

**Preventable Incidents, Survival and Mortality  
Study 2 (PRISM)**

**Medical Record Review Manual**

**Dr Helen Hogan, Jan 2014**

## Introduction

Public and policy interest in hospital death rates has risen sharply, particularly following the recent investigations into the Mid Staffordshire NHS Trust and 14 other acute Trusts around the country. For the last decade the Department of Health (DH) has advocated the use of hospital wide measures of mortality such as HSMR and SHMI to provide an early warning system of quality and safety problems within hospitals and to compare performance across hospitals. However, intense debate surrounds whether the "excess deaths" detected by these measures are a valid indicator of the safety of a hospital. Many factors beyond patient safety impact on HSMR/SHMI including coding standards and depth, or the local provision of services for the dying that divert patients from hospitals. Such factors can lead to higher scores for some hospitals which have nothing to do with quality and safety of healthcare provision

Only four published studies, all in N America, have looked at the association between HSMR and avoidable deaths determined by case record review. Three of the studies either found no correlation,<sup>1,2</sup> or a negative correlation.<sup>3</sup> Only one study found a significant positive association with deaths in a single disease group (pneumonia).<sup>4</sup> This was also the smallest study. (Two additional unpublished studies have found no association). In 2009, we undertook the PRISM 1 to obtain a national estimate of hospital avoidable deaths using case note review of a 1000 deaths across 10 acute hospital sites. By extending the sample size of our previous study from 10 hospitals (1000 deaths) to 34 hospitals (3400 deaths (2400 new reviews across another 24 Trusts)) we will achieve sufficient statistical power to determine the degree of correlation between avoidable death rates at hospital level and HSMR/SHMI.

The PRISM 2 correlation study will inform policy makers' decisions on approaches to tracking hospital quality and safety. It will also provide a national baseline for avoidable deaths against which NHS England will compare future estimates derived from a new national measure of avoidable deaths due to be introduced in 2014/15.

## Aims and Objectives of the Study

### Aim

To ascertain the relationship between hospital avoidable deaths identified by retrospective case record review and HSMR/ SHMI

### Objectives

To determine the proportion of patients dying in hospital who experience a problem in healthcare including acts of omission (inactions) or acts of commission (affirmative actions) and the proportion of such deaths that are avoidable

To determine the strength of correlation between the proportion of avoidable deaths at hospital level and HSMR/ SHMI

To inform policy makers whether "excess deaths" identified by HSMR/SHMI are correlated with avoidable deaths determined by retrospective case record review

## Study Design

The methodology for retrospective case record review (RCRR) was first developed in California in the mid-seventies and used to identify the burden of healthcare-related harm as part of an investigation into the costs of a no-fault insurance scheme for hospitals.<sup>5</sup> The method and review forms were further developed in the two largest RCRR studies of adverse events to date: the Harvard Medical Practice Study<sup>6</sup> and the Quality in Australian Healthcare Study.<sup>7</sup> The design of PRISM 2 also draws on the first British RCRR study, conducted by Vincent et al, which examined the incidence of adverse events in 1014 admissions to two London hospitals in 1999.<sup>8</sup> The design has also been influenced by the methodology used by Hayward et al<sup>9</sup> in a US study focused on preventable deaths and a Dutch RCRR<sup>10</sup> which sampled 2000 deaths.

In PRISM 2, case record reviews will be conducted in 24 English acute hospital Trusts. One hundred randomly selected admissions of adult medical and surgical patients who have died during hospitalisation in the financial year 2012/2013 will be reviewed at each site. Obstetric, psychiatric and paediatric patients are excluded. The exclusion of these patient populations, which account for less than 5% of all hospital deaths in England and Wales, is in line with previous studies and will aid comparison with death rates found in such studies.<sup>11</sup>

## Admission Selection and Record Collection

The study sample will be drawn from each Trust's Patient Administration System. The Chief Investigator (CI) will develop a joint protocol with each site which covers sampling, location, tracing and retrieval of medical records. The Trusts will be instructed to check that any records which are not traceable do not vary substantially from the rest of the sample in terms of age, sex, specialty, medico-legal investigation or coroners' case. Each Trust will be asked to ensure that any selected medical records subject to medico-legal issues are made available for review.

The reviews will take place at each study hospital. Trusts will be asked to facilitate access to case records, to provide reviewers with desk space to undertake the reviews and help reviewers to access missing lab or imaging information via the Trust computer system. They will also be asked to help orientate reviewers to Trust organisation including names and types of wards and consultant lists. Reviewers will not be expected to be on site at the same times but can coordinate their reviews with others if there is adequate space available. Ten per cent of all records will be double reviewed.

## The Review Process

For each case the reviewer will complete a Key Code document which links the patient's hospital number to a unique study number and indicates the date the review. This code remains at the Trust on completion of the reviews, normally within the Clinical Governance Department. Unique study numbers and reviewer ID numbers will be allocated before reviews commence at a site. Reviewers should maintain oversight of the security of both case records and the medical review forms whilst undertaking reviews.

Once reviews are complete the reviewers will contact their nominated lead reviewer to agree a time to discuss any avoidable deaths found (usually by phone). Following these conversations completed forms will be transported back to the London School of Hygiene and Tropical Medicine (LSHTM) by secure courier or by hand (with prior arrangement).

## Confidentiality

The PRISM 2 study is required to comply with guidance set out in the NHS Code of Confidentiality and the GMC's Good Research Practice Guidance. The Research Passport

and “Letter of Access” binds each reviewer to a code of confidentiality, both for the selected Trusts and the patients reviewed. Care should be taken to ensure that no patient identifiable information is retained on the Review Forms. Care should also be taken that no Trust, doctor or patient identifiable information is disclosed when using email to discuss cases with other reviewers (as in the case of asking a speciality specific question of a colleague). In the case of a breach of confidentiality, a reviewer will immediately be asked to leave the project and the General Medical Council will be informed.

The Key Code document links a patient’s unique study number to their hospital number. This code will be stored in the Trusts’ Clinical Governance Department after the study finishes. The code will only be broken if there are serious concerns of negligence in relation to the care of a patient which need to be fed back to the Trust. If a reviewer uncovers such an issue they should report it to the key Trust contact who will be nominated prior to the start of the reviews. The Trust will then be expected to deal with the issue according to their own internal policies and procedures.

## Contacts

For questions arising during the review period please contact:

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## Operational Definitions

To identify avoidable deaths it is important to initially establish whether there were problems in the way healthcare was delivered to the patient (the processes of care). If a patient is harmed by healthcare but the care was delivered to an acceptable standard, this harm is known as a complication. A death following a complication, such as intracerebral bleeding after appropriate administration of thrombolysis would not be regarded as avoidable.

PRISM 2 defines a problem in healthcare as **‘any point where the patient’s healthcare fell below an acceptable standard and led to harm’**. Problems include:

- An omission or inaction such as failure to diagnose and treat
- An act of commission or affirmative actions related to the delivery of care such as incorrect treatment or management

We have chosen to use the term “problems in healthcare” rather than the more traditional term “adverse event” because this latter term tends to be associated with discrete incidents and is more likely to identify acts of commission than omission. The term “problem/s in healthcare” allows a reviewer to broaden their perspective and assess the impact of multiple small events (usually omissions) across the patient journey.

It may be difficult to identify one clear cut problem or even identify the point at which things went wrong. Avoidable deaths are more likely to result from a combination of problems in healthcare, such as in the example below:

*An 82 year old female on regular warfarin developed an infected finger and was prescribed two antibiotics (flucloxacillin and sodium fusidate) (**problem 1/drugs and fluids**) by her GP, leading to an increase in the coagulant effect of warfarin. On admission the patient was commenced on intravenous antibiotic treatment for osteomyelitis. Two days passed without an assessment of clotting status (**problem 2/clinical monitoring**) whilst warfarin was continued at her standard dose. On day three the patient developed gastrointestinal bleeding and her level of anticoagulation was found to be well above the therapeutic range. The preferred treatment to reverse the effect of warfarin was not available on the ward overnight (**problem 3/drugs & fluids**) and the patient was given a second line alternative. Despite treatment including transfusion of blood she continued to bleed and died.*

The Review Form provides space to capture these complex scenarios in Section C.

## **Instructions on how to undertake the review**

Before the review commences reviewers should check that the record is complete, the death occurred at some point in the financial year 2012/13 and that the patient was not admitted for Obstetric, Psychiatric or Paediatric care. If a post mortem report is found in the medical records this **should not** be read until the end of the review. The review will be primarily focused on the admission in which the patient's death occurred. The focus of the review will be on those problems in healthcare that were associated or contributed to the death rather than any that are more minor.

Ensure you review all documentation related to that admission, including GP referral letter, ambulance summary, A&E summary, etc. and including death certification and any post mortem reports. All healthcare records should be reviewed, not solely records completed by medical staff.

To avoid hindsight bias i.e. judging the care provided to be deficient because the outcome is poor (death), reviewers should follow the patient journey from the beginning, examining how healthcare was delivered at each stage. Imagining "walking in the shoes" of the clinical team as the story unfolds can be a helpful technique.

A systematic approach to the review would include:

1. A review of the initial presentation with special attention to the GPs referral letter, recent outpatient care, the need for admission, timeliness of initial assessment, diagnostic evaluation and management plan.
2. Review of the rest of the doctors' record to determine if appropriate and timely care was given and to evaluate the reasons for continued hospitalisation, testing and treatment. If there are any causes for concern, these can be marked with sticky notes during the initial read through and returned to for more detailed assessment later.
3. Review of the laboratory and radiology records to determine if important abnormalities were reported and acted on and whether appropriate/ inappropriate testing was performed.
4. Review of the nursing notes and monitoring charts to determine if the management plan was adhered to and that new patient signs and symptoms were dealt with appropriately.
5. Review of the medication record to determine if appropriate/ inappropriate medicines were given

6. Completion of the Review Form making sure that each one is labelled with Reviewer ID and the patient's unique study number.

### **The timing of the problem/s in healthcare**

We are interested in problems in healthcare as a consequence of health care management prior to the index hospitalisation and discovered during the index hospitalisation e.g. a person taking a prescribed drug at home who develops side effects that cause death, and; those that occur during the index hospitalisation and are discovered during the index hospitalisation. We accept only a minority of problems in healthcare occurring outside hospital will be detected in this way, and that without access to previous admission notes from other hospitals/primary care records detail may be unclear, but want to learn from any issues that can be identified.

Reviewers should note that if the problem in healthcare occurred prior to the index hospitalisation there is no time limit on its inclusion in the study. The problem does however need to be related to the patient's death. If there have been multiple admissions as a consequence of a problem in healthcare, the problem is counted only once.

### **Determination of a problem in healthcare**

Some useful approaches:

- a. Change analysis: Think about how care should have been for this patient and compare it to how care was
- b. Consider what would have been an acceptable standard of care for this patient and consider how the healthcare received fell below this standard
- c. Did something happen that could have been averted by different management?
- d. Would this have happened under your watch?
- e. Would you be happy if a relative of yours received this standard of care?

The Review Form includes a section for a narrative account of the problems in healthcare the patient experienced, which allows the reviewer to tell the story of the admission and what went wrong. This is followed by a section where problems in healthcare are listed and categorised and contributory factors (underlying reasons why the problem occurred) are noted (if they can be determined from the records- which is not always the case) in a table. To complete the table, the reviewer needs to refer to the separate problem category list provided.

## Determination of avoidability

The following questions can be useful in helping to identify avoidable deaths:

- Was the death expected or unexpected at the outset?
- Was the death related to a healthcare intervention rather than the natural progression of the patient's disease?
- Did any avoidable events cause harm to the patient
- Was there a deviation from the accepted norms of practice?
- Were there extenuating factors that reduce preventability (co-morbidity, nature of acute illness, urgency of situation)
- Were there mitigating factors which decrease preventability (appropriate use of pressure relieving mattress in case of pressure ulcer, evidence of falls prevention strategies)
- Consider if better care had a reasonable chance of preventing the patient's death
- Is there enough evidence to justify your decision

It is important to gather enough evidence to justify the judgement of avoidability. Don't second guess when it comes to judging the acceptability of care. If enough detail is not found in the record then a judgement cannot be made. This situation is more common when determining whether there was a problem in care prior to the index admission as in the case below:

*A patient is admitted with acute myocardial infarction and dies. The history mentions that the patient visited his GP twice in the two weeks before admission complaining of upper gastrointestinal pain.*

The reviewer has no knowledge as to whether appropriate examination and tests were undertaken by a GP prior to the admission. If a reviewer's judgement is hampered by lack of evidence this should be recorded in Part E.

## Avoidability Ratings

Two scales are provided for making ratings of avoidability. The 1 to 6 Likert scale is the standard approach, but the continuous linear scale will allow for additional analysis. Each scale should be completed independently. Outlined below are some examples of cases rated at different levels of avoidability.

### Low avoidability

40 year old with congenital hydrocephalus, cerebellar hypoplasia, epilepsy unable to walk and requiring full time care. Admitted with fever and drowsy. Pelvic CT suggested abscess. Taken to theatre by SpR who drained pelvic abscess and undertook salpingo-oophorectomy plus appendicectomy. Over next few days patient became increasingly acidotic and febrile. Second laparotomy by another SpR revealed a leak at appendicectomy site and bowel necrosis which was dealt with. In the post op period the patient remained in a poor condition with pancytopenia and wound sepsis. Active treatment discontinued after 2 weeks.

### Mid

80 year old admitted following fall resulting in fractured neck of femur. Initially thought patient may have had a stroke but signs changed over days. In addition there were problems normalising electrolytes and patient developed a chest infection. Heparin commenced but

stopped after 4 days. Operated on day 17. Sudden collapse after 24 hours, presumed pulmonary embolus.

High avoidability

74 year old man admitted for elective fem-pop bypass. Haemoglobin immediately post op was 9.9 g/dl. Developed acute coronary syndrome 12 hours later and haemoglobin found to be 7.4 g/dl. Plans for angiography were never fulfilled as despite blood transfusion the team were not able to get on top of the falling haemoglobin. No bleeding site was identified over 10 post-operative days and patient died with a haemoglobin of 3g/dl. Post mortem showed a bleeding peptic ulcer. Patient was known to take aspirin prior to surgery and was given heparin and clopidogrel on ward following development of cardiac problems. Record of low haemoglobin was found in record two months before operation but this was not followed up.

### **Estimation of impact of avoidable death on length of life**

Reviewers are asked to provide a quantitative estimate of the degree to which a patient's life was shortened by their avoidable death. We accept that this subjective judgement may be difficult, but the findings from this question will be useful in helping to estimate the total number of years of life lost as a result of avoidable deaths. Life tables and other prognostication tools are difficult to apply in the acutely ill elderly with multiple co-morbidities that are likely to form a large proportion of the cases reviewed. You may wish to consider expected prognosis for a patient presenting with this condition and co-morbidities who received an acceptable standard of healthcare, and/or average life expectancy alongside consideration of whether the patient had better or worse general health and capacity to recover than average

### **Avoiding future deaths**

Suggestions for specific improvements that might avoid future deaths might come from any of the following categories:

- a. Through improved equipment or procedures e.g. via better design or ensuring correct use.
- b. Through improved organisation and management e.g. improved transfer of knowledge or information, the quality and availability of protocols, addressing other management issues such as staffing levels or addressing organisational cultural issues impacting on safety.
- c. Through steps to limit human error e.g. through ensuring staff who conduct a task have suitable qualifications, training or supervision, improved task planning, coordination or execution.

### **Seeking further opinions**

Each review should initially be conducted independently. If, after full review, a reviewer is uncertain as to whether a death was caused by a problem in healthcare, then a conversation with your lead reviewer can take place. If judgement is hampered by a specialty-specific question, contact can be made with another PRISM 2 reviewer who is a specialist in that area. Dr Hogan will facilitate this contact.



## More space

If more space is needed to complete the free text elements of the review form, please attach additional sheets securely to the Review Form. These sheets should be labelled with:

- Patient Unique Identifier
- Reviewer Identifier
- Number of question

## References

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7. Wilson, R., W. Runciman, R. Gibberd, et al., *Quality in Australian Health Care Study*. Med J Aust, 1995. **163**(9): p. 472-5.
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