STUDY PROTOCOL

Long-term outcomes after hip fracture in Ireland: a protocol for a systematic review of traditional and grey literature

[version 1; peer review: 1 approved with reservations]

Mary E. Walsh1, Caitriona Cunningham1, Louise Brent2, Bibiana Savin3, Michelle Fitzgerald4, Catherine Blake1

1School of Public Health, Physiotherapy and Sports Science, University College Dublin, Dublin 4, Ireland
2National Office of Clinical Audit, Royal College of Surgeons in Ireland, Dublin 2, Ireland
3Sage Advocacy, 24-26 Upper Ormond Quay, Dublin 7, Ireland
4Peamount Healthcare, Peamount Road, Newcastle, County Dublin, Ireland

Abstract

Background: Hip fracture is experienced by almost 3,500 older people in Ireland annually. The Irish Hip Fracture Database (IHFD), which drives clinical improvements in acute hospitals, aims to allow recording of longer-term outcomes. Feasible and robust methods of data collection need to be identified to inform this activity. The aim of this systematic review is to identify, describe and appraise studies that have collected long-term outcomes after hip fracture in Ireland in the last 15 years and to generate pooled estimates of outcomes if appropriate.

Methods: A search of electronic databases (MEDLINE, Embase, Scopus, Web of Science and CINAHL) and grey literature sources will be conducted for journal articles, conference abstracts, academic theses, and reports. Search terms related to hip fracture and Ireland will be included for most sources. The search will be supplemented by email contact with relevant professionals. Observational and interventional studies published between 2005 and 2021 will be included if outcome data were collected in the Republic of Ireland in patients with hip fracture. Outcomes of interest will include data collected after discharge from an inpatient setting or at a fixed time-point greater than 30 days after fracture, hospital admission or surgery. Information relating to study characteristics, description of researchers, data collection methods, patient characteristics and long-term outcomes will be extracted from each study and summarised in tables. Studies will be assessed for risk of bias by two review authors. Where outcomes are sufficiently homogeneous, meta-analyses of estimates will be conducted.

Conclusion: Results from this study will inform the planning of further qualitative research to explore barriers and facilitators of long-term
outcome collection in Ireland. It will form the basis of education and training for future data collectors in this setting.

**Keywords**
hip fracture, femoral fracture, Ireland, patient-reported outcomes, mortality, systematic review protocol.

**Corresponding author:** Mary E. Walsh (m.walsh@ucd.ie)

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Introduction

Hip fracture is experienced by almost 3,500 older people in Ireland annually. It is a serious event with a 20% one-year mortality rate and unfortunately it often results in significant long-term functional limitations for survivors. The Irish Hip Fracture Database (IHFD) was established in 2013 and since then it has driven service improvement in hospitals in Ireland through benchmarking of quality care standards. Up to this point, all data reported by the IHFD has been collected during patients’ initial inpatient stay. In line with international recommendations, the IHFD aims to allow for and facilitate recording of post-discharge information in the near future. Similar work in the UK has shown that achievement of acute hip fracture care standards is associated with improved patient quality of life at four months. Furthermore, collection of longer-term data in Ireland could highlight areas of concern that emerge in the post-acute period. In order, to inform organisational and clinical decision making, data submitted to the IHFD audit needs to be of sufficient quality and the coverage should be representative of all patients in the audit. Local structures, governance and support as well as education, and feedback from the National Office of Clinical Audit have contributed to the IHFD achieving 99% coverage of hip fracture inpatient data in 2018. Those responsible for longer term data reporting will also require education and support to maximise the quality and coverage of post-discharge data. We still need to identify methods of collection that are feasible within the Irish setting, are robust, valid and minimally biased, and that do not place a high burden on patients, clinical staff or services.

There is good consensus internationally on the outcomes to be recorded in the year after hip fracture to broadly monitor recovery rates and adverse events. The World Hip Trauma Evaluation (WHiTE) study is a large multi-centre cohort study in the UK that has published long-term outcomes at 120 days post hip fracture on over 6,500 patients to date. In the development of the WHiTE cohort study, a comprehensive systematic review of hip fracture outcome measures was conducted, as well as a consensus exercise with professionals and an in-depth qualitative study with patients. A Core Outcome Set was developed and psychometric properties of outcome measures assessed. Data fields for national audit have also been recommended by an international Fragility Fracture Network working group. Outcomes of interest include mortality, readmission, re-operation, place of residence, bone-protection, pain, mobility, functional ability, and quality of life. Time-points for post-discharge data collection recommended by core outcome sets include 30 days, 90 days, 120 days and one year after fracture. Few studies have successfully collected outcomes for more than one year after hip fracture with acceptable follow-up rates. In advance of introducing the collection of longer-term hip fracture outcomes in Ireland, it is important to understand the feasibility and challenges associated with data collection at a local and national level. Appropriate methods and mechanisms will likely differ across jurisdictions which have different systems of health data management and interconnectedness of databases. For example, while some European databases record mortality and re-admission rate though registry linkage, the absence of a unique health identifier in Ireland hinders follow-up across and outside of hospitals.

Several research studies in Ireland have recorded local long-term outcomes after hip fracture. A national literature review is required to identify and summarise data collection methods used in different circumstances and to describe Irish findings. This review will provide evidence based data on methods of outcome collection that could be adopted at hospital sites across Ireland, capitalising on valuable local and contextual information. It is hoped that initial estimates of outcomes captured from existing studies will provide a benchmark for future data when collected. This review will also inform the planning of a proposed qualitative study to identify barriers and facilitators to longer term outcome collection after hip fracture in Ireland. It is planned that both studies will then inform advice and education around collection of data for audit purposes. It is hoped that this framework could help other countries to implement long-term outcome collection after hip fracture which is an important goal of the international Fragility Fracture Network.

The aim of this systematic review is to identify, describe and appraise studies that have collected long-term outcomes after hip fracture in Ireland. Objectives include: i) to describe long-term outcomes collected and methods of recruitment and collection after hip fracture in Ireland; ii) to identify common sources of bias with regards to collection of outcomes in this setting; iii) to summarise recorded parameters for specific dichotomous and continuous outcomes after hip fracture in Ireland and to generate pooled estimates where appropriate.

Protocol

Study design

A systematic review of studies that have collected long-term outcomes after hip fracture in Ireland will be conducted. This protocol follows the PRISMA-P Reporting Guidelines. We have applied for registration with PROSPERO (ID Pending). If applicable, important protocol updates will be registered via PROSPERO.

Eligibility criteria

Studies will be included if:

- Data were collected in the Republic of Ireland. Studies conducted in multiple jurisdictions will be included if data collected in the Republic of Ireland is presented separately within the study/publication. Only studies published since 2005 will be included as the review aims to identify recent practices in outcome collection.

- Over 80% of the sample population has experienced a hip fracture and are over the age of 60 years. In line with the IHFD, hip fracture will be defined as a fracture of head or neck of femur, per trochanteric fracture or...
subtrochanteric fracture of femur, including periprosthetic or pathological fractures within these regions. Studies of pelvic fractures or femoral shaft fractures in isolation will be excluded. Studies of multiple conditions will be included if patients are selected due to hip fracture diagnoses and data on patients with hip fracture is presented separately. Studies focussing only on younger people and children will be excluded.

• One or more long-term outcomes have been collected. This will be defined as any data collected after discharge from an inpatient setting or at a fixed time-point at least 30 days after fracture, admission to hospital or surgery. It is anticipated that this will include (but will not be limited to) mortality, readmission rate, re-operation rate, residence, bone-protection medication, pain, mobility, functional ability and quality of life. Studies that collect data only within the initial inpatient setting will be excluded.

• Randomised or non-randomised controlled trials, prospective or retrospective cohort studies, cross-sectional studies, prevalence studies and case-control studies will be included. Other study designs will be considered if they meet other inclusion criteria.

• Studies published in the English or Irish language will be considered for inclusion.

• Studies published in journal articles, conference abstracts, academic theses and reports will be considered for inclusion. Where studies are duplicated in different publication forms, only one form will be included, with the journal article prioritised for inclusion, followed by longer reports and theses.

Information sources
Traditional and grey literature sources will be searched for this review. A search of electronic databases will be conducted including MEDLINE (Ovid), Embase, Scopus, Web of Science and CINAHL between the years 2005 and 2021. The Irish research repository Rian (rian.ie) will be searched for journal articles, reports and conference abstracts. A search of Rian and ProQuest Dissertations and Theses will be conducted for academic theses. Relevant reports will be searched on the Lenus Irish repository (www.lenus.ie). In addition, an advanced Google search will be conducted for reports on the websites of the governmental Department of Health (gov.ie) the Health Service Executive (hse.ie) and the Health Information Quality Authority (hiqa.ie). Ongoing and unpublished research will be identified through HRB Open Research, by searching publications. Authors of theses and abstracts will be contacted to identify full-text journal publications.

Search strategy
The search strategy will be broad for optimal sensitivity and will be adapted for each data source. For electronic databases and international sources, the search will contain two components related to hip fracture and Ireland. For Irish data sources, only search terms for hip fracture will be used. Table 1 shows the search strategy for MEDLINE (Ovid). See Extended data for full search strategy for all sources. Ireland-specific search terms are based on the locations of hip fracture care in the country, with omission of names that are not unique to Ireland (For example the terms “Mayo”, “James” and “Vincent” are names of Irish hospitals but are also commonly used internationally). Hip-fracture terms were adapted from other relevant systematic reviews. The search string was piloted and amended with the advice of a librarian.

Study records
Data management. All records from database searching, and other sources where feasible, will be uploaded to Covidence Systematic Review Software and duplicates removed. Records will be accessed in Covidence by review authors for screening, full-text review and quality appraisal.

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<th>Table 1. Search strategy for MEDLINE (Ovid).</th>
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<td>1. exp Femoral Fractures/</td>
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<td>2. ((hip or hips or cervical or femoral$ or infracapsular or “extra capsular” or subcapital or “subcapital” or transcervical or “trans cervical” or basicervical or “basi cervical” or extracapsular or “extra capsular” or trochant$ or subtrochant$ or pertrochant$ or intertrochant$) adj5 (fracture$ or break$ or broke$)).ti,ab,kf.</td>
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<td>3. (((head or neck or proximal) adj5 (fracture$ or break$ or broke$)) and (femoral$ or femur$)).ti,ab,kf.</td>
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<td>5. (Ireland or Irish or Dublin or Cork or Limerick or Galway or Waterford or Sligo or Donegal or Louth or Wexford or Tallaght or Beaumont or Tallagore or Connolly or Drogheda or Letterkenny).af</td>
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<td>6. 4 and 5</td>
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Title and abstracts will be screened using Covidence by two designated authors from this study. Full texts will be retrieved for all studies that appear to be eligible or where there is uncertainty. Two authors will review each of the retrieved full texts to decide on eligibility. Reasons for exclusion of full texts will be recorded. Disagreements will be resolved through discussion and a third author if necessary. Study authors will be contacted if further information is required to determine eligibility.

**Data collection process.** The draft data extraction form (see Extended data) will be piloted on two included papers by two review authors independently. Discrepancies will be discussed, and the form amended for clarity and completeness.

**Data items**

The following data items will be extracted from each study:

- **Characteristics of studies:** First author, publication year, publication type, county, eligibility criteria, method of recruitment, number of participants, demographics of included sample (age, sex, fracture types), setting of data collection, period of outcome collection, outcomes collected.

- **For each outcome collected:** method of data collection, proxy collection details, specific outcome measure and definition used, time-points collected, results of outcome at each time point collected (for continuous outcomes: mean/median, SD/IQR; for categorical outcomes: numerator, denominator, percentage estimates and 95% confidence intervals).

- **Additional risk of bias items:** sampling method, response rate overall, response rate by subgroup, uniformity of data collection methods across participants.

**Risk of bias in individual studies**

Risk of bias assessment will focus on representativeness of sample, completeness of follow-up and outcome ascertainment and will include five questions. Out of these five questions, four were developed for a similar international review of long-term outcomes after hip fracture:\(^\text{12}\).

1. Is it a representative sample? (Yes if recruitment was consecutive or random.)
2. Were patients followed from inception? (Yes if baseline time was same for all patients and close to fracture time.)
3. Is it a clearly defined sample? (Yes if inclusion defined by hip fracture hospital diagnosis with an age limit.)
4. Was there adequate follow-up? (Yes if long-term outcomes collected for at least 80% of recruited participants.)
5. Are outcomes clearly defined? (Yes if valid objective/broadly accepted measure used.)

A further question will be asked to determine the applicability of the study to the Irish Hip Fracture Database to support the focus of the systematic review i.e., Are inclusion criteria generalisable to a broad older hip fracture population? (Yes if inclusion criteria not narrowly focussed.)

All included studies will be appraised independently by two designated authors. Disagreements will be resolved through discussion and a third author if necessary.

**Data synthesis**

Characteristics and results of all studies will be narratively synthesised and outcome collection methods and results will be presented in tables. Where the same dichotomous outcome is reported in multiple studies with similar inclusion criteria, a meta-analysis of the estimates will be conducted. This may include mortality, readmission, re-operation, bone-protection but also the proportion of patients who return to baseline on categorical and continuous measures at a given time-point (e.g., place of residence, mobility, functional ability, and quality of life). Two designated authors will independently decide on appropriateness of inclusion in meta-analyses and discrepancies will be resolved through discussion and a third review author if necessary. Data will be entered into a Microsoft Excel worksheet, cleaned and imported into Stata version 16.1. The binomial equation for variance (expressed as a proportion) will be used to obtain the individual study weights: \(\text{Var}(p) = \frac{p(1-p)}{N}\)

where \(p\) is the outcome proportion, and \(N\) the population size:\(^\text{30}\).

The overall estimate for each outcome will be pooled based on random-effects models and 95% confidence interval (CI) calculated using the DerSimonian and Laird estimation:\(^\text{31}\). Results will be presented by narrative synthesis and forest plots. Heterogeneity between included studies will be assessed with the I\(^2\) statistic.

**Study Status**

Pilot searches were conducted in June 2021. Main searches were conducted in July 2021. As of August 2021, title and abstract screening is ongoing. Final study selection, data extraction and quality appraisal will be completed in August and September 2021.

**Conclusions**

The aim of the current study is to identify, describe and appraise studies that have collected long-term outcomes after hip fracture in Ireland in order to inform education for collectors of data for audit purposes. The study will describe outcomes collected and methods of recruitment and collection over the past 15 years. It will identify common sources of bias with regards to data collection of generalisable outcomes in this setting. It will also describe estimates (and calculate pooled estimates if appropriate) for specific long-term outcomes after hip fracture in Ireland. Including grey literature and conference abstracts will maximise learning from local studies but it is acknowledged that quality of reporting may vary. Results from this study will inform the planning of further qualitative research to explore barriers and facilitators of long-term outcome collection in Ireland. It will form the basis of education and training for future data collectors in this setting.
This study is a key initial step in identifying optimal methods for collecting long-term data after hip fracture in Ireland.

**Data availability**

**Underlying data**

No data are associated with this article.

**Extended data**


This project contains the following extended data:

- Full Search Strategy
- Data Extraction Template

**Reporting guidelines**


References


Lauren Beaupre  
Department of Physical Therapy, Faculty of Rehabilitation Medicine, University of Alberta,  
Edmonton, AB, USA

The Irish Hip Fracture Database was established in 2013 and has been highly successful in measuring in-patient care and outcomes for Irish people experiencing a hip fracture. However, international standards encourage expansion of data collection and evaluation into the post-discharge time period to understand long term patient outcomes.

The authors propose to undertake a systematic review of Irish studies of long term outcomes after hip fracture to identify methods used to collect data as well as outcome ascertained. Their intention is to use these data to inform education and training on how to collect long term outcomes after hip fracture in Ireland.

The rationale for review is well-justified and the methods appear appropriate. However, there are some minor concerns listed below:

1. Eligibility Criteria - The authors indicate that they will only consider Irish studies so that they will retrieve studies with long-term outcome data collection approaches that have previously worked in Ireland. However, I wonder if such a narrow approach will omit international studies that may be relevant and generalizable to Ireland. I encourage the authors to consider including international studies that have evaluated programs, registries or audits with established processes of collecting long-term outcomes following hip fracture as a secondary objective. There may be some important learnings in these papers that would be applicable to Ireland and inform their educational and training initiatives. I would suspect that there are not a lot of international studies with long-term outcome data collection. If registry data are not possible in Ireland due to the lack of an individual health identifier, such studies could be excluded, but it would be unfortunate to miss international studies that are performing primary data collection for long-term outcomes.

2. Under their risk of bias in individual studies, they should also look at analytic approach. At the very least, they should consider if reported outcomes are risk adjusted or not.
Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Partly

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: I perform clinical outcome and health services research with patients who have experienced a hip fracture.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.