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Title Page

Prevalence and severity of patient harm in a sample of UK hospitalised

children detected by the Paediatric Trigger Tool.

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Prevalence and severity of patient harm in a sample of UK hospitalised children detected by the Paediatric Trigger Tool.

Abstract

Patient safety is the now a key priority of health care. The measurement and examination of adverse events that occur to children during hospital admissions is essential if we are to prevent, reduce or ameliorate the harm experienced. The UK Paediatric Trigger Tool (UKPTT) is a method for measuring harm in hospitalised children.

Objectives

To examine the rate and nature of harm in hospitalised children from centres providing data to the NHS Institute UKPTT data portal, to understand the positive predictive values of triggers, and to make recommendations for the use and further development of the trigger tool.

Results

Data from 3992 patient admissions were reviewed from 25 hospitals and submitted to the trigger tool portal from February 2008 to November 2011. The hospitals included secondary, tertiary and quaternary centers. At least one adverse event (AE) was reported for 567 (14.2%) patients, with 211 (5.3%) experiencing more than one event. There were 1001 adverse events identified. Where harm occurred it was considered temporary for 923 (92.2%) AEs, however 43 (4.3%) AEs resulted in the need for life-sustaining interventions, 18 (1.8%) AEs led to permanent harm and for 17 children (1.7% of AEs) the AE was believed to have contributed to death. The positive predictive values (PPV) for the triggers ranged from 0 to 80%.

Conclusions

There is a significant, measurable level of harm experienced by children admitted

to hospitals in the UK. While most of this harm is temporary, some is serious.

The UKPTT offers organisations the means to measure and examine the

adverse events occurring in their hospital in order to reduce harm.

Article Summary

Article Focus

Trigger tool review is a method applied to the examination of medical records that facilitates the identification and measurement of harm that occurred from the delivery of care. This knowledge can be used to learn about harm and to identify and monitor interventions that might prevent, reduce or ameliorate adverse events (AE).

The purpose of this study was to estimate the rate of harm (AE per admission) occurring to children during admission to hospital in the UK. The study also set out to learn about the outcomes of these AEs and the usefulness of each trigger, calculating their positive predictive values (PPV).

Summary

The study examined harm as detected by a recently developed paediatric trigger tool in 3992 patient admissions across 25 paediatric centres in secondary, tertiary and quaternary care settings in the UK.

At least one AE was reported for 14.2% of patients, with 5.3% experiencing more than one event.

Where harm occurred it was considered temporary for 92.2% of AEs however for 3.5% of AEs it was associated with permanent injury or death.

Strengths

Trigger tool methodology is proven to be a sensitive and efficient means of detecting harm. This study examines a large number of admissions across multiple care settings and provides important information about the extent and nature of harm experienced by children during hospital care. This information will stimulate discussion about medical harm in paediatrics and how it can be prevented or reduced.

Limitations

There was significant variation between sites regarding the detection of harm. This reflects the primary purpose of the trigger tool review, which is to help local teams learn about the harm in their organisation rather than being a method for benchmarking between organisations.



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Introduction

Providing care that is safe and reliable are fundamental goals of modern healthcare. Patient safety is the prevention, reduction and amelioration of medical harm [1, 2]. Medical harm (synonymous with the terms patient harm and adverse event, AE) is defined as unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment or hospitalisation, or that results in death [3]. Efforts to improve patient safety have been hampered by a lack of reliable data on the prevalence and nature of harm in all areas of practice. Patients and healthcare professional need to understand the burden of harm in healthcare in order to develop effective interventions[4].

The complexity of uncovering harm is reflected in the numerous ways that one has to measure it [5]. Traditional methods such as incident reporting, have limitations, especially that of underreporting, due to the reliance on individual clinicians to recognise and report adverse events, as well as a tendency to focus on error, rather than harm. The measurement and examination of harm, rather than that of error, recognises that efforts to improve patient safety benefit from focusing on incidents that result in actual harm, identifying high risk situations, considering preventability and looking for means of early detection and harm limitation[6]. This deeper understanding of the harm to which patients are exposed is a recent phenomenon and in paediatrics the potential risks to safety are multiple [7]. The call for Zero Harm and the focus on safety in recent reports [8,9], reflects the importance of the identification and understanding of harm as an essential part of patients care. Clinicians have not known the actual levels of harm caused and have relied on a reporting system for clinical incidents. In this

paper we assess the introduction of the UK Paediatric Trigger Tool, which aims to provide clinicians with a methodology to detect of harm and facilitates the development of interventions to decrease identified harm and provide safer care.

Measurement of harm is a complex task and requires a number of different methods. Harm rates vary widely because of multiple factors such as the definition of harm used, the methodology employed and the populations selected. Until recently most studies sought to establish harm rates for benchmarking purposes over large populations with suggestions that between 3-17% of patients experience an adverse event during a hospital admission[10]. Most of these studies used retrospective, unstructured case note reviews which are labourintensive, costly and impractical for the routine monitoring of harm[11]. Trigger tool methodology is accepted as one of the ways to measure harm in a way that allows local learning[1, 3, 12]. Trigger tools have also been reported to provide consistent reliable and relevant data at low cost [3,12], although the cost may vary between different hospitals.

Development of the Trigger Tool methodology

The Global Trigger Tool (GTT) was developed by the Institute for Healthcare Improvement (IHI) for use in adult care settings [3]. Triggers tools have also been developed for specific populations and settings, including acute hospitals, surgery [13], critical care [14] and primary care [15]. One study used the GTT to measure harm at a large academic children's hospital in the USA and recommended the development of a paediatric specific tool [16]. Paediatric specific trigger tools have been developed for neonatology [17], paediatric

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critical care [18, 19] and medications [20, 21] and a trigger tool for harm in hospitalised children was developed in Canada [22]. A UK version of the acute adult GTT had already been developed but this was not applicable to a paediatric population. In 2008, the NHS Institute for Innovation and Improvement undertook to develop a UK paediatric trigger tool that could be applied to all levels of acute paediatric care.

Trigger tool Method for reviewing case notes.

The trigger tool method consists of a retrospective review of a 20 sets of medical records each month using a standardised methodology. A random sample of 20 in-patient case notes is selected using a randomisation matrix on a monthly basis. The medical record is examined in a structured process for 20 minutes to search for "triggers". A "trigger" is a predefined event that alerts the reviewer to the possibility of patient harm. Once a trigger is identified, the reviewer uses clinical expertise to examine the records in more detail to understand the circumstances around the event. If harm is suspected a second reviewer (usually a physician) is consulted to confirm and grade the adverse event using the NCC MERP grading system [23]

An example of a trigger is the administration of the antidote medication naloxone (a trigger) to reverse the effects of opiates. This alerts the reviewer of a possible overdose of opioids. The reviewer examines the relevant parts of the healthcare record to assess whether the use of naloxone was for this reason or not. If this is the reason then the harm is graded.

Development of the UK PTT

The NHS Institute sponsored the development of a paediatric trigger tool based on the preliminary findings from the Canadian pediatric trigger tool [22] and the UK Acute Trigger Tool [24]. The development was a co-production involving the collaboration of patient safety experts from the NHS Institute, international leaders in paediatric trigger tool development and clinical experts from nine UK hospitals including children's hospitals and district general hospitals. Following discussion and testing the group agreed on 40 paediatric oriented triggers to be included in the UKPTT. These were based on the triggers used in other tools, UK evidence of adverse events and the experience of the reference group in harm and adverse events (a subset of the co-production group). The UK tool was developed to increase ownership by clinicians who would use it. The Canadian tool had not been published and no other paediatric trigger tools were available.

The UKPTT advocates a working definition of patient harm as "*anything, which you would not like to happen to yourself or a member of your family as a result of, or contributed to by, medical care*". The decision to aim for a broad definition was to focus on the patient rather than on the medical system – a less defensive approach. This is a broader definition than that given by Griffin et al [3] and aimed to encourage clinicians to explore a holistic concept of harm than that traditionally reported. It allows the inclusion of acts of omission as well as commission. The definition include missed or delayed diagnosis along with physical and psychological harm, which could be identified by additional triggers.

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Through the coproduction support was developed for UK PTT users such as face-to-face training, on line and printed guidance and standardised data collection forms. The tool and guidance for its use remains freely available at www.institute.nhs.uk/paediatrictriggertool or from the authors.

Data Collection

As part of the UKPTT development, the NHS Institute created a web-based trigger tool portal into which participating hospitals entered anonymised data. The portal calculated harm rates and produced run charts that hospitals could download. Contributing hospitals consented to their data being collated and published to further the understanding of harm in hospitalised children in the UK. Participating hospitals developed local administrative and governance arrangements for PTT reviews following the standard guidance.

Aims and methodology

The aims of this study are to:

- Describe the rate and severity of harm occurring in hospitalised children from UK centres submitting data to the NHS Institute's Trigger Tool portal.
- Report the frequency and positive predictive value (PPV) of triggers to detect harm.
- Make recommendations for further application and development of the tool.

Participating hospitals, which included secondary, tertiary and quaternary centers, were trained in trigger tool methodology either by experts at the NHS

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Institute or by using on-line resources with telephone support. Data was collected through the on-line trigger tool portal.

Results

Data from 3992 case note reviews from 25 hospitals submitted to the trigger tool portal between February 2008 and November 2011 were analysed. Nine hospitals were children's hospitals; the remainder were classed as district general hospitals. Data from four additional hospitals that used the portal were excluded because they each submitted less than 10 case entries. Harm was recorded as occurring for 567 patients (14.2%) while the majority (85.8%) of patients experienced no evidence of harm. Reviewers identified 1001 adverse events, an average of 1.8 events per patient experiencing harm.

There was considerable variation between hospitals in the number of case notes reviewed (12 - 622), the number of triggers detected (17 - 1877) and overall harm rate reported (0% - 100%). Results from each hospital are reported in Table 1. Of the 567 children who suffered an AE, the majority (n=356, 63%) experienced a single event. However 211 (37%) of patients suffered more than one AE within the same admission. One patient was reported to have suffered 10 AEs in a single admission. A summary of the number of adverse events per case is presented in Table 2.

Individual triggers varied in their ability to lead to detection of harm. The trigger *Complications of procedure or treatment* yielded the greatest amount of harm (182 AEs). The PPV varied from 80.0% for *surgical site infection* to 2.62% for

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missing observations/early warning scores. The PPV was generally low in frequently identified triggers, such as *missing observations/early warning scores* (PPV 2.6%) and *unplanned admission* (PPV 4.0%). The positive triggers, adverse events and PPV for each trigger are displayed in Table 3.

The majority of adverse events (n=923, 92.2%) resulted in temporary harm to the patient (grade E and F – see Table 5 [23]), 43 AEs required life-sustaining interventions and 18 resulted in permanent harm. In 17 cases, the adverse event was believed to have contributed to the child's death (Table 4).

Discussion

This paper represents the largest report of paediatric harm using trigger tool methodology in the United Kingdom. Whilst the primary purpose of a trigger tool is to gain local data for understanding harm in order to improve patient safety locally, we can learn about harm by examining the pooled experiences of the contributing hospitals. The ability to capture, measure and view the results of case notes review using the PTT on a routine basis is a cost effective method of data capture and analysis and of significant value to individual hospitals.

The overall harm rate (the percentage of children experiencing one or more AEs during an admission) identified in this study was 14.2%. Previous studies focusing on hospitalised children have identified harm rates of between 1% and 25.8% per admission for the general paediatric hospital population [6, 20, 21] and higher rates within the paediatric intensive care population of 26.1% to 62% [18,19,26]. Two recent studies have examined harm in paediatric hospital

populations using trigger tool methodology. The Canadian Paediatric Trigger Tool (CPTT) [25] found a physician reported harm rate of 15.1% of admissions during a validation study across six paediatric hospitals in Canada. Like the UKPTT the CPTT has been adapted to make triggers more sensitive and specific to paediatric situations. The second study, at a single paediatric academic medical center in the US using the adult Global Trigger Tool (GTT) found an overall harm rate of 25.8% [16].

Variation in harm rates may reflect a number of factors. Different methodologies yield different rates of AE identification. Trigger tools are reported to yield higher rates of AE identification than traditional methods such as self-reporting and unstructured case note review [1,26]. Definitions of harm vary as do their interpretation. Professional groups may interpret AEs differently [25]. Assessments of inter-rater reliability have reported high levels of agreement between review team members [16,27,28], but variability between different hospital departments teams [29]. In addition some organisations or teams set a lower threshold for what they see as harm and they may change this over time. Finally, different populations are exposed to different levels of harm depending on the complexity of their illness and the intensity and duration of their care[20]. Most studies report a harm rate per admission meaning that longer admissions are more exposed to opportunity for harm.

The same reasons that explain the variation between international studies explain much of the variation between hospitals in this study. Training was provided but no independent assessment was made of reviewer's interpretations

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or competence. The extremes of harm reported or its absence were seen in hospitals uploading low volumes of reviews and may be interpreted as the relative inexperience of the reviewers [30]. There is also a wide variety across the level of hospital represented with the corresponding impact on risk due to patient complexity, need for surgery or critical care and length of stay.

One could ask whether this level of variation diminishes the findings of the study. On the contrary, we believe it represents a real portrayal of complex issues. It is also a taste of what individual organisations can expect if they start to use the PTT to help understand and reduce the harm in their institution. They will need to consider all of these issues as they interpret their own findings.

The majority (92.3%) of AEs identified in this study represented temporary harm resulting in the child either requiring an intervention, admission to hospital or prolongation of their hospital stay. Whilst severe harm (permanent harm or harm that requiring life sustaining measures or contributed to death) was rare, it still constituted 7.8% of harm identified. Similar findings with respect to severity have been reported with 10% of AEs classified as severe in one study of harm in PICU [18]. A study of AEs in hospitalised children reported that clinicians do not always recognize harm, even when the consequences to the child are severe [31]. In this study multiple AE were relatively common, with 37% of those experiencing harm suffering two or more AE in the same admission, far higher than previous studies [16,25].

Triggers varied in their positive predictive values for AEs. Screening for triggers is the key task of the trigger tool method. Triggers that infrequently identify harm could be removed to increase the efficiency of the tool. Some triggers may be important markers of care quality, such as the *missing /incomplete early warning score or baseline observations* despite the inability of the trigger to identify specific patient harm [32]. This will influence the next iteration of the trigger tool as we refine the triggers and consider taking out some of those that had a low PPV.

A number of studies have examined the possibility of automated trigger detection from electronic medical records which may make the process easier [21,33]. We believe that there is value in the manual approach, and that it will be some time before hospitals in the UK are converted to electronic medical records. Users of the UKPTT have expressed to us the benefits of having an opportunity to examine the quality of medical and nursing note keeping and observations, which in some centers has resulted in initiatives to improve these elements.

Limitations

There are a number of limitations to this study. Although the methodology is standard, we did not attempt to revalidate it. The UKPTT differs from other trigger tools only in the constituent triggers. This study has provided PPVs for the 40 triggers included in the UKPTT, which may be used to consider changes to the trigger profile. Other triggers may be more useful and could be tested for future versions of the tool.

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The determination of inter-rater reliability may be important within departments but not necessarily between hospitals. The UKPTT is not recommended for benchmarking as the focus is on developing data for improvement rather than data for judgment [34]. The methodology recommends consistency in the reviewing teams so that intra-reliability is not an issue [35]. We did not attempt to standardise the method of PTT data collection outside of the support provided and the recommendation on randomisation. Individual institutions made their own arrangements in terms of choosing and training reviewers. There were no checks of competence of reviewers or inter-rater reliability or of the accuracy of the data entered via the portal.

Strengths

Parry et al [36] note that the approach should be to look at all harm not only preventable harm. We believe every AE provides insight for improvement, whether deemed preventable or not [18].

We did not attempt to find out how many of these AE were detected through other methods such as incident reporting (we expect that many were). The purpose of the UKPTT is to extend the ability to detect harm rather than replace other approaches.

Conclusions and recommendations

In the context of the increasing demands to improve quality and safety for patients, the UK PTT provides a framework for paediatric clinicians to assess the rate of harm for their individual units, and the quality of their record keeping. This study highlights that currently there is a significant, measurable level of harm, which is sometimes severe, experienced by children admitted to hospitals in the UK. There is a range of predictive values for the triggers and some may be more useful than others. These findings will inform future modifications of the PTT including modifying or removing triggers. It will be important to test any new or augmented triggers with paediatric teams to assess their usefulness.

The recognition and examination of adverse events through methods such as the UK PTT offers the potential to improve paediatric patient safety by concentrating efforts on strategies that reduce patient harm, rather than errors. The key is to produce information that promotes learning and improvement with clinicians accepting their role to decrease harm from the perspective of the patient rather than that of the healthcare provider.

We recommend that the UK PTT be used routinely in hospitals to assess harm and to help develop improvement interventions to reduce it. Although the PTT has been mainly used in children's hospitals, it can be used in District General or community hospitals with a different spectrum of harm being detected. The UK PTT does not replace other reporting mechanisms but is a useful addition to the methods already used to understand the harm caused to children in hospital care. Harm needs to be detected and assessed through a number of lenses and this lens allows clinicians to further understand what they do and how it impacts

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on children. It provides a way to move from a reactive approach to safety to one that is more proactive and founded in harm free care.

Susan Chapman and John Fitzsimons are joint first authors

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Competing Interest:

None known.

Table 1: Number of case reviews, positive triggers and adverse events by individual hospital

Hospital	Case notes reviewed	Positive triggers	Average number of triggers per case note review	Adverse events	Average number of AE per case note review	Number of individual patients harme
Å	622	1877	3.02	309	0.50	. 162
В	369	579	1.57	66	0.18	31
С	321	415	1.29	60	0.19	37
D	309	481	1.56	117	0.38	49
E	285	414	1.45	84	0.29	43
F	271	454	1.68	112	0.41	54
G	260	484	1.86	48	0.18	39
Н	241	418	1.73	6	0.02	4
	195	432	2.22	14	0.07	14
J	195	52	0.27	3	0.02	3
К	190	446	2.35	45	0.24	40
L	124	173	1.40	17	0.14	15
Μ	71	52	0.73	0	0.00	0
Ν	70	171	2.44	8	0.11	7
0	68	141	2.07	8	0.12	7
Р	68	107	1.57	1	0.01	1
Q	66	79	1.20	15	0.23	11
R	62	84	1.35	15	0.24	12
S	60	121	2.02	32	0.53	15
Т	59	90	1.53	2	0.03	1
U	23	22	0.96	4	0.17	3
V	19	14	0.74		0.05	1
W	17	26	1.53	4	0.24	4
X	15	50	3.33	27	1.80	11
Y	12	17	1.42	3	0.25	3
Overall	3992	7199	1.65	1001	0.26	567
				1001	0.20	

Table 2: Number of adverse events per patient

7 8	Number of AE per case	Number of Patients (n= 3992)	% of patient who suffered harm (n=567)
9 10	0	3425	N/A
11	1	356	62.8%
12	2	111	19.6%
13 14	3	40	7.0%
15	4	28	4.9%
16	5	16	2.8%
17	6	8	1.4%
19	7	5	0.9%
20	9	2	0.4%
∠1 22	10	1	0.2%

Table 3: Trigger descriptors, AE and positive predictive value

Trigger Code	Trigger description	Adverse events	Positive Triggers	Severity of harm			Trigger PPV		
				Е	F	G	Н	1	
PG8	Complication of procedure or treatment	182	257	99	63	6	11	3	70.8%
PG3	Readmission to hospital within 30 days	107	462	36	68	0	1	2	23.2%
PG2	Tissue damage or pressure ulcer	81	250	66	12	0	1	2	32.4%
PG4	Unplanned admission	68	1668	23	41	0	3	1	4.1%
PO1	Other (specify)	60	425	48	10	0	1	1	14.1%
PS3	Surgical site infection	48	60	24	22	0	1	1	80.0%
PM5	Anti-emetic given	41	507	40	1	0	0	0	8.1%
PG10	Hypoxia O ₂ sat <85%	36	157	31	2	3	0	0	22.9%
PG1	EWS or baseline observations missing/incomplete or score/observation requiring response	35	1362	26	8	0	1	0	2.6%
PG9	Transfer to higher level of care (inc admission to specialist unit, ICU/HDU)	35	273	15	14	0	5	1	12.8%
PS1	Return to theatre	33	75	15	15	2	1		44.0%
PM7	IV Bolus ≥ 10ml/kg colloid or crystalloid given	31	386	22	5	1	1	2	8.0%
PG11	Cancelled elective procedure/ delayed discharge	24	55	10	12	1	0	1	43.6%
PL14	Positive blood culture	23	55	18	4	0	1	0	41.8%
PL13	Nosocomial Pneumonia	21	28	8	10	0	2	1	75.0%
PL5	Na ⁺ <130 or >150	14	71	12	1	0	1	0	19.7%
PG5	Cranial Imaging	10	141	4	2	3	0	1	7.0%
PL8	Hyperglycaemia (>12mmol/l)	11	65	10	1	0	0	0	16.9%
PS2	Change in planned procedure	11	37	6	5	0	0	0	29.7%

PL3	Abrupt drop in Hb or Hct (>25%)	10	65	9	1	0	0	0	15.4%
PM8	Abrupt medication stop	10	52	8	2	0	0	0	19.2%
PL8	Hypoglycaemia (<3mmol/l)	10	46	9	1	0	0	0	21.7%
PL9	Drug level out of range	10	32	8	2	0	0	0	31.3%
PL6	K ⁺ <3.0 or >6.0	9	69	8	0	0	1	0	13.0%
IP1	Readmission to ICU or HDU	9	16	5	1	0	3	0	56.3%
PS4	Removal/Injury or repair of organ	9	43	3	5	1	0	0	20.9%
PG6	Respiratory/Cardiac arrest/crash call	9	41	0	2	0	7	0	22.0%
PM5	Chlorpheniramine given	9	82	7	2	0	0	0	11.0%
PL2	Transfusion	8	143	6	1	0	1	0	5.6%
PL4	Rising urea or creatinine (>2x baseline)	6	54	4	2	0	0	0	11.1%
PL15	Thrombocytopenia	6	54	4	1	0	0	1	11.1%
PL1	High INR (>5) or APTT > 100 sec	6	31	6	0	0	0	0	19.4%
PM4	Glucagon or glucose ≥ 10% given	6	50	6	0	0	0	0	12.0%
PG7	Diagnostic imaging for embolus/thrombus +/- confirmation	4	24	2	1	1	0	0	16.7%
PM2	Naloxone given	4	16	3	0	0	1	0	25.0%
PL11	C Difficile	4	12	3	1	0	0	0	33.3%
PM1	Vitamin K given (except routine neonatal dose)	1	33	1	0	0	0	0	3.0%
PM3	Flumazanil given	0	2	0	0	0	0	0	N/A
PL10	MRSA bacteraemia	0	0	0	0	0	0	0	N/A
PL12	Vancomycin resistant enterococcus	0	0	0	0	0	0	0	N/A
	TOTAL	1001	7199	605	318	18	43	17	

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Table 4: Severity of Adverse Events

Grade*	Descriptor	Adverse Events	% of Total Adverse Events
E	Temporary harm to the patient and required intervention	605	60.4%
F	Temporary harm to the patient and required initial or prolonged admission	318	31.8%
G	Permanent patient harm	18	1.8%
Η	Intervention required to sustain life	43	4.3%
l	Patient death	17	1.7%
Total		1001	

• National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Index[23]

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Contributorship Statement

The authors contributed to the paper as outlined in the table below.

15							
16		Author	Contribution				
17	1	Susan Chapman	Development of paediatric trigger tool, study concept,				
10 19			data collection, data analysis and manuscript				
20			preparation				
21	2	John Fitzsimons	Development of paediatric trigger tool, study concept,				
22			data analysis and manuscript preparation.				
23	3	Nicola Davey	Development of paediatric trigger tool, study concept,				
24 25			data collection, data analysis and manuscript revision				
26	4	Peter Lachman	Development of paediatric trigger tool, Study concept,				
27			data analysis and manuscript revision				
28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44	C4 N4 D3 Th	ompeting Interests one ata Sharing here is no additional data av	ailable.				
46 47	For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtm						

Ethics

Contributing hospitals consented to their data being collated and published. Individual hospitals developed local administrative and governance arrangements for trigger tool reviews following the standard guidance.

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Title Page

Prevalence and severity of patient harm in a sample of UK hospitalised

children detected by the Paediatric Trigger Tool.

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Abstract

The measurement and examination of adverse events that occur to children during hospital admissions is essential if we are to prevent, reduce or ameliorate the harm experienced. The UK Paediatric Trigger Tool (UKPTT) is a method of retrospective case note review that measures harm in hospitalised children.

Objectives

To examine the harm resulting from the processes of healthcare in hospitalised children from centres providing data to the NHS Institute UKPTT data portal, to understand the positive predictive values of triggers and to make recommendations for the further development of the trigger tool.

Setting:

Twenty-five hospitals across the UK, including secondary, tertiary and quaternary paediatric centres.

Participants:

Randomly selected children who were admitted to hospital for longer than 24hrs.

Outcome measures:

The primary outcome measure was the rate of harm (the percentage of children experiencing one or more adverse event during a hospital admission). Secondary measures were the severity of harm and performance of triggers.

Results

Data from 3992 patient admissions were reviewed across the hospitals and submitted to the trigger tool portal from February 2008 to November 2011. At

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least one adverse event (AE) was reported for 567 (14.2%) patients, with 211 (5.3%) experiencing more than one event. There were 1001 adverse events identified. Where harm occurred it was considered temporary for 923 (92.2%) AEs, however 43 (4.3%) AEs resulted in the need for life-sustaining interventions, 18 (1.8%) AEs led to permanent harm and for 17 children (1.7% of AEs) the AE was believed to have contributed to death.

Conclusions

There is a significant, measurable level of harm experienced by children admitted to hospitals in the UK. While most of this harm is temporary, some is serious. The UKPTT offers organisations the means to measure and examine the adverse events occurring in their hospital in order to reduce harm.

Strengths:

- This study estimates that 1 in 7 children experience harm during admission to hospital in the UK. Most of this harm is temporary but a significant minority is serious. This should generate discussion about patient safety in paediatrics.
- The study used the UK Paediatric Trigger Tool that can be used by any hospital to learn about harm in order to prevent or reduce it.

Limitations

 The study does not distinguish between preventable and non-preventable harm however we believe there is an opportunity to learn from any harm event.

Introduction

The provision of care that is safe and reliable is a fundamental goal of modern healthcare. Patient safety is the prevention, reduction and amelioration of medical harm.[1, 2] Medical harm (synonymous with the terms patient harm and adverse event, AE) is defined as unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment or hospitalisation, or that results in death.[3] Efforts to improve patient safety have been hampered by a lack of reliable data on the prevalence and nature of harm in all areas of practice. Patients and healthcare professionals need to understand the burden of harm in healthcare in order to develop effective interventions.[4]

Development of Trigger Tool methodology

The Global Trigger Tool (GTT) for measuring harm was developed by the Institute for Healthcare Improvement (IHI) for use in adult care settings [3]. Triggers tools have also been developed for specific populations and settings, including acute hospitals, surgery,[5] critical care,[6] and primary care.[7] One study used the GTT to measure harm at a large academic children's hospital in the USA and recommended the development of a paediatric specific tool.[8] Paediatric specific trigger tools have been developed for neonatology,[9] paediatric critical care,[10,11] medications,[12, 13] and a general trigger tool for harm in hospitalised children,[14] A UK version of the acute adult GTT had already been developed but this was not applicable to a paediatric population. In 2008, the NHS Institute for Innovation and Improvement undertook to develop a

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UK paediatric trigger tool that could be applied to all levels of acute paediatric care.

Trigger tool Method for reviewing case notes.

The trigger tool method is a retrospective review of 20 sets of healthcare records each month, using a standardised methodology. A random sample of 20 inpatient case notes is selected using a randomisation matrix on a monthly basis. The healthcare record is examined in a structured process for 20 minutes to search for "triggers". A "trigger" is a predefined event that alerts the reviewer to the possibility of patient harm. Once a trigger is identified, the reviewer uses clinical expertise to examine the records in more detail to understand the circumstances around the event. If harm is suspected a second reviewer (usually a physician) is consulted to confirm and grade the adverse event using the NCC MERP grading system (Table 4).[15]

An example of a trigger is the administration of the antidote medication naloxone (a trigger) to reverse the effects of opiates. This alerts the reviewer to a possible overdose of opioids. The reviewer examines the relevant parts of the healthcare record to assess whether the use of naloxone was for this reason or not. If this is the reason then the harm is graded.

Development of the UK PTT

In 2008 the NHS Institute sponsored the development of a paediatric trigger tool because at the time there was no tool available for hospitalised children. The tools design was informed by the early (and pre-publication) findings of a

Canadian pediatric trigger tool study,[14] and the UK Acute Trigger Tool for adults.[16] The development was a co-production involving the collaboration of patient safety experts from the NHS Institute, international leaders in paediatric trigger tool development and clinical experts from nine UK hospitals including children's hospitals and district general hospitals. Following discussion and testing, the group agreed on 40 paediatric oriented triggers to be included in the UKPTT. These were based on the triggers used in other tools, UK evidence of adverse events and the experience of the reference group in harm and adverse events (a subset of the co-production group). Production of a UK tool was intended to enhance ownership by the clinicians, who would use it in practice and to modify triggers that were not appropriate for the UK setting. We also added a category for "other harm" to capture harm that was not detected by one of the listed triggers.

The UKPTT advocates a working definition of patient harm as "anything, which you would not like to happen to yourself or a member of your family as a result of, or contributed to by, medical care". The decision to aim for a broad definition was to focus on the patient rather than on the medical system – a less defensive approach. This is a broader definition than that given by Griffin et al[3] or the Canadian tool and aimed to encourage clinicians to explore a holistic concept of harm than that traditionally reported. It allows the inclusion of acts of omission as well as commission. The definition includes missed or delayed diagnosis along with physical and psychological harm.
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Through the coproduction, support was developed for UK PTT users such as face-to-face training, online and printed guidance, and standardised data collection forms.

Data Collection

As part of the UKPTT development, the NHS Institute created a web-based trigger tool portal into which participating hospitals entered anonymised data. The portal calculated harm rates and produced run charts that hospitals could download. Contributing hospitals consented to their data being collated and published to further the understanding of harm in hospitalised children in the UK. Participating hospitals developed local administrative and governance arrangements for PTT reviews following the standard guidance.

Aims and methodology

The aims of this study are to:

- Describe the rate and severity of harm occurring in hospitalised children from UK centres submitting data to the NHS Institute's Trigger Tool portal.
- Report the frequency and positive predictive value (PPV) of triggers to detect harm.
- 3. Make recommendations for further application and development of the tool.

Participating hospitals, which voluntarily decided to use the PTT, included secondary, tertiary and quaternary centers. Reviewers were trained in trigger tool methodology either by experts at the NHS Institute or by using on-line resources with telephone support. Data was collected through the on-line trigger tool portal that opened in Feb 2008.

Results

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 Data from 3992 case note reviews from 25 hospitals submitted to the trigger tool portal between February 2008 and November 2011 were analysed. Nine of the hospitals were children's hospitals; the remainder was classed as district general hospitals. Data from four additional hospitals that used the portal were excluded because they each submitted less than 10 case entries. Harm was recorded as occurring for 567 patients (14.2%) while the majority (85.8%) of patients experienced no evidence of harm. Reviewers identified 1001 adverse events, an average of 1.8 events per patient experiencing harm.

There was considerable variation between hospitals in the number of case notes reviewed (12 - 622), the number of triggers detected (17 - 1877) and overall harm rate reported (0% - 73.3%). Results from each hospital are reported in Table 1. Of the 567 children who suffered an AE, the majority (n=356, 63%) experienced a single event. However 211 (37%) of patients suffered more than one AE within the same admission. One patient was reported to have suffered 10 AEs in a single admission. A summary of the number of adverse events per case is presented in Table 2.

Individual triggers varied in their ability to lead to detection of harm. The trigger *Complications of procedure or treatment* yielded the greatest amount of harm (182 AEs). The PPV varied from 80.0% for *surgical site infection* to 2.62% for *missing observations/early warning scores*. The PPV was generally low in frequently identified triggers, such as *missing observations/early warning scores*

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(PPV 2.6%) and *unplanned admission* (PPV 4.0%). The positive triggers, adverse events and PPV for each trigger are displayed in Table 3.

The majority of adverse events (n=923, 92.2%) resulted in temporary harm to the patient (grade E and F – see Table 5[15]), 43 AEs required life-sustaining interventions and 18 resulted in permanent harm. In 17 cases, the adverse event was believed to have contributed to the child's death (Table 4).

Discussion

The complexity of uncovering harm is reflected in the numerous ways that one has to measure it.[17] Traditional methods such as incident reporting have limitations, especially that of underreporting, due to the reliance on individual clinicians to recognise and report adverse events, as well as a tendency to focus on error, rather than harm. The measurement and examination of harm, rather than that of error, recognises that efforts to improve patient safety benefit from focusing on incidents that result in actual harm, identifying high risk situations, considering preventability and looking for means of early detection and harm limitation.[18] This deeper understanding of the harm to which patients are exposed is a recent phenomenon and in paediatrics the potential risks to safety are multiple.[19] The call for Zero Harm and the focus on safety in recent reports,[20, 21] reflects the importance of the identification and understanding of harm as an essential part of patients care. Clinicians have not known the actual levels of harm caused and have relied on a reporting system for clinical incidents.

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Harm rates vary widely because of multiple factors, such as the definition of harm used, the methodology employed and the population studied. Until recently most studies sought to establish harm rates for benchmarking purposes over large populations with suggestions that between 3-17% of patients experience an adverse event during a hospital admission.[22] Most of these studies used retrospective, unstructured case note reviews which are labour-intensive, costly and impractical for the routine monitoring of harm.[23] Trigger tool methodology is accepted as one of the ways to measure harm in a way that allows local learning,[1,3,2] Trigger tools have also been reported to provide consistent reliable and relevant data at low cost,[2,3] although the cost may vary between different hospitals.

This paper represents the largest study of paediatric harm using trigger tool methodology in the United Kingdom. Whilst the primary purpose of a trigger tool is to gain local data for understanding harm in order to improve patient safety locally, we can learn about harm by examining the pooled experiences of the contributing hospitals.

The overall harm rate (the percentage of individual children experiencing one or more AEs during an admission) identified in this study was 14.2%. Previous studies focusing on hospitalised children have identified harm rates of between 1% and 25.8% per admission for the general paediatric hospital population,[12, 13, 18] and higher rates within the paediatric intensive care population of 26.1% to 62%.[10,11,24] Two recent studies have examined harm in paediatric hospital populations using trigger tool methodology. The Canadian Paediatric Trigger

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Tool (CPTT) found a physician reported harm rate of 15.1% of admissions during a validation study across six paediatric hospitals in Canada.[25] Like the UKPTT the CPTT has been adapted to make triggers more sensitive and specific to paediatric settings. The second study, at a single paediatric academic medical center in the US using the adult Global Trigger Tool (GTT) found an overall harm rate of 25.8%.[8]

Variation in harm rates may reflect a number of factors. Different methodologies yield different rates of AE identification. Trigger tools are reported to yield higher rates of AE identification than traditional methods such as self-reporting and unstructured case note review.[1,24] Definitions of harm vary as do their interpretation. Professional groups may interpret AEs differently.[26] Assessments of inter-rater reliability have reported high levels of agreement between review team members, [8, 26, 27] but variability between different hospital departments teams, [28] In addition, some organisations or teams set a lower threshold for what they see as harm and they may change this over time. Finally, different populations are exposed to different levels of harm depending on the complexity of their illness and the intensity and duration of their care.[2] Most studies report a harm rate per admission, meaning that longer admissions are more exposed to opportunity for harm.

The same reasons that explain the variation between international studies explain much of the variation between hospitals in this study. Training was provided, but no independent assessment was made of reviewer's interpretations or competence. The extremes of harm reported or its absence were seen in

hospitals uploading low volumes of reviews and may be interpreted as the relative inexperience of the reviewers.[29] There is also a wide variety across the level of hospital represented with the corresponding impact on risk due to patient complexity, need for surgery or critical care and length of stay. Whilst we had no means of adjusting for acuity because of the random selection of notes from within hospitals we believe that the overall group is broadly representative of the population of hospitalised children in the UK.

One could ask whether this level of variation diminishes the findings of the study. On the contrary, we believe it represents a real portrayal of complex issues. It is also a taste of what individual organisations can expect if they start to use the PTT to help understand and reduce the harm in their institution. They will need to consider all of these issues as they interpret their own findings.

The majority (92.3%) of AEs identified in this study represented temporary harm resulting in the child either requiring an intervention, admission to hospital or prolongation of their hospital stay. Whilst severe harm (permanent harm or harm that requiring life sustaining measures or contributed to death) was rare, it still constituted 7.8% of harm identified. Similar findings with respect to severity have been reported with 10% of AEs classified as severe in one study of harm in PICU.[10] A study of AEs in hospitalised children reported that clinicians do not always recognize harm, even when the consequences to the child are severe.[30] In this study multiple AE were relatively common, with 37% of those experiencing harm suffering two or more AE in the same admission, far higher than previous studies.[8,25]

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Triggers varied in their positive predictive values for AEs. Screening for triggers is the key task of the trigger tool method. Triggers that infrequently identify harm could be removed to increase the efficiency of the tool. Some triggers may be important markers of care quality, such as the *missing /incomplete early warning score or baseline observations* despite the inability of the trigger to identify specific patient harm.[31] This will influence the next iteration of the trigger tool as we refine the triggers and consider taking out some of those that had a low PPV.

A number of studies have examined the possibility of automated trigger detection from electronic medical records which may make the process easier.[13,32] We believe that there is value in the manual approach, and that it will be some time before hospitals in the UK are converted to electronic medical records. Users of the UKPTT have expressed to us the benefits of having an opportunity to examine the quality of medical and nursing note keeping and observations, which in some centers has resulted in initiatives to improve these elements.

Limitations

There are a number of limitations to this study. The validity of trigger tool methodology is well established and we did not attempt to revalidate it again against another form of medical notes review for harm, as we did not believe this was necessary. The UKPTT differs from other trigger tools only in the constituent triggers. This study has provided PPVs for the 40 triggers included in the UKPTT. This validates the choice of high performing triggers and raises questions about

the continued inclusion of low performing ones, which may be used to consider changes to the trigger profile. New triggers may also be suggested and could be tested for future versions of the tool.

The determination of inter-rater reliability may be important within departments but not necessarily between hospitals. The UKPTT is not recommended for benchmarking as the focus is on developing data for improvement rather than data for judgement.[33] The methodology recommends consistency in the reviewing teams so that intra-reliability is not an issue.[34] We did not attempt to standardise the method of PTT data collection outside of the support provided and the recommendation on randomisation. Individual institutions made their own arrangements in terms of choosing and training reviewers. There were no checks of competence of reviewers or inter-rater reliability or of the accuracy of the data entered via the portal.

Strengths

Parry et al,[35] note that the approach should be to look at all harm, not only preventable harm. It is our belief that the ability to measure harm and examine case notes using the UKPTT on a regular basis is an effective method of data capture and analysis, which provides hospitals with valuable insights into their quality of care, as every AE provides insight for improvement, whether deemed preventable or not.[10]

We did not attempt to find out how many of these AEs were detected through other methods, such as incident reporting (we expect that many were). The

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purpose of the UKPTT is to extend the ability to detect harm rather than replace other approaches.

Conclusions and recommendations

In the context of the increasing demands to improve quality and safety for patients, the UK PTT provides a framework for paediatric clinicians to assess the rate of harm for their individual units, and the quality of their record keeping. This study highlights that currently there is a significant, measurable level of harm, which is sometimes severe, experienced by children admitted to hospitals in the UK. There is a range of predictive values for the triggers and some may be more useful than others. These findings will inform future modifications of the PTT including modifying or removing triggers. It will be important to test any new or augmented triggers with paediatric teams to assess their usefulness.

The recognition and examination of adverse events through methods such as the UK PTT offers the potential to improve paediatric patient safety by concentrating efforts on strategies that reduce patient harm, rather than errors. The key is to produce information that promotes learning and improvement, with clinicians accepting their role to decrease harm from the perspective of the patient, rather than that of the healthcare provider.

We recommend that the UK PTT be used routinely in hospitals to assess harm and to help develop improvement interventions to reduce it. Although the PTT has been mainly used in children's hospitals, it can be used in District General or community hospitals, with a different spectrum of harm being detected. The UK

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PTT does not replace other reporting mechanisms, but is a useful addition to the methods already used to understand the harm caused to children in hospital care. Harm needs to be detected and assessed through a number of lenses and this lens allows clinicians to further understand what they do and how harm impacts on children. It provides a way to move from a reactive approach to safety to one that is more proactive and founded in harm free care.

Susan Chapman and John Fitzsimons are joint first authors

The tool and guidance for its use is available from the corresponding author, Peter Lachman.

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Contributorship Statement:

Susan Chapman Development of paediatric trigger tool, study concept, data collection, data analysis and manuscript preparation

John Fitzsimons Development of paediatric trigger tool, study concept, data analysis and manuscript preparation.

Nicola Davey Development of paediatric trigger tool, study concept, data collection, data analysis and manuscript revision

Peter Lachman Development of paediatric trigger tool, Study concept, data analysis and manuscript revision

Competing Interest:

None known.

Data Sharing Statement

No additional data available

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Table 1: Number of case reviews, positive triggers and adverse events by individual hospital

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Hospital	Case notes reviewed	Positive triggers	Average number of triggers per case note review Adverse events		Average number of AE per case note review	Number of individual patients harmed (%)	
Α	622	1877	3.02	309	0.50	162 (26%)	
В	369	579	1.57	66	0.18	31 (8%)	
С	321	415	1.29	60	0.19	37 (11.5%)	
D	309	481	1.56	117	0.38	49 (15.9%)	
E	285	414	1.45	84	0.29	43 (15.1%)	
F	271	454	1.68	112	0.41	54 (20%)	
G	260	484	1.86	48	0.18	39 (15%)	
Н	241	418	1.73	6	0.02	4 (1.7%)	
	195	432	2.22	14	0.07	14 (7.2%)	
J	195	52	0.27	3	0.02	3 (1.5%)	
K	190	446	2.35	45	0.24	40 (21%)	
L	124	173	1.40	17	0.14	15 (12.1%)	
М	71	52	0.73	0	0.00	0 (0%)	
Ν	70	171	2.44	8	0.11	7 (10%)	
0	68	141	2.07	8	0.12	7 (10.3%)	
Р	68	107	1.57	1	0.01	1 (1.5%)	
Q	66	79	1.20	15	0.23	11 (16.7%)	
R	62	84	1.35	15	0.24	12 (19.3%)	
S	60	121	2.02	32	0.53	15 (25%)	
Т	59	90	1.53	2	0.03	1 (1.7%)	
U	23	22	0.96	4	0.17	3 (13%)	
V	19	14	0.74	1	0.05	1 (5.2%)	
W	17	26	1.53	4	0.24	4 (23.5%)	
X	15	50	3.33	27	1.80	11 (73.3%)	
Y	12	17	1.42	3	0.25	3 (25%)	
Overall	3992	7199	1.65	1001	0.26	567 (14.2%)	

Table 2: Number of adverse events per patient

Number of AE per case	Number of Patients (n= 3992)	% of patient who suffered harm
		(n=567)
0	3425	N/A
1	356	62.8%
2	111	19.6%
3	40	7.0%
4	28	4.9%
5	16	2.8%
6	8	1.4%
7	5	0.9%
9	2	0.4%
10	1	0.2%

Table 3: Trigger descriptors, AE and positive predictive value

Trigger Code	Trigger description	Adverse events	Positive Triggers	Severity of harm			Trigger PPV		
				Е	F	G	Н	I	
PG8	Complication of procedure or treatment	182	257	99	63	6	11	3	70.8%
PG3	Readmission to hospital within 30 days	107	462	36	68	0	1	2	23.2%
PG2	Tissue damage or pressure ulcer	81	250	66	12	0	1	2	32.4%
PG4	Unplanned admission	68	1668	23	41	0	3	1	4.1%
PO1	Other (specify)	60	425	48	10	0	1	1	14.1%
PS3	Surgical site infection	48	60	24	22	0	1	1	80.0%
PM5	Anti-emetic given	41	507	40	1	0	0	0	8.1%
PG10	Hypoxia O ₂ sat <85%	36	157	31	2	3	0	0	22.9%
PG1	EWS or baseline observations missing/incomplete or score/observation requiring response	35	1362	26	8	0	1	0	2.6%
PG9	Transfer to higher level of care (inc admission to specialist unit, ICU/HDU)	35	273	15	14	0	5	1	12.8%
PS1	Return to theatre	33	75	15	15	2	1		44.0%
PM7	IV Bolus ≥ 10ml/kg colloid or crystalloid given	31	386	22	5	1	1	2	8.0%
PG11	Cancelled elective procedure/ delayed discharge	24	55	10	12	1	0	1	43.6%
PL14	Positive blood culture	23	55	18	4	0	1	0	41.8%
PL13	Nosocomial Pneumonia	21	28	8	10	0	2	1	75.0%
PL5	Na ⁺ <130 or >150	14	71	12	1	0	1	0	19.7%
PG5	Cranial Imaging	10	141	4	2	3	0	1	7.0%
PL8	Hyperglycaemia (>12mmol/l)	11	65	10	1	0	0	0	16.9%
PS2	Change in planned procedure	11	37	6	5	0	0	0	29.7%

PL3	Abrupt drop in Hb or Hct (>25%)	10	65	9	1	0	0	0	15.4%
PM8	Abrupt medication stop	10	52	8	2	0	0	0	19.2%
PL8	Hypoglycaemia (<3mmol/l)	10	46	9	1	0	0	0	21.7%
PL9	Drug level out of range	10	32	8	2	0	0	0	31.3%
PL6	K ⁺ <3.0 or >6.0	9	69	8	0	0	1	0	13.0%
IP1	Readmission to ICU or HDU	9	16	5	1	0	3	0	56.3%
PS4	Removal/Injury or repair of organ	9	43	3	5	1	0	0	20.9%
PG6	Respiratory/Cardiac arrest/crash call	9	41	0	2	0	7	0	22.0%
PM5	Chlorpheniramine given	9	82	7	2	0	0	0	11.0%
PL2	Transfusion	8	143	6	1	0	1	0	5.6%
PL4	Rising urea or creatinine (>2x baseline)	6	54	4	2	0	0	0	11.1%
PL15	Thrombocytopenia	6	54	4	1	0	0	1	11.1%
PL1	High INR (>5) or APTT > 100 sec	6	31	6	0	0	0	0	19.4%
PM4	Glucagon or glucose ≥ 10% given	6	50	6	0	0	0	0	12.0%
PG7	Diagnostic imaging for embolus/thrombus +/- confirmation	4	24	2	1	1	0	0	16.7%
PM2	Naloxone given	4	16	3	0	0	1	0	25.0%
PL11	C Difficile	4	12	3	1	0	0	0	33.3%
PM1	Vitamin K given (except routine neonatal dose)	1	33	1	0	0	0	0	3.0%
PM3	Flumazanil given	0	2	0	0	0	0	0	N/A
PL10	MRSA bacteraemia	0	0	0	0	0	0	0	N/A
PL12	Vancomycin resistant enterococcus	0	0	0	0	0	0	0	N/A
	TOTAL	1001	7199	605	318	18	43	17	

Table 4: Severity of Adverse Events

Grade*	Descriptor	Adverse Events	% of Total Adverse Events
E	Temporary harm to the patient and required intervention	605	60.4%
F	Temporary harm to the patient and required initial or prolonged admission	318	31.8%
G	Permanent patient harm	18	1.8%
Н	Intervention required to sustain life	43	4.3%
1	Patient death	17	1.7%
Total		1001	

National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Index[23]

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children detected by the Paediatric Trigger Tool.	
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Abstract

Patient safety is the now a key priority of health care. The measurement and examination of adverse events that occur to children during hospital admissions is essential if we are to prevent, reduce or ameliorate the harm experienced. The UK Paediatric Trigger Tool (UKPTT) is a method for measuring fretrospective case note review that measures harm in hospitalised children.

Objectives

To examine the rate and nature of harm in hospitalised children from centres providing data to the NHS Institute UKPTT data portal, to understand the positive predictive values of triggers, and to make recommendations for the use and further development of the trigger tool.

Results

Data from 3992 patient admissions were reviewed from 25 hospitals and submitted to the trigger tool portal from February 2008 to November 2011. The hospitals included secondary, tertiary and quaternary centers. At least one adverse event (AE) was reported for 567 (14.2%) patients, with 211 (5.3%) experiencing more than one event. There were 1001 adverse events identified. Where harm occurred it was considered temporary for 923 (92.2%) AEs, however 43 (4.3%) AEs resulted in the need for life-sustaining interventions, 18 (1.8%) AEs led to permanent harm and for 17 children (1.7% of AEs) the AE was believed to have contributed to death. The positive predictive values (PPV) for the triggers ranged from 0 to 80%.

Conclusions

There is a significant, measurable level of harm experienced by children admitted to hospitals in the UK. While most of this harm is temporary, some is serious. The UKPTT offers organisations the means to measure and examine the adverse events occurring in their hospital in order to reduce harm.

Strengths:

- This study estimates that 1 in 7 children experience harm during admission to hospital in the UK. Most of this harm is temporary but a significant minority is serious. This should generate discussion about patient safety in paediatrics.
- The study used the UK Paediatric Trigger Tool that can be used by any
 hospital to learn about harm in order to prevent or reduce it.

Limitations

The study does not distinguish between preventable and non-preventable
 harm however we believe there is an opportunity to learn from any harm
 event.

Introduction

Providing <u>The provision of</u> care that is safe and reliable <u>areis a</u> fundamental goalsgoal of modern healthcare. Patient safety is the prevention, reduction and amelioration of medical harm-[.[1, 2]-] Medical harm (synonymous with the terms patient harm and adverse event, AE) is defined as unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment or hospitalisation, or that results in death-[.[3]- Efforts to improve patient safety have been hampered by a lack of reliable data on the Formatted: Justified

prevalence and nature of harm in all areas of practice. Patients and healthcare professional professionals need to understand the burden of harm in healthcare in order to develop effective interventions [.[4]...]

The complexity of uncovering harm is reflected in the numerous ways that one has to measure it [5]. Traditional methods such as incident reporting, have limitations, especially that of underreporting, due to the reliance on individual clinicians to recognise and report adverse events, as well as a tendency to focus on error, rather than harm. The measurement and examination of harm, rather than that of error, recognises that efforts to improve patient safety benefit from focusing on incidents that result in actual harm, identifying high risk situations, considering preventability and looking for means of early detection and harm limitation[6]. This deeper understanding of the harm to which patients are exposed is a recent phenomenon and in paediatrics the potential risks to safety are multiple [7]. The call for Zero Harm and the focus on safety in recent reports [8,9], reflects the importance of the identification and understanding of harm as an essential part of patients care.

Development of Trigger Tool methodology

<u>The Global Trigger Tool (GTT) for measuring harm</u>Clinicians have not known the actual levels of harm caused and have relied on a reporting system for clinical incidents. In this paper we assess the introduction of the UK Paediatric Trigger Tool, which aims to provide clinicians with a methodology to detect of harm and facilitates the development of interventions to decrease identified harm and provide safer care.

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> Measurement of harm is a complex task and requires a number of different methods. Harm rates vary widely because of multiple factors such as the definition of harm used, the methodology employed and the populations selected. Until recently most studies sought to establish harm rates for benchmarking purposes over large populations with suggestions that between 3-17% of patients experience an adverse event during a hospital admission[10]. Most of these studies used retrospective, unstructured case note reviews which are labourintensive, costly and impractical for the routine monitoring of harm[11]. Trigger tool methodology is accepted as one of the ways to measure harm in a way that allows local learning[1, 3, 12]. Trigger tools have also been reported to provide consistent reliable and relevant data at low cost [3,12], although the cost may vary between different hospitals.

Development of the Trigger Tool methodology

The Global Trigger Tool (GTT) was developed by the Institute for Healthcare Improvement (IHI) for use in adult care settings [3]. Triggers tools have also been developed for specific populations and settings, including acute hospitals, surgery [13], critical care [14] and primary care [15]. One study used the GTT to measure harm at a large academic children's hospital in the USA and recommended the development of a paediatric specific tool [16]. Paediatric specific trigger tools have been developed for neonatology [17], paediatric critical care [18, 19] and medications [20, 21] and a trigger tool for harm in hospitalised children was developed in Canada [22]. A UK version of the acute adult GTT had already been developed but this was not applicable to a paediatric population. In 2008, the NHS Institute for Innovation and Improvement undertook

to develop a UK paediatric trigger tool that could be applied to all levels of acute paediatric care.

was developed by the Institute for Healthcare Improvement (IHI) for use in adult care settings [3]. Triggers tools have also been developed for specific populations and settings, including acute hospitals, surgery,[5] critical care,[6] and primary care.[7] One study used the GTT to measure harm at a large academic children's hospital in the USA and recommended the development of a paediatric specific tool.[8] Paediatric specific trigger tools have been developed for neonatology,[9] paediatric critical care,[10,11] medications,[12, 13] and a general trigger tool for harm in hospitalised children,[14] A UK version of the acute adult GTT had already been developed but this was not applicable to a paediatric population. In 2008, the NHS Institute for Innovation and Improvement undertook to develop a UK paediatric trigger tool that could be applied to all levels of acute paediatric care.

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Trigger tool Method for reviewing case notes.

The trigger tool method consists of a retrospective review of a 20 sets of medical healthcare records each month, using a standardised methodology. A random sample of 20 in-patient case notes is selected using a randomisation matrix on a monthly basis. The medical healthcare record is examined in a structured process for 20 minutes to search for "triggers". A "trigger" is a predefined event that alerts the reviewer to the possibility of patient harm. Once a trigger is identified, the reviewer uses clinical expertise to examine the records in more detail to understand the circumstances around the event. If harm is

suspected a second reviewer (usually a physician) is consulted to confirm and grade the adverse event using the NCC MERP grading system [23](Table 4).[15]

An example of a trigger is the administration of the antidote medication naloxone (a trigger) to reverse the effects of opiates. This alerts the reviewer <u>effo</u> a possible overdose of opioids. The reviewer examines the relevant parts of the healthcare record to assess whether the use of naloxone was for this reason or not. If this is the reason then the harm is graded.

Development of the UK PTT

The NHS Institute sponsored the development of a paediatric trigger tool based on the preliminary findings from the Canadian pediatric trigger tool [22] and the UK Acute Trigger Tool [24]. In 2008 the NHS Institute sponsored the development of a paediatric trigger tool because at the time there was no tool available for hospitalised children. The tools design was informed by the early (and prepublication) findings of a Canadian pediatric trigger tool study. [14] and the UK Acute Trigger Tool for adults. [16] The development was a co-production involving the collaboration of patient safety experts from the NHS Institute, international leaders in paediatric trigger tool development and clinical experts from nine UK hospitals including children's hospitals and district general hospitals. Following discussion and testing, the group agreed on 40 paediatric oriented triggers to be included in the UKPTT. These were based on the triggers used in other tools, UK evidence of adverse events and the experience of the reference group in harm and adverse events (a subset of the co-production group). <u>TheProduction of a</u> UK tool was <u>developedintended</u> to <u>increaseenhance</u> ownership by the clinicians,

who would use it. The Canadian tool had not been published in practice and no to modify triggers that were not appropriate for the UK setting. We also added a category for "other paediatric trigger tools were availableharm" to capture harm that was not detected by one of the listed triggers.

The UKPTT advocates a working definition of patient harm as "anything, which you would not like to happen to yourself or a member of your family as a result of, or contributed to by, medical care". The decision to aim for a broad definition was to focus on the patient rather than on the medical system – a less defensive approach. This is a broader definition than that given by Griffin et al-[3] or the Canadian tool and aimed to encourage clinicians to explore a holistic concept of harm than that traditionally reported. It allows the inclusion of acts of omission as well as commission. The definition includeincludes missed or delayed diagnosis along with —physical and psychological harm, which could be identified by additional triggers.

Through the coproduction, support was developed for UK PTT users such as face-to-face training, on line<u>online</u> and printed guidance, and standardised data collection forms. The tool and guidance for its use remains freely available at www.institute.nhs.uk/paediatrictriggertool or from the authors.

Data Collection

As part of the UKPTT development, the NHS Institute created a web-based trigger tool portal into which participating hospitals entered anonymised data.

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The portal calculated harm rates and produced run charts that hospitals could download. Contributing hospitals consented to their data being collated and published to further the understanding of harm in hospitalised children in the UK. Participating hospitals developed local administrative and governance arrangements for PTT reviews following the standard guidance.

Aims and methodology

The aims of this study are to:

- <u>•1.</u> Describe the rate and severity of harm occurring in hospitalised children from UK centres submitting data to the NHS Institute's Trigger Tool portal.
- -2. Report the frequency and positive predictive value (PPV) of triggers to detect harm.
- *3. Make recommendations for further application and development of the tool. Participating hospitals, which <u>voluntarily decided to use the PTT</u>, included secondary, tertiary and quaternary centers₇. <u>Reviewers</u> were trained in trigger tool methodology either by experts at the NHS Institute or by using on-line resources with telephone support. Data was collected through the on-line trigger tool portal- that opened in Feb 2008.

Results

Data from 3992 case note reviews from 25 hospitals submitted to the trigger tool portal between February 2008 and November 2011 were analysed. Nine<u>of the</u> hospitals were children's hospitals; the remainder <u>werewas</u> classed as district general hospitals. Data from four additional hospitals that used the portal were excluded because they each submitted less than 10 case entries. Harm was

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recorded as occurring for 567 patients (14.2%) while the majority (85.8%) of patients experienced no evidence of harm. Reviewers identified 1001 adverse events, an average of 1.8 events per patient experiencing harm.

There was considerable variation between hospitals in the number of case notes reviewed (12 - 622), the number of triggers detected (17 - 1877) and overall harm rate reported ($0\% - \frac{10073.3}{3}\%$). Results from each hospital are reported in Table 1. Of the 567 children who suffered an AE, the majority (n=356, 63%) experienced a single event. However 211 (37%) of patients suffered more than one AE within the same admission. One patient was reported to have suffered 10 AEs in a single admission. A summary of the number of adverse events per case is presented in Table 2.

Individual triggers varied in their ability to lead to detection of harm. The trigger *Complications of procedure or treatment* yielded the greatest amount of harm (182 AEs). The PPV varied from 80.0% for *surgical site infection* to 2.62% for *missing observations/early warning scores*. The PPV was generally low in frequently identified triggers, such as *missing observations/early warning scores* (PPV 2.6%) and *unplanned admission* (PPV 4.0%). The positive triggers, adverse events and PPV for each trigger are displayed in Table 3.

The majority of adverse events (n=923, 92.2%) resulted in temporary harm to the patient (grade E and F – see Table 5-[23[15]), 43 AEs required life-sustaining interventions and 18 resulted in permanent harm. In 17 cases, the adverse event was believed to have contributed to the child's death (Table 4).

Discussion

The complexity of uncovering harm is reflected in the numerous ways that one has to measure it.[17] Traditional methods such as incident reporting have limitations, especially that of underreporting, due to the reliance on individual clinicians to recognise and report adverse events, as well as a tendency to focus on error, rather than harm. The measurement and examination of harm, rather than that of error, recognises that efforts to improve patient safety benefit from focusing on incidents that result in actual harm, identifying high risk situations, considering preventability and looking for means of early detection and harm limitation.[18] This deeper understanding of the harm to which patients are exposed is a recent phenomenon and in paediatrics the potential risks to safety are multiple.[19] The call for Zero Harm and the focus on safety in recent reports.[20, 21] reflects the importance of the identification and understanding of harm as an essential part of patients care. Clinicians have not known the actual levels of harm caused and have relied on a reporting system for clinical incidents.

Harm rates vary widely because of multiple factors, such as the definition of harm used, the methodology employed and the population studied. Until recently most studies sought to establish harm rates for benchmarking purposes over large populations with suggestions that between 3-17% of patients experience an adverse event during a hospital admission.[22] Most of these studies used retrospective, unstructured case note reviews which are labour-intensive, costly and impractical for the routine monitoring of harm.[23] Trigger tool methodology is accepted as one of the ways to measure harm in a way that allows local

learning,[1,3,2] Trigger tools have also been reported to provide consistent reliable and relevant data at low cost, [2,3] although the cost may vary between different hospitals.

This paper represents the largest reportstudy of paediatric harm using trigger tool - - - - Formatted: Justified methodology in the United Kingdom. Whilst the primary purpose of a trigger tool is to gain local data for understanding harm in order to improve patient safety locally, we can learn about harm by examining the pooled experiences of the contributing hospitals. The ability to capture, measure and view the results of case notes review using the PTT on a routine basis is a cost effective method of data capture and analysis and of significant value to individual hospitals.

The overall harm rate (the percentage of children experiencing one or more AEs during an admission) identified in this study was 14.2%. Previous studies focusing on hospitalised children have identified harm rates of between 1% and 25.8% per admission for the general paediatric hospital population [6, 20, 21] and higher rates within the paediatric intensive care population of 26.1% to 62% [18,19,26]. Two recent studies have examined harm in paediatric hospital populations using trigger tool methodology. The Canadian Paediatric Trigger Tool (CPTT) [25] found a physician reported harm rate of 15.1% of admissions during a validation study across six paediatric hospitals in Canada. Like the UKPTT the CPTT has been adapted to make triggers more sensitive and specific to paediatric situations. The second study, at a single paediatric academic medical center in the US using the adult Global Trigger Tool (GTT) found an overall harm rate of 25.8% [16].

Variation in harm rates may reflect a number of factors. Different methodologies yield different rates of AE identification. Trigger tools are reported to yield higher rates of AE identification than traditional methods such as self-reporting and unstructured case note review [1,26]. Definitions of harm vary as do their interpretation. Professional groups may interpret AEs differently [25]. Assessments of inter-rater reliability have reported high levels of agreement between review team members [16,27,28], but variability between different hospital departments teams [29]. In addition some organisations or teams set a lower threshold for what they see as harm and they may change this over time. Finally, different populations are exposed to different levels of harm depending on the complexity of their illness and the intensity and duration of their care[20]. Most studies report a harm rate per admission meaning that longer admissions are more exposed to opportunity for harm.

The same reasons that explain the variation between international studies explain much of the variation between hospitals in this study. The overall harm rate (the percentage of individual children experiencing one or more AEs during an admission) identified in this study was 14.2%. Previous studies focusing on hospitalised children have identified harm rates of between 1% and 25.8% per admission for the general paediatric hospital population,[12, 13, 18] and higher rates within the paediatric intensive care population of 26.1% to 62%.[10,11,24] Two recent studies have examined harm in paediatric hospital populations using trigger tool methodology. The Canadian Paediatric Trigger Tool (CPTT) found a physician reported harm rate of 15.1% of admissions during a validation study

across six paediatric hospitals in Canada.[25] Like the UKPTT the CPTT has been adapted to make triggers more sensitive and specific to paediatric settings. The second study, at a single paediatric academic medical center in the US using the adult Global Trigger Tool (GTT) found an overall harm rate of 25.8%.[8]

Variation in harm rates may reflect a number of factors. Different methodologies yield different rates of AE identification. Trigger tools are reported to yield higher rates of AE identification than traditional methods such as self-reporting and unstructured case note review.[1,24] Definitions of harm vary as do their interpretation. Professional groups may interpret AEs differently.[26] Assessments of inter-rater reliability have reported high levels of agreement between review team members,[8,26,27] but variability between different hospital departments teams,[28] In addition, some organisations or teams set a lower threshold for what they see as harm and they may change this over time. Finally, different populations are exposed to different levels of harm depending on the complexity of their illness and the intensity and duration of their care.[2] Most studies report a harm rate per admission, meaning that longer admissions are more exposed to opportunity for harm.

<u>The same reasons that explain the variation between international studies</u> <u>explain much of the variation between hospitals in this study.</u> Training was provided, but no independent assessment was made of reviewer's interpretations or competence. The extremes of harm reported or its absence were seen in hospitals uploading low volumes of reviews and may be interpreted as the relative inexperience of the reviewers [30].[29] There is also a wide variety

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> across the level of hospital represented with the corresponding impact on risk due to patient complexity, need for surgery or critical care and length of stay. Whilst we had no means of adjusting for acuity because of the random selection of notes from within hospitals we believe that the overall group is broadly representative of the population of hospitalised children in the UK.

> One could ask whether this level of variation diminishes the findings of the study. On the contrary, we believe it represents a real portrayal of complex issues. It is also a taste of what individual organisations can expect if they start to use the PTT to help understand and reduce the harm in their institution. They will need to consider all of these issues as they interpret their own findings.

> The majority (92.3%) of AEs identified in this study represented temporary harm resulting in the child either requiring an intervention, admission to hospital or prolongation of their hospital stay. Whilst severe harm (permanent harm or harm that requiring life sustaining measures or contributed to death) was rare, it still constituted 7.8% of harm identified. Similar findings with respect to severity have been reported with 10% of AEs classified as severe in one study of harm in PICU [18]..[10] A study of AEs in hospitalised children reported that clinicians do not always recognize harm, even when the consequences to the child are severe [31]..[30] In this study multiple AE were relatively common, with 37% of those experiencing harm suffering two or more AE in the same admission, far higher than previous studies-[16.[8,25].-]
Triggers varied in their positive predictive values for AEs. Screening for triggers is the key task of the trigger tool method. Triggers that infrequently identify harm could be removed to increase the efficiency of the tool. Some triggers may be important markers of care quality, such as the *missing /incomplete early warning score or baseline observations* despite the inability of the trigger to identify specific patient harm [32]..[31] This will influence the next iteration of the trigger tool as we refine the triggers and consider taking out some of those that had a low PPV.

A number of studies have examined the possibility of automated trigger detection from electronic medical records which may make the process easier [21,33]..[13,32] We believe that there is value in the manual approach, and that it will be some time before hospitals in the UK are converted to electronic medical records. Users of the UKPTT have expressed to us the benefits of having an opportunity to examine the quality of medical and nursing note keeping and observations, which in some centers has resulted in initiatives to improve these elements.

Limitations

There are a number of limitations to this study. Although the The validity of trigger tool methodology is standard, well established and we did not attempt to revalidate it again against another form of medical notes review for harm, as we did not believe this was necessary. The UKPTT differs from other trigger tools only in the constituent triggers. This study has provided PPVs for the 40 triggers included in the UKPTT. This validates the choice of high performing triggers and

raises questions about the continued inclusion of low performing ones, which may be used to consider changes to the trigger profile. Other<u>New</u> triggers may also be more usefulsuggested and could be tested for future versions of the tool.

The determination of inter-rater reliability may be important within departments but not necessarily between hospitals. The UKPTT is not recommended for benchmarking as the focus is on developing data for improvement rather than data for judgment [34].judgement.[33] The methodology recommends consistency in the reviewing teams so that intra-reliability is not an issue [36]..[34] We did not attempt to standardise the method of PTT data collection outside of the support provided and the recommendation on randomisation. Individual institutions made their own arrangements in terms of choosing and training reviewers. There were no checks of competence of reviewers or interrater reliability or of the accuracy of the data entered via the portal.

Strengths

Parry et al [36] note that the approach should be to look at all harm not only preventable harm. We believe every AE provides insight for improvement, whether deemed preventable or not [18].

Parry et al.[35] note that the approach should be to look at all harm, not only preventable harm. It is our belief that the ability to measure harm and examine case notes using the UKPTT on a regular basis is an effective method of data capture and analysis, which provides hospitals with valuable insights into their

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guality of care, as every AE provides insight for improvement, whether deemed preventable or not.[10]

We did not attempt to find out how many of these AEAEs were detected throughtother methods, such as incident reporting (we expect that many were). The purpose of the UKPTT is to extend the ability to detect harm rather than replace other approaches.

Conclusions and recommendations

In the context of the increasing demands to improve quality and safety for patients, the UK PTT provides a framework for paediatric clinicians to assess the rate of harm for their individual units, and the quality of their record keeping. This study highlights that currently there is a significant, measurable level of harm, which is sometimes severe, experienced by children admitted to hospitals in the UK. There is a range of predictive values for the triggers and some may be more useful than others. These findings will inform future modifications of the PTT including modifying or removing triggers. It will be important to test any new or augmented triggers with paediatric teams to assess their usefulness.

The recognition and examination of adverse events through methods such as the UK PTT offers the potential to improve paediatric patient safety by concentrating efforts on strategies that reduce patient harm, rather than errors. The key is to produce information that promotes learning and improvement, with clinicians

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accepting their role to decrease harm from the perspective of the patient, rather than that of the healthcare provider.

We recommend that the UK PTT be used routinely in hospitals to assess harm and to help develop improvement interventions to reduce it. Although the PTT has been mainly used in children's hospitals, it can be used in District General or community hospitals, with a different spectrum of harm being detected. The UK PTT does not replace other reporting mechanisms, but is a useful addition to the methods already used to understand the harm caused to children in hospital care. Harm needs to be detected and assessed through a number of lenses and this lens allows clinicians to further understand what they do and how itharm impacts on children. It provides a way to move from a reactive approach to safety to one that is more proactive and founded in harm free care.

Susan Chapman and John Fitzsimons are joint first authors

The tool and guidance for its use is available from the corresponding author, Peter Lachman.

Acknowledgement:

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The authors would also like to thank all the participating institutions whose unidentifiable data has been made available for the analysis, and those who participated in the development of the UKPTT. Formatted: Justified

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Table 1: Number of case reviews, positive triggers and adverse events by individual hospital

Hospital	Case notes reviewed	Positive triggers	Average number of triggers per case note review	Adverse events	Average number of AE per case note review	Number of individual patients harmed <u>(%)</u>
Α	622	1877	3.02	309	0.50	162 <u>(26%)</u>
В	369	579	1.57	66	0.18	31 <u>(8%)</u>
С	321	415	1.29	60	0.19	37 <u>(11.5%)</u>
D	309	481	1.56	117	0.38	49 <u>(15.9%)</u>
E	285	414	1.45	84	0.29	43 <u>(15.1%)</u>
F	271	454	1.68	112	0.41	54 <u>(20%)</u>
G	260	484	1.86	48	0.18	39 <u>(15%)</u>
Н	241	418	1.73	6	0.02	4 <u>(1.7%)</u>
I	195	432	2.22	14	0.07	14 <u>(7.2%)</u>
J	195	52	0.27	3	0.02	3 <u>(1.5%)</u>
K	190	446	2.35	45	0.24	40 <u>(21%)</u>
L	124	173	1.40	17	0.14	15 <u>(12.1%)</u>
М	71	52	0.73	0	0.00	0 <u>(0%)</u>
Ν	70	171	2.44	8	0.11	7 <u>(10%)</u>
0	68	141	2.07	8	0.12	7 <u>(10.3%)</u>
Р	68	107	1.57		0.01	1 <u>(1.5%)</u>
Q	66	79	1.20	15	0.23	11 <u>(16.7%)</u>
R	62	84	1.35	15	0.24	12 <u>(19.3%)</u>
S	60	121	2.02	32	0.53	15 <u>(25%)</u>
Т	59	90	1.53	2	0.03	1 <u>(1.7%)</u>
U	23	22	0.96	4	0.17	3 <u>(13%)</u>
V	19	14	0.74	1	0.05	1 <u>(5.2%)</u>
W	17	26	1.53	4	0.24	4 <u>(23.5%)</u>
X	15	50	3.33	27	1.80	11 <u>(73.3%)</u>
Y	12	17	1.42	3	0.25	3 (25%)
Overall	3992	7199	1.65	1001	0.26	567 <u>(14.2%)</u>

Table 2: Number of adverse events per patient

Number of AE per case	Number of Patients (n= 3992)	% of patient who suffered harm (n=567)
0	3425	N/A
1	356	62.8%
2	111	19.6%
3	40	7.0%
4	28	4.9%
5	16	2.8%
6	8	1.4%
7	5	0.9%
9	2	0.4%
10	1	0.2%

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Table 3: Trigger descriptors, AE and positive predictive value

Trigger Code	Trigger description	Adverse events	Positive Triggers	Severity of harm					Trigger PPV
				E	F	G	н	I	
PG8	Complication of procedure or treatment	182	257	99	63	6	11	3	70.8%
PG3	Readmission to hospital within 30 days	107	462	36	68	0	1	2	23.2%
PG2	Tissue damage or pressure ulcer	81	250	66	12	0	1	2	32.4%
PG4	Unplanned admission	68	1668	23	41	0	3	1	4.1%
PO1	Other (specify)	60	425	48	10	0	1	1	14.1%
PS3	Surgical site infection	48	60	24	22	0	1	1	80.0%
PM5	Anti-emetic given	41	507	40	1	0	0	0	8.1%
PG10	Hypoxia O ₂ sat <85%	36	157	31	2	3	0	0	22.9%
PG1	EWS or baseline observations missing/incomplete or score/observation requiring response	35	1362	26	8	0	1	0	2.6%
PG9	Transfer to higher level of care (inc admission to specialist unit, ICU/HDU)	35	273	15	14	0	5	1	12.8%
PS1	Return to theatre	33	75	15	15	2	1		44.0%
PM7	IV Bolus ≥ 10ml/kg colloid or crystalloid given	31	386	22	5	1	1	2	8.0%
PG11	Cancelled elective procedure/ delayed discharge	24	55	10	12	1	0	1	43.6%
PL14	Positive blood culture	23	55	18	4	0	1	0	41.8%
PL13	Nosocomial Pneumonia	21	28	8	10	0	2	1	75.0%
PL5	Na ⁺ <130 or >150	14	71	12	1	0	1	0	19.7%
PG5	Cranial Imaging	10	141	4	2	3	0	1	7.0%
PL8	Hyperglycaemia (>12mmol/l)	11	65	10	1	0	0	0	16.9%
PS2	Change in planned procedure	11	37	6	5	0	0	0	29.7%

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	Abrupt drop in Hb or Hot (>25%)			-		_			15 /0/
PLJ		10	65	9	1	0	0	0	15.4%
PM8	Abrupt medication stop	10	52	8	2	0	0	0	19.2%
PL8	Hypoglycaemia (<3mmol/l)	10	46	9	1	0	0	0	21.7%
PL9	Drug level out of range	10	32	8	2	0	0	0	31.3%
PL6	K ⁺ <3.0 or >6.0	9	69	8	0	0	1	0	13.0%
IP1	Readmission to ICU or HDU	9	16	5	1	0	3	0	56.3%
PS4	Removal/Injury or repair of organ	9	43	3	5	1	0	0	20.9%
PG6	Respiratory/Cardiac arrest/crash call	9	41	0	2	0	7	0	22.0%
PM5	Chlorpheniramine given	9	82	7	2	0	0	0	11.0%
PL2	Transfusion	8	143	6	1	0	1	0	5.6%
PL4	Rising urea or creatinine (>2x baseline)	6	54	4	2	0	0	0	11.1%
PL15	Thrombocytopenia	6	54	4	1	0	0	1	11.1%
PL1	High INR (>5) or APTT > 100 sec	6	31	6	0	0	0	0	19.4%
PM4	Glucagon or glucose ≥ 10% given	6	50	6	0	0	0	0	12.0%
PG7	Diagnostic imaging for embolus/thrombus +/- confirmation	4	24	2	1	1	0	0	16.7%
PM2	Naloxone given	4	16	3	0	0	1	0	25.0%
PL11	C Difficile	4	12	3	1	0	0	0	33.3%
PM1	Vitamin K given (except routine neonatal dose)	1	33	1	0	0	0	0	3.0%
PM3	Flumazanil given	0	2	0	0	0	0	0	N/A
PL10	MRSA bacteraemia	0	0	0	0	0	0	0	N/A
PL12	Vancomycin resistant enterococcus	0	0	0	0	0	0	0	N/A
	TOTAL	1001	7199	605	318	18	43	17	

Table 4: Severity of Adverse Events

Grade*	Descriptor	Adverse Events	% of Total Adverse Events
E	Temporary harm to the patient and required intervention	605	60.4%
F	Temporary harm to the patient and required initial or prolonged admission	318	31.8%
G	Permanent patient harm	18	1.8%
Н	Intervention required to sustain life	43	4.3%
I	Patient death	17	1.7%
Total		1001	

National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Index[23]

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Trigger

Tool

PAEDIATRIC TRIGGER TOOL

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www.institute.nhs.uk/safercare/portal

	Patient Age	years, months
trics	Date Of Discharge:	
ediat	Length Of Stay:	days



and Improvement

	Full Description	Trigger	Adverse Event	Seve	rity	of A	٨dve	erse	Event	Comment on this	trigger
PG1	EWS or baseline obs missing or incomplete OR score/observation requiring response	No Yes	No Yes	N/A	E	F	G	н	I		
PG2	Tissue damage or pressure ulcer	• No • Yes	No Yes	N/A	E	F	G	н	I		
PG3	Readmission to hospital within 30 days	No Yes	No Yes	N/A	E	F	G	н	I		
PG4	Unplanned admissions	• No • Yes	● No ● Yes	N/A	E	F	G	н	I		
PG5	Cranial Imaging	No Yes	No Yes	N/A	E	F	G	н	I		
PG6	Respiratory/Cardiac arrest/crash call	No Yes	No Yes	N/A	E	F	G	н	I		
PG7	Diagnostic imaging for embolus/thrombus +/- confirmation	No Yes	No Yes	N/A	E	F	G	н	I		
PG8	Complication of procedure or treatment	No Yes	• No • Yes	N/A	E	F	G	н	I		
PG9	Transfer to higher level of care (inc admission to specialist unit, ICU/ HDU)	No Yes	No Yes	N/A	E	F	G	н	I		
PG10	Hypoxia O ₂ sat <85%	No Yes	No Yes	N/A	E	F	G	н	I		
PG11	Cancelled elective procedure/ delayed discharge	No Yes	No Yes	N/A	E	F	G	н	I		
PS1	Return to theatre	No Yes	No Yes	N/A	E	F	G	н	I		
PS2	Change in planned procedure	No Yes	No Yes	N/A	E	F	G	н	I		
PS3	Surgical site infection	No Yes	No Yes	N/A	E	F	G	н	I		
PS4	Removal/Injury or repair of organ	No Yes	No Yes	N/A	E	F	G	н	I		
IP1	Readmission to ICU or HDU	No Yes	No Yes	N/A	E	F	G	н	I		
	Adverse Event Score (N E Temporary harm	leasure of Harm to the patient ar) Id required intervention		G		Perm	naner	nt patient ha	ırm	

- Temporary harm to the patient and required intervention E
- н Intervention required to sustain life

Temporary harm to the patient and required initial or prolonged F hospitalisation

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	Full Description	Trigger	Adverse EvBMJ Op	enveri	ty c	of A	dver	se E	vent	Comment on this t Page 58 of 81
PM1	Vitamin K given (except for routine neonatal dose)	No Yes	No Yes	N/A	E	F	G	н	I	
PM2	Naloxone given	No Yes	No Yes	N/A	E	F	G	н	I	
PM3	Flumazenil given	No Yes	No Yes	N/A	E	F	G	н	I	
PM4	Glucagon or glucose ≥ 10% given	No Yes	No Yes	N/A	E	F	G	н	I	
PM5	Chlorphenamine given	No Yes	No Yes	N/A	E	F	G	н	I	
PM6	Anti-emetic given	No Yes	No Yes	N/A	E	F	G	н	I	
PM7	IV Bolus ≥ 10ml/kg colloid or crystalloid given	No Yes	No Yes	N/A	E	F	G	н	I	
PM8	Abrupt medication stop	No Yes	No Yes	N/A	E	F	G	н	I	
PL15	Thrombocytopenia (<100)	No Yes	No Yes	N/A	E	F	G	н	I	
PL1	High INR (>5) or APTT > 100 sec	No Yes	● No ● Yes	N/A	E	F	G	н	I	
PL2	Transfusion	No Yes	No Yes	N/A	E	F	G	н	I	
PL3	Abrupt drop in Hb or Hct (>25%)	No Yes	● No ● Yes	N/A	E	F	G	н	I	
PL4	Rising urea or creatinine (>2x baseline)	No Yes	No Yes	N/A	E	F	G	н	I	
PL5	Na ⁺ <130 or >150	No Yes	No Yes	N/A	E	F	G	н	I	
PL6	K ⁺ <3.0 or >6.0	No Yes	No Yes	N/A	E	F	G	н	I	
PL7	Hypoglycaemia (<3mmol/l)	No Yes	No Yes	N/A	E	F	G	н	I	
PL8	Hyperglycaemia (>12mmol/l)	No Yes	No Yes	N/A	E	F	G	н	I	
PL9	Drug level out of range	No Yes	No Yes	N/A	E	F	G	н	I	
PL10	MRSA bacteraemia	No Yes	No Yes	N/A	E	F	G	н	I	
PL11	C. difficile	No Yes	No Yes	N/A	E	F	G	н	I	
PL12	Vanc resistant enterococcus	No Yes	No Yes	N/A	E	F	G	н	I	
PL13	Nosocomial pneumonia	No Yes	No Yes	N/A	E	F	G	н	I	
PL14	Positive Blood Culture	No Yes	No Yes	N/A	E	F	G	н	I	
P01	Other (specifiy)	No Yes	No Yes	N/A	E	F	G	н	I	

TOTALS For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtmfompleted portal entry

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The Paediatric Trigger Tool User guide







Acknowledgements

Introduction

- 1. What is the Paediatric Trigger Tool?
- 2. Why use it?
- 3. 7-step user guide
- 4. Trigger definitions
- 5. Further help and support

Incident reporting typically identifies 5-10% of harm events.

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Trigger Tools typically detect harm rates in excess of 30%.

Together, these two diagnostic measures can help you focus your improvement work to reduce your rate of harm.



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Acknowledgements

With the support of clinicians in nine hospitals across the UK, we have developed the UK paediatric trigger tool in order to detect adverse events in paediatric care provided in district general hospitals, acute teaching hospitals and specialist paediatric centres.

This work has built on the original work of the Institute for Healthcare Improvement, in developing the Global Trigger Tool™ for use in adults, the Acute Trigger Tool an adaption for use in UK Hospitals, and original research led by Professor Anne Matlow to develop a Canadian Paediatric Trigger Tool.

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- Birmingham Children's Hospital NHS Foundation Trust
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- Sheffield Children's NHS Foundation Trust
- The Royal Free Hospital NHS Trust
- University Hospital Bristol NHS Foundation Trust

Scotland

- NHS Greater Glasgow & Clyde
- Royal Hospital for Sick Children, Edinburgh

IHI Global Trigger Tool for Measuring Adverse Events was developed by IHI. "Global Trigger Tool" is a common law trademark of the Institute for Healthcare Improvement.

The Acute Trigger Tool is the approved UK version of IHI Global Trigger Tool.™



Introduction

Welcome to the **Paediatric Trigger Tool (PTT) User's Guide**. Produced by the Safer Care Team at the NHS Institute for Innovation and Improvement, it is a practical guide to support anyone who is using, or thinking about using, the PTT.

The guide is arranged in five sections:

1.	What is the Paediatric Trigger Tool?	page: 4
2.	What are the benefits of using it?	page: 6
3.	7-step user guide	page: 8
4.	Trigger definitions	page: 14
5.	Further help and support	page: 21

Complete newcomers to the Paediatric Trigger Tool may want to learn more about what the PTT is (and isn't), and what benefits it can bring.

See Sections 1 and 2

Teams about to go live with the tool for the first time will benefit from the '7-step user guide'.

See Section 3

Those already using the PTT may just want to use the 'Trigger definitions' to check or refresh their understanding of the triggers and what to look out for in case note reviews.

See Section 4

'It pulls back the curtain to show us where the major problems really are'

Trigger Tool user

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1. What is the Paediatric Trigger Tool?

The Paediatric Trigger Tool (PTT) is a rapid, structured case note review tool to help you measure the rate of harm in your organisation. It provides paediatric teams with an unbiased measure of the incidence of iatrogenic harm experienced by their patients (ie harm caused by medical care).

Most importantly, the PTT allows you to prioritise your safety improvement activity and track these improvements over time.

'The PTT brings highlysensitive and specific adverse event measurement within reach of every paediatric team'

Co-produced by the NHS Institute's Safer Care Team and NHS clinicians, the PTT draws on the large and growing body of research and evidence exploring the benefits of trigger tool methodology¹.

And now, the PTT is also supported by the NHS Institute's **Trigger Tool Portal** – an easyto-use, web-based facility that allows you to capture, automatically analyse and present the valuable data generated through using the trigger tool. There is more about the Trigger Tool Portal in **Section 3. '7-step user guide'.**

What it isn't...

The Paediatric Trigger Tool is **not** a benchmarking tool for making comparisons between paediatric teams or trusts. This is because:

- Counting adverse events relies on a series of clinical judgements by individual clinical reviewers. While use of the trigger tool methodology has been shown to enhance reliability between reviewers at organisational level, this does not extend to comparisons between reviewers in different organisations - except in the most highlycontrolled situations (eg controlled trials).
- The adverse event rate in any given healthcare team will be influenced by a number of important factors outside the control of that team, such as patients' health and social status and local provision of other health and social care services.

As a quantitative tool, the PTT does not help you understand the detailed causes of specific adverse events. For this, we recommend using the PTT alongside other incident analysis techniques and other sources of information about patient safety - eg staff reports and patient complaints or comments.

¹ Resar RK, Rozich JD, Classen D. Methodology and rationale for the measurement of harm with trigger tools. *Quality and Safety in Health Care*. 2003; 12; Suppl 2:39-45.



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How does it work?

The PTT uses random sampling and rapid, structured case note review to bring very sensitive and specific adverse event measurement within reach of every paediatric team. Each review should take a maximum of 20 minutes per patient, and often less.

The object of the review is to identify harm – not to determine whether the event was preventable.

In our experience, the discussion about the **preventability** of an adverse event is often a barrier to determining the **cause** of an adverse event.

The full detail of how the PTT works is set out in **Section 3: 7-step user guide**. In essence, though, the process involves four key stages:

- I. A structured manual review of each case note (patient record), looking for any of the triggers listed in the tool eg INR level greater than 5.
- II. Where a positive trigger is identified, carrying out a closer examination of the case notes to determine whether an adverse event has occurred eg bleeding or haematoma.
- III. Where an adverse event has occurred **and** harm has resulted, assigning a category of harm based on the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Index for Categorising Errors.
- IV. Capturing the data using the NHS Institute's Trigger Tool Portal and reviewing the analysis of harm generated by the case note reviews.

What defines an 'adverse event'?

The Paediatric Trigger Tool defines an adverse event as any physical harm to the patient (limiting the scope to physical rather than emotional harm).

However, a question many users have found useful in identifying an adverse event is: '*Would you be happy if the event happened to you or to your child?*' If the answer is no, then it probably is an adverse event.

The next question would be whether the event was part of the natural progression of the disease, or a complication of the treatment related to the disease process.

Admittedly the decision at times will be difficult and subjective, but experience has found the process to be reliable.

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2. Why use it?

Traditional efforts to detect adverse events (AEs) have focused on voluntary reporting and tracking of errors. However, public health researchers have established that only 10 to 20% of errors are ever reported and, of those, 90 to 95% cause no harm to patients².

In order to select and test the changes that will reduce harm and improve safety and reliability, hospitals and healthcare teams need a more effective way to identify events that do cause harm to patients.

The use of triggers to identify adverse events from a manual case note review has been used extensively in the UK and elsewhere to measure the overall level of harm in a healthcare organisation.

Recognising the potential of the methodology, the NHS Institute for Innovation and Improvement is developing a suite of trigger tools for the UK to measure harm in paediatrics, primary care, mental health, community hospitals and in the community.

What is a trigger?

The Paediatric Trigger Tool is made up of a series of triggers grouped together to reflect different aspects or components of care. The groupings used in the PTT reflect five broad aspects of care in a child's hospital stay:

- 1. general care
- 2. surgical care
- 3. intensive care
- 4. medication
- 5. laboratory tests.

The trigger is a signpost, or clue, to help the reviewer find any adverse events that have resulted from any medical care provided.

For example...

An INR > 5 is not an adverse event in its own right, as the patient has not been harmed by it (even though it is unwanted). The majority of patients whose INR is over 5 do not suffer an adverse event as actions are taken to normalise the result. However, a patient with an INR over 5 who suffered a bleeding event has suffered an adverse event linked to that trigger.

The role of the INR trigger is to identify patients who through drug treatment are over anti-coagulated – these patients have a higher chance of suffering an adverse event. The level of 5 is chosen as the use of a lower level such as 4 would lead to the trigger being less sensitive in identifying an adverse event (ie the trigger would be identified frequently and lead to a detailed note review, but with few adverse events detected). This would make the tool much less efficient.

² Sari A, Sheldon TA, Cracknell A, Turnbull A. Sensitivity of routine system for reporting safety incidents in an NHS hospital: retrospective patient case note review. *BMJ*. 2007 doi: 10.1136/bmj.39031.507153.AE <u>http://www.bmj.com/cgi/content/abstract/334/7584/79</u>



By themselves triggers are not adverse events. Their purpose is to allow the case note review to be completed fast enough to be feasible in everyday practice, while remaining reliable enough to pick up adverse events in the case notes and full patient record.

What benefits will come from using the tool?

These are just some of the benefits you can expect to gain through using the PTT:

- The PTT can **re-ignite** staff's passion and enthusiasm for improving the quality and safety of care they deliver to their patients.
- Having an internal, confidential and non-benchmarking tool allows paediatric teams to be **open and honest** about their overall rate of harm. The PTT is not about attributing blame, but wholly about safety improvement.
- Trigger methodology is a **tested and validated** tool for measuring harm and tracking improvements in patient safety. It is a valuable partner to other techniques for understanding threats to patient safety, including staff reporting and patient complaints.
- Safer care is **better for everyone**. Reducing harm results in safer care for the patient; improved professional satisfaction for clinicians; and less waste of healthcare resources.

Before you get started...

The following section takes you through the 7step PTT process. But before you get started for the first time, you and your review team should ideally have had some initial training in case note review and trigger tool methodology.

This does not have to be onerous and we suggest participation in programmes or online tutorials listed on our web site at: www.institute.nhs.uk/triggertool

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3. 7-step user guide

Step 1: Select your reviewers

The review team should consist of two reviewers and a doctor who have been trained in case note review and trigger tool methodology. The two initial reviewers should also have extensive experience of paediatric care, and may include nurses and pharmacists. A paediatrician is needed to concur with the identification and severity of the adverse event, and to lead discussions regarding adverse events with other doctors in the organisation. The paediatrician will also play a lead role in supporting the reviewers during the training phase as this helps to improve inter-reviewer reliability.

TIP: Reviewers may need to negotiate protected time to carry out the reviews. A sample business case is available at <u>www.institute.nhs.uk/paeds</u>. In paediatrics, it is not generally possible to undertake the type of mortality review that is generated before commencing acute adult trigger tool programmes. You will need to review a baseline of 20 records to start with and then 20 per month thereafter. This can be split into 10 records, twice a month if necessary. Remember, reviewers will need 20 minutes for each review; time to discuss the findings; time for data input; and time to prepare data presentations.

Step 2: Select your case notes

It is critical to select the initial case notes in a truly random fashion. You can use any method, as long as it is random and the patients selected have a minimum LOS (length of stay) of at least eight hours (currently under review). Case notes should be selected at least 30 days after discharge. This is because one of the triggers (readmitted within 30 days of discharge) cannot otherwise be determined.

So what makes a selection process random? A selection process is random as long as every case note has an equal opportunity of being chosen.

- TIP: One method might include generating random numbers between one and nine and selecting 10 patient records that end in the random number.
- TIP: Alternatively, you could print out all discharges (if deaths are included) and select every 10th case note for review.
- ✓ TIP: It is also useful to pull all prior case notes for the selected patients, allowing the reviewer to see any readmissions.

Once you know how you want to randomise your notes, you need to decide how you will get them. Will you approach your medical records department, or do you have a data clerk or secretary who can pull the notes for you?

TIP: Select more than 20 cases as some notes will be unavailable – but do check that lack of availability does not result in the sample being skewed over time (eg notes for frequently-seen children may always be in the 'pending' tray in preparation for a clinic appointment, and never therefore sampled).

Step 3: Start reviewing

You will find an example of the **PTT worksheet** at the back of this guide. Hard copies (pdf files) can also be down loaded from our web site <u>www.institute.nhs.uk/paeds</u> or viewed on the **NHS Trigger Tool Portal**. Alternatively, you may find it easier to input the data directly into the **NHS Trigger Tool Portal**. To use the Trigger Tool Portal see page 12.

Whichever way you access it, you will need to complete a separate worksheet for each case note and you will need to review a minimum of 20 records per month thereafter.

✓ **TIP:** These reviews can be split into two sessions to be more resource friendly.

You should review only 'completed' case notes (those that have been processed and include the discharge summary and all diagnosis and procedure coding).

And, each case note should be reviewed for a maximum review time of 20 minutes. Less than 20 minutes is fine, but never more than 20 minutes.

TIP: When you start out, both reviewers may wish to review the same set of notes independently for the first 20 patient records, and then discuss their findings with the paediatrician. This helps ensure the reviewers are thinking and working in a broadly similar way, thus establishing inter-reviewer reliability more quickly.



Step 4: Follow a consistent process

The case note review process should be consistent. The following pathway might be useful to follow:

- Discharge diagnoses (looking particularly for infections, complications or certain diagnoses).
- Discharge summary (looking for specifics of the assessment and treatment during the hospital stay).
- Medication orders and the medication administration documentation form.
- TIP: If your organisation uses electronic prescribing, download the prescription forms beforehand or arrange to have direct screen access.
- Laboratory results
- TIP: Again, if you use electronic reporting, download the reports beforehand or arrange to have direct screen access.
- Operative theatre documentation
- Nursing documentation.
- Physician case notes.
- If time permits, any other areas of the case notes.

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Step 5: Find the positive triggers

As a minimum, all reviews should involve looking for triggers in the PTT's **General Care**, **Laboratory Test** and **Medication** components. The other components should only be used

if applicable; for example, the **Intensive Care** component should be used when reviewing a chart for a patient who spent any days in an intensive care unit.

The new **NHS Trigger Tool Portal** (see 'Step 7') allows you to customise the review process and specify your own additional triggers. This is only advisable once you've gained more experience in trigger tool methodology and use within your organisation. 'A positive trigger is not an adverse event in itself; it is just a clue that one may have occurred'

A positive trigger is the presence of that item (eg INR level greater than 5). However, a positive trigger is not an adverse event in itself; it is just a clue that one may have occurred.

When you find a positive trigger, tick 'Yes' against it on the worksheet and then review the relevant portion of the case note to determine whether an adverse event has occurred. In the example of INR greater than 5, the reviewer should look for bleeding, decreased haemoglobin, haematoma and other adverse events that can result from over-anticoagulation.

 TIP: The object is not to find every possible adverse event in every case note you review. The tool is designed to produce a reliable sample that is sufficient to inform safety improvements in the hospital.

If no adverse event is found, move on and continue looking for other triggers.

TIP: Be sure to include every adverse event you find, even if not identified by a trigger. Occasionally, you will come across an adverse event while looking for triggers or other details. All adverse events should be included and there is a component on the PTT worksheet to accommodate this (see PO1 'Other' at the bottom of the worksheet).

Where you do find evidence of an adverse event, tick 'Yes' on the worksheet in corresponding column.

Next you need to assign a **category of harm** using the NCC MERP Index categories listed in the tool and shown in the table below.



Step 6: Assign a 'category of harm'

The PTT uses an adapted version of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) 'Index for Categorising Errors'. However, the

Paediatric Trigger Tool counts *any* adverse events causing harm to the patient, whether or not they are the result of an error.

Accordingly, the PTT excludes the first four categories in the NCC MERP Index because they describe medication errors that **do not** cause harm. The PTT does include categories E, F, G, H, and I of the index because these categories describe errors that **do** cause harm.

If an adverse event has occurred, but no harm has resulted then tick the N/A (not applicable) box.

Category	Description
E	Temporary harm to the patient and required intervention
F	Temporary harm to the patient and required initial or prolonged hospitalisation
G	Permanent patient harm
Н	Intervention required to sustain life
1	Patient death

The review team will need to establish their own process if serious harm is identified, particularly where this has not previously come to the attention of clinicians and managers. The tool is not designed to establish accountability for error or harm. There are other tools such as the **National Patient Safety Agency (NPSA) Incident Decision Tree** or **Root Cause Analysis Toolkit** that provide useful frameworks for exploring and learning from incidents.

- Find both resources on the NPSA website at: <u>http://www.npsa.nhs.uk/nrls/improvingpatientsafety/patient-safety-tools-and-guidance/incidentdecisiontree/</u>
- http://www.nrls.npsa.nhs.uk/resources/?entryid45=59847&



Step 7: Capture and view your data via the NHS Trigger Tool Portal

After all case notes have been reviewed, you can then calculate the overall rate of harm. You can do this manually, but it is easier to use the new NHS Institute's **Trigger Tool Portal** <u>www.institute.nhs.uk/triggertoolportal</u>.

Co-designed by the NHS Institute's Safer Care Team and practicing paediatricians, the portal (shown below) allows you to capture and analyse the harm data generated from your case note reviews. Using it regularly will allow you to see whether your service is getting safer and more reliable.

PAEDIATRIC TRIGGER TOOL

www.institute.nhs.uk/safercare/portal

Time	Patient Age	years, months	NHS
Tool	Date Of Discharge:		Institute for Innovation
1	Length Of Stay:	days	and Improvement

		Full Description	Trigger	Adverse Event	Severity of Adverse Event	Comment on this trigger
General	PG1	EWS or baseline obs missing or incomplete OR score/observation requiring response	No Yes	No Yes	N/AEFGHI	
	PG2	Tissue damage or pressure ulcer	No Yes	No Yes	N/AEFGHI	
	PG3	Readmission to hospital within 30 days	No Yes	No Yes	N/A E F G H I	
	PG4	Unplanned admissions	No Yes	No Yes	N/A E F G H I	
	PG5	Cranial Imaging	No Yes	No Yes	N/AEFGHI	
	PG6	Respiratory/Cardiac arrest/crash call	No Yes	No Yes	N/AEFGHI	
	PG7	Diagnostic imaging for embolus/thrombus +/- confirmation	No Yes	No Yes	N/AEFGHI	
	PG8	Complication of procedure or treatment	No Yes	No Yes	N/A E F G H I	
	PG9	Transfer to higher level of care (inc admission to specialist unit, ICU/ HDU)	● No ● Yes	No Yes	N/AEFGHI	

The Trigger Tool Portal is easy to use and puts you in complete control of your data. It also enables you to drill down and identify the prevalence of specific triggers or groups of triggers. This unique analysis capability will help you focus your service improvement efforts where they're needed most.

The portal will also automatically generate SPC (statistical process control) charts and other visual data charts to help you understand and communicate your results. These can be easily exported into your own reports and presentations – giving you a powerful new tool to engage others in your safety improvement work, and prove progress.

Find out more about the NHS Trigger Tool Portal and how to register at: <u>http://www.institute.nhs.uk/triggertoolportal</u>



The Trigger Tool Portal will automatically generate charts like these – helping you understand, illustrate and communicate your data.



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4. Trigger definitions

This section lists all the triggers used in the five components of the PTT, giving a brief explanation of why each may indicate an adverse incident and what to look out for during your reviews.

General care component

PG1 Early warning score

If an early warning scoring risk or standard baseline observation assessment system is in use, then the lack of a score or incomplete observations, or a score or observation requiring a response, may be a precursor to an adverse event. Note: if you do not use an early warning score, then consider adapting one from elsewhere.

PG2 Tissue damage or pressure ulcer

Tissue damage or pressure ulcer may be difficult to define. All children who are admitted to hospital and who have difficulty in turning will need to be assessed for pressure ulcers on admission and throughout their stay. Look for assessments and, in particular, look in nursing notes for comments on reddening of the skin and early development of tissue damage. Also look for tissue damage as a result of IV therapy.

PG3 Readmission within 30 days

An adverse event may not manifest itself until after the patient has been discharged from the hospital, especially if the length of stay is minimal. As the chart is reviewed, look to see if this admission was within 30 days of a previous hospitalisation. Or, did the current admission result in another future hospitalisation? Examples of adverse events may include surgical site infection, recurrent infections, relapses and ongoing seizures. This is easier to detect if all the patient's records are pulled along with the case note currently being reviewed.

PG4 Unplanned admission

Any unscheduled admission for a known or previously-diagnosed condition could be an indication of an adverse event. The fact that it was unscheduled may be as a result of sub-optimum treatment which would be considered as an adverse event. Consider the reason for the admission and whether it was related to an adverse event or not.

PG5 Abnormal cranial imaging

Any abnormal cranial imaging (including, but not limited to, cranial imaging with evidence of significant ischemia or grade 3-4 hemorrhage) may be the result of fluctuations in blood pressure, cardio-respiratory arrest, or electrolyte imbalances. The adverse event will be intra-ventricular hemorrhage. Congenital anomalies should not be considered as adverse events.



PG6 Respiratory or cardiac arrest / crash calls

All respiratory or cardiac arrests need to be carefully reviewed as they may represent the end event of a flawed care process. Not all crash calls are adverse events. However, cardiac or pulmonary arrest occurring intra-operatively, or in the post-anaesthesia care unit, should always be considered an adverse event. If these occur in the first 24 hours post-operatively, they are also very likely to be an adverse event. A sudden cardiac arrhythmia, with a resulting crash call, may well be associated with no adverse event. But failing to rescue a patient, due to lack of recognition of physiological change in signs and symptoms, would definitely be an adverse event.

PG7 Diagnostic imaging for embolus / thrombus +/- confirmation

Development of a DVT or pulmonary embolism (PE) during a hospital stay should be considered as an adverse event. Even if all appropriate preventive measures appear to have been taken, from a patient's perspective this is a harmful event. If the hospitalisation occurs due to a DVT or emboli, look for drug-related or other cause (at previous admission or outside of the hospital).

PG8 Complication of procedure or treatment

Evaluate the reason for the procedure. The procedure itself may be required due to an adverse event. Look for complications from any procedures. Procedure notes do not always note the complications, especially if the complication occurs hours or days after the procedure note has been documented.

PG9 Transfer to higher level of care (including specialist unit/ICU/HDU)

Transfers include those that occur within hospital, to another hospital, or to your hospital from another. Transfer to an intensive care unit or high dependency unit, or step up to 'specialising' on the same ward, is a trigger that indicates an adverse event may have occurred. Admissions to intensive care or HDU, or the decision to give specific intensive nursing input on the same ward, may have occurred when a patient's clinical condition deteriorated, perhaps secondary to an adverse event.

When reviewing this trigger, look for the reasons for the transfer and the change in condition. For example, in the case of admission to intensive care following respiratory arrest and intubation, if the respiratory arrest was a natural progression of an exacerbation of chronic disease, it would not be an adverse event. But if it was caused by a post-operative event (eg a pulmonary embolus, or over-sedation) it would be an adverse event.

PG10 Hypoxia O₂ sat <85%

Hypoxia that is not in keeping with the condition of the child (eg in congenital heart disease or chronic lung disease) could be an indication of an adverse event such as a cardiac or respiratory arrest.

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PG11 Cancelled elective procedure / delayed discharge

Cancellation of an elective procedure might indicate that the patient has experienced an adverse event that compromised their procedure. Alternatively, the patient may experience and adverse event as a result of waiting longer than planned for the procedure. Delayed discharge for non-clinical reasons can result in an adverse event. This includes discharges to home or to another clinical area (eg a delay of six hours from the time of being classified as clinically fit for discharge home, due to waiting for medications to be released from pharmacy). Reviewers should agree what is reasonable for their organisation.

Surgical care component

PS1 Return to theatre

A return to surgery is a trigger and means you should check whether an adverse event occurred during the previous surgery.

An example of an adverse event is a patient who had internal bleeding following the first surgery and required a second surgery to stop the bleeding. Where patients have a second surgery that is exploratory, but does not reveal anything (looking for bleeding, or a suspected retained surgical instrument) this would still be considered an adverse event.

Sometimes a return to theatre after a previous surgical procedure is planned and is therefore not an adverse event. For example, a procedure that must be completed in stages, or a procedure that is completely unrelated to the first procedure, and the result of another diagnosis - such as pacemaker insertion after a bowel resection. It is important to distinguish whether the additional procedure was planned.

PS2 Change in planned procedure

An unexpected change in surgical procedure can be the result of unexpected findings after the procedure has started; a change in clinical condition during the procedure; or an adverse event occurring during the procedure. When the procedure on the post-operative note is different from the procedure planned in the pre-operative note, or documented in the surgical consent, a reviewer should look for details as to why the change occurred.

An unexpected change in procedure, due to equipment failure or missing equipment, is an adverse event if the patient experienced additional pain, time in the hospital or other harm as a result of the different procedure.

PS3 Surgical site infection or hospital acquired urinary tract infection

Surgical site infections are the second most common type of adverse events in adult hospitalised patients, increasing the length of stay and morbidity. (Few studies are available on children.) Look for any nosocomial infections, surgical site infections, or urinary tract infections. Any infection occurring in hospital is an adverse event. The infection may occur after discharge, so look at visits to the emergency department, community nursing, or outpatient visits.



PS4 Removal / injury/ repair of organ

Review theatre notes and post-operative notes for evidence that the procedure included repair, injury or removal of any organ. Except in cases of trauma, where organ injury or a suspicion of organ injury is the reason for surgery, this may indicate an operative event damaging the organ.

Intensive care component

IP1 Readmission to Intensive Care or High Dependency Care

Any readmission to the ICU indicates a high probability of an adverse event occurring on the ward or outside the hospital. Look for a relationship with an adverse event. Examples might be pulmonary oedema, secondary to excess fluid administration, or an aspiration.

Medication component

PM1 Vitamin K (except for routine dose in neonates)

If vitamin K was administered as a response to a prolonged INR, review the chart for evidence of bleeding. The laboratory reports should indicate a lowered haematocrit or presence of faecal occult blood (blood in stools). Check the progress notes for evidence of excessive bruising, gastrointestinal (GI) bleed, hemorrhagic stroke, large haematomas, or other bleeding episodes.

PM2 Naloxone

Naloxone is a powerful opiate antagonist. Determine why the drug was used. If it has been used because of opiate overdose or overuse, an adverse event has occurred.

PM3 Flumazenil (Romazicon)

Flumazenil reverses benzodiazepine drugs. Determine why the drug was used. If hypotension or marked, prolonged sedation occurred following benzodiazepine administration, an adverse event has occurred.

PM4 Glucagon or glucose ≥ 10%

The administration of glucagon or glucose \geq 10% (oral or intravenous), may indicate that the patient has received too much or too little insulin or oral hypoglycemic. They may also have experienced symptoms as a result of this. Both the symptoms and the administration of additional medication are adverse events.

PM5 Chlorphenamine or antihistamine

Although frequently used for allergic reactions to drugs, these drugs can also be prescribed as a sleep aid, a pre-op/pre-procedure medication, or for seasonal allergies. If the drug has been administered, review the chart to determine if it was ordered for symptoms of an allergic reaction to a drug administered, either during the hospitalisation or before admission.

PM6 Anti-emetics

All administration of anti-emetics should be recorded as a trigger and professional judgment needs to be exercised to determine if an adverse event has occurred. Nausea and vomiting can be the result of drug toxicity or overdose, particularly in patients with impaired renal function. Some drugs, such as theophylline, frequently cause nausea and vomiting when levels are out of the therapeutic range. Anti-emetics are also commonly administered to patients post-operatively, or those receiving chemotherapy or PCA. Where these have not been administered in advance of nausea and vomiting, you may wish to consider this as an adverse event. In some instances, clinicians judge that potential side effects from prophylactic use of anti-emetics may outweigh the potential benefits and may not consider any resulting nausea or vomiting in these circumstances to be an adverse event.

PM7 IV Bolus ≥ 10ml/kg colloid or crystalloid given

Administration of the colloid or crystalloid is an indication of possible collapse/shock and is an indication of a possible adverse event. It may be detected separately under PG6.

PM8 Abrupt medication stop

While some medication courses, such as antibiotics, are for a limited duration, the cessation of several medications at once, or cessation of a long-term medication (eg an antihypertensive) is a trigger requiring further investigation. It may indicate an adverse drug reaction, drug interaction, or sudden change in the patient's condition.

Lab test component (Use the local laboratory upper limit for children)

Haematology

PL15 Thrombocytopenia (platelets <100)

Abnormal coagulation or platelet counts (due to sepsis or ITP) that requires treatment with clotting products or platelet transfusions, may not be an adverse event as it is part of a pathological process. But if it is left untreated and the child suffers a bleed as a consequence, you should record an adverse event.

PL1 High INR >5 or aPTT >100

Look for evidence of bleeding to determine if an adverse event has occurred. An elevated INR in itself is not an adverse event.

PL2 Transfusion

Procedures can require intra-operative transfusion of blood products for replacement of estimated blood lost, but this has become less common with 'bloodless surgery'. Any transfusion of packed red blood cells (RBCs), or whole blood, should be investigated for causation, including excessive bleeding, unintentional trauma of a blood vessel, etc. Transfusion of many units within the first 24 hours of surgery, including intra-operatively and post-operatively, will commonly be related to a peri-operatively. Fresh frozen plasma and platelets can reflect system problems that include failure to plan changes in anticoagulants prior to surgery, and the need to reverse quickly in order to carry out the surgery.



PL3 Abrupt drop in Hb or Hct (>25%)

Any drop of 25% or greater in Hb grams or Hematocrit (Hct) requires an explanation. All bleeding-associated events might commonly be identified by this trigger. Smaller 'drops' can obviously also be associated with adverse events, but the question as to whether harm has occurred needs to be answered subjectively. Anticoagulant use is frequently found to be associated with this particular trigger.

Biochemistry

PL4 Rising urea or creatinine (>2x baseline)

Review laboratory records for rising levels of either BUN or serum creatinine. If a change of two times greater than baseline levels is found, review medication administration records for medications known to cause renal toxicity. Review medical progress notes and the history, seeking physical and other causes of renal failure, such as pre-existing renal disease or diabetes that could have put the patient at greater risk of renal failure. If multiple factors are identified, subjective judgment may be needed to determine whether renal failure was an adverse event.

PL5/PL6 Electrolyte abnormalities (Na+ <130 or >150, K+ <3.0 or >6.0)

Electrolyte imbalance can either precede or be associated with adverse events. Not all patients with electrolyte abnormalities will be symptomatic. Review the case notes for evidence of symptoms.

PL7 Hypoglycaemia (<3mmol/l)

Not all patients will be symptomatic; if the patient is not symptomatic there is probably no adverse event. Review for associated use of insulin, or oral hypoglycemics with evidence of symptoms and commonly followed by administration of glucose (oral or intravenous). Signs and descriptions of symptoms such as lethargy, shakiness, etc, will be described by nurses in the notes.

PL8 Hyperglycaemia (>12mmol/l)

Glucose greater than 12mmol/l requiring treatment in the non-diabetic could be the result of IV fluid/TPN error, nosocomial infection, steroid overdose, osmotic dieresis or sepsis - all of which are adverse events.

PL9 Drug level out of range

Where a drug level has been taken and the result is a subtherapeutic level or a toxic level, this may imply harm to the patient. For example, a subtherapeutic level of an anticonvulsant may result in the patient having seizures and may be due to poor management of, or compliance with, treatment. A toxic level of an antibiotic, such as gentamicin, may result in renal failure or deafness. A toxic level of paracetamol may result in acute liver damage and death.

These may be due to a drug interaction that alters the metabolism of a drug; the prescription of an incorrect dose; or lack of recognition of impending organ failure which would have required a lower dosage of drug to be prescribed. If a patient has recently started a drug


which takes a while to achieve steady state, then subtherapeutic levels may be an expected part of monitoring, and would not necessarily imply harm. This should be at the discretion of the reviewer.

Microbiology

PL10 MRSA bacteraemia

Review for any positive MRSA bacteraemia.

PL11 C. difficile

If a patient is on, or has been on, multiple antibiotics, this adverse event can be observed. A positive C. difficile result is an adverse event.

PL12 Vanc resistant enterococcus (VRE)

Review for any nosocomial infections, central line infection, surgical site infection, or urinary tract infections. Any infection occurring in hospital is an adverse event. Exceptions might be the urinary tract infection from outside the hospital, or infection being treated but not contracted in hospital.

PL13 Nosocomial pneumonia

Look for x-ray or lab reports that suggest pneumonia. Any pneumonia diagnosed in the hospital needs to be looked at carefully. Any infection starting in hospital needs to be considered nosocomial and an adverse event, unless clearly contracted from outside the hospital. Re-admissions could also represent pneumonia from a previous hospitalisation, particularly if antibiotic resistant.

PL14 Positive blood culture

A positive blood culture at any time during hospitalisation must be investigated as an indicator of an adverse event. A surgical site infection, sepsis, infected lines, or any other hospital acquired infection is an adverse event.

PO1 Other event

Any other event that has not been detected by the trigger tool but is an adverse event.





5. Further help and support

Training

We recommend that each organisation has at least one person who has received formal training in trigger tool methodology and case note review. Together with the resources provided, including this guide, this person can then train others within the organisation.

At the time of writing, the Safer Care programme offers a limited number of one day 'quick start' training events as well as more comprehensive patient safety improvement programmes. We are also investing in Webex tutorials and hope to offer these as an alternative or top-up option in the future.

www.institute.nhs.uk/triggertool

Measurement for improvement

Measurement for improvement uses Statistical Process Control (SPC) to determine whether or not a trend is actually demonstrating a sustained change (improvement or deterioration) or just natural variation.

More information on SPC and variation can be found via this link: <u>http://www.institute.nhs.uk/quality_and_service_improvement_tools/quality_and_service_improvement_tools/statistical_process_control.html</u>

Methods for implementing service improvement

The methodology for implementing and sustainable improvement is based on the model for improvement. Also known as PDSA cycles, this model describes the cycle of Plan, Do, Study and Act. Further information can be found via this link:

http://www.institute.nhs.uk/quality_and_service_improvement_tools/quality_and_service_imp rovement_tools/plan_do_study_act.html

Institute for Innovation and Improvement

Additional Resources

Rozich JD, Haraden CR, Resar RK. Adverse drug event trigger tool: A practical methodology for measuring medication related harm. *Quality and Safety in Health Care*. 2003; 12:194-200.

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Matlow A. et al. The Development of the Canadian Paediatric Trigger Tool for Identifying Potential Adverse Events Healthcarequarterly 2005; 8: 90-93

Matlow A and Cronin G, Reducing Harm in Paediatric Care: Learning about Adverse Events using a Validated Canadian Paediatric Trigger Tool For the CAPHC Paediatric Trigger Tool Research Group Montreal, October 14, 2007 <u>http://www.caphc.org/documents_annual/2007/conference_ppts/14_10_2007/patient_safety/</u> <u>matlow_cronin.pdf</u>

