home implementation models were in place for primary care settings in the Army, Navy, and Air Force by 2011. According to a Government Accountability Office report issued last year, DoD expects its investment in medical homes to total about $570 million through fiscal year 2016 and to reap about $40 million in savings for the military health system by that time.

McGinnis said DoD pharmacists have only recently been working in medical homes, but that work will expand.

"This is extremely important to the medical personnel in the medical homes," McGinnis said. He explained that adding pharmacists to these teams should reduce unnecessary and costly medication-related hospital visits and readmissions.

He said that military pharmacy pays attention to approaches that have proved beneficial elsewhere.

"What we try to do is follow the best commercial practices, when possible," he said.

McGinnis pointed to the increased use of pharmacist–vaccinators in community pharmacies as a positive practice change that DoD pharmacy has embraced.

Since December 2009, he said, pharmacists in DoD's community pharmacy network have administered more than 1 million vaccine doses of all types to military families. He expects to break the 2 million mark by the end of this flu season.

McGinnis said 40,000 pharmacists in all 50 states are involved in this effort.

"The goal is to get our vaccination rate as high as possible. This will save us quite a bit of money in the long term, when we're not treating beneficiaries for the flu or complications of flu," he said.

The population health focus fits in with the military's quadruple aim of improved health for service members, an enhanced experience of care, and lower per capita costs, all in support of readiness.

"Our highest priority is our troops," McGinnis said. "Keeping them ready to go to war is our highest priority. Keeping their family members in good health is important, too, so the active duty [person] doesn't have to worry about the family members."

—Kate Traynor

DOI 10.2146/news130082

Informed consent remains a work in progress

Although patients who participate in research have been providing informed consent for decades, the issue of how to define consent and properly obtain it remains murky.

"Informed consent is certainly not perfect in medical practice," said Christine Grady, chief of the bioethics department at the National Institutes of Health Clinical Center, during an October 30 presentation for a course on ethics and clinical research.

"We need new ways to present information and help people understand what studies are about before they enroll," she said.

For research involving FDA-regulated drugs, informed consent entails providing patients with all of the information they need to decide whether to enroll in a study or continue participating in it. Federal regulations require that patients understand the potential risks and benefits of participating in research and also that they can decide to drop out of a study at any time.

But Grady said that the research that's been done on the consent process shows wide variation in what patients understand about their participation in clinical studies.

She cited reports showing that 28–100% of patients in different studies were able to name adverse events related to their experimental therapy, and 21–42% correctly answered questions about randomization. In other studies, the percentage of patients who knew that they could quit their study ranged from 44% to 90%.

Grady encouraged researchers to develop new ways to help patients understand what study participation means for them.

"There are many ways to present information besides written information, and we need to be creative with these," she said.

Limited evidence suggests that audiovisual interventions may improve the informed-consent process, according to a 2008 Cochrane Review.

That's one approach taken for a study at St. Jude Children's Research Hospital in Memphis, Tennessee, where the pharmacist-led research team has created an educational video for potential participants in the Clinical Implementation of Pharmacogenetics (PG4KDS) study.

The video is publicly available on the hospital's website and features discussions among the study investigators and family members of patients.

Led by Pharmaceutical Sciences Chair Mary Relling, PG4KDS is a study in which genotyping of patients is done prospectively to test for gene variations that may affect the response to drug therapy.

"PG4KDS is a protocol where we ask the patients to participate in the study so that we can use their pharmacogenetic profile to determine if there are certain medications that they should not receive, because they might be at increased risk of having toxicity or not benefiting because of their genetic profile," said Cyrine-Eliana Haidar,

Photo courtesy of Peter Barta, St. Jude Children's Research Hospital

Cyrine-Eliana Haidar

clinical pharmacogenetics coordinator for St. Jude.

Study data are kept behind a research firewall unless it's determined that incorporating specific genetic information into patients' medical records may help to guide current or future therapy. So far, four genes affecting 12 drugs have made the move from the research lab to the clinical care setting.

Relling, in the video, said that although no adverse consequences are expected to result from having the information in the medical record, once it's there, it stays there, and patients need to know that.

Haidar said the discussions in the video were presented in nontechnical terms as much as possible to help viewers understand the inherently complex topic of pharmacogenetics.

"We think about consent here as more than them signing the piece of paper," Haidar said.

Haidar serves on the institutional review board at St. Jude, which ensures that the content of consent forms is clear and complete and matches the study protocol.

For PG4KDS, she educates the study's nurses about pharmacogenetics so that they can accurately describe the study protocol to patients during enrollment.

Haidar said that although pharmacists don't typically participate in obtaining informed consent from patients, they can help make the process better.

"A lot of times we get called in during the consent process when patients are being enrolled on a study, because the parents or the teenager asks a question about how the medicine works, or what the major side effects of the medicine are," she said. "So I definitely think there's a role for the pharmacist to be available during the consent process and help explain to the patients the adverse effects of the medicines that they're going to receive."

In addition to clinical research, informed consent is also a key element in certain FDA-mandated risk evaluation and mitigation strategies (REMS). Nearly all informed-consent elements found in REMS deal with teratogenicity, and the prescriber must obtain the informed consent.

Informed consent is required in some states for patients to receive collaborative drug therapy management services from a pharmacist. Pharmacists' direct involvement in this process varies by state.

The Institute for Safe Medication Practices last year raised the issue of whether informed consent should be required before patients receive compounded sterile products. This issue was also discussed a decade ago in *AJHP* News.

At presstime, federal legislation that is meant to improve the safety and quality of compounded medications had passed the House and Senate. The legislation does not mention informed consent.

—Kate Traynor

DOI 10.2146/news130083

News Briefs

• **Revision of the Basel Statements from the Global Conference on the Future of Hospital Pharmacy** in 2008 is underway. The Hospital Pharmacy Section of the International Pharmaceutical Federation (FIP) has launched an online survey, at www.surveymonkey.com/s/FIPBaselStatementSurvey, to collect input from any individual interested in global pharmacy. Section leaders will use that information to propose changes to the Basel Statements and then conduct discussions on those proposed changes. The plan is to finish revising the statements at the 2014 FIP World Congress of Pharmacy and Pharmaceutical Sciences in Bangkok, Thailand.

ASHP Chief Executive Officer Paul W. Abramowitz, Pharm.D., Sc.D. (Hon), FASHP, attended the Virginia Society of Health-System Pharmacists (VSHP) Fall Meeting in Norfolk on October 18. He delivered the keynote presentation, "Transforming Patient Care: Paramount Issues and Opportunities in Pharmacy Practice," and met with VSHP leadership.

• ***Pharmacy Forecast 2014-2018: Strategic Planning Advice for Pharmacy Departments in Hospitals and Health Systems*** becomes available in December. This report, from the ASHP Foundation Center for Health-System Pharmacy Leadership, presents the results of a survey of trend watchers in health-system pharmacy (see figure for an excerpt), analyzes their predictions, and presents strategic recommendations to pharmacy practice leaders. The intent of the report is to help pharmacy practice leaders assess the external environment in their strategic planning for the next five years. The entire report is available at www.ashpfoundation.org/pharmacyforecast.

Quality of Care: In at least 75% of hospitals, pharmacy departments will be accountable for contributing measurably to improvement of institutional performance on externally reported "core" indicators of quality and safety.