercising reasonable due diligence would not have known) that he or she violated the law, the penalty shall be at least \$100 for each violation not to exceed \$25,000 for all such identical violations during a calendar year, but may be no more than \$50,000 for each violation not to exceed \$1.5 million for all such violations of an identical requirement or prohibition during a calendar year.
2. If the violation was due to reasonable cause and not to willful neglect, the penalty shall be at least \$1000 for each violation not to exceed \$100,000 for all such identical violations during a calendar year, but may be no more than \$50,000 for each violation not to exceed \$1.5 million for all such violations of an identical requirement or prohibition during a calendar year.
3. If the violation was due to willful neglect AND the violation was corrected, the penalty shall be at least \$10,000 for each violation not to exceed \$250,000 for all such identical violations during a calendar year, but may be no more than \$50,000 for each violation not to exceed \$1.5 million for all such violations of an identical requirement or prohibition during a calendar year.
4. If the violation was due to willful neglect and was not corrected, the penalty shall be at least \$50,000 for each violation not to exceed \$1.5 million for all such violations of an identical requirement or prohibition during a calendar year.
5. The HITECH Act requires all civil monetary penalties collected as a result of privacy or security violations to be transferred to OCR to be used for purposes of enforcing the Privacy and Security Rules. The HITECH Act also requires the U.S. Comptroller General to issue a report to HHS by Aug. 17, 2010 (18 months after the law's enactment) that includes recommendations for a methodology under which an individual who is harmed by a HIPAA violation may receive a percentage of the civil monetary penalty collected with respect to that violation. Based on this U.S. Government Accountability Office (GAO) report, the HITECH Act requires the secretary of HHS to issue regulations by Feb. 17, 2012, setting forth a methodology under which the individual harmed may receive a percentage of the civil monetary penalties collected.
6. Significantly, the HITECH Act resolves a point of longstanding confusion in the industry by clarifying that persons who are not covered entities (but who may be employees of covered entities or other individuals) may be found to have violated HIPAA if the PHI is

maintained by a covered entity and the person obtained or disclosed such information without authorization.

Richard L. Goldberg, M.D.
President

*Related Policies: 130 Patients Involved in Biomedical Research
402 Release of Information to the News Media
410 General Use and Disclosure of Protected Health Information
457 Patient Privacy Rights*

Exhibit 25

CONFIDENTIALITY STATEMENT

CONFIDENTIAL INFORMATION

I understand that the patient expects to communicate with health care practitioners with confidence that none of the information communicated will be released without appropriate authorization.

I understand that the information considered confidential involves all reports within medical records, employee health records, and/or automated information systems concerning examinations, tests, treatments, observations, and diagnosis of the patient/employee. It also includes information I learn in conversations with the patient/employee. I understand that patient demographic information, including all financial data, is private.

I understand that employee Human Resource/Payroll information will be released only according to MedStar guidelines.

I understand that information about physician credentialing, quality improvement, utilization management, risk management, and business information of the organization are to be treated as confidential and may only be released by those authorized to do so.

DUTIES AND OBLIGATIONS

I understand and agree that as an employee of Georgetown University Hospital, I must hold certain confidential information in strict confidence, regardless of the method of communication, including but not limited to hard copy, faxed electronically transmitted, oral conversations, or any printed data. This confidence must be kept when performing my duties, as well as during breaks, rest periods and time away from work. I understand that I may not seek access to or release written or computerized confidential information unless my work assignment specifically authorizes me to do so.

I understand that discussions concerning confidential information are not to occur in hallways, elevators, or other public areas where confidential information can be inadvertently overheard by someone not authorized to receive the information. I understand that when I discuss confidential information, I must take precautions so that unauthorized persons will not overhear my discussion.

SYSTEMS ACCESS/ELECTRONIC SIGNATURE

I will use my e-mail account/internet access only for business purposes, and I understand that MedStar Health, Inc. management and designated system administrators may read all messages. I understand that the combination of log on and password codes forms my electronic signature. Divulging my password code or that of another, or utilizing the password code of another, or allowing someone else to use my password is not permitted. I will change my password if someone else has knowledge of my password. I will limit system and network usage to functions necessary to perform my job responsibilities. If I leave the work area, I will sign off the application/system to prevent unauthorized access.

CONSEQUENCES

I understand that violation of the terms of this statement may result in disciplinary action up to and including dismissal. Additional information is available in Hospital policies.

Employee Name (printed)

Employee Social Security Number

Employee Signature

Date

Supervisor's Signature

Date

Exhibit 26



Georgetown
University
Hospital 

MedStar Health

CONFIDENTIALITY STATEMENT STUDENTS AND VISITORS

CONFIDENTIAL INFORMATION

I understand that the patient expects to communicate with health care practitioners with confidence that none of the information communicated will be released without appropriate authorization.

I understand that the information considered confidential involves all reports within medical records, employee health records, and/or automated information systems concerning examinations, tests, treatments, observations, and diagnosis of the patient/employee. It also includes information I learn in conversations with the patient/employee. I understand that patient demographic information, including all financial data, is private.

DUTIES AND OBLIGATIONS

I understand and agree that as a visitor of Georgetown University Hospital, I must hold certain confidential information in strict confidence, regardless of the method of communication, including but not limited to hard copy, faxed electronically transmitted, oral conversations, or any printed data. This confidence must be kept when observing or performing my duties, as well as during breaks, rest periods and time away from direct patient care. I understand that I may not seek access to or release written or computerized confidential information.

I understand that discussions concerning confidential information are not to occur in hallways, elevators, or other public areas where confidential information can be inadvertently overheard by someone not authorized to receive the information.

Name (printed)

Signature

Date

Exhibit 27

GOVERNMENT OF THE DISTRICT OF COLUMBIA

Advisory Neighborhood Commission 2E

★ ★ ★



Representing the communities of Burleith, Georgetown and Hillandale

3265 S Street, NW • Washington, DC 20007

(202) 724-7098 • anc2e@dc.gov

July 17, 2012

Mr. Amha Selassie
Director
State Health Planning and Development Agency
2nd Floor
825 North Capitol Street, NW
Washington, DC 20002

**RE: Certificate of Need for Proton Therapy Capability at the Lombardi Cancer
Center, Med Star/Georgetown University Hospital**

Dear Mr. Selassie:

On July 2, 2012, ANC 2E held a regularly scheduled public meeting which was duly noticed and attended by four of seven commissioners, constituting a quorum. At the meeting the Certificate of Need for Lombardi Cancer Center was discussed. After the presentation, Commissioner Solomon made the following motion (Commissioner Birch seconded), which passed by a vote of 4-0:

ANC 2E is highly supportive of the request by MedStar and the Georgetown University Hospital for a certificate of need for proton therapy capability at the Lombardi Cancer Center.

We trust you will give ANC 2E's support for this project the "great weight" it deserves.

Sincerely,



Ron Lewis
Chair, ANC 2E

COMMISSIONERS:

Ed Solomon, District 1 Ron Lewis, District 2 Jeff Jones, District 3 Jake Sticka, District 4
Bill Starrels, District 5 Tom Birch, District 6 Charles Eason, District 7

Exhibit 28

**Division of Nursing
Standard of Nursing Care**

Title: Transfer of Care
Standard Number: 10
Issued: 2005
Reviewed/Revised: 2011

Purpose: To ensure the effectiveness of communication among caregivers upon patient care transfer

Related Documents:

Hospital Policy #412: Communication between Caregivers
Nursing Policy # 15: Pre Procedure Patient Preparation
Protected Time for Hand Off of Care Guidelines

Attachments:

Pre-Operative/Pre-Procedure Fax Report
Post-Operative / Post- Procedure Fax Report
Emergency Department Nurse hand Off of care Fax Report
Nurse Hand Off of Care Fax Report for Adults
Dialysis Fax Report
Radiation Oncology Hand Off of Care Report

NOTE: At each transfer of care, time will be reserved for questions, answers, and clarifications. Additionally, upon physical transfer of the patient to the receiving unit, there will be a face to face hand-off of care between the person transferring (nurse, tech, transporter) and a nurse of the receiving unit.

Standard of Care

Report from nurse to nurse will be given in the suggested SBAR format and will include:

1. Situation
 - a. Nurses name
 - b. The situation that the patient is experiencing
 - c. Code status
2. Background
 - a. Vital signs
 - b. Mental Status
 - c. Allergies
 - d. Other pertinent assessment
3. Assessment
 - a. The problem in relationship to systems

- b. Assessment information
- 4. Recommendation
 - a. Tests scheduled
 - b. Labs to be done
 - c. Documented Nursing Plan of Care for shift

Transfer to and from Dialysis:

1. Dialysis nurse will call the inpatient unit the evening before the scheduled dialysis treatment and speak with either the charge nurse or the nurse assigned for the patient to ensure that patient has no other procedures scheduled. The call will be made on Saturdays for treatment scheduled on Mondays.
2. Dialysis staff will then fax the am dialysis schedule which is in the teletracking system to the respective units.
3. For treatments scheduled in the afternoon, dialysis staff will call the units with the expected scheduled times.
4. Inpatient unit nurse will complete the pre-dialysis section of the fax report and fax it to Dialysis at least 30 minutes prior to scheduled treatment followed by a call to confirm receipt of fax report.
5. Dialysis nurse will call unit nurse for any clarification (usually within 10 minutes from receipt of fax report) to ensure that all verification/clarification is done prior to transporter arriving to pick up patient.
6. The sending unit's nurse will notify the dialysis nurse of any changes in patient condition/status or delays via telephone
7. Upon completion of treatment, the dialysis nurse will complete the post dialysis section of the report and fax it to floor followed by a call to confirm receipt of fax.
8. The inpatient staff member checking receipt of fax report will hand the fax report to the nurse assigned to that patient or designee.
9. The patient's nurse or designee will call dialysis nurse for any clarification

Transfer to and from Radiation Oncology:

The Department of Radiation Oncology has developed a unit specific hand of care report. The purpose is to assist with assurance of patient safety with improving communication between the inpatient nursing units and the radiation oncology staff.

The form was modeled after the current hospital approved Adult Hand Off of Care Fax Report for Adults (form# GUH 18027400). It was individualized to capture the critical information pertinent to inpatients undergoing radiation treatments. Additionally, the form is organized in SBAR format.

The process for the form to be utilized is as follows:

1. Radiation transportation personnel will contact inpatient nurse by telephone at least 15 minutes prior to pick up time.
2. Inpatients coming to the department for the first time, the radiation oncology nurse will contact the inpatient nurse to get a verbal report on day one in order to identify any

special needs or potential problems ahead of time. The inpatient nurse will be asked to complete the process on a daily basis as outlined in #3 below.

3. Inpatient unit nurse will complete the Pre Daily Radiation side of the report prior to the patient leaving the unit. The report will be placed ON TOP of the inpatient chart.
4. When treatment complete with no changes in the patient status, the radiation therapist will fill out the Post Radiation side part "S" and part "R". A copy of the report will go ON TOP of the inpatient chart. Also, additional copy to go into the radiation chart under the nursing section.
5. For weekly on treatment visits (OTV) with the radiation oncologist, the radiation physician and/or nurse will complete the post daily radiation column "B" "A" and "R". A copy of the report will go ON TOP of the inpatient chart. Also, additional copy to go into the radiation chart under the nursing section.
6. For unexpected interventions, the radiation physician and/or nurse will complete the post daily radiation column "B" "A" and "R". A copy of the report will go ON TOP of the inpatient chart. Also, additional copy to go into the radiation chart under the nursing section.

Significant interventions requiring urgent communication to appropriate medical staff will take place by telephone along with written report.

Transfer from Inpatient Unit to Pre-Operative Care Unit (OR Holding or Surgery Center Pre-Op Area) or Procedural Area (Cath Lab, Endoscopy, Radiology)

1. Upon request by the receiving nurse, the sending nurse will complete the Pre-Operative/ Pre-Procedure Fax Report form and fax it to the appropriate pre-op or pre-procedure area.
2. Verbal confirmation of receipt of fax is obtained by the sending unit's nurse (or charge nurse) and then documented as such on the fax report sheet.
3. The receiving unit staff member confirming the receipt of fax report will ensure that the fax report is handed to the patient's nurse or designee.
4. Receiving unit nurse or designee will call sending unit for any clarification
5. If unable to fax report, a verbal report will be given to the receiving nurse using the completed fax report form as a guide. The form will then be placed in the patient's chart.
6. The sending unit's nurse will notify the receiving unit's nurse of any changes in patient condition/status or delays via telephone.
7. Upon physical transfer of patient care, the receiving nurse will counter-sign the original fax report form and place it in the patient's chart.

Transfer from the Emergency Department, Post Anesthesia Care Unit (PACU) or Procedure Recovery Unit to Inpatient Unit:

1. The sending nurse will complete either the Emergency Department Fax Report form or the Post-Operative/ Post-Procedure Fax Report form. The sending nurse will then fax the report to the receiving unit. Note: The ED will call report on patients transferring to either the ICU or to Pediatric units.
2. Verbal confirmation of receipt of fax is obtained by the sending unit's nurse (or charge nurse) and then documented as such on the fax report sheet.

3. The receiving unit staff member confirming the receipt of fax report will ensure that the fax report is handed to the patient's nurse or designee
4. Receiving unit nurse or designee will call sending area for any clarification (Refer to "Protected Time for Hand Off of Care Guidelines"). *Note that clarification may be done at the same time verbal confirmation of receipt of fax is obtained if the situation allows.*
5. If unable to fax report, a verbal report will be given to the receiving nurse using the completed fax report form as a guide. The form will then be placed in the patient's chart.
6. After the process of verification and clarification via interactive communication has occurred, the sending nurse will make every effort to transfer the patient within a timely manner-ideally *within 30 minutes-* (Refer to "Protected Time for Hand Off of Care Guidelines"). Transporting nurse will let a nurse know when the patient arrives on the unit.
7. The sending unit's nurse will notify the receiving unit's nurse of any changes in patient condition/status or delays via telephone.
8. Upon physical transfer of patient care, the receiving nurse will counter-sign the original fax report form and place it in the patient's chart.

Transfer from Inpatient to Inpatient Nursing Unit (Including Inpatient Boarders):

1. The sending nurse will complete the Nurse Hand Off of Care Fax Report for Adults and fax it to the receiving unit (if unable to fax report, a verbal report will be given to the receiving nurse).
2. The sending nurse will call the receiving unit and speak with the nurse accepting the patient. Another unit nurse can be substituted to either give or receive report as determined by the unit needs.
3. If deemed necessary, an oral report will be given on the patient. This is appropriate in any circumstance where additional information must be conveyed to the accepting nurse that is not included in the fax report.
4. If the faxed report is deemed a complete summation of patient information, important information on the faxed report will be reviewed via telephone, including issues for follow-up and a complete review of medications and orders.
5. The receiving nurse will be given adequate time for questions and an appropriate transfer time will be set (Refer to "Protected Time for Hand Off of Care Guidelines").
6. Upon physical transfer of patient care, the receiving nurse will counter-sign the original fax report form and place it in the patient's chart.

Hand Off of Care Guidelines

Subject: Protected Time for Hand Off

Purpose: To improve nurse to nurse communication upon hand off of care and enhance patient safety.

The following guidelines will be adhered to unless an emergency exists, the ORs are backed up, and/or the ED has a combination of 5 or more admission assignments and greater than 10 patients in the waiting room. If this exists, the ED, PACU or sending unit will call the CA to facilitate the need.

1. Admissions from ED or PACU to inpatient units, transfers from unit to unit, (excluding the ICUs), will not take place between 7 A/P and 7:30 A/P. This will enable the nurse assigned to that patient to receive report on his/her other patients. This protected time also covers admissions/transfers that require nurse to nurse direct report.
2. Admissions from ED or PACU to inpatient units, transfers from unit to unit, (excluding the ICUs), between the hours of 6:30 A/P and 7 A/P may occur only if the faxed report was received prior to 6:30 A/P and the process of verification and clarification via interactive communication has occurred prior to patient arriving in unit.
3. For successful implementation of this protected time, any verification and clarification needed regarding the report will be done by the receiving unit within 10 minutes from receipt of the fax report.
4. Placing a transport call should occur only after faxing of hand off form and the verification/clarification has occurred between the sending and receiving units.
5. To ensure that the above protected time is honored, and because of the average time it takes to transport patients, whenever a report is faxed after 6:30 A/P, it is the expectation that the patient will not arrive before 7:30 A/P.
6. For patients set to arrive after 7:30 A/P, it will be the receiving unit's responsibility to ensure that the fax report is handed to the oncoming nurse assigned to admit this patient and that this nurse calls the sending unit between 7 A/P and 7:05 A/P acknowledging receipt of fax and clarifying any uncertainty.
7. Bed assignments will not be withheld by bed placement at change of shift or any other times.

Exhibit 29

**Division of Nursing
Policy & Procedure**

Title: Admission, Transfer, and Discharge of a Patient

Procedure Number: 1

Issued: 2006

Revised/ Reviewed: 2008, 2009

I. Patient Admission

Steps of Procedure

1. Alert the house officer of the patient's arrival if necessary or begin to review orders written for the patient
2. Report will be called or faxed to the receiving nurse before the patient arrives on the floor
3. On arrival to the floor, the Unit Secretary or other staff member will greet the patient and introduce themselves. The admission chart will be received by the Unit Secretary. The patient will be taken to his or her assigned room
4. Verify that a Georgetown ID bracelet is in place and assist patient to change into hospital gown
5. If patient is not able to speak English or has severe hearing impairment, arrange for translation service
6. Obtain a set of baseline vital signs. Assess general appearance noting for signs and symptoms of physical distress
7. Orient patient and family to the hospital room
8. Explain the hospital routine and hospital/unit rules to the patient
9. Interview the patient or family to complete the nursing database within 24 hours of patient's arrival. Database should be completed regardless of date initiated
10. A contact person will be elected and provided with the patient's HIPPA code (The last four digits of the patient's medical record)
11. Conduct physical assessment
12. Complete the belongings sheet and have the patient/family sign the sheet to acknowledge responsibility for any belongings they wish to keep. Encourage family to take belongings home. Alert patients that belongings can be sent to security if they desire
13. Document admission note

II. Patient Transfer Between Different Medical Services

Steps of Procedure

1. Obtain and verify an order to transfer the patient to another medical service from the sending physician.
2. The receiving physician will write new transfer orders upon acceptance to the service.
3. Notify patient and family of the need for and purpose of transfer
4. Help patient to gather his or her belongings and obtain method of transferring patient
5. The licensed nurse will provide report to the receiving unit and ensure that the unit is ready for the patient. Refer to Nursing Standard #10 *Transfer of Care* and Hospital Policy #412 *Communication Between Caregivers*
6. The licensed nurse will ensure that transfer orders are present in the chart (when indicated) and the house officer is aware of patient's transfer
7. Assist the patient to the new unit and help settle him or her
8. The receiving and transfer staff will ensure that all of patient's belongings come with him or her and that the belongings sheet is completed
9. On arrival to a new unit, vital signs are taken, the patient is assessed, and orders are reviewed and carried out
10. Document transfer of care note

III. Patient Discharge

Steps of Procedure

1. From admission, assess patient's living situation and anticipate home health care needs. Maintain contact with the healthcare team including case management to be adequately prepared for discharge
2. On the day of discharge, verify the physician's order for discharge and the availability of appropriate discharge paperwork
3. If patient is going home, discuss with patient when transportation can be arranged. If patient is having ambulance transport to another facility, determine the time of this transportation
4. Provide discharge instructions to patient and family and allow adequate time for questions
5. Ensure that patient has all the proper prescriptions and belongings (obtain from security if necessary)
6. Remove peripheral access devices and any other devices as indicated
7. Assist patient to transporter's stretcher (if going by ambulance) or offer a wheelchair to the patient when transportation arrives
8. Document

Exhibit 30

CRITICAL SITUATION - NURSE TO A PHYSICIAN COMMUNICATION

Situation

I am calling about <patient name and location>.

The patient's code status is <code status>.

The problem I am calling about is _____.

I am concerned the patient is going to arrest.

I have assessed the patient:

Vital signs are: BP _____ / _____, Pulse _____, Respiration _____ and temperature _____

I am concerned about the:

BP because it is over 200 or less than 90 or 30 mmHg below usual

Pulse because it is over 140 or less than 40

Respirations because it is less than 5 over 40

Temperature because it is less than 96 or over 104

Background

The patient's mental status is:

Alert and oriented to person, place and time.

Confused and cooperative or non-cooperative

Agitated or combative

Lethargic but conversant and able to swallow

Stuporous and not talking clearly and possibly not able to swallow

Comatose. Eyes closed. Not responding to stimulation.

The skin is:

Warm and dry

Pale

Mottled

Diaphoretic

Extremities are cold or warm

The patient is not or is on oxygen.

The patient is on _____ (l/min) or (%) oxygen for _____ minutes (hours)

The oximeter is reading _____ %.

The oximeter does not detect a good pulse and is giving erratic readings.

Assessment

This is what I think the problem is: <say what you think is the problem>.

The problem seems to be cardiac infection neurologic respiratory.

I am not sure what the problem is, but the patient's condition is deteriorating.

The patient seems to be unstable and may get worse. We need to take action.

Recommendation

I suggest or request that you <say what you would like to see done>.

Transfer the patient to the ICU

Come to see the patient at this time

Talk to the patient or family about code status

Are any tests needed:

Do you need any tests like CXR, ABG, EKG, CBC, or BMP? Others?

If a change in treatment is ordered then ask:

How often do you want vital signs? How long do you think this problem will last?

If the patient does not get better, when do you want to be called again?

Exhibit 31



Georgetown
University
Hospital 

MedStar Health

Title:	Policy Number:
PATIENT REFERRAL/TRANSFER TO OTHER FACILITIES OR AGENCIES	156
Issued:	Page:
May 1, 1969	1 of 2
Last Reviewed:	Attachment:
July 28, 2009	
Last Revised:	
August 24, 2010	

POLICY:

It is the policy of Georgetown University Hospital that when a Hospital patient is referred to an outside health care facility or home health agency, appropriate clinical information is forwarded to the receiving agency or facility. All such transactions are done in accordance with HIPPA laws.

PROCEDURE:

- I. The physician will inform the appropriate case manager or social worker as soon as he/she determines that a patient is ready for transfer to another facility or outside agency.
- II. The case manager or social worker will discuss plans for disposition with patient and/or family and will consider the patient's stability, medical needs, and choice and reimbursement sources when reviewing options.
- III. As required by the accepting agency, a discharge summary should be dictated within 24 hours of expected discharge. This must be updated if there is a delay. Upon completion, the discharge summary should be placed in the chart. In situations where the actual discharge occurs in less than 24 hours a discharge summary should be dictated STAT with request for immediate transcription.
- IV. The social worker, case manager or registered nurse will review the medical record and identify any additional documents that need to be copied and sent with the patient. The documents sent will include the patient's History & Physical, summary of care provided, medication reconciliation, recent labs, chest x-ray, Physical Therapy/Occupational Therapy/Speech Therapy notes, and progress notes.
- V. All copies of documents are placed in a mailing envelope with:
 - A. A photocopy of the dictated discharge summary (the original remains in the patient's medical record).
 - B. A copy of the completed Patient Discharge Education and Information form.

VI. Transfer of the Patient


- A. The Case Management Department will arrange transportation when an ambulance or wheelchair van is required. The transportation company shall be notified that they are responsible for the care of the patient during transport.
- B. Nursing personnel are responsible for collecting the patient's personal effects prior to transfer and verifying that all paperwork is complete.
- C. At the request of the receiving facility, an oral nursing report will be given to the nurse at the receiving facility. Documentation of this report should be placed in the patient's record including the name and title of nurse the report was given to .
- D. As required, a non-emergency physician's certification statement for ambulance transport form will be completed by a case manager, discharge planner, nurse, physician, or nurse practitioner.

Richard L. Goldberg, M.D.

President

Exhibit 32



**Georgetown
University
Hospital** 

MedStar Health

Title:	Policy Number:
PATIENT AND FAMILY EDUCATION	201
Issued:	Page:
August 9, 1993	1 of 3
Last Reviewed:	Attachment:
July 28, 2009	
Last Revised:	
July 28, 2009	

POLICY:

It is the policy of Georgetown University Hospital that the patient and/or significant other be provided education to enhance the knowledge, skills, and behaviors necessary to benefit from the health care interventions provided throughout the Hospital.

PROCEDURE:

- I. Upon admission, the learning needs, abilities and readiness of each patient and/or significant other to learn are assessed and documented upon admission. Each healthcare provider or department involved with the patient contributes to this assessment. The assessment includes but is not limited to:
 - A. Cultural and religious practices
 - B. Emotional barriers
 - C. Desire and motivation to learn
 - D. Physical and cognitive limitations
 - E. Language barriers
 - F. Financial implications of care choices
 - G. Literacy and educational level
 - H. Knowledge and skills for health care
- II. Based on the assessment data, the learning needs of the patient are prioritized. Learning needs are prioritized according to:
 - A. Immediate needs such as the reason for hospitalization, clinic appointment or other health care encounter
 - B. Survival information or what the patient needs to know to go home safely
 - C. Information for well being, such as coping with financial aspects of illness or care of dependents during hospitalization

- D. Disease-specific information or individualized information about the disease (e.g. teaching of specialized diets)
- E. General information about disease or facts about the disease that apply to all patients (e.g. the need for a diabetic to have routine eye exams)
- III. Based on assessment data, each appropriate health care provider/department provides education that includes instruction in the specific knowledge and/or skills needed by the patient or significant other to meet the patient's on-going health care needs. Health care providers and departments involved in the education of each patient collaborate to ensure comprehensiveness, appropriateness, consistency and effectiveness of teaching.
- IV. Patient education is an interactive process eliciting feedback to ensure understanding, appropriateness, usefulness and practicality of information. Each individual who instructs the patient documents such teaching and the patient's response.
- V. The specific education includes but is not limited to:
 - A. Disease process
 - B. Safe and effective use of medication, if any
 - C. Safe and effective use of medical equipment, if any
 - D. Potential drug/food interactions and modified diets as appropriate
 - E. Rehabilitation techniques to help independent functioning
 - F. Resources in the community
 - G. When and how to obtain further treatment if needed
 - H. Personal hygiene and grooming
 - I. Patient and/or significant other responsibilities regarding ongoing health care needs
- VI. Patient and/or significant other responsibilities include:
 - A. Providing accurate and complete information
 - B. Asking questions when information is not understood
 - C. Following instructions
 - D. Accepting the consequences of not following instructions
 - E. Following Hospital rules and regulations
 - F. Acting with consideration and respect

- VII. Written discharge/treatment instructions are given to the patient and/or significant other. If another individual or organization is responsible for continuing care of the patient, written information about discharge/treatment instructions is provided to that caregiver.
- VIII. When a patient who is school aged is hospitalized, Medicine, Nursing, Social Work and Child Life monitor the length of stay. If it is determined that the length of stay is likely to interfere with a patient's academic education, Child Life will contact the parent or guardian to facilitate the provision of educational services.

Richard L. Goldberg, M.D.
President

Exhibit 33



Georgetown
University
Hospital



MedStar Health

Title: DISCHARGE PLANNING	Policy Number: 154
Issued: August 9, 1993	Page: 1 of 2
Last Reviewed: July 28, 2009	
Last Revised: November 5, 2009	Attachment: A

POLICY:

It is the policy of Georgetown University Hospital to provide, as an integral part of patient care, comprehensive discharge planning services to all patients in need of such services, and maintain compliance with the standards of appropriate regulatory agencies and accrediting bodies.

PROCEDURE:

- I. Discharge planning will be comprehensive, coordinated and multidisciplinary, with case specific input from individual members of the health care team. Assessment and identification of individuals requiring discharge planning should occur as soon after admission as appropriate to the patient's medical situation.
- II. **THE ROLE OF THE PROFESSIONALS INVOLVED IN THE DISCHARGE PLANNING PROCESS**
 - A. The **Attending Physician** oversees the medical care of the patient with the discharge planning activities carried out by the health care team. The physician establishes an appropriate discharge date and formulates a plan for medical follow-up including medically appropriate referrals and home care.
 - B. The **Case Manager** coordinates the discharge planning process and assists patient and families to determine a plan of care after hospitalization which utilizes appropriate and available community services for which they are eligible. The case manager identifies patients in need of discharge planning services through the following mechanisms:
 1. Multidisciplinary communication on inpatient units
 2. Physician and nursing referrals
 3. Patient self referral
 4. Referrals by Patient Accounts
 - C. The **Registered Nurse** identifies specific functional or psychosocial areas of need and collaborates with the case manager and the physician in the development of a plan to meet these needs. The nurse also provides support, education, and direction to the patient/family.

- D. **Other ancillary departments including Nutrition, Social Work, Rehabilitation Services and Respiratory Care** participate in the discharge planning process by providing case specific services to patients in conjunction with overall discharge planning and in accordance with their respective departmental policies and procedures.
- E. Documentation of the overall discharge plan, as well as all discharge planning activities by professionals, will be completed in the patient's medical record in accordance with respective departmental policy.


III. **ADULT PATIENTS REQUIRING HOMECARE**

- A. The Attending Physician will complete Discharge Orders for Adult Homecare (*Attachment A*) indicating the anticipated date of discharge, rationale for homebound status, and indicate Nursing orders, Order for an Aide, Order for a Medical Social Worker and/or Home Care Therapy Orders.
- B. The completed order is faxed to the Home Care Office at (202) 444-4521.
- C. After reviewing the orders, a Home Care staff member or Case Manager will meet with the patient to review available choices of home care providers.
- D. Once the patient chooses a home care provider the Home Care Office will arrange the care and provide a completed homecare discharge instruction sheet detailing the arrangements for the patient.

Richard L. Goldberg, M.D.
President

Exhibit 34



Georgetown
University
Hospital 

MedStar Health

Title:	Policy Number:
DISCHARGE OF PATIENTS	155
Issued:	Page:
May 1, 1969	1 of 2
Last Reviewed:	Attachment:
July 28, 2009	
Last Revised:	
May 15, 2001	

POLICY:

It is the policy of Georgetown University Hospital that the attending physician give as much notice as possible to ensure an 1100 hour discharge to facilitate patient comfort and convenience and to assist staff in carrying out comprehensive discharge planning tasks outlined in *Policy 154, Discharge Planning*.

PROCEDURE:

- I. The attending physician or designee will:
 - A. Document in the medical record the tentative discharge plan within 24 hours of admission or transfer.
 - B. Document the actual discharge plan and inform the patient/family at least 24 hours prior to discharge.
 - C. Write the discharge order by 1000 hours of the day of discharge, noting parameters if pending the results of blood work, diagnostic studies, diet toleration, etc.
 - D. Document the following in the medical record and on the Patient Discharge/Transfer form:
 1. Discharge Instructions (diet, medications, activity parameters, and follow-up appointments)
 2. Discharge Diagnoses
 - E. Authorize referrals to community agencies as necessary.
 - F. Complete and give to the patient/family all necessary prescriptions and paperwork by 1000 hours on the day of discharge.
 - G. In most circumstances, dictate a discharge summary within 24 hours of discharge to include discharge instructions given to the patient.

II. The nurse will:

- A. Initiate the Interdisciplinary Patient Education Form including anticipated discharge needs within 24 hours of admission.
- B. Ensure that all required instructions and paperwork are given to the patient/family or receiving facility by 1000 hours on the day of discharge:
 - 1. Clarify all follow-up appointments
 - 2. Ensure that patient receives needed prescriptions
- C. Ensure that the patient is escorted to a Hospital exit.

III. The case manager will:

- A. Document anticipated discharge needs regarding transport, home care, and disposition within 24 hours of admission and ongoing as needed.
- B. Complete final arrangements for transport, disposition and home care by 1000 hours on the day of discharge.

IV. The unit staff will:

- A. Enter the discharge information into SMS immediately upon discharge.
- B. Notify housekeeping personnel to prepare the room for the next admission.
- C. Prepare the patient record for pickup by Medical Records.

Richard L. Goldberg, M.D.
President

Related Policy: 154 Discharge Planning

Exhibit 35



Georgetown
University
Hospital
MedStar Health

MEDSTAR HEALTH VISITING NURSE ASSOCIATION

Discharge Orders for Adult HOMECARE

(10/8/09)

GUH17071700

Orders with a ☐ must be checked to be carried out. Information in brackets [] is informational only and not an order.

Anticipated date of discharge: _____

Reason for Homebound Status (check all that apply):

- ☐ Experience considerable effort when leaving the home and leaves home primarily to receive medical care.
- ☐ Requires the assistance from other person(s) and/or devices to leave the home for any amount of time.

Home Care Nursing Orders:

- ☐ Skilled Nursing [i.e. medication management; wound care – wound care orders must be specified]

☐ Telemonitoring

☐ Infusion Therapy

☐ IV medications (i.e. antibiotics)

Name and dosage: _____

Frequency and duration: _____

Type of line: _____ Location: _____ Date of Insertion: _____

☐ IV medications (i.e. antibiotics)

Name and dosage: _____

Frequency and duration: _____

Type of line: _____ Location: _____ Date of Insertion: _____

☐ TPN (requires completion of TPN Order Set GUH.180.120.00)

Start Date: _____

Type of line: _____ Location: _____ Date of Insertion: _____

☐ Tube Feeding (requires completion of Enteral Feeding Orders GUH.170.338.00)

Start Date: _____

Type of tube: ☐ PEG ☐ PEJ ☐ Other _____ Date of Insertion: _____

☐ Venipunctures: Specify labs and frequency _____

Results to be sent to: _____ Phone and fax # _____

☐ Home Health Aide for personal care

☐ Medical Social Worker for long-term planning/community resources

Home Care Therapy Orders:

☐ Physical Therapy ☐ Occupational Therapy ☐ Speech Therapy

☐ Durable Medical Equipment (specify type): _____

☐ Oxygen Therapy: _____

[most common qualification is arterial oxygen saturation on room air at or below 88% at rest]

☐ Other pertinent information for home care: _____

Attending Physician following patient after discharge: _____ Contact# _____

SIGNATURE/TITLE

PAGER NO.

TRANSCRIBING NURSE

DATE/TIME

Faxed to _____ at 202-444-4521 (fax)

Exhibit 36



MEDSTAR HEALTH, INC.

Consolidated Financial Statements

June 30, 2011 and 2010

(With Independent Auditors' Report Thereon)

MEDSTAR HEALTH, INC.

Table of Contents

	Page
Independent Auditors' Report	1
Consolidated Financial Statements:	
Consolidated Balance Sheets	2
Consolidated Statements of Operations and Changes in Net Assets	4
Consolidated Statements of Cash Flows	6
Notes to Consolidated Financial Statements	7



KPMG LLP
1 East Pratt Street
Baltimore, MD 21202-1128

Independent Auditors' Report

The Board of Directors
MedStar Health, Inc.:

We have audited the accompanying consolidated balance sheets of MedStar Health, Inc. (the Corporation) as of June 30, 2011 and 2010 and the related consolidated statements of operations and changes in net assets, and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Corporation's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Corporation's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of MedStar Health, Inc. as of June 30, 2011 and 2010, and the results of their operations and their cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

KPMG LLP

October 3, 2011

MEDSTAR HEALTH, INC.

Consolidated Balance Sheets

June 30, 2011 and 2010

(Dollars in millions)

Assets	2011	2010
Current assets:		
Cash and cash equivalents	\$ 498.6	509.6
Investments	18.0	16.8
Assets whose use is limited or restricted	36.7	40.8
Receivables:		
From patient services (less allowances for uncollectible accounts of \$238.6 in 2011 and \$211.0 in 2010)	515.5	438.1
Other	58.7	64.6
	574.2	502.7
Inventories	47.2	50.4
Prepays and other current assets	41.8	40.9
Total current assets	1,216.5	1,161.2
Investments	603.8	509.2
Assets whose use is limited or restricted	390.4	358.0
Property and equipment, net	1,031.8	1,023.4
Interest in net assets of foundation	49.2	41.1
Other assets	135.1	119.6
Total assets	\$ 3,426.8	3,212.5

MEDSTAR HEALTH, INC.

Consolidated Balance Sheets

June 30, 2011 and 2010

(Dollars in millions)

Liabilities and Net Assets	2011	2010
Current liabilities:		
Accounts payable and accrued expenses	\$ 282.0	284.2
Accrued salaries, benefits, and payroll taxes	233.6	204.6
Amounts due to third-party payors, net	45.4	42.0
Current portion of long-term debt	37.0	265.8
Current portion of self insurance liabilities	58.0	56.3
Other current liabilities	94.2	81.9
Total current liabilities	750.2	934.8
Long-term debt, net of current portion	1,007.5	795.8
Self insurance liabilities, net of current portion	196.6	190.9
Pension liabilities	307.9	401.3
Other long-term liabilities, net of current portion	129.3	125.4
Total liabilities	2,391.5	2,448.2
Net assets:		
Unrestricted net assets:		
MedStar Health, Inc.	904.4	643.9
Noncontrolling interests	7.8	9.4
Total unrestricted net assets	912.2	653.3
Temporarily restricted	85.4	74.0
Permanently restricted	37.7	37.0
Total net assets	1,035.3	764.3
Total liabilities and net assets	\$ 3,426.8	3,212.5

See accompanying notes to consolidated financial statements.

MEDSTAR HEALTH, INC.

Consolidated Statements of Operations and Changes in Net Assets

Years ended June 30, 2011 and 2010

(Dollars in millions)

	<u>2011</u>	<u>2010</u>
Operating revenues:		
Net patient service revenue:		
Hospital inpatient services	\$ 2,157.6	2,176.6
Hospital outpatient services	1,227.6	1,100.8
Physician services	205.7	175.5
Other patient service revenue	119.6	114.4
Total net patient service revenue	3,710.5	3,567.3
Premium revenue	118.7	102.0
Other operating revenue	182.5	186.1
Net operating revenues	4,011.7	3,855.4
Operating expenses:		
Personnel	2,057.1	1,988.7
Supplies	633.4	619.9
Purchased services	499.1	461.1
Other operating	360.8	354.7
Provision for bad debts	190.7	182.5
Interest expense	44.2	39.0
Depreciation and amortization	153.0	146.5
Total operating expenses	3,938.3	3,792.4
Earnings from operations	73.4	63.0
Nonoperating gains (losses):		
Investment income	28.5	21.3
Net realized gains on investments	9.1	0.7
Unrealized gain (loss) on derivative instruments	2.7	(4.1)
Unrealized gains on trading investments	89.4	60.9
Income tax benefit (provision)	0.5	(1.9)
Equity interest in net earnings of affiliates and other	8.6	5.7
Total nonoperating gains	138.8	82.6
Excess of revenue over expenses	\$ 212.2	145.6

See accompanying notes to consolidated financial statements.

MEDSTAR HEALTH, INC.

Consolidated Statements of Operations and Changes in Net Assets

Years ended June 30, 2011 and 2010

(Dollars in millions)

	<u>2011</u>	<u>2010</u>
Unrestricted net assets:		
Excess of revenue over expenses	\$ 212.2	145.6
Addition of St. Mary's net assets	—	72.2
Change in funded status of defined benefit plans	47.4	(121.3)
Distributions to noncontrolling interests	(5.7)	(2.4)
Change in unrealized gains on investments	—	0.1
Net assets released from restrictions used for purchase of property and equipment	5.0	7.6
Increase in unrestricted net assets	<u>258.9</u>	<u>101.8</u>
Temporarily restricted net assets:		
Addition of St. Mary's net assets	—	3.8
Contributions	11.3	8.5
Realized net gains on restricted investments	7.2	2.1
Change in unrealized gains on restricted investments	5.3	4.9
Net assets released from restrictions	(12.4)	(14.3)
Increase in temporarily restricted net assets	<u>11.4</u>	<u>5.0</u>
Permanently restricted net assets:		
Addition of St. Mary's net assets	—	0.1
Contributions	0.3	2.0
Realized net gains on marketable restricted investments	0.1	0.1
Change in unrealized gains on restricted investments	0.3	0.2
Increase in permanently restricted net assets	<u>0.7</u>	<u>2.4</u>
Increase in net assets	271.0	109.2
Net assets, beginning of year	<u>764.3</u>	<u>655.1</u>
Net assets, end of year	<u>\$ 1,035.3</u>	<u>764.3</u>

See accompanying notes to consolidated financial statements.

MEDSTAR HEALTH, INC.
Consolidated Statements of Cash Flows
Years ended June 30, 2011 and 2010
(Dollars in millions)

	<u>2011</u>	<u>2010</u>
Cash flows from operating activities:		
Change in net assets	\$ 271.0	109.2
Adjustments to reconcile change in net assets to net cash provided by operating activities:		
Net assets of St. Mary's Hospital	—	(76.1)
Depreciation and amortization	153.0	146.5
Amortization of bond financing costs and bond premiums	0.4	0.3
Loss on sale of property and equipment	0.3	0.3
Change in funded status of defined benefit plans	(47.4)	121.3
Realized net gains on marketable investments	(16.4)	(2.9)
Change in unrealized gains of marketable investments	(95.0)	(66.1)
Unrealized (gain) loss on derivative instruments	(2.7)	4.1
Net settlement payment on derivative instrument	4.2	4.4
Distributions to noncontrolling interests	5.7	2.4
Deferred income tax (benefit) provision	(1.4)	1.4
Provision for bad debts	190.7	182.5
Temporarily and permanently restricted contributions	(11.6)	(10.5)
Changes in operating assets and liabilities:		
Receivables	(262.2)	(244.0)
Inventories and other assets	(3.6)	(5.8)
Accounts payable and accrued expenses	30.3	27.5
Amounts due to third-party payors	3.4	(1.8)
Other liabilities	(23.3)	39.2
Net cash provided by operations	<u>195.4</u>	<u>231.9</u>
Cash flows from investing activities:		
Cash from acquisition of St. Mary's Hospital	—	20.9
Purchases of investments and assets whose use is limited or restricted, net	(20.8)	(47.6)
Net settlement payment on derivative instrument	(4.2)	(4.4)
Purchases of property and equipment and other	(170.2)	(203.6)
Net cash used in investing activities	<u>(195.2)</u>	<u>(234.7)</u>
Cash flows from financing activities:		
Repayment of long-term borrowings	(17.1)	(56.4)
Temporarily and permanently restricted contributions	11.6	10.5
Distributions to noncontrolling interests	(5.7)	(2.4)
Net cash used in financing activities	<u>(11.2)</u>	<u>(48.3)</u>
Decrease in cash and cash equivalents	(11.0)	(51.1)
Cash and cash equivalents at beginning of year	509.6	560.7
Cash and cash equivalents at end of year	<u>\$ 498.6</u>	<u>509.6</u>
Supplemental disclosure of cash flow information:		
Interest paid	\$ 45.5	44.8
Noncash investing and financing activities:		
Accounts payable for fixed asset purchases	\$ 5.4	7.4

See accompanying notes to consolidated financial statements.

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

(1) Description of Organization and Summary of Significant Accounting Policies

(a) Organization

MedStar Health, Inc. (the Corporation) is a tax-exempt, Maryland membership corporation which, through its controlled entities and other affiliates, provides and manages healthcare services in the region encompassing Maryland, Washington D.C. and Northern Virginia. The Corporation became operational on June 30, 1998 by the transfer of the membership interests of Helix Health, Inc. (Helix – a not-for-profit Maryland Corporation) and Medlantic Healthcare Group, Inc. (Medlantic – a not-for-profit Delaware Corporation) in exchange for the guarantee of the debt of both Helix and Medlantic by the Corporation. The principal tax-exempt and taxable entities of the Corporation are:

Tax-Exempt

- Bay Development Corporation
- Church Home and Hospital of the City of Baltimore, Inc.
- Franklin Square Hospital Center, Inc.
- Harbor Hospital, Inc.
- HH MedStar Health, Inc.
- MedStar-Georgetown Medical Center, Inc.
- MedStar Health Research Institute, Inc.
- MedStar Health Visiting Nurse Association, Inc.
- MedStar Surgery Center, Inc.
- Montgomery General Hospital, Inc.
- National Rehabilitation Hospital, Inc.
- The Good Samaritan Hospital of Maryland, Inc.
- The Union Memorial Hospital
- St. Mary's Hospital of St. Mary's County, Inc.
- Washington Hospital Center Corporation

Taxable

- Greenspring Financial Insurance, LTD.
- MedStar Enterprises, Inc. and Subsidiaries
- MedStar Physician Partners, Inc.
- Parkway Ventures, Inc. and Subsidiaries

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

(b) *Changes in Organizational Structure*

On September 30, 2009, the Corporation and St. Mary's Hospital of St. Mary's County, Inc. and Subsidiaries (St. Mary's Hospital) closed on an affiliation transaction that substituted the Corporation as sole member of St. Mary's Hospital. St. Mary's Hospital includes a 103-bed acute care hospital located in Leonardtown, Maryland, in St. Mary's County.

The Corporation's affiliation with St. Mary's Hospital was accounted for as an "as-if pooling of interests" in accordance with U.S. generally accepted accounting principles. Accordingly, the assets and liabilities of St. Mary's Hospital and its subsidiaries were recorded at their carrying values. The financial position and results of operations of St. Mary's Hospital are included in the accompanying consolidated financial statements for the period beginning on or after July 1, 2009. Net assets increased by \$76.1 on July 1, 2009 due to the affiliation.

(c) *Basis of Presentation*

The consolidated financial statements are prepared on the accrual basis of accounting in accordance with U.S. generally accepted accounting principles. All majority owned and direct member entities are consolidated. All entities where the Corporation exercises significant influence but for which it does not have control are accounted for under the equity method. All other entities are accounted for under the cost method. All significant intercompany accounts and transactions have been eliminated.

(d) *Use of Estimates*

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

(e) *Cash Equivalents*

All highly liquid investments with a maturity date of three months or less when purchased are considered to be cash equivalents.

(f) *Investments and Assets whose use is Limited or Restricted*

The Corporation's investment portfolio is considered trading and is classified as current or noncurrent assets based on management's intention as to use. All debt and equity securities are reported at fair value principally based on quoted market prices on the consolidated balance sheets.

The Corporation has investments which under U.S. generally accepted accounting principles are considered alternative investments, including commingled equity funds totaling \$95.2 and \$32.4 at June 30, 2011 and 2010, respectively; inflation hedging equity, commodity, and fixed income funds totaling \$64.9 and \$35.5 at June 30, 2011 and 2010, respectively, and hedge fund of funds and private equity totaling \$108.4 and \$91.4 at June 30, 2011 and 2010, respectively. These funds utilize

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

various types of debt and equity securities and derivative instruments in their investment strategies. Alternative investments are recorded under the equity method.

Investments in unconsolidated affiliates are accounted for under the cost or equity method of accounting, as appropriate and are included in other assets in the consolidated balance sheets. The Corporation utilizes the equity method of accounting for its investments in entities over which it exercises significant influence. The Corporation's equity income or loss is recognized in nonoperating gains (losses).

Investments limited as to use or restricted include assets held by trustees under bond indenture, self-insurance trust arrangements, assets restricted by donor, and assets designated by the Board of Directors for future capital improvements and other purposes over which it retains control and may, at its discretion, use for other purposes. Amounts from these funds required to meet current liabilities have been classified in the consolidated balance sheets as current assets. Purchases and sales of securities are recorded on a trade-date basis.

Investment income (interest and dividends) including realized gains and losses on investment sales are reported as nonoperating gains or losses in the excess of revenues over expenses in the accompanying consolidated statements of operations and changes in net assets unless the income or loss is restricted by the donor or law. Investment income on funds held in trust for self-insurance purposes is included in other operating revenue. Investment income and net gains (losses) that are restricted by the donor are recorded as a component of changes in temporarily or permanently restricted net assets, in accordance with donor imposed restrictions. Realized gains and losses are determined based on the specific security's original purchase price or adjusted cost if the investment was previously determined to be other-than-temporarily impaired. Unrealized gains and losses are included in nonoperating gains (losses) within the excess of revenue over expenses.

(g) *Inventories*

Inventories, which primarily consist of medical supplies and pharmaceuticals at many of the operating entities, are stated at the lower of cost or market, with cost being determined primarily under the average cost or first-in, first-out methods.

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

(h) Property and Equipment

Property and equipment acquisitions are recorded at cost and are depreciated or amortized over the estimated useful lives of the assets. Estimated useful lives range from three to forty years. Amortization of assets held under capital leases are computed using the shorter of the lease term or the estimated useful life of the leased asset and is included in depreciation and amortization expense. Interest cost incurred on borrowed funds during the period of construction of capital assets is capitalized as a component of the cost of acquiring those assets. Interest expense capitalized totaled \$1.3 and \$7.0 for 2011 and 2010, respectively, which was offset by investment earnings of \$0.1 and \$1.2, respectively. Depreciation is computed on a straight-line basis. Major classes and estimated useful lives of property and equipment are as follows:

Leasehold improvements	Lease term
Buildings and improvements	10 – 40 years
Equipment	3 – 20 years

Gifts of long-lived assets such as land, buildings, or equipment are reported as unrestricted support, and are excluded from the excess of revenues over expenses, unless explicit donor stipulations specify how the donated assets must be used. Gifts of long-lived assets with explicit restrictions that specify how the assets are to be used and gifts of cash or other assets that must be used to acquire long-lived assets are reported as restricted support. Absent explicit donor stipulations about how long those long-lived assets must be maintained, expirations of donor restrictions are reported when the donated or acquired long-lived assets are placed in service.

(i) Interest in Net Assets of Foundation

The Corporation recognizes its rights to assets held by recipient organizations, which accept cash or other financial assets from a donor and agree to use those assets on behalf of or transfer those assets, the return on investment of those assets, or both, to the Corporation. Changes in the Corporation's economic interests in these financially interrelated organizations are recognized in the consolidated statements of operations and changes in net assets as a component of changes in temporarily restricted net assets.

(j) Internal-Use Software

The Corporation capitalizes the direct costs, including internal personnel costs, associated with the implementation of new information systems for internal use. The Corporation capitalized \$1.1 and \$1.6 during the years ended June 30, 2011 and 2010, respectively. Capitalized amounts are amortized over the estimated lives of the software, generally three to five years.

(k) Financing Costs

Financing costs incurred in issuing bonds have been capitalized and included in other assets. These costs are being amortized over the estimated duration of the related debt using the effective interest method. Accumulated amortization totaled \$4.6 and \$4.2 at June 30, 2011 and 2010, respectively.

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

(l) *Estimated Professional Liability Costs*

The provision for estimated self-insured professional liability claims includes estimates of the ultimate costs for both reported claims and claims incurred but not reported. These estimates are based on actuarial analysis of historical trends, claims asserted and reported incidents.

(m) *Leases*

Lease arrangements, including assets under construction, are capitalized when such leases convey substantially all the risks and benefits incidental to ownership. Capital leases are amortized over either the lease term or the life of the related assets, depending upon available purchase options and lease renewal features. Amortization related to capital leases is included in the statements of operations within depreciation and amortization expense.

(n) *Derivatives*

The Corporation utilizes derivative financial instruments to manage its interest rate risks associated with tax-exempt debt. The Corporation does not hold or issue derivative financial instruments for trading purposes. The derivative instruments are recorded on the balance sheet at their respective fair values. The Corporation's current derivative investments do not qualify for hedge accounting; therefore, the changes in fair value have been recognized in the accompanying consolidated statements of operations and changes in net assets as mark-to-market adjustments. The fair market value of the derivative instruments are included in other long-term liabilities in the accompanying consolidated balance sheets.

(o) *Net Patient Service Revenue*

Net patient service revenue is reported at the estimated net realizable amounts from patients, third-party payors, and others for services rendered, including estimated retroactive adjustments due to future audits, reviews and investigations. The differences between the estimated and actual amounts are recorded as part of net patient service revenue in future periods as the amounts become known, or as years are no longer subject to audit, review or investigation. Payment arrangements include prospectively determined rates per discharge, fee-for-service, discounted charges, and per diem payments. Hospital inpatient services, hospital outpatient services, the physician component of physician/managed care networks, and other patient services consists of revenue, which is recognized when the services are rendered based on billable charges. Other patient service revenue primarily consists of home care, long-term care and other nonhospital patient services.

Premium revenue consists of amounts received from the State of Maryland by the Corporation's managed care organization for providing medical services to subscribing participants, regardless of services actually performed. The managed care organization provides services primarily to enrolled Medicaid beneficiaries. This revenue is recognized ratably over the contractual period for the provision of services. Medical expenses of the managed care organization include a provision for incurred but unreported claims.

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

(p) Charity Care

The Corporation provides care to patients who meet certain criteria under its charity care policies without charge or at amounts less than established rates. Because the Corporation does not pursue collection of amounts determined to qualify as charity care, they are not reported as revenue.

(q) Grants

Federal grants are accounted for as either an exchange transaction or as a contribution based on terms and conditions of the grant. If the grant is accounted for as an exchange transaction, revenue is recognized as other operating revenue when earned. If the grant is accounted for as a contribution, the revenues are recognized as either other operating revenue, or as temporarily restricted contributions depending on the restrictions within the grant.

(r) Contributions

Unconditional promises to give cash and other assets to the Corporation are reported at fair value at the date the promise is received. Conditional promises to give and indications of intentions to give are reported at fair value at the date the gift is received. The gifts are reported as either temporarily or permanently restricted support if they are received with donor stipulations that limit the use of the donated assets. When a donor restriction expires, that is, when a stipulated time restriction ends or purpose restriction is accomplished, temporarily restricted net assets are reclassified as unrestricted net assets and reported in the consolidated statement of operations as net assets released from restrictions in other operating revenue. Donor-restricted contributions whose restrictions are met within the same year as received are reported as unrestricted contributions in the accompanying consolidated financial statements.

(s) Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that includes the enactment date. Any changes to the valuation allowance on the deferred tax asset are reflected in the year of the change. The Corporation accounts for uncertain tax positions in accordance with the FASB Accounting Standards Codification (ASC) Topic 740, *Income Taxes*.

(t) Excess of Revenue over Expenses

The consolidated statements of operations and changes in net assets includes a performance indicator, which is the excess of revenue over expenses. Changes in unrestricted net assets that are excluded from excess of revenue over expenses, include unrealized gains and losses on investments classified as other-than-trading securities, contributions of long-lived assets (including assets acquired using contributions that by donor restriction were to be used for the purpose of acquiring

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

such assets), certain changes in accounting principle and defined benefit obligations in excess of recognized pension cost, among others.

(u) Temporarily and Permanently Restricted Net Assets

Temporarily restricted net assets are those whose use by the Corporation or individual operating units has been limited by donors to a specific time period or purpose. Permanently restricted net assets have been restricted by donors to be maintained by the Corporation or individual operating units in perpetuity.

(v) Fair Value of Financial Instruments

The following methods and assumptions were used to estimate the fair value of financial instruments:

Cash and cash equivalents, receivables, other current assets, other assets, current liabilities and long-term liabilities: The carrying amount reported in the consolidated balance sheets for each of these assets and liabilities approximates their fair value.

The fair value of investments, assets whose use is limited or restricted and the interest rate swap is discussed in note 3. The fair value of long term debt is discussed in note 6.

(w) Reclassifications

Certain prior year amounts have been reclassified to conform with current period presentation, the effect of which is not material.

(x) New Accounting Pronouncements

In July 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2011-07, *Health Care Entities (Topic 954), Presentation and Disclosure of Patient Service Revenue, Provision for Bad Debts, and the Allowance for Doubtful Accounts for Certain Health Care Entities (ASU 2011-07)*, which requires a health care entity to change the presentation of their statement of operations by reclassifying the provision for bad debts associated with patient service revenue from an operating expense to a deduction from patient service revenue (net of contractual allowances and discounts). Additionally, enhanced disclosures about an entity's policies for recognizing revenue, assessing bad debts, as well as qualitative and quantitative information about changes in the allowance for doubtful accounts are required. The adoption of ASU 2011-07 is effective for the Corporation beginning July 1, 2012.

In August 2010, the FASB issued ASU No. 2010-24, *Health Care Entities (Topic 954), Presentation of Insurance Claims and Related Insurance Recoveries (ASU 2010-24)*, which clarified that a health care entity should not net insurance recoveries against a related claim liability. Additionally, the amount of the claim liability should be determined without consideration of insurance recoveries. The adoption of ASU 2010-24 is effective beginning July 1, 2011 and is not expected to have an impact on the Corporation's consolidated financial statements.

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

In August 2010, the FASB issued ASU No. 2010-23, *Health Care Entities (Topic 954), Measuring Charity Care for Disclosure*. ASU 2010-23 is intended to reduce the diversity in practice regarding the measurement basis used in the disclosure of charity care. ASU 2010-23 requires that cost be used as the measurement basis for charity care disclosure purposes and that cost be identified as the direct and indirect cost of providing the charity care, and requires disclosure of the method used to identify or determine such costs. The adoption of ASU 2010-23 is effective for the Corporation beginning July 1, 2011.

In January 2010, FASB issued ASU No. 2010-07, *Not-for-Profit Entities (Topic 958), Not-for-Profit Entities: Mergers and Acquisition (ASU 2010-07)*, which codified previous guidance on accounting for a combination of not-for-profit entities and applies to a combination that meets the definition of either a merger of not-for-profit entities or an acquisition by a not-for-profit entity. ASU 2010-07 also amends previous guidance for the reporting of goodwill and other intangibles and noncontrolling interests in consolidated financial statements to make their provisions fully applicable to not-for-profit entities. This guidance establishes that goodwill be tested annually for impairment and an impairment loss be recognized if it is determined that the carrying amount of the reporting unit's net assets exceeds its fair value. Beginning on July 1, 2010, the Corporation applied the transition provisions of the guidance which requires the Corporation to cease amortization of previously recognized goodwill and to test goodwill for impairment annually or more frequently if events or circumstances indicate that the carrying value of an asset may not be recoverable. The Corporation completed a transitional and annual goodwill impairment test. No adjustments to the carrying value of previously recognized goodwill were recorded during the year ended June 30, 2011. The guidance also requires the presentation of noncontrolling interests in the net assets of consolidated subsidiaries be reported as a separate component of the appropriate class of net assets in the consolidated balance sheets and the amount of consolidated excess of revenues over expenses attributable to the Corporation and to the noncontrolling interest be disclosed. The provisions of the standard related to the presentation and disclosure of noncontrolling interests are to be applied retrospectively to all periods presented. The adoption of this standard did not have a material impact on the Corporation's consolidated financial statements, except the following:

- (a) Noncontrolling interests of \$8.2 as of July 1, 2009 were reclassified from other long-term liabilities to unrestricted net assets, separate from the Corporation's unrestricted net assets.
- (b) Consolidated excess of revenues over expenses includes excess of revenues over expenses attributable to both the Corporation and noncontrolling interests.

In January 2010, the FASB issued ASU 2010-06, *Improving Disclosures about Fair Value Measurements*. ASU 2010-06 amends ASC Topic 820, *Fair Value Measurements and Disclosures*, to require a number of additional disclosures regarding fair value measurements. Effective fiscal year 2010, ASU 2010-06 required disclosure of the amounts of significant transfers between Level I and Level II investments and the reasons for such transfers, the reasons for any transfers in or out of Level III investments and disclosure of the policy for determining when transfers among levels are recognized. ASU 2010-06 also clarified that disclosures should be provided for each class of assets and liabilities and clarified the requirement to disclose information about the valuation techniques

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

and inputs used in estimating Level II and Level III measurements. Effective in fiscal year 2011, ASU 2010-06 also requires that information in the reconciliation of recurring Level III measurements about purchases, sales, issuances and settlements be provided on a gross basis. The adoption of ASU 2010-06 only required additional disclosures and did not have an impact on the consolidated financial statements. As the Corporation does not have significant transfers between Levels, or any Level III measurements, no additional disclosures were necessary.

(2) Investments and Assets Whose Use Is Limited or Restricted

Investments and assets whose use is limited or restricted as of June 30, 2011 and 2010, at fair value or under the equity method of accounting in the case of alternative investments, consist of the following:

	2011	2010
Collateralized guaranteed investment contract and cash	\$ 77.1	119.8
Fixed income securities and funds	314.3	377.3
Equity securities	389.0	268.4
Alternative investments:		
Commingled equity funds	95.2	32.4
Inflation hedging equity, commodity, fixed income fund	64.9	35.5
Hedge fund of funds and private equity	108.4	91.4
Total investments and assets whose use is limited or restricted	1,048.9	924.8
Less short-term investments and assets whose use is limited or restricted	(54.7)	(57.6)
Long-term investments and assets whose use is limited or restricted	\$ 994.2	867.2

Assets whose use is limited or restricted as of June 30, 2011 and 2010, included in the table above, consist of the following:

	2011	2010
Funds held by trustees	\$ 17.0	31.1
Self-insurance funds	163.1	145.1
Funds restricted by donors for specific purposes and endowment	63.8	58.1
Funds designated by Board and Management	183.2	164.5
	427.1	398.8
Less assets required for current obligations	(36.7)	(40.8)
	\$ 390.4	358.0

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

Investment income and realized and unrealized gains for assets whose use is limited, cash equivalents and investments are comprised of the following for the years ending June 30, 2011 and 2010:

	2011	2010
Other operating revenue:		
Investment income	\$ 6.5	2.4
Nonoperating gains:		
Interest income and dividends	28.5	21.3
Net realized gains on sale of investments	9.1	0.7
Unrealized gains on trading investments	89.4	60.9
	<u>127.0</u>	<u>82.9</u>
Other changes in net assets:		
Changes in unrealized gains on other-than-trading investments	—	0.1
Realized net gains on temporarily and permanently restricted net assets	7.3	2.2
Changes in unrealized gains on temporarily and permanently restricted net assets	5.6	5.1
Total investment return	\$ <u>146.4</u>	<u>92.7</u>

(3) Fair Value of Financial Instruments

The Corporation adopted ASC Topic 820, *Fair Value Measurements and Disclosures* on July 1, 2008. The guidance provides for the following:

- Defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, and establishes a framework for measuring fair value;
- Establishes a three-level hierarchy for fair value measurement;
- Requires consideration of the Corporation's nonperformance risk when valuing liabilities; and
- Expands disclosures about instruments measured at fair value.

The three-level valuation hierarchy for fair value measurements is based upon observable and unobservable inputs. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect the Corporation's market assumptions. The three level valuation hierarchy is defined as follows:

- Level 1 – Quoted prices for identical instruments in active markets;
- Level 2 – Quoted prices for similar instruments in active markets; quoted prices for identical or similar investments in markets that are not active; and model derived valuations whose significant inputs are observable; and

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

- Level 3 – Instruments whose significant inputs are unobservable.

The Corporation has incorporated an Investment Policy Statement (IPS) into the investment program. The IPS, which has been formally adopted by the Corporation's Board of Directors, contains numerous standards designed to ensure adequate diversification by asset class and geography. The IPS also limits all investments by manager and position size, and limits fixed income position size based on credit ratings, which serves to further mitigate the risks associated with the investment program. At June 30, 2011 and 2010, management believes that all investments were being managed in a manner consistent with the IPS.

The table below presents the Corporation's investable assets and liabilities as of June 30, 2011, aggregated by the three level valuation hierarchy:

		<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
Assets:					
Cash and cash equivalents	\$	575.7	—	—	575.7
U.S. treasury bonds		55.3	—	—	55.3
U.S. agency mortgage backed securities		75.9	—	—	75.9
Corporate bonds		—	73.9	—	73.9
Fixed income mutual funds		1.0	70.4	—	71.4
All other fixed income securities		—	37.8	—	37.8
Equity mutual funds & ETF's		106.4	—	—	106.4
Common stocks		282.6	—	—	282.6
Total assets	\$	<u>1,096.9</u>	<u>182.1</u>	<u>—</u>	<u>1,279.0</u>
Liabilities:					
Interest rate swap	\$	<u>—</u>	<u>15.4</u>	<u>—</u>	<u>15.4</u>
Total liabilities	\$	<u>—</u>	<u>15.4</u>	<u>—</u>	<u>15.4</u>

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

The table below presents the Corporation's investable assets and liabilities as of June 30, 2010, aggregated by the three level valuation hierarchy:

	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
Assets:				
Cash and cash equivalents	\$ 629.4	—	—	629.4
U.S. treasury bonds	53.0	—	—	53.0
U.S. agency mortgage backed securities	101.5	—	—	101.5
Corporate bonds	—	58.9	—	58.9
Fixed income mutual funds	1.1	121.2	—	122.3
All other fixed income securities	—	41.6	—	41.6
Equity mutual funds & ETF's	77.7	—	—	77.7
Common stocks	190.7	—	—	190.7
Total assets	<u>\$ 1,053.4</u>	<u>221.7</u>	<u>—</u>	<u>1,275.1</u>
Liabilities:				
Interest rate swap	\$ —	18.1	—	18.1
Total liabilities	<u>\$ —</u>	<u>18.1</u>	<u>—</u>	<u>18.1</u>

See note 1(f) for information on investments of the Corporation which are treated under the equity method and not reported above.

For the years ended June 30, 2011 and 2010, there were no significant transfers into or out of Levels 1, 2 or 3.

(4) Property and Equipment

Property and equipment as of June 30, 2011 and 2010 is as follows:

	<u>2011</u>	<u>2010</u>
Land	\$ 60.8	51.7
Buildings and improvements	1,131.9	1,042.6
Equipment	1,464.1	1,351.7
Equipment under capital leases	1.5	1.5
	<u>2,658.3</u>	<u>2,447.5</u>
Less accumulated depreciation and amortization	<u>(1,689.5)</u>	<u>(1,594.4)</u>
	968.8	853.1
Construction-in-progress	63.0	170.3
	<u>\$ 1,031.8</u>	<u>1,023.4</u>

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

Construction-in-progress includes a variety of ongoing capital projects at the Corporation as of June 30, 2011 and 2010. In connection with the Franklin Square Hospital project (see note 6), the Corporation has unspent commitments of \$1.6 and \$23.5 as of June 30, 2011 and 2010, respectively. Depreciation and amortization expense related to property and equipment amounted to \$152.8 and \$146.4 for the years ended June 30, 2011 and 2010, respectively.

(5) Other Assets

Other assets as of June 30, 2011 and 2010 consist of the following:

	<u>2011</u>	<u>2010</u>
Deferred financing costs, net	\$ 13.3	13.8
Investments in unconsolidated entities	16.0	16.1
Reinsurance receivables	37.6	28.5
Goodwill, net	7.6	7.2
Deferred tax asset	21.4	21.1
Other assets	39.2	32.9
	<u>\$ 135.1</u>	<u>119.6</u>

The Corporation has investments in other healthcare related organizations that are accounted for under the equity method that total \$16.0 and \$16.1 at June 30, 2011 and 2010, respectively. Under the equity method, original investments are recorded at cost and adjusted by the Corporation's share of the undistributed earnings or losses of these organizations. The related ownership interest in these organizations ranges from 8% to 50%. The Corporation's share of earnings in these organizations was \$5.5 and \$3.9 for the years ended June 30, 2011 and 2010, respectively. Certain other nonconsolidated entities are recorded under the cost method.

Goodwill represents the excess of the cost to acquire businesses over the estimated fair market value of the net tangible and identifiable intangible assets acquired. The Corporation recognized amortization expense of \$0.2 and \$0.1 for the years ended June 30, 2011 and 2010, respectively, related to identifiable intangible assets. In accordance with guidance issued by FASB, the Corporation annually evaluates goodwill for impairment based upon a earnings multiple factor and operating income for each reporting unit. At July 1, 2010 and June 30, 2011, the Corporation had one reporting unit, which included all subsidiaries of the Corporation. No impairment was recognized for the years ended June 30, 2011 or 2010.

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

(6) Debt

At June 30, 2011 and 2010, the Corporation's outstanding borrowings include the following:

	<u>2011</u>	<u>2010</u>
Maryland Health and Higher Educational Facilities		
Authority Revenue Bonds:		
4.25% – 5.75% Serial bonds (Series 2004, due 2009 – 2025)	\$ 33.5	37.1
5.375% Term bonds (Series 2004, due 2024)	49.7	49.7
5.50% Term bonds (Series 2004, due 2033)	80.1	80.1
4.25% – 5.25% Serial bonds (Series 1998A, due 2009 – 2013)	8.8	12.8
4.75% – 5.25% Term bonds (Series 1998A, due 2019, 2029, and 2039)	146.2	146.2
4.00% – 5.25% Serial bonds (Series 1998B, due 2007 – 2008 and 2014 – 2016)	14.8	14.8
4.75% – 5.25% Term bonds (Series 1998B, due 2029 and 2039)	88.5	88.5
4.75% – 5.25% Term bonds (Series 2007, due 2042 and 2046)	145.0	145.0
0.08% – 0.40% St. Mary's Hospital Variable Rate bonds (Series 2009, due 2010 – 2039)	15.5	15.8
Plus unamortized net premium	5.8	6.0
	<u>587.9</u>	<u>596.0</u>
District of Columbia Hospital Revenue Bonds:		
Multimodal Revenue bonds:		
0.04% – 0.15% at June 30, 2011 Serial bonds (Series 1998A due 2008-2039) (and 0.14% – 0.30% at June 30, 2010)	134.4	137.0
2.75% – 5.00% Serial bonds (Series 1998B, due 2008 – 2020)	13.5	14.7
5.00% Term bonds (Series 1998B, due 2029 and 2039)	54.1	54.1
2.75% – 5.00% Serial bonds (Series 1998C, due 2008 – 2020)	13.5	14.8
5.00% – 5.50% Term bonds (Series 1998C, due 2029 and 2039)	54.1	54.1
Less unamortized net discount	(1.0)	(1.0)
	<u>268.6</u>	<u>273.7</u>

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

	<u>2011</u>	<u>2010</u>
County Commissioners of St. Mary's County General Obligation Hospital Bonds of 2002: (Rates ranging between 3.58% – 3.78% due, 2005 – 2022)	\$ 15.0	16.0
St. Mary's Hospital notes payable and other	4.0	5.1
Other:		
Notes payable to financial institutions or State Agencies under mortgages (floating rates ranging between 0.5% – 8.2%) and other	14.0	15.8
Line of credit due November 2013 (0.25% – 0.90% at June 30, 2011 and 0.03% – 0.92% at June 30, 2010)	<u>155.0</u>	<u>155.0</u>
	<u>188.0</u>	<u>191.9</u>
Total debt	1,044.5	1,061.6
Less current portion of long-term debt	<u>(37.0)</u>	<u>(265.8)</u>
Long-term debt, net	<u>\$ 1,007.5</u>	<u>795.8</u>

Scheduled maturities on borrowings, for the next five fiscal years and thereafter are as follows:

2012	\$ 37.0
2013	17.5
2014	172.9
2015	17.3
2016	18.1
Thereafter	<u>776.9</u>
Total	<u>\$ 1,039.7</u>

The fair value of outstanding tax exempt publicly traded bonds is estimated to be \$865.4 and \$900.8 as of June 30, 2011 and 2010, respectively. The fair value of other long-term debt approximates its carrying value.

In December 1998, the Maryland Health and Higher Education Facilities Authority (MHHEFA) and the District of Columbia (District) issued bonds (Series 1998 Bonds) on behalf of the Corporation. Bond proceeds of approximately \$588.6 were loaned to the Corporation under separate loan agreements with MHHEFA and the District upon execution of obligations pursuant to the Master Trust Indenture. The District issued \$300.0 of Multimodal Revenue Bonds, including \$150.0 Series 1998A (\$18.3 repaid through August 2011), \$75.0 Series 1998B (\$8.6 repaid through August 2011), and \$75.0 Series 1998C (\$8.6 repaid through August 2011).

The Series 1998A bonds, which consist of three tranches totaling \$131.7 at August 2011, were converted to Variable Rate Demand Obligations backed by bank letters of credit in May 2008 and the municipal bond

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

insurance policy was terminated. The Series 1998A Tranche I bonds which remained outstanding in August 2011 consisted of approximately \$43.9 bonds trading in a daily mode backed by a letter of credit issued by Wells Fargo Bank, National Association (formerly Wachovia Bank, National Association) and remarketed by J.P. Morgan Securities Inc. The letter of credit was renewed in fiscal 2011 and now expires in May 2014. In the event of a failed remarketing, the Tranche I bonds would be tendered to the bank and repaid over a four-year period, beginning 367 days following the date of the failed remarketing. The Series 1998A Tranche II bonds totaled \$43.9 in August 2011. These bonds trade in a weekly mode backed by a letter of credit issued by Bank of America, N.A. and remarketed by Citigroup Global Markets Inc. The term of the letter of credit was renewed in fiscal 2011 and now expires in May 2014. In the event of a failed remarketing, the Tranche II bonds would be tendered to the bank and repaid over a five-year period, beginning 367 days following the failed remarketing. The Series 1998A Tranche III bonds totaled \$43.9 in August 2011. These bonds trade in a weekly mode backed by a letter of credit issued by Bank of America, N.A. and remarketed by Citigroup Global Markets Inc. The term of the letter of credit is five years, expiring in May 2013. In the event of a failed remarketing, the Tranche II bonds would be tendered to the bank and repaid over a five-year period, beginning at the time of the failed remarketing. No portion of the Series 1998A bonds has been put at June 30, 2011 and 2010, respectively. The \$66.4 Series 1998B and \$66.4 Series 1998C bonds (as of August 2011) were converted to a fixed rate in May 2008 and remain insured by Assured Guaranty, Ltd. (Assured) (formerly Financial Security Assurance, Inc.). The reimbursement obligation with respect to the letters of credit are evidenced and secured by obligations issued by the Corporation under the Master Trust Indenture.

MHHEFA issued \$283.5 of Revenue Bonds, including the \$166.6 Series 1998A (\$15.9 repaid through August 2011) and \$116.9 Series 1998B (\$13.6 repaid through August 2011). All Series 1998 MHHEFA bonds were issued at fixed rates. Principal and interest under the Series 1998 MHHEFA bonds are insured under municipal insurance policies with Assured and Ambac.

Related to the District borrowings, the Corporation entered into an interest rate swap with Wells Fargo Bank, National Association in a notional amount totaling \$150.0 (reduced to \$114.5 at August 2011). The swap agreement expires in fiscal year 2027. The interest rate swap is part of a comprehensive and long-term capital structure strategy. The purpose of the swap is to mitigate the effect of potential interest rate volatility and minimize the variability of the Corporation's average cost of capital. Under the terms of the swap, the Corporation pays a fixed rate and receives a variable rate. Collateral is only required to be posted under the swap in the event that the Corporation's credit ratings are downgraded by two rating agencies below the BBB – or Baa2 – level. To date, no collateral postings have been required. At June 30, 2011 and 2010, the variable interest rate under these agreements was 0.12% and 0.23%, respectively. The fixed rate was 3.69% as of June 30, 2011 and 2010. The variable rates are capped at 14.0%. The fair value of the interest rate swap at June 30, 2011 and 2010 was \$15.4 and \$18.1, respectively, and is included in other long-term liabilities. The change in fair value of the swap is reported in nonoperating gains (losses) in the statements of operations and changes in net assets.

In February 2004, MHHEFA issued \$170.3 in bonds (Series 2004 Bonds) on behalf of the Corporation. The proceeds of the Series 2004 Bonds were loaned to the Corporation pursuant to a loan agreement with MHHEFA upon execution of an obligation pursuant to the Master Trust Indenture. The Series 2004 Bonds were issued as \$40.5 serial bonds maturing 2009 through 2025 (\$10.8 repaid through August 2011), \$49.7

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

term bonds maturing 2024 and \$80.1 term bonds maturing 2033. Such Bonds were issued at fixed rates. Series 2004 Bonds maturing on or after August 2015 are subject to redemption or purchase at the option of the Corporation prior to maturity beginning in 2014.

In January 2007, MHHEFA issued \$145.0 in bonds (Series 2007 Bonds) on behalf of the Corporation. The Series 2007 Bonds were issued at a net premium of \$3.6, resulting in total proceeds of \$148.6. The proceeds of the Series 2007 Bonds were loaned to the Corporation pursuant to a loan agreement with MHHEFA upon execution of an obligation pursuant to the Master Trust Indenture. The proceeds from the offering, in conjunction with an equity contribution from the Corporation, have been used at Franklin Square Hospital to fund the construction of a seven-story patient tower, expanded parking, a new power plant, renovation of certain contiguous areas to the patient tower, site design, and to fund capitalized interest and transaction costs for the project. The Series 2007 Bonds were issued as \$56.0 term bonds maturing 2042 and \$89.0 term bonds maturing 2046. Such Bonds were issued at fixed rates. Series 2007 Bonds maturing on or after May 2042 are subject to redemption or purchase at the option of the Corporation prior to maturity beginning in 2016.

The Corporation, which is currently the sole member of an "obligated group" as defined in the Master Trust Indenture, is bound by the provisions of the Master Trust Indenture for payment of any outstanding obligations under existing loan agreements. All of the hospitals except Montgomery General Hospital (MGH), St. Mary's Hospital, and certain other affiliates (the guarantors) of the Corporation are parties to a guaranty agreement pursuant to which they jointly and severally guaranty the payment and performance of the obligations under the Master Trust Indenture. The obligations of the guarantors under the Guaranty Agreement are collateralized by deeds of trust granted by the hospitals. Under the Master Trust Indenture and the deeds of trust, as collateral for the payments due thereunder, the Corporation and certain hospital affiliates, have granted a security interest in their revenues subject to permitted encumbrances.

Under the Master Trust Indenture, the Corporation is required to maintain, among other covenants, a maximum annual debt service coverage ratio of not less than 1.10 to 1.0. Under the loan agreements relating to the Series 1998 Bonds, the Corporation is required to maintain a historical debt service coverage ratio of not less than 2.0 to 1.0 and to maintain at least 65 days cash on hand. In the event the Corporation does not meet either of these requirements, it is required to fund a trustee-held debt service reserve fund securing the Series 1998 Bonds. The amount to be deposited shall equal the lesser of: 10% of the principal amount of such outstanding bonds, or the largest annual debt service with respect to such bonds in any future year, or 125% of the average annual debt service of future years. At June 30, 2011 and 2010, there were no funds required to be held in the debt service reserve fund for the Series 1998 Bonds.

The Corporation maintains a \$250.0 revolving credit agreement provided by a group of banks. The facility was restructured in fiscal 2011 and now expires November 2013. The facility is evidenced by an obligation issued under the Master Trust Indenture. The outstanding balance on the facility was \$155.0 at June 30, 2011 and June 30, 2010. Of the outstanding balance, \$47.8 and \$48.9 was being held in operating cash at June 30, 2011 and 2010, respectively, in order to maximize the Corporation's liquidity. Proceeds were also utilized in fiscal 2008 and 2009 to retire Montgomery General Hospital's tax-exempt debt and interest rate hedge, and to fund a portion of a project on Montgomery General Hospital's campus. The facility includes certain covenants, including a requirement to maintain Days Cash on Hand of 70 days, measured

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

semi-annually at each June 30 and December 31, and a Debt Service Coverage ratio of 1.25, measured quarterly on a rolling four quarters basis. In addition, the Corporation is required to maintain a minimum credit rating of Baa2 from Moody's Investor's Service, and BBB from Standard & Poor's and Fitch Ratings.

In addition, the Corporation maintains a \$30.0 letter of credit facility, provided by a single lender, which is also evidenced by an obligation issued under the Master Trust Indenture. This facility is principally used to securitize certain regulatory obligations under various insurance programs. This facility, which has terms and conditions similar to the revolving credit agreement, was restructured in fiscal 2011 and now expires in November 2013. However, the standby letters of credit issued under the facility can be canceled at the bank's option each year. At June 30, 2011 and 2010, standby letters of credit issued pursuant to the facility were \$16.8 and \$17.0, respectively. However, no amounts have been drawn by the beneficiaries under the standby letters of credit.

St. Mary's Hospital has certain debt outstanding, including 2002 St. Mary's County General Obligation bonds with an outstanding balance of \$15.0 at August 2011 and Series 2009 MHHEFA bonds with an outstanding balance of \$15.4 at August 2011. The bonds are secured by a mortgage on the real property of St. Mary's Hospital and a pledge of St. Mary's Hospital's revenues. Under terms of the financing documents, St. Mary's Hospital is required to maintain days cash on hand of 85 days, and to maintain a historical debt service coverage ratio in excess of 1.10. St. Mary's Hospital is also subject to certain additional covenants and tests on an ongoing basis. The 2009 bonds trade in a weekly mode backed by a letter of credit issued by Bank of America, N.A. and remarketed by Merrill Lynch, Pierce, Fenner & Smith, Incorporated. The term of the letter of credit is three years, expiring in February 2012. Management expects to extend the letter of credit or refinance the bonds. In the event of a failed remarketing, the 2009 bonds would be tendered to the bank and repaid under the normal amortization schedule for the bonds. The 2009 bonds are included in the current portion of long-term debt in the consolidated balance sheets.

(7) Retirement Plans

The Corporation has two qualified defined benefit pension plans (MedStar Health, Inc. Pension Equity Plan (PEP) and MedStar Health, Inc. Cash Balance Retirement Plan (CBRP)) covering substantially all full-time employees hired before 2005, and a supplemental executive pension plan (SEPP) for certain executive management employees. St. Mary's Hospital also has a defined benefit plan that substantially covers all employees of St. Mary's Hospital.

Benefits under the plans are substantially based on years of service and the employees' career earnings. The Corporation contributes to the plans based on actuarially determined amounts necessary to provide assets sufficient to meet benefits to be paid to plan participants and to meet the minimum funding requirements of the Employee Retirement Income Security Act of 1974, as amended by the Pension Protection Act of 2006, and Internal Revenue Service regulations. Effective July 1, 2000, employees of the Transferred Businesses (see note 17) became participants in one of the Corporation's pension plans and are reflected in the pension information provided below.

The Corporation's investment policies are established by the MedStar Health, Inc. Investment Committee, comprised of members of the board of directors, other community leaders, and management. Among its

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

responsibilities, the Investment Committee is charged with establishing and reviewing asset allocation strategies, monitoring investment manager performance, and making decisions to retain and terminate investment managers. Assets of each of the Corporation's pension plans are managed in a similar fashion by the same group of investment managers. The Corporation has incorporated an Investment Policy Statement (IPS) into the investment program. The IPS, which has been formally adopted by the Corporation's Board of Directors, contains numerous standards designed to ensure adequate diversification by asset class and geography. The IPS also limits all investments by manager and position size, and limits fixed income position size based on credit ratings, which serves to further mitigate the risks associated with the investment program. At June 30, 2011 and 2010, management believes that all investments were being managed in a manner consistent with the IPS.

The Investment Committee has adopted certain target ranges for various asset classes within the pension portfolio. At June 30, 2011, these targets included the investment of approximately 49% of the portfolio in publicly traded equities, 25% in fixed income securities, 12% in hedge funds, 3% in private equity, 10% in inflation hedging strategies (including real estate), and 1% in cash. At June 30, 2010, these targets included the investment of approximately 52.5% of the portfolio in publicly traded equities, 24% in fixed income securities, 10% in hedge funds, 5% in private equity, 7.5% in inflation hedging strategies (including real estate), and 1% in cash. Actual asset allocations fluctuate depending upon gains and losses within asset classes over periods of time, the timing of plan contributions and distributions, and rebalancing decisions. Due to these fluctuations, actual asset allocations could exceed these levels over certain periods in time.

The following table illustrates the actual allocations at June 30:

	Actual allocation June 30, 2011	Actual allocation June 30, 2010
Publicly traded equities – domestic	36%	35%
Publicly traded equities – international	8	5
Fixed income securities	23	33
Alternative investments:		
Commingled equity funds	10	3
Inflation hedging equity, commodity, fixed income fund	6	4
Hedge funds	8	9
Private equities	2	2
Cash	7	9
Total	100%	100%

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

The table below presents the Corporation's pension plans' investable assets as of June 30, 2011 aggregated by the three level valuation hierarchy:

	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
Assets:				
Cash and cash equivalents	\$ 50.1	—	—	50.1
U.S. treasury bonds	44.6	—	—	44.6
U.S. agency mortgage backed securities	23.1	—	—	23.1
Corporate bonds	—	30.6	—	30.6
Fixed income mutual funds	—	49.9	—	49.9
All other fixed income securities	—	16.6	—	16.6
Equity mutual funds and ETF's	72.0	—	—	72.0
Common stocks	249.1	—	—	249.1
Alternative investments:				
Commingled equity funds	—	74.4	—	74.4
Inflation hedging equity, commodity, fixed income fund	—	39.2	—	39.2
Private equity	—	—	15.1	15.1
Hedge funds	—	—	61.1	61.1
Total assets	<u>\$ 438.9</u>	<u>210.7</u>	<u>76.2</u>	<u>725.8</u>

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

The table below presents the Corporation's pension plans' investable assets as of June 30, 2010 aggregated by the three level valuation hierarchy:

		<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
Assets:					
Cash and cash equivalents	\$	50.6	—	—	50.6
U.S. treasury bonds		36.1	—	—	36.1
U.S. agency mortgage backed securities		30.5	—	—	30.5
Corporate bonds		—	22.5	—	22.5
Fixed income mutual funds		0.4	81.1	—	81.5
All other fixed income securities		—	19.0	—	19.0
Equity mutual funds and ETF's		65.8	—	—	65.8
Common stocks		168.3	—	—	168.3
Alternative investments:					
Commingled equity funds		—	16.5	—	16.5
Inflation hedging equity, commodity, fixed income fund		—	23.6	—	23.6
Private equity		—	—	14.2	14.2
Hedge funds		—	—	52.7	52.7
Total assets	\$	<u>351.7</u>	<u>162.7</u>	<u>66.9</u>	<u>581.3</u>

For the years ended June 30, 2011 and 2010, there were no significant transfers between Levels 1, 2 or 3.

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

Changes to the fair values based on the Level 3 inputs, are summarized as follows:

	<u>Private equity</u>	<u>Hedge funds</u>	<u>Total</u>
Balance as of June 30, 2009	\$ 11.6	26.5	38.1
Additions:			
Contributions/purchases	0.9	41.6	42.5
Disbursements:			
Withdrawals/sales	(0.7)	(18.0)	(18.7)
Net change in value	<u>2.4</u>	<u>2.6</u>	<u>5.0</u>
Balance as of June 30, 2010	14.2	52.7	66.9
Additions:			
Contributions/purchases	0.5	4.6	5.1
Disbursements:			
Withdrawals/sales	(1.0)	(0.7)	(1.7)
Net change in value	<u>1.4</u>	<u>4.5</u>	<u>5.9</u>
Balance as of June 30, 2011	<u>\$ 15.1</u>	<u>61.1</u>	<u>76.2</u>

The following summarizes redemption terms for the hedge fund-of-funds vehicles held as of June 30, 2011:

	<u>Fund 1</u>	<u>Fund 2</u>	<u>Fund 3</u>	<u>Fund 4</u>
Redemption timing:				
Redemption frequency	Quarterly	Monthly	Quarterly	Quarterly
Required notice	70 days	90 days	90 days	65 days
Audit reserve:				
Percentage held back for audit reserve	10%	10%	10%	10%
Gates:				
Potential gate holdback	—	7%	—	—
Potential gate release timeframe	—	2011	—	—

Investments in hedge fund-of-funds are typically carried at estimated fair value. Fair value is based on the Net Asset Value (NAV) of the shares in each investment company or partnership. Such investment companies or partnerships mark-to-market or mark-to-fair value the underlying assets and liabilities in accordance with GAAP. Realized and unrealized gains and losses of the investment companies and partnerships are included in their respective operations in the current year. Changes in unrealized gains or losses on investments, including those for which partial liquidations were effected in the course of the year, are calculated as the difference between the NAV of the investment at year-end less the NAV of the

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

investment at the beginning of the year, as adjusted for contributions and redemptions made during the year and certain lock-up provisions. Generally, no dividends or other distributions are paid.

The following summarizes the status of contributions to the private equity fund-of-funds vehicles held as of June 30, 2011:

	Total commitment	Percentage of commitment contributed	Percentage of commitment remaining
Fund 1	\$ 9.0	82.7%	17.3%
Fund 2	8.5	88.7	11.3
Fund 3	8.5	47.5	52.5
Total	<u>\$ 26.0</u>		

Investments in limited partnership interests are carried at fair value as determined by the General Partner in the absence of readily ascertainable market values. The fair value of limited partnership interests is generally based on fair value capital balances reported by the underlying partnerships, subject to management review and adjustment. Security values of companies traded on exchanges, or quoted on NASDAQ, are based upon the last reported sales price on the valuation date. Security values of companies traded over the counter, but not quoted on NASDAQ, and securities for which no sale occurred on the valuation date are based upon the last quoted bid price. The value of any security for which a market quotation is not readily available may be its cost, provided however, that the General Partner adjusts such cost value to reflect any bona fide third party transactions in such a security between knowledgeable investors, of which the General Partner has knowledge. In the absence of any such third party transactions, the General Partner may use other information to develop a good faith determination of value. Examples include, but are not limited to, discounted cash flow models, absolute value models, and price multiple models. Inputs for these models may include, but are not limited to, financial statement information, discount rates, and salvage value assumptions.

The valuation of both marketable and nonmarketable securities may include discounts to reflect a lack of liquidity or extraordinary risks, which may be associated with the investment. Determination of fair value is performed on a quarterly basis by the General Partner. Because of the inherent uncertainty of valuation, the determined values may differ significantly from the values that would have been used had a ready market for those investments existed.

The Corporation has established a long-term investment return target of 8.25% and 8.50% for PEP and CBRP in 2011 and 2010, respectively. These assumptions are based on historical returns achieved in the investment portfolios over the last ten years and represent the return that can reasonably be expected to be generated on a similarly structured portfolio in the future.

The Corporation recognizes the funded status of defined benefit pension plans in the balance sheet and the recognition in unrestricted net assets of unrecognized gains or losses, prior service costs or credits and transition assets or obligations. The funded status is measured as the difference between the fair value of

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

the plan's assets and the projected benefit obligation of the plan. The measurement date for the plans is June 30. In April 2009, the Corporation announced a freeze to benefit accruals in the CBRP and PEP, except for certain union-represented employees covered by the CBRP. The freeze was effective December 31, 2009. Effective January 1, 2010, affected associates earn all future benefits through the Corporation's defined contribution retirement savings plan.

In March 2011, the Corporation terminated the SEPP plan effective December 31, 2011. The freeze constitutes a curtailment and as such, the Corporation remeasured the lump sum value of participants' benefits as of March 31, 2011. The remeasurement and curtailment accounting resulted in an increase to net assets of approximately \$3.4. Participants will be paid their accrued benefit, in the amount of \$7.6, in March 2012, which is included in other current liabilities in the consolidated balance sheets.

In May 2011, the National Nurses United employees at the Washington Hospital Center entered into a new collective bargaining agreement whereby they agreed to a freeze of their benefit accruals in the CBRP (see note 9). The freeze was effective December 31, 2010. Effective January 1, 2011, National Nurses United employees earn all future benefits through the Corporation's defined contribution retirement savings plan. The freeze constitutes a curtailment and as such, the Corporation remeasured the plans' assets and projected benefit obligations at May 1, 2011. The remeasurement and curtailment accounting resulted in a reduction to net assets of approximately \$2.2.

The following are deferred pension costs which have not yet been recognized in periodic pension expense but instead are accrued in unrestricted net assets, as of June 30, 2011 and 2010. Unrecognized actuarial losses represent unexpected changes in the projected benefit obligation and plan assets over time, primarily due to changes in assumed discount rates and investment experience. Unrecognized prior service cost is the impact of changes in plan benefits applied retrospectively to employee service previously rendered. Deferred pension costs are amortized into annual pension expense over the average remaining assumed service period for active employees.

	Amounts in unrestricted net assets to be recognized during the next fiscal year	Amounts recognized in unrestricted net assets at June 30, 2011	Amounts recognized in unrestricted net assets at June 30, 2010
Net prior service cost	\$ 0.3	(0.1)	4.1
Net actuarial loss	22.2	403.6	446.8
Total	<u>\$ 22.5</u>	<u>403.5</u>	<u>450.9</u>

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

The following table sets forth the plans' funded status and amounts recognized in the accompanying consolidated financial statements as of June 30, 2011 and 2010:

	<u>2011</u>	<u>2010</u>
Change in benefit obligation:		
Benefit obligation at beginning of year	\$ 982.6	765.1
Addition of St. Mary's Hospital benefit plan	—	21.8
Adjusted benefit obligation at beginning of year	982.6	786.9
Service cost	7.2	18.7
Interest cost	56.3	54.2
Participants contributions	0.9	3.6
Actuarial loss	29.0	145.1
Benefits paid	(26.2)	(23.5)
Curtailments	(10.1)	(2.4)
Benefit obligation at end of year	<u>1,039.7</u>	<u>982.6</u>
Change in plan assets:		
Plan assets at fair value at beginning of year	581.3	465.0
Addition of St. Mary's Hospital benefit plan assets	—	18.9
Adjusted plan assets at fair value at beginning of year	581.3	483.9
Actual return on plan assets	101.4	59.0
Company contributions	68.4	58.3
Plan participants' contributions	0.9	3.6
Benefits paid	(26.2)	(23.5)
Plan assets at fair value at end of year	<u>725.8</u>	<u>581.3</u>
Funded status/net amount recognized	\$ <u>(313.9)</u>	<u>(401.3)</u>

The amounts recognized in the consolidated financial statements consist of the following at June 30:

	<u>2011</u>	<u>2010</u>
Pension assets (included in other assets)	\$ 1.6	—
Pension current liabilities (included in other current liabilities)	7.6	—
Pension liabilities	307.9	401.3

Expected contributions for the defined benefit plans are \$70.3 for the year ended June 30, 2012.

The accumulated benefit obligation is \$1,013.9 and \$968.6 at June 30, 2011 and 2010, respectively.

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

Expected fiscal year benefit payments for all defined benefit plans is as follows:

2012	\$	42.6
2013		50.6
2014		53.5
2015		55.3
2016		56.4
2017 – 2018		332.8
Total	\$	<u>591.2</u>

Net periodic pension expense for the years ended June 30, 2011 and 2010 is as follows:

	<u>2011</u>	<u>2010</u>
Service cost – benefits earned during the year	\$ 7.2	18.7
Interest cost on projected benefit obligation	56.3	54.2
Return on plan assets	(55.7)	(49.9)
Net amortization and deferral	0.6	0.4
Recognized actuarial loss	18.8	11.7
Curtailment charges	1.2	—
Net periodic pension expense	\$ <u>28.4</u>	<u>35.1</u>

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

The assumptions used in determining net periodic pension expense and accrued pension costs shown above are as follows:

	2011	2010
Discount rates for obligations at year end:		
MedStar Health, Inc. Pension Equity Plan	5.85%	5.95%
MedStar Health, Inc. Cash Balance Retirement Plan	5.70	5.75
MedStar Health, Inc. Supplemental Executive Pension Plan	0.80	5.20
St. Mary's Hospital Pension Plan	5.60	5.40
Rate of compensation increase for obligations at year end:		
MedStar Health, Inc. Pension Equity Plan	N/A	4.00%
MedStar Health, Inc. Cash Balance Retirement Plan	4.00%	4.00
MedStar Health, Inc. Supplemental Executive Pension Plan	3.50	3.50
St. Mary's Hospital Pension Plan	N/A	4.00
Discount rates for pension cost:		
MedStar Health, Inc. Pension Equity Plan – July 1 – June 30	5.95%	7.20%
MedStar Health, Inc. Cash Balance Retirement Plan – July 1 – April 30	5.75	N/A
MedStar Health, Inc. Cash Balance Retirement Plan – May 1 – June 30	5.65	N/A
MedStar Health, Inc. Cash Balance Retirement Plan – July 1 – June 30	N/A	6.95
MedStar Health, Inc. Supplemental Executive Pension Plan – July 1 – March 31	5.30	N/A
MedStar Health, Inc. Supplemental Executive Pension Plan – April 1 – June 30	0.75	N/A
MedStar Health, Inc. Supplemental Executive Pension Plan – July 1 – June 30	N/A	6.45
St. Mary's Hospital Pension Plan – July 1 – June 30, 2010	5.40	6.25
Expected long-term rate of return on plan assets – PEP and CBRP	8.25%	8.50%
Expected long-term rate of return on plan assets – St. Mary's Hospital	7.75	8.00
Rate of compensation increase for pension cost:		
MedStar Health, Inc. Pension Equity Plan – July 1 – June 30	N/A	4.00%
MedStar Health, Inc. Cash Balance Retirement Plan – July 1 – June 30	4.00%	4.00
MedStar Health, Inc. Supplemental Executive Pension Plan	3.50	3.50
St. Mary's Hospital Pension Plan	N/A	4.00

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

The Corporation also has various contributory, tax deferred annuity and savings plans with participation available to certain employees. The Corporation matches employee contributions up to 3.0% of compensation in certain plans. The Corporation contributed approximately \$25.7 and \$19.4 during the years ended June 30, 2011 and 2010, respectively. The Corporation approved the temporary suspension of the 2-3% fixed tenure-based contribution to the 403(b) plan for the calendar years 2010 and 2011.

(8) Business and Credit Concentrations

The Corporation provides healthcare services through its inpatient and outpatient care facilities located in the State of Maryland and the District of Columbia. The Corporation generally does not require collateral or other security in extending credit; however it routinely obtains assignment of (or is otherwise entitled to receive) patients' benefits receivable under their health insurance programs, plans or policies (e.g., Medicare, Medicaid, Blue Cross, Workers' Compensation, health maintenance organizations (HMOs) and commercial insurance policies).

A summary of net patient service revenue by major category of payor for the years ended June 30, 2011 and 2010 is as follows:

	2011	2010
Medicare	34%	34%
Medicaid	14	12
Carefirst Blue Cross Blue Shield	18	19
Other commercial and managed care payors	27	29
Self-pay	7	6
	<u>100%</u>	<u>100%</u>

A summary of net patient service receivables by major category of payor as of June 30, 2011 and 2010 is as follows:

	2011	2010
Medicare	23%	24%
Medicaid	14	12
Carefirst Blue Cross Blue Shield	13	16
Other commercial and managed care payors	36	34
Self-pay	14	14
	<u>100%</u>	<u>100%</u>

The Corporation's policy is to write-off all patient accounts that have been identified as uncollectible. An allowance for uncollectible accounts is recorded for accounts not yet written off which are expected to become uncollectible in future periods.

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

Under the Maryland Health Services Cost Review Commission (the Commission) rate methodology, amounts payable for services in 2011 and 2010 to Maryland hospital patients under the Medicare and Medicaid insurance programs are computed at 94% of regulated charges and hospital patients under the Blue Cross and approved health maintenance organization insurance programs are computed at 98% of regulated charges. Maryland accounts receivable from these third-party payors have been adjusted to reflect the difference between charges and the payable amounts.

Certain Maryland-based hospital charges are subject to review and approval by the Maryland Health Services Cost Review Commission (HSCRC).

The HSCRC has jurisdiction over hospital reimbursement in Maryland by agreement with the Centers for Medicare and Medicaid Services (CMS). This agreement is based on a waiver from the Medicare Prospective Payment System reimbursement principles granted under Section 1814(b) of the Social Security Act. The waiver will continue as long as cumulative comparisons of cost per admission between Maryland and the nation continue to be favorable. Management believes that the waiver will remain in effect at least through June 30, 2012.

Effective July 1, 2000 through June 30, 2003 under a contract with the HSCRC and the Maryland Hospitals, a charge per case methodology was implemented to more effectively tie compliance standards to waiver performance. Under this methodology, actual charges per case are required to meet hospital specific targets established by the HSCRC, which are adjusted for changes in actual case-mix. The HSCRC and Maryland Hospitals completed a three year contract that expired on June 30, 2006. The contract has been renewed yearly and this methodology will continue through June 30, 2012. The HSCRC implemented an observation status change that became effective July 1, 2010 in which one-day stay cases that used to be counted as admissions are now considered outpatient visits.

Laws and regulations governing the Medicare and Medicaid programs are extremely complex and subject to interpretation. As a result, there is at least a reasonable possibility that recorded estimates will change by a material amount. Management periodically reviews recorded amounts receivable from or payable to third party payors and may adjust these balances as new information becomes available. In addition, revenue received under certain third-party agreements is subject to audit. During 2011 and 2010, certain of the Corporation's prior year third party cost reports were audited and settled, or tentatively settled, by third party payors. Adjustments resulting from such audits and management reviews of unaudited years and open claims are reflected as adjustments to revenue in the year that the adjustment becomes known. The effect of these adjustments was to increase net patient service revenue by \$6.0 and \$2.3 during the years ended June 30, 2011 and 2010, respectively. Although certain other prior year cost reports submitted to third party payors remain subject to audit and retroactive adjustment, management does not expect any material adverse settlements.

Through its MedStar Family Choice, Inc. subsidiary, the Corporation enters into fee-for-service and capitation agreements with independent health professionals and organizations to provide covered services to eligible enrollees where such services cannot be provided by its employed physicians or controlled entities. Medical and clinical expenses from these agreements include claim payments, capitation payments, and estimates of outstanding claims liabilities for services provided prior to the balance sheet date. The estimates of outstanding claims liabilities (\$14.9 and \$11.7 at June 30, 2011 and 2010,

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

respectively) are based on management's analysis of historical claims paid reports and as well as review of health services utilization during the period. Changes in these estimates are recorded in the period of change. Claims payments and capitation payments are expensed in the period services are provided to eligible enrollees.

Visiting Nurse Association (VNA) has resolved the investigation by the Office of Inspector General (OIG) of the Department of Health and Human Services related to its cost reports for the years 1998 through 2000. This investigation resulted in VNA entering into a five-year Corporate Integrity Agreement (CIA). The VNA ended the term of the CIA in May 2010 and submitted its final report in June 2010. A letter from the OIG was received by the VNA dated November 9, 2010, confirming that the VNA satisfied the obligations of the CIA and that the VNA has been removed from the OIG's website.

(9) Certain Significant Risks and Uncertainties

The Corporation provides general acute healthcare services in the State of Maryland and the District of Columbia. The Corporation and other healthcare providers are subject to certain inherent risks, including the following:

- Dependence on revenues derived from reimbursement by the Federal Medicare and state Medicaid programs;
- Regulation of hospital rates by the State of Maryland Health Services Cost Review Commission;
- Government regulation, government budgetary constraints and proposed legislative and regulatory changes, and;
- Lawsuits alleging malpractice or other claims.

Such inherent risks require the use of certain management estimates in the preparation of the Corporation's consolidated financial statements and it is reasonably possible that a change in such estimates may occur.

The Medicare and state Medicaid reimbursement programs represent a substantial portion of the Corporation's revenues and the Corporation's operations are subject to a variety of other Federal, state and local regulatory requirements. Failure to maintain required regulatory approvals and licenses and/or changes in such regulatory requirements could have a significant adverse effect on the Corporation.

Changes in federal and state reimbursement funding mechanisms and related government budgetary constraints could have a significant adverse effect on the Corporation.

The healthcare industry is also subject to numerous laws and regulations from federal, state and local governments, and the government has aggressively increased enforcement of Medicare and Medicaid anti-fraud and abuse laws. The Corporation's compliance with these laws and regulations is subject to periodic governmental review, which could result in enforcement actions unknown or unasserted at this time. Management is aware of certain asserted and unasserted legal claims by the government, and is presently unable to determine the outcome of these claims. Management has provided requested information to the government in conjunction with certain government investigations. The final outcomes of these government investigations cannot be determined at this time.

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

The federal government and many states have aggressively increased enforcement under Medicare and Medicaid anti-fraud and abuse laws and physician self referral laws (STARK law and regulation). Recent federal initiatives have prompted a national review of federally funded healthcare programs. In addition, the federal government and many states have implemented programs to audit and recover potential overpayments to providers from the Medicare and Medicaid programs. In September 2009, the Corporation was notified that the recovery audit contractors (RAC) would begin auditing company operations in 2010 and the Corporation received its first request for records in the fourth quarter of fiscal year 2010. The Corporation continues to receive these requests from the RAC and has implemented a response program as well as a compliance program to monitor conformance with applicable laws and regulations, but the possibility of future government review and enforcement action exists.

As a result of recently enacted and pending federal health care reform legislation, substantial changes are anticipated in the United States health care system. Such legislation includes numerous provisions affecting the delivery of health care services, the financing of health care costs, reimbursement to health care providers and the legal obligations of health insurers, providers and employers. These provisions are currently slated to take effect at specified times over the next decade. This federal health care reform legislation did not affect the 2011 or 2010 consolidated financial statements.

The Corporation and one of its' hospitals have been notified of a wage-hour lawsuit brought by a few of its employees. This is in the initial stages of investigation, thus the final outcome of this matter cannot be determined at this time.

(10) Self-Insurance Programs

The Corporation maintains self-insurance programs for professional and general liability risks, employee health and workers' compensation. Estimated liabilities have been recorded based on actuarial estimation of reported and incurred but not reported claims. The combined accrued liabilities for these programs as of June 30, 2011 and 2010 were as follows:

	2011	2010
Professional and general liability	\$ 207.4	205.2
Employee health	19.3	17.3
Workers' compensation	27.9	24.7
Total liabilities	254.6	247.2
Less current portion	(58.0)	(56.3)
	<u>\$ 196.6</u>	<u>190.9</u>

The Corporations' self insurance program for professional and general liability is responsible for the following exposures at June 30, 2011:

- (a) For professional liability, the first \$5.0 exposure for each claim with an inner aggregate of \$2.5 for the period July 1, 2010 through December 31, 2010. For the period January 1, 2011 through June 30,

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

2011, the Corporation is responsible for the first \$5.0 exposure for each claim plus an inner aggregate (effective January 1, 2011, the inner aggregate was changed from a \$2.5 annual inner aggregate to a \$5.0 inner aggregate spread over a 24-month exposure period ending December 31, 2012). For Montgomery General Hospital (MGH), the Corporation is responsible for the first \$2.0 exposure for each claim (also subject to the inner aggregate structures noted above).

- (b) For general liability, the Corporation is responsible for the first \$3.0 exposure for each claim (for MGH, the first \$2.0 exposure for each claim).

Commercial excess re-insurance has been purchased above this self-insured retention in multiple layers and in twin towers. Each tower has seven layers of excess re-insurance coverage. These seven layers combine to provide up to \$100.0 per claim and \$100.0 in the annual aggregate for professional liability and general liability exposure. The Corporation maintains reinsurance contracts with various highly rated commercial insurance companies.

The professional and general liabilities at June 30, 2011 and 2010 have been discounted at a rate of 3.75%. The workers' compensation liabilities at June 30, 2011 and 2010 have been discounted at a rate of 3.5%.

Assets available to fund these liabilities are held in separate accounts (see note 2). Contributions required to fund professional and general liability, employee health benefits and workers' compensation programs are determined by the plans' administrators based on appropriate actuarial assumptions. The professional and general liability programs are administered through an offshore wholly owned captive insurance company, Greenspring Financial Insurance Limited (GFIL) domiciled in Grand Cayman Island.

Effective March 1, 2010, MGH transitioned from its previous professional liability coverage under Freestate Healthcare Insurance Company, Ltd., (Freestate) to coverage under GFIL. Through this program, MGH maintained professional liability insurance coverage of \$1.0 per occurrence with a \$3.0 aggregate limit. MGH maintained an umbrella policy to cover the periods prior to joining GFIL with coverage of \$10.0 per claim and \$10.0 in the annual aggregate. In addition, also effective January 1, 2009, MGH was brought into the coverage provided to the Corporation under its commercial excess re-insurance program with coverage of \$100.0 per claim and \$100.0 in the annual aggregate.

St. Mary's Hospital maintains professional liability coverage with a commercial insurer. St. Mary's Hospital professional liability insurance coverage is on a claims made basis, with \$1.0 per incident coverage, up to a maximum of \$3.0 annually. The policy contains a per incident deductible and includes prior acts coverage. St. Mary's Hospital also maintains an umbrella excess policy in the amount of \$5.0 and accrues for the estimated cost of uninsured asserted and unasserted malpractice claims when incidents occur.

The Corporation, in the normal course of business, is a party to a number of legal and regulatory proceedings. Management does not expect that the results of these proceedings will have a material adverse effect on the consolidated financial position or results of operations of the Corporation.

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

(11) Unrestricted Net Assets

Effective July 1, 2010, the Corporation adopted new accounting guidance (applied retroactively to July 1, 2009) that requires a not-for-profit reporting entity to account for and present noncontrolling interests in a consolidated subsidiary as a separate component of the appropriate class of consolidated net assets. The income attributable to noncontrolling interests is excluded from operating income and included within other nonoperating gains on the consolidated statements of operations and changes in net assets. The following table presents a reconciliation of the changes in consolidated unrestricted net assets attributable to the Corporation's controlling interest and noncontrolling interest, including amounts such as the performance indicator and other changes in unrestricted net assets as of and for the years ended June 30, 2011 and 2010:

	MedStar Health, Inc.	Noncontrolling interests	Total Unrestricted net assets
Balance as of June 30, 2009	\$ 543.3	8.2	551.5
Excess of revenues over expenses	142.0	3.6	145.6
Addition of St. Mary's net assets	72.2	—	72.2
Change in funded status of defined benefit plans	(121.3)	—	(121.3)
Change in unrealized gains on investments	0.1	—	0.1
Net assets released for property and equipment	7.6	—	7.6
Distributions to noncontrolling interests	—	(2.4)	(2.4)
Increase in unrestricted net assets	100.6	1.2	101.8
Balance as of June 30, 2010	643.9	9.4	653.3
Excess of revenues over expenses	208.1	4.1	212.2
Change in funded status of defined benefit plans	47.4	—	47.4
Net assets released for property and equipment	5.0	—	5.0
Distributions to noncontrolling interests	—	(5.7)	(5.7)
Increase (decrease) in unrestricted net assets	260.5	(1.6)	258.9
Balance as of June 30, 2011	\$ 904.4	7.8	912.2

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

(12) Temporarily and Permanently Restricted Net Assets

Temporarily and permanently restricted net assets as of June 30, 2011 and 2010 are available for the following purposes:

	2011	2010
Temporary restrictions:		
Interest in net assets of foundation	\$ 49.2	41.1
Other	36.2	32.9
	<u>\$ 85.4</u>	<u>74.0</u>
Permanent restrictions:		
Investments to be held in perpetuity, the income from which is available to support health care services	\$ 37.7	37.0

Temporarily restricted net assets are available for the purposes of purchasing property and equipment, providing health education, research and other healthcare services.

(13) Endowment Net Assets

The Corporation's endowments consist of individual donor-restricted funds established for a variety of purposes. Net assets associated with endowment funds are classified and reported based on the existence or absence of donor-imposed restrictions.

(a) Interpretation of Relevant Law

The Corporation has interpreted the State Prudent Management of Institutional Funds Act (SPMIFA) as requiring the preservation of the fair value of the original gift as of the gift date of the donor-restricted endowment funds absent explicit donor stipulations to the contrary. As a result of this interpretation, the Corporation classifies as permanently restricted net assets (a) the original value of gifts donated to the permanent endowment, (b) the original value of subsequent gifts to the permanent endowment, and (c) accumulations to the permanent endowment made in accordance with the direction of the applicable donor gift instrument at the time the accumulation is added to the fund. The remaining portion of the donor-restricted endowment fund that is not classified in permanently restricted net assets is classified as temporarily restricted net assets until those amounts are appropriated for expenditure by the organization in a manner consistent with the standard of prudence prescribed by SPMIFA. In accordance with SPMIFA, the Corporation considers the following factors in making a determination to appropriate or accumulate donor-restricted endowment funds:

- (1) The duration and preservation of the fund
- (2) The purposes of the Corporation and the donor-restricted endowment fund
- (3) General economic conditions

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

- (4) The possible effect of inflation and deflation
- (5) The expected total return from income and the appreciation of investments
- (6) Other resources of the Corporation
- (7) The investment policies of the Corporation.

(b) Endowment Net Assets Consist of the Following at June 30, 2011

	<u>Unrestricted</u>	<u>Temporarily restricted</u>	<u>Permanently restricted</u>	<u>Total</u>
Donor-restricted endowment funds	\$ <u>(0.2)</u>	<u>1.7</u>	<u>37.7</u>	<u>39.2</u>
Total endowed net assets	\$ <u><u>(0.2)</u></u>	<u><u>1.7</u></u>	<u><u>37.7</u></u>	<u><u>39.2</u></u>

(c) Endowment Net Assets Consist of the Following at June 30, 2010

	<u>Unrestricted</u>	<u>Temporarily restricted</u>	<u>Permanently restricted</u>	<u>Total</u>
Donor-restricted endowment funds	\$ <u>(2.4)</u>	<u>0.8</u>	<u>37.0</u>	<u>35.4</u>
Total endowed net assets	\$ <u><u>(2.4)</u></u>	<u><u>0.8</u></u>	<u><u>37.0</u></u>	<u><u>35.4</u></u>

(d) Funds with Deficiencies

From time to time, the fair value of assets associated with individual donor-restricted endowment funds may fall below the level that the donor or SPMIFA requires the Corporation to retain as a fund of perpetual duration. In accordance with GAAP, deficiencies of this nature that are reported in unrestricted net assets were \$0.2 and \$2.4 as of June 30, 2011 and 2010, respectively. These deficiencies resulted from unfavorable market fluctuations.

(e) Investment Strategies

The Corporation has adopted policies for corporate investments, including endowment assets, that seek to maximize risk-adjusted returns with preservation of principal. Endowment assets include those assets of donor-restricted funds that the Corporation must hold in perpetuity or for a donor-specified period(s). The endowment assets are invested in a manner that is intended to hold a mix of investment assets designed to meet the objectives of the account. The Corporation expects its

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

endowment funds, over time, to provide an average rate of return that generates earnings to achieve the endowment purpose.

To satisfy its long-term rate-of-return objectives, the Corporation relies on a total return strategy in which investment returns are achieved through both capital appreciation (realized and unrealized) and current yield (interest and dividends). The Corporation employs a diversified asset allocation structure to achieve its long-term return objectives within prudent risk constraints.

The Corporation monitors the endowment funds returns and appropriates average returns for use. In establishing this practice, the Corporation considered the long-term expected return on its endowment. This is consistent with the Corporation's objective to maintain the purchasing power of the endowment assets held in perpetuity or for a specified term as well as to provide additional real growth through new gifts and investment return.

(14) Income Taxes

The Corporation and the majority of its subsidiaries are not-for-profit corporations as defined in Section 501(c)(3) of the Internal Revenue Code and are exempt from federal income taxes under Section 501(a) of the Code. The Corporation's tax-exempt businesses generate nominal amounts of unrelated business income subject to income tax. For corporate income tax purposes, the Corporation has two consolidated groups of for-profit, taxable entities. The parent companies of these groups are Parkway Ventures, Inc. and MedStar Enterprises, Inc.

The Corporation's taxable subsidiaries have approximately \$249.6 of net operating loss (NOL) carryforwards as of June 30, 2011, which expire in varying periods through 2031, available to offset future taxable income. This NOL carryforward represents \$94.8 of gross deferred tax assets. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. At June 30, 2011, the Corporation increased its net deferred tax asset by \$1.4, which was recorded in nonoperating income. At June 30, 2010, the Corporation decreased its net deferred tax asset by \$1.4, which was recorded in nonoperating income. The remaining amount of the deferred tax asset considered realizable, \$25.4, could be reduced if estimates of future taxable income during the carry forward period are reduced. The current tax provisions for the years ended June 30, 2011 and 2010 were immaterial.

(15) Charity Care

In addition to charity care, the Corporation funds numerous programs designed to benefit the healthcare interests of the communities it serves, examples of which are: health education programs and services, health information and referral services, school-based clinics, public health screenings and home care. The costs associated with these programs are recorded in the appropriate operating expense categories. The Corporation provided \$80.5 and \$74.5 of charity care during the years ended June 30, 2011 and 2010, respectively, based on charges foregone (based on established rates).

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

(16) Leases

The Corporation is obligated under various operating leases with initial terms of one year or more. Aggregate future minimum payments as of June 30, 2011 are as follows:

2012	\$	39.9
2013		28.5
2014		24.3
2015		15.8
2016		12.6
2017 and thereafter		<u>36.6</u>
Total minimum lease payments	\$	<u>157.7</u>

Certain leases include provisions allowing the minimum rental payments to be adjusted annually for increases in operating costs and, in some cases, real estate taxes attributable to leased property. Total rental expense for all operating leases amounted to approximately \$59.1 and \$55.3 during the years ended June 30, 2011 and 2010, respectively.

(17) Commitments and Contingencies

In February 2000 and on June 30, 2000, the Corporation and Georgetown University (the University) signed certain definitive agreements whereby the Corporation would receive through purchase or capital lease substantially all of the assets (including working capital) owned by the University that constitutes the Georgetown University Hospital, the Community Practice Network, the Faculty Practice Group and certain office buildings and a parking lot on the campus (collectively referred to as the Transferred Businesses). These agreements became effective July 1, 2000 and transferred control of the identified physical plant and other real property assets of the Transferred Businesses to the Corporation for use as an academic medical center for a minimum of ninety-eight years. At the end of the one hundred and fifty year lease term (including a fifty-two year renewal), the University shall convey all leased assets, excluding the underlying land, to the Corporation for a nominal amount and enter into a rent-free ground lease for the Corporation's use. This transaction was accounted for under the purchase method of accounting effective July 1, 2000.

In recognition of the value of the transaction, the Corporation shall annually pay the University 50% of the amount by which the combined operating earnings before interest, taxes, depreciation and amortization (EBITDA), as defined in the asset purchase agreement, of certain entities of the Corporation in the Washington D.C. area (collectively referred to as the Washington Clinical Enterprises) exceeds \$60.0, subject to certain adjustments. These additional payments expire when cumulative payments reach \$70.0. No amounts were due under these agreements at June 30, 2011. The Corporation paid \$1.7 to the University through the year ended June 30, 2011.

The Corporation also entered into an Academic Affiliation and Operations Agreement (Affiliation Agreement) with the University. The purpose of this agreement is to make available to the University the facilities of the Transferred Businesses and provide the Corporation with a first-class University medical

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

center. The University shall make payments to the Corporation determined by multiplying the University School of Medicine's total undergraduate tuition revenue by 36% for providing teaching services. The Corporation recognized \$15.0 and \$10.2 of tuition revenue during the years ended June 30, 2011 and 2010, respectively. In support of academic programs at the University, for each fiscal year following the termination of the additional payment terms in the asset purchase agreement described above, the Corporation shall pay to the University 17.5% of the operating EBITDA of the Washington Clinical Enterprises in excess of \$60.0, subject to certain adjustments. No amounts were due under this Affiliation Agreement at June 30, 2011.

The Corporation and the University also entered into a Research Agreement to sustain and advance a program of health-related University research at the Transferred Business facilities. Under this agreement the University is required to reimburse the Corporation for certain costs incurred by the Corporation in support of University sponsored research. Amounts reimbursed to the Corporation were \$2.9 for the years ended June 30, 2011 and 2010.

Georgetown University Hospital and the University are parties to a fixed fee shared services agreement. Georgetown University provided to Georgetown University Hospital the following services: utilities, telephone/IT services, transportation services and library services. Expenses charged for such services were \$11.9 and \$13.4 for 2011 and 2010, respectively.

The WHC campus is subject to the lien of a Permitted Encumbrance in the amount of \$21.5 to the United States government. This encumbrance was created in the deed of the hospital property from the United States government to WHC in February 1960. There is no repayment date for this lien stated in the deed. Under enabling legislation, repayment could be required after a determination that the property is no longer required for hospital services or the property is disposed of, in which event all or a portion of the lien may be payable to the government. This lien is subordinated to the Deed of Trust on the WHC campus.

(18) Functional Expenses

The Corporation considers integrated health services, research and management and general to be its primary functional categories for purposes of expense classification. Management and general include information systems, general corporate management, advertising and marketing. Functional categories of expenses for the years ended June 30, 2011 and 2010 are as follows:

	2011	2010
Integrated health services	\$ 3,180.0	3,087.9
Management and general	717.4	662.5
Research	32.5	35.4
Fundraising	8.4	6.6
	<u>\$ 3,938.3</u>	<u>3,792.4</u>

MEDSTAR HEALTH, INC.

Notes to Consolidated Financial Statements

June 30, 2011 and 2010

(Dollars in millions)

(19) Subsequent Events

Management evaluated all events and transactions that occurred after June 30, 2011 and through October 3, 2011. The Corporation did not have any subsequent events that were required to be recognized or disclosed during this period.

Exhibit 37

**CURRICULUM VITAE
ANATOLY DRITSCHILO, M.D.**

PERSONAL INFORMATION

Work Address: Georgetown University Hospital
3800 Reservoir Road, NW
Washington, D.C. 20057
(202) 444-3320

Home Address: 8101 Fenway Road
Bethesda, MD 20817
(301) 469-9635

Place of Birth: Reigersfeld, Germany

Citizenship: USA

CERTIFICATION

American Board of Radiology (Therapeutic Radiology) (1977)
Licensed to practice in Massachusetts (1974), D.C. (1979), Maryland (1980) and Virginia (1997)

EDUCATION

1967 B.S., University of Pennsylvania, Philadelphia, PA
1969 M.S., Newark College of Engineering, Newark, NJ
1973 M.D., College of Medicine of New Jersey, Newark, NJ
1973-1974 Intern, Cincinnati General Hospital, Cincinnati, OH
1974-1977 Resident in Radiation Therapy, Joint Center for Radiation Therapy, Harvard Medical School, Boston, MA

PROFESSIONAL EXPERIENCE

2010-present Professor and Chairman, Department of Radiation Medicine, Georgetown University School of Medicine, Washington, DC
2005-2007 Interim Director of the Lombardi Sector and Lombardi Comprehensive Cancer Center, Interim Associate Vice President, GUMC and Chair of the Department of Oncology, Georgetown University Medical Center, Washington, D.C.
1994-1997 Dean, Graduate Medical Education, Georgetown University School of Medicine, Washington, D.C.
1994-1997 Medical Director, Georgetown University Hospital, Washington, D.C.
1988-1994 Clinical Director, Vincent T. Lombardi Comprehensive Cancer Research Center, Washington, D.C.
1987-1988 Acting Co-Director, Vincent T. Lombardi Comprehensive Cancer Research Center, Washington, D.C.
1980-2005 Chairman, Department of Radiation Medicine, Georgetown University School of Medicine, Washington, D.C.
1979-2005 Chief, Department of Radiation Medicine, Georgetown University Hospital, Washington, D.C.
1979-2005 Director, Radiation Oncology, Vincent T. Lombardi Cancer Research Center, Washington, D.C.
1977-1979 Radiotherapist, Tufts-New England Medical Center, Boston, MA

HONORS AND AWARDS

1990 AOA Alumnus Member
1992 Fellow, American College of Radiology

ACADEMIC APPOINTMENTS

2010-present Professor, Departments of Radiation Medicine (primary) and Oncology,
 Georgetown University School of Medicine, Washington, DC
2005-2010 Professor, Departments of Oncology (primary) and Radiation Medicine,
 Georgetown University Medical Center, Washington, DC
1987-present Professor, Department of Radiation Medicine, Georgetown University School of
 Medicine, Washington, D.C.
1980-1987 Associate Professor, Department of Radiation Medicine, Georgetown University
 School of Medicine, Washington, D.C.
1979-1980 Associate Professor, Department of Radiology, Georgetown University School of
 Medicine, Washington, D.C.
1977-1979 Assistant Professor, Tufts University School of Medicine, Boston, MA
1974-1977 Fellow in Radiation Therapy, Harvard Medical School, Boston, MA

PROFESSIONAL SOCIETIES (National)

1974-1985 American Medical Association
1977-present American Society of Therapeutic Radiologists (ASTR, ASTRO)
 ASTRO's ad hoc Committee on Radiation Oncology Initiatives (1996)
 ASTRO Radiation Biology Committee (1996)
1977-present American Association for Cancer Research
1978-present American College of Radiology
1978-present Radiation Research Society
 Member, Awards Monitoring Committee (1989)
 Member, Program Committee (1989)
 Member, Research Award Selection Committee (1989)
 Chair, Nominating Committee (1992)
 Chair, Fund Raising Committee (1995-1996)
 Research Support Committee (1997)
 Radiation Biology Committee (1997)
1979-present District of Columbia Medical Society
1981-present American Society of Clinical Oncologists
1981-present Society of Chairmen of Academic Radiation Oncology Programs
1982-present American College of Radiation Oncology
1989-present American Cancer Society
 Member, Prevention, Diagnosis, and Treatment Grant Review Committee (1989-
 90)
 Member, Committee on Clinical Investigators II - Prevention, Diagnosis and
 Therapy (1990-1992)
 Ad Hoc Reviewer, Cancer Control and Epidemiology Committee (1996)
 Ad Hoc Member, Clinical Research, Cancer Control and Epidemiology
 Committee (1997)
1990-present National Institutes of Health/National Cancer Institute
 Ad Hoc Reviewer, Cancer Centers and Program Projects (1987-1990)
 Member, NIH Radiation Research Study Section (1990-1994)
 Site Visitor, NCI Cancer Center Program, Ad Hoc Reviewer (1993-present)
 Ad Hoc Reviewer, SPORE in Lung Cancer (1995)
 NIH Consultant Pool in Radiation Oncology and Radiation Biology (1995-present)

- Member, NCI Initial Review Group, Subcommittee C (Basic and Preclinical Science) (1997-present)
- Member, NIH Radiation Study Section (RTB) 2007-present
- Ad Hoc Reviewer, SPOREs in Prostate, Cancer
- 1994-present Member, Roster of Distinguished Scientific Advisors, RSNA Research and Educational Fund
- 1995-present Reviewer of Grant Applications, RSNA Research and Education Fund
- 1996-present American Radiation Society
- 1996-present Expert Consultant, American Medico-Legal Foundation, Philadelphia, PA
- 1996-present Consultant in Research, Department of Physics, George Washington University
- Dissertation Co-Director for PhD candidate Dalong Pang (1996)

PUBLIC SERVICE/CONSULTANT APPOINTMENTS

- 1980-1988 Associate Editor, *Computerized Tomography*
- 1984-1986 PDQ Editorial Board, National Cancer Institute
- 1985-1987 National Council, Radiation Protection and Measurements, Scientific Committee 81
- 1986-1988 Chief Co-Proctor, American Board of Radiology
- 1987-present Manuscript Reviewer for the following journals: *Cancer Research; Radiation Research; International Journal of Radiation Oncology, Biology and Physics; Cancer Communications; The Cancer Journal from Scientific American; Oncogene; Gene Therapy, Proceeding National Academy of Science*
- 1990-2000 Member, Board of Directors, Neopharm Incorporated
- 1992-1995 Member, Editorial Board, Radiation Oncology Investigations
- 1992-1996 Member, Scientific Board, Oxigene Incorporated
- 1992-1996 Member, Scientific Advisory Committee, University of Wisconsin Comprehensive Cancer Center
- 1995-2000 Associate Editor, Radiation Oncology Investigations

Current Editorial Positions

- Frontiers in Radiation Oncology, Associate Editor
- Cancer Therapy, Editorial Board
- Advances in Medical Physics, Editorial Board

Reviewer for professional journals

- Cancer Biology & Therapy
- Clinical Cancer Research
- Cancer Chemotherapy and Pharmacology
- International Journal of Radiation Biology
- Journal of Clinical Oncology
- Molecular Cancer Research
- Molecular Cancer Therapeutics
- PNAS
- Radiation Research

SERVICE (NATIONAL/SOCIETIES)

- 1990-present Ad Hoc Site Visitor and Residency Reviewer
- 1990 Reviewer/Consultant, Department of Radiation Oncology, University of Massachusetts, MA
- 1990 Member, Local Organizing Committee, ASCO Meeting, Washington, DC
- 1990 Member, Nominating Committee, Radiation Research Society

- 1992 Reviewer, Department of Radiation Therapy, University of Texas Medical Branch at Galveston, TX
- 1994-present Member, Roster of Distinguished Scientific Advisors, RSNA Research and Education Fund
- 1997 AAPM/IOUP International Scientific Exchange Programs for Radiation Physics
- 1997 Reviewer/Consultant Division of Radiation Oncology, Case Western Reserve University, Cleveland, OH

UNIVERSITY SERVICE

- 1979-1996 Executive Committee, Vincent T. Lombardi Comprehensive Cancer Research Center, Georgetown University Medical Center, Washington, D.C.
- 1979-present Executive Staff, Georgetown University Hospital, Washington, D.C.
- 1979-present Other university, hospital, society and public service committees including research finance and planning committees, and various ad hoc committees
- 1980-present Executive Faculty, Georgetown University School of Medicine, Washington, D.C.
1987-present Executive Committee of the Executive Faculty, Georgetown University School of Medicine, Washington, D.C.
- 1987-1988 Chairman, Cancer Committee, Georgetown University Hospital
- 1988-1994 Chairman, Hospital Fiscal Affairs Committee
- 1989-present Member, Faculty Practice Association Committee
- 1989 Member, Presidential Search Committee, Georgetown University
- 1989-present Member, Radiation Safety Committee
- 1990-1995 Member, Medical Center Research Committee D.C.
- 1992-1994 Chairman, Faculty Practice Association Fiscal Affairs Committee MD/PhD Admissions and Mentorship Committee, Georgetown University School of Medicine

VISITING PROFESSORSHIPS

- 1990-Present: University of Arizona Cancer Center, University of Cincinnati, University of Virginia, University of Pennsylvania, Medical College of Virginia, Johns Hopkins University, Duke University, Thomas Jefferson University Hospital, University of Texas, Southwestern Medical Center

LECTURES (Selected)

- Invited Speaker, "Interstitial Radiation Therapy of Hepatic Metastases from Colorectal Carcinoma," The Future of Brachytherapy Conference, Humana Hospital, Phoenix, AZ
- Invited Speaker, "Molecular Aspects of Resistance of Tumor Cells to Killing by Ionizing Radiation," Human Cancer Colloquium, University of Wisconsin Clinical Cancer Center
- Invited Speaker at Current Topic "Oncogenes" Session at the 38th Annual Meeting of the Radiation Research Society
- Invited Speaker, NCI-DCT Workshop on Radioresistance, Washington, D.C.
- Invited Speaker at The Fifth Annual Symposium of Endocurietherapy: New Techniques in Adjuvant Therapy of Cancer at The Ohio State University Hospital; Topic: "Intraoperative HDR Brachytherapy in Liver Tumors"
- Invited Speaker, Combined Oncology Rounds, Washington Hospital Center; "Radiation Therapy of Primary and Secondary Hepatobiliary Malignancies"
- ASTRO, Refresher Course Number 410; "Treatment of Malignancies of the Liver and Biliary Tract"
- American Society of Therapeutic Radiology Clinical Review Course: "Intraoperative Radiation Therapy of Hepatic Tumors"

- Invited Speaker for the 43rd Annual Midwinter Oncology Conference, Los Angeles Radiological Society; CME Lecture Topics: "Interstitial Intraoperative Radiation in the Management of Primary and Secondary Hepatic Tumors"; "Molecular Biology as Applied to Radiation Oncology"; "Future Prospects in Radiation Oncology"
- Invited Speaker for the 17th Annual Mid-Pacific Oncology Conference, Hawaii; CME Lecture Topics: "Stereotactic Radiation Therapy of Brain Tumors and Vascular Malformations"; "Prostate Cancer: The Current Role of Radiation Therapy"; "Intraoperative Radiation Therapy"; "Molecular Biology as Applied to Radiation Therapy"
- Speaker, CME Course: "Radiation Therapy Update - 1991", Georgetown University Medical Center
- Invited Speaker, Radiotherapy 2001: "Molecular Directions into the Future," Conference at Stanford University
- Keynote speaker at the 23rd Annual Symposium of the National Institute of Radiological Sciences, Chiba, Japan. "Modulation of the Radiation Response of Mammalian Cells by Oncogenes"
- Invited Speaker, Workshop III: NASA Design Study Molecular and Cellular Studies. Data Requirements Regarding Particle Carcinogenesis in the Space Radiation Environment. Armed Forces Radiobiology Research Institute.
- Chairperson "Radiation-induced Gene Expression" minisymposium session. Eighty-sixth Meeting of the American Association for Cancer Research, Toronto, Canada.
- ASTRO, Refresher Course, Lecture, New York City, NY.
- Invited Speaker, Italian Society of Radiation Research, Workshop Lectura Magistralis "Basic Radiobiology and Perspectives for Radiotherapy". "Radiation Inducible Signal Transduction Targets for Radiation Sensitization and Gene Therapy", Padua, Italy, 1999.
- Invited Speaker, "Radiation therapy for colon cancers". LCCC Ruesch Community Outreach Symposium (November 6, 2010), Washington, DC.
- "Radiation Biology of Prostate Cancer", Speaker at Advances in Prostate Cancer 2011 GUH/WHC-Medstar CME Course, Washington, DC.
- "Human Fibroblasts for Large-Scale "Omics" Investigations of ATM Gene Function". Speaker at the Human Cell Transformation: Role of Stem Cells and the Microenvironment 2010 Symposium, Oct 18-19, Montreal, Canada.

OTHER EDUCATIONAL ACTIVITIES

- Lectures to medical students: "Introduction to Clinical Science", Radiation Pathology
- Lecturer to graduate students in "Radiation Biology Principles"
- Organizer and Moderator of CME Course; "Radiation Oncology Update - 1989", Georgetown University Medical Center
- Lecturer in the Graduate Program for Radiation Science, Georgetown University, "Radiation Biology"
- Co-Organizer and Moderator of Oncogene Symposium at the 38th Annual Meeting of the Radiation Research Society
- Moderator/Organizer of Panel on "Oncogenes", Annual Meeting of ASTRO
- Lecturer in the General and Systemic Pathology Course, Georgetown University School of Medicine on "Radiation Pathology"
- Co-Chairman/Organizer, "A Workshop on Neoplastic Transformation in Human Cell Systems In Vitro: Mechanisms of Carcinogenesis", Georgetown University Medical Center
- Contributed chapter to ASCO Educational Book and gave lecture on "Oncogenes and Radiation Therapy" at Annual Meeting
- Lecturer at Health Physics Society Sciences School Course "Cancer and Carcinogenesis"

Panel speaker, ASTRO Annual Meeting "Influence of Oncogenes on the Shoulder and the Terminal Slope of the Radiation Survival Curve"

Radiation Oncology Update

Invited lecturer, ASTRO Annual Meeting, Panel VIII: Oncogene, Signal Transduction and Radiation Response

Lecturer, "Radiation Pathology" in the First Academic Quarter--General Pathology Course, Georgetown University School of Medicine

Speaker, CME Course: "Radiation Therapy Update - 1995", Georgetown University Medical Center

Fourth Bi-Annual Radiation Oncology Update Lecture. "Overview of Molecular Oncology"

Co-Chair: Workshop on Neoplastic Transformation in Human Cell Systems in Culture: Mechanisms of Carcinogenesis. Jointly sponsored by Georgetown University and University of Chicago

Co-Chairman/Organizer, "A Workshop on Neoplastic Transformation in Human Cell Systems In Culture: Mechanisms of Carcinogenesis", Georgetown University Medical Center/ University of Chicago

"Meet the Professor" at the ASTRO annual meeting, Miami Beach, Florida Department of Pathology Invited Guest Speaker, "Molecular basis of Radiation Sensitivity

44th Annual Meeting of the Radiation Research Society, Symposium Chair: "Ataxia Telangiectasia: Recent Molecular Discoveries"

Chairman, "Radiation Signal Transduction" Radiation Research Meeting, Providence, RI

Co-Inventor on Patents

U.S. **Patent 5,756,122** "Liposomally encapsulated nucleic acids having high entrapment efficiencies, method of manufacture and use thereof for transfection of targeted cells"

U.S. **Patent 5,560,923** "Method of encapsulating anthracyclines in liposome"

U.S. **Patents 6,126,965 and 6,333,314** "Liposomes containing oligonucleotides"

U.S. **Patent 6,559,129** "Cationic liposomal delivery system and therapeutic use thereof"

U.S. **Patent 7,842,835** "Deacetylase isoform specific inhibitors and methods of use thereof".

U.S. Patent Application 50/835,259 "Isoform selective HDAC inhibitors". Kozikowski A, Dritschilo A, Jung M, Bakin RE, Tueckmantel W, Gaysin A.

U.S. Patent Application 61,013,866 "Histone deacetylase inhibitor". Brown M, Jung M, Dritschilo A, Kong Y.

U.S. Patent Application 12/375,348 "Isoform selective HDAC inhibitors". Kozikowski A, Jung M, Dritschilo A, Gaysin A, Petukov PA, Tueckmantel W, Yuan H.

U.S. **Patent 6,665,555** "Radiosurgery Methods that Utilize Stereotactic Methods to Precisely Deliver High Dosages of Radiation Especially to the Spine."

PUBLICATIONS

1. Flessa HC, Glick GI, **Dritschilo A**: Thromboembolic disorders in pregnancy: Pathophysiology, diagnosis and treatment with emphasis on heparin. Clin Obstet Gynecol 17:195-235, 1974.
2. **Dritschilo A**, Cassady JR, Camitta B, Jaffe N, Furman L, Traggis D: The role of irradiation in central nervous system treatment and prophylaxis for acute lymphoblastic leukemia. Cancer 37:2735-2739, 1976.
3. **Dritschilo A**, Piro AJ, Belli JA: Repair of radiation damage in plateau-phase mammalian cells: Relationship between sublethal and potentially lethal damage states. Int. J Radiat Biol 30:565-569, 1976.
4. **Dritschilo A**, Chaffey JT, Bloomer W, Marck A: The complication probability factor: A method for radiation treatment plan selection. Br J Radiol 51:370-374, 1978.

5. **Dritschilo A**, Weichselbaum R, Cassady JR, Jaffe N, Green D, Filler RM: The role of radiation therapy in the treatment of soft tissue sarcomas of childhood. Cancer 42:1192-1203, 1978.
6. **Dritschilo A**, Piro AJ, Belli JA: Interaction between radiation and drug in mammalian cells. III The effect of adriamycin and actinomycin-D on the repair of potentially lethal radiation damage. Int J Radiat Biol 35:549-560, 1979.
7. **Dritschilo A**, Sherman D, Emami B, Piro AJ, Hellman S: The cost effectiveness of a radiation therapy simulator: A model for the determination of need. Int J Radiat Oncol Biol Phys 5:243-247, 1979.
8. **Dritschilo A**, Piro AJ, Kelman AD: The effect of cis-platinum on the repair of radiation damage in plateau-phase Chinese hamster (V-79) cells. Int J Radiat Onc Biol Phys 6:723-728, 1980.
9. Wolbarst AB, Sternick ES, Curran BH, Kosinski RJ, **Dritschilo A**: Optimized radiotherapy treatment planning using the complication probability factor (CPF). Int J Radiat Onc Biol Phys 6:723-728, 1980.
10. Wolbarst AB, Sternick ES, Curran BH, Kosinski RJ, **Dritschilo A**: A FORTRAN program for the optimization of radiotherapy treatment planning using the complication probability factor (CPF). Comput Progr Biomed 11:99-104, 1980.
11. Emami B, Nussbaum GH, Hahn N, Piro AJ, **Dritschilo A**, Quimby F: Histopathological study of the effects of hyperthermia on microvasculature. Int J Rad Onc Biol Phys 7:343-348, 1981.
12. Strauss A, **Dritschilo A**, Nathanson L, Piro AJ: Radiation therapy of malignant melanomas. Cancer 47(6):1262-1266, 1981.
13. Strauss A, **Dritschilo A**, Carter B, Nathanson L, Piro AJ: Diagnostic testing for radiation treatment planning of malignant melanoma with special emphasis on CT scanning. Comp Tom 5:37-42, 1981.
14. Abayomi O, **Dritschilo A**, Emami D, Watring WG, Piro AJ: The value of routine tests in the staging evaluation of gynecologic malignancies: A cost effectiveness analysis. Int J Radiat Oncol Biol Phys 8:241-244, 1981.
15. **Dritschilo A**, Bruckman JE, Cassady JR, Belli JA: Tolerance of brain to multiple courses of radiation therapy I. Clinical Experiences, Br J Radiol 54:781-786, 1981.
16. **Dritschilo A**, Sreevalsan T, Gray M, Mossman K: Potentiation of radiation injury by interferon. Am J Clin Oncol (CCT) 5:79-82, 1982.
17. Mossman KL, Hill LT, **Dritschilo A**: Utility of interferons in clinical radiotherapy. JNMA 74:1083-1087, 1982.
18. Stefanik DF, Brereton HD, Lee TC, Chun BK, Cigtay OS, **Dritschilo A**: Fat necrosis following breast irradiation for carcinoma: Clinical presentation and diagnosis. Breast 8:4-6, 1982.
19. Woolley PV, Ayoob MD, Smith FP, **Dritschilo A**: A clinical trial of the effect of S-2-(3 aminoprophlamino)-ethyl phosphorothioic acid (WR 2721) (NSC 296961) on the toxicity of cyclophosphamide. J Clin Oncol 1:198-203, 1983.
20. Grant EG, Richardson JD, Cigtay OS, **Dritschilo A**, Lee TC: Sonography of the breast: Findings following conservative surgery and irradiation for early carcinoma. Radiol 147:535-539, 1983.
21. Delgado G, Butterfield AB, **Dritschilo A**, Hummel S, Harbert J, Petrilli ES, Kot PA: Measure of blood flow by the multiple radioactive microsphere technique in irradiated gastrointestinal tissue. Am J Clin Oncol (CCT) 6:463-467, 1983.
22. **Dritschilo A**, Brennan T, Weichselbaum RR, Mossman KL: Response of human fibroblasts to low dose rate gamma irradiation. Rad Res 100:387-395, 1984.
23. Heywang SH, **Dritschilo A**, Cigtay O: Calcifications following tylectomy and radiation therapy for breast cancer. Fortschr Rontgenstr 141(4):438-441, 1984.

24. Stefanik D, Goldberg R, Byrne P, Smith F, Ueno W, Smith L, Harter K, Bachenheimer L, Beiser C, **Dritschilo A**: Local-regional failure in patients treated with adjuvant chemotherapy for breast cancer. J Clin Oncol 3:660-665, 1985.
25. Kattah JC, Silgals RM, Manz H, Toro JG, **Dritschilo A**, Smith FP: Presentation and management of parasellar and suprasellar metastatic mass lesions. J Neurol Neurosurg Psych 48:44-49, 1985.
26. Kasid UN, Hough C, Thraves, **Dritschilo A**, Smulson M: The association of human c-Ha-ras sequences with chromatin and nuclear proteins. Biochem Biophys Res Comm 128(1):226-232, 1985.
27. Hummel S, Delgado G, Butterfield A, **Dritschilo A**, Harbert J: Measurement of blood flow through surgical anastomosis using the radioactive microsphere technique. Obstet Gynecol 66:579-581, 1985.
28. Lvovsky EA, Mossman KL, Levy HB, **Dritschilo A**: Response of mouse tumor to interferon inducer and radiation. Int J Rad Oncol Biol Phys 11:1721-1725, 1985.
29. Heywang SH, **Dritschilo A**, Cigtay O: Early experience in the mammographic diagnosis of recurrences following tylectomy and irradiation. Fortschr Rontgenstr 142(4):457-460, 1985.
30. Torrisi J, Berg C, Harter K, Lvovsky E, Yeung K, Woolley P, Bonnem E, **Dritschilo A**: Phase-I combined modality clinical trial of alpha-2-interferon and radiotherapy. Int J Rad Oncol Biol Phys 12:1453-1456, 1986.
31. **Dritschilo A**, Grant EG, Harter KW, Holt RW, Rustgi SN, Rodgers JE: Interstitial radiation therapy for hepatic metastasis: Sonographic guidance for applicator placement. AJR 146:275-278, 1986.
32. Thraves P, Mossman K, Brennan T, **Dritschilo A**: Radiosensitization of human fibroblasts by 3-aminobenzamide: An inhibitor of poly(ADP-ribosylation). Radiat Res 104:119-127, 1986.
33. Thraves P, Mossman K, Fraizer D, **Dritschilo A**: Inhibition of potentially lethal damage repair in normal and neoplastic human cells by 3-aminobenzamide: An inhibitor of poly(ADP-ribosylation). Int J Radiat Oncol Biol Phys 12:1541-1545, 1986.
34. Thraves P, Mossman K, Brennan T, **Dritschilo A**: Differential radiosensitization of human tumor cells by 3-aminobenzamide and benzamide: Inhibitors of poly(ADP-ribosylation). Int J Radiat Biol 50:961-972, 1986.
35. Kasid UN, Stefanik DF, Lubet RA, **Dritschilo A**, Smulson ME: Relationship between DNA strand breaks and inhibition of poly(ADP-ribosylation): Enhancement of carcinogen-induced transformation. Carcinogenesis 7:327-330, 1986.
36. McRae D, Rodgers, J, **Dritschilo A**: Dose-volume and complication in interstitial implants for breast cancer. Int J Rad Oncol Biol Phys 13:525-529, 1987.
37. Kasid U, **Dritschilo A**, Rhim J: Human epidermal keratinocytes retain radiation resistance following *in vitro* immortalization and malignant transformation. Radiat Res 111:565-571, 1987.
38. Kasid U, Pfeifer A, Weichselbaum RR, **Dritschilo A**, Mark G: The Raf oncogene is associated with a radiation-resistant human laryngeal cancer. Science 237:1039-1041, 1987.
39. Torrisi J, Treat J, Zeman R, **Dritschilo A**: Radiotherapy in the management of pancreatic islet cell tumors. Cancer 60:64-69, 1987.
40. Nauta RJ, Heres EK, Thomas DS, Harter KW, Rodgers JE, Holt RW, Lee TC, Walsh DB, **Dritschilo A**: Intraoperative single-dose radiotherapy. Arch Surg 122:1392-1395, 1987.
41. **Dritschilo A**, Harter KW, Thomas D, Nauta, Holt R, Lee TC, Rustgi S, Rodgers J: Intraoperative radiation therapy of hepatic metastases: Technical aspects and report of a pilot study. Int J Rad Oncol Biol Phys 14:1007-1011, 1988.

42. Holt RW, Nauta RJ, Lee TC, Heres EK, **Dritschilo A**, Harter KW, Rustgi SN, Rodgers JE: Intraoperative interstitial radiation therapy for hepatic metastases from colorectal carcinomas. Am Surg 54:231-233, 1988.
43. Weichselbaum RR, Beckett MA, Dahlberg W, **Dritschilo A**: Heterogeneity of radiation response of a parent human epidermoid carcinoma cell line and four clones. Int J Rad Oncol Biol Phys 14:907-912, 1988.
44. Weichselbaum RR, Beckett MA, Simon MA, McCauley C, Haraf D, Awan A, Samuels B, Nachman J, **Dritschilo A**: *In vitro* radiobiological parameters of human sarcoma cell lines. Int J Rad Oncol Biol Phys 15:937-942, 1988.
45. Weichselbaum RR, Beckett MA, Schwartz JL, **Dritschilo A**: Radioresistant tumor cells are present in head and neck carcinomas that recur after radiotherapy. Int J Rad Oncol Biol Phys 15:575-579, 1988.
46. Prasad SC, Boyle J, **Dritschilo A**: Quantitation of strand breaks in human DNA using ³²P-ALU hybridization: Application to exponential and plateau-phase cells. Rad Res 117, 538-546, 1989.
47. Prasad S, Thraves P, Kanai Y, Smulson M, **Dritschilo A**: A dot-blot method for screening polyclonal and monoclonal antisera to poly(ADP-ribose). J Immuno Meth 116:79-85, 1989.
48. Cumberlin RL, **Dritschilo A**, Mossman KL: Carcinogenic effects of scattered dose associated with radiation therapy for cancers in the United States. Int J Rad Oncol Biol Phys 17:623-629, 1989.
49. Pfeifer AMA, Kasid U, Tskos MG, Kessler DK, Weichselbaum RR, Thorgeirsson SS, **Dritschilo A**, Mark GE: Implication of the c-raf-1 proto-oncogene in neoplastic transformation *in vivo* and *in vitro*. Cancer Cells 7:177-181, 1989.
50. Kasid U, Pfeifer A, Brennan T, Beckett M, Weichselbaum RR, **Dritschilo A**, Mark GE: Effect of antisense c-raf-1 on tumorigenicity and radiation-sensitivity of a human squamous carcinoma. Science 243:1354-1356, 1989.
51. Kasid U, Weichselbaum RR, Brennan T, Mark G, **Dritschilo A**: Sensitivities of NIH/3T3-derived clonal cell lines to ionizing radiation: Significance for gene transfer studies. Cancer Res 49:3396-3400, 1989.
52. Prasad SC, Thraves PJ, Bhatia KG, Smulson ME, **Dritschilo A**: Enhanced poly(ADP-ribose) polymerase activity and gene expression in Ewing's sarcoma cells. Cancer Res 50:38-43, 1990.
53. Kasid UN, Halligan B, Liu LF, **Dritschilo A**, Smulson M: Poly(ADP-ribose)-mediated post-translational modification of chromatin-associated human topoisomerase I. J Biol Chem 264:18687-18692, 1989.
54. Weichselbaum RR, Beckett MA, Vijayakumar S, Ahmed-Swan S, **Dritschilo A**, Schwartz JL, Moran WJ, Goldman ME, Tybor AG, Vokes EE, Panja WR: Radioresistant tumor cells may be cultured from head and neck carcinoma that fail radiotherapy. Head & Neck Surg 11(4):343-348, 1989.
55. Zeman RK, **Dritschilo A**, Silverman PM, Clark LR, Garra BS, Thomas DS, Ahlgren JD, Smith FP, Korec SM, Nauta RJ: Dynamic CT vs. 0.5 TMR imaging in the detection of surgically proven hepatic metastases. J Comput Assist Tomogr 13(4):637-644, 1989.
56. Thierry AR, Jorgensen TJ, Forst D, Belli JA, **Dritschilo A**, Rahman A: Modulation of multidrug resistance in Chinese hamster cells by liposome-encapsulated doxorubicin. Cancer Commun 1:311-316, 1990.
57. Thraves P, Salehi Z, **Dritschilo A**, Rhim J: Neoplastic transformation of immortalized human epidermal keratinocytes by ionizing radiation. Proc Natl Acad Sci (USA) 87:1174-1177, 1990.

58. Jorgensen TJ, Prasad S, Brennan T, **Dritschilo A**: Constraints to DNA unwinding near radiation-induced strand breaks in Ewing's sarcoma cells. Radiat Res 123:320-324, 1990.
59. Rhim JS, Yoo JH, Park JH, Thraves P, Salehi Z, **Dritschilo A**: Evidence for the multistep of in vitro human epithelial cell carcinogenesis. Cancer Res 50:5653s-5657s, 1990.
60. Prasad SC, Thraves PJ, Bhatia KG, Smulson ME, **Dritschilo A**: Enhanced poly (ADP-ribose) polymerase activity and gene expression in Ewing's sarcoma cells. Cancer Res 50:39-43, 1990.
61. Torrisi J, **Dritschilo A**, Harter K, Helfrich B, Berg B, Whitfield G, Stablein D, Alijani M: A randomized study of the efficacy of adjuvant local graft irradiation following renal transplantation. Int J Rad Oncol Biol Phys 18:1027-1031, 1990.
62. Jorgensen TJ, Leonard JC, Thraves PJ, **Dritschilo A**: Baseline sister chromatid exchange in human cell lines with different poly(ADP-ribose) polymerase levels. Radiat Res 127:107-110, 1991.
63. Weichselbaum RR, Hallahan DE, Suhtahme V, **Dritschilo A**, Sherman MK, Dufe DW. Biological consequences of gene regulation after ionizing radiation exposure. J Natl Cancer Inst 83:480-484, 1991.
64. Pirkowski M, Holloway R, Delgado G, Barnes W, Thomas DS, Torrisi J, Popescu G, Rodgers J, **Dritschilo A**: Radiotherapy of malignant subdiaphragmatic implants in advanced ovarian carcinoma: A new technique. Int J Rad Oncol Biol Phys 5:1105-1108, 1992.
65. Ramsamoj P, Kasid U, **Dritschilo A**: Differential expression of proteins in radioresistant and radiosensitive human squamous carcinoma cells. J Natl Cancer Inst 84:622-628, 1992.
66. Jung M, **Dritschilo A**, Kasid U: Reliable and efficient direct sequencing of PCR amplified double-stranded genomic DNA template. PCR Meth and Appl 1:171-174, 1992.
67. Thierry AR and **Dritschilo A**. Liposomal delivery of antisense oligodeoxynucleotides: Application to the modulation of multidrug resistance in cancer cells. Ann NY Acad Sci 660:300-302, 1992.
68. Thierry AR, **Dritschilo A**, Rahman A. Effect of liposomes on P-glycoprotein function in multidrug resistance cells. Biochem Biophys Res Comm 187:1098-1105, 1992.
69. Thierry AR and **Dritschilo A**. Intracellular availability of unmodified, phosphorothioated and liposomally encapsulated oligodeoxynucleotides for antisense activity. Nucleic Acids Res 21:5691-5698, 1992.
70. Yang JH, Thraves PJ, **Dritschilo A**, Rhim JS: Neoplastic transformation of immortalized human keratinocytes by 2,3,7,8-Tetrachlorodibenzo-p-dioxin. Cancer Res 52:3478-3482, 1992.
71. Prasad SC and **Dritschilo A**: High resolution two-dimensional electrophoresis of nuclear proteins: A comparison of HeLa nuclei prepared by three different methods. Anal Biochem 207:121-128 1992.
72. Jung M, Notario V, **Dritschilo A**: Mutations in the p53 gene in radiation-sensitive and -resistant human squamous carcinoma cells. Cancer Res 52:6390-6393, 1992.
73. Thomas DS, Nauta R, Rodgers JE, Popescu G, Nyguen H, Lee TC, Petrucci P, Harter KW, Holt R, **Dritschilo A**: Intraoperative high dose rate interstitial irradiation of hepatic metastases from colorectal carcinoma: Results of a Phase I-II trial. Cancer 71:1977-1981, 1993.
74. Thierry AR, Rahman A, **Dritschilo A**: Overcoming multidrug resistance in cancer cells using free or liposome-encapsulated antisense oligodeoxynucleotides. Biochem Biophys Res Comm 190:952-960, 1993.

75. Kasid U, Pfeifer A, Merlino G, Mark GE, **Dritschilo A**: Correlation of DNA-transfection and activation of *c-raf-1*, but not EGF receptor, with certain head and neck squamous cell carcinoma-derived cell lines. Radiat Oncol Invest 1:1-13, 1993.
76. Kasid U, Pirollo K, **Dritschilo A**, Chang E: Oncogenic Basis of Radiation Resistance. Advances in Cancer Res 61:195-233, 1993.
77. Thierry AR, Vige D, Belli JA, **Dritschilo A**, Rahman A: Modulation of doxorubicin resistance in multidrug resistant cancer cells. FASEB J 7:572-579, 1993.
78. Rhim JS, Thraves PJ, **Dritschilo A**, Kuettel MR, Lee MS: Radiation-induced neoplastic transformation of human cells. Scanning Microscopy 7(1):209-216, 1993.
79. Jung M, **Dritschilo A**, Mark G, Kasid U: Identification of multiple repeat sequences and transcription-related elements within introns 4,8, and 9 of human *raf-1*. Biochem Biophys Res Comm 190:462-469, 1993.
80. Parda D, Thraves PJ, Lee MS, Kuettel M, Kaighn ME, Rhim JS **Dritschilo A**: Neoplastic transformation of a human prostate epithelial cell lines by the *Ki-ras* oncogene. The Prostate 23(2):91-98, 1993.
81. Jorgensen TJ, Notario V, Thraves PJ, **Dritschilo A**: Radiation response of NIH/3T3 mouse fibroblasts overexpressing human poly(ADP-ribose) polymerase. Radiat Oncol Invest 1:189-197, 1993.
82. Avila MA, Otero G, Cansado J, **Dritschilo A**, Velasco JA, Notario V: Activation of phospholipase D: Alternative signal transduction pathway responsive to gamma radiation. Cancer Res 53:4474-4476, 1993.
83. Jung M, Kondratyev AD, **Dritschilo A**: Elongation factor-1 is enhanced following exposure to ionizing radiation. Cancer Res 54:2541-2543, 1994.
84. Avila MA, Velasco JA, Smulson ME, **Dritschilo A**, Castro R, Notario V: Functional expression of human poly(ADP-ribose) polymerase in *Schizosaccharomyces pombe* results in mitotic delay at G₁, increased mutation rate, and sensitization to radiation. Yeast 10:1003-1017, 1994.
85. Prasad SC, **Dritschilo A**, Rhim J, Worland P, Thraves PJ: Protein expression patterns of radiation transformed human epidermal keratinocytes: A two-dimensional gel electrophoretic approach. Radiat Oncol Invest 1:314-324, 1994.
86. Jung M and **Dritschilo A**: Modification of radiosensitivity of human testicular cancer cells by simian virus 40 sequences. Radiat Res 140:186-190, 1994.
87. Jung M, Kern FG, Jorgensen TJ, McLeskey SW, Blair, OC, **Dritschilo A**: Fibroblast Growth factor-4 enhanced G₂ arrest and cell survival following ionizing radiation. Cancer Res 54:5194-5197, 1994.
88. Thraves PJ, Varghese S, Jung M, Grdina DJ, Rhim JS, **Dritschilo A**: Transformation of human epidermal keratinocytes with fission neutrons. Carcinogenesis, 15:2867-2873, 1994.
89. Varghese S, Jung M, Prasad S, Rhim J, **Dritschilo A**: The role of p53 and ras genes in radiation-induced transformation of immortalized human epidermal keratinocytes. Radiat Oncol Invest 2:119-125, 1994.
90. Al-Nabulsi I, Takamiya Y, Voloshin Y, **Dritschilo A**, Martuza RL, Jorgensen T: Expression of thymidine kinase is essential to low dose radiation resistance of rat glioma cells. Cancer Res 54:5614-5617, 1994.
91. Prasad SC, Notario V, Sherareh S, **Dritschilo A**: Poly(ADP-ribose) polymerase in HeLa cells: a high resolution two-dimensional gel analysis. Applied and Theor Electroph 4:30-10, 1994.
92. Thierry AR, Rahman A, **Dritschilo A**: A new procedure for the preparation of liposomal doxorubicin: biological activity in multidrug-resistant tumor cells. Cancer Chemother Pharmacol 35:84-88, 1994.

93. Prasad SC, Walent J, **Dritschilo A**: ADP-ribosylation of heterogeneous ribonucleoproteins in HeLa cells. Biochem Biophys Res Commun 204:772-779, 1994.
94. Stevens CW, Velasco JA, DiPaolo JA, **Dritschilo A**, Notario V: Radiation response of human cervical carcinoma cells transfected with sense and antisense p53 retroviral constructs. Radiat Oncol Invest 2:212-218, 1995.
95. Jung M, Lee SA, Zhang Y, **Dritschilo A**: Correction of radiation sensitivity in ataxia telangiectasia cells by I κ B- α expression corrects. Science 268:1619-1621, 1995.
96. Velasco JA, Ramsamooj P, Thraves PJ, Eva A, **Dritschilo A**, Notario V: Co-regulated expression of db1 and poly(ADP-ribose) polymerase in Ewing's sarcoma cells and db1-transformed NIH/3T3 fibroblasts. Oncogene 10:2253-2258, 1995.
97. Jung M, Zhang Y, Salehi Z, Kern FG, **Dritschilo A**: Modification of ataxia telangiectasia cellular radiation sensitivity by transformation with episomally maintained vectors. Radiat Oncol Invest 2:257-263, 1995.
98. Ramsamooj P, Notario V, **Dritschilo A**: Enhanced expression of calreticulin in the nucleus of radioresistant squamous carcinoma cells in response to ionizing radiation. Cancer Res 55:3016-3021, 1995.
99. Soldatenkov VA, Velasco JA, Avila MA, **Dritschilo A**, Notario V: Cloning and characterization of *SpTRK*, a gene coding for a putative potassium transporter from *Schizosaccharomyces pombe*s. Gene 161:97-101, 1995.
100. Soldatenkov VA, Prasad S, Notario V, **Dritschilo A**: Radiation-induced apoptosis of Ewing's sarcoma cells: DNA fragmentation and proteolysis of poly (ADP-ribose) polymerase. Cancer Res 55:4240-4242, 1995.
101. Ramsamooj P, Notario V, **Dritschilo A**: Modification of nucleolar protein B23 after exposure to ionizing radiation. Radiat. Res 143:158-164, 1995.
102. Velasco JA, Stevens CW, Esteban JM, Ruthsatz MKJ, Ramsamooj P, **Dritschilo A**, Notario V: Modulation of proliferation and tumorigenic potential of cervical carcinoma cells by the expression of sense and antisense p53. Int J Oncol 7:883-888, 1995.
103. Kuettel MR, Thraves P, Prasad S, Varghese S, **Dritschilo A**: Molecular Characterization of Radiation-Induced Transformation of Human Prostate Epithelial Cells. Int J Radiat Oncol Invest Phys 32:345, 1995.
104. Kuettel MK, Thraves PJ, Jung M, Prasad S, Varghese S, Rhim JS, **Dritschilo A**: Radiation-induced neoplastic transformation of human prostate epithelial cells. Cancer Res 56:5-10, 1996.
105. Ramsamooj P, Prasad S, **Dritschilo A**, Notario V: Cell-cycle specific patterns of ADP-ribosylation and the effect of ionizing radiation: cyclins A, B1 and D1, cdc2, and PCNA are not ADP-ribosylated. Int J Oncol 8:803-808, 1996.
106. Soldatenkov V, **Dritschilo A**, Notario V: Identification of a rearrangement in the 5' upstream region of the poly (ADP-ribose) polymerase pseudogene on chromosome 13 in Ewing's sarcoma cells. Oncology Reports 3:651-654, 1996.
107. Kuettel M, Jung M, Thraves PJ, Prasad S, Varghese S, Rhim JS, **Dritschilo A**: Human prostate epithelial cell model system for carcinogenic studies. Radiat Oncol Invest 3:340-345, 1996.
108. Jung M, Dimtchev A, Zhang Y., **Dritschilo A**: Identification of gene(s) involved in carcinogenic progression of ataxia telangiectasia cells. Radiat Oncol Invest 3:272-278, 1996.
109. Thraves PJ, Varghese S, Jung M., Prasad S, Rhim J, **Dritschilo A**: Molecular and genetic characterization of human keratinocytes transformed with ionizing radiation. Radiat Oncol Invest 3:392-397, 1996.
110. Soldatenkov VA, Notario V, **Dritschilo A**: Expression of the human Bcl-2 increases resistance of Ewing's sarcoma cells to apoptosis and inhibits poly (ADP-ribose) polymerase cleavage induced by radiation. Intl J Oncology 9:547-551, 1996.

111. Gokhale PC, Radhakrishnan B, Husain SR, Abernethy DR, Sacher R, **Dritschilo A**, Rahman A: An improved method of encapsulation of doxorubicin in liposomes: pharmacological, toxicological, and therapeutic evaluation. Br J Cancer 7:43-48, 1996.
112. Albor A, Thraves PJ, **Dritschilo A**, Notario V. Oncogenic activation of the tyrosine kinase domain of the human trk proto-oncogene by fusion to a cell adhesion molecule. Oncogene 13:1755-1763, 1996.
113. Pang D, Popescu GF, Rodgers J, Berman BL, **Dritschilo A**: Atomic force microscopy investigation of radiation-induced DNA strand breaks. Scanning Microscopy vol 3-5, 1996.
114. Prasad S, Thraves PJ, **Dritschilo A**, Rhim J, Kuettel M: Cytoskeletal changes during radiation-induced neoplastic transformation of human prostate epithelial cells. Scanning Microscopy, 10:1093-1104, 1996.
115. Hukku B, Thraves PJ, **Dritschilo A**, Rhim JS: Chromosomal changes observed in immortalized human keratinocytes transformed by ionizing radiation. Cancer Genet Cytogenet 93:125-139, 1997.
116. Jung M, Kondratyev A, Lee SA, Dimtchev A, **Dritschilo A**: ATM gene product phosphorylates I κ B- α . Cancer Res 57:24-27, 1997.
117. Jung M, Lee SA, Zhang Y, **Dritschilo A**: Regulation of p53 in response to ionizing radiation in ataxia telangiectasia (AT) fibroblasts. Int J Radiat Oncol 37:417-422, 1997.
118. Soldatenkov VA, **Dritschilo A**, Wang F-H, Olah Z, Anderson WB, Kasid U: Inhibition of Raf-1 protein kinase by antisense phosphorothioate oligodeoxynucleotide is associated with sensitization of human laryngeal squamous carcinoma cells to gamma radiation. The Cancer Journal of Scientific American 3:13-20, 1997.
119. Soldatenkov VA and **Dritschilo A**: Apoptosis of Ewing's sarcoma cells is accompanied by accumulation of ubiquitinated proteins. Cancer Res 57:3881-3885, 1997.
120. Pang D, Yoo Sunghan, Dynan WS, Jung M, **Dritschilo A**: Ku proteins join DNA fragments as shown by atomic force microscopy. Cancer Res 57:1412-1415, 1997.
121. Jung M, Zhang Y, **Dritschilo A**: Expression of a dominant negative I κ B- α modulates hypersensitivity of AT fibroblasts to streptonigrin-induced apoptosis. Radiat Oncol Invest 5:265-268, 1997.
122. Gokhale PC, Soldatenkov VA, Wang F-H, Rahman A, **Dritschilo A**, Kasid U: Antisense raf oligodeoxyribonucleotide is protected by liposomal encapsulation and inhibits Raf-1 protein expression in vitro and in vivo: implication for gene therapy of radioresistant cancer. Gene Ther 4:1289-1299, 1997.
123. Pang D, Vidic B, Rodgers J, Berman BL, **Dritschilo A**: Atomic force microscopy imaging of DNA and DNA repair proteins: applications in radiobiological research. Radiat Oncol Invest 5:163-169, 1997.
124. Prasad S, Thraves PJ, **Dritschilo A**, Kuettel MR: Protein expression changes associated with radiation-induced neoplastic progression of human prostate epithelial cells. Electrophoresis 18:629-637, 1997.
125. Ramsamooj P, Kuettel M, **Dritschilo A**, Jung M: p53 independent tumorigenic progression of human prostate cells. Radiat Oncol Invest 5:269-274, 1997.
126. Soldatenkov VA and **Dritschilo A**: Apoptosis of Ewing's sarcoma cells is accompanied by accumulation of ubiquitinated proteins in human breast carcinoma cells. Cell Death Differ 5:307-312, 1998.
127. Prasad S, Thraves PJ, Kuettel MR, **Dritschilo A**: Cytoskeletal and adhesion protein changes during neoplastic progression of human prostate epithelial cells. Crit Rev Oncol Hemat 27:69-79, 1998.
128. Prasad S, Thraves PJ, **Dritschilo A**, Kuettel MR: Expression of cytokeratin-19 as a marker of neoplastic progression of human prostate epithelial cells. The Prostate 35:203-211, 1998.

129. Jung M, Zhang Y, Dimtchev A, **Dritschilo A**: Impaired NF- κ B regulation results in ionizing radiation-induced apoptosis. Radiat Res, 149:596-601, 1998.
130. Lee SJ, Dimtchev A, **Dritschilo A**, Jung M: A novel ionizing radiation-induced signaling pathway that activates the transcription factor NF- κ B. Oncogene, 17:1821-1826, 1998.
131. Smulson ME, Pang D, Jung M, Spoonde A, Rosenthal D, Yakovlev A, **Dritschilo A**: Irreversible binding of Poly(ADP-ribose) polymerase cleavage product to DNA ends revealed by atomic force microscopy: possible role in apoptosis. Cancer Res, 58:3495-3498, 1998.
132. Prasad S, Soldatenkov VA, Srinivasarao G, **Dritschilo A**: Identification of keratins 18, 19 and heat-shock protein 90 as candidate substrates of proteolysis during ionizing radiation-induced apoptosis of estrogen-receptor negative breast tumor cells. Intl J Oncol 13:757-764, 1998.
133. Prasad S, Thraves PJ, Kuettel MR, Srinivasarao G, **Dritschilo A**, Soldatenkov VA: Apoptosis-associated proteolysis of vimentin in human prostate epithelial tumor cells. Biochem Biophys Res Comm 249:332-338, 1998.
134. Pang D, Berman BL, Chasovskikh S, Rodgers JE, **Dritschilo A**. Investigation of Neutron-induced damage in DNA by atomic force microscopy: experimental evidence of clustered DNA lesions. Radiat Res 150:612-618, 1998.
135. Lee SA, **Dritschilo A**, Jung M: Impaired ionizing radiation-induced activation of a nuclear signal essential for phosphorylation of c-Jun by dually phosphorylated c-jun amino-terminal kinases in ataxia telangiectasia fibroblasts. JBC 273:32889-32894, 1998.
136. Prasad SC, Soldatenkov VA, Notario V, Smulson M, **Dritschilo A**.: Detection of poly(ADP-ribose) polymerase fragments during ionizing radiation-induced apoptosis of MDA-MB-468 breast cancer cells: epitope specific antibody blotting of two dimensional gels. Electrophoresis 20: 618-625, 1999.
137. Prasad S, Thraves PJ, Soldatenkov VA, Varghese S, **Dritschilo A**. Differential expression of stathmin during neoplastic conversion of human prostate epithelial cells is reversed by hypomethylating agent, 5-azacytidine. Intl J Oncol 14:529-534, 1999.
138. Prasad S, Soldatenkov VA, Srinivasarao G, **Dritschilo A**. Intermediate filament proteins during carcinogenesis and apoptosis. Int J Oncol Mar;14:563-70, 1999.
139. Prasad SC, Soldatenkov VA, Kuettel MR, Thraves PJ, Zou X, **Dritschilo A**: Protein changes associated with ionizing radiation-induced apoptosis in human prostate epithelial tumor cells. Electrophoresis 20:1065-1074, 1999.
140. Gokhale PC, McRae D, Monia BP, Bagg A, Rahman A, **Dritschilo A**, Kasid U. Antisense raf oligodeoxyribonucleotide is a radiosensitizer *in vivo*. Antisense and Nucleic Acid Drug Development 9:191-201, 1999.
141. Varghese S, Schmidt-Ulrich R, **Dritschilo A**, Jung M. Enhanced radiation late effects and cellular radiation sensitivity in an ATM heterozygous breast cancer patient. Radiat Oncol Invest. 7:231-237, 1999.
142. Soldatenkov VA, Albor A, Patel BKR, Dreszer R, **Dritschilo A**, Notario V: Regulation of the human poly(ADP-ribose) polymerase promoter by the ETS transcription factor, Oncogene 18: 3954-3962, 1999.
143. Soldatenkov VA, **Dritschilo A**, Ronai Z, Fuchs SY: Inhibition of homologue of slim (HOS) function sensitizes human melanoma cells for apoptosis. Cancer Res 59:5085-5088, 1999.
144. Kim GD, Choi YH, Dimtchev A, Jeong SJ, **Dritschilo A**, Jung M. Sensing of ionizing radiation-induced DNA damage by ATM through interaction with histone deacetylase. J Biol Chem, 274:31127-31130, 1999.
145. **Dritschilo A**. Radiosensitivity and Transcription Factor NF- κ B Inhibition--Progress and Pitfalls. J Natl Cancer Inst 91:1910-1911, 1999.

146. Gagnon GJ, Harter KW, Berg CD, Lynch JH, Cornell DR, Kuettel MR, **Dritschilo A**. Limitations of reduced-field irradiated volume and technique in conventional radiation therapy of prostate cancer: implications for conformal 3-D treatment. Int J Cancer 90:265-74, 2000.
147. Smulson ME, Simbulan-Rosenthal CM, Boulares AH, Yakovlev A, Stoica B, Iyer S, Luo R, Haddad B, Wang ZQ, Pang T, Jung M, **Dritschilo A**, Rosenthal DS. Roles of poly(ADP-ribosyl)ation and PARP in apoptosis, DNA repair, genomic stability and functions of p53 and E2F-1. Review: Adv Enzyme Regul 40:183-215, 2000.
148. Pang D, Chasovskikh S, Cohen JS, Obcemea C, **Dritschilo A**. Atomic force microscopy examination of conformations of polynucleotides in response to platinum isomers: significance of GC content at broken ends. Int J Cancer 90:68-72, 2000.
149. Valerie K, **Dritschilo A**, McKenna G, Schmidt-Ullrich RK. Novel molecular targets for tumor radiosensitization: Molecular Radiation Biology and Oncology Workshop: translation of molecular mechanisms into clinical radiotherapy. Int J Cancer 90(1):51-8, 2000.
150. Jung M, Dimtchev A, Zhang Y, **Dritschilo A**. Expression cloning to identify candidate genes involved in prostate carcinogenesis. Radiat Res, 568-570, 2000.
151. Lee SA, **Dritschilo A**, Jung M. Role of ATM in oxidative stress-mediated c-Jun phosphorylation in response to ionizing radiation and CdCl₂. J Biol Chem 276:11783-90, 2001.
152. Simbulan-Rosenthal CM, Rosenthal DS, Luo R, Samara R, Jung M, **Dritschilo A**, Spoonde A, Smulson ME. Poly(ADP-ribosyl)ation of p53 *in vitro* and *in vivo* modulates binding to its DNA consensus sequence. Neoplasia 3:179-188, 2001.
153. Zhang Y, Dimtchev A, **Dritschilo A** and Jung M. Ionizing radiation-induced apoptosis in ataxia telangiectasia: Roles of caspase-9 activation and cellular inhibitor of apoptosis protein-1. J Biol Chem 276:28842-28848, 2001.
154. Jung M and **Dritschilo A**. NF- κ B Signaling Pathway as a Target for Human Tumor Radiosensitization. Invitation review, Seminars in Radiation Oncology 2001.
155. Trofinova I, **Dritschilo A**, Soldatenkov VA. Poly(ADP-ribose) polymerase and transcriptional regulation in DNA-damage response. Anticancer Res 21:1535-1536, 2001.
156. Newman R, Soldatenkov VA, **Dritschilo A**, and Notario V. PARP overexpression in Ewing's sarcoma cells is not regulated by decreased turnover of *de novo* synthesized polymerase. Oncol Rep 9:529-532, 2002.
157. Soldatenkov VA, Trofimova I, Rouzaut A, McDermott F, **Dritschilo A**, and Notario V: Differential regulation of the response to DNA-damage response in Ewing's sarcoma cells by ETS-1 and EWS/FLI-1 transcription factors. Oncogene 21: 2890-2895, 2002.
158. Soldatenkov VA, Chasovskikh S, Potaman VN, Trofimova I, Smulson ME, **Dritschilo A**. Transcriptional repression by binding of poly(ADP-ribose) polymerase to promoter sequences. J Biol Chem 277(1):665-670, 2002.
159. Sommer S, Buzin CH, Jung M, Zheng J, Liu Q, Jeong SJ, Moulds J, Nguyen VQ, Feng J, Bennett WP, **Dritschilo A**. Elevated frequency of ATM gene mutations in breast cancer relative to ethnically matched controls. Cancer Genetics Cytogenet 134:25-32, 2002.
160. S. Chasovskikh, **Dritschilo A**. Magnesium concentration effects on cruciform extrusion in supercoiled DNA examined by atomic force microscopy. Applied Surface Science 188:481-485, 2002.
161. Kim BY, Gaynor RB, Song K, **Dritschilo A** and Jung M. Constitutive activation of NF- κ B in Ki-ras-transformed prostate epithelial cells. Oncogene 21:4490-4497, 2002.
162. Trofimava I, Dimtchev A, Jung M, Rosenthal D, Smulson M, **Dritschilo A**, Soldatenkov VA. Gene therapy for prostate cancer by targeting poly(ADP)-ribose polymerase. Cancer Res 62:6879-6883, 2002.

163. Gokhale PC, Zhang C, Newsome J, Pei J, Ahmad I, Rahman A, **Dritschilo A**, Kasid U. Pharmacokinetics, toxicity, and efficacy of ends-modified raf antisense oligodeoxyribonucleotide encapsulated in a novel cationic liposome (LErafAON). Clin Cancer Res 8:3611-3621, 2002.
164. Kasid, U and **Dritschilo A**. RAF antisense oligonucleotide as a tumor radiosensitizer. Oncogene 22:5876-5884, 2003.
165. Pei J, Zhang C, Gokhale PC, Rahman A, **Dritschilo A**, Ahmad I, Kasid UN. Combination with liposome-entrapped, ends-modified raf antisense oligonucleotide (LErafAON) improves the anti-tumor efficacies of cisplatin, epirubicin, mitoxantrone, docetaxel and gemcitabine. Anticancer Drugs 5(3):243-253, 2004.
166. Zhang Y, Jung M, **Dritschilo A**, Jung M. Enhancement of radiation sensitivity of human squamous carcinoma cells by histone deacetylase inhibitors. Radiat Res 161:667-674, 2004.
167. Jung M, Zhang Y, Dimtchev A, Subramanian MR, Suthanthiran K, **Dritschilo A**. Interstitial gene delivery in human xenograft prostate tumors using titanium metal seeds. Mol Cancer Ther 3:655-659, 2004.
168. Zhang L, Yoo S, **Dritschilo A**, Belyaev I, Soldatenkov V. Targeting Ku protein for sensitizing of breast cancer cells to DNA-damage. Int J Mol Med 14:153-159, 2004.
169. Kim KM, Zhang Y, Kim BY, Jeong SJ, Lee SA, Kim GD, **Dritschilo A**, Jung M. The p65 subunit of nuclear factor-kappaB is a molecular target for radiation sensitization of human squamous carcinoma cells. Mol Cancer Ther 3:693-698, 2004.
170. Broustas CG, Gokhale PC, Rahman A, **Dritschilo A**, Ahmad I, Kasid U. BRCC2, a novel BH3-like domain-containing protein, induces apoptosis in a caspase-dependent manner. J Biol Chem 279:26780-26788, 2004.
171. Mewani RR, Tang W, Rahman A, **Dritschilo A**, Ahmad I, Kasid UN, Gokhale PC. Enhanced therapeutic effects of doxorubicin and paclitaxel in combination with liposome-entrapped ends-modified raf antisense oligonucleotide against human prostate, lung and breast tumor models. Int J Onc 24:1181-1188, 2004.
172. Singh AM, Gagnon G, Collins B, Niroomand-Rad A, McRae D, Zhang Y, Regan J, Lynch J, **Dritschilo A**. Combined external beam radiotherapy and Pd-103 brachytherapy boost improves biochemical failure free survival in patients with clinically localized prostate cancer: Results of a matched pair analysis. Prostate 62(1):54-60, 2005.
173. Chen B, Petukhov PA, Jung M, Velena A, Eliseeva E, **Dritschilo A**, Kozikowski AP. Chemistry and biology of mercaptoacetamides as novel histone deacetylase inhibitors. Bioorg Med Chem Lett. 15(5):1389-92, 2005.
174. Jung M, Velena A, Chen B, Petukhov PA, Kozikowski AP, **Dritschilo A**. Novel HDAC inhibitors with radiosensitizing properties. Radiat Res. 163(5):488-93, 2005.
175. Chasovskikh S, Dimtchev A, Smulson M, **Dritschilo A**. DNA transitions induced by binding of PARP-1 to cruciform structures in supercoiled plasmids. Cytometry A, 68(1):21-27, 2005.
176. Pang D, Rodgers JE, Berman BL, Chasovskikh S, **Dritschilo A**. Spatial distribution of radiation-induced double-strand breaks in plasmid DNA as resolved by atomic force microscopy. Radiat Res. 164(6):755-65, 2005.
177. Jung M, Kozikowski A, **Dritschilo A**. Rational Design and Development of Radiation-Sensitizing Histone Deacetylase Inhibitors. Chemistry & Biodiversity. 2:1452-1461, 2005.
178. Mewani RR, Tian S, Li B, Danner MT, Carr TD, Lee S, Rahman A, Kasid UN, Jung M, **Dritschilo A**, Gokhale PC. Gene expression profile by inhibiting Raf-1 protein kinase in breast cancer cells. Int J Mol Med. 17(3):457-63, 2006.
179. **Dritschilo A**, Huang CH, Rudin CM, Marshall J, Collins B, Dul JL, Zhang C, Kumar D, Gokhale PC, Ahmad A, Ahmad I, Sherman JW, Kasid UN. Phase I study of liposome-encapsulated c-raf antisense oligodeoxyribonucleotide infusion in combination with

- radiation therapy in patients with advanced malignancies. *Clin Cancer Res.* 12(4):1251-9, 2006. Zhang Y, Carr T, Dimtchev A, Zaer N, **Dritschilo A**, Jung M. Attenuated DNA damage repair by trichostatin A through BRCA1 suppression. *Radiat Res* 168: 115-124, 2007. PMID: 17722998.
180. Gagnon GJ, Henderson FC, Gehan EA, Sanford D, Collins BT, Moulds JC, **Dritschilo A**. Cyberknife radiosurgery for breast cancer spine metastases: a matched-pair analysis. *Cancer* 110(8):1796-802, 2007. PMID: 17786939.
 181. Collins SP and **Dritschilo A**. The mismatch repair and base excision repair pathways: an opportunity for individualized (personalized) sensitization of cancer therapy. *Cancer Biol Ther* 8(12):48-50, 2009. PMID: 19421005.
 182. **Dritschilo A**. Ablative RT protects immune responses. *Blood* 114(3):497-498, 2009. PMID: 19608755.
 183. Timofeeva OA, Zhang X, Ransom HW, Varghese RS, Kallakury B, Wang K, Ji Y, Rhim JS, Cheema A, Jung M, Brown M, and **Dritschilo A**. Enhanced expression of survival, migration, and invasion genes in prostate cancer cells from African American men. *Int J Oncol* ;35(4):751-60, 2009. PMID: 19724911.
 184. Park HU, Suy S, Danner , Dailey V, Zhang Y, Li H, Hyde DR, Collins BT, Gagnon G, Kallakury B, Kumar D, Brown ML, Fornace A, **Dritschilo A**, and Collins SP. AMP-activated protein kinase promotes human prostate cancer cell growth and survival. *Mol Cancer Ther* 8:733-741, 2009. PMID: 19372545.
 185. Oermann EK, Slack RS, Hanscom HN, Lei S, Suy S, Park HU, Kim JS, Sherer BA, Collins BT, Satinsky AN, Harter KW, Batipps GP, Constantinople NL, DeJter SW, Maxted WC, Regan JB, Pahira JJ, McGeagh KG, Jha RC, Dawson NA, **Dritschilo A**, Lynch JH, Collins SP. A pilot study of intensity modulated radiation therapy with hypofractionated stereotactic body radiation therapy (SBRT) boost in the treatment of intermediate- to high-risk prostate cancer. *Technol Cancer Res Treat* 9(5):453-62, 2010. PMID: 20815416
 186. Taylor KL, Davis KM, Lamond T, Williams RM, Schwartz MD, Lawrence W, Feng S, Brink S, Birney A, Lynch J, Regan J, **Dritschilo A**. Use and evaluation of a CD-ROM-based decision aid for prostate cancer treatment decisions. *Behav Med.* 2010 Oct-Dec; 36(4):130-40. PMID: 21186436
 187. Suy S, Oermann E, Hanscom H, Lei S, Vahdat S, Yu X, Park HU, Chen V, Collins BT, McGeagh K, Dawson N, Jha R, Azumi N, **Dritschilo A**, Lynch J, Collins SP. Histopathologic effects of hypofractionated robotic radiation therapy on malignant and benign prostate tissue. *Technol Cancer Res Treat.* 2010 Dec; 9(6):583-7. PMID: 21070080
 188. Cheema AK, Timofeeva OA, Varghese RS, Dimtchev A, Sheikh KD, Shulaev V, Suy S, Collins S, Ransom HW, Jung M, **Dritschilo A**. Integrated analysis of ATM mediated gene and protein expression impacting cellular metabolism. *J Proteome Res.* 2011 Feb 15. [Epub ahead of print] PMID: 213226492.
 189. Jung M, Dimtchev A, Velen A, **Dritschilo A**. Combining radiation therapy with interstitial radiation-inducible TNF- α expression for locoregional cancer treatment. *Cancer Gene Ther.* 2011 Mar; 18(3):189-95. Epub 2010 Nov 5. PMID: 21052099
 190. Unger K, Ju A, Oermann E, Suy S, Yu X, Vahdat S, Subramaniam D, Harter KW, Collins SP, **Dritschilo A**, Anderson E, Collins BT. CyberKnife for hilar lung tumors: report of clinical response and toxicity. *J Hematol Oncol.* 2010 Oct 22; 3:39. PMID: 20969774
 191. Kosti O, Xu X, Veenstra TD, Hsing AW, Chu LW, Goldman L, Bebu I, Collins S, **Dritschilo A**, Lynch JH, Goldman R. Urinary estrogen metabolites and prostate cancer risk: A pilot study. *Prostate.* 2011 Apr;71(5):507-16. doi: 10.1002/pros.21262. Epub 2010 Sep 30. PMID: 20886539

192. Varghese RS, Cheema A, Cheema P, Bourbeau M, Tuli L, Zhou B, Jung M, **Dritschilo A**, Ressom HW. Analysis of LC-MS data for characterizing the metabolic changes in response to radiation. *J Proteome Res.* 2010 May 7;9(5):2786-93.PMID: 20329776
193. Oermann EK, Suy S, Hanscom H, Kim JS, Lei S, Yu X, Zhang G, Ennis B, Rohan JP, Piel N, Sherer BA, Borum D, Chen VJ, , Batipps GP, Constantinople NL, Dejter SW, Bandi G, Pahira J, McGeagh K, Adams-Campbell L, Jha R, Dawson N, Collins BT, **Dritschilo A**, Collins, Lynch JH, Collins SP. Low incidence of new biochemical and clinical hypogonadism following hypofractionated stereotactic body radiation therapy (SBRT) monotherapy for low-to intermediate risk prostate cancer. *J Hematol & Oncol* 2011 Mar 27; 4(1): 12. Epub ahead of print.
194. Cheema A, Timofeeva O, Varghese R, Shiekh K, Shulaev V, Suy S, Collins S, Ressom H, Jung M, **Dritschilo A**. Technical notes: Integrated analysis of ATM mediated gene and protein expression impacting cellular metabolism. In-press. *J. of Proteomic Research* 2011.
195. Pang D, Winters T A, JUNG M, Purkayastha S, Cavalli L R, Chasovkikh S, Haddad B R and **Dritschilo A**, Radiation-generated short DNA fragments may perturb non-homologous end-joining and induce genomic instability *J. of Radiation Res.* In Press. 2011/01/13
196. Hu ZZ, Huang H, Wu CH, Jung M, **Dritschilo A**, Riegel AT, Wellstein A. Omics-Based Molecular Target and Biomarker Identification. *Bioinformatics for Omics Data: Methods Mol Biol.* 719:547-71, 2011. Humana Press. PMID: 21370102.

REVIEWS AND BOOK CHAPTERS

1. **Dritschilo A** and Piro AJ: Clinical combinations of radiation and drugs in the management of tumors in adults: Radiation-drug interactions in the treatment of cancer. GH Sokol and RP Maickel, eds., John Wiley & Sons, Inc., 1980.
2. **Dritschilo A** and Piro AJ: Therapeutic implications of heat as related to radiation therapy. *Seminars in Oncology* 8(1):83-91, March 1981.
3. **Dritschilo A** and Sherman DS: Radiation and chemical injury in the bone marrow. *Environmental Health Perspectives* 39:59-64, June 1981.
4. Smulson ME, Hough C, Kasid U, **Dritschilo A**, Lubet R: DNA strand breaks and poly(ADP-ribosylated) mediation of transcriptionally active chromatin and transforming gene stability. In *ADP-Ribosylation of Proteins* (FR Althaus, H Hilz, and S Shall), Springer-Verlag, Berlin Heidelberg, pp. 207-216, 1985.
5. Torrisi J, Berg C, Bonnem E, **Dritschilo A**: The combined use of interferon and radiotherapy in cancer management. *Seminars in Oncology* 3(2):78-83, September 1986.
6. Mossman KL, Thomas DS, **Dritschilo A**: Environmental radiation and cancer. *Environmental Carcinogenesis Reviews* (J. Envir. Sci. Hlth.) C4(2):119-161, 1986.
7. **Dritschilo A**, Harter KW, Grant E, Holt R, Lee TC, Nauta R, Rustgi S, Rodgers J: Techniques for percutaneous and intraoperative interstitial radiation therapy of hepatic metastases. In *Proceedings of the First International Meeting of GammaMed Users* (SM Shah, ed.), Mick Radio-Nuclear, Inc., pp. 112-118, 1987.
8. Prasad SC, Thraves PJ, Boyle J, **Dritschilo A**: Heterogeneity of Polyclonal Antisera to ADP-ribose and Their Use as Probes for ADP-Ribosylation in Human Tumor Cells. In: *ADP-Ribose Transfer Reactions: Mechanisms and Biological Significance* (MK Jacobson and EL Jacobson, eds), 1989.

9. Thraves PJ, Bhatia K, Smulson ME, **Dritschilo A**: Radiation Sensitivity of Human Cells and the Poly(ADP-Ribose) Polymerase Gene. In: ADP-Ribose Transfer Reactions: Mechanisms and Biological Significance (MK Jacobson and EL Jacobson, eds), 1989.
10. Smulson M, Alkhatib H, Bhatia K, Chen D, Cherney B, Notario V, Tahourdin C, **Dritschilo A**, Hensley P, Breitman T, Stein G, Pommier Y, McBride O, Bustin M, Giri C: The Cloning of the cDNA and Gene for Human Poly(ADP-Ribose) Polymerase: Status on the biological Function(s) Using Recombinant Probes. In: ADP-Ribose Transfer Reactions: Mechanisms and Biological Significance (MK Jacobson and EL Jacobson, eds), 1989.
11. Smulson M, Alkhatib H, Bhatia K, Chen D, Cherney B, Notario V, Tahourdin C, **Dritschilo A**, Hensley T, Breitman T, Stein G, Pommier Y, McBride O, Bustin M, Giri G: The cloning of cDNA and gene for human poly(ADP-ribose) polymerase: Status on the biological function(s) using recombinant probes. In: ADP-Ribose transfer reactions (MK Jacobson and EL Jacobson, eds), 1989.
12. Harter KW and **Dritschilo A**: Cancer of the Pancreas: Are Chemotherapy and Radiation Appropriate? Oncology 3:27-30, 1989.
13. Rhim JS, Yoo JH, Park JH, Thraves PJ, Salehi Z, **Dritschilo A**: Evidence for the Multistep Nature of In Vitro Human Epithelial Cell Carcinogenesis. In: Proceedings of the XIV International Symposium, International Association for Comparative Research on Leukemia and Related Diseases. Cancer Res. (Suppl.) 50:5653s- 5657s, 1990.
14. Weichselbaum RR, Hallahan DE, Sukhatme V, **Dritschilo A**, Sherman M, Kufe D: Biological consequences of gene regulation by ionizing radiation. JNCI 83:480-484, 1991.
15. Rhim JS and **Dritschilo A**: Neoplastic Transformation in Human Cell Culture: Mechanisms of Carcinogenesis. Humana Press, Totowa, NJ, 1991.

Including the following individual chapters in this book:

- Rhim JS and **Dritschilo A**: Neoplastic transformation in human cell systems - An overview, pp xi-xxxi.
- Thraves JS, Reynolds S, Salehi Z, Kim WK, Yang JH, Rhim JS, **Dritschilo A**: Detection of transforming genes from radiation transformed human epidermal keratinocytes by a tumorigenicity assay, pp. 93-102.
- Salehi Z, Ramos S, Pearson G, Jung M, **Dritschilo A**, Kern FG: Construction of a unidirectional cDNA library from a radioresistant laryngeal squamous cell carcinoma cell line in an Epstein Barr virus shuttle vector, pp. 377-386.
16. Thierry AR, Rahman A, **Dritschilo A**. Liposomal delivery as a new approach to transport oligonucleotides, in gene regulation by antisense RNA and DNA. Edited by Erickson R.P. and Izant J., Raven Press, Ltd., New York, Vol. 1, pp. 147-161, 1992.
 17. Thierry AR, Rahman A, **Dritschilo A**. Liposomal delivery as a novel approach to transport oligodeoxynucleotides into cells. Application to the inhibition of the MDR gene expression. NY. Acad. Sci. Conferences, Antisense Strategy, Philadelphia, PA, 1992.
 18. Torrisi J and **Dritschilo A**: Radiotherapy in the Treatment of Sarcoma of the Forearm and Hand. In: Tumors of the Hand and Upper Limb (G Bogumill and EJ Fleegler), Churchill Livingstone, NY pp 436-444, 1993.
 19. Jung M. and **Dritschilo A**. Signal transduction and cellular responses. Invited review article in Seminars in Radiation Oncology 6:268-272, 1996.
 20. Prasad S, **Soldatenkov VA**, Srinivasarao G, **Dritschilo A**: Intermediate filament proteins during carcinogenesis and apoptosis (Review). Intl J. Oncology 14: 563-570, 1999.
 21. Smulson ME, Simbulan-Rosenthal CM, Boulares AH, Yakovlev A, Stoica B, Iyer S, Luo R, Haddad B, Wang ZQ, Pang T, Jung, M, **Dritschilo A**, Rosenthal DS. Roles of

- poly(ADP-ribosyl)ation and PARP in apoptosis, DNA repair, genomic stability, and functions of p53 and E2F-1. *Adv. Enzyme Regul.* (Weber, G. (ed.)), 40:183-215, 2000.
22. Jung M and **Dritschilo A.** NF- κ B Signaling Pathway as a Target for Human Tumor Radiosensitization. Invitation review, *Seminars in Radiation Oncology* 2001.
 23. Subramanian M, Suthanthiran K, **Dritschilo A.** Radioactive sources for interstitial brachytherapy, in *Basic and Advanced Techniques in Prostate Brachytherapy*, Dicker, A. et al., Martin Dunitz and Parthenon, London, 2004, pp. 369-374. In **Human cell transformation: role of stem cells and the microenvironment** Springer Science 2011.
 24. Konsoula Z, Velena A, Dritschilo A and Jung M. Histone Deacetylase Inhibitor: Anti-Neoplastic Agent and radiation modulator. In **Human cell transformation: role of stem cells and the microenvironment** Springer Science 2011.

RESEARCH SUPPORT (PAST AND PRESENT)

D. Research Support

1. Principal Investigator **"Dose Rate Effects on the Radiation Response of Human Diploid Fibroblasts and Defective Repair Systems"** NCI/NIH CA262256 (\$73,764 Direct Costs) 1979-1982.
2. Principal Investigator **"The Interaction of Interferon with x-ray Damage and Repair"** BSRG (\$2,840) 1979-1980.
3. Co-Investigator **"Radiotherapy of Ocular Tumors"** BSRG (\$3,670) 1981-1982.
4. Co-Investigator **"Core Support"** Vincent T. Lombardi Comprehensive Cancer Research Center Grant, (\$14,000) 1979-1981.
5. Co-Investigator **"Study of Blood Flow in Radiated Bowel after Staple Anastomosis"** Industrial Grant (\$8,000) 1981.
6. Co-Investigator (grant through Medical Oncology Division) **"Patients with Early Stage Colon and Rectal Cancer"** NCI/NIH CA27587 (3-318-0102) (\$69,730) 1982.
7. Co-Investigator (grant through Medical Oncology Division Southeastern Cancer Study Group) NCI/NIH R10 CA27587 (3-318-102) (\$61,730) 1982.
8. Principal Investigator **"A Phase I Trial of Alpha-2-Interferon and Radiation Therapy"** Schering Corporation (\$49,500 Total Costs) 1984-1985.
9. Principal Investigator **"Radiation-Interferon Laboratory Studies"** Schering Corporation (\$9,000) 1985.
10. Principal Investigator **"The Role of ADP-Ribose Metabolism in the Radiosensitivity of Human Tumors"** American Cancer Society Grant PDT-279A (\$180,397 - Total Costs) 1985-1987. Renewed PDT-279B (\$198,000 - Total Costs). Renewed PDT-379C (\$203,000 - Total Costs) 1989-1991.
11. Principal Investigator **"Molecular Studies of Radiation-Resistant Tumor Cells"** NCI/NIH CA45408 (\$329,965 - Direct Costs) 1987-1990. Renewed (\$1,312,778 - Direct Costs) 1990-1995. Renewed (\$1,022,210 - Direct Costs) 1996-2001.
12. Principal Investigator **"Support Grant"** for the Vincent T. Lombardi Comprehensive Cancer Research Center. NCI/NIH 5P30 CA14626 (\$605,904 - Direct Costs) 1987-1988.
13. Co-Investigator **"Cancer Center Support Grant"** (Marc Lippman, PI) NCI/NIH 1P030 CA51008 (\$2,503,392 - Direct Costs) 1990-1993.
14. Program Director **"Molecular Basis of Tumor Resistance to Ionizing Radiation"** NCI/NIH P01 CA52066 (\$675,492 - Direct Costs) 1990-1993.
15. Principal Investigator **"Radiation Resistance and ADP-Ribose Metabolism"** NCI/NIH R01 CA58986 (\$438,273 - Direct Costs) 1987-1995.
16. Co-Investigator **"Cancer Center Support Grant"** (Marc Lippman, PI) NCI/NIH 2P030 CA51008 (\$7,449,213 - Direct Costs) 1993-1998.

17. Principal Investigator **"Oligonucleotide Manipulation of Tumor Cell Radioresistance"** NCI/NIH R41 CA65012-01 (\$100,000) 1994-1995.
18. Program Director **"Mechanisms of Cellular Responses to Ionizing Radiation"** NCI/NIH P01 CA47174 (\$8,027,948 - Total Costs) (Total Direct \$5,012,268) 1997-2002. Renewed (\$8,951,009) 2002-2007.
19. Principal Investigator: **"Liposome-encapsulated c-raf antisense oligonucleotide (LErafAON) – Phase I studies in patients with advanced malignancies: Daily IV infusion during radiotherapy"** Neopharm, Inc. Neo-AS-01 (\$82,792) 11/00– 31/01.
20. Principal Investigator: **"Developmental Therapeutics/Gene Discovery: Core facilities for microarray analysis of gene expression"**, Neopharm, Inc. (\$1,500,000) 1/1/01 – 12/31/03.
21. Co-Investigator: **"Development of an Interstitial Gene Delivery for Prostate Tumor Radiosensitization"** U.S. Army Medical Research and Materiel Command, DAMD17-02-1-0059, (\$375,000) 1/14/02 – 2/14/05.
22. Principal Investigator: **Georgetown University AP4 Center Plan U56 CA109954-01** (\$50,000) 07/1/04-6/31/05.
23. Co-Investigator, Program Director (Pestell) **"Cancer Center Support Grant"** NIH/NCI 2P30CA51008-12 (\$1,822,297, Annual total direct) 5/1/03 – 4/30/07.
24. Co-Investigator (Jung): PC03471 (Jung) **"Inhibitors of histone deacetylases for radiosensitization of prostate cancer"** (\$375,000, total costs) 1/1/04 -12/31/07
25. Co-Investigator: **Gynecologic Disease Program DOD** (Maxwell (Walter Reed), Mun (GU)) (\$860,668, total costs) 6/1/05 – 5/31/06.
26. Co-Investigator (PI Notario): **Targeting EWS/FL1-driven pathways to improve therapeutic gains in Ewing's Sarcoma** NIH/NCI CA-134727-01 7/01/08-06/30/13
27. Principal Investigator: **"Cancer Center Support Grant"** NIH/NCI 2P30CA51008-13
28. Principal Investigator: **"Mechanisms of Cellular Responses to Ionizing Radiation"** P01 CA74175 06/01/97-06/30/08

Exhibit 38

CURRICULUM VITAE

Amal Mousa Abu-Ghosh, MD

Personal Information:

Home Address: 3401 38th St. NW #805
Washington, DC 20016
Phone: 202-537-3832

Office Address: Department of Pediatrics,
Georgetown University Medical Center
3800 Reservoir Rd NW
Washington, DC 20007
Phone: 202-444-2224
Fax: 202-444-8817

Licensure:

State: Maryland
License No: D0065405
Initial date:
Expiration Date: 9/30/08

State: District of Columbia
License No: MD31353
Initial date: 01/08/1999
Expiration Date: 12/31/2010²

State: California:
License No: A 55246
Initial date: 11-22-1995
Expiration Date: 03-31-1999

Country: Jordan
License#: 5590
Initial date: 08-26-1986

Certification:

Board Certification: Jordan Board of Pediatrics
Date of Certification: 6/30/1991
Date of Re-certification:

Board Certification: American Board of Pediatrics
Date of Certification: 10/9/1996
Date of Re-certification:

Specialty Board: American Board of Pediatric
Hematology/Oncology
Date of Certification: 11/18/2002
Date of Re-certification:

Education:

Medical Education: Jordan University School of Medicine
Amman, Jordan
August, 1979- June, 1985
M.B.B.S.

Graduate Education:

Jordan University School of Medicine
Amman, Jordan
July, 1985- June, 1989
Masters in Pediatrics

Rotating Internship: Jordan University Hospital
Amman, Jordan
July, 1985- June, 1986
M. Abu-Khalaf, M.D.

Residency: Jordan University Hospital
Pediatrics,
Amman, Jordan
July, 1986-June, 1990
F. Madanat, M.D.

Internship: University of Texas Medical Branch at

Pediatrics
Galveston, TX
June 1993- June 1994
P. Ogra, M.D.

Residency: University of Texas Medical Branch at

Pediatrics
Galveston, TX
July, 1994- December, 1995
P. Ogra, M.D.

Fellowship: Children's Hospital of Orange County
Hematology/Oncology Fellowship
Orange, CA
January, 1996- June, 1998
M.S. Cairo

NIH/Georgetown University
Hematology/Oncology Fellowship
Washington, DC
June, 1998- December, 1998
M.S. Cairo

Professional Experience:

May 2008- Present Associate Professor of Pediatrics
Division of Pediatric Hematology/Oncology, Blood
and Marrow Transplantation
Department of Pediatrics,
Georgetown University Hospital,
Washington, DC

October 2007-present Director of the Outpatient Clinic
Division of Pediatric Hematology/Oncology, Blood
and Marrow Transplantation, Lombardi
Comprehensive Cancer Center, Georgetown
University Hospital, Washington, DC

March 2005-present Director of the joint INCTR-sponsored Pediatric
Hematology/Oncology Fellowship Program for
KHCC* and LCC**

	Division of Pediatric Hematology/Oncology, Blood and Marrow Transplantation Lombardi Comprehensive Cancer Center, Georgetown University Hospital, Washington, DC
2004-present	Member of the INCTR Educational Committee
2004-present	Director of the Retinoblastoma Program, Division of Pediatric Hematology/Oncology, Blood and Marrow Transplantation Lombardi Comprehensive Cancer Center, Georgetown University Hospital, Washington, DC
July 2001-present	Assistant Director, Leukemia Lymphoma Program Division of Pediatric Hematology/Oncology, Blood and Marrow Transplantation Lombardi Comprehensive Cancer Center, Georgetown University Hospital, Washington, DC
July 2000- present	Attending Physicians Division of Pediatric Hematology/Oncology, Blood and Marrow Transplantation Department of Pediatrics, Georgetown University Hospital, Washington, DC
1999-present	Member, Lombardi Comprehensive Cancer Center, Georgetown University School of Medicine, Washington, DC
February 1999- June 2000	Research Instructor Division of Pediatric Hematology/Oncology, Blood and Marrow Transplantation Lombardi Cancer Center, Georgetown University School of Medicine, Washington, DC

* KHCC: King Hussein Cancer Center, ** LCC: Lombardi Cancer Center

Honors and Awards:

2004	Georgetown University Hospital "Caring Star Award"
------	--

2007 Georgetown University Hospital "Caring Star Award"
2007 Excellence in Teaching Award, Georgetown University School of Medicine, 2006/2007

Professional Societies:

2001-present American Society of Hematology (ASH)
2000-present Children's Oncology Group (COG)
1999-2006 American Society of Clinical Oncology (ASCO)
1996-2000 American Association for Cancer research (AACR)
1993-2003 American Academy of Pediatrics (AAP)
1985-present Jordan Medical Association

Public Service:

2006-present Journal Reviewer: 'Annals of Saudi Medicine'
2006-present Member, Middle East Cancer Consortium (MECC), a National Cancer Institute (NCI) sponsored program for cancer in the Middle East
2005-present Member, Supportive Care Committee, International Network for Cancer Treatment and Research (INCTR), USA, a National Cancer Institute (NCI) sponsored program for Cancer in Developing Countries
2004-present Journal Reviewer: "Pediatric Blood and Cancer"
2004 Visiting Pediatric Hematology /Oncology Consultant, Thalassemia Society of Palestine, Ramallah, Palestine
2003-present Member, Pediatric Education Committee, International Network for Cancer Treatment and Research (INCTR), USA, a National Cancer Institute (NCI) sponsored program for Cancer in Developing Countries
2002/2003 Visiting Pediatric Hematology /Oncology Consultant, Thalassemia Society of Palestine, Ramallah, Palestine

Invited Lectures:

1. Acute Lymphoblastic Leukemia: Updates to Therapy. Nursing Orientation Course, Georgetown University Medical Center, Washington, DC. October 4, 2010.
2. Pediatric Cancers; An Overview of Common Childhood Cancers and Advances in Therapy. PERI Cancer 101: A Basic Overview of Current Therapies for New Oncology Researchers. Rosslyn, VA July 19, 2010.
3. Acute Lymphoblastic Leukemia: Updates to Therapy. Nursing Orientation Course, Georgetown University Medical Center, Washington, DC. April 2010.
4. Infections in the Immunocompromised Host. Resident Lecture, Georgetown University Medical Center, Washington, DC. March 2010.
5. Acute Lymphoblastic Leukemia: Current Approach to Risk Assessment and Risk Adapted Therapy. First Palestine Oncology Society meeting, Ramallah, Palestine. April 17, 2008
6. Pediatric Cancers. First Palestine Oncology Society meeting, Ramallah, Palestine. April 17, 2008
7. Pediatric Oncology: A Basic Overview for New Oncology Researchers. PERI Cancer 101; Rosslyn, VA, USA. July 17, 2007
8. Cultural Aspects in Pediatric Palliative Care: MECC Second Meeting; Larnaka, Cyprus. June 25, 2006
9. Childhood Acute Lymphoblastic Leukemia: First Regional Congress of Cancer and Blood diseases of Childhood, Amman, Jordan. September 1st, 2005.
10. Immune Thrombocytopenic Purpura in Children: First Regional Congress of Cancer and Blood diseases of Childhood, Amman, Jordan. September 2nd, 2005.
11. Immune Thrombocytopenia and Current Therapy: Palestine Pediatric Medical Association, Ramallah, Palestine. August 25, 2004.
12. Indications for Pediatric Blood Transfusions: INCTR sponsored Pediatric Oncology Educational Workshop for Iraqi Oncologists, Amman, Jordan. April 18, 2004

13. Acute Lymphoblastic Leukemia: INCTR sponsored Pediatric Oncology Educational Workshop for Iraqi Oncologists, Amman, Jordan. April 19, 2004.
14. Cervical Lymphadenopathy in Children: Department of Otolaryngology Head and Neck Surgery Grand Rounds at Georgetown University Hospital, Washington DC, USA. January 22, 2004.
15. Acute Lymphoblastic Leukemia, Recent Advances and Targeted Therapy: Al-Maqased Islamic Hospital, Jerusalem, Palestine. December 25, 2003.
16. Acute Lymphoblastic Leukemia: Targeted Therapy: INCTR Pediatric Workshop at the 5th National Chinese Pediatric Oncology Conference in Chongqing, Sichuan Province, China. November 20-23, 2003
17. Thalassemia Major and Sickle Cell Disease: a Clinical Update and Required Patient Monitoring: The Thalassemia Society of Palestine, Ramallah, Palestine. January, 2003.
18. Sickle Cell Disease- New therapies: Arlington Hospital Grand Rounds, Arlington, VA, USA. May, 2001
19. Bleeding Disorders in Children: Al-Mustakbal Hospital Grand Rounds, Ramallah, Palestine. January, 2001
20. Umbilical Cord Blood Transplantation: American Red Cross and Georgetown University Medical Center Symposium. May, 1999.

Invited Reviewer:

1. Pediatric Blood and Cancer: Osteonecrosis in Children Treated for Solid Tumours. August 31st, 2007.

2. Pediatric Blood and Cancer: Progressive vacuolar myelopathy and leukoencephalopathy in childhood acute lymphoblastic leukemia and transient improving effect of vitamin B12. September 7, 2005.
3. Pediatric Blood and Cancer: Evaluation of left ventricular myocardial performance in long-term survivors of childhood Hodgkin's Disease. June 24, 2004.
4. Pediatric Blood and Cancer: Portal hypertention develops in a subset of children with standard risk acute lymphoblastic leukemia treated with oral 6-thioguanine during maintenance therapy. May 27, 2004.
5. Pediatric Blood and Cancer: Outcome of Children with primary resistant or relapsed non-Hodgkins lymphoma and mature B-cell leukemia after intensive first-line treatment. February 23, 2004.
6. Hemophilia: Cranial Pseudotumor in Hemophilia. September 30, 2003.

Workshops and Symposia Participation:

2006	Workshop on "Palliative Care for Cancer Patients", co-organized with the Middle East Cancer Consortium (MECC), Larnaca, Cyprus, June 2006.
2004	Workshop on "Pediatric Oncology Update" for Iraqi Pediatric Oncologists. Collaborative project of the NCI and King Hussein Cancer Center (KHCC). Amman, Jordan. April 2004.
2003	NCI sponsored Pediatric Oncology Educational Workshop. Collaborative project of the INCTR and the Chinese Pediatric Oncology Society. Chongqing, China. November 2003.

University Service:

Department:

2003-present	Member, Parent Advisory Board
2001-present	Georgetown University Faculty Advisor for Pediatric Residents

2000-present Member, Pediatric Administrative Staff Committee

2000-present Member, Pediatric Q&A Committee

School:

2001-present Georgetown University Faculty Advisor for Medical Students

University:

2005 Member, Faculty Evaluation Task Force

2001-present Member, Georgetown University Society for Medical Women Faculty

Hospital:

2005-present Member, Chemotherapy Advisory Committee

2007-present Member, Georgetown University Hospital Blood Utilization Review Committee.

Teaching Activities:

Medical Courses:

Medical Biochemistry: Course# 4220-109-06
Clinical correlation on sickle cell anemia for first year medical students.
Lecturer: one lecture/course, 2 hours/lecture
2007
Overall evaluation score:3.8-4.3

Ambulatory Care: Course # 4255106-12
Perceptor of 1-2 students/semester: 18 hours/student
2001-present
Overall evaluation score:

Pediatrics 3rd year: Course # 4280-300
Faculty; 12 months/year, clinic in 2-3 students/week
1999-present
Overall evaluation score:

Teaching Recognition Awards:

2007

Excellence in Teaching Award, Georgetown
University School of Medicine, 2006/2007**Publications:****Original Papers:**

- 1- K E Shattuck, A Abu-Ghosh, S Wilden, S H Landry, K E Smith, Respiratory morbidity in three year old children born preterm. Neonatal Intensive Care (Jan/ Feb 1998).
- 2- A Abu-Ghosh, S Goldman, V Sloan, C van de Ven, J Joubran, Y Suen, L Murphy, L Sender, M S Cairo. Analysis of immune recovery and mediators associated with acute graft versus host disease (aGVHD) during the first one hundred days following unrelated umbilical cord blood transplant (UCBT) in children. Bone Marrow Transplantation 24: 535-544, 1999.
- 3- Abu-Ghosh, S. Goldman, M. Krailo, I Rimm, G. Davenport, E Morris, J. Laver, G. Reaman, M. Cairo. Excellent response (91%) to Ifosfamide, Carboplatin, and Etoposide in children with relapsed Wilm's tumor. Annals of Oncology, Mar; 13 (3): 460-9, 2002.
- 2- K Braithwaite, BS, A Abu-Ghosh, MD, L Anderson, RN, BSN, MS Cairo, MD. The use of Interleukin-11 to treat severe thrombocytopenia associated with Wiscott-Aldrich Syndrome prior to allogeneic stem cell transplantation : Decreased bleeding and platelet transfusions. Journal of Pediatric Hematology/Oncology, May- June; 24 (4): 323-6, 2002.
- 4- S Baker, A Abu-Ghosh, A Shad. Giant Cell Tumors and Interferone Therapy. In press, 2007.

Books or Chapters:

1- A. Abu-Ghosh, F Bracho, I Kirov, MS Cairo. Hematopoietic Colony-Stimulating Factors. Textbook of Critical Care, 4th edition, Grenvik, A, Ayres, SM, Holbrook, PR, Shoemaker, WC, eds, WB Saunders Co., Philadelphia, PA, 542-560, 1999.

2- A Angiolillo, A. Abu-Ghosh, V Davenport, MS Cairo. General Aspects of Thrombocytopenia, Platelet Transfusions and Thrombopoietic Growth Factors. Consultative Hemostasis and Thrombosis, CS Kitchens, B Alving, C Kessler, ed, WB Saunders Company, Philadelphia, PA 19106, 103-116, 2002

3- A. M. Abu-Ghosh, J Toretsky: Childhood Cancer. Cancer Encyclopedia, 2007

4- Aziza T Shad, Amal M Abu-Ghosh. Emergency Management of Lymphoid Malignancies. The Lymphoid Neoplasms, 3rd Edition, Ian T Magrath, Kishor Bhatia, Paolo Boffetta, Claire Dearden, Volker Diehl, Randy Gascoyne, Hans K Muller-Hermelink, Michael Potter, Ama Rohatiner, eds, Hodder Arnold, London, England, , 847-871, 2010.

Abstracts:

1. Abu-Ghosh A, Shattuck KE, Wilden S, Smith KE, Anderson A, Landry SH. Long term respiratory outcome in three year old children with history of Bronchopulmonary Dysplasia. Presented, Southern Society for Pediatric Research, 1996.
2. Slone V, Abu-Ghosh, A Goldman S, Murphy L, Sender L, van de Ven C, Cairo MS. Delayed platelet, but comparable myeloid engraftment following unrelated cord blood transplantation (UCBT): decreased megakaryocytic lineage (CD34⁺/CD41⁺) stem cells in cord blood. Presented, American Society of Hematology, 1996. Blood, 88: 114a, 1996.

3. A Abu-Ghosh, V Slone, S Goldman, L Murphy, LS Sender, C van de Ven, MS Cairo. Decreased megakaryocytic lineage stem cells (CD34/CD41) in cord blood may contribute to delayed platelet engraftment following unrelated cord blood transplantation. Presented, Marrow Transplantation in Children, 1997.
4. A Abu-Ghosh, V Slone, S Goldman, L Murphy, L Sender, C van de Ven, MS Cairo. Delayed platelet engraftment observed in unrelated cord blood transplant (UCBT) may be due to decreased megakaryocytic progenitors. Presented, Keystone Symposia, 1997.
5. A Abu- Ghosh, S Goldman, V Sloan, C van de Ven, J Joubran, Y Suen, L Murphy, L Sender, MS Cairo. Delayed T cell reconstitution but normal phagocytic and humoral immune recovery during the first one hundred days following unrelated umbilical cord blood transplant in children(UCBT). Presented, American Society of Hematology, 1997. Blood: 90: 541a, 1997.
6. A Abu- Ghosh, C Torres, J Qian, C van de Ven, MS Cairo. Ex- vivo expansion and activation of peripheral blood T lymphocytes for cancer immunotherapy using IL-2, IL-12 and anti-CD3. Presented, American Society for Blood and Marrow Transplantation, 1998. Biology of Blood and Marrow Transplantation 4:103, 1998.
7. MS Cairo, A Abu-Ghosh, F Bracho. Significant ex vivo expansion of cord blood dendritic cells by Flt-3L, GM-CSF, TNF-a, IL-4, and autologous cord blood plasma, and peripheral blood T cells by IL-2, IL-12, and anti-CD3: Development of ex-vivo cancer vaccine therapy. Presented, International Society of Experimental Hematology, 1998. Experimental Hematology 26:770, 1998.
8. A.M. Abu-Ghosh, C. van de Ven, P.L. Rhodes, Y Miao, K. R. Meehan, M. S. Cairo. Ex vivo expansion and activation of T lymphocytes using IL-2, IL-12, and anti-CD3:

- Development of adoptive cancer cellular immunotherapy. **Presented, American Society of Hematology, 1998.** Blood 92 (10): 2231, 1998.
9. K. L. Robinson, P. L. Rhodes, **A. M. Abu-Ghosh**, D. Bell, M. S. Cairo. Ex vivo expansion of umbilical cord blood (UCB) with XLCM™ leads to preferential expansion, activation and maturation of CD4+ and CD8+ T lymphocytes: Development of UCB specific CTLs. **Presented, American Society of Hematology, 1998.** Blood 92 (10): 2230, 1998.
10. **A. Abu-Ghosh**, S. Goldman, M. Krailo, I Rimm, G. Davenport, E Morris, J. Laver, G. Reaman, M. Cairo. Excellent response (91%) to Ifosfamide, Carboplatin, and Etoposide in children with relapsed Wilm's tumor. **Presented, American Society of Clinical Oncology, 1999.** Program/Proceedings, American Society of Clinical Oncology 18:559a, 1999.
11. MS Cairo, **A Abu-Ghosh**, F Bracho, K Robinson, E Areman, P Rhodes. Ex vivo expansion and activation of cord blood antigen presenting and immune effector cells. **Presented, European Society for Paediatric Haematology and Immunology, 1999.** Pediatric Research 45:771, 1999.
12. **A Abu-Ghosh**, L Belinsky, R Hughes, KR Meehan, MS Cairo. Significant ex-vivo generation and activation of antibody /cytokine activated T-cells (ACATC) (TH1) from mobilized peripheral blood stem cells (PBSC) of cancer patients for adoptive cellular immunotherapy with tandem stimulation with IL-2, IL-12, Anti-CD3, and IL-18. **Presented, American Society of Hematology, 1999.** Blood 94 (10): 4561, 1999.
13. K Braithwaite, **A Abu-Ghosh**, L Anderson, MS Cairo. The use of Interleukin-11 to treat severe thrombocytopenia (TCP) associated with Wiscott-Aldrich syndrome (WAS) prior to allogeneic stem cell transplantation (ALLO SCT): Decreased bleeding

and platelet transfusions. Presented, American Society of Hematology, 1999.
Blood 94 (10): 1999.

14. K Braithwaite, A Abu-Ghosh, L Anderson, MS Cairo. Effect of IL-11 in decreasing the need for platelet transfusions in children with severe thrombocytopenia (TCP) secondary to Wiscott-Aldrich syndrome (WAS) prior to allogeneic stem cell transplantation (Allo SCT). Presented, Society for Pediatric Research, 2000.

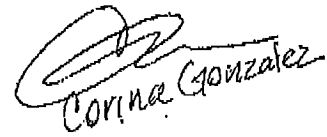
15 A.Abu-Ghosh, L. Belinsky, R Hughes, KR Meehan, MS Cairo. Significant ex-vivo generation and activation of antibody /cytokine activated T-cells (ACATC) (TH1) from mobilized peripheral blood stem cells (PBSC) of cancer patients for adoptive cellular immunotherapy with tandem stimulation with IL-2, IL-12, Anti-CD3, and IL- 18.
Presented, Keystone symposia, 2000.

16 A.Abu-Ghosh, L. Belinsky, R Hughes, KR Meehan, MS Cairo. Ex-vivo expansion and activation of cytotoxic T-lymphocytes (CTLs) into Th1 cells from mobilized peripheral blood stem cells (PBSC). Presented, American Association for Cancer Research, 2000.

17 MS Cairo, A. Abu-Ghosh, M. Krailo, P. Van Winkle, V. Davenport, F. Bracho, A. Martorella, R. Slack, A. Angiolillo, and G. Reaman. Ifosfamide, carboplatin, and etoposide (ICE) is an excellent retrieval therapy for patients with refractory/relapsed Ewing's and Rhabdomyosarcoma: The Children's Cancer Group experience.
Presented, American Society of Clinical Oncology, 2000.

18 A Abu-Ghosh, S Goldman, M Krailo, G Davenport, E Morris, J Laver, G Reaman, M S Cairo. Improved long term progression free survival in children with poor risk relapsed/refractory Wilms tumor after initial therapy with ifosfamide, carboplatin, and etoposide (ICE): Children's Cancer Group Experience. Presented, American Society of Clinical Oncology, 2000.

19 A M Abu-Ghosh, Stephen J Latimer, Agnieszka Z Pluta, Zain I Shad, Benjamin Somers, Rabia Mir, Francisco Bracho, Aziza T Shad. Intravenous Iron Dextran Therapy for the Correction of Iron Deficiency Anemia in Children with Inflammatory Bowel Disease: A single institution study. Pediatric Academic Societies Annual meeting, 2003.

CURRICULUM VITAE
Corina Gonzalez**NAME:** Corina Elena Gonzalez**CONTACT INFORMATION:**

Work Address: Georgetown University Hospital
Division of Pediatric Hematology Oncology
Blood and Marrow transplantation
3800 Reservoir Road N.W.
Washington DC, 20007
Telephone: (202) 444-7599
Fax: (202) 444-8817
E-mail: gonzalec@georgetown.edu

Home Address: 3317 17th St, N.W.
Washington DC, 20010

Date and Place of Birth November 3, 1963; Lobos, Argentina

LICENSURE:

Medical License Washington DC license # 33089, expiration date 12/31/10¹²
initial date 08/01/04

EDUCATION:

1982 – 1987: M.D. University of Buenos Aires School of Medicine, Argentina
Paraguay 2251, 1120 Buenos Aires, Argentina
Upper 5% of the class

POSTDOCTORAL TRAINING:

1999 - 2001: Residency in Pediatrics (PL-2 PL-3)
Children's National Medical Center
111 Michigan Ave, N.W.
Washington DC, 20010, USA
George Washington University

- 1996 - 1997: Visiting Associate. Pediatric Hematology Oncology Fellowship, Pediatric Oncology Branch, National Cancer Institute, National Institutes of Health. Bldg 10 Room 13N 240, 9000 Rockville Pike, Bethesda, MD 20892, USA
Hematology training at Johns Hopkins University Hospital, Department of Pediatric Hematology
- 1993 - 1996: Visiting Fellow. Infectious Diseases Section, Pediatric Branch, National Cancer Institute, National Institutes of Health. Bldg 10 Room 13N 240, 9000 Rockville Pike, Bethesda, MD 20892, USA
- 1988 - 1992: Residency in Pediatrics (PL1-PL-4).
University of Buenos Aires. Hospital Italiano de Buenos Aires Gascon 450, 1181 Buenos Aires, Argentina

BOARD CERTIFICATIONS:

American Boards of Pediatric Hematology / Oncology
Passed November 2002

American Boards of Pediatrics
Passed October 2001

Federal License Examination (FLEX)
I.D. No: 640810014, New York.
Component 1 (Basic Sciences) passed November 1993.
Component 2 (Clinical Sciences) passed November 1993.

ECFMG-FMGEMS, applicant number: 437-073-0
Basic Science Component passed in July 1989.
Clinical Science Component passed in January 1990.

Title of Specialist in General Pediatrics, awarded by the Argentine Society of Pediatrics, December 1991.

PROFESSIONAL EXPERIENCE:

- 2007- to date Medical Director, Bone Marrow /Apheresis Collection Center
Department of Pediatrics
Georgetown University Hospital

2007- to date Director, Solid Tumor Program
Pediatric Hematology Oncology
Georgetown University Hospital

2002 – to date Assistant Professor of Pediatrics
Pediatric Hematology Oncology
Lombardi Cancer Center
Georgetown University Hospital

2003 – 2005: Special Volunteer
Pediatric Oncology Branch, National Cancer Institute,
National Institutes of Health, Bldg 10 Room 13N 240,
9000 Rockville Pike, Bethesda, MD 20892, USA

1999 - 2001: Special Volunteer
Pediatric Oncology Branch, National Cancer Institute,
National Institutes of Health, Bldg 10 Room 13N 240,
9000 Rockville Pike, Bethesda, MD 20892, USA

1997- 1999: Attending Physician.
HIV/AIDS Malignancy Branch, National Cancer
Institute, National Institutes of Health, Bldg 10 Room 13N 240,
9000 Rockville Pike, Bethesda, MD 20892, USA

1991 - 1992: Staff member, Neonatal Intensive Care Unit, Hospital Italiano de
Buenos Aires, Gascon 450, 1181 Buenos Aires, Argentina.

PROFESSIONAL SOCIETY MEMBERSHIP:

2005 to date Fellow of the American Academy of Pediatrics (FAAP)
2002 to date Children's Oncology Group (COG)
2002 to date International Network of Cancer Treatment and Research (INCTR)
2003 to date: American Society of Pediatric Hematology and Oncology (ASPHO)
2000 to date: American Academy of Pediatrics (AAP)
1994 to 1996: American Society for Microbiology
1995 to date: Sociedad Latinoamericana de Infectologia Pediatrica
1994 – 1996: Latin American Councilor, Medical Mycology Society of the
Americas

AWARDS AND HONORS

Honors "Honor Diploma", University of Buenos Aires, School of Medicine, November 28, 1994.

Awards: Individual Research Trainee Award, International Fogarty Fellowship, National Institutes of Health. August 1, 1993.

Scientific and Academic Achievement Award
Children's National Medical Center, May 4, 2000

2008 National Marrow Donor Program (NMDP) Donor Management Innovation Award.

OTHER PROFESSIONAL ACTIVITIES:**Board Memberships:**

2009 to date: Center for International Blood & Marrow Transplant Research
Advisory Committee Member

2004 to 2008: Data Safety and Monitoring Board member for the Cooperative
International Neuromuscular Research Group (CINRG)

National Committees:

2009 to date: Facility – Bed Capacity Working Group
National Marrow Donor Program

2004 to 2005: Data Review Committee member for Posaconazole (SCH 56592)
Protocol PO02952. Schering-Plough Research Institute

2002 to 2003: Data Review Committee member for Posaconazole (SCH 56592).
Protocol PO1899. Schering-Plough Research Institute

Institutional Committees:

2009 to date: Faculty representative to the Georgetown University Medical
Center Research Committee on behalf of the Medical Center
Caucus of the Faculty Senate.

2004 to date: Education Subcommittee in Pediatric Oncology, International
Network for Cancer Treatment and Research (INCTR)

2002 to date: Education Committee member, Department of Pediatrics.
Georgetown University Hospital

2002 to date: Pediatric Research Committee member, Department of Pediatrics. Georgetown University Hospital

Research:

2008-2010: A Randomized, Phase II Study of Monoclonal Antibody 3F8 plus Granulocyte-Macrophage Colony-Stimulating Factor (GM-CSF) Compared to 13-*cis*-Retinoic Acid plus GM-CSF in High Risk Stage 4, Primary Refractory Neuroblastoma Patients. Sponsor: United Therapeutics Corporation. Role: Principal Investigator.

2008 Phase 1B Study of the Safety, Tolerance, and Pharmacokinetics of Oral Posaconazole (POS) in Immuno-compromised Children With Neutropenia. Sponsor: Schering-Plough Research Institute. Role: Principal Investigator.

2004 to date: Screening and treatment of silent cerebral infarcts for children with sickle cell disease, a Phase III multi-center study. Sponsored by NINDS. Role: Principal Investigator

2002 to date: Pediatric hydroxyurea Phase III clinical trial "BABY HUG". Sponsored by NHLBI. Role: Principal Investigator

2002- to date: Co-Investigator on all active Children's Oncology Group clinical trials at Georgetown University Hospital.

2003 – 2004: Phase I /II study of the safety, tolerance and pharmacokinetics of anidulafungin in immunocompromised children with fever and neutropenia. Role: Principal Investigator

2003: An open label, single arm, multicenter, safety, pharmacokinetic and pharmacodynamic, phase II study of anagrelide hydrochloride in pediatric and adult subjects with thrombocythemia secondary to myeloproliferative disorders. Sponsored by Shire Pharmaceutical Development. Role: Principal Investigator.

2003: A prospective randomized, double-blind, multicenter pilot study of the safety and efficacy of interferon gamma-1b plus voriconazole in the treatment of invasive aspergillosis and other filamentous fungal infections. Role: Principal investigator.

INVITED LECTURES:

- May 1995:** Guest Speaker: Fungal Infections in Children. VII Panamerican Infectious Diseases Society VII General Meeting, Latin American Pediatric Infectious Disease Society VI General Meeting, and II Colombian Meeting in Infectious Diseases, Cartagena, Colombia.
- April 2000:** Guest Speaker: Lipid Formulations of Amphotericin B 9th International Congress on Infectious Diseases, International Society for Infectious Diseases. Buenos Aires, Argentina.
- September 2000:** Guest Speaker: Zygomycoses: Emerging Pathogens and New Treatment Strategies. 38th Annual Meeting of the Infectious Diseases Society of America. New Orleans, USA.
- June 2001:** Guest Speaker: New Antifungal Agents. Jornadas de Actualizacion Pediatrica, Sociedad Argentina de Pediatria. Buenos Aires, Argentina
- May 2002:** Pediatric Grand Rounds. Sickle cell disease in children, advances in management and therapy. Virginia hospital Center, Department of Pediatrics
- July 2002:** Pediatric Grand Rounds. Sickle cell disease in children, advances in management and therapy. Georgetown University Hospital, Department of Pediatrics.
- December 2002:** Special Research Seminar, Department of Pediatrics New antifungal drugs. Georgetown University Hospital, Department of Pediatrics.
- July 2003:** Guest Speaker: Fungal Infections: Recent advances in Aspergillosis therapy. Infection and Immunity in Children 2003. British Paediatric Infection, Immunity, and Allergy Group (BPAIIG), European Society for Paediatric Infectious Diseases (ESPID), and the Department of Pediatrics, University of Oxford.
- February 2004:** Grand Rounds: New Antifungal Agents. Hospital del Nino de Panama. Panama City, Panama.
- April 2004:** Guest Speaker: Infections in the neutropenic host. Pediatric Hematology Pediatric Oncology Educational Workshop for Iraqi Hematologists/oncologists. Sponsored by the Office of International Affairs, National Cancer Institute, National Institutes

of Health and International Network for Cancer Treatment and Research (INCTR), Amman, Jordan.

- October 2004: Guest Speaker: Multidisciplinary Conference: Management of Hodgkin's disease with mediastinal involvement in children and adults. Annual Meeting of the International Network for Cancer Treatment and Research (INCTR). Cairo, Egypt.
- October 2010: Guest Speaker: Quality Assurance in Collection of Bone Marrow and Apheresis hematopoietic Stem Cell Products. Annual American Association of Blood Banks (AABB) Annual Meeting, Baltimore, MD
- October, 2010: Guest Speaker: Maintaining Quality Practice in the Collection Center Setting. 23rd Annual Council Meeting, National Marrow Donor Program, Minneapolis, Minnesota.

PUBLICATIONS:

1. TJ Walsh, CE Gonzalez, E Roilides, BU Mueller, N Ali, LL Lewis, T Whitcomb, D Marshall and P Pizzo. Fungemia in children infected with HIV: new epidemiologic patterns, emerging pathogens, and improved outcome with antifungal therapy. Clin. Infect. Dis. 1995;20:900-6.
2. TJ Walsh, CE Gonzalez, CA Lyman, S Chanock, and PA Pizzo. Invasive fungal infections in children: recent advances in diagnosis and treatment. Advances in Pediatr Infect Dis 1995;11: 187-290.
3. Gonzalez CE, C, Shetty D, Lewis L, Mueller B, Pizzo PA, Walsh TJ: Cryptococcosis in HIV-infected children. Pediatr Infect Dis J. 15: 796-800, 1996.
4. Gonzalez CE, Venzon D, Lee S, Mueller BU, Pizzo PA, Walsh TJ: Risk factors for fungemia in pediatric HIV-infection: a case control study. Clin Infect Dis. 1996; 23: 515-521, 1996.
5. Gonzalez CE and Walsh TJ: Fungemia in HIV-Infected Children. Cliniguide to Fungal Infections 1996; 7:1-5.
6. Gonzalez CE, Couriel DR, and Walsh TJ: Successful treatment of disseminated zygomycosis in a neutropenic patient with amphotericin B lipid complex and granulocyte colony-stimulating factor. Clin Infect Dis 1997; 24:192-6.

7. Shetty D, Giri N, Gonzalez CE, Pizzo, PA and Walsh, TJ: Invasive aspergillosis in HIV-infected children. *Pediatr Infect Dis J* 1997, 16:216-21.
8. Walsh TJ, Yeldani V, McEvoy M, Gonzalez CE, Chanock S, Freifeld A, Seibel N, Whitcomb T, Jarosinski P, Boswell G, Bekersky I, Alak A, Buell D, Barret J, and Wilson W. Safety tolerance and pharmacokinetics of a small unilamellar liposomal formulation of amphotericin B (ambisome) in neutropenic patients. *Antimicrob Agents and Chemother* 1998, 42:2391-98.
9. Gonzalez CE, Groll A, D Shetty, N Giri, T Sein, J Bacher, Walsh TJ. Antifungal activity and single dose pharmacokinetics of the pradimicin derivative BMS-181184 in treatment of experimental pulmonary aspergillosis in persistent neutropenic rabbits. *Antimicrob Agents Chemother* 1998, 42:2399-2404.
10. Groll AH, Sein T, Petraitis V, Petraitiene R, Callender D, Gonzalez CE, Giri N, Bacher J, Piscitelli S, Walsh TJ. Compartmental pharmacokinetics and tissue drug distribution of the pradimicin derivative BMS 181184 in rabbits. *Antimicrob Agents Chemother* 1998; 42:2700-2705.
11. Groll AH, Gonzalez CE, Giri N, Kligys K, Love W, Peter J, Feuerstein E, Bacher J, Piscitelli S, Walsh TJ. Liposomal Nystatin against experimental pulmonary aspergillosis in persistent neutropenic rabbits: efficacy, safety, and non-compartmental pharmacokinetics. *J Antimicrob Chemother*, 1999, 43:95-103.
12. Lyman CA, Gonzalez CE, Schneider M, Lee J, Walsh TJ. Effects of the hematoregulatory peptide SK&F 107647 alone and in combination with amphotericin B against disseminated candidiasis in persistently neutropenic rabbits. *Antimicrob Agents Chemother*, 1999, 43:2165-2169.
13. Lyman CA, Garrett KF, Peter J, Gonzalez CE, Walsh TJ. Increased adherence of fluconazole-resistant isolates of *Candida* species to explanted esophageal mucosa. *Eur J Microbiol Infect Dis* 1999, 18:213-216.
14. Pelletier R., Peter J, Antin C, Gonzalez CE, Wood L, Walsh TJ. Emergence of resistance of *Candida Albicans* to clotrimazole in HIV-infected children: in vitro and clinical correlations. *J of Microbiol*, 2000, 38: 1563-1568.
15. Roilides E, Lyman CA, Sein T, Gonzalez CE, Walsh TJ. Antifungal activity of splenic, liver, and pulmonary macrophages against *Candida albicans* and effects of macrophage colony-stimulating factor. *Med Mycol* 2000, 38:161-168.
16. Walsh TJ, Gonzalez CE, Piscitelli S, Bacher JD, Peter J, Torres R, Shetti D, Katsov V, Kligys K, Lyman C. Correlation between in vitro and in vivo antifungal

activities in experimental fluconazole-resistant oropharyngeal and esophageal candidiasis. *J Clinical Microbiol* 2000;38:2369-2373.

17. Chiou CC, Groll A, Gonzalez CE, Callender D, Venzon D, Pizzo PA, Wood LV, Walsh TJ. Esophageal candidiasis in pediatric acquired immunodeficiency syndrome: clinical manifestations and risk factors. *Ped Infect Dis J*, 2000;19:729-734.
18. Gonzalez CE, Boler A.M, Samakoses R, Hill S, Wood L.V. Lymphoid interstitial pneumonitis in pediatric AIDS: natural history of the disease. *Ann N Y Acad Sci*, 2000;918:358-361.
19. Gonzalez CE, Adde M, Taylor P, Wood LV, Magrath I. HIV-1 RNA levels during chemotherapy for HIV-related malignancies in children with HIV-infection. *Ann N Y Acad Sci*, 2000;918:362-366.
20. Gonzalez CE, Shad A, Adde M, Mueller B, Venzon DJ, Avila N, Jaffe ES, Kingma D, Wood LV, Pizzo PA, Smithson WA, Sleasman JW, Magrath I. A pilot study for the treatment of Non-Hodgkin,s lymphoma in children with acquired immunodeficiency syndromes. *Int J Pediatr Hematol Oncol*. 2001
21. Gonzalez CE, Lyman CA, Lee S, Del Guercio C, Roilides E, Bacher J, Gehrt A, Feuerstein E, Tsokos M, and Walsh TJ: Human recombinant macrophage colony-stimulating factor augments pulmonary host defenses against *Aspergillus fumigatus*. *Cytokine*, 2001;15:87-95.
22. Gonzalez CE, Rinaldi MG, Sugar AM. Zygomycosis. *Infectious Diseases Clinics of North America*, 2002;16:895-914.
23. Gonzalez CE. Review: the Kell, Duffy, and Kidd blood group systems. *Immunohematol*. 2004; 20: 37-49.
24. Gonzalez CE. Recent advances in the therapy against invasive aspergillosis. *Adv Exp Med Biol*. 2004; 549:237-247.
25. Shad AT, Gonzalez CE, Sandler SG. Treatment of Immune thrombocytopenic purpura in children. *Pediatric Drugs*, 2005, 7:325-336.
26. Gonzalez CE and Pengetnze YM. Post-transfusion purpura. *Current Hematology reports*. 2005, 4:154-159.
27. R. N. Greenberg, K. Mullane, J.-A. H. van Burik, I. Raad, M. Abzug, G. Anstead, R. Herbrecht, A. Langston, K. A. Marr, G. Schiller, M. Schuster, J. R. Wingard, C. E. Gonzalez, S. G. Revankar, G. Corcoran, R. J. Kryscio, and R. Hare. Posaconazole

as Salvage Therapy for Zygomycosis. *Antimicrob Agents Chemother* 2006, 50:126-133.

28. D. K. Benjamin Jr, T. Driscoll, N.L. Seibel, C.E. Gonzalez, M.M. Roden, R. Kilaru, K. Clark, J.A. Dowell, J. Schranz, T.J. Wasich. Safety and Pharmacokinetics of intravenous anidulafungin in children with neutropenia at high risk for invasive fungal infections. *Antimicrob Agents Chemother* 2006, 50:632-638.
29. Wnt10b induces chemotaxis of osteosarcoma and correlates with reduced survival
Kevin Chen, BS, Shannon Fallen, BS, Hatice Özel Abaan, MS, Mutlu Hayran, MD, PhD, Corina Gonzalez, MD, Felasfa Wodajo, MD, Tobey MacDonald, MD, Jeffrey A. Toretsky, MD, Aykut Üren, MD. *Pediatr Blood Cancer* 2008;51:349-355.
30. Participated on a CME E-mail case series for Imedex, focused on fungal infections and echinocandin therapy. This was an Accreditation Council for Continuing Medical Education (ACCME) accredited activity. September 2008

Chapters

1. Gonzalez CE. Fungal infections in HIV-infected children. *Manual of Pediatric AIDS*. Baltimore: Lippincott-Williams & Wilkins, 1999, pp 492-511.
2. Walsh TJ, Mueller FMC, Groll A, Gonzalez CE, Roilides E. Fungal infections in children with human immunodeficiency virus infection. In: Pizzo PA, Wilfert CM, eds. *Pediatric AIDS. The challenge of HIV infection in infants, children, and adolescents*, ed 3. Baltimore: Williams & Wilkins, 1998, pp 183-204.
3. Gonzalez CE and Walsh TJ. Zygomycosis. In: Yu VL, Merrigan Jr., TC, Barriere SL, eds. *Antimicrobial Therapy and Vaccines*, ed 2. Baltimore: Williams & Wilkins. Section V, pp 1127.
4. Gonzalez CE. Fungal infections in HIV-infected children. *Handbook of Pediatric HIV Care*. Cambridge, UK: Cambridge University Press, 2005 (In press).
5. Gonzalez CE. Fungal infections in HIV-infected children. *Textbook of Pediatric HIV Care*. Cambridge UK: Cambridge University Press, 2005 pp589-603.
6. Gonzalez CE. Recent advances in Aspergillosis therapy. In: J Pollard, G.H, McCracken Jr, A. Finn, eds. *Hot topics in Infection and Immunity in Children*. British Paediatric Infection, Immunity, and Allergy Group (BPAIG), European Society for Paediatric Infectious Diseases (ESPID), and the Department of

Pediatrics, University of Oxford. New York: Kluwer Academics/Plenum Publishers, 2004, pp 237-247.

7. Walsh TJ., Roilides E., Groll A., Gonzalez CE., Pizzo PA. Infectious complications in pediatric cancer patients. In: Pizzo PA, Poplack DG., eds. Principles and Practice of Pediatric Oncology 5th edition. Lippincott Williams and Wilkins, 2006, pp 1269-1329.

Book Reviews:

Pediatric transfusion therapy. Jay H Herman, MD and Catherine Manno, MD, eds. Bethesda MD, American Association of Blood Banks, Press, 2003. Immunohematology, 2004; 20: 74.

As of June 2012

CURRICULUM VITAE

Aziza Tahir Shad, M.D.

PERSONAL INFORMATION:

HOME ADDRESS: 13512 Potomac Riding Lane
Rockville, Maryland, 20850
(301) 762-1088

OFFICE ADDRESS: Division of Pediatric Hematology/Oncology,
Blood and Marrow Transplantation
Department of Pediatrics
Lombardi Comprehensive Cancer Center
Georgetown University Hospital
3800 Reservoir Road, NW
Washington, DC 20007-2197
(202) 444-2224

PLACE OF BIRTH: Karachi, Pakistan

MARITAL STATUS: Married, three children

CITIZENSHIP: USA

LICENSURE: Pennsylvania#: MD 040875-E, issued July 1987
(Inactive)
District of Columbia#: MD 21500,
issued November 1995
(Active, expires December 2012)
Maryland#: D0065484, issued April 2007
(Expired September 2011)

CERTIFICATION:

1981

Professional and Linguistic Assessment Board,
London, United Kingdom

1983	ECFMG, Pittsburgh, Pennsylvania
1984	FLEX, Seattle, Washington
1985	FEMGEMS, Pittsburgh, Pennsylvania
1989	Diplomate, American Board of Pediatrics.
1994	Diplomate, American Board of Pediatric Hematology Oncology
2011	Recertification

EDUCATION:

1969	I. Sc. (Intermediate Science) (Honors), St. Joseph's College for Women, Karachi Board of Secondary Education, Karachi, Pakistan
1977	M.B., B.S. (Honors), Dow Medical College, Karachi University, Karachi, Pakistan
1977	Internship, Dept of Internal Medicine, Civil Hospital, Karachi, Pakistan Chairman: Professor S. Memon
1977-78	Internship, Dept. of Surgery, Civil Hospital, Karachi, Pakistan Chairman: Professor F. Elahi
1978-79	Residency Pediatrics, Dept. of Pediatrics Civil Hospital, Karachi, Pakistan Chairman: Professor A. G. Billoo
1979-80	Postgraduate Student Pediatrics, Dept. of Pediatrics, Civil Hospital, Karachi, Pakistan Chairman: Professor A. G. Billoo
1980	D.C.H. (Honors) (Postgraduate Diploma in Child Health), Karachi University, Karachi, Pakistan

- 1981 Postgraduate Study, Pediatrics, London, United Kingdom
- 1982 Senior House Physician, Pediatrics, Kingston Hospital,
London, United Kingdom
Consultant: Dr. T. Hanid
- 1982-85 Postgraduate study and exams (ECFMG, FEMGEMS, FLEX)
Pittsburgh, Pennsylvania
- 1985-86 Conferences, Clinics, Pediatric Grand Rounds, Children's
Hospital, University of Pittsburgh, Pennsylvania
Program Director: Dr. T. Oliver
- 1986-89 Pediatric Residency, Children's Hospital, Pennsylvania State
University College of Medicine, The Milton S. Hershey
Center, Hershey, Pennsylvania
Chairman: Dr. N. Nelson
- 1989-92 Visiting Associate, Pediatric Oncology Branch, National
Cancer Institute, National Institutes of Health, Bethesda,
Maryland
Chief, Pediatric Branch: Dr. P. Pizzo
- 1992-95 Visiting Scientist, Lymphoma Biology Section, Pediatric
Oncology Branch, National Cancer Institute, National
Institutes of Health, Bethesda, Maryland
Section Head: Dr. Ian T. Magrath

PROFESSIONAL EXPERIENCE:

- 2007 Professor of Pediatrics and Oncology, Division of
Pediatric Hematology/Oncology, Blood and Marrow
Transplantation, Lombardi Comprehensive Cancer
Center, Georgetown University School of Medicine,
Washington, DC

2005-pres	Co-Director, Division of Neuro-Oncology and Childhood Cancer Research, Lombardi Comprehensive Cancer Center, Georgetown University Medical Center, Washington, DC
2000-pres	Director, Cancer Survivorship Program, Division of Pediatric Hematology/Oncology, Blood and Marrow Transplantation, Lombardi Comprehensive Cancer Center, Georgetown University Hospital, Washington, DC
1999-pres	Chief, Division of Pediatric Hematology/Oncology, Blood and Marrow Transplantation, Lombardi Comprehensive Cancer Center, Georgetown University Hospital, Washington, DC
1998-pres	Director, Leukemia/Lymphoma Program, Division of Pediatric Hematology/Oncology, Blood and Marrow Transplantation, Lombardi Comprehensive Cancer Center, Georgetown University Hospital, Washington, DC
1998-2001	Chairperson, Pediatric Tumor Board, Division of Pediatric Hematology/Oncology, Blood and Marrow Transplantation, Lombardi Comprehensive Cancer Center, Georgetown University Hospital, Washington, DC
1995-pres	Assistant Professor of Pediatrics, Division of Pediatric Hematology/Oncology, Blood and Marrow Transplantation, Lombardi Comprehensive Cancer Center, Georgetown University School of Medicine, Washington, DC
1995-pres	Member, Lombardi Comprehensive Cancer Center, Georgetown University School of Medicine, Washington, DC
1994-95	Assistant Professor of Pediatrics, Uniformed Services University of Health Sciences, Bethesda, Maryland

1992 -95	Attending Physician, Pediatric Oncology Branch, National Cancer Institute, National Institutes of Health, Bethesda, Maryland.
1980-81	Junior Consultant, Pediatrics, Medicare Clinic, Karachi, Pakistan

HONORS AND AWARDS:

2012	Hope Award 2012, Ulman Cancer Fund for Young Adults, Washington DC
2011	Community Service Award, Gemini Health Care Group, Washington DC
2010	2010 Leukemia Lymphoma Society 'Relentless for a Cure' Award.
2010	Listed in "Top Doctors of Washington", Washingtonian Magazine.
2009	2009 Leonard Tow Humanism in Medicine Award, Georgetown University School of Medicine, Washington DC.
2009	Listed in 'Top Doctors of Northern Virginia'. Northern Virginia Magazine.
2009	Listed in 'Best Doctors in America'.
2009	Georgetown University Hospital "Caring Star Award."
2008	2008 Estelle Ramey Mentorship Award, Georgetown Women in Medicine, Georgetown University School of Medicine, Washington, DC.
2008 - 2010	Hyundai Research Scholar, Hyundai Motors, USA.

- 2008 Listed in 'Best Doctors in America'.
- 2008 2008 Outstanding Achievement Award, Association of Physicians of Pakistani Descent of North America (APPNA), Washington, DC.
- 2008 ICRET Fellow, International Union against Cancer (UICC), Geneva, Switzerland.
- 2008 Listed in "Top Doctors of Washington", Washingtonian Magazine.
- 2008 Georgetown University Hospital "Caring Star Award."
- 2007 2007 Alumni Fellow, Penn State Alumni Association, Penn State University, Hershey and State College, PA.
- 2007 2007 GRAVITAS Award for Outstanding Humanitarian Work, GRAVITAS International, Washington DC.
- 2007 Listed in "Best Doctors in America."
- 2007 Georgetown University Hospital "Caring Star Award."
- 2006 Endowed Professorship: Amey Distinguished Professor of Neuro-Oncology and Childhood Cancer. Lombardi Comprehensive Cancer Center, Georgetown University Medical Center, Washington DC.
- 2006 Distinguished Alumni, Penn State Childrens Hospital, Penn State University, Hershey, PA.
- 2006 ICRET Fellow, International Union against Cancer, (UICC), Geneva, Switzerland.

2006	Georgetown University Hospital "Caring Star Award."
2005	Listed in "Top Doctors of Washington", Washingtonian Magazine.
2005	Georgetown University Hospital "Caring Star Award."
2004	Georgetown University Hospital "Caring Star Award."
2003	Georgetown University Hospital "Caring Star Award."
2002	1 st Annual John Eisenberg Memorial Career Development Award, Georgetown University Medical Center, Washington, DC. Awarded by The Society for Medical Women Faculty.
2002	Listed in "Top Doctors of Washington", Washingtonian Magazine.
2001	2001 Humanism in Medicine Award, Georgetown University Medical Center, Washington, DC. Awarded by The Healthcare Foundation of New Jersey.
2001	Nominee, AAMC Humanism in Medical Education Award, Georgetown University School of Medicine, Washington, DC.
2001	Nominee, Golden Apple Award for Excellence in Teaching, Georgetown University School of Medicine, Washington, DC. (Class of 2000 and 2001)
2001	Teacher of the Year Award, Department of Pediatrics, Georgetown University Hospital, Washington DC - 2000-2001

- | | |
|------|---|
| 2000 | Nominee, Golden Apple Award for Excellence in Teaching, Georgetown University School of Medicine, Washington, DC. (Class of 2000) |
| 1999 | Teacher of the Year Award, Department of Pediatrics, Georgetown University Hospital, Washington DC - 1998-1999 |
| 1997 | Teacher of the Year Award, Department of Pediatrics, Georgetown University Hospital, Washington DC - 1996-1997 |
| 1980 | D.C.H. (Honors) (Postgraduate Diploma in Child Health), Karachi University, Karachi, Pakistan. |
| 1971 | Recipient of Pakistan Council for National Integration Scholarship in Medicine, Sindh, Pakistan - 1971-1977 |

PROFESSIONAL SOCIETIES:

American Academy of Pediatrics
 American Society of Hematology
 American Society for Clinical Oncology
 Pakistan Society of Pediatric Oncology
 International Society of Pediatric Oncology

PUBLIC SERVICE:

- | | |
|------|---|
| 2010 | President, INCTR USA. |
| 2008 | Member, Lance Armstrong Campaign Advisory Committee, Columbus, Ohio. |
| 2008 | Member, Global Educational Resources for Cancer (EORC) Consortium, VA. |
| 2007 | Member, Board of Directors, Cancer Institute for Fertility Preservation, Washington DC. |

- 2007 Member, Steering Committee, District of Columbia Pediatric Palliative Care Collaborative, (DCPPCC) Washington DC.
- 2007 Journal Reviewer, 'Annals of Saudi Medicine'.
- 2006 Member, Steering Committee, Blood Club, Washington DC.
- 2006 Member, Technical Review Board of Dow University of Health Sciences, Karachi, Pakistan.
- 2006 Scientific Reviewer for Scientific Peer Review, Neurofibromatosis Research Program, Department of Defense, Congressionally Directed Medical Research Programs (CDMRP).
- 2006 Journal Reviewer, 'American Journal of Perinatology'.
- 2006 Participant, 'Implementing Cancer Survivorship Care Planning', An Institute of Medicine, National Cancer Policy Forum Workshop. Sponsor: National Coalition for Cancer Survivorship, Lance Armstrong Foundation and National Cancer Institute.
- 2006 Member, Expert Registry of the Center for the Evaluation of Risks to Human Reproduction (CERHR), National Toxicology Program NIEHS.
- 2006 Chair, Palliative Care Steering Committee, Middle East Cancer Consortium (MECC), a National Cancer Institute (NCI) sponsored program for Cancer in the Middle East.
- 2006 Member, International Organizing Committee, Society for International Pediatric Oncology (SIOP), SIOP Asia 2008, Muscat, Oman.

2006	Member, DC-GAPS Advisory Board, Howard University, Washington DC.
2006	Member, 'Tracy's Kids' Steering Committee, Washington DC.
2005	Director, International Network for Cancer Treatment and Research (INCTR), USA, a National Cancer Institute (NCI) sponsored program for Cancer in Developing Countries.
2005	Coordinator, Global Alliance for Cure of Children with Cancer, a joint collaboration of OAI, NCI, CURE, COG, INCTR, St Judes Hospital and Lombardi Cancer Center.
2005	Scientific Reviewer for Scientific Peer Review, Neurofibromatosis Research Program, Department of Defense, Congressionally Directed Medical Research Programs (CDMRP)
2005	Journal Reviewer, 'Core Evidence'
2004	Consultant, District of Columbia Comprehensive Cancer Control Plan, Washington DC
2004-pres	Journal Reviewer, 'Pediatric Blood and Cancer'
2004	Scientific Reviewer for Scientific Peer Review, Neurofibromatosis Research Program, Department of Defense, Congressionally Directed Medical Research Programs (CDMRP.)
2003-pres	Incharge, 'Operation Iraq Lifeline', a training program for Iraqi Oncologists, sponsored by Office of International Affairs, NCI, NIH.
2003-pres	Member, Board of Directors, 'Hope for Henry Foundation', Washington, DC

2003-pres	Member, Medical Advisory Board, 'Casey Cares' Foundation, Baltimore MD.
2003-pres	Member, Medical Advisory Panel, Children's Road to Recovery, Inc. Baltimore, MD.
2001-pres	Chair, Pediatric Education Committee, The International Network for Cancer Treatment and Research (INCTR), a National Cancer Institute (NCI) sponsored program for Cancer in Developing Countries, Brussels, Belgium.
2001-pres	Member, Foreign Membership Task Force, Children's Oncology Group (COG).
1999-pres	International Scientific Advisor, International Committee for Establishment and Development of Oncology Centers (ICEDOC).
1998-pres	Member, Medical Advisory Board, Children's Cancer Research Foundation, Baltimore, MD.
1997-2002	Medical Director, The Children's Cancer Center Project, St Petersburg, Russia. A sponsored project of The World Bank and Vishnevskaya Rostropovich Foundation.
1996-pres	Governing Council Member, The International Network for Cancer Treatment and Research (INCTR), a National Cancer Institute (NCI) sponsored program for Cancer in Developing Countries, Brussels, Belgium.
1996-pres	Mayor of District of Columbia Committee for Metabolic and Hematological Disorders
1996-2003	Member, Medical Advisory Board, Children's Brain Tumor Foundation, Washington DC.

- | | |
|-----------|--|
| 1995 | Visiting Consultant, Pediatric Hematology Oncology, King Faisal Specialist Hospital and Research Center, Riyadh, Saudi Arabia. |
| 1995 | Consultant, Pakistan Middle East Cancer Cooperative Group, Karachi, Pakistan. |
| 1993 | Consultant, Pediatric Oncology Group (POG), Islamabad, Pakistan |
| 1991-pres | Consultant, Shaukat Khanum Memorial Cancer Hospital, Lahore, Pakistan. |
| 1980 | Pediatric Consultant, Child Welfare Clinics, Karachi, Pakistan. |

INVITED LECTURES:

1. Dermatological Complications of Chemotherapy: Seminar, National Cancer Institute, Pediatric Oncology Branch, National Institutes of Health, Bethesda, MD, January 1990.
2. Late Effects of Cancer Chemotherapy: Silver Jubilee Conference. Tata Memorial Cancer Center, Mumbai, India, November 1991.
3. Pathogenesis of HIV Associated Lymphomas: Silver Jubilee Conference, Tata Memorial Cancer Center, Mumbai, India, November 1991.
4. Anaplastic Large Cell Lymphomas: First Annual Cancer Conference, Pakistani Society of Clinical Oncology, Karachi, Pakistan, December 1991.
5. A Successful Treatment Protocol for B-cell Lymphomas. International Pediatric Conference, SIOP and Indian Pediatric Society, New Delhi, India, January 1994.
6. Childhood Lymphomas: Grand Rounds, Children's Hospital of Islamabad, Islamabad, Pakistan, January 1994.

7. An Effective protocol for the Treatment of Non-Hodgkin's Lymphomas in Developing Countries: XIII Biennial Conference of Pakistan/British Pediatric Association. Lahore, Pakistan, January 1994.
8. Lymphoid Malignancies: 4th Annual Cancer Conference, Pakistan Society of Clinical Oncology, Karachi, Pakistan, January 1995.
9. Childhood Lymphomas: Grand Rounds, King Faisal Specialist Hospital and Research Center. Riyadh, Saudi Arabia, September 1995.
10. HIV Lymphomas: Pathogenesis and Treatment: Seminar, King Faisal Specialist Hospital and Research Center, Riyadh, Saudi Arabia, September 1995.
11. Treatment of Pediatric B-Cell Lymphomas: 2nd Annual Cancer Conference, Shaukat Khanum Memorial Cancer Center, Lahore, Pakistan, February 1996.
12. Molecular Pathogenesis of B-Cell Lymphomas: Molecular Oncology Workshop, Tata Memorial Cancer Center, Mumbai, India, February 1996.
13. Childhood Lymphomas: Pediatric Grand Rounds, Georgetown University Medical Center, Washington, DC, USA, April 1996.
14. Iron Deficiency Anemia: Pediatric Grand Rounds, Arlington Hospital, Arlington, VA, USA, April 1996.
15. Pediatric Oncology Overview: Board Review Course, Department of Pediatrics, Georgetown University Medical Center, Washington, DC, USA, May 1996.
16. Pediatric Lymphomas - An Overview: Pediatric Hematology Oncology Summer Teleconference Series. Pediatric Oncology Branch, National Cancer Institute, National Institutes of Health and John's Hopkins University, Washington, DC, USA, August 1996.

17. Treatment of Pediatric and Adult B-Cell Lymphomas in Developing Countries: Grand Rounds, Children's Hospital, Jinnah Post Graduate Medical Center. Karachi, Pakistan, February 1997.
18. Successful Treatment of Pediatric Lymphomas: Grand Rounds, King Faisal Specialist Hospital and Research Center. Riyadh, Saudi Arabia, March 1997.
19. Additional Chemotherapy Agents Improve Treatment Outcome for Children and Adults with Advanced B-Cell Lymphomas: Satellite Symposium, European Cancer Conference (ECCO), Hamburg, Germany, September 1997.
20. Results of Dose Intensive Chemotherapy in Children and Adults with B-Cell Lymphomas: 29th Conference of the International Society for Pediatric Oncology. Istanbul, Turkey, September 1997.
21. Acute Lymphoblastic Leukemia in Children: Special Seminar, Children's Hospital # 1, St Petersburg, Russia, October 1997.
22. Overview of Pediatric Lymphomas: Special Seminar, Children's Hospital # 1, St Petersburg, Russia, October 1997.
23. B-Cell Lymphomas – Results of Dose Intensive Chemotherapy in Children and Adults: 1st Annual Conference of Middle East Cancer Society, Sharm El Sheikh, Egypt, August 1998.
24. Pediatric Hematology Oncology Review: Board Review Course, Department of Pediatrics, Texas Tech University, El Paso, Texas, May 1998.
25. Advances in the Treatment of Pediatric Lymphomas: Grand Rounds, Department of Pediatrics, Georgetown University Medical Center, Washington, DC, USA, September 1998.
26. Molecular Abnormalities in HIV Associated Lymphomas: Molecular Oncology Conference, Middle East Cancer Society, Dubai, UAE, November 1998.

27. Concept of an International Program for Cancer Treatment and Research: Grand Rounds, King Faisal Specialist Hospital and Research Center. Riyadh, Saudi Arabia, November 1998.
28. Infectious Complications of Dose Intensive Chemotherapy: Seminar, Children's Hospital, Jinnah Post Graduate Medical Center. Karachi, Pakistan, July 1999.
29. Evaluation of Coagulation Disorders: Pediatric Grand Rounds, Arlington Hospital, Arlington, VA, USA, September 1999.
30. Pediatric Lymphomas-Advances in Therapy: Special Seminar, Children's Hospital # 1, St Petersburg, Russia, January 2000.
31. Evans Syndrome-Case Presentation: Special Seminar, Children's Hospital # 1, St Petersburg, Russia, January 2000.
32. Infections in Immunocompromised Hosts following Bone Marrow Transplantation: Ist International Bone Marrow Transplant Conference, Russian Society of Hematology Oncology, St Petersburg, Russia, June 2000.
33. Acute Lymphoblastic Leukemia of Childhood: Grand Rounds, Children's Hospital, Tbilisi, Georgia, July 2000.
34. An International Program for Cancer Treatment and Research: Special Seminar, Health, Ministry of Georgia, Batumi, Georgia, July 2000.
35. Difficult Conversations with Pediatric Families: Panel Presentation, Access and Quality in End of Life Care, 2nd Annual Conference, Hospice of Northern Virginia, September 2000.
36. How to Break Bad News: Grand Rounds, Department of Pediatrics, Georgetown University Medical Center, Washington, DC, USA, November 2000.
37. How to Break Bad News: Grand Rounds, Department of Pediatrics, Arlington Hospital, Arlington, VA, February 2001.

38. How to Break Bad News: Grand Rounds, Department of Neonatology, Washington Hospital Center, Washington DC, June 2001.
39. Pediatric Leukemia: Grand Rounds, Department of Pediatrics, The Aga Khan University of Health Sciences, Karachi, Pakistan, July, 2001.
40. Overview of Pediatric Lymphomas: Grand Rounds, Children's Hospital, Jinnah Post Graduate Medical Center. Karachi, Pakistan, July 2001.
41. Side Effects of Chemotherapeutic Agents: Special Seminar, Karachi Institute of Radiotherapy and Nuclear Medicine, Karachi, Pakistan, July 2001.
42. Cystic Fibrosis - Case Presentation: Teaching Seminar for 2nd Year Medical Students, Hematopathology Course, Georgetown University School of Medicine, Washington, DC, USA, October 2001.
43. Evaluation of Coagulation and Bleeding Disorders in Infants and Children: Grand Rounds, Alexandria Hospital, Alexandria, VA, November 2001.
44. Late Effects of Treatment in Childhood Cancer Survivors: Grand Rounds, Department of Pediatrics, Georgetown University Medical Center, Washington, DC, USA, May 2002.
45. How to Break Bad News: Teaching Seminar for 2nd Year Medical Students, Georgetown University School of Medicine, Washington, DC, USA, May 2002.
46. Late Effects of Treatment in Childhood Cancer Survivors- Concept of a Late Effects Program. Annual Oncology Conference, King Faisal Specialist Hospital and Research Center and Middle East Cancer Society, Riyadh, Saudi Arabia, September 2002.
47. Coagulation and Bleeding Disorders: Teaching Seminar for 2nd Year Medical Students, Hematopathology Course, Georgetown University School of Medicine, Washington, DC, USA, October 2002.

48. Anemias of Childhood – Case Presentation: Teaching Seminar for 2nd Year Medical Students, Hematopathology Course, Georgetown University School of Medicine, Washington, DC, USA, October 2002.
49. Late Effects of Treatment in Childhood Cancer Survivors - Concept of a Late Effects Program: 11th Annual Cancer Conference, Pakistan Society of Clinical Oncology, Karachi, Pakistan, December 2002.
50. Infections in Immunocompromised Hosts: Infectious Disease Guidelines for 2002, Presidential Seminar, 11th Annual Cancer Conference, Pakistan Society of Clinical Oncology, Karachi, Pakistan, December 2002.
51. American Society of Infectious Diseases: Guidelines for Treatment of Infections in Immunocompromised Hosts: Grand Rounds, Children's Hospital, Jinnah Post Graduate Medical Center. Karachi, Pakistan, December 2002.
52. Infections in Immunocompromised Hosts: Infectious Disease Guidelines for 2002, Grand Rounds, Shaukat Khanum Memorial Cancer Hospital and Research Center, Lahore, Pakistan, January 2003.
53. How to Break Bad News: Teaching Seminar for 2nd Year Medical Students, Georgetown University School of Medicine, Washington, DC, USA, March 2003.
54. Leukemias and Lymphomas: Cancer: Pathophysiology, Current Therapies, Clinical Trials and Drug Development Training Course, Pharmaceutical and Research Institute, Arlington, VA, USA, April 2003.
55. Late Effects of Cancer Treatment: Presentation to Parents Support Group, Leukemia and Lymphoma Society, Georgetown University Hospital, Washington, DC, USA, May 2003.
56. Oncological Emergencies: NCI sponsored Pediatric Oncology Educational Workshop. Dubai, UAE, October 2003.
57. Overcoming barriers to care for Children with Cancer around the World: Symposium on Pediatric Oncology in Developing Countries.

International Society for Pediatric Oncology (SIOP) Annual Congress, Cairo, Egypt, October 2003.

58. Pediatric Oncology in Developing Countries: Presentation to Child Foundation, Washington DC, USA, October 2003.
59. Leukemias and Lymphomas and Drug Development: Cancer: Pathophysiology, Current Therapies, Clinical Trials and Drug Development Training Course, Pharmaceutical and Research Institute, Arlington, VA, USA, October 2003.
60. Pediatric Oncology in Pakistan: Seminar Leader, 10TH Annual National Conference of Asian Pacific American Medical Students Association (APAMSA), Washington DC, November 2003.
61. Treatment of Pediatric B-Cell Lymphomas: VIII Reunion Internacional de Oncologia Pediatrica. Instituto Nacional de Pediatria, Mexico City, Mexico, November 2003.
62. Lymphoma of the Central Nervous System: VIII Reunion Internacional de Oncologia Pediatrica. Instituto Nacional de Pediatria, Mexico City, Mexico, November 2003.
63. Sharing Bad News with Families: Pediatric Grand Rounds, Children's Hospital, Penn State University, Hershey PA, January 2004.
64. Breaking Bad News: Teaching Seminar for 2nd Year Medical Students, Georgetown University School of Medicine, Washington, DC, USA, February 2004.
65. Children's International Health: Discussion on Georgetown University Forum, National Public Radio, Washington DC, USA, March 2004.
66. Management of High-grade B-cell lymphomas of Childhood: International Oncology Conference, King Hussein Cancer Center, Amman, Jordan, April 2004.
67. Pediatric Oncology at Georgetown: Panel Presentation at Georgetown Alumni Association Meeting, Philadelphia, PA, USA, April 2004.

68. Leukemias and Lymphomas: Cancer: Pathophysiology, Current Therapies, Clinical Trials and Drug Development Training Course, Pharmaceutical and Research Institute, Arlington, VA, USA, April 2004.
69. Importance of Educating Cancer Survivors on Late Effects: Lecture to Cure Search Teen Cancer Survivors, Washington DC, April 2004.
70. Pediatric Oncology in Developing Countries – Pakistan. Seminar on Health and Human Rights. Third Annual International health Conference, Johns Hopkins University School of Medicine, Baltimore, MD, USA, May 2004.
71. Overcoming Barriers in International Health: Seminar on Health and Human Rights. Third Annual International health Conference, Johns Hopkins University School of Medicine, Baltimore, MD, USA, May 2004.
72. Late Effects in Cancer Survivors: Cancer Survivorship Workshop. Cure Search National Cancer Foundation's Gold Ribbon Days, Capitol Hill, Washington DC, June 2004.
73. Healthy Living in Young Cancer Survivors: Importance of Long-term Follow-up. Parent Support Group, Special Love for Children with Cancer, Winchester, VA, USA, June 2004.
74. Pediatric Oncology in Developing Countries: The Role of International Organizations. Grand Rounds, Department of Pediatrics, Georgetown University Hospital, Washington DC, USA, July 2004.
75. Role of the Research Team: Clinical Trials Workshop, Brazilian Society for Pediatric Oncology, Sao Paulo, Brazil, September 2004.
76. Cancer in Children: INCTR Annual meeting, Cairo, Egypt, October 2004.

77. Current Updates on Adult and Pediatric Leukemia and Lymphoma: Cancer: Pathophysiology, Current Therapies, Clinical Trials and Drug Development Training Course, Pharmaceutical and Research Institute, Arlington, VA, USA, October 2004.
78. Anemias of Childhood: Teaching Seminar for 2nd Year Medical Students, Hematopathology Course, Georgetown University School of Medicine, Washington, DC, USA, November 2004.
79. Coagulation and Bleeding Disorders: Teaching Seminar for 2nd Year Medical Students, Hematopathology Course, Georgetown University School of Medicine, Washington, DC, USA, November 2004.
80. Recent Advances in the Treatment of Idiopathic Thrombocytopenic Purpura in Children and Adolescents. Grand Rounds, Department of Pediatrics, Georgetown University Hospital, Washington DC, USA, November 2004.
81. Pediatric Oncology in Developing Countries: Seminar, Kanti Children's Hospital, Kathmandu, Nepal, January 2005.
82. Pediatric Palliative Care: Kanti Children's Hospital, Kathmandu, Nepal, January 2005.
83. Difficult patients: Pediatric Ethics Rounds, Georgetown University Hospital, Washington DC, January 2005.
84. The Clinical Research Team: A Workshop on Research Methodology, Annual Meeting, Shaukat Khanum Cancer Hospital and Research Center, Lahore, Pakistan, March 2005.
85. Recent Advances in the Treatment of Idiopathic Thrombocytopenic Purpura in Children and Adolescents. Grand Rounds, Department of Pediatrics, Virginia Hospital Center, Arlington VA, March 2005.
86. Educating Young Cancer Survivors: Survivor Advocacy Program, Cure Search, Chevy Chase, MD, April 2005.
87. Current Updates on Adult and Pediatric Leukemia and Lymphoma: Cancer: Pathophysiology, Current Therapies, Clinical Trials and Drug

Development Training Course, Pharmaceutical and Research Institute, Arlington, VA, USA, May 2005.

88. Pediatric Leukemia: LeadAmerica Medicine and Healthcare Conference, Georgetown University, June 2005.
89. Late Effects in Cancer Survivors: Seminar on Cancer Survivorship. Cure Search National Cancer Foundation's Gold Ribbon Days, Capitol Hill, Washington DC, June 2005.
90. Unusual Pediatric Lymphomas: Cancer 2005: 3rd International Oncology and Nuclear Medicine Conference and 1st International Conference on Pediatric Oncology, Karachi, Pakistan, July 2005.
91. Research Team: Individuals Roles and Responsibilities: Research Methodology Workshop, Cancer 2005: 3rd International Oncology and Nuclear Medicine Conference and 1st International Conference on Pediatric Oncology, Karachi, Pakistan, July 2005.
92. Pediatric Leukemia and Lymphoma: "Meet the Experts", Cancer 2005: 3rd International Oncology and Nuclear Medicine Conference and 1st International Conference on Pediatric Oncology, Karachi, Pakistan, July 2005.
93. Management of Febrile Neutropenia: Cancer 2005: 3rd International Oncology and Nuclear Medicine Conference and 1st International Conference on Pediatric Oncology, Karachi, Pakistan, July 2005.
94. Long Term Effects of Cancer Therapy: First Regional Congress of Cancer and Blood Diseases of Childhood, King Hussein Cancer Center, Amman, Jordan, September 2005.
95. Modern Concepts in Supportive Care: First Regional Congress of Cancer and Blood Diseases of Childhood, King Hussein Cancer Center, Amman, Jordan, September 2005.
96. Bleeding and Clotting Disorders in the Surgical Patient: Otolaryngology Head and Neck Surgery Grand Rounds, Georgetown University Hospital, September 2005.

97. Management of Hodgkins Disease: International Teleconference Grand Rounds, Lombardi Cancer Center, Washington DC and The Peter Maccallum Cancer Center, Melbourne, Australia, October 2005.
98. Communicating Bad News: Workshop on Palliative Care for the Cancer Patient, Middle East Cancer Consortium (MECC), Larnaca, Cyprus, November 2005.
99. Current Updates on Adult and Pediatric Leukemia and Lymphoma: Cancer: Pathophysiology, Current Therapies, Clinical Trials and Drug Development Training Course, Pharmaceutical and Research Institute, Arlington, VA, USA, November 2005.
100. Breaking Bad News: Teaching Seminar for 2nd Year Medical Students, Georgetown University School of Medicine, Washington, DC, USA, November 2005.
101. Caring for Young Patients with Cancer: Georgetown University Mini Medical School, Washington DC, November 2005.
102. Coagulation and Bleeding Disorders: Teaching Seminar for 2nd Year Medical Students, Hematopathology Course, Georgetown University School of Medicine, Washington, DC, USA, November 2005.
103. Thrombophilia: Teaching Seminar for 2nd Year Medical Students, Hematopathology Course, Georgetown University School of Medicine, Washington, DC, USA, November 2005.
104. Communicating Bad News: Radiology Grand Rounds, Georgetown University Hospital, Washington DC, January 2006.
105. Current Advances in the Treatment of ITP in Children: Platelet Disorders Support Association and ITP Support Group, Lombardi Cancer Center, Washington DC, February 2006.
106. The Interaction of the Environment with Cancer: Keynote Lecture, Turkish National Cancer Week, Ankara, Turkey, April 2006.

107. Oncology Education in the United States: Keynote Lecture, TUBA Oncology Education Symposium, Turkish Academy of Sciences, Ankara, Turkey, April 2006.
108. Taking Charge: Education of Young Cancer Survivors, Survivor Advocacy Program, Cure Search, Chevy Chase, MD, April 2006.
109. Current Updates on Adult and Pediatric Leukemia and Lymphoma: Cancer: Pathophysiology, Current Therapies, Clinical Trials and Drug Development Training Course, Pharmaceutical and Research Institute, Arlington, VA, USA, April 2006.
110. Pediatric Oncology in Developing Countries: Grand Rounds, Pediatric Oncology Branch, NCI, NIH, Bethesda MD, May 2006.
111. Childhood Cancer Survivorship: Invited Speaker, Childhood Cause for Cancer Advocacy, Washington DC, June 2006.
112. 'Lion in the House': Panelist in Forum on Cancer Survivorship, Disparity in Cancer Treatment and End of Life Care, United States Congress, Washington DC, June 2006.
113. 'Lion in the House': Panelist in Forum on Cancer Survivorship, Disparity in Cancer Treatment and End of Life Care, Leukemia Lymphoma Society, Arlington Library, VA, June 2006.
114. Communication Issues facing the Pediatric Oncology Team: Workshop on Communication Issues in Pediatric Oncology, Middle East Cancer Consortium (MECC), Larnaca, Cyprus, June, 2006.
115. New Treatments for Chronic ITP in Children: Platelet Disorders Support Association and ITP Support Group, Lombardi Cancer Center, Washington DC, September 2006.
116. Patients, Physicians and Behavior: How to Break Bad News. Teaching Seminar for 2nd Year Medical Students, Georgetown University School of Medicine, Washington, DC, September, 2006.
117. Role of INCTR in International Oncology: Special Symposium on Pediatric Oncology in Developing Countries, International Societe' for

Pediatric Oncology (SIOP) Annual Meeting, Geneva, Switzerland, September 2006.

118. Supportive Care in Oncology Practice: Physicians Education Resources Seminar, Richmond, VA, USA, September 2006.
119. Long Term Follow-up for Pediatric Cancer Survivors: Rise to Action, Washington DC – Conference for Childhood Cancer Survivors and Families, Washington DC, October 2006.
120. Current Updates on Adult and Pediatric Leukemia and Lymphoma: Cancer: Pathophysiology, Current Therapies, Clinical Trials and Drug Development Training Course, Pharmaceutical and Research Institute, Arlington, VA, USA, November 2006.
121. Coagulation and Bleeding Disorders: Teaching Seminar for 2nd Year Medical Students, Hematopathology Course, Georgetown University School of Medicine, Washington, DC, USA, November 2006.
122. Thrombophilia: Teaching Seminar for 2nd Year Medical Students, Hematopathology Course, Georgetown University School of Medicine, Washington, DC, USA, November 2006.
123. Use of Colony Stimulating Factors in Oncology: Physicians Education Resources Seminar, Cleveland, Ohio, USA, November 2006.
124. Supportive Care in Pediatric Oncology – An Update: Physicians Education Resources Seminar, Chicago, Illinois, November 2006.
125. Pediatric Oncology in Countries with Limited Resources – Problems and Solutions: Grand Rounds, Texas Childrens' Hospital Cancer Center, Baylor University, Houston, Texas, USA, January 2007.
126. Advances in Supportive Care: Symposium on Recent Developments in Hematological Malignancies, Washington DC, USA, February 2007.
127. Communicating Bad News: 1st Workshop on Palliative Care in Pakistan, Pakistan Society of Pediatric Oncology, Karachi, Pakistan, February 2007.

128. Pediatric Oncology Education in Developing Countries – An Update: International Network for Cancer Treatment and Research Annual Meeting, Sao Paolo, Brazil, March 2007.
129. Advances in Supportive Care: Pediatric Oncology Seminar, Charleston, South Carolina, USA, March 2007.
130. Late Effects in Cancer Survivors: Straight Talk Lecture Series, Georgetown University, Washington DC, USA, April, 2007.
131. Histiocytic Syndromes: Keynote Lecture, 17th National Cancer Congress of Turkey, Antalya, Turkey, April 2007.
132. Relapsed Non Hodgkin's Lymphomas of Childhood: Meet the Expert Series, 17th National Cancer Cancer Congress of Turkey, Antalya, Turkey, April 2007.
133. Targeted Therapy for Childhood Cancers: Keynote Lecture, 17th National Cancer Cancer Congress of Turkey, Antalya, Turkey, April 2007.
134. Current Updates on Adult and Pediatric Leukemia and Lymphoma: Cancer: Pathophysiology, Current Therapies, Clinical Trials and Drug Development Training Course, Pharmaceutical and Research Institute, Arlington, VA, USA, April 2007.
135. INCTR and Global Alliance – Pediatric Oncology in Developing Countries: 2007 Pediatric Academic Societies Annual Meeting, Toronto, Canada, May 2007.
136. Childhood Cancer Survivors and Importance of Long Term Follow-up: Childrens' Cause for Cancer Advocacy Annual Meeting, Washington DC, USA, May 2007.
137. Stress and Burnout in Oncology Caregivers: Workshop on Palliative Care, Middle East Cancer Consortium (MECC), Larnaca, Cyprus, June, 2006.

138. Palliative Care in Developing Countries – A Global Perspective. Invited Lecture, APPNA Annual Meeting, Orlando, Florida, June 2006.
139. Advances in Supportive Care in Pediatric Malignancies: Pediatric Oncology Seminar, Richmond, VA, USA, July 2007.
140. Colony Stimulating Factors and their use in Oncology: PER Talk Series for Community Oncologists, San Francisco, CA, July 2007.
141. Supportive Care in Cancer in Developing Countries: INCTR Focused Workshop on Cancer Control in East Africa, Dar es Salaam, Tanzania, August 2007.
142. Communication, Empathy, Compassion and Professionalism - Quality of Life for the Children: First Pediatric Palliative Care Conference, Washington DC, USA, September 2007.
143. Practicing Fair and Ethical Patient Recruitment in Pediatric Oncology Trials: 5th Annual Patient Recruitment and Retention Conference, Washington DC, USA, September 2007.
144. Advances in Supportive Care in Pediatric Malignancies: Pediatric Oncology Seminar, Denver, CO, USA, September 2007.
145. Patients, Physicians and Behavior: Communication Issues in Pediatric Oncology. Teaching Seminar for 1st Year Medical Students, Georgetown University School of Medicine, Washington, DC, USA, October 2007.
146. Pediatric Palliative Care: Difficult Decisions and Choices. Grand Rounds, Department of Pediatrics, Georgetown University, Washington DC, USA, October 2007.
147. Colony Stimulating Factors and their use in Oncology: PER Talk Series for Community Oncologists, PER lecture, El Paso, TX, USA, October 2007.
148. Advances in Supportive Care in Pediatric Malignancies: Indian Association of Oncology meeting, American Society of Hematology (ASH) Annual Meeting, Atlanta, GA, USA, December 2007.

149. Controversies in Growth Factor Support for Hematological Toxicities: ASH Update 2008, Boston MA, USA, January 2008.
150. Management of Procedural Pain in Children and Adolescents: Nursing Seminar, SIOP ASIA Meeting, Muscat, Oman, February 2008.
151. Pediatric Palliative Care: Difficult Decisions and Choices. Pediatric Palliative Care Symposium, SIOP ASIA Meeting, Muscat, Oman, February 2008.
152. Long Term Follow-up Care for Pediatric Cancer Survivors: Keynote Lecture, SIOP ASIA Meeting, Muscat, Oman, February 2008.
153. Pediatric Oncology in Countries with Limited Resources: Problems and Solutions. Invited Lecture, South Asia Program, Seminar Series, Penn State University, McKeesport, PA, March 2008.
154. Importance of Long Term Follow-up Care for Pediatric Cancer Survivors: Invited Lecture, National Healthcare Journalism Conference, Crystal City, VA, March 2008.
155. Pediatric Cancer Survivors: Why do they need Follow-up? 2nd Rise to Action Conference for Childhood Cancer Survivors, Washington DC, April 2008.
156. Current Updates on Adult and Pediatric Leukemia and Lymphoma: Cancer: Pathophysiology, Current Therapies, Clinical Trials and Drug Development Training Course, Pharmaceutical and Research Institute, Arlington, VA, USA, April 2008.
157. Pediatric Palliative Care: Difficult Decisions and Choices. Workshop on Palliative Care, Middle East Cancer Consortium (MECC), Larnaca, Cyprus, May 2008.
158. Long Term Management of Cancer Survivors for Primary Care: The 30th Annual Internal Medicine Conference 'Back to the Patient-2008'. Orlando Regional Health Care Continuing Medical Education, University of South Florida, College of Medicine, Orlando, Florida, July 2008.

159. Communicating Bad News to Families: Seminar on Patient Care and Ethics. APPNA Annual Meeting, Washington, DC, July 2008.
160. Acute Leukemia: Pediatric Residency Core Curriculum Education Series. Georgetown University Hospital, Washington DC, August 2008.
161. Patients, Physicians and Behavior: Communication Issues in Pediatric Oncology. Teaching Seminar for 1st Year Medical Students, Georgetown University School of Medicine, Washington, DC, USA, September 2008.
162. Structuring a Pediatric Oncology Unit in a Developing Country: Bases for PODC Tomorrow. 40th Congress of International Society of Pediatric Oncology, Berlin, Germany, October 2008.
163. Fungal Infections in the Immunocompromised Host: Merck Medical Forum. New York, New York, October 2008.
164. Current Updates on Adult and Pediatric Leukemia and Lymphoma: Cancer: Pathophysiology, Current Therapies, Clinical Trials and Drug Development Training Course, Pharmaceutical and Research Institute, Arlington, VA, USA, October 2008.
165. Febrile Neutropenia: Pediatric Residency Core Curriculum Education Series. Georgetown University Hospital, Washington DC, October 2008.
166. Fungal Infections in the Immunocompromised Host and Stem Cell Transplant Recipients: Merck Medical Forum. Columbus, Ohio, November 2008.
167. Pediatric Oncology INCTR Educational Program for Iraq: NCI Seminar for Visiting Iraqi Oncologists. POB, NCI, Bethesda, MD, November 2008.
168. What Schools Need to know about Children with Cancer: 2008 Back to School Leukemia Lymphoma Society Conference. University of MD, College Park, MD. November 2008.

169. Fungal Infections in the Immunocompromised Host and Stem Cell Transplant Recipients: Merck Medical Forum. Indianapolis, IN, December 2008.
170. Hemostasis and Thrombosis: Cardiopulmonary Physiology Module. 1st Year Medical Students Lecture, Georgetown University School of Medicine. Washington DC, December 2008.
171. Pediatric Palliative Care: Special Lecture. Palliative Care Symposium, 8th Shaukat Khanum Memorial Cancer Center Cancer Symposium, Lahore, Pakistan, February 2009.

WORKSHOPS AND SYMPOSIA ORGANIZED:

- 2002: Symposium on Late Effects of Cancer Treatment in Pediatric Cancer Survivors. Lombardi Cancer Center, Georgetown University, Washington DC, September 2002.
- 2003: Symposium on Cancer Treatment and Late Effects in Pediatric Cancer Survivors. INCTR Annual Meeting, Brussels, Belgium, June 2002.
- NCI sponsored Pediatric Oncology Educational Workshop. Collaborative project of INCTR and Shaukat Khanum Memorial Cancer Center, Lahore, Pakistan. Dubai, UAE, October 2003.
- NCI sponsored Pediatric Oncology Educational Workshop. Collaborative project of INCTR and Chinese Pediatric Oncology Society. Chongqing, China, November 2003.
- 2004: Pediatric Oncology Update for Iraqi Pediatric Oncologists. Collaborative Project of NCI and King Hussein Cancer Center, Jordan. Amman, Jordan, April 2004.
- First INCTR Multidisciplinary Conference on Management of Hodgkin's Lymphoma and Mediastinal Involvement, INCTR 5TH

Annual Meeting, Cairo, Egypt, October 2004.

Symposium on Role of High Dose Therapy Requiring Stem Support in Resource-poor Countries. INCTR 5TH Annual Meeting, Cairo, Egypt, October 2004.

Pediatric Oncology Update on Transfusion Medicine for Iraqi Pediatric Oncologists. Cairo, Egypt, October 2004.

2005: First Scientific Retreat of the Division of NeuroOncology and Childhood Cancers, Great Falls, VA, May 2005.

1st International Conference on Pediatric Oncology, Karachi, Pakistan, Co-organized with Pakistan Society of Pediatric Oncology, July 2005.

Research Methodology Scientific Workshop, Co-organized with Pakistan Society of Pediatric Oncology, July, 2005.

Symposium on Regional and International Collaboration in Pediatric Oncology, Pediatric Oncology Open Forum: INCTR 6TH Annual Meeting, Chennai, India, December 2005.

2006: Workshop on 'Palliative Care for the Cancer Patient', co-organized with the Middle East Cancer Consortium (MECC), Larnaca, Cyprus, June 2006.

'Rise to Action': Conference for Childhood Cancer Survivors and Families, Washington DC, October 2006.

2007: Symposium on 'Introduction to Palliative Care', co-organized with Pakistan Society of Pediatric Oncology, Karachi, Pakistan, February 2007.

Symposium on 'Transfusion Medicine in Developing Countries', INCTR 7TH Annual Meeting, Sao Paulo, Brazil, March 2007.

Workshop on 'Stress and Burnout in Oncology Caregivers', co-organized with the Middle East Cancer Consortium (MECC), Larnaca, Cyprus, June 2007.

INCTR Focused Workshop on Cancer Control in East Africa in collaboration with PACT, IAEA and Ocean Road Cancer Institute, Dar es Salaam, Tanzania, July 2007.

2008: INCTR Pediatric Palliative Care Symposium: SIOP ASIA Meeting, Muscat, Oman, February 2008.

PODC Special Symposium on Pediatric Oncology Units and Training of Pediatric Oncologists in Developing Countries. 40th Congress of International Society of Pediatric Oncology, Berlin, Germany, October 2008.

INCTR Focused Workshop on Nasopharyngeal Carcinoma and Supportive Care in Developing Countries. Brussels, Belgium, November 2008.

2009: INCTR Symposium on Palliative Care, Lahore, Pakistan, November 2009.

2010: 1st Pediatric Oncology Symposium, University of Addis Ababa, Ethiopia, January 2010.

UNIVERSITY SERVICE:

Department:

2005-pres	Member, Board of Georgetown Pediatrics, Georgetown University Hospital
2004-pres	Member, Child Health and Human Development Research Initiative Committee, Department of Pediatrics, Georgetown University Medical Center
2002-pres	Member, Strategic Planning Steering Committee, Department of Pediatrics, Georgetown University Hospital

2002-pres	Member, Fund Raising Task Force Steering Committee, Department of Pediatrics, Georgetown University Hospital
2002-pres	Chair, International Task Force Steering Committee, Department of Pediatrics, Georgetown University Hospital
2002-pres	Member, Parent Advisory Board, Department of Pediatrics, Georgetown University Hospital
2001-pres	Member, Finance Committee, Department of Pediatrics, Georgetown University Hospital
1996-pres	Georgetown University Faculty Advisor for Pediatric Residents

School:

2004	Member, Committee on Values and Attitudes, Curriculum Reform Task Force, Georgetown University School of Medicine
2002-2008	Member, Committee on Medical Education, Georgetown University School of Medicine
2002-2003	Member, Committee on Student Appeals, Georgetown University School of Medicine
1996-pres	Georgetown University Pre-Med Society, Physician Shadowing Program
1996-pres	Georgetown University Faculty Advisor for Medical Students
1996-pres	Georgetown University AMWA Mentor for Medical Students

University:

2008	Member, Clinical Faculty Development Task Force.
------	--

2007	Member, Lombardi Executive Committee
2007	Member, Search Committee for Director, Lombardi Cancer Center
2007-pres	Member, General Clinical Research Center Advisory Committee
2005	Member, Lombardi Working Group, Lombardi Cancer Center
2004	Member, Search Committee for Chair, Department of Medicine, Georgetown University Hospital
2003-2004	Member, Faculty Senate Steering Committee, Georgetown University School of Medicine
2002-2008	Member, Faculty Senate, Georgetown University
2002-2008	Member, Medical Center Caucus of the University Faculty Senate, Georgetown University Medical Center
2002-2006	Member, Committee for Faculty Development, Georgetown University School of Medicine
2001-2005	Clinical Vice President, Georgetown University Society for Medical Women Faculty
2000-pres	Lombardi Cancer Committee, Pediatric Representative
2000-pres	Lombardi JHACO Committee, Pediatric Representative
1996-2000	Member, Lombardi Cancer Center Clinical Research Committee (CRC)

Hospital:

2000-pres	Member, Georgetown University Hospital Blood Utilization Review Committee
2000-pres	Member, Georgetown University Hospital Pain and Sedation Committee

TEACHING ACTIVITIES:

Medical Courses:

Introduction to Health Care II: Course # 4255103-12

Lecturer: 2 hours/lecture

2003 – 2005

Overall evaluation score: 3.5/4.0, 3.7/4.0, 3.6/4.0

Patients, Physicians and Behavior: Course # 4295-104-06

Lecturer: 2 hours/lecture

2005 – present

Overall evaluation score: 4.5/5.0

Pathology: Course # 4225222-06

Lecturer and CPC Instructor: 3 lectures/course, 2 hours/lecture

2003 – present

Overall evaluation score: 3.4/4.0, 3.3/4.0, 4.5/5.0

Ambulatory Care: Course # 4255106-12

Preceptor to 2 students /semester: 10 hours/student

2001 – present

Overall evaluation score: 4.7/5.0, 5.0/5.0, 5.0/5.0

Pediatrics 3rd year: Course # 4280-300

Faculty: 12 months/year in clinic with 2-3 students/week

1995 – present

Overall evaluation score: 3.9/4.0, 5.0/5.0

Teaching Recognition/Awards:

2001	Nominee, Golden Apple Award for Excellence in Teaching, Georgetown University School of Medicine, Washington, DC. (Class of 2000 and 2001)
2001	Teacher of the Year Award, Department of Pediatrics, Georgetown University Hospital, Washington DC - 2000-2001
2000	Nominee, Golden Apple Award for Excellence in Teaching, Georgetown University School of Medicine, Washington, DC. (Class of 2000)
1999	Teacher of the Year Award, Department of Pediatrics, Georgetown University Hospital, Washington DC - 1998-1999
1997	Teacher of the Year Award, Department of Pediatrics, Georgetown University Hospital, Washington DC - 1996-1997

COLLABORATIVE ACTIVITIES:

Joint Grants:

1. Role: Co-Principal Investigator with Dr Judith Jones (Degge Group)

Title: Knowledge Empowerment for Youth with Solid Tumors

Agency: NIH, SBIR

Identifying Number: R44CA86686-02

Dates: 2/03 –6/05

Percent effort: 5%

Total dollar amount: \$1,069,000 (Georgetown \$55,000)

2. Role: Co-Investigator with Dr Kenneth Tercyak (LCCC)

Title: Promoting Healthy Behaviors Among Pediatric Cancer Survivors

Agency: Lance Armstrong Foundation

Dates: 2/02 – 6/04

Percent Effort: 5%

Total Dollar Amount: \$150,000

3. Role: Co-Investigator with Dr Offie Solden (LCCC)
Title: Urban Environmental exposures and Childhood Cancer risk
Agency: Lombardi Cancer Center Developmental Grant
Dates: 07/04 –07/07
Percent Effort: 2%
Total Dollar Amount: \$120,000

Joint Publications:

1. Offie P. Soldin, Hala Nsouly-Maktabi, Jeanine M. Genkinger, Christopher A. Loffredo, Juan Antonio Ortega-Garcia, Drew Colantino, Dana B. Barr, Naomi L. Luban, **Aziza T. Shad**, and David Nelson. Pediatric Acute Lymphoblastic Leukemia and Exposure to Pesticides. Ther Drug Monit, 2009 – in print.
2. Soldin Offie, Shields PG, Loffredo CA, Barr D, Luban N, **Shad A**, Nelson D. Childhood Cancer and Possible Gene Environment Interactions. Presented at Society of Toxicology 46th Annual Meeting, Charlotte, North Carolina, March 2007.
3. Tercyak KP, Donze JR, Prahlad S, Mosher RB, **Shad AT**. Multiple behavioral risk factors among adolescent survivors of childhood cancer in the Survivor Health and Resilience Education (SHARE) Program. Pediatr Blood Cancer. 2006 Nov; 47(6): 825-30.
4. Tercyak KP, Donze JR, Prahlad S, Mosher RB, **Shad AT**. Identifying, Recruiting, and Enrolling Adolescent Survivors of Childhood Cancer into a Randomized Controlled Trial of Health Promotion: Preliminary Experiences in the Survivors Health and Resilience Education (SHARE) Program. J Pediatr Psychol. 2006 Apr; 31(3): 252-61.
5. **Aziza T. Shad, MD**, Karen A. Hennessy, RN, MS, CPNP, Sharmila Kamani, BA, Judith K. Jones, MD, PhD, Aditya Marfatia, BS Pharm, MS. A Multi-Media Interactive CD-ROM to Educate and Empower Adolescents with Cancer. Presented at the 9th International Conference on Long – Term Complications of Treatment of Children and Adolescents with Cancer, Niagara, Ontario, June 2006.

6. Kenneth Tercyak, PhD, Sowmya Prahlad, MS, Jessica R. Donze, MPH, Lauren A. Wine, BA, Bryn D. Mars, BA, Revonda B. Mosher, RN, MSN, Tracy Councill, MA, **Aziza T. Shad, MD**. Bone Health Beliefs and Behaviors Among Children who have Survived Cancer. Presented at the 8th International Conference on Long – Term Complications of Treatment of Children and Adolescents with Cancer, Niagara, Ontario, June 2004.
7. **Aziza T. Shad, MD**, Karen A. Hennessy, RN, MS, CPNP, Sharmila Kamani, BA, Patricia J. Bush, PhD, Judith K. Jones, MD, PhD. Knowledge Empowerment for Survivors with Cancer. Presented at the 8th International Conference on Long – Term Complications of Treatment of Children and Adolescents with Cancer, Niagara, Ontario, June 2004.
8. Kenneth P. Tercyak, PhD, Sowmya Prahlad, MS, Jessica R. Donze, MPH, Lauren A. Wine, BA, Bryn D. Mars, BA, Revonda B. Mosher, RN, MSN, Tracy Council, MA, **Aziza T. Shad, MD**. Bone Health Beliefs and Behaviors Among Children who have Survived Cancer. Presented at National Conference on Child Health Psychology, Washington DC, April 2004.

SCHOLARSHIP AND RESEARCH:

Current Active:

1. Agency: Hyundai Motor Corporation
 Title of Project: Pediatric Oncology Palliative Care Program
 Dates of Project Period: 12/10 – 12/12
 Role on Project: Study Leader
 Percent Effort: 5%
 Total Dollar Amount: \$ 100,000
2. Agency: NCCF Childrens Oncology Group Grant
 Title of Project: Pediatric Cancer Studies / Clinical Trials
 Dates of Project Period: 3/03 – present
 Role on Project: Principal Investigator
 Percent Effort: 5%
 Total Dollar Amount: \$156,873.20
3. Agency: Children's Cancer Foundation and Hyundai Corporation
 Identifying Number: RT 4395053

Title of Project: Late Effects Research in Pediatric Cancer Survivors

Dates of Project Period: 9/04 – present

Role on Project: Study Leader

Percent Effort: 5%

Total Dollar Amount: \$145,000

4. Agency: Hyundai Motor Corporation

Title of Project: Late Effects Research in Pediatric Cancer Survivors

Dates of Project Period: 5/06 – 6/11

Role on Project: Study Leader

Percent Effort: 5%

Total Dollar Amount: \$ 220,000

5. Agency: Chip in for Kids with Cancer

Title of Project: Pediatric Cancer Research

Dates of Project Period: 6/05 – present

Role on Project: Principal Investigator

Percent Effort: 5%

Total Dollar Amount: \$55,500

6. Agency: DYAX, USA

Title of Project: EDEMA 4: A Randomized, Double Blind, Placebo-Controlled, Multi-Center Study to Assess the Efficacy and Safety of DX-88 (Ecallantide) for the Treatment of Acute Attacks of Hereditary Angioedema.

Dates of Project Period: 8/07

Role on Project: Principal Investigator (Georgetown)

Total Dollar Amount: \$11,095

7. Agency: DYAX, USA

Title of Project: DX-88/19: Open-label Patient Continuation of DX-88 (Ecallantide) for Acute Hereditary Angioedema (HAE) Attacks.

Dates of Project Period: 8/07

Role on Project: Principal Investigator (Georgetown)

Total Dollar Amount: \$13,812

8. Agency: Prevent Cancer Foundation

Title of Project: Cancer Survivorship – A Guide for Childhood Cancer Survivors and Families

Dates of Project Period: 12/07

Role on Project: Study Leader

Percent Effort: 5%

Total Dollar Amount: \$ 55,000

Previous:

1. Agency: DYAX, USA

Title of Project: DX-88/14: EDEMA 3: Evaluation of DX-88's Effects in Mitigating Angioedema. A double-blind, placebo controlled study followed by a repeat dosing phase to assess the efficacy and safety of DX-88 (recombinant plasma kallikrein inhibitor) for the treatment of Acute attacks of Hereditary Angioedema

Dates of Project Period: 2005 - 2007

Role on Project: Principal Investigator (Georgetown)

Total Dollar Amount: \$74,565

2. Agency: DYAX, USA

Title of Project: EDEMA 2: An Open Label Study to Assess the Efficacy and Tolerability of Repeated Doses of DX-88 (recombinant plasma kallikrein inhibitor) in Patients with Hereditary Angioedema

Dates of Project Period: 2004 - 2005

Role on Project: Principal Investigator (Georgetown)

Total Dollar Amount: \$36,565

3. Agency: NIH, SBIR

Title of Project: Knowledge Empowerment for Youth with Solid Tumors.

Dates of Project Period: 2003 - 2005

Role on Project: Principal Investigator (Georgetown)

Total Dollar Amount: \$1,069,000 (Georgetown \$55,000)

4. Agency: DYAX, USA

Title of Project: EDEMA 1: An Ascending Four Dose Placebo Controlled Study to Assess the Efficacy and Tolerability of DX-88 (recombinant plasma kallikrein inhibitor) Administered Following Onset of Acute Attacks of Hereditary Angioedema.

Dates of Project Period: 2002 - 2004

Role on Project: Principal Investigator (Georgetown)

Total Dollar Amount: \$37,740

5. Agency: NHLBI

Title of Project: Optimizing Primary Stroke Prevention in Children with Sickle Cell Anemia: STOP II Study

Dates of Project Period: 2001 - 2004

Role on Project: Principal Investigator (Georgetown)

Total Dollar Amount: Nil

6. Agency: NCCF Childrens Oncology Group

Title of Project: Pediatric Cancer Studies

Dates of Project Period: 3/98 – 3/03

Role on Project: Principal Investigator

Percent Effort: 5%

Total Dollar Amount: \$74,415

7. Agency: Merck, USA

Title of Project: A Multi-center, Open, Non-Comparative, Sequential Dose Escalation Study to Investigate The Safety, Tolerability and Pharmacokinetics of Two Separate Doses of MK-0991 in Children with New Onset Fever and Neutropenia.

Dates of Project Period: 2000 - 2002

Role on Project: Principal Investigator (Georgetown)

Total Dollar Amount: \$15,500

8. Agency: Fujisawa, USA

Title of Project: Phase I-II Study of the Safety and Phamacokinetics of an anti-fungal agent FK-463 in Immunocompromised Children.' Multi-center Pharmaceutical Industry Study

Dates of Project Period: 1999 - 2001

Role on Project: Principal Investigator (Georgetown)

Total Dollar Amount: \$20,000

9. Agency: NIH, SBIR

Title of Project: Levels of Learning about Cancer by Pediatric Patients. Childhood Leukemia Project –Phase I-II Study

Dates of Project Period: 1998 - 2000

Role on Project: Principal Investigator

Total Dollar Amount: \$850,000 (Georgetown \$81,000)

10. Agency: Fujisawa, USA

Title of Project: Phase I-II Study of the Safety and Pharmacokinetics of a Small Unilamellar Vesicle formulation of Liposomal Amphotericin (Ambisome) in Immunocompromised Children. Multi-center Pharmaceutical Industry Study

Dates of Project Period: 1997-1999

Role on Project: Principal Investigator (Georgetown)

Total Dollar Amount: \$35,000

11. Agency: Sanofi, Winthrop, USA

Title of Project: An Open Label Randomized Multi-Center Comparison of SR29142 vs. Allopurinol for the Prophylaxis and Treatment of Hyperuricemia in Pediatric Patients with Leukemia and Lymphoma.

Dates of Project Period: 1997-1999

Role on Project: Principal Investigator (Georgetown)

Total Dollar Amount: \$10,000

12. Agency: NCI, NIH

Title of Project: 89-C-41 Pilot Protocol for the Treatment of Patients with Small non-cleaved and Large cell Lymphomas". National Cancer Institute Multi-center Study.

Dates of Project Period: 1989 -1995

Role on Project: Associate Investigator (POB, NCI))

Total Dollar Amount: Nil

13. Agency: NCI, NIH

Title of Project: Pilot Protocol for the Treatment of Non Hodgkin's Lymphoma in Patients with Inherited and Acquired Immunodeficiency Syndromes. National Cancer Institute Multi-center Study

Dates of Project Period: 1992 -1995

Role on Project: Protocol Chair (POB, NCI))

Total Dollar Amount: Nil

PUBLICATIONS:

Original Papers:

1. Shad A, Myers SN, Hennessy K. Late Effects in Cancer Survivors: 'The Shared Care Model'. Curr Oncol Rep. 2012 January 28 ; (epub ahead of print).

2. Madhavan S, Sanders AE, Chou WY, Shuster S, Boone KW, Dente MA, **Shad AT**, Hesse BW. Pediatric palliative care and eHealth opportunities for patient-centered care. *Am J Prev Med*. 2011 May; 40(5 Suppl 2): S208-16.
3. Mays D, Black JD, Mosher RB, Heinly A, **Shad AT**, Tercyak KP. Efficacy of the Survivor Health and Resilience Education (SHARE) Program to improve Bone Health Behaviors Among Adolescent Survivors of Childhood Cancer. *Am Behav Med*. 2011 Feb 17.
4. Magrath I, Bey P, **Shad A**, Sutcliffe S. Cancer Funding in developing countries; the next health care crisis. *Lancet*. 2010 Nov 27; 376(9755):1827. No abstract available.
5. Corn M, Gustafson DH, Harris LM, Kutner JS, McFarren AE, **Shad AT**. Survey of consumer informatics for palliation and hospice care. *Am J Prev Med*. 2011 May; 40(5 Suppl 2):S173-8.
6. Silbermann M, Khleif A, Tuncer M, Pitsillides B, **Shad A**, Oberman A, Elshami M, Gultekin M, Daher M, Tarawneh M, Harford J. Can We Overcome the Effect of Conflicts in Rendering Palliative Care? An Introduction to the Middle Eastern Cancer Consortium (MECC). *Curr Oncol Rep*. 2011 May 3 [Epub ahead of print]
7. **Shad A**, Ashraf MS, Hafeez H. Development of palliative-care services in a developing country: Pakistan. *J Pediatr Hematol Oncol*. 2011 Apr; 33 Suppl 1:S62-3.
8. Sathiyamoorthy S, **Shad A**, Ozdemirli M. Acute promyelocytic leukemia following chemotherapy for EBV-associated hemophagocytic lymphohistiocytosis. *Pediatr Blood Cancer*. 2011 May; 56(5):850-2 doi:10.1002/pbc.22718. Epub 2011 Jan 16.
9. Saadiya Haque; Bhaskar Kallakury; **Aziza Shad**; Kristen Snyder. A 5-year old male with "leukemic form" of disseminated post-transplant lymphoproliferative disorder. *Pediatr Repo*. 2010 Jun 18; 2(11):e6. No abstract available.

10. Offie P, Soldin, Hala Nsouli-Maktabi, Jeanine M. Genkinger, Christopher A. Loffredo, Juan Antonio Ortega-Garcia, Drew Colantino, Dana B. Barr, Naomi L. Luban, **Aziza T. Shad**, and David Nelson. Pediatric Acute Lymphoblastic Leukemia and Exposure to Pesticides. *Ther Drug Monit*, 2009 Aug; 31(4):495-501.
11. Baker SB, Parikh PM, Rhodes DN, Abu-Ghosh A, **Shad AT**. Aggressive central giant cell lesion of the maxilla: surgical management and the use of adjuvant interferon alfa-2a. *Plast Reconstr Surg*. 2008 Aug;122(2):77e-9e.
12. Mays D, Black JD, Mosher RB, **Shad AT**, Tercyak KP. Improving short-term sun safety practices among adolescent survivors of childhood cancer: a randomized controlled efficacy trial. *J Cancer Surviv*. 2011 Feb 27.
13. Jones JK, Kamani SA, Bush PJ, Hennessy KA, Marfatia A, **Shad AT**. Development and evaluation of an educational interactive CD-ROM for teens with cancer. *Pediatr Blood Cancer*. 2010 Sep; 55(3):512-9.
14. Haque SA, Xiang Y, Ozdemirili M, **Shad AT**, Kallakury B. A seventeen-year-old female with hepatosplenic T-cell lymphoma associated with parvovirus infection. *Pediatr Rep*. 2010 Jun 18; 2(1):e11.
15. **Aziza Shad** and Amal Abu-Ghosh. Emergency Management of Non-Hodgkin's Lymphoma. *The Lymphoid Neoplasms*, 3rd Edition, Ed. Ian Magrath. Hodder Arnold Health Sciences, London UK; 2009.
16. Karen Hennessy, Nabeel Arastu and **Aziza Shad**. *The Next Step...Crossing the Bridge to Survivorship*. Lombardi Comprehensive Cancer Center, Washington DC, USA, April 2008.
17. Hope WW, Seibel NL, Schwartz CL, Arrieta A, Flynn P, **Shad A**, Albano E, Keirns JJ, Buell DN, Gumbo T, Drusano GL, Walsh TJ. Population Pharmacokinetics of Micafungin in Pediatric Patients and the Implications for Antifungal Dosing. *Antimicrob Agents Chemother*. 2007, Oct; 51 (10):3714-9.

18. Liebelt EL, Balk SJ, Faber W, Fisher JW, Hughes CL, Lanszkron SM, Lewis KM, Marchetti F, Mehendale HM, Rogers JM, **Shad AT**, Skalko RJ, Stanek EJ. NTP-CERHR Expert Panel Report on the Reproductive and Developmental Toxicity of Hydroxyurea. *Birth Defects Res B Dev Reprod Toxicol*. 2007 Aug; 80(4):259-366.
19. Tercyak KP, Donze JR, Prahlad S, Mosher RB, **Shad AT**. Multiple behavioral risk factors among adolescent survivors of childhood cancer in the Survivor Health and Resilience Education (SHARE) Program. *Pediatr Blood Cancer*. 2006 Nov; 47(6): 825-30.
20. Tercyak KP, Donze JR, Prahlad S, Mosher RB, **Shad AT**. Identifying, Recruiting, and Enrolling Adolescent Survivors of Childhood Cancer into a Randomized Controlled Trial of Health Promotion: Preliminary Experiences in the Survivors Health and Resilience Education (SHARE) Program. *J Pediatr Psychol*. 2006 Apr; 31(3): 252-61.
21. Walsh TJ, Adamson PC, Seibel NL, Flynn PM, Neely MN, Schwartz C, **Shad A**, Kaplan SL, Roden MM, Stone JA, Miller A, Bradshaw SK, Li SX, Sable CA, Kartsonis NA. Pharmacokinetics, Safety and Tolerability of caspofungin in children and adults. *Antimicrob Agents Chemother*. 2005 Nov 49; (11): 4536-45.
22. Seibel NL, Schwartz C, Arrieta A, Flynn P, **Shad A**, Albano E, Keirns J, Lau WM, Facklam DP, Buell DN, Walsh TJ. Safety, Tolerability and Pharmacokinetics of Micafungin (FK463) in febrile neutropenic pediatric patients. *Antimicrob Agents Chemother*. 2005 Aug; 49(8): 3317-25.
23. Tercyak, KP, Nicholas, M, Councill, T, Prahlad, S, Taylor, K. L., and **Shad, A. T**. Brief Report: Health Beliefs among survivors of Childhood Cancer. *J Pediatr Psychol*. 2004. July-Aug; 29(5): 397-402.
24. Corina E. Gonzalez, **Aziza Shad**, Melissa Adde, Brigitta U Muller, David Venzon, Nilo Avila, Elaine Jaffe, Douglas Kingma, Lauren Wood, Philip Pizzo, William Smithson and Ian Magrath. A Pilot Study for the Treatment of Non-Hodgkin's Lymphomas in Children with Acquired Immunodeficiency Syndromes. Published, *International Journal of Oncology*, 2003.

25. Scott M. Klein, Gabriel J. Hauser, Barry D. Anderson, **Aziza T. Shad**, Joseph E. Gootenberg, Heidi J. Dalton, James H. Hertzog. Comparison of intermittent versus continuous infusion of propofol for elective oncology procedures in children. *Pediatric Critical Care Medicine*, 4:78-82, 2003.
26. James H Herzog, Heidi J Dalton, Barry D Anderson, **Aziza T Shad**, Joseph E Gootenberg, Gabriel J. Hauser. Prospective Evaluation of Propofol Anesthesia in the Pediatric Intensive Care Unit for Elective Oncology Procedures in Ambulatory and Hospitalized Patients. *Pediatrics*, 106 (4), 2000.
27. Barry Anderson, **Aziza Shad**, Joseph E. Gootenberg and S. Gerald Sandler. Successful Prevention of Post-Transfusion Rh Alloimmunization by Intravenous Rho (D) Immune Globulin (WinRho SD). *American Journal of Hematology*, 60:245-247, 1999.
28. Terry Haddy, Melissa Adde, June McCalla, Detiles Damansky, K Meehan, A Pikus, **Aziza Shad**, J Valdez, Lopez Vivieno and Ian Magrath. Late Effects in Long Term Survivors of High Grade Non Hodgkin's Lymphoma. *Journal of Clinical Oncology*, 16 (6): 2070-9; 1998.
29. Melissa Adde, **Aziza Shad**, David Venzon, Carola Arndt, Joseph Gootenberg, John Neely, Michael Neider, William Owen, Nita Seibel, Wyndham Wilson, Ivan Horak and Ian Magrath. Additional Chemotherapy Agents improve treatment outcome for Children and Adults with Advanced B-Cell Lymphomas. *Seminars in Oncology*, 25(2 Suppl 4): 33-9; 1998.
30. Metin Ozdermirli, Julie Fanberg-Smith, Dan-Paul Hartmann, **Aziza Shad**, Janice Lage, Ian Magrath, Norio Azumi, Nancy Harris, Jeffrey Cossman and Elaine Jaffe. Precursor B - Lymphoblastic Lymphoma/Leukemia presenting as a Solitary Bone Tumor and mimicking Ewings Sarcoma. A Report of Four Cases and Review of the Literature. *American Journal of Surgical Pathology*. 22(7): 795-804; 1998.

31. **Aziza Shad**, Brigitta Mueller, Melissa Adde, Nilo Avila, John Sleasman, Philip Pizzo, Ian Magrath. Results of a Treatment Protocol for Children with HIV and non Hodgkins Lymphomas. *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology*. 1997. 14(4): A54.
32. Kingma DW, **Shad A**, Tsokos M, Fest T, Otsuki T, Frekko EK, Werner E, Werner A, Magrath I, Raffeld M and Jaffe ES. Epstein Barr Virus (EBV) associated Smooth Muscle Tumor arising in Post Transplant Patient treated successfully for two PT-EBV associated Large cell lymphomas. *The American Journal of Surgical Pathology* 20 (12): 1511-1519. 1996.
33. Magrath I, Adde M, **Shad A**, Venzon D, Seibel N, Neeley J, Gootenberg J, Arndt C, Nieder M, Jaffe E, Wittes R and Horak I. Adults and children with small non-cleaved cell lymphoma have a similar outcome when treated with the same chemotherapy regimen. *Journal of Clinical Oncology*, 3:925-934; 1996.
34. Weintraub M, Adde M, **Shad AT**, Venzon D, Horak I, Seibel N, Neeley J, Magrath IT et al. Severe atypical neuropathy associated with the administration of both colony stimulating factors and vincristine. *Journal of Clinical Oncology*, 3:934-37; 1996.
35. Izraeli S, Mueller BU, Ling A, Temeck B, Lewis L, Chang R, **Shad A**, Pass H, and Pizzo P. Pulmonary involvement in pediatric HIV infection - the evolving role of tissue diagnosis. *Journal of Pediatric Infectious Diseases*, 15:112-116, 1996.
36. Mackall CL, Fleisher RA, Brown MR, Magrath IT, **Shad AT**, Horowitz ME, Wexler LH, Adde MA, McClure L, Gress RE. Lymphocyte depletion during treatment with intensive chemotherapy for cancer. *Blood*, 84:7:pp2221-8; 1994.
37. Mackall CL, Fleisher TA, Brown M, Magrath IT, **Shad AT**, Wexler LH, Horowitz ME, Andrich MP, Chen CC, Fuerstein IA, and Gress RE. Age, thymopoiesis and CD4+ lymphocyte regeneration. *N Engl J Med*, 332:3:pp 182-3; 1994.

Reviews:

1. **Shad AT**, Gonzalez CE, Sandler SJ. Treatment of Immune Thrombocytopenic Purpura in Children: Current Concepts. *Pediatr Drugs*. 2005; 7(5): 325-36.
2. **Aziza Shad** and Ian Magrath. Pediatric non-Hodgkin's Lymphomas. *Pediatric Clinics of North America*. 44(4): 863-90; 1997.
3. **Shad AT**, Jain V, and Magrath IT. Small non-cleaved cell lymphomas. In *Current Therapy in Hematology-Oncology* (5th edition) Eds. M.C. Brain and P.P. Carbone. B.C. Decker, Philadelphia. pp. 326-335, 1995.

Books and Book Chapters:

1. Karen Hennessy, Nabeel Arastu and **Aziza Shad**. The Next Step...Crossing the Bridge to Survivorship. Lombardi Comprehensive Cancer Center, Washington DC, USA, April 2008.
2. **Aziza Shad**, Deborah Boyle and Men-Jean Lee. Fast Facts: Religion and Medicine. Health Press, London UK; January 2008.
3. **Aziza Shad** and Amal Abu-Ghosh. Emergency Management of Non-Hodgkin's Lymphoma. *The Lymphoid Neoplasms*, 3rd Edition, Ed. Ian Magrath. Hodder Arnold Health Sciences, London UK; 2009.
4. **Aziza Shad** and Ian T Magrath. Malignant non-Hodgkin's lymphomas in children. In: *Principles and Practice of Pediatric Oncology*, 3rd edition (eds) PA Pizzo, D Poplack, Lippincott-Raven, 22: 545-549, 1997.
5. Ian T Magrath, **Aziza Shad**, Sidnei Epelman, Beatriz de Camargo, Antonio Sergio Petrilli, Nazli Gad el Mawla, Hai Peng Lin, Blanca Diez, Luiz Becu and Christopher Williams. Pediatric Oncology in Countries with Limited Resources. In: *Principles and Practice of Pediatric Oncology*, 3rd edition (eds) PA Pizzo, D Poplack, Lippincott-Raven, 56:1395-1421, 1997.

6. **Shad AT.** Complications in the management of non-Hodgkin's lymphomas. *The Non-Hodgkin's Lymphomas* (2nd edition) Ed. I.T. Magrath, Edward Arnold. 27: 597-631, 1996.
7. Magrath IT, **Shad AT**, Sandlund J. Lymphoproliferative disorders in immunocompromised individuals. *The Non-Hodgkin's Lymphomas* (2nd edition) Ed. I.T. Magrath, Edward Arnold. 45:955-975, 1996.
8. **Shad AT**, Magrath IT. Diagnosis and treatment of non-Hodgkin's lymphomas in childhood. *Neoplastic Diseases of the Blood* (3rd edition) Ed. Peter H. Wiernik, Churchill Livingstone, 1995.
9. Mueller BU, **Shad AT**, Magrath IT, Horowitz M. Malignancies in children with HIV infection. In: *Pediatric AIDS: The Challenge of HIV Infection in Infants, Children, and Adolescents*, 2nd edition, Eds. Philip A. Pizzo, Catherine M. Wilfert, Williams & Wilkins, Baltimore; pp. 603-622; 1993.
10. **Shad AT**, and Magrath IT. The non-Hodgkin's lymphomas in children. *Hematology: Clinical and laboratory practices*; vol 2, Ed Roger Bick, Mosby, St. Louis; pp 895-930; 1993.
11. **Shad AT**, and Magrath IT. Hodgkin's disease in childhood. *Hematology: Clinical and laboratory practices*; vol 2, Ed Rodger Bick, Mosby, St. Louis; pp 955-971; 1993.

Abstracts:

1. SA Haque, B Kallakury, **A Shad**, V Shanmugam. A Thirteen-Year-Old Female with an Unusual Case of Primary T-Cell Rich B-Cell Lymphoma of Bone. Accepted for presentation at Current Concepts in Pathology Meeting, University of Chicago, Illinois, April 2008.
2. **Aziza Shad.** Palliative Care in Pediatric Patients. Presented at The 1st International Evidence-Based Palliative Care Awareness Symposium, National Guard Hospital, Jeddah, Saudi Arabia, May 2009.

3. **Aziza Shad.** Communication with Palliative Care Patients. Presented at The 1st International Evidence-Based Palliative Care Awareness Symposium, National Guard Hospital, Jeddah, Saudi Arabia, May 2009.
4. Soldin Offie, Shields PG, Loffredo CA, Barr D, Luban N, **Shad A**, Nelson D. Childhood Cancer and Possible Gene Environment Interactions. Presented at Society of Toxicology 46th Annual Meeting, Charlotte, North Carolina, March 2007.
5. **Aziza T. Shad, MD**, Karen A. Hennessy, RN, MS, CPNP, Sharmila Kamani, BA, Judith K. Jones, MD, PhD, Aditya Marfatia, BS Pharm, MS. A Multi-Media Interactive CD-ROM to Educate and Empower Adolescents with Cancer. Presented at the 9th International Conference on Long – Term Complications of Treatment of Children and Adolescents with Cancer, Niagara, Ontario, June 2006.
6. Kenneth Tercyak, PhD, Sowmya Prahlad, MS, Jessica R. Donze, MPH, Lauren A. Wine, BA, Bryn D. Mars, BA, Revonda B. Mosher, RN, MSN, Tracy Councill, MA, **Aziza T. Shad, MD**. Bone Health Beliefs and Behaviors Among Children who have Survived Cancer. Presented at the 8th International Conference on Long – Term Complications of Treatment of Children and Adolescents with Cancer, Niagara, Ontario, June 2004.
7. **Aziza T. Shad, MD**, Karen A. Hennessy, RN, MS, CPNP, Sharmila Kamani, BA, Patricia J. Bush, PhD, Judith K. Jones, MD, PhD. Knowledge Empowerment for Survivors with Cancer. Presented at the 8th International Conference on Long – Term Complications of Treatment of Children and Adolescents with Cancer, Niagara, Ontario, June 2004.
8. Kenneth P. Tercyak, Phd, Sowmya Prahlad, MS, Jessica R. Donze, MPH, Lauren A. Wine, BA, Bryn D. Mars, BA, Revonda B. Mosher, RN, MSN, Tracy Council, MA, **Aziza T. Shad, MD**. Bone Health Beliefs and Behaviors Among Children who have Survived Cancer. Presented at National Conference on Child Health Psychology, Washington DC, April 2004.
9. Amal M Abu-Ghosh, Stephen J. Latimer, Agnieszka Z Pluta, Zain I. Shad, Benjamin Somers, Rabia Mir, Francisco A. Bracho, **Aziza T. Shad**. Intravenous Iron Dextran Therapy for the correction of Iron Deficiency Anemia in children with Inflammatory Bowel Disease: A Single Institution

Study. Presented at Pediatric Academic Societies' Annual meeting, May 2003.

10. Val Abbassi, **Aziza Shad**. Co-existent Graves' Hyperthyroidism and Agranulocytosis, a Diagnostic and Therapeutic Challenge. Presented at ENDO 2003, Endocrine Society Annual Meeting, June 2003.
11. **Shad, A. T.**, Nicolas, M., Donnelly, T., Council, K., Taylor, Tercyak, K.P. Identification of Pediatric Cancer Survivors and their family members eligible to participate in the behavioral outcomes research: Access and barriers to study. Presented at 7th International Late Effects in Cancer Survivors meeting, Niagara, Ontario, June 2002.
12. Kenneth P. Tercyak, Marsha Nicolas, Jessica Donnelly, Kathryn Taylor, Elizabeth Kaufman, Tracy Council, Jessica Donze, and **Aziza T. Shad**. Health Behaviors and Psychosocial Functioning Among Pediatric Cancer Survivors: Opportunities for Patient Education and Counseling. Presented at NCI/ACS co-sponsored conference, 'Cancer Survivorship: Resilience across the Lifespan', Bethesda, Maryland, June 2002.
13. James Herzog, Heidi Dalton, Barry Anderson, **Aziza Shad**, Joseph Gootenberg, Gabriel Hauser. Propofol Anesthesia for Bone Marrow Aspiration/Biopsy and Intrathecal Chemotherapy in the Pediatric Intensive Care Unit. Presented at the Society for Pediatric Research, Baltimore, MD. Pediatric Research 43(4) pp 133A, 1998.
14. Magrath I, Adde M, **Shad A**, Venzon D, Arndt C, Gootenberg J, Neely J, Neider M, Owen W, Seibel N, Wilson W and Horak I. Additional Chemotherapy Agents improved Treatment Outcome for Children and Adults with Advanced B-Cell Lymphomas. Oral Presentation at Satellite Symposium at ECCO, Hamburg, Germany, September 1997.
15. **Shad A.**, Adde M., Mueller B., Avila N., Smithson W., Pizzo P. and Magrath I. Results of a Pilot Study for the treatment of Children with HIV and Post-Transplant Lymphomas. Oral Presentation at American Society of Clinical Oncology, Denver, Colorado, May 1997.
16. **Shad A.**, Mueller B., Adde M., Avila N, Sleasman H, Pizzo P and Magrath I. Results of a Treatment Protocol for Children with HIV and non-

Hodgkin's Lymphomas. Oral Presentation at the National AIDS Malignancy Conference, Bethesda, MD, April 1997.

17. Adde M, Venzon D, Horak I, **Shad A**, Arndt C, Gootenberg J, Seibel N, Neely J, Neider M, Owen W and Magrath I. The Comparison of the ability of GMCSF and GCSF to ameliorate toxicity from an intensive treatment protocol for non-Hodgkin's Lymphomas. Presented at the 4th International Conference on Malignant Lymphomas. June 1996.
18. Weintraub M, Magrath IT, Adde M, **Shad AT**. Genetic alterations in long-term survivors of non-Hodgkin's lymphoma. Presented at American Society of Clinical Oncology, Philadelphia, PA, May 1996.
19. **Shad A**, Mueller B, Adde A, Avila N, Pizzo P, Magrath IT. Preliminary results of a protocol for the treatment of non-Hodgkin's lymphoma (NHL) in children with immunodeficiency syndromes. Presented at American Society of Hematology, 1995 - Seattle, WA. December 1995.
20. Mackall CL, Fleisher TA, Brown MR, Andrich MP, Chen CC, Feuerstein IM, Horowitz ME, Magrath IT, **Shad AT**, Steinberg SM, Wexler LH, Gress RE. Age-related decline in thymic-dependent regeneration of CD4 cells after intensive chemotherapy. Accepted for presentation at SPIRAT/NCDDG-HIV Conference, Novel HIV Therapies: From Discovery to Clinical Proof-of-Concept, Bethesda, MD, July 1995.
21. Weintraub M, Adde M, **Shad A**, Horak I, Seibel N, Neely J, Magrath IT. Profound peripheral neuropathy associated with the administration of colony stimulating factors. American Society of Hematology, December, 1994 - Nashville, TN, U.S.A., Blood 84:10(suppl 1) pp128a
22. Magrath IT, Adde M, **Shad A**, Wittes R, Horak I. Results in adults with small non-cleaved cell (SNCL) lymphoma treated with a short duration, intensive chemotherapy protocol also used in pediatric patients. American Society of Clinical Oncology, May 1994 - Dallas, TX, U.S.A., Proceedings, American Society of Clinical Oncology, vol 13; p371, 1994.
23. **Shad A**, Bhatia K, Hamdy N, Mueller B, Pizzo P, Whang-Peng J, Jaffe E, Magrath IT. Pediatric HIV associated non-Hodgkin's lymphomas. American Association for Cancer Research, April 1994 - San Francisco,

CA, U.S.A., American Association for Cancer Research Proceedings, vol 35; p191; 1994.

24. **Shad A**, Adde M, Advani S, Gad-el-Mawla N, Santa V, Vats T, Magrath IT. An effective protocol for the treatment of NHL in developing countries. XII Biennial Conference of Pakistan/British Pediatric Association, January 1994 - Lahore, Pakistan.
25. **Shad A**, Bhatia K, Hamdy N, Mueller B, Pizzo P, Whang-Peng J, Knutsen T, Jaffe E, Magrath IT. Molecular characterization of pediatric HIV associated non-Hodgkin's lymphomas. American Society of Hematology, December 1993 - St. Louis, MO, U.S.A., Blood 82:10 (suppl 1) pp578a.
26. **Shad A**, Adde M, and Magrath I. Results of NCI protocol 77-04 for treatment of lymphoblastic lymphoma in children. American Society of Hematology, December 1993 - St. Louis, MO, U.S.A., Blood 82: 10 (suppl 1) pp 387a.
27. Mackall CL, Fleischer TA, Brown MR, Magrath T, Wexler L, **Shad A**, Gress R. Age dependent differences in CD4+ T cell regeneration are associated with increased thymopoiesis in younger vs. older patients. American Society of Hematology, December 1993 - St. Louis, MO, U.S.A., Blood 82:10 (suppl 1) pp243a.
28. Magrath IT, Adde M, **Shad A**, Neely J, Seibel N, Gootenberg J, Arndt C, Kiwanuka J, Horak I. A new short duration chemotherapy protocol for the treatment of small non-cleaved cell (SNCC) and large cell (LC) lymphomas. American Society of Clinical Oncology. May 1993 - Orlando, FL, U.S.A. Proceedings, American Society of Clinical Oncology, vol 12, p 385.
29. **Shad A**, Magrath I, Gutiérrez M, Raffeld M, Bhatia K. Association of a p53 mutation with progression of a Ki-1+ lymphoma but not with primary Ki-1+ lymphomas. American Association for Cancer Research. May 1992 - San Diego, CA, U.S.A. Proceedings, American Association for Cancer Research, vol 33, p 372.
30. **Shad A**, Magrath I, Goldschmidts W, Gutiérrez M, Felix C, Raffeld M, and Bhatia K. Association of a p53 mutation with recurrence of a Ki-1+

(CD30+) lymphoma of childhood. American Society of Hematology. December 1991 - Denver, CO, U.S.A. Blood 78:10 (suppl 1) p. 446a

31. Magrath I, Adde M, **Shad A**, Horak I, Seibel N, Reaman G, and Neely J. Preliminary results of an intensive protocol, including GM-CSF, for patients with small, non-cleaved cell and immunoblastic lymphomas. American Society of Hematology, December 1991 Denver, CO, U.S.A. Blood 78:10 (suppl 1) p.114a.
32. Gutiérrez M, Bhatia K, Huber B, **Shad A**, and Magrath I. " A clustering of breakpoints 5' of the *c-myc* locus in some sporadic Burkitt's lymphomas and its relations to various regulatory domains". NIH Research Festival. Feb. 1991 - Bethesda, MD, U.S.A.

Exhibit 39

Brian Timothy Collins, MD, FCCP
Georgetown University Hospital
Department of Radiation Medicine
3800 Reservoir Rd. NW
Washington, DC 20007
Date of Birth: 03/10/69

PROFESSIONAL POSITION

Assistant Professor, Department of Radiation Medicine, (2000-Present)

EDUCATION

Fordham University, Bronx, NY: BS, Biology (1987 – 1991)
State University of New York at Stony Brook: M.D. (1991 –1995)

HOSPITAL TRAINING

Internship: St. Vincent's Hospital, New York, NY (1995 – 1996)
Residency: Georgetown Hospital, Radiation Medicine (1996 – 2000)

CERTIFICATION

American Board of Radiology, Board Certified, 2000

LICENSURE

Virginia, 1999
Maryland, 1999
District of Columbia, 1999

PROFESSIONAL SOCIETY MEMBERSHIP

CyberKnife Society
American College of Chest Physicians (ACCP)
Metropolitan DC Thoracic Society
Radiological Society of North America (RSNA)
American Society for Radiation Oncology (ASTRO)
American Society of Clinical Oncology (ASCO)

COMMITTEE

Medstar Research Institute-Georgetown University Oncology IRB (2008-present)
Lombardi Cancer Center Clinical Research Committee (2002-2007)

HONORS AND ACHIEVEMENTS

CyberKnife Society Grant (2008)
Best Static Poster, CyberKnife User's Meeting (2008)
Fellow American College of Chest Physicians (2007)
ACCURAY Clinical Advisor (2006-2008)
CyberKnife Society Grant (2006)
Best Thoracic Presentation, CyberKnife User's Meeting (2006)
RSNA Research and Education Foundation Research Resident Grant (1998-1999)

Publications:

- S. Vahdat, Collins SP, Yousefi S, Banovac F, Anderson E, BT Collins. CyberKnife radiosurgery for inoperable stage IA non-small cell lung cancer: 18F-fluorodeoxyglucose positron emission tomography/computed tomography serial tumor response assessment. *Journal of Hematology & Oncology* 2010, 3:6
- Park, H.U., Suy, S., Danner, M., Daily, V., Zhang, Y., Li, H., Hyduke, D.R., Collins, B.T., Gagnon, G.J., Kallakury, B., Kumar, D., Brown, M.L., Fornace, A., Dritschilo, A., Collins, S.P. (2009). AMP-activated protein kinase promotes human prostate cancer cell growth and survival. *Molecular Cancer Therapeutics*. 8:733-741.
- Coppa ND, Raper ND, Zhang Y, Collins BT, Harter KW, Gagnon G, Collins SP, Jean W. Treatment of malignant tumors of the skull base with multi-session radiosurgery. *Journal of Hematology & Oncology* 2009, 2:16
- BT Collins, S. Vahdat, K Erickson, C Reichner, Collins SP, Zhang Y, Yousefi S, Jamis-Dow C, Banovac F and Anderson E. Radical cyberknife radiosurgery with tumor tracking: an effective treatment for inoperable small peripheral stage I non-small cell lung cancer. *Journal of Hematology & Oncology* 2009, 2:1.
- Strulik KL, Cho MH, Collins BT, Khan N, Banovac F, Slack R and Cleary K. Fiducial migration following small peripheral lung tumor image-guided CyberKnife stereotactic radiosurgery. In *Proceedings of SPIE Medical Imaging*, volume 6918-45, pages 1-9, 2008.
- BT Collins, K Erickson, C Reichner, Collins SP, Gagnon GJ, Dieterich S, McRae D, Zhang Y, Yousefi S, Levy E, Chang T, Jamis-Dow C, Banovac F and E Anderson. Radical Stereotactic Radiosurgery with Real-Time Tumor Motion Tracking in the Treatment of Small Peripheral Lung Tumors. *Radiation Oncology* 2007; 2:39.
- GJ Gagnon, FC Henderson, EA Gehan, D Sanford, BT Collins, JC Moulds, A Dritschilo. Cyberknife radiosurgery for breast cancer spine metastases: a matched-pair analysis. *Cancer*. 2007; 110(8):1796-802.
- Yousefi S, Collins BT, Reichner CA, Anderson ED, Jamis-Dow C, Gagnon G, Malik S, Marshall B, Chang T, Banovac F. Complications of thoracic computed tomography-guided fiducial placement for the purpose of stereotactic body radiation therapy. *Clin Lung Cancer*. 2007; 8(4):252-6.
- Collins SP, Coppa ND, Zhang Y, Collins BT, McRae DA, Jean, WC. CyberKnife® radiosurgery in the treatment of complex skull base tumors: analysis of treatment planning parameters. *Radiation Oncology* 2006:1:46.

Pishvaian AC, Collins B, Gagnon G, Ahlawat S, Haddad NG. EUS-guided fiducial placement for CyberKnife radiotherapy of mediastinal and abdominal malignancies. *Gastrointestinal Endoscopy*. September 2006; 64(3):412-7.

Dritschilo A, Huang C, Rudin C, Marshall J, Collins B, Dul J, Zhang C, Kumar D, Gokhale P, Ahmad A, Ahmad I, Sherman J, Kasid U. Phase I Study of Liposome-encapsulated c-raf antisense oligodeoxynucleotide Infusion in Combination with Radiation Therapy in patients with advanced Malignancies. *Clinical Cancer Research*. February 15 2006; 12(4):1251-1259.

CA Reichner, BT Collins, GJ Gagnon, S Malik, C Jamis-Dow, and E Anderson. The Placement of Gold Fiducials for Cyberknife Stereotactic Radiosurgery Using a Modified Transbronchial Needle Aspiration Technique. *Journal of Bronchology*, October 2005; 12(4):193-5.

AM Singh, G Gagnon, B Collins, A Niroomand-Rad, D McRae, Y Zhang, J Regan, J Lynch and A Dritschilo. Combined external beam radiotherapy and Pd-103 brachytherapy boost improves biochemical failure free survival in patients with clinically localized prostate cancer: results of a matched pair analysis. *Prostate*. January 2005;62(1):54-60.

Singer EA, Warren RD, Pennanen MF, Collins BT, Hayes DF. Tamoxifen-induced radiation recall dermatitis. *Breast J*. 2004;10(2):170-1.

Collins B, Reddy A, Akyurekli D, Ayoob M, Harter K W. Radiation Therapy for Metastatic Disease of the Spine. Weisel S and Boden S (eds), *Seminars in Spine Surgery* 2000; 12(1):17-20.

Book Chapters:

ED Anderson, BT Collins, GJ Gagnon, SP Collins, T Mahoney, F Banovac, C Jamis-Dow, S Malik, and CA Reichner. Thoracic Fiducial Placement via Flexible Bronchoscopy. In: H. Urschel, ed. Robotic Radiosurgery: Treating Tumors that Move with Respiration. Berlin/Heidelberg, Springer, 2007:105-10.

BT Collins, K Erickson, SP Collins, GJ Gagnon, S Dieterich, DA McRae, CA Reichner, T Chang, C Jamis-Dow, F Banovac, S Malik, and ED Anderson. Fractionated Stereotactic Radiosurgery with the Synchrony Motion Tracking Module in the Treatment of Single Small Peripheral Lung Tumors. In: H. Urschel, ed. Robotic Radiosurgery: Treating Tumors that Move with Respiration. Berlin/Heidelberg, Springer, 2007:145-53.

Abstracts:

- Oermann, E., Hanscom, H., Lei, S., Suy, S, Collins, B., Batipps, G., Dunne, E., Constantinople, N., Dejter, S., Regan, J., McGeagh, K., Pahira, J., Dawson, N., Dritschilo, A., Collins, S.P. and Lynch, J. Hypofractionated Robotic Radiosurgery for the Treatment of Prostate Cancer: Acute Toxicity and Early Biochemical Results. ASCO 2010.
- BT Collins, S Vahdat, SP Collins, E Oermann, X Yu, F Banovac, C Reichner, ED Anderson, F Gharagozloo, M Margolis. CyberKnife Radiosurgery for Inoperable Patients with Peripheral Stage IA Non-small Cell Lung Cancer. Plenary Session. MIRA 5th International Congress, 2010.
- Oermann, E., Hanscom, H., Lei, S., Suy, S, Collins, B., Batipps, G., Dunne, E., Constantinople, N., Dejter, S., Regan, J., McGeagh, K., Pahira, J., Dawson, N., Dritschilo, A., Collins, S.P. and Lynch, J. Hypofractionated Robotic Radiosurgery for the Treatment of Prostate Cancer: Acute Toxicity and Early Biochemical Results. Society of Urologic Oncology Meeting, Poster Presentation, 2009.
- E Oermann, SP Collins, D Subramaniam, X Yu, A Eldabh, S Yousefi, C Kalhorn, K McGrail, ND Coppa, W Jean and BT Collins. CyberKnife Enhanced Conventionally Fractionated Chemoradiation for High-grade Gliomas in Close Proximity to Critical Structures. Poster presentation. RSNA 2009.
- Lominska, C.E., Unger, K., Jean, W.C., Chanyasulkit, J., Collins, B.T., Collins S.P., Gagnon, G. Multisession Stereotactic Radiosurgery for Meningioma Results in Low Rates of Post-treatment Edema. ASTRO, Poster Presentation, 2009.
- K Erickson, S. Vahdat, S.P. Collins, S. Suy, Y. Xia, C.J. Gutierrez, G. Esposito, F. Banovac, A. Dritschilo, B.T. Collins. Radical Robotic Radiosurgery for Inoperable Patients with Small Peripheral Stage IA Non-small Cell Lung Cancer: Exceptional Local Control and Survival Despite Prolong Fraction Times. Poster presentation. ASTRO 2009.
- S Vahdat, BT Collins, M Margolis, C Gutierrez, G Esposito, F Banovac, CA Reichner, ED Anderson, M Salvatore. Radical Robotic Radiosurgery: An Attractive Treatment Alternative for Inoperable Patients with Peripheral Stage IA Non-Small Cell Lung Cancer. Poster presentation. 20th International Conference on Screening for Lung Cancer, Washington, DC. April 27-28, 2009.
- S Vahdat, BT Collins, M Margolis, C Gutierrez, G Esposito, F Banovac, CA Reichner, ED Anderson, M Salvatore. Radical Robotic Radiosurgery: An Attractive Treatment Alternative for Inoperable Patients with Peripheral Stage IA Non-Small Cell Lung Cancer. Poster presentation. Metropolitan DC Thoracic Society Annual Meeting and Research Competition 2009.
- ED Anderson, BT Collins, G Gagnon, T Chang, C Jamis-Dow, F. Banovac. Thoracic Fiducial Placement: CT versus Bronchoscopy. Oral presentation. CyberKnife User's Meeting 2009.
- E Oermann, SP Collins, D Subramaniam, X Yu, A Eldabh, S Yousefi, C Kalhorn, K McGrail, ND Coppa, W Jean and BT Collins. CyberKnife Enhanced Conventionally Fractionated Chemoradiation for High-grade Gliomas in Close Proximity to Critical Structures. Oral presentation. CyberKnife User's Meeting 2009.

- BT Collins, SP Collins, E Oermann, X Yu, H Ji, S Vahdat, S Yousefi, C Jamis-Dow, F Banovac and ED Anderson. Radical CyberKnife Radiosurgery: An Effective Treatment for Inoperable Patients with Pheripheral Stage IA Non-small Cell Lung Cancer. Oral presentation. CyberKnife User's Meeting 2009.
- S. Vahdat, S Yousefi, F Banovac, C Jamis-Dow, BT Collins. Radical Robotic Radiosurgery for Inoperable Patients with Small Peripheral Stage I Non-small Cell Lung Cancer: Safely Delivering Adequate Doses with Sufficient Margin to Control Both Gross and Microscopic Disease. Oral presentation. RSNA 2008.
- I. Sarikaya, S. Vahdat, C Jamis-Dow, F Banovac, G. Esposito, BT Collins. Radical Robotic Radiosurgery for Inoperable Patients with Stage IA Non-small Cell Lung Cancer: Preliminary 18F-FDG PET/CT Findings. Oral presentation. RSNA 2008.
- S Yousefi, I. Sarikaya, S. Vahdat, K Strulik, BT Collins, E Anderson, F Banovac, K Cleary, C Jamis-Dow. CT Appearances and Fiducial Migration Patterns Following Radical Stereotactic Radiosurgery of Small Peripheral Lung Tumors. Oral presentation. RSNA 2008.
- ED Anderson, K Erickson, SP Collins, S Yousefi, C Jamis-Dow, K Sharma, F. Banovac, C Reichner. BT Collins. Radical Robotic Radiosurgery for Inoperable Patients with Peripheral Stage IA Non-small Cell Lung Cancer: Preliminary Lung Function and Survival Outcomes. Poster presentation. Chest 2008.
- S Yousefi, K Strulik, BT Collins, E Anderson, F Banovac, K Cleary and C Jamis-Dow. CT Imaging Changes and Fiducial Migration Following Radical Small Peripheral Lung Tumor CyberKnife Radiosurgery. Poster presentation. CyberKnife User's Meeting 2008.
- BT Collins, SP Collins, K Erickson, N Hailu, S Suy, Y Zhang, X Yu, H Ji, S Yousefi, C Jamis-Dow, F Banovac, CA Reichner and ED Anderson. Radical CyberKnife Radiosurgery with Tumor Tracking: An Effective Treatment for Small Peripheral Stage I Non-small Cell Lung Cancer. Poster presentation. CyberKnife User's Meeting 2008.
- B Berger, R Wood, E Anderson, J O'Connor, K Erickson and B Collins. Pooled Report of Tumor-Tracked Stereotactic Body Radiotherapy for Stage I Non-small Cell Lung Cancer. Poster presentation. ASTRO 2007.
- BT Collins, C Reichner, J Liao, F Xia, H Ji, N Hailu, C Jamis, SP Collins, G Gagnon and E Anderson. Radiosurgery with Real-Time Tumor Motion Tracking: An Effective Non-surgical Treatment Alternative for Small Peripheral Stage I Non-small Cell Lung Cancer. Oral presentation at Chest 2007.
- B Berger, B Collins, R Wood, S Cheek, J O'Connor, S Malik, E Anderson and H Urschel. First Report of Tumor-Tracked Radiosurgery for Stage IA Non-small Cell Lung Cancer. Oral presentation 8TH International Stereotactic Radiosurgery Society Congress. San Francisco, June 23 2007.
- S Malik, K Erickson, SP Collins, C Reichner, C Jamis-Dow, F. Banovac, ED Anderson, FP Smith and BT Collins. CyberKnife® High-dose Fractionated Stereotactic Radiosurgery with Tumor Tracking: An Effective Non-surgical Treatment Alternative for Single Small Peripheral Lung Tumors. ASCO 2007.
- ND Coppa, LM Dias, SP Collins, W Jean and BT Collins. Image Guided Radiosurgery Boost as an Adjunct Treatment for High-grade Gliomas. Poster presentation at American Association of Neurological Surgeons /CNS Section on Tumors 2007.

- BT Collins, K Erickson, F Xia, H Ji, N Hailu, C Jamis, C Reichner, E Anderson and H Fernando. CyberKnife® Radiosurgery with Tumor Tracking: A Noninvasive Treatment Alternative for Inoperable Peripheral Stage IA Non-small Cell Lung Cancer. Oral presentation at Cyberknife User's Meeting 2007.
- ED Anderson, BT Collins, K Erickson, G Gagnon, SP Collins, C Jamis-Dow, F. Banovac, S Malik, N. Haddad, M. Margolis and C Reichner. Fiducial Placement for CyberKnife Stereotactic Radiosurgery using Flexible Bronchoscopy and a Modified Transbronchial Aspiration Needle Technique. Oral presentation at Chest 2006.
- BT Collins, K Erickson, SP Collins, Gagnon G, S Dieterich, C Reichner, MA Elsayaf, D Earl-Graef, C Jamis-Dow, F. Banovac, S Malik and E Anderson. CyberKnife® Frameless Image-guided Radiosurgery with The Synchrony™ Motion Tracking Module in the Definitive Treatment of Small Peripheral Lung Tumors. Oral presentation at Chest 2006.
- BT Collins, K Erickson, S Malik, M Margolis, MB Marshall, C Jamis-Dow, S Dieterich, C Reichner, and E Anderson. CyberKnife® Frameless Image-guided Radiosurgery with The Synchrony™ Motion Tracking Module in the Definitive Treatment of Small Peripheral Lung Tumors. Oral presentation at Cyberknife User's Meeting 2006.
- A Patel, B Collins, S Malik, C Jamis-Dow, D Earl-Graef, G Gagnon, and E Anderson. Efficacy of CyberKnife Stereotactic Radiosurgery with Synchrony Motion Tracking Module for Treatment of Malignancies in the Thorax. Chest, 2005; 128(4):338S.
- CA Reichner, BT Collins, GJ Gagnon, S Malik, C Jamis-Dow, and E Anderson. Comparison of Fiducial Placement for CyberKnife Stereotactic Radiosurgery using CT-Guidance or Flexible Bronchoscopy. Chest, 2005; 128(4):162-3S.
- BT Collins, K Erickson, S Malik, M Margolis, MB Marshall, C Jamis-Dow, S Dieterich, C Reichner, and E Anderson. CyberKnife® Frameless Image-guided Radiosurgery with The Synchrony™ Motion Tracking Module in the Definitive Treatment of Small Peripheral Lung Tumors. Poster presentation at the 11th World Conference on Lung Cancer (IASLC) Barcelona, Spain July 2005.
- CA Reichner, BT Collins, GJ Gagnon, S Malik, C Jamis-Dow, and E Anderson. Placement of Fiducials via Flexible Bronchoscopy for the Treatment of Lung Cancer with Cyberknife. Poster presentation at the 11th World Conference on Lung Cancer (IASLC) Barcelona, Spain July 2005.
- A Patel, E Anderson, S Malik, and B Collins. Efficacy of Cyberknife Stereotactic Radiosurgery with Synchrony Motion Tracking Module for Treatment of Malignancies in the Thorax. Poster presentation at the 11th World Conference on Lung Cancer (IASLC) Barcelona, Spain July 2005.
- Dritschilo A, C. H. Huang, C. Fleming, C. M. Rudin, J. Marshall, B. Collins, C. Zhang, D Kumar, P. Gokhale, U. Kasid. Infusion of Liposome-encapsulated c-raf antisense oligodeoxynucleotide (LerafAON) during radiation therapy in patients with advanced malignancies: Phase I study. Proceedings from the 39th Annual Meeting of the American Society of Clinical Oncology, Chicago, Illinois, (2003).

Collins B. Profiles of Radiation Resistant Prostate Cells. Second International Conference on Translational Research and Pre-Clinical Strategies in Radiation Oncology, Lugano, Switzerland (2003)

Dritschilo A, Huang C, Strauss L, Fleming C, Rahman A, Rudin C, Collins B, Marshall J, Singh A, Zhang C, Kumar D, Gokhale P, Kasid U. Liposome-encapsulated c-raf antisense oligodeoxynucleotide (LerafAON) in patients with advanced solid tumors: Phase I study of daily infusion during radiation therapy. Proceedings from the 38th Annual Meeting of the ASCO, Orlando, FL, (2002).

Collins B. Identification of Radiation Resistant Genes in Human Prostate Cancer Cells. 11th International Congress of Radiation Research, Dublin, Ireland (1999)

Invited Presentations:

CyberKnife: An Effective Alternative to Wedge Resection for High-Risk Patients with Peripheral Stage I NSCLC. Garfield Medical Center. San Marino, CA. July 11, 2010.

CyberKnife: An Effective Alternative to Wedge Resection for High-Risk Patients with Peripheral Stage I NSCLC. Second Chinese SBRT/SRS Group Meeting. Qingdao, China. June 18, 2010.

CyberKnife: An Effective Alternative to Wedge Resection for High-Risk Patients with Peripheral Stage I NSCLC. St. Mary's of Michigan. Saginaw, Michigan. May 18, 2010.

CyberKnife Radiosurgery for Peripheral Stage I NSCLC. East Carolina University, Greenville, North Carolina. May 12, 2010.

CyberKnife: The Ideal Thoracic Radiosurgery Tool. St. Elizabeth Regional Medical Center. Lincoln, Nebraska. November 12, 2009.

CyberKnife: The Ideal Radiosurgery Tool. Apollo Speciality Hospital. Chennai, India. July 31, 2009.

CyberKnife: The Ideal Thoracic Radiosurgery Tool. University of Massachusetts Medical School. Worcester, Massachusetts. May 21, 2009.

PET/CT Imaging: What do Thoracic Oncologists Want? The Mid-Eastern Chapter of the Society of Nuclear Medicine 39th Annual Spring Meeting. Ocean City, Maryland. April 19, 2009.

CyberKnife: The Ideal Thoracic Radiosurgery Tool. The Embassy of the Republic of Poland, Washington, DC. March 28, 2009.

Radical CyberKnife Radiosurgery for Peripheral Stage IA NSCLC. Annual Vokeman Lecture, East Carolina University, March 06, 2009.

Radical CyberKnife Radiosurgery for Peripheral Stage IA NSCLC. Grand Rounds, Department of Medicine, Georgetown University Hospital, February 26, 2009.

Radical CyberKnife Radiosurgery for Peripheral Stage IA NSCLC Patients: A Translational Research Opportunity? Lombardi Cancer Center, Washington, DC. January 21, 2009.

CyberKnife: The Ideal Thoracic Radiosurgery Tool. Hospital of St. Raphael, New Haven, CT. October 15, 2008.

CyberKnife: An Ideal Thoracic Radiosurgery Tool. Lahey Clinic, Burlington, MA. June 13, 2008.

CyberKnife: An Ideal Thoracic Radiosurgery Tool. 38th Sao Paulo Radiology Meeting (JPR 2008). Sao Paulo, Brazil. May 02, 2008.

CyberKnife with Tumor Tracking: An Effective Non-surgical Treatment for Small Peripheral Stage I NSCLC. Taipei Medical University-Municipal Wan Fang Hospital. April 26, 2008.

The Descendants of "Therapeutic Radiology". 33RD Annual Society of Interventional Radiology Scientific Meeting. Washington, DC. March 18, 2008

The Role of CyberKnife in the Management of Early Stage Lung Cancer. Christiana Care Health System, Delaware. February 6, 2008.

CyberKnife Radiosurgery with Tumor Tracking in the Treatment of Small Peripheral Stage I NSCLC. RuiKang Hospital CyberKnife Symposium, China. December 09, 2007

CyberKnife Radiosurgery with Tumor Tracking in the Treatment of Small Peripheral Stage I NSCLC. Washington Adventist Hospital First Annual Lung Cancer Symposium. November 02, 2007

CyberKnife Radiosurgery with Tumor Tracking in the Treatment of Small Peripheral Stage I NSCLC. University of Southern California. October 29, 2007

Radiosurgery with Real-Time Tumor Motion Tracking: An Effective Non-surgical Treatment Alternative for Small Peripheral Stage I Non-small Cell Lung Cancer. Fresno Community Regional Medical Center. October 25, 2007.

CyberKnife in the Treatment of Thoracic Malignancies. Grand Rounds, Department of Medicine, Georgetown University Hospital, October 11, 2007.

Radical Stereotactic Radiosurgery with Real-Time Tumor Motion Tracking in the Treatment of Small Peripheral Lung Tumors. West Coast Robotic Radiosurgery Course. Las Vegas, NV. October 05, 2007.

Radical Stereotactic Radiosurgery with Real-Time Tumor Motion Tracking in the Treatment of Small Peripheral Lung Tumors. Konyang Univeristy Hospital, Korea. September 28, 2007.

CyberKnife Radiosurgery with Real-Time Tumor Tracking in the Treatment of Small Peripheral Lung Tumors. 8TH International Stereotactic Radiosurgery Society Congress. San Francisco, June 23, 2007.

CyberKnife Radiosurgery with Tumor Motion Tracking in the Treatment of Small Peripheral Lung Tumors. CCMC-Bay Area Tumor Conference, Corpus Christi, Texas. June 14, 2007

CyberKnife Radiosurgery with Tumor Tracking for Thoracic and Abdominal Tumors ASTRO Image Guided Radiotherapy (IGRT II) Symposium. April 23, 2007

CyberKnife Radiosurgery with tumor tracking in the treatment of small peripheral lung tumors. Franklin Square Hospital. Baltimore, Maryland. January 15, 2007.

Stereotactic Radiosurgery in the Treatment of Inoperable Chest Tumors. Satellite Symposium, Chest. October 24, 2006.

CyberKnife Frameless Image-guided high-dose fractionated Stereotactic Radiosurgery With the Synchrony motion tracking module in the treatment of single small peripheral lung tumors. MASRO Autumn meeting. October 7, 2006.

CyberKnife Stereotactic Radiosurgery in the Treatment of Metastatic Basal Cell Carcinoma. 83rd Atlantic Dermatological Conference, Washington, D.C. April 28-30, 2006.

CyberKnife Stereotactic Radiosurgery in the Treatment of Small Peripheral Lung Tumors. Robotic Radiosurgery Course, Chicago, IL. April 8, 2006.

CyberKnife in the Treatment of Lung Cancer. Grand Rounds, Department of Medicine, Fairfax Hospital, March 21, 2006.

CyberKnife in the Treatment of Lung Cancer. Grand Rounds, Department of Medicine, Washington Veteran's Hospital, February 8, 2006.

CyberKnife in the Treatment of Lung Cancer. District of Columbia Thoracic Society Annual Dinner Meeting. April 13, 2005.

Radiotherapy as Part of the Multimodality Approach to Higher Stage Lung Cancer. Harbor Hospital Advanced Course in Diagnosis, Staging and Multimodality Treatment of Lung Cancer. October 30, 2004.

CyberKnife Frameless Image-guided stereotactic radiosurgery with the synchrony motion tracking module in the treatment of small lung tumors. Eleventh International Conference on Screening for Lung Cancer. Rome, Italy. October 16, 2004.

SEAN PHILIP COLLINS, M.D., PH.D.

**PERSONAL
INFORMATION:**

Home Address: 4155 Kentmere Square
Fairfax, VA 22030
(703) 273-3030

Office Address: Radiation Oncology
Georgetown University Hospital
3800 Reservoir Road, NW
Washington, DC 20007
(202) 444-3320
(202) 444-9323

LICENSURE:

Virginia, License
0101236960
Initial Date: 7/23/2004
Renewal/Expiration Date: 3/31/2010

Maryland, License
D0062102
Initial Date: 7/15/2004
Renewal/Expiration Date: 9/30/2012

District of Columbia
MD035170
Initial Date: 10/1/2004
Renewal/Expiration Date: 12/31/2010

CERTIFICATION:

Virginia, License
0101236960

Maryland, License
D0062102

District of Columbia
MD035170

EDUCATION:

Undergraduate: Tufts University
Boston, MA
1987-1991
Bachelor of Science summa cum laude in Chemistry

Medical Education: University of Michigan
Ann Arbor, MI
M.D., Ph.D. June 2001

Internship: Georgetown University Hospital

Washington, DC

2002-2006

Residency:

Georgetown University Hospital

Washington, DC

2001-2002

**PROFESSIONAL
EXPERIENCE:**

2010-present

Assistant Professor in Radiation Medicine

Georgetown University Hospital

Washington, DC

2006-2010

Instructor in Radiation Medicine

Georgetown University Hospital

Washington, DC

2006-present

Director, CyberKnife Prostate Program

Georgetown University Hospital

Washington, DC

2006-present

Member, Prostate Program

Georgetown University Hospital

Washington, DC

2006-present

Member, Drug Discovery Program

Georgetown University Hospital, Lombardi Cancer Center

Washington, DC

**HONORS AND
AWARDS:**

1995

Christenson Award, Biochemistry Research Award

University of Michigan

1991

Max Tishler Award, Excellence in Chemistry Research

Tufts University

1990

Phi Beta Kappa Honorary

Tufts University

PROFESSIONAL SOCIETIES:

2006-Present
Cancer and Leukemia Group B

2006-Present
American Society for Therapeutic Radiology and Oncology

2006-Present
CyberKnife Society
Georgetown University Hospital

2006-Present
CyberKnife Coalition
Georgetown University Hospital

2006-Present
Radiation Research Society
Georgetown University Hospital

2006-Present
Lombardi Cancer Center Clinical Research Committee
Georgetown University Hospital

2008-Present
Radiation Safety Committee
Georgetown University Hospital

2010-Present
Radiation Safety Committee
Georgetown University Hospital

PUBLIC SERVICE:

Straight Talk
2006-2008

Heritage Charity Golf Classic
2007-2008

Men's Event
2006-2009

TEACHING ACTIVITIES:

2006-Present

Neurosurgery Resident Lecture Series
Georgetown University Hospital

2006-present.
Urology Resident Lecture Series
Georgetown University Hospital

2006-present.
Tumor Cell Biology Lecture Series
Georgetown University Hospital

2009-present.
Plastic Surgery Resident Lecture Series
Georgetown University Hospital

Medical Courses

Radiation Biology, RASC-520
Faculty
Georgetown University
2006-present

THESIS WORK:

Doctor of Philosophy (Biological Chemistry)

Thesis: Compartmentalization of the Cyclic Nucleotide-dependent Protein Kinases and their Substrates

Advisor: Michael D. Uhler, Ph.D.

RESEARCH GRANTS:

CURRENT ACTIVE

Prospective Evaluation of Intensity Modulated Radiation Therapy with Hypofractionated Radiosurgical Boosts in the Treatment of Clinically Localized Prostate Cancer

Prospective Endoscopic Safety Evaluation of Late Rectal Mucosal Injury Following CyberKnife Radiosurgery For Clinically Localized Prostate Cancer

Full Dose Gemcitabine and Hypofractionated Radiosurgery in the Treatment of Unresectable Pancreatic Cancer

A Pilot Study to establish a Standardized Protocol for Omic Analysis of Patients with Clinically Localized Prostate Cancer Receiving Radiation Therapy

A Pilot Study of Intensity Modulated Radiation Therapy with Hypofractionated Radiosurgical Boosts in the Treatment of Clinically Localized Prostate Cancer.

Prospective Evaluation of CyberKnife Stereotactic Radiosurgery for Low and Intermediate Risk Prostate Cancer: Homogeneous Dose Distribution-ACCP001.0.

RTOG 0524: A Phase I/II Trial of a Combination of Paclitaxel and Trastuzumab with Daily Irradiation or Paclitaxel Alone With Daily Irradiation Following Transurethral Surgery for Non-Cystectomy Candidates With Muscle-Invasive Bladder Cancer (Co-investigator with Nancy Dawson, M.D.)

Prostate Cancer Symptom Monitoring Study (Co-investigator with Kimberly Davis, Ph.D.)

Prostate Cancer CyberKnife Consortium-PC3: A Multi-institutional Phase I Feasibility Study. IRB 2007-028.

A Pilot Study to Establish a Standardized Protocol for Magnetic Resonance Spectroscopy Imaging and Gene Microarray Analysis of Patients with Anticipated Localized Prostate Cancer. IRB 2004-304

CURRENT PENDING

A Pilot Study of In Vivo Dosimetry during CyberKnife Radiosurgery for Clinically Localized Prostate Cancer Utilizing an Implantable Dosimetric Device (In Preparation)

PUBLICATIONS

Collins, S. P., Oermann, E., Hanscom, H., Lei, S., Suy, S., Park, H.U., Chen, V., Collins, B.T., McGeagh, K., Dawson, N.A., Jha, R., Azumi, N., Dritschilo, A., Lynch J. (2009) Histopathologic Changes Following Hypofractionated Robotic Radiation Therapy. BMC Urology (Under Review)

Dawson, N.A. and **Collins, S.P.** (2009). Novel treatment methods for localized prostate cancer: hypofractionated robotic radiation therapy and adjuvant chemotherapy. Expert. Rev. Anticancer Ther. 9(7):953-962.

Collins, S.P. and Dritschilo, A. (2009). The mismatch repair and base excision repair pathways: an opportunity for individualized (personalized) sensitization of cancer therapy. Cancer Biol Ther. 8(12):48-50.

Park, H.U., Suy, S., Danner, M., Daily, V., Zhang, Y., Li, H., Hyduke, D.R., Collins, B.T., Gagnon, G.J., Kallakury, B., Kumar, D., Brown, M.L., Fornace, A., Dritschilo, A., **Collins, S.P.** (2009). AMP-activated protein kinase promotes human prostate cancer cell growth and survival. Molecular Cancer Therapeutics. 8:733-741.

Coppa, N.D., Raper, D.M., Collins, B.T., Harter, K.W., Gagnon, G.J., **Collins, S.P.**, and Jean, W.C. (2009). Treatment of malignant tumors of the skull base with multi-session radiosurgery. Journal of Hematology & Oncology. 2:16.

Collins, B.T., Vahdat, S., Erickson, K., **Collins, S.P.**, Suy S., Yu X., Zhang Y., Subramaniam D., Reichner C.A., Sarikaya I., Esposito G., Yousefi S., Jamis-Dow C., Banovac F., Anderson ED. (2008).

Radical CyberKnife Radiosurgery with Tumor Tracking: An Effective treatment for Small Peripheral Stage I Non-small Cell Lung Cancer. Journal of Hematology & Oncology, 2:1.

Hirschbein M.J., **Collins S.P.**, Jean W.C., Chang S.D., Adler J.R. Jr. (2008). Treatment of intraorbital lesions using the Accuray CyberKnife system. Orbit. 27:97-105

Collins B.T., Erickson K., Reichner C.A., **Collins S.P.**, Gagnon G.J., Dieterich S., McRae D.A., Zhang Y., Yousefi S., Levy E., Chang T., Jamis-Dow C., Banovac F. and Anderson E.D. (2007). Radical stereotactic radiosurgery with real-time tumor motion tracking in the treatment of small peripheral lung tumors. Radiat. Oncol. 2:39

Dagvadorj, A., **Collins, S.P.**, Jomain, J-B., Abdulghani, J., Karras, J., Zellweger, T., Li, H, Nurmi, M., Alanen, K., Mirtti, T., Visakorpi, T., Bubendorf, L., Goffin, V. and Nevalainen, M.T. (2007). Autocrine prolactin promotes prostate cancer cell growth via Jak2-Stat5a/b Signaling Pathway. Endocrinology 148:3089-101.

Collins, S.P., Coppa, N.D., Zhang, Y., Collins B.T., McRae, D. A., Jean, W. C. (2006). CyberKnife® radiosurgery in the treatment of complex skull base tumors: analysis of treatment planning parameters. Radiat. Oncol. 1:46.

Collins, S.P., Reoma, J., Gamm, D.M. and Uhler, M.D. (2000). LKB1, a novel serine/threonine protein kinase and potential tumor suppressor, is phosphorylated by cyclic-AMP-dependent protein kinase and prenylated *in vivo*. Biochem. J. 345:673-680.

Collins, S.P., and Uhler, M.D. (1999). Cyclic-AMP- and cyclic-GMP-dependent protein kinases differ in their regulation of cyclic-AMP response element-dependent gene transcription. J. Biol. Chem. 274:8391-8404.

Hall, K.U., **Collins, S.P.**, Gamm, D.M., Massa, E. and Uhler, M.D. (1999). Phosphorylation-dependent inhibition of protein phosphatase-1 by G-substrate: a Purkinje cell substrate of the cyclic-GMP-dependent protein kinase. J. Biol. Chem. 274:3485-3495.

Collins, S.P., and Uhler, M.D. (1997). Characterization of PKI gamma, a novel isoform of the protein kinase inhibitor of cyclic-AMP-dependent protein kinase. J. Biol. Chem. 272:18169-18178.

INVITED PRESENTATIONS:

Collins, S.P., CyberKnife monotherapy for low to intermediate risk prostate cancer. Urologic Nursing Society, Washington, DC, November 19, 2009.

Collins, S.P., A Pilot Study of Intensity Modulated Radiation Therapy (IMRT) plus CyberKnife Boost for Clinically Localized Prostate Cancer, CALGB Fall Group Meeting. Phoenix, AR, November 14, 2009.

Collins, S.P., CyberKnife monotherapy for low to intermediate risk prostate cancer. Grand Rounds, Department of Medicine, Washington Veteran's Hospital, March 25, 2009.

BOOK CHAPTERS:

Collins, S.P., McRae, D. A., Gagnon, G., and Dritschilo, A. New directions in radiation therapy of prostate cancer: brachytherapy and intensity modulated radiation therapy. Chapter in: Nevalainen M.T. and Pestell R.G., eds. Prostate Cancer: Signaling Networks, Genetics and New Treatment Strategies. Humana Press, 2007.

Anderson, E.D., Collins, B.T., Gagnon, G.J., **Collins, S.P.**, Mahoney, T., Banovac, F., Jamis-Dow, C., Malik, S. and Reichner, C.A. Thoracic Fiducial Placement via Flexible Bronchoscopy. Chapter in: H. Urschel, ed. Robotic Radiosurgery: Treating Tumors that Move with Respiration. Berlin/Heidelberg, Springer, 2007:105-10.

Collins, B.T., Erickson, K., **Collins, S.P.**, Gagnon, G.J., Dieterich, S., McRae, D.A., Reichner, C.A., Chang, T., Jamis-Dow, C., Banovac, F., Malik, S. and Anderson, E.D. Fractionated Stereotactic Radiosurgery with the Synchrony Motion Tracking Module in the Treatment of Single Small Peripheral Lung Tumors. Chapter in: H. Urschel, ed. Robotic Radiosurgery: Treating Tumors that Move with Respiration. Berlin/Heidelberg, Springer, 2007:145-53.

POSTERS AND ORAL PRESENTATIONS:

Oermann, E., Hanscom, H., Lei, S., Suy, S., Collins, B., Batipps, G., Dunne, E., Constantinople, N., Dejter, S., Regan, J., McGeagh, K., Pahira, J., Dawson, N., Dritschilo, A., **Collins, S.P.** and Lynch, J. Hypofractionated Robotic Radiosurgery for the Treatment of Prostate Cancer: Acute Toxicity and Early Biochemical Results. Society of Urologic Oncology Meeting, Poster Presentation, 2009.

Lominska, C.E., Unger, K., Jean, W.C., Chanyasulkit, J., Collins, B.T., **Collins S.P.**, Gagnon, G. Multisession Stereotactic Radiosurgery for Meningioma Results in Low Rates of Post-treatment Edema. ASTRO, Poster Presentation, 2009.

Erickson, K., Vahdat S., **Collins, S.P.**, Suy, S., Xia, Y., Gutierrez, C.J., Esposito, G., Banovac, F., Dritschilo, A. and Collins, B.T. Radical Robotic Radiosurgery for Inoperable Patients with Small Peripheral Stage IA Non-small Cell Lung Cancer: Exceptional Local Control and Survival Despite Prolong Fraction Times. ASTRO, Poster Presentation, 2009.

Lei S, Harter KW, **Collins S.P.**, Xia, F., Pang, D. and Gagnon, G. Head-and Neck IMRT without Beam Splitting. American Association of Physicists in Medicine, Poster presentation, 2009.

Gagnon, G., Unger, K., Collins, B.T., **Collins S.P.**, Henderson, F. and Jean, W. Evaluation of a Predictive Model for Brain Necrosis Using CyberKnife Radiosurgery Based on the Integral Logistic Formulation. CyberKnife User's Meeting, Oral presentation, 2009.

Haddad, N., Charalambopoulos, J., Gupta, N.K., Charbel, H., Lominska, C., **Collins S.P.** and Gagnon G. Endoscopic Ultrasound Guided Fiducial Placement is Safe and Effective in Facilitating Respiratory Tracking for CyberKnife Radiosurgery. CyberKnife User's Meeting, Oral presentation, 2009.

Bonslaver, J., **Collins, S.P.**, Lei, S., Suy, S., Anderson, E., Satinsky, A., Collins, B.T., Gagnon, G., Dritschilo, A., Lynch, J. and McGeagh, K. A Novel Technique for Prostatic Fiducial Placement. CyberKnife User's Meeting, Poster presentation 2009

Collins, B.T., **Collins, S.P.**, Oermann, E.K., Yu, X., Vahdat, S., Yousefi S., Jamis-Dow C., Banovac F., Anderson ED. Radical CyberKnife Radiosurgery: An Effective Treatment for Inoperable Patients with Peripheral Stage IA Non-small Cell Lung Cancer. CyberKnife User's Meeting, Oral presentation 2009

Oermann, E.K., **Collins, S.P.**, Eldabh A., Coppa, N., Kalhorn, K., McGrail, K., Jean, W. and Collins B.T. CyberKnife Enhanced Conventionally Fractionated Chemoradiation for High-Grade Glioma in Close Proximity to Critical Structures. CyberKnife User's Meeting, Oral presentation 2009.

Hyduke, D.R., Li, H.H., Park, H.U., **Collins, S.P.**, Suy, S., Aubrecht, J. and Fornace, A. J. A Network Based Approach for the Identification of Stress Responses in Lead Compound Transcriptome Profiles. American Institute of Chemical Engineers (Bioengineering Division), Oral presentation 2008.

Park, H.U., Suy, S., Collins, B.T., Brown, M.L., and **Collins, S.P.** AMP-activated protein kinase inhibitors as potential chemoprevention agents for human prostate cancer. American Chemical Society, Poster Presentation, 2008.

Suy, S., Kong, Y., Collins, B.T., **Collins, S.P.**, Brown, M.L. A Novel Boronic Acid Bioisostere of Combrestatin A-4 Sensitizes Human Lung Carcinoma Cells to Ionizing Radiation. American Chemical Society, Poster Presentation, 2008.

Patacsil, D., Osayi, S., Shajahan, A.N., Suy, S., **Collins, S.P.**, Gokhale, P. C., Verma, M., Clarke, R. and Kumar, D. Vitamin E Succinate Inhibits the Inhibitor of Apoptosis Proteins (IAPs) and Induces Apoptosis in Pancreatic Cancer Cells. Cancer Health Disparities Summit, Poster Presentation, 2008

Collins, B.T., Reichner, C., Liao, J., Xia, F. Ji, H., Hailu, N. Jamis, C., **Collins, S.P.**, Gagnon, G. and Anderson, E. Radiosurgery with Real-Time Tumor Motion Tracking: An Effective Non-surgical Treatment Alternative for Small Peripheral Stage I Non-small Cell Lung Cancer. Chest. Oral presentation, 2007.

Malik, S., Erickson, K., **Collins, S.P.**, Reichner, C., Jamis-Dow, C., Banovac, F., Anderson, E.D. Smith, F. and Collins, B.T. CyberKnife® High-dose Fractionated Stereotactic Radiosurgery with Tumor Tracking: An Effective Non-surgical Treatment Alternative for Single Small Peripheral Lung Tumors. ASCO, Poster Presentation, 2007.

Coppa, N.D., Dias, L.M., **Collins, S.P.**, Jean, W. and Collins, B.T. Image Guided Radiosurgery Boost as an Adjunct Treatment for High-grade Gliomas. American Association of Neurological Surgeons. Poster Presentation, 2007.

Anderson, E.D., Collins, B.T., Erickson K., Gagnon G., **Collins S.P.**, Jamis-Dow. C., Banovac, F., Malik, S., Haddad, N., Margolis M. and Reichner, C. Fiducial placement for cyberknife stereotactic radiosurgery using flexible bronchoscopy and a modified transbronchial aspiration needle technique. Chest. Oral presentation, 2006.

Collins, B.T., Erickson, K., **Collins, S.P.**, Gagnon G., Dieterich, S., Reichner, C., Elsayaf M.A., Earl-Graef, D., Jamis-Dow, C., Banovac F., Malik S. and Anderson, E. CyberKnife® frameless image-guided radiosurgery with the synchrony™ motion tracking module in the definitive treatment of small peripheral lung tumors. Chest. Oral presentation, 2006.

Coppa N, **Collins S.P.**, Erickson K, Jean W, Collins B. CyberKnife radiosurgery boost as an adjunct to surgical resection, chemotherapy and conventional radiation therapy in the treatment of completely resected anaplastic astrocytomas, anaplastic oligodendrogliomas and anaplastic oligoastrocytomas. CyberKnife Users Meeting, Poster Presentation, 2006.

Coppa N.D., **Collins, S.P.**, Sanborn M.R., Collins B.T., Harter K.W., Jean W.C. CyberKnife radiosurgery for malignant tumors of the skull base. Congress of Neurological Surgeons, Poster Presentation, 2005.

Lundsten, M., **Collins, S.P.**, McRae D., and Harter, K.W. Feasibility of noninvasive fixation and fiducial placement for postoperative fractionated stereotactic radiosurgery of extremity tumors. CyberKnife Users Meeting, Poster Presentation, 2005.

Collins, S.P., Fricke, S.T., Catalina Rodriguez, O., Hailu, A., Ileva, L., Wong, K.H., Sutherland, D., McRae, D.A., Gagnon G.J., Lynch, J.H., Dritschilo A. and Albanese C. High field magnetic resonance spectroscopic imaging (MRSI) of the prostate: translational research from murine prostate cancer models to human subjects. implications for safe dose escalation to dominant intraprostatic lesions using cyberknife radiosurgery. ASTRO Translational Research in Radiation Oncology. Poster Presentation, 2005.

Jean W.C., Voyadzis J.M., **Collins S.P.**, Harter K.W., Gagnon G.J., Collins B.T., CyberKnife radiosurgery for metastatic brain tumors after failure of whole brain radiotherapy: The application of image-guided, robotic radiosurgery for salvage treatment. Congress of Neurological Surgeons, Poster Presentation, 2003.

HARTER, K. WILLIAM, M.D.

**PERSONAL
INFORMATION:**

Home Address: 1 Franklin Street
Alexandria, VA 22314
Telephone: 240 994-9040

Office Address: Department of Radiation Medicine
Lombardi Cancer Center
Georgetown University Hospital
3800 Reservoir Road, N. W.
Washington, D.C. 20007
Telephone: 202 444-3320
Fax: 202-444-0067

LICENSURE:

State: DC
License No: MD13299
Initial Date: 03/26/1982
Renewal/Expiration Date: 12/31/10

State: MD
License No: D0028178
Initial Date: 08/05/82
Renewal/Expiration Date: 09/30/10

State: VA
License No: 0101243816
Initial Date: 06/04/08
Renewal/Expiration Date: 09/03/10

CERTIFICATION: Board Certification: National Board of Medical Examiners
Date of Certification: 07/02/79

Specialty Board Certification: American Board of Radiology-
Radiation Oncology
Date of Certification: 06/04/1982

EDUCATION:

Undergraduate: Dartmouth College
Hanover, NH 03755
September 1967- June 1971
B.A., History

Medical Education: Louisiana State University
New Orleans, LA 70803
August 1974- May 1978
M.D.

Internship: Mayo Clinic
General Surgery
Rochester, MN 55905
July 1979-June 1979

Residency: Mayo Clinic
Radiation Oncology
Rochester, MN 55905
July 1978- October 1980

Harvard Medical School
Joint Center for Radiation Therapy
Boston, MA 02138
October 1980- July 1982

Fellowship: Massachusetts General Hospital
Radiation Oncology
55 Fruit Street
Boston, MA 02114
1982

**PROFESSIONAL:
EXPERIENCE**

Date(s) of Service: 1991 to Present
Title: Vice Chairman, Department of Radiation Medicine
Institution: Georgetown University Hospital
Address: 3800 Reservoir Rd, NW, Washington, DC 20007

Date(s) of Service: 1989 to Present
Title: Associate Professor, Department of Radiation Medicine
Institution: Georgetown University Hospital
Address: 3800 Reservoir Rd, NW, Washington, DC 20007

Date(s) of Service: 1986-1987
Title: Acting Chairman, Department of Radiation Medicine
Institution: Georgetown University Hospital
Address: 3800 Reservoir Rd, NW, Washington, DC 20007

Date(s) of Service: 1985 to Present
Title: Assistant Professor, Department of Radiation Medicine
Institution: Georgetown University Hospital
Address: 3800 Reservoir Rd, NW, Washington, DC 20007

Date(s) of Service: 1985
Title: Director, Residency Training Program, Department of
Radiation Medicine
Institution: Georgetown University Hospital
Address: 3800 Reservoir Rd, NW, Washington, DC 20007

Date(s) of Service: 1984
Title: Chief of Clinical Services, Department of Radiation
Medicine
Institution: Georgetown University Hospital
Address: 3800 Reservoir Rd, NW, Washington, DC 20007

Date(s) of Service: 1983
Title: Instructor, Department of Radiation Medicine
Institution: Georgetown University Hospital
Address: 3800 Reservoir Rd, NW, Washington, DC 20007

Date(s) of Service: 1982
Title: Clinical Fellow
Institution: Harvard Medical School
Address: 25 Shattuck Street, Boston, MA 02115

PROFESSIONAL SOCIETIES: American Society of Clinical Oncology
American Society of Therapeutic Radiology and Oncology
American College of Radiology
Massachusetts Medical Society
Mid-Atlantic Society of Radiation Oncology
Society of Chairmen of Academic Radiation Oncology Programs

PUBLICATIONS:

- Vera Z., Gray DR, **Harter K W**, Janzen DA, Masumi RA. Mason, DT.
Electrophysiologic properties of perhexiline., *Clin Pharmacol Ther.*,
(5Pt 1):623-8, 1975 Nov 18.
- Bamberg E, Alpes H, Apell HI, Bradley R, **Harter KW**, Quelle MJ, and Very D W,
"Formation of ionic channels in black lipid membranes by succinic derivatives of
gramicidin a". *J. Membrane Bio.*, 50:257-270,1979.
- Stefanik D, Goldberg R, Byrne R, smith F, Ueno W, Smith L, **Harter K W**,
Bachenheimer, I, Beiser C, and Dritschilo A, Local-regional failure in patients
treated with adjuvant chemotherapy for breast cancer., *Clin. Oncol.*, 3:660-665,
1985.
- Le Chavlier T, Smith E F, **Harter K W**, and Schein PS, Chemotherapy and combined
modality therapy for locally advanced and metastatic gastric carcinoma.,
Seminars in Oncol., Vol 12(1):46-53, 1985.
- TorrisiJ, Berg C, **Harter K W**, Lvovsky E, Yeung K, Wolley P. Bonnem E, and
Dritschilo A, Phase I combined modality clinical trial of alpha-2-interferon and
radiotherapy., *Int. Rad. Oncol. Biol. Phys.*, Vol.12(8):1453-1457, 1986.

- Dritschilo A, Grant EG, **Harter K W**, Holt RW, Rustgi SN, and Rodgers JE, Interstitial radiation therapy for hepatic metastases: sonographic guidance for applicator placement, *Am. J. Roent.*, Vol. 146, 275-278, 1986.
- Nauta R, Heres K, Thomas D, **Harter K W**, Rodgers J, Holt R, Lee TC, Walsh D, and Dritschilo A, Intraoperative single dose radiation therapy: Observations of staging and interstitial treatment of unresectable liver metastases, *Arch. Surg.* 122:1392-1395, 1987.
- Dritschilo A, **Harter K W**, Grant e, Holt R, lee TC, Nauta R, Rustgi S, and Rodgers J E, Techniques for percutaneous and intraoperative radiation therapy of hepatic metastases. In Proc. 1st Intl. Meeting of GammaMed users (SM Shah, ed.) Mick
- Holt R, Nauta R, lee TC, Heres E, Dritschilo A, **Harter K W**, Rustgi S, Rodgers J E, Intraoperative interstitial radiation therapy for hepatic metastases from colorectal Carcinomas, *American Surgeon* , 54:231-233, 1988.
- Dritschilo A, **Harter K W**, Thomas D, Nauta R, Holt R, Lee TC, Rustgi S, Rodgers JE, Intra-operative radiation therapy of hepatic metastases: Technical aspects and report of a pilot study, *Int. J. Rad. Onc. Biol.*, 14:1007-1011, 1988.
- Chin LM, **Harter K W**, Svensson GK, and Cassady JR, An external beam treatment technique for retinoblastoma, *Int. J., Rad. Onc. Biol. Phys.*, 15:455-460, 1988.
- Harter K W** and Dritschilo A, Cancer of the pancreas: Are chemotherapy and radiation appropriate?, *Oncology*, 3:27-30, 1989.
- Stevens C, Torrasi, J, Berg C, Thomas D, **Harter K W**, Cumberlin R, and Dritschilo A, The use of radiotherapy with alpha 2B-interferon sensitization in locally advanced unresectable non-small cell carcinoma of the lung- a pilot study, ASCO, 1990.
- Torrasi I, Dritschilo A, **Harter K W**, Helfrich B, Berg C, Whiffield O, Stablein D, Alijani M, A Randomized study of the efficacy of adjuvant local graft irradiation following renal transplantation., *Int. J. Rad. Oncol. Bio. Phys.*, 18:1027-1031, 1990.
- Leighton T, **Harter K W**, Cansado J, and Notario V, Molecular characterization of cell quercetin and quercetin glycosides in Allium vegetables and their effects on malignant cell transformation. In: Phenolic compounds and human health (American Chemical Society Symposium Series), 1991.
- Leighton T, Ginther C, Fluss L, **Harter K W**, Cansado J, and Notario V, Molecular characterization of quercitin and quaercitin glycosides in Allium vegetables, and their effects on malignant cell transformation, In "Phenolic Compounds in Foods

and Health", CE Ho and MT Huang Eds. American Chemical Society Symposium Series, Vol. 507: pp. 220-230, 1992.

Thomas DS, Nauta R, Rodgers JE, Popescu GF, **Harter K W**, and Dritschilo A: Intraoperative interstitial HDR radiation therapy for unresectable abdominal tumors, IORT '92, 4th Intern, Symposium, Sept. 13-16, Munich, Germany, 1992.

Thomas DS, Nauta R, Rodgers SE, Popescu GF, Nyguen H, Lee TC, Petrucci P, **Harter K W**, Holt R, and Dritschilo A, Intraoperative high dose rate interstitial irradiation of hepatic metastases from colorectal carcinoma. Results of a Phase-II trial, *Cancer*, 71:1977-1981, 1993.

Niroomand-Rad A, **Harter K W**, Tliobeiauc S, Bertrand K, Air cavity effects on the radiation dose to the larynx using co-60, 6 MV, and MV photon beams, *Int. J. Radiat. Oncol. Biol. Phys.*, 29(5): 1139-46, 1994 Jul 30.

Razavi R, Niroomand-Rad A. Sessions RB, **Harter K W**, Use of dental implants for rehabilitation of mandibulectomy patients prior to radiation therapy, *Oral Implantol*, 21(2): 138-4i, 1995.

Niramood-Rad A. Razavi, R Thobjane S. **Harter K W**, Radiation dose perturbation at tissue- titanium dental interfaces in head and neck cancer patients, *Int. J. Radiat. Oncol. Biol. Phys.*, 34(2): 475-80, 1996 Jan 15.

Avila MA, Cansado J, **Harter K W**, Velasco JA, Notario V, Quercetin as a modulator of the cellular neoplastic phenotype. Effects on the expression of mutated H-ras and p53 in rodent and human cells, *Adv Exp Med Biol.*, 401-10, 1996.

Niramood-Rad A. Javedan K, Rodgers J E, **Harter K W**, Effects of beam spoiler on radiation dose for head and neck irradiation with 10-MV photon beam, *Int. J. Radiat. Oncol. Biol. Phys.*, 37(4): 935-40, 1997 Mar1.

Kuettel MR, Parda D S, **Harter K W**, Rodgers, JE, Treatment of female urethral carcinoma in medically inoperable patients using external beam irradiation and high dose intracavitary brachytherapy, *I Urot*, 157 (5): 1669-71, 1997 May.

Davidson BJ, Newkirk KA, **Harter K W**, Picken CA, Cullen KJ, Sessions RB, Complications from planned, post-treatment neck dissections. *Arch Otolaryngology - Head & Neck Sur*, 125(4):401-5, 1999 Apr.

Collins B, Reddy A. Akyurekli D, Ayoob M, **Harter K W**, Radiation Therapy for Metastatic Disease of the Spine, *Spine Therapy*, (1):17-20, 2000 March 12.

Gagnon GJ, **Harter K W**, Berg CD, Lynch JH, Cornell DR, Kuettel MR, Dritschilo A,

Limitations of reduced-field irradiated volume and technique in conventional radiation therapy of prostate cancer: implications for conformal 3-D treatment, *Int J Cancer*, 90 (5): 265-74, 2000 Oct 20.

Newkirk K A, Cullen K J, **Harter K W**, Picken C A, Sessions R B, Davidson B J, Planned neck dissection for advanced primary head and neck malignancy treated with organ preservation therapy: disease control and survival outcomes, *Head Neck*, 23 (2): 73-9, 2001 Feb.

Newkirk K A, Reddy A, **Harter K W**, Pickens C, Sessions R B, Davidson B J, Brachytherapy for Base of Tongue Squamous Cell Carcinoma, *Arch of Otolaryngology - Head and Neck Surgery*, 2001.

Rassaei N, Frye DA, **Harter K W**, Troost TR, Ozdemirli M, Acinic Cell Carcinoma of the Glottis: Case Report. *Amer J of Otolaryngology*, Vol. 24(4): 258-260, July-August 2003.

Posner MR, Hershock DM, Blajman CR, Mickiewicz E, Winkquist E, Gorbounova V, Tjulandin S, Shin DM, Cullen K, Ervin TJ, Murphy BA, Racz LE, Cohen RB, Spaulding M, Tishler RB, Roth B, del Carmen Viroglia C, Venkatesan V, Romanov I, Agarwala S, **Harter K W**, Dugan M, Cmelak A, Markoe AM, Read PW, Steinbrenner L, Colevas AD, Norris CM, Haddad RI, Cisplatin and Fluorouracil Alone or with Docetaxel in Head and Neck Cancer, *N Engl J Med*, Vol 357:1705-15, 2007.

Henderson FC, McCool K, Seigle J, Jean W, **Harter KW**, Gagnon GJ, Treatment of chordomas with CyberKnife: Georgetown University experience and treatment recommendations, *Neurosurgery*; 64 (2 Suppl):A44-53, 2009 Feb.

Coppa ND, Raper DM, Zhang Y, Collins BT, **Harter KW**, Gagnon GJ, Collins SP, Jean WC, Treatment of malignant tumors of the skull base with multi-session radiosurgery, *J Hematol Oncol*, 2:16 April 2009.

Unger KR, Lominska CE, Deeken JF, Davidson BJ, Newkirk KA, Gagnon GJ, Hwang J, Slack RS, Noone AM, **Harter KW**, Fractionated stereotactic Radiosurgery for Reirradiation of Head-and-Neck Cancer, *Int J Radiat Oncol Biol Phys*, 2010 Jan 5.

Book Chapters

Gastrointestinal Oncology MacDonald and Ahlgren (eds.), **Harter, K W**, (assoc. ed.), Lippincott, Philadelphia, 1992.

Chapter titles:

- 1.) General Principals of Gastrointestinal Radiation Oncology
- 2.) Cancer of the Esophagus
- 3.) Cancer of the Pancreas
- 4.) Cancer of the Anus

Radiation Therapy in Pediatric Oncology Cassady (ed.), Springer-Verlag, Berlin, 1994

Chapter Titles

- 1.) Osteogenic Sarcoma
- 2.) The less common soft tissue sarcomas
- 3.) Thyroid sarcomas
- 4.) Nasopharynx Carcinoma
- 5.) Adrenal Carcinoma
- 6.) Colon Carcinoma

Head and Neck Cancer: A Multidisciplinary Approach Harrison, Sessions and Hong (eds.), Lippincott-Raven, Philadelphia, 1999, 2004 (2nd ED.)

Chapter Title

Cervical lymph Node Metastasis from Squamous Cell Carcinoma with Unknown Primary Site

Rev.2/18/10

Curriculum Vitae
Dalong Pang, Ph.D, M.Phil.
Diplomat, American Board of Radiology

Home Address: 4201 Cathedral Ave., NW, 709 W, Washington, DC 20016
561-251-1404

Office Address: Georgetown University Hospital, Department of Radiation Medicine,
Medicine, 3800 Reservoir Road, NW, L.L. Bless, Washington, DC
20007
Office Phone: 202-444-4069, Office Fax: 202-444-9323

Licensure: Florida, Therapeutic Radiological Physics, License No. RTP-212
Expiration Date: January 31, 2009

Certification: American Board of Radiology, Date of Certification: June 26, 2002, Date
of Re-certification: June 26, 2012

Education: Undergraduate: Sichuan University, Chengdu, Sichuan, China,
9/1979-6/1983, B.S. Electrical Engineering.
Graduate: University of Electronic Science and Technology, Chendu,
Sichuan, China (1985-1987), M.S. Electrical Engineering.
Graduate: The George Washington University, 2025 I Street, NW
Washington, DC 20015, 9/1990-1/1998
M.Phil. (1993), Ph.D. (January 31, 1998)

Pre-doctoral Fellowship:

Georgetown University Medical Center, Department of Radiation Medicine
3800 Reservoir Road, NW, L.L. Bless, Washington, DC 20007
January, 1995- December 1997, Department Chair: Anatoly Dritschilo, MD

Postdoctoral Fellowship:

Georgetown University Medical Center, Department of Radiation Medicine
3800 Reservoir Road, NW, L.L. Bless, Washington, DC 20007
January, 1998- December 1998, Department Chair: Anatoly Dritschilo, MD

Professional Experience:

September 15, 2008 - Present, Chief, Division of Radiation Physics, Department
of Radiation Medicine, Georgetown University Hospital, 3800 Reservoir Road,
NW, Washington, DC 20007

March 1, 2007 - August 31, 2008, Chief Physicist, Medical Physic Solutions,
7018 Houlton Circle, Lake Worth, FL 33467

November 1, 2004 - February 28, 2007 Chief Physicist, Wellington Regional
Medical Center, West Palm Beach, FL 33414

November 1, 2003 – October 30, 2004. Clinical Physicist, Boca Raton Community Hospital, Boca Raton, FL 33815

December 15, 2000 – October 30, 2003. Clinical Physicist, Department of Radiation Oncology, University of Washington Medical Center, Seattle, Washington, 98185

November 1, 1999–October 30, 2000. Clinical Physicist, US Oncology, Austin, TX

January 1, 1999– October 30, 1999. Research Assistant Professor, Department of Radiation Medicine, Georgetown University Medical Center

Honors and Awards:

January 30, 2008 Outstanding Ph.D. Dissertation, Columbian School of Arts and Sciences, The George Washington University

Professional Societies:

American Society of Therapeutic Radiology and Oncology, Jan, 2006-present

American Association of Physicists in Medicine, 1998-present

Radiation Research Society, July, 2009-present

Invited Lectures and Poster Presentations:

1. "Short DNA Fragments are Critical Lesions of Ionizing Radiation Induced DNA Damage" *Invited Talk*, Center for Radiological Research, Columbia University, August, 2009.
2. "Large Field IMRT Without Beam Splitting" S. Lei, W. Harter, S. Collins, F. Xia, D. Pang, G. Gagnon. *Poster Presentation*, 51st AAPM Annual Meeting, Anaheim, CA, July 2009.
3. "Optimal Needle and Dwell Positions in Prostate HDR": D. Pang, R. Robin, K. Dass; *Poster Presentation*, 48th Annual Meeting of American Society of Therapeutic Radiology and Oncology, Philadelphia, PA, November, 2006.
4. "Beam Selections in Prostate IMRT: a Dosimetric Comparison Between 5 And 7 Fields With 6 And 18 MV Photons" C. Shang and D. Pang. *Poster Presentation*, 46th AAPM annual meeting, Pittsburgh, PA, July 2004.
5. "IMRT of Lung Cancer," D. Pang, M. Phillips, D. Schwartz, and G. Laramore. *Poster Presentation*, 44th AAPM annual meeting, Montreal, Canada, July, 2002.
6. "Ultrasound-Guided Prostate Implant Brachytherapy at Georgetown University: A Physicist's Perspective" *Oral Presentation*, AAPM Mid-Atlantic Chapter Meeting, June, 1999.
7. "Atomic Force Microscopy in Biological Research" *Invited Talk*, National Cancer Institute, SAIC, Frederick, MD, February, 1997
8. "Atomic Force Microscopy in Radiation Research" *Invited Talk*, Armed Forces Radiobiology Research Institute, Bethesda, MD, February, 1998

9. "Atomic Force Microscopy in Radiation Research" *Invited Talk*, National Institute of Standards and Technology, Gaithersburg, MD, April, 1998
10. "Biological Applications of Atomic Force Microscopy", *Invited Talk*, Department of Physics, University of Paris, Paris, France, October, 1996
11. "Atomic Force Microscopy Investigation of Electron Induced DNA Double Strand Breaks" *Oral Presentation*, 12th Symposium on Microdosimetry, Oxford, UK, October, 1996

Teaching Activities:

Radiation Physics for Medical Residents, Department of Radiation Medicine, Georgetown University Hospital, October, 2008 – Present

Publications:

1. D. Pang, F.W. Winters, M. Jung, S. Purkayastha, L. R. Cavalli, S. Chasovskikh, B. R. Haklad, and A. Dritschilo, Radiation-generated short DNA fragments may perturb non-homologous end-joining and induce genomic instability. *Journal of Radiation Research*. Under review (2010).
2. D. Pang, J.E. Rodgers, B.L. Berman, S. Chasovskikh, and A. Dritschilo, Spatial distribution of radiation-induced double-strand breaks in plasmid DNA as resolved by atomic force microscopy. *Radiation Research*, 2005 Dec; 64(6):755-65 (2005).
3. Pang D, Chasovskikh S, Cohen JS, Obcemea C, Dritschilo A. Atomic force microscopy examination of conformations of polynucleotides in response to platinum isomers: significance of GC content at broken ends. *Int J Cancer*. Apr 20;90(2):68-72. (2002)
4. D. Pang, B.L. Berman, S. Chasovskikh, J.E. Rodgers, and A. Dritschilo, Investigation of neutron-induced damage in DNA by atomic force microscopy: Experimental evidence of clustered DNA lesions. *Radiation Research* 150: 612-618 (1998).
5. M. Smulson, D. Pang, M. Jung, A. Dimitchev, S. Chasovskikh, A. Spoonde, Simbulan-Rosenthal, D. Rosenthal, A. Yakovlev, and A. Dritschilo, Irreversible binding of Poly(ADP)ribose polymerase cleavage product to DNA ends revealed by atomic force microscopy: Possible role in apoptosis. *Cancer Research* 58: 3495-3498 (1998).
6. D. Pang, B. Vidic, J. E. Rodgers, B. L. Berman, and A. Dritschilo, Atomic force microscope imaging of DNA and DNA repair proteins: applications in radiobiological research. *Radiation Oncology Investigations* 5: 163-169 (1997).
7. D. Pang, S. Yoo, W. Dynan, M. Yung, and A. Dritschilo, Ku protein joins DNA fragments as shown by atomic force microscopy. *Cancer Research* 57:1242-1245 (1997)
8. D. Pang, G.F. Popescu, J. E. Rodgers, B. L. Berman, and A. Dritschilo, Atomic force Microscopy investigation of radiation induced DNA double strand breaks. *Scanning Microscopy* 10: 1105-1110 (1996)
9. D. Pang, Electron Scattering. *Internal Report*, The George Washington University, May, 1994.

ABDUL RASHID, M. Phil., Ph.D.

Contact Information

Georgetown University Hospital
Department of Radiation Oncology
3800 Reservoir Road, NW
LL Bless Building
Washington, DC 20007-2113
Phone: 202-444-3064
Axr11@gunet.georgetown.edu

Home

1325A North Rolling
Catonsville, MD 21228
Phone: (410) 747-2707
Phone Cell: (443) 834-4647
skp1325@hotmail.com

EDUCATION

2000 - 2002	Post Doc Fellows (Medical Physics) Radiation Oncology, Johns Hopkins University School of Medicine	Baltimore, MD
1994 - 1999	Ph.D. (Atomic and Molecular Physics) Quaid-i-Azam University	Islamabad
1991 - 1994	DAAD Fellows (Magneto-Optics) Wilhelm University,	Bonn, Germany
1986 - 1988	M. Phil. (Experimental Atomic and Molecular Physics) Quaid-i-Azam University	Islamabad

Professional Appointments

Oct 2007- Present	Georgetown University Hospital Lead Stereotactic Radiosurgery Cyberknife Department of Radiation Oncology	Washington, DC
June 2006- Sep 2007	Sinai Hospital of Baltimore Sr. Medical Physicist Radiation Oncology	Baltimore, MD
2006 - June 2006	University of Virginia Assistant Professor of Radiation Oncology and Neurosurgery	Charlottesville, VA
2006 - June 2006	University of Virginia Radiation Safety Officer (Gamma Knife)	Charlottesville, VA
2003 - 2006	Johns Hopkins Hospital Radiation Oncology Senior Clinical Physicist	Baltimore, MD
2003 - 2006	Johns Hopkins Hospital Radiation Oncology Radiation Safety Officer (Gamma Knife)	Baltimore, MD
2000 - 2002	Johns Hopkins Hospital Radiation Oncology Medical Physics Resident	Baltimore, MD
Sep. 2000 to Dec. 2000	Bowie State University Adjunct Faculty	Bowie, MD

Clinical Experience:

- Perform routine clinical physics support for teletherapy and brachytherapy
- Perform routine QA of teletherapy and brachytherapy machine
- Lead and established physics project for stereotactic radiosurgery program using Gamma knife, Cyberknife and Linac Base Radiosurgery, (from construction to installed)
- Shielding Calculations for Gamma Knife and Cyberknife Vaults
- Commissioned and upgrade Gamma Knife systems
- Commissioned and upgrade Cyberknife systems
- Commissioned and upgrade linear accelerators include Varian 600C, 2100C, 2300CD (3), 21EX, 4-100, Trilogy, Elekta SL-18, SLP (multi-leaf millennium, enhanced/dynamic wedge, portal vision)
- Commissioned ADAC/PINNACLE 3.0, 5.2, 7.2, 7.6, BrainLab 5.21, Leksell Gamma Plan, Multiplan 2.0, 2.1 and ECLIPSE 8.1 planning systems
- Commissioned Varian LINACS base stereotactic BrainLab for IMRS
- Lead Physicist for Stereotactic Radiation Therapy and Radiosurgery (LINAC, GAMMA KNIFE CYBERKNIFE)
- Cyberknife physicist duties includes, treatment planning using Cyris Multiplan, cyberknife daily, weekly, monthly QA, scheduling, planning
- Involved in the process of acquired and commissioned the second cyberknife at Sinai
- Involved in the process of acquiring second Gamma knife at UVA
- IGRT QA and Implementation: CBCT, 2D kV
- External Beam Planning and delivery ; 3DCRT, IMRT, SRT, gated RT
- Brachytherapy planning, delivery; HDR (microSelectron Nucletron and Gamma Med Plus ix), LDR, Prostate seed implant Veriseed.
- Radiopharmaceuticals delivery; Gliasite, ^{131}I , Delivery, QA, Calculations
- Involvement in research and application of radioisotopes: Gliasite, ^{153}Sm , ^{89}Sr , ^{90}Sr , ^{131}I , and ^{32}P and radioimmunotherapy involving ^{90}Y and ^{118}Ho
- Generate programs calculating time/activity for ^{32}P , ^{90}Sr , ^{192}Ir
- Generate brachytherapy treatment plans for: Fletcher-Suit ^{137}Cs gynecological applications and ^{192}Ir ribbons used for nasopharynx applications
- Linear Accelerator, Gamma Knife, Cyberknife, Tomotherapy treatment planning and IMRT QA development
- Record and Verify: Varian Varis4, Gen6, ARIA, IMPAC
- Commissioned Total Body Irradiation
- Supervised and direct Physicist / Dosimetrist

Research Interests / Experience:

- Involve in the development of Image guided radiotherapy and radiosurgery for intracranial and extracranial lesions.
- Working on a grant for the magnetic nanoparticles that enable to developed multifunctional capabilities for intracellular molecular imaging and more robust anatomic true markers which serves as a platform for tracking and treating tumors –associated biologic processes that will enable early detection of response to radiation therapy.
- Stereotactic Breast Radiosurgery
- Prostate radiosurgery for localized and elective nodal irradiation
- Acute Radiation Induced Syndromes and their treatment in Non-Human Primates
- Brain functional and Vascular disease

Teaching Experience:

- Teach routinely medical residents and medical physics residents
- Taught radiation therapist students at Baltimore County Community College

OTHER HEALTH RELATED PROFESSIONAL TRAININGS:

HDR After loader and applicator trainings	
Nucletron Corporation	Baltimore, MD
Intravascular brachytherapy training (Beta Cath)	
Novoste	Baltimore, MD
Training course for Planning and Delivering DynArt Treatments	Baltimore, MD
3D Line Medical Systems	
Varian Trouble Shooting Training	Baltimore, MD
Varian Medical Systems	
Principles and Practice of Gamma Knife Radiosurgery	Pittsburgh, PA
University of Pittsburgh	
Principles and Practice of Cyber Knife Radiosurgery	Sunnyvale, CA
Accuray Inc.	
Nucletron MammoSite Training	Columbia, MD
Nucletron.	
Cyberknife Prostate Radiosurgery Course	Long Island, NY
Winthrop University Hospital	
Varian Respiratory Gating Course	Las Vegas, NV
Varian Medical Systems.	
Varian On Board Imaging (OBI Physicist) Training	Las Vegas, NV
Varian Medical Systems.	
Eclipse Inverse Planning Administration and Physics Training	Las Vegas, NV
Varian Medical Systems.	

**PROFESSIONAL
ACTIVITIES
COLLEGIANT
HONORS AND
AWARDS**

American Association of Physicists in Medicine (AAPM), *full member*.
American Academy of Nanomedicine (AANM), *founding member*
DAAD (German Academic Exchange Service) Fellowship (1991-1994).
Quaid-i-Azam University Full Scholarship (1987)
University Grants Commission Govt. of Pakistan Fellowship (1986).
German Language Course, the Goethe-Institute, Mannheim, Germany. (1991)

CURRICULUM VITAE

ANDREW SATINSKY

Personal:

Date of Birth: October 21, 1963
Place of Birth: Philadelphia, Pennsylvania
Spouse: Marla Satinsky
Children: Evan, age 14; Milo, age 11

Home Address: 8027 Ellingson Drive
Chevy Chase, MD 20815
301-608-0124
asatin1@yahoo.com

Work Address: Clinical Director
Joseph E. Coad Radiation Treatment Center
Southern Maryland Hospital Center
7501 Surratts Road, Suite 108
Clinton, MD 20735
301-868-1100

Attending Radiation Oncologist
Department of Radiation Medicine
Georgetown University Hospital
3800 Reservoir Rd. NW; LL Bles Building
Washington, DC 20007
202-444-3320

**Previous Work
Experience:**

2001-2007: Medical Director
Rieman Center for Cancer Care
7410 West Rawson Avenue
Franklin, Wisconsin 53132

1993-2001: Radiation Oncologist
St. Michael's Hospital
Milwaukee, WI

1993-2001: Radiation Oncologist
St. Joseph Hospital
Milwaukee, WI

Education:

1990-1993: Radiation Oncology Residency
Georgetown University Hospital Washington, DC

1989-1990, Medical Internship
George Washington University Hospital
Washington, DC

1985-1989: M.D., 1989
University of Chicago Pritzker School of Medicine
Chicago, Illinois

1981-1985: A.B., 1985
University of Chicago
Chicago, IL

State licensure: Maryland, District of Columbia, Wisconsin

Board Certification: American Board of Radiology: Board Certified, July 1994
Diplomate. National Board of Medical Examiners, 1990

Clinical Experience: Permanent Prostate Brachytherapy
Intensity-Modulated Radiation Therapy
CyberKnife Stereotactic Cranial and Body Radiosurgery
Low and High Dose Rate Gynecologic Brachytherapy

Current Hospital Positions: Co-Chair, Southern Maryland Hospital Cancer Committee
Cancer Liaison Physician, Southern Maryland Hospital Cancer Committee

Previous Hospital Positions: Chair, St. Francis Hospital Cancer Committee
Chair, Wheaton Franciscan Task Force on the Wisconsin Comprehensive Cancer Control Plan
Vice-Chair, Wheaton Franciscan Investigative Review Committee
Member, Wheaton Franciscan Palliative Care/End of Life Steering Committee
Member, Milwaukee Regional Cancer Care Network Panel
Member, Wheaton Franciscan Medical Group Quality Council

Professional Affiliations: American Society for Therapeutic Radiology and Oncology
American Medical Association

Honors and Awards: Chief Resident, 1992-1993
Graduated with Collegiate and Divisional Honors in the Biological Sciences, University of Chicago: June, 1985
Divisional Honors Awarded for Senior Thesis: The Use of a Clonotypic Antibody Specific for a Cytolytic T Cell Clone to Probe Activation Requirements of T Lymphocytes," University of Chicago: June, 1985
Dean's List, University of Chicago: 1982-1985

Publication: Jacobson, S., Richert, J.R., Biddison, W.E., Satinsky, A., Hartzmann, R.J., McFarland, J.F. "Measles Virus-Specific- T4+ Human Cytotoxic T Cell Clones are Restricted by Class II HLA Antigens." Journal of Immunology. 133(2): 754, 1984

Research Funding: MedImmune Oncology (3/01/05 - 3/01/07); Site Principal Investigator: "Open-Label, Multicenter Trial of Amifostine in the Prevention of Radiation-Induced Esophagitis and Pneumonitis in Patients with Non-Small Cell Lung Cancer"; \$30,000

Research Experience: Review of Pulmonary Patients Treated with Radiation Therapy at Georgetown Between 1981 and 1990

Activation Requirements of T Lymphocytes. Preceptors: Frank Fitch, M.D., David Lancki, Ph.D. Department of Immunology, University of Chicago: 1984-1985

Possible Measles-Virus Etiology of Multiple Sclerosis. Preceptors: Henry McFarland, M.D., Steven Jacobson, Ph.D. NeuroImmunology Branch of NINCDS of National Institutes of Health: Summers of 1981-1983

Keith R. Unger, M.D.

PERSONAL INFORMATION:

Home Address: 5324 Pooks Hill Rd.
Bethesda, MD 20814
202-657-3581

Office Address: Department of Radiation Medicine
Georgetown University Hospital
3800 Reservoir Rd. NW
Washington, DC 20007
202-444-3320
202-444-4227

LICENSURE:

District of Columbia
License No: MD037664
Initial Date: 10/6/08
Renewal/Expiration Date: 12/31/12

Maryland
License No: D72381
Initial Date: 5/25/11
Renewal/Expiration Date: 9/30/11

Virginia
License No: 0101244480
Initial Date: 9/29/08
Renewal/Expiration Date: 5/31/12

CERTIFICATION:

N/A

EDUCATION:

Undergraduate: University of Virginia
Charlottesville, VA
07/1998 – 05/2002
B.A., Biology

Medical Education: University of Virginia School of Medicine
Charlottesville, VA
06/2002 - 06/2006
Doctorate of Medicine

Internship: Washington Hospital Center
Department of Medicine
Washington, DC
07/2006 – 06/2007

Residency: Georgetown University Hospital
Department of Radiation Medicine
Washington, DC
07/2007 – 06/2010
07/2010 – 07/2011 (Chief Resident)

**PROFESSIONAL
EXPERIENCE:**

Instructor (appointment pending)
Georgetown University
Washington, DC
07/2011 - present

**HONORS and
AWARDS:**

Dean's List
University of Virginia
1999-2002

College of Arts and Science Undergraduate Research Award
University of Virginia
2001

Golden Key National Honor Society
University of Virginia
2002

Bachelor of Arts with Distinction
University of Virginia
2002

Phi Beta Kappa
University of Virginia
2002

Association of Pathology Honor Society Award
University of Virginia School of Medicine
2004

Chief Resident
Georgetown University Hospital
2010 - 2011

**PROFESSIONAL
SOCIETY
MEMBERSHIP:**

American Society for Therapeutic Radiology and Oncology
2007 – present

American Society of Clinical Oncology
2007- present

Radiological Society of North America
2007- present

Radiation Research Society
2009 – present

PUBLIC SERVICE N/A

INVITED LECTURES: N/A

**UNIVERSITY
SERVICE:** N/A

**TEACHING
ACTIVITIES:** N/A

MENTORING: N/A

**COLLABORATIVE
ACTIVITIES:** N/A

**SCHOLARSHIP AND
RESEARCH:**

RESEARCH GRANTS

PUBLICATIONS

Original Papers in Refereed Journals

Unger K, Lominska C, Deeken J, Davidson B, Newkirk K, Gagnon G, Hwang J, Slack R, Noone A, Harter K. "Fractionated stereotactic radiosurgery for reirradiation of head-and-neck cancer." *Int J Radiat Oncol Biol Phys*, 77(5):1411-9, 2010.

Unger K, Ju A, Oermann E, Suy S, Yu X, Vahdat S, Subramaniam D, Harter K, Collins S, Dritschilo A, Anderson E, Collins B. "CyberKnife for hilar lung tumors: report of clinical response and toxicity," *J Hem Onc*, 3:39, 2010.

Unger K, Romney D, Koc M, Moskaluk C, Friel C, Foley E, Rich T. "Preoperative chemoradiation for rectal cancer using capecitabine and celecoxib correlated with post treatment assessment of thymidylate synthase and thymidine phosphorylase expression," *Int J Radiat Oncol Biol Phys*, 80(5):1377-82, 2011.

Unger K, Lominska C, Chanyasulkit J, Randolph P, White R, Aulisi E, Jacobson J, Jean W, Gagnon G. "Risk factors for post-treatment edema in patients treated with stereotactic radiosurgery for meningiomas," *Neurosurgery*, Accepted, 2011.

Reviews or Editorials in Refereed Journals

Books or Chapters in books, and publications in other journals

Abstracts

Unger K, Romney D, Moskaluk C, Rich T. "Thymidylate synthase and thymidine phosphorylase expression after preoperative chemoradiation in rectal cancer," American Society of Clinical Oncology GI symposium, 7/2006.

Unger K, Gagnon G, Harter K, Jean W, Alyeshmerni D, McRae D. "Cyberknife radiosurgery for tumors of the orbit," Oral Presentation, Cyberknife Users Meeting, 2/2008.

Lominska C, Unger K, Jean W, Chanyasulkit J, Collins B, Collins S, Gagnon G. "Multisession Stereotactic radiosurgery for meningioma results in low rates of post-treatment edema." American Society for Therapeutic Radiology and Oncology, Annual Meeting, 11/2009.

Unger K, Lominska C, Deeken J, Newkirk K, Davidson B, Liao J, Harter K. "Reirradiation using hypofractionated stereotactic radiosurgery for squamous cell carcinoma of the head and neck." 2nd annual International Conference of Innovative Approaches in Head and Neck Oncology, 2/2009.

Unger K, Lominska C, Deeken J, Newkirk K, Davidson B, Harter K. "Reirradiation of head and neck cancer: Dose predicts response to radiosurgery," Cyberknife User's Meeting, 2/2009.

Gagnon G, Unger K, Collins B, Collins S, Henderson F, Jean W. "Evaluation of a predictive model for brain necrosis using CyberKnife radiosurgery based on the integral logistic formulation," CyberKnife User's Meeting, 2/2009.

Unger K, Walls T, Grindrod S, Jung M, Dritschilo A, Brown M. "Drug development of a novel radiosensitizing histone deacetylase inhibitor with fluorescent properties," Radiation Research Society Annual Meeting. 9/2010.

Unger K, Ju A, Oermann E, Suy S, Yu X, Vahdat S, Subramaniam D, Harter K, Collins S, Dritschilo A, Anderson E, Collins B. "CyberKnife for hilar lung tumors: report of clinical response and toxicity." American College of Physicians, CHEST, Annual Meeting. 11/2010.

Unger K, Howard M, Slack R, Hartmann D, Newkirk K, Davidson B, Berkowitz F, Steadman K, Lockard D, Deeken J, Harter K. "Improved outcomes in HPV-positive head and neck squamous cell carcinoma treated with concurrent cetuximab and radiation therapy." American Society for Therapeutic Radiology and Oncology, Annual Meeting. 11/2010.



BINBIN WU, Ph.D.
Department of Radiation Medicine
Georgetown University Hospital
3800 Reservoir Road, NW, Washington, DC 20007
(O)202-444-3048 (C)610-547-1148 binbin.wu@gunet.georgetown.edu

ABR CERTIFICATION:

Passed Radiologic Physics Step 1 exam

EDUCATION

Ph.D., 09/2005--12/2007

Electrical Engineering, Pennsylvania State University, University Park

Major: Communications Minor: Electromagnetics

Advisor: Mohsen Kavehrad, Ph.D., W.L. Weiss Endowed Chair Professor, IEEE fellow

Thesis: Free-space Optical Communications through the Scattering Medium: Analysis of Signal Characteristics

M.S., 08/2002--08/2004

Electrical Engineering, University of Alabama in Huntsville, Huntsville

Major: Communications Minor: Electromagnetics

Advisor: John Stensby, Ph.D.

Thesis: The Stability of a First-order Phase Locked Loop with Interfering Signal Input

B.Eng., 08/1997--07/2001

Communications Engineering, Yunnan University, China

PROFESSIONAL EXPERIENCE

Medical Physicist, 1/2011-present

Department of Radiation Medicine, Georgetown University Hospital

Engaging in routine clinical work and research

- Expertise in CyberKnife treatment planning including prostate, cranial, pancreas and head and neck. Experience in prostate and cranial fusion (MRI+CT).
- Routine clinical work in weekly chart check review, IMRT QA and Monthly QA

Post-doctor fellow, 04/2008—12/2010

Department of Radiation Oncology, Johns Hopkins University

Trained as a medical physicist engaging in routine clinical work

- Proficient in Pinnacle scripting; built an automated IMRT planning into Pinnacle³ treatment planning system
- Experienced in IMRT treatment planning; independently completed over 30 clinical head-and-neck treatment plans
- In charge of the QAs and routine clinical work for 21EX and INFINITY since July 2008 under the direction of board certified medical physicists; responsible for weekly chart review, IMRT QA, CBCT QA, monthly QA and annual QA

Leading the department research effort in developing an automated IMRT treatment planning system

- Invented a novel shape relationship descriptor, overlap volume histogram (OVH), to describe the relative geometric configurations between organs and targets; a patent application based on this invention is under preparation
- Developed a clinical database containing the geometric and dosimetric information of prior patients and allowing retrieval of the information of geometrically similar patients to serve as a reference for new patients
- Created an OVH-driven automated IMRT treatment planning system; approved by IRB for clinical trial study

Curriculum Vitae
BINBIN WU, Ph.D.

Research Assistant, 06/2006--12/2007

Center for Information and Communications Technology Research, Electrical Engineering, Pennsylvania State University

Leading researcher for a DARPA (Defense Advanced Research Projects Agency) project involving statistical modeling of light signals transmitted through scattering media. My proposal superseded the theory of a principal scientist and led to tremendous savings in field experiments for the Department of Defense

- Developed an innovative physical model of Monte Carlo ray-tracing to investigate photon-medium interactions
- Successfully applied theoretic findings to build a "cloud chamber" emulator in the lab to test the model proposed in my Ph.D. thesis

Research Assistant, 08/2004--08/2005

Integrated Biometrics Laboratory, Electrical and Computer Engineering, University of Alabama in Huntsville

Leading lab researcher for a project in digital image processing area

- Manifested strong ability in algorithm development: created a new method for image segmentation and designed adaptive Gabor filter banks for image enhancement
- Applied proficient Matlab and C++ skills to develop a GUI-based fingerprint recognition system

Research Assistant, 08/2003--08/2004

Communications Laboratory, Electrical and Computer Engineering, University of Alabama in Huntsville

Conducted research in the phase locked loop applied to radar. Research results were the basis of my master thesis and a presentation to an IEEE conference

- Developed a mathematical model of the phase locked loop with jamming signal input
- Created a phase locked loop communications circuit in the communications lab to test the model

System Engineer, 08/2001--05/2002

China Mobile, Beijing, China

Supervised the central mobile network (GSM cellular network) of Beijing area

- Provided solutions to emergent system failure; supported the customer service with technical solutions
- A great team player as highly recognized by colleagues; rewarded a bonus of 20% of annual salary for excellent performance

HONORS

- 2011 American Society for Therapeutic Radiology and Oncology (ASTRO) Annual Meeting Scientific Abstract Award
- Second position in the competition for the Best Young Investigators of 2009 Mid-Atlantic American Association of Physicists in Medicine (AAPM) chapter meeting, College Park, Maryland

SOCIETY MEMBERSHIPS

- Full member of the American Association of Physicists in Medicine
- Associate member of the American Society for Therapeutic Radiology and Oncology

PATENTS

- System and method for shape based retrieval of prior patients for automation and quality control of radiation therapy treatment plans, submitted to the Tech Transfer Office at JHU: ref.c10761

CLINICAL STUDY PROTOCOLS

- Automated IMRT planning for head-and-neck cancer, approved by IRB at JHU in May 2010; study No: NA_00037675

PUBLICATIONS

Journal Articles

1. Giuseppe Sanguineti, Shanthi Marur, Arlene Forastiere, **Binbin Wu**, Todd McNutt, Gunn Brandon, Rao Nikhil "Volumetric change of HPV-related neck lymph nodes before, during and shortly after IMRT," accepted by Head & Neck; to be published
2. **Binbin Wu**, Giuseppe Sanguineti, Misha Kazhdan, Patricio Simari, Steven Petit, Russell Taylor and Todd McNutt, "A Knowledge-based and Patient-geometry-specific Automated IMRT Treatment Planning System," submitted to Med Dos, accepted as major revision.
3. Giuseppe Sanguineti, Shanthi Marur, Arlene Forastiere, **Binbin Wu**, Todd McNutt, Gunn Brandon, Rao Nikhil, "Effect of Radiotherapy and Chemotherapy on the Risk of Mucositis during IMRT for Oropharyngeal Cancer," accepted by *Int J Radiat Oncol Biol Phys* 2011. To be published.
4. **Binbin Wu**, Francesco Ricchetti, Giuseppe Sanguineti, Misha Kazhdan, Patricio Simari, Robert Jacques, Russell Taylor & Todd McNutt, "Data-driven approach to generating achievable dose-volume histogram objectives in intensity modulated radiation therapy treatment planning," *Int J Radiat Oncol Biol Phys* 2011; 79: 1241-7.
5. Francesco Ricchetti, **Binbin Wu**, Todd McNutt, John Wong, Arlene Forastiere, Shanthi Marur, Heather Starmer & Giuseppe Sanguineti, "Volumetric change of selected organs at risk during IMRT for oropharyngeal cancer," *Int J Radiat Oncol Biol Phys* 2011; 80: 161-168.
6. Stefania Clemente, **Binbin Wu**, Todd McNutt, Vincenzo Fusco, Francesco Ricchetti, John Wong & Giuseppe Sanguineti, "Volumetric Modulated Arc therapy (VMAT) versus Intensity Modulated Radiation Therapy and Helical Tomotherapy for oropharyngeal cancer: a planning comparison study," *Int J Radiat Oncol Biol Phys* 2011; 80: 1248-1255.
7. Steven F. Petit, **Binbin Wu**, Michael Kazhdan, André Dekker, Patricio Simari, Rachit Kumar, Russel Taylor, Joseph M. Herman, Todd McNutt, "Increased organ sparing using shape-based treatment plan optimization for intensity modulated radiation therapy of pancreatic adenocarcinoma," *Radiother Oncol* 2011; article in press, online version.
8. Patricio Simari, **Binbin Wu**, Robert Jacques, Alex King, Todd McNutt, Russell Taylor, and Michael Kazhdan, "A Statistical Approach for Achievable Dose Estimation in IMRT Planning," *Lecture Notes in Computer Science* 2010; 6362: 521-528.
9. Misha Kazhdan, Patricio Simari, Todd McNutt, **Binbin Wu**, Robert Jacques, Ming Chuang & Russell Taylor, "A shape relationship descriptor for radiation therapy planning," *Lecture Notes in Computer Science* 2009; 5762: 100-108.
10. **Binbin Wu**, Francesco Ricchetti, Giuseppe Sanguineti, Misha Kazhdan, Patricio Simari, Robert Jacques, Ming Chuang, Russell Taylor & Todd McNutt, "Patient geometry-driven information retrieval for IMRT treatment plan quality control," *Med Phys* 2009; 36:5497-5505
11. **Binbin Wu**, Zeinab Hajjarian, & Mohsen Kavehrad, "Free-space optical communications through clouds: analysis of signal characteristics," *Applied Optics* 2008; 47: 3168-3176.
12. **Binbin Wu**, Brian Marchant, & Mohsen Kavehrad, "Channel modeling of light signals propagating through battlefield environment: analysis of channel spatial, angular and temporal dispersion," *Applied Optics* 2007; 46: 6442-6448.

Conference Proceedings (Full paper; Not Abstracts)

1. **Binbin Wu**, Misha Kazhdan, Patricio Simari, Russell Taylor & Todd McNutt, "A Geometry-driven Approach for Predicating DVHs of Organs at Risk in IMRT Planning," Proceedings of the XVth ICCR, Amsterdam, Netherlands, 2010
2. **Binbin Wu**, Brian Marchant & Mohsen Kavehrad, "Dispersion analysis of 1.55um free-space optical communications through a heavy fog medium," Proceedings of IEEE GLOBECOM, Washington D.C., 2007
3. **Binbin Wu**, Brian Marchant & Mohsen Kavehrad, "Optical scattering in battlefield obscurants: analysis of channel spatial, angular and temporal dispersion," Proceedings of IEEE MILCOM, Orlando, FL, 2007
4. Mohsen Kavehrad, Sangwoo Lee & **Binbin Wu**, "Frequency domain equalization of optical channel distortion in free-space optical wireless communications," Proceedings of SPIE Optics East, Boston,

Curriculum Vitae
BINBIN WU, Ph.D.

MA, 2006

5. **Binbin Wu** & John Stensby, "The stability of a first-order phase locked loop with interfering signal input," Proceedings of IEEE SSST, Atlanta, GA, 2004

Abstracts (Only first author shown here)

Oral presentation

1. A Geometry-driven Approach for Predicating DVHs of Organs at Risk in IMRT Planning, hard-core planning session, the XVth ICCR, Amsterdam, Netherlands, 2010
2. Knowledge-based and patient-geometry specific IMRT treatment planning, IMRT: Novel Planning and Delivery Techniques I session, the 52th AAPM Annual Meeting, Philadelphia, PA, 2010
3. The use of patient geometric information and a database of prior patients for IMRT treatment plan quality control, IMRT I session, the 51st AAPM Annual Meeting, Anaheim, CA, 2009
4. A data-driven approach to generating achievable dose volume histogram (DVH) objectives in Intensity Modulated Radiation Therapy (IMRT) treatment planning, PHYSICS III - IMRT and ART session, the 51st ASTRO Annual Meeting, Chicago, IL, 2009

Poster discussion

1. Fully automated IMRT planning is feasible for head-and-neck cancer: a prospective study using an overlap volume histogram (OVH) strategy, Advanced Intensity Modulation Techniques session, the 53th ASTRO annual meeting, Miami, FL, 2011
2. An OVH-driven Automated IMRT Treatment Planning System, Image guided and adaptive therapy session, the 52th ASTRO Annual Meeting, San Diego, CA, 2010

Guowei Zhang, PhD

Email: Guowei_zhang@yahoo.com

Address: 8734 Wethered Dr, Ellicott City, MD 21043

Phone: 202-444-3581 (Office), 410-349-7021 (Cell)

OBJECTIVE Per HR request

EDUCATION

- **Post-doctoral fellow**, 08/2003 – 07/2005, Medical Physics, University of Maryland, Baltimore, MD. Supervisor: Dr. Cedric Yu
- **Ph.D.** Physics, University of Ottawa, Ottawa, Canada
- **M.Sc.** Physics, University of Science and Technology Beijing, Beijing, China
- **B.Sc.** Physics, Peking University, Beijing, China

WORK EXPERIENCE

06/2009 – present, Clinical Physicist

Dept. Radiation Medicine, Georgetown University Hospital, Washington, DC

07/2005 – 06/2009, Assistant Professor (Tenure-track)

Dept. Radiation Oncology, University of Maryland School of Medicine, Baltimore, MD

Research:

- **Effects of beamlet size on IMRT plan quality.** Beamlets are used for the convenience of IMRT optimization. By modifying a TPS software system and optimized IMRT plans with different beamlet sizes, I discovered significant and continuous reduction in objective function value, mean dose to the organ at risk, and the maximum dose to the tumor target with decreases in the beamlet size.
- **Breast IMRT.** Created a motion model to calculate the severity of dose distortion due to breath motion. I found that a DAO based IMRT plan with tangential fields provides a robust and efficient technique for breast IMRT planning and delivery when the open segment weight is between 65% and 80%. Also investigated three-field IMRT for large breasts.

- **MLC tracking of respiration-related moving target.** Developed a new technique to convert static MLC segments into dynamic segments, based on the motion trajectories, for tracking the moving target. This technique improved dose coverage from 68% for no-tracking to 91% in terms of Gamma index value and improved the dose conformity.
- **MLC based grid therapy.** Programmed the Varian MLC as a grid device so that grid therapy can be preformed using the common-purposed MLC. The size of the grid openings and shape of the treatment field can be programmed. This significantly improved treatment efficiency, reduced clinical complications, and extended the availability of grid therapy.
- **Reducing intra-fraction organ motion effects using segment size constraint.** Modified a commercial TPS system to assess the clinical impact of breathing motion on the plans optimized with and without imposing segment size constraints. The plan quality was found unaffected by segment size constraints but the delivered doses under respiratory motion are far more conformal (increasing V95 by 9%) when small segments are discouraged during optimization.

Clinic:

Capable of providing independent medical physics coverage of radiotherapy operation with safety compliance, external beam irradiation, brachytherapy, and HDR, including:

- Managing a QMP program, material license application and renewal, and machine registration.
- IMRT planning on Prowess and Eclipse TPS, and IMRT verifications on various TPS.
- Brachytherapy procedures including radioactive source preparation and handling, planning and assist in prostate implant in the OR.
- HDR procedure including source calibration, QA, and treatment administration.
- Acceptance and commissioning of Eclipse 8.1 with configuration of Aria and Elekta Linac.
- Weekly, monthly and annual QAs for Elekta and Varian linacs, including TG-51.
- Routine chart checks and dosimetry and physics consultations.

Teaching:

- Supervised a PhD student on his Ph.D. research.
- Offered teaching assistance in physics course for resident.

- Conducted in-service training in IMRT planning and verification for dosimetrists and physicists.

Before 2002:

Senior Software Engineer, Sycamore Networks, Chelmsford, MA

Senior Software Engineer, Alcatel, Milpitas, CA

Software Designer, Nortel Networks, Ottawa, Canada

Software Designer, National Research Council, Ottawa, Canada

Graduate assistant, University of Ottawa, Ottawa, Canada

- Research assistant in solid state physics
- Teaching assistant in physics laboratory for undergraduate students.

Lecturer, Dept. Physics, University of Science and Technology Beijing, Beijing, China

- Research in physical properties of permanent magnetic materials of Nd-Fe-B
- Teaching physics laboratory for undergraduate students and group theory for graduate students.
- Supervised undergraduate students for graduation thesis

PROFESSIONAL MEMBERSHIP

- Member of American Association of Physicists in Medicine (AAPM) since 8/2003.

SELECTED PUBLICATIONS

Peer-reviewed journal articles

1. **G. Zhang**, Z. Jiang, D. Shepard, B. Zhang, and C. Yu "Direct aperture optimization of breast IMRT and dosimetric impact of respiration motion," *Phys. Med. Biol.* **51** N357-N369 (2006)
2. Z. Stadnik and **G. Zhang**, "Mössbauer effect study of the decagonal quasicrystal Al₆₅Co₁₅Cu₂₀," *Hyperfine Interact* (2006) 169:1291–1294
3. **G. Zhang**, Z. Jiang, D. Shepard, M. Earl, and C. Yu, "The Effect of beamlet step-size on IMRT plan quality," *Med. Phys.* **32**, 3448-3454 (2005)

4. Z. Stadnik and **G. Zhang**, "The decagonal quasicrystal $\text{Al}_{65}\text{Co}_{15}\text{Cu}_{20}$ studied by the Mössbauer," J. Phys.: Condens. Matter **17** 6599-6608 (2005)
5. Z. Stadnik and **G. Zhang**, "Mössbauer effect study of the decagonal quasicrystal $\text{Al}_{70}\text{Co}_{15}\text{Ni}_{15}$," J. Phys. Condens. Matter **16** 7303-7312 (2004)
6. **G. Zhang**, Z. Stadnik, A-P. Tsai, A. Inoue, and T. Miyazaki "Electronic Structure of Icosahedral Alloys: the Case of $\text{Al}_{65}\text{Cu}_{20}\text{Os}_{15}$," Z. Phys. B **97** 439-452 (1995)
7. Z. Stadnik, **G. Zhang**, A-P. Tsai, and A. Inoue, "Electronic Structure of Decagonal $\text{Al}_{65}\text{Co}_{15}\text{Cu}_{20}$ and $\text{Al}_{70}\text{Co}_{15}\text{Ni}_{15}$," Phys. Rev. B **51** 11 358-11 368 (1995)
8. Z. Stadnik, **G. Zhang**, A-P. Tsai, and A. Inoue, "Electronic Structure of Icosahedral $\text{Al}_{65}\text{Cu}_{20}\text{Ru}_{15}$ Studied by Photoemission Spectroscopy," Phys. Rev. B **51** 4023-4041 (1995)
9. Z. Stadnik, **G. Zhang**, A-P. Tsai, and A. Inoue, "Are Decagonal Quasicrystals the Hume-Rothery Phases?" Phys. Lett. A **198** 237-242 (1995)
10. **G. Zhang**, Z. Stadnik, A-P. Tsai, and A. Inoue, "Electronic Structure of Icosahedral $\text{Al}_{70}\text{Pd}_{20}\text{Mn}_{10}$, Phys. Rev." B **50** 6696-6708 (1994)
11. **G. Zhang**, Z. Stadnik, A-P. Tsai, and A. Inoue, "Photoemission Study of $\text{Al}_{70}\text{Pd}_{20}\text{Mn}_{10}$ Quasicrystal," Phys. Lett. A **186** 345-350 (1994)
12. **G. Zhang**, Z. Stadnik, A-P. Tsai, and A. Inoue, "Photoemission Study of Icosahedral $\text{Al}_{70}\text{Pd}_{20}\text{Mn}_{10}$," Sci. Rep. RITU **A39** 169-173 (1994)
13. Z. Stadnik, **G. Zhang**, A-P. Tsai and A. Inoue, "A Resonant Photoemission Study of the $\text{Al}_{65}\text{Cu}_{20}\text{Ru}_{15}$ Icosahedral Alloy," J. Phys. Condens. Matter **6** 6885-6893 (1994)
14. S. Luo, **G. Zhang**, Z. Liu, X. Pei, and W. Jiang, "Crystal Structure and magnetic properties of $\text{Sm}_3\text{Fe}_{20}\text{C}_x$ intermetallic Compounds," J. Mag. Mag. Matter. **70** 311-312 (1987)

Abstracts

1. **G. Zhang**, Y. Niu, Z. Jiang, B. Yi, D. Kessel, L. Ampey III, and C. Yu, "Three-Field IMRT for Large Breasts", *Med Phys.* **35** (2008)
2. **G. Zhang**, B. Yi, Z. Jiang, and C. Yu, "Reducing intra-fraction organ motion effects using segment size constraint in direct aperture optimization", *Med. Phys.* **34** 2524 (2007)
3. **G. Zhang**, J. Ha, B. Yi, D. Nazareth, S. Van Liew, W. D'Souza, Z. Jiang, and C. Yu, "MLC tracking of respiration-related target motion", *Med Phys.* **33** 2042 (2006)
4. J. Ha, **G. Zhang**, S. Naqvi, W. Regine, and C. Yu, "Feasibility of delivering grid therapy using a multileaf collimator," *Med. Phys.* **33** 76-82 (2006)
5. **G. Zhang**, Z. Jiang, D. Shepard, B. Zhang, C. Yu, "The Effect of breast motion on dose distribution in tangential IMRT with direct aperture optimization," *Med. Phys.* **32** 1970 (2005)
6. J. Ha, **G. Zhang**, S. Naqvi, W. Regine, C. Yu, "Dosimetric Study of Grid Therapy Using a Multileaf Collimator," *Med. Phys.* **33** 2021 (2005)
7. **G. Zhang**, and C. Yu, "The Effect of beamlet size on IMRT," *Med. Phys.* **31** 1920 (2004)
8. **G. Zhang**, Z. Stadnik, "Partial and Total Densities of States in Icosahedral $\text{Al}_{70}\text{Pd}_{20}\text{Mn}_{10}$," *Proc. 5th Intl. Conf Quasicrystals*, Avignon, France, edited by CH Janot, 552-555 (1995)
9. Z. Stadnik, **G. Zhang**, A-P Tsai, and A. Inoue, "Synchrotron-Radiation Studies of Valance bands in Stable, Decagonal Electronic Structure of Decagonal $\text{Al}_{65}\text{Co}_{15}\text{Cu}_{20}$ and $\text{Al}_{70}\text{Co}_{15}\text{Ni}_{15}$," *Aperiodic'94, Proc., Intl. Conf. Aperiodic Crystals*, edited by G. Chapuis 254-258 (1995)
10. Z. Stadnik, **G. Zhang**, A-P. Tsai, and A. Inoue, "Photoemission Studies of Stable, Icosahedral Alloys," *Aperiodic'94, Proc., Intl. Conf. Aperiodic Crystals*, edited by G. Chapuis 249-253 (1995)
11. Z. Stadnik, **G. Zhang**, A-P. Tsai, and A. Inoue, "Physical properties of Al-Cu-Fe-Mn Icosahedral Alloys," *Proc., 5th Intl. Conference on Quasicrystals*, Avignon, France, edited by CH Janot, 530-533 (1995)

Exhibit 40

Proton Accelerator on the Way to Siteman

Contact:

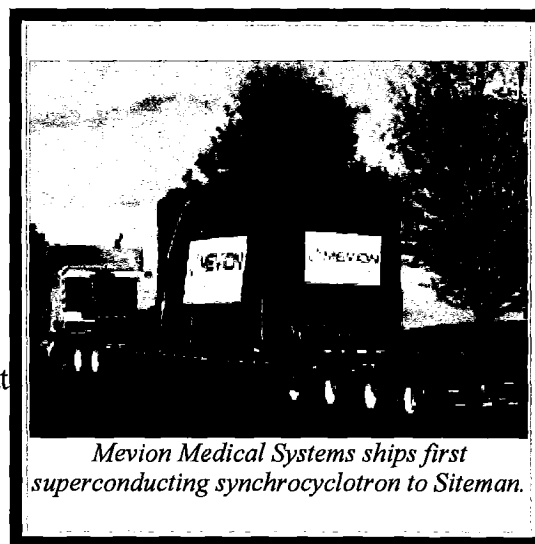
Jason Merrill

314-286-0302

jmerrill@bjc.org

Oct. 27, 2011 – The cross-country delivery of a technology that could revolutionize radiation therapy for many cancer patients is making its way to St. Louis and the Siteman Cancer Center at Barnes-Jewish Hospital and Washington University School of Medicine.

The world's first superconducting synchrocyclotron proton accelerator is scheduled to arrive at Siteman's Kling Center for Proton Therapy at the corner of Euclid and Forest Park avenues on Sunday, Oct. 30. The accelerator is a key component of the Mevion S250 Proton Therapy System that is currently being installed at the Kling Center. It left the headquarters of manufacturer Mevion Medical Systems in Littleton, Mass., on Oct. 25.



Proton therapy is a highly accurate form of radiation therapy used to treat tumors near vital organs like the spine, brain, heart and eye in adult and pediatric patients.

"Protons allow us to target tumors with greater precision because we can adjust the depth of the radiation," says Washington University radiation oncologist Jeffrey Bradley, MD, Kling Center director. "We then avoid a collateral dose that exposes other organs and healthy tissue."

The issue that has hindered the technology's expansion is expense. Existing proton facilities in the U.S. have cost in excess of \$150 million to build due to the size of the current generation of cyclotrons. So far these cyclotrons have required free-standing, football field-sized buildings that deliver protons to three or four "vaults" for patient treatment. Currently, the closest location to St. Louis offering proton therapy is more than 220 miles away.

The Kling Center for Proton Therapy will cost about \$25 million and will employ a superconducting cyclotron that is so small, it will be housed in a single room not much larger than a traditional radiation therapy room. The cost of this single-vault proton therapy approach – the first of its kind in the nation – will be only a fraction of the investment needed for current proton therapy systems.

"Our role in helping bring this technology from laboratory to clinical use should eventually make this treatment available to many more across the country," Bradley says. "It is much more affordable than the current delivery system and occupies a fraction of the space."

The Mevion S250 Proton Therapy System has not been cleared by the U.S. Food and Drug Administration (FDA) for clinical use. Administrators at Siteman and Barnes-Jewish Hospital hope to begin treating patients by the end of 2012. Once FDA approval is obtained, the center should treat about 25 patients a day, primarily children and adults with brain tumors or cancers of the skull base,

head and neck area, spinal cord and eye. The center also will offer new therapies for lung, abdominal, prostate and other cancers.

“This therapy will allow us to offer new ways to treat many types of cancers,” says Bradley, who serves as the S. Lee Kling Associate Professor of Radiation Oncology. Through the named professorship, he receives permanent support to lead a team of researchers who investigate how to best use proton therapy to meet patient needs.

From the St. Louis Business Journal

:<http://www.bizjournals.com/stlouis/print-edition/2012/05/25/siteman-cancer-center-preps-proton.html>

Siteman Cancer Center preps proton therapy treatment

Premium content from St. Louis Business Journal by Vince Brennan, Section Editor

Date: Friday, May 25, 2012, 5:00am CDT



Vince Brennan

Section Editor- *St. Louis Business Journal*

Email | Twitter

After six years of planning, training and waiting, the Siteman Cancer Center at Barnes-Jewish Hospital and Washington University School of Medicine is finally ready to unveil its new proton beam accelerator later this year. Dr. Jeffrey Bradley, Washington University associate professor, Siteman Cancer Center radiation oncologist and director of the Kling Center for Proton Therapy, said the new proton therapy technology, called a superconducting synchrocyclotron proton accelerator, could begin treating cancer patients in October, pending FDA approval. The \$20 million system, which arrived at Siteman last October, is the first of its kind in the world because of its small size compared to existing proton beams that are typically housed in football field-sized buildings.

Proton therapy is a form of radiation therapy used to shrink tumors near vital organs like the spine or brain.

Bradley spoke with the *Business Journal* about the process of bringing the technology to St. Louis and its projected ability to treat cancer patients.

Can you give me some background on your involvement in bringing the technology to St. Louis?

As the director of the Kling Center for Proton Therapy, I was part of the initial planning process to bring the technology to the center. Discussions began in 2006 and the contract started in 2008. The process has been a long time coming.

Why has the process to bring this kind of technology to St. Louis taken so long?

This is the first single-room proton therapy unit in the world. The type of equipment is called a synchrocyclotron, and usually, they are large proton generating units that take up several buildings in a hospital. This unit is about the size of your kitchen table, much smaller. It's small enough that it can rotate around the room and provide treatment at different areas.

Is the schedule on track for an October opening?

We are aiming for October or November. There is a little bit of leeway with the FDA (Food and Drug Administration) approval process. We are not allowed to schedule a patient without FDA approval. We haven't talked to any patients about setting up appointments, but we have done a bit of referring physician education on it.

How is this system different than other proton therapy systems?

All existing facilities in the world have these synchrocyclotrons that occupy a space the size of a football field. The proton beam goes from one room to the second room and the third and it rotates to each room. This unit is much smaller. The beam characteristics are the same as other units, and because it's smaller, it can rotate around the room so it can be used at different angles.

Explain how this is a more effective method for treating cancer patients.

Protons have a charge and a weight/mass. Because it has a charge and a mass it can go inside a patient and you can choose how far you would like the beam to go. Unlike an X-ray which goes all the way through, protons stop in tissue and you can avoid normal tissue that doesn't need to be treated. Because of the accuracy of the beam, you can drastically reduce side effects.

Who are the target patients for this type of therapy?

The patients who will benefit the most are children. Given that we have **St. Louis Children's Hospital** nearby, we expect about 25 percent of our patient volume to be kids. We expect many kids to come from outside the St. Louis area for this kind of treatment. Of course, we will use it for other things. It will also be used to treat sarcoma and there is substantial literature out there for treating lung and liver cancer with protons. We will not be targeting prostate cancer unless the patient is in some sort of research study.

What type of increase do you expect in the number of patients Siteman treats due to proton therapy?

Most proton centers would start slower and you build up to a number of patients. We plan on getting up to full speed in three months and our average number of patients would be about 20 to 25 in a day, which is typical for a radiation machine. Like other cancer treatment centers, it will take some time to ramp up to that level.

What is the latest with the unit's approval by the FDA?

FDA approval could come within a month. Any new medical device has to get approval by the FDA before it's offered to the public. What is different about this is that it isn't the first proton device out there, but we're approving an existing methodology. This process has a little shorter track than if it was a completely new technology. Mevion (the company who makes the unit) has been working closely for the past two years with the FDA and they have had ongoing dialogue back and forth. We are expecting a ruling in June and it could be approved or they could request more info. That decision should happen well before we are open.

Any additional staff or training necessary for the new technology?

The center will hire about six additional staff members that would run the new treatment room. There is ongoing training and that is part of my job to direct. We have hired three new staff members and sent them around the country for additional training at other proton therapy centers.

Exhibit 41

K120676



JUN - 4 2012

February 29, 2012

**S-250, Proton Radiation Beam Therapy System
Premarket Notification (510(k)) Summary**

Introduction

This document provides a summary of the safety and effectiveness information contained in the Mevion S-250 Proton Radiation Beam Therapy System Premarket Notification (510(k)). This Premarket Notification (510(k)) Summary contains no confidential or trade secret information and is intended for full public disclosure and distribution. For addition information, please contact the Establishment's contact listed below, Thomas H. Faris.

Premarket Notification Information

1. Previous Notificaton Information:
 - a. Previous Submission #: I060690, K093347, K082165
 - b. Previous FDA Clearance Date None
 - c. Product Name S-250

2. Product Information
 - a. Product Name S-250
 - b. Common/Usual Name Proton Radiation Beam Therapy System

3. Classification Informaiton
 - a. Classification Name Charged Particle Radiation Therapy System
 - b. Product Code LHN
 - c. CFR Reference 21 CFR 892.5050
 - d. Product Classification Class II
 - e. Review Panel Office of In Vitro Diagnostic Device Evaluation and Safety



4. Establishment Information

- | | |
|------------------------------------|---|
| a. Submitter | Mevion Medical Systems |
| b. Submitter Type | Manufacturer (no sterilization) |
| c. Establishment Number registered | TBD (not registered yet, to be post submission) |
| d. Establishment Contact | Thomas H. Faris |
| e. Contact Title | VP RA/QA |
| f. Contact Phone | 650-996-1192 |
| g. Contact Email | tfaris@Mevion.com |

S-250 Intended Use Statement

The S-250 is intended to deliver proton radiation treatment to patients with localized tumors or any other conditions susceptible to treatment by radiation.

S-250 Indications for Use Statement

The S-250 is a medical device indicated for the delivery of radiation for the treatment of patients with localized tumors or other conditions susceptible to treatment by radiation.

Description of the Product / Technological Characteristics

The S-250 is a low cost, one-room integrated device designed to administer proton radiation treatments to patients through delivery of a predetermined radiation dose to a pre-determined three dimensional treatment target volume in a manner that protects the patient, and hospital staff, from unnecessary exposure to radiation and other hazards.

The S-250 design requires a very compact proton accelerator which is supported on a rotating gantry such that a proton treatment beam can be directed toward the rotational center of the gantry over a range of about 180 degrees (straight up to straight down). The gantry holds the cyclotron at a large enough distance from the rotating arm(s) that a full treatment room floor can be extended around the treatment center and a treatment couch can support a patient over a large rotational (couch) range at isocenter.

The system will be a completely integrated system incorporating all functionality necessary to efficiently treat patients with proton beams. As such it incorporates near real time radiographic based patient alignment and coupled patient support



devices (couch) with broad flexibility for supporting the patient relative to the treatment beam. The couch is capable of six-degree-of-freedom adjustment and be able to rotate about a vertical axis in a range of about 270 degrees, so as to provide full coverage of beam directions typically used in radiation therapy

To keep high precision of alignment of the field specific device (range compensator and apertures) to the patient, these devices will be supported on a separate gantry, close to the treatment center and not physically connected to the large gantry supporting the cyclotron. This will lighten the aiming requirements for the large gantry.

The S-250 is a proton beam irradiation system, which provides a therapeutic proton beam for clinical treatment. It is designed to deliver a proton beam with the prescribed dose and dose distribution to the prescribed patient treatment site as provided by a separately marketed Treatment Planning System (TPS) not distributed by Mevion Medical Systems. The S-250™ is comprised of two main components. One is a beam delivery system whose primary responsibility is to ensure that the prescription parameters are properly delivered. The other is the beam generating system whose function is to generate the proton beam and direct it to the beam delivery system.

Technological Comparison:

The Mevion S-250 does not require new technical innovations beyond existing technologies, as described below:

High field magnet - A magnetic field of sufficient strength everywhere in the cyclotron to meet the requirements for reasonable single treatment room implementation. Magnets of this field strength are made with superconducting wire.

Radiofrequency System - Rapidly varying radiofrequency systems have been constructed for synchrocyclotrons in the past.

Ion Source and Cyclotron Central Region - The Ion Source / Central region takes into account the very small radius of curvature of the low energy ion beam in very high magnetic fields. This will require that any physical object spanning the acceleration plane to be much smaller than the orbit to orbit spacing achieved with the given radiofrequency power / voltage.

Beam Extraction System - Follows the design of previous synchrocyclotrons and superconducting cyclotrons. However this will be the highest magnetic field cyclotron so that design of the magnetic field perturbations with machined steel magnet pole pieces will be more constrained than in prior experience.

The Vacuum System - designed using conventional components.



The Gantry - constructed of steel and aluminum components fastened together by welds and/or bolts in conventional fashion.

Field Shaping - a straightforward design extension of the double scattering systems developed by Gottschalk et al at the Harvard Cyclotron.

Dosimetry - designed and constructed following conventional radiotherapy beam dosimetry standard techniques.

C-Inner Gantry, Applicator and Applicator Changing System - does not require any advanced design or fabrication techniques.

Radiographic systems - straightforward adaptation of existing digital radiographic systems (x-ray tubes, generators, and amorphous silicon imaging panels).

Predicate Devices and Substantial Equivalence Determination

1) Harvard Cyclotron Lab

- Harvard Cyclotron
- Pre-Amendment

2) IBA

- Proteus 235 Proton Therapy System
- K060695, K053641, K061913, K053641, K983332, K983024

3) LLUMC, Fermi National Accelerator Lab

- Loma Linda University Proton Therapy System
- K872369

4) Indiana University Cyclotron Facility

- Proton Therapy System
- K062891

5) Hitachi

- PROBEAT
- K053280

6) Varian

- pt2 varian proton therapy system
- K101294

The S-250 and the device predicates produce a clinically viable proton beam to be delivered to provide radiation therapy. The S-250 is Substantially Equivalent to the



above listed devices. The proton therapy systems have substantially the same Intended Use and principles of operation, and are substantially equivalent in terms of performance and technological characteristics. All of these medical devices comprise proton beam production technology and delivery systems that localize proton radiation at the patient's treatment site. Patients are put into correct treatment location by positioning and targeting systems.

Like each of the predicate devices, the S-250 is designed to produce and deliver a proton radiation beam for patient treatment, when radiation therapy is indicated as an appropriate course of treatment. And, equivalent to predicate Indications For Use statements, the S-250 is intended for the therapeutic delivery of proton beam radiation for the treatment of localized tumors or other conditions that are susceptible to radiotherapy treatment.

There are no technological differences between the S-250 and its predicate devices that raise new questions of safety or efficacy. Performance data demonstrates that the S-250 is as safe and effective as the predicate devices listed herein. Thusly, the S-250 is substantially equivalent to the listed predicate devices.

Clinical Demonstration of Efficacy

The S-250 Proton Beam Radiation Therapy System offers no additional or changed diagnostic or therapeutic claims beyond the stated predicate devices. Therefore, demonstration of clinical efficacy is not a required element of this premarket notification. However, this Premarket Notification includes a Clinical Data Evaluation Report that summarizes peer-reviewed literature related to the clinical efficacy and safety proton beam radiation therapy systems.

Device Safety

The S-250 is a medical device that is to be used in a treatment or therapy setting under the supervision and control of appropriately trained health care professionals who are responsible for the correct performance and delivery of radiation therapy.

The S-250 System Hazard Analysis was performed to determine and evaluate all potential health and safety hazards associated with treatment system use and operation. All foreseeable system hazards, effects, and causes have been evaluated to determine necessary and appropriate risk mitigations. Verification and validation, risk mitigation traceability, design review, and final reporting have been performed to ensure effective implementation of the stated risk mitigations. Risk analysis shall be evaluated incident to all product design and development changes. The design and development teams have determined that the product does not pose unreasonable health or safety risk to patients, users, other bystanders.



Quality System

The Mevion quality system is committed to creating and continually improving quality products, processes, and services to promote safety, effectiveness, and customer satisfaction. Mevion Medical Systems seeks to continually strive for more efficient and effective processes, as well as comply with regulatory requirements. All employees receive extensive training and management holds high the concept of a quality culture. The company takes great pride in the value that is contributed to its products, processes, and eventually to be realized by its customers and their patients.

The Mevion Medical Systems' quality system was developed and maintained in compliance with the following standards and regulations:

- FDA's Quality System Regulations
- ISO 9001
- ISO 13485
- ISO 62304
- ISO 14971
- 93/42/EEC – The Medical Device Directive (MDD)

Verification and Validation Testing

Design Reviews have been held at pertinent phase passage points to review and validate the fulfillment of all of the phase requirements and deliverables, always including product safety and efficacy consideration. Verification and Validation Plans have been created to define the overall plan for completing product/project modular, integration, and full system testing and assessment. Verification and Validation Protocols have been prepared to ensure adequate testing of all defined product design requirements and specifications. A Traceability Matrix has been created to ensure fulfillment of all design requirements. Verification and Validation Test Reports are created to evaluate the acceptability of test results and product module / product release preparedness. All applicable design and development and verification and validation activities and records have been completed to ensure safety and efficacy of the final S-250 Proton Beam Radiation Therapy System (or will be completed prior to submission of the applicable records).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Mr. Thomas H. Faris
Vice President, RA/QA
Mevion Medical Systems, Inc
300 Foster Street
LITTLETON MA 01460

JUN - 4 2012

Re: K120676

Trade/Device Name: S-250 Proton Beam Radiation Treatment System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LHN
Dated: May 23, 2012
Received: May 25, 2012

Dear Mr. Faris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

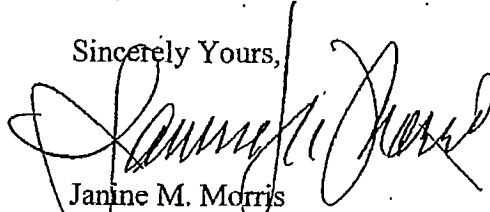
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name and title.

Janine M. Morris
Acting Director

Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K120676

Device Name: **S-250 Proton Beam Radiation Treatment System**

Indications for Use:

The S-250 is intended to deliver proton radiation treatment to patients with localized tumors or any other conditions susceptible to treatment by radiation.

The S-250 is a medical device indicated for the delivery of radiation for the treatment of patients with localized tumors or other conditions susceptible to treatment by radiation.

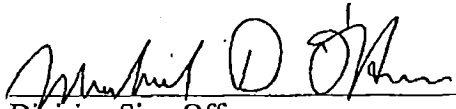
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety


Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K120676

DISTRICT OF COLUMBIA
DEPARTMENT OF HEALTH
STATE HEALTH PLANNING AND DEVELOPMENT AGENCY
899 North Capitol Street, NE
WASHINGTON, DC 20002

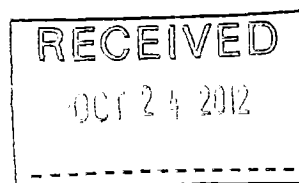
APPLICATION FOR CERTIFICATE OF NEED

Registration No. 12-3-9

Establishment of a Proton Therapy Service at
MedStar Georgetown University Hospital (MGUH) /
Lombardi Comprehensive Cancer Center (LCCC)

PROTON BEAM THERAPY ARTICLES

October 24, 2012



**APPLICATION FOR CERTIFICATE OF NEED
Registration No.12-3-9**

TABLE OF CONTENTS

1. "Number of Patients Potentially Eligible for Proton Therapy" (*Acta Oncologica*)
2. "Explaining Proton Therapy" (American Society of Clinical Oncology)
3. "Proton Therapy: What is Proton Therapy and How Is It Used?"
(Radiological Society of North America)
4. "Proton Therapy" (U.S. National Library of Medicine)
5. "Proton Therapy" (NewsChannel 5 WTVF-TV Nashville)
6. "The Power of Proton Therapy" (*Symmetry*)
7. "Mevion S-250 Receives FDA 510(k) Clearance" (The Advisory Board Company)

Attachment 1

ORIGINAL ARTICLE

Number of patients potentially eligible for proton therapy

BENGT GLIMELIUS¹, ANDERS ASK², GÖRAN BJELKENGREN³, THOMAS BJÖRK-ERIKSSON⁴, ERIK BLOMQUIST¹, BENGT JOHANSSON⁵, MIKAEL KARLSSON⁶ & BJÖRN ZACKRISSON⁷

¹Department of Oncology, Radiology and Clinical Immunology, Akademiska sjukhuset, Uppsala and Department of Oncology and Pathology, Karolinska Institutet, Stockholm, ²Department of Oncology, University Hospital, Lund, ³Department of Oncology, University Hospital, Malmö, ⁴Department of Oncology, University Hospital, Gothenburg, ⁵Department of Oncology, University Hospital, Örebro, ⁶Department of Radiation Physics, University Hospital, Umeå and ⁷Department of Oncology, University Hospital, Umeå, Sweden

Abstract

A group of Swedish radiation oncologists and hospital physicists have estimated the number of patients in Sweden suitable for proton beam therapy in a facility where one of the principal aims is to facilitate randomized and other studies in which the advantage of protons can be shown and the magnitude of the differences compared with optimally administered conventional radiation treatment, also including intensity-modulated radiation therapy (IMRT) and brachytherapy, can be shown. The estimations have been based on current statistics of tumour incidence in Sweden, number of patients potentially eligible for radiation treatment, scientific support from clinical trials and model dose planning studies and knowledge of the dose-response relations of different tumours together with information on normal tissue complication rates. In Sweden, it is assessed that between 2200 and 2500 patients annually are eligible for proton beam therapy, and that for these patients the potential therapeutic benefit is so great as to justify the additional expense of proton therapy. This constitutes between 14–15% of all irradiated patients annually.

Radiation therapy plays an important role in curative and palliative tumour treatments and projections show that it will in the future play an even increasingly important role [1–3]. It has continuously improved ever since radiation beams were detected more than a century ago, and this improvement is likely to continue. Radiation therapy research and development, however, also faces many challenges, some of them financial [2]. In spite of large investment costs, radiation therapy remains a comparatively low-cost curative treatment modality [4]. In radiation therapy, investment costs of equipment have to be borne by the hospitals/providers of health care, in contrast for example to medical oncology, where all investment costs are borne by the drug companies, in the hope of new drugs being paid for by hospitals for each individual patient as a result.

Protons have physical properties that will confer dose distribution advantages compared to the conventional rays, photons and electrons. These

advantages will result in lower doses to surrounding, non-tumour-containing tissues with reduced acute and late toxicities, and/or higher doses to the tumour with increased probabilities of tumour control. The lower doses to normal tissues may also result in improved tolerance of chemotherapy or other drugs which are being increasingly given with radiation [5]. The distribution advantages may convince fellow radiation oncologists, and thus the experts, but a proven effect on patient-related outcomes must be shown to convince the non-experts [6–8]. Still, dose distribution advantages have generally been sufficient in the past to motivate new investments in high technology treatments. This is no longer the case, partly because of financial constraints, but mainly due to recognition of the importance of evidence-based medicine [6,9,10]. The dose distribution advantages using protons, seen in a number of comparative dose planning studies, must be explored in properly controlled clinical trials to prove

a sufficiently increased clinical gain in increased tumour cure or improved tolerability.

In spite of almost 43 000 patients being treated with protons worldwide [11], there is an almost complete lack of controlled clinical trials. This is not to say that conclusions cannot be drawn regarding the value of proton therapy from this extensive clinical experience. The many thousand patients with uveal melanoma who have been treated have given 95% local tumour control after 15 years and a retained eye in 84% of cases [4,12]. These results are unlikely to be achieved with any other technique, at least not in cases of larger tumours and tumours located close to the optic nerve. Similarly, the results from the thousands of patients with skull base tumours who have received proton or ion beam treatment have shown clear advantages in the form of better tumour control with unchanged risk of complications compared with those attainable with conventional types of radiation [6,13,14]. Similar experience has been achieved in several studies in the treatment of solid tumours in children. Some improvements in oncology are so evident that randomized clinical trials are impossible to run, being actually unethical. However, patient selection is also important for outcome, and apparently marked improvements may frequently turn out to be absent or at best marginal when the properly controlled clinical trials are performed. This also applies to radiation therapy.

In order to provide better knowledge about the clinical value of proton therapy, prior to a decision to invest in a facility capable of running large clinical trials, i.e. to create better scientific evidence, a national group of experts evaluated the entire literature to estimate the potential number of patients for whom there are potentially sufficient clinical gains to motivate the higher investment costs. A report was originally written in Swedish (available at <http://qp1.lul.se/QuickPlace/sptc/Main.nsf>) and has now been partly translated and updated to June 2005.

Methods

Estimation of potential number of patients

The number of patients for a new therapy, in this case proton therapy, depends on the number of patients with diseases where the treatment in clinical trials has proved to be better than previous therapies. Since this investigation was made to provide support for an investment in a research facility capable of revealing improved treatment results in clinical trials, the estimations cannot be based upon strong evidence from clinical trials.

A systematic approach to the literature was used [10,15]. A computerized search of the literature was performed in Medline and in the Cochrane Library. These searches had to include mainly clinical trials providing limited scientific information (phase I and II trials) as well as model studies comparing dose distributions achieved with conventional techniques and protons. These model studies have, in one or a limited number of patients, compared the dose distributions achieved with different radiation techniques. They have generally evaluated the physical dose distributions but sometimes also used biological models, estimating the probability of tumour control (TCP) and the probability of normal tissue complications (NTCP).

The number of patients of different ages with a certain type of cancer is obtained from population statistics, and these are well developed in the Nordic countries (e.g. Cancer Incidence in Sweden). Evidence-based indications for radiotherapy in general [16] and in specific tumour types have been estimated in several studies [17–35], and this information was used by the group to get an estimate of the number of patients with the different cancer types in different stages treated with radiation therapy. The differences between these sources of radiotherapy utilization and evidence-base have been discussed [36]. The most relevant information, for this investigation, about the number of patients irradiated was obtained from the 12-week survey performed by the Swedish Council on Technology Assessment in Health Care (SBU) group [37].

Evaluation of the literature and evidence-base for the estimations

The literature for the various diagnoses of interest for radiation therapy was first evaluated by one member of the team. A preliminary draft with conclusions was prepared. This was then scrutinized by the rest of the group and a joint manuscript prepared. The manuscript was sent to all Swedish radiation therapy experts in the different diagnoses, and modifications were made. Finally, the writing was evaluated by invited specialists from the other Nordic countries and a joint decision was taken.

The scientific evidence for proton therapy is not very high according to generally held agreements [10]. In Table I, describing the potential number of patients eligible for proton therapy, the tumour types are ranked according to the clinical experience reported so far, albeit from phase I and II trials only, differences seen in the dose planning model studies, and knowledge about dose-response relationships. For those listed in the top there is very high or high support that protons will be used in

Table I. Estimate of the number of cases from Sweden eligible for proton beam therapy.

Tumour type ¹⁾	No. new cases in Sweden per annum	No. radiotherapy treatments in Sweden per annum ²⁾	Suitable no. patients proton therapy
Intraocular melanoma	75	?	15
Skull-base chordoma/chondrosarcoma	30	?	20–25
Meningeoma	300	40	30–40
AVM	70	?	20–25
Medulloblastoma	30	30	20
Reirradiations		?	150–400
Paediatric cancer (not incl. medulloblastoma)	300	90–100	60–80
Pituitary adenoma	?	?	10–15
ENT cancer-nasopharynx/sinus	80	80	60
Sarcoma	375	175	40
ENT cancer-others	920	570	240
Oesophageal cancer	400	150	80
Rectal cancer	1800	830	150
Breast cancer	6300	3370	300
Thymoma	30	?	20
Lung cancer	2850	485	350
Gynaecological cancer	2700	650	50
Malignant gliomas	375	200	50–75
Cancer of the liver	400	70?	65+
Mesothelioma	100	?	20
Prostate cancer	7800	1420	300
Malignant lymphomas	2000	460	20
Urinary bladder cancer	2300	180	?
Pancreatic cancer	800	50	50?
Gastric cancer	1100	70?	?
Palliations			90
	31 050	7650 ³⁾	2220–2475+

¹⁾ The tumour types are listed according to the support in favour of these treatments being given with protons in routine medical care (at the top) or that there are very good (middle) and good prospects (bottom), respectively, of clinical studies showing clinically relevant, "cost-effective" benefits.

²⁾ The number of patients, according to the SBU survey, receiving external radiotherapy with a curative purpose in the diagnoses evaluated.

³⁾ 9100 treatments were given to 7650 patients.

routine health care, whereas for those listed in the middle and lower part of the table there are very good or good possibilities that randomized clinical trials could show clinically relevant and "cost-effective" gains.

Results

The number of patients potentially eligible for proton therapy each year in Sweden amounts to between 2200 and 2500 (Table I). This figure constitutes about 14–15% of the number of patients ($n=16\,000$ in the year 2001 according to the SBU-survey [37]), who each year receive radiation therapy in Sweden. A brief summary is given below for each of the diagnoses. A more complete description of the various diagnoses will be found in separate articles. The diagnosis articles also contain a description of the results seen in the model dose planning studies which, without exception, reveal potential advantages using proton beams in one or several aspects compared to the conventional beams. The identified model studies

are listed in Table II, which also includes a brief description of the main results.

Intraocular melanoma

Proton irradiation is an established therapy for intraocular melanoma, mainly for large melanomas and melanomas located on or adjacent to the optic nerve and iris. Some 15 patients annually may be eligible.

Base of skull chordoma and chondrosarcoma

Better dose distribution means greater tumour control and less risk of long-term side-effects in the majority of these patients, i.e. 20–25 patients per annum. These tumours are routinely treated with protons wherever possible. Encouraging experiences have also been reported using ion therapy.

Meningeoma

Better dose distribution with less risk of long-term side-effects can imply clear advantages to 30 or 40

Table II. Comparative dose planning studies.

Reference	Year	Tumour type	Number of patients planned	Photons		Protons		Comments
				3D-CRT	IMXT	Regular	Scanned	
Suit et al. [59]	1988	Cervical cancer	1	X		X		Better dose distributions with improved local control, less toxicity
Brown et al. [60]	1989	Nasopharynx	2	X		X		Better dose distributions with improved local control, less toxicity
Urie + Gotein [61]	1989	Chordoma/ chondrosarcoma	12	X		X	X	Variably (intensity) modulated protons reduce dose to normal tissues (integral dose by 3–12%-units) compared to fixed (SOBP) protons, however, the largest difference was between protons and photons (2 patients)
Austin-Seymour et al. [62]	1990	Skull base	1	X		X		Less dose to OARs, e.g. the optic nerve
Austin-Seymour et al. [62]	1990	Prostate	1	X		X		Less dose to OARs
Tatsuzaki et al. [63]	1991	Rectum	1	X		X		Reduced dose to small bowel using protons
Archambeau et al. [64]	1992	Thalamic pediatric astrocytoma	1	X		X		Improved dose distribution, lower normal brain dose, higher tumour dose possible
Gademann & Wannenmacher [65]	1992	Pediatric retroperitoneal tumour	1	X		X		Better dose localization, less second cancers
Levin [66]	1992	Para-aortic nodes, cervical cancer	1	X		X		Higher doses could be reached using protons, improved tumour control by 10–20%
Miralbell et al. [67]	1992	Maxillary sinus	1	X		X		Less dose to OARs using a proton boost
Slater et al. [68]	1992	Tonsil	2	X		X		Superior dose distributions, higher tumour doses, less doses to OARs (chiefly mandible parotid glands)
Smit [69]	1992	Cervical cancer	1	X		X		Higher doses (by 20%) could be reached using protons, 40% increase in tumour control
Tatsuzaki et al. [70]	1992	Glioblastoma	1	X		X		Less dose to non-target brain using protons
Wambersie et al. [71]	1992	Pediatric brain tumours	3	X		X		Less dose to non-target brain using protons
Miralbell & Urie [72]	1993	Large AVM	1	X		X		Less dose to non-target brain, brain stem and optic chiasm using protons
Lee et al. [73]	1994	Prostate	12	X		X		Distinctly reduced rectal NTCP using protons in one-third of the cases, minimal gain in the remaining
Isacsson et al. [74]	1996	Rectum	6	X		X		At 5% NTCP in any organ, TCP is increased by 14%-units with protons
Isacsson et al. [75]	1997	Ewing/paraspinal	1	X		X		At 1% NTCP in spinal cord, TCP is increased by 5%-units
Miralbell et al. [76]	1997	Medulloblastoma-supratentorial target	1	X	X		X	Better sparing of normal tissues with protons and IMXT compared to conventional with less IQ-reduction
Miralbell et al. [77]	1997	Medulloblastoma-spina-techa target	1	X	X		X	Decreased dose to all OARs using protons
Sandison et al. [78]	1997	Chest wall	1	X		X		Less lung dose using protons
Isacsson et al. [79]	1998	Oesophagus	5	X		X		At 5% NTCP in any organ TCP is increased by 20%-units (from 2 to 25%) with protons
Verhey et al. [80]	1998	CNS	5	X		X		Less dose to normal brain
Fuss et al. [81]	1999	Optic nerve, gliomas	7	X		X		CI 2.9 photons, 2.3 protons, larger differences in larger tumours

Number of patients potentially eligible for proton therapy 839

Table II (Continued)

Reference	Year	Tumour type	Number of patients planned	Photons		Protons		Comments
				3D-CRT	IMXT	Regular	Scanned	
Glimelius et al. [47]	1999	Sacral chordoma	1	X		X		Lower doses to rectum and urinary bladder using one proton beam compared to 3D-CRT photons
Lee et al. [82]	1999	Lung	13	X		X		More patients could be treated to higher tumour doses using protons compared to any photon technique
Lomax [83]	1999	Nasopharynx	1			X	X	Intensity modulation show advantages when few beams are used
Lomax et al. [84]	1999	Various	9	X	X		X	Reduced medium to low dose for protons compared to IMXT
Fuss et al. [85]	2000	Pediatric optic nerve glioma	7	X		X		Reduced NTCPs, likely clinically significant for cognitive impairment
Lin et al. [86]	2000	CNS, pediatric fossa	9	X		X		Protons result in increased normal tissue sparing, e.g. the cochlea (25% of dose compared to 75% of prescribed dose)
Miralbell et al. [87]	2000	Orbital and paraorbital	4		X		X	Similar PTV coverage, lower integral doses to OARs (x1.5–1.9), predicted NTCPs (severe late tox) similarly low
Oelfke+Bortfeld [88]	2000	–			X	X	X	IMPT advantages to SOBP protons and IMXT in a theoretical study, integral dose 30% lower using IMPT vs SOBP, a factor 2–3 vs IMXT
Paulino et al. [89]	2000	Medulloblastoma	5	X		X		Lower doses to all OARs
Smith et al. [90]	2000	Multiple sites	10+	X	X	X	X	Improved clinical outcomes at all sites, reduced NTCPs/higher TCPs
Zurlo et al. [91]	2000	Pancreas/biliary	4	X	X		X	Protons allowed delivery of planned dose in all patients, not or barely possible with photons
Baumert et al. [92]	2001	CNS	7	X			X	For complex PTV shapes and when PTV close to critical organs, protons yield better dose distributions than photons for SRT
Cella et al. [93]	2001	Prostate	1	X	X	X	X	Both IMXT and IMPT gave better dose distributions than non-IM plans and less NTCP in rectum, all proton plans improved PTV homogeneity and reduced medium-low dose in normal tissues compared to the photon plans
Cozzi et al. [94]	2001	Head and neck	5	X	X		X	Protons give improved dose homogeneity, higher EUD, better preserved organ function and quality of life
Johansson et al. [95]	2002	Breast	11	X	X	X		Lowest NTCP values for protons for the heart (0.5 vs 2.1%) and lung (0.6 vs 124.7%) compared with the best other plan
Miralbell et al. [96]	2002	Pediatric rhabdomyosarcoma	1	X	X	X	X	Reduced risk of sec. malignancy by ≥ 2
Miralbell et al. [96]	2002	Medulloblastoma	1	X	X	X		Reduced risk of sec. malignancy by a factor of 8–15
Bolsi et al. [97]	2003	Small intracranial, different tumours	12	X	X	X	X	Improved CI, reduced OAR dose at all sites, less sec. cancer induction
Lomax et al. [98]	2003	Breast	1	X	X	X		Protons spare lungs and heart better than IMXT/standard treatment
Lomax et al. [99]	2003	Paranasal sinus	1		X		X	Critical structures could be spared best by protons at all dose levels
Suir et al. [14]	2003	Rectum	1		X	X		Improved dose distribution, less toxicity
Johansson et al. [100]	2004	Hypopharynx	5	X	X	X	X	Protons give lower non-target doses compared to 3D-CRT/IMXT. NTCP parotid glands 40–43% protons, 51–65% IMXT, 93+% 3D-CRT

Table II (Continued)

Reference	Year	Tumour type	Number of patients planned	Photons				Comments
				3D-CRT	IMXT	Regular	Scanned	
Mock et al. [101]	2004	Paranasal sinus	5	X	X	X		Similar CI but reduced doses to OAR (by 60%) and integral doses using protons
St Clair et al. [102]	2004	Medulloblastoma	1	X	X	X		Substantial normal tissue sparing, e.g. to the cochleas and the heart
Weber et al. [103]	2004	Paraspinal sarc	5		X		X	Similar conformity, reduced integral dose to OARs, dose escalation to 93 CGE possible with protons
Yoch + Tarbell [104]	2004	Pediatric, CNS	2	X	X	X		Better dose homogeneity and conformity
Krengli et al. [105]	2005	Retinoblastoma	3	X		X		Protons can achieve significant lens sparing and reduced risk of second malignancies
Mu et al. [106]	2005	Medulloblastoma	5	X	X		X	Risk second cancer conv RT 18%, IMXT 28%, IMPT 4%

Abbreviations: CI = conformity index; IMXT = intensity-modulated photon therapy; IMPT = intensity-modulated proton therapy; TCP = tumour control probability; NTCP = normal tissue complication probability; SRT = stereotactic radiotherapy; OAR = organ at risk; EUD = equivalent uniform dose; SOBP = spread-out Bragg peak.

patients annually. There is good experience of administering proton therapy for one week instead of the conventional five or so.

Arteriovenous malformations (AVMs)

For AVMs exceeding 10 cm³ in size, protons afford a better possibility than any other technique of achieving complete obliteration. Some 20 or 25 patients annually are potentially eligible.

Medulloblastoma

Patients with medulloblastoma and related tumours, occurring mainly in children, derive benefit from the improved dose distribution of protons. There is a degree of uncertainty regarding the number of cases, but it is estimated that at least 20 patients per annum can be treated.

Reirradiation

It is estimated that about 150 patients in need of reirradiation are potentially eligible for proton therapy every year, since the volume of tissue irradiated has to be limited according to the radiation therapy administered previously. In this way the chances of local tumour control and, accordingly, cure should be increased, at the same time as adverse effects should be reduced.

Paediatric cancer (other than medulloblastoma)

Between about 60 and 80 of the 100 or so children irradiated annually for a malignancy of one kind or another (excluding medulloblastoma) are suitable for proton therapy, since the risk of serious late complications can be reduced. It is theoretically possible to raise the radiation dose for radio-resistant paediatric tumours and achieve better tumour control.

Pituitary adenoma

Some 10 or 15 patients with endocrinologically active adenoma which, despite medical treatment, cannot be adequately controlled are suitable for proton therapy as routine treatment.

Cancer of the ear, nose and throat region

Some 30% or about 300 of the almost 1100 new cases of these cancers diagnosed annually in Sweden are judged to benefit from a higher radiation dose for better tumour control, at the same time as the radiation dose to critical organs can be reduced, and with it the risk of long-term side-effects, e.g.

xerostomia. Tumours growing in and near the base of the skull, e.g. nasopharyngeal cancer and paranasal sinus tumours are likely treated as a part of routine medical care, while other treatments should be given in studies where it is possible to show either greater tumour control or fewer long-term side-effects.

Sarcoma

Proton therapy for sarcoma is of great importance for tumours close to critical risk organs, e.g. tumours in the base of the skull, the orbit and the spine. Proton therapy may possibly also have advantages in advanced unresectable retroperitoneal sarcomas. The number of patients, however, is small, totalling about 40 per annum (skull base chordoma and chondrosarcoma are not included in this figure).

Oesophageal cancer

Increased radiation dose to the tumour simultaneously with the possibility of reducing the dose to adjacent sensitive structures may mean improved treatment outcomes. About 80 patients are judged eligible for inclusion in a clinical study.

Rectal cancer

It is estimated that primarily 150 patients annually with primarily unresectable rectal cancer growing onto adjacent organs may be eligible for proton therapy. If so, treatment of this kind can give greater tumour control, at the same time as the acute and long-term side-effects can be limited.

Breast cancer

It is estimated that primarily 300 patients in Sweden who are at risk of heart and lung adverse effects can be eligible for proton therapy, given the possibility. The risks of heart/lung complications and the risk of secondary malignancy should then be reduced to very low levels. The treatment should take place in a prospective study where the risk of complications with advanced 3D-CRT/IMRT can be quantified according to the dose to these organs, and in which the outcome for proton-treated patients can be observed after prolonged follow-up.

Thymoma

It is estimated that more than half the thymoma cases diagnosed in Sweden, corresponding to 20 patients, would be eligible for proton therapy within the framework of clinical studies, if treatment of this kind were available in Sweden. Potential benefits of

such treatment mainly comprise reduction of acute and long-term side-effects prominently occurring in connection with the large treatment volumes of the thoracic cavity and the radiation doses used today.

Lung cancer

An estimated 350 lung cancer patients annually are eligible for proton therapy. Most of them should be included in clinical studies. Proton therapy is judged in the majority of cases to present advantages in the form of less radiation to surrounding risk organs and the possibility of dose escalation, which can mean better long-term survival.

Gynaecological cancer

Brachytherapy plays an important role in the treatment of gynaecological cancer, for the achievement of local tumour control. There is very great uncertainty concerning the value of protons, but their use is unlikely to become widespread. In cases where, for some reason, brachytherapy is not technically feasible, protons can offer a possibility of increased local control compared with conventional external radiotherapy. At the present state of knowledge, the number is of the order of 50.

Malignant glioma

There is great uncertainty regarding the value of protons in cases of malignant glioma. Better dose distribution with a lower dose administered to an adjacent and apparently normal brain, and a high dose to a visible tumour with a margin, can mean better quality of life and possibly prolonged survival for 20 or 25% of the patients. This applies above all to younger patients with astrocytoma grade III, among whom survival can sometimes be long. Between 50 and 75 patients annually may become eligible for treatment, all of them in prospective studies. The number of patients potentially includable in a randomized study comparing protons with photons is 100–150.

Liver cancer

It is estimated that primarily 65 Swedish patients annually with primary cancer of the liver can be eligible for proton therapy, given the possibility. The chances of local tumour control and, accordingly, survival prospects, might then increase. The treatments should take place in randomized studies. There is a future potential here for a much greater number of patients, above all patients with metastases from colorectal cancer, than stated above.

Mesothelioma

At present this is a grim disease with a grim prognosis and little possibility of treatment. Only about 20 patients annually can be judged eligible for proton therapy, which should make possible a higher dose without any additional risk of complications.

Prostate cancer

It is estimated that in the first instance some 300 patients in Sweden annually are eligible for proton therapy, given the possibility. This therapy can give increased probability of tumour control without increased side-effects compared with the present therapy. About 200 of the 300 patients are primarily at stage T3N0, and the remainders have undergone non-radical surgery. The larger the tumour is locally, the greater the role which protons are capable of playing, but in that case the risk of distant metastasis is also greater, and the impact on total survival is impossible to assess. Local tumour control, however, is a precondition of long-term survival.

Malignant lymphoma

An estimated 20 or so patients annually with Hodgkin's lymphoma (HL) can be treated with reduced risks of long-term complications. If, however, a proton facility is available, more patients can be considered, i.e. including also certain patients with non-Hodgkin lymphoma. Knowledge based on randomized studies will probably be unobtainable, since conclusive results concerning reduced long-term complications can only be expected after 10 or 20 years follow-up.

Cancer of the urinary bladder

It is estimated that between 100 and 150 bladder cancer patients in Sweden per annum undergo radiotherapy with a curative purpose. It is impossible to judge the fraction of these patients who may benefit from proton therapy. Ion therapy is hardly to be considered, since it is uncertain whether the bladder wall can tolerate the higher biological doses which are then administered against the primary tumour located in the bladder wall.

Pancreatic cancer

Potentially up to 240 patients annually may be eligible for a clinical study evaluating proton therapy. This figure is, however, probably too high in relation to the present state of knowledge and therapy tradition, but pancreatic cancer is a diagnosis for which a clinical facility in Sweden can mean the

possibility of carrying out randomized studies to judge whether long-term survival can increase for one of the diagnoses having the worst prognosis of all cancers.

Gastric cancer

There is great uncertainty regarding the value of irradiation for gastric cancer, although a major American study has shown such a survival gain that post-operative radiation therapy in large volumes is routinely administered by many centres all over the world. Potentially, proton therapy (but not ion therapy) may prove better than any other radiation therapy, since with better tolerance the dose load can probably be reduced. Because of the great uncertainty prevailing, no attempt has been made to estimate the number of patients, and post-operative radiation therapy has yet to be accepted as routine treatment in Sweden.

Palliation

It is estimated that approximately 90 patients in need of palliation from an advanced malignant tumour should be offered symptom relief with proton therapy within the framework of clinical studies if such treatment was available in Sweden. The potential benefits of such treatment are a reduction of the acute side-effects and the possibility of improved quality of life.

Discussion

Since protons interact with tissues in much the same way as photons and electrons but with better dose distribution, it is arguable that they are virtually always at least as good as conventional radiation therapy. If the tissue surrounding the tumour is highly heterogeneous and is liable to vary, e.g. different quantities of air, there is some risk of protons giving a less certain and, consequently, inferior dose distribution in a few cases. Further, the skin-sparing effect of proton beams is less than that of photon beams, which may be of clinical importance in some instances for the cosmetic results. Since, on the other hand, protons are hardly ever inferior but can only be better, it is arguable that, if supply and cost were equal, protons would generally be used instead of photons and electrons. Thus the potential number of patients is the same as the majority of patients treated with external radiation therapy.

Since proton facility investments will always be higher and the cost of running the treatments probably also somewhat higher (it remains uncertain

by how much, especially as compared with IMRT), the cost in relation to the potential gains, i.e. cost-effectiveness, must always decide which patients protons are indicated for [38–41]. Because our knowledge of cost-effectiveness is limited, all estimates of the proportion of potentially eligible patients will be very tentative. There is no sound knowledge of what is cost-effective, and so all assessments are open to criticism. Our premises are based on the point at which we believe the medical profession will find the potential benefits great enough to justify the extra trouble and expenses entailed by “sending patients for proton therapy in a national facility”.

Similar attempts to estimate the number of patients suitable for hadrons (protons and ions, generally not separated in the studies) therapy have likely been performed by several groups prior to decisions to proceed with the process towards realisation of a treatment facility. Three such investigations have been performed in other European countries and, at least partly, published.

The Centro Nazionale Adroterapia Oncologica (CNAO) separated patients for whom hadron therapy was indicated into two categories. Category A included all tumours in which the use of proton therapy had clearly demonstrated superiority and category B tumours where improved locoregional control, possible with protons, likely would result in more patients cured. The study was originally published in 1998 [42] and updated, based upon more recent statistics and knowledge, in 2004 [43]. According to the update, 830 patients, constituting 44% of the number of patients with these diagnoses in Italy per year were candidates for elective proton therapy (category A) and more than 15 000 patients (13% of the population) for therapy in clinical trials (category B). It was totally estimated that about 16% of the irradiated patients were candidates for proton therapy. The most common diagnoses in category A (corresponding to those listed in the upper part of Table I) were uveal melanomas, paranasal sinus tumours and meningiomas of the base of the skull. In category B (middle, lower part of Table I), prostate cancer constitutes the largest group (5600 patients, 25% of irradiated patients) followed by pancreatic cancer (1800, 20%), bladder carcinoma (1700, 10%), lung cancer (1550, 5%), liver cancer (1300, 10%) and head and neck tumours (1000, 15%). In the update, an estimate was also made for the number of Italian patients eligible for carbon ion therapy of those eligible for proton therapy. About 3700, or between 3000–4000 patients, were considered as such candidates, constituting 23% of those considered candidates for proton therapy (5% of all irradiated patients). Lung cancer (1550

patients) followed by prostate cancer (1100 patients) and liver cancer (500 patients) were the most common diagnoses.

The French ETOILE project made a “one day survey” at five university hospitals, identifying 77 patients, mainly head and neck cancers ($n=31$), gliomas ($n=8$), lung cancer ($n=6$), uterus ($n=5$), gastric ($n=5$) and prostate ($n=3$), being potential candidates for hadron therapy. This figure constituted 14.5% of the number of patients irradiated. Extrapolated to 160 000 irradiated patients per year in France, 23 000 were potential candidates for hadron (proton or carbon) therapy each year [44].

A nationwide Austrian survey (MedAustron) identified all new patients starting radiotherapy during a three months period. It was then estimated that about 2000 patients, representing 5.6% of all newly diagnosed cancer patients and 13.5% of all irradiated cancer patients, were candidates for hadron (proton and ions) therapy [45]. The most common diagnoses suitable were prostate cancer (470 patients, 29% of all irradiated), head and neck tumours (251, 25%) and lung cancer (239, 27%). Primary breast cancer was not considered a candidate.

Thus we find that this Swedish study and three separate other European investigations, having very different designs, reach the conclusion that between 13–16% of all irradiated patients are suitable for proton therapy. A proportion of these, not always accurately estimated, are also suitable for ion therapy. Ideally, any estimate of the potential number of patients for a new treatment should be made by a prospective assessment during a prolonged time period. Although the figures reached in such a recording can always be criticized, since there is no clear definitions of what criteria are set for an improvement (higher TCP and/or lower NTCP) of such a magnitude that the increased costs are motivated, this was done in the MedAustron project. In order to get a reasonable estimate also of uncommon tumour types, frequently suitable for proton therapy, the estimates must be made during a prolonged time period. In this respect, three months appears reasonable. The French investigation was also made after a prospective assessment, but only of one day's duration, which makes all estimations very unreliable. The SPTC estimate was based upon a recording of all irradiated patients within the SBU report [37], but the estimations of the number of patients eligible for proton therapy was made retrospectively, based upon a literature review. In the evaluations of the potential value of proton beams for improved tumour control, we considered the SBU-estimations of gains after dose escalation [46].

Given the lack of relevant clinical information for most tumour types, we also evaluated the results of

dose-planning model studies. Similar to the differences in scientific quality between clinical trials with different designs and performance, these model studies can also be conducted with varying quality [47]. The physical evaluations can only provide an idea of whether one technique confers dose distribution advantages over another, but cannot tell how much better one treatment can be. This is possible using biological models, but, since knowledge of the size of the coefficients in the different models still is limited, these estimations must be carefully interpreted [48,49]. Relative differences between different techniques are probably more robust than absolute differences. However, absolute differences are fundamental in order to evaluate the potential number of patients gaining sufficiently from a new treatment. Due to the variability between patients and tumours, it is then necessary to include and plan several patients in order to arrive at a reasonable estimate of the absolute differences. This has rarely been done (Table II). The body of evidence from the literature that proton beams confer physical dose distribution advantages is at present so extensive that further studies provide only limited new information. Rather, they must focus on the absolute gains from proton beams to aid in the decision of what clinical study designs should be used and in the dimension of the randomized trials.

Protons or ions?

The capacity of protons and ions for improving cancer treatment has been a topic of widespread discussions in Sweden and elsewhere in recent years. These discussions have also proceeded within the Swedish Proton Therapy Centre (SPTC) project. No further description of the arguments for and against one or the other kind of radiation will be presented here. Instead, we refer to the report published by the Swedish Cancer Society [49] and to the Proceedings of the heavy charged particles in Biology and Medicine (HCPBM) and ENLIGHT meetings in Baden and Lyon, published in a supplement of Radiotherapy and Oncology in December 2004 [50].

Our primary concern being to show in clinical studies whether particle radiation offers such great therapeutic advantages that it should be part of the routine care of cancer patients, protons are the natural choice. Proton therapy is already a practical clinical treatment for a number of tumour indications, and clinical experience of proton therapy greatly exceeds that of light ion therapy. We consider that the use of ions presently is clinically immature. Furthermore, a proton therapy facility is to a great extent based on proven technology and system-

atically co-ordinated individual main components. The great difference today between proton and light ion radiation is perhaps one of facility design and operational dependability. It is reasonable to assume that necessary clinical studies, prompted for example by the great explosion of knowledge in imaging techniques, cell-, tumour- and molecular biology, can be started and completed much faster with protons than with ions.

Ions, with their high LET (linear energy transfer) component, offer potential advantages in the treatment of hypoxic and slow-growing, radiation-resistant tumours [8]. The physical advantages of ions (sharper penumbras at greater depths) over protons are probably limited and are unlikely ever to be a sole reason for the choice of ions rather than protons [52]. The biological consequences of the high LET of light ions make it of scientific interest to explore, in greater depths, the possibilities of ions improving treatment outcomes. In the long term it is very interesting to carry out comparable clinical studies of protons and ions. This is also the focus of the facility under construction in Heidelberg, Germany [51].

Given our great uncertainties concerning the relative biological effect of different parts of the ion beam, as well as the other biological effects of the high LET component, it is very hard to judge the number of cases in which ions are potentially better than protons. Light ions are contraindicated for some tumour sites, for example, for virtually all pediatric tumours, for AVMs, and for sites where the tumour is intimately connected to sensitive tissues, like oesophagus and other parts of the gastrointestinal tract, pancreas, and urinary bladder, whose preservation is important. The three estimates performed in Austria, France and Italy have considered the use of both protons and ions, but with the exception of the Italian study [43], the published material has not been detailed enough to estimate what proportion would do sufficiently better with ions than with protons. The investigations have, however, resulted in decisions to invest in combined proton and ion facilities in Vienna, Austria (MedAustron) [53], Pavia, Italy (TERA/CNAO project) [54], and Lyon, France (ETOILE) [55] within the ENLIGHT project.

Development of methods of diagnosis and tumour characterisation

Adequate delineation of tumour extent is fundamental to all radiation therapy. The requirements in this respect do not differ essentially from those for other advanced (locally) curative radiation treatment. Since, however, protons (and ions) confer very good possibilities of saving adjacent normal

tissue; the diagnostic requirements must be very high and at least on a par with those indicated by the world's leading centres. The Cancer Society, in its report on radiation therapy research in Sweden, has referred to problems with tumour imaging in Sweden [56]. Regardless of whether a proton therapy facility is built in Sweden, local tumour diagnosis needs to be reviewed and necessary improvements made. A national proton therapy facility will provide a strong incentive for co-ordinating this on a national basis. Given the purpose of most patients being examined and their treatment fully planned at their (university) home clinic, all equipment and competence must in principle be universally available.

Future development of image-based adapted radiotherapy

The possibilities of PET for staging and target definition are currently under discussion [57,58], and it seems reasonable to suppose that PET is at least superior to other staging methods for several diagnoses. Although certain studies assert that targets can be drawn better, either smaller or larger, with PET in connection, for example, with ear, nose and throat tumours and lung cancer, it is still unclear whether this entails a better treatment outcome. The importance of PET and magnetic resonance imaging (MRI) for target drawing must be studied further, primarily in prospective studies. The potential of PET, MRI and other techniques for revealing areas of the tumour which require deviations from the usual mean dosage must be investigated more closely. There is a need here for more research in Sweden, research which the proton therapy initiative may serve to accelerate.

Clinical therapy research

One express purpose of the dedicated proton beam therapy facility is to show in clinical studies how great are the advantages of protons compared to conventional radiation. The aim is to treat the majority or at least 80% of Swedish patients in clinical prospective protocols. We have identified the need of clinical therapy research for each diagnosis separately and have also briefly described suitable study designs. In certain cases randomized studies are desirable and necessary in which proton therapy, partly or completely, is one experimental arm, compared with a control arm without protons. In other case randomization can take place between protons only or as a boost treatment, or alternatively with different proton dose levels etc. There are many cases where randomized studies are neither necessary nor possible. For these cases, prospective

protocols are to be drawn up in which staging and the implementation and follow-up of therapy are defined and subjected to research-ethical review. Protocols of this kind are to be drawn up for the majority of clinical situations which can come into question for proton therapy. There will always be unusual cases where a clinical study is not feasible, e.g. extremely uncommon forms of tumour, reirradiations and special cases due to anatomical idiosyncrasy.

The Swedish Health Care system is well suited for this type of clinical trials as all citizens are fully covered by the national social security system. Patient selection will thus be based solely on clinical and scientific grounds. Efficient inclusion of patients and complete follow-up will further be secured by the planned infrastructure of the SPTC where all planning and full responsibility for the patient will remain with the regional university hospitals. Only the actual proton beam treatment will be performed at SPTC.

It is assumed that the studies will be worked out through discussions on a national (Nordic) basis, e.g. under the aegis of regional/national therapy programme groups or the planning groups supported by the Swedish Cancer Society. Mandators and peer assessors for the studies comprise those who are most interested in and suited to this function. It is hoped that responsibility for the studies and their implementation will be decentralised in Sweden, according to the research interest and competence existing.

Conclusions

After an extensive literature review, including clinical trials and model dose planning studies, it is estimated that in Sweden between 2200 and 2500 patients annually are eligible for proton beam therapy. For these patients, the potential therapeutic benefit appears to be so great as to justify the additional expense of proton beam therapy. The assessed number constitutes between 14–15% of all irradiated patients annually. Similar proportions have been reached in three other similar European investigations. Even if these four, very differently designed investigations, reached the same overall results (13–16%), major differences were found though, regarding which patient subgroups would benefit the most. These discrepancies can only be resolved in properly designed clinical trials.

A facility based on the SPTC-concept, with a distributed logistics and expert support, will offer a unique base for conclusive randomized clinical trials. Inclusion of patients in the trials will not depend on individual economical input. Further, general access

to this type of high precision therapy for all university hospitals will accelerate research in image-based individualisation of cancer therapy.

The present estimations of patients suitable for proton therapy are based on a large collection of calculations and clinical experience. Future research and development in a dedicated clinical proton facility will hopefully result in more individually adapted high precision therapy based on verified clinical evidence.

References

- [1] Hellman S. Technology, biology and traffic. *Acta Oncol* 2001;40:679–81.
- [2] Mattsson S, Brahme A, Carlsson J, Denekamp J, Forsell-Aronsson E, Hellström M, et al. Swedish Cancer Society radiation therapy research investigation. *Acta Oncol* 2002;41:596–603.
- [3] World Health Organization. www.who.int/mediacentre/news/releases/2003/pr27/en.
- [4] Norlund A. Costs of radiotherapy. *Acta Oncol* 2003;42:411–5.
- [5] Yuh GE, Loreda LN, Yonemoto LT, Bush DA, Shahnazi K, Preston W, et al. Reducing toxicity from craniospinal irradiation: using proton beams to treat medulloblastoma in young children. *Cancer J* 2004;10:386–90.
- [6] Bentzen SM. High-tech in radiation oncology: should there be a ceiling? *Int J Radiat Oncol Biol Phys* 2004;58:320–30.
- [7] Johansson KA, Mattsson S, Brahme A, Carlsson J, Zackrisson B, Turesson I, et al. Radiation therapy dose delivery. *Acta Oncol* 2003;42:85–91.
- [8] Turesson I, Johansson K-A, Mattsson M. The potential of proton and light ion beams in radiotherapy. *Acta Oncol* 2003;42:107–14.
- [9] Glimelius B, Steineck G. Low evidence of radiation therapy in prostate cancer—a plea for intensified scientific activity. *Acta Oncol* 2004;43:311–5.
- [10] Bentzen SM. From clinical trials to clinical practice: A user's guide to evidence-based oncology. *Eur J Cancer Suppl* 2003;1:77–91.
- [11] Sisterson J. World-wide charged particle patient totals. July 2005. *Particles* 2005;33:11.
- [12] Egger E, Zografos L, Schalenbourg A, Beati D, Bohringer T, Chamot L, et al. Eye retention after proton beam radiotherapy for uveal melanoma. *Int J Radiat Oncol Biol Phys* 2003;55:867–80.
- [13] Noel G, Habrand JL, Mammar H, Pontvert D, Haie-Meder C, Hasboun D, et al. Combination of photon and proton radiation therapy for chordomas and chondrosarcomas of the skull base: the Centre de Protontherapie D'Orsay experience. *Int J Radiat Oncol Biol Phys* 2001;51:392–8.
- [14] Suit H, Goldberg S, Niemierko A, Trofimov A, Adams J, Paganetti H, et al. Proton beams to replace photon beams in radical dose treatments. *Acta Oncol* 2003;42:800–8.
- [15] Goodman C. Literature searching and evidence interpretation for assessing health care practices. Swedish Council on Technology Assessment in Health Care. Stockholm: Norstedts; 1993. p. 81.
- [16] Ringborg U, Bergqvist D, Brorsson B, Cavallin-Ståhl E, Ceberg J, Einhorn N, et al. The Swedish Council on technology assessment in health care (SBU) systematic overview of radiotherapy for cancer including a prospective survey of radiotherapy practice in Sweden – 2001 summary and conclusions. *Acta Oncol* 2003;42:357–65.
- [17] Foroudi F, Tyldesley S, Barbera L, Huang J, Mackillop WJ. Evidence-based estimate of appropriate radiotherapy utilization rate for prostate cancer. *Int J Radiat Oncol Biol Phys* 2003;55:51–63.
- [18] Foroudi F, Tyldesley S, Barbera L, Huang J, Mackillop WJ. An evidence-based estimate of the appropriate radiotherapy utilization rate for colorectal cancer. *Int J Radiat Oncol Biol Phys* 2003;56:1295–307.
- [19] Foroudi F, Tyldesley S, Walker H, Mackillop WJ. An evidence-based estimate of appropriate radiotherapy utilization rate for breast cancer. *Int J Radiat Oncol Biol Phys* 2002;53:1240–53.
- [20] Tyldesley S, Boyd C, Schulze K, Walker H, Mackillop WJ. Estimating the need for radiotherapy for lung cancer: an evidence-based, epidemiologic approach. *Int J Radiat Oncol Biol Phys* 2001;49:973–85.
- [21] Nilsson S, Widmark A, Norlén BJ. A systematic overview of radiation therapy effects in prostate cancer. *Acta Oncol* 2004;43:316–81.
- [22] Zackrisson B, Mercke C, Strander H, Wennerberg J, Cavallin-Ståhl E. A systematic overview of radiation therapy effects in head and neck cancer. *Acta Oncol* 2003;42:443–61.
- [23] Ask A, Albertsson M, Järhult J, Cavallin-Ståhl E. A systematic overview of radiation therapy effects in oesophageal cancer. *Acta Oncol* 2003;42:462–75.
- [24] Glimelius B, Grönberg H, Järhult J, Wallgren A, Cavallin-Ståhl E. A systematic overview of radiation therapy effects in rectal cancer. *Acta Oncol* 2003;42:476–92.
- [25] Sirzén F, Kjellen E, Sörenson S, Cavallin-Ståhl E. A systematic overview of radiation therapy effects in non-small cell lung cancer. *Acta Oncol* 2003;42:493–515.
- [26] Strander H, Turesson I, Cavallin-Ståhl E. A systematic overview of radiation therapy effects in soft tissue sarcomas. *Acta Oncol* 2003;42:516–31.
- [27] Rutqvist LE, Rose C, Cavallin-Ståhl E. A systematic overview of radiation therapy effects in breast cancer. *Acta Oncol* 2003;42:532–45.
- [28] Einhorn N, Trope C, Ridderheim M, Boman K, Sorbe B, Cavallin-Ståhl E. A systematic overview of radiation therapy effects in uterine cancer (corpus uteri). *Acta Oncol* 2003;42:557–61.
- [29] Einhorn N, Trope C, Ridderheim M, Boman K, Sorbe B, Cavallin-Ståhl E. A systematic overview of radiation therapy effects in ovarian cancer. *Acta Oncol* 2003;42:562–6.
- [30] Einhorn N, Trope C, Ridderheim M, Boman K, Sorbe B, Cavallin-Ståhl E. A systematic overview of radiation therapy effects in cervical cancer (cervix uteri). *Acta Oncol* 2003;42:546–56.
- [31] Widmark A, Flodgren P, Damber J, Hellsten S, Cavallin-Ståhl E. A systematic overview of radiation therapy effects in urinary bladder cancer. *Acta Oncol* 2003;42:567–81.
- [32] Berg G, Blomquist E, Cavallin-Ståhl E. A systematic overview of radiation therapy effects in brain tumours. *Acta Oncol* 2003;42:582–8.
- [33] Gustavsson A, Osterman B, Cavallin-Ståhl E. A systematic overview of radiation therapy effects in non-Hodgkin's lymphoma. *Acta Oncol* 2003;42:605–19.
- [34] Gustavsson A, Osterman B, Cavallin-Ståhl E. A systematic overview of radiation therapy effects in Hodgkin's lymphoma. *Acta Oncol* 2003;42:589–604.
- [35] Falkmer U, Järhult J, Wersäll P, Cavallin-Ståhl E. A systematic overview of radiation therapy effects in skeletal metastases. *Acta Oncol* 2003;42:620–33.

- [36] Bentzen SM, Heeren G, Cottier B, Slotman B, Glimelius B, Lievens Y, et al. Towards evidence-based guidelines for radiotherapy infrastructure and staffing needs in Europe: the ESTRO QUARTS project. *Radiother Oncol* 2005;75: 355–65.
- [37] Möller TR, Brorsson B, Ceberg J, Frodin JE, Lindholm C, Nylen U, et al. A prospective survey of radiotherapy practice 2001 in Sweden. *Acta Oncol* 2003;42:387–410.
- [38] Lundkvist J, Ekman M, Rehn Ericsson S, Isacson U, Jönsson B, Glimelius B. Economic evaluation of proton radiation therapy in the treatment of breast cancer. *Radiother Oncol* 2005;75:179–85.
- [39] Lundkvist J, Ekman M, Rehn Ericsson S, Jönsson B, Glimelius B. Proton therapy of cancer: Potential clinical advantages and cost-effectiveness. *Acta Oncol* 2005;44: 850–61.
- [40] Lundkvist J, Ekman M, Rehn Ericsson S, Jönsson B, Glimelius B. Cost-effectiveness of proton radiation in the treatment of childhood medulloblastoma. *Cancer* 2005; 103:793–801.
- [41] Lievens Y, Van den Bogaert W. Proton beam therapy: too expensive to become true? *Radiother Oncol* 2005;75: 131–3.
- [42] Orrecchia R, Krengli M. Number of potential patients to be treated with proton therapy in Italy. *Tumori* 1998;84: 205–8.
- [43] Krengli M, Orrecchia R. Medical aspects of the National Centre for Oncological Hadrontherapy (CNAO-Centro Nazionale Adroterapia Oncologica) in Italy. *Radiother Oncol* 2004;73(Suppl 2):21–8.
- [44] Baron MH, Pommier P, Favrel V, Truc G, Balosso J, Rochat J. A “one-day survey”: As a reliable estimation of the potential recruitment for proton- and carbon-ion therapy in France. *Radiother Oncol* 2004;73(Suppl 2): 15–7.
- [45] Mayer R, Mock U, Jäger R, Pötter R, Vutuc C, Eiter H, et al. Epidemiological aspects of hadron therapy: A prospective nationwide study of the Austrian project MedAustron and the Austrian Society of Radiooncology (OEGRO). *Radiother Oncol* 2004;73(Suppl 2):24–8.
- [46] Svensson H, Möller T. Developments in radiotherapy. *Acta Oncol* 2003;42:430–42.
- [47] Glimelius B, Isacson U, Blomquist E, Grusell E, Jung B, Montelius A. Potential gains using high-energy protons for therapy of malignant tumours. *Acta Oncol* 1999;38:137–45.
- [48] Zackrisson B, Mattsson S, Kjellén E, Glimelius B, Swedish Cancer Society Investigation Group. Research and development of radiation therapy in clinical routines. *Acta Oncol* 2003;42:115–22.
- [49] Turesson I, Carlsson J, Brahme A, Glimelius B, Zackrisson B, Stenerlow B, et al. Biological response to radiation therapy. *Acta Oncol* 2003;42:92–106.
- [50] Proceedings of the heavy charged particles in Biology and Medicine (HCPBM) and ENLIGHT meetings in Baden and Lyon. Amaldi U, Auberger T, Debus J, Francois G, Gerard JP, Heeren G, et al, editors. *Radiother Oncol* 2004;73(Suppl 2):S1–S217.
- [51] Haberer T, Debus J, Eickhoff H, Jakel O, Schulz-Ertner D, Weber U. The Heidelberg Ion Therapy Center. *Radiother Oncol* 2004;73(Suppl 2):S186–90.
- [52] Weyrather WK, Debus J. Particle beams for cancer therapy. *Clin Oncol (R Coll Radiol)* 2003;15:S23–8.
- [53] Griesmayer E, Auberger T. The status of MedAustron. *Radiother Oncol* 2004;73(Suppl 2):S202–5.
- [54] Amaldi U. CNAO—The Italian Centre for Light-Ion Therapy. *Radiother Oncol* 2004;73(Suppl 2):S191–201.
- [55] Bajard M, De Conto JM, Remillieux J. Status of the “ETOILE” project for a French hadrontherapy centre. *Radiother Oncol* 2004;73(Suppl 2):S211–5.
- [56] Forssell-Aronsson E, Kjellén E, Mattsson S, Hellström M, Swedish Cancer Society Investigation Group. Medical imaging for improved tumour characterisation, delineation and treatment verification. *Acta Oncol* 2002;41:604–14.
- [57] Gregoire V. Is there any future in radiotherapy planning without the use of PET: unraveling the myth. *Radiother Oncol* 2004;73:261–3.
- [58] Facey K, Bradbury I, Laking G, Payne E. Positron Emission Tomography (PET) in Cancer Management. Health Technology Assessment, NHS R&D HTA Programme July 2004.
- [59] Suit HD, Becht J, Leong J, Stracher M, Wood WC, Verhey L, et al. Potential for improvement in radiation therapy. *Int J Radiat Oncol Biol Phys* 1988;14:777–86.
- [60] Brown AP, Urie MM, Chisin R, Suit HD. Proton therapy for carcinoma of the nasopharynx: a study in comparative treatment planning. *Int J Radiat Oncol Biol Phys* 1989;16: 1607–14.
- [61] Urie MM, Goitein M. Variable versus fixed modulation of proton beams for treatments in the cranium. *Med Phys* 1989;16:593–601.
- [62] Austin-Seymour M, Urie M, Munzenrider J. Considerations in fractionated proton radiation therapy: clinical potential and results. *Radiother Oncol* 1990;17:29–35.
- [63] Tatsuzaki H, Urie MM, Willett CG. 3-D comparative study of proton vs. x-ray radiation therapy for rectal cancer. *Int J Radiat Oncol Biol Phys* 1992;22:369–74.
- [64] Archambeau JO, Slater JD, Slater JM, Tangeman R. Role for proton-beam irradiation in treatment of pediatric CNS malignancies. *Int J Radiat Oncol Biol Phys* 1992;22: 287–94.
- [65] Gademann G, Wannenmacher M. Charged particle therapy to pediatric tumors of the retroperitoneal region: a possible indication. *Int J Radiat Oncol Biol Phys* 1992;22:375–81.
- [66] Levin CV. Potential for gain in the use of proton-beam boost to the para-aortic lymph nodes in carcinoma of the cervix. *Int J Radiat Oncol Biol Phys* 1992;22:355–60.
- [67] Miralbell R, Crowell C, Suit HD. Potential improvement of three dimension treatment planning and proton therapy in the outcome of maxillary sinus cancer. *Int J Radiat Oncol Biol Phys* 1992;22:305–10.
- [68] Slater JM, Slater JD, Archambeau JO. Carcinoma of the tonsillar region: potential for use of proton-beam therapy. *Int J Radiat Oncol Biol Phys* 1992;22:311–9.
- [69] Smit B. Prospects for proton therapy in carcinoma of the cervix. *Int J Radiat Oncol Biol Phys* 1992;22:349–54.
- [70] Tatsuzaki H, Gregoire V, Linggood R. Comparative treatment planning: proton vs x-ray beams against glioblastoma multiforme. *Int J Radiat Oncol Biol Phys* 1992;22:265–74.
- [71] Wambersie A, Gregoire V, Brucher JM. Potential clinical gain of proton (and heavy ion) beams for brain tumors in children. *Int J Radiat Oncol Biol Phys* 1992;22:275–86.
- [72] Miralbell R, Urie M. Potential improvement of three dimension treatment planning and proton beams in fractionated radiotherapy of large cerebral arteriovenous malformations. *Int J Radiat Oncol Biol Phys* 1993;25:353–8.
- [73] Lee M, Wynne C, Webb S, Nahum AE, Dearnaley D. A comparison of proton and megavoltage X-ray treatment planning for prostate cancer. *Radiother Oncol* 1994;33: 239–53.
- [74] Isacson U, Montelius A, Jung B, Glimelius B. Comparative treatment planning between proton and x-ray therapy in locally advanced rectal cancer. *Radiother Oncol* 1996;41: 263–72.

- [75] Isacsson U, Hagberg H, Johansson KA, Montelius A, Jung B, Glimelius B. Potential advantages of protons over conventional radiation beams for paraspinal tumours. *Radiother Oncol* 1997;45:63-70.
- [76] Miralbell R, Lomax A, Bortfeld T, Rouzaud M, Carrie C. Potential role of proton therapy in the treatment of pediatric medulloblastoma/primitive neuroectodermal tumors: reduction of the supratentorial target volume. *Int J Radiat Oncol Biol Phys* 1997;38:477-84.
- [77] Miralbell R, Lomax A, Russo M. Potential role of proton therapy in the treatment of pediatric medulloblastoma/primitive neuro-ectodermal tumors: spinal theca irradiation. *Int J Radiat Oncol Biol Phys* 1997;38:805-11.
- [78] Sandison GA, Papiez E, Bloch C, Morphis J. Phantom assessment of lung dose from proton arc therapy. *Int J Radiat Oncol Biol Phys* 1997;38:891-7.
- [79] Isacsson U, Lennernäs B, Grusell E, Jung B, Montelius A, Glimelius B. Comparative treatment planning between proton and x-ray therapy in esophageal cancer. *Int J Radiat Oncol Biol Phys* 1998;41:441-50.
- [80] Verhey LJ, Smith V, Serago CF. Comparison of radio-surgery treatment modalities based on physical dose distributions. *Int J Radiat Oncol Biol Phys* 1998;40:497-505.
- [81] Fuss M, Hug EB, Schaefer RA, Nevinny-Stickel M, Miller DW, Slater JM, et al. Proton radiation therapy (PRT) for pediatric optic pathway gliomas: comparison with 3D planned conventional photons and a standard photon technique. *Int J Radiat Oncol Biol Phys* 1999;45:1117-26.
- [82] Lee C, Tait D, Nahum A, Webb S. Comparison of proton therapy and conformal x-ray therapy in non-small cell lung cancer (NSCLC). *Br J Radiat* 1999;72:1078-84.
- [83] Lomax A. Intensity modulation methods for proton radiotherapy. *Phys Med Biol* 1999;44:185-205.
- [84] Lomax AJ, Bortfeld T, Goitein G, Debus J, Dykstra C, Tercier PA, et al. A treatment planning inter-comparison of proton and intensity modulated photon radiotherapy. *Radiother Oncol* 1999;51:257-71.
- [85] Fuss M, Poljanec K, Miller DW, Archambeau JO, Slater JM, Slater JD, et al. Normal tissue complication probability (NTCP) calculations as a means to compare proton and photon plans and evaluation of clinical appropriateness of calculated values. *Int J Cancer* 2000;90:351-8.
- [86] Lin R, Hug EB, Schaefer RA, Miller DW, Slater JM, Slater JD. Conformal proton radiation therapy of the posterior fossa: a study comparing protons with three-dimensional planned photons in limiting dose to auditory structures. *Int J Radiat Oncol Biol Phys* 2000;48:1219-26.
- [87] Miralbell R, Cella L, Weber D, Lomax A. Optimizing radiotherapy of orbital and paraorbital tumors: intensity-modulated X-ray beams vs. intensity-modulated proton beams. *Int J Radiat Oncol Biol Phys* 2000;47:1111-9.
- [88] Oelfke U, Bortfeld T. Intensity modulated radiotherapy with charged particle beams: studies of inverse treatment planning for rotation therapy. *Med Phys* 2000;27:1246-57.
- [89] Paulino AC, Wen BC, Brown CK, Tannous R, Mayr NA, Zhen WK, et al. Late effects in children treated with radiation therapy for Wilms' tumor. *Int J Radiat Oncol Biol Phys* 2000;46:1239-46.
- [90] Smith AR, Loeffler JS, Adams JA, Lomax AJ, Niemierko A. The potential for proton therapy to improve clinical outcomes: Comparisons of proton and x-ray treatment plans for the purpose of tumor dose escalation and/or reduction of treatment-related morbidity. *Int J Radiat Oncol Biol Phys* 2000;48(Suppl 338 abstr 2150).
- [91] Zurlo A, Lomax A, Hoess A, Bortfeld T, Russo M, Goitein G, et al. The role of proton therapy in the treatment of large irradiation volumes: a comparative planning study of pancreatic and biliary tumors. *Int J Radiat Oncol Biol Phys* 2000;48:277-88.
- [92] Baumert BG, Lomax AJ, Miltchev V, Davis JB. A comparison of dose distributions of proton and photon beams in stereotactic conformal radiotherapy of brain lesions. *Int J Radiat Oncol Biol Phys* 2001;49:1439-49.
- [93] Cella L, Lomax A, Miralbell R. Potential role of intensity modulated proton beams in prostate cancer radiotherapy. *Int J Radiat Oncol Biol Phys* 2001;49:217-23.
- [94] Cozzi L, Fogliata A, Lomax A, Bolsi A. A treatment planning comparison of 3D conformal therapy, intensity modulated photon therapy and proton therapy for treatment of advanced head and neck tumours. *Radiother Oncol* 2001;61:287-97.
- [95] Johansson J, Isacsson U, Lindman H, Montelius A, Glimelius B. Node-positive left-sided breast cancer patients after breast-conserving surgery: potential outcomes of radiotherapy modalities and techniques. *Radiother Oncol* 2002;65:89-98.
- [96] Miralbell R, Lomax A, Cella L, Schneider U. Potential reduction of the incidence of radiation-induced second cancers by using proton beams in the treatment of pediatric tumors. *Int J Radiat Oncol Biol Phys* 2002;54:824-9.
- [97] Bolsi A, Fogliata A, Cozzi L. Radiotherapy of small intracranial tumours with different advanced techniques using photon and proton beams: a treatment planning study. *Radiother Oncol* 2003;68:1-14.
- [98] Lomax AJ, Cella L, Weber D, Kurtz JM, Miralbell R. Potential role of intensity-modulated photons and protons in the treatment of the breast and regional nodes. *Int J Radiat Oncol Biol Phys* 2003;55:785-92.
- [99] Lomax AJ, Goitein M, Adams J. Intensity modulation in radiotherapy: photons versus protons in the paranasal sinus. *Radiother Oncol* 2003;66:11-8.
- [100] Johansson J, Blomquist E, Montelius A, Isacsson U, Glimelius B. Potential outcomes of modalities and techniques in radiotherapy for patients with hypopharyngeal carcinoma. *Radiother Oncol* 2004;72:129-38.
- [101] Mock U, Georg D, Bogner J, Auberger T, Potter R. Treatment planning comparison of conventional, 3D conformal, and intensity-modulated photon (IMRT) and proton therapy for paranasal sinus carcinoma. *Int J Radiat Oncol Biol Phys* 2004;58:147-54.
- [102] St Clair WH, Adams JA, Bues M, Fullerton BC, La Shell S, Kooy HM, et al. Advantage of protons compared to conventional X-ray or IMRT in the treatment of a pediatric patient with medulloblastoma. *Int J Radiat Oncol Biol Phys* 2004;58:727-34.
- [103] Weber DC, Trofimov AV, Delaney TF, Bortfeld T. A treatment planning comparison of intensity modulated photon and proton therapy for paraspinal sarcomas. *Int J Radiat Oncol Biol Phys* 2004;58:1596-606.
- [104] Yock TI, Tarbell NJ. Technology insight: proton beam radiotherapy for treatment in pediatric brain tumours. *Review. Nat Clin Pract Oncol* 2004;1:97-103.
- [105] Krengli M, Hug EB, Adams JA, Smith AR, Tarbell NJ, Munzenrider JE. Proton radiation therapy for retinoblastoma: comparison of various intraocular tumor locations and beam arrangements. *Int J Radiat Oncol Biol Phys* 2005;61:583-93.
- [106] Mu X, Björk-Eriksson T, Nill S, Oelfke U, Johansson K-A, Gagliardi G, et al. Does electron and proton therapy reduce the risk for late-effects after spinal irradiation for childhood medulloblastoma? A comparative treatment planning study. *Acta Oncol* 2005;44:554-62.

Attachment 2



Printed October 24, 2012 from <http://www.cancer.net/all-about-cancer/cancernet-feature-articles/treatments-tests-and-procedures/explaining-proton-therapy>

Explaining Proton Therapy

Proton therapy (also called proton beam therapy) is a type of radiation treatment that uses protons rather than x-rays to treat cancer. A proton is a positively charged particle that is part of an atom, the basic unit of all chemical elements, such as hydrogen or oxygen. At high energy, protons can destroy cancer cells.

Proton therapy was first used for cancer treatments in the United States in 1974 at a physics research laboratory. In 1990, the first U.S. hospital-based proton facility began treating patients. Since then, tens of thousands of people in the United States have received proton therapy. The number of U.S. centers that offer this specialized treatment is growing but is still small.

How proton therapy differs from other radiation treatments

Like standard x-ray radiation, proton therapy is a type of external-beam radiation therapy. It painlessly delivers radiation through the skin from a machine outside the body. Protons, however, can target the tumor with lower radiation doses to surrounding normal tissues—approximately 60% lower, depending on the location of the tumor.

Traditional radiation treatment can damage the tissue around the tumor. However, with proton therapy, the protons' energy hits the tumor site, delivering a smaller dose to surrounding healthy tissue. With standard treatment, doctors may need to reduce the radiation dose to limit side effects, resulting from damage to healthy tissue. With treatment using protons, on the other hand, doctors can select an appropriate dose, knowing that there will likely be fewer early and late side effects of radiation on the healthy tissue.

How proton therapy works

A machine called a synchrotron or cyclotron accelerates (speeds up) the protons. The speed of the protons is a sign of their high energy. The protons travel to a specific depth in the body based on their energy. After the protons reach the desired distance, they deposit the specified radiation dose around the tumor, leaving minimal radiation doses behind. In contrast, x-rays continue to deposit radiation doses in healthy tissues beyond the tumor as they exit the patient's body, potentially causing side effects.

Before treatment, the health care team plans the proton treatment by locating the tumor using computed tomography [1] (CT) or magnetic resonance imaging [2] (MRI) tests and marks the tumor's location on the patient's body. This technique is similar to the process

for planning radiation therapy with x-rays. The patient will often be fitted with a device that restricts the patient's movement to keep the tumor from moving out of the proton beam. The type of device depends on where the tumor is located. For example, a patient may wear a custom-made mask for a tumor in the eye, brain, or head.

Treatment is then delivered in a treatment room where the protons leave the machine and magnets direct them to the tumor. During the treatment, the patient must remain still to avoid moving the tumor out of the focused proton beam.

Patients often receive proton therapy in an outpatient setting, meaning that it does not require hospital admission. The number of treatment sessions depends on the type and stage of the cancer. Sometimes, doctors deliver proton therapy in one to five proton beam treatments, generally using larger daily radiation doses. This is typically referred to as stereotactic body radiotherapy. If the proton therapy is given at the same time as surgery, it is called radiosurgery.

Cancers treated with proton therapy

Proton therapy goes to a specific area of the patient's body, so this therapy can best shrink tumors that have not spread to other parts of the body. It is especially useful for treating a tumor next to critically important tissues (such as the optic nerves that travel between the eye and brain) that need protection from radiation damage. Doctors may use proton therapy alone, or they may combine it with standard radiation therapy, surgery, and/or chemotherapy.

Proton therapy is particularly useful for treating cancer in children because it lessens the chance of harming healthy, developing tissue. Children may receive proton therapy for rare cancers of the central nervous system (brain and spinal cord) and the eye, such as retinoblastoma and orbital rhabdomyosarcoma.

In addition, proton therapy may be used to treat these cancers:

- Central nervous system cancers (including chordoma, chondrosarcoma, and malignant meningioma)
- Eye cancer (including uveal melanoma or choroidal melanoma)
- Head and neck cancers (including nasal cavity and paranasal sinus cancer and some nasopharyngeal cancers)
- Lung cancer
- Liver cancer
- Prostate cancer
- Spinal and pelvic sarcomas (cancers that occur in the soft-tissue and bone)

Some noncancerous tumors of the brain may also benefit from proton therapy.

Advantages and disadvantages

Compared with standard radiation treatment, proton therapy has several benefits. It reduces the risk of radiation damage to healthy tissues; may allow a higher radiation dose to be directed at some types of tumors, which may keep the tumor from growing or spreading; and may result in fewer and less severe side effects (such as low blood counts, fatigue, and nausea) during and after treatment.

However, there are some drawbacks:

Limited availability. This treatment requires highly specialized, expensive equipment. As a result, proton therapy is available at just a few medical centers in the United States. Find a list of medical centers that currently offer proton therapy [3].

Higher expense. Proton therapy costs more than conventional radiation therapy, and insurance providers have varying rules about which diagnoses are covered and how much patients need to pay. Talk with your insurance provider to learn more.

Research and future applications

Researchers are studying proton therapy for cancers in other parts of the body, including those listed below:

- Breast cancer
- Esophageal cancer
- Pancreatic cancer
- Rectal and anal cancer
- Sarcoma

Some scientists are trying to find out if proton therapy can be more effective by combining it with other treatments, such as chemotherapy and targeted therapy (treatment that targets the cancer's specific genes or proteins or the tissue environment that contributes to cancer growth and development). Currently, there is no evidence that proton therapy cures more people or is more effective at prolonging a person's life than other standard forms of therapy.

In addition, more research is needed to see if proton therapy has fewer long-term side effects than x-rays.

More Information

Understanding Radiation Therapy [4]

Radiation Therapyâ What to Expect [5]

Additional Resources

RadiologyInfo: Proton Therapy [6]

Last Updated: January 31, 2012

Links:

[1] <http://www.cancer.net/node/24486>

[2] <http://www.cancer.net/node/24578>

[3] <http://www.proton-therapy.org/map.htm>

[4] <http://www.cancer.net/node/24728>

[5] <http://www.cancer.net/node/24661>

[6] <http://www.radiologyinfo.org/en/info.cfm?pg=protonthera&bhcp=1>


Attachment 3

RadiologyInfo.org

(the radiology information resource for patients)

Proton Therapy

What is proton therapy and how is it used?

Protons are atoms that carry a positive charge. Just as x-rays (also known as photons) are used to treat both benign and malignant tumors, protons beams can be used to irradiate tumors in a similar way. There is no significant difference in the biological effects of protons versus photons (x-rays). However, protons deliver a dose of radiation in a much more confined way to the tumor tissue than photons. After they enter the body, protons release most of their energy within the tumor region and, unlike photons, deliver only a minimal dose beyond the tumor boundaries. Therefore, especially for smaller tumor sizes, the dose of radiation may conform much tighter to the tumor and there may be less damage to healthy tissue. As a result, the treating physician (a radiation oncologist) can potentially give an even greater dose to the tumor while minimizing unwanted side effects. This is especially important when treating children, because protons help  reduce radiation to growing and developing tissues.

Proton therapy is being used to treat tumors in these areas of the body with encouraging early results:

- Lung - see the Lung Cancer page (www.RadiologyInfo.org/en/info.cfm?pg=lungcancer)
- Prostate - see the Prostate Cancer page (www.RadiologyInfo.org/en/info.cfm?pg=pros_cancer)
- Brain - see the Brain Tumors page (www.RadiologyInfo.org/en/info.cfm?pg=thera-brain)
- Spinal or vertebral body tumors
- Skull base sarcomas
- Pediatric brain tumors
- Head and neck - see the Head and Neck Cancer page (www.RadiologyInfo.org/en/info.cfm?pg=hdneck)
- Eye melanomas

Protocols are being developed to explore the use of protons in other parts of the body.

Who will be involved in this procedure?

Proton beam therapy requires a treatment team, including a radiation oncologist, radiation physicist, dosimetrist, immobilization specialist, radiation therapist, and nurse. The radiation oncologist is a specially trained physician who evaluates the patient and determines the appropriate therapy, specific area for treatment, and radiation dose. Working together, the radiation oncologist, radiation physicist, dosimetrist and radiation therapist establish the best way to deliver the prescribed dose. The radiation physicist and the dosimetrist then make detailed treatment calculations. Radiation therapists are specially trained technologists who perform the daily radiation treatments. Imaging studies are very important in delivering this treatment and a diagnostic radiologist is often involved with planning, too. Radiation therapy nurses are team members who tend to your day-to-day concerns and help to manage the side effects of the treatment.



What equipment is used?

Proton beam therapy uses a special machine called a cyclotron or a synchrotron to generate and accelerate protons. The protons leave the machine and are steered by magnets toward the treatment area. Other pieces of equipment are used to modify the range of the protons, shape of the beam, and to compensate for organ location to focus the beam to the tumor.

Who operates the equipment?

With backgrounds in mechanical, electrical, software, hardware and controls, specialized operators maintain, upgrade and repair the cyclotron or synchrotron and radiation

delivery system. They are also present in the facility's main control room during treatments in order to monitor the performance of the radiation delivery system.



Copyright © 2012 Radiological Society of North America, Inc. (RSNA)

Is there any special preparation needed for the procedure?

Before a patient begins proton therapy, there are a few preparation steps. First, the patient will be fitted for an immobilization device to put his or her body in the exact same position for each therapy treatment. The device used will depend upon the location of the tumor. Patients with a tumor below the neck may have a full-body mold made of foam liners surrounded by rigid plastic shells. Patients with a tumor in the eye, brain or head will be fitted with a custom-made mask.

Once the immobilization device is constructed, patients will often undergo computed tomography (CT) or magnetic resonance imaging (MRI) scanning to create a 3-D reconstruction of the tumor and normal tissues to define its boundaries with the surrounding normal structures. The patient has the CT scan performed in exactly the same position as for treatment, using the device, so that it can be taken into account for treatment planning. Sometimes a CT or MRI scan is done prior to mask-fitting. In the case of eye melanoma patients with tantalum rings sutured, simple x-rays may be taken to image the rings' placement.

The radiation oncologist uses a computer to trace and outline the tumor and the surrounding normal tissues on the imaging CT and/or MRI. Physicists and dosimetrists create a treatment plan on the computer that outlines a single or multiple proton beams entering at various angles. They use this to compute and optimize the radiation dose to the tumor, while minimizing the dose received by normal tissues. After the physician reviews this plan, it is transferred to automated machines that make the special devices, apertures and tissue-compensating filters that will be used during therapy. All of these devices are calibrated by the physics support staff before the patient's first treatment to ensure that the planning and fabrication have been done correctly.

How is the procedure performed?

The procedure is performed on an outpatient basis. For most tumor sites, the average course of treatment is usually five to seven weeks, but rarely, certain tumors treatment may last only a few days. The length of each treatment will vary depending upon the tumor type and stage. The delivery of the proton beam to the patient lasts only a few minutes, although the total time spent in the treatment room will be longer (about 15 to 20 minutes) for positioning and adjustments to the equipment settings.

For daily treatments, the patient enters the treatment room and is fitted with his or her personal immobilization device. The patient is positioned with the aid of laser sights to within a few millimeters accuracy. The radiation therapist then takes several low-energy diagnostic radiographs (x-rays) or digital images to insure the patient is properly aligned. In some cases a fan beam CT system will be used to image the target before each treatment. This special alignment and imaging process is repeated before each treatment to assure the highest precision.

Special apertures and filters that are made for each patient are loaded into the beam line. A computer may be used to scan and verify the individual bar codes on these devices. Once positioning and treatment parameters are verified, the radiation oncologist and technologists step out into a control room located next to the treatment room and begin the treatment. After the prescribed radiation dose has been delivered, the computer shuts off the proton beam and the technologists re-enter the room to assist the patient in removing the mask or immobilization device.

What will I feel during and after the procedure?

You should not feel any pain or discomfort during the procedure. Afterward, there may be some side effects, and they will be managed by your radiation oncologist in the same way they would be for any course of radiation. Other factors that may influence how well you feel after treatment are how big a dose you are given and whether you are also getting chemotherapy at the same time. Common side effects include temporary hair loss and skin reactions in the direct path of the radiation and fatigue, especially when a large area is being treated.

Side effects of radiation treatment include problems that occur as a result of the treatment itself as well as from radiation damage to healthy cells in the treatment area.

The number and severity of side effects you experience will depend on the type of radiation and dosage you receive and the part of your body being treated. You should talk to your doctor and nurse about any side effects you experience so they can help you manage them.

Radiation therapy can cause early and late side effects. Early side effects occur during or immediately after treatment and are typically gone within a few weeks. Common early side effects of radiation therapy include tiredness or fatigue and skin problems. Skin in the treatment area may become more sensitive, red, irritated, or swollen. Other skin changes include dryness, itching, peeling and blistering.

Depending on the area being treated, other early side effects may include:

- hair loss in the treatment area
- mouth problems and difficulty swallowing
- eating and digestion problems
- diarrhea
- nausea and vomiting
- headaches
- soreness and swelling in the treatment area
- urinary and bladder changes

Late side effects, which are rare, occur months or years following treatment and are often permanent. They include:

- brain changes
- spinal cord changes
- lung changes
- kidney changes
- colon and rectal changes
- infertility
- joint changes
- lymphedema
- mouth changes
- secondary cancer

There is a slight risk of developing cancer from radiation therapy. Following radiation treatment for cancer, you should be checked on a regular basis by your radiation oncologist for recurring and new cancers.

Using techniques such as proton therapy, imaging specialists are maximizing the cancer-destroying capabilities of radiation treatment while minimizing its effect on healthy tissues and organs and the side effects of the treatment itself.

Locate an ACR-accredited provider: To locate a medical imaging or radiation oncology provider in your community, you can search the [ACR-accredited facilities](#) database.

Exam costs: The costs for specific medical imaging tests and treatments vary widely across geographic regions. Many—but not all—imaging procedures are covered by insurance. Discuss the fees associated with your medical imaging procedure with your doctor and/or the medical facility staff to get a better understanding of the portions covered by insurance and the possible charges that you will incur.

Web page review process: This Web page is reviewed regularly by a physician with expertise in the medical area presented and is further reviewed by committees from the American College of Radiology (ACR) and the Radiological Society of North America (RSNA), comprising physicians with expertise in several radiologic areas.

Outside links: For the convenience of our users, *RadiologyInfo.org* provides links to relevant websites. *RadiologyInfo.org*, ACR and RSNA are not responsible for the content contained on the web pages found at these links.

Images: Images are shown for illustrative purposes. Do not attempt to draw conclusions or make diagnoses by comparing these images to other medical images, particularly your own. Only qualified physicians should interpret images; the radiologist is the physician expert trained in medical imaging.

This page was reviewed on May 15, 2012

Attachment 4



U.S. National Library of Medicine
NIH National Institutes of Health

URL of this page: <http://www.nlm.nih.gov/medlineplus/ency/article/007281.htm>

Proton therapy

Proton therapy is a kind of radiation used to treat cancer. Like other types of radiation, proton therapy kills cancer cells and stops them from growing.

Information

Unlike other types of radiation therapy that use x-rays to destroy cancer cells, proton therapy uses a beam of special particles called protons. Doctors can better aim proton beams onto a tumor, so there is less damage to the surrounding healthy tissue. This allows doctors to use a higher dose of radiation with proton therapy than they can use with x-rays.

Proton therapy is used to treat cancers that have not spread. Because it causes less damage to healthy tissue, proton therapy is often used for cancers that are very close to critical parts of the body.

Doctors may use proton therapy to treat the following types of cancer:

- Brain (acoustic neuroma, childhood brain tumors)
- Eye (ocular melanoma, retinoblastoma)
- Head and neck
- Lung
- Spine (chordoma, chondrosarcoma)
- Prostate

Researchers are also studying whether proton therapy might be used to treat other noncancerous conditions, including macular degeneration.

HOW IT WORKS

Your health care provider will fit you with a special device that holds your body still during treatment. The actual device used depends on the location of your cancer. For example, patients with head cancers may be fitted for a special mask.

Next, you will have a computed tomography (CT) or magnetic resonance imaging (MRI) scan to map out the exact area to be treated. During the scan, you will wear the device that helps you stay still. The radiation oncologist will use a computer to trace the tumor and outline the angles at which the proton beams will enter your body.

Proton therapy is performed on an outpatient basis. The treatment takes a few minutes a day over a period of 6 to 7 weeks, depending on the type of cancer. Before the treatment begins, you will get into the device that will hold you still. The radiation therapist will take a few x-rays to fine-tune the treatment.

You will be placed inside a donut-shaped device called a gantry. It will rotate around you and point the protons in the direction of the tumor. A machine called a synchrotron or cyclotron creates and speeds up the protons. Then the protons are removed from the machine and magnets direct them to the tumor.

Attachment 5

[<< Back](#)MEMBER CENTER: [Create Account](#) | [Log In](#)☐ SITE SEARCH ☐ WEB SEARCH BY 

NewsChannel5.com

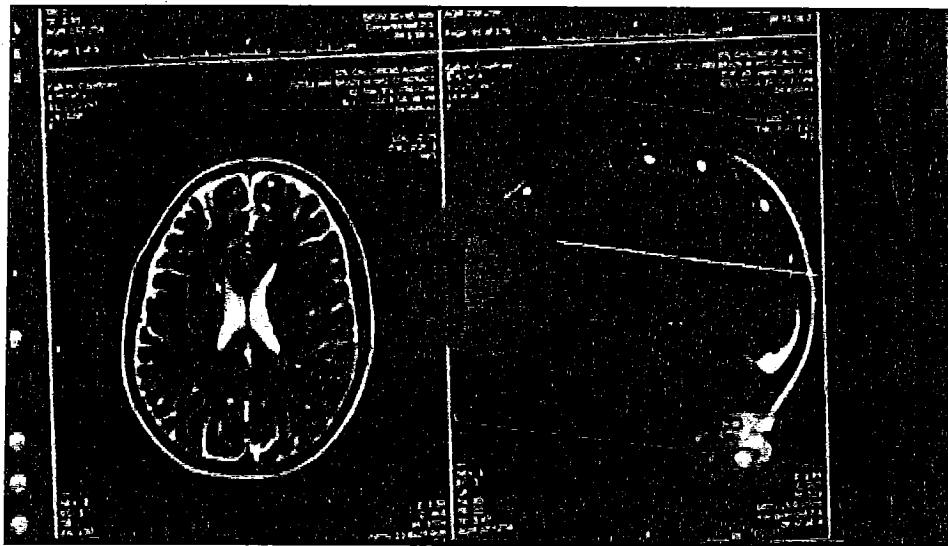


Proton Therapy

[Recommend](#)[Sign Up to see what your friends recommend.](#)

Posted: Aug 17, 2012 12:34 PM EDT

Updated: Aug 17, 2012 5:15 PM EDT



ST. LOUIS, Mo. (Ivanhoe Newswire) - The latest projections show that ten years from now, 18 million Americans could be living with cancer. But now there's a new machine that may help destroy tumors more efficiently than ever before.

Dr. Jeffrey Bradley, Professor of Radiation Oncology at the Washington University School of Medicine, is anxious to show off his new toy. This mini proton accelerator has been years in the making.

"It's a first of its kind," he told Ivanhoe.

While it looks like something that should be blasting into space, this 50-ton machine that's 12 feet underground will soon be zapping potential killers "beyond what current cancer therapies can."

With traditional therapies like X-ray, a patient's healthy tissues are often hit by radiation. This machine is so precise that doctors can hit tumors with higher doses--without damaging surrounding organs.

"For a tumor that's near the eye, you don't want to spray it with excess radiation," said Dr. Bradley.

Until now, proton beam facilities in the United States would cost more than 150 million dollars and require the space of a football field. This machine cost 75 percent less and fits into a single room. While it could cost up to 20 percent more than traditional treatments, for some patients it could be worth it.

"Less side effects. There should be less side effects because you have less normal tissues that are getting hit," Dr. Bradley said.

Kids who receive radiation for brain tumors are at risk of long term disability and stunted growth.

"Protons are actually ideal for many pediatric patients," he added.

While not everyone will benefit from proton therapy, a machine like this could give more patient more options.

"You might seek it out. As a parent I imagine I would. Now we can provide that," said Dr. Bradley.

Proton therapy is especially useful to treat cancers around the eyes, face, base of the brain and spine.

Over the next few years, more of the machines are expected to pop up across the country. Dr. Bradley said as that happens, treatment will become more affordable. He plans to begin treating his first patients within the next few months.

RESEARCH SUMMARY

PROTON THERAPY: Proton therapy is a type of radiation treatment that uses protons rather than x-rays to treat cancer. A proton is a positively charged particle that is part of an atom, the basic unit of all chemical elements, such as hydrogen or oxygen. At high energy, protons can destroy cancer cells.

Proton therapy was first used for cancer treatments in the United States in 1974 at a physics research laboratory. In 1990, the first U.S. hospital-based proton facility began treating patients. Since then, tens of thousands of people in the United States have received proton therapy. (SOURCE: www.cancer.net)

HOW PROTON THERAPY DIFFERS FROM OTHER RADIATION TREATMENTS: Like standard x-ray radiation, proton therapy is a type of external-beam radiation therapy. It painlessly delivers radiation through the skin from a machine outside the body. Protons, however, can target the tumor with lower radiation doses to surrounding normal tissues—approximately 60 percent lower, depending on the location of the tumor. (SOURCE: www.cancer.net)

HOW IT WORKS: A machine called a synchrotron or cyclotron accelerates (speeds up) the protons. The speed of the protons is a sign of their high energy. The protons travel to a specific depth in the body based on their energy. After the protons reach the desired distance, they deposit the specified radiation dose around the tumor, leaving minimal radiation doses behind. In contrast, x-rays continue to deposit radiation doses in healthy tissues beyond the tumor as they exit the patient's body, potentially causing side effects.

Patients often receive proton therapy in an outpatient setting, meaning that it does not require hospital admission. The number of treatment sessions depends on the type and stage of the cancer. Sometimes, doctors deliver proton therapy in one to five proton beam treatments, generally using larger daily radiation doses. (SOURCE: www.cancer.net)

FIRST OF ITS KIND: After six years of planning, training and waiting, the Siteman Cancer Center at Barnes-Jewish Hospital and Washington University School of Medicine received its new proton beam accelerator last October. Dr. Jeffrey Bradley, Washington University associate professor, Siteman Cancer Center radiation oncologist and director of the Kling Center for Proton Therapy, said the new proton therapy technology, called a superconducting synchrocyclotron proton accelerator, could begin treating cancer patients in October, pending FDA approval. The \$20 million system, which arrived at Siteman is the first of its kind in the world because of its small size compared to existing proton beams that are typically housed in football field-sized buildings. This is the first single-room proton therapy unit in the world. The type of equipment is called a synchrocyclotron, and usually, they are large proton generating units that take up several buildings in a hospital. This unit is about the size of your kitchen table. It's small enough that it can rotate around the room and provide treatment at different areas. (SOURCE: www.bizjournals.com)

INTERVIEW

Jeffrey Bradley, M.D., Professor of Radiation Oncology at Washington University School of Medicine, talks about a new machine that could revolutionize the way doctors treat cancer.

What exactly are you building?

Dr. Bradley: We're building a proton therapy facility that is the first of its kind. It's a single room proton therapy facility that is adjacent to our existing radiation, oncology facility that will be for treatment of special cases that need protons to treat their cancer.

What are these special cases?

Dr. Bradley: Protons are primarily used for children mainly or for tumors that are around critical structures, just like around the brain, the base of skull, the eye, and the spinal cord. It's also very useful for types of cancers called sarcomas, chondral sarcoma or osteosarcoma. It's also commonly used now in lung cancer. They're starting to be used in other types of cancers like esophagus cancer, pancreas cancer and things like that. We like to try to treat patients who need protons that can help them beyond what current cancer therapies can.

What makes this so effective?

Dr. Bradley: Protons are unique because they have a mass and a charge so that you can tell the proton machine that you need to treat a tumor at a certain depth beyond the skin. Let's say its five centimeters deep, so the proton machine shoots the protons in to the patient about five centimeters deep and the protons stop. They have a mass and a charge so they can stop, whereas x-rays don't stop. They go from before hitting the patient all the way through the patient and beyond the patient. The advantage of the protons is they stop at a desired depth.

How does radiation and other therapies compare to this?

Dr. Bradley: We use radiation therapy for probably seventy percent of patients who are diagnosed solid tumor type of cancers, so most patients get radiation therapy. We expect patients will still need radiation therapy but some of the patient's radiation therapy may not be ideal, for patients with cancers that are near critical structures. Let's choose the eye for example, for a tumor that's near the eye you don't want to spray the eye with excess radiation therapy. If you had a tool that could pinpoint the radiation more precisely like a proton machine you would like to use it in that patient so that you could spare their vision.

Are there any additional side effect?

Dr. Bradley: There should be less side effects because you have less normal tissues that are getting hit by the radiation beam.

Would you say it is more effective than traditional therapies?

Dr. Bradley: It's probably as effective at killing the cancer. The advantage is it probably causes less side effects to the patient receiving treatment.

Talk about how children can benefit from this?

Dr. Bradley: We treat pediatric patients today that might be anywhere from six months old to eighteen years old. Pediatric patients with cancer get treated all the time, but they have special issues when you're thinking about treating them with radiation therapy because radiation therapy has negative effects on their growth. They don't grow properly, they don't grow symmetrically. If you treat a tumor around their brain, their gland that produces growth hormone and other types of hormones that are necessary for normal growth and maturation don't work. You'd like to try to avoid hitting those critical tissues so that they don't have problems growing up. Protons are actually ideal for many pediatric cancer patients.

What percent of the current patients that you treat now with other treatments would benefit more with this?

Dr. Bradley: We anticipate about twenty five percent of our patients that we currently treat now in our center could benefit from proton therapy.

What are maybe some of the hesitations of using this instead of traditional therapy?

Dr. Bradley: Sometimes proton therapy may not be as advantageous as you might expect it to be. We've done all kinds of plans for many different types of patients that are currently getting treatment and we just ran a proton plan on paper to see if protons would work better. Sometimes there are advantages and disadvantages to using x-rays or protons. It doesn't work out that every patient has an advantage to protons. But there are some marked examples where protons provide a huge advantage. An example might be a patient with prostate cancer. Patients with prostate cancer x-ray treatment plans look pretty much equivalent to proton treatment plans.

How many times does the patient have to go in to the room and how long does it last?

Dr. Bradley: The radiation therapy typically lasts anywhere from four weeks to seven weeks depending on what type of cancer you have. Whether that treatment is given with x-rays or protons, that probably doesn't matter. The duration or the length of treatment over days to months is probably about the same. Treatment times are about the same as well. In a typical x-ray radiation therapy unit treatment takes about fifteen minutes, we expect with our proton machine treatment to take about twenty minutes per day or so.

How much does it cost?

Dr. Bradley: This particular unit costs about twenty five percent of what it costs to put in a larger proton unit. The large ones are a big cyclotron occupying that football field type space and three or four treatment rooms. Ours is a single treatment room with a single proton making unit called the cyclotron. It's about twenty five percent of the cost of a larger facility.

It's cheaper and it's smaller and it is equally as effective?

Dr. Bradley: Yes. I would say it's an advantage. One of the drawbacks in the press to proton therapy today is how expensive it is. It's been cited as one of the problems with healthcare because as technology gets better and treatment gets better, expense goes way up. But imagine if you could build a facility at twenty five percent of the cost of another facility, you make treatment more efficient. It becomes a more efficient treatment and it could be advantageous to cancer therapy in general because it enables other facilities to buy a single room unit at a lower cost and implement proton therapy at their site for a larger number of patients on the whole.

Is it going to cost patients just as much as it would for traditional therapy?

Dr. Bradley: For x-ray radiation therapy, this may cost about ten to twenty percent more. That's a fluctuating situation. With these fifteen units coming on board, protons are really exploding and multiple sites are opening up around the country. With that, Medicare and the other insurance providers are reforming their policies. What the future holds with reimbursement for protons or cost for protons I don't know. But today it's about ten percent more.

What other specific treatments is this good for?

Dr. Bradley: It's known for tumors around the eye, so melanomas that occur on the eye. It's also known for tumors that are in the base of skull. Anything around the spinal cord as well. The spinal cord is a critical structure and it keeps our arms and our legs moving and us to be able to stand up right and walk and things like that. So any tumors around the spinal cord no matter what they are probably would benefit from protons because they can spare the spinal cord from radiation therapy.

How about kids?

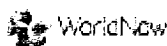
Dr. Bradley: Kids especially because of growth and neighboring critical structures. You don't want to treat their spine, you don't want to treat their heart, you don't want to treat their liver, you want to minimize what normal tissues you treat.

Is this something you would use on your own kids?

Dr. Bradley: I was told by one of our pediatric oncologists that most families that come to Children's Hospital and see our pediatric oncology group ask about protons. It's the medical literature now in terms of if you knew your child was getting radiation therapy you would look in to it on the Internet. You would see that protons are used for that so you would probably walk in the door and say okay, what advantage do protons have for our situation. You might seek it out as a parent. I would imagine I would. Now we can provide that. Or we will be able to provide that.

FOR MORE INFORMATION, PLEASE CONTACT:

Judy Martin
Director, Media Relations
(314) 286-0105
martinju@wustl.edu



[Contact Us](#) | [Advertise](#) | [Mobile](#) | [RSS Feeds](#) | [Facebook](#) | [Twitter](#) | [Email Alerts](#) | [Jobs](#) |
[Privacy Policy](#) | [Terms Of Use](#) | [Public File](#)

© 2012 NewsChannel5.com | NewsChannel 5 WTVF-TV Nashville TN | Site hosted by WorldNow.
All Rights Reserved.

Attachment 6

The power of proton therapy

by Anne Chui

When it comes to fighting cancer, the sharpest scalpel in the medical beam technology conceived and refined in high-energy physics is now treating thousands of patients per year, with fewer side effects. And a new technology is under way promises a new generation of smaller, cheaper, more effective radiotherapy systems.



SYMPOSIUM: Volume 11, Issue 11, December 1998

Forty years ago, doctors broke the news to the family of a small boy: Their five-year-old had cancer. Fortunately it was a type of cancer, called lymphocyte predominant Hodgkin's disease, that responded well to radiation treatment.

The doctors repeatedly beamed X-rays at the areas where cancer had infiltrated the boy's lymph nodes—under his arms, on his neck, and in the middle of his chest—and the cancer went away.

The boy was cured, but his health would never be the same.

When he had a growth spurt at puberty, the irradiated parts of his body didn't grow as much or as fast as the rest. His neck was unnaturally skinny, his shoulders too narrow. Strange depressions appeared on his chest, like divots carved in a golf course green, where stem cells had been wiped out and muscles and other tissues failed to grow, says one of his physicians, Dr. Nancy Price Mendenhall, medical director of the University of Florida Proton Therapy Institute.

The boy's damaged thyroid gland no longer put out enough hormone; left untreated, this makes people fat and lethargic. He would have to take thyroid medication for the rest of his life.

By age 34, his heart valves leaked so badly that they had to be replaced. Even today he has a higher-than-normal chance of having heart attacks and developing new cancers.

While the bodies of growing children are especially vulnerable to the life-changing side effects of radiation therapy—including lower IQ from treating the brain—it also leaves a dismal trail in adults, from rectal bleeding in the case of prostate cancer to serious lung inflammation from radiating the chest.

Recent studies show that "for every unit of radiation there is a certain amount of damage. There's no threshold," Price Mendenhall says. It's just that the lower the dose, the longer it takes for injuries to show up. That's why doctors didn't appreciate how serious the fallout from radiation treatment can be until five or six years ago.

Even before radiotherapy became widespread, a young particle physicist named Robert Wilson came up with a better way—one that delivers more radiation to the tumor while sparing healthy tissue. Instead of using X-rays, he said, use protons.

Soon a handful of physics labs were offering experimental proton therapy on the side. In the late 1980s, Fermi National Accelerator Laboratory in Illinois built a proton accelerator for Loma Linda University Medical Center in southern California, making it the first hospital in the world to offer proton treatment.

Today, with five proton therapy centers operating in the United States and 26 world-wide, scientists are working on ways to make it cheaper, more compact, and more efficient.

Proton therapy is "a pure case of accelerator technology being used for the health of human beings," says Jay Flanz, an accelerator physicist and technical director of the Francis H. Burr Proton Therapy Center at Massachusetts General Hospital.

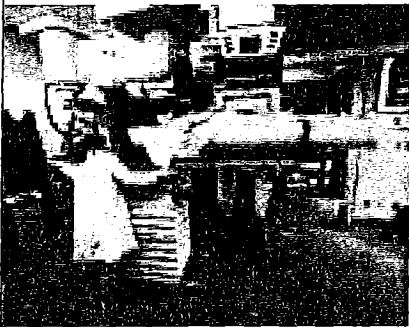
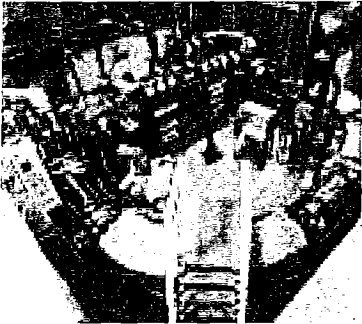
While the first wave of proton therapy was based on machines designed for physics research, he says, people are starting to tailor accelerator systems for the needs of medicine: "That's what's causing this breakthrough right now."

Reducing collateral damage

Doctors have treated cancer with radiation for more than 100 years by implanting small pieces of radioactive material in tumors, for instance. But the invention of the linear accelerator ushered in a new age and has saved many thousands of lives. Originally developed to accelerate particles for physics experiments, linacs can also generate X-rays for zapping tumors. The first routine treatments with the new technology began in 1953 at London's Hammersmith Hospital; the first in the United States took place three years later at the Stanford Department of Radiology. Today these machines are the work horses of radiotherapy.

The Loma Linda medical accelerator being built at Fermilab in 1989.

Photo: Reidar Hahn, Fermilab



Pete Freeman prepares for treatment for prostate cancer in a fixed-beam room at Loma Linda Medical Center in Loma Linda, California.

Photo: Marissa Roth/
The New York Times/Radux

The technology has come a long way since. Doctors can now get a clear 3-D picture of the tumor with CT or MRI scans and shape the radiated area to fit the tumor, using advanced treatment-planning software.

But collateral damage is still inevitable because most X-rays deposit their destructive energy in healthy tissue before they even get to the tumor, and some cause additional damage on the way out of the body.

In a seminal 1946 paper called "Radiological Use of Fast Protons," Robert Wilson, then based at Harvard University, laid out an alternative.

Wilson noted that people had never considered using protons in medicine because these massive particles slow down when they hit the body and quickly stop. However, a new generation of accelerators would soon push protons to high enough energies to penetrate deep into the body and reach tumors that had been out of range.

What's more, protons lose energy at an increasing rate as they slow down. So they would deposit very little of that damaging energy going in and deliver most of their punch when they come to a stop inside the tumor. By changing the protons' energy, doctors could get them to stop at any depth they chose.

"In the final half centimeter of a proton track," Wilson wrote in the journal *Radiology*, "the average dose is 16 times the skin dose."

The first experimental proton treatments took place in 1954 at what is now Lawrence Berkeley National Laboratory. Wilson went on to build research synchrotrons that were also used for proton therapy at Harvard and at Cornell University, and in 1967 became the founding director of Fermilab.

"He had the vision of having proton therapy done in a hospital, where it would be available only for proton therapy treatment and could be done on a large scale," recalls Phil Livdahl, former deputy director of Fermilab.

But it would take more than 40 years for Wilson's dream to be realized. He had already retired when a doctor at Loma Linda University Medical Center approached Fermilab for help.

From lab to hospital

Dr. James Slater, who was in charge of radiation medicine at Loma Linda, had sent cancer patients to Lawrence Berkeley and Los Alamos national laboratories for experimental treatment with protons and other particles. Since research took priority at the labs, patients had to be fit in between experiments; sometimes they were turned away.

Working with patients and physicists at the two labs "was priceless experience, really," Slater says. "I came to the conclusion, working with them, that this was really the way to go—that X-rays had been brought to their limits and we needed a new particle."

So in the early 1980s Slater invited about 30 representatives of leading medical technology firms to a meeting.

"They all came here to Loma Linda and they sat around the table and I told them what I wanted to do, and they turned it down. I was really surprised," he recalls. Later, he says, an engineer for one of the firms told him none of the companies were ready to jump into proton therapy; "Financially nobody thought it was worth it. I came to the conclusion that Fermilab was best equipped to do something for us."

Slater approached Livdahl, who became a key figure in the effort. It was agreed that Fermilab would build a synchrotron to accelerate the protons—"a big ring, just like a donut," Slater says, 20 feet in diameter and about five feet tall. He asked the lab to build it to last 50 years, "because there's going to be enormous room for improvement."

With \$19.5 million in seed funding from the US Department of Energy, crews designed, built, and tested the machine at Fermilab, and broke it down into pieces for the move to Loma Linda. The new center treated its first patient in October 1990.

As it turned out, Livdahl was diagnosed with prostate cancer just before the center opened and became one of its first patients. When the cancer recurred in 1996, he went back for a second round.

Thinking back, "it really gives you a great feeling knowing that something you've done in your career is saving the lives of people on a daily basis," says Livdahl, now 86 and living in Dallas. And the life he feels best about saving is his own.

Pros and cons

Studies have shown the effectiveness of proton therapy, especially where there's an urgent need to spare healthy tissue—for instance, in treating children, the eye, the base of the skull, the prostate, and tumors very close to sensitive organs. "Protons are especially good with large tumors that wrap around critical structures," Flanz says.

But the technology does have its critics.

The biggest drawback is the cost. Proton therapy centers are the size of a football field and cost in the neighborhood of \$120 million to \$180 million, including the building and all the associated medical equipment.

On the other hand, hospitals no longer have to design treatment systems from scratch. They can buy ready-to-install systems from companies such as IBA, Siemens Medical Solutions, Hitachi, and Varian Medical Systems.

That's the approach the Northern Illinois Proton Treatment and Research Center is taking. Now under construction in West Chicago, it will buy treatment equipment from Varian. The \$160 million, 130,000-square-foot center expects to open by early 2010 and, when it's in full swing, treat up to 1500 patients per year.

The center will also perform "a fair amount of research in terms of advancing the technology," says John Lewis, associate vice president for outreach at Northern Illinois University, which will build and operate the center. Although there is no formal relationship between the two labs, he added, "We think the proximity to Fermilab and expertise at Fermilab will be very fundamental to research projects going forward."

Skeptics say traditional radiation therapy has improved so much that in many cases it's just as effective, and much cheaper. The high cost and reluctance of some insurance companies to pay mean some people just can't afford proton therapy, raising equity issues. Further, there haven't been enough studies directly comparing the effectiveness of proton therapy to radiotherapy, chemotherapy, and other types of treatment.

Supporters counter that proton therapy is so much more precise, and can be given in such big doses while sparing normal tissue, that it would be unethical to ask patients to undergo an inferior treatment so the two could be compared.

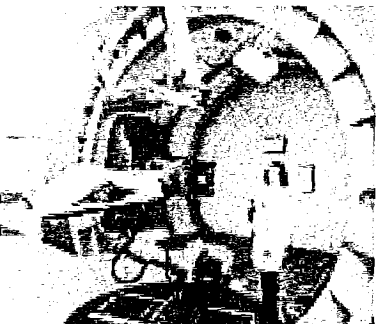
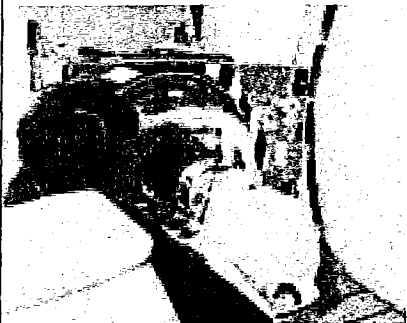
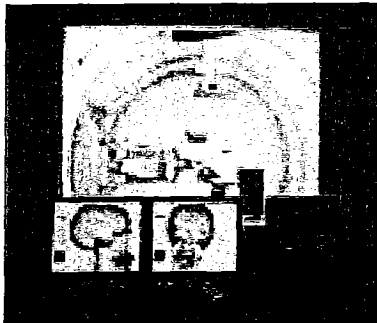
Medical physicist George Coutrakon takes that position. He was involved in developing the Loma Linda center and left there last fall to work on the one in Northern Illinois. "Proton therapy is a sharper instrument," he says. "Would you ever test it against a duller instrument in a randomized trial? Would you ever use a machine that gives a higher dose to normal tissue? You can't just roll the dice when you have a better treatment."

Further, the economic comparisons are not as simple as they've been made out to be, according to Price Mendenhall.

Standard radiation treatment machines have to be replaced every seven or eight years, usually operate one shift a day and treat one patient at a time. Proton therapy equipment is built to last at least 30 years, operates two shifts a day and often feeds into three or more treatment rooms. This reduces replacement costs and allows proton centers to treat at least twice as many patients per year.

And because proton therapy spares healthy tissue, doctors can give higher doses and increase the cure rate, Price Mendenhall says. This has also cut the length of prostate cancer treatment from 8.5 to 6.5 weeks, and doctors at Loma Linda think they can prune that to just four weeks. If they succeed, she says, proton treatment for prostate cancer will cost less than conventional X-rays.

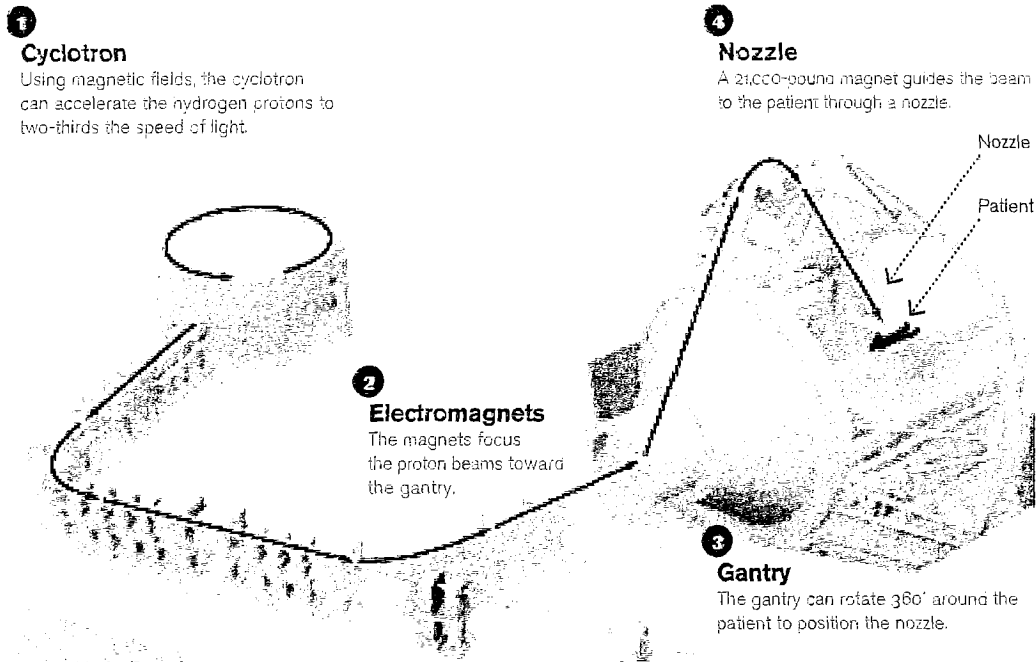
Then there's the much higher cost of treating side effects from radiation, she says, not to mention the cost of treating cancers that recur at higher rates than they would after proton treatment.



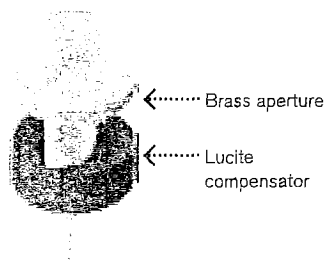
From top: Images of a patient's skull show the area to be treated with protons; a patient is put into position; the treatment setup.

Photos courtesy of Kendall Reeves Spectrum Studio and the Midwest Proton Radiotherapy Institute

Proton radiation therapy is potentially a better way to treat cancer because it has fewer side effects, but the technology is still very expensive. The University of Florida Proton Therapy Institute required eight years and \$125 million to build, and it can serve up to 150 patients a day.

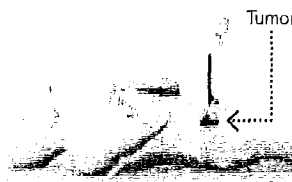


The Nozzle



The brass aperture and the Lucite compensator are designed to squeeze the proton beam to the size and shape of the area being treated.

Proton radiation therapy



By adjusting the speed of the protons, a physician can control how deep their penetration will be. The protons then release their energy at the tumor and cause less damage to the surrounding tissue.

Conventional X-ray therapy



Because conventional radiation doesn't release its energy at a specified depth, it can cause more damage to the tissue surrounding the tumor.

Credits: The New York Times and University of Florida Proton Therapy Institute

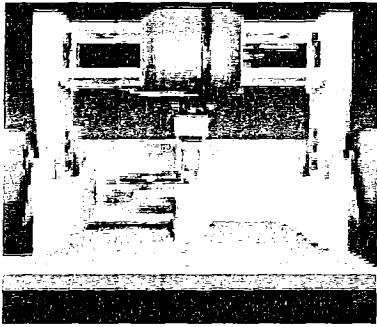
For all the advantages proton therapy has, researchers think it could be a lot better. Cheaper, for one thing: The high price tag is the main reason more centers haven't been built. A number of groups are hoping to cut the cost by delivering the same capabilities in smaller, lighter, simpler, more robust packages.

Still River Systems, for instance, is a small Massachusetts firm that is developing a proton therapy system that it says will weigh and cost one-tenth as much as today's technology. The approach was developed in partnership with the Massachusetts Institute of Technology Plasma Science and Fusion Center. It uses superconducting magnets rather than conventional magnets to accelerate protons around a cyclotron. This allows the protons to make tighter turns and the cyclotron to shrink to the point that it can fit into a treatment room, at a cost of about \$20 million per room. However, since most proton therapy centers have multiple treatment rooms, some experts say it is not clear how these costs will compare with those of current proton treatment.

"We have a very flexible, very modular approach," Lionel Bouchet, the company's director of product management, says. "In this economy it does not make sense to go with a \$200 million project when you can start with one room and expand from there."

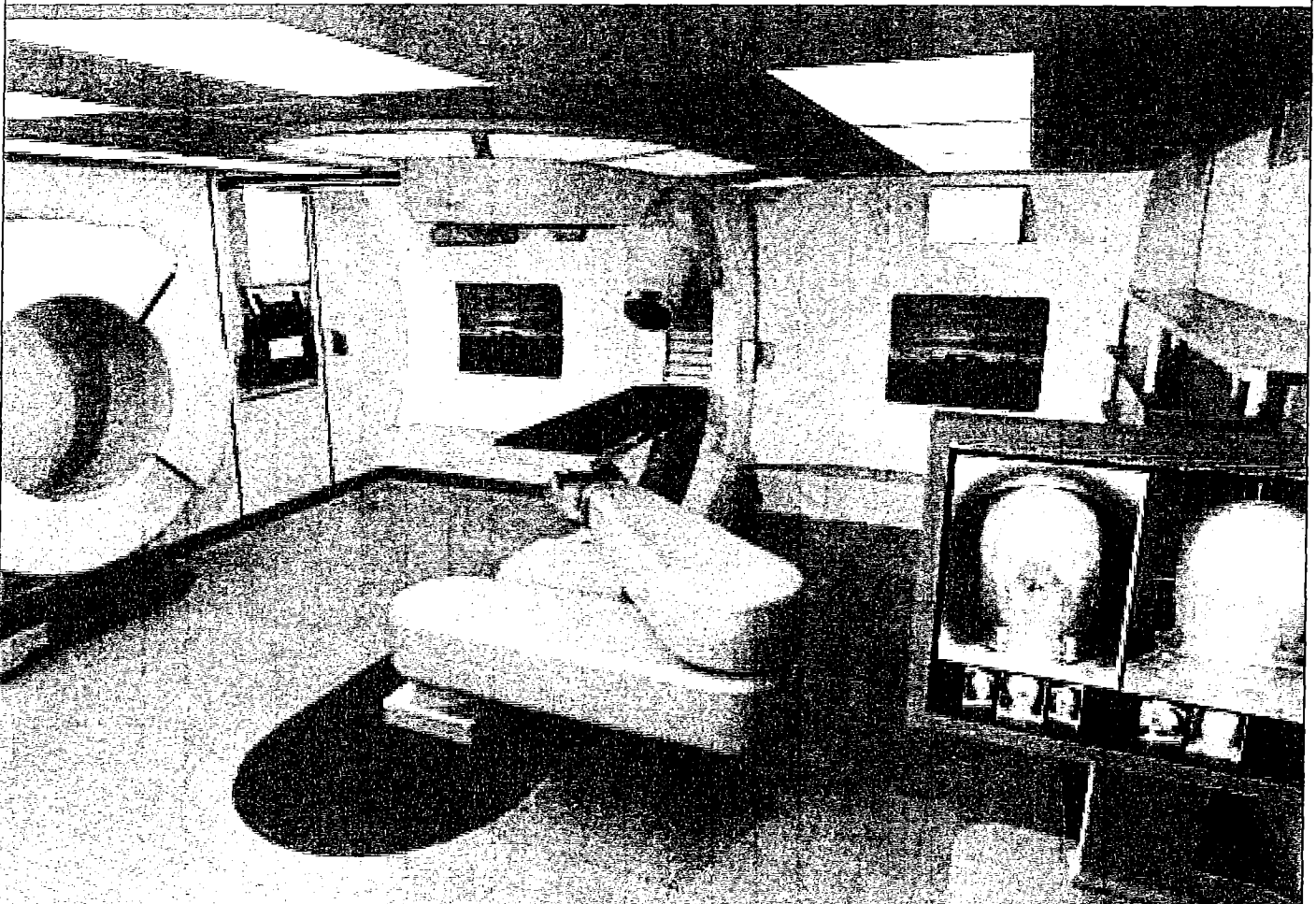
Although the technology is still waiting for US Food and Drug Administration approval, the company recently announced it will begin delivery of its first system in 2009 to Barnes-Jewish Hospital at Washington University Medical Center in St. Louis, Missouri.

Flanz of Massachusetts General says, "In my view, attempts to build smaller systems—and I'm involved in some of them—result in giving up some of the features the bigger systems have. But their low cost will allow local hospitals and clinics to offer basic proton therapy, referring the most complicated cases to larger academic medical centers."



Above and below: Artist renderings of proton therapy equipment being developed by Still River Systems that's small enough to fit into a treatment room.

Images courtesy of Still River Systems



Another approach comes out of the US nuclear weapons testing program. Since there's a ban on testing the actual weapons, researchers use model bombs that contain only conventional explosives. (In a real bomb the job of the explosives is to compress and implode the nuclear inner core.) Scientists set off these dummy bombs in thick-walled buildings at Lawrence Livermore and Los Alamos national labs; and they use a particle accelerator to generate X-rays for documenting the implosions.

While looking for ways to make this accelerator smaller and cheaper, scientists came up with the Dielectric Wall Accelerator. It's basically a tube for carrying a particle beam, explains George Caporaso, beam research program leader at Lawrence Livermore. What's different about this beam tube is that the inner wall consists of alternating rings of electrical insulators and conductors. This allows the creation of a very strong electric field that permeates the inside of the tube; in principle it could boost protons to the energies needed for cancer treatment in just two meters.

"That's a very enabling technology," Caporaso says. "There's nothing exotic about the material; it's just the configuration that's novel. Pick your favorite insulator, and you can just slice and dice it and make this configuration." The technology is being developed by Compact Particle Accelerator Corp. in Madison, Wisconsin, a spinoff of the radiation therapy company TomoTherapy.

Scientists at Brookhaven National Laboratory are looking for commercial partners to develop a technology they just patented. It has two advantages: By focusing the proton beam to a much finer point than today's machines, it would reduce collateral damage and allow most of the system's components, such as pipes and beams, to shrink as well, says physicist Stephen Peggs, one of the project's lead scientists. And it can deliver 60 pulses of protons per second, compared to one pulse every four seconds now. The result, he says, is "a very sharp knife and a very flexible knife" that should be simpler, more robust, and more reliable.

Those are just a few of about a dozen projects aimed at cutting the cost, and in some cases increasing the effectiveness, of proton therapy.

Sharpening the proton knife

Meanwhile Loma Linda, true to James Slater's original vision, is undergoing a major upgrade that should increase the number of patients treated per day from 150-180 to more than 200, reducing the cost per treatment.

Changing the energy of the proton beam, and thus how far it penetrates the body, used to take an hour; now it's instantaneous. In 2009, Slater says, controllers will be able to do "spot scanning"—treating the deepest layer of the tumor, then the next deepest layer, and so on until the whole thing has been bombarded with protons. "We can move them in any direction so we can paint in virtually any configuration the tumor is growing in," he says. And robotic systems will be in place to position patients for treatment.

Loma Linda is developing a CT scanner that uses protons, rather than X-rays, to make detailed images of the area under treatment; this should reduce distortion and allow more precise placement of the beam.

Its researchers are also investigating the biological effects of proton treatment on both cancerous and healthy cells. Some of these experiments use technology directly borrowed from high-energy physics, such as silicon microstrip detectors, calorimeters, and GEANT4 software for modeling the paths of particles through tissue, says Vladimir Bashkurov, who worked as an experimental particle physicist before joining Loma Linda 10 years ago.

Flanz says he finds it interesting that all these advances—and many yet to come—are based on Robert Wilson's original idea, and on the foresight of administrators at Lawrence Berkeley and other national labs who made room for patients in their research halls.

"Basically, everything he said in his 1946 paper is used now," Flanz says. "It's incredible."

Attachment 7

Oncology Rounds

MEVION S250 receives FDA 510(k) clearance

on June 19, 2012 | [Permalink](#) | [Comments \(1\)](#)

Megan Bailey, Oncology Roundtable

The FDA has recently approved the MEVION S250 proton therapy system, which aims to reduce costs and make proton beam therapy more widely available.

View the post below to see an analysis of the FDA's decision from our colleagues in Technology Insights.

After eight years, the proton therapy system becomes available in the U.S.

On June 11, Mevion Medical Systems (formerly Still River Systems) announced the MEVION S250 system's FDA 510(k) clearance. A milestone eight years in the making, the proton therapy system will now be approved for use in the U.S.

The news comes just three months after the company's CE certification, which had granted the S250 access to the European Union market. This clearance will allow providers to initiate treatment upon installation of the system, with the first S250 nearing completion at the Kling Center for Proton Therapy at Washington University in St. Louis, Missouri. Over the next two years, Mevion plans to establish the system in over a dozen locations internationally, with plans for several U.S. sites in locations such as New Jersey, Oklahoma, Florida, and California.

Proton beam therapy considered the superior treatment for several indicators

Proton beam therapy is considered to offer more precise radiation delivery to the target area, with minimal exposure to surrounding tissue. Although the clinical benefits of protons compared to traditional photon based radiation therapy systems have been widely debated, protons are often considered the superior treatment for certain indications, such as pediatric oncology patients. Ongoing clinical investigation of protons, a hot topic in the oncology community, will continue to weigh heavily upon the rate of expansion of these treatments.

Small-scale technology with a large-scale interest level

Although it has been pending FDA clearance for a number of years, this small-scale proton technology has generated significant interest from many institutions, including some of the most progressive cancer centers in the world.

Until now, the major barriers to widespread adoption have been:

- Large capital costs
- Technical complexity
- Extensive training demanded by existing proton therapy systems

The MEVION S250, however, aims to substantially reduce the upfront and recurring costs associated with offering proton therapy. While still anticipated to be many multiples of the costs required for offering conventional X-ray radiation therapy, small-scale systems have driven an evolution in the types of hospitals considering this modality.

Learn more

For more information on proton therapy, view Technology Insights' blog post, "[Proton therapy update](#)."

[Older Entries](#)[Newer Entries](#)