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RESEARCH PROTOCOL

19th October 2021

General Information

Title: Patient reported pain in pre-hospital emergency care in Ireland – an epidemiological analysis of 212,334 patient care episodes.

Name and address of the sponsor: Principal Investigator-led project on behalf of the National Ambulance Service.

Principal Investigator: Professor Cathal O'Donnell

Co-investigators: Mr Rory Quinn (NAS), Dr Siobhán Masterson (NAS), Mr David Willis (NAS), Mr David Hennelly (NAS) and Professor Conor Deasy (UCC/HSE).

Rationale & Background Information

Pain can be defined as *'an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage'*. [1] Pain is a personal experience and may be influenced by several factors: biological, psychological and social. Access to pain management has been accepted as a fundamental human right by the United Nations and regional human rights bodies. [2] Acute pain that is not managed properly can have negative consequences on patient's quality of life and increase the patient's risk of developing chronic pain. [3] This includes the prehospital setting where under treatment of pain (oligoanalgesia) (Wilson & Pendleton, 1989), appears to be common. [4-6]

Pain management in prehospital settings starts with assessment of pain. [7] Studies using the results of pain score assessments to estimate the prevalence and severity of pain in prehospital patients are difficult to compare as they may have different inclusion criteria for age and complaint type. [8] An analysis of more than 14 million patient records in the US found that 20% of patients transported by ambulance were in moderate to severe pain and just over a third (34.5%) were experiencing some degree of pain. [9] An analysis of records from Denmark found that 27.7% of patients reported moderate to severe pain during ambulance transport. [10] Other estimates for the proportion of patients experiencing at least some degree of pain who are transported by ambulance are: 42% in France; [11]

39% in Portugal; [12] and 34.5% in Australia. [13] Some studies in the UK have reported higher rates e.g. 54%, [14] and 53%. [15] though sample sizes were small in these studies.

The rate of pain documentation in the prehospital setting may also vary. For example, children may be less likely to have documented pain assessment when compared to adults with similar injuries or complaints. [16] In Ireland, a study with paediatric patients in the Irish prehospital setting showed that the likelihood of having a pain score assessment performed decreased with the age of the patient. [17]

There is limited published research examining the incidence of pain in the pre-hospital emergency care setting in Ireland. However, electronic patient care record (ePCR) use has been comprehensively implemented with emergency patients attended by NAS practitioners. These records include information about the level of pain (where present) experienced by the patient and how this was assessed and treated. There now exists a repository of electronic clinical records documenting the vast majority of emergency calls attended by the National Ambulance Service since 1st January 2020. Using the ePCR data repository, the purpose of this study is to describe how pain assessment in pre-hospital emergency care is recorded, and to describe the incidence and severity of pain reported by pre-hospital emergency care patients in Ireland.

Study Goals and Objectives

The primary aim of this study is to investigate how pain is recorded and assessed in pre-hospital emergency care and to describe the incidence and severity of pain reported by pre-hospital emergency care patients in Ireland.

1. For all episodes of care included in the ePCR data repository:
    - Describe the proportion of prehospital emergency patients who have a pain score recorded in their ePCR as part of their care episode.
    - Describe the differences in characteristics between care episodes where pain was or was not recorded. Characteristics will include: Response Priority of Call; Location of Call (Urban/Rural settlement/Rural); Hour of Day of Call; Highest Practitioner Level of Crew; Duration on Scene; Duration from Scene to Hospital; Patient Age; Patient Gender; Patient Primary Working Diagnosis Category.
    - Assess whether individual patient and/or care episode characteristics are more likely to be associated with recording of pain assessment.

2. For all episodes of care that have a pain score recorded as part of patient care:
    - Describe the distribution of pain severity among pre-hospital emergency care patients.
    - Describe differences in care episode and patient characteristics between none/mild/moderate/severe pain categories.
    - Assess whether individual patient and/or episode characteristics are more likely to be associated with differing levels of pain severity.

Study Design

This will be a retrospective cohort study of all emergency patient care episodes recorded by NAS emergency practitioners from the 1st January 2020 to 31st December 2020. Any records created

during this time that are not finalized by extraction date or where treatment was declined will be excluded from the review. The study will assess the presence of a documented pain score for each episode of patient care, the severity of documented pain and whether either of these are associated with patient, practitioner or care episode characteristics.

Methodology

Data for all finalised records created in 2020 calendar year will be extracted from the ePCR repository. The data extracted from the data warehouse for each record will include where recorded: Patient Age in Years, Patient Gender, Patient Primary Working Diagnosis Category, Time of Call, Longitude and Latitude of Call, Response Priority of Call, Transport Outcome of Call, Duration practitioner spent on scene, Duration of transport from scene to destination, Highest Practitioner Level, First Pain Score recorded for Patient and Highest Pain Score Recorded for Patient.

Any records not meeting the qualifying criteria will be removed at this point. These will be records where the care episode was not an emergency, records where the practitioners were stood down from the call and care episodes where the patient refused treatment.

Once the qualifying set of records are identified the following variables will be created.

- Pain Score Documented Yes/No – This is a categorical variable with two levels, pain score documented and pain score not documented. Any records with a NULL value for First Pain Score will be assigned to the pain not documented category. All records containing a First Pain Score value will be assigned to the pain documented category.
- Location of Call – This is a categorical variable with three levels, urban, rural settlement and rural. Using the latitude and longitude of call, and data from the Central Statistics Office re Settlement Areas and Population, records will be assigned to the relevant location type.
- Hour of Call – This is a numeric variable. Records will be assigned a numeric value based on the hour value in the Time of Call timestamp.
- Severity of Pain – This is an ordinal variable ranging from 0 to 10. Records will be assigned a value corresponding to the Highest Pain Score recorded for them, records with No Pain Score Documented will receive a NULL value.
- Patient Age – This is a numeric variable. Values are assigned based on age at last birthday using the Age in Years field. This is necessary as where age was recorded in weeks or months in the ePCR the value for Age in Years extracted from the repository is a decimal, this created variable contains integers only.

Once the extra variables have been created from the extracted data, the following analyses will be carried out.

- Descriptive analysis of each of the variables in the dataset.
- Tests of association between each of the independent variables and each outcome variable (Pain Score Documented and Pain Severity)
- Logistic regression analysis of independent variables with binary categorical outcome variable Pain Score Documented Yes/No

- Multivariate regression analysis of the association between patient and case characteristic variables and pain severity.

Safety Considerations

- This study will involve retrospective chart review and will be carried out in compliance with Amendment No.2 to the Health Research Regulations 2021. [18]
- Data that is extracted from the ePCR will be anonymised before analysis is performed. All analysis will be carried out on computers that have been encrypted to HSE standards.
- Results will be reported in aggregate form only and no identifying information will be contained therein.

Follow up

This is a retrospective analysis of anonymised data that does not involve patient contact and no follow-up is required.

Data Management and Statistical Analysis

- Population-based study (sample size not applicable)
- Data extracted will be confined to those variables listed in methodology above and will be anonymous. This data will be extracted using IBM Cognos software and stored as an excel spreadsheet on HSE encrypted drive. This will be the master data file.
- Records not meeting the qualifying criteria will be removed from the master data file. The remaining data will be imported into R software for variable creation and the updated data exported as a csv file stored on HSE encrypted drive. This will be the file for data analysis.
- Descriptive analysis will include mode, median, mean, standard deviation, proportions and ratios as appropriate.
- Tests of association will include chi-square and odds ratio as appropriate. Results of tests of association will include confidence intervals and significance. These will be corrected for multiple comparisons if appropriate.
- Complete case analysis will be used for multivariate regression. Separate regression analyses to be carried out for each outcome variable. Results will include estimates of model fit, model coefficients, standard errors and significance. If necessary, missing case analyses will be used to test the sensitivity of results.

Quality Assurance

The data extraction process will be agreed, tested and validated by the NAS Clinical Directorate Data Team to ensure the extraction process is reliable. A detailed data analysis plan will be produced so that the analysis process is reproducible.

Expected Outcomes of the Study

This study will add to NAS understanding of the epidemiology of pain in the prehospital emergency patient population. Results will be of assistance to NAS in planning any required improvements in pain management in the prehospital setting. The study will also contribute to the wider knowledge base on the assessment, incidence, severity of pain in the pre-hospital emergency care population, particularly within Ireland.

Dissemination of Results and Publication Policy

The NAS Corporate Governance Group will be advised of the intention to carry out the study and provided with regular updates on study progress. Prior to study commencement and after research ethics approval and NAS Research Committee approval has been obtained, the study plan will be published on the NAS website and shared with NAS practitioners via the usual in-service communication channels.

The results of this study will be submitted for peer-reviewed publication in an appropriate international prehospital journal. Opportunities to present results at national or international conferences will be actively sought. Following acceptance in a peer-reviewed journal, results will be disseminated within NAS through in-service publications and via the usual in-service communication channels.

Duration of the Project

It is estimated that the study will take approximately six months to complete.

Problems Anticipated

At present, problems are not anticipated. However, the project duration may be affected if other priorities arise for the research team.

Project Management

- Ethics Application: Siobhan Masterson and Conor Deasy
- Study Design and Methodology: Rory Quinn and Siobhan Masterson
- Literature Review: David Hennelly
- Data Preparation and Analysis: David Willis, Rory Quinn
- Results Write Up and Discussion: Collaborative
- Final Review before Submission: Collaborative

Ethics

Ethical approval for the study has been obtained from Clinical Research Ethics Committee, University College Cork (May 2021).

Informed Consent Forms

Not applicable

Budget

This project will be carried out as part of the NAS Clinical Directorate workload. A dedicated budget has not been requested.

Other support for the Project

Not applicable.

Links to other projects

This project is linked to the NAS Clinical Effectiveness programme.

Financing and Insurance

Additional financing and indemnity insurance are not required for this study.

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