Iatrogenic events in admitted neonates: a prospective cohort study

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See **Comment** page 364

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Summary

Background **Iatrogenic events are increasingly recognised as an important problem in all people admitted to hospital. However, few epidemiological data are available for iatrogenic events in neonatal high-risk units. We aimed to assess the incidence, nature, preventability, and severity of iatrogenic events in a neonatal centre and to establish the association of patient characteristics with the occurrence of iatrogenic events in neonates.**

Methods **We undertook an observational, prospective study from Jan 1, 2005, to Sept 1, 2005, including all neonates admitted in the Division of Neonatology of an academic, tertiary neonatal centre in southern France. Iatrogenic events were defined as any event that compromised the safety margin for the patient, in the presence or absence of harm. The report of an iatrogenic event was voluntary, anonymous, and non-punitive. The primary outcome was the rate of iatrogenic events per 1000 patient days.**

Findings **A total of 388 patients were studied during 10 436 patient days. We recorded 267 iatrogenic events in 116 patients. The incidence of iatrogenic events was 25·6 per 1000 patient days. 92 (34%) were preventable and 78 (29%) were severe. Two iatrogenic events (1%) were fatal, but neither was preventable. The most severe iatrogenic events were nosocomial infections (49/62 [79%]) and respiratory events (nine of 26 [35%]). Cutaneous injuries were frequent (n=94) but generally minor (89 [95%]), as were medication errors (15/19 [76%]). Most medication errors occurred during administration stage (12/19 [63%]) and were ten-fold errors (nine of 19 [47%]). The major risk factors were low birthweight and gestational age (both p<0·0001), length of stay (p<0·0001), a central venous line (p<0·0001), mechanical ventilation (p=0·0021), and support with continuous positive airway pressure (p=0·0076).**

Interpretation **Iatrogenic events occur frequently and are often serious in neonates, especially in infants of low birthweight. Improved knowledge of the incidence and characteristics of iatrogenic events, and continuous monitoring could help to improve quality of health care for this vulnerable population.**

Introduction

During the past few decades, rapid advances in neonatal medicine have caused a substantial reduction in neonatal mortality, especially in premature infants. However, new therapeutic strategies might result in adverse side-effects or cause iatrogenic damage. Iatrogenic injury is defined as an unintended harm or suffering arising from any aspect of health-care management.[1] The report *To Err Is Human*[2] has shown the serious problem of medical errors and estimated that more than 44 000 deaths were caused by medical errors in the USA every year. Since this report, control of iatrogenesis has become an important challenge for public health and patient safety. However, available reports have focused primarily on adult and paediatric care.[3–6] Although newborn babies represent a high-risk population, data are still scarce. The Harvard Medical Practice Study[4,6] and the Health Cost and Utilization Project (HCUP) study,[7] have estimated that between 1·2% and 1·4% of neonates admitted to hospital have been affected by medical errors at discharge. However, these studies described retrospectively rates of medical error on the basis of the International Classification of Diseases (ICD)-9 and possibly underestimated the incidence of iatrogenic events in neonates.

There is general agreement that the incidence of the most common complications of care in high-risk nurseries needs to be precise, but methodology is crucial in obtaining accurate information about the issue of iatrogenesis. Reporting systems are a key strategy for learning from errors, as emphasised by the Institute of Medecine.[2] Mandatory reporting systems, on the basis of retrospective chart reviews, focus on errors associated with serious injuries or death. But errors resulting in serious harm are only part of the problem, and iatrogenesis is certainly underestimated by these systems. By contrast, voluntary reporting systems, which are widely used in aviation, focus on incidents that often result in slight injury or no harm (so-called near misses). The intent is to identify and remedy vulnerabilities in systems to improve patients' safety. Leape and colleagues[8] reported the importance of a non-punitive, anonymous, and timely reporting system to effectively monitor adverse events, which seems to be more efficient than medical chart review.[9] Thus, to improve understanding of the nature and importance of iatrogenesis in neonatal units and to improve the quality of care, we undertook a prospective study with a voluntary, non-punitive, and anonymous reporting system. We aimed to define the epidemiological characteristics (incidence, severity,

preventability, and risk factors) of iatrogenesis in neonates admitted to hospital in a high-risk neonatal centre.

Methods

Setting and patients

The study was done in a 54-bed (15 beds in intensive-care unit) level 3 neonatal centre in a university hospital in Marseille (southern France), from Jan 1, 2005, to Sept 1, 2005. All neonates admitted in the centre were included in the study. The clinical risk index for babies was used to assess illness severity.[10] Patients who had just had surgery or those requiring extracorporeal membrane oxygenation were excluded from the study. The medical staff consisted of nine neonatologists and eight paediatric residents. A 24-h dedicated physician and intern cover was present in the neonatal division. The patient to nurse ratio in the intensive-care unit ranged from 2:1 to 3:1. All orders were handwritten by physicians. The duration of the inclusion period took into account the usual length of hospital stay of the patients, especially those who were extremely premature. The length of stay of such patients being several weeks or months, the desired study period thus approached 12 months.

The study was approved by the Medical Evaluation Department and was integrated in the quality improvement plan, which was coordinated by the Public Health Department of the Hospital.

Definitions

We used the following definitions: iatrogenic event—any event that compromised the safety of the patient, in the presence or absence of harm. It may or may not have been preventable and may or may not have involved an error by the health-care team. The intercepted and spontaneously prevented events were not regarded as an incident and were not reported. Severe iatrogenic event—any unintended injury or complication that resulted in disability, death, or extended hospital stay, and which was caused by health-care management. Preventable iatrogenic event—any avoidable iatrogenic event based on available knowledge and accepted practices.[3] Adverse drug event—any injury resulting from medical intervention related to a drug.[11] Medication error—any preventable event that occurs in the process of ordering, transcribing, dispensing, administering, or monitoring a drug, irrespective of whether an injury occurred or the potential for injury was present.[5] Iatrogenic nosocomial infection—all hospital-acquired infections related to care that become evident 48 h or more after admission. Standard definitions from the CDC were used.[12]

Procedures

Our incident monitoring was based on the standard Australian incident monitoring study of patients in intensive care.[13] The incident reporting system was anonymous, non-punitive, and voluntary. The incident reporting form had been composed by a work group that consisted of neonatologists, one epidemiologist, and referent nurses on the basis of published work, professional expert devices, and a pilot study undertaken in 2003. The form consisted of three sections: administrative data (neonatal unit, patient identification, date of birth, discharge date, and hospital length of stay or eventual death), patient clinical characteristics (birthweight, gestational age, sex, mechanical or continuous positive airway pressure [CPAP] ventilation, central venous line), and narrative sections about incidents (date, age and weight of patient, description, and how the incident arose). At the back of the form, a predetermined, but not exclusive list of 53 potential incidents was established (seven categories: iatrogenic nosocomial infections, airway/ventilation incidents, catheter incidents, drug or therapeutics incidents, cutaneous events, digestive incidents, unclassified incidents) to help reporting and collecting data. Because of their multifactorial origins, bronchopulmonary dysplasia, retinopathy of prematurity, and necrotising enterocolitis were not included. The webtable shows the full list of reported iatrogenic events by category.

See Online for webtable

Before the start of the study, several tutorial sessions and group discussions were held to familiarise nursing and medical staff with the incident report and to describe the non-punitive nature of the study to encourage reports. The form was placed in the baby's chart from the time the neonate entered the unit until his or her discharge or death. Staff members were encouraged to immediately

	All patients
Males	221 (57%)
Gestational age (weeks)	34 (30–39)
≤28	53 (14%)
29–32	91 (24%)
33–37	138 (36%)
≥38	106 (27%)
Birthweight (g)	1890 (1280–2750)
≤1250	89 (23%)
1251–2499	181 (47%)
≥2500	117 (30%)
Small for gestational age*	59 (15%)
Duration of exposure to invasive procedures (days)	
Central venous line	22 (12·5–64)
Umbilical venous catheter	4 (3–4·5)
Mechanical ventilation	1 (0·3–4)
CPAP support	3 (1–5·2)
Outcomes	
Length of stay (days)	14 (4–31)
Death	17 (4%)

Data are number (%) or median (IQR). CPAP=continuous positive airway pressure. *Defined by Leroy and Lefort.[16]

Table 1: **Patient characteristics: demographics, procedures, and outcome**

	Severe	Preventable	Severe iatrogenic events that were preventable
Vascular (n=38)	5 (13%)	13 (34%)	2 (40%)
Nosocomial infection (n=62)	49 (79%)	9 (15%)	6 (12%)
Adverse drug event (n=34)	8 (24%)	19 (56%)	4 (50%)
Cutaneous (n=94)	5 (5%)	32 (34%)	5 (100%)
Respiratory (n=26)	9 (35%)	17 (65%)	3 (33%)
Digestive (n=11)	0	1 (9%)	0
Others* (n=2)	2 (100%)	1 (50%)	1 (50%)
Total (n=267)	78 (29%)	92 (34%)	21 (27%)

Data are number (%). *Including one peritoneal dialysis incident and one neurological incident.

Table 2: **Distribution of severe and preventable iatrogenic events by category**

report any awareness of an incident that did or could potentially affect patient safety.

To improve data collection, a single and independent observer (a physician) visited the ward 2 days a week to detect or add additional incidents to the baby's form.[14] The physician was allowed to complete additional clinical data about the incident by discussing with the staff member involved.

Review process

Two paediatricians independently reviewed the suspected iatrogenic event, confirmed the diagnosis, and rated its severity and preventability at the end of the study. In case of disagreement between these paeditricians, a third paediatrician reviewed the event. Preventability of the iatrogenic event was rated with a 6-point Likert scale.[6,15] A score of 4 or higher was needed to assign preventability. Inter-rater judgments were compared for level of agreement with use of the κ statistic for severity (0·94) and preventability (0·84).

During the study, the group worked out organisational measures to prevent incident recurrence. Every second month, rates were discussed by the group and measures were decided by consensus. Emergency measures were immediately enacted. A staff meeting was organised every 4 months with the nursing and medical team to discuss the rates and measures.

Statistical analysis

We calculated rates of iatrogenic event, preventable iatrogenic event, and specific rates per 1000 patient days, per 1000 catheter days, or per 1000 ventilation days. Data are given as median (IQR), or frequency (percentages) as appropriate. We analysed categorical variables with the χ^2 test (or Fischer's exact test if the expected value was less than 5). Median's test was used to compare medians in two populations (with no normality of variables). We did logistic regression analysis to establish the significant risk factors associated with iatrogenic events, using patients with an iatrogenic event as the dependent variable and various potential risk factors (birthweight and gestation, duration of ventilation or central venous catheter, length of stay) identified by univariate analysis (with p<0·25). Odds ratios (95% CI) were calculated. A p value less than 0·05 was regarded as statistically significant. For statistical analysis we used the statistical package SPSS version 11.5 (SPSS Inc, Chicago, Illinois, USA).

Role of the funding source

There was no funding source for this study. All contributors had full access to all the data in the study and the corresponding author had final responsibility for the decision to submit for publication.

Results

388 neonates were admitted to the study, with a total of 10 436 patient days. Table 1 shows the characteristics of the study population. Of the 388 patients admitted, 116 had one or more iatrogenic event, and 56 of these 116 patients had more than one event. In total, 267 iatrogenic events were detected. The incidence of iatrogenic events was 25·6 per 1000 patient days. 92 (34%) were preventable, resulting in a preventable iatrogenic event incidence of 8·8 per 1000 patient days. 78 (29%) iatrogenic events were severe; two (1%) were fatal but neither was preventable. The incidence of severe iatrogenic events was 7·6 per 1000 patient days. Severe iatrogenic events were less frequently preventable than were minor events (21/78 [27%] *vs* 70/189 [37%], p=0·042).

Table 2 shows the distribution, severity, and preventability of the categories of iatrogenic events. Cutaneous events and nosocomial infections were the most common, and nosocomial infections and respiratory iatrogenic events were the most severe (p<0·0001; table 2). Respiratory and adverse drug events were significantly more often preventable (p<0·0001) than were other categories—half of severe adverse drug events were preventable (table 2). Vascular line occlusion and thrombosis were the most frequent vascular iatrogenic events (12 [32%]), followed by extravasation of infusion solute (seven [18%]) and accidental loss of vascular access (seven [18%]). In seven of eight cases, extravasation occurred with catheter placed more than 3 weeks previously in babies with very low birthweight.

The incidence of medication errors was 4·9 per 100 admissions. The most frequent errors were administration errors, almost all of which were programming mistakes of pumps. Sedative and cardiovascular drugs were most commonly involved in medication errors, followed by fluids and electrolytes (data not shown). Ten-fold drug dosing errors were frequent (cause of medication errors nine of 19 [47%]).

Cutaneous injury occurred in 94 (24%) patients. Peripheral catheter-related lesions were most frequent cause of cutaneous injury (31 patients [33%]) followed by respiratory prosthesis-related lesions (23 patients

	All patients			Patients with at least one IE					
	With IE	Without IE	p value	>1 IE	1 IE	p value	Severe	Minor	p value
Total	116	272		56	60		48	68	
Sex									
Female	53 (46%)	114 (42%)	0·4914	28 (50%)	25 (42%)	0·3679	23 (48%)	30 (44%)	0·6858
Male	63 (54%)	158 (58%)		28 (50%)	35 (58%)		25 (52%)	38 (56%)	
Birthweight (g)									
≤1250	62 (53%)	27 (10%)	<0·0001	39 (70%)	23 (38%)	0·0033	34 (71%)	28 (41%)	0·0064
1251–2499	41 (35%)	140 (52%)		13 (23%)	28 (47%)		10 (21%)	31 (46%)	
≥2500	13 (11%)	105 (38%)		4 (7%)	9 (15%)		4 (8%)	9 (13%)	
Gestational age (weeks)									
≤28	39 (34%)	14 (5%)	<0·0001	28 (50%)	11 (18%)	0·0030	24 (50%)	15 (22%)	0·0074
29–32	44 (38%)	47 (17%)		18 (32%)	26 (43%)		16 (33%)	28 (41%)	
33–37	22 (19%)	116 (43%)		7 (13%)	15 (25%)		4 (8%)	18 (27%)	
≥38	11 (10%)	95 (35%)		3 (5%)	8 (13%)		4 (8%)	7 (10%)	
Small for gestational age	20 (17%)	39 (14%)	0·4748	13 (23%)	7 (12%)	0·0999	38 (79%)	58 (85%)	0·3895
Appropriate for gestational age	96 (83%)	232 (86%)		43 (77%)	53 (88%)		10 (21%)	10 (15%)	
Length of stay (days)	36 (20–66)	9·5 (3–22)	<0·0001	63 (33–105)	28 (15–47)	0·0003	58 (34–99)	31 (20–55)	0·0005
Durations of exposure to invasive procedures (days)									
Central catheter	25 (18–40)	14 (9·5–21)	<0·0001	37 (20–57)	23 (12–30)	0·0049	36 (23–55)	23 (13–40)	0·1148
Umbilical catheter	4 (3–4)	3 (3–5)	0·6129	4 (3–5)	4 (3–4)	0·9714	3 (3–5)	4 (3–5)	0·4773
Mechanical ventilation	4 (1–19)	1 (0·3–3·0)	0·0021	20 (6–31)	3 (2–8)	0·0039	8 (2–22)	2 (1–9)	0·1118
CPAP support	8 (3–25)	2 (1–4)	0·0076	7 (2–24)	2 (1–9)	0·0001	19 (4–29)	4 (2–20)	0·0019

Data are number (%) or median (IQR). CPAP=continuous positive airway pressure. IE=iatrogenic event.

Table 3: **Occurrence, number, and severity of iatrogenic events according to patient characteristics**

[24%]). Necrosis represented 16/94 (17%) of the lesions (four per 100 admissions). Eight of 16 (50%) were related to extravasation of fluids from peripheral venous catheters and five of eight (63%) occurred in neonates who were older than 32 weeks. The incidence of necrosis was 2·7 per 1000 CPAP days and 4·5 per 1000 mechanical ventilation days.

Low gestational age and low birthweight were significantly related to iatrogenic events (p<0·0001)—the lower the gestational age, the higher the risk of occurrence of iatrogenic events (table 3). Compared with full-term neonates, the odds ratio (OR) for occurrence of iatrogenic events was 24·1 (95% CI 10–57·6, p<0·0001) for premature infants born at less than 28 weeks of gestation and 8·1 (3·8–17·1, p<0·0001) for those born between 29 and 32 weeks. The risk was not increased for babies born between 32 and 37 weeks compared with full-term neonates (OR 1·6, 0·7–3·5, p=0·211). Patients who had an iatrogenic event were also more likely to have an increased length of stay, duration of vascular catheter, and mechanical ventilation or CPAP support (table 3). When birthweight was less than 1500 g, a higher score on the clinical risk index for babies was associated with a higher risk of occurrence of iatrogenic event (p<0·0001; data not shown). Extremely low gestational age (p=0·0030), low birthweight (p=0·0033), a longer length of stay (p=0·0003), a longer duration of respiratory support (CPAP; p=0·0001) or conventional ventilation (p=0·0039), and a longer duration with indwelling central (but not umbilical) catheter (p=0·0049) were associated with more than one iatrogenic event during admission. Patients with at least one severe iatrogenic event had a significantly higher length of stay (p=0·0005) and were smaller (p=0·0064) than those who had at least one minor iatrogenic event; these data were independent from sex (p=0·686), intrauterine growth retardation (p=0·390), or score on clinical risk index for babies (p=0·356). Preventability was independent of all variables tested. After logistic regression analysis, which was undertaken to adjust for significant differences of variables associated with the outcome of an iatrogenic event but which excluded invasive procedures, birthweight less than 1250 g (OR 5·2, 2–13·7, p=0·0004) and length of stay (OR 1·04, 1·02–1·06, p<0·0001) were associated with the occurrence of an iatrogenic event.

Discussion

Our study has shown that a substantial proportion of neonates admitted to hospital had iatrogenic events, a significant proportion of which were preventable. The most severe iatrogenic events were nosocomial infections and respiratory events. Cutaneous injuries and medication errors were common, but generally minor. We identified the major risk factors of iatrogenic events as low birthweight and gestational age, use of a central venous line, and mechanical ventilation.

Kanter and colleagues'[7] and Brennan and co-workers'[4] retrospective studies based on ICD-9 have suggested that medical errors were a fairly rare event occurring in less than 1·5% of discharges in premature neonates. There might be several reasons for our higher reporting rate. First, the definition of iatrogenic event used in this study could have been more inclusive, since it focused on incidents rather than complications, and we reported minor incidents, even in the absence of injury. Indeed, we regarded all adverse events related to care—in the presence or the absence of injury to the patient—as iatrogenic, without judgment of fault. Similar to Frey and colleagues,[17] we believe that minor but repeated incidents are due to system failures. With use of this definition, Frey and co-workers also reported a high incidence of 45 critical incidents per 100 neonatal admissions in their multidisciplinary neonatal and paediatric intensive-care unit. Sharek and colleagues' cross-sectional study[18] showed an incidence of 74 adverse events per 100 patients. Second, our study is a prospective study, which seems the best method to identify preventable events.[14,19] Undoubtedly, medical errors are under-reported in administrative databases, and iatrogenic events without injury or with minor results cannot be detected this way. Third, we used a trigger-based method (ie, a list of typical iatrogenic events was included in the reporting form) that is more efficient than is an unfocused report.[18] Lastly, we chose to use a non-punitive, anonymous, and voluntary reporting system. This choice of approach has been shown to be efficacious and better than other methods: it encourages and improves the report.[8,17] Like Frey and co-workers, we noted a high incidence of iatrogenic events because of an exhaustive definition and a prospective and stimulating reporting system.

This study allows the cause, severity, and preventability of iatrogenic events in neonatology to be defined. A third of all iatrogenic events and more than a quarter of severe iatrogenic events were preventable. Iatrogenic events seem to be less preventable in neonates than in adults and children, in whom 40–60% of adverse events are preventable.[3,20] The most commonly reported preventable iatrogenic events were respiratory and drug events. Accidental drain withdrawals and unplanned extubations were frequent, although unplanned extubations (six per 1000 ventilation days) were less frequent than have been described elsewhere.[17,21,22] As in previous studies, medication errors were common, whereas adverse drug events that resulted from medication errors were fairly infrequent.[5,23] Moreover, ten-fold medication errors were frequent, which many investigators have shown to be potentially dangerous.[5,24,25] Since the neonatal intensive-care unit does not have a pharmacist, prescriptions were not checked before drug administration. However, dosing errors were not due to prescription errors, but were mainly related to errors in the programming of flow rates of electric infusion pumps. However, although ten-fold dosing errors represented nearly half of medication errors in our study, they seldom resulted in adverse events. Just less than a third of iatrogenic events were considered to be severe, which is similar to the findings of Frey and colleagues.[17]

Nosocomial iatrogenic events were the most severe. Nosocomial infections are a major problem in neonatal units, especially in infants of very low birthweight. Although a few of these infections might be endogenous, efforts should focus on prevention since around 15% of these iatrogenic events in our study could have been prevented. Our study shows that cutaneous injuries were the most common iatrogenic adverse event recorded in neonates. Although skin necrosis was rare, scars constituted a severe and significant event with aesthetic and sometimes functional troubles.[26]

We noted that several factors were associated with increased rates of iatrogenic events. An inverse relation was recorded between birthweight and the rate, multiplicity, and severity of iatrogenic events. As expected, patients with the lowest birthweight who require complex interventions and substantial physiological support and invasive procedures are more likely to have iatrogenic events than are those whose birthweight is higher.[18] Limitations of invasive procedures for premature neonates should be a priority, since such procedures frequently induce comorbidity, whereas the complications (and mortality) directly due to preterm birth keep decreasing. By contrast with the findings of Kanter and co-workers,[7] we did not note that male gender was a risk factor for iatrogenic events. Furthermore, we noted no increased occurrence of iatrogenic events in infants who were small for gestational age. Conversely, we reported an association between the incidence of iatrogenic events, their multiplicity, their severity, and length of stay. However, whether the occurrence of iatrogenic events is a cause or result of length of stay cannot be clearly established.

There are several limitations in this study that need to be considered. First, the study is limited to one centre, and results may not be generalised to other neonatal level 3 centres. Nevertheless, we have shown a trend towards a high incidence of iatrogenic events in neonatal units and specific characteristics such as the high incidence of cutaneous injury. Second, this study may not be exhaustive and iatrogenic events, particularly minor incidents, could have been under-reported. This limitation could have been because of the voluntary reporting system. Moreover, some iatrogenic events, especially adverse drug effects, might have been unnoticed. However, we recorded a steadily increasing rate throughout our study, which could have been related to better identification of iatrogenic events during the study, as well as an increasing commitment of the medical and nursing staff, and parents and family members understanding the importance of such reporting to

improve quality of care. After the first 4 months of the study, a plateau was reached in the number of reported iatrogenic events (although this result was not statistically significant). We therefore cannot exclude the possibility of bias due to under-reporting during the first part of our study. Overestimation of severe iatrogenic events might characterise this study, since minor iatrogenic events are less easily detected than are serious events and are therefore under-reported because of less consideration. Third, the incidence of rare iatrogenic events might have been underestimated because of the short time period of our study. Lastly, we were surprised that iatrogenic events were often reported by the nursing staff. We assume that medical errors were under-reported. Clearly, reports of iatrogenic events by both doctors and nurses are not similar, but are complementary. We thus believe that reporting by both is necessary to limit under-reporting or over-reporting of particular categories of iatrogenic events.

Classification bias could also have affected our findings for preventability and severity of iatrogenic events, since we used expert clinical judgment and consensus to classify incidents. However, correlation between both expert findings was high.

Our high reporting rate shows the efficacy, acceptance, and feasibility of a prospective, anonymous, and non-punitive reporting system. We obtained an estimation of baseline rates and epidemiology of iatrogenic events in our unit. This prospective method will allow the effect of prevention strategies to be assessed, by use of a continuous monitoring method. The next step in creation of a safer environment is the development of targeted interventions for patient safety, and analysis of events to establish timing and causality is crucial. The prospective reporting and non-punitive system used in the study was based on the participation and motivation of the entire staff in a collaborative and non-hierarchical process. Such sensitisation (ie, making staff more sensitive to the importance of reporting iatrogenic events) cannot be obtained with a data-based or cross-sectional reporting system. The reporting system we used creates a real group dynamic, which helps with implementation of the report, increases communication between nurses and physicians, and develops a culture of prevention for iatrogenic events. The critical incident report can be used as an educational process and can be seen as a positive means to improve quality of health care, as shown by Ahluwalia[27] and others.[28] The prospective reporting system has many advantages: effectiveness in identification of preventable events, reliability of judgments on the iatrogenic nature of events, paedagogical virtues (ie, didactical or educational virtues), appreciation of chains of events, and a real red-flag role (ie, a warning system) for care providers. The workload, even if heavier than other methods of estimation of iatrogenic events, is in our opinion acceptable.[19]

The high risk of iatrogenic events draws attention to the importance of developing, testing, and implementing effective error-prevention strategies in paediatric medicine. Prospective, anonymous incident reporting offers both a means to monitor and prevent iatrogenic events, and an educational advantage to staff. Reduction of the rate of iatrogenic events in vulnerable, neonatal patients should be one of the main aims in providing best possible quality of health care for children.

Contributors

IL and FA contributed to the design of the study, did data collection, and contributed to data analysis. IL wrote the first draft of the report and its revised version. EJ designed and did the statistical analysis. ST and RS set the methods and contributed to the organisation, in the neonatal division, of the study itself as well as the quality improvement programme the study is part of. US contributed to the study design and supervision, and to the final writing of the report.

Conflict of interest statement

We declare that we have no conflict of interest.

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