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Medical Device Research at a Regional Health System

The Mercy experience

Mercy's research department develops information from electronic information systems to support quality improvement and operational efficiencies that generate revenue. A major research effort was a Unique Device Identifier (UDI) project which resulted in operational efficiencies and a database that is being used for comparative effectiveness and safety analyses.

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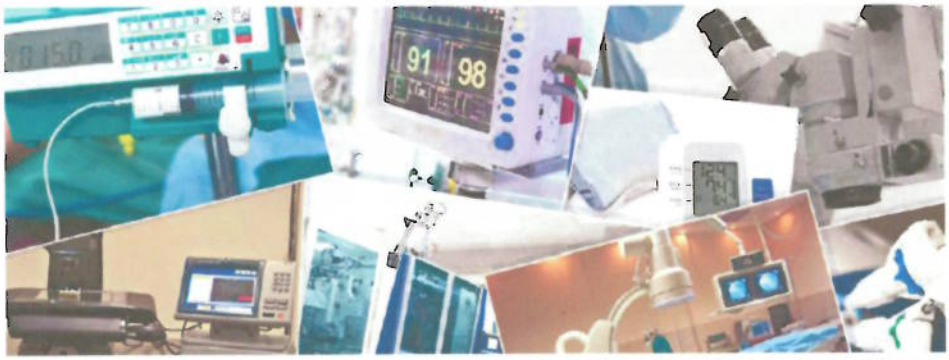


In 2009, Mercy made the decision to embark on a research programme involving implanted medical devices by employing Unique Device Identifiers (UDIs). Mercy is a four-state regional health system headquartered in St. Louis, Missouri that serves communities in Arkansas, Kansas, Missouri, and Oklahoma through 40 hospitals ranging from small, critical access facilities to large tertiary medical centres. In addition, Mercy employs over 2,000 physicians specialised in multiple disciplines and generates in excess of US$4 billion annually.

Mercy's Information Journey

In 2006, Mercy began implementing EpicCare (Epic, Verona, WI) Electronic Health Record (EHR) in all of the system's hospitals and employed physician practices - a process that took over six years to complete which resulted in a 'fully connected' health system generating a significant amount of clinical data across the healthcare spectrum. Despite this success, Mercy continues to face challenges in turning these data into actionable information due in part to free-standing clinical and administrative databases such as those contained in the cardiac catheterisation laboratory (Cath Lab) software and the Enterprise Resource Planning (ERP) solution. These 'data islands' make it difficult to establish a comprehensive view of administrative, clinical processes and of patient outcomes necessary for Mercy leaders to manage in the changing healthcare environment created by US Affordable Care Act (ACA).

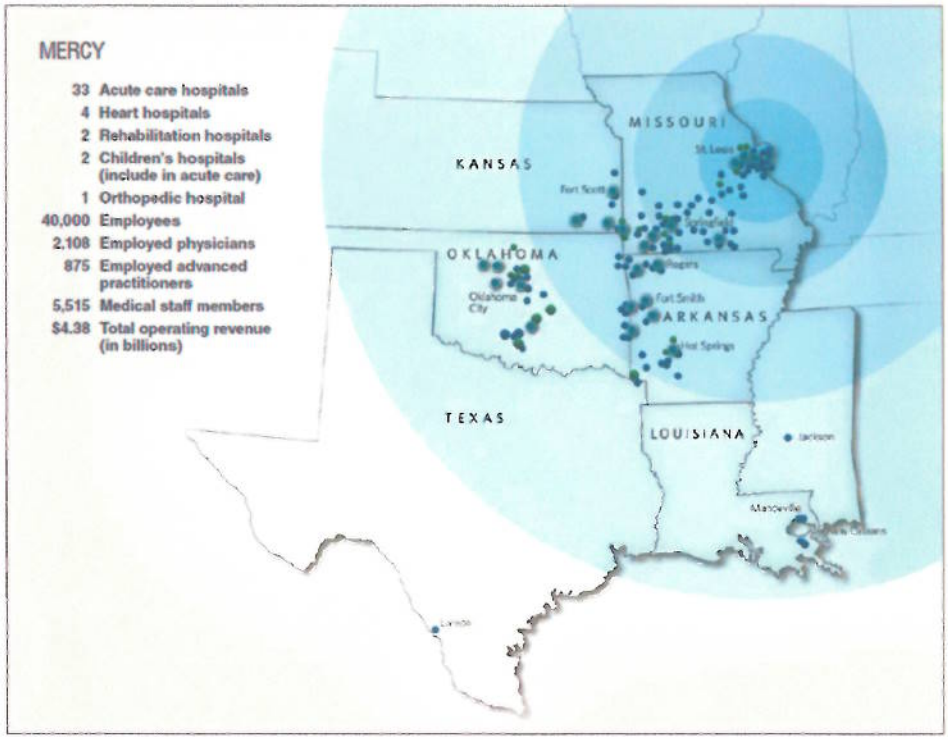
New Business Environment and Need for Actionable Information

As healthcare reforms proceed, Mercy must learn to deal with US Centers for Medicare and Medicaid Services (CMS) programmes such as value-based purchasing, and public reporting of hospital and physician performance, along with different delivery models, such as patient centered medical homes and Accountable Care Organisations (ACOs). Mercy's Springfield (Missouri) network is participating in CMS's ACO programme building on experience gained from the network's successes as part of the earlier CMS Physician Group Practice demonstration. Finally, CMS is also working on new reimbursement strategies meant ultimately to replace fee for service. These include shared savings, bundled payments, and, potentially, monthly payments per assigned beneficiary (capitation). All of these changes will require an in-depth understanding of both the clinical and administrative aspects of the business and how the two interrelate.

Overall Data and Information Strategy at Mercy

To gain the in-depth business intelligence needed by an American hospital system in a post-ACA world, Mercy has undertaken a comprehensive data strategy that begins with optimising data flow through all of its electronic information systems organised around the individual patient. This data is then channeled through a data warehousing solution called the Integrated Patient Datamart (IPD) from which data sets can be created that contain information from multiple source systems being available for analysis and use at the point of care. As a means of extending and strengthening this strategy, Mercy is developing data partnerships with national registries such as the American College of Cardiology's National Cardiovascular Registry (NCDR), and with like-minded health systems, such as the Healthcare Transformation Group (HTG), which, in addition to Mercy, is composed of Geisinger Health System, Intermountain Healthcare, Kaiser-Permanente, and Mayo Clinic.

Through this comprehensive data strategy, Mercy is achieving a number of patient care and business goals. Mercy is improving care quality and gaining clinical efficiencies by bringing actionable information to clinicians at the point of care and by performing sophisticated clinical analyses. Detailed knowledge of costs in relationship to clinical outcomes greatly assists Mercy leaders in working with clinicians to optimise resource utilisation. The knowledge gained includes results of comparative effectiveness research of various diagnostic and therapeutic approaches including the use of expensive technologies as employed by Mercy clinicians. Finally, the data constitutes a business asset which is of value to third parties presenting a revenue generating business opportunity. In summary, the Mercy information strategy is designed to help ensure that the system thrives in any business environment.



Mercy's information strategy is enabled by automated capture of high quality data and by rigorous attention to data standards. This includes control points embedded within care processes enabling better decision making and improved documentation. One outcome is the creation of integrated data sets through IPD that are highly scalable.

Medical device information as prototype

Mercy identified implanted medical devices as a priority area for converting data into information since these devices are not only expensive but the appropriateness of their use and their in-vivo performance also has significant implications for the quality of patient care. Several groups of Mercy stakeholders identified information needs relative to medical devices. Mercy's supply chain leaders were concerned that the premium prices attached to some devices within a class, were not supported by data establishing superior effectiveness when used in the real world by Mercy physicians. Clinical support personnel in Mercy's Cath Labs faced obstacles in managing inventories of implanted devices because of highly manual processes that were cumbersome and inefficient. Physicians faced a number of challenges when caring for patients with implanted devices. They often did not have ready access to critical device information needed for diagnostic and therapeutic decision making. When devices were recalled, physicians found it difficult to determine which of their patients, if any, were affected by the recall. Finally, physicians faced challenges in reporting adverse events related to devices because of lack of ready access to device information. Mercy's Research Department identified a need for device data infrastructure to support health services and comparative effectiveness research along with safety surveillance. The requisite infrastructure would include automated capture of significant clinical and device variables along with linkage to external databases such as Health Information Exchanges (HIEs) and national registries. In summary, robust device information would support three of Mercy's fundamental goals: superior patient care experience including outcomes, care provider satisfaction, and optimal financial performance.

Mercy assembled a multi-disciplinary team under the leadership of the Research Department to create a system for tracking implanted medical devices from product receipt through implantation to post-implant patient follow up. The team included clinicians, information system architects, and supply chain and performance optimisation personnel. The new system was to be modelled after one that was already in use at Mercy for tracking medications and that was built on National Drug Codes (NDCs) which are specific to individual drugs.

FDA Demonstration Project

In 2012 Mercy had the opportunity to accelerate its medical device information strategy through participation in the U.S. Food and Drug Administration's (FDA) Medical Device Epidemiology Network (MDEpiNet). As a subcontractor to the MDEpiNet Methodology Center at Harvard University, Mercy performed a demonstration project whereby UDIs were integrated into Mercy's electronic information systems. Details of the demonstration project are described in detail elsewhere. 1 A UDI is a unique numeric or alphanumeric code that contains 2 types of information: a Device Identifier, which is specific to a device model, and a Production Identifier, which includes the current production information for that specific device, such as the lot or batch number, the serial number and/or expiration date. The FDA requires product labellers to put UDIs on most medical devices beginning from September, 2014, with the highest risk devices (Class III) UDIs, then, have the potential to function for devices as NDCs do for medications. Additionally, the FDA has also created a database of device attributes (the Global UDI Database or GUDID) linked to the UDIs.

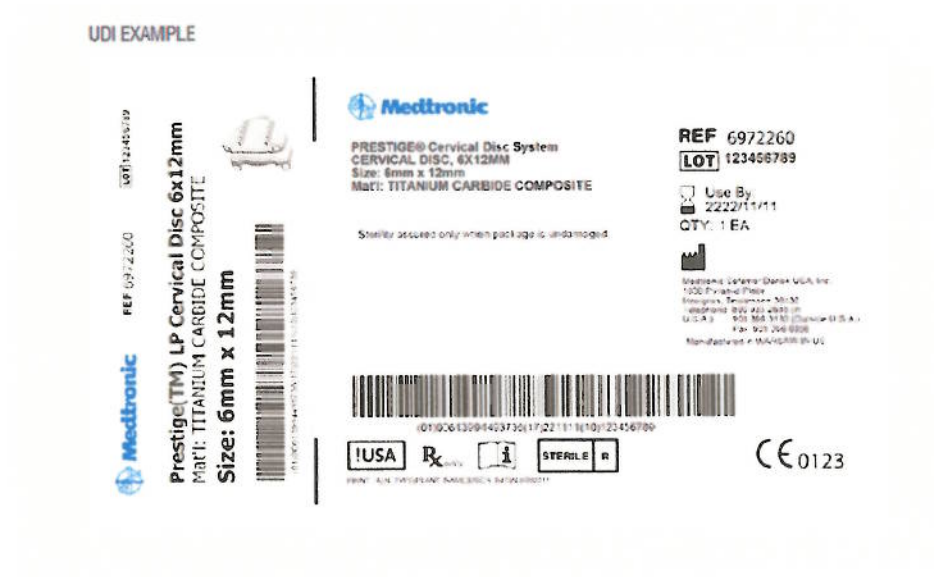
To achieve the demonstration's aims the Mercy team accomplished a number of tasks. The first was to create Draft UDIs since the project was carried out before the FDA's UDI requirements were in place and to associate them with the attributes in the FDA's GUDID. This was accomplished with the cooperation of the coronary stent manufacturers (Abbott, Boston Scientific, and Medtronic) using GS1 barcode standards (GS1, Brussels). The FDA supplied Mercy with GUDID information since the database was not fully functional during the time of the project.

Mercy also worked with an expert panel of cardiologists to create supplemental attributes to be stored in a reference database (supplemental UDI database or SUDID). These attributes are specific to coronary stents and significantly affect device performance but are not found in the GUDID.

Mercy system architects then created a UDI data flow through ERP to Cath Lab hemodynamic software to EHR and ultimately to a UDI research data set (UDIR) generated by the IPD and useful for research and safety surveillance. The data flow is hinged on implementation of a Cath Lab barcode scanning point of use system (OptiFlexsm, Omnicell, Mountain View, CA). The UDIR contains device attributes drawn from the GUDID and SUDID together with clinical data from the hemodynamics software and EHR and mortality data obtained from the Social Security Death Master File. Patient data isadded to the UDIR on a weekly basis to enable longitudinal patient and device follow up.

Mercy also worked with the NCDR to create UDI fields in the NCDR's CathPCI Registry. Mercy's Cath Labs report their coronary stent cases to the CathPCI Registry, which captures in excess of 85 per cent of such procedures performed in the United States. This was an important task for two reasons. It was the first step in developing a system for automated reporting to the registry, which now requires manual data entry. Secondly, Mercy's goal and that of its partner health systems is to create a data network using the CathPCI Registry as the hub.

Once the UDIR was in place Mercy researchers performed studies to demonstrate the validity and reliability of data. The plan is to publish results in the near future. Finally, Mercy has also identified obstacles to incorporating UDIs in our electronic information systems, explored solutions, and will publish these findings as well. In the meantime, Mercy is taking the learnings from this project and beginning implementation of a point of use system in its operating rooms.



UDI Phase 2

During the demonstration, Mercy's HTG health system partners helped ensure the project's generalisability with the intent of expanding the work to include all five systems at some point. The plan for UDI Phase 2 is to replicate Mercy's UDIR at each of 3 additional HTG systems (Geisinger, Intermountain, and Mayo) and to create a distributed data network using the CathPCI Registry as the hub with the NCDR providing network coordination, business rules, and a common data model to support analytics. The distributed data model has been advocated by the U.S. Agency for Healthcare Quality and Research (AHRQ) for data sharing and research by provider networks. It has the advantage of keeping sensitive information behind the 'firewalls' of the data owners while still being available for combining with data from all network members for research purposes. The resulting robustness of the combined datasets greatly enhances their ability to answer questions on product performance and safety as compared to the smaller datasets from individual health systems.

In order for Phase 2 to be successful, an alliance of key stakeholders will be assembled. Besides the HTG health systems, these include national medical societies (ACC and the Society for Cardiovascular Angiography and Interventions), the pertinent national registry (NCDR), coronary stent manufacturers (Medtronic, Abbott, and Boston Scientific), and consumer groups representing patients. Mercy utilised a similar partnership during the demonstration project and found that no system of device surveillance and research is viable without the active participation of these important constituencies. The intent is to employ the template created and tested in Phase 2 for developing similar systems for use with all implanted medical devices using national registries when they are available.

Summary and Conclusions

As other American hospital systems have also discovered, Mercy recognises that actionable information for all members of the healthcare team is critical in this new era of healthcare reform and accountable care with its emphasis on improved patient experience, improved health of communities, and lower per capita costs. With these exigencies in mind, Mercy has embarked on a strategy of information creation and analytics to take advantage of the vast amount of data it is capturing in its electronic information systems. The field of implanted medical devices is an area where both clinicians and administrators will require in depth information and analysis if patients are to be provided with high quality care that is affordable. With that in mind, Mercy and its HTG partners have embarked on an ambitious programme of UDI-based device surveillance and research that is anticipated to yield many operational and clinical benefits.

Author BIO

Joseph P Drozda *is a Cardiologist and Director, Outcomes Research at Mercy. His group at Mercy performed an FDA demonstration on incorporation of Unique Device Identifiers (UDIs) into Mercy information systems for purposes of surveillance and research. He leads a team from 5 health systems developing an extension of the demonstration.*

Timothy R Smith *is Vice President - Research at Mercy. His enterprise - level research leadership provides strategic and tactical support for Mercy's Unique Device Identification project. His team of researchers and other personnel provide support for database development, analytics, research conduction and investigator development Mercy-wide.*

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