New Medical Device Management & Processes (including Consignment, New Loan Equipment & Consumable and Samples)

Singapore Healthcare Management 2017

Mr. Tong Shao Chuen
Dr. Chow Wai Leng
EASTERN HEALTH ALLIANCE
A/Prof Peter Lu
Ms. Ler Sock Hoon
Ms. Samantha Ng
Ms. Nurfariha Bte Ab Rashid
Changi General Hospital

Introduction

Medical devices can enter the hospital inventory via multiple avenues. As the receiving parties of these devices are in different departments and in different parts of the hospital, it is sometimes difficult for the hospital to have oversight of all the medical devices that are currently utilized in the hospital. This may have implications on patient safety and medico-legal issues.

Aims

The aim of this poster is to detail the establishment of a medical device management framework and supporting processes to improve the governance of the introduction and utilization of new medical devices within the hospital.

Methodology

Initial Interviews

Interviews were conducted with clinicians, nurse managers and other departments to identify the different pathways which medical devices may enter the system and the key stakeholders who would likely receive information about the medical devices.

Identification of stakeholders

From the interviews, it was determined that several departments were vital in ensuring that information on new devices entering the hospital were collected. These departments were:

1)Operating Theatre

2)Cardiac Catheterisation Lab

3)Supply Chain Management (SCM)

4)Biomedical Engineering Department (BME)

Data Gathering

To gather more information on the new devices entering the hospital, a registration process was piloted to obtain more information on the nature and type of medical devices entering the hospital. Vendors were required to enter information about the device before it could be used in the hospital. This included the Health Sciences Authority registration status of the device; the therapeutic function of the device and the information on the storage condition. In addition, users were also required to report on the number of devices they were bringing in and the therapeutic area of the devices. The information collected from the register advised the stakeholders on the different avenues the devices were entering the hospital and helped identify the key departments that were being in new devices.

Process Mapping

With these departments engaged, processes were developed to ensure that the four main avenues through which medical devices are entered are strengthened. These avenues are:

1)Request For Proposal /Tender Process for New Devices

2)Consignment

3)Loan

4)Samples and Consumables

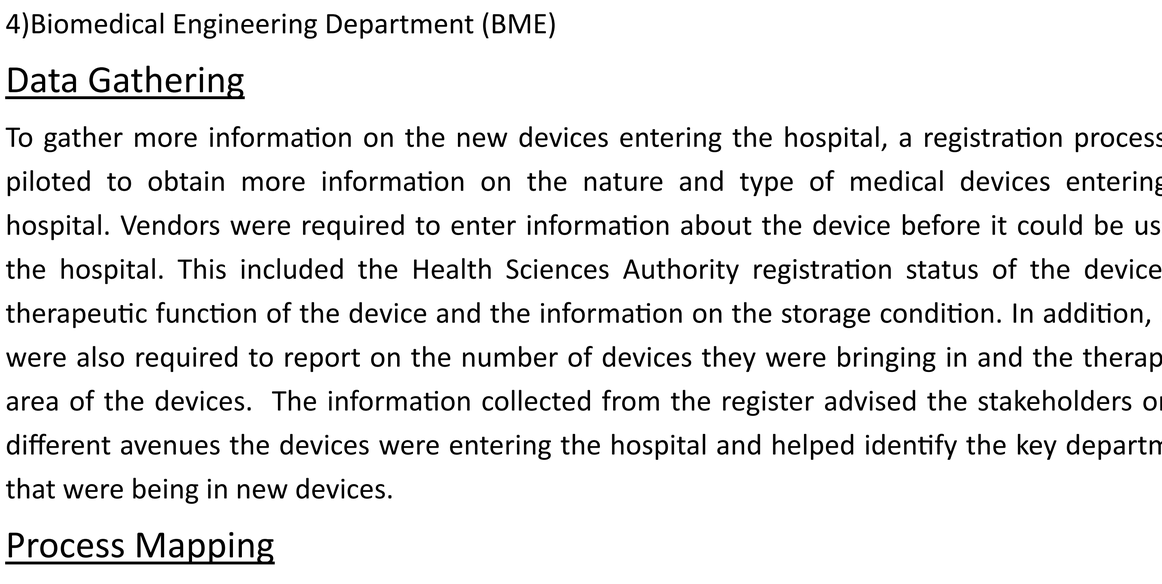

Figure 1: Sample Process Map of the Procurement Process for Consignment

Results

Establishment of a Medical Device Governance Framework

A medical device framework was developed based on the following guidelines:

1) A single point of contact for vendors in order to ensure that proper terms and conditions are in place to protect the hospital.
2) A Medical Device Oversight Committee (MDOC) chaired by the Deputy Chairman Medical Board (Surgery) and comprising senior clinicians, nurse managers, supply chain management, data management and other key stakeholders to oversee the introduction of high-risk and high cost medical devices that is guided by Health Technology Assessment (HTA).
3) A platform for registering new devices and monitoring device utilization to inform decision making.

Roles for each stakeholder were also mapped out for each stakeholder (Table 1 below). The framework, processes and roles were endorsed by senior management and user engagement sessions were conducted.

Stakeholder	Roles played
Senior management	To be updated on new additions to/ removals from the inventory To be informed of adverse events Makes decisions of high cost additions to inventory
Medical Board	Makes the decision on appeals for the addition/ removal of devices from the inventory
Medical Device Oversight Committee	Evaluates and makes decisions on the addition/ removal of devices from inventory Monitors the overall utilisation of new devices Monitors adverse events related to devices Credentials doctors for the use of new devices Conducts reviews of the new devices before they are added into the inventory
Supply Chain Management	Be the primary point of contact for vendors Maintains the device register and inventory Drives the procurement process of new devices Reports on the utilisation of non-evaluated devices to MDOC
Biomedical Engineering	Ensure that the incoming devices are safe for use Ensure that devices are registered with SCM before evaluating devices for use
Operating Theatre/ Cardiac Catherisation Lab	Ensure that devices are registered with SCM before using Keep track of the utilisation of new devices
EHA Health Services Research	Performs independent HTAs as directed by MDOC Makes recommendations to the evaluation/ monitoring framework for the new medical device as directed by MDOC
CGH Data Management & Informatics	Develop and maintain device utilisation registry Facilitate device data collation and integration Creation and amendments to device data e-forms Generate reports for MOH and senior management
CGH Finance	Assists the doctor in determining the financial viability and budget impact of the device Advises the MDOC on cost of care
Clinical Departments	Submission of application for introduction of new device to SCM and MDOC complete with an evidence based evaluation of the new device and a detailed implementation plan Submit utilisation and outcomes data of new device to MDOC

Table 1: Roles of Stakeholders in Medical Device Governance

Implementation of the Framework

Since the establishment of the MDOC to review and approve the introduction of new devices into the hospital, there have been 280 new medical devices have been registered with SCM in May 2016. 33 devices were considered higher clinical risk and were reviewed by MDOC. HTAs were conducted for 3 devices. 11 devices have been identified for regular monitoring.

Conclusions

The implementation of this framework and processes ensure that devices entering the hospital are more closely monitored and reduces the risk of unsafe devices being used.

Next Steps

With the initial implementation of the framework complete, the next steps would be to further strengthen the utilization data collection and to determine how to build the framework into the current hospital budget process.