GE Healthcare

Structuring a Clinical Evaluation Plan

Best Practice

Many clinicians find it is most effective to conduct a robust clinical evaluation before making a decision on what device to purchase. After all, no one wants to invest capital equipment dollars only to discover later it is not the best fit for their practice or patients.

Compiled here are best practices, gleaned from many customers, for a clinical evaluation plan. This need not be a time-consuming exercise. Creating a high-level plan with members of your team will go a long way to help ensure your investment will secure technology that delivers the greatest impact to your patients, clinical team and unit initiatives.

QUESTIONS TO DISCUSS INCLUDE:

1. **What would you like this technology to help improve?** Consider the problems you are encountering in your unit today and where technology can help. Review your key initiatives, such as patient safety, outcomes, family centered care, and clinical workflow. What do you need the device to achieve for your patients, their families, and your staff?
2. **What clinical use scenarios and patient types will help reveal the device's impact on these goals?** Consider aspects such as your primary patient populations, gestational ages, and frequent interventions.
3. **Which of your patient populations will benefit most?** Select the population that best represents your unit's more challenging or sensitive patients, for example, ELBW/ELGAN babies. Your investment may not go far if it is only suitable for one patient type or only for your less acute patients.
4. **How long might it take to ensure the device is used on multiple patient populations of differing acuity levels?** Different device models may be better suited for some patient populations than others. Ensuring clinical use with multiple patient types may require an evaluation lasting more than 1-2 weeks. Using each device with several different patient types will provide key insights into its suitability for all your primary patient populations.
5. **Who will be using the device?** Consider a breadth of caregivers and ensure a large portion of them will have the opportunity to interact clinically with the device. Your bedside nurses can critically evaluate through everyday delivery of care. However, don't forget other key users who may have differing needs, such as respiratory therapists, x-ray technicians, and environmental services.
6. **Other points to consider:**

a. **Evaluate all contenders at the same time, when possible** (as opposed to one after another). This allows the same clinicians to have frequent interaction with each and the ability to compare and provide feedback in real time, while experiences and memories are fresh.

b. **Create an evaluation form** to facilitate the collection of valuable insights in real-time. This form should include questions around types of care and interventions that are common for all your primary patient populations. Be sure to include how the device:

- Improves patient safety initiatives
- Helps protect neurodevelopment
- Enhances the family experience through involvement at the bedside, bonding and creating a less intimidating environment
- Improves clinical workflow
- Supports the initiatives most critical to your unit's success

c. **Investigate the full cost of ownership** to understand the full financial investment and impact to workflow, such as:

- Disposables & Accessories – How many are there, at what cost and replacement frequency? Are they compatible with existing devices? What is their effect on standardization, especially if devices are unable to be replaced at once?
- Refresh & Upgrades – Are there enhancement options for existing equipment when you are on a variable replacement plan?
- Preventative Maintenance Schedule – How frequently do parts need replacing and what is the cost over a 5 year period? Are service agreements available to reduce costs?
- Cleaning schedule – How frequently does the device need to be removed from clinical service to be cleaned? What is the maximum time to clean and return it to clinical service?

Be sure the clinical evaluation conducted can assess for and demonstrate the primary benefits you seek. No device is perfect. Each unit must determine the device that best aligns with their patient populations, key initiatives, workflow, and culture.

Evaluating a Device Through the Lens of Patient Safety

Watch the video

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Best Practice

A defining characteristic of modern healthcare is the near constant use of technology. Today there are many choices available for any new piece of equipment but not unlimited funding. And you, of course, want to achieve the greatest impact for your dollars.

Every interaction between a human and a device holds an opportunity for mishaps. An often overlooked aspect of choosing new medical devices is their potential impact on your patient safety initiatives.

There are key considerations that can actually help your day-to-day delivery of care, with the goal of more effectively evaluating a medical device purchase decision through the lens of Patient Safety.

1. **Device design can minimize opportunities for cross-contamination.** Infants, especially in their first days of life, are vulnerable to infection. Eliminating opportunities for cross contamination is essential for minimizing nosocomial infection. Take, for example, that in the NICU the reduction of a single nosocomial bloodstream infection could potentially reduce medical expenses of a VLBW infant by thousands of dollars and reduce the length of stay by 4 to 7 days.[1]

   It is important to evaluate the ways in which a device can help minimize cross-contamination and infection, particularly during typical daily care. Consider, for example, how the device mitigates these risks around the most frequent points of contact, such as an alarm silence button, and how its overall design can help you interact with the patient and device without needing to re-glove or break the sterile field.

2. **Ease of use and intuitive design can minimize human error.** Human error is a critical factor in the safety and efficacy of medical devices, and accounts for nearly 70% of all patient injuries in the hospital.[2]

   Add to this that 40% of product recalls and adverse events have roots in user-device interaction, according to the FDA.[3]

   Consider how the user interface presents its information:

   - Is information difficult to locate, illegible and cluttered?
   - Is it delayed, complex, inconsistent or require mental computation?
   - Do users have opportunities to inadvertently touch and contact sensitive parts of the device? Are the controls difficult to reach and operate?

   When medical devices are designed to be intuitive and easy to use through the adoption of these types of human factors design principles, they can reduce cognitive workload and errors by 50%, and improve efficiency by 15%.[4]

3. **Smarter alarm management and customizable parameters can help reduce alarm fatigue.**[5] Consider how the device minimizes the steps required to silence an alarm, the format in which it communicates critical alarm information, as well as how it limits disruption to workflow.

   Additionally:

   - How does it manage multiple alarms?
   - How does it convey information around the severity or urgency of each alarm?
   - Does it offer alarm prioritization or escalation? Visual and audible alarm differentiation can rapidly convey critical information to the clinician.

4. **Minimizing repetitive motions improves caregiver ergonomics;** Work-related injuries have direct consequences on quality of care and patient safety.[6]

   For example, injuries to the shoulder and neck are prevalent amongst nurses in hospitals[7] and repetitive work in awkward postures is one of the primary contributing factors to physical fatigue and injury development.[8]

   Consider how the device's design can help reduce or minimize repetitive and strenuous work. This type of caregiver ergonomics may reduce direct and indirect costs associated with neck and shoulder injuries, ultimately benefiting patient care.

The next time you have the opportunity to purchase new equipment, we hope these insights will help you and your team provide the greatest benefit to your most fragile patients.

(1) Payne NR, Carpenter JH, Badger GJ, Horbar JD, Rogowski J. Marginal increase in cost and excess length of stay associated with nosocomial bloodstream infections in surviving very low birth weight infants. Pediatrics. 2004;114:348-355.

(2) Weingart, Sual N., et al. Epidemiology of medical error. Western Journal of Medicine. 2000; (172.6): 390.

(3) Understanding Barriers to Medical Device Quality. Food and Drug Administration. Oct. 31, 2011. https://www.fda.gov/media/82284/download.

(4) Lin, Laura, et al. Applying human factors to the design of medical equipment: patient-controlled analgesia. Journal of Clinical Monitoring and Computing. 1998;(14.4):253-263.

(5) Sendelbach, Sue, and Marjorie Funk. Alarm fatigue: a patient safety concern. AACN Advanced Critical Care. 2013;(24.4): 378-386.

(6) Wicker, P. Manual handling in the perioperative environment. British Journal of Perioperative Nursing. 2000;10(5): 255-259.

(7) Smedley, Julia, et al. Risk factors for incident neck and shoulder pain in hospital nurses. Occupational and Environmental Medicine. 2003;(60.11): 864-869.

(8) Mehta, Jay P., Steven A. Lavender, and Richard J. Jagacinski. Physiological and biomechanical responses to a prolonged repetitive asymmetric lifting activity. Ergonomics. 2014;(57.4): 575-588.

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