

Adverse Events – One of the Most Important Health Care Quality Indicators: A Case Study

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Abstract

The aim of study: to evaluate inpatients, experienced adverse events (AE) in Klaipeda university hospital (KUH) contingent, healthcare profiles, location and causal factors, the degree of risk, possibility to avoid it, and to compare assessment of doctors and experts, and estimate their changes in different analyzed periods. **Material and methods.** The study carried out by analyzing the AE reporting forms in KUH at 2000-2014 time period. Exploring and comparing 1690 patients, experienced AE data by age, gender, health care profile, the reasons. **Results.** The survey showed that AE was 0.3 % of hospitalized patients, most of them (54.9 %) – associated with surgery. The largest group of AE – repeated operations (44.8 %), related to childbirth AE (26.2 %) and related to infection – (13.1 %). Almost half (43.2 %) AE were medium risk, one-third (33.8 %) – minimal and one-fifth (21.6 %) – high risk. Doctors (nurses) and experts opinions on the major causative factors of AE – the individual characteristics of the patients (88.5 % and 90.3 %) basically was similar. However, due to the individual characteristics of doctors (nurses) – experts often (14.2 %) could see them as causal factor than doctors or nurses (9.8 %). Due possibility of AE avoidance – doctors (nurses) and experts opinion that almost half of them (44.7 % and 48.8 %) were avoidable was the same, but stood for full possibility of avoidance (11.2 % doctors (nurses) and 16.9 % experts) and complete inevitability (44.1 % doctor (nurses) and 34.3 % experts) of AE. **Conclusions:** Long-term operating adverse events reporting and registration system and analysis showed that adverse events in KUH is much less than in comparable large multiprofile hospitals of other countries. The structure of AE have advantages with structure in other countries – the most adverse events related to surgery, infections, nursing, but there are significant differences – reported little adverse events related to drugs, diagnostics, and a small number of falls compared with many births related AE. The majority – almost four fifths of the AE was minimal or medium risk, one-fifths – high-risk. The AE related

with deaths were few. The main causal factors of AE – individual characteristics of the patients and the doctors, and team work failure. A two-thirds of AE could be fully or partially prevented.

Keywords: Adverse Event, Health Care Quality, Adverse Event Reporting

1. Introduction

Various events and phenomena, including the occurrence of AE, science explains the relatively limited or completely unable to explain.

As one of the main causes of these events, the human factor – the possibility of human mistakes, limited or improper use of the knowledge and scientific evidence or to be aware of such evidence (Reason, 2000; Smith et al., 2011; Walsh, Smith, 2011). Recently, more and more scientists emphasize the systemic factors in the occurrence of AE in the process of health care (Vincent, 2010; Spath, 2011; Williams, 2011; Kavalier, Aleksander, 2014; Janušonis, 2016.).

Systemic and organizational factors closely related to the quality of healthcare.

Adverse events influence the quality of healthcare through the whole range of its signs - hospital length of stay, patient satisfaction, costs, legal claims, patients flows and their choice of health care organizations.

Unacceptable number of AE and its structure is highly dependent on the concept and definition – there are many concepts and definitions of AE, but there is almost no specific. In addition, basic health care process participants – doctors, nurses and patients perceive them differently (patients – much more widely and subjective) (O'Connor et al., 2010; Janušonis, 2016.).

Health care quality improvement associated with a number of environmental and organizational factors, one of them – the AE. Therefore, its prevention, reduction of harm to patients and health care organizations is possible only by the existing AE reporting systems, their documentation, expertise, root-cause analysis and public (patients) information about them.

The aim of study: to evaluate inpatients, experienced AE in KUH contingent, healthcare profiles, location and causal factors, the degree of risk, possibility to avoid it, and to compare assessment of doctors and experts, and estimate their changes in different analyzed periods.

2. Material and methods

From January 2000 to December 2014 a continuous survey was carried out in Klaipeda University Hospital (KUH), a multiprofile 998 bed hospital. Material – KUH inpatients in analyzed period.

The object of research – adverse events (AE).

Research methods – analysis of literature, AE reporting forms analysis, statistical grouping, comparative analysis of the content.

Information was collected via KUH AE reporting forms. This form is prepared by the author. It consists of seven parts: patient and AE information (a), phase, which took place in an AE (b), the stage of health care process, which took place in an AE (c), the level of risk and consequences of AE (d), causal factors of AE (e), the possibility of avoidance an AE (f), and expert conclusion (g).

Forms are filled by doctors or nurses, who perceived, notice an event. AE with minimal risk – is an event that could cause or lead to health problems which are resolved without further treatment or other action. Medium risk AE – when to remove or reduce the consequences of the AE additional treatment and prolonged patient hospitalization time is needed. High risk AE – an event was caused loss of function of one or more organs, loss of working capacity (temporary or permanent); for eliminate or reduce the consequences of the AE, inpatient need for additional treatment and care. Death associated with AE or caused of its.

The paper analyzes the systemic causes of AE – individual patients and doctors (nurses) characteristics, teamwork, management factors, working conditions and tools, technologies.

Individual patient characteristics include age, gender, disease, exhaustion and various other risk factors.

Individual doctors (nurses) characteristics are knowledge, skills, physical - emotional readiness for work, the ability to communicate with the patients (sociability), a sense of duty and discipline (compliance with the rules of procedures, etc.).

Teamwork – it's generally carried out the patient's health care by doctors, nurses, nursing assistants.

Management factors – various managers' decisions and actions that help staff to perform their duties properly.

Working conditions, tools, technologies – this is the environment, working tools, modern (IT, MRI, KT, PET, robots, etc.) and routine (beds, patient lifts, toilets and showers, adapted to the patient's needs, etc.) equipment.

During the analyzed period 2736 AE was reported, but for the study was selected 1690 AE, which corresponded to AE concept and was occurred with hospitalized patients. Not to analyze reports of first-degree perineal tears during childbirth, planned reoperations, some infectious diseases that have occurred at home after childbirth and its causes was unclear, out-patient adverse events, reports about the same AE and so on. The 1101 (65.1 % of respondents) were women, 589 (34.9 %) – men. Analyzed and compared the inpatients, experienced AE of 2000-2004, 2005-2009 and 2010-2014 periods

of the year according to age, gender, causes of AE and the health care profile groups. It should be noted that during the analysis period KUH has increased the number of patients, the number of operations and its complexity, patients have been treated with more severe and complex diseases. Doctors (nurses) and expert assessments on the AE causative factors and possibilities of their avoidance are compared. Statistical analysis was performed using SPSS 17.0 for Windows and Microsoft Office Excel 2003 programs. Data difference was considered statistically significant at $p < 0.05$ (statistical confidence level of 95 %).

3. Methodological limitations of the study. Until end of 2003 (2000-2003) AE have been reported in a separate written statement, and not formalized in the form of reports, and such reports in the forms were drawn up later and this could lead to some AE, especially in the low-risk not to include in the accounts.

In the KUH, as an AE, reported and recorded unplanned re-operation, which in some countries are not considered AE and is not registered. KUH not registered potential (could have happened, but incurred) AE that's reported and registered in some countries. KUH not registered as an AE re-hospitalization.

The study, although the long-term, carried out in a one hospital, which, although it is similar in structure and activity to other large multiprofile university hospitals, but may also have special features.

4. Results

During the analyzed period, the KUH treated 645 839 inpatients, 1690 (0.3 %) of which had AE (0.27 % for women and 0.24 % for men) (0.2 % 2000-2004, 0.3 % 2005-2009, and 0.2 % 2010-2014). The number of patients hospitalized during the analyzed period grew – in 2000-2004 – 202459, 2005-2009 – 215344, 2010-2014 – 228036. At the same time increasing the number of operations – 247 050 operations carried out during the analysis period (2000-2004 it was performed 54242, 2005-2009 – 91046, 2010-2014 – 101762 operations. Reoperations in the analyzed period accounted for 757 (0.3 %). During the analyzed period gave birth to 63937 women, 443 (0.7 %) of which have experienced an AE [(2000-2004 – 167 (1.2 %), 2005-2009 – 237 (1.4 %), and 2010-2014 – 39 (0.2 %)].

The part of inpatients who occurred AE in the separate analyzed periods unchanged. Nearly two-thirds-1100 (65.1%) of its where women, the average age 36.3 years. The most common AE occurred in 20-39 years of age and the vast majority of them related to childbirth. Excluding the childbirth-related adverse events, other events are particularly vulnerable to patients 50-79 years of age more women than men.

Most number of AE in surgery (54.9 %) and gynecology and obstetrics (27.1 %) profiles (Table 1).

Table 1. Distribution of adverse events in accordance with healthcare profiles.

Years Profiles	2000-2004yr.		2005-2009yr.		2010-2014yr.		Total	
	n=459		n=746		n=485		n=1690	
	n	%	n	%	n	%	n	%
Surgery	216	47,1	392	52,5	319	65,8	927	54,9
Obstetrics and gynecology	167	36,4	245	32,8	46	9,5	167	27,1
Maintenance treatment and care	59	12,8	49	6,6	62	12,8	170	10,1
Internal medicine	10	2,2	36	4,8	33	6,8	79	4,7
Anesthesiology and intensive care	5	1,1	18	2,4	17	3,5	40	2,4
Others	2	0,4	6	0,9	8	1,6	16	0,8

More than half (52.7 %) AE observed during normal office hours (8 am – 4 pm.), least (17.9 %) during the night time (10 pm – 06 am).

The majority of AE – 92.6 % notes and report doctors. 65.8 % of AE occur in the unit location, 27.3 % – at the time of operation or immediately afterwards, 2.8 % – at the time of anesthesia, 3.1 % – at home, 1.0 % elsewhere (the patient is removed from the unit and AE occurs in the hospital area). The majority of AE involves repeated operations (44.8 %), followed AE related to childbirth (26.2 %), the third – associated with infection (13.1 %), least AE associated with nursing care (no falls) – 2.0 % and the pharmaceutical (2.1 %) (Table 2).

Table 2. Distribution of adverse events by groups.

Years Groups*	2000-2004yr.		2005-2009yr.		2010-2014yr.		Total	
	n=459		n=746		n=485		n=1690	
	n	%	n	%	n	%	n	%
Reoperations	179	39	283	37,9	295	60,8	757	44,8
AE associated with childbirth	167	36,4	237	31,8	39	8	443	26,2
AE associated with infection	60	13,1	106	14,2	55	11,3	221	13,1
AE associated with operation	49	10,7	109	14,6	45	9,3	203	12
Falls	52	11,3	44	5,9	51	10,5	147	8,7
AE associated with diagnostics	9	2	30	4	9	1,9	48	2,8
AE associated with anesthesia	6	1,3	28	3,8	13	2,7	47	2,8
AE associated with procedure	7	1,5	30	4	17	3,5	44	2,6
AE associated with pharmaceutical (drugs)	14	3,1	16	2,1	5	1	35	2,1
AE associated with	7	1,5	20	2,7	7	1,4	34	2

nursing care								
Other AE	6	1,3	36	4,8	31	6,4	73	4,3

*The same AE may fall in to a different groups (e.g. related to delivery and infection, with drugs and anesthesia, etc.)

The main differences in the analyzed period, and by age and gender were not observed. Almost half of AE (43.2 %) attributable to the medium risk, a third (33.8 %) – to the minimal and one-fifth (21.6 %) – high risk level group (Table 3).

Table 3. Distribution of adverse events by risk level

Risk level	Years	2000-2004yr.	2005-2009yr.	2010-2014yr.	Total
		n=459	n=746	n=485	n=1690
Minimal risk		231 (50,3%)	226 (30,3 %)	114 (23,5 %)	571 (33,8 %)
Medium risk		161 (35,1 %)	369 (49,5 %)	200 (41,2 %)	730 (43,2 %)
High risk		63 (13,7 %)	140 (18,8 %)	162 (33,4 %)	365 (21,6 %)
Death related AE		4 (0,9 %)	11 (1,4 %)	9 (1,9 %)	24 (1,4 %)

With AE related deaths was 24 (1.4 %), most of them after reoperation as a result of severe patient's clinical condition (oncological diseases, etc.). The analysis of the separate periods of time, showed a statistically significant decrease in the minimum risk of AE, and high-risk AE grew. This explains the growing and increasing the complex hospital patients flow, increasing operational activity. The analysis of AE risk category, age and gender interfaces, provides that the AE with a minimal risk occur more in the young age (up to 30 yr.) of women and are associated with childbirth.

Causative factors study (Table 4) – the doctors (nurses) and expertevaluation analysis showed that the most common cause of AE – the individual characteristics of the patients (88.5 % doctors and 90.3 % experts evaluation).

Table 4. Adverse events causative factors by doctors nurses and experts evaluation.

Evaluation	Doctors (nurses)	Experts	Significance of statistical difference
	n=1690	n=1690	
Causative factors			
Individual patients characteristics	1496 (88,5 %)	1526 (90,3 %)	p>0.05
Individual doctors characteristics	165 (9,8 %)	240 (14,2 %)	p<0.05
Team work factors	61 (3,6 %)	128 (7,6 %)	p<0.05
Management event and	8 (0,5 %)	37 (2,2 %)	P<0.05

organizational factors			
Working conditions	11 (0,6 %)	2 (0,1 %)	p>0.05
Working equipment	45 (2,7 %)	20 (1,2 %)	p<0.05
Other	127 (7,5 %)	44 (2,6 %)	p<0.05

In the second place – the individual characteristics of doctors (9.8 % doctors and 14.2 % experts evaluation), the third – the team work factors (3.6 % doctors and 7.6 % experts evaluation). Experts and doctors evaluation of some positions were different – experts as causes of AE often could see individual doctors characteristics, teamwork and management and organizational failure. The analysis of AE causal factors in different periods showed, the doctors as the cause of AE sometimes seen equipment, what the experts are not always confirmed (Table 5).

Table 5. The causative factors of adverse events by doctors (nurses) and experts evaluation.

Evaluation	Doctors (nurses)			Experts			Significance of statistical difference (doctors and experts evaluation)		
	2000-2004yr.	2005-2009yr.	2010-2014yr.	2000-2004yr.	2005-2009yr.	2010-2014yr.	2000-2004yr.	2005-2009yr.	2010-2014yr.
	n=459	n=746	n=485	n=459	n=746	n=485			
Individual patients characteristics	418 91,1 %	646 86,6 %	432 89,1 %	419 91,3 %	653 87,5 %	454 93,6 %	p>0.05	p>0.05	p>0.05
Individual doctors characteristics	52 11,3 %	76 10,2 %	37 7,6 %	97 21,1 %	94 12,6 %	49 10,1 %	p<0.05	p<0.05	p<0.05
Team work factors	26 5,7 %	23 3,1 %	12 2,5 %	59 12,9 %	47 6,3 %	22 4,5 %	p<0.05	p<0.05	p<0.05
Management and organizational factors	1 0,2 %	6 0,8 %	1 0,2 %	19 4,1 %	10 1,3 %	8 1,6 %	p<0.05	p>0.05	p>0.05
Working conditions	1 0,2 %	7 0,9 %	3 0,6 %	1 0,2 %	0	1 0,2 %	p>0.05	p>0.05	p>0.05
Working equipment	7 1,5 %	18 2,4 %	20 4,1 %	5 1,1 %	6 0,8 %	9 1,9 %	p>0.05	p<0.05	p<0.05
Other	18 3,9 %	54 7,2 %	55 11,3 %	6 1,3 %	31 4,2 %	7 1,4 %	p<0.05	p<0.05	p<0.05

*The one AE can influence a few causative factors.

Due to avoidable adverse events the opinion of doctors and experts concurred in one aspect – almost half of them (48.8 %) partially have been avoided (Table 6).

Table 6. The possibility of adverse events avoidance by doctors (nurses) and experts evaluation

Evaluation	Doctors (nurses)	Experts	Significance of statistical difference
	n=1690	n=1690	
Possibility of avoidance			
Avoidable	189 (11,2 %)	285 (16,9 %)	p<0.05
Partially avoidable	756 (44,7 %)	825 (48,8 %)	p>0.05
Not avoidable	745 (44,1 %)	580 (34,3 %)	p<0.05

However, because of the AE could have been avoided of all the evaluation of doctors and experts completely disagreed - doctors such opportunities seen by 11.2 % cases, the experts – 16.9 % cases. That the part of AE could not to avoid thought 44.1 % of doctors and 34.3 % of experts.

The analysis of various periods showed, the doctors and experts opinions differences was not statistically significant due to the avoidance of adverse events opportunities for 2010-2014, but in 2000-2004 and in 2005-2009 experts seen greater opportunities to avoid adverse events than the doctors (Table 7).

Table 7. The possibility of adverse events avoidance by doctors (nurses) and experts evaluation in separate periods.

Evaluation	Doctors (nurses)			Experts			Significance of statistical difference		
	2000-2004yr.	2005-2009yr.	2010-2014yr.	2000-2004yr.	2005-2009yr.	2010-2014yr.	2000-2004yr.	2005-2009yr.	2010-2014yr.
	n=459	n=746	n=485	n=459	n=746	n=485			
Possibility of avoidance									
Avoidable	51 (11,1 %)	83 (11,1 %)	55 (11,3 %)	85 (18,5 %)	150 (20,1 %)	50 (10,3 %)	p<0.05	p<0.05	p>0.05
Partially avoidable	168 (36,6 %)	361 (48,4 %)	227 (46,8 %)	194 (42,3 %)	376 (50,4 %)	255 (52,6 %)	p>0.05	p>0.05	p>0.05
Not avoidable	240 (52,3 %)	302 (40,5%)	203 (41,9%)	180 (39,2%)	220 (29,5%)	180 (37,1%)	p<0.05	p<0.05	p>0.05

5. Discussion

AE in different countries' hospitals occurs between 3.2 to 16.6% of hospitalizations (Brady et al., 2009), EU – 8-12% (Special Eurobarometer 327, 2010; 411, 2014). According to the KUH survey adverse events was 0.3 % of hospitalizations – this is significantly less. In part this may be due to the failure notification, reports and registration. But on the other hand, the study found only 2.1% AE related to drugs (majority of them related to anesthesia, only 5 of the 44 report cases – allergic reactions). In the US drugs related adverse events is the largest group (Kolin et al., 2010). AE

related to diagnostics was 2.8 %, e.g. in Germany – 33 % (Bundesärztekammer, Behandlungsfehlerstatistic, 2014).

The fact that the majority of AE related to surgery (56.8 %), a lot with infections (13.1%), and falls (8.7%) corresponds to the literature data. Zegers et al. (2011) argue that the surgery related to three-quarters of AE, in Germany – 63% (Bundesärztekammer, Behandlungsfehlerstatistic, 2014). Naessens et al. (2009) study of adverse events in Mayo Clinic – (USA), found that with surgery associated 43%, the drugs – 23 %, with the falls - 21 % of AE.

The study found repeated operations part of all operated patients (0.3 %) is small compared with other countries, where repeated operations ranging from one to 9 %, depending on the length of time elapsed after the operation (Haynes et al., 2011, Kwok et al., 2012).

A lot of AE (26.2 %) associated with childbirth - most of them perineal tears and birth-related infection.

Although some authors (Millar, Mattke, 2004) obstetrical adverse events (birth trauma, vaginal and perineal tears, Caesarean section, problems associated with childbirth newborns) release as a distinct group, but in the scientific literature, they analyzed relatively rarely and incompletely treated as complications or just difficult childbirth.

Forster et al. (2011) indicates that the obstetrics AE was only 1.4% of hospitalizations, while other authors (Reason, 2000; Studdert et al., 2004; Vincent, 2010) indicates that the obstetrics and gynecology, and surgery - the highest risk of AE fields.

This is partly related to frequent legal claims for AE related to childbirth (Vincent, 2010).

Some AE related with infections – 13.1 % in our study. In the EU countries with infections related to 5 % AE (Special Eurobarometer 327, 2010; 411, 2014).

It should be noted that the study identified only individual nosocomial infections (only 7 out of 221 infections). As far as is known, a similar situation is in Lithuania. Very low rate of bedsores, ventilator-associated pneumonia, infection after central venous catheter.

The surgery-related infections (without obstetrics profile) was 106 cases (6.3 %), most of them associated with re-operations – 85 cases (5.0 %).

The re-operated patients related with infections were 11.2 %. This is consistent with results of other authors studies – with an infection related to 14.9 % of reoperations (Kwok et al., 2012).

Certain of AE (complications) – 139 (8.2 %), patients found themselves at home. Most of them - relating to childbirth and reoperations. This is broadly in line with the literature data. Skoufalos et al. (2012)

indicate that about half of the surgery related AE occur patients being at home.

Distribution of AE by risk groups in our study is similar to the data published by other authors (National Patient Safety Agency, 2006; Vincent, 2010).

The analysis of separate periods showed a high risk AE group is increasing and the number of minimal risk events is decreasing. Complexity of patients' diseases, their ages, the expansion of health care services in the risk scale this explains.

Our study showed the number of AE related deaths was low – 24(1.4 %). By the data of others authors, the surgery-related AE resulted the death of patients is up 4.9 % (Wilson et al. 1995; 2012) and a similar situation in the EU (Special Eurobarometer 327, 2010; 411, 2014).

By the data of study the main causative factors of AE – individual patients characteristics (1), and the individual doctors characteristics (2), and team work factors (3). Experts believe the team work factors are more important than doctors think.

Most scientists agree that the principal cause of AE in hospitals – individual patient characteristics (Hauck, Zhao, 2010).

Such factors of AE in hospitals as the main lodges and other authors (Smith et al., 2010; Vincent, 2010; Kavalier, Alexander 2014).

The avoidance of AE – one of the most discussed problem (Vincent, 2010; Bown et al., 2013; Janušonis, 2005; 2016). The study found that two-thirds (65.7 %) of AE experts believe could be completely or partially avoided.

The fact that the majority of AE in health care can be avoided, provides other authors (Soop et al., 2009; Schildmeijer et al., 2012). However, discussed the methodology of the expert conclusions justification (Norman, 2006; Sharek et al., 2010).

More than one third (34.3 % expert opinion) of AE could not be avoided. This is consistent with other authors' data – about one fifth of AE in obstetrics and gynecology, about two-thirds of the surgery is unavoidable (Morris et al., 2003; White et al., 2005). Doctors and experts are in different starting positions – retrograde evaluation of events is always easier and simpler than to make decisions in real time in a real situation. In summary, it can be said that AE definitions, their reports and registration (repeated surgeries and re-hospitalizations, potential adverse events and so on) assigning or exclusion to adverse, possibility of avoidance, methods of analysis and results from authors in different countries fairly markedly different.

6. Conclusion

Long-term operating adverse events reporting and registration system and analysis showed that adverse events in KUH is much less than in comparable large multiprofile hospitals of other countries.

The structure of adverse events have advantages with structure in other countries – the most adverse events related to surgery, infections, nursing, but there are significant differences - reported little adverse events related to drugs, diagnostics, and a small number of falls compared with many births related adverse events.

The majority – almost four fifths of the adverse events was minimal or medium risk, one-fifths – high-risk. The adverse events related with deaths were few.

The main causal factors of adverse events – individual characteristics of the patients and the doctors, and team work failure.

A two-thirds of adverse events could be fully or partially prevented.

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