WHITE PAPER

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LACK OF KEY DATA

Leaves areas of uncertainty within set level tracking

Facts

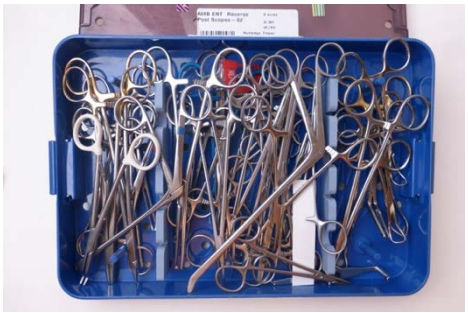
Set level tracking of surgical instruments can collect vast amounts of data.

The problem is the data collected at the set level is not all-encompassing. Vital information regarding the individual instruments is missing. Without key data about specific instruments, accuracy and reliability is lost in exchange for uncertainty and convenience.

Data is a powerful tool that can improve the quality of decision-making. It can help institutions identify trends, optimize solutions, and create a better plan for the future, subsequently saving time, money, and even lives. However, being accurate in judging what is known and unknown is critical for data-driven decision-making. Incomplete or inaccurate data about a subject allows for assumptions and human error. Consequently, this leaves room for uncertainty in areas where reliability and zero defects are imperative, such as in hospital operating rooms.

The current standard for surgical instrument management is set level tracking. The issue is that surgical instruments within a set may be packaged incorrectly, become mixed up in their sets, migrate to other sets, or become lost altogether. How does this prevailing standard introduce uncertainty that leads to these errors?

At the Sterile Processing Department (SPD), instruments are compiled into a set by manually clicking a checkbox for each instrument as it is identified and assembled into its set. Given that there are hundreds of thousands of surgical instrument catalog references and variations by different manufacturers, a large assumption is made that the SPD technician can correctly distinguish



similar instruments. By this system it is impossible to know with absolute certainty that the correct instrument is selected and placed in the correct set. Further assumptions are made during the decontamination process. Instruments may be mixed up—

Set level tracking cannot trace unique surgical instruments with absolute certainty.

There are hundreds of thousands of instruments and variations with different manufacturers and unique catalog numbers.

Instruments migrate from their original set, whether intentionally or not.

“Good data provides indisputable evidence while anecdotal evidence, assumptions, or abstract observation might lead to wasted resources due to taking action based on an incorrect conclusion” [1].

either within their own set or with other sets during this step [2].

Instruments may migrate to other sets in various scenarios. An instrument may need to be borrowed from a set for a different procedure at the last minute, for a surgeon-based preference, or to replace an instrument in need of repair. Additionally, there is no guarantee that a borrowed instrument or an instrument needing repair makes it back into its original set. At any point in the multi-stage life cycle of an instrument, any number of people could influence what happens to the instrument regardless of the set level tracking. This reality—that set level tracking cannot ensure with confidence the identification and history of a single, unique instrument—exposes the institution to the possibility of errors and wasted resources due to assumptions and uncertainty.

Consequences of decisions based on assumptions rather than reliable data extend beyond wasted resources to the potential exposure of patients to disease and institutional liability. For example, the contraction of diseases like Creutzfeldt-Jakob disease (CJD) and toxic anterior segment syndrome (TASS) are associated with the inadequate cleaning of contaminated surgical instruments [3]-[6]. A lack of adequate (and potentially inaccurate) data regarding the unique instruments associated with a potential exposure incident risks patient safety. Further, exposure incidents may have been minimized or even avoided if the specific instruments in question could be traced and decontaminated according to appropriate protocol. Without reliable data about key variables for each potentially contaminated instrument (successive patients and procedures, sterilization procedures undergone, etc.), informed decisions about transmission risk and patient notification are left to uncertainty. The basis of these decisions becomes a matter of conjecture. Moreover, exposure incidents like CJD and TASS may necessitate the suspension of hospital procedures for the quarantining of potentially exposed instruments [6]. The result is disruption to scheduled services and risk to patients in emergencies. Sometimes, if there are no readily functional alternative instruments, hospitals must make the difficult decision between halting operations and continuing despite the exposure risk to patient safety [1]. Again, these decisions may be difficult to make as there is not reliable data to help identify and trace the potentially contaminated instruments.

Surgical preferences and idiosyncrasies may also be subject to errors due to a lack of reliable data. Whether learned from surgical instructors, amassed with years of experience, or to keep up with advances in medicine, surgeon-specific instrument preferences are important to approach with accuracy. If a requested instrument is not in a set, time must now be spent searching for a correct instrument. Besides the disruption of a procedure, there may not be an

In a study of 19 incidents of patient exposure to potentially CJD-contaminated instruments reported to the CDC, “[a]t least 12 of the hospitals had multiple neurosurgical sets… [T]he CJD-contaminated instruments could not be identified in 11 of the 19 hospitals” [3].

Research has found that individual instrument preferences play a significant role in procedural outcomes [7].

Under 21 CFR 801.45(a), “[a] device that must bear a unique device identifier (UDI) on its label must also bear a permanent marking providing the UDI on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use” [8], [9].

The Global Unique Device Identification Database (GUDID) recorded over 4 million device identifier records as of July 2024 (GUDID download) [10].

easily locatable and correct instrument readily available for use. At risk are time, money, patient outcome, tension in the operating room, and surgeon performance to the highest degree of excellence. The elimination of uncertainty regarding surgical instruments is crucial for the safety of patients and the effectiveness of surgeons performing procedures.

Instrument level tracking identifies pivotal data for the life of an instrument involving the specific processing methods performed on the instrument (temperatures and pressures), the instrument's procedural history (sterilization batch, operating room, surgeon, patient), and its location at any given time (operating room, clinic, room, cart, shelf, set). These key datasets enable hospitals to identify the exact instruments associated with specific patients and surgeons.

It is important to collect meaningful data tracked at the instrument level to ensure accuracy. Beyond accuracy in what information is known, it is critical to determine what is not known to avoid assumption-driven decision-making. An absence of data at the instrument level may lead to uncertainty. Therefore, to achieve a higher level of reliability, accuracy at the instrument level is imperative for making data-driven decisions.

Regarding CJD, when asked "[s]hould hospitals track the use of surgical equipment to determine which instruments were used for which patients?" the North Carolina Division of Public Health responded "Yes." [4]

Instrument level tracking procedures should be implemented to reduce uncertainty and inform decisions with relevant, reliable data.

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