REVIEW ARTICLE

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Incidence and Nature of Dosing Errors in Paediatric Medications

A Systematic Review

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Abstract

In paediatric medicine, drug doses are usually calculated individually based on the patient's age, weight and clinical condition. Therefore, there are increased opportunities for, and a relatively high risk of, dosing errors in this setting. Consequently, a systematic literature review using several databases was conducted to investigate the incidence and nature of dosing errors in children; 16 studies were found to be relevant.

Eleven of the 16 studies found that dosing errors are the most common type of medication error, three of the remaining studies found it to be the second most common type. This review of published research on medication errors therefore suggests that dosing errors are probably the most common type of error in the paediatric population. In addition, there was a great variation in the error rates reported; this is likely to be due to the differences in the medication error definitions and methodologies employed. For example, the dosing error rate determined using spontaneous reporting ranges from 0.03 per 100 admissions in the UK to 2 per 100 admissions in the US. Extrapolating this, if the under-reporting rate is about 1 in 100, then the true incidence would be around 50 000 paediatric dosing errors per year in England.

The information available shows that dosing errors are not uncommon and that 10-fold overdoses caused by calculation errors have led to serious consequences. There is an urgent need to develop methods to reduce medication errors in children and dosing errors should be the first priority.

In recent years, governments and researchers in different countries have spent a great deal of resources in the study of medication errors[1-3] and have shown that they cause a worrying amount of harm. Medication errors are a large problem in the UK and in other countries such as the US in both primary and secondary care, and policy initiatives have been implemented to reduce them.[1-3] Medication errors are probably the most common type of medical error.[1-3] By far the majority of medication error studies have been carried out in adults. However, a recent study from the US has suggested that medication errors are not uncommon in children and may be three times more common in children than adults.[4] A 1-week study covering many UK hospitals and involving more than 10 000 beds, showed that the number of prescriptions changed following pharmacists' interventions in the paediatric wards was second only to those in the intensive care units. The number was higher than that in geriatric, medical or surgical wards and most of the pharmacists' interventions were prescribing-error related.[5] The available evidence therefore suggests that the epidemiological characteristics of medication errors may differ between adults and children.

Although research into paediatric medication errors is scarce, there are different types of error reported in the literature, which include dosing errors, incorrect drug administration, incorrect route of administration, errors in medication record transcription or documentation, erroneous frequency of administration, missed dose, wrong patient, intravenous incompatibility and incorrect rate of intravenous drug administration.

Medication calculation and dosing errors in children have been frequently reported in the mass media. Usually these cases have been fatal.[6-8] Calculation errors can occur at various stages including prescribing, dispensing and administration. For example, one patient had acute aminophylline poisoning after receiving five intravenous doses of the drug at a dosage ten times higher than prescribed due to a calculation error during dilution.[9] Drug doses in the paediatric population are usually calculated individually, based on the patient's age, weight or body surface area and clinical condition, leading to increased opportunities for error and a relatively high risk of dosing errors.[10,11] We therefore wished to conduct a systematic review to establish the strength of the evidence base to support the notion that dosing errors are a significant problem in paediatric practice and to establish the incidence and nature of those dosing errors in paediatric patients.

1. Methods

1.1 Database and Search Engine

We used several databases available in the British Library, including: Medline (1966-week 14, 2003); Embase (1980-week 14, 2003); International Pharmaceutical Abstracts (1970–2000); Pharmline (1978–2002); Cumulative Index to Nursing and Allied Health Literature (1982–2002); British Nursing Index (2001–2002).

The search engine used (SilverPlatter) allowed us to search all the databases at the same time.

1.2 Search Strategy

The search was limited to studies in the English language because of limited time and resources for translation and its quality control. The following search strategy was developed based on discussion between the authors and previous literature reviews conducted by our team.

The keywords used in the literature search were: 'medication error(s)' or 'administration error(s)' or 'prescribing error(s)' or 'medication mishap(s)' or 'administration mistake(s)' or 'dispensing mistake(s)' or 'prescribing mistake(s)' or 'dispensing error(s)' or 'drug error(s)' or 'drug mistake(s)' or 'drug mishap(s)' or 'medication mistake(s)' and 'paediatric(s)' or 'paediatric(s)' or 'child'' or 'infant(s)' or 'adolescent(s)' or 'neonates(s)' or 'neonatal'.

The reference lists of the selected papers were also reviewed in order to identify additional relevant studies. A hand search of two journals related to drug safety was also performed. These journals were *Drug Safety* and *Quality and Safety in Health Care*; volumes published from 1997–2002 were searched.

1.3 Review Procedure

The review is divided into two sections: (i) the incidence of dosing errors and the percentage of all reported errors that relate to dosage errors; (ii) case reports on dosing errors. The first part of the review therefore gives information on the methodology used in the study of paediatric dosing errors and the extent of paediatric dosing errors. The second part focuses on the nature and consequences of paediatric dosing errors.

1.3.1 Incidence and Percentage of Dosing Errors

Based on our experience in medication error research in the adult population, we had anticipated that the paediatric studies would be very heterogeneous due to the lack of standard methodologies and outcome measures. We therefore did not attempt to summarise the data statistically. We decided instead to summarise the information and report the incidence and percentage of dosing errors in each study, together with the characteristics of each study, in a table format.

Inclusion Criteria

- Only studies reporting the number of dosing errors and/or percentage of all errors that were dosing errors were included in this part of the review.
- If studies included both children and adults, the data relating to paediatrics were extracted and reported. If it was not possible to extract data for the paediatric population, the study was discarded for this part of review.

Calculation of Incidence and Percentage of Dosing Errors

The incidence of dosing errors in each study was calculated using the following equation (equation 1):

$$\text{Incidence} = \frac{\text{No. of dosing errors}}{\text{No. of admissions, medication orders or drug charts in the study period}}$$

The percentage of all medication errors that were dosing errors in each study was calculated using the following equation (equation 2):

$$\text{\% of dosing errors} = \frac{\text{No. of dosing errors}}{\text{Total no. of reported medication errors in the study period}} \times 100$$

1.3.2 Summary of Case Reports

Case reports of dosage errors in children reported in the relevant papers were summarised in another table. The objective of this table is to inform readers of the nature of dosing errors. Only cases that fulfilled the following inclusion criteria were included.

Inclusion Criteria

Cases reported the following details:

- age of the patient
- drug or class of drug involved
- nature of the dosing error
- patient outcome.

There are some methodological issues in the medication error literature that have significant effects on the interpretation of the findings. We will discuss such issues next, before presenting the results obtained.

2. Methodological Issues

2.1 Definitions of Medication Error in the Literature

There is great variation in the definitions and categories of medication errors used in the literature.[12,13] The use of different definitions can change the reported error rate several-fold. Furthermore, a 'medication error' study could include any of the following errors: prescribing, transcribing, monitoring, dispensing and drug administration errors. Some studies include errors in all of these categories; others focus only on one. There are also studies that do not give a definition,[9,14-16] while others use very broad definitions which include giving a dose half an hour late, or non-adherence by patients. In addition, some studies link the definition to local practice, while others do not. Such a wide variation can make interpretation of the literature very difficult and thus, comparison of results obtained in different studies must be done with extreme caution.

2.2 Methods for Measuring Medication Errors

Three methods for measuring medication errors have been used in most medication error research: spontaneous reporting, chart review and observation.[13] These three methods will be described briefly to assist readers in the interpretation of this review.

2.2.1 Spontaneous Reporting

This requires the person who witnessed, committed or discovered an error to fill in an incident report. The major problem with this system is under-estimation due to inability to recognise errors and many other reasons for under-reporting. Previous studies have shown that spontaneous reporting systems grossly underestimate the incidence of drug administration errors compared with observation.[13,17-20]

2.2.2 Chart Review

This involves researchers reviewing prescriptions, prescribing charts or computer prescribing records to identify medication errors. Chart review may be useful for detecting prescribing errors; however, it relies on the clinical skills of the researchers to detect the error. Chart review is only marginally effective in detecting errors in drug administration;[21] a previous study from our research team has shown that many drug administration errors would be missed if chart review alone was employed.[22] Chart review may also detect transcribing errors, depending on the specific methods used.

2.2.3 Observation

This involves researchers observing health professionals while they are preparing and administering medication to patients. The researcher records details of all doses administered, and compares this information with the doses prescribed. A major concern with the observation method is the potential effect of the researcher on the individuals under observation. Therefore, many observational studies involved the use of disguised techniques where the nurses were aware of the observation but unaware of its true purpose.[13,16,23] Previous research has shown that observation is a valid method for measuring error and there is no evidence to suggest that it affects the error rate detected.[24]

Each method of error measurement is best equipped to detect certain types of error.[21] The three approaches mentioned are all process-based methods for detecting errors. There are other outcome-based methods, which are used to identify harm that could be drug related. These methods include self-reporting and review of charts or medical records. Studies that employ these methods are useful in that they study the harm caused by medication errors, which is the main target for reduction. However, harm occurs in a relatively small proportion of cases and hence, outcome studies are expensive and difficult to conduct. Instead, researchers tend to use detailed studies of the process as a substitute.[25]

2.3 Setting and Country in Which the Study Was Conducted

The incidence of medication errors is likely to vary depending on the setting in which the research was conducted. For example, the dosing error rate in a neonatal intensive care unit may be very different from that in a paediatric asthma clinic.

The systems of prescribing, dispensing and drug administration vary significantly between different counties, hence the frequency and causes of error in each country are likely to be different.

In UK hospitals, clinicians usually prescribe using a pro-forma drug chart, which is also used to document drug administration. A ward pharmacist usually visits the ward daily to see the patient and check the appropriateness of prescribing. Through this process, a ward pharmacist can prevent both adverse drug reactions and medication errors.[5]

In US hospitals, clinicians traditionally prescribe on a blank 'doctor's order' sheet, on which all the doctors' orders are written, including blood tests, observations to be made and referrals to other health professionals. Ward staff such as ward clerks or nurses will order the medication from the pharmacy and ward or pharmacy staff will transcribe it to a medication administration record used for drug administration. There is limited ward stock and drugs are generally supplied from the pharmacy as unit doses dispensed for individual patients.

In European hospitals, for example in Germany,[26] clinicians prescribe medications in a section of the patient's medical notes with other instructions to nurses. Nursing staff will then transcribe the prescriptions onto drug administration charts in the patient's notes and use these to administer drugs to patients. Each ward keeps a large floor stock of formulary drugs and pharmacists visit each ward about twice a year.

Considering the above differences, the epidemiology, causes of errors and potential solutions are likely to be different. For example, transcribing errors could occur in the US and German systems; however, they have little relevance to the UK system.

3. Results

The search strategy produced 165 references. The title, abstract or the full text article was then reviewed for relevance and 118 references excluded. Of these, 33 were excluded because they were not related to medication errors in children. Another 85 were related to adverse effects commonly occurring with certain drugs, or were letters and opinions about medication errors in general. As a result, 47 references were deemed relevant. The reference lists of these papers were reviewed to identify other relevant studies; only one additional paper was identified, resulting in 48 studies. A hand search of *Drug Safety* and *Quality and Safety in Health Care* identified no additional relevant studies.

On reading of the full paper, only 15[4,9,14-16,27-36] of the 48 studies specifically investigated the incidence of medication errors in children and also reported the incidence of dosing errors. However, during the writing up of the manuscript (November 2003), an automatic search update identified another study.[37] This study also fulfils the inclusion criteria. Therefore, the total number of reports included in the review of the incidence and percentage of dosing errors was 16; the results are summarised in table I.

Eleven of the 16 studies found that dosing errors are the most common type of medication error.[4,9,14,27-30,32-35] Three of the remaining five studies found it to be the second most common type.[15,31,36] In addition, there was a great variation in the dosing error rates reported, for example, results range from 0.03 per 100 admissions in the UK[31] to 2 per 100 admissions in the US[15] using spontaneous reporting. Additionally, 17 case reports of dosing errors in children were found in five of the 49 papers. These cases are summarised in table II.

4. Discussion

4.1 Incidence of Dosing Error

This review has shown that dosing error is probably the most common medication error in children. Eleven of the 16 studies found that dosing errors are the most common type of errors. The evidence so far therefore suggests that dosing errors are the most common type of paediatric medication error across a range of methodologies and definitions. This finding strongly suggests there is an urgent need to research interventions to reduce dosing errors.

Table I shows great variation in the dosing error rates reported. This variation is most likely to be due to the differences in methodologies employed. There is no doubt that a spontaneous reporting system significantly under-estimates the incidence of errors,[13,17-20] furthermore, studies only investigating prescribing errors or drug administration errors yield a lower incidence of dosing errors than studies investigating all types of medication error. However, even based on the figure from Ross et al.,[31] that there are three dosing errors reported per 10 000 admissions (the lowest reporting rate amongst all the spontaneous reporting studies in table I) and approximately 1.6 million hospital admissions for children (aged 0–14 years) in the 2001–2002 financial year in

Table I. Incidence of dosing errors reported in each study

Study	Method used to measure medication errors	Country	Setting	Type of medication errors included	Percentage of total errors (%)	Incidence of dose error per dose, patient or admission	Order of frequency compared with other errors
Fontan et al.[37]	Chart review	France	Paediatric and maternity hospital – nephrology unit	Administration	0.4[a] 0.3[b]		Third
				Prescribing	0.8[a] 2.7[b]		
Kozer et al.[14]	Chart review	Canada	Paediatric hospital – emergency department	All types	49.1	8.7 per 100 drug charts reviewed	First
Kaushal et al.[4]	Chart review	US	One paediatric hospital and all paediatric wards in a general hospital	All types	28	1.62 per 100 medication orders	First
Bordun and Butt[27]	Chart review	Australia	Paediatric hospital – intensive care unit	All types	66.2	2.6 per 100 medication orders	First
Blum et al.[28]	Chart review	US	University hospital (for both adults and children)	Prescribing	45	0.37 per 100 medication orders	First
Folli et al.[29]	Chart review	US	Two paediatric hospitals	Prescribing	82	0.39 per 100 medication orders	First
Cowley et al.[30]	Spontaneous reporting	US	US Government (US Pharmacopeia)	All types	47		First
					25		
Ross et al.[31]	Spontaneous reporting	UK	Paediatric hospital and a NICU in a maternity hospital	All types	14.8	0.03 per 100 admissions	Second
Selbst et al.[9]	Spontaneous reporting	US	Paediatric hospital – emergency department	All types	36		First
Wilson et al.[32]	Spontaneous reporting	UK	University hospital – congenital heart disease centre (PCW + PCICU)	Administration	4.6	0.73 per 100 admissions	First
				Prescribing	22.5	10 per 100 admissions	
Paton and Wallace[33]	Spontaneous reporting	UK	Paediatric hospital	All types	29		First
Aneja et al.[34]	Spontaneous reporting	India	Paediatric hospital – general paediatric ward	All types	37.8	2.43 per 100 admissions	First

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Table I. Contd

Study	Method used to measure medication errors	Country	Setting	Type of medication errors included	Percentage of total errors (%)	Incidence of dose error per dose, patient or admission	Order of frequency compared with other errors
Jonville et al.[35]	Spontaneous reporting	France	14 French poison control centres	All types	31.5		First
Raju et al.[15]	Spontaneous reporting	US	University hospital – NICU + PICU	Drug administration	13.7	2 per 100 admissions	Second
Schneider et al.[36]	Observational	Switzerland	University hospital – PICU	Drug administration	8		Second
Tisdale[16]	Observational	Canada	Paediatric hospital – PICU + ICN	Drug administration	0.3		Fourth

a Computerised prescriptions.

b Handwritten prescriptions.

ICN = intensive care nursery; **NICU** = neonatal intensive care unit; **PCICU** = paediatric cardiac intensive care unit; **PCW** = paetiatric cardiac ward; **PICU** = paediatric intensive care unit.

England,[40] the estimated number of paediatric dosing errors reported in England would be approximately 500 in the 2001–2002 financial year. Limited evidence has suggested that a spontaneous reporting system results in under-reporting by a magnitude of 1 in 1000,[13] if this is the case, the true incidence of dosing error would be approximately 500 000 per year in England. If the under-reporting rate is only 1 in 100, then the true incidence would still be around 50 000 paediatric dosing errors per year. Although not all dosing errors are serious, some have been reported to have fatal consequences (table II). We believe this is a serious public health issue that needs to be investigated urgently.

4.2 Case Reports

Epidemiological studies tend to focus on the incidence and type of dosing errors but lack details about the nature of the errors identified. In this regard, case reports are useful as they provide us with more information on the nature of dosing errors. Unfortunately, most of these case reports resulted in fatal consequences; these probably attracted more attention and hence were more likely to be reported in the literature, especially in the mass media. It is important to note that 10 of the 17 cases summarised in table II are 10-, 100- or 300-fold overdoses due to calculation errors; this is an indication of the seriousness of this type of calculation error.

4.3 Causes of Dosing Errors

The dosing of medication for children is usually based on weight or body surface area, clinical condition and age. For potent drugs, when only small fraction of the adult dose is required for children, it becomes very easy to cause 10-fold dosing error because of miscalculation.[16,34,41] Furthermore, Selbst and colleagues[9] have suggested that the incorrect recording of patients' weights can also contribute to incorrect dosing. Other sources of dosing errors include misplacement of the decimal point, incorrect expression of dosage regimen and incorrect units.[42]

Most formulations are designed for use in adults and very few drugs are commercially available in ready to administer unit doses or dosage forms that

Table II. Case reports of dosing medication errors in children

Patient involved (country)	Drug involved	Nature of the error	Outcome	References
3-month-old baby (UK)	Sodium nitroprusside	4 times overdose and given in wrong administration system	Death	7
9-year-old (UK)	Diamorphine	6 times overdose	Death	7
1-day-old infant (US)	Benzathine benzylpenicillin (penicillin G benzathine)	10 times overdose	Death	38
10-month-old baby (US)	Theophylline	10 times overdose	Vomiting, tachycardia, and hypertension. Patient admitted to ICU for 3 days but no permanent harm	9
1-year-old male (US)	Ciclosporin	10 times overdose	Facial flushing and irritability	39
1-day-old baby (UK)	Digoxin	10 times overdose	Death	7
Neonate (UK)	Diamorphine	10 times overdose	Death	7
5-year-old girl (UK)	Tacrolimus	10 times overdose	Death	7
13-year-old (UK)	Epinephrine (adrenaline)	10 times overdose	Allergic reaction (rash and wheezing)	7
17-year-old (UK)	Intravenous fluids	10 times overdose	Death	7
1-day-old premature neonate (UK)	Morphine	100 times overdose	Death	7
17-month-old infant (UK)	Benzylpenicillin	300 times overdose and injected the drug into spine	Death	7
5-year-old (UK)	Anaesthetic, atropine, epinephrine (adrenaline)	Incorrect dose	Heart attack	7
9-year-old (UK)	Oral corticosteroid	Overdose	Died from chickenpox	7
4-year-old (UK)	Growth hormone test	Overdose	Death	7
3-year-old boy (UK)	Aciclovir	Overdose	No harm to patient	8
3-day-old triplet (UK)	Phenytoin	Overdose	Death	7

ICU = intensive care unit.

are appropriate for children. This creates more opportunities for dosing errors. This problem is clearly demonstrated by the examples of diamorphine and morphine injections in the UK. The lowest strength of licensed diamorphine and morphine injections are 5mg and 10mg, respectively; one such ampoule is sufficient to cause a 10 or 100 times overdose in neonates. Table II illustrates the devastating effects of such an overdose. Lack of appropriate paediatric formulations is mainly a consequence of low financial returns for pharmaceutical companies to develop and market such formulations.[43] It is important for governments to work with the pharmaceutical industry and healthcare providers to make sure more medicines will be available for children in appropriate concentrations and formulations.

The fewer calculations that have to be performed by healthcare professionals, the lower the risk of errors. Electronic prescribing systems can potentially reduce dosing and calculation errors by prescribers;[37] however, such systems would not be able to prevent dosing errors during drug administration. Furthermore, very little research has been conducted to study the effectiveness and risks of electronic prescribing in medication error reduction.

Finally, there is evidence to show that some healthcare professionals have difficulties in calculating the correct dose.[44-46] These calculation errors could easily cause 10-fold errors as shown in table II. We recommend that professional regulatory bodies and academic institutions review both pre-registration and post-registration education to ensure sufficient mathematical training and assessment for healthcare professionals dealing with paediatric medications.

4.4 Methodological Shortcomings of Dosing Error Studies

Although some epidemiological studies assessed the severity of the reported error, none of the studies classified the harm according to type of error. As a result, we were unable to assess the incidence of harm due to dosing errors. Similarly, we were unable to identify at which stage (prescribing, transcribing, dispensing or administration) most of the dosing errors occurred due to lack of information in the original reports. Based on the above observation, we suggest future research should attempt to address these two important issues.

A further problem in the interpretation of the epidemiology of dosing error is the definitions. Prescribing errors involving dose often include any variance from the norm as an error, however, with no commonly accepted standard such as how much variance constitutes an error. Similarly, administration errors involving drug dose will often record variance from the prescribed dose, again there is no commonly accepted standard. All of these important points should be explored further.

5. Conclusion

This review of published research on medication errors suggests that dosing errors are probably the most common type of medication error in the paediatric population. There was a great variation in the error rates reported, which is likely to be due to differences in the populations sampled, definitions used, health systems studied, research questions and methodologies employed. There is a need for international uniform definitions and reporting pathways of medication errors to allow rate comparison. The available information clearly shows that dosing errors are not uncommon. Ten-fold or greater overdoses, caused by calculation errors, occur relatively frequently in this group and have led to serious consequences. There is an urgent need to develop methods to reduce dosing errors in children.

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