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Safer healthcare at home: Detecting, correcting and learning from incidents involving infusion devices

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ABSTRACT

Objective: Complex medical devices such as infusion pumps are increasingly being used in patients' homes with little known about the impact on patient safety. Our aim was to better understand the risks to patient safety in this situation and how these risks might be minimised, by reference to incident reports.

Design: We identified 606 records of incidents associated with infusion devices that had occurred in a private home and were reported to the UK National Reporting and Learning Service (2005–2015 inclusive). We used thematic analysis to identify key themes.

Results: In this paper we focus on two emergent themes: detecting and diagnosing incidents; and locating the patient, lay caregivers and their family in incident reports. The majority of incidents were attributed to device malfunction, and resulted in the patient being under-dosed. Delays in recognising and responding to problems were identified, alongside challenges in identifying the cause. We propose a process model for fault diagnosis and correction.

Patients and caregivers did not feature strongly in reports; we highlight how the device is *in* the home but *of* the care system, and propose an agent model to describe this; we also identify ways of mitigating this disjoint.

Conclusion: Devices need to be appropriately tailored to the setting in which they are employed, and within a system of care that ensures they are used optimally and safely. Suggested features to improve patient safety include devices that can provide better feedback to identify problems and support resolution, alongside greater monitoring and technical support by care providers for both patients and frontline professionals. The proposed process and agent models provide a structure for reviewing safety and learning from incidents in home health care.

1. Introduction

Globally, there is a trend toward healthcare in the home rather than hospital (NRC, 2011; RCN, 2014). Changing patient demographics, patient preferences, economic pressures to reduce hospital admissions and length of stay, along with medical and technological advances, have all contributed to the growth of home care. Alongside growing numbers of patients receiving care for chronic conditions, earlier hospital discharge has increased the acuity of homecare patients (Lang et al., 2008). Consequently, complex medical devices such as infusion pumps, feeding pumps, ventilators, etc., often designed for use by trained professionals in clinical settings, are increasingly used in the home (Leff and Burton, 2001; NRC, 2011; Beer et al., 2014). As well as bringing benefits, these advances pose challenges for safety and effectiveness, and bring new risks (Weick-Brady and Lazerow, 2006). The aim of the work reported here was to better understand how safety is managed when infusion devices are deployed in people's homes.

2. Background

The home environment differs from the hospital in important ways (NRC, 2011). Typically, patients and caregivers are left alone with medical devices for lengthy periods with limited, if any, training. Consequently, technical or clinical problems may not be as promptly identified and resolved as in hospital, where patients are continuously monitored (Hilbers et al., 2013). Furthermore, home

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healthcare professionals (HCPs) work in relative isolation, without immediate supervision or support, and often lack timely, convenient access to equipment and resources (Lang et al., 2008). They typically visit the home singly, or occasionally in pairs, and are responsible for all aspects of a patient's nursing care; thus, the HCP is responsible for the effective operation of all devices needed to support a patient at home. However, they may have insufficient opportunities to develop skills with all the devices they encounter (Hilbers et al., 2013).

Despite the growing prevalence of home healthcare, patient safety research and human factors research in healthcare focus predominantly on institutional settings (Macdonald et al., 2013; Valdez et al., 2017; Werner et al., 2017). Some researchers have suggested that the less structured nature of home care carries more potential for adverse events than traditional care settings (Masotti et al., 2010). There is, therefore, a need to better understand medical device use in private homes and how people manage when things go wrong.

Beer et al. (2014) report on challenges experienced by home health care workers, considering a range of tasks (from wound care and bathing through to managing infusion administration). They relate their findings to a model of human factors for health care in the home that centres on the people, tasks and equipment involved in home care. For infusion devices, the main challenges identified by Beer et al. relate to set-up (e.g., clearing air from the line) and troubleshooting; they highlight the need for more instructional material and better training in these areas, and advocate standardisation of equipment as far as possible, to minimise the number of devices each HCP needs to be familiar with. Vincent and Blandford (2017) describe the work of home nurses, particularly focusing on the use of ambulatory syringe drivers for palliative care; they highlight the adaptations that caregivers have to make so that devices are fit for purpose in the home setting and when patients are outdoors. The main safety feature discussed is the design and use of a lockbox so that only designated health care professionals can access the device. However, neither of these studies focused specifically on how HCPs manage device failures or recover from incidents involving infusion devices (or similar technology).

Others (e.g., Carayon et al., 2014; Wooldridge et al., 2017) have advocated taking a human factors systems approach to patient safety. They focus on describing the work system, the processes involved in care, and the outcomes. Their focus is on the overall system, and designing it to improve quality; this is a broader question than that which we address in this paper. In this study, we also adopt a human factors systems approach, but focus on the causes of and recovery from incidents involving infusion devices that occur in home health care. We propose process and agent models that encapsulate key phenomena and support reasoning about patient safety in this context.

In this study we examined incidents related to infusion device use in private homes, reported to the UK National Reporting and Learning System (NRLS). While in principle the NRLS accepts reports from anyone, in practice nearly all reports are submitted by HCPs (including all the reports analysed in this study). We focused on infusion pumps because they have previously been identified as a common cause of problems (Beer et al., 2014), are safety-critical, and have been found to feature in more reports of incidents at home than any other device (NRC, 2011). While the most common use of infusion pumps at home is for palliative care near end of life, they are increasingly being used at home to deliver other medications: e.g., for the management of long term conditions. Our aim was to explore the characteristics of reported incidents associated with infusion devices, and the circumstances surrounding their causes, detection and resolution, to inform the design of future devices and the systems of care in which they are used.

3. Methods

Since this study involved the use of anonymised records where permission had been obtained from the data provider (data sharing agreement 002.13.DSA.UCL) and it was not possible to identify individuals from the information provided, it was determined that the study complied with exemption 2 under the UCL code of ethics (https://ethics.grad.ucl.ac.uk/exemptions.php).

3.1. Study design and context

We undertook a retrospective analysis of data from the NRLS, which records patient safety incidents within NHS organisations in England and Wales. The NRLS has defined a patient safety incident as any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving NHS-funded healthcare (NPSA, 2011). Staff typically submit reports via a local reporting system; these are subsequently uploaded to the NRLS (Panesar et al., 2009; Thomas and Panchagnula, 2008). The list of recognised incident types is long, from “Absconder/missing patient” to “Unplanned return to theatre” (NRLS, n.d.). Thus, the NRLS is a comprehensive source of incident reports, covering all healthcare settings across England.

3.2. Search strategy and sample selection

17,741 anonymised reports from the NRLS were retrieved (see Appendix A for search terms). The search covered 1st January 2005 to 31st December 2015. The data was provided as an Excel spreadsheet; each record comprised 25 data items. Of these items, two were identifiers (organisation and incident number); 16 had originally been entered as a selection from a menu (defining date, location, incident type, etc.) and the remaining seven were free text fields (enabling the reporter to add details). The majority of incidents reviewed in this study were classified as “Medication” or “Medical device/equipment” incident types.

We selected all 982 incidents categorised as occurring in a “private house, flat, etc.” These reports were reviewed; 177 were excluded as the incident was not associated with an infusion device or did not occur in a private home; six duplicates were also excluded, leaving 799 reports, each relating to a unique incident.

3.3. Data analysis

Our analysis focussed on data from three of the free text fields: ‘Description of what happened’, ‘Actions Preventing Reoccurrence’, and ‘Apparent Causes’. While the shortest report comprised only 20 words (across all three fields), the majority were 200–500 words in total, and the longest was over 800 words.

We undertook a thematic analysis (Braun and Clarke, 2006) to identify and report important themes within the data. Analysis began by reading through each report and noting broad patterns. Since our focus was on managing patient safety in therapies involving the use of infusion devices, incidents that did not directly involve the device (e.g., prescribing errors or poor documentation of drugs in the home) were excluded. Incidents in which the patient had, or might have, received more or less medication than intended had greatest safety implications; therefore, reports on other incident types (e.g., keypad not locked) were also excluded. In total, a further 193 reports were excluded, leaving 606 reports in the final analysis. The analysis was completed by hand. We generated preliminary codes, starting with a random sample of reports, revising codes and organizing them into broader themes as further reports were reviewed. The first author conducted the analysis of reports up to 2011, with discussion of emerging themes and interpretation

of data between authors throughout. Reports 2012–2015 were then analysed by the second author, starting with (and refining) the coding scheme. Reports were re-analysed using the refined and agreed coding scheme (see appendix B). The coding of 10% of reports (every 10th record from the 6th record in the dataset) was checked in detail by the other author. Across these, 5 minor coding discrepancies were identified and corrected. On this basis, we judged the coding to be reliable.

Our initial focus was on trying to understand the causes of incidents that occur in the home, with a view to developing recommendations for mitigating such incidents; as the analysis proceeded, it became increasingly apparent that reports yield much more insight into detection and recovery than to causes. As health professionals typically only visit the home occasionally, we had implicitly expected that patients, their families or lay caregivers would be the "first line of defence" in detecting incidents (and might also be implicated in the causes of those incidents), and we were surprised at how many reports did not mention these people at all; this led us to analyse how lay people featured in reports.

4. Results

Two principal themes emerged from the analysis, and are discussed below:

- Detecting and diagnosing incidents
- Locating the patient, family and lay caregivers in reports

Before discussing those themes, we summarise the kinds of incidents that featured in reports. Illustrative extracts from reports are reproduced verbatim, including spelling and grammatical errors and capitalisation as written by the original reporter. Where a section of text has been removed to make an illustrative extract more succinct, this has been marked by "[…]", and " …" indicates that more text preceded or followed the extract taken from a report.

Over 75% of incidents reported involved an under-dose. In some cases the patient received none of the prescribed medication. In almost half of infusions involving an under-dose, patients had received some medication before the infusion terminated unexpectedly. A smaller number of patients received the infusion at a slower rate or were administered a lower dose than prescribed. Over-infusions were often identified when the infusion finished ahead of schedule. Incident types and examples are reported in Table 1.

Nearly half the incidents were attributed to equipment malfunctioning. Devices were frequently observed to be 'not working' or have 'stopped', without further explanation. In several cases the device functioned once re-started, suggesting use errors or occlusions, although this was rarely stated explicitly.

Table 1
Number and examples of incident types reported.

Incident type	Number	Example extracts
Device malfunctioned	278	Visited to reload syringe driver, noted driver malfunctioned. Approx 25 mm fluid remained in syringe, therefore syringe driver had malfunctioned approx 23.00h. Alarm had not sounded on driver, light was not flashing on unit. Needle site checked found to be satisfactory […] Sryinge driver replaced with functioning unit … (Report 173)
Wrong dose administered e.g. Dose calculation or preparation error, wrong concentration used, etc.	87	The midazolam was prescribed at 30 mg and came in vials of 10 mg in 2 ml. The error had occurred as the nurse thought this was prepared as 10 mg in 1 ml therefore 20 mg in the 2 ml vial and drew up 2 vials and wasted half instead of 3 vials. (Report 113)
Interactions (accidental or intentional) with the device by a non-health professional, including use of "boost" function where this conflicts with policies of the reporters' organisations	37	… the patient stated that when handling the driver, she accidentally touched the 'stop' button and stopped the infusion. (Report 112) … on arrival the syringe had delivered the total dose already and had remained empty for ? How long (due to complete at 1700). On questioning the [home] care staff, they had been informed by GP to administer medication via the boost button when the patient was in pain. (Report 103)
Device programmed incorrectly e.g. wrong rate/volume entered, rate calculated incorrectly (including where automatically calculated by the pump), wrong syringe type selected, etc.	56	… dosage had been changed from 50 mgs in 100 ml at a rate of 4 mgs per hour to 60 mgs in 11 ml at a rate of 5 mgs per hour. The flow rate on the pump was changed from 4 mgs per hour to 5 mgs per hour but the volume was not altered. (Report 87) Patient syringe driver to be re - sited as skin tissued. Re - sited using medication drawn up in the syringe in the morning, primed line and re - started the McKinley T34. Therefore, remaining medications were calculated over 24 h automatically via the pump, rather than the remaining 16 h … (Report 297)
Incorrect set up of device and/or accessories e.g. incompatible syringe size used, wrong battery used, pump not fully closed, clamp not opened	42	… it was discovered that the syringe was not correctly positioned in the syringe driver and that a clamp was positioned over the extension tubing occluding the flow of drugs from syringe driver to patient. (Report 160)
Occlusion e.g. crystallisation of drugs, kinks or bends in the giving set or needle, etc.	54	Syringe driver check - light flashing, machine whirring, but 17 mls loading dose not reduced since initial set up late afternoon. Syringe buckled and bent at an angle away from machine. On removal of soft set it was noted that soft set had not pierced skin and was curled up in a tiny ball pressed against the skin, (leaving a red indentation. Medication unable to flow through soft set and therefore backed up causing syringe to buckle. (Report 201) The 12 ml syringe supplied with the pump contained a mixture of 4 different drugs mixed with sterile water. The drugs had precipitated within the syringe and had crystallised around the exit port of the syringe and luer connector of the infusion line. It was not possible to push the plunger of the syringe with normal force expected … Current practice would advise that no more than 3 drugs are to be mixed within a single syringe … (Report 172)
Start button (presumed) not pressed	10	Visited patient to check syringe driver which had been set up the evening before, only to find none of the medication had infused as it appeared the syringe driver had not been started. I started the S/D and checked the light was flashing, all appeared in order and the alarm did not go off … (Report 285)
Damage and degradation e.g. broken equipment, water damage, etc.	8	Patient provided with syringe driver with no battery cover … Device stopped working during night as battery kept popping out. Patient attempted to tape syringe driver battery to try and keep it in place to no avail. As a result he had breakthrough pain and nausea. (Report 37)

Multiple issues sometimes occurred within the same incident; e.g.:

> … *syringe driver infusion line was leaking . the night nurses changed the line and refilled the syringe driver with half the prescribed dosage which resulted in client receiving only half the prescribed dose as the infusion rate was not changed …*
>
> (Report 200).

Overall, incidents varied widely and it was frequently difficult to determine causes or contributing factors from the reports. Reports give greater insights into the process of detecting and troubleshooting, as discussed in the following section.

4.1. Detecting and diagnosing incidents

Three themes emerged on detecting and diagnosing incidents: cues that alert nurses, patients or relatives to a problem; detective work undertaken by nurses investigating the incident; and delays and missed opportunities. Some reports also discussed remedial actions, as discussed at the end of this section.

4.1.1. Cues and signals

Incident reports reveal various strategies to determine whether a device was functioning correctly. The most common reported signal of a problem was an unexpected amount of fluid remaining (Table 2). This was frequently reported with other visual and auditory cues, most notably the presence or absence of a light, motor noise or alarm. Following a Rapid Response Report (NPSA, 2010), healthcare providers in the UK replaced many of the pumps used at home (Vincent and Blandford, 2017), resulting in a shift in the type of visual and auditory cues most commonly reported (more references to alarms; fewer to flashing lights or motor noises); this highlights the importance of interaction design for helping people detect and diagnose incidents. Indirect cues included deterioration in the patient's condition and nurses' reflections on their own or others' actions.

According to incident reports, informal caregivers rarely detected any cues and signals other than device alarms: other cues were noticed by health professionals when visiting. E.g.:

> *The family informed me the syringe driver had been making noises and flashing red lights. On inspection the syringe driver was not administering the medication.*
>
> (Report 460)

4.1.2. Detective work

Nurses were rarely present when incidents occurred, so subsequently played a detective role, piecing together information from different sources to diagnose the problem (Table 3). Common checks included the physical and mechanical set-up, and programming of the device, the battery, and condition of the infusion site. In more recent reports, there are occasional references to accessing a device log for information. Conversely, in earlier reports there are more references to nurses replacing the battery or repositioning the syringe. These trends are probably due to changes in the devices most commonly used for palliative care in the UK (NPSA, 2010; Vincent and Blandford, 2017). Other than these specific issues, there are no discernible differences in the nature or volume of reports over the 11 years covered in the analysis reported here.

Nurses also sought information from others present – e.g., whether patients or caregivers had heard the device alarm or reported pressing buttons. Nursing notes, documentation, and medication stock counts sometimes helped with piecing together what had happened, or the device's service history was checked.

Table 2
Signals and cues used to determine functioning of infusion devices.

	Number
Unexpected volume of fluid remaining (including finishing early)	232
Device alarm	145
(Absence of) flashing light	88
Patient's condition or symptoms	64
Screen displaying fault, error or incorrect information (including blank screen)	56
(Absence of) motor or 'whirring' noise	39
Review of documentation and stock, checking programming, reviewing device log	39
Physical appearance of the device or contents e.g. positioning of the syringe, crystallisation	37
Reflection on practice	7

4.1.3. Delays and missed opportunities in recognising, reporting and resolving errors

A tiny minority of reported incidents were detected and addressed while the infusion was being set up (possibly because such incidents are not reported if they are resolved quickly). Typically, these near misses involved calculation or preparation errors, detected by the person responsible. Incidents were more commonly discovered during scheduled visits, resulting in a significant delay before the problem was identified (Table 4).

Several factors contribute to delays and missed opportunities for resolving problems. Firstly, the frequency and quality of checking processes: many infusions were not monitored over 24 h. Incidents where no prescribed medication was delivered suggests inadequate checking when the infusion was set up. In several instances, problems were misdiagnosed and troubleshooting efforts failed, delaying resolution of the problem. E.g.:

> *night nurse visited to given planned stat dose of medication . found syringe driver to be faulty and alarming . records showed she attempted to fix but unsuccessful, therefore turned device off . This left the patient without continuous pain relief and antiemectic . No evidence that the nurse thought to swap the device to another driver (spare was available in the home !)*
>
> (Record 620)

Delays also occurred when patients or caregivers failed to recognize or respond appropriately when the device alarmed. People sometimes ignored or silenced alarms, or attempted to troubleshoot themselves; in some cases this exacerbated the problem or created additional problems. However, in many cases this was a deliberate decision: e.g., at night when patients felt symptoms were adequately controlled. E.g.:

> *Patient stated she ' pressed' buttons to resume the infusion . […] The log has been noted and an occlusion and antibolus reverse occured 9 times over the 12 hours . […]appeared that the rate of the pump was changed by the family*
>
> (Record 484)

> *Patient states the syringe driver had been alarming through the night, however the patient had pressed the button to silence the alarm rather than call the evening service*
>
> (Record 566)

4.1.4. Remedial or corrective actions

Remedial actions were reported in approximately 60% of reports. The most commonly reported actions were replacing, re-

Table 3
Sources of information for detecting and diagnosing incidents.

Information source	Example extracts
Device checks	Arrived to replenish syringe driver and +15.5 mls of original 17 mls of medication remained unadministered in 20 ml syringe in driver. Light not flashing, motor not going, no crystallisation in syringe, access site in tact nil tissueing, nil alarm had been heard … (Report 180)
Information from patient, family or lay caregivers	… Patient states that the syringe was over filled + therefore not positioned in the driver correctly. Because the plunger was still moving along the alarm did not sound + alert the patient to the problem Patient did not receive any of her medication overnight. . Factors: Patient states that the nurse seemed very unsure of herself when setting up the syringe driver. . (Report 240)
Review of documentation and medication	Visited patient on [date] to re - load his syringe driver. In carrying out the task I noted that a drug calculation error had occurred. Patient was due to received 150 mg Morphine Sulphate and 150 mg cyclizine over 24 h. Morphine Sulphate available was 30 mg/ml −5 amps needed cyclizine is 50 mg/nl - 3 amps needed. On the previous 3 days 5 amps of cyclizine had been used each day alongside the 5 amps morphine sulphate … (Report 211)
Reference to event log	the staff member changed the site but failed to switch off the driver so 1.5 mls was lost - this was confirmed with the download from the driver (Report 562)

Table 4
Sources of Delays and missed opportunities in detecting and resolving errors.

	Example extracts
Delayed detection	District nurse arrived at patient home to re - change two syringe drivers. On arrival patient complaining nausea had vomited previous day and also complaining of pain. Syringe driver sites checked and not tissued, syringe drivers both checked, when checked noticed both drivers were still full of medication ad both drivers were at 14 mls 48 mm) therefore the patient had not received any medication since 11:00am the previous day … (Report 177)
Inadequate checking	… On assessment of syringe driver on [date] at 1100 h, syringe driver switched off with a full syringe of medication not administered … Discussion held with member of staff involved to ensure that she is up to date with syringe driver training and that she is aware of the need to press the boost button to restart the syringe driver again and to ensure that the syringe driver check list is completed each time. (Report 238)
Misdiagnosis and failed troubleshooting	Patients son rang OOH D/N between 00:01 and 01:00 [date] reporting that the syringe driver alarm was sounding. Incident reporter advised him to change the battery, this appeared to work as the light was flashing and motor sounding. 08:30 [date−next day] message received reporting patient was agitated and in pain. IR attended at 08:50 to assess and give subcutaneous medication as prescribed, patient was comfortable and settled within 10 min. Syringe driver checked had 8 ml left and was due for re - priming in 2 h - light flashing and motor sounding. Vistaed to re - prime driver at 12:00 noted that syringe plunger was engaged with the drive screw, the patient had not been receiving medication from the driver. (Report 228)

starting or resetting the device. Others included replacing the battery or giving set, re-siting the cannula, or stopping the infusion. In many cases, there was a need to supplement the patient's medication (e.g. with oral doses). E.g.:

> *I tried numerous times to get the machine started and used about 4 new batteries . I encountered the same problem each time . In the end I had to administer stat doses of Midazolam and Oxynorm*
>
> (Report 625)

Fewer than 10% reported any monitoring or follow-up to check the problem was fully resolved (reporters may not consider it necessary to include such information in incident reports).

4.2. Locating the patient, lay caregivers and family in incident reports

About a third of reports contained no reference to the patient involved. In a further third the patient was only mentioned as an object. This may be because many incidents involved patients receiving end-of-life care. However, a small proportion of patients played an active role in detecting and reporting problems, facilitating investigation and monitoring the infusion. Conversely, 29 patients had an active, although not necessarily intentional, role in triggering the incident through interference with the device (e.g., over-use of a boost function).

Caregivers, family and occasionally friends also identified and reported issues, and provided information to assist investigations in about 25% of incidents. In under 10% of reports, the family were instructed on how to monitor for or avoid future incidents. Conversely, some HCPs refused to train patients or families in how to fix problems when they occurred, as they considered it to be a HCP responsibility. Examples of these different kinds of incidents are included in Table 5.

5. Discussion

In this study, we analysed records of incidents associated with infusion device use in private homes, aiming to better understand risks to patient safety, how these risks might be minimised, and how both practices and technology might better accommodate the realities of home care. The majority of incidents were attributed to equipment failures. Our analysis revealed delays in identifying problems and missed opportunities for resolution. Based on our analysis, we propose a process model of incident occurrence, detection, recovery and learning.

Despite incidents usually occurring in the absence of health professionals, patients and caregivers did not feature strongly in reports. Based on our analysis, we also propose an agent model, highlighting the overlap between the home system and the care system. We highlight implications for the design of medical devices for home use and the broader systems of care in which they are employed.

5.1. Detecting, recovering from, and learning from incidents

Based on the analysis summarised above, we developed a process model of incident occurrence, detection, troubleshooting, and learning. This model is derived from the coding scheme that was developed in this study (Appendix B). The following outlines

Table 5
Example extracts locating the patient, lay caregivers and their family in incident reports.

No reference to the patient in report	On [date] unable to ascertain amount of drug used due to omission of documentation on [detail removed] Controlled Drugs Record sheet. Unclear notes made in [detail removed] Evaluation sheet. . On [date + 1day] unable to ascertain amount of drugs used as no documentation on [controlled drug record sheet]. Syringe driver not left in working order as found on [date + 2 days]. . Syringe driver re - primed with drug as prescribed, loaded onto machine. Start button pressed and infusion began. Unused syringe removed from house, solution discarded, syringe put aside. Documentation removed. (Report 135)
Patient mentioned as an object	Visited patient to check syringe driver and I noticed the driver was off, no display and the patient was groaning in pain. On checking the patient notes it was documented in the evaluation notes that the district nurses had visited and set up the driver at 12.15 h, however on looking at the syringe it appeared that none of the medication had gone through and there was still approximately 21.4 mls of medication in the syringe driver since it was set up. The relatives said the patient was in pain all day … (Report 505)
Involvement in detection and investigation	… The syringe driver had switched itself off and the family stated that they had heard the motor working until around 12am midnight but had not noticed it working in the morning. (Report 98)
Troubleshooting	… Family noted the syringe driver was not working they had changed battery but pump continued to alarm and then stop completely. DN team contacted and when driver checked intermittently showing battery flashing and then stopping (Report 370) When the nurse arrived the patients wife reported that she had turned the driver off as the bleeping was distressing the patient; she then turned it back on again and stated that she just kept pressing the yes button until it started working. (Report 469)
Patient or family "tampering" with device	… ONCE SYRINGE REMOVED PATIENT SILENCED ALARM BY PRESSING BUTTONS ON THE DRIVER PUMP WHICH UNFORTUNATELY RESET DRIVER BACK TO 24 HOURS WHEN SYRINGE INSERTED RATHER THAN REDUCING BY THE PRIMING LINE. AS NIL MORE DRUGS WERE IN THE HOUSE DRIVER UNABLE TO BE RE DONE. PATIENT INFORMED OF THE ERROR WHICH SHE ADMITTED SHE HAD INFACT PRESSED BUTTONS AND WAS HAPPY TO TAKE ORAL PAIN KILLERS IF NECESSARY. . (Report 590)
Patient/family intentionally not informed	… on replenishing the syringe driver I noted that the syringe driver had been set up incorrectly and was running at 2 mls per 24 h. There was over 14 mls of medication remaining which the patient had not received, the patient had remained unsettled and needed several additional doses to settle him that day. Previously [patient name] wife had mentioned that the out of hours nurses were laughing in the bedroom and that she felt this was a little inappropriate under the circumstances, she also commented that they were in the room an awfull long time. The family were unaware of the mistake as I felt it would be inappropriate under the circumstances and only cause further distress to an already tense situation. (Report 340).
Family requested incident report	Syringe driver checked on my arrival showing 44 h 03 min left to run. Volume to be infused 12.7 ml Volume infused 4.7 ml at a rate of 0.29 ml per hour. Yellow label syringe barrel stated 60 mg Diamorphine and Haloperidol 10 mg and water for injection made up to 18 ml so Patient not getting the correct prescription. […] The daughter of the Patient also made a specific request that incident forms were completed, I assured her they would be. […] (Report 397)
Family recruited for subsequent monitoring of device	All staff made aware of incident and patient reinstructed on how to monitor the driver and to contact his nurses if any concerns (Report 616)
Patient requested training; request refused by HCP	Patient asked if he could try sorting it out himself if it happend again. I informed the patient that he should call out a district nurse to sort the problem if it happend again and documented this in the notes. [next day] T34 syringe pump had been alarming all night with occlusion. Patient informed me that he had been tampering with the pump throughout the night but could not stop it from alarming (Report 492)

the steps of the process model for error identification and recovery (Fig. 1):

1. The first step is the setting up of the device to administer medication. The details of this step are beyond the scope of this paper (and are rarely recorded in incident reports); this is the first point at which either equipment malfunction or human error might be detected.
2. More commonly, the device is left running, and its performance is monitored (by patient or family) to a greater or lesser degree. The running device is systematically monitored during subsequent visits from a HCP; failures are most commonly detected during a routine visit from a HCP.
3. Occasionally, a patient or family member interacts with the device (e.g., to administer a bolus dose, or moving the device and accidentally knocking or dropping it). This is (in principle, though rarely in practice) another opportunity to monitor actions and the device state, to detect failure.
4. In practice, failure can occur during any of setup, running, or subsequent interaction. Failure is only acted on once it has been detected.
5. Once a failure has been detected, there is usually an attempt diagnose the cause, drawing on sources of evidence as discussed above, in order to correct the failure. Diagnosis sometimes involves further interaction with the device (Feedback loop 1) – whether by patient, family member, or HCP.
6. All failures need to be corrected. In practice, nurses often prioritise correction over diagnosis (e.g., by replacing a device without fully understanding the cause of failure, or by simply restarting the device and allowing it to run again – Feedback loop 2).
7. Once a particular incident has been resolved, it might be a source of more general learning: about how to avoid a similar incident in future, or how to detect and correct it more quickly if it does occur. This learning might pertain to the individual, but more commonly involves review and reflection at a team or organisational level (Feedback loop 3).

The two key stages in this process are detection of failures (or errors) and correction. In principle, learning is also important, but incident reports contain relatively little information about organisational learning. This model highlights the different opportunities for providing feedback mechanisms that can help people to detect, correct and learn from incidents.

5.1.1. Timely error detection

Previous studies have identified routine checks as the most prevalent error-detection mechanism. Thomas and Panchagnula (2008) reported that, in critical care, routine checking of infusions at handover, breaks or patient transfer often limited patient harm. Opportunities for checks are more limited in homecare (Lang et al., 2008). Although nurses detected most incidents during routine

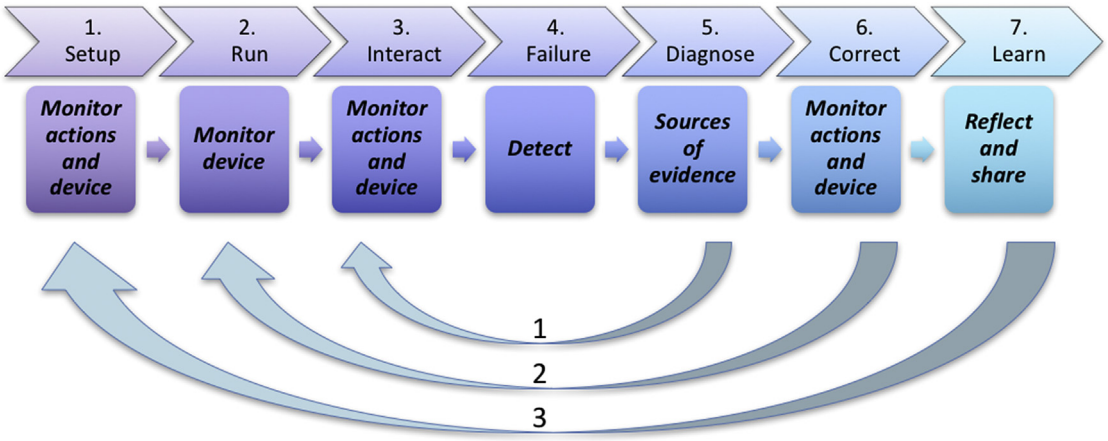

Fig. 1. A process model of incident occurrence, detection, management and learning.

home visits, those visits were infrequent (often once a day). Many incidents involved infusions in which no medication was delivered; Keay and Callander (2004) suggest a final check should be carried out 10 min after starting an infusion. Current UK nursing standards stipulate all intravenous dose calculations should be independently checked and, where possible, double-checking of administrations is recommended (Keers et al., 2015). This could reduce delays in error detection and recovery. However, such recommendations have resource implications. Technological innovations could have an important role; for example, remotely connected devices could allow professionals to monitor the progress of an infusion, be alerted when something goes wrong, and support troubleshooting from a distance.

Where patients or relatives detected a problem, the most common indicator was a device alarm. Conversely, failures of alarms to sound delayed problem identification. Efforts have recently focussed on reducing device alarms in hospitals where alarm fatigue may cause nurses to become desensitized (Sendelbach and Funk, 2013). In home care, where routine checks are infrequent, alarms are vital for identifying problems. Alarms should be tailored to the demands of the situation (ECRI, 2014); our study highlights the value of device alarms in homes (but also the importance of people being able to silence them when needed).

More effective feedback through stages 1–4 (Fig. 1) could help with timely error detection by both health professionals and patients/family. This should include easier ways to identify discrepancies between the intended and actual infusion rate and more informative device feedback (particularly alarms).

5.1.2. Diagnosis and correction

The number of incidents associated with device failures highlights the need for devices for home use to be robust. However, there is insufficient information in reports to understand how or why devices failed, or whether particular devices were more likely to malfunction. Previous studies suggest that staff assume equipment is faulty while subsequent review found it was used incorrectly (Thomas and Galvin, 2008); incident reports rarely include that kind of follow-up. Reports do show that health professionals often struggle to identify the cause of problems (Stage 5, Fig. 1).

This has implications for device design and procurement. Twenty years ago, Obradovich and Woods (1996, p.584) highlighted the problem of poor device feedback in home infusions:

> "… the device often provides little or no feedback to help the user realize that an error has occurred or to aid her in understanding what has led to surprising changes in device behavior. There is little feedback about the amount of medication being delivered and whether it matches the therapy plan."

Little has changed in the intervening years. Devices with an easily accessed log that records settings and alarms can facilitate diagnosis in some circumstances; just 15 reports referred to this feature. Easier availability, and more systematic use, of reports could reduce reliance on second-hand information from patients and relatives.

In addition, these findings highlight the need for accessible and immediate specialist technical support. The most common corrective action reported was replacement of the device. Whilst this may be a justified response, it represents inefficient resource use if the device is not faulty. A quick conversation with a technician or specialist nurse could help identify and rectify problems without needing to source a new device or, conversely, recognize a need to replace the device immediately to avoid further incident (Stage 6, Fig. 1). Such a service could benefit patients and caregivers, as well as nurses who encounter an unfamiliar problem or device and, for efficiency, could be coordinated across different organisations or regions.

Every incident potentially represents an opportunity for learning (Stage 7, Fig. 1); while incident reports give little information on broader learning from incidents, this process model highlights this as an essential step in making any Health Service into a learning organisation.

5.2. The infusion device at the boundary of home and care

Beer et al. (2014) propose a model of health care in the home (key features reproduced in Fig. 2). Their model emphasises the different attributes of nurse and patient as people within the care system, and the role of the device in supporting the task (in this case, of medication administration).

Our analysis, particularly focusing on how patients and family are located in reports, leads us to propose an alternative model for infusion devices, which are controlled by the nurse (or other HCP). Given that all the incidents involved infusion devices supporting the task of medication administration, we merge device and task, for simplicity. We propose an agent model locating the device, patient and nurse straddling the home and care systems, while other elements of the home system are excluded from the care system, and other elements of the care system fail to support the home system well (Fig. 3).

As Beer et al. (2014) note, the home care nurse is, in many

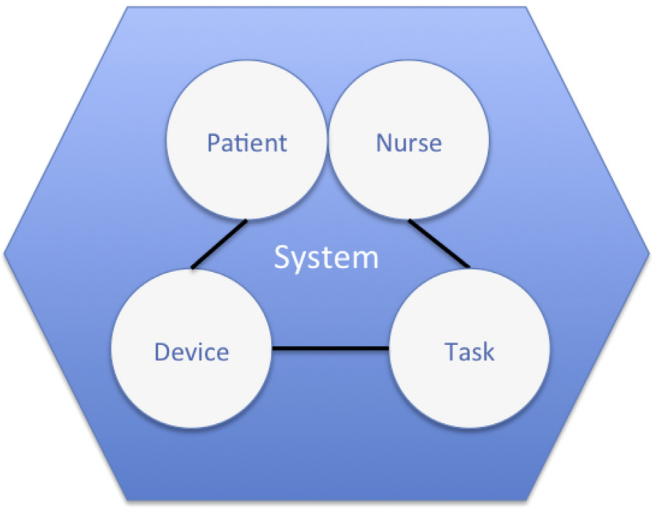

Fig. 2. Proposed model of health care in the home (adapted from Beer et al., 2014).

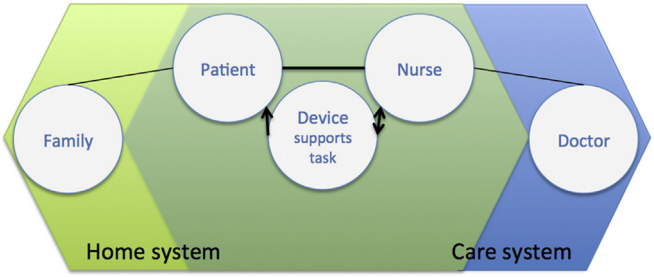

Fig. 3. The principal agents (human and technology) and lines of communication in the home care system focused around medication delivery via infusion device.

respects, at the heart of the system. Our data highlight an important role of the nurse as mediating between doctor and patient, at least in the task of medication administration: while the doctor has other involvement with the patient, s/he has little direct contact with the device or involvement in the details of care delivery where that involves infusion devices. The nurse is responsible for delivering care to the patient and for managing and troubleshooting the infusion device. The patient is attached to, and therefore potentially aware of the state of, the device, but rarely interacts with it directly; family members may be caring informally for the patient, and may be aware of (or even interact with) the device, but are largely excluded from the aspects of care that involve the medical device.

Importantly, although the infusion pump is *in* the home, it is not *of* the home; rather, it is *of* the care system, but physically removed from that system. This highlights the potential value of reviewing the role of patients and family as contributors to patient safety and aligning the home system and the care system (as medical devices play an increasingly important role within that system) more closely.

5.3. The role of patients and caregivers in patient safety

Patients and relatives can have an important role in patient safety, and be a source of resilience in healthcare (Schubert et al., 2015; Holme, 2009). For instance, Unruh and Pratt (2007) identified examples of patients detecting, preventing and recovering from medical errors in outpatient cancer care. In our study, some patients and family were important actors in detecting the problem and alerting professionals. However, this was not commonly reported. Similarly, Saranto et al. (2012) found 82 of 785 incident reports from one Finnish hospital contained information about patients' and relatives' involvement in events reported by staff; in more than half of those reports the patient themselves noticed the incident and notified the hospital.

Introducing medical technology in the home changes not only the care setting but also the roles and information needs of patients, relatives and professionals; which must be considered in strategies for improving safety in home care (Obradovich and Woods, 1996; Blais et al., 2013; NRC, 2011). Unruh and Pratt (2007) suggest that to contribute to safer healthcare, patients need more information. The NRC (2011) report also highlights the importance of training for both professional and lay caregivers (including patients self-managing) that is focused specifically on the circumstances of the home environment. Our analysis shows that lay people could have a proactive role in monitoring infusions by attending to cues frequently used by nurses, but first need to be made aware of the amount of fluid that should have infused in a given period, as well as what actions to take if they observe a discrepancy. Beer et al. (2014) caution that untrained patients or caregivers are more likely to misinterpret information and risk making an incorrect judgement in response to a malfunction. We found relatives' efforts at troubleshooting were largely unsuccessful and sometimes detrimental (successful troubleshooting may not be reported as an incident). Additionally, it may be inappropriate to further burden patients, especially those at the end of life, and families with this work (Mair & May 2014). In a study of patient and caregiver perspectives on home haemodialysis, Rajkomar et al. (2014) recommended that device alarms should not just signal a problem but also provide information about likely causes and solutions; they observed one device that featured an alarm showing whether to call a nurse or technician for guidance. Designing devices in this way could improve safety and reduce the burden on all users when things go wrong. Designing devices and training families so that devices fit better within the "home system" (Fig. 3) could contribute significantly to patient safety.

Revisiting Fig. 1 (the process model of diagnosis, correction and learning), we can identify stages where the patient or family do or could have an important role; this is summarised in Table 6.

5.4. Limitations

Researchers using incident report data have consistently acknowledged the poor quality of this data (Panesar et al., 2009; Sevdalis et al., 2010; Thomas et al., 2015). In common with other studies, we found reports typically contained limited information to understand causal or contributory factors, or to inform prevention (Thomas et al., 2011; Cousins et al., 2011; Rees et al., 2015). Nevertheless, they provide substantial information about the experiences of nurses and, to a lesser extent, patients in troubleshooting when things go wrong.

The data covers 11 years. Some of the earlier reports related to a type of syringe driver which has since been phased out (NPSA, 2010). Some issues (e.g., over-use of the "boost" button, and battery problems) are more prevalent in earlier reports than more recent ones. However, dominant issues such as delays in detecting problems and difficulties in troubleshooting have persisted over the 11 years of reports analysed.

Under-reporting of incidents is widely acknowledged. Our aim in this study was not to quantify the frequency of these events but to explore and better understand the types of incidents that occur and how such risks might be mitigated in future.

Finally, Interactions with infusion devices are, with the exception of patient controlled analgesia, almost exclusively the responsibility of HCPs. The agent model presented above does not

Table 6
Locating professionals, patients and families in the process of detecting, diagnosing and recovering from incidents.

Process step	Roles for HCPs	Roles for patients and family
Setup	Setting up and monitoring for any errors. Double checking recommended where possible	Currently no role. Could monitor or work with HCP if trained to do so to spot any unexpected actions or outcomes
Run	Typically absent so cannot monitor except when visiting. Remote monitoring might alert staff earlier to problems.	Little evidence that patients or families are actively monitoring device to check correct performance. They could be trained to be more aware of the device state.
Interact	Few instances of failure being caused by HCP interaction after setup were identified	Failures were occasionally caused by patients or families interacting with a device (e.g., knocking it or pressing buttons)
Failure	HCPs note various cues and signals as presented above (Table 3).	Typically aware of audible and visual alarms but not of other indicators of failing device. Should alert HCP to problems
Diagnose	HCPs sometimes struggle to diagnose problems properly. Better support from the care system (e.g., technical backup) and/or training and/or device design could support diagnosis.	Devices could be designed to support people in diagnosing problems and knowing how to resolve them or who to call. Training could also help.
Correct	HCPs often either replace or restart the device	Patients and families might try restarting the device, but cannot replace without help.
Learn	Learning can involve the individual, team or organisation, but depends on the HCPs being able to understand what went wrong well enough to make it a learning experience.	There are few examples of families/patients being given guidance on how to monitor or troubleshoot devices. Training could be improved.

generalise to medical devices that have traditionally been the responsibility of the patient (such as blood glucose meters for people managing diabetes); for those, the agent model proposed by Beer et al. (2014) represents the situation more accurately. We anticipate that the agent model identified in this study will generalise to other complex medical devices where responsibility for their use resides with HCPs. We believe that the process model presented in Fig. 1 generalises well – not just to other medical devices, but to other systems that involve setup and monitoring.

6. Conclusion

Research in hospital settings suggests that infusion devices are associated with risks to patient safety. Risks associated with devices used in the home are poorly understood. Despite their limitations, incident reports help us to understand the types of incidents that occur, and identify areas of concern and potential solutions. In this paper, we have identified considerations for the design and procurement of medical devices for home use, for training (Table 6), and for the broader system of care to improve patient safety, with a particular emphasis on strategies for timely detection, investigation and mitigation when incidents occur. We have proposed two models, derived from our analysis, of the process of fault detection, remediation and learning (Fig. 1) and of the overlapping systems of home and care (Fig. 3).

Devices should be designed for the unique environment of the home, be more robust and provide feedback that helps users to identify and troubleshoot problems. Care services should also provide greater monitoring and oversight of medical devices used in the home setting, whether remotely, in person, or by further training and engaging patients and caregivers, and should provide easy access to specialist technical support when required.

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Appendix A. Search terms

The search terms used to retrieve data from NRLS (at least one item from list A AND one from list B).

Incident date between 01-Jan-2005 and 31-Dec-2015 (inclusive).

List A	List B
/\bAbbott\b/i	/\bVTBI\b/i
/\bAlaris\b/i	/\bvolume(\s)to(\s)be(\s)infused/i
/\bArcomed\b/i	/\binfusion(\s)rate/i
/\bArgus\b/i	/\bpressed\b/i
/\bAscor\b/i	/\bbutton/i
/\bAtom(\s)medical\b/i	/\bdevice/i
/\bB(\s)Braun\b/i	/\bprogrammed\b/i
/\bBaxa\b/i	/\bdisplay/i
/\bBaxter(\s)Colleague\b/i	/\binterface/i
/\bBaxter(\s)Ipump\b/i	/\bmiscalculation/i
/\bBodyguard\b/i	/\bcalculated/i
/\bBraun\b/i	/\bcalculation/i
/\bCADD(-|\s)Legacy\b/i	/\bover(-|\s)?infus(?:ed|ion)/i
/\bCADD(-|\s)Prizm\b/i	/\bunder(-|\s)?infus(?:ed|ion)/i
/\bCADD(-|\s)Solis\b/i	/\broller(\s)clamp/i
/\bCarefusion\b/i	/\buser(\s)error/i
/\bMcKinley\b/i	/\bfree(\s)flow/i
/\bCME\b/i	/\balarm\b/i
/\bCMExpress\b/i	/\bover(-|\s)?dose/i
/\bCodan(\s)argus\b/i	/\bunder(-|\s)?dose/i
/\bCurlin\b/i	
/\bDai(\s)wha\b/i	
/\bDelphi\b/i	
/\bDeltec\b/i	
/\bEden\b/i	
/\bEureka\b/i	
/\bFoures\b/i	
/\bFresenius(\s)Kabi\b/i	
/\bGemini\b/i	
/\bGrasby\b/i	
/\bgraseby\b/i	
/\bGreen(\s)pump\b/i	
/\bHospira\b/i	
/\bInfusa\b/i	
/\bInfusion(\s)pump\b/i	
/\bIradimed\b/i	

(*continued*)

List A	List B
/\bIvac\b/i	
/\bIvantage\b/i	
/\bJMS\b/i	
/\bLMA\b/i	
/\bM16\b/i	
/\bMedifusion\b/i	
/\bMedima\b/i	
/\bMedis\b/i	
/\bMedrad\b/i	
/\bMicrel\b/i	
/\bMicrofuse\b/i	
/\bMicropump\b/i	
/\bMoog(-|\s)?aitecs\b/i	
/\bMP100\b/i	
/\bMP101\b/i	
/\bMPdaily\b/i	
/\bOmnifuse\b/i	
/\bPainsmart\b/i	
/\bPCA\b/i	
/\bPEGA\b/i	
/\bPega\b/i	
/\bPhoenix\b/i	
/\bPump\b/i	
/\bSamtronic\b/i	
/\bSigma\b/i	
/\bSmiths(\s)MS\b/i	
/\bSummit\b/i	
/\bSyramed\b/i	
/\bSyringe(\s)driver\b/i	
/\bSyringe(\s)pump\b/i	
/\bT34\b/i	
/\bTerumo\b/i	
/\bUniversal(\s)medical(\s)technolog/i	
/\bVen(n)?er(\s)medical\b/i	
/\bVolumed\b/i	
/\bVolumetric(\s)infusion(\s)pump\b/i	
/\bWalkmed\b/i	
/\bZimed\b/i	
/\bZol(l)?(\s)medical\b/i	

Appendix B. Final codes

Incident type

Wrong dose administered (not right wrt prescription).
Device malfunction, including:

Battery failed
Device leaking
Occlusion (at set up or later)

Incorrect set up of the device and/or accessories, including:

Extravasion
Syringe or giving set incorrectly positioned or loaded in the device
Device programmed incorrectly (e.g. incorrect calculation)
Start button not pressed

Interference or tampering with device (including use of boost).
Unclear (including multiple incidents and cascading events).

Outcome

Under infusion – including no medication delivered.
Over infusion – including delivered too fast.

Detecting and diagnosing incidents

Cues and signals
Alarm.
Flashing light.
Screen displaying fault or error.
Physical appearance of device, accessories or contents.

including evidently off

Motor noise.
Unexpected volume remaining.
Patient condition or symptoms.
Routine review of documentation and stock (inc. Device log and programming).
Reflection on practice.

including reports from others on their practices

Not reported.

Detective work

Device checks and trouble shooting
Visual and aural cues.
Physical set up.
Pump programming.
Condition of site.
Checking or replacing battery.
Turning off and on.

Second hand information
Other professionals.
Patient or family.
Review of documentation or stock.
Event log.

Delays or missed opportunities
Detected on routine visit.
Patient/family or professionals failed or delayed reporting.
Adequacy of checking.
Misdiagnosis or failed troubleshooting.
Absence of, or inadequate, alarm.
Unavailability of staff.
Family locked out from fixing.
No replacement available.

Remedial or corrective actions
None reported.
Device reset or restarted.
Infusion stopped.
Battery replaced.
Device replaced.
Syringe or giving set replaced.
Cannula re-sited.
Monitoring or follow upchecking back later.
Alternative medication administered.

Actions preventing reoccurrence
Device sent for further investigation or servicing.
Staff training and development.
MHRA report/manufacturer informed.
Focus on process rather than learning.
Individual responsibility (emphasis on staff vigilance and double checking).

Review or change practices, including:

keeping spare device/stocks to hand
upgrading device/giving set

Staff member suspended.

Locating the patient and family in reports

Patient

No reference.
Subject only.
Active role:

Detection/reporting
Investigation
Interactions with device

Family/Caregivers

Detection/reporting.
Investigation.
Monitoring.
Interactions with device:

Troubleshooting
Not informed
Informed about incident

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