

Intravenous infusion practices across England and their impact on patient safety: a mixed-methods observational study

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Scientific summary

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Scientific summary

Background

Infusion devices have been identified as an important source of errors, potentially compromising patient safety. The use of smart pumps, in which the infusion device is integrated with information systems and drug libraries to set safe limits on medication administration, has been advocated as a key technology to block critical medication administration errors. Take-up of this technology in England has been patchy and, even where smart pumps have been introduced, drug libraries may be only partially implemented.

No previous studies on the role of infusion devices in ensuring safe medication administration practices have been conducted in England. This study was therefore designed to better understand current intravenous (IV) infusion medication practices in England and the possible role of smart pumps in managing patient safety.

Objectives

The study aims were to describe the rates, types, clinical importance and causes of errors involving infusion of IV medication in English hospitals, and to propose interventions to minimise harm from the errors identified. Our objectives were to:

1. describe how IV infusions are administered in a sample of 16 English hospital trusts, focusing on differences in terms of nursing practice, equipment, policies and processes
2. describe the rates, types, and clinical importance of errors associated with infusion delivery in critical care, general surgery, general medicine, paediatrics and oncology, in our sample of hospitals, including gravity administration, standard infusion devices (pumps and syringe drivers) and 'smart' infusion devices
3. explore variance in the rates, types and clinical importance of errors in relation to mode of delivery and clinical area
4. explore the causes of the errors and the extent to which innovations in technology or practice could have prevented such errors
5. identify best practices in safe and effective IV medication administration across different hospital contexts, including issues that are important to patients as well as staff
6. compare findings with those of an ongoing US study, and explore the reasons for any differences identified
7. propose recommendations to prevent IV infusion errors across different hospital settings in England.

In response to early discussions with participating sites, the definition of 'error' was revised: all deviations from a prescriber's written or electronic medication order, the hospital's IV policy and guidelines, or the manufacturer's instructions were termed 'deviations'; those that were assessed as 'having capacity to cause error' (but not being errors) were classed as 'discrepancies' and those that were judged as possibly resulting in patient harm were classed as 'errors'.

It was found that the observations on IV medication practices could be accounted for only by considering IV medication administration as a complex adaptive system, so the second aim (proposing interventions) was revised, as discussed below.

Methods

The study comprised two main phases, plus supplementary studies and analyses and engagement with stakeholder groups.

Phase 1 was a mixed-methods study involving 16 NHS trusts in England. Hospitals were chosen purposively for maximum variation. Thirteen acute hospitals, two specialist children's hospitals and one specialist cancer hospital trust participated. Point-prevalence observations were conducted in general medicine, general surgery, critical care, paediatrics and oncology day care. Across participating sites, at least 13 days' observation was conducted in each clinical area.

The point-prevalence study used quantitative observational methods to document the prevalence, types and clinical importance of deviations associated with the infusion of IV medication. This involved trained staff systematically reviewing details of each IV infusion in progress at the time of observation and recording any deviations using an adaptation of the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) severity index. Deviations were classed as discrepancies if they were rated A1 or A2, and as errors if they were rated C to I.

Once a preliminary analysis of quantitative data had been conducted and a draft site report had been produced, debriefs and focus groups were held with key staff at each hospital trust to relate point-prevalence results to details of hospital IV practices. If needed, data were adjusted in response to the debriefs and focus groups at each trust; further adjustments were made across the entire data set to ensure that classifications were as consistent as possible.

Error and discrepancy rates were calculated as the proportion of infusions with at least one deviation. Variations in deviation rates between clinical areas, delivery modes and infusion types were explored.

We compared the assessment of clinical importance of deviations based on the NCCMERP severity index with the Dean and Barber method (Dean BS, Barber ND. A validated, reliable method of scoring the severity of medication errors. *Am J Health Syst Pharm* 1999;**56**:57–62) for assessing the severity of medication administration errors. This involved four experienced health-care professionals assessing each error on a scale of 0–10. Correlation between the two sets of scores was assessed using Spearman's rank-order correlation.

Our point-prevalence data were compared with those from a recent US study conducted using a similar protocol. Once the separate studies had been completed, members of both study teams identified themes for comparison and contrast across the two studies. The analysis focused on which factors might be related to differences across countries, levels of technological maturity and other factors.

Debrief and focus group data were analysed inductively to contextualise the quantitative data and provide explanatory detail about differences within and across trusts. Three independent analyses of the qualitative data were conducted, all based on variants of thematic analysis. The first focused on the type and frequency of procedural and documentation deviations alongside the variance of local policy. This analysis related the quantitative data on these deviations with the qualitative data. The second analysis focused on nursing staff behaviour that contributed to system resilience in IV therapy. The third analysis took a broad view of what staff perceived to influence IV medication deviations.

We conducted two further analyses specifically focusing on possible roles for smart pumps. The first was based on the point-prevalence data set from phase 1 and the second on incident reports from the National Reporting and Learning System (2005–15 inclusive) relating to infusion devices. These analyses focused on the more serious incidents: phase 1 observations classed C and above, and National Reporting and Learning System reports classed as moderate harm or above. The focus of these analyses was on the

extent to which these errors may have been prevented by use of a smart pump or, for those that were given by a smart pump, the extent to which the smart pump may have contributed to the error.

Phase 2 involved ethnographic observations and interviews on selected wards at five of the participating hospitals. The aim was to identify what aspects of the sociotechnical system have positive and negative effects on error types and rates and to develop a rich understanding of the factors that influence performance around IV infusion administration.

Observations included staff administering IV infusions and setting up pumps, supplemented by interviews with staff to further understand their practices. Data gathering and analysis were driven from human factors and sociotechnical system perspectives; that is, the ways we planned and conducted observations and interviews were informed by the literature and practices of research in these areas, as reviewed in *Chapter 1*. The analysis focused on the causes of deviations, the need for any workarounds in practice, and identifying best practices in safe IV infusion administration. We also interviewed patients about their IV infusion experiences, and analysed these data separately using thematic analysis.

Thematic analysis was used to explore themes and patterns that emerged from the observational and interview data. Where applicable, we employed relevant theory to gain further insight and give theoretical weight to our analysis. Two analyses were conducted focusing on different aspects of the data: understanding how the design of the work system shapes outcomes, and understanding infusion administration as a complex adaptive system.

We also engaged with stakeholders throughout the project, including the public and patients, health-care professionals and industry (this was referred to as 'phase 3' in our original proposal). Two workshops involved public and patients; one explored their experiences of IV therapy and reviewed the patient-facing material for phases 1 and 2; the second sought feedback on our emerging findings. Patient representatives were also included on our advisory group and study steering committee. Various opportunities (including workshops, conferences and other meetings) were taken to engage with professionals, and a workshop for manufacturers was co-organised with the UK National Association of Medication Device Educators and Trainers (NAMDET), focusing on our findings and implications for industry.

Results

Point-prevalence data were collected from 1326 patients and 2008 infusions. A total of 240 errors were observed in 231 (11.5%) infusions, and 1489 discrepancies were observed in 1065 (53%) infusions. Twenty-three errors (1.1% of all infusions) were considered potentially harmful (category D or above); none was judged likely to prolong hospital stay or result in long-term harm.

Types and prevalence of deviations varied widely among trusts, as did local policies. Deviations from medication orders and local policies were sometimes made for efficiency or responding to patient need.

There was no evidence of a relationship between error and discrepancy rates. Infusions observed in critical care had a significantly lower error rate (7.0% of infusions) than in other clinical areas. Patient-controlled analgesia pumps and syringe drivers had the lowest error rates of 6.4% and 5.1%, respectively, with infusions delivered via gravity having the highest (21.5% of 163 infusions). Maintenance fluids had a high error rate (18.5%) compared with other medications (6.9%), blood products (9.1%) and parenteral nutrition (2.9%).

Eleven out of 16 hospitals (69%) used smart pumps (defined as an infusion pump with a drug library and/or dose-error reduction software enabled) in at least one clinical area. However, just 640 (32%) infusions were administered using smart pumps. Infusions delivered using smart pumps had similar error rates to those using other pumps (10.3% vs. 10.8%; $p = 0.8$).

Comparing our data with those from the USA, we did not find significant differences in the kinds of errors most likely to result in patient harm (such as wrong rate), which smart pumps are specifically designed to reduce. The largest differences were in documentation and patient identification errors (both higher in the English study); and labelling and tube-tagging errors (higher in the US study).

To compare the NCCMERP severity index assessment method with the Dean and Barber method, 155 errors were assessed. Scores from the two methods were significantly but weakly correlated (Spearman's rank-order correlation = 0.36; $p < 0.01$), highlighting challenges in comparing studies using different severity assessment methods.

Information provided by observers and in focus groups at each site revealed some reasons for deviations. Some were slips or lapses such as confusing diluents or forgetting to open roller clamps to start the infusion; others involved a lack of knowledge of policy requirements. Staff also reported deliberate deviations that would benefit patients but conflicted with official rules and formal procedures, for example giving patients fluids that had not yet been prescribed when a doctor was unavailable and keeping lines patent by switching to a low infusion rate in anticipation of another infusion being needed. In reporting, it was evident that staff actively tried to balance risk and efficiency rather than follow procedures mechanically. For example, staff reported stopping infusions when patients left the ward for investigations so that a nurse did not have to accompany the patient. In addition, some nurses objected to spending time labelling administration sets and writing batch numbers on additive labels for short infusions that would soon be discarded.

Interviews with patients ($n = 35$) suggested four underlying and interlinked themes: patients' knowledge about IV infusions (with wide interpatient variation in the amount of information required), challenges associated with the infusion process (mainly around frequent alarms and the effect on mobility), attitudes towards receiving infusions ('you just get on with it') and, with some exceptions, generally feeling safe.

In the analysis of the in-depth observational data, it was evident that IV medication administration could not be analysed as an isolated function, independent of context. This led us to reframe one of our questions from whether or not smart pumps can improve patient safety to how IV infusion administration can be understood as a complex adaptive system. This includes possible roles for advanced technology (smart pumps, bar code medication administration, computerised prescriber order entry, etc.). However, it ultimately depends on the complex interplay between policies, practices, staff and technology, which should be designed to enhance the competencies of staff and of the overall system, to maximise resilience in a system that our data indicate is safer than previous literature would suggest. No complex system can be completely safe (i.e. error-free, and, correspondingly, harm-free); the challenge is to create local systems that learn from each other and from both incidents and good practices, so that they evolve over time, becoming safer and more effective.

Conclusions

Errors and discrepancies are common in everyday IV infusion administration but most have low potential for patient harm. We identified many variations in practices across both wards and hospitals. We also identified many opportunities for learning by reflecting on local practices, reviewing the practices of others (locally and nationally) and exploiting informative variability. We identified good practices such as ensuring that the infusion pump, prescription and patient are co-located and that the prescriber can be contacted to clarify any prescription queries. Innovative technologies such as smart pumps may have a role to play in supporting the work of clinicians and enhancing the experience of patients. However, they are not a 'plug and play' technology, and considerable work is needed to align pump use and working practices. IV infusion administration is a complex adaptive system; it is necessary to set up the conditions for success, develop standards for policies and adopt strategies to discover what factors contribute to success in locally contextualised situations. This involves developing technological and practice-based 'probes' to identify what configurations are most likely to succeed, and finding ways to amplify positive effects.

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