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Identification, assessment and verification of current technical failure modes at automated infusion systems

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ABSTRACT: *A basic requirement for the identification, assessment and verification of current failure modes in automated infusion systems is a scientific survey of the status quo in clinical practice. The rise in critical incidents involving automated infusion technology from 2000 to 2009 was disclosed at 63 %. This remarkable rise requires a precise analysis of the error causes. The identification and evaluation of these technical failure modes is the primary aim of this study.*

Keywords: *Infusion pump, Survey, Technical sources of error, Verification.*

I. INTRODUCTION

Today, automated infusion systems are indispensable and routinely used in clinics for the parenteral infusion of fluid substances into the blood circulation of the human body. Infusion therapy plays an important role during the treatment of patients. Almost 90 % of all patients who undergo stationary treatment receive infusion solutions. More than 600 million infusion solutions flow into the veins of patients every year.

Infusion therapy supported by medical technology is used whenever the mechanisms in the metabolism of the human body have become unbalanced. Infusion therapy enables maintaining, correcting and substituting the necessary quantities of substances. Infusion systems are used, for example, to compensate for dehydration, normalize the electrolyte metabolism, maintain the acid-base balance and to administer drugs. Automated infusion systems allow the infusion of fluids at a certain rate, certain quantity and in different types of application.

In order to minimize risks in the application of automated infusion systems, it is imperative to investigate and analyse failure modes. The aim of this study is to identify and evaluate the frequency and type of occurrence of device failures in automated infusion systems under safety-related aspects. Primarily, the technical failure modes of infusion sets will be investigated and not the possible medical hazards for the patient.

I. CURRENT STATE OF RESEARCH

At present, there is no analysis of technical sources of errors in automated infusion systems. According to the data-recall facility, only a few comparable investigations need to be examined.

The following key facts indicate the acuteness of the planned thesis:

- 90 % of all patients, treated in stationary wards, receive infusion solutions [1]
- More than 600 million infusion solutions/year flow into the veins of patients [2]
- The announced rise in critical incidents involving automated medical devices, between 2000 and 2009 in Germany was 255 % [3]
- The announced rise in critical incidents involving automated infusion technology between 2000 and 2009 in Germany was 63 % [4]
- More than 10.000 complaints were received annually with regard to infusion pumps between 2005 and 2009 in the USA [5].

In the "Patient Security Agenda 2008", the Action Alliance Patient Security stated that there are large gaps in information for the current study situation with regard to compiling safety-related data concerned with medical products [6].

II. PROCEDURAL METHOD

The aim of this study was to observe and analyse the error frequency of infusion system equipment. In order to obtain data concerning sources of errors in respect of infusion equipment, the first step here is to define the most frequently used infusion equipments. They are generally arranged according to their application technology:

- Gravity feed infusion with infusion control
- Infusion Pumps with rotating peristaltic
- Infusion pumps with linear peristaltic
- Infusion pumps with volume chamber
- Syringe pumps.

In the inquiries the different applications techniques of the infusion pumps were not differentiated, because all defined and asked sources of errors are to be found with all pump types.

This study is only concerned with the aspect of technical errors (mechanical, electronic) on infusion devices. There is no attempt to include “accidents” which have occurred during the use of such equipment on patients. The analysis of events (injury to patients due to a technical medical device) is not a part of this study.

The sources of errors considered in this study are purely technical faults within infusion equipment itself and have no direct relation to the application of the equipment on patients.

The data with which to analyse the error frequency of infusion system equipment was gathered by means of anonymous surveys in 100 hospitals throughout Germany. The surveys to be evaluated were from the years 2006 and 2010. A standard questionnaire was drawn up provided with a clear grading scheme. This ruled out

misinterpretation by those questioned to a large extent. The used questionnaire was the same for both surveys. The implementation of an anonymous questionnaire meant that no conclusions could be drawn regarding the hospital questioned (technical service centre), the persons questioned (service personnel) and the infusion pump manufacturer.

An "anonymous" questionnaire was used "deliberately" in order to compile realistic, undistorted data. By being non-traceable, staff in service centres could analyse the device errors freely. Thus, they were instruction-free and not influenced in their evaluation of the error frequencies. This fact supported compilation of a realistic analysis of the error frequencies. The persons questioned (medical engineers at the respective service centres) were requested to answer the questions with a grade between *one* and *nine*. The grading key should reflect the error frequency regarding the respective infusion pump types; whereby the grade *one* represented a very low error frequency and *nine* a very high error frequency. The grade *zero* was considered as not assessable. The first of all defined, then asked and rated Sources of Errors were:

- Drive: Motor, gear, motion unit
- Power supply: Mains cable, IEC socket, power adapter, battery
- Software: Type-specific device software
- Keyboard: Keys, switches, pressure point, membrane keyboard
- Body: Cracks, brittleness, breakage, leakage
- Holder: Fixation to infusion stands, threaded rod
- Hose system: Accessories, type-specific transfer systems
- Handling: Operating errors by personnel
- Dirt: Labels illegible, soiled sensors, smeared display.

Using the grades (1 to 9) from the predefined grading scheme ensured that only the error frequency (the frequency with which a technical error occurred) was assessed. The number of different types of infusion pumps used in the various hospitals and the frequency with which the pump systems are used on patients was not an aspect for consideration through the questionnaire.

III. EVALUATION OF THE INQUIRIES

Of the 50 questionnaires sent for the survey in 2006, 23 were returned plausibly answered and evaluated, resulting in a response rate of 46 %. Of the 50 questionnaires sent for the survey in 2010, 24 were returned plausibly answered and evaluated, resulting in a response rate of 48 %.

The relatively high and good response rate of both inquiries, were certainly partly due to the stamped addressed envelope enclosed with the questionnaire. All the questionnaires returned, were sensibly answered and could be evaluated.

Up to now, the frequency with which the technical error sources predefined in the questionnaire occurred has been evaluated. The evaluation is presented per individual infusion pump type and as an overall comparison. The frequency of use of the various infusion pump types in everyday work in hospitals was not taken into account in the evaluation. The primary objective of the exercise was to compile the frequency of sources of errors not the frequency of use of various pump systems.

The following graph (Fig. 1) shows a comparison of the frequency of all sources of errors, year 2006 to 2010.

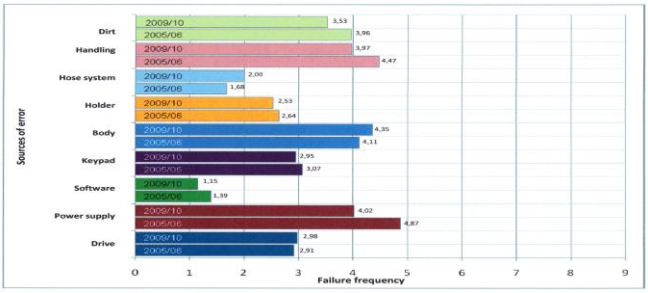

Fig. 1. Comparison, as arithmetic average, of the frequency of sources of errors of all type of pumps, survey 2006 to survey 2010

For the compiling of the statistical evaluation of the surveys, "IBM SSPS Statistics 18" software was used. Initially, the data records were gathered, samples of which were analysed with regard to normal population. The "Shapiro-Wilk test" was used here. During analysis with "SPSS", the significances were mainly $p < 0.05$, i.e. significant and, thus, not a normal distribution.

During the subsequent group comparisons (comparison of pump types per potential source of error), an evaluation using the "Kruskal-Wallis test" was implemented for not normally distributed samples.

The significance was established as a rank comparison. The statistical evaluations have been arranged individually according to the sources of errors and totalled in the following tables. The statistical evaluation per source of error is represented by average values, standard deviations, medians and significances (p-value).

Level of significance [7]:

- $p \geq 0{,}05$ is equivalent to not significant
- $p < 0{,}05$ is equivalent to significant
- $p \leq 0{,}01$ is equivalent to very significant
- $p \leq 0{,}001$ is equivalent to very highly significant.

The following table (TABLE 1) is an example of 18 statistically evaluated tables with different sources of errors at different automated infusion systems. The evaluation of the significance of this sample table, shows a significance to "Kruskal-Willis" of p= 0.123. It is equivalent to not significant.

TABLE 1
Comparison of all infusion pumps, source of error "Drive", 2006

Infusion system	Arithmetic average	Standard deviation	Median	Minimum	Maximum	N
Syringe pumps	3.04	1.22	3.00	1	5	23
Finger pumps	3.21	1.55	3.00	1	6	19
Roller pumps	2.29	0.76	2.00	1	3	7
Piston pumps	3.50	2.12	3.50	2	5	2
Infusion control	1.50	1.00	1.00	1	3	4
Total	2.91	1.37	3.00	1	6	55

In the next two tables (TABLE 2 and TABLE 3), the results of the evaluated ranking of the sources of errors, by sequence of occurrence, is shown.

TABLE 2
Weighting of the sources of errors and statistic in 2006

Weighting by rank	Survey in 2006	Statistic Test Kruskal-Wallis Significance per error source	Statistic Test Friedman Significance correlate
1. rank	Power supply	p= 0.017	p ≤ 0.001 very highly significant
2. rank	Handling	p= 0.569	
3. rank	Body	p= 0.007	
4. rank	Dirt	p= 0.068	
5. rank	Keypad	p= 0.089	
6. rank	Drive	p= 0.123	
7. rank	Holder	p= 0.119	
8. rank	Infusion hose system	p= 0.436	
9. rank	Software	p= 0.537	

TABLE 3
Weighting of the sources of errors and statistic in 2010

Weighting by rank	Survey in 2010	Statistic Test Kruskal-Wallis Significance per error source	Statistic Test Friedman Significance correlate
1. rank	Body	p= 0.269	p ≤ 0.001 very highly significant
2. rank	Power supply	p= 0.021	
3. rank	Handling	p= 0.337	
4. rank	Dirt	p= 0.458	
5. rank	Drive	p= 0.428	
6. rank	Keypad	p= 0.753	
7. rank	Holder	p= 0.149	
8. rank	Infusion hose system	p= 0.653	
9. rank	Software	p= 0.707	

The tables above give a good overview about the ranking of the sources of errors and their statistical evaluation in the different years 2006 to 2010. For analyzing the discrepancies between groups (in our case the sources of errors) the "Friedman-test" was used. The statistic test-result is shown as a very highly significance correlate of $p \leq 0.001$.

In the following tables (TABLE 4 and TABLE 5) present the contrasting juxtapositions of the sources of errors between the inquiries in 2006 and 2010. The shifting of the ranking is clearly shown by different colours.

TABLE 4
Comparative Weighting of the sources of errors in 2006 and 2010

Weighting by rank	Survey in 2006	Survey in 2010
1. rank	Power supply	Body
2. rank	Handling	Power supply
3. rank	Body	Handling
4. rank	Dirt	Dirt
5. rank	Keypad	Drive
6. rank	Drive	Keypad
7. rank	Holder	Holder
8. rank	Infusion hose system	Infusion hose system
9. rank	Software	Software

TABLE 5
Weightage of the evaluation-change of the inquiries 2006 to 2010 as ranking, positive to negative change

Weightage Evaluation-change positive change to negative change	Change of evaluation 2006 to 2010 Δ arithmetic mean	trend	Sources of errors
1. rank	- 0.85	↓	Power supply
2. rank	- 0.50	↓	Handling
3. rank	- 0.43	↓	Dirt
4. rank	- 0.24	↓	Software
5. rank	- 0.12	↓	Keypad
6. rank	- 0.11	↓	Holder
7. rank	+ 0.07	(↑)	Drive
8. rank	+ 0.24	↑	Body
9. rank	+ 0.32	↑	Hose system

Comparison of the evaluations of the years 2006 and 2010 indicates a clear trend within the error source rankings. Despite the distinct time gap between the two years in which the questionnaires were issued, the top three error sources (rankings) have clearly remained the most significant. Although there is a slight shift in the ranking positions (TABLE 4). The error sources "Power supply", "Handling" and "Body" prove the most serious sources of faults in both questionnaires.

IV. CONCLUSION

The primary objectives of this study were to complete a compilation of data regarding the sources of errors which frequently occur in technical infusion devices.

The increasing use of technical infusion equipment does not only raise the demands of technical safety but also on the functionality and operational availability of the various devices. A negative consequence of the increase in use of technical devices in infusion therapy is the increased occurrence of technical error sources in everyday clinic life.

The motivation behind this study was that the stock and compilation of data on the problems outlined above, was not available and/or was very fragmentary. Research on the subject showed that the basic theme of this study is highly topical and has not been dealt with to any significant degree. All the literature sources researched indicated a definite lack of information acquired from the compilation and analysis of sources of technical errors in technical infusion equipment. Some of the relevant literature sources urgently recommended the acquisition of data to discover the gaps in error source data and fill them.

The data used in this study was gathered by means of two separate and independent, anonymous questionnaires. Both questionnaires, one from the year 2006 and the other from 2010, were completed as part surveys within a total of 100 hospitals and their service centres. The questionnaires contained standardised questions and had a fixed method of assessment. The standardised questions and defined assessment scheme was intended to eliminate any possibility of false interpretation. By issuing the identical questionnaires to different hospitals in two different years, an attempt could be made to evaluate the results. A comparison of the results shows, that an evaluation by

means of a second questionnaire was both useful and effective.

Distinct sources of errors became apparent which topped the list in a negative sense in both questionnaires. The most distinct, highest placed sources of errors were:

- Power supply
- Body (housing)
- Handling
- Dirt.

As a result of the scientific survey extracts compiled in 2006 and 2010, this study has contributed to updating the status quo in respect of error source analysis. A survey of data, of the subject described, did not exist before. The results of the questionnaires and analysis of the data have enabled the error sources related to infusion pumps to be ranked, information which can then be used for improvements in design and development.

The results of this study indicate considerable potential in the objective of minimising and preventing technical sources of errors in infusion systems by applying the relevant measures presented in this work. But the results of this study also uncover more questions in need of research which it is hoped will be answered in follow-up studies:

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- Is it realistic to propose worldwide error manage-ment of error sources in associated with infusion pumps?
- On what legal foundation or platform should this error management be based?
- Can worldwide recommendations regarding the design and development of infusion pumps contribute to a reduction in the sources of errors and thus to a preventation of incidents involving patients?

These are questions, which could be answered in next studies soon.

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