FIXED CONCENTRATION INFUSIONS:
A national consensus for paediatric and neonatal care in the United Kingdom
Introduction
It has been established that the continued use of weight-based dosing and dilution of continuously infused medicines should be phased out of routine paediatric practice because it is inaccurate, inefficient and incompatible with future information technology developments.

Key stakeholders (the Neonatal and Paediatric Pharmacists Group (NPPG); the Paediatric Chief Pharmacists Group (PCPG) and the Royal College of Paediatrics and Child Health (RCPCH)) are committed to improving medication safety for children and improving access to good quality medicines for children. They view standardisation as a strategic goal and a consensus of concentrations highly desirable in stimulating implementation, developing ready-to-use formulations and reducing variation between centres. All three have endorsed the aims of a single standardisation project, following the example set by adult Intensive Care in 2007.

Many organisations are already reviewing the feasibility of moving to fixed concentration (standardised) infusions however implementation and adoption has been inconsistent. A key benefit of using standard concentrations is access to ready-prepared infusions but this is not cost-effective in the current health environment and this is an obstacle to on-going adoption. The manufacturing sector view ready-prepared infusions as a growth area, however the diversity of paediatric concentrations prevents them from producing suitable products for use in paediatric care. In the Republic of Ireland standardised concentrations are defined nationally by consensus and are delivered via “smart-pump” technology. This will soon include neonatal infusions. In view of their experience and success, colleagues from the Republic of Ireland have therefore been invited to participate in this project.

The Making it Safer Together (MiST) collaborative have adopted standardisation of infusions as one of their core projects.
The standardisation project group:

Project Leads:

Adam Sutherland
(Royal Manchester Children’s Hospital/University of Manchester)

Andrew Wignell
(Nottingham University Hospitals)

David Harris
(University Hospitals Leicester)

Nanna Christiansen
(National Injectable Medicines Guide)

Expert Advisory Group (EAG):

Pharmacy:

Sara Arenas-Lopez
(Evelina Children’s Hospital/University College London)

Moninne Howlett
(Our Lady's Hospital for Sick Children, Dublin, Ireland)

Virginia Aguado-Lorenza
(Guys and St Thomas’s Hospital)

Medical:

Mark Hayden
(Great Ormond Street Hospital)

Mirjana Cvetkovic
(University Hospitals Leicester)

Cormac Breatnach
(Our Lady’s Hospital for Sick Children, Dublin, Ireland)

NEONATAL

GENERAL PAEDIATRICS

Nursing (to be completed):

RETRIEVAL SERVICES

NEONATAL

ACUTE PAIN SERVICES

PAEDIATRIC INTENSIVE CARE
**Scope and Range**

- To develop a consensus list of standardised concentrations and diluents for continuous infusions of medicines used in all fields of paediatric care.
- To facilitate the development of ready-prepared solutions for use in the near patient setting
- To support the implementation of these changes in practice across the UK.

**Key phases of the project**

1. **Initial scoping**
   
   An initial literature review to formalise the evidence base for change will be carried out. Concentration options will be presented by weight groups as defined by the data collected. These weight groups must feasibly include the following patient types:
   - Neonates (term, pre-term, extreme pre-term)
   - Infants to 2 years (cardiac and non-cardiac)
   - Children (cardiac and non-cardiac)
   - Adolescents
   
   All units (PICU, NICU and anaesthetics) in the UK will be surveyed (through pharmacy, nursing and medical networks) to assess current practice including syringe driver equipment in use (manufacturer, model.) Information will be gathered from those centres that the group identify as using standard concentrations. The following data will be extracted: weight bands, concentrations and diluents. Data will also be collected from international centres that the EAG and project team identify as using standardised concentrations using personal and professional networks.

Where there is consensus (defined as >70% agreement within the data) on individual drugs and weight bands these will automatically be passed through to the First Consultation.
Where there is no consensus, the group will decide a suitable range of concentrations for these drugs based on the data collected, and data for physicochemical stability. Data will be presented in tabular format with the following variables:

- Concentration
- Dose range
- Patient group by weight

2. First consultation

This table will be presented electronically to clinicians, pharmacists and nurses accessed through established networks (with denominator based on number of formally registered individuals in each network) and respondents will be asked to state the acceptability of the concentration and volume by using only Yes or No. Where respondents state “No” they will be asked to provide a brief description of why.

Consensus will be defined as those concentrations that 70% of respondents agree with in ALL patient groups.

3. Second consultation

Those products that do not reach consensus will be adjusted in line with the feedback received, and then will be sent out for further rating. The previous percentage score for each patient group will be provided. Consensus will be defined as those concentrations that 70% of respondents state in ALL patient groups.

4. Final consensus

Those products that fail to reach consensus in the Second Consultation will then be presented to the EAG for final review and decision. The final draft will then be presented to a MiST consensus conference in February 2017 (to be confirmed) for final ratification.

5. Production of Meta-Data

Throughout the project the project group will liaise with industry stakeholders to facilitate production of appropriate meta-data to ensure
that the consensus can be programmed into syringe driver software accurately.

Key outcomes and performance indicators

1. Presentation of evidence base for change in peer reviewed journal
2. Consensus for at least 20 drugs, concentrations and diluents. The list MUST include morphine.
3. Presentation of meta-data for programming into smart-pump systems.

The group are accountable to MiST for management of the project and its delivery. Progress reports must be submitted to the MiST organising committee every 3 months.

Ethical Considerations

This project is service evaluation as no interventions are planned, no patient data is collected and the outcome consensus provides a theoretical framework only. No ethical review is required.

1. Confidentiality
The data collected from centres will be anonymised once entered into the database. Original copies of documents will be destroyed once data in the database is validated.

2. Document quality
Only formally ratified and approved guidelines (evidenced by date of approval, authorship, and organisational adoption) will be accepted for analysis.

Dissemination

The outcome of the project can be disseminated via any method that the project group and the MiST collaborative decides appropriate.

The project outcomes must be shared using the MedsIQ® database.

Progress reports and results will be made available on the MiST website.

An executive summary of the final outcome of the project will be made available to key stakeholders as described below.

Key stakeholders

- NPPG
- PCPG
- Paediatric Intensive Care Society (PICS)
• British Association of Perinatal Medicine (BAPM)
• Association of the British Pharmaceutical Industry (ABPI)
• NHS England Patient Safety Expert Group (PSEG)
• Medicines and Healthcare Products Regulatory Agency (MHRA)
• Medusa – the National Injectable Medicines Guide
• The Standing Committee on Medicines, RCPCH
• NHS Specialist Pharmacy Services