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THOUGHT LEADERSHIP

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Minimizing HAIs by Design

How good design practices can help reduce healthcare-associated infections

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Healthcare-associated infections (HAIs) related to medical device implantation, use, and reprocessing present major challenges to the healthcare community. Device-related infections have numerous significant consequences, including increased patient morbidity and mortality rates, high costs to the healthcare system, and growing litigation risks for manufacturers. Overall, HAIs cost US hospitals $37B–$58B annually.

At the same time, it is estimated that as many as 70% of HAIs may be preventable. Device manufacturers, hospital risk managers, and global health authorities are actively seeking to improve their understanding of the root causes of HAIs and to develop effective strategies for HAI prevention. The potential exists for significant improvement in patient outcomes as well as cost savings. Realizing that potential in the face of a multi-faced problem like HAIs requires taking a multi-disciplinary approach to device design and risk management.

The Roots of the Problem

The root causes of infections directly or tangentially related to medical devices may include device, environmental, or patient-related factors. Examples include antibiotic resistance, ineffective sterilization, inadequate cleaning and reprocessing, and poor aseptic technique.

Significant media coverage has been devoted to reprocessed devices such as duodenoscopes used to diagnose or treat pancreatic or biliary disease. These products have complex designs and cannot be disassembled for reprocessing in the hospital setting. In general, medical devices that feature long interior channels, ridges, sharp angles, O-rings, hinges, or fluid regulating valves can complicate both manual and automated processes for cleaning and disinfection. One consequence of these types of design elements may be the retention of biological debris that promotes the development of bacterial biofilms and results in cross-contamination between patients.

Starting at the Beginning

While prevention of device-related wound infections and effective reprocessing of reusable instruments are essential in the healthcare setting, reducing the risks of HAIs may be approached by device manufacturers as a priority at the design stage depending upon a product's intended use and patient population. HAIs can be minimized through a combination of intentional design practices, including incorporation of technologies that inhibit bacterial growth on implanted devices, human factors engineering of products, and usability testing to ensure compliance with instructions for use related to reprocessing or cleaning.

Design innovation is creating more options for reducing HAIs. For reusable instruments, research by health authorities has identified design features that should be avoided in order to facilitate cleaning and disinfection. Additionally, single-use (i.e., disposable) product solutions have recently been introduced. For implantable and percutaneous devices, new technologies include controlled release of antibiotics and antiseptics, low-friction hydrophilic coatings to reduce bacterial adhesion, and alternative designs that obviate the need for tubes or cables that exit the skin.

Each of these design approaches requires careful evaluation and integration within a risk management framework. As technologies for the prevention of device-related infections evolve, so too does the need for novel testing and regulatory strategies. Design verification and validation, including usability testing, is essential for advancing development and assuring device safety and

effectiveness. By employing a testing strategy that is appropriately structured and powered to demonstrate HAI reduction, manufacturers can have confidence that their product portfolios will meet the intensified regulatory scrutiny of global health authorities.

How Exponent Can Help

Exponent consultants have deep knowledge and experience in all aspects of healthcare product design, development, testing, and risk management particularly as applied to addressing the root causes of healthcare related infections. In each of these areas, Exponent understands the impact of and connection to regulatory considerations in global markets and is uniquely positioned to leverage their multi-disciplinary expertise to help clients clarify, understand, and formulate optimal strategies to effectively comply with pre- and post-market regulatory obligations.

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