

EVIDENCE BASED ASSESSMENT OF NEW MEDICAL TECHNOLOGY THROUGH TEST OF CHANGE CASE OF PATIENT MONITORING IN NICU UNIT

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Abstract—

Traditional or ‘off the shelf or out of box’ method of acquisition of medical devices and technology is currently being challenged by clinical users. Currently there is a need for flexibility in acquisition patient monitoring systems that is tailored to clinical needs of the healthcare organisation. Driven by accreditation, regulation, and technology, clinical practices are constantly changing. To align with the National Health Service Scotland (NHSS) transformation strategy, Clinical Engineering is recommending test of change prior to major acquisitions of medical devices with organisation wide clinical impact. Future technology need to be safely tested in clinical settings to gain knowledge of its capability, the innovation that are likely to have a positive impact on patient outcome and the value for money. Evidence should be provided to justify the investment.

The purpose of this paper is to open up a discussion and share ideas on how test of change can predict the efficacy of a technology prior to acquisition. It provides insight about efficiency, deficiencies, current practices, changes that are required, and issues that may arise during the acquisition, implementation, go live and beyond.

In this case study, Neonatal Intensive care unit (NICU) is used assess the introduction of an integrated patient monitoring system into NHS Tayside. The approach taken to conduct the test of change is discussed, documented lessons learned are highlighted. Innovative changes in clinical practices that may allow improvement in effectiveness of patient monitoring with wider impact on the entire organisation are presented.

This exercise brought together a large number of stakeholders. Including those who are still interested in the old way of working, to come together and be part of the evaluation. As a result, a final paper will be presented with request for funding to the senior management for the next capital cycle.

Keywords— Test of change, evidence-based assessment, integrated patient monitoring system.

I. INTRODUCTION

NHS Tayside provides a comprehensive range of primary, community-based and acute hospital services for an estimated population of 415,470 over 2,182 square kilometers of land area, covering Dundee City, Angus and Perth & Kinross. (National Record of Scotland, 2017).

As existing standalone patient monitoring systems across the organisation are reaching their end of life. Clinical Engineering has recommended to conduct a test of change to assess that new patient monitoring technology currently available in the market will be suitable to meet clinical needs of NHS Tayside where the impasse is on interoperability with other devices and integration with Health Electronic Records. As well as the demonstration of evidence based acquisition, effectiveness of service delivery and best value for money procurement. As the Neonatal Intensive Care Unit (NICU) was preparing for decant, it was selected as an ideal clinical area for this exercise.

This discussion paper provides some answers to the following questions:

- What is the current status of patient monitoring system?
- Is the out of box technology still a viable option for patient monitoring in large teaching hospitals?
- Is our current IT infrastructure capable of handling new patient monitoring system?
- What are the mutual benefits between NHS Tayside and manufacturers or vendors in conducting a test of change?
- Are there any clinical benefits identified that will enhance patient care of the future and allow NHS Tayside to select a technology that meet the needs of the population?

The findings of this study shows that the test of change allows flexibility between clinical users and manufacturer to come up with a solution that meet the needs of patients and clinicians; highlight the enhancement required to e-Health, IT, and information governance to accommodate modern patient monitoring into existing healthcare IT domain;

changes required of old clinical practices; demonstrate new way of working to allow remote monitoring, interoperability and data transfer; a greater collaboration between, clinical engineering, IT and clinical users to provide the full benefits of modern technology. The increasing need for new skills in Health informatics where, withing Clinical Engineering knowledge combined with a greater understanding of clinical applications, Information technology, Medical devices usability and regulatory compliance is also identified.

II. MATERIALS & METHODS

Clinical Engineering approached different vendors with a proposal to use their new patient monitoring system on loan and at no cost, to conduct a test of change and assess the effectiveness of new patient monitoring system. The aim is to use the system during the NICU decant. The solution could be used until NHS Tayside is in the position of replacing these standalone systems with a fully integrated system wide Patient Monitoring that will meet our current future clinical and technological needs.

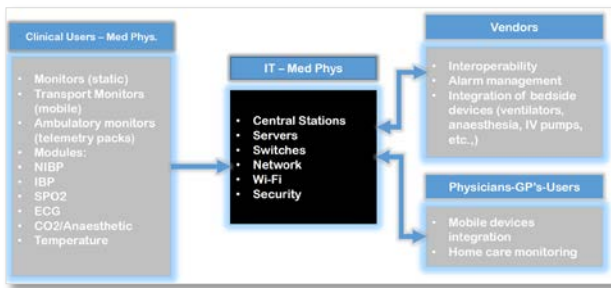


Figure 1. Ideal integrated monitoring system requested

A. Vendor selection

As part of a request for information (RFI), Clinical Engineering approached five vendors or manufacturers of patient monitoring systems and requested to conduct a test of change at no cost to gain insight on new developments in patient monitoring. As well as to learn the strength and vulnerability of the NHS Tayside Information Technology (IT) infrastructure that will house a suggested fully integrated patient monitoring system. A vendor was selected based on the flexibility of the technology to accommodate clinical needs and the adaptability into NICU environment.

B. Technical Specification

The specifications included into the request included the clinical requirements such as: Nine Intensive Care Neonatal Monitors, network and central station; high quality networked system to monitor and record full data from neonates, using a wireless network to a central station; large color flat screen display with high resolution and large text options. Among technical specifications the emphasis was on: The ability to interface in real time physiological trend monitoring (ideally at 1/sec) and medical equipment data to the Electronic Patient Record; Ability to interface with other medical devices in the clinical areas as well as the patient management system; the flexibility of the system to be configured to accommodate changes in clinical setting without major disruption. Finally we requested to include parameters such as EEG and p-EEG.

An agreement was reached with the vendor to supply the equipment as per specification. Also to supply a support team to help with implementation, clinical training and validation. A project team made of NHS Tayside members from NICU Clinical team, Clinical engineering, Information Governance, e-Health and IT as well as the vendor support team.

C. Implementation

A networked patient monitoring system which interfaces to Badgernet, the Neonatal Patient Information System was implemented. Nine bed side monitors, using a wired network to a Central Monitoring Station (CMS) within NICU, with interoperability capability to interface with Ventilators and infusion devices in patient care areas of NICU went live in early December 2018. See the project timeline below:

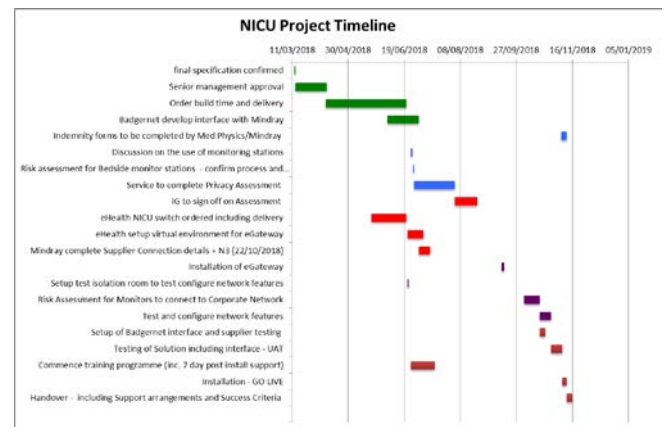


Figure 2: Project Gantt chart

III. DISCUSSION

This test of change has allowed Clinical Engineering to gain insight on concepts and challenges of the adoption and implementation of Healthcare wide patient monitoring system. With the hope that this paper will support colleagues during the selection of the new system that will replace the existing and obsolete standalone monitoring systems within NHS Tayside. The acquisition of off the shelf monitoring system does not provide the full benefit of innovation and flexibility in improving efficiency and providing effective patient care. In this study we answered some fundamental questions:

- *What is the status of our current monitoring system?*
NHS Tayside has many legacy standalone monitoring systems, most of them are already obsolete by the manufacturer and spare parts are no longer available. As such they do present a high risk to the organisation. A failure of any central station will have a wider implication on patient care and hospital operations.
- *Is the out of box technology still a viable option for patient monitoring in large teaching hospitals?*
Currently like for like replacement of monitoring system is not an option. The new development in IT network and wireless capability have created a new environment where monitoring systems can be managed from the same network, same central server, using a system approach to security and patches. In addition clinical users are able to take advantage of mobile applications to acquire vital signs of their patients directly and securely from their mobile devices. As different users have different requirements, the configuration of out of box does not allow flexibility to meet new clinical needs.
- *Is our current IT infrastructure capable of handling new patient monitoring system?*
Currently, our IT infrastructure will require upgrade to accommodate the new monitoring system. During this implementation, it was decided to connect the monitors directly to the network via Ethernet cables. With the possibility of reconnecting the monitors wirelessly during decant of the NICU unit in March 2019. This is because, currently there is no adequate wireless capability within the QVLAN. There is a need to upgrade our systems to accommodate not only the monitoring system, but any future medical technology with IT capability. Therefore, Corporate IT strategy should include medical devices and technology into their long term plan for network upgrades as part of the core corporate expansions plan. The core of the healthcare business is patient care,

increasingly networked medical devices and equipment which are considered enablers are needed for diagnosis and treatment of patients.

New technology designed with new operating systems are becoming a challenge to implement. In this case monitors are designed with Windows 10 operating system. Currently there is no full support model in place to manage patches and upgrades of these devices. As medical devices are licensed, downgrade the operating system is not an option. Work around is also not a permanent solution. There is a clear need for a systematic upgrade plan for the IT infrastructure.

- *What are the mutual benefits between NHS Tayside and manufacturers or vendors in conducting a test of change?*

So far we have learned about our infrastructure and the need for upgrade to accommodate new technology. The vendor managed to integrate with BadgerNet and enhance its capability, gain knowledge and experience. This will put them ahead for any sale of similar system in any UK NICU unit.

The vendor had access to healthcare professionals who provided them with their needs and they managed to incorporate those needs into the development of the solution for NHS Tayside test of change. NICU unit managed to remove obsolete equipment and replace with newer and more modern technology. Interoperability with other devices such as ventilators, infusion pumps is now a reality in NICU. This will save time and improve patient safety as clinical users are now be able to see all the parameters on one screen. BadgerNet is now able to capture these parameters. The key risk related to patches of the legacy systems which use to cause a loss of data during patches is now eliminated.

Lack of understanding of complexity of medical devices and equipment with IT capability is a challenge for Clinical Engineering, e-Health and Information Governance. Traditionally the clinical application dictates the level of intervention and support by Clinical Engineering. An emerging and essential discipline is emerging under the name of Health Informatics to fill the gap in knowledge of these disciplines. This test of change managed to highlight this need as with an additional member of staff with these skills we transitioned to a better implementation of this project. In the future, this role will be essential for any successful intervention by Clinical Engineering in implementation of medical technology with IT capability.

- *Are there any clinical benefits identified that will enhance patient care of the future and allow NHS Tayside to select a technology that meet the needs of the population?*

As the test of change has just started, it is too early to predict all the clinical benefits. However, currently Paediatric consultants, head of nursing and NICU charge nurse are able to view the full central station from their own office computers. This allows flexibility, quick decision making and fast intervention. In anticipation that patients in remote hospitals could be monitored directly from Ninewells, on the go from clinician's mobile devices or from their respective office desks.

IV. CONCLUSION

The acquisition of healthcare wide technology is a very complex task for clinical engineering. Test of change appears to be a new way that allows Clinical Engineering and industry to establish a more collaborative approach to assessment of new medical technology prior to acquisition.

Through collaboration between different groups, real innovation is possible. In this case the understanding of interoperability was made possible by the willing of NICU clinical team to work differently and all the vendors of medical equipment willing to collaborate and share ideas on how to interface their devices with the monitoring system.

Collaboration between e-Health, Procurement, IT, IG, Clinical Engineering, clinical users, and others came with the benefit of understanding our environment and new resources required for future implementations. NHS Tayside network is in need for upgrade. There is a need to review the skills required by different groups. The emerging need for Health informatics where the understanding of technology, clinical application, data and IT systems is needed to facilitate the multiple transactions that individual groups cannot solve without knowledge and exposure to other working environments.

The test of change provide insurance to the senior managers that the technology has been tested clinically, potential problems have been identified and where applicable resolved. Lessons learned have been discussed and documented. Clinical practices are being aligned. Potential innovations that will drive efficiency and effectiveness of patient monitoring across the system have been identified. Issues of infrastructure, patient information, interface and interoperability have been looked at. New resources and skills that can

facilitate the implementation and maintenance of services are documented and presented. Then a case can be put forward for a smart acquisition of a new integrated patient monitoring with confidence. (Ison, 2015)

This exercise should not constitute in any case an endorsement for a particular product. The exercise, although expensive and time consuming, allows the healthcare to learn about the technology and prepare for acquisition of the same or similar system for a wider use. It helps the industry to better understand the needs of clinicians as well as what is required to gain advantage by providing technological solutions that are considered fit for purpose with future sale advantage when compared to similar product.

ACKNOWLEDGEMENT

I would like to acknowledge my colleagues in NHS Tayside Medical physics, NICU, e-Health and IG for their dedication, support and availability. Also colleagues from the manufacturer who are still on site working with us. They could not be named in order to keep the independence of this case study.

CONFLICT OF INTEREST

The author declare that he has no conflict of interest

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