Analysis of infusion pump error logs and their significance for health care

Paul T Lee, Frankie Thompson and Harold Thimbleby

Abstract

Infusion therapy is one of the largest practised therapies in any healthcare organisation, and infusion pumps are used to deliver millions of infusions every year in the NHS. The aircraft industry downloads information from 'black boxes' to help design better systems and reduce risk; however, the same cannot be said about error logs and data logs from infusion pumps. This study downloaded and analysed approximately 360 000 hours of infusion pump error logs from 131 infusion pumps used for up to 2 years in one large acute hospital. Staff had to manage 260 129 alarms; this accounted for approximately 5% of total infusion time, costing about £1000 per pump per year. This paper describes many such insights, including numerous technical errors, propensity for certain alarms in clinical conditions, logistical issues and how infrastructure problems can lead to an increase in alarm conditions. Routine use of error log analysis, combined with appropriate management of pumps to help identify improved device design, use and application is recommended.

Key words: Infusion pump alarm ■ Error log ■ Incident analysis

utomatic logs and voice recorders are widely used in aviation to help give investigators insight into real-time events surrounding incidents, near misses and for accident investigation. However, logs have also been influential in determining the outcome of incident investigations and have contributed to improving safety for passengers and employees (Reason, 1990; Shappell et al, 2006). This paper reports on a study of nearly 400 000 hours of infusion pump logs, and draws conclusions on user interaction, typical alarms and errors that are faced by all infusion pump users, even those without supportive medication safety software. Recommendations made by the author are aimed particularly at infusion device management groups, users, and equipment purchasers.

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Background

Despite individual investigations into healthcare errors and incidents, there is negligible use or review of error logs in the healthcare sector. Staff re-training has often been cited as the solution to improving healthcare error rates (Johnson et al, 2007). Although device logs can be accessed and downloaded to computers as and when required, this is often reserved for retrospective analysis of specific events rather than assessment of long-term user interaction and improved design. Nevertheless, the ultimate goal of incident analysis is prevention; the challenge is to learn lessons from each event (Bitan and Nunally, 2007; Medicines and Healthcare products Regulatory Agency (MHRA), 2010).

Poorly designed devices can lead to confusion, errors and dissatisfaction among health professionals (Dougherty, 2010). Human interaction is now being researched and publications are beginning to surface to help designers, manufacturers and users better understand each other's input to the process (Computer-Human Interaction for Medical Devices (CHI+MED), 2010; National Patient Safety Agency (NPSA), 2010; Thimbleby and Cairns, 2010; Money et al, 2011).

In an effort to help the medical device industry take account of human factors, a range of European standards, design recommendations and research protocols have also been established (NPSA, 2010; BS EN 62366: 2007; Kaye et al, 2011), and much has been written in the literature about the evolution of medication libraries and dose error reduction safety software to improve medication safety (Quinn, 2011). Despite these efforts, a lack of effective standardisation exists, and almost nothing is concerned with logs. The error log download tools often differ, extrapolation software is non-standard, and user-friendly reporting formats are essentially non-existent.

The NPSA (2004) previously highlighted poor infusion device management, pointing out the lack of standardisation, risks posed by a variety of device type (including software variations of the same device type) and suggested centralising devices into well-stocked infusion device libraries. Benefits included reducing waste, harmonising training, overall risk reduction and significant cost savings at the same time (NPSA, 2004). However, many organisations still lack infusion device libraries and are yet to tackle the wide variety and mix of infusion devices still in clinical use. In 2009, the MHRA completed a total of 1828 investigations in the UK for all medical device incidents involving serious injury (MHRA, 2010). Of these, 1476 (81%) had no established link between the incident and the device involved. In response, corrective actions included alerts, field safety corrective actions, advice
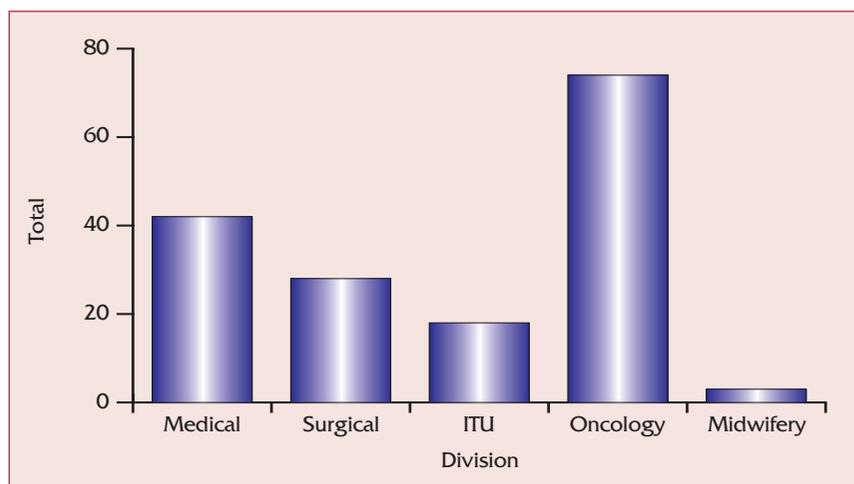
Figure 1. Number of error log files by area

regarding safer device use, improved staff training and on manufacturer undertakings to improve designs, processes and quality systems. Infusion devices continue to be one of their most active areas, with over 375 adverse incident reports investigated during 2009.

Although user error may sometimes be cited as the cause of an adverse incident, it may have simply contributed to the cause; there are often other underlying reasons that may relate to device management, equipment maintenance, adequacy of training for users, sleep deprivation, or the device design and human interaction (Thimbleby and Cairns, 2010). Infusion devices continue to be used extensively in healthcare, are considered as high-risk in organisational risk management programmes and need to be safely managed (Lee, 2010). Monitoring errors and alarms, users reactions, and how infusion devices are used in a clinical setting, might help designers, trainers and purchasers ensure safer, better designed infusion devices for the future.

Study
The aim of the study was to download and analyse the error logs from one type of volumetric infusion pump (Smiths/ Graseby 500) used as standard in a large, 500-bed acute hospital. The logs record the frequency, type of alarms and common errors that occurred while in use in the clinical setting. The log data were compared for common alarms across each department and clinical disciplines.

Method
Error logs were downloaded during annual maintenance checks and 165 logs from 131 different devices were selected for study. The pumps are only used by registered practitioners and have been used as standard across the organisation since their purchase in 2007.

Only pumps configured for adult patients were selected and as no software was available, a bespoke programme was developed to perform data analysis and tabulate the results of the downloaded error logs.

The infusion pumps store the most recent 200 events throughout their period of use, dated and timed, plus a cumulative total for each of 99 event codes. All devices had the same software version (v3.66, 0.71) and motor software

(v1.10) installed, avoiding potential discrepancies that might exist between different models of the same device type.

Event logs between 2009 and 2011 were selected for this study. A small number (*n*=7) were removed as they contained errors and significantly high numbers for each error code, suggesting a fault or software corruption. Devices tested in quick succession were also removed. In total, 165 data files out of 191 were accepted for the final analysis.

The error log data files were converted into Microsoft Excel spreadsheets for ease of analysis. The manufacturer's service manual was used to identify each of the event codes and their indicative meaning, together with any corrective actions. The error logs were stored on a file server at each annual maintenance check, and then cleared from each pump to reset the counter. Any pumps that were sent for investigation, repair, or maintenance, during the annual period also had their data files downloaded, and these were processed in the same way.

Figure 1 shows the total number of files, and their respective care areas used for the final analysis. The data files were sorted by error code, clinical area, ward and frequency of alarms. Additional analysis helped compare and contrast average usage figures and frequency of alarms by divisions and department speciality.

Results
Total time spent infusing medication/fluids
The total time spent infusing medication or fluids (*Table 1*) exceeded 21 million minutes (362 778 hours), equivalent to a single device being used non-stop for 41 years. Administration sets were loaded 127 767 times and infused 40 155 litres of intravenous medications/fluid across all disciplines. Devices were used only 44% of their available time and indicated extensive use on battery power, often exceeding manufacturers' maximum recommendation.

Advanced features
Additional software features are often supplied free of charge by manufacturers; for example, the volume over time (VOT) calculator, which helps calculate infusion rates. Previous studies have shown low confidence levels exist for maths and drug calculations in the nursing profession (Hutton, 1998; Medical Devices Agency (now replaced by Medicines and Healthcare products Regulatory Agency), 2005; Lee, 2008), and despite the pump having this built-in feature it was only accessed for 6% of all infusions (n=7660). The lack of use may simply be because users feel confident with their own calculations, or they are unable to easily access the feature, or

Table 1. Event codes and total time

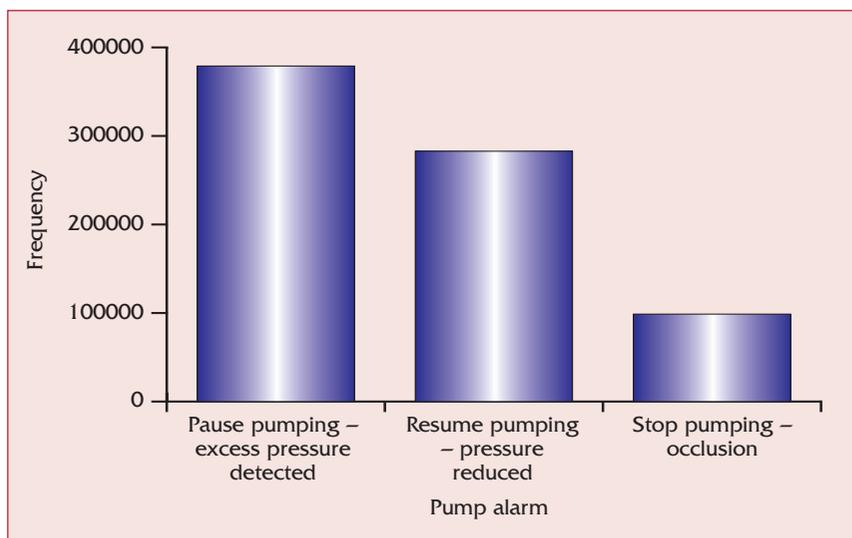| Code	Event	Total
85	Cumulative run time (minutes)	21 766 717
82	AC on time (minutes)	19 956 746
84	Charge time (minutes)	48 936 973
83	Battery On time (minutes)	2 649 082
88	Loading cycles	127 767
87	Cumulative volume (litres)	40 155
	Volume over Time (VOT) calculations	7 660

Figure 2. Top 10 alarm codes

Figure 3. Occlusion settings

generated when the device has been left unattended for 2 minutes; they are part of the normal operating and set up procedure. No-flow alarm conditions can be generated by empty infusion bags, clamps left closed (above the pump) or insufficient height of bag above the pumping mechanism; they are difficult to interpret for this study, but their frequency can be noted.

Occlusion alarms

Infusion devices attempt to maintain sufficient pressure on the medication or fluid to enable it to flow through all restrictions (given the length/diameter of the tubing and any valves/filters), automatically increasing pumping pressure to maintain the set flow rate. When the occlusion alarm is activated, the patient receives no or severely reduced infusion therapy. In the case of the infusion of medications with a short half-life this is critical, as it may result in plasma concentrations of a medication falling rapidly, with an associated adverse physiological response.

The correct occlusion alarm level setting is an essential part of the set-up procedure, and should be included during training sessions and competency assessment strategies. Indeed, the MHRA include a large section in their Infusion Devices Bulletin (MHRA Device Bulletin, 2003) and go into great detail around this clinical setting and its importance. Occlusion alarms can help the clinical team determine whether the default alarm setting needs to be altered, or that an error has occurred, such as clamps left closed or infusion lines have become obstructed.

Manufacturers use a variety of displays to help indicate this important feature, ranging from graphical displays, numerical readings (in millimetres of mercury: mmHg) and pumping pressure indicators. However, the pump studied here has no visual display of pressure but has three built–in occlusion level options for the user to select from high, medium and low.

In the logs, occlusion has far the highest prevalence of alarms for all conditions, being 37% of the top ten alarms for this device (*n*=98 762). *Figure 3* shows the total number of pauses, restarts and subsequent occlusion alarms, while *Figure 4* shows the number of times the occlusion alarm level was changed. There were only 437 changes to these default settings for this alarm (0.4%); this begs the question whether this setting should be automated, or perhaps is not really fully understood by its users.

The devices' built–in pause function for occlusion shows the highest number of events in the study (*n*=379 000), and note that the device does not actually alarm for this condition. The pump pauses during infusion if the pressure sensors detect a momentary occlusion or blockage in the infusion line. Should the blockage or occlusion clear itself within 10 seconds (for example, as would occur if the patient rolled onto the infusion line then off it again), the pump will resume with all preset limits intact. The resume function was activated in 74% of all infusions and the full occlusion alarm occurred in 26% of all pauses in therapy. Should infusion devices not have this 'pause and restart' function, then the number of alarms would be significantly increased in each care area and this should be noted.

they use standard infusion settings so this function may not be required.

In the authors' study, the use of this additional feature varied considerably. Within oncology, the VOT calculator was used on average 69 times for each device, about 1.3% of infusions (total use = 5153); while in the anaesthetics division the average use was 18 times per device: about 5.3% of infusions (total use = 336). These seem to be low rates of use, and suggest a range of further studies to explore issues such as: Does VOT provide a useful service for clinicians improving safety for patients? Is its low use a symptom of training or bad design? These are important questions; the device logs studied only record how often these additional features are used, and are unable to provide insight into which infusions are being calculated using this method.

Alarms

Figure 2 summarises the top ten most frequent alarm conditions arising when the pump is stopped by the safety mechanism or by the user. Note that on–hold alarms are

Air in line

There are clinical differences of opinion on the volume of air required to cause patient injury. Morling (1998) suggested that a large single bolus of air potentially presents a higher risk than a similar volume of air made up of smaller bubbles. Certainly, in neonates a 0.5 mL air bubble can cause serious injury, and accidental infusions of air into the bloodstream (air embolism) have been highlighted as a significant risk to health and listed in a number of investigations and fatalities by both the MDA and NPSA.

In volumetric infusion devices, air can enter the administration set from various sources, including incorrect priming of the set, loose connections, inversion of the set during use, infusion fluid degassing, or the administration set running dry. The pump has a built-in safety function that automatically traps smaller air bubbles until a preset volume has been collected, which can be removed using the automated feature built into the door mechanism without the need to disconnect the administration set connected to the patient.

Although the device studied here has a 'no-flow above pump' alarm that should sound first, the logs show 55 308 incidences of this occurring.

Figure 5 shows a high number of alarms (*n*=20 180) despite the device's ability to collect small air bubbles that would otherwise result in an alarm. The number of alarms per device is also shown (only one device studied had no alarms for this condition.) The highest number of alarms (*n*=7865) occurred in oncology. Each alarm should require intervention by the clinical team, and applying a nominal 5 minutes to deal with each alarm. There are effectively over 45 weeks of nursing time silencing and dealing with this alarm alone.

Door–open alarm

In human error terms, the door-open alarm can be considered as a workaround or violation of practice. There are no situations where a door-open alarm makes operational sense, even if a patient is not currently being infused, and if a patient is being infused it represents an unacceptable risk of uncontrolled infusion.

Although the safety clip (which reduces the risk of fluid free-flow) should remain in place, the manufacturer is clear in its instruction manual that the clip should not be relied on to stop the flow of medication (Smiths Medical Ltd., 2008). They go further and warn that the roller-clamp must be closed in all instances and that misuse may lead to death. Incidents have been recorded elsewhere when medications have been accidentally delivered at high flow rates owing to doors being inadvertently being opened during infusion therapy. Such safety features carry a high weighting factor in ensuring safer infusion devices are purchased in the NHS (MDA Device Bulletin, 2003; Lee, 2010).

Despite a dedicated training programme, manufacturer instructions, and posters across the organisation, the door-open alarm condition occurred in all clinical areas. *Figure 6* shows the number of door open alarms per device (*n*=9386).

Wards that admit patients into the hospital as well as the oncology service have a high number of alarms. One device had 335 door-open alarms when used for 2623 loading cycles
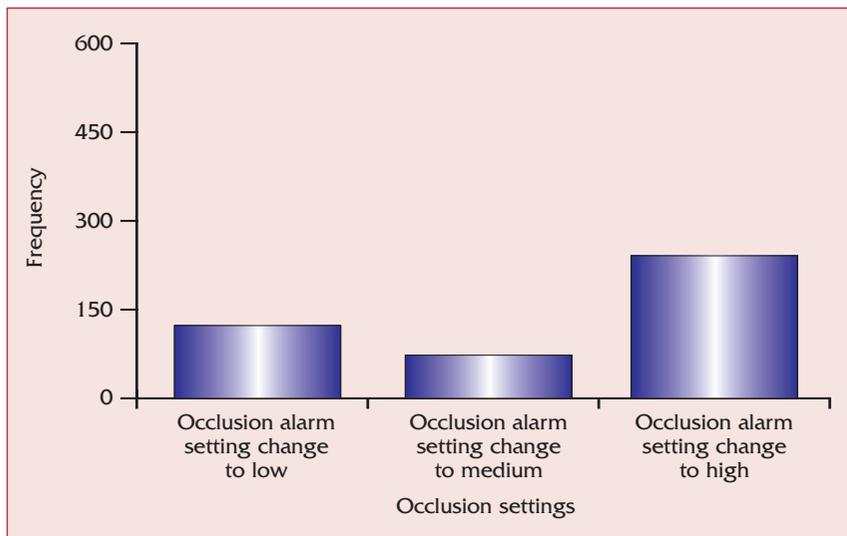

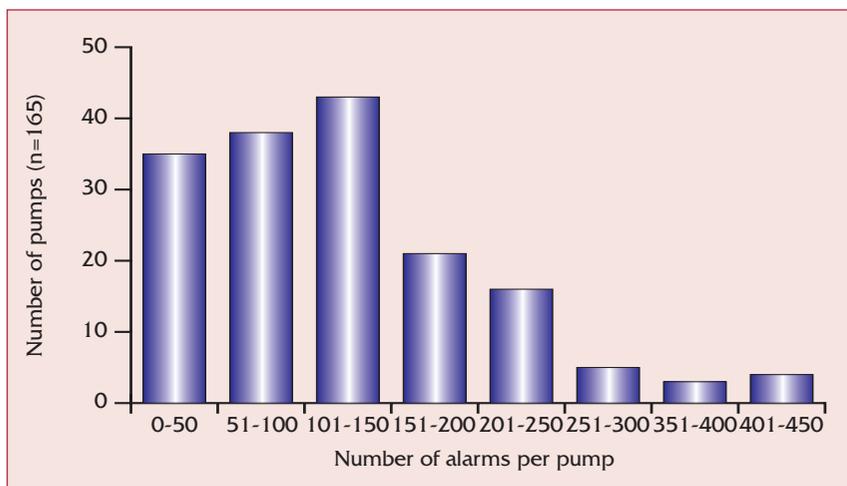Figure 4. *Occlusion level changes by users*
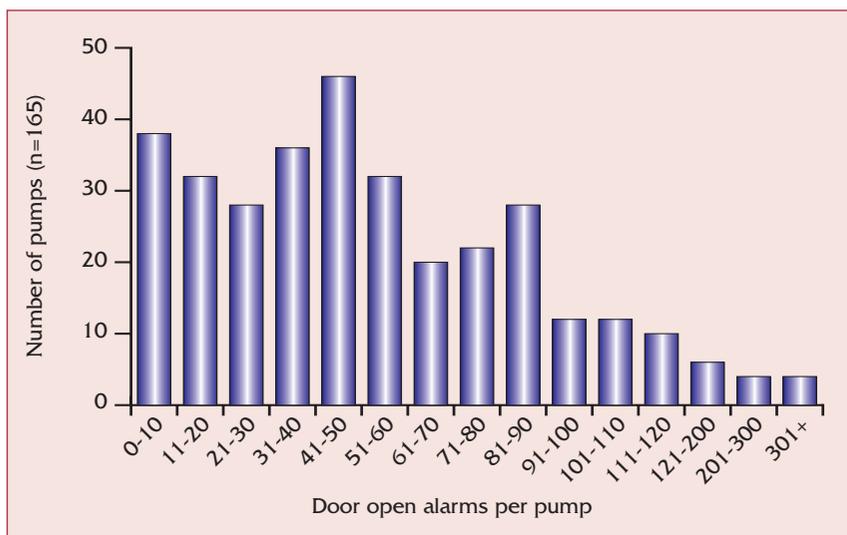

Figure 5. *Air in line alarms*

Figure 6. *Door open alarms*

(i.e. occurring in 1 out of 8 infusions). Medical and surgical ward areas accounted for 20% and 18.5% respectively, and midwifery accounted for less than 1% of this alarm condition.

It is clear, then, that log analysis highlights important issues of clinical practice. While it is not clear when, and
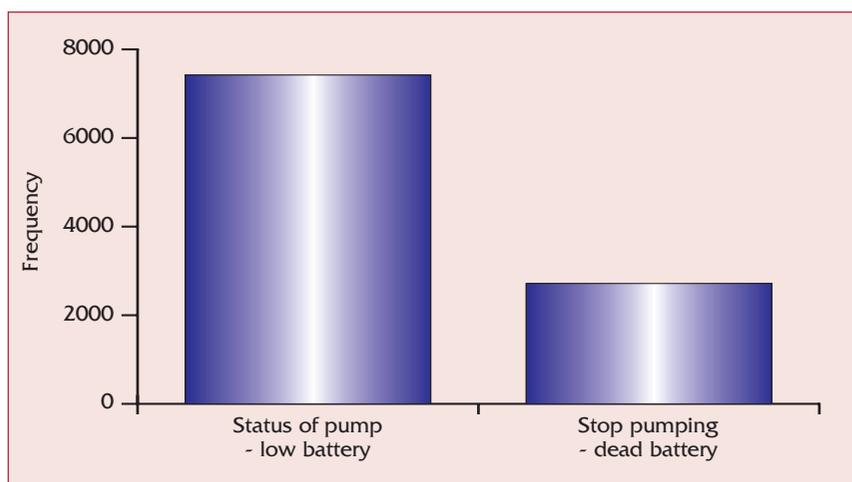
Figure 7. Battery alarms

by whom, the alarm is activated, the fact that it occurs at all raises concern around clinical practice — and perhaps a misunderstanding around how the door open feature should be correctly activated. The organisation may need to investigate further ways in which to manage this risk.

Battery use and alarms

The importance of effective battery management has been previously highlighted by the Department of Health and devices have been known to fail in use and to lead to serious harm (MDA, 2005).

Average battery use (known as the battery bucket), frequency of low battery alarms, and recharge time were identified via the error codes. For all devices, there were over 55 000 separate occasions where pumps were used solely on battery. In total, 77.9% of all devices were used on battery for up to 1 hour with 3.65% (n=2017) used for between 4 and 7 hours infusing. Evidently, the manufacturer's maximum recommended battery usage of 6 hours (longer on standby) was frequently exceeded.

The ratio of low battery to dead battery alarms was 3:1 (*Figure* 7). Although each low battery alarm could not be directly linked from the logs to the corresponding dead battery alarm for each device, the data clearly indicate a high number of safety critical events for these devices.

Factors to consider in the day-to-day management of battery capacity include electrical infrastructure (i.e. amount of available sockets in each ward area), the provision of a battery management policy, an infusion devices library service to help rotate stock and recharge batteries on a regular basis, and the lack of low battery indicator on each device. It should be noted that the pump has an internal battery test option but has no constant visual display during operation to show the user the battery charge level.

Further analysis showed that 8 out of 10 of the highest errors in the battery use category appeared in the oncology department. The highest single number of alarms for low battery condition (n=198) also resulted in 81 alarms for dead battery — just on a single infusion pump.

Note that the hospital studied has an electrical infrastructure built in the 1950s. Bedside mains sockets are limited and some bedsides have only two sockets per

bed. Standardising to electrical beds with air mattresses meant that these two sockets are frequently in use. Other devices commonly used such as nebulisers, ECG monitors, non-invasive blood pressure machines, and personal phone chargers may also account for the increased demand on bedside sockets and their impact may be an area for further analysis. Such factors may account for the reliance, and over-use, of infusion pumps' internal batteries, as the logs indicate.

Discussion

There is both a professional and regulatory interest in investigating the cause of incidents involving medical infusion devices in health care (The Joint Commission, 2009; MHRA, 2010). Ongoing analysis of user interactions, errors and common faults may point toward premature component failure, and design shortcomings, as well as gaps in training. As suggested by the authors' findings, error logs may help in this process. Better device management, measuring mean time between failures, tracking progress of repairs, or highlighting clinical practice issues can also be achieved using error log analysis.

Equipment libraries that loan pumps to many clinical areas will find it harder to analyse their logs and track where issues of concern may be, as they will typically not be able to pin down where each device is located for each logged episode. The authors suggest that new designs of pump should be able to log the start and end of loan periods, and in particular which medical speciality they are being used in.

The findings, even though based on just one device type in use in one hospital, especially in relation to the lack of data integration and device logs, are likely to be relevant to many other similar devices. The management and analysis of the logging process needs to be included in annual maintenance protocols to ensure consistency, as this paper has shown the substantial insights that can be obtained. Despite the emergence of dose error reduction software (DERS), issues with device usability, with how staff access features, number of alarms and time management have been noted throughout this paper. Ensuring timely download and analysis of log files is important, however, it has yet to be adopted as standard practice in the UK.

In the authors' logs, there were 260 129 alarms for all conditions, including technical errors, breakdowns, and call-back situations (e.g. no flow, occlusions, air-in-line). Assuming an average 5 minutes to deal with each alarm, a total nursing staff time of over 13 staff years (at 37 hours/week, 44 week/year) can be attributed to dealing with these alarm conditions for all intravenous infusions — costing perhaps £260 000 in staffing hours alone.

Such gross figures relate to the incidents in the logs analysed, and are relative to the number of pumps, the time periods covered by the logs, and the size of the hospital. However, the numbers can be generalised, making the insights much more generic, but obviously less precise, for example:

■ A nominal 5 minutes recovery time per alarm accumulates to the equivalent of 6% of the total time spent infusing
■ Approximately £1000 per pump per year is spent on staffing time managing or recovering from alarm conditions.

Limitations

Error logs are often large, difficult to interpret, and lack convenient software to present the data into an easy-to-understand format. Diagrams like those presented in this paper ought to be generated automatically from logs. Although the alarms identified are easily categorised, the specific clinical circumstances leading to them are not. Error logs are rarely reported in this graphical format, and this may be useful for annual reports and help organisations clearly identify, and target those errors of most significance. The devices in this study represent less than a quarter of all devices in clinical use, but the actual cause of each alarm cannot be ascertained, as it was not directly observed. However, the implications remain the same throughout; namely, any alarm that pauses or stops an infusion interrupts patient therapy and costs staff time. While a nominal 5 minutes was used to estimate the time taken to deal with each alarm in this paper, times vary in reality and depend on various factors, including the experience of the operator and the type of alarm (for example, the time taken to find another device in the event of a flat battery may take longer than the nominal 5 minutes). Alarms at initial set up can generally be dealt with in short periods of time, while alarms activated after set up would require the nurse to leave the central area, identify the device location, deal with and correct the alarm condition and re-instigate each infusion. Where there are infrastructure issues (as in this study, a lack of sufficient mains sockets) devices would also have to be swapped with fully-charged devices and the discharged devices moved to other locations for recharging.

Recommendations

While it is impossible to ascertain what caused each of the alarm codes, the context in which they occurred, or how their frequency could be reduced, the fact that such large numbers occur does raise concerns. In particular, without analysing logs, one cannot know how many alarms are being raised.

The findings of this paper have shown the value of analysing infusion pump logs. Analysis can pinpoint areas for improvement and cost savings, as well as facilitate informed training and other operational improvements. How users react to alarms, how many features are used in practice, and whether users access additional features have been highlighted by this study. This analysis can help target training and ensure timely staff education to meet changes in practice and demands of the service.

This study has raised a number of key issues and to further support the timely download, and ongoing analysis of error logs, the authors suggest the following:

- Infusion pump logs should be easier to analyse without developing bespoke software (the authors had to build their own spreadsheet)
- Manufacturers should provide easy-to-use analysis software, preferably conforming to a standard (yet to be defined) so that logs from different device manufacturers can be combined for analysis
- Pumps should log more details of their use, such as keystroke events (this may help identify key bounce and other known problems)
- Pumps should be location aware, so that logged incidents can be related more easily to clinical contexts

- The use and analysis of error logs should be promoted to help inform and direct staff education and training
- Many alarm conditions could be avoided by better training and compliance and better infrastructure.

Conclusions

Bitan and Nunnally (2007) pointed out that infusion device logs are not the same as black boxes for the purposes of medication safety, nor can they be expected to be. The aviation industry places great emphasis on the recovery of data logs (black boxes) to help review major incidents. Similarly, the data files and error logs in medical devices can be used to bridge the gap that appears to exist between the manufacturers, users, and service personnel. If the purpose of error analysis is to improve safety and organisational learning (Reason, 1990; Shappell et al, 2006; Johnson et al, 2007; MHRA, 2010) then device logs, their capture and ongoing analysis, must be re-examined.

Manufacturers should work more closely with health professionals to help better interpret logs and to understand the real-life situations that are recorded as occurring during device use. Pressures of work, infrastructure issues, and unused features were found to exist in this study — raising questions around whether some features of infusion devices are fully understood, or required, or should be better automated.

Ongoing analysis of error logs and data files will help the understanding of how devices are used and should be designed. The study presented here shows that not all features provided are being used, staff are adopting workarounds while exposing patients to risk, ignoring persistent alarms, and collectively spending huge amounts of time recovering from a variety of alarm conditions. It is beyond the scope of this paper to speculate which problems are caused more by poor use and training (or learning) or by poor design itself causing the poor work practices.

For example, 'not using all features' may be caused by lack of awareness of users, work pressures, poor training, or merely that the features provided are difficult to access or are inappropriate. The analysis shows that manufacturers are designing devices where features (e.g., VOT calculator) are not widely used, and overall are not being used safely and effectively — and on a scale that was not previously

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KEY POINTS

- Infusion pump error logs are a valuable resource and can be used to help identify common alarms and themes for device users and managers

- Many thousands of alarms occur and go unreported and these can be a valuable resource to equipment trainers, managers and device designers

- Infusion pump design issues and shortcomings can be highlighted by the systematic analysis of error logs

- The cost of dealing with alarms on infusion pumps should be considered by all purchasers

- Manufacturers should be approached to supply full support for the ongoing download and ongoing analysis of infusion pump error logs

appreciated. Clearly, both hospitals and manufacturers can benefit from thoughtful analysis of medical device data files and error logs. The hospital must react by improving training and awareness, and, equally, manufacturers must consider the implications for new, safer, designs.

In summary, infusion pump error logs have considerable scope to allow more insight into the actual, real-life events and environmental conditions that face health professionals on a day-to-day basis, and this must be a good thing for the future. It should not be necessary to wait for isolated adverse incidents to occur and then analyse them; instead, widespread and routine error log analysis will strategically lead to improved device interaction, reduced errors, and generally making things better for patients, equipment purchasers, users, designers, trainers and maintenance personnel. **BJN**

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