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Patient Safety in Ambulance Services – a scoping review

Chief investigator Professor Matthew Cooke

Sponsor University of Warwick

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NIHR Portfolio number

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Patient Safety in Ambulance Services – a scoping review

1. Aims/Objectives:

The research questions are:

1. What is the national and international evidence base for patient safety in Ambulance Services (AS)?
2. What are the significant gaps in the evidence base where research might add value, either through addressing new questions or replicating international research in an NHS setting?
3. What are the priorities for future policy and research

The objectives are:

1. To undertake a systematic literature review and seek advice from ambulance experts to identify the current body of evidence related to patient safety and identify gaps in the evidence base in UK AS and their international equivalents;
2. To review and analyse documents/reports/data from AS to determine patient safety processes in English AS;
3. To synthesise the evidence to determine significant gaps in evidence and where research might add value, either through addressing new questions or replicating international research in an NHS setting;
4. To undertake a formal prioritisation exercise, using the Delphi process, to gain consensus for future policy and research with key stakeholders from AS to consider the findings of the evidence synthesis at a consensus conference;
5. To disseminate the findings of this scoping exercise, evidence synthesis and prioritisation exercise on patient safety to AS and relevant related emergency services, setting out the recommendations for best use of available evidence to direct policy and practice, highlighting gaps in the evidence base and indicating prioritised future research needs.

2. Background:

The costs of medical errors are considerable both at a personal and institutional level (1). It is estimated that one in ten patients in UK hospitals suffers an adverse event (1) yet 50% of such incidents could be avoided if lessons had been learnt from previous incidents [Safety First, DH, 2006]. The incidence of adverse events in patient safety in Ambulance Services is unknown.

The publication of two seminal reports 'To err is human' (2) and 'An Organisation with a Memory' (3) ten years ago highlighted the fact that there was an urgent need to understand systematically the extent and nature of harm that patients suffer during their contact with healthcare services. These reports led to research which aimed to quantify the incidence of harm, predominantly in hospital-based care, followed by more qualitative studies which tried to understand the mechanisms for failure which give rise to patient harm.

It soon became clear that the underlying attitudes and assumptions about failures and safety within the NHS and healthcare in general are a serious obstacle to sustainable improvements in patient safety. The ability to quantify safety culture (i.e. the safety-related attitudes, values and beliefs of staff) of an organisation and the development of a systems-oriented safety culture became a major aim. There is a growing focus on patient safety interventions themselves, with some literature describing interventions qualitatively, but the majority of papers attempting to quantify the benefit to patient outcomes of certain interventions.

However, although patient safety has moved higher up the agenda for some healthcare sectors e.g. hospitals, it appears to be much less of a priority within NHS Ambulance Services. Fewer than 50% of Ambulance Services and none of their related professional bodies signed up to the Patient Safety First Campaign. Given that safety is a national priority, and there is an increase in litigation rates, it is unclear why Ambulance Services are not prioritising this issue. It is possible that Ambulance Services are instead prioritising targets (4), or that the culture in the Ambulance Services may not be conducive to disclosure of adverse events. A further reason may be a lack of evidence of the impact of adverse events within the Ambulance Services upon patient safety. A recent PhD thesis highlighted the adverse effects of national performance targets on clinical quality approaches in Ambulance Services (Parekh, pers. comm., 2010) and suggested that over-prioritisation of work to improve target performance may be taking attention away from patient safety. There is clearly a need for further work to explore the factors that contribute to the lack of engagement by Ambulance Services in patient safety issues and to understand how to increase engagement.

In order to explore these factors this team has undertaken two evidence reviews: the first, a rapid review of the published evidence on patient safety in Ambulance Services, and the second a review of websites related to patient safety. We have also made a preliminary investigation of English Ambulance Services reporting rates to the National Reporting and Learning Service to discover the number and variability of reporting.

3. Need:

The evidence base for patient safety in Ambulance Services is clearly lagging behind other healthcare sectors and there is no systematic review of the evidence to direct policy, service delivery and future research. In addition, it is of concern that there is wide variation between Ambulance Services reporting, and, overall fewer incidents are reported than from other healthcare sectors. The reason for this remains unclear. It is widely accepted that low reporting rates are usually due to poor reporting rather than because incidents are not occurring. There is a growing focus on patient safety in healthcare sectors and although litigation in the Ambulance Services is low (2.8% of NHSLA reports) (5) it is increasing, therefore there is an urgent need for robust evidence synthesis in order to make "... *patient care safer*" [NPSA, 2003].

4. Methods:

a. Setting

Patient safety in ambulance services

b. Design

Systematic review, and review and analysis of ambulance services documents/reports/data

c. Data collection

Data will be collected from all 11 ambulance services in England. Data Sources: Annual reports, Trust Board meeting minutes, Trust Quality and effectiveness policies, national quality indicators, Care Quality Commission Indicators, National Staff Survey, and National Reporting & Learning Service Database (NRLS).

d. Data analysis

Data will be collated and tabulated based on the London Protocol, and a 2-stage thematic analysis undertaken: conceptual analysis to quantify data into conceptual categories, followed by relational analysis of relationships between and within conceptual categories (5). Data will be mapped against known frameworks. The NPSA NRLS database will be interrogated to identify number and themes of patient safety incidents reported during 2010.

Descriptive statistics will be used to summarise incidents reported. Results will be mapped against the domains of the AHRQ.

5. Contribution of existing research:

In order to explore these factors this team has undertaken two evidence reviews: the first, a rapid review of the published evidence on patient safety in Ambulance Services, and the second a review of websites related to patient safety. We have also made a preliminary investigation of English Ambulance Services reporting rates to the National Reporting and Learning Service to discover the number and variability of reporting.

1. Rapid Review

We searched the MEDLINE database using the following strategy ((pre hospital or pre-hospital or prehospital).mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]) OR ambulance.mp. or exp Ambulances/ OR emergency.mp. or exp Emergencies/ OR emergency medicine.mp. or exp Emergency Medicine/ OR paramedic.mp. or exp Allied Health Personnel/ OR emergency medical services.mp. or exp Emergency Medical Services/ OR emergency medical technicians.mp. or exp Emergency Medical Technicians/) AND (exp Safety/ed, lj, st, sn, td [Education, Legislation & Jurisprudence, Standards, Statistics & Numerical Data, Trends]). No design or language restrictions were applied and additional studies were identified from the reference lists of eligible citations and from experts on the team.

Studies were selected by one reviewer (JDF) and were included if they reported data on any aspect of patient safety in the Ambulance Services.

Studies focusing on safety in relation to road/air collisions were excluded as these were beyond the definition of patient safety.

The National Patient Safety Agency (2003) has described patient safety as the *"process by which an organisation makes patient care safer. This should involve risk assessment, the identification and management of patient related risk, the reporting and analysis of incidents and the capacity to learn from and follow up incidents and implement solutions to minimise the risk of them recurring."*

The search revealed 185 studies of which 24 were identified as relevant and included in the review (Figure 1). Excluded studies and the reasons for exclusion are listed in **Table 4** of the full report of this review, appended as a supplementary document to our original application in section D of the online application form.

The evidence base was mapped according to research area, specific element studied, and research design (Figure 2). The literature formed two categories; one that explored issues related to patient safety and the other relating to staff safety and wellbeing. The review revealed a small number of studies that explored safety in healthcare that focussed on a number of broad topic areas: assessment and treatment (6-13), moving and transporting patients (14-20), patient/staff well-being (21), education (22-26), and planning (27-29) (**Error! Reference source not found.**). The majority of the studies were interventional with few exploring safety-related culture, attitudes and behaviour. There was a paucity of literature reporting methodological approaches to analysing patient and staff safety and well-being in Ambulance Services. No relevant methodological papers were found; two studies were identified that explored the application of tools designed by the AHRQ for patient safety but these reported data in other healthcare sectors. Although no formal evaluation of the literature was undertaken in this rapid review the quality of the retrieved studies varied markedly.

The review found a paucity of evidence with no overall systematic review of the evidence. However, it should be noted that this research is limited in that only one database was interrogated and no search of grey literature was undertaken, therefore a full systematic literature review is required to search out further evidence, including evidence not available on electronic databases.

2. Website Review

We searched the following websites for evidence and resources related to patient safety in the Ambulance Services: National Patient Safety Agency (NPSA); The NHS Institute Safer Care Programme (ISCP); Patient Safety First campaign and the NHS Litigation Authority using the search term 'safety'. The NPSA website (30) identified only ten resources (alerts/guidance/reports) relevant to Ambulance Services in comparison to over 140 such resources for acute hospitals and community services. The National Patient Safety First Campaign interventions appear to make no specific mention of Ambulance Services and there is little consideration of Ambulance Services issues in their generic interventions. The NHS ISCP makes no mention of Ambulance

Services; patient safety trigger tools are being developed for most areas except Ambulance Services. Human Factors guidance from Patient Safety First does not relate to, or use examples from, Ambulance Services. NPSA does include Ambulance Services in its reports on incident reporting rates (see below) and categories. One Ambulance Services won an NHS safety award for systems to ensure restocking of ambulances in 2008, and one for infection control in 2010.

3. National Reporting and Learning System (NRLS)

The NPSA hosts the NRLS which allows patient safety incident reports to be recorded in a national database. Patient safety incidents are defined as any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving NHS-funded healthcare. This data are then analysed to identify hazards, risks and opportunities to improve the safety of patient care. Since the NRLS was established, over four million incident reports have been submitted by healthcare staff. From 1st April 2010 it became mandatory for NHS Trusts in England to report all serious patient safety incidents to the Care Quality Commission as part of their registration process.

As a measure of safety culture within Ambulance Services Trusts, we interrogated the NRLS over 6 months. We identified marked variation between Ambulance Services in indicators such as incident reporting rates and timeliness of those reports amongst Ambulance Services in England (Figure 3 and Figure 4). This provides evidence of inconsistencies in patient safety focus and activities between Ambulance Services.

6. Plan of Investigation:

Ethics Approval

The proposed research has been discussed with the National Research Ethics Service and the opinion has been provided that this project is categorised as service evaluation.

Project Overview

A scoping study aims to discover existing literature and also to understand our needs for further knowledge. Because our initial rapid review has failed to reveal significant numbers of studies we believe we will need to undertake more than just a systematic review in order to find the existing literature. Work Package (WP)1 is the systematic literature review, but further evidence will be found by WP2 which explores other documents and data within Ambulance Services and other organisations including reviews of data held by NPSA and NHSLA. In WP1 we will be contacting opinion leaders in patient safety and ambulance services (including all medical directors) to help in discovering the grey literature. This will include phone or WebEx interviews with ambulance experts to explore where we can find grey literature, which internal documents they think will help the scoping exercise, and to check what the interviewees believe are the important issues in ambulance service patient safety. We will also hold a focus group of lay people to explore the same issues. We will use documents examined during WP2 and the contacts with opinion leaders to

help form a framework that will reveal the gaps in the literature as well as the known literature. WP3 will collate the information from all these sources and WP4 will provide consensus on how the results of the scoping study should be taken forward and what areas should be prioritised.

Overview of research methods

In Work package 1 we will undertake a systematic review designed to identify, categorise and summarise current research evidence; inform the identification of gaps where future research may add value. In Work package 2 we will analyse Ambulance Services safety reports, and other data sets.

The findings of all the Work packages will feed into Work package 3, with reports on the scope and scale of existing knowledge and its best use in policy and practice and with detailed recommendations for future research needs ranked in order of importance. At each key stage, (design of research instruments, triangulation of findings, and synthesis following consensus conference) we will ensure review by our Advisory Group.

Work Package 1 (WP1) Systematic Literature Review [JDF/AC/research fellow KF] (Months 1-8).

Objective: to undertake a systematic literature review to identify the current body of evidence related to patient safety and to identify gaps in the evidence base in UK Ambulance Services and their international equivalents.

Search strategy: The development of the search strategy will be iterative; initially based on the search developed for the rapid review (see above) will be expanded by further exploring the database thesaurus for MeSH terms and key words to identify evidence related to safety and ambulance services. The strategy will be developed in consultation with the Advisory Group and reviewed by an information specialist from the NHS Evidence-Health Information Resources: Emergency and Urgent Care Specialist Collection, based at Warwick University. [The searches will not be restricted by publication type, date or language.

Data Sources: Relevant studies will be identified from a search of MEDLINE, EMBASE, Web of Science, HMIC, NHS Evidence-Health Information Resources Specialist Collections: emergency and urgent care, health management, (Cochrane Database of Systematic Reviews (CDSR) of systematic reviews in the Database of Abstracts of Reviews of Effect (DARE) via NHS Evidence), FADE, CASH, King's Fund Library Catalogue, OpenDOAR, OpenSIGLE, DH publications library (previously COIN and PIONT), NHS Confederation reports, plus major journals in the field, abstract books, conference proceedings and reference lists of retrieved publications. A list of experts in the field will be compiled and contacted in order to identify unpublished material. Because of the paucity of evidence in our rapid review, we will contact a wide variety of opinion leaders to ensure the grey literature is fully explored; this will include experts in patient safety, academics interested in prehospital care, all medical directors of UK ambulance services and authors of key articles found in the literature review. The WP will also include phone or WebEx interviews with ambulance experts to explore where we can find grey literature, which internal documents they think will help the scoping

exercise, and to check what the interviewees believe are the important issues in ambulance service patient safety. We will also hold a focus group of lay people to explore the same issues. We will test our search strategy with the interview and lay groups, and the user forum will be asked to be involved in the prioritisation exercise. NPSA have already given us access to the national incident reporting data relating to ambulance services, and the NHS litigation Authority has given us a spreadsheet of litigation involving ambulance services for analysis.

Data review and analysis: KF will undertake the initial sift of the retrieved citations for subject relevance. KF and JDF will screen the remaining citations. A study will be included if it explores issues related to patient safety within the Ambulance Services environment. Studies will be excluded if they explore safety issues related to staff safety, road or air collisions. Disagreements will be resolved by discussion with MWC/AC. The following data: study design, environment, type of participants, interventions and outcomes will be extracted by KF. It is anticipated that the search will retrieve interventions utilising a wide variety of methodologies. The quality of the evidence will be appraised based on the methodology adopted and using the SIGN critical appraisal tools (<http://www.sign.ac.uk/guidelines/fulltext/50/annexc.html>). Reports and policy documents will be appraised using Wallace and Wray's (2006) generic checklist. The AHRQ framework will be used to map the review evidence if appropriate and the data synthesised using narrative review techniques. The Advisory Group will be invited to comment on the review, and the scope of the remaining project redefined if necessary to ensure that any important issues are covered in appropriate depth. This decision will be made in conjunction with the SDO commissioning team.

Output: A report will be written, form part of the overall project report, and the review submitted to a high-ranking journal for publication.

Expertise: This team has previously undertaken SDO-funded literature reviews in emergency care which incorporated major grey literature contributions. AC is leading Warwick Evidence (<http://www2.warwick.ac.uk/fac/med/research/hsri/warwickevidence/>), a National Institute for Health and Clinical Excellence Health Technology Assessment Programme-funded evidence synthesis service to support health technology assessments.

Work Package 2 (WP2) A review and analysis of documents/reports/data [GP/AC/KF/RJ] (Months 2-8)

Objective: to identify, characterise, and compare patient safety processes in English Ambulance Services.

Data Sources: A review of annual reports, Trust Board meeting minutes, Trust Quality and Effectiveness policies, national quality indicators, Care Quality Commission (CQC) Indicators, The National Staff Survey, and the National Reporting & Learning Service Database (NRLS).

Data review and analysis: We will look for evidence of work being

undertaken in patient safety including leadership culture and an environment to promote quality and patient safety. Data will be collated and tabulated based on the London protocol (31). Where appropriate a two-stage thematic analysis will be undertaken. Firstly a conceptual analysis will be undertaken to quantify the data into conceptual categories, followed by a relational analysis to explore the relationships between and within conceptual categories. Data from Board meetings and Quality and Effectiveness policies will be analysed for how risk and harm are reported. They will be subjectively classified by two readers using the Manchester Patient Safety Framework (MaPSaF) (Pathological, Reactive, Calculative, Proactive or Generative) (32) These data will also be mapped against the AHRQ framework and the Patient Safety First Leadership for Safety domains (33). The extent of and processes through which feedback from service users informs the local patient safety agenda will be examined. Examples of good practice will be summarised as case studies. Warwick Medical School is the National Coordinating Centre for the UK Ambulance Clinical Guidelines and the team has good networks and contacts with all eleven Ambulance Services Medical Directors and their support teams which will facilitate access to information.

We will assess Ambulance Services' CQC performance ratings for domains relevant to safety and the national staff survey. The NPSA NRLS database will be interrogated to identify the number and themes of patient safety incidents reported during 2010. We have agreement from NPSA for access to these data. Descriptive statistics will be used to summarise incidents reported by each trust. We will compare findings with other NHS organisations as similar measures are used for all organisations. We will map results against the AHRQ domains.

We have agreement from NHS litigation Authority to obtain summary data of all litigation involving or mentioning ambulance services. This will update previous work in this area undertaken by MWC [30].

Output: A report will be written describing the current landscape of Ambulance Services safety culture and processes. It will be presented to the Advisory Group, form part of the overall project report and submitted for publication in a peer reviewed publication.

Expertise: We have previously undertaken this type of review of evidence within organisations including an SDO-funded study of hospital reconfiguration, and an EPSRC-funded study of lean thinking in healthcare. Professor Peter Spurgeon, an expert on organisational research, who works closely with this team on other projects, has also offered to advise in this area.

Work Package 3 (WP3) Evidence Synthesis [MWC/AC/MAS/JDF/PS/RJ/KF] (Months 8-10)

Objective: Synthesise the evidence to determine significant gaps in evidence and where research might add value, either through addressing new questions or replicating international research in an NHS setting.

Analysis: We will map the data from the documentary and literature reviews

using the London Protocol framework to form the three superordinate categories so that significant gaps in the evidence base are highlighted, to understand Ambulance Service safety processes and priorities, to evaluate Ambulance Services safety culture and to make recommendations regarding the prioritisation of research and policy needs in order to improve patient safety. The information from the Sheffield study will also be integrated into this evidence synthesis. The triangulation of data in this way will increase the validity of the finding of this scoping exercise. We will identify and classify the main organisational deficiencies that impact on ambulance safety and describe the impact of organisational models of care delivery on safety.

Output: A report of this synthesis will be written.

Expertise: MWC and JDF have undertaken SDO-funded evidence syntheses and scoping exercises, and AC is leading Warwick Evidence; PS is an expert on organisational aspects of safety.

Work Package 4 (WP4) Prioritisation Exercise [MWC/RJ/JDF/MS/KF] (Month 11)

Objective: Undertake a formal prioritisation exercise, using the Delphi process, to gain consensus for future policy and research with key stakeholders from Ambulance Services.

Design: Delphi Consensus Approach.

Participants: Participants will include a broad range of staff from Ambulance Services who are clinically active including paramedics, technicians, dispatchers, clinical supervisors and medical and lay responders, together with the lay forum used in WP1.

Procedure: The evidence synthesis in WP3 will create a series of headlines that will be used as round one of the Delphi consensus. The second and third rounds will be undertaken at a breakout session of a national pre-hospital conference scheduled to take place in 2012. The rationale for creating the first round questions will be presented using the evidence from the study. Electronic voting will then be utilised to enable the next two stages to be completed in one session. Each item in the Delphi will be presented as a question asking participants to rate the importance of different dimensions/elements of patient safety in Ambulance Services. Having received the scoring for this round they will be asked to make any comments to the audience and the researchers may give feedback from the research. The next round will then be carried out by asking them to re-vote. This process will be repeated for each question. The session will be concluded by asking the audience to complete a feedback form that will cover any additional comments on the results of the Delphi, any issues that they think were omitted and will give opportunity for free text to feed back any other patient safety issues. A conference will be held at the University of Warwick with representatives of ambulance staff as well as users, policy makers, professional organisations and those responsible for education and development, to consider the findings for future policy and research in the UK.

Analysis: The results of the formal prioritisation exercise will be available from the electronic voting system and will be synthesised, together with comments made by participants.

Output: Additions to final report detailing findings on potential future research, policy and practice, prioritised by stakeholders.

Expertise: We have used prioritisation techniques in previous studies, including the SDO-funded scoping study of fallers' clinics and SDO-funded review of A&E innovations. The team has previously undertaken and participated in many projects using Delphi-type techniques.

Dissemination [MWC/AC/MAS/RJ/MS/GP/GA/JDF/PS/KF] (Month 12)

The final report, due to be completed in Month 12, will report the evidence synthesis and prioritisation exercise on patient safety to Ambulance Services and relevant related emergency services. This will set out the recommendations for best use of available evidence to direct policy and practice, highlighting gaps in the evidence base and indicating prioritised future research needs. Findings will be presented in various formats, academic peer-reviewed publications and as accessible publications in policy briefings and at methodological- as well as content-based seminars, conferences and meetings. A website will be created from the home page at www.warwick.ac.uk/go/emergencycare which will provide a summary of the project, updates on progress, access to the final report and newsletter and links to publications resulting from the project. A copy of the report will be sent to the INVOLVE registry and key findings communicated to the public via The University of Warwick's very successful media office. The website will also host a web forum to facilitate communication between the project team and members of the Advisory Group on issues such as the scope and protocol for the systematic review. We will present the findings at national and international conferences. A newsletter will be published dedicated to the findings of the project, and copies will be sent to every Ambulance Services in the UK, every SHA (or future equivalent) and lead commissioners, The Joint Royal Colleges Ambulance Committee, Faculty of Prehospital Care, Directors of Clinical Care and to the British Paramedic Association/College of Paramedics for distribution. We will submit articles to peer-reviewed journals such as the British Medical Journal and Quality and Safety in Healthcare to ensure a permanent archive of the work is freely available. The new National Institute for Health Research award assessment toolkit will also be kept updated with all outputs from this study.

7. Project Management:

A monthly minuted project meeting involving all the co-investigators will be held to monitor progress of the project and resolve any developing issues. Work package leaders will also ensure their individual packages are managed by regular meetings with the researcher responsible for that component, and the Chief Investigator and Project Manager have weekly meetings to discuss issues as they arise. The Advisory Group will meet four times throughout the duration of the project: they will review the strategy for the literature review, and meet following the review to determine whether the future scope of the

project should be amended. Meetings will also be held after the completion of and WP3 and a final meeting held close to the creation of the Final Report. SDO will be welcome to attend any of these meetings. Progress reports will be prepared for submission to SDO at six months.

8. Service users/public involvement:

We have had a service user as one of the co-applicants of the research, but he has unfortunately had to withdraw due to ill-health. We are seeking a replacement for him. The service user will advise on possible improvements throughout the project, and at the end of the project s/he will ensure that findings are appropriately patient-focussed. S/he will receive all appropriate documentation and invitations to all meetings. S/he will co-chair the Advisory Group, and will have the discretion to co-opt other lay people to advise on specific aspects of the project.

The lay Advisory Group of the College of Emergency Medicine will be invited to the consensus conference and asked to give feedback on the emerging findings.

9. References:

Please see below

This protocol refers to independent research commissioned by the National Institute for Health Research (NIHR). Any views and opinions expressed therein are those of the authors and do not necessarily reflect those of the NHS, the NIHR, the SDO programme or the Department of Health.

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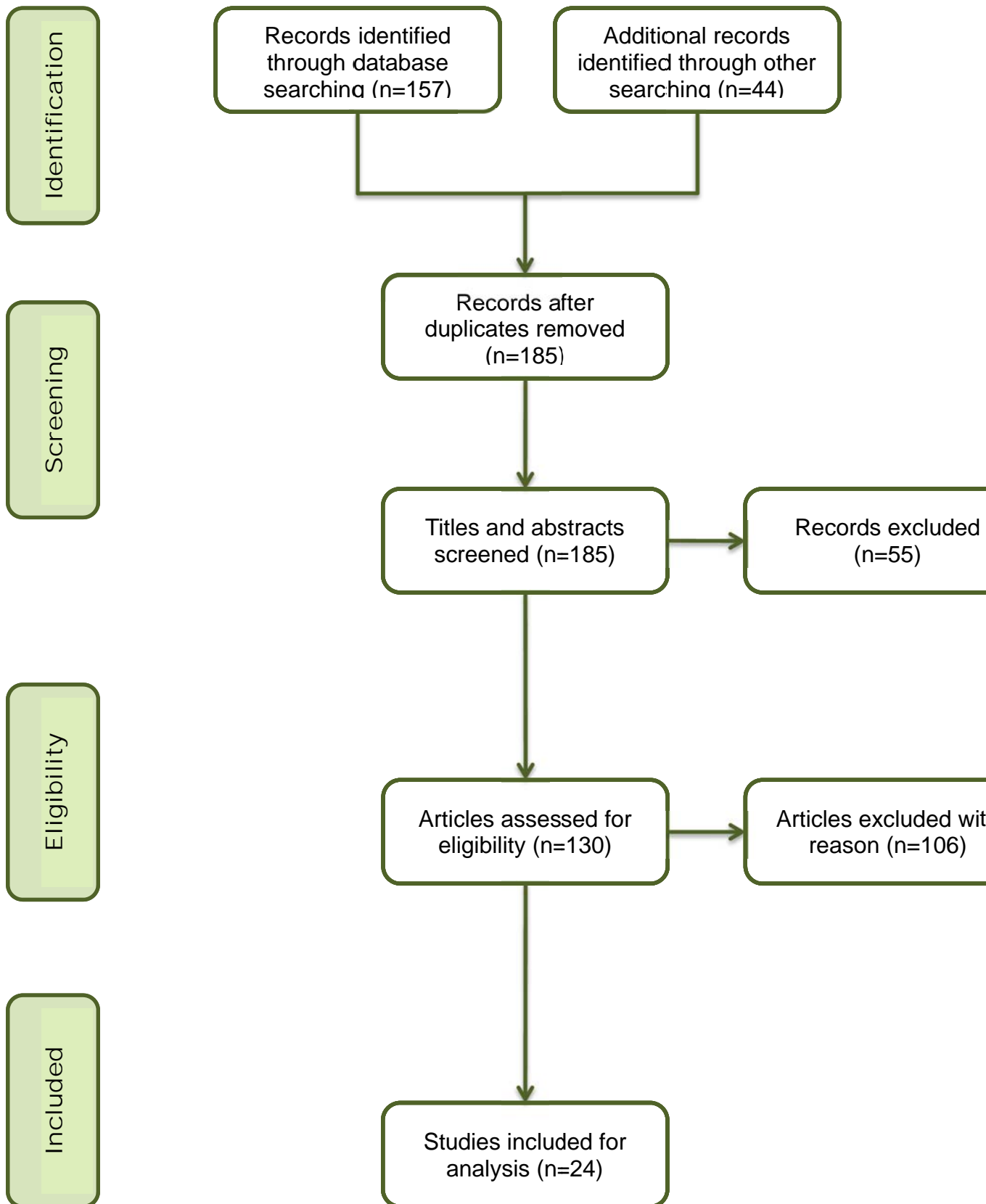


Figure 1 Evidence selection process for the preliminary search of MEDLINE-Based on PRISMA

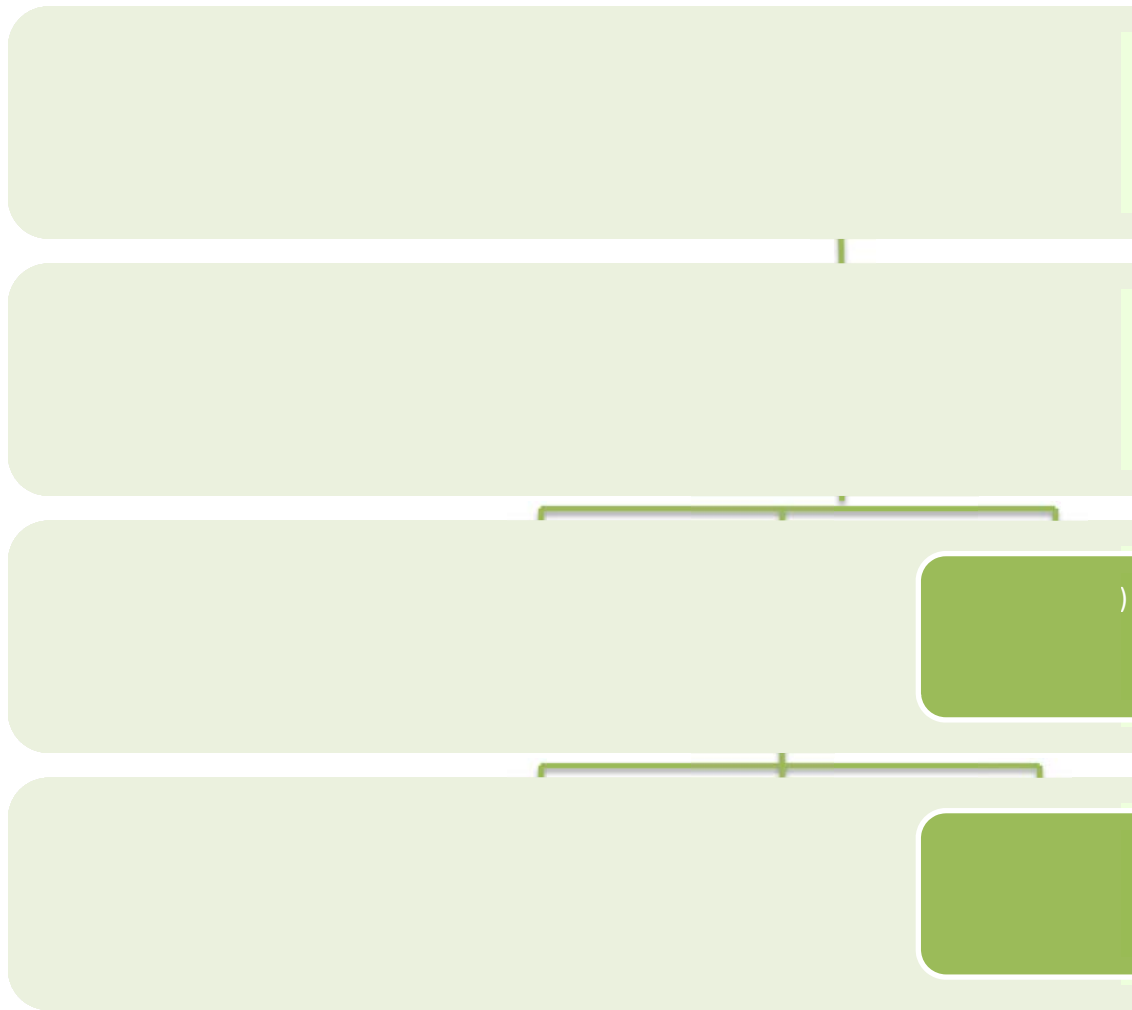


Figure 2 Evidence framework for mapping ambulance service safety literature

Figure 2: Evidence Framework for mapping ambulance service safety literature

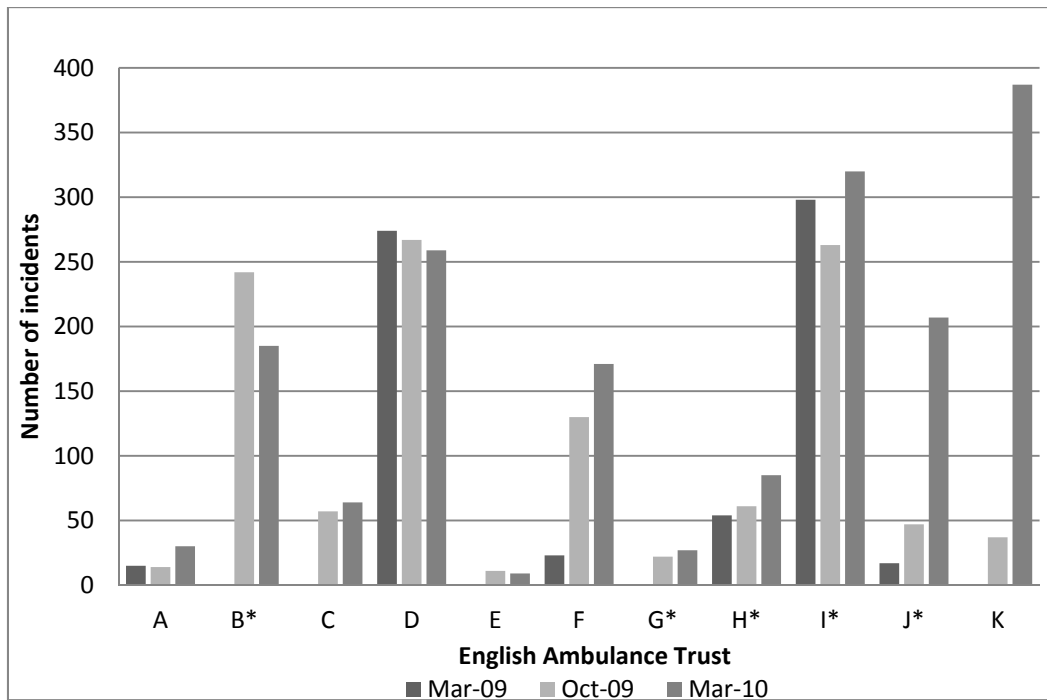


Figure 3 Incidents over six monthly periods reported to NPSA by each Ambulance Services [*denotes organisation signed up to Patient Safety First Campaign]

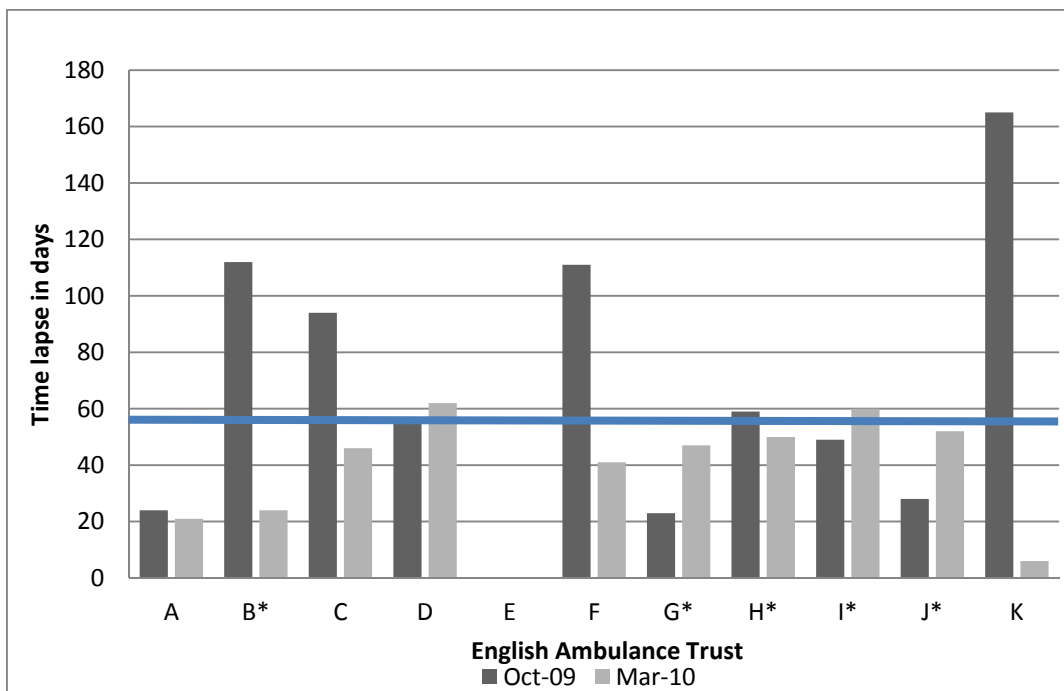


Figure 4 Time-lapse for 50% of incidents to be reported to NPSA [Standard is 57 days, denoted by blue bar; [*denotes organisation signed up to Patient Safety First Campaign]