

Research Review

A BED for Every BODY

Clinical Specialist Project Brings New Expertise to Gillette

For years, Gillette Children's Specialty Healthcare has offered seating evaluations for patients who use wheelchairs. The evaluations — done by therapists, seating specialists and vendors expert in wheelchair options — help determine how best to support users and decrease opportunities for pressure sores to develop.

"We were very concerned about pressure sores developing from wheelchairs, but we hadn't paid much attention to beds, where people spend eight hours at a time," says Nancy Mitchell, occupational therapist. "We also had limited knowledge about choosing appropriate beds and mattresses." To fill those gaps, Mitchell recently completed a clinical specialist project on selecting beds for people who have disabilities.

She learned early on that expertise on beds, and published research on the topic, was virtually nonexistent. "Families were really on their own," she says. "The vendors could order beds, but few could offer guidance in meeting patients' needs."

Children and adults who have disabilities need special beds for various reasons:

- A bed that's too high or too low prevents people from independently transferring between their beds and wheelchairs. (And beds of improper height make it difficult for caregivers to safely transfer larger children and adults.)
- People who repeatedly roll out of bed need beds with rails strong enough to keep them in place.

- People — particularly those with autism or brain injuries — who wander at night need enclosed beds to keep them safe.
- People who can't move easily risk developing pressure sores and skin irritations — especially if they also experience incontinence.

For her project, Mitchell teamed up with Advanced Therapy Services to offer bed evaluations for Gillette families. "We learned together," Mitchell recalls. She and the vendor met with families to determine needs and make recommendations. They also helped address funding issues for families that can't afford specialized beds. "We had to figure out what questions we had to ask to justify the expenditure for insurance companies," she says.

To cap the project, Mitchell developed a form for therapists to use when evaluating beds; a schedule of protocols; and a book describing and picturing bed options. She also trained other therapists to conduct bed evaluations. As a result, more doctors, therapists, patients and families are asking for the service.

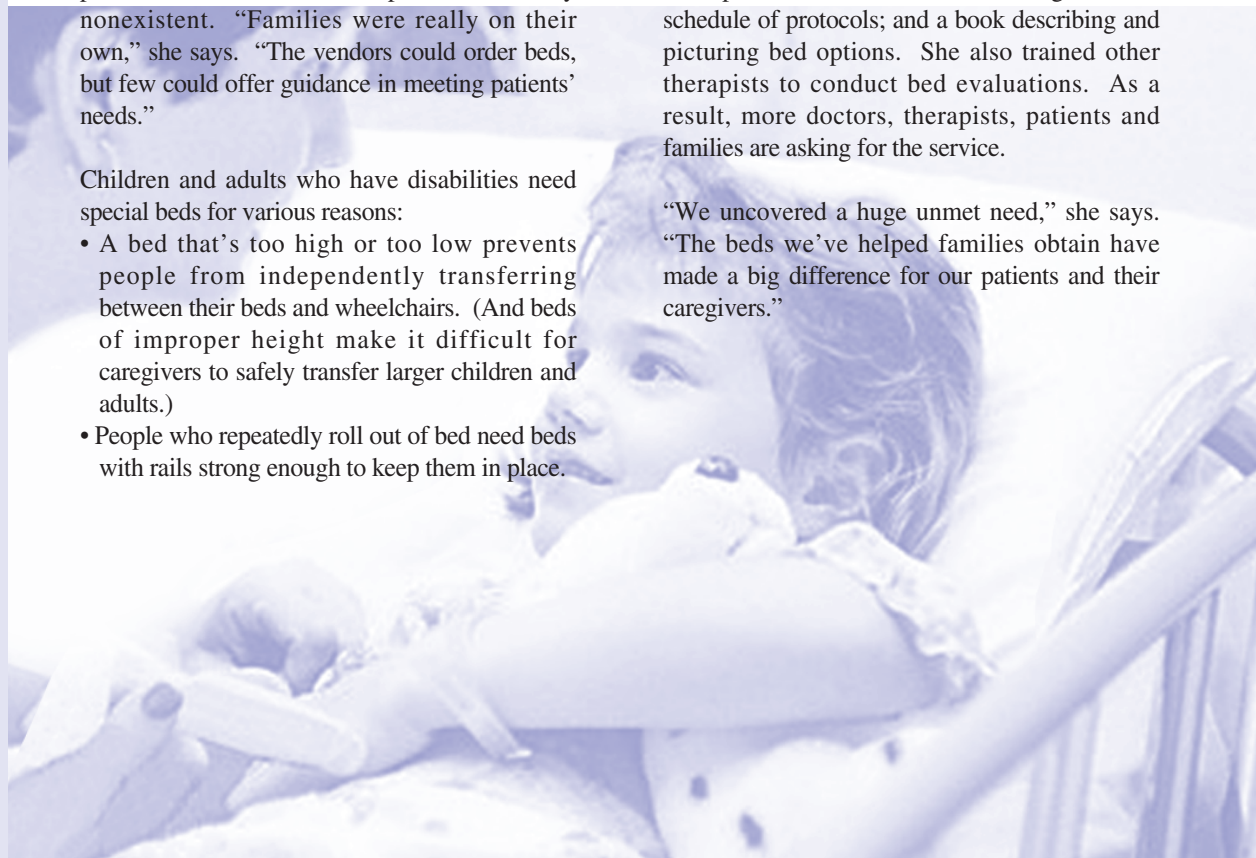
"We uncovered a huge unmet need," she says. "The beds we've helped families obtain have made a big difference for our patients and their caregivers."

"People in general have no notion of the sort and amount of evidence often needed to prove the simplest fact."

Peter Mere Latham, 1872

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HIPAA Simplified

First of three parts

The U.S. Department of Health and Human Services published final privacy regulations concerning the Health Insurance Portability and Accountability Act (HIPAA) in August. The regulations, effective April 14, 2003, create a national standard to protect patients' medical records and other personal information.

Background

The HIPAA "privacy rule" establishes the conditions under which covered entities (such as Gillette) may use or disclose protected health information (PHI) for research purposes. The rule doesn't apply to health information that has been "de-identified" (stripped of all individually identifiable information) in accordance with the rules 164.502(d) and 164.513(a)-(c).

The privacy rule also defines how to inform people when their medical information is used or disclosed for research purposes, and it covers their right to access the information that covered entities hold about them. Currently, most research involving human subjects operates under the "common rule" (45 CFR Part 46, Subpart A) and/or Food and Drug Administration regulations (21 CFR Parts 50 and 56), which have privacy provisions that are similar to, but separate from, the privacy rule. The privacy rule builds on existing protections and affects research that isn't covered under current federal regulations. It also encourages patients to participate in research by providing new assurances about the privacy of their health information.

To comply with the new rules, medical providers must significantly change the ways in which they manage electronic and paper-based patient data. The regulations, which have wide regulatory impact, define new methods for accessing patient data for medical research and education. Look for new policies in all areas of research as local medical centers and institutional review boards interpret the final rulings. It's anticipated that waivers and authorizations to use PHI for research will become standard elements of the institutional review board process.

Using Information to Prepare for Research

Researchers who wish to use PHI to prepare or develop research projects must acknowledge, in writing or orally, that:

- The use or disclosure of the PHI is solely to prepare a research protocol or similar information preparatory to research
- The research will not remove any PHI from the covered entity
- The use of the PHI is necessary for the research purpose

Using and Disclosing PHI for Research

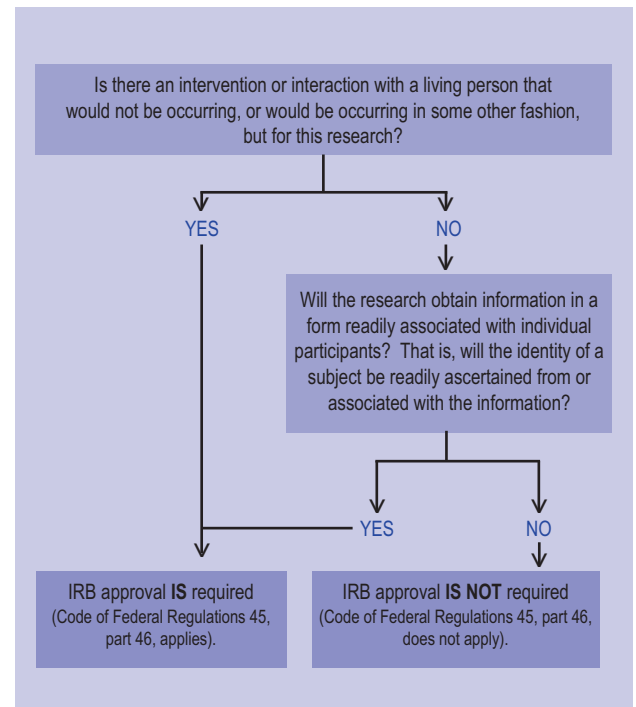
In the course of conducting research, researchers may create, use and/or disclose individually identifiable health information. Under the privacy rule, covered entities may use and disclose PHI for research with individual authorization or without individual authorization under limited, defined circumstances. In the next issue of Research Review, we'll take a closer look at when researchers can use protected health information without authorization.

There are thousands of pages of regulations governing research on human subjects. Many of the regulations are (intentionally) vague. Others appear to be contradictory. In this column, we'll periodically answer frequently asked questions regarding research regulations.

We'll begin with the most common question:

"Do I need institutional review board (IRB) approval for my project?"

The best answer is that, when in doubt, consult the IRB. First, however, consider the guidance offered by the Office for Human Research Protections (OHRP) at <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/decisioncharts.htm>.



One important ramification of this process stems from the use of patient medical records. The interpretation of most IRBs (including the University of Minnesota IRB, to which we are contractually bound) is that medical record review does involve data that can be associated with individual participants. Chart review research, therefore, requires IRB approval. The approval can almost always be gained in an expedited manner.



RESEARCH IN Review

Linda E. Krach, M.D., Director of Research

On Nov. 1, Gillette Research sponsored an educational activity about research and the rules and regulations relating to it. We were very pleased with the turnout from the Gillette community — members of the medical staff, various nursing areas, Rehabilitation Therapies, the Assistive Technology Department, and some departments that don't routinely care for patients, including Medical Records, Finance and Administration. We obtained information through small-group discussions that will help us plan Research activities for 2003. Thanks to everyone who participated. We hope to hold a similar event each year.

On another note, I recently served as a substitute member of a National Institutes of Health (NIH) scientific review committee. It was very worthwhile to be one of 14 participants on the medical rehabilitation research subcommittee of the National Institute of Child Health and Human Development. The day and a half were extremely busy, as were the weeks leading up to it. We reviewed about 30 grant proposals for scientific merit. Although the committee doesn't make funding decisions, we were well aware of the competitive nature of the process. Each of us was assigned specific grants to review and critique before the meeting, but we were expected to be familiar with all of them. It was very informative to see the wide variety of funding mechanisms and the differing areas being funded, to participate in discussions about the proposals, and to meet others who have been on the committee and involved in research at institutions around the country. It gave me some ideas for Gillette and possible funding for our activities.

ANNOUNCEMENT

Effective Jan. 1, 2003, Gillette Children's Specialty Healthcare has signed an agreement with the University of Minnesota Institutional Review Board (UMIRB) Research Subjects' Protection Program to review and monitor all of Gillette's human subject research projects. Application forms are available on GilletteNet and at the UMIRB site, <http://www.irb.umn.edu/>. Projects will no longer be submitted to the Children's Hospitals and Clinics IRB for review.

In addition, Gillette has filed a federal-wide assurance (FWA) for the protection of human subjects with the U.S. Department of Health and Human Services. This filing formally documents our assurance that all Gillette activities related to human-subject research — regardless of funding source — will be guided by the ethical principles of the Belmont Report, 45 CFR 46, and all of its subparts.

EVENTS

FEBRUARY

Feb. 19, 2003

Clinic Research 101

DoubleTree Park Place Hotel, St. Louis Park

Registration: 7:30 a.m.

Program: 8:00 a.m. - 4:30 p.m.

Cost: Members \$215, Non-member \$290.

Hosted by the Medical Alley's Clinical Studies Special Interest Group
Speakers: Ann Quinlan Smith, VP, Alquest, Inc., Dale Hammerschmidt, MD, Director of Education in Research Ethics and Compliance, University of Minnesota, Ruth Stovall, PhD, Clinical Research Manager, 3M HealthCare, Sarah Moeller, Senior Clinical Quality Specialist, Medtronic, Linda (Linn) Laak, VP, Eminent Research Systems, and Kim Oleson, Director, Clinical and Regulatory Affairs, EP Systems, Medtronic.

For information or registration, contact Medical Alley at 952-542-3077.

Feb. 20, 2003

Intro to IND/IDE Submissions

Dwan Conference Center at Park Nicollet Clinic, St. Louis Park

Registration and buffet dinner: 5:30 - 6:30 p.m.

Program: 6:45 - 8:15 p.m.

Hosted by the Minnesota chapter of ACRP

Speaker: Harvey M. Arbit, Pharm., MBA, IND/IDE Assistance Program director, University of Minnesota Academic Health Center

For information or registration, contact Julie Toth at 952-967-7569.

APRIL

Apr. 5 - 9, 2003

27th Annual North American ACRP Conference and Exposition Advancing Research Today for a Healthier Tomorrow

Philadelphia, Pa.

The program includes speakers, education, training, and networking events. Speakers include Arthur Caplan, Ph.D., a prominent voice in medical ethics. (CME, ACPE, CEUs available.)

For information or registration, call 703-254-8100 or e-mail office@acrpnnet.org.

Apr. 10, 2003

Fraud and Misconduct at Investigator Sites

Dwan Conference Center at Park Nicollet Clinic, St. Louis Park

Registration and buffet dinner: 5:30 - 6:30 p.m.

Program: 6:45 - 8:15 p.m.

Hosted by the Minnesota chapter of ACRP

Speakers: Kerrin Young, CRA, and Jeri Weigand, compliance auditor, 3M Pharmaceuticals

For information or registration, contact Julie Toth at 952-967-7569.

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ONGOING Clinical RESEARCH Projects

Clinical Trials in Pediatric Spinal Muscular Atrophy, Phase III.

Multi-site clinical trial funded by the National Institutes of Health.

Stephen A. Smith, M.D., PI, Mark E. Gormley, Jr., M.D., Ralph Faville, M.D.

Effects of Neuromuscular Electrical Stimulation (NMES) on Strength and Function in Independently Ambulatory Children with Cerebral Palsy. A Pilot Study.

Joyce P. Trost, RPT, PI, Kathryn J. Walt, RPT, Linda E. Krach, M.D., and Tom Novacheck, M.D.

Multi-Center, Randomized Trial Comparing Intralesional Methylprednisolone and Autogenic Bone Marrow Injections for Treatment of Simple Bone Cyst.

A national multi-site project sponsored by Pediatric Orthopaedic Society of North America.

Investigators: Kevin Walker, M.D., PI, Stephen Sundberg, M.D., Deborah Quanbeck, M.D., Lael Ludke, M.D., Steven Koop, M.D., Tom Novacheck, M.D., James Gage, M.D. and Stephen England, M.D.

Prospective Analysis of Selectively Eliminating Bacterial Carrier States to Reduce Infections of Implanted Programmable Pumps for Continuous Infusion of Intrathecal Baclofen.

Funded by Medical Education and Research Association of Gillette.

Ralph Faville, M.D., PI, Linda E. Krach, M.D., Michael Partington, M.D., Kent Crossley, M.D. For information contact Kim Marben, project coordinator, at 651-229-3878.

Retrospective Analysis of Children with CP.

Project is being sponsored by grant from Allergan.

Mark E. Gormley, Jr., M.D., PI, Jacalyn Kawiecki, M.D. and Michael Schwartz, Ph.D.

Projects Recently Submitted to Institutional Review Board

National Airway Clearance Registry.

A national multi-site project funded by Advanced Respiratory.

Jean Stansbury, R.N., PNP, PI, Paul T. Kubic, M.D. and Linda E. Krach, M.D.

National Cooperative Growth Study.

A national multi-site project funded by Genentech.

Kevin Sheridan, M.D., PI, Holly Cain, coordinator.

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