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Safer Patient Care

The Development of a Quality Management Framework for Evaluating Medical Device Reprocessing Practice in Healthcare Facilities

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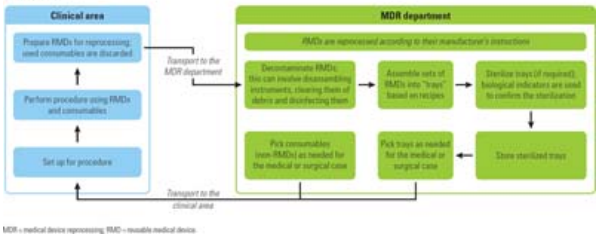
Abstract

There is increasing awareness of the importance of medical device reprocessing (MDR) for the provision of safe patient care. Although industry service standards are available to guide MDR practices, there remains a lack of published key performance indicators (KPIs) and targets that are necessary to evaluate MDR quality for feedback and improvement. This article outlines the development of an initial framework that builds on established guidelines and includes service standards, KPIs and targets for evaluating MDR operations. This framework can support healthcare facilities in strengthening existing practices and enables a platform for collaboration towards better MDR performance management.

Background

Reusable medical devices (RMDs) are used in a variety of medical and surgical procedures, including the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury (Public Health Ontario 2013). Medical device reprocessing (MDR) is the preparation of RMDs for their re-use. MDR is a critical service that many healthcare facilities rely on for the provision of safe, high-quality patient care. It is a complex process that includes cleaning, disinfecting, sterilizing and maintaining instruments to prevent microbial transmissions during use and reduce the risk of infection to patients (Figure 1). Improper handling and sterilization of RMDs can spread pathogens that can cause patient harm (MacKay and Burton 2015; U.S. Food and Drug Administration 2015) and is recognized as among the top patient safety concerns at hospitals (ECRI Institute 2015). Issues in MDR can also impact hospital operations through delayed and cancelled cases or extended patient anaesthesia time during surgery as RMDs are replaced or urgently "flash" sterilized for use.

FIGURE 1.
MDR basics



MDR = medical device reprocessing; RMD = reusable medical device

Increasing awareness of the risks associated with MDR errors has led to greater attention being paid to the quality of MDR practices (Blackmore et al. 2013). In the United States, patient safety incidents related to improper MDR practice, including instances of patient death (MacKay and Burton 2015; U.S. Food and Drug Administration 2015), have prompted the Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) to strongly advise healthcare facilities to review MDR protocols and ensure their policies and procedures are in compliance with current standards and guidelines (Centers for Disease Control and Prevention 2015). More recently in Canada, MDR-related incidents at Eastern Health led to over 500 delayed and cancelled surgical procedures (CBC News 2016), reiterating the urgency for tighter MDR quality control.

Given the intricate, multistep nature of MDR, careful control at every step of the process is imperative to the safe preparation of RMDs. In Canada, Accreditation Canada guidelines for MDR, which are based on Canadian service standards set by the Canadian Standards Association (CSA), are available to guide minimum acceptable practices. Although changes and additions to the 2015 guidelines reflect the broader movement towards more comprehensive and robust practices (Accreditation Canada Qmentum Program 2015a, 2015b), there remains a lack of published performance measures and industry benchmarks to support evaluation of current MDR practices and drive improvement.

Access to measurements and benchmarks are important, as they support MDR facilities in identifying the key metrics that define operational performance and ensuring acceptable standards of performance are being met. Accordingly, defined measurements and outcomes such as key performance indicators (KPIs) and targets for compliance are integral for monitoring operations. They offer clear, quantifiable assessments of performance quality and permit capacity for improvement by furthering capability to manage issues, identify process efficiencies and evaluate process change. From a broader perspective, measurements and benchmarks enable opportunity for standardized, controlled MDR practices across facilities.

Trillium Health Partners (THP) is committed to providing the highest quality of care to our patients. THP is a multi-site, academically affiliated community hospital in Mississauga, Ontario, that maintains the largest surgical program in the province. In 2014/2015, THP handled 63,525 surgical cases, which

corresponded to the use of 410,427 sets of RMDs. Sets of instruments are organized in over 6,000 configurations and reprocessed across multiple sites. To enable this large and complex surgical platform, a robust supply chain is maintained with MDR being a critical component.

The current gap in published MDR evaluation tools created an opportunity for THP to build on established service standards and construct an initial MDR quality management framework that includes metrics and targets for supporting high-quality MDR practice. The MDR Quality Management Framework presented in this report incorporates: a) existing best practice, namely, an index of proposed service standards constructed from and referencing established service standards and guidelines; and b) objective, clearly defined KPIs, targets and an accompanying reporting tool to review and manage MDR performance on a routine basis.

High-quality MDR practices are integral to patient safety and effective hospital operations. THP recognizes that to maintain our commitment to exceptional patient care, there is a need to think and act differently and to take new and innovative approaches to deliver on the objectives of our strategic plan—to create a new kind of healthcare for a healthier community. We also recognize that doing so requires collaboration with our patients and partners in the healthcare community. By sharing this initial MDR Quality Management Framework, our intent is to encourage cooperative efforts that will initiate development of industry standards and benchmarks and set the foundation for standardized process and best practices across MDR facilities. Ultimately, the presented tools will support other healthcare facilities in better understanding their own MDR practices and build capacity for feedback and corrective actions that will collectively promote proactive performance management, continuous improvement and high-quality patient care services.

The Development of a Medical Device Reprocessing Quality Management Framework

The process of constructing our MDR Quality Management Framework began by identifying the needs of our patients and front-line staff who routinely use RMDs. Together, it was agreed that this initial framework must adhere to principles of quality and reliability in order to: 1) guarantee the highest standards of safety for our patients, and 2) deliver process efficiency ensuring that RMDs would be readily and reliably available to impacted stakeholders as needed.

Using these guiding principles, we derived service standards, KPIs and targets that would form the foundation of our framework to guide MDR performance management. We jointly referenced the 2015 Accreditation Canada guidelines (Accreditation Canada 2015a; 2015b) and the CSA Service Standards (Canadian Standards Association 2015) for MDR. Additionally, we included items that THP deemed important for review, specifically those that governed the quality of MDR output, such as MDR process error rates and surgeries impacted by these errors. A total of 25 service standards and 10 KPIs were identified and included in our framework. These service standards and KPIs represented the range of policies, procedures, outcomes and practices required to manage and monitor performance of a high-quality, reliable MDR operation. A detailed, full document with items referenced to their respective 2015 Accreditation Canada guidelines and CSA Service Standards is attached in Appendix 1.

Medical Device Reprocessing Service Standards

An index of service standards that assessed adherence to Accreditation Canada guidelines and CSA Service Standards for MDR were aggregated (Accreditation Canada 2015a; 2015b; Canadian Standards Association 2015). These proposed service standards were developed to govern MDR operations, staff development and performance improvement and should be assessed based on documented adherence to respective policies or processes evaluated at predefined intervals. An index of proposed service standards, categorized and with their recommended review schedule, is presented in Table 1. The use of process checklists, which are also periodically reviewed, has been a demonstrated, effective strategy for enhancing compliance to MDR best practices (Patterson 2013).

TABLE 1. Summary of MDR service standards

PROGRAM OPERATIONS

These service standards relate to programs operations including quality control and resource management practices that should be conducted and documented routinely for effective daily operations. Service standards also include process checkpoints and preventative measures that ensure RMD, equipment and output integrity.

Service standard	Target compliance	Review schedule
Maintenance and availability of SOPs	100% of necessary SOPs are documented, maintained and available to staff	Annual
Daily review of booked medical and surgical procedures	Review is completed daily 100% of the time	Monthly + annual
Daily review of instrument par levels	Review is completed daily 100% of the time	Monthly + annual
Daily supervisor huddles with MDR and OR staff	Daily huddles are completed daily 100% of the time	Monthly + annual
Daily maintenance &	Daily audits to confirm	Monthly +

inspection	clean and dirty work areas are kept separate 100% of the time.	annual
Prepare recall report during event of instrument recall	100% completion of a recall report following circumstances requiring a recall	Monthly + annual
MIFU availability	100% of MIFUs for all instruments are reviewed and updated annually	Annual
Documentation of daily BI testing	100% completion of documented daily BI testing	Monthly + annual
Daily Bowie-Dick test in sterilizer	100% completion of daily Bowie-Dick test in sterilizer with documentation	Monthly + annual
BI use whenever change in sterilization process is implemented	100% completion of documented BI testing following a change implementation	Annual
IUSS biological testing records	100% completion of daily biological testing for all IUSS	Monthly + annual
Bowie–Dick and BI testing following major equipment or environment change	100% completion of documented Bowie–Dick and BI testing following a major equipment or environmental change	Annual
BI use in every production load	100% of production loads have documented BI use	Monthly + annual
Routine/preventative maintenance	100% completion of preventative maintenance and cleaning program records (both planned and unplanned)	Monthly + annual
BI = biological indicator; IUSS = immediate-use steam sterilization; MDR = medical device reprocessing; MIFU = manufacturer's instructions for use; OR = operating room; SOPs = standard operating procedures.		

Medical Device Reprocessing Key Performance Indicators

KPIs evaluated MDR process and operation outcomes, e.g., MDR process errors, and their impacts on patients. KPIs were chosen, as they represented the measurable output of MDR that could be reviewed to quantify performance and identify issues. Considerations for defining KPIs were based on validity, simplicity and practicality. Measurements for KPIs were defined in partnership with industry experts and designed to be intuitive and objective. To maintain accessibility, we ensured that KPIs were based on data that could be readily quantified and generated by hospitals, such as from operating room management and incident reporting management systems. Next, KPI target levels required to achieve compliance were developed and assigned based on specification from the referenced 2015 Accreditation Canada guidelines, CSA Service Standard or hospital need. Derived targets were based on thresholds supported by MDR expert advice that would maintain patient safety and operational effectiveness. We recommend that KPIs are reviewed on a monthly basis in order to assess and mitigate issues and risk. An index of KPIs, measurements and targets is presented in Table 2.

TABLE 2. Summary of KPIs

KPI	Measurement	KPI target	Review schedule

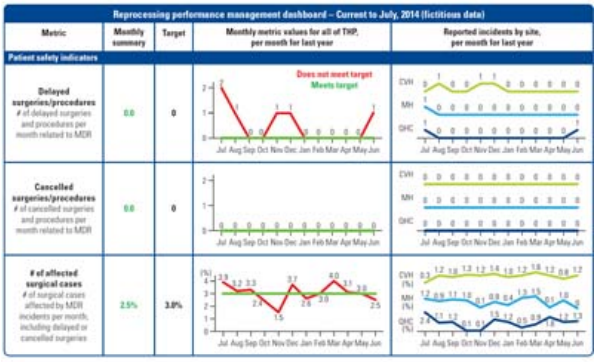
Patient safety incidents	# of patient safety incidents per month	0 patient safety incidents per month	Monthly + annual
Delayed surgical cases	# of surgical cases or procedures delayed by reprocessing incidents per month	0 delayed surgical cases or procedures as a result of reprocessing incidents per month	Monthly + annual
Cancelled surgeries and procedures	# of cancelled surgeries and procedures as a result of reprocessing incidents per month	0 cancelled surgeries and procedures as a result of reprocessing incidents per month	Monthly + annual
% of affected surgical cases	# of surgical cases affected by reprocessing incidents as % of total monthly surgical cases	Less than 3% of surgical cases affected by MDR incidents as % of total surgical cases	Monthly + annual
Total reprocessing error rate	# of total errors as % of monthly trays reprocessed	Less than 0.6% errors as % of monthly trays reprocessed	Monthly + annual
Utilization of immediate-use steam sterilization	# of occurrences requiring Immediate-use steam sterilization per month	0 occurrences requiring immediate-use steam sterilization per month	Monthly + annual
Decontamination time	% of instruments decontaminated within 2 hours after receipt by MDR department	100% of instruments to be decontaminated within 2 hours after receipt by MDR department	Monthly + annual
Sterilization time	% of instruments to be sterilized within 8 hours after decontamination	100% of instruments to be sterilized within 8 hours after decontamination	Monthly + annual
Instrument available for use time	% of instruments to be shelved, accounted for and available within 6 hours after sterilization	100% of instruments are shelved, accounted for and available for use within 6 hours after sterilization	Monthly + annual
Tray turnaround time	% of trays turned around within 18 hours of total trays reprocessed	100% of trays turned around within 18 hours as % of total trays reprocessed	Monthly + annual

Key Performance Indicator Reporting Dashboard

To promote tracking of KPIs and targets, THP has taken preliminary steps in developing a reporting process and template to implement information into practice. THP set out to create a Monthly MDR Performance Dashboard ("MDR Monthly Dashboard") based on the recommended monthly reporting schedules for KPIs, which has been implemented since May 2014. The objective of the MDR Monthly Dashboard is to enhance performance management through a summary of MDR operational outcomes and their impact on patient safety. It permits timely feedback and the capability to gauge and review MDR operations, determine areas of improvement and generate action items for addressing issues that impact service.

Furthermore, the MDR Monthly Dashboard supplements current incident management processes by providing an intuitive overview of MDR process and operational outcomes. Currently, our hospital incident reporting system is set up to track and monitor specific MDR incidents and any follow-up activities according to international best practice (WHO Patient Safety 2009). The MDR Monthly Dashboard is programmed to filter and aggregate this information with our operating room management system to display summary statistics of KPIs against their respective targets tracked within time ranges of interest for comparison (e.g., from the past year). This report was designed to be reviewed by leadership within the MDR Department on a monthly basis to quantify issues for mitigation. However, the MDR Monthly Dashboard can also be presented to key stakeholders, such as leadership from impacted departments and surgeons routinely, and as needed (e.g., on a quarterly basis), to promote transparency into MDR operations and to create opportunities for inter-professional feedback. A truncated sample of the Monthly MDR Performance Dashboard with fictitious data is presented in Figure 2.

FIGURE 2.
Truncated monthly MDR performance dashboard presented with fictitious data



CVH = Credit Valley Hospital; MDR = medical device reprocessing; MH = Mississauga Hospital; QHC = Queensway Health System; THP = Trillium Health Partners

Discussion and Conclusions

MDR is a critical service for the delivery of safe, high-quality patient care. Issues in MDR can have considerable impact on patient safety and hospital operations. During analysis of our own MDR practices, we consulted with industry experts and performed site visits across Canada to better understand practices and challenges in other organizations. A common theme from these experiences was a culture dedicated to service quality but that lacked the tools to objectively evaluate performance and guide improvements. Additionally, we discovered that although outcomes of MDR issues, such as delayed and cancelled surgeries, are carefully monitored by healthcare organizations, oftentimes not enough attention is given to monitoring the quality of MDR work needed to mitigate problems in the RMD supply chain. To facilitate MDR performance management, published performance measures such as KPIs and targets are invaluable in supporting healthcare organizations in adhering to recommended practices and notifying leadership of risks and/or deficient processes that require investigation. These tools also build capacity for process efficiencies by helping to identify process improvements and evaluate process change.

To better support MDR performance management, our goal was to share our experiences and a developed initial framework with the intent to initiate development of industry standards and benchmarks. The presented quality management framework consists of recommended service standards, objectives, clearly defined KPIs and targets and an accompanying reporting tool for implementing KPIs into practice. This framework was built upon established best practices and can strengthen existing MDR operations by enabling measurement of MDR quality and alignment of MDR operations to recommended quality standards. This framework can serve as a preliminary base for industry standards and benchmarks and provides a common platform for shared insights and collaboration. We encourage other MDR facilities to adopt this framework, as collaboration will better refine the framework, KPIs and targets and shape best practices across healthcare facilities.

Two aspects of this initial framework we want to highlight are its benefits to MDR safety and improvement, and emphasis on partnership. Safety is improved by better understanding the factors that contribute to errors. Our framework acts as a tool for continuous and purposeful evaluation of MDR in order to predict and proactively manage issues. Simultaneously, this framework, with its index of recommended service standards, serves as a supporting mechanism to ensure that the correct processes are in place to maintain safety and for staff to identify, understand and mitigate risks. Further, this framework has better equipped THP to systematically review our own practices and drive process improvement by helping to identify process efficiencies and providing a baseline for evaluating their implementation. Several applications that have resulted from this work and that we intend, in future publications, to evaluate and share as lessons and considerations for other healthcare facilities include:

1. Standardization of RMDs and instrument sets. THP currently uses nearly 100,000 unique instruments presented in over 6,000 configurations. Having a great variety of instrumentation and user preferences increases the complexity of MDR practice. This complexity increases the likelihood of error and reduces efficiency of operations. Instrument standardization is a key enabler to simplifying and reducing instrument inventory and work

processes, thereby reducing errors and increasing quality and efficiency of MDR practices. Further, having fewer types of instruments and sets allows greater inter-operability of RMDs and reduces the risks of instrument unavailability.

2. Options for different models of multi-site MDR, their benefits (e.g., redundancy), risks (e.g., transport, database alignment) and considerations (e.g., inventory, contingency, layout) for maintaining process quality and minimizing delays and errors.
3. Contingency planning for maintaining MDR operations in both planned (e.g., routine and preventative maintenance) and unplanned (e.g., environment or infrastructure issues or equipment malfunction) situations. Considerations for effective plans include flexibility and multi-dimensionality to mitigate disruptions to clinical operations, and can include the development of partnerships with other healthcare organizations for reciprocal MDR support.
4. Full implementation of an integrated IT system to help manage RMD inventory and life cycles. This system also facilitates RMD tracking at different stages of reprocessing and use.
5. Development of a predictive model for estimating MDR demand based on historical case volumes and patterns. Demand modelling enables proactive alignment of staffing and resource allocation.
6. Further development of our MDR Quality Management Framework to improve capability in reviewing different types of errors, determine their root causes, document trends and manage these issues, including product recall. Improved analytics permit proactive identification of problems before they impact cases or reach the patient and help determine direct and indirect cost of MDR-related issues.

Nevertheless, despite adherence to identified service standards and regularly reported metrics, it is important that information collected from this framework not supersede the judgement of front-line staff, who should remain final decision-makers in assessing RMD safety before use. Accordingly, there is a need for front-line staff to remain vigilant and engaged. A critical feature of this framework is the emphasis on partnership between the MDR Department and its key stakeholders, such as the Surgical Department. In building this framework, we recognized the opportunity to change the perception of MDR as a peripheral service within the hospital to one that provides a critical service and is a partner in enabling and enhancing the hospital's core functions. When we designed this framework, we looked to strengthen the relationship between the MDR Department and their partners and better integrate them. Accordingly, this framework was developed with input from key partners and reviewed by them throughout the development process. This process encouraged collaboration through transparency and continuous improvement based on their feedback. Finally, elements of this framework, such as KPIs and the MDR Monthly Dashboard, benefit as educational tools to engage our partners and heighten their awareness of service expectations and how the MDR process is incorporated in their operations. For example at THP, KPIs are incorporated in our hospital quality framework and shared at team huddles that MDR and OR staff jointly attend.

THP recognizes the importance of high-quality MDR practices to patient safety and effective hospital operations. In alignment with our vision to work better together, we wanted to share this initial framework, including service standards, KPIs and targets, to support our partners in ensuring the best care for patients. As work continues in refining and implementing our framework to better match the needs of our organization, we encourage other facilities to adopt and refine these tools for their own uses. Adoption of this framework provides an opportunity to make MDR operations more transparent, strengthen existing MDR practices and foster partnership with stakeholders. This framework also enables a common platform for MDR facilities to share analytics and insights for comparison to complement the adoption of CSA and Accreditation Canada service standards and guidelines. Through broader collaboration, we move towards stronger MDR performance management and standardized practice shaped by collective experience and industry standards and benchmarks.

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