Standardising neonatal respiratory support: a quality improvement initiative

Neonatal units typically employ a variety of respiratory support equipment with differing capabilities, user interfaces, training needs and consumables. A structured and multidisciplinary approach to the specification, evaluation and implementation of change in this critical and complex medical device can yield multiple benefits in terms of staff training time and cost while offering the opportunity to reduce error and introduce desirable technical features.

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Key points

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1. Neonatal units typically employ a variety of respiratory support equipment, which may increase the risk of clinical error.
2. Supporting multiple respiratory devices can increase costs in terms of consumables, maintenance and staff training.
3. A structured multidisciplinary quality improvement project can be used to select and manage the change to a new single respiratory support device.
4. The input of a neonatal clinical technologist is invaluable in facilitating medical device change.

Background

Respiratory technology is an integral part of modern newborn intensive care. In recent years, there has been an increase in both the types and the modalities of respiratory support equipment available to clinicians and it is now commonplace for neonatal units to utilise many different respiratory support machines, from different manufacturers, for different respiratory modalities. This is despite limited evidence as to which respiratory support method is best with respect to long-term health outcomes.[1-3]

Standardisation can provide benefits in efficiency, patient safety and in the reduction of human factor errors.[4] It has successfully been utilised in the aviation[5] and automotive[6] industries.

In 2012 the authors noted that much of the neonatal respiratory equipment used within East Kent Hospitals University NHS Foundation Trust (EKHUFT) was approaching or beyond its expected useful life cycle. There was also increasing clinical interest in the use of newer evidence-based respiratory modalities that had entered mainstream use, such as nasal high flow humidified oxygen therapy[7] and volume guarantee/volume targeted ventilation,[8] neither of which were consistently available for use. Furthermore, there was a desire to improve patient safety and mitigate against human factors that may lead to clinical error in the use of medical devices. It was recognised that updating the respiratory support equipment might be approached as a quality improvement initiative rather than simply an exercise in updating obsolete equipment.

Aims

This article describes a single hospital trust's experience of standardisation of neonatal respiratory support equipment for use throughout the patient journey in order to facilitate this process for other NHS trusts. The benefits realised in terms

Equipment	Modalities used
Carefusion Viasys Infant Flow system	Nasal CPAP
Carefusion SiPAP	Nasal CPAP and nasal bi-level CPAP
Dräger Babylog 8000 Plus	CMV, SIMV, HFOV
SLE2000	CMV, SIMV, PTV
Carefusion Sensormedics 3100A	HFOV
Stephan F-120 Globetrotter	CMV, CPAP for transport

TABLE 1 Respiratory support equipment utilised at East Kent Hospitals University NHS Foundation Trust prior to 1 March 2013.
Key: CPAP = continuous positive airway pressure, CMV = continuous mandatory ventilation, SIMV = synchronised intermittent mandatory ventilation, HFOV = high frequency oscillatory ventilation, PTV = patient triggered ventilation.

of cost savings, staff training and patient safety are highlighted, along with the potential pitfalls in successfully completing such a quality improvement initiative.

According to the policy activities that constitute research at EKHUFT, this work met criteria for operational improvement activities exempt from ethics review, and therefore ethics approval was not sought.

Methods

EKHUFT provides neonatal services at two separate sites approximately 40 miles apart. There is a neonatal intensive care unit (NICU) at the William Harvey Hospital in Ashford and a special care unit (SCU) at the Queen Elizabeth the Queen Mother Hospital in Margate.

Prior to 1 March 2013 the two neonatal units within the Trust used six different items of respiratory support equipment to deliver a range of invasive and non-invasive modalities (**TABLE 1**). The Institute of Medicine's 'six aims for improvement'[9] (safe, effective, patient-centred, timely, efficient, equitable) can be used to assess the legacy equipment, revealing the significant challenges presented by the use of multiple devices from different manufacturers (**TABLE 2**).

Design

There are no clear guidelines in building or outfitting a new hospital or department with medical devices,[8,10] however it has been shown that it is valuable to develop a standardised methodology for the evaluation of the quality of medical devices and the analysis of complications resulting from their use.

The Trust's supplies and procurement department was invited to be involved at an early stage to facilitate the process of specification, tender and trials of equipment. The Clinical Technologist wrote the ventilator specification with input from the neonatal consultants and supplies department. An implementation group was set up that included representation of all the professionals that would be supporting and using the new device.

The items in the detailed specification were then assigned a weighting from 1 to 3 by consensus, based on the clinical and operational significance of each criterion, and an evaluation score from 0 to 5 provided by each participant (with 0 indicating that the feature cannot be provided). This enabled a more objective approach to assessing the equipment that was loaned for trial by producing an overall score for each piece of equipment as the summed products of the weightings and scores.

A company presentation day was organised and attended by a multidisciplinary team. The top four ventilators from this event were then each trialled for a fixed term, with a loan machine being used clinically with the support of the Clinical Technologist and company representatives. The ventilators were used opportunistically with the aim of using all clinically appropriate ventilation modes and with the option of reverting to local equipment if necessary. The implement-

Aim	Assessment
Safe	The older equipment in use is more prone to failure Multiple equipment types with different terminology, measurement units and user interfaces present a risk of harm from suboptimal settings and misunderstanding of measured parameters and feedback Differing circuit configurations and cotside equipment test protocols present a risk of harm from incorrectly configured or malfunctioning equipment Changing of respiratory circuit and swapping of equipment for modality change is an intrinsically risk-prone process
Effective	Some desirable respiratory support modalities are not available Multiple equipment types could limit clinicians to the most familiar, rather than the scientifically best, choice of equipment and modality Modality choice by available equipment rather than clinically most effective
Patient-centred	The potential time, cost and hassle associated with swapping equipment for modality changes might encourage sticking with the status quo Trials of an alternative modality may be impossible or problematic depending on the equipment used on a particular patient Parents may lose confidence in their baby's care if they see other babies connected to equipment that appears newer or more technically advanced
Timely	Older equipment taken out of use more often for servicing, causing treatment delays Setting up a cot space for a new admission entails guessing the equipment needed then potentially changing it when a treatment decision has been made Setting up different equipment for changes of modality causes treatment delay
Efficient	Multiple respiratory support circuits and spare parts must be purchased and stored with systems to record and track many different reusable parts Maintenance requires electro-biomedical engineering staff to either be trained and certified on multiple equipment types, or multiple third-party maintenance contracts must be held Multiple equipment types require more complex staff training and assessment
Equitable	The equipment and hence modalities available to each patient varies geographically within the Trust, and is affected by the other patients on the unit A patient may be 'downgraded' to a potentially less effective modality if another patient is deemed to have a greater need Babies transferred in from other units will be unable to continue the same respiratory support modality if it is not available locally

TABLE 2 The local assessment of areas for improvement based on the Institute of Medicine's 'six aims for improvement'.[9]

ation group evaluated each machine according to the specification, with a formal score recorded both for clinical suitability and safety, and for operational criteria including company training and support. Each manufacturer provided training for staff using and evaluating their loan equipment.

Alongside this, each ventilator was modelled financially over the expected ten-year lifespan to take into account:

- capital purchase cost
- ongoing repair
- maintenance and training
- consumables and cleaning of reusable single patient parts.

The number of items of equipment required was decided upon by the maximum number of cots the Trust could staff for all forms of respiratory support, plus three spare to facilitate training, breakdown and maintenance across both sites.

Strategy

A new medical device should not be introduced without a thorough evaluation of its functionality (a technical evaluation), followed by monitoring its use in clinical practice (health technology assessment). An electro-biomedical engineer (EBME) or similar healthcare professional can facilitate these evaluations. If the benefit of a device cannot be proven through these assessments, it should not be introduced. Factors to consider include:[11]

- suitability for purpose
- safety
- software compatibility
- data protection
- ease of use
- availability of advice and help.

A detailed business case was compiled that included:

- clinical risk assessments
- cost benefit analysis
- training needs analysis
- incident reports for unavailable equipment
- details of current equipment (value, age and replacement due date).

Financial model

Projected costs for the chosen ventilator model were tabulated over an expected ten-year lifespan, with consumables, based on the usual activity of the two neonatal units (**TABLE 3**).

The usual practice of the finance department would be to spread capital outlay over a number of years, replacing the oldest equipment first. However, the predicted savings and the clinical benefits of investing to replace all the ventilation equipment at one time swayed opinion and the finance department was prepared to accept the cyclical nature of the procurement strategy.

With the clinical and operational evaluation, and financial modelling in place, the decision was made with the procurement department on which ventilator to purchase. The implementation group set a time frame with goals for staff training, equipment introduction and removal of the obsolete equipment. The implementation group members discussed it with all staff that were not part of the group, which proved a very effective tool for building enthusiasm and addressing staff concerns.

Staff training

Equipment that is not used daily is particularly prone to user error.[12] Continuous expansion of knowledge and skills in medical device training and current trends are needed if practitioners are to maintain competence, thus addressing clinical governance and risk management issues. Training equipment users to operate medical equipment effectively and safely is one of the most important and difficult tasks for clinical technologists and other EBME staff.[13] With this in mind, a programme of ventilation study days with practical hands-on sessions were set up for all staff to attend over a short period (**FIGURE 1**). Intensive care and high dependency nursing staff were released from clinical duties for training, with the implementation group covering their clinical work while training was undertaken.

FIGURE 1 Learning to use the new ventilator.

It was decided that the new ventilators would not be released for use after purchase until 75% of nursing staff and 100% of medical staff were trained. Newly employed staff were covered by an updated ventilation session in the existing induction programme. It was agreed that unfamiliar features, such as volume guarantee and the non-invasive nasal high flow humidified oxygen mode, would be held back until further staff training could be organised to support this.

Results

The new ventilators were introduced over a one-week period with continual clinical technologist presence during the day and full 24-hour on-call support from the company. A reserve of old equipment was held to fall back on if problems occurred, but it was stipulated that it would not be set up for admission or used routinely.

In the first month a Sensormedics Oscillator was used three times on very sick infants because the medical staff did not feel that the new ventilator would be adequate. However, it was found that with use of appropriate settings, the new ventilator could readily achieve the same level of ventilatory support for the patient population, which is in line with emerging research.[14]

	Like-for-like	Single device
Consumable costs per year	£49,300	£30,862
Consumable costs over ten-year lifespan	£493,000	£308,620
Capital purchase cost	£482,000	£414,250
Total cost over ten-year lifespan	£975,000	£722,870
Total savings over ten-year lifespan		**£252,130**

TABLE 3 Projected cost savings over an expected ten-year lifespan for changing to a single respiratory support device.

Ongoing issues were overcome by staff training, careful review of ventilator settings on ward rounds and at shift handover, and by checklists attached to the machines. It is well established that the performance of different models of oscillatory ventilator varies significantly for apparently similar settings, and that knowledge of the idiosyncrasies of a particular machine is essential.[15] As confidence in the new machine increased, staff began to feel comfortable with adjusting its settings directly rather than working by analogy with the old equipment. Ultimately, a Sensormedics Oscillator was kept for one year but was never used after the first month and has since been removed from service.

Standardising to a single piece of respiratory support equipment has realised a number of additional benefits:

- Replacing all of the equipment across two sites has made the Trust a major customer for one company, giving early access to software updates and leverage to feed back issues and development ideas. The Trust has been able to customise consumables to meet the units' needs, specifically developing a disposable circuit with a larger water trap for catching humidity rain-out during high frequency oscillatory ventilation.
- Change of invasive or non-invasive modality and trial of extubation are facilitated by avoiding the swapping-over and potentially swapping-back of different respiratory support devices in response to clinical decisions.
- In the case of equipment failure, the ventilator can be switched for an identical model rather than potentially changing the baby to a different machine and having to re-optimise.
- Induction of new trainee medical staff has been positively affected by the single device solution, with equipment familiarity being transferrable across the gamut of clinical scenarios, from the sickest acute presentation through to babies weaning on non-invasive modalities. By learning one user interface, trainees may be able to focus less on machine-specific knowledge and more on understanding the underlying pathophysiology and potential approaches to respiratory support.
- It is estimated that the time spent training and updating staff for respiratory equipment has decreased by 60% (from 1,560 hours per annum to 624) releasing time for patient care.
- As the nursing and medical staff took ownership and felt involved in the decision-making process, the usual feelings of resentment (financial restraint imposed by others; not getting the equipment you wanted) were lifted.

Lessons

The management of change is often a challenging task, with a natural tendency towards maintaining the status quo. It was expected that internal resistance to change would be a major hurdle, however the strategy of including representation of all stakeholders in a structured process led to little resistance in practice. Problems did arise from external pressures exerted by the tender process. One hurdle involved the NHS supply chain and its limited clinical understanding of the difference between term and preterm infant respiratory support requirements, as ventilators specified as suitable for 'newborn' babies may not be suitable for preterm neonates. One vendor felt that the purchasing decision should be made on cost alone rather than the overall evaluation score. These challenges illustrates the importance of clinicians being directly involved in the process of specifying and procuring complex medical devices, and creating formal specifications and scoring systems to ensure a robust process.

Conclusion

This quality improvement exercise resulted in the replacement of a diverse range of neonatal respiratory support equipment with a single multipurpose device. This produced considerable financial savings over a ten-year expected life span, with significant reduction in staff training time. Furthermore, improvements were realised that are expected to reduce risk and increase clinical efficacy and equity of treatment. Careful planning and communication, expectation management and good multidisciplinary involvement mitigated the potential pitfalls of such a wide-reaching change. The structured approach described may be applied to medical device procurement both within neonatal medicine and across paediatric and adult specialties wherever such a 'once in a decade' opportunity presents itself.

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