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# Facilitating clinical trials in hip fracture in the UK

## THE ROLE AND POTENTIAL OF THE NATIONAL HIP FRACTURE DATABASE AND ROUTINELY COLLECTED DATA

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### Aims

The aim of this study was to evaluate the suitability, against an accepted international standard, of a linked hip fracture registry and routinely collected administrative dataset in England to embed and deliver randomized controlled trials (RCTs).

### Methods

First, a bespoke cohort of individuals sustaining hip fractures between 2011 and 2016 was generated from the National Hip Fracture Database (NHFD) and linked to individual Hospital Episode Statistics (HES) records and mortality data. Second, in order to explore the availability and distribution of outcomes available in linked HES-Office of National Statistics (ONS) data, a more contemporary cohort with incident hip fracture was identified within HES between January 2014 and December 2018. Distributions of the outcomes within the HES-ONS dataset were reported using standard statistical summaries; descriptive characteristics of the NHFD and linked HES-ONS dataset were reported in line with the Clinical Trials Transformation Initiative recommendations for registry-enabled trials.

### Results

Case ascertainment of the NHFD likely exceeds 94%. The assessment of the robustness, relevance, and reliability of the datasets was favourable. Outcomes from the HES-ONS dataset were concordant with other contemporaneous prospective cohort studies with bespoke data collection frameworks.

### Conclusion

Our findings support the feasibility of the NHFD and HES-ONS to support a registry-embedded, data-enabled RCT.

**Cite this article:** *Bone Joint J* 2025;107-B(2):229–238.

### Introduction

Hip fracture in older adults is a pressing global population health challenge. Hip fracture causes a 25% decrement in an individual's health-related quality of life; current direct social and healthcare costs make up 1.4% of total expenditure in established market economies, and hip fracture incidence is estimated to double to 6.26 million globally in 2050.<sup>1–3</sup> Given the impact of hip fracture on individuals and healthcare systems, it has been the focus of major international efforts to advance evidence-based care through the conduct of high-quality randomized controlled trials (RCTs), meta-analyses, and clinical guidance from health technology appraisal organizations.<sup>4–11</sup>

RCTs, although the gold-standard evaluative approach and the source of much of the underlying data in these reviews and guidelines, are notoriously difficult to deliver and are expensive. They are also often criticized that their inferences may not generalize to real-world populations. Ideally, trials would harness the power, scale, and wide coverage of routinely collected health data to provide reliable evidence for clinicians and policymakers more quickly while retaining the crucial advantage of randomization.<sup>12</sup>

One such modification might be through hosting or embedding trials within registries. The Clinical Trials Transformation Initiative (CTTI) have suggested guidelines for the appraisal of

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© 2025 Webster et al.  
doi:10.1302/0301-620X.107B2.  
BJJ-2024-0846.R1 \$2.00

*Bone Joint J*  
2025;107-B(2):229–238.

**Table I.** Summary of the assessment of the robustness, relevance, and reliability of the registry and linked outcome datasets.

Requirements	Recommendations	Assessment
Registry data must demonstrate relevancy and robustness to support regulatory decision-making	Data are relevant: <ol style="list-style-type: none"> <li>1. Data are adequate in scope and content</li> <li>2. Data are generalizable: registry reflects high site and patient participation rates compared with total population</li> </ol> Data are robust and acceptable for use in one or more of the following: <ol style="list-style-type: none"> <li>1. Validated risk prediction</li> <li>2. Quality assurance</li> <li>3. Performance improvement</li> <li>4. Benchmarking</li> <li>5. Informing practice guidelines</li> <li>6. Post-market surveillance</li> <li>7. Generating peer-reviewed publications</li> <li>8. Comparative effectiveness research</li> </ol>	<ol style="list-style-type: none"> <li>1. The NHFD is a national audit commissioned by HQIP and has exceptional and widespread clinical engagement. Registry content is agreed by key opinion leaders and has broad clinical acceptability; the 8 KPIs are recognized as key components of good clinical practice</li> <li>2. Case ascertainment within NHFD probably exceeds 94%</li> <li>1. NHFD has been the source of multiple, highly impactful publications</li> <li>2. Key data linkages are feasible; linkage success rate was 98% with HES and ONS</li> <li>3. Linked outcome data are clinically relevant, statistical analyses of HES and ONS are well established. Outcome distributions are presented for trial planning</li> </ol>
Registry data must reliably be able to support regulatory decision-making	Design: the registry should be designed to capture reliable data from real-world practice (no protocol-driven treatment) Patient population: the patient population should be limited to those with specific diseases, conditions, or treatment exposure(s) Data collection forms: the data collection forms should be standardized  Datasets: data elements should be able to be mapped to industry standards to allow for more direct comparison of data analyses Timing of endpoints/outcomes: the timepoints of each endpoint/outcome in the data collection form should be documented Timing of data collection: data collection/entry can occur at any time Data completeness and accuracy: data should be complete, accurate, and attributable	Registry data reflect real-world clinical practice and are benchmarked against agreed KPIs Concordant with international definitions of fragility hip fracture with explicit eligibility criteria  Standardized, publicly available case reporting forms. Annual updates are disseminated and recorded. Web-based data uploads with electronic audit of case reporting Publicly available data dictionaries and internationally recognized data vocabularies  Relationship between incident fracture and outcome is clearly captured  Live, web-based tool  Baseline registry data are more than 95% complete. Followup data within registry are unreliable. HES and ONS are mandatory, nationally curated datasets
Registry has assurance of patient protections	<ol style="list-style-type: none"> <li>1. Documentation of informed consent or IRB waiver of informed consent is needed for access to the data (e.g. by investigators, patients, regulators)</li> <li>2. Patient privacy must be assured: assess for use of de-identified data vs line-item data (informed consent is required for line-item data)</li> </ol>	<ol style="list-style-type: none"> <li>1. Transparent processes in place for access to, and regulatory approvals required for, processing any data</li> <li>2. Governance arrangements in place to assure legally compliant access to the data with processes to deidentify and minimize data released</li> </ol>

HQIP, Healthcare Quality Improvement Partnership; IRB, institutional review board; KPI, key performance indicator; NHFD, National Hip Fracture Database.

the suitability of a registry to host trials.<sup>13</sup> They undertook a review of registry-embedded clinical trials and commentaries, semi-structured interviews with experts, and a multistakeholder expert meeting, and developed tools to identify and describe essential registry characteristics, practices, and processes required for conducting embedded clinical trials.<sup>14</sup>

Worldwide, there are multiple nationally hosted hip fracture registries. Efforts to bring together a collaboration of these working groups have been highly successful under the umbrella of the Fragility Fracture Network Special Interest Group;<sup>15</sup> recently, an agreed minimum common dataset has been adopted.<sup>16</sup> Such registries may be suitable for hosting future RCTs in hip fracture.

The National Hip Fracture Database (NHFD) is the register of hip fractures occurring in England, Wales, and Northern Ireland. It has been previously linked with routinely collected national hospital administrative data (RCD) and national mortality records to facilitate a number of large observational studies.<sup>17–24</sup> Here, we evaluate the suitability of a linked NHFD

and English RCD to embed and deliver RCTs against the CTTI evaluation framework.<sup>13</sup>

## Methods

**Data sources.** The National Hip Fracture Database (NHFD)<sup>25</sup> is a hip fracture registry which began in 2007. Data are recorded from patients admitted with hip fracture in England, Wales, and Northern Ireland. Data include patients' characteristics, fracture pattern, surgical interventions, and measures of process such as time to theatre. These details are typically collected by specialist nurses within each hospital who provide continuity of care to patients with hip fractures and manage submissions to the NHFD. Data from patients aged under 60 years and those treated without an operation are not captured within the database. The database now has data from almost one million unique incident hip fracture episodes.

The Hospital Episode Statistics (HES) Admitted Patient Care database, administered by NHS England, contains records of every day-case and inpatient admission from all NHS hospitals

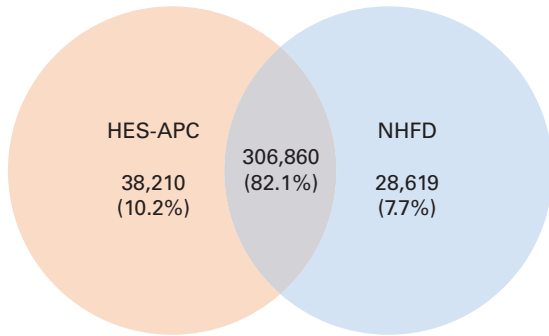


Fig. 1

Case ascertainment in National Hip Fracture Database (NHFD) and Hospital Episode Statistics Admitted Patient Care (HES-APC).

in England since 1990. Information is recorded on the principal reason for admission (the primary diagnosis) alongside secondary diagnoses coded using the International Classification of Diseases (ICD) (version 10 since 1995).<sup>26</sup> Information is also available regarding procedural codes for surgery (OPCS) and direct hospital care costs. HES became record-linkable from 1998 onwards.

Civil Registration (Deaths) provides a complete register of date and cause of death in England and Wales and is administered by the Office of National Statistics (ONS). Extracts of death registration records from the General Register Office’s Registration Online system are encoded daily. Causes of death are categorized into the disease or condition immediately causing death (1a), the underlying cause of 1a (1b), the underlying cause of 1b (1c), and any disease or condition that did not cause death but contributed in some way (2).

**Design.** The quantitative and descriptive characteristics of a proposed registry and linked outcome dataset using the NHFD, HES and ONS data sources (herein termed NHFD-HES-ONS) were explored following the CTTI recommendations for registry-enabled trials.<sup>13</sup>

The CTTI recommendations suggest assessing the potential suitability of a registry to host a RCT based on a set of core assessment criteria including: suitability of registry for supporting the proposed clinical trial – including that the registry is appropriately focused on the patient population of interest, the evidence collected in the registry is robust, and that historical evidence generated from the registry is robust; relevance of the registry (is it fit for purpose for a trial) – including that processes are available for identification and assignment of patients; appropriate data elements and outcomes are collected; reliability of the registry – including that data must be sufficient to support decision-making; be sufficiently complete and accurate; have adequate data quality assurance processes; and accessibility of the registry – including availability of data with appropriate confidentiality; have suitable linkage to other relevant data sources.

We used these criteria in our assessment of the suitability of the linked NHFD registry. They were operationalized in this study as outlined in Table I.

**Table II.** Concordance of incident hip fracture events in the National Hip Fracture Database (NHFD) and Hospital Episode Statistics (HES) allowing for varying time mismatches.

Time between hip fracture date in NHFD and hip fracture date in HES	n (%)
Exact match	225,629 (73.5)
± 1 day	282,852 (92.2)
± 3 days	285,989 (93.2)
± 7 days	288,922 (94.2)
± 30 days	293,744 (95.7)
± 90 days	296,160 (96.5)
± 365 days	300,690 (98.0)
Total (no date restriction)	306,860 (100)

In order to report components of this assessment, a cohort of individuals sustaining hip fracture between 2011 and 2016 was generated and linked to individuals’ HES records and mortality data from ONS. Individuals and incident hip fracture events were identified in the linked dataset as recorded in the NHFD, recorded in HES, or both. Details of the linkage process and definitions of an incident hip fracture event within HES are in the Supplementary Material. All data were analyzed using Stata v. 18 (StataCorp, USA).

Then, in order to explore the availability and distribution of outcomes available in linked HES-ONS data, we generated a more contemporary cohort of 336,534 individuals with incident hip fracture identified within HES between 2014 and 2018, where incident hip fracture was defined as the first-recorded hip fracture admission per individual.

**Quantitative analyses.** Using the linked NHFD-HES dataset from 2011 to 2016, we ascertained numbers of hip fracture cases in each dataset (Figure 1). The NHFD dataset contained unique IDs for each fracture. The HES dataset contained unique person IDs along with their reasons for hospital admission and dates of admission and discharge. Where successfully linked to a person in HES, a hip fracture event in NHFD was attributed a person ID from HES. The extent to which NHFD and HES were concordant was ascertained by counting the number of hip fracture events in NHFD that were successfully linked to individuals in HES who had a relevant hip fracture code, irrespective of matching dates. Among these individuals, the concordance of matching dates was then assessed. For the ascertainment of hip fracture events that appeared in NHFD but did not appear in HES, all unique hip fracture IDs were counted. For the ascertainment of hip fracture events that appeared in HES but did not appear in NHFD, in order to avoid over-counting readmissions for the same hip fracture event, only emergency admissions were counted, and any emergency hip fracture admissions that occurred within 90 days of a patient’s previous hip fracture admission were discounted. We report characteristics of hip fracture patients using standard statistical summaries.

**Outcomes.** Using the more contemporary linked HES-ONS dataset of individuals with a hip fracture from 2014 to 2018, we reported clinically relevant events following the first recorded hip fracture event per individual within 28, 90, 120, and 365 days, presented as crude percentages. The outcomes were selected through consultation with expert trialists and

**Table III.** Descriptive characteristics of hip fracture patients at index admission, 2014 to 2018.

Characteristic	Overall	Males	Females
n (%)	336,534	105,242 (31.3)	231,292 (68.7)
Median age, yrs (IQR)	83.0 (75.0 to 88.0)	81.0 (71.0 to 87.0)	84.0 (77.0 to 89.0)
<b>Age, n (%)</b>			
< 60 yrs	23,099 (6.9)	13,150 (12.5)	9,949 (4.3)
60 to 70 yrs	30,129 (8.6)	11,228 (10.7)	18,901 (8.2)
70 to 80 yrs	71,952 (21.4)	23,500 (22.3)	48,452 (21.0)
80 to 90 yrs	141,606 (42.1)	40,766 (38.7)	100,840 (43.6)
90+ yrs	69,748 (20.7)	16,598 (15.8)	53,150 (23.0)
<b>Region, n (%)</b>			
North East	18,637 (5.5)	5,698 (5.4)	12,939 (5.6)
North West	47,038 (14.0)	14,604 (13.9)	32,434 (14.0)
Yorkshire and Humber	33,255 (9.9)	10,284 (9.8)	22,971 (9.9)
East Midlands	24,722 (7.3)	7,628 (7.2)	17,094 (7.4)
West Midlands	36,583 (10.9)	11,664 (11.1)	24,919 (10.8)
East of England	39,471 (11.7)	12,148 (11.5)	27,323 (11.8)
London	32,022 (9.5)	10,568 (10.0)	21,454 (9.3)
South East	56,586 (16.8)	17,354 (16.5)	39,232 (17.0)
South West	39,707 (11.8)	12,447 (11.8)	27,260 (11.8)
Missing	8,513 (2.5)	2,847 (2.7)	5,666 (2.4)
<b>Ethnicity, n (%)</b>			
White	312,129 (92.7)	96,942 (92.1)	215,187 (93.0)
Asian	5,090 (1.5)	2,064 (2.0)	3,026 (1.3)
Black	1,359 (0.4)	682 (0.6)	677 (0.3)
Other	2,989 (0.9)	1,131 (1.1)	1,858 (0.8)
Mixed	621 (0.2)	265 (0.3)	356 (0.2)
Unknown	14,346 (4.3)	4,158 (4.0)	10,188 (4.4)
<b>IMD, n (%)</b>			
1 (most deprived)	63,234 (18.8)	21,278 (20.2)	41,956 (18.1)
2	63,778 (19.0)	20,416 (19.4)	43,362 (18.7)
3	69,563 (20.7)	21,407 (20.3)	48,156 (20.8)
4	69,397 (20.6)	20,724 (19.7)	48,673 (21.0)
5 (least deprived)	66,407 (19.7)	19,971 (19.0)	46,436 (20.1)
Missing	4,155 (1.2)	1,446 (1.4)	2,709 (1.2)
<b>Year, n (%)</b>			
2014	70,418 (20.9)	21,498 (20.4)	48,920 (21.2)
2015	67,785 (20.1)	20,885 (19.8)	46,900 (20.3)
2016	66,250 (19.7)	20,864 (19.8)	45,386 (19.6)
2017	66,346 (19.7)	21,021 (20.0)	45,325 (19.6)
2018	65,735 (19.5)	20,974 (19.9)	44,761 (19.4)

IMD, Index of Multiple Deprivation.

clinicians, and from review of major contemporary RCTs in hip fracture.

Events were venous thromboembolism, bleeding, infection, acute myocardial infarction, and stroke; case-fatality for these outcomes and any cardiovascular death; all-cause readmissions; hip fracture recurrence; and incidence of a major adverse cardiac event (MACE). Readmissions and recurrence were defined as any hospital admission (or those where a hip fracture was recorded for recurrence) occurring at least one day after the discharge date from the index admission for hip fracture. Information on how each outcome was derived is available in the Supplementary Material.

We report medians and IQRs alongside frequency distributions for days alive out of hospital (DAOH) within 28, 90, 120, and 365 days of index fracture, termed 'DAOH unweighted'.

These are also reported for a modification of DAOH where individuals who died during the follow-up period after their index admission were attributed 0 DAOH to weight death more than hospitalization, termed 'DAOH weighted', and for a final modification restricted to only patients alive at the end of follow-up, termed 'DAOH (survivors only)'. Information on how DAOH was defined is available in the Supplementary Material, as is an illustrative example of calculating the effect of a 'treatment' on DAOH after an index admission for hip fracture. In this proof-of-concept example, the win ratio is derived for the effect of age (above or below the median age at hip fracture) on a composite outcome of death and DAOH (unweighted) within 28, 90, 120, and 365 days after index admission after matching individuals in each group on sex and year of index admission. The win ratio<sup>27</sup> allows the trialist to estimate a treatment effect where

**Table IV.** Binary outcomes in 336,534 hip fracture patients derived from the linked Hospital Episode Statistics-Office for National Statistics dataset (2014 to 2018). Overall, 311,920 patients were discharged alive.

Event	Days after hip fracture admission date, n (%)			
	28	90	120	365
<b>Incidence*</b>				
VTE admission (any diagnosis) or death (any cause)	6,751 (2.0)	9,600 (2.9)	10,285 (3.1)	12,687 (3.8)
VTE admission (any diagnosis) or death (underlying cause)	6,266 (1.9)	8,783 (2.6)	9,405 (2.8)	11,632 (3.5)
Bleed admission† or death (any cause)	7,364 (2.2)	10,328 (3.1)	11,258 (3.3)	16,517 (4.9)
Bleed admission† or death (underlying cause)	7,287 (2.2)	10,181 (3.0)	11,096 (3.3)	16,250 (4.8)
Infection admission‡ (any diagnosis) or death (any cause)	125,556 (37.3)	141,795 (42.1)	146,087 (43.4)	167,614 (49.8)
Infection admission‡ (any diagnosis) or death (underlying cause)	124,238 (36.9)	139,463 (41.4)	143,524 (42.6)	164,085 (48.8)
AMI admission (any diagnosis) or death (any cause)	5,956 (1.8)	7,238 (2.2)	7,624 (2.3)	9,912 (2.9)
AMI admission (any diagnosis) or death (underlying cause)	5,663 (1.7)	6,810 (2.0)	7,157 (2.1)	9,312 (2.8)
Stroke admission (any diagnosis) or death (any cause)	4,795 (1.4)	7,062 (2.1)	7,852 (2.3)	12,507 (3.7)
Stroke admission (any diagnosis) or death (underlying cause)	4,274 (1.3)	6,060 (1.8)	6,710 (2.0)	10,699 (3.2)
<b>Readmissions</b>				
Hip fracture readmission	7,667 (2.3)	10,904 (3.2)	11,832 (3.5)	16,943 (5.0)
Hip fracture readmission in patients discharged alive*	7,667 (2.5)	10,904 (3.5)	11,832 (3.8)	16,943 (5.4)
Any readmission	23,340 (6.9)	76,546 (22.7)	92,013 (27.3)	156,905 (46.6)
Any readmission in patients discharged alive*	23,340 (7.5)	76,546 (24.5)	92,013 (29.5)	156,905 (50.3)
<b>Case-fatality</b>				
All-cause death	23,446 (7.0)	49,570 (14.7)	57,049 (17.0)	90,102 (26.8)
All-cause death in patients discharged alive*	5,398 (1.7)	25,455 (8.2)	32,615 (10.5)	65,504 (21.0)
Hip fracture death (any cause)	13,525 (4.0)	20,495 (6.1)	21,307 (6.3)	22,621 (6.7)
Hip fracture death (underlying cause)	0	0	0	0
VTE death (any cause)	861 (0.3)	1,713 (0.5)	1,920 (0.6)	2,546 (0.8)
VTE death (underlying cause)	86 (0.0)	303 (0.1)	378 (0.1)	579 (0.2)
Bleed death (any cause)	418 (0.1)	856 (0.3)	997 (0.3)	1,822 (0.5)
Bleed death (underlying cause)	245 (0.1)	518 (0.2)	625 (0.2)	1,236 (0.4)
Infection death (any cause)	9,524 (2.8)	19,467 (5.8)	22,124 (6.6)	33,470 (9.9)
Infection death (underlying cause)	2,152 (0.6)	5,372 (1.6)	6,423 (1.9)	11,140 (3.3)
AMI death (any cause)	1,833 (0.5)	2,606 (0.8)	2,803 (0.8)	3,761 (1.1)
AMI death (underlying cause)	1,195 (0.4)	1,711 (0.5)	1,847 (0.5)	2,544 (0.8)
Stroke death (any cause)	1,367 (0.4)	3,016 (0.9)	3,573 (1.1)	6,340 (1.9)
Stroke death (underlying cause)	599 (0.2)	1,519 (0.5)	1,851 (0.6)	3,581 (1.1)
Any CVD death (any cause)	12,945 (3.8)	24,218 (7.2)	27,472 (8.2)	42,433 (12.6)
Any CVD death (underlying cause)	5,194 (1.5)	9,974 (3.0)	11,511 (3.4)	18,880 (5.6)
<b>Composite outcomes</b>				
MACE	19,863 (5.9)	31,655 (9.4)	35,120 (10.4)	52,175 (15.5)

\*Incidence includes episodes occurring during the hip fracture index stay and those occurring after discharge.

†Bleed admission: upper gastrointestinal (any diagnosis), intracranial (any diagnosis), lower gastrointestinal (primary diagnosis), respiratory (primary diagnosis), haematuria (primary diagnosis), other major (primary diagnosis).

‡A further breakdown of the top ten infection diagnoses can be found in the Supplementary Material.

AMI, acute myocardial infarction; CVD, cardiovascular disease; MACE, major adverse cardiac event; VTE, venous thromboembolism.

there is a hierarchy in the different components of the composite outcome (i.e. where death is weighted more than hospitalization days) while accounting for confounding.

**Results**

Table I contains a summary of the assessment of the NHFD-HES-ONS registry and dataset.

**Scope and content.** The NHFD is part of the Falls and Fragility Fracture Audit Programme (FFFAP) commissioned by the Healthcare Quality Improvement Partnership (HQIP) and managed by the Royal College of Physicians. FFFAP is supported by a Board, clinical advisory groups, and a patient and carer panel. These clinical advisory teams have specified the data that are collected within NHFD, which are orientated towards the reporting of eight key performance indicators:

admission to a specialist ward, prompt orthogeriatric review, prompt surgery, NICE-compliant surgery,<sup>10,11</sup> prompt mobilization, not delirious postoperatively, return to original residence, and bone medication prescription. The dataset contains all of the items required in the internationally agreed minimum core dataset for hip fracture.<sup>16</sup>

The data reported by NHFD are used for evaluating ongoing clinical care in all reporting hospitals as part of the mandatory national audit programme. The NHFD also administers NHS England’s ‘Best Practice Tariff’ programme, with trusts receiving reimbursement based on the quality of care provided to individual patients, as recorded in the NHFD dataset.

Benchmarking tables and ‘caterpillar plot’ graphical presentations allow individual hospitals to set their performance against national figures for England, Wales, and Northern

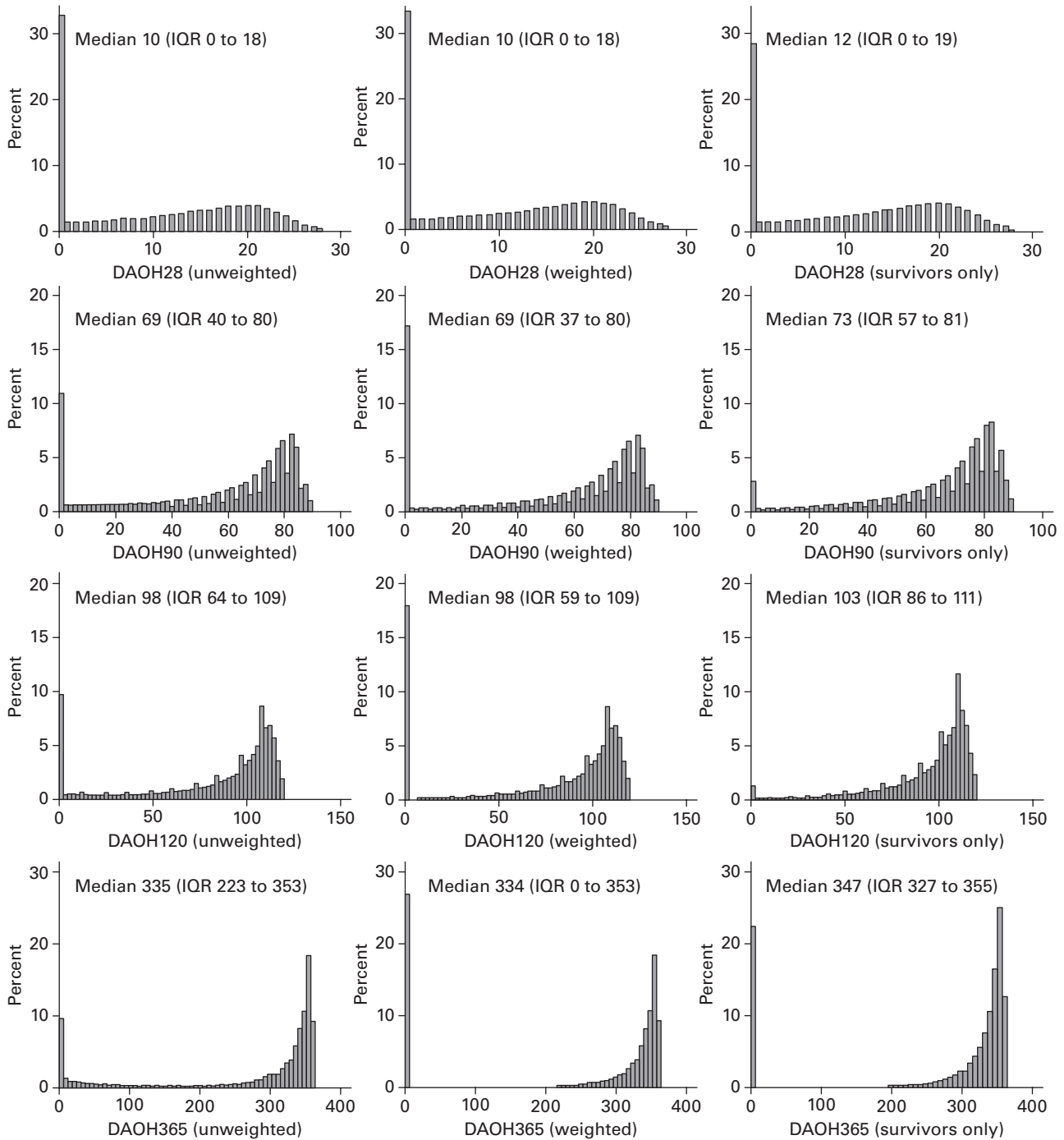


Fig. 2

Frequency distribution of the outcome days alive out of hospital (DAOH) over the first 28, 90, 120, and 365 days following index hip fracture admission.

Ireland as a whole, as well as that in other hospitals with which they might wish to collaborate in improvement work, or from which they might wish to learn.

Every quarter, the NHFD examines mortality figures for each hospital, casemix-adjusts these using demographic and clinical descriptors of admitted patients, then identifies ‘outlier’

hospitals that move outside the 3SD control limit for casemix-adjusted mortality. Such hospitals are identified in real time, so their clinical teams are made aware of the issue before the end of the next quarter, and can take action to address any identified failings. Persistent ‘outlier’ status over two or more quarters is brought to the attention of the trusts’ medical director and



**Table V.** Illustrative example of deriving the effect of age on days alive out of hospital in 131,945 pairs of younger (age ≤ 84 years) and older (age > 84 years) hip fracture patients matched on sex and year of admission.

Variable	28 days	90 days	120 days	365 days
Pairs, n	131,945	131,945	131,945	131,945
Wins on death in younger adults	13,314	27,085	30,806	45,771
Wins on death in older adults	5,392	10,952	12,414	18,558
Wins on DAOH in younger adults	66,955	59,454	56,109	42,609
Wins on DAOH in older adults	34,609	32,522	30,894	23,841
Overall wins in younger adults	80,269	86,539	86,915	88,380
Overall wins in older adults	40,001	43,474	43,308	42,399
Tied	11,675	1,932	1,722	1,166
Win ratio (95% CI)	2.00 (1.98 to 2.03)	1.99 (1.97 to 2.01)	2.01 (1.99 to 2.03)	2.08 (2.06 to 2.11)
Win difference (%)	30.5	32.6	33.0	34.8

DAOH, days alive out of hospital.

executives, and the Care Quality Commission (CQC), and the NHFD clinical leads meet with all parties and use the NHFD website to identify key areas for improvement.

**Generalizability and case ascertainment.** The NHFD collected data successfully from all 163 NHS hospitals in England, Wales, and Northern Ireland treating acute hip fracture in 2022. The median number of episodes reported per hospital in 2022 was 365 (IQR 277 to 455).

Among the hospitals in England, we were able to link data from 306,860 unique incident hip fracture events in a combined NHFD-HES-ONS dataset (Table II). Overall, 91.5% of hip fracture events identified within the NHFD (306,860/335,479) were successfully linked to a person in HES who had an ICD-10 or OPCS-4 code specific to hip fracture. For 28,619 hip fractures in the NHFD, there was no corresponding record in HES. For 38,210 hip fracture events in HES, there was no corresponding record in NHFD.

**Data robustness.** Data from the NHFD have been widely used for a number of research study applications. These include observational studies that have defined the extent of variation in patient characteristics, and the quality and outcome of different aspects of care for the hip fracture population in different hospitals and different parts of the country.

The face validity of NHFD data is demonstrated by the way in which these have permitted the development of the outcome prediction and casemix-adjustment models,<sup>28</sup> which are routinely used to identify those hospitals which are ‘outliers’ for poor performance (30-day mortality), and to draw such findings to the attention of local clinicians, hospital managers, NHS leaders, and Care Quality Commission. The NHFD’s open access, public-facing website provides benchmarking data and run charts that are used to drive local improvement and innovations inspired by the NHFD’s annual reports,<sup>25</sup> and the many peer-reviewed publications and comparative natural experimental studies that have been supported by its data.<sup>29</sup>

In the linked HES-ONS population (Table III), crude percentages for incidence, all-cause readmissions, hip fracture recurrence, and cause-specific case-fatality rates within 28, 90, 120, and 365 days after first hip fracture index admission are reported in Table IV. For example, rates of MACE over these follow-up periods were 5.9% (n = 19,863), 9.4% (n = 31,655), 10.4% (n = 35,120), and 15.5% (n = 52,175), respectively. Hip

fracture recurrence rates were 2.3% at 28 days (n = 7,667), 3.2% at 90 days (n = 10,904), 3.5% at 120 days (n = 11,832), and 5.0% at 365 days (n = 16,943). All-cause mortality rate over 28, 90, 120, and 365 days following index admission was 7.0% (n = 23,446), 14.7% (n = 49,570), 17.0% (n = 57,049), and 26.8% (n = 90,102), respectively.

DAOH unweighted, DAOH weighted, and DAOH (survivors only) within 28, 90, 120, and 365 days after first hip fracture admission are reported in Figure 2. The proportion of patients who spent 0 DAOH at 28 days was similar across DAOH definitions (109,432 (32.5%), 112,745 (33.5%), and 89,299 (28.5%) for DAOH unweighted, DAOH weighted, and DAOH (survivors only), respectively). In contrast, by day 365, the proportion of patients with 0 DAOH was 28,261 (8.4%) for DAOH unweighted, 90,297 (26.8%) for DAOH weighted, and 195 (0.1%) for DAOH (survivors only).

A proof-of-concept example of deriving the win ratio for the effect of age (above or below the median age at hip fracture of 84 years) on DAOH (unweighted) is reported in Table V. The number of ‘wins’ for each age group on death, DAOH, and overall is reported alongside the number of ties, the win ratio, and the crude win difference rate. Younger patients were at greater odds of ‘winning’ overall, that is, were less likely to die first, more likely to spend more days out of hospital, or both at 28 days (WR 2.00 (95% CI 1.98 to 2.03)), 90 days (1.99 (95% CI 1.97 to 2.01)), 120 days (2.01 (95% CI 1.99 to 2.03)), and 365 days after their index admission for hip fracture (2.08 (95% CI 2.06 to 2.11)), with corresponding win difference rates of 30.5%, 32.6%, 33.0%, and 34.8%, respectively.

**Design.** A standard operating procedure for data collection for the NHFD is available. This is updated annually with an update to any changes to the items collected. The data are collated by Crown Informatics who are commissioned by FFFAP as the data processors. The annual report is prepared by the NHFD team, reviewed by the NHFD Advisory Group, and analyzed by the Bristol National Institute for Health and Care Research (NIHR) Biomedical Research Centre.

**Population.** NHFD records are restricted to individuals with incident native hip fractures managed operatively in NHS hospitals in individuals aged 60 years and older.

**Data collection.** Designated audit staff at each participating hospital are provided with user-specific access to an online

webtool that allows uploading of new episodes. Data can be uploaded in real time and can be edited at any point following the index admission. Data items are defined in a data dictionary with an accompanying user guide. An electronic audit trail is available for any changes to the record. Paper forms to facilitate alternative approaches to data collection are available for audit staff to use. A bulk upload facility is available for hospitals which use alternative electronic systems for data capture.

**Datasets.** NHFD captures all data items described within the internationally agreed minimum core dataset for hip fracture registries,<sup>16</sup> which facilitates international comparisons of hip fracture care and outcomes.<sup>30</sup> However, while the NHFD collects a number of fields beyond this minimum requirement, some demographic data, processes of care, and outcomes are not recorded to avoid placing an unrealistic burden on the clinical staff who collect and enter the data. The definitions and coding for the NHFD dataset are supported by the online data entry portal, which challenges unlikely data. The dataset is detailed in the data collection sheets which are publicly available on the NHFD website. HES and ONS are structured, reproducible datasets with published data dictionaries and internationally recognized vocabularies.<sup>31,32</sup>

**Chronology and data completeness.** Baseline data item reporting is mandatory and overall completeness of baseline data in NHFD exceeds 95%. Outcome data collected at 120 days are variable and not reliable. HES and ONS are mandatory nationally curated datasets. Dates of index fracture and outcomes are clearly captured so that chronology assessment and time-to-event analyses are possible.

**Patient-protection assurances.** The legal basis for the NHFD to collect personal data is Section 251 of the NHS Act 2006 (CAG 8-03(PR11)/2013). The existing approval for the NHFD is in place for the duration of the audit providing there is no deviation from the terms of the original approval; annual reviews are submitted each year to confirm compliance with the conditions of support. The legal basis under which this application for the transfer of data from NHFD to NHS England takes place, and to enable them to perform linkage on our behalf, is section 251 of the NHS Act 2006 and the Health Service (Control of Patient Information) Regulations 2002. A fair processing statement and description of the data flows for the NHFD is publicly available.<sup>33</sup> Given these approvals, there is no requirement for individual informed consent to be given by patients for the core processing purposes of the NHFD.

Applications to use the data for research purposes can be made to the Scientific Committee of the FFFAP where appropriate ethical, governance, and legal approvals are in place for the data processing. Recommendations from the committee are considered by the data controller, the HQIP, and underpin the data sharing agreement between the controller and proposed processor prior to release of any data.

## Discussion

We have reported the characteristics of a linked registry and outcome dataset for the population of individuals sustaining fragility hip fractures against the internationally accepted CTTI standards and find it to have performed well. The registry is broadly adopted, captures a defined and generalizable popula-

tion, and has clear processes in place for data collection, reporting, and access. Clinically relevant outcomes can be feasibly derived from the linked national RCD and we have provided distributions for key outcomes. These outcomes are concordant with other contemporaneous prospective cohort studies with bespoke data collection frameworks.<sup>34</sup> These characteristics support the feasibility of the NHFD and HES-ONS to support a registry-embedded, data-enabled RCT.

There has been a major uplift in the number of high-quality trials in hip fracture worldwide; the challenge of larger, more representative trials designed to detect ever smaller effects as care improves is substantial. Two major international efforts, Fixation using Alternative Implants for the Treatment of Hip fractures (FAITH) and Hip Fracture Evaluation with Alternatives of Total Hip Arthroplasty versus Hemi-Arthroplasty (HEALTH), took six and eight years, respectively, to reach their recruitment targets.<sup>6,35</sup> Such long study durations severely slow the implementation of evidence-based care, hamper innovation, and risk the irrelevance of trial findings if practice evolves faster than the evidence. Registry-embedded and data-enabled designs offer the possibility of faster, bigger trial delivery to mitigate these risks.

Efficient designs are being championed by expert groups such as Health Data Research UK report “Better, Faster and More Efficient Clinical Trials”<sup>36</sup> and by funders such as the NIHR in targeted funding rounds. However, our experience is that few data are available to researchers to plan such major prospective studies. PRIMORANT, a working group of researchers using or keen to adopt such methods highlighted additional barriers to implementation, commenting that access to healthcare data systems for study planning was costly and often slow yet crucial to study design.<sup>37</sup> Others have called for more systematic assessment of routinely collected datasets for determining outcome or Data Utility Comparison Studies (DUCKS).<sup>38</sup> Here we have undertaken the necessary preparatory work to support researchers in this field by providing critical planning information for studies in hip fracture using a UK registry and RCDs.

We recognize limitations both in the application of our findings to specific research questions and in our study methodology. Routinely collected datasets are often not designed to address novel research questions and so the data collected may not be those required for the proposed trial, at sufficient completeness, or using appropriate agreed vocabularies or definitions. HES and NHFD both focus on the inpatient period; HES is necessarily limited in granularity as a generic dataset and even NHFD, a population-specific registry, does not capture the totality of outcomes or complications that may be relevant to people following hip fracture such as pressure sores, community rehabilitation, or late-onset cognitive decline. NHFD is a well-established registry with excellent community compliance, but this may not be true of other more immature registries. These limitations are true of potentially all registry-embedded or data-enabled designs, and the CTTI framework provides an internationally accepted set of standards for this critical benchmarking prior to trial setup. We have only reported English data from HES and ONS. NHFD has a wider geographical footprint, and indeed with inclusion of the Scottish Hip Fracture Audit and the relevant administrative hospital databases for Northern



Ireland, Scotland, and Wales, it would be possible to explore the generalization of our approach across all four devolved nations of the UK.

The NHS England Outcomes and Registries Programme is a major new four-nations initiative to deliver against the challenges laid out in the Cumberlege<sup>39</sup> and Paterson<sup>40</sup> reports.<sup>41</sup> We recommend that this programme, the embedded clinical steering groups, and existing registry steering committees undertake similar assessments in order to facilitate the embedding of high-quality RCTs for their patient groups.



### Take home message

- The National Hip Fracture Database is broadly adopted, captures a defined and generalizable population and has clear processes in place for data collection, reporting and access.
- Outcome data can be sourced from linkable, routinely collected datasets.
- These features mean that the database is a capable framework for the delivery of registry-embedded, data-enabled randomized controlled trials.

### Social media

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### Supplementary material



Data item definitions and further detail of analyses performed.

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#### Funding statement:

The authors disclose receipt of the following financial or material support for the research, authorship, and/or publication of this article: X. L. Griffin received funding for this work from the National Institute of Health and Social Care Research (Clinician Scientist CS-2017-17-020) and was supported by NIHR Barts Biomedical Research Centre (NIHR203330). J. Webster and R. Goldacre are supported by NIHR Oxford Biomedical Research Centre and Health Data Research UK. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

#### ICMJE COI statement:

J. Webster and R. Goldacre reports institutional payments from NIHR Oxford Biomedical Research Centre and Health Data Research UK, related to this study. J. C. E. Lane reports institutional grants from UKRI, the Academy of Medical Sciences, Orthopaedic Research UK, and NIHR, unrelated to this study. M. Mafham reports institutional payments from Health Data Research UK, related to this study. M. K. Campbell reports grants from NIHR, unrelated to this study. A. Johansen is a clinical lead for the National Hip Fracture Database. X. L. Griffin reports institutional payments from NIHR, related to this study, and multiple grants from UKRI and support for attending meetings and/or travel, all of which are unrelated to this study.

#### Data sharing:

The datasets generated and analyzed in the current study are not publicly available due to data protection regulations. Access to data is limited to the researchers who have obtained permission for data processing. Further inquiries can be made to the corresponding author.

#### Ethical review statement:

The study and the explicit data linkages sought were approved by the Health Research Agency (HRA), Confidential Advisory Group (Ref 17.CAG.0125) and Healthcare Quality Improvement Partnership (Ref HQIP326).

#### Open access funding:

National Institute for Health and Social Care Research award CS-2017-17-020.

#### Open access statement:

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This article was primary edited by M. Hossain.