Shine 2012 final report

Safe, patient controlled intravenous pain relief in children

Evelina London Children's Hospital, Guy's & St Thomas' NHS Foundation Trust

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Part 1. Abstract

Project title:
Safe, patient controlled intravenous pain relief in children

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Partner organisation:
King's College London
Lead Clinician:
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Background
Morphine intravenous infusions are essential therapy in severe pain, yet the process of preparing and administering IV infusions is complex with multiple error-prone steps, which is potentially dangerous, especially in children due to complex calculation of dosages, manipulation of small volumes, rate adjustment. The most complex system of administration is via nurse or patient controlled analgesia (N/PCA) due to the need to deliver infusions and boluses from the same syringe.

Local problem
Previous work by our research team has identified morphine as: (a) the drug associated with the highest number of drug related problems; (b) more frequently prescribed for paediatric patients in UK compared to other countries.[1-3][1]. Evelina London Children's Hospital (ELCH) pharmacy have also conducted a study investigating the accuracy of morphine infusions prepared by nurses for neonates. They found that the smaller volumes used to prepare the infusions, the greater the magnitude and frequency of deviation from the intended concentration.[4][2] A project has also been undertaken in the paediatric intensive care unit (ELCH) to convert continuous (non-PCA) morphine infusions from the named patient model to dose-banded concentrations of morphine prepared by pharmacy. Safety pumps, with safety software features, were used to deliver the infusions. Preliminary results showed a decreased number of errors, two years post implementation (unpublished data).

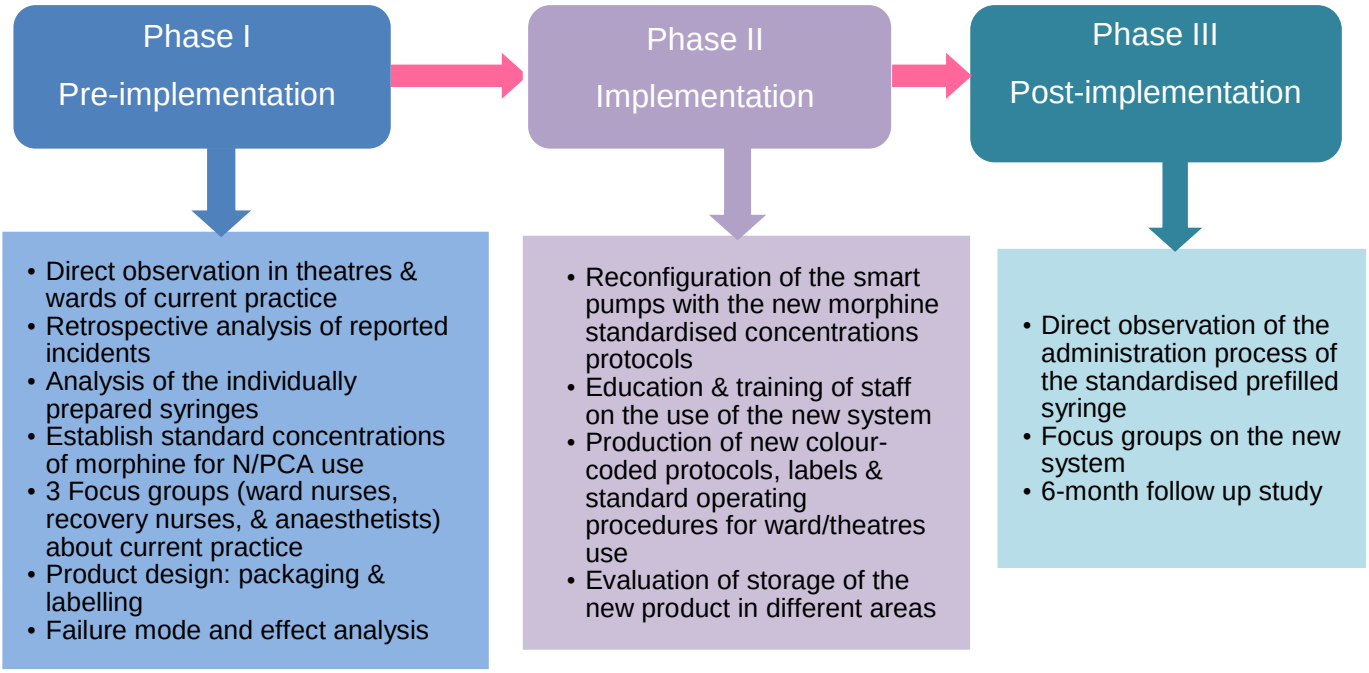
Description of innovation
The project aimed to minimise the risk of medication errors in one of the most challenging settings: nurse- or patient-controlled analgesia (N/PCA) for children. A system management approach was developed to minimise complex calculations and individualised medicine manufacture at the point of administration (inaccuracy of concentrations and microbiological risk) by providing standard dose-banded concentrations of morphine infusion for N/PCA, made aseptically and administered using pre-programmed safety pumps.
The implementation of a standardised dose-banded infusion system for morphine delivery by N/PCA for children has not, to our knowledge, been implemented anywhere in the world to date.

[1]1. Rashed AN, Wong ICK, Cranswick N, et al. Adverse Drug Reactions in Children - International Surveillance and Evaluation (ADVISE): a multicentre cohort study. *Drug Saf* 2012; 35(6):481-94.
2. Rashed AN, Wong ICK, Cranswick N, et al. Risk factors associated with adverse drug reactions in hospitalised children: international multicentre study. *Eur J Clin Pharmacol* 2012, 68(5):801-10.
3. Rashed AN, Neubert A, Tomlin S, et al. Epidemiology and potential associated risk factors of drug-related problems in hospitalised children in United Kingdom and Saudi Arabia. *Eur J Clin Pharmacol* 2012; 68(12):1657-66.
[2]4. Aguado-Lorenzo V, Weeks K, Tunstell P, et al. Accuracy of the concentration of morphine infusions prepared for patients in a neonatal intensive care unit. Arch Dis Child 2013; **98**:975-9.

Methods

The new system was implemented in three phases which are summarised in figure 1.

Figure 1: Phases of the project implementing a safer system for administering opiate infusions for pain relief in children



As the observation study pre- and post-implementation involved participation of NHS staff, only research and development (R&D) approval was required. The project has also been registered on the NIHR portfolio database (appendix 2).

Achievement

<u>Established morphine standard concentrations</u>

Three standardised concentrations of morphine were established for N/PCA (table 1). We reached to these concentrations having reviewed all possible strengths from 1mg to 50 mg in 50 mL. The established standards considered:

- the ability of the pumps to deliver both the infusion rate and the bolus (minimum volume of 0.1mL;
- the need to produce as few different concentration syringes as possible (from a safety and cost perspective);
- to be able to deliver daily treatment with no more than three syringes to reduce risks and workload due to multiple syringe changes; and
- total daily volume of morphine infusion should not account for more than 15% of child's total daily fluid allowance

Table 1: Weight bands and morphine standardised prefilled syringe strengths established for nurse- or patient-controlled analgesia (N/PCA)

Weight band	Morphine PFS strength	Protocol
Weight ≤ 3 kg	3mg in 50 mL Glucose 5%	NCA
Weight ≥ 4 kg – 19.9 kg	10mg in 50 mL Sodium Chloride 0.9%	NCA
Weight ≥ 20 kg	50mg in 50 mL Sodium Chloride 0.9%	NCA
Weight ≥ 25 kg		PCA

Implementation of morphine standard Prefilled Syringes (PFS) for N/PCA use in children

- Following the risk assessment the project team including ward sisters, paediatric pain nurse, and lead pain anaesthetist decided to conduct a pilot implementation of the standard concentrations of morphine PFS.
- The pilot implementation was designed in 3 stages.
    - Stage I: dummy run of whole system (using a teddy bear patient)
    - Stage II: involving one list of paediatric orthopaedic operations, each week.
    - Stage III: list extended to include other orthopaedic operations and spinal cases.

  The pilot implementation is to highlight any practical issues that might arise when using the standardised morphine PFS before extending the implementation to all other wards and theatres. The staggered implementation will also aid training of healthcare professionals on the new system as we go along in the implementation phases.

Implementing of the new system of morphine PFS has been successful despite the multifarious challenges. So far, 15 paediatric patients received morphine PFS for N/PCA since the start of the pilot implementing.

Challenges

- We needed to extend the observation to theatres because the majority of the morphine N/PCA syringes were being made there, so in order to capture as many N/PCA infusions as possible the researcher conducted the observation in theatres as well as on all paediatric wards (deviation from initial protocol).
- Anaesthetists queried if published results on accuracy of the ward-made infusions would be similar to these made up in theatres. An extra task was added to the project. This involved analysing syringes made by anaesthetists in theatres and by nurses on wards. The analysis of these syringes was carried out by the Pharmacy Quality Control (QC) department at Guy's and St Thomas NHS Trust (GSTT).
- Safe storage of prefilled syringes is another challenge which slowed down the implementation stage of the standard prefilled syringes (PFS). Storage area for the syringes on wards and theatres (compliant with controlled drug storage requirements) needed to be found. Thus, in order to be able to test the new system and overcome this problem, the project team with pain management lead decided to pilot the standardised syringes in selected area for selected operation list while working on the storage issue.

Part 2. Quality impact: outcomes

The primary quality issue was to demonstrate a new system of administering N/PCA to children; avoiding large variations (from prescribed) of morphine concentrations in syringes.

Quality improvement expected:

- Risk reduction during the process of preparation and administration of N/PCA morphine infusions. Sterile, accurate, consistent and ready-to-use product delivered via a pre-programmed infusion pumps.
- Syringes will be 100% British Pharmacopeia compliant from PFS batch manufactured (confirmed QC certificates).

This is set against our study results:- analysis of 78 morphine syringes: 61.5% had a concentration outside the acceptable range (92.5%-107.5%) of labelled strength (%LS), with 28% deviating by more than +20% and one being 100% deviation.

Adjustments made to the original application

We made several adjustments and/or added new steps to the original application because the project was considered a big change in practice and would have a great impact of safety and service provided to paediatric patients. These included:

- Product review:
    - Storage conditions: Whilst similar syringes were already in manufacture at the hospital, these syringes had a relatively short expiry (3 months) and needed to be store in the fridge. Thus, further work was required to extend the expiry date and assess storage at room temperature for a more practical, and cost effective product.
    - Labelling: Work also had to be undertaken on the labelling of the syringes to adapt them to the new indication.
- Analysing syringes made by anaesthetists in theatres and nurses on wards was added to the phase I of the project. Whilst there is local and international data on the lack of syringe accuracy at ward level this work has not been shown for our own theatres. It was seen as important to demonstrate this to ensure buy-in from staff for the new process.
- The implementation process has been redesigned to be conducted in stages and to start with selected list of operations rather than implement the new system across the hospital at once. This process was implemented to ensure all staff involved were fully trained and ensure that learning could be captured easily.

Effect of the project on the quality of the service

Early anecdotal data from the implementation suggest that the system is easy to use, safe and much quicker than the old system with the knowledge of using the correct concentration of morphine. However more formal analysis is still underway. The impact on safety of the new system will be measured by the number of medication errors e.g. preparation errors before vs after implementation. Also user satisfaction, i.e practitioners' satisfaction will also be determined using focus groups.

Part 3. Cost impact

Potential cost impact of the new system

Although reduced cost is not the primary aim of our project, introducing the new system, is expected to have impact on cost saving. However much of the cost saving is indirect such as reducing practitioner's time as a result of eliminating the morphine preparation stage and less potential for errors.

Table 2 shows the estimated average cost of setting up a N/PCA syringe per patient in the old and new systems.

Table 2: Potential cost impact of using morphine PFS

Systems	Average cost of setting up N/PCA syringe per syringe by nurses	Estimated annual cost per 1000 child†
Old system* (individualised syringe)	£14	£28,000
New system of using PFS	£7	£14,000

*Old system cost calculated considering the average time (10 minute) needed by nurse to prepare a syringe, cost of drug, and consumables used.

†Annual cost calculated based on 2 syringes per child used for N/PCA, i.e 2000 syringes annually

The table shows that by eliminating the preparation stage of a morphine syringe on the ward, the cost of the practitioner time spent on setting up a PFS for a patient is almost half the time associated with the old system. Thus, we are saving a large amount of healthcare professionals' time.

The estimated average cost of PFS by manufacturing unit is £6, however, once implementation of PFS across ELCH is complete, it is expected that the all-inclusive manufacturing cost per syringe is expected to be significantly lower. Therefore, an overall review of cost implications for implementation of the new system for morphine standardised PFS will be determined after full implementation i.e. following the move from making individualised syringes for N/PCA morphine at wards and theatres levels to batch manufactured standard concentrations by pharmacy manufacturing unit at GSTT.

Potential cost of manufacturing standard morphine concentrations in vial

Cost of morphine pre-made standard concentrations is estimated to be lower if manufactured in vials as shown in table 3. Vials would have a longer expiry with easier storage and transport. Table 4 shows the estimated annual cost of PFS and vials.

Table 3: Estimated cost of morphine standard concentrations manufactured in vials

Strength made	Cost per unit	Estimated annually cost/1000 child[†]
Morphine 50mg in 50 mL	£ 1.9[*]	£ 3,800
Morphine 10mg in 50 mL or Morphine 3mg in 50 mL	£ 3.5	£ 7,000

[†]Annual cost calculated considering 2 vials/child, i.e 2000 vials used annually for N/PCA

[*]this cost is based on the current cost of NHS manufacture of an adult morphine vial 50mg/50mL

Table 4: Comparison of the estimated annual cost[1] between PFS and vial

New system (standard morphine)	
PFS[2]	**Vial[3]**
£12,000	7,000

[1]Annual cost calculated per 1000 child considering 2 PFS or vials/child

[2]Estimated cost provided by manufacturing unit £6/syringe

[3]Vial annual cost calculated based on the annual cost £3.5/vial (table 3)

Implementation costs

As staff training will be integrated into the existing training programmes within the Trust, there is no expected cost related to the staff training on the new system.

Part 4: Learning from your project

To our surprise this project has helped us gain significantly more knowledge than we were expecting from the initial proposal: particularly related to standard clinical practice.

1. Understanding the current practice and behaviour of healthcare professionals

We have learnt that the current system was sub optimal. As shown by the results of content analysis of the morphine syringes, direct observation and focus groups.

From the focus groups and risk assessment meetings with healthcare we found that:

- Healthcare professionals, particularly anaesthetists were not aware that morphine ampoule contains overage.
- The current N/PCA worksheets were too complicated and not user friendly.
- Poor work environment leading to distractions affecting the calculations of bolus and continuous doses on the worksheet as well as calculation of the amount of the drug needed to be drawn up.
- The current mixed system (PICU using standard syringes for infusions and the wards using individualised N/PCA system) causes a confusion for doctors and nurses.
- Protocols terms ‘under 12 years or under 40 kg’ or ‘above 12 years and over 40 kg’, causes confusion.
- Inconsistency in choosing the appropriate syringe size to draw up the exact amount of drug from its ampoule.
- Following the risk assessment of the new system performance against the new worksheets was an important step required to address any possible failure modes.

From the observation of the current practice of preparing and administering morphine PCA/NCA in children at ELCH:

- Various techniques or manipulations were observed.
- Lack of appreciation of the overage in morphine ampoules which identified from the confusion about the exact content of the morphine ampoule.
- Clarification on the need to purge the syringe or give a bolus once connected into the syringe driver was encountered. (This has led to a secondary piece of research which is describing the considerable time it takes to deliver a dose via a syringe driver if the line isn’t properly primed and the infusion rates are very low).
- Some staff were unsure whether to prepare the drug in 50 mL of the diluent or total volume of drug and dilute to 50 mL.
- Analysis of syringes prepared in theatres and/or wards shows that more than 61% were outside the British Pharmacopoeia acceptable limits (±7.5) for morphine sulphate injection.
- Gaps in the current Trust policy around the aseptic non-touch technique and clinical guidelines were identified.

2. Implementing the new system of morphine standardised PFS

- Stage I of the pilot implementation determined that the new system works for N/PCA use in children.
- Introduction of morphine standardised PFS encouraged healthcare professionals to review their practice of preparing and administering morphine for N/PCA use.
- Introduction of standardised PFS would reduce the infection control risk by eliminating the preparation step in ward/theatres
- Improved paper work and documentations.
- From the stage I of the pilot, the colour coded protocols and labels were considered better than the old system as it reduced the chance of wrong selection, especially by nurses.

- The new system is less complicated for staff as only 4 protocols are programmed into the pump compared with the old system which had many protocols.
- Investigating the use of automated medication storage (Omnicell) and bar-coding technology to minimise errors related to picking the wrong syringe. This aspect is seen as crucial before full implementation and will be developed further after the Shine period.

Challenges and barriers:
As this project involved a big change in a well-established healthcare system, several challenges and a many adjustments were needed to overcome the challenges, as we progresses through different phases of the project. However, the engagement and support of staff from different clinical areas and the need to improve the current system facilitating the adjustments, and consequently implementation of the new system helped facilitate obtaining the primary goal of this project.

Having adequate storage facilities for the syringes is a practical issue that all centres will need work through to implement the system.

Bar-coding of syringes is an issue that needs to be tackled as soon as possible to limit the chances of wrong strength syringe selection.

Different approach next time we implement an improvement project:
Implementing an improvement project involving such a big change in practice in a health care environment, needs to be conducted over a longer time period. Thus, a time frame of a minimum two years would be more realistic and would allow for any changes or addition steps identified during the process to be executed.

Part 5. Plans for sustainability and spread

Sustainability beyond Shine

The sustainability of the implemented morphine PFS for N/PCA use is assured based on the evidence of the sustainability of previously implemented standardised dose-banded concentrations of morphine infusion in paediatric and neonatal intensive care units at ELCH. However, as this project involves implementing a new system and change in practice in all clinical areas, a minimum of six months will be needed before implementation had occurred across the whole hospital. A follow up study is planned to ensure the sustainability of the new system before this innovation is disseminated to another site.

During the implementation of morphine dose-banded PFS, fentanyl came up as an issue and we received many enquiries from healthcare staff about dose-banding fentanyl for N/PCA use in children. Fentanyl is the second most frequently used opiate drug for pain management. It is the therapy of choice for severe pain when morphine is contraindicated such as kidney transplant patient or in the cases where patient is allergic to morphine. It is important to standardise fentanyl for N/PCA use to avoid having two systems in place and to eliminate the consequent risk of errors.

Additional resources

We are investigating funding to continue the implementation of the new system across the whole hospital, to conduct the follow up study, and to research the implementation of fentanyl dose-banded PFS. Sources such as the Health Foundation and other funding bodies will be approached.

Resources to implement and research bar-coding to ensure the system has full safety plans in place.

Innovation spreading

- Upon successful completion of morphine PFS implementation across ELCH, King's College Hospital (KCH) is the first site to which this innovation will be disseminated, as KCH part of King's Health Partners (KHP).
- Publications and conferences will be used to disseminate the findings and as a means to encourage other paediatric hospitals to adopt the same practice. A short report highlighting the problems with current practices of using N/PCA in hospitalised children in the UK and advocating for the new system we are implementing was submitted to the European Journal of Hospital Pharmacy as part of a special issue on Paediatric Pharmacy (appendix 2). Also, we will be submitting an abstract to the Neonatal and Paediatric Pharmacists Group (NPPG) conference which will take place in November 2014, and the BMJ International Forum on Quality and Safety in Healthcare in April 2015.
- Also, following stage I of the pilot of implementing morphine standard PFS this innovation was presented to healthcare professionals across KHP, when the project team ran a workshop on 6th March at St Thomas Hospital. The objective of this workshop was to share the findings from the observation of current practice and PFS pilot with healthcare professionals and to have an open discussion about the future of this new practice and the implications for the future.

External interest/potential contacts

Morphine standardised PFS is already gaining external interest for dissemination and adoption across the local network and nationally. This facilitated by the position of the project PI on national boards and committees, e.g lead for medicines within the Child Health Safety Board hosted by NHS England. The recommended dose bands will also now be an entry in the National Intravenous Medicines Guide (MEDUSA) and discussions are happening with the British National Formulary for Children (BNF-C).

Appendix 2: Resources from the project

Please attach any leaflets, posters, presentations, media coverage, blogs etc you feel would be beneficial to share with others

1. The observational study, part of the project, is registered on UK Clinical Research Network (UKCRN) portfolio database:
http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=14364

2. Submitted short report:
Rashed AN, Whittlesea C, Forbes B, Tomlin S. Patient-controlled opiate analgesic infusions in children should be safer and more widely available. *Eur J Hosp Pharm* 2014 (submitted: under review).