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Study suggests routine use of blood transfusions during CABG surgery poses significant risk of complications and death

A new study that reviewed the records of almost 25,000 patients suggests that blood transfusions during coronary bypass graft (CABG) surgery may double the risk of infection and increase the risk of death by almost five times.

"Transfusion has been a standard medical practice for almost 100 years, and changing the liberal use of transfusions is going to be difficult despite the evidence showing that it is usually not essential," says co-investigator Neil Blumberg, M.D., professor of pathology and laboratory medicine, and director of transfusion medicine, University of Rochester Medical Center (Rochester, NY, USA). The current study adds to a growing body of evidence demonstrating that "transfusions should be a last resort, not a first resort, as they often are," Blumberg told *Health Technology Trends*.

"For most types of surgery, blood transfusions are not required; however, transfusions may still be required in some major operations that can involve significant blood loss, like hip replacement, open-heart surgery, and some neurosurgical procedures," Blumberg explains. "By and large, the best approach would be to stop the routine use of blood transfusions unless you have a clinically compelling reason to use them," he states. "Historically, physicians were trained to use transfusions with the belief that they would prevent bad things from happening, but in most cases, transfusions are actually causing bad things to happen" without consistently providing a significant benefit, says Blumberg.

Latest evidence

In the current study (*BMC Medicine*, 2009 Jul 31;7:37), Blumberg, Principal Investigator Mary A.M. Rogers, Ph.D., M.S., and colleagues at the University of Michigan Health System (Ann Arbor, MI, USA) reviewed patient records from 24,789 Medicare beneficiaries who underwent CABG at 40 hospitals across the state of Michigan between 2003 and 2006. Researchers designed the retrospective analysis to assess hospital variation in blood use and outcomes in cardiac surgery patients.

Investigators found considerable variation in transfusion practice among hospitals, with 30% of the variance attributable to hospital site. Depending on local practice, the use of allogeneic (i.e., donated) blood ranged from 72.5% to 100% in women, and from 49.7% to 100% in men. In elective surgeries, allogeneic, but not autologous (i.e., patient's own), blood transfusion increased the likelihood of in-hospital infection by 2 times ($p < 0.001$), in-hospital mortality by 4.7 times ($p < 0.001$), 30-day readmission by 1.4 times ($p < 0.001$), and 30-day postoperative mortality by 2.9 times ($p = 0.005$). Allogeneic transfusion was associated with infections of the genitourinary system (1.3 times more likely, $p = 0.023$), respiratory tract (2.5 times more likely, $p < 0.001$), bloodstream (3.7 times more likely, $p < 0.001$), digestive tract (2.1 times more likely, $p = 0.048$), and skin (2.3 times more likely, $p < 0.001$), as well as infection with

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Inpatient computer-assisted coding system developed at UPMC shows promise six months after deployment

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Natural language processing (NLP) software, which can abstract and convert and/or classify unstructured electronic information such as words and phrases into structured, usable data, holds promise in a number of areas in healthcare. Aside from the more ambitious pursuits of health informaticists who use NLP to abstract clinical data from patient records to conduct epidemiological studies, NLP software has been around for at least 10 years in the health information management (HIM) sector, according to Mark L. Morsch, vice president NLP and software engineering, A-Life Medical, Inc. (San Diego, CA, USA). Companies like his have been developing NLP to process physician notes and patient records in order to generate treatment, diagnosis, and reimbursement codes (e.g., CPT, ICD-9-CM, HCPCS II). Known as computer-assisted coding (CAC), thus far its use has been limited to outpatient radiology, pathology, cardiology, and emergency department (ED) settings. But recently A-Life, along with other companies such as CodeRyte (Bethesda, MD, USA) and Dolbey, Inc. (Cincinnati, OH, USA) have begun to compete in the inpatient arena with proprietary versions of NLP-based CAC engines that the companies claim can cut staffing costs, improve coding quality and accuracy, and ultimately increase reimbursement for hospitals.

In 2007, A-Life partnered with University of Pittsburgh Medical Center (UPMC, Pittsburgh, PA, USA), a large integrated non-profit health system in western Pennsylvania, to develop ACTUS, an inpatient NLP-based CAC engine. *Health Technology Trends* spoke with Adele L. Towers, M.D., M.P.H., medical director, HIM, UPMC Presbyterian/Shadyside, and Nancy Soso, senior director, HIM operations, about some of the six-month results they presented at the American Health Information Management Association (AHIMA) annual convention in Grapevine, TX, USA, held October 3-8, 2009.

Scope of the project

The HIM department at UPMC's Presbyterian/Shadyside handles more than 100,000 discharges a year from 5 different UPMC facilities, Towers told *Health Technology Trends*. It's also a number she expects to grow as several more hospitals join the centralized HIM department.

ACTUS was deployed in mid-December 2008 at UPMC for all inpatient cases. "We're very satisfied with it because we were extensively involved in the development process. Coders, coding management, and department management participated in every aspect of development," explains Soso. "We worked hand in hand to develop a product that would do well in a real live production environment."

Prior to implementation, Soso says her department's charts-per-hour standard was two. This may sound low, she says, however, UPMC sees a large volume of complex cases as a tertiary academic medical center. In addition, the medical coders work with a hybrid medical record system that comprises paper and electronic records from various sources, which complicates the review of the record for coding. After implementing ACTUS, "Our productivity rose steadily," she says. "We've seen our productivity rate climb to 2.4 charts an hour at 4 months post implementation, a rise of 20%, so that was an impressive bump up." Soso has seen productivity continue to increase as they work with the vendor to improve the product and make it more beneficial to users.

The increased productivity has allowed the department to cut overtime, another metric they looked at, according to Towers. "Overtime went down by 85%, which for us was an annual savings of \$200,000," she notes.

Quality has also improved, according to Soso. "We have auditors who we engage as part of our coding compliance program to

look at post-discharge/post-coding records from a sample of Medicare discharges, as well as samples for some other payers." In monitoring their progress, she says, "We noticed that the number of findings in the coding variances continued to decrease, almost in half from where they had peaked," Soso observes. As a result of the improved coding accuracy, "We changed our contract with that vendor and now they're reviewing [fewer] cases for us," says Soso. "Our expenses decreased by about 50%."

Towers estimates the annual savings to be more than \$500,000.

"Of course," Towers, cautions, "the CAC is not an encoder [a computerized coding reference tool], so currently our auditors still find a number of cases in which the codes are correct but there are sequencing errors." However, she adds, "Where we're really seeing improvement is in the capturing of diagnosis codes . . . ones that generate income, which are tied to changes in the DRG [diagnosis-related group]." Towers says this is the main reason UPMC cut back on auditor utilization. "We are capturing codes that we previously were not."

Another metric that Towers says they are tracking with regard to CAC implementation is the hospital's case mix index (CMI), the average DRG weight for all of a hospital's Medicare volume. "It's what's tied to our reimbursement," she explains. "Our CMI increased significantly from June 2008, which was prior to the implementation, so we saw a partial increase with partial implementation, and now we're seeing a steady increase, so it's roughly been 4%, which translates roughly to \$400 per Medicare case if you annualize that, which could mean up to a \$9.6 million increase in revenue due to better capturing of secondary diagnosis," Towers projects. "That's our CFO's favorite slide."

Soso says that data for the AHMIA presentation only go up to June 2009; however, CMI is still on the rise.


The software also has a dashboard feature for managers, according to Towers, which allows them to track how many charts have been coded, need coding, or are still in the NLP. "This helps us to quickly analyze coding progress and adjust the work distribution schedule for the coders," she said.

Change in responsibilities

Before implementation, Towers says the medical coders' biggest fear was that CAC would eliminate their jobs. Human coders have been successfully replaced by software in outpatient, radiology, and ED settings. Thus far, however, the complexities of inpatient coding still require the medical coders' expertise. "They still have to review documentation and validate the codes submitted by the application," she says, "but it's a much quicker process." And because the NLP cannot read human handwriting, some documents need to be scanned into an imaging system and reviewed by the coders manually.

Overall, Soso says that during the development phase of the software, "We kept in mind—which was very difficult to do—that this product will be deployed far beyond UPMC, so it's not built with 1,000 UPMC-specific nuances. It is an application that could be very beneficial in most HIM departments."

A-Life purchased the remaining rights to the ACTUS inpatient product in May 2009, which it is now marketing to hospitals.

One of the earliest adopters of inpatient NLP-based CAC is Robert Wood Johnson University Medical Center (New Brunswick, NJ, USA). The facility began beta-testing EMscribe Dx, developed by Artificial Medical Intelligence (Eatontown, NJ, USA) in 2005. The hospital officially deployed the system a year later. The product is now marketed as Dolbey's Fusion-CAC. 

"We've seen our productivity rate climb to 2.4 charts an hour at 4 months post implementation, a rise of 20%, so that was an impressive bump up."

Structured versus unstructured data in EHRs: Is 'meaningful use' in the eye of the beholder?

Summary

As more clinicians begin to adopt electronic health records in clinical practice, Health Technology Trends spoke to clinicians using speech-recognition technology to capture patient data to find out how this affects downstream processes, from workflow to the generation of meaningful patient data.

One perception that exists about electronic health record (EHR) adoption and implementation is that electronic patient data are more easily accessible, searchable, and portable. However, the value of the data is in the eye of the beholder and subject to the context and format of the information that is captured. Point-and-click templates, popular in many EHRs, offer structured documentation formats; however, not all clinicians like the data-entry aspect of the workflow. Technologies, such as voice-recognition software, which convert speech to text, continue growing in popularity, despite the unstructured or narrative text format. *Health Technology Trends* spoke to stakeholders about how these varying formats affect workflow and the value of the data in EHRs. We also looked at documentation standards under development, along with developments in natural language processing (NLP), which could foster true meaningful use of unstructured data as providers prepare to comply with the HITECH portion of the American Recovery and Reinvestment Act of 2009 to be eligible for incentive payments.

Speech to text

The healthcare industry is still awaiting a final definition of "meaningful use" as it relates to EHR adoption and utilization. In the interim, health technology vendors like Nuance Communications, Inc. (Burlington, MA, USA), emphasize the cost-cutting potential of its solutions, which are incorporated into a wide range of software vendors' products. Nuance's marketing strategy for its speech-recognition software, Dragon Naturally Speaking, includes testimonials from large institutions citing millions of dollars saved in medical transcription costs.

Andrew S. Fireman, M.D., a cardiologist with Abington Medical Specialists (AMS) affiliated with Abington Memorial Hospital (Abington, PA, USA) told *Health Technology Trends* his busy cardiology practice has completely eliminated medical transcription. WellSpan Health (York, PA, USA) has

reported that its transcription costs have dropped between 90% and 95% at the large integrated delivery network, according to R. Hal Baker, M.D., F.A.C.P., WellSpan Health vice president and chief information officer. Yet while these facilities have cut costs and streamlined the documentation process, the impact their narrative notes may have on the quality of the information within the EHRs they've adopted is unclear.

"Speech-recognition software, to a certain degree, goes against what EHRs are designed to do," says AMS's Fireman. Yet most of the 19 clinicians in his practice use the technology to dictate patient notes. "Our practice implemented a [template-based] EHR about two years ago," he explains. "If we didn't have speech-recognition software, I don't think we could have done it." While Fireman recognizes the value of structured data from templates, he adds, "We are more efficient with immediately accessible, quality dictated data."

But measuring outcomes in a narrative format is another story, and Fireman admits that outside of these internal efficiencies, "creating unstructured data may not satisfy third-party requirements."

Baker says WellSpan Health was also faced with rolling out an EHR system that featured templates. "We were going to use point-and-click templates, and this would be fine for billing," but when it comes to sharing records with clinicians, "there's only so much you can get out of reading a structured data note." Therefore, Baker says, "In rolling this out, we recognized that some parts of the note needed to be done in a narrative fashion. Trying to fit the patient into the template was going to bastardize the process."

Templates are designed to generate accurate data but often don't, as Baker illustrates. "Is the patient a smoker? 'Yes' or 'no'? That seems easy." However, he questions, "What do I do if they chew tobacco? What do I do if they have three cigars a year? What do I do if they smoke a pipe?"

► ECRI Institute perspective on EHRs' unstructured data and meaningful use

"We do have a draft of the meaningful use requirements," notes ECRI Institute's Jason Launders, M.Sc., senior project officer and medical physicist. Launders is referring to the electronic health record (EHR) stipulation in the HITECH portion of the American Recovery and Reinvestment Act of 2009. "While it is not finalized, we have a fairly good idea about what will be included in the rule" to which providers must comply to be eligible for incentive payments. Launders says that one of the requirements will be to report general health data. "This type of data must be captured in check boxes from template-based EHRs," he says. Although, he acknowledges, "These check boxes cannot be used to record the full patient encounter." Some providers have expressed concern about the limited amount of detail that such a structured format offers. Although, Launders points out, "absolute accuracy isn't really a problem when dealing with population statistics, [because] they do not directly affect individual patient care."

Today, Launders notes that in some cases, the dictated notes are transcribed and printed and sometimes imported into an EHR by scanning the documents. However, "the database will treat it like an image, not text," he explains. Scanned documents may be useful for the care of the individual patient, "but they cannot be searched and used for population-based analysis, drug-interaction identification, etc." Launders compares it to search engines like Google. "It is really easy to find song lyrics, but difficult to find a picture, unless it is labeled with text." As Launders sees it, "Unstructured reports, that is, scanned documents, are likely to be allowed in the first year of 'meaningful use;' however, structured reports will likely become necessary later on."

Smoke marijuana but don't smoke tobacco? It gets complicated, and if everybody makes their own determination, you don't get accurate data out."

Fireman stresses the immediate availability of the narrative. "If I see a patient, within an hour of the visit, I've documented my entire visit with my thoughts, my descriptions, my plans, and those data are available to anybody else in the practice." He adds that on-call physicians also have immediate access to the primary doctor's plans and thought process.

The patient can also leave with a detailed document if the clinician dictates at the point of care. Fireman says this helps with a lot of his patients in long-term care facilities. "They require a lot of paperwork to be filled out." But with the speech-recognition software, "I just complete my letter with a combination of structured data entry and dictation and give them that letter."

Baker also dictates in front of his patients. "When my patients go to check out, they get a copy of my note. In the old days, I would tell the patient and then go tell the transcriptionist." Baker adds, "I may say it a little more slowly, but that probably isn't a bad thing, and it sometimes has odd typos, but patients heard me say it so they know what I said."

Baker recognizes the push for hospitals to report quality measures and metrics, something narrative text alone prohibits. Still, he questions the accuracy of some of today's data. "Financial recording systems require *an answer*, not *the answer*." For example, he offered, "I need a list of three diagnoses; they don't have to be precise. Is it diabetes uncontrolled? Diabetes controlled? Diabetes type II controlled? Diabetes type II controlled with nephropathy? I only have to put one of these down; it really doesn't matter which one," says Baker. "But if you want to do analysis, you really have to break that down, so you need to have reliable input of data." And it has to be structured, he adds. "Unless you have natural language processing to pull it out, you don't get the structured data out of a narrative note."

Narrative text needs NLP

Theoretically, speech recognition introduces error, providing more opportunity to dilute the value of the data (misheard or

misinterpreted text). But users claim that today's advanced software requires less editing from clinicians or medical transcriptionists before the narrative becomes part of the medical record.

Work is being done on academic and research frontiers to tie speech-recognition technology to NLP engines, which can mine clinical text and classify and format it into structured usable data, according to Mark L. Morsch, vice president NLP and software engineering at A-Life Medical (San Diego, CA, USA). Realistically, Morsch says the work hasn't yet trickled down to vendors' respective proprietary products. However, he says his company has joined the ranks of a small but growing group of healthcare documentation and software vendors, professional societies, and providers who support the adoption of documentation standards that could make narrative text meaningful.

Health Story Project

Health Story Project was launched in 2007 as CDA4CDT (Clinical Document Architecture [CDA] for Common Document Types). The standards are based on Health Level Seven's (HL7) CDA standard. "The goal was to create something that would enable dictation and narrative text to be included in the electronic health record," explains Susan M. Lucci, RHIT, CMT, AHDI-F, senior vice president, field operations, Webmedx, Inc. (Atlanta, GA, USA). "The concept of just having a few words, or a point-and-click solution, doesn't give you the level of detail you can get from a physician dictating the entire event, and circumstances of each patient situation," says Lucci, also the president of the Association for Healthcare Documentation Integrity, one of the founders of the Health Story Project.

"Developers of the Health Story Project discovered that with CDA language, you could use that as a tagging process so that the narrative text could be pulled right into the EHR in structured headings, without [requiring] a physician [to] self-enter the data, or implementing some other process . . . to get it in there," Lucci explains. The initiative is targeting EHR software

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“The concept of just having a few words, or a point-and-click solution, doesn’t give you the level of detail you can get from a physician dictating the entire event, and circumstances of each patient situation.”

developers, documentation vendors, and medical transcription service providers.

Lucci said that data standards have already been developed for the consultation note, the history and physical, the operative note, and the diagnostic imaging report. Balloting has begun related to a standardized discharge summary.

Health Story Project stakeholders argue that adoption of the standards will unlock valuable data from narrative documents and will “enlarge and enrich the flow of data into the EHR,” ultimately facilitating the goal of interoperable data repositories.

“I think it was an ‘ah ha!’ moment for us to say, ‘Look, we can have technology do this for us and at the same time, not change physicians’ usual process of dictation,’” said Lucci. “The point-and-click methods are shortcuts, but physicians went to medical school . . . to take care of patients and not to enter data into a computer terminal.”

Mining narrative data with NLP

Brian Hazlehurst, Ph.D., senior investigator at Kaiser Permanente Center for Health Research (Portland, OR, USA), has observed in his research that clinicians often find coded data entry cumbersome. Furthermore, it captures only a fraction of the information produced in the clinical encounter. “With EHRs, we do a lot of work to try and create structured data that can be entered with the use of point-and-click boxes, discrete data that can easily be queried to answer questions at a population level,” he explains. However, “physicians still write the narrative note because . . . it’s an important aspect of their providing care.”

Rather than interrupting clinicians’ workflow, “My work looks at how much data we can get out of the narrative note,” explains Hazlehurst. He developed Medi-Class, a knowledge-based NLP system that automatically classifies the content of a clinical encounter captured in the medical record. The NLP engine can process data from any EHR system that uses HL7’s CDA data standard.

The extracted data are used in epidemiological research. “We do studies with epidemiological questions like, ‘Who has asthma? How severe is it? Is it persistent? How often does it flare up?’” volunteered

Hazlehurst. “These are questions that, when you get very specific, are not all captured in the coded data that are entered in the medical record, but are often in the note.” Another example of a study using NLP is “how well we could identify the delivery of smoking cessation care.” Yet another example looks at possible vaccine adverse events. “As you can imagine, those are difficult for clinicians to code because there’s a delay in events from the vaccination event to the action event, which might be several days later.” In this case, research indicated that clinicians rarely identified a possible reaction from a vaccine in a coded field, yet would capture relevant symptoms, findings, and even clinical reasoning indicating a possible adverse event in their text note.

NLP’s role in meaningful use?

Some health informaticists believe NLP could be the answer to convert unstructured clinical data from the EHR into meaningful data. But how this technology fits in with the U.S. government’s definition of “meaningful use” at it relates to EHR adoption is speculative, says Hazlehurst. “Certainly, high on the priority list of questions are ones related to the quality of care being delivered and how we measure that,” he offers. “Insofar as NLP is critical to using EHRs for quality research, which I think it is, then it’s going to have a big role to play in meaningful use of EHRs,” he theorizes. However, he concedes that mandates related to NLP are not likely now.

Asked whether NLP and narrative text plays any role in interoperability (the ability of disparate systems to exchange information), Hazlehurst responded, “Questions of interoperability are largely driven by the data needing to mean the same thing at different places, and there are a lot of variations that creep in. Some are from vendors’ technology and the way it captures data, and some are from the practices that the organizations themselves promote [such as] the way they train clinicians to document events.” Still others emanate from regional variations in patient populations, adds Hazlehurst. That said, “throughout the working world, we do a pretty good job in narrative of speaking to people in different places [and conveying similar meaning], as long as we’re all speaking the same language.”

*Transfusions during CABG surgery
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Clostridium difficile (3.2 times more likely, $p=0.008$). Furthermore, for each 1% increase in hospital transfusion rates, investigators observed a 0.13% increase in predicted infection rates.

Changing minds?

"Today, most transfusion practices are not based on solid evidence, yet they have endured throughout general clinical practice," says Blumberg, who has been studying transfusion safety for about 30 years.

Although Blumberg believes that too many patients still receive transfusions, the total volume of donor blood that a typical transfusion recipient receives today is less than what a recipient received a couple of decades ago. "When the AIDS epidemic emerged in the 1980s, more people began thinking about cutting back on transfusion due to the risk of disease transmission," says Blumberg. However, as better blood screening techniques improved the safety of the donated blood supply in terms of infectious diseases, the concern over transfusions diminished as other new issues arose. "Reducing the number of unnecessary transfusions should be a very high priority, but unfortunately, it is not in many places," Blumberg states. "It requires a lot of time and resources to educate staff on this issue," he says. "Are we doing better than we were 30 years ago? Absolutely. Could we do more to reduce the number of transfusions? Probably," Blumberg states.

"However, I believe that we are finally starting to get some traction on this issue" as research like the current study adds weight to the argument in favor of more judicious use of transfusions, Blumberg explains. "The anesthesiologists and critical care physicians are very concerned about the risks of adverse effects from transfusions," he says. "Now the treating physicians are starting to collect data that support concerns that other physicians who study this area have had for some time," says Blumberg. "Although we are getting more data establishing that blood transfusions can cause various problems, we still are not always sure what the exact sources of those problems are," he says. "You could describe the current state of transfusion research as 'the end of the beginning,'" he says.

At the University of Rochester Medical Center, Blumberg and colleagues have revised clinical guidelines for the use of blood transfusions. So far, the changes have resulted in about 15% fewer transfusions at the facility, and investigators will continue to monitor progress at the hospital.

Other options

Blumberg explains that physicians can employ several techniques to reduce risks from allogeneic transfusions, including more conservative (lower hematocrit) transfusion trigger thresholds, autologous banking, leukoreduction, hemodilution, and blood salvage. "It is clear that formerly accepted thresholds for transfusion in non-bleeding, stable patients, such as a hematocrit of 30, are much too liberal and likely provide no benefit with increased risk," he notes. Many facilities are moving towards a transfusion threshold for red cells of a hematocrit of 21 in stable, nonbleeding patients without active coronary artery disease symptoms, says Blumberg.

In some cases, patients who may require transfusion during elective surgery can collect and store their own blood far ahead of the scheduled procedure so a supply of autologous blood is available if the need for transfusion arises. Another process called leukoreduction removes the white cells from donated blood in an effort to reduce the risk of infection and inflammation from transfusion. In hemodilution, anesthesiologists collect autologous whole blood and replace it with saline or other fluids just before surgery; after surgery, physicians reinfuse the patient's stored blood to restore red cells lost during surgery. Physicians may also use autologous blood salvage techniques to recover blood lost during surgery and to reinfuse it to the patient.

Furthermore, Blumberg notes that most transfusions today typically involve only certain blood components rather than whole blood. "It is hard to generalize the risks from allogeneic blood since each blood component can be associated with different risks. For example, plasma can have a lot of antibodies, and platelets can have a lot of immunologically active cells," he says.

“Historically, physicians were trained to use transfusions with the belief that they would prevent bad things from happening, but in most cases, transfusions are actually causing bad things to happen.”

Transfusions during CABG surgery (continued from page 7)

► Blood transfusions more than double since 1997, AHRQ reports

Inpatient blood transfusions increased by 140% between 1997 and 2007, from 1.1 million to nearly 2.7 million, according to the Agency for Healthcare Research and Quality (AHRQ). This represents the largest increase in procedures over the 11-year period not involving pregnancy or childbirth, according to AHRQ's HCUP [Healthcare Cost and Utilization Project] Facts and Figures: Statistics on Hospital-Based Care in the United States, 2007.

Blood transfusions occurred in 1 of every 10 hospital stays that included a procedure. Transfusions are one of the fastest growing top-5 procedures across many age groups: there was a 72% increase for patients age 1 to 17, a 187% increase for patients age 45 to 64, a 127% increase for patients age 65 to 84, and a 156% increase for patients age 85 years or older.

So what's the reason for the increase? "The short answer is we do not really know," says Claudia A. Steiner, M.D., M.P.H., senior research physician, Center for Delivery, Organization, and Markets, HCUP, AHRQ. "I am actually in the midst of an analysis to try to answer this question, but that will take another month or so," she told Health Technology Trends in an e-mail. "We have run several years of data, and are investigating exactly what you are asking: What conditions or procedures seem to be associated with this acute rise in transfusion?" Steiner says they're also looking across conditions, procedures, and age groups.

Blood transfusions are most often performed because patients suffer a sudden loss of blood from injuries; experience low red blood cell count before, during, or after surgery; for cancer; or in cases of moderate to severe anemia.

The information is part of a larger report of statistics on hospital-based care in the United States. To access HCUP Facts and Figures, visit http://www.hcup-us.ahrq.gov/reports/factsandfigures/2007/TOC_2007.jsp.

Blood substitutes

Over the past few months, Biopure Corporation (Cambridge, MA, USA) and Northfield Laboratories Inc. (Evanston, IL, USA), two leading developers of hemoglobin-based blood substitutes, filed for Chapter 11 bankruptcy relief in the United States. In April 2009, the U.S. Food and Drug Administration (FDA) denied Northfield's Biologics License Application for its PolyHeme product. FDA concluded, "The safety data of all controlled studies reveal that the administration of PolyHeme places the patients at a higher risk of significant adverse events... therefore, in the absence of clinical benefit, the risk-benefit assessment of the product in trauma is unfavorable."

Given this history, Blumberg doubts whether another hemoglobin-based blood substitute will be commercially developed in the near future. Although controversy still exists, "there is some speculation that free hemoglobin itself might be dangerous, and hemoglobin could be a major reason why transfusion of stored blood causes morbidity and mortality," he says. "If that is true, then it is possible that a hemoglobin-based blood replacement might be inherently toxic," Blumberg suggests.

Likewise, "the Teflon-like perfluorocarbon-based blood substitutes, such as Fluosol, have not really performed that much better than hemoglobin-based products," says Blumberg.

"So far, it appears that no synthetic or artificial blood products perform as well as the real thing, and I do not expect that to change in the near future—especially products intended for use in a typical civilian trauma population," says Blumberg. "There has been some interesting *in-vitro* work using stem cells to grow new blood cells,

but that approach probably has a long way to go before it can be perfected," he notes.

Cost control

Aside from the primary patient safety aspect, reducing transfusions can produce economic benefits. When transfusions are required, Blumberg is a strong advocate of leukoreduction, which adds about \$20 to \$30 per unit to the cost of blood. The relatively small additional cost is likely to be cost-effective if you can significantly reduce the need to treat transfusion-related complications, Blumberg says. In past research, Blumberg and colleagues demonstrated that treating complications from blood transfusions using nonleukoreduced blood could add about \$1,000 to \$2,000 in treatment costs. Although leukoreduced blood tends to produce fewer complications, they can still occur. "So, even a couple hundred dollars more [to treat transfusion-related complications] will add up over time," Blumberg notes.

"About 1% of our national healthcare budget goes toward treating transfusion-related complications, but we could minimize that if we stopped performing unnecessary transfusions and had universal leukoreduction of blood transfusions," says Blumberg. "I don't think this fact has caught the eye of hospital administrators yet, but evidence is building that reducing transfusions makes economic sense," he says. "Not only will reducing the number of transfusions reduce death and morbidity from [transfusion-related] complications, but fewer transfusions will reduce the cost of collecting, storing, and handling the blood used for those transfusions," he says. "Cost has not been a driver in the discussion over transfusion practice," says Blumberg, "but cost definitely should be a factor to consider." ►