Perspectives Recovery Strategies from the OR to Home

A B S T R A C T

uring past recessions, the financial stability of hospitals seemed to be nearly indestructible. But researchers at the University of Michigan Health System and St. Joseph Mercy Health System¹ say the current national economic crisis may be an exception. Hospitals are reporting declining profits. The researchers that speculate hospital cutbacks may risk the quality and safety of healthcare delivery, resulting in overcrowding emergency services and lower nurse-to-patient ratios. In some cases, to achieve short-term cost reductions, some facilities have opted to purchase products that offer savings but may jeopardize the safety of healthcare workers and their patients. In this issue of Perspectives, we have asked a panel of experts in infection control, risk management, and nursing management how they are coping with the challenges to balance costs and ensure the safety of healthcare delivery.

 Fry, J. is the current recession comprimising hospital quality. UMHS Newsroom. June 2010

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Ensuring Involvement of the Frontline Healthcare Worker in Product Decisions

Moderator: Mary Foley, RN, PhD
Panelists: Kathleen Arias, MS, CIC

Victoria Rich, RN PhD, FAAN Georgene Saliba, RN, BSN, FASHRM Susan Gallagher, RN, PhD, CPHRM Daphne Stannard, RN, PhD, CCRN, CCNS,

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am pleased to introduce a panel of nurse experts in the areas of research, management, and practice. Funded through an education grant from Dale Medical Products, Inc., this important dialogue examines issues associated with product selection and purchasing practices in the healthcare sector at this time. There are increasing pressures on hospitals and health settings to ensure safe patient care, and worker safety demands equal attention. At the same time, a depressed economic climate has forced hospitals to reduce services and staff and to streamline processes in other ways. Additional areas of interest include frontline and clinician staff involvement in product design and selection and how those opportunities are built into the purchasing process. These five experts skillfully discuss the balances being struck each day as healthcare leaders strive to achieve their organizations' goals. I hope you enjoy the discussion as much as I have enjoyed moderating it.

What is the current climate in healthcare regarding the overall effectiveness of the system and the cost of care?

Arias: The recent active debate about healthcare reform has included much discussion on efficiency, quality and the high cost of healthcare in the United States. Healthcare spending in the United States amounts to approximately 17% of the gross domestic product (GDP) and is expected to reach 19.3% of GDP (\$4.5 trillion) by 2019. According to the World Health Organization, in 2006, the United States had the highest per-capita total health expenditures of its 193 member states. However, millions of people in the United States have inadequate or no healthcare coverage. The Patient Protection and Affordable Care Act that President Obama signed into law in March 2010 aims to provide affordable, quality healthcare for all Americans and reduce the growth in healthcare spending. As a result, "[h]ealthcare reform will eventually pit the goal of expanding health insurance coverage against strong pressure to reduce the growth in healthcare costs." There are provisions in the Patient Protection and Affordable Care Act that address quality improvement and public reporting of healthcare-associated infections and call for the establishment of a Center for Quality Improvement and Patient Safety within the Agency for Healthcare Research and Quality (AHRQ) (Title III, Subtitle F, Section 3501). Although there are many uncertainties about how the new law will be implemented, we can be relatively confident that hospitals and other healthcare providers will experience funding restrictions, declining reimbursement, and increased scrutiny related to the cost and quality of care.

Rich: The current climate of healthcare in the United States is based on beliefs such as (1) patients expect the best care at the lowest cost; (2) prescriptions for medications or diagnostic interventions are the panacea for all maladies; and (3) prevention of illness and living a healthy lifestyle "are more often reactive rather than proactive responses to maladies."

In 2005, the United States spent 2 trillion dollars on healthcare. This was approximately \$7000 per person and 16% of the GDP.⁴ This cost is more than any of the 30 plus countries in the Organization for Economic Cooperation and Development (OECD) spent on healthcare. In addition, more than 42 million Americans younger than 65 years of age do not have healthcare insurance.

The good news is that, in 2009, improvements were demonstrated in 12 key measures related to heart attacks, heart failure, and ventilator-related pneumonia.⁵
The Obama plan will provide coverage to 32 million uninsured people and provide funds for technology and education, but if the industry does not change how it delivers care across the continuum, higher access and higher cost will not necessarily translate to improved outcomes.

Saliba: Despite the 1999 landmark paper "To Err is Human," medical errors may have decreased somewhat 10 years later. However, there is still a gap in the system between what we know and do. This gap is characterized by the underuse, overuse, misuse, and variation of services. Underuse can lead to additional complications, higher costs, and premature deaths. A study of heart attack patients found that nearly 80% did not receive life-saving beta-blocker treatment, leading to as many as 18,000 unnecessary deaths each year. Unnecessary services add costs and can lead to complications that undermine the health of patients. For example, half of all patients diagnosed with a common cold are incorrectly prescribed antibiotics. Overuse of antibiotics has been shown to lead to resistance and as much as \$7.5 billion per year in excess costs. Errors in healthcare delivery lead to missed or delayed diagnoses, higher costs, and unnecessary injuries and deaths. A study of New York State hospitals found that 1 in 25 patients was injured by the care he or she received and that death occurred

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in 13.6% of those cases. Negligence was blamed for 27.6% of the injuries and 51.3% of the deaths. Based on this study, researchers estimated that preventable errors in hospital care led to 180,000 deaths per year. There are significant variations in the practice of medicine across the United States, among regions, and even within communities. For example, hospital discharge rates are 49% higher in the Northeast than they are in the West.

Gallagher: Public and private agencies are scrambling to make sense of the largely chaotic healthcare delivery system in the United States. This is not to say there are not pockets of efficiency; however, there simply are no long-term studies that help us truly understand cost of care and how our care affects cost.

Stannard: Given that healthcare spending is expected to rise to 20% of the GDP by 20178 it is safe to say that many healthcare providers are concerned about the overall health and stability of the healthcare industry and its impact on the greater economy. The sheer cost of our current system, coupled with unacceptable patient outcomes in some areas and patient populations, is, of course, a great cause for concern and a clarion call for healthcare reform.

How have the current cutbacks in healthcare spending affected the decision-making process and product choices?

Arias: Cutbacks in spending and reimbursement have increased the pressure on hospitals to decrease expenses. Because approximately 20% to 25% of a hospital's operating budget can be attributed to sup-

ply costs, 10 hospital administrators target this expenditure for expense reduction. This usually results in close scrutiny of potential new products and an evaluation of current products to determine if they can be replaced with those of equal performance that are less expensive. Some type of product evaluation or value analysis committee is commonly used to accomplish the decision-making process and select products. It is important that these committees ensure that product evaluation and choices are based not only on cost but also on clinical effectiveness, patient and healthcare worker safety, and user acceptability. They should play a role in scrutinizing and evaluating both "inexpensive" patient care products, such as vascular access site dressings, and "expensive" products such as pain pumps.

There are also several purchasing groups and commercial enterprises that offer clinical quality value analysis (CQVA) programs aimed at improving the efficiency of decision making, increasing the participation of staff in the process, and decreasing supply costs.

To reduce costs, some hospitals have decided to reuse single-use devices (SUDs). These products range from relatively simple items for external use, such as inflatable compression sleeves, to complex invasive devices, such as electrophysiology catheters. Reprocessing of SUDs is regulated by the US Food and Drug Administration (FDA) and is defined by the FDA as any activity needed to render a used SUD ready for use on a subsequent patient.11 Only SUDs that have been approved by the FDA may be reprocessed. 11 In addition, any healthcare provider or facility, including a hospital, that reprocesses an SUD must meet the strict requirements the FDA imposes on device manufacturers and must be approved by the FDA as a reprocessor.¹² Because hospitals rarely can meet these stringent requirements, they must use a third-party reprocessor. Unfortunately, to reduce costs, some facilities are inappropriately reprocessing SUDs instead of discarding them and purchasing new products or sending them to a third-party processor.

Rich: As operating margins have eroded over recent years, competition for both operational and capital dollars has been continuous and politically charged. The C-Suite struggles to balance the multiple competing needs of high-profile physicians, employee wages and benefits, physical plant updates, regulatory and risk requirements, technology must-haves, and consumer requests.

Decision making and product choices many times are negotiated according to acquisition of new revenue or what we must we spend to avoid patient harm. Unfortunately, monies spent on preventing patient harm too often come as a reactive fix to an error that could have been prevented or mitigated proactively if money had been preallocated.

The gradient power base of decision making must be transformed to a tightly coupled crew management approach to ensure safe products for patients and healthcare workers.

Saliba: The current cutbacks in healthcare have had an effect on capital spending that is occurring in hospitals. The process has needed to become more streamlined and prioritized as to what will be replaced or bought. Standardization of products to decrease waste and improve efficiency needed to be undertaken. This entailed a value analysis process for reviewing products to ensure standardization to decrease cost and to introduce products in a safe, efficient manner while providing the best quality for the patient. No longer can hospitals afford to have multiple, same-type products on their shelves.

Gallagher: Decisions are made irrespective of the evidence, simply because of the pressure to cut costs; and I mean the very realistic need to balance the benefit and burden of a particular product.

Stannard: The recession has affected our overall patient volume for the year, and that always leads to an examination of which areas can be trimmed without causing a disruption in patient care. Standardizing products and maintaining a disciplined reliance on supply formularies can lead to a reduction in redundant products and cost savings, as well as increased efficiency and reliability for material services and clinicians alike. When a healthcare facility creates a supply formulary or catalog (much like a pharmacy formulary), there is a defined set of supplies that are approved for use in that institution. Nonformulary or noncatalog items must go through an approval process. Formal review and value analysis are required to place a new product or device in the supply formulary.

Within my institution, we have had several different evaluation committees in place for many years that have focused on specialty areas and populations, such as the perioperative area, the children's hospital, and the radiology department, among others. With the economic downturn, a new, housewide multidisciplinary supply evaluation committee was formed, composed of nurse representatives from nursing areas as well as representatives from infection control, environmental services, respiratory therapy, and others. One of the purposes of this committee is to propose new, less costly items that can be tested in the

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nursing areas to ensure that we are not giving up desirable characteristics—such as durability, usability, and quality—simply for the sake of saving a few pennies per item. Obviously, over the long term, if a new disposable bedpan, for example, breaks or is uncomfortable for the patient, clinicians will use more of the product or will use other, perhaps costlier products to avoid using the inferior product, thereby erasing any potential savings. Thus, clinician feedback and buy-in with any product substitution is crucial to successful implementation of any new product.

Do purchasing decisions and product selection include frontline clinicians? Are evaluations of products made by an evaluation committee composed of nursing as well as other stakeholders?

Arias: In most hospitals, a product evaluation or value analysis committee is used to evaluate and select clinical and patient care-related products, and frontline workers are generally involved in the process. As Dr. Stannard's example illustrates, these committees usually consist of a core group of representatives from materials management, purchasing, nursing, safety, infection prevention and control, risk management, and performance improvement/quality management. Additional stakeholders, such as medical staff or operating room personnel, are asked to participate as needed, depending on the product. Once the committee selects a potential product, a formal product evaluation trial is conducted on one or more patient care units where the product will be used. Feedback from those testing the product is generally provided using standardized forms. Once the feedback is received and analyzed, the committee will make recommendations for product selection; however, the final purchasing decision may be made by an administrator or the purchasing department rather than by committee consensus. In my experience, laboratory equipment selection and purchasing decisions have not gone through the product/value analysis committee.

The Occupational Safety and Health Administration (OSHA) requires that sharp devices, such as syringes and catheters used for injections and intravascular access, have safety mechanisms for protecting healthcare workers. OSHA requires that the workers who use these devices be involved in evaluating them, so this must be kept in mind when purchasing these types of products. ¹³

Rich: In top-performing organizations, such as Magnet-designated facilities, Nursing Governance Council members are key stakeholders in product decisions. A vision that is shared is developed because the "sharp-end caregivers" know the "why" and "what" of the decision. They are engaged from the beginning and feel part of the solution because they are.

However, shared governance is just not a nursing initiative. An interdisciplinary shared governance council best provides a framework for sustainable, accountable patient care decisions. This approach empowers the sharp-end caregiver voice to be heard and respected by external nonclinical decision makers, such as supply chain managers, CFOs, and CEOs. This exemplary process demonstrates an efficacious approach for choosing products for improved patient care outcomes. The final accountability for the decision and the subsequent success or failure of the product or technology is assumed by all.

Saliba: Purchasing decisions and product selections should include frontline users. Clinicians must be involved from the onset to help assess the operational impact of any system and/or product. All products entering the system should be evaluated for their impact to patient safety and actual bedside practice. Healthcare facilities should have a multidisciplinary committee in place composed of key stakeholders—that is, nursing, physicians, perioperative areas, materials management, risk management, care management, infection control, et cetera. This committee sets priorities for new, emerging, and replacement products in concert with the organizations' mission and operational constraints, including such factors as standard of care, clinical need, safety, reliability, and recommendations from physicians, clinicians, and ancillary staff. The committee should also establish criteria for evaluation or trial of new products with clear acceptance criteria, evaluation terms and conditions, start and end dates, and cost.

Gallagher: Frontline clinicians are the voice of the patient. As a CNS-certified bariatric nurse concerned with reasonable accommodation for patients of size, I am often met by nonclinical team members who believe there is no need for size-sensitive products and equipment, whereas some clinicians report that as many as 50% of the patients require some degree of accommodation because of weight or weight misdistribution. The value analysis or product analysis team is composed of nurses and other relevant clinical team members. In a perfect world, a frontline clinician who has hands-on contact with the patient and who understands economics and the research process is an invaluable asset to the product evaluation committee. Healthcare organizations that nurture and respect this role serve their patients, caregivers, and leaders well.

Stannard: Our Value Analysis Committee (VAC) is committed to ensuring that clinicians are involved in the trial of any new products. For that reason, we developed a VAC algorithm to assist members and non-members of the committee to be fully informed of the processes involved in the pretrial, trial, and posttrial phases of any product evaluation (Figure 1).

Is an evidence-based practice approach used in decisions about medical products, equipment, et cetera? Are brand names and generic names equally evaluated?

Arias: The value analysis approach for product selection is not new and is used in many hospitals. For many years, value analysis has been promoted by organizations such as the Association for Healthcare Resource and Materials Management (www.ahrmm.org) and discussed in trade publications such as Healthcare Purchasing News and Materials Management in Health Care. In many hospitals, the process has been expanded and refined to include a clinical quality value analysis.14 CQVA adds another dimension to product evaluation by evaluating equipment, supplies, and services based not only on price and personnel preference but also on their quality and safety attributes and evidence that they are clinically and cost effective and operationally acceptable. The goal of CQVA is to provide cost reduction while maintaining or improving the quality of care. CQVA applies to both brand names

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and generic items.

Rich: The current healthcare system is fragmented, lacks parity between cost and quality, and badly needs a system that is accessible, nondiscriminatory, transparent, and universal. Currently, the nursing profession provides the best linkages for transitions in care and patient safety.

To implement an authentic, evidencebased approach to clinical decision making, there must be mutual respect and understanding between various professions. A shared value system must be created that integrates multiple perspectives.

The all-encompassing format is to make a blind evaluation of products and technology, both branded and generic, using an assessment framework that includes examination of (1) efficacy; (2) effectiveness; (3) safety; (4) cost, and (5) social impact. It is crucial to know whether the products and

technology have been previously tested in the intended patient population.

Saliba: Evidence-based practice should be part of the evaluation criteria as determined by the standard of care. All products should undergo a value-based analysis to assess impact on patient safety and bedside practice. This should include tracking of costs and utilization. This systematic process is best set up at the onset of use so that all factors are reviewed together. The key to any evaluation must be based on the product's effectiveness, clinical necessity, safety, education needs, usage, and compatibility with other products and systems. The process for brand names and generic names should be the same.

Gallagher: Certainly, there are occasions when generic products may be interchangeable with branded products. However, I advise caution in this practice. Consider the long-term care facility that carefully evaluated a floor lift to supplement its ceiling-mounted lifts as part of its safe patient handling and movement effort. A team was assembled, and 5 different lifts were evaluated using a process agreed on by the organization. One lift clearly provided better ease of use, movement along all floor coverings, turning ability, and more. The science and practical applicabilities supported this product. The lift of choice was priced in the mid-range. Imagine the team's disappointment when the lowestpriced generic lifts were delivered. These lifts were noisy, had poor turning ability, and had casters that were difficult to roll on the carpeted area. In fact, the lifts were so noisy that the patients refused their use. Caregivers lacked confidence in the product. The point of this story is to illustrate that generic products may pose risks to patients, caregivers, and the overall economic health of the organization. Substituting "like" products because of price can be very costly.

Stannard: Our facilities should routinely utilize only the safest and most effective medical devices, procedures, and drugs. Additionally, available research evidence should guide product decisions. This has been referred to as technology assessment. Many facilities utilize third-party services, such as the ECRI Institute, to assist with value and efficacy analysis.

What are your recommendations to improve the process and ensure safer patient and worker care environments?

Arias: Hospitals must move beyond traditional product analysis to a clinical quality value analysis process that assesses the product, procedure, evidence, and user. They must implement a consistent and effective program that reviews new and current products, technologies, and

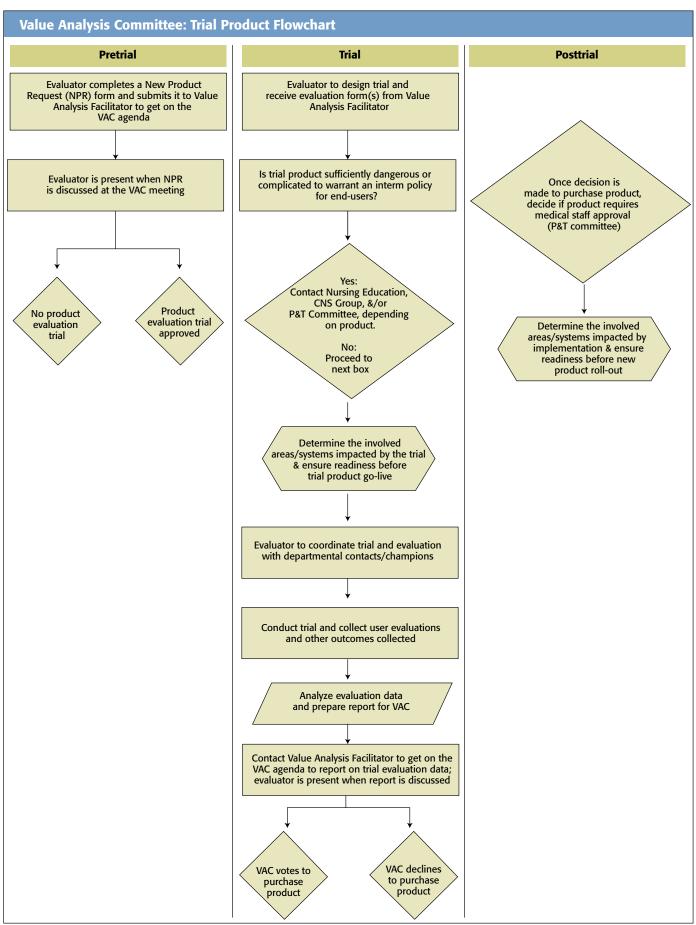


Figure 1. Value Analysis Committee: Trial Product Flowchart

procedures to ensure that they are safe, in accordance with evidence-based practices, and a good fit for patients, healthcare workers, and the organization. The program should include the following: an ongoing system for identifying and analyzing products, technologies, applications, and procedures; the use of multidisciplinary healthcare teams that include nursing and other frontline workers; evaluation of clinical research findings for evidence supporting use of products, procedures, et cetera; cost-benefit and other financial analyses of the team findings; training for all involved in the process, including users, team members, and administrators; communication of the process and any changes being made to all departments and services involved; and a mechanism for follow-up evaluation to ensure that changes made are safe, effective, and acceptable. CQVA team members should be selected based not on their title or position in the organization but on the skills that they bring to the process. They should be knowledgeable of the products and services assessed, highly organized, analytical thinkers, trusted and respected by their colleagues and other stakeholders, enthusiastic, and open to challenge and change.

There should also be mechanisms for periodically evaluating the program to verify that it can drive significant supply cost savings while either maintaining or improving the quality of care and for ensuring that personnel do not introduce new products, instruments, devices, et cetera or negotiate contracts without going through the formal CQVA process.

Rich: My recommendations are to (1) maintain a strong voice of nursing within organizations. The CNO/CNE participates in all executive clinical decisions; (2) include nurses and/or other clinician caregivers in crucial clinical decisions that impact direct care providers and patients and families; (3) provide education and mentorship to clinician committee members on committee protocol and approaches to decisions based on shared wisdom and consensus; (4) listen to healthcare workers when concerns are expressed regarding products and technology and provide authentic feedback that is action oriented; (5) include patients and families as well as nurses and other direct caregivers in operational decisions that will impact them directly; (6) seek feedback and solutions from patients and families and workers at levels of impact to provide input into safe and efficient designs of workflow and processes; and (7) respect, trust, reevaluation, and follow-up by senior leaders. Even after all assessments, evaluations, and purchases are made and the product or technology is "not doing what it is supposed to do"the sharp-end providers are given satisfacHospitals must move beyond traditional product analysis to a clinical quality value analysis process that assesses the product, procedure, evidence, and user.

- Arias -

tion that they can return it for something else or get their money back!

Saliba: From a risk management and patient safety perspective, my recommendations include ensuring you have a solid process in place for the selection of products and equipment with the stakeholders actively involved. This includes frontline staff, because they are in the best position to determine the product's usability and compatibility and are the clinical experts with respect to its ultimate implementation. I liken this process to a root cause analysis that occurs in hospitals. Without engagement of the frontline staff, action steps to improve the process might look good on paper but in practice are not able to implemented or perhaps make the process more problematic. The frontline staff provides the needed input to validate that the process makes sense and actually promotes safe patient care. Through careful testing and evaluation of products by frontline staff, needless cost can be avoided, and it can be ensured that patient care, comfort, and safety remain at the forefront.

Gallagher: In healthcare, where stakes are high, opinions vary, and emotions run strong, it becomes important to take communication to a new and higher level. Unfortunately, when dialogue becomes charged, people often avoid direct conversations, become angry, or simply alienate others because of their inability to communicate at this necessary level. Recall

the frustration felt by the caregivers described earlier who were faced with the unsafe lifts. Many nurses explain that they feel ill equipped to engage in a face-to-face accountability discussion. This situation lends itself to a crucial confrontation in which those responsible for purchasing unsafe or inappropriate equipment must be held accountable for the situations that are created (sometimes unknowingly). Many problems within organizations stem from the inability to have these discussions. This hesitation is likely due to past experience and, most commonly, a lack of skill to speak up effectively. Often, people simply don't know what to say or how to say it. Consequently, bad behavior remains unchecked, and organizations-or ultimately the patients—pay the price. Research suggests that disappointments and miscommunication threaten organizational performance, and furthermore, these tough encounters do not have to be uncomfortable or awkward. When handled effectively, these interactions can strengthen relationships and improve organizational outcomes such as safety, quality, and satisfaction—patient and caregiver satisfaction. Crucial conversation training for frontline employees has been an important risk management strategy on many levels and lends itself to better understanding of ways to advocate for access to special patient equipment and products.

Stannard: It is challenging to determine on a prospective basis which products have clinically significant downstream effects, especially given the volume of products brought into our institution on an annual basis. The term "downstream effects" refers to the intended and unintended consequences of any decision. Allowing nursing education and clinical nurse specialists to assist in ranking the degree of downstream effects for any given product may help facilities prioritize product trials and stage initiatives. Multidisciplinary evaluation committees are an excellent beginning; however, it is also crucial to involve the frontline practitioners in any product evaluation trial. As with any other facet of healthcare, supply purchases should support the 6 healthcare quality goals of the Institute of Medicine: safety, effectiveness, patient centeredness, timeliness, efficiency, and equitability.15

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PANEL

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- Faculty disclosures: No conflicts were disclosed.
- * Approval does not imply ANCC or VSNA

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- A gap still present in today's healthcare system is the overuse, underuse, misuse, and variation in services.
 - a. True
 - b. False
- 2. What percent of a hospital's operating budget can be attributed to supply cost?
 - a. 50%-75%
 - b. 40%-60%
 - c. 10%-15%
 - d. 20%-25%
- 3. As a way to save money, hospitals should reprocess single-use devices.
 - a. True
 - b. False
- 4. Reprocessing of single -use devices is regulated by:
 - a. Centers for Disease Control and Prevention (CDC)
 - b. Center for Medicare/Medicaid Services (CMS)
 - c. Environmental Protection Agency (EPA)
 - d. Food and Drug Administration (FDA)

- 5. A crucial component for the successful implementation of any product or technology is:
 - a. cost
 - b. ease of use
 - c. clinician feedback
 - d. the product in on the contract
- 6. The Occupational Safety and Health Administration (OSHA) requires:
 - a. that the use of safety features is optional
 - b. syringes and catheters used for injection and intravascular access have safety mechanisms
 - c. employees who use the devices are involved in the evaluation of them
 - d. Both B & C
- All products entering a health system should be evaluated for the following:
 - a. Impact on patient safety
 - b. Actual bedside practice
 - c. Both A & B
 - d. None of the above
- 8. It is not necessary to know if a product has been previously tested in the intended patient populations:
 - a. True
 - b. False

- A clinical quality value analysis process for product evaluation includes assessing:
 - a. the product
 - b. procedure
 - c. user
 - d. All the above
- A solid process for selection of products and equipment include the involvement of frontline workers who will use the product.
 - a. Tru
 - b. False
- 11. Clinical nurse specialists and nursing education can assist with:
 - a. Ranking downstream effects
 - b. Helping to prioritize product trials
 - c. Staging initiatives
 - d. All the above

Participant's Evaluation							Mark your answers with an X in the box next to the correct answer		
What is the highest degree you have earned (circle one)? 1. Diploma 2. Associate 3. Bachelor's 4. Master's 5. Doctorate					A B C D	A B C D			
Indicate to what degree you met the objectives for this program: Using $1 = \text{strongly disagree}$ to $6 = \text{strongly agree}$ rating scale, please circle the number that best reflects the extent of your agreement to each statement.						A B C D 2	10 A B C D		
		Stror	Strongly Disagree			Strongly Agree		3 B C D	A B C D
	Be able to identify 2 current trends in the healthcare economic climate.	1	2	3	4	5	6	A B C D 4	A B C D
2.	Be able to identify 2 effects on purchasing trends and patterns in healthcare.	1	2	3	4	5	6	A B C D	A B C D
3.	Be able to identify at least 1 advantage of user-based evaluation and the application of evidence-based decision making.	1	2	3	4	5	6	A B C D	A B C D
4.	Be able to identify 2 contributions to patient safety that can be attributed to purchasing practices and product selection.	1	2	3	4	5	6	7	15 A B C D
Νa	ame & Credentials							8	16

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How long did it take you to complete this home-study program?

home study?

What other areas would you like to cover through

/11

Position/Title ___

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