Neonatal and Paediatric Pharmacists Group, 12th Annual Conference

The 12th Annual Conference of the NPPG was held in Harrogate in November 2006. The theme of the conference was improving safety and reducing risk. Speaking on the subject of 'Safe medication practice initiatives for children' Professor David Cousins (Head of Safe Medication Practice, National Patient Safety Agency) said that the agency received around 50–60,000 incident reports each month, of which about 8% are medication related, and rising. Around 7% of these relate to children. 80% of reports are 'no harm' and 14% 'low harm'. However 'no harm' does not mean no consequence. More than 75% of reports are from acute care, with 60% of reports being related to administration, 16% dispensing and 16% prescribing. Reports are not always complete, e.g. only 30% of reports have the drug name field completed. The age section is often not completed, making it difficult to analyse across the age range. There has been progress towards medicine safety but further analysis of the National Reporting and Learning System (NRLS) database is required with both better quality, and quantity, of data required.

Tony Nunn (Associate Director, Medicines for Children Research Network, University of Liverpool) presented an update on the Medicines for Children Clinical Research Network (MCRN). Pharmacists working in paediatrics and neonatology are familiar with the lack of authorised medicines, suitable age-adapted formulations and with the difficulty in obtaining relevant drug information. Recent Department of Health strategy has emphasised the need for more clinical research and established the UK Clinical Research Network involving six topic specific networks including one for 'Medicines for Children'. MCRN is co-ordinated from Liverpool and has six local research networks (LRN), a dedicated paediatric clinical trials unit (CTU) in Liverpool and perinatal CTU in Oxford. The network will facilitate both investigator-led (charity or grant funded) and commercial research (industry-funded and collaborative) and should provide a competitive research environment to undertake the clinical trials associated with the new EU regulation on paediatric medicines. MCRN has Clinical Studies Groups (CSG) to establish research priorities and develop studies. Clinical Studies Groups are the drivers of the network and are the primary route by which clinical studies are considered in the development of the MCRN research portfolio. They will identify research priorities within their speciality area and propose and develop trial ideas and proposals. A Pharmacy and Pharmacology group and Methodologies group will provide

Professor David Cousins, National Patient Safety Agency

Tony Nunn, Medicines for Children Research Network

cross-cutting support to each. The aim of the MCRN is: "To facilitate the conduct of randomised trials and other well-designed studies of medicines for children, including those for prevention, diagnosis and treatment". Recognising the need to improve formulations of medicines for children, MCRN will appoint three formulation fellows to assist in the investigation of extemporaneous formulations, 'adult' dosage forms adapted for children and clinical trial requirements.

Steve Tomlin spoke about the development of an electronic based learning and assessment package for 'responding to symptoms of childhood ailments'. Community pharmacists are faced with a challenging situation – to provide high quality patient care to all customers with limited time. Responding to minor symptoms and referring major illness is a major part of community pharmacist's role. The trend of self-care has prompted an increasing number of people to visit their local pharmacies for initial medical advice that is recognised as a valuable resource. However, community pharmacists are under more pressure than ever to be armed with the knowledge to manage a growing number of symptoms not just for adults but for children as well, and to recommend appropriate advice and treatments. This free online self-learning package is designed with the special needs of children and their carers in mind: supporting community pharmacists in acquiring knowledge of childhood ailments, their treatments and when it is appropriate to refer. The package can be done in your own time, and is designed to make the process of learning fun, easy and meaningful (www.paedpharm.org.uk).

There were six oral presentations and 10 poster presentations, which are listed below. The Special Products award for best oral presentation was won by Niall Corry (Antrim Hospitals) for his work on 'Reducing the risk of hospital acquired hyponatraemia developing in children receiving fluid therapy' (O1). The Special Products award for best poster presentation was won by Vicky Holden and colleagues (Leeds Teaching Hospitals) for their work on 'Moving the care of children and young adults with acute lymphoblastic leukaemia closer to home, the development of a model for home based maintenance therapy' (P8).

O1
Reducing the risk of hospital acquired hyponatraemia developing in children receiving fluid therapy

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Background: The international literature cites more than 50 cases of child death or neurological injury from hospital acquired hyponatraemia over the past decade associated with the use of hypotonic IV solutions. In 2002 the DHSSPS in Northern Ireland issued general guidance on the prevention of hyponatraemia in children receiving prescribed fluids[1].

Objective: To produce a more specific, short, user friendly, safe prescribing tool complementary to this regional guidance.

Methods:

1. A literature review via MEDLINE to identify relevant evidence.
2. Paediatric anaesthetic electronic discussion to collate expert opinion on the subject.
3. A review of the learning points identified during the inquest into the deaths of three local children alleged to have died unnecessarily due to the inappropriate use of IV fluids.
4. A review of the points to be addressed following a regional audit[2] of adherence to the DHSSPSNI guidance.
5. A review of the NPSA Draft Patient Safety Alert 'Reducing the risk of harm when administering intravenous fluids to children. Consultation document January – March 2006'.
6. A review of clinical guidelines from The Royal Children's Hospital, Melbourne.

Results: An algorithm guideline for parenteral fluid therapy for the initial management of previously well children, 1 month–16 years was produced. The types and amounts of fluids required for bolus, maintenance and deficit, along with the monitoring required has been incorporated into the algorithm. In order to complement the algorithm a new fluid prescription sheet was also drafted. In April 2006, the Acting CMO for Northern Ireland wrote to the Chief Executives of all Acute Trusts in Northern Ireland requesting implementation of this new guideline.

Conclusion: The algorithm provides a structure for assessment, decision-making and monitoring. However it is not a replacement for individual patient assessment and treatment or for consultation with a senior. Also our group is of the opinion that the limited availability of licensed isotonic solutions with a range of glucose and potassium concentrations constitutes a significant obstacle to further reducing the associated risks of IV therapy and this problem also requires to be addressed.

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O2
Evaluation of ward based pharmacy service on two paediatric wards

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Objective: The objective of the study was to evaluate the impact of a ward based pharmacy service to two paediatric wards. Parameters measured were: comparisons between the quality of drug history (DH) and allergy as compiled by the pharmacist and junior doctor; improvements in medicines management through "one-stop" dispensing; pharmacy contributions to patient care and identification of any interface issues.

Methods: Ward B is an eight-bed ambulatory ward; ward C is a 17-bed general medical ward for patients under 2 years old. All patients admitted to these wards during a 2 week period in December 2005 were eligible for inclusion in the study. Exclusion criteria included patients who did

not need any pharmaceutical treatment during their stay in hospital. Patients who were transferred from ward B to ward C for inpatient stay were counted as part of C group. Statistical Package for the Social Sciences version 13 was used for data entry and analysis.

Results: Fifty-six children were recruited for study during the 2 week study period. In line with local policy, 86% of the drug histories (DHs) were completed by the ward pharmacist within 48 hours of patient admission. The success rate for completing DHs was (56) 100% for pharmacists and (50) 89% for junior doctors respectively; of which 40% were incorrect and five allergies were missed. The most common error was a missing drug.

Pharmaceutical contributions were diverse in nature. 75 pharmacy interventions were reported; 48 were annotations on drug chart for safe administration, four were drug errors, 18 included drug rationalisation and monitoring, five were regarding IV drug/fluid compatibility and stability.

60% of the patients' own drugs brought into the hospital by parents/carers were suitable for in-patient and discharge use, which contributes to preventing wastage and annual drug savings of £18,980. Since the pharmacist screened all the prescriptions on the ward and with the introduction of "one-stop" dispensing, in-patient and discharge prescription (TTA) dispensing times were significantly reduced compared to pre-implementation of ward-based services. In-patient medication dispensing time was decreased from 80 minutes (min) (± 15) to 36 min (± 13) on ward-B and 90 min (± 32) to 48 min (± 17) on ward-C. TTA dispensing time for ward-B was reduced from 120 min (± 30) to 45 min (± 12) and from 145 min (± 22) to 60 min (± 16) for ward-C. Out of the 27 TTAs issued 40% of them were ready on the ward.

There were three interface issues identified during the study highlighting that children, especially those on complex medication regimes or unlicensed medications required a comprehensive handover into the primary care for continuation of pharmaceutical care.

Conclusion: The study concluded that re-designing the pharmacy services around the patient has not only benefited the parents through a reduction in drug related incidences and faster discharge prescriptions, but also, the drug budget by saving drug costs through improved medicines management.

O3
Using failure mode and effect analysis (FMEA) to reduce the risk of IV potassium administration on a paediatric intensive care unit (PICU)

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Background: Failure mode and effect analysis (FMEA) is a quality improvement tool that was developed in the 1960s by the aerospace industry. It has since been modified for use in several other areas including the healthcare setting[1,2]. FMEA can be used to identify the potential errors in a process and then try and determine their effects in a proactive way.

Southampton University Hospital Trust is a large teaching hospital. Its PICU deals with about 700 admissions each year, of which approximately a third are post cardiac surgery. Many of the patients require potassium supplementation using the intravenous route. Currently this is administered by diluting strong potassium chloride injection to a concentration of 1mmol/ml and then the appropriate dose given as small boluses over an appropriate period via a central line.

Following an error in potassium administration relating to an equipment malfunction we decided to take the opportunity to look at the system in more detail using FMEA.

Methods: A multidisciplinary group was convened and we dissected in great detail the process of potassium supplementation. It was agreed to split the process into the following stages:

- Prescribing
- Dilution of the injection
- Administration
- Monitoring

For each part of the process we agreed on what failures could occur, what the causes of those failures could be and the effects this could have on the patient i.e. a failure mode and effect.

Then we scored each failure for likelihood of occurring, severity and likelihood of detection. These scores were then multiplied out and the failures ranked. By highlighting the parts of the process with the greatest risk we have been able to prioritise areas for particular attention.

Conclusion: The process has allowed a multidisciplinary team to openly question the way potassium is used on our PICU and we hope this will lead to reducing the risk for our patients.

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O4
Safety of diclofenac for acute pain in children

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Objective: Diclofenac is unlicensed for acute pain in children yet commonly used[1]. The objective of this study is to investigate the possibility of collecting Phase II-type (intensive monitoring of relatively few patients) safety data from routine clinical practice.

Methods: A prospective observational study was performed. Written informed consent was obtained from parents of children (≤12 years) who were scheduled for elective surgery. If diclofenac was prescribed during the inpatient stay, information on all adverse events was recorded. Each adverse event was given a measure of seriousness. Data were collected from medical/nursing notes, pathology reports, and patient/parent questioning during the inpatient stay, and by telephone post discharge. Detailed demographic information, past medical history and current/recent drug therapy was recorded. Causality assessment[2] was used to determine which adverse events could be attributed to diclofenac.

Results: A total of 398 patients were recruited, 306 were prescribed diclofenac. Only two adverse events were classed as probably due to diclofenac.

Table 1 Summary of key findings

	Proportion of patients (95% CI)
At least one AE	36% (29–43%)
At least one 'serious' AE	5% (3–8%)
At least one 'probable' serious ADR	0%
At least one 'probable' ADR	0.7% (0.08–2.4%)
At least one 'possible' ADR	25% (20–32%)

AE, adverse event; ADR, adverse drug reaction attributed to diclofenac.

Discussion: The main difference between a 'probable' and 'possible' causal relationship lies in the presence of other potential causes[2]. In the peri-operative period, there are multiple factors which may be causative. This made attributing causality impossible for most minor adverse events; it is not expected that 25% of children who receive diclofenac will suffer an adverse reaction caused by diclofenac. A 'serious' event requires medical/surgical intervention to prevent further morbidity or mortality. None of the 'serious' events were typical of known diclofenac adverse effects (bronchospasm, renal failure, gastrointestinal bleed), or were attributable to diclofenac using causality assessment.

Conclusions: There were no 'serious' diclofenac adverse reactions; it can be inferred such reactions occur in <1/100 children[3]. Causality assessment tools do not greatly aid the determination of adverse effects in the peri-operative period, where multiple factors can be causative. Further studies to determine the incidence of diclofenac's 'serious' adverse effects are required.

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O5
Quality assurance of paediatric parenteral nutrition solutions: the use of end-product testing

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Objective: To identify methods used for the quality assurance of compounded paediatric parenteral nutrition mixtures and to recommend a method/s that is practical to perform and sensitive enough to detect a variation in any of the compounded ingredients.

Method: A literature search and a telephone survey identified five methods of quality assurance: visual check, gravimetric check, osmolality, refractive index and chemical analysis. US guidelines emphasise the importance of end-product checks by visual verification, final weight and refractive index measurement to verify the addition of ingredients[1]. Visual and gravimetric checking methods were already in use within the department but it was our experience that an incorrect bag could still pass these checks. A critical appraisal of the production process highlighted many different types of errors, this report focused on 'confusion errors' associated with the use of an automated compounder. Erroneous formulations were prepared to mimic five different confusion errors; each error assumed that the correct volume and specific gravity values were keyed into the compounder but the solutions were not connected to the correct station of the compounder. The ability of the quality assurance method to detect the erroneous formulation was assessed.

Results: The visual check method was not sufficiently sensitive because only one ingredient was coloured. It was proven that transposition of solutions on the automated compounder resulted in a final bag of the correct weight. A gravimetric check would not detect the error if the volume and specific gravity values were keyed in correctly. Refractive index measurement detected four out of the five confusion errors. Osmolality was difficult to calculate and measurement of dextrose concentrations above 30% was not possible. The osmolality method did detect all five confusion errors. Chemical analysis was sensitive enough to detect the confusion errors but in some cases the glucose reading was outside a 5% error range. This method had the advantage of also measuring electrolyte concentrations.

Conclusion: A quality assurance method should ideally be non-invasive, quick to perform, not require the purchase of equipment and sufficiently sensitive to determine a variation in any one ingredient.

Visual and gravimetric checking although easy to perform and non invasive would not detect confusion errors. Osmolality was a sensitive method but required a complex calculation to determine the theoretical value. A combination of osmolality and chemical analysis methods should detect all confusion errors but further experimentation is needed to challenge the chemical analysis method with electrolyte errors. An 'ideal' method was not determined but the limits of detection of the current methods were identified. Since this report was written a pilot study using the chemical analysis method has been introduced in the production process.

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O6
Reconstitution and measurement of the dose of ampicillin-cloxacillin dry syrup by mothers of babies attending paediatric clinic at Lagos University Teaching Hospital

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Introduction: Ampicillin-cloxacillin dry syrup is one of the most frequently dispensed [used] antibiotic preparations for treatment of common bacterial infections in children. It is usually dispensed to mothers or other caregivers as dry powder for reconstitution, both in hospital and community health care. Mothers, often uneducated, are relied upon to effectively administer reconstituted syrup to their babies with only limited instructions at dispensing, brief manufacturers' information on the product, and sometimes-past experience. No study has been reported [to investigators' knowledge] to assess mothers' knowledge and practice of preparing and measuring the doses of this medicine, in Nigeria or elsewhere.

Objectives: This study therefore investigated the knowledge and practice of reconstitution, storage, measurement of the dose and use of ampicillin–cloxacillin dry syrup by mothers for their babies.

Methods: One hundred and seven mothers admitted into the study based on defined inclusion and exclusion criteria were provided ampicillin-cloxacillin dry syrup, and all other requirements for reconstitution including a suitable work area, at no cost. Their knowledge and skills were simultaneously assessed and corrected while they each reconstituted syrup and measured one dose the way they would normally do at home.

Results: About 91%[97] of mothers either completed secondary education alone, 34[31.8 %] or had tertiary education, 63[58.9%] in addition. The majority of mothers, 97[91.5%] had past experience with reconstitution of this medicine, while only 9 [8.5%] had no previous experience. Only about 50%[54] of mothers gradually added sufficient water initially, to uniformly disperse powder in the bottle before further additions to reach the marked levels, and only 22[20.5%] knew the crucial importance of viewing the lower meniscus of water at eye level to obtain correct volumes of liquids in glass bottles or vessels. To administer reconstituted syrup to their babies, only 83[77.6%] shook the bottle before measuring the dose volumes, which implies that their doses would be correct.

Conclusions: Only a relatively small proportion of mothers in this study demonstrated a real capacity to properly reconstitute and correctly measure the dose volumes of ampicillin-cloxacillin dry syrup without assistance. They, however, have the potential to learn quickly. Extensive education and assistance by paediatric pharmacists will be most useful in this regard. For the uneducated or inexperienced mothers, reconstitution in the hospital by pharmacists is recommended, while alternative formulations should be considered.

P1
A real time assessment of the impact of electronic prescribing on medication errors in a paediatric intensive care unit

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Introduction: An electronic prescribing system was launched on a large PICU in Scotland in November 2005. It was thought that this step would reduce medication errors on the unit, and thus improve patient safety.

Objectives: After 1 year of operation, a large study was carried out with two aims:

- Establish baseline standards of prescribing to initiate a full audit cycle.
- Quantify the impact of electronic prescribing on patient medication errors per patient bed day, and as a function of the number of episodes of medication administration.

Results: Results of a small pilot study showed that the rate and incidence of medication errors related to prescribing remained static, however the nature and focus of these medication errors had changed surprisingly. The pilot study was not sufficiently powered to be reliable. The full study shall review a cross section of patients from both before and after electronic prescribing, and will be statistically powered to produce reliable information.

P2
TPN from birth to 2 years old – a standard bag approach

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Objective: The preparation of Total Parenteral Nutrition (TPN) for children up to the age of two has historically involved the aseptic compounding of up to 15 individual ingredients to provide two solutions for infusion – aqueous and fat bags, both tailor-made to contain the correct nutritional requirements in an exact volume of fluid. Our objective was to investigate whether a standard off-the-shelf aqueous bag could be devised and used in this age group. The bag had to fulfil the nutritional requirements of the patients whilst reducing the number of aseptic manipulations carried out in the Pharmacy department.

Methods: A review of the past year's RHSC TPN prescriptions for patients in this age group revealed that 80–90% received regimens that were theoretically amenable to standardisation. Discussion with peers in other paediatric centres and a supplier of unlicensed "TPN Specials" revealed that none had a single standard bag catering for all children under two years old. There is a Scottish Neonatal TPN bag (SNB) but this provides insufficient calories in the volume provided for all but the most premature of neonates. Current national nutrition guidelines for the age group were reviewed and a 1 litre TPN regimen formulated.[1] This formulation allowed patients to start on the SNB and transfer after 1 to 2 days to the 1 litre standard formulation. Fresenius Kabi provided chemical stability information for the formulation, with and without the addition of a range of electrolytes, vitamins and trace elements. The 'Specials' Manufacturer, Intra-Tech, agreed to batch prepare the bag, whose cost was similar to compounding various "tailor-made" formulations in-house. A written TPN prescribing scheme was developed and agreed with the RHSC Nutrition Team. Setting up the TPN formulation on the Pharmacy computer system allowed electronic production of TPN worksheets and labels. Patients started using the new prescribing scheme and standard RHSC bag in January 2006.

Results: During the first 6 months of trialling, 96% of TPN patients under 2 years old received the standard bag. The remaining 4%, mostly fluid-restricted ICU patients, received tailor-made bags as previously.

Conclusion: This new working practice has many benefits including:

- A reduction in aseptic manipulations for TPN preparation, thereby reducing the risk of repetitive strain injury for Pharmacy personnel.
- Reductions in time spray/wiping ingredients and sundries into the clean room and clean-air devices.
- A streamlining of electronic production of TPN worksheets and labels allowing improved efficiency.
- A ready-to-use bag for new patients starting TPN at weekends

To date, the RHSC Nutrition Team and Pharmacy staff has detected no clinical problems using the new standard TPN bags.

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P3
An audit of the paediatric conscious sedation guidelines at Sheffield Children's Hospital

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Objective: Safe and effective sedation for undertaking procedures is important in the care of children. The decision to use sedation depends on the procedure, the suitability of the child and the available personnel. Sedation may be for painful, e.g. suturing, biopsies, or painless procedures, e.g. CT and bone scans. In 2005 guidelines were introduced at SCH on the use of pharmacological sedation which covered the choice and dosing of available drugs and guided the prescriber through the decision making process. Six months after the guidelines were introduced an audit was undertaken to address the following questions:

- Are the correct sedatives being used for specific indications within the hospital?
- Is the sedative dose and time of administration correct?
- What action is being taken if the use of a particular sedative drug is unsuccessful?

Methods: Data collection, with a target of 40 patients, was undertaken via a specifically designed form by Clinical Pharmacists or in the case of the Day Care Unit by nursing staff. Pharmacists were able to record information on an electronic version of the form via a hand held computer.

Results: Forty cases of sedation for procedures were recorded involving patients between the ages of 8 months and 16 years. Prescribing was undertaken by a full range of medical staff (SHO to consultant) and sedation was necessary for a variety of procedures on different wards. Oral midazolam (M) was the sedative of choice in 31/40 cases all of whom were undergoing procedures lasting less than 20 minutes, 7/40 received secobarbital (S) for sedation prior to CT or bone scan and 2/40 were younger children sedated with chloral hydrate (CH). The doses of M, S and CH were within ±20% of the guidelines in 90%, 86% and 100% respectively (90% overall). There were 8/31 cases where M was given too early prior to procedure according to the guidelines (>30 minutes) and 5/31 cases where it was given too late (<15 minutes). S and CH were given too early before procedure in 2/7 and 1/2 cases respectively. Two out of four cases of sedation failure may have been caused by non compliance with the hospital sedation guidelines. Of the treatment failures the procedure was rearranged in two cases and continued with in two cases after general anaesthetic.

Conclusions: Overall despite the errors in dose and timing, the use of drugs for conscious sedation in children was successful in the majority (90%) of cases. The main problems appear to be related to the timing of doses in relation to the procedure. The results of this audit have been taken forward in the form of a wider audit of sedation in the hospital involving anaesthetic, nursing and pharmacy staff.

P4
Experiences of 21 children aged 5–16 years on prolonged medication in three paediatric wards of Lagos University Teaching Hospital

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Objective: The study investigated the experiences of children of various ages on prolonged drug therapy in three paediatric wards of Lagos University Teaching Hospital.

Methods: An in-Departmenth interview using 70 validated questions was carried out between August and September 2006 to document 21 hospitalised children's experiences with their medicines, food, the ward environment and illness. Their perceptions on health care providers and quality of care, as well as recommendations for improved care were also investigated.

Results: The mean age was 9.4±2.7 years with a male to female ratio of 2:1. Twelve children had a pleasant experience with the taste of their medicines, 16 liked the colour of their medicines, and 13 had medicines with nice odour. Thirteen did not like injections and 15 missed their family the most while on admission. Seventeen liked doctors, 17 liked nurses, while 19 did not have any experience with pharmacists while in the hospital. Twenty children, however, wanted to know the name of their illness and its cause. All children wanted to know how the medicines would make them feel better, and 20 the reason why they must always take their medicines. Twenty children said they wanted the pharmacist, whoever he/she was, to talk with them about their medicines, and 19 wanted their mother to stay in the hospital with them.

Conclusions: Children like adults require health education. They are curious, want to participate in their own care, and should not be treated as passive consumers of health services. Pharmacists need to be actively involved in the care of hospitalised children in the developing world, as in developed countries. The presence of mothers should be accepted as a necessary part of treatment for hospitalised children.

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P5
Predictability of renal drug clearance of aminoglycosides and glycopeptides in preterm neonates

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Introduction: The administration of aminoglycosides or glycopeptides in preterm neonates necessitates therapeutic drug monitoring (TDM) for both efficacy and toxicity until renal drug clearance can be predicted accurately. We therefore investigated the possibility to use clinical co-variables to predict drug clearance in preterm neonates in the first month of life.

Methods: Data collected in two population pharmacokinetic studies[1,2] in preterm neonates (24–34 weeks GA at birth) investigating amikacin and vancomycin clearance in the first month of life were used to evaluate the contribution of co-variables to predict renal drug clearance.

Results: 1212 drug assay samples (vancomycin 648, amikacin 564) in 531 (vancomycin 249, amikacin 282) subjects were available to estimate clearance. At birth, the co-variables size (48%) postmenstrual age (PMA)(15%) and co-administration of a non-selective cyclo-oxygenase inhibitor (NS-COX)(2%) contributed to clearance variability leaving still 35% of variability unexplained. After the first days of life, 85.2% of overall variability was explained based on size (47.3%), PMA (25.2%), NS-COX administration (3.5%), renal function (7.6%) and being small-for-gestational age (SGA)(1.7)%.

Conclusions: In contrast to the important unexplained variability at birth (35%), the unexplained variability in clearance (15%) in preterm neonates is limited. These observations suggest that routine TDM for aminoglycosides and glycopeptides is no longer warranted after the first days of life as size, age, renal function, co-administration of a NS-COX and the presence of SGA can be used to predict the appropriate dose.

References

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P6
Maturational pharmacokinetics of single intravenous bolus administration of propofol

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Background: The aim of this study is to describe maturational aspects of propofol pharmacokinetics following single intravenous bolus administration in childhood.

Methods: Seventy propofol blood–time profiles were collected in nine neonates (mean weight 2.4, range 0.91–3.8 kg) by arterial blood samples up to 24 hours after administration of a single intravenous bolus of propofol (3 mg/kg over 10 seconds) before elective chest tube removal. Concentration–time curves obtained for every individual neonate were interpreted by two-stage analysis as two- and three- compartment open models. These newly collected observations following intravenous bolus administration of propofol in preterm and term neonates (n = 9) were combined with individual pharmacokinetic estimates in toddlers (n = 12) and young children (n = 10)[1,2]. Data were reported by median and range. Wilcoxon test or linear correlation was used to analyse the pharmacokinetic findings in neonates, toddlers and young children.

Results: The blood–concentration curves obtained for every individual patient were interpreted by two–stage analysis as a three compartment open model in a cohort of 31 patients with a median weight of 11.2 (range 0.91–24) kg and median postmenstrual age (PMA) of 108 (range 27–405) weeks. Median clearance (Cl) was 36.8 (range 3.7–78.1) ml/kg/min, median apparent volume of distribution at steady state (Vss) was 7.6 (1.33–15.6) l/kg and median final serum elimination half life ($t_{½}$ gamma) was 377 (range 27–1134) minutes. Median clearance was significantly lower in neonates compared to toddlers and older children (P< 0.01) and these differences remained significant after allometric scaling (ml/kg 0.75/min). A significant correlation between Vss and PMA (r = 0.61, 95 % CI 0.32 – 0.8, P<0.004) was observed.

Conclusions: Propofol disposition is significantly different in neonates compared to toddlers and young children, reflecting both ontogeny and differences in body composition. Based on the reduced clearance of propofol, accumulation during repeated administration and longer recovery time are more likely to occur in neonates.

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P7
Is the use of clopidogrel as an alternative to warfarin or as a part of anti-platelet therapy safe in paediatric cardiac patients?

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Objective: Given the risks involved and the poor compliance of many paediatric patients with warfarin based anticoagulation regimens and the possible need for improved anti-platelet cover following evidence of aspirin resistance in adult cardiac patients, we investigated the safety of clopidogrel use in paediatric patients with heart disease.

Methods: A retrospective review of hospital records of all children with congenital or acquired heart disease who received clopidogrel, with or without aspirin treatment, between January 2004 and February 2006 in a tertiary paediatric cardiac referral centre. Patients were identified via Pharmacy records and further information obtained from their medical notes.

Results: Twent-one children (3–200 months; median 60 months) receiving clopidogrel were identified. The maximum follow up was 12 months. 19 children (90%) also received low dose aspirin in combination. Anti-platelet therapy was for primary prevention in all but 1 child. Clopidogrel was used with low dose aspirin as an alternative to warfarin following total cavopulmonary connection in seven children (33%). Two children (9%) received clopidogrel and aspirin for dilated cardiomyopathy. The remaining children received clopidogrel as part of anti-platelet therapy following various procedures including central and modified Blalock-Taussig shunts, and vascular stenting. No children received clopidogrel following artificial valve insertion. The dose of clopidogrel ranged from 6 mg to 75 mg once daily (mean daily dose 1.5 mg/kg, range 1.0–2.4 mg/kg). No patients developed a thrombus. One child died during the study period, cause unrelated to clopidogrel use, and one child developed bruising and slightly reduced platelets. No other adverse clinical events attributable to the use of clopidogrel were encountered throughout the study period.

Conclusion: Based on our preliminary data, the use of clopidogrel with aspirin as an alternative to warfarin or as a part of anti-platelet therapy is safe and effective in children with congenital or acquired heart disease and without artificial valves. However, this is limited by the sample size and retrospective nature of the study. Follow up would need to be extended to be able to comment on the efficacy of this combination in preventing thrombotic events. Dose finding studies and randomised controlled trials comparing clopidogrel and aspirin to warfarin alone and aspirin alone are needed for the select conditions where anti thrombotic therapy is warranted in children.

P8
Moving the care of children and young adults with acute lymphoblastic leukaemia closer to home, the development of a model for home based maintenance therapy

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Objective: The aim of the project was to develop and establish a system of home based maintenance therapy for children and adolescents treated for acute lymphoblastic leukaemia (ALL) at the Yorkshire Regional Centre for Paediatric and Adolescent Oncology. Patients on maintenance therapy previously attended the outpatient clinic in Leeds on a weekly or fortnightly basis, resulting in disruption to family life and schooling. It was hoped that this project would reduce hospital appointments and travelling, making maintenance therapy more convenient for patients and their families, and also help to manage the workload in an increasingly busy outpatient clinic.

Method: A multidisciplinary steering group with medical, nursing and pharmacy representatives from the regional centre and shared care centres in the Yorkshire Region was formed to develop the service. A designated project nurse who reviewed models of care at other United Kingdom Children's Cancer Study Centres (UKCCSG) centres led this and the steering group developed a model for use in Leeds, which was approved by the local risk management committee. This was based on monthly visits to Leeds for vincristine administration and medical review, with local full blood count monitoring in between visits.

Pharmacy dispensing procedures were written to enable the dispensing of a months supply of maintenance chemotherapy at each visit, accounting for any possible dose modifications needed during the following month. Following local full blood count checks, a weekly meeting is held with nursing, pharmacy and medical staff to review results and adjust maintenance therapy accordingly. Blood results and drug doses are communicated to parents by telephone and in writing. Unused medication is returned to Leeds at the following clinic visit, and tablets counted to audit compliance.

Results: The project has now been implemented for over a year, and 63 patients have been recruited on to the scheme. Patient/parent questionnaires show that families are happy with the scheme. It has helped patients to attend school more frequently with less disruption to family life. The outpatient clinic has benefited, as clinic lists are now shorter, resulting in shorter waiting times.

The compliance audit, assessed by tablet counting has revealed some compliance issues in some families. Reviewing the patient/parent education and counselling regarding maintenance therapy have addressed this. Poor compliance has led to the removal of two patients from the scheme.

Conclusion: The home maintenance scheme has been successful and is to continue with ongoing audit.

It is planned to introduce pharmacist supplementary prescribing for maintenance therapy dose modifications between clinic visits. The steering group is reviewing the feasibility of transferring some of the maintenance prescribing to selected shared care centres in the Yorkshire region.

Reference

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P9
An audit of the anti-emetic policy for the treatment of chemotherapy induced nausea and vomiting for children and young people with cancer

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Objectives: Nausea and vomiting are major side effects of chemotherapy in children and young adults with cancer. The anti-emetic policy on the paediatric and adolescent oncology unit was reviewed and updated by a multi-disciplinary working group based on local experience, published evidence and review of practice at other regional paediatric oncology centres in the United Kingdom. The aim of the audit was to determine the efficacy and toxicity of the anti-emetic policy and to identify any recommendations for policy review.

Methods: The audit was based on the paediatric and adolescent oncology wards at St James' University Hospital, Leeds. All paediatric and adolescent inpatients receiving chemotherapy over a six month period were included in the audit. The effectiveness of therapy was monitored using pre-designed anti-emetic diary cards. Diary cards were completed every shift by the name nurse for the patient and episodes of nausea, vomiting, retching and the child's eating and drinking pattern were recorded. The effectiveness of the policy was classified by each patient's worst day of antiemetic control. This was defined as total control, major response and failure.

Results: Over 100 patients, aged between 6 months and 19 years of age, were included in the audit. Patients were given chemotherapy based on the United Kingdom Children's Cancer Study Group protocols. Chemotherapy emetogenicity ranged from moderate to very high and treatment duration from one to ten days. The most common course of treatment was high dose methotrexate, 3–12 g/m^2. Good response rates for total control and major response were seen in all age groups. The policy was well tolerated with minimal side effects. The use of low dose levomepromazine as salvage therapy in adolescents and older children was shown to be effective. The diary cards were easy to complete and were shown to be a useful assessment tool.

Conclusion: The aims and objectives of the audit were satisfied with very encouraging results. The policy has been shown to be effective and a number of recommendations have also been made for policy review. Low dose levomepromazine was shown to be effective and well tolerated in adolescent patients and its role in younger children is now being investigated.

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P10
Dosing chemotherapy in obese children and young people

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Background: In paediatric oncology obesity has implications for the safe dosing of chemotherapy as doses are calculated according to body surface area or weight[1]. With no national guidelines other than those in UKALL2003[2], management of these patients is likely to vary between Paediatric Oncology Centres (POCs) in the UK and Ireland.

Objective: To determine existing practice in the 21 POCs, in order to identify any similarities and differences.

Method: Questionnaires were sent to the Lead Paediatric Oncology Pharmacist at each of the 21 POCs. Questions focused on the existence of local policies, methods of and criteria for dose adjusting and comments.

Results: Pharmacists at 17 centres (81%) returned questionnaires. Patients treated are aged from birth to 25 years. Three of the 17 centres had a local policy for dosing in obesity, seven centres stated all prescribers adopted the same practice.

Pharmacists at 15 centres responded that they modified the dose of all or some drugs, no centre never dose adjusted. Criteria and method for dose adjustment varied between centres; 10 applied the guidelines produced by the UKALL2003 taskforce. Twelve centres used paediatric weight centile charts for dose adjusting.

Although obese children were rarely treated, pharmacists suggested national guidelines would be valuable.

Conclusions: Practice for dosing chemotherapy in obese children and young people varied between POCs. Lead pharmacists commented on the lack of available data. The guidelines produced by the UKALL2003 Taskforce[2] were well received amongst the group. A lack of other guidance meant many centres applied the guidelines to other protocols.

More specific guidelines for dose adjustment would ensure a uniform approach to managing obese patients and is likely to be well received.

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