There’s been a flood of different measures and metrics in recent years. CMS, Joint Commission, hospital organizations, and vendors each have their own way of calculating a hospital’s ranking and improving patient care.

While hospitals are already expected to conduct certain surveys by various agencies, how often should they conduct their own research? What measures should they use? And how do they use the information they have to drive improvement?

The difference between them

There are two definitions that are used often in conjunction with a hospital’s merit: patient satisfaction and quality of care. Patient satisfaction measures how a patient feels about the care they received. Care quality measures whether the care given was any good.

Janiece Gray, a founding partner of DTA Associates and author of the HCPro book Beyond CAHPS: A Guide to Achieving Patient- and Family-Centered Care, says that it’s important to know the differences between the two measures, as they aren’t always in alignment. She points to her experience with a former chiropractor as an example. She had been going to this person for about two years for a medical issue and from a satisfaction perspective, couldn’t have been happier.

“But after about a year and a half of going to this person and paying out-of-pocket for this issue [I had] that wasn’t getting any better, I finally woke up and was like, ‘It doesn’t really matter how much I like her, I don’t think she’s able to fix the issue that’s going on,’ ” she says. “I was referred by a friend to a new provider and that person didn’t have the greatest bedside manner at all. She was kind of rough or abrupt, almost rude sometimes. But she knows her stuff and is helping me make progress on this same issue in a much shorter period of time.”

It’s important to recognize the differences between the measures, says Craig Deao, MHA, senior leader at Studer Group. Although the two measure different things, it’s a mistake to think one of them is more important, he notes. In fact, the two often correlate.
patients, she says, and there’s no point in asking them a bunch of extra questions on the survey if the responses are never going to be looked at.

“You never really want to go to a group of patients and ask them something if you don’t intend to do anything with the information,” she says. “The patients say ‘well that’s worse than if you hadn’t even asked anything in the first place.’ ”

“It’s just a waste of that patient or family member’s time,” she added. “So, you want to be strategic and thoughtful focusing on what are we trying to improve, what changes can we make, and how do we measure that success. It’s making sure you survey process lines up with those goals.”

The feedback loop

To get from data collection to decisive action, facilities need to create a feedback loop, says Deao. A feedback loop is created when a person is able to adjust their behavior, see how that changes the data, and then uses that new data to adjust their behavior (and so on.)

As an example, he cites a Wired magazine article about methods of reducing speeding on the highway. Option A was a just a speed limit sign (35 mph). Option B was a sign that showed the speed limit and the speed that you’re actually traveling at (42 mph in the 35). And Option C was a law enforcement officer with a radar gun. Option B gave the best results, he says, because the flashing sign allowed people to adjust their actions and see the results within moments.

“When I change my behavior, I see how it changes the data,” he says. “So I take my foot off the gas and I see that I come into alignment with that expected performance norm. And it triggers in your brain an ‘Atta’ boy, nice job.’ That hardwires intrinsically that that’s good behavior and so it actually causes that effective speed correction to last the longest compared to the other two.”

For a feedback loop to be viable, it requires data that’s timely, relevant, and credible. Too often when it comes to patient satisfaction data, it’s the lack of those three attributes that makes it hard to act on data.

“Consider timeliness: if this information is from patients you saw nine months ago, that’s not very helpful to make improvement,” he says. “Is it creditable data? Well if it’s an n of three and I saw 4,000 patients in that period, that’s not really good creditability.

Is this compared to something that I care about? For example, if you’re collecting physician-specific data and comments, and you’re comparing my results to all the physicians in the organization, most of whom aren’t in my specialty, I’m going to say that’s not very relevant data to my patient population.”

USP <800>: Protecting healthcare workers from hazardous drugs

According to the National Institute for Occupational Safety and Health (NIOSH), approximately 8 million American healthcare workers are potentially exposed to hazardous drugs each year. And in May, the Department of Health and Human Services (HHS) released a report critical of CMS surveyors’ oversight of hospitals’ use of compounded, sterile drugs. The report recommended that surveyors receive proper training on safe compounding practices.

While there have been numerous guidelines and recommendations on how to safely handle, transport, and dispose of potentially harmful chemicals and drugs, none of them have been enforceable. That was until the U.S Pharmacopeial Convention (USP) published its newest chapter on February 1, 2016. With USP General Chapter <800> Hazardous Drugs; Handling in Healthcare Settings, the organization hopes to promote worker safety, patient safety, and environmental protection using evidence-based practices and quality standards.

Chapter <800> covers from the moment a hazardous drug is received at the loading dock all the way
through to the medicine’s disposal. Its standards apply to anyone who comes into contact with hazardous drugs: nurses, physicians, pharmacists, pharmacy technicians, loading dock personnel, etc.

And on July 1, 2018 the chapter will become fully enforceable by regulators. With 18 months (as of January) until the chapter goes into effect, what do healthcare facilities need to know about USP <800>?

**The goal of USP <800>**

**Rick Schnatz, PharmD,** senior manager with the Healthcare Quality & Safety program at USP, says there are many sources that led to the creation of USP <800>, although a big influence was feedback from stakeholders. He recalls an encounter he had with a pharmacist and a veterinarian who represented a compounding pharmaceutical group in Arizona.

“At the end of the first meeting with these folks, I said, ‘I have to ask, I’ve never known a veterinarian to work for a pharmacist, can you tell me why?’ ” he says. “[The vet] said, ‘When I was 35, I had a very active veterinary practice and I developed thyroid cancer. The first question my oncologist asked me was, ‘Do you work with hazardous drugs?’ ”

The veterinarian told his physician that he worked with hazardous drugs regularly at his practice, Schnatz says. When asked if he was using any PPE, the vet had said, “Of course I do, I wear gloves.”

Schnatz says this lack of awareness resonated with the compounding expert committee that wrote USP <800>. The committee members had already been thinking along these lines, he says, and the veterinarian’s story definitely convinced them to move forward.

**Patricia Kienle, RPh, MPA, FASHP,** director of accreditation and medication safety at Cardinal Health, says that the new standards should be a boon to worker health and safety.

“I think people need to recognize that hazardous drugs are not limited to chemo,” she says. “And that there is an internationally accepted definition of hazardous drugs that includes other agents. Folks absolutely need to look at the latest NIOSH list of hazardous drugs from 2016. And in that NIOSH document, along with what’s in USP <800>, there’s a listing of why certain drugs are hazardous.”

It’s also important to note that there’s a difference between “hazardous drugs” and the EPA’s “hazardous materials.” It can be a little bit confusing, she says, because the word “hazardous” appears in both terminologies and there are some drugs that appear on both lists.

“But there is a distinct difference between the drugs that we are talking about and in USP <800> they aren’t limited to chemo,” she says. “There’s a number of other drugs; there’s antipsychotics, antibiotics, benzodiazepines. There are all sorts of other drugs that are listed in there. Folks need to understand why they are on that list, and those reasons are provided by NIOSH.”

That said, she adds that nothing in USP <800> should really come as a major surprise to anyone.

“Though it’s much more detailed in USP <800>, there’s been information on hazardous drugs since May 1, 2004 when the first USP <797> chapter was published,” she says. “And when USP <797> was revised in 2008, there was a larger section on hazardous drugs included. So this really isn’t a surprise to hospitals.”

**Getting ready**

Here are some things hospitals should go over before the July 2018 deadline:

1. **Read and have a copy of the NIOSH hazardous drug list.**

Schnatz say that clinics, hospitals, and pharmacies need to take a close look at the NIOSH *List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings*, 2016. The list is updated every two years and facilities need to compare the items in their inventory to the list.

“Some of these [drugs] aren’t marked as hazardous,” he says. “For example, hormones. Hormones are used in compounding quite frequently in the outpatient world, bioidentical hormones. And they aren’t marked as hazardous drugs, but they are on the [NIOSH] list and they can cause reproductive problems.”
2. **Have a compliant clean room**

“Most hospitals should at this point because it’s been a requirement since 2004,” Kienle says. “So if they have a compliant clean room that meets the requirements that are in USP <797> for chemo, they will be compliant with <800>. With a couple of little exceptions. If they’ve chosen to use some of the not-optimal but possible design characteristics that are in <797>. But if they have an anteroom and a negative pressure buffer-room that meets <797> requirements, that’s the same as what’s in <800>.”

3. **Do a risk assessment**

This is new for USP <800>, Kienle says, because the chapter defines specific containment properties and work practices that have to be used when dealing with hazardous drugs.

“USP <800> also allows organizations to carve out some of those specific dosage forms of the drugs that aren’t antineoplastic agents and deal with them differently if they can identify strategies that they take to protect their employees,” she says. “That’s all wrapped up in this assessment of risk and folks need to be doing that. They certainly need to do it before July 1, 2018 when USP <800> goes into effect. But I would recommend that they start that quickly; I think it will put their mind at ease on how they are going to handle some of these other drugs that aren’t antineoplastic agents.”

4. **Examine your closed system drug transfer devices**

These devices are already required in limited circumstances under USP 797, Kienle says. The difference is that USP <800> now requires the use of closed system drug transfer devices (CSTD) for the administration of agents.

“They need to look at this from a hospitalwide perspective, it can’t just be done by pharmacy alone or nursing alone,” she says. “It has to be done as part of a coordinated effort because the pieces that are used in these devices certainly need to match between pharmacy and administration of the drug.”

**Finding resources**

Schnatz doesn’t expect facilities to have trouble finding the resources to help meet USP <800> standards. There are a lot of good training resources out there from national pharmacy organizations as well as USP itself.

“We do training, we’ve already conducted classes on USP <800>,” he adds. “It’s didactic, folks can attend in person, and live over the web, things of that sort. And there are many equipment manufacturers that make the hoods and devices that these folks will need in order to safely protect their workers and their environment when they are compounding these preparations.”

Kienle says a few things come to mind when she thinks of the resources needed. There’s the cost of upgrading facilities and equipment, meeting new requirements like CSTDs, and training of personnel.

However, she points out a lot of what’s in USP <800> was already required under previous USP chapters. If a facility already has a clean room for chemotherapy medication compounding that meets USP <797> standards, it may need only minimal changes to be USP <800> compliant.

“There are plenty of places that will say, ‘Oh, it’s going to cost me X number of dollars to do this for my system,’ ” she says. “But it really should have been done more than 10 years ago. I don’t mean to be callous about that, but people need to remember this isn’t entirely new.”

**Training staff**

USP <800> requires that every organization have a designated person who’s trained and qualified to:

- Develop and implement appropriate hazardous drug and compounding procedures
- Ensuring compliance with USP <800> as well as all applicable laws, regulations, and standards
- Ensuring personnel are properly trained and educated
- Ensures environmental control of the storage and compounding areas
- Maintaining reports of testing/sampling performed in facilities
However, the chapter doesn’t specify how many hours or what types of training the designated person needs. Schnatz says this is partly because the standards apply to so many different types and sizes of settings, it would be difficult to come up with a set of training requirements that would apply equally to all of them. It’s also because they can’t guess at the training the designated person has already received, he adds.

“If you’ve got someone who just graduated school or just became a technician, they’ll need more training than someone who has been in this field for a number of years,” Schnatz says. “It also depends on the environment that they’re in. If they’re doing sterile, they might need more training than if they’re doing non-sterile because of complexities unto itself of making a sterile product at the end of the time you’re compounding.”

Schnatz notes that no matter what level of education the designated person receives, USP <800> requires that the person refresh training every 12 months.

Kienle says that typically it’s up to state enforcement agencies (e.g., Boards of Pharmacy) to determine specific amounts and types of training hours. Certain states (e.g., Texas) are very specific about how much training the designated person needs, she says. Facilities and clinics need to be aware of their state requirements.

“But [training] really depends on the scope of services that are being provided,” Kienle says. “There are a number of hospitals that limit their IV preparation to fairly simple compounds. There are others that have automated compounding devices that do a lot of total parenteral nutrition, neonates, respiratory mixtures, ophthalmic mixtures. It really depends on the scope of services provided.”

But there’s a growing number of training courses that are out there.

“Particularly if people are not comfortable that they know all that they need to, I would really encourage them to go to one of the courses that includes hands-on training, not just video or didactic training,” she says.

Enforcement

In Schnatz’s view, the biggest change that USP <800> makes is the fact that it will be enforceable by a number of government and private agencies.

“The first [hazardous drugs] guidance was by the Oncology Nursing Society (ONS) in 1984,” he says. “And in 1986 OSHA also came out with guidance, and then the American Society of Hospital Pharmacists (ASHP) Technical Advisory Bulletin on Cytotoxic Agents in 1985 was published. But these were guidelines. They weren’t standards and they weren’t enforceable. And that’s how we got into it.”

However, while USP sets the standards that hospitals will be expected to follow, the organization itself won’t be the one to enforce the chapter, says Kienle.

Enforcement will be left up to various regulators such as CMS, and many different state boards including pharmaceutical, nursing, and veterinary boards. This also includes the various accreditation organizations, such as The Joint Commission, DNV Healthcare, and HFAP. Many of these organizations already require compliance with USP chapters and guidelines.

“We’ve seen CMS, for example, in the last year and a half or so put in almost everything that’s in USP <797> and add that into the Conditions of Participation,” she says. “There are pieces of hazardous drugs [standards] in that language right now, so we’ll have to see how CMS approaches that. Certainly, most state boards of pharmacy implement Chapter <797>, or even a much broader perspective of USP chapters, in their pharmacy regulations.”

Patient safety is the most important thing, she says, and USP <800> will certainly make improvements in that area. What makes USP <800> unique is that it’s the first required standard whose main goal is to protect healthcare workers and the environment from hazardous drug effects.

“We’ve known there have been issues for decades,” she says. “In fact, in 1985 ASHP put out its first technical assistance bulletin on cytotoxic agents. And we’ve known well before that [the dangers], but that was the
first one put out for the pharmacy and the medical community specifically. But none of these were enforceable because they were only guidelines from professional organizations, even the NIOSH’s alert from 2004. NIOSH is an advisory group so it wasn’t a requirement."

Loredana Jinga, BSN, MPH, USP’s marketing director, says USP <800> brings value across the organization. Often, hazardous drugs aren’t clearly labelled as such, she says. Without the proper procedures healthcare workers might not necessarily know they are in contact with a potentially hazardous drug. “For example, nurses may not know that non-chemotherapeutic drugs are on the NIOSH hazardous drug list or the type of risk these may pose in the short and long term,” she says. “I think it’s really important to bring awareness to some of these blind spots to protect all healthcare workers—nurses, physicians, environment of services, everyone.”

PPE

It should go without saying that PPE compliance has a major role in USP <800>. One of the chapter’s requirements is that proper gowns, gloves, masks, hair covers, goggles, and respirators be worn when administering injectable antineoplastic hazardous drugs. When it comes to getting staff to follow USP PPE best practices, Schnatz says, hospitals and clinics should be compliant by this point. There have been PPE requirements for hazardous drugs and compounding for decades, going back to the Oncology Nursing Society’s PPE document in 1984, and OSHA’s document in 1986.

“Hospitals are already ahead of the game in a big way,” Schnatz says. “Because they’ve lived with <797> since 2004, and they lived with <795> since 1995. So they’re already using protective equipment: the gloves, the guards, the shoe covers, facial covers, those types of things. We’re pretty far down the road with that.”

While hospitals should be ready for USP <800>’s PPE requirement, he says, other types of facilities or organizations such as smaller clinics, veterinary offices, and pharmacies might need more education on PPE. Kienle says that she almost thinks there needs to be two different terms. One term for the protective garb worn to protect the sterility of the products one is making, (e.g., IVs) and a term for the PPE used to protect the handler.

“For example, there is confusion with some of the devices in which IVs are mixed because manufacturers of those devices have provided information that you don’t have to wear certain articles of garb,” she says. “That may be true for the protection of the preparation that you’re making. But what USP <800> brings in is that it’s protecting us as healthcare workers, so PPE has to be worn.”

Kienle repeats that this is still no different than what’s been in USP <797> since 2008. That said, people still sometimes miss that they need to protect themselves as well. Though the importance of PPE in environment and patient safety can’t be ignored either.

Resources

**USP:** FAQs on USP <800> ([www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings#personal](http://www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings#personal))

USP <800> training: USP has several courses on its <800> chapter. This includes 6.5-hour didactic course offered both live and on demand. The organization also plans to release a modular version of the course around February. All have continuing education credits available which pharmacists and techs need to maintain their licenses ([www.education.usp.org](http://www.education.usp.org)).

**NIOSH:** List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016 ([www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf](http://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf))

**Critical Point:** Runs a boot camp for sterile compounding which includes hands-on learning. The hands-on piece includes properly donning and doffing PPE, physical tests like media fills and glove fingertip tests, how to place things in the hood, understanding air handling. ([www.criticalpoint.info/boot-camp/](http://www.criticalpoint.info/boot-camp/))

**American Society of Health-System Pharmacists:** Sterile Compounding Resource Center ([www.ashp.org/sterilecompounding](http://www.ashp.org/sterilecompounding))
The benefits of patient engagement

Editor’s note: The following is a lightly edited Q&A with Craig Deao, MHA, senior leader at Studer Group, on the role of patient engagement in care quality.

**PSMJ**: How big a role does patient engagement have in care quality?

**Deao**: It’s significant. I really view this as the missing variable that we haven’t sufficiently studied or acted upon. If you just think about how much time we emphasize on chronic disease for example, where it’s responsible for about 40% of the deaths in the U.S. and maybe 70%-80% of the costs. Those are largely preventable. We talk so much about improving quality outcomes but gosh, if we could prevent some of these conditions in the first place, wouldn’t that be great? And big levers of those are things like nutrition, and exercise, and not smoking. Which are directly a result of the behaviors and actions we take as people. The healthcare system can facilitate that. It can’t take the place of it, but engagement of the person is going to be critical for that. It all comes down to an individual’s choices and actions.

And big levers of those are things like nutrition, and exercise, and not smoking. Which are directly a result of the behaviors and actions we take as people. The healthcare system can facilitate that. It can’t take the place of it, but engagement of the person is going to be critical for that. It all comes down to an individual’s choices and actions.

So [patient engagement] has a role to play in quality, prevention, and certainly from an improvement and treatment standpoint. This is about whether the patient actually takes the medication, comes back for that follow-up appointment, adheres to the treatment advice, asks questions, makes informed decisions, all that. It’s a huge component of quality.

**PSMJ**: Can you talk about some of the specific benefits of patient engagement? Have these results ever been shown empirically?

**Deao**: I’m a huge [W. Edwards] Deming fan and if you can’t measure it, you can’t manage it. Because I started learning about this and I wanted to reach out and figure out what the analytics said about qualifying patient engagement. The best I’ve found is the PAM score, the Patient Activation Measure. Judith Hibbard at the University of Oregon developed [PAM], a self-reported questionnaire that you or I could take and our responses categorize us into one of four levels of “activation,” which is sort of a proxy for engagement.

There have been over 200 studies published in the period literature looking at outcomes when patients are more or less engaged, and they’re really profound. For example, more engaged patients are more likely to manage their cholesterol and diabetes, use preventive tests like mammography, appropriately use the emergency department, and not have as many hospitalizations. [They’re] less likely to smoke and be obese. So exactly the kind of thing that we are trying to affect.

And engagement correlates with quality and with costs. I always tell audiences the name of the game in healthcare right now is producing value. Values, quality over cost—and engagement drives both sides of that.

And the data is certainly there to prove potential for contamination when they are making IVs, for example, and it’s primarily on their gloves, gowns, and shoe covers,” she says. “Those are really critical pieces of PPE that need to be worn appropriately; not only donned, but also doffed. [They need to be] taken off before they leave the negative pressure area so they’re not tracking potential contamination into other areas.”

**Expert Q&A**

“...And the data is certainly there to prove potential for contamination when they are making IVs, for example, and it’s primarily on their gloves, gowns, and shoe covers,” she says. “Those are really critical pieces of PPE that need to be worn appropriately; not only donned, but also doffed. [They need to be] taken off before they leave the negative pressure area so they’re not tracking potential contamination into other areas.”

“...And engagement correlates with quality and with costs. I always tell audiences the name of the game in healthcare right now is producing value. Values, quality over cost—and engagement drives both sides of that.

And the data is certainly there to prove potential for contamination when they are making IVs, for example, and it’s primarily on their gloves, gowns, and shoe covers,” she says. “Those are really critical pieces of PPE that need to be worn appropriately; not only donned, but also doffed. [They need to be] taken off before they leave the negative pressure area so they’re not tracking potential contamination into other areas.”

“...And engagement correlates with quality and with costs. I always tell audiences the name of the game in healthcare right now is producing value. Values, quality over cost—and engagement drives both sides of that.

And the data is certainly there to prove potential for contamination when they are making IVs, for example, and it’s primarily on their gloves, gowns, and shoe covers,” she says. “Those are really critical pieces of PPE that need to be worn appropriately; not only donned, but also doffed. [They need to be] taken off before they leave the negative pressure area so they’re not tracking potential contamination into other areas.”

“...And engagement correlates with quality and with costs. I always tell audiences the name of the game in healthcare right now is producing value. Values, quality over cost—and engagement drives both sides of that.

And the data is certainly there to prove potential for contamination when they are making IVs, for example, and it’s primarily on their gloves, gowns, and shoe covers,” she says. “Those are really critical pieces of PPE that need to be worn appropriately; not only donned, but also doffed. [They need to be] taken off before they leave the negative pressure area so they’re not tracking potential contamination into other areas.”

“...And engagement correlates with quality and with costs. I always tell audiences the name of the game in healthcare right now is producing value. Values, quality over cost—and engagement drives both sides of that.

And the data is certainly there to prove potential for contamination when they are making IVs, for example, and it’s primarily on their gloves, gowns, and shoe covers,” she says. “Those are really critical pieces of PPE that need to be worn appropriately; not only donned, but also doffed. [They need to be] taken off before they leave the negative pressure area so they’re not tracking potential contamination into other areas.”