Mike Giles

Medical Device Management & Procurement Innovations

Operational Contracts Programme Manager

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Responsible for:

- Oversight and assurance to our Executive Directorate that our out-sourced Clinical Engineering Services are being delivered in a safe and cost efficient manner including:

  - Developing and modifying infrastructure and Governance to most effectively and efficiently guide and manage the whole life-cycle of our medical devices..

  - Overseeing expenditure of Revenue & Capital Budgets for our medical device replacement programme.

NHS
Royal National
Orthopaedic Hospital
NHS Trust

ebme Expo

Overview of The Royal National Orthopaedic Hospital

- The largest orthopaedic hospital in the UK, working closely with other hospitals and Trusts.

- Regarded as a leader in the field of orthopaedics both in the UK and worldwide providing a comprehensive range of neuro-musculoskeletal health care services.

- Plays a major role in teaching, with 20% of all UK orthopaedic surgeons receiving their training there.

NHS

Session Objectives:

- To share key core evaluation principles and governance structures we have found effective in managing medical devices with particular emphasis on our annual replacement programme.

- To share our experience of how using a largely simple mathematical model for an initial overview of all medical devices to identify those with the highest risks, combined with intelligent clinical lead dialogue, is able to provide a high level of ongoing whole life medical device confidence at Clinician, Middle/Senior Management and Executive Director Level.

Context - RNOH Journey – 2014/15

- Limited Clinical Engineering Personnel – One excellent Engineer with various levels of ad hoc support from Agencies.

- Lack of confidence in medical device database accuracy so audit commissioned to secure confidence.

- Disparate non-centralised procurement and maintenance management.

- Planned Periodic Maintenance Levels at ~55% of *known* devices. CQC Minimum had been 80% - Poor CQC Medical Device management review.

- Lack of confident risk based medical device replacement plan- largely reactive – limited on budget.

- Lack of clear robust Medical device procurement approval process

- No identified contingency funding for replacing devices uneconomical to repair.

- Lack of robust assurance of Medical Device whole-life management for Finance Department & Corporate confidence.

- Lack of clinical and corporate confidence in training compliance as few records kept and many of those out of date.

- Limited and unstructured device sharing between clinical areas.

Review & Transition

- Clinical Engineering Procurement Consultant engaged to review site & provide suitable options to increase confidence.

- Basic Risk Assessment Model developed for *known* medical devices to provide better understanding & confidence.

- Options paper resulted in recommendation to outsource Clinical Engineering function utilising a hybrid service model requiring provider to undertake all aspects of device management “but” with the devices remaining the property of the RNOH. A type of Managed Equipment Service(MES) minus.

- TBS GB, (Althea UK & Ireland), awarded the contract and began operations in June 2015.

- TBS GB inundated our site with their Engineers to undertake a full audit revealing that they had been unable to find ~600 of the devices recorded on our database; but that had found ~ 600 more that weren't!

- TBS GB merged their own replacement model with the one I'd created to enable maximum local confidence and benefit.

- Our original Medical Equipment Group was divided into two to reflect the different responsibilities of our Operational and Executive personnel.

- Medical Device (Management and Training) Policies were reviewed & significantly updated to strengthen the infrastructure & credibility around Device Management.

Medical Equipment Governance Groups

MEG(Exec) – Executive oversight of device management/procurement/governance.
Members: Chief Operating Officer; Directors of Finance, Nursing, Imaging, Clinical Governance, Head of Procurement, Clinical Engineering Manager and Operational Contracts Programme Manager

MEG(Ops) – Operational oversight of ongoing clinical issues and procurement.
Members: Imaging Manager, Anaesthetic Consultants, Head of Theatres, Head of Operations, Clinical Engineering Manager(Chair) and Operational Contracts Programme Manager.

MEG(Train) – Training oversight - risk assessment/management
Members: Clinical Educators, Lead Nursing Managers, Training Co-Ordinator, Clinical Engineering Manager and Operational Contracts Programme Manager.

Medical Device Risk Evaluation

- RNOH committed through it's MEG (Exec) Group to replacement process (2016) of devices being ideally replaced when 4 years beyond the Original Equipment Manufacture's quoted life span. E.g. 7 Year Life span risk replaced at 11 years. Devices falling into this category are seen as 'at risk'. Final risk assessment uses risk evaluation model to prioritise risk order. (Possibility of devices being less than +4 years over OEM life span if unreliable.)

- Resultant values create a risk priority order for replacement consideration overall. The full list of devices informs our *ideal* Medical Device Replacement Programme (MDRP) budget requirements.

- Audit of all Medical Devices was *crucial* to integrity of evaluation.

Medical Device Replacement Programme (MDRP)

- MDRP budget requirements for given year initially ratified by Head of Clinical Engineering and myself and then presented to our Capital Planning Group for broader Trust risk consideration & evaluation. Capital & Revenue budgets are subsequently set in the light of RNOH's highest overall priorities.

- Budget line *drawn* on MDRP list and circulated to MEG(Ops) & MEG(Exec) for review and risk sign off for those devices that will **not** be replaced. (We seek clinical assurance as part of this process). The overall resultant risk from insufficient budgets is recorded on our Risk Register.

- Risk Assessment Model output is from ‘simple’ algorithm so helpful first step but further intelligent consultation required to verify and ratify actual requirements.

- Clinical Engineering Manager discusses with Clinical Heads of departments ‘their’ devices on the MDRP to review and agree final requirements. E.g. device numbers, upgrade opportunities, requirement for clinical trials etc.

- Device standardisation crucial part of MDRP process and so we maintain that objective throughout all new or replacement decision discussions.

Budget Management for Device Procurement

- **MDRP**
  - **Planned** Risk Assessed Replacement (Agreed budget)
- **Emergency**
  - **Unplanned** procurement of devices uneconomical to repair (Q4 of MDRP Budget reserved until end of Q3)

- **Service Improvements (Planned)** • Approved increase in numbers or introduction of planned new devices. Assessed and ratified via annual Business planning process. (Agreed Budget)

- **Service Improvements (Unplanned)** • Mid-year request for increase in device numbers or introduction of new devices not approved as part of annual Business planning. Reviewed. If < £250 & in-line with standardisation programme authorised, otherwise Business case required for assessment.

Importance of Policies/Governance Groups

- Provide more consistent/unified approach, encouraging shared professional ownership of the broader trust-wide risks and responsibilities.

- Provides confidence at Executive level that there are clear and robust processes in place for managing whole life-cycle of medical devices.

- Holds all parties accountable to agreed basis for procurement and training.

- Provides clear assurance to our Executive and the CQC that we have relevant and robust Governance around device management.

Risk Register

- Critical to recognise risks, ensure they are recorded, understood, mitigated and resolutions tracked/managed for patient and clinician safety and for commercial assurance.

- Important and helpful reminder at all levels of any given risks history:

  - Elapsed time issues have been a risk;
  - Honest reminder of actual risk progress;
  - Clearly defines ownership and oversight responsibilities.

Benefits

- Increase in clinical morale - Not having to ‘beg/lobby’ for replacement devices. MDRP is seen as fair and device procurement polices as clear and credible.

- Improved patient confidence – Newer equipment provides visible assurances.

- Significant increase in Finance’s confidence in assessment robustness.

- Greater confidence and assurance at Director level of sustained and managed replacement governance for planned and unplanned procurements.

- Standardisation is a real and achievable aspiration year on year providing:

  - Bulk device and consumable procurement savings and associated reduction in management overheads;

  - Training benefits including the reduction of nursing/clinician absence from clinical areas and the reduction of associated risks of numerous devices within any given modality.

- Provides greater assurance to our Charity of ‘real’ issues and priorities. (Resulted in funding of our Equipment Library)

- <u>We are far better assured of optimal patient care and safety.</u>

Summary

- Significant journey for RNOH, now acknowledged as significant improvement and success, providing confidence at all levels that suitable policies and governance processes are in place. Other Trusts have taken an interest in our journey.

- Continue to refine processes to better suit clinical requirements and improve ‘intelligence’ of algorithm for MDRP.

- Improvements have been attributable to TBS GB’s experience, empathy, engagement and shared vision with the RNOH; and RNOH’s leadership and management of their overall aspirations.

Credits

Commissioning and Leading this transition has been a large project that would not have been possible or as successful without the tireless support of TBS GB's (Althea UK & Ireland) on site Clinical Engineering Managers (and teams) over these past 4 years. I'd like to especially recognise the work of:

Mr Yoryd Khatri

Mr Muneeb Shamim

Thank You.

Any questions?