Abstract

Background: Patients receiving palliative care are vulnerable to patient safety incidents but little is known about the extent of harm caused or the origins of unsafe care in this population.
Aim: To quantify and qualitatively analyse serious incident reports in order to understand the causes and impact of unsafe care in a population receiving palliative care.
Setting and participants: Reports to a national database of "serious incidents requiring investigation" involving patients receiving palliative care in the National Health Service (NHS) in England during the twelve year period, April 2002 to March 2014.
Design: A mixed methods approach was used. Following quantification of type of incidents and their location, a qualitative analysis using a modified framework method was used to interpret themes in reports to examine underlying causes and the nature of resultant harms.
Results: A total of 475 reports were identified: 266 related to pressure ulcers, 91 to medication errors, 46 to falls, 21 to healthcare associated infections (HCAIs), 18 were other instances of disturbed dying, 14 were allegations against health professions, 8 transfer incidents, 6 suicides and five other concerns. The frequency of report types differed according to the care setting. Underlying causes included lack of palliative care experience, under-resourcing and poor service coordination. Resultant harms included worsened symptoms, disrupted dying, serious injury and hastened death.
Conclusions: Unsafe care presents a risk of significant harm to patients receiving palliative care. Improvements in the coordination of care delivery alongside wider availability of specialist palliative care support may reduce this risk.

Keywords: Patient safety, Palliative Care, Palliative Medicine, Medical errors, Risk management, Qualitative research

What is already known about the topic?

- Patients receiving palliative care are vulnerable to inadvertent harm during the course of their medical and nursing care, with some risks specific to this patient population.
- Previously, no studies have examined the nature and sources of inadvertent harm in a population of patient receiving palliative care across a healthcare system.

What this paper adds

- Patients receiving palliative care are at risk of harm due to shortfalls in their care, this harm manifests as worsened symptoms, serious injury and hastened or disrupted death.

- Factors underlying harm include a lack of palliative care experience, under-resourcing of health services and poor service coordination.

Implications for practice, theory or policy

- Better coordination of the delivery of palliative care and wider availability of specialist palliative care advice and support may make care safer.

Introduction

Avoidable harm during the course of healthcare provision has been shown to be an important source of mortality and morbidity worldwide.[1-2] The realisation of the scale of the human and financial costs resulting from this preventable harm has led to the growth of the discipline of patient safety, which can be defined as "the prevention of avoidable errors and adverse effects to patients associated with health care".[3] Palliative care is not immune to these risks; the use of strong opioids and sedatives,[4] care outside specialist settings,[5] reliance on informal carers[6] and promoting patient choice[7] all contribute to the risk of adverse events occurring. The fragile physical, psychological, social and spiritual state of palliative care patients reduces their resilience to unsafe care[7-10] and it is also apparent that the changing goals of therapy towards the end of life may create conflicts with measures to prevent adverse events such as pressure sores and falls that are considered standard in other areas of healthcare.[3] When asked about patient safety, patients receiving palliative care identify specific risks with poor communication, hastened death and the failure to provide a good death identified as potential harms.[8,11-15]

Previous studies of patients with progressive and life-limiting illness have documented specific risks towards the end of life.[16] Pressure ulcers affect a quarter of patients receiving hospice care.[17-19] Suicide is a heightened risk in patients receiving palliative care.[20-21] The use of opioids[22] and syringe-drivers to deliver medication can result in harm.[23] However, health system-wide studies of patient safety incidents or opportunities to improve safety in the delivery of palliative care are uncommon[24] and attempts to quantify and qualify the burden of unsafe care in palliative populations have been unsatisfactory, even when focussed on a specific type of risk.[25]

The aims of this study were to quantify and qualitatively analyse serious incident reports from a national database in order to understand the causes and impact of unsafe care in a population receiving palliative care, including the underlying system factors as well as the more obvious immediate human factors.[26] Our findings provide insights into the nature and causes of inadvertent harm to this vulnerable patient population and offer a foundation for building safer care.

In the United Kingdom context, and hence this study:

- "Hospice" refers to institutions, usually predominantly charity-funded, that provide inpatient and outpatient palliative care including day therapy and home-based community services.

- Palliative medicine exists as a distinct medical specialty. Whilst we recognise that many clinicians will provide some palliation, we defined specialist palliative care as the involvement of clinicians with specialist training in, and working predominantly or exclusively in palliative care.

Methods

We conducted a mixed-methods analysis of reports of serious patient safety incidents from a database of all such incidents relating to patients treated in the National Health Service (NHS) in England during the period 2002 to 2014. The need for ethical approval was waived by the Cardiff University School of Medicine's Research Ethics Committee (SMREC Ref 16/59, Nov 2016).

Data source

Since 2002, hospitals and other NHS organisations in England have been required to record, report, and investigate any *serious incident requiring investigation (SIRI*).[27-28] The resulting database, the Strategic Executive Information System (STEIS), is the source of our study population. Each report in STEIS contains categorical information and free-text commentary. The categorical information covers: administrative data, the care sector and clinical area involved, the location of the incident and the type of incident. Free text fields record what occurred, what immediate action was taken and a summary of the case although the detail contained is highly variable with some fields being left blank. The reporting organisation is later expected to complete further free-text fields detailing the investigation carried out, root causes identified, and lessons learned following the incident, again these fields can be left blank. STEIS had accumulated over 120,000 reports by April 2014 (further information on STEIS is available in the online appendix).

Inclusion and exclusion criteria

The database was searched to extract reports that had been filed with any of the following criteria: 'Hospice' as Location of incident, 'Palliative Medicine' as Clinical area or contained any of the terms 'palliat*', 'terminal', 'hospice', 'end-of-life' or 'care pathway'. The following criteria were applied to extracted reports (Figure 1). Criteria for inclusion (any of): a) care provided in a hospice inpatient unit; b) care provided by a specialist palliative medicine team; c) a clear statement of a decision to treat with palliative (as opposed to life-prolonging) intent prior to the incident occurring. The criteria for exclusion were: a) reports where a patient was receiving treatment delivered with palliative rather than curative intent and the incident related solely to disease-modifying treatment (e.g.

chemotherapy drug errors); b) the event reported occurred prior to a decision to treat with palliative intent (e.g. a patient who fell in hospital, sustained a severe head injury and was given palliative care from that point onwards); c) incidents not related to patient care (e.g. statutory reporting of deaths in state facilities such as prisons). We included all reports related to patient care, regardless of whether the events described appeared to contain a safety incident in order to capture the breadth of concerns triggering reporting from frontline clinical practice. Reports were allocated a unique identifier with four letters related to the location the report arose from (Hosp = Hospice inpatient unit, Acut= Acute hospital, Comm = Community hospital, Nurs = Nursing or care home, Home = Patient's own home) and a non-consecutive number.

Data analysis

Two concurrent forms of analysis were employed: All reports were included in a descriptive quantitative analysis of the nature and location of the incident. Where reports contained sufficient detail, the verbatim free text fields were analysed qualitatively using a modified Framework Method.[29-31] We applied the method combining deductive and inductive approaches[32] through the five steps in Table 1. Further details are available in the online appendix.

Results

Altogether, 475 unique reports fulfilling our inclusion criteria were identified. Figure 1 shows how the study population was derived from the main database. 78 (16%) reports were excluded from the qualitative analysis because they lacked sufficient detail in the free text sections. Overall, 423 (89%) of the reports included in the study were in one of five categories: pressure ulcer development or worsening, medication errors for end of life drugs, falls, healthcare associated infections, and disturbed dying. Pressure ulcers alone accounted for 266 (56%) reports. Shortfalls in care fell into five themes: Care planning, where the lack of or failures in, the plan for a patient's care caused harm, for example where an absence of anticipatory prescribing led to poor symptom control. Individual care-giver, where shortfalls in care were directly attributable to an individual, for example drug prescribing or administration errors. Communication, where poor communication led to harm, for example a failure of communication with relatives. Care coordination and delivery, where the systems in which care was provided did not function properly and led to harm, for example poor handover between care providers causing disruptions in care. Equipment, where a specific item of equipment, or the lack of equipment, was implicated in causing harm, for example the malfunction of a syringe driver.

There was variation in the type of report from different locations. Medication errors and allegations against health professionals were more likely to occur during care at home than in any other environment, falls were disproportionately reported from hospice settings and healthcare associated infections from acute settings (Table 2). Patterns emerged linking types of incident with shortfalls in standards of care in different care settings and different underlying contextual factors. These themes are presented, considering each incident type in turn.

Pressure ulcers

All the reports involving pressure ulcers were made after the regulator of healthcare in England (the Care Quality Commission) established mandatory reporting of this outcome of care. Of the 266 reports of pressure ulcers from the qualitative analysis, 65 were excluded because the free text sections of the report were incomplete. In 136 (68%) of the 201 reports of pressure ulcers analysed, no shortfall in the standard of care was identified. In some, it was clear that the nature of the patient's condition made the development of pressure ulcers unavoidable despite maximal pressure relief therapy, for example this case in a terminally ill elderly lady who was being cared for in a hospice:

> "*This case is an example of the physiological changes that are commonly seen during the last weeks of life. It highlights the difficulties in pressure ulcer prevention despite appropriate risk assessment and care planning being undertaken.*'' Hosp25

In other cases where pressure damage resulted despite appropriate care, a decision not to apply pressure-relieving care aligned with patient goals, for example:

> "*Discussed possibility of having profiling bed and superior mattress but patient wants to spend remaining time in her own double bed to be close to her husband.*" Home16

A decision to alter the care plan to respond to the wishes of a patient appeared in 100 reports; of these 85 (85%) had received specialist palliative care input.

When shortfalls in standards of care were identified in reports of pressure ulcers, this often resulted from uncertainty about what was appropriate for palliative care. This was most apparent in acute hospitals and in nursing homes amongst non-specialist palliative care clinical staff (medical and nursing), for example:

> *"Early liaison with the tissue viability nurse … is not implemented when patient is on the end of life tool. Discuss with palliative care regarding review of end-of-life toolkit to include when it is appropriate and how frequently assessment should be done."* Acut25

Among patients cared for in their own home, the unavailability of pressure relieving equipment was the principal factor in the development of pressure ulcers in 14 (48%) of 29 cases; for example:

"…a fax was received stating that no mattress was available…the patient developed a grade 3 pressure ulcer whilst awaiting delivery of mattress. An 8 day delay in the delivery of essential equipment…contributed to a further breakdown in the pressure ulcer" Home70

Medication errors

Of the 86 medication errors analysed, 76 (88%) exclusively involved the use of opioids or sedatives and half (43, 50%) were when non-palliative care specialists provided care. Comparison of the quantitative data analysis with our qualitative themes showed that shortfalls were concentrated in the theme of *Individual caregiver* followed by *Care coordination and delivery.* This was usually due to medication being unavailable (not prescribed, difficult to access supply, lack of professionals to administer) to patients being cared for in their own homes (not reported from any other sites).

Errors in medicine prescription (38 (44%) cases) and medicine administration (19 (22%) cases) were the commonest shortfalls in standards of care across all settings; for example:

"Prescribing error occurred when general practitioner incorrectly converted oral morphine to diamorphine for a syringe driver. Three times recommended dosage was prescribed…. Patient was administered the syringe driver and became drowsy, so duty nurse contacted duty doctor and it was identified that incorrect dose had been prescribed. Ambulance called and patient was admitted to hospital." Home86

Confusion in the selection of, or conversion between, different opioids occurred in medication administration as well as prescription, as here:

"They should have given 0.15mg of Alfentanyl 1mg/2ml instead they administered 0.30ml of Alfentanyl 5mg in 1ml" Comm25

The patient's own home was the location of care in a disproportionate number (52, 60%) of reports of medication errors. Of these 52, only two (4%) described errors by non-professional care-givers. Syringe drivers were implicated in 23 (27%) medication errors. All but three were due to errors in the set-up and use of the driver; for example:

"Evening Service arrived at 20.10, syringe driver barrel empty and it was noted that rate had been set incorrectly…Staff Member B changed rate of administration of the MS16A believing it was the same device as the MS26" Home47

The risk of a lack of understanding of different models of syringe driver arose when either patients or staff moved between organisations using different drivers. Errors in the use of syringe drivers

mostly resulted in overdoses of medication although on two occasions a syringe driver failed to deliver adequate dosing, leading to a worsening of the patient's symptoms.

Where harm was reported, it disrupted patient care by causing an unplanned readmission to hospital (seven cases) and worsened symptom management (19 cases). Many medication errors were close to the moment of death; for example:

> "*The patient was prescribed 5mg Morphine Sulphate subcutaneously. The nurse administered 5 mg Diamorphine in error. The medication was administered at 08.45hrs. The patient died at 10.07hrs."* Comm13

In 23 (27%) instances the incident report recorded concerns that medications had hastened the death of the patient, and in three instances these concerns came from the patients' families. For example;

> "*Registered Nurse administered inappropriate prescription dose of midazolam. Patient died 14 hours later… informed [local] Police and Coroners Officer"* Home96

In all but four of these 23 cases, a referral to the coroner was mentioned in the report.

Falls

Falls were the third most frequent category of report with 39 instances. Inadequate staffing was the most commonly identified shortfall in standard of care (18 cases, 46%). Overall, 29 (74%) of the falls resulted in an injury, most commonly fractured neck of femur or intra-cranial haemorrhage. In five cases, a decision was made not to investigate possible injuries; for example:

> *"On examination it was felt that she might have fractured her hip. In discussion with her family I, as the consultant, decided that the best course of action was to keep her in the hospice and treat her conservatively with bed rest and analgesia…The following day she died."* Hosp12

These five cases were all in a hospice setting. In 14 other cases, the fall led to an unplanned admission to an acute hospital for treatment; for example:

> *"Patient was transported to the acute hospital where it has been confirmed that the patient has a fracture of the left hip and will require surgery."* Hosp68

In twelve cases the fall was considered to have hastened the death of the patient and a referral to the coroner was made in eleven, as described later.

Healthcare associated infections

Twenty-one reports concerning healthcare associated infections were included, all related to methicillin resistant Staphylococcus aureus (MRSA) or Clostridium difficile (C. difficile) infections. In all but three (14%) the incident appeared to be unavoidable due to contextual factors such as the patients' overall clinical condition. Delays in the diagnosis and management of C. difficile infection were identified in the other three cases: this was caused by misdiagnosis following an assumption that symptoms were due to underlying disease or side effects from medication rather than a reversible infective cause; for example:

> *"Admitted to [hospice] due to uncontrolled pain, confusion and diarrhoea. … Impression was that the patient had overflow diarrhoea secondary to opiate constipation… The Cdifficile toxin positive result was communicated [five days later]"* Hosp05

C. difficile infection caused worsened symptom control in six cases and was reported to have hastened the death of ten patients.

Allegations against health professionals

Allegations of unprofessional nursing behaviour (five cases) and of acceleration of death (6 cases, three regarding general practitioners and three nursing staff) occurred across settings. For example:

> *"Overnight family claim that patient was left in pain with no adequate pain relief. Also complain that the nursing staff lacked compassion. They believe that the patient died "writhing in pain and agony and that the nurses did not do anything"* Hosp16

> *"Relatives of a patient on end of life care and on s/c morphine pump have made allegations that the patient was murdered by nursing staff. He died about 45 minutes after a prn dose of morphine for distress. Police attended the ward at the request of the family."* Acut63

The five reported allegations of unprofessional behavior were all upheld and resulted in disciplinary action. Police investigation of the six reports of potentially hastened death did not result in any further action being taken.

Disturbed dying

Reports categorised as "disturbed dying" related to events at the moment of, or immediately after a patient's death that did not fit into other categories. They arose from all care settings other than acute hospital units.

Most such reports from an institutional setting were associated with failures to plan care, including unclear goals of care and failures to document advance care planning. Harmful consequences included patients dying during the process of attempted transfer to hospital, attempts at cardiopulmonary resuscitation when this was not clinically appropriate, and distress in bereavement from unnecessary involvement of the police or coroner following expected deaths; for example:

> *"… a patient was hypoglycaemic and unresponsive. The patient was not for resuscitation. The paramedics took the patient to A&E... The patient died in the corridor on the stretcher ..."* Nurs12

Ten reports were associated with failures in care delivery and coordination with poor interagency working and handover in seven of the ten cases, for example:

> *"Terminally ill patient discharged from [acute hospital ward name] without being referred to DN [district nursing] service. Patient died on floor at home the next day."* Home10

Reports of disturbed dying in a patient's own home (three cases) were associated with delays in care during an out-of-hours period leading to poor symptom management; for example:

> *"Daughter has reported that she tried to contact District Nurses and Out-of-hours GP and Paramedics to get some pain relief for her mother, but her mother continued to be in pain."* Home82

The relative had recognised the need to escalate care but was unable to access out-of-hours care provision this led to patients dying in pain.

Other causes of disturbed dying included suicide and unnecessary police or coronial involvement. Five suicides and one attempted suicide were reported. In one of these cases a shortfall in care was identified by the reporter:

> *'The medical and nursing assessment of [the patient] did not indicate a patient with suicidal ideation; however this was apparently a concern of the MacMillan nurse …. Communication between the Acute team and the Macmillan nurse here leaves room for improvement.'* Acut95

The police or coroner were involved following the death of the patient in 69 cases (39 (57%) were drug incidents) although the outcome was often not recorded. Coroners' involvement frequently led to distressing delays in funeral arrangements being described. Early contact and discussion of the case with the coroner by a member of the clinical team usually pre-empted the need for a more thorough investigation.

Discussion

We believe that our study is the first to empirically examine all reports received by a national reporting system of serious incidents occurring during the provision of palliative care. The population studied encompassed a range of conditions, both malignant and non-malignant, a range of settings and both specialist and non-specialist palliative care providers. The reports demonstrated harm arising from a combination of shortfalls in the standards and provision of care and the intrinsic vulnerability of this patient population.

Pressure ulcers were the commonest category of incident identified in our study and this is consistent with previous research in palliative care populations.[17-19] Others have rightly challenged the application of generic standards and quality markers, such as pressure ulcer avoidance, to a palliative care setting because of the altered goals of treatment compared to non-palliative settings.[7] To some extent, our study supports this view; we found pressure ulcer-related harm in dying patients, despite excellent care where shared decision making led to pressure relieving measures not being applied in order to align management plans with patient priorities. However, pressure ulcers are not just a source of pain and discomfort, they can erode a person's dignity and morale. Thus, the recognition of altered care goals in palliative care should not be allowed to generate complacency and an attitude of passivity emerge regarding pressure sore prevention. Indeed, we found instances of uncertainty and assumptions about patients in this population among non-specialist palliative care clinical staff leading to oversights in the application of appropriate tools to reduce risk and harm.

The extensive use of opioids in palliative care is known to carry risks, at least one prescribing error was found in 70% of cases in a prospective series of nearly 200 patients with cancer-related pain referred to a specialist palliative medicine service, with multiple errors common.[22] Another study found prescription errors and medication omissions occurred frequently in a specialist palliative care unit.[34] Our findings are consistent with this. We also found further vulnerability of palliative care patients to medication-related harm due to drug administration errors, particularly when occurring close to the moment of death. Nevertheless, concerns in this area must not lead to underuse of effective symptom control measures, failure to use opioids and other medications where necessary will lead to harm from poor symptom control. Reports of incidents involving syringe drivers in the

United Kingdom, such as those described in our study, led to guidance in 2010 on the standardisation of purchasing of syringe drivers to improve safety,[35] interestingly, none of the reports concerning syringe drivers included in our study occurred after 2010.

We termed a group of reports that could not easily be categorized as "Disruption to the dying process". Certainty in their final moments is an issue that other qualitative studies have found to be important to patients receiving palliative care.[14-15] The process of care at the end of life being unnecessarily dysfunctional or disrupted was a theme in many reports, for example failure to document a plan for death despite it being acknowledged that a patient was at the end of life led to inappropriate attempts at transfer to an acute setting and a disturbed dying and bereavement process, scenarios that patients receiving palliative care fear.[15] A lack of experience in palliative care provision, under-resourcing, and poorly coordinated services were underlying themes. These were apparently particularly at the interfaces between different care sectors, between acute care providers and community providers, both at discharge and admission, for example.

Strengths and limitations

We believe this to be the first national analysis of patient safety reports focusing on palliative care patients. The data capture a cross-section of authentic reporting in a large healthcare system, enabling the examination of events and the organisational factors underlying them. Exploring problems at a national level, with a mixed methods approach provides insights into the interaction of factors between various settings of care delivery that underlie unsafe care.[36]

All systems of incident reporting, whether in healthcare or other industries, suffer from under-reporting and the consequent problem of selection bias (i.e. incidents reported may not be typical of all that occur).[37] It is not possible to comment on variation in underreporting between incident types or settings, given the unknown denominator of patient safety incidents occurring to palliative care patients; therefore, we cannot comment on the relative safety of different healthcare settings. This uncertainty, combined with a lack of a reliable denominator for the number of clinical contacts in any given palliative care setting, also makes an estimate of the prevalence of safety incidents impossible. However, it is important to note that incident report data provide a considerable body of granular information on events and contributory factors perceived to be important by front-line healthcare professionals and staff, this means that a qualitative approach alongside any attempts at quantification is vital.

Practical implications

Some of the most influential work in safety has focused on the role of systems in the generation of adverse incidents.[26] There is an understanding that "human factors" such as lapses in memory or concentration and errors in execution, such as mis-writing a prescription, are inevitable. Trying to eliminate these errors is doomed to failure and so efforts to improve safety have concentrated on strengthening the systems workers operate within and creating means by which the adverse influence of human factors can be mitigated.[38] Our study demonstrates the role of the system in the generation of safety incidents during palliative care, revealing models of care that are disjointed, poorly coordinated and unable to provide vital medication, equipment or personnel, particularly out of hours and in the community. Even where individual care-givers' actions were the apparent cause of an incident, these errors occurred in a system unsupportive of individual clinicians that required them to practice in unfamiliar areas using inconsistent equipment.

Those responsible for the management of palliative care provision should ensure that the systems of care they oversee are adequately integrated in order to provide continuing care as patients pass between providers. Local healthcare leaders must give strong and visible commitment to patient safety. This should include specialist support for palliative care, not just in direct delivery but also in offering training and advice for non-specialists who also provide palliative treatment, for example in the appropriateness of modifying standard patterns of care in palliative situations and advance planning for anticipated dying. This requires the development of systems of care that are well coordinated and able to provide vital medication, equipment or personnel, including out-of-hours and in patients' own homes. Doing so will help assure the safety of many patients who are currently inadvertently harmed by the care that they receive.

Declarations

Authorship: IY, SY and LD conceived and designed the study, analysed and interpreted the data. AC-S and HW assisted in interpreting the analysis. IY drafted the manuscript. All authors critically reviewed and revised the final manuscript and have approved it for publication.
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Ethics: The need for full ethical review was waived by the Cardiff University School of Medicine's Research Ethics Committee (SMREC Ref 16/59), November 2016.

Data management and sharing: The STEIS database is controlled by NHS England. Due to the level of detail contained in reports to the database, individual patients may be identifiable and so access is restricted.

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