Prospective pilot intervention study to prevent medication errors in drugs administered to children by mouth or gastric tube: a programme for nurses, physicians and parents

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ABSTRACT

Background Drug administration in children is an error-prone task for nurses and parents because individual dose adjustment is often necessary, and suitable formulations for children are frequently lacking. Hence, in the absence of measures for their prevention, medication errors are likely to occur.

Objective To assess the error prevalence in drug administration by mouth or gastric tube before and after implementing a programme for quality improvement for nurses and parents.

Design, setting and participants Prospective, two-period cohort intervention study on a paediatric neurology ward of a university hospital where drug administration procedures of nurses and parents were consecutively monitored during the routine drug administration hours.

Main outcomes measure Prevalence of administration errors before and after implementing instructions for appropriate drug administration, and a teaching and training programme supported by information pamphlets.

Results Altogether, 1164 predefined administration tasks were assessed, 675 before and 489 after the intervention. Of these, 95.7% (after the intervention: 92.6%) were performed by nurses. Errors addressed by the intervention were reduced from 261/646 tasks (40.4%) to 36/453 (7.9%, $p<0.001$) in nurses and from 28/29 (96.6%) to 2/36 (5.6%, $p<0.001$) in parents. Errors in predefined categories concerning tablet dissolution, tablet storage, oral liquids, tablet splitting, administration by gastric tube and others were all considerably less frequent after the intervention (each $p<0.001$).

Conclusion Errors of drug administration by mouth and gastric tube represent a considerable and often neglected drug-related problem in paediatric inpatients. Targeted quality-improvement programmes can substantially and rapidly reduce error prevalence. Appropriate teaching and training of both nurses and parents supported by pamphlets was a highly efficient way to reduce error prevalence.

Medication errors frequently cause preventable adverse drug events (ADEs) if they occur during drug prescription or administration. The substantial costs of those ADEs demand investment in preventive strategies.[1 2]

Numerous causes for prescription errors have been identified.[3–6] In adults, electronic strategies prevented half of the serious prescription errors,[7 8] and pharmacists participating in ward rounds reduced such ADEs by 66%.[9] In children, similar interventions together with improved communication between physicians, nurses and pharmacists successfully reduced overall error rates by up to 96%.[10–12]

However, preventive strategies should also address drug administration because one-third of the medication errors leading to ADEs occur at that stage.[13] In contrast, strategies preventing administration errors are rare, although those errors are frequent.[14–19] For many reasons, paediatric patients are at particular risk for administration errors. Off-label administration of drugs not designed for use in children is frequent,[20–22] and parenteral infusions,[23 24] administration of oral liquids and tablet splitting are often inevitable to individualise doses,[25 26] which are all error-prone.[17 18] In addition, in paediatric patients, errors are three times more likely than in adults,[27] with younger and critically ill children being particularly susceptible to adverse outcomes.[27]

Given the multitude of different handling steps, error detection will require comprehensive monitoring strategies.[19] Administration is only fragmentarily documented in patient charts, making associated errors less suitable for electronic decision support and more difficult for interception.[15] Quality assurance of the administration process therefore requires well-tailored strategies and may be even more intricate in children because care givers, parents, siblings or even secretaries at schools are involved in drug administration.[28 29] Education programmes for paediatric nurses can promote adherence to medication policies,[30] and nurses play an important role in patient education.[13] In addition, parental training programmes to manage fever[31] or to avoid dosing errors[32] substantially improved knowledge and skills.

We aimed to assess the quality of drug administration by mouth and tube to children, and to improve it by combining several previously effective intervention strategies. Hence, this intervention consisted of pamphlets,[33] teaching and training programmes for healthcare providers,[34] and train-the-trainer[35] courses, in which nurses and physicians were trained to teach the parents.

METHODS

Setting

After approval of the study by the Ethics Committee of the University of Heidelberg, we

performed a prospective intervention study in a paediatric neurological ward (19 beds). Informed consent was obtained from all participants, and the monitoring of the professional staff was approved by the local employee committee. All nurses and parents were invited to participate in the study if they administered drugs to patients admitted to the study ward.

Definitions

We defined all processes related to drug preparation and administration as drug administration. Medication errors were defined as deviations from general standards or the drug label (table 1).

Study protocol

During a first 2-week test phase on the ward, monitoring procedures were developed. On the basis of those results, a two-phase study was performed consisting of a baseline phase and a subsequent postintervention phase in which medication handling was monitored. The two monitoring periods were separated by a corrective intervention that consisted of a targeted teaching and training programme for nurses, physicians and parents supported by information pamphlets.

Monitoring procedure

In the first phase, two pharmacy students were trained to act as monitors of drug handling on the ward, and good performance to detect all relevant errors was ascertained by a senior clinical pharmacist. An expert panel, consisting of a head nurse, two physicians including a senior physician and a clinical pharmacist, developed a list for the monitors to document drug handling. The monitoring was then conducted prospectively during two 3-week periods separated by a 10-day training period, which was necessary to conduct the training sessions for all physicians and members of the nursing staff. The students were present on the ward during all hours of drug administration in the morning (07:00 to 11:00) and afternoon (16:00 to 20:00). They documented all procedures, and documentation was jointly reviewed with a clinical pharmacist to assure accordance with the predefined error categories. The monitors were obliged to intervene if they witnessed errors potentially resulting in serious ADEs.

Table 1 Definition of the drug administration errors assessed in this survey

Category of medication administration error	Definition
Tablet dissolution	Not the entire dissolution/suspension was administered, or undissolved tablet fragments were left
Tablet storage	Tablets stored outside the blister after splitting
Oral liquids	Inappropriate administration of oral liquids—for example, remaining liquids once out of the bottle were poured back into the storage bottle after administration of the intended amount to the patient
Tablet splitting	Inappropriate splitting of tablets according to drug label or splitting of different tablets for different patients without cleaning the tablet splitter
Gastric tube	Combined preparation and administration of drugs via gastric tube that must be administered separately or, when milling tablets, active ingredient was left in the mortar after use
Others	Other errors not predefined, such as the number of administered tablets not kept at a minimum—for example, two tablets, instead of one (double strength) tablet, were administered

Intervention

Healthcare providers

On the basis of the errors detected in the first phase, a pamphlet was developed consisting of general (table 1) and drug-related (table 2) recommendations on how to prepare and administer drugs. In a 30 min lecture, the content of this pamphlet was presented (to improve knowledge) followed by 90 min practical training using dummy preparations (to improve skills). This training was repeated in individual 10 min training sessions conducted by pharmacists on the ward.

Parents

After the teaching and training of the healthcare provider (train-the-trainer), nurses and physicians acted as teachers themselves and trained parents involved in drug administration. The practical training, which was given individually to each parent during 2 min to 5 min training sessions on the ward, explained the need for correct drug administration and was supported by handover of the pamphlet. In an accompanying letter, parents were invited to contact nurses or physicians if further advice was needed.

Statistics

Assuming a prevalence of at least one error in 50% of the administration procedures of drugs administered by mouth or tube in patients before intervention and a relative reduction of about 60%, that is, an error prevalence of not more than 20% of the administration procedures after the intervention in an independent patient group,[36 37] evaluation of at least 39 drug administration tasks per group was needed to detect significant prevalence differences (χ^2 test, $\alpha=0.05$; $1-\beta=0.80$). Data are reported as the mean value with SD for participants' data and 95% CI for outcomes. Frequencies are presented as a percentage. Changes were analysed by χ^2 test or Fisher Exact test as appropriate. A p value ≤ 0.05 was considered significant.

RESULTS

Participants

All 17 nurses involved in drug administration agreed to participate. Their mean age was 34.3±10.7 years, their mean professional experience was 12.4±10.5 years, and 15 were specialised in paediatric care. All 30 parents of consecutive patients, who were directly involved in drug administration, agreed to take part. All drugs administered by mouth and gastric tube were monitored in all patients who were present on the ward during either study phase. Drug administration was observed in 47 (21 female) patients with a mean age of 6.4±1.5 years. They suffered from epilepsy (51.1%), infections (17.0%), cerebral tumours (6.4%), dysplasia (6.4%), encephalitis (4.3%), metabolic diseases (4.3%), pneumonia (4.3%), migraine disorders (2.1%) or other diseases (4.3%) as principal diagnosis.

Medication errors

Altogether 1164 predefined administration tasks were assessed, 675 before and 489 after the intervention. Among them, 646 (95.7%, after the intervention: 453 (92.6%)) were performed by nurses and 29 (4.3%, after: 36 (7.4%)) by parents. Whereas, before the intervention, 289 (42.8%) administration tasks were affected by errors, the number decreased to 38 (7.8%, $p<0.001$)

Table 2 Ten most frequently administered drugs and associated administration errors

Drugs (brand name)	Route of administration mainly involved in errors	Dose form mainly involved in errors	Committed errors	No (prevalence (%)) before intervention (N=213 drugs)	No (prevalence (%)) after intervention (N=174 drugs)
Colecalciferol/sodium fluoride (D-Fluoretten)	By tube	Tablet	Dissolution/suspension was not immediately used	7 (3.3)	6 (3.4)
Dexamethasone (Fortecortin)	By mouth	Tablet	Tablets were stored outside the blister after splitting	13 (6.1)	0 (0)
Levetiracetam (Keppra)	By mouth	Dissolution	Remaining liquids once out of the bottle were poured back into the storage bottle	13 (6.1)	23 (13.2)
L-thyroxine (L-Thyroxin)	By mouth	Tablet	Administration together with food without appropriate interval	11 (5.2)	0 (0)
Metoprolol (Beloc-ZOK)	By mouth/by tube	Tablet	Not the entire dissolution/suspension was administered, or undissolved tablet fragments were left	5 (2.3)	5 (2.9)
Omeprazole (Antra)	By mouth/by tube	Tablet	Preparation by mortar or administration together with dairy products	15 (7.0)	18 (10.0)
Oxcarbazepine (Trileptal)	By tube	Suspension	Remaining liquid once out of the bottle was poured back into the storage bottle	2 (0.9)	9 (5.2)
Pyridoxin (different brands)	By tube	Tablet	Preparation by mortar, administration together with other drugs, and storage before use without protection from light	5 (2.3)	11 (6.3)
Sucralfate (Ulcogant)	By tube	Suspension	Remaining liquid once out of the bottle was poured back into the storage bottle	7 (3.3)	4 (2.3)
Topiramate (Topamax)	By mouth	Tablet	Inappropriate splitting of tablets according to drug label	13 (6.1)	17 (9.8)

after the intervention (table 3). The intervention shifted administration from nurses to parents (p=0.025). Errors were reduced by 32.5% in nurses and by 91.0% in parents (each p<0.001). All predefined subcategories decreased (figure 1). No errors potentially resulting in serious ADEs were observed. The 10 most frequently prescribed drugs and associated errors are shown in table 2.

DISCUSSION

This study reveals that in the absence of specific measures, administration errors are alarmingly frequent. Indeed, nearly all administrations by parents and a significant fraction of those performed by nurses contained errors. Many errors had the potential to cause treatment failure, dose dumping or erratic release of the active ingredient, thus modulating effectiveness and safety. In contrast to previous studies aimed at reducing the risk for medication errors,[38 39] we intended to actually prevent errors. Indeed, a structured intervention substantially reduced error prevalence, and the intervention was effective in both nurses and parents. Except for some limited data showing that educational programmes for parents can be effective,[31 32] relatives are not regularly involved in quality ensuring measures despite their central role in paediatric pharmacotherapy.

Table 3 Administration errors committed by nurses and parents

Persons involved in drug administration	Errors (absolute no (%)) in predefined administration processes (N=total no of observed processes)		p Value (before vs after intervention)
	Before intervention	After intervention	
Nurses	261 (40.4%) N=646	36 (7.9%) N=453	<0.001
Parents	28 (96.6%) N=29	2 (5.6%) N=36	<0.001
Total	289 (42.8%) N=675	38 (7.8%) N=489	<0.001

Our study was performed on a ward caring for children with neurological disorders. This population is a high-risk group for clinical consequences,[24] and errors are more likely to cause ADEs because many of the drugs commonly applied, for example, anticonvulsants, have a narrow therapeutic range. Errors in paediatric patients more often result in serious ADEs because functional physiological capabilities such as drug elimination are limited.[27] Hence, another challenge is the need to consequently tailor dosage regimens to the changing elimination capacity of a growing child and to administer drugs in a galenic formulation acceptable for both child and care giver.

Error rates in our study reached 96.6%. In previous studies, errors were particularly frequent with parenteral drugs.[19 36 37] However, compared with error rates in intravenous drug administration (49%),[40] the baseline error rate in our study (43%), which focused on drug administration by mouth or tube, was remarkably similar.

In agreement with earlier studies,[3 19] monitoring was efficient in gathering objective information on a large number of drug administrations within a short period of time. While the training of nurses and physicians by a limited number of clinical pharmacists was rather standardised, there might be a greater variability in the training of the parents which was conducted by different nurses and physicians. However, the high impact on the parents' actions subsequent to the intervention indicates that it was notably effective. Interventions for error prevention were also very effective in other paediatric studies resulting in error reductions of up to 75%.[41] In contrast to earlier studies focusing on healthcare professionals,[10] however, our intervention also included parents, who were involved in up to one-third of all drug administration tasks. Given the high error rate of care givers, the need to include relatives in quality-improvement programmes for children appears mandatory. Indeed, counselling by trained nurses eliminated administration errors by parents almost completely. Additionally, parents more often administered drugs as shown by a shift in drug administrations from nurses to parents. Even if counselling is a time-consuming process, it is desirable that parents start taking responsibility for their children's therapies already in the hospital. The results of

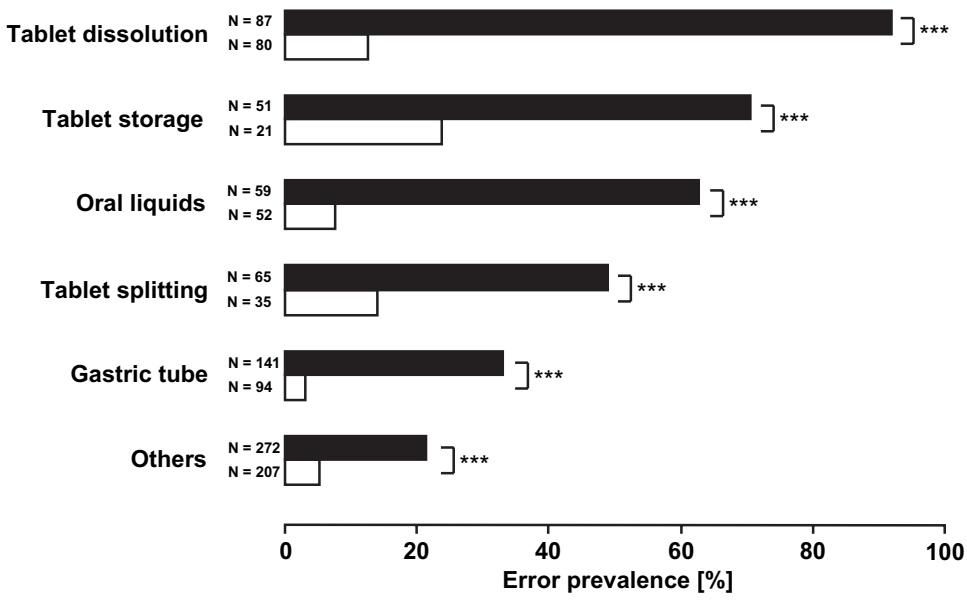

Figure 1 Categories of drug administration errors governed by the intervention and detected by monitoring on the ward before (black bar) and after a teaching and training intervention (white bar). ***p<0.001. N, total number of observed processes in the respective categories.

this study prompted us to develop an intervention covering all wards of the children's hospital. Taking into account that administration errors will depend on the nature and route of administration of the drugs needed to treat the respective patients, the intervention strategies were adapted to cover the prevalent administration types on the different wards.

A potential limitation of this study is that our patients may differ from ambulatory patients. However, because the intervention was highly successful in a complex setting, it appears likely that it will also work in other settings. Moreover, many of the assessed administration tasks are characteristic of all paediatric pharmacotherapies. Our study was not powered and not designed to detect actual clinical events derived from medication errors. The range of observed errors suggests that most of them had a low to moderate potential impact on patient safety, while no high-risk events occurred mandating immediate interception. A further limitation concerns a potential observation bias possibly induced by the presence of a monitor (Hawthorne effect). However, if an influence occurred at all, it is expected to increase awareness of the monitored staff, reduce rule-based errors, and underestimate the intervention's impact further stressing the need for intervention. Another potential bias is the occurrence of a learning effect of the monitor. In our study, this was avoided by practical training of the monitors and documentation of optimum performance. Finally, as in many other studies, recruitment bias and confounding by indication may distort the findings. In our study, all parents and all nurses agreed to participate, and so such a bias can be ruled out.

In conclusion, this study revealed that drug administration errors in children pose a considerable problem for drugs administered by mouth or by gastric tube. It highlights both the need and effectiveness of quality-improvement programmes that also involve parents in a paediatric setting. Additionally, it was shown that monitoring by clinical pharmacists is an effective method to detect administration errors on the ward including also errors that escaped the attention of the nurses.

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Competing interests None.

Patient consent Obtained.

Ethics approval This research was approved by the Ethics Committee of the Medical Faculty of the University of Heidelberg.

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