



■ HIP

Utilization and costs of formal and informal care, home adaptations, and physiotherapy among older patients with hip fracture

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Aims

This feasibility study investigates the utilization and cost of health resources related to formal and informal care, home adaptations, and physiotherapy among patients aged 60 years and above after hip fracture from a multicentre cohort study (World Hip Trauma Evaluation (WHiTE)) in the UK.

Methods

A questionnaire containing health resource use was completed at baseline and four months post-injury by patients or their carer. Completion rate and mean cost of each health resource item were assessed and sensitivity analysis was performed to derive a conservative estimate of the informal care cost. All costs are presented in 2017/18 pound sterling.

Results

A total of 4,183 patients from the WHiTE cohort completed the baseline questionnaire between May 2017 and April 2018, of whom 3,524 (84.2%) completed the four-month health resource section. Estimated mean costs of formal and informal care, home adaptations, and physiotherapy during the four months following injury were £2,843 (SD 5,467), £6,613 (SD 15,146), £706 (SD 1,706) and £9 (SD 33), respectively. Mean cost of informal care decreased to £660 (SD £1,040) in the sensitivity analysis when informal care was capped at 17.2 hours per day.

Conclusion

Informal care is a significant source of costs after hip fracture and should therefore be included in future economical analyses of this patient group. Our results show that there is considerable variation in the interpretation of time-use of informal care among patients and further work is needed to improve how data regarding informal care are collected in order to obtain a more accurate cost estimate.

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Article focus

■ What is the utilization rate and cost of formal and informal care, home adaptations, and physiotherapy among hip fracture patients aged 60 years and above?

- There is considerable variation in the interpretation of informal care requirements among patients.
- The design of health resource utilization section in the questionnaire needs to take these factors into account in order to obtain a more accurate cost estimate.

Key messages

■ Formal and informal care are significant sources of cost following hip fracture in older patients.

Strengths and limitations

■ First study to estimate the cost of informal care as a result of a hip fracture in the UK.

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- Patients had difficulty reporting their use of informal care and tended to report ‘care availability’, hence the cost of informal care could be overestimated.

Introduction

Each year approximately 1.6 million hip fractures occur worldwide,¹ and the figure could reach between 4.5 million² and 6.3 million³ by 2050 due to rising life expectancy. Fractures are associated with significant morbidity and premature mortality,⁴ loss of independence, development of chronic pain, diminished quality of life,⁵ and as a result increased financial burden.⁶ This is especially true in older adults where hip fractures are becoming more common and complex in an ageing and increasingly frail population.⁷⁻⁹

According to a recent systematic review conducted by Williamson et al¹⁰ regarding the cost of fragility hip fractures globally, the pooled estimate of health and social care costs in the first 12 months following a hip fracture was \$43,669. In this evaluation, inpatient care was the main cost driver, responsible for 31% of total cost, with index hospitalization accounting for approximately 80% of the total inpatient cost in the first year.¹⁰ However, none of the studies included in the review investigated productivity loss or the cost of informal care for patients after a fragility hip fracture.

In the UK, over 65,000 hip fractures occur each year¹¹ at an annual cost of £1 billion.¹¹ Given the profound loss of function and independence following a hip fracture, manifested in around 50% of older patients unable to mobilize independently afterwards,¹² patients need support once they leave the hospital. This support takes a different form for every patient, largely depending on their overall health and immediate environment, but it is usually a combination of formal (i.e. paid) care, informal care (unpaid, generally provided by family and/or relatives), and/or physical adaptations to their home. These are significant cost drivers, but are not routinely provided by the NHS. Furthermore, as elderly patients report being more concerned with potential loss of independence rather than the risk of mortality after a hip fracture, success in rehabilitation has been a key marker of quality of care used by the National Hip Fracture Database (NHFD).¹³ In this feasibility study, we therefore sought to estimate the level and costs associated with the utilization of formal and informal care, home adaptations, and physiotherapy, as a key component of rehabilitation among older patients with hip fractures in the UK.

Methods

Study population. The multicentre World Hip Trauma Evaluation (WHiTE) cohort was set up in 2014 to measure outcomes, including health-related quality of life, among UK patients with hip fracture.¹⁴ It uses the same eligibility criteria as the NHFD, so all patients with a hip fracture

are included unless they are younger than 60 years or are treated nonoperatively. The data in WHiTE are broadly representative of the UK hip fracture population captures in the NHFD.^{15,16} The detailed study protocol has been described elsewhere.¹⁷ A number of randomized controlled trials are embedded within the WHiTE cohort (WHiTE 3,¹⁸ WHiTE4,¹⁹ WHiTE Five,²⁰ WHiSH,²¹ and WHiTE 8 COPAL²²). Patients included in this study were a subset of the full WHiTE cohort as the health economics component of the questionnaire was introduced to the cohort in April 2017. Hence, only patients who had completed their baseline questionnaire between May 2017 and April 2018 were included in this study.

Collection of health resource use data. Patients, or their main carer for those with cognitive impairment, completed a questionnaire at baseline, reflecting pre-injury status and four months post-injury. In the baseline resource use section of the questionnaire, patients were asked about their use of a formal full-time or part-time home care, informal care if they were not in a residential care home or nursing home, or in a hospital in the four months leading up to their hip fracture. In the four-month questionnaire, the same questions were asked in the resource use section, with participants reporting on their use based on their recall since the time of discharge from their acute hospital stay. Additional health resource items in the four-month health resource section included home adaptations as well as NHS-funded and privately funded physiotherapy sessions.

Cost of health resources. A descriptive cost analysis of formal and informal care, home adaptations, and physiotherapy, based on available cases, was performed. Available case analysis refers to analysis of all observed data at each timepoint from participants who completed baseline and/or four-month health resource section. The cost of formal care included cost of residential care facilities such as residential or nursing homes, as well as full- or part-time formal care at home.

The unit costs of health resources were obtained from the 2018 Personal Social Services Research Unit (PSSRU)²³ publication (Table I).²³⁻³⁰ The estimated cost of each health resource item per patient was calculated by multiplying the frequency of resource use by the unit cost per resource (where applicable) and were expressed in 2017/2018 pound sterling (£). Unit costs were adjusted to 2017/2018 prices using the 2018 NHS Hospital & Community Health Services (HCHS) index²³ for health service resources as necessary. No discounting of costs was applied since the time horizon was only four months.

In order to compute the estimated cost of health resource per patient, the following assumptions were made: 1) patients who reported living in residential care facilities at four months were assumed to have lived there since discharge from the acute hospital and hence not to have received any formal or informal care at their own home;

Table I. Unit cost of health resource (in 2017/18 £)²³⁻³⁰

Resource item	Unit type	Unit cost, £	Source
Formal care			
Residential care facilities			
Residential home	Week	847.00	PSSRU 2018 p.27 ²³
Nursing home	Week	698.80*	PSSRU 2010 p.49 ²⁴
Full-time home	Hour	18.93	UKHCA, 2019 ²⁵
Part-time home	Hour	26.36*	PSSRU 2017 p.125 ²⁶
Informal care			
Median wage	week	569.00	Office for National Statistics, 2019 ²⁷
Home adaptation			
Bathroom	each	4,563.00*	Garrett, 2016: Table 11 ²⁸
Bedroom	each	118.00	PSSRU 2018 p.92 ²³
Fixed hoist	each	3,194.10*	Garrett, 2016: Table 11 ²⁸
Grab rail	each	99.90	PSSRU 2018 p.92 ²³
Level-access shower	each	5,078.00	PSSRU 2018 p.92 ²³
Outdoor rail	each	95.80	PSSRU 2018 p.92 ²³
Ramp	each	906.00	PSSRU 2018 p.92 ²³
Stair lift	each	2,046.00	PSSRU 2018 p.91 ²³
Steps	each	879.00	PSSRU 2018 p.92 ²³
Toilet	each	2,535.00*	Garrett, 2016: Table 11 ²⁸
Physiotherapy			
NHS	hour	38.53*	PSSRU 2015 p.217 ²⁹
Private	hour	75.00	The Physio Centre, 2018 ³⁰

*Inflated to 2017/18 cost using hospital and community health services' pay and price inflation.

PSSRU, Personal Social Services Research Unit; UKHCA, United Kingdom Home Care Association.

2) patients who reported staying in residential care facilities since discharge were assumed not to have any home adaptations; 3) patients who reported having formal full-time care were assumed not to have any informal care; 4) patients who reported staying in residential care facilities/hospitals or had formal full-time care were assumed not to have any physiotherapy; 5) among patients who indicated they received formal care, unless otherwise stated, they were assumed to have only one formal (full-time/part-time) carer; 6) if patients indicated receiving formal part-time care from more than one carer at a time, their reported use of formal part-time care was based on the carer who provided the longest duration of care; 7) no gender wage gap was applied during computation of the cost of informal care; 8) mean physiotherapy duration was one hour per session, and the number reported per week applied to each week within the four months; and 9) 37.5 working hours per week was assumed.

Statistical analysis. Descriptive statistics such as percentage, mean, and SD for normally distributed variables, as well as median and interquartile range (IQR) for non-normally distributed variables were used to describe the patients' baseline characteristics. Costs were expressed in mean (SD) but the median and IQR were also presented in the tables since the cost was positively skewed. Statistical analysis was performed using R (version 3.5.2; R Foundation for Statistical Computing, Vienna, Austria).

Some patients reported that they received informal care 24 hours per day in the previous four months. This could be due to the difficulty in defining informal care in terms of the nature of the caring tasks and the care intensity, for example when a carer lived at the same address.³¹ Therefore, we performed a sensitivity analysis where we categorized patients who reported receiving informal care for more than 17.2 hours per day as outliers. After considering the mean UK sleep time of 6.8 hours,³² we capped their amount of informal care to waking hours at 17.2 hours per day.

Results

Study population. A total of 4,183 patients completed the baseline questionnaire, including the health economics component, between May 2017 and April 2018. Of these, 3,524 patients (84.2%) completed the four-month health economics component. At baseline, the majority of the patients were female (69.6%, n = 2,913), were non-smokers (79.1%, n = 3,310), were mobile outdoors with one or two aid(s) (60.9%, n = 2,546), and had severe systemic disease (53.5%, n = 2,238) based on the American Society of Anesthesiologists (ASA) physical status grade.^{33,34} Based on the Abbreviated Mental Test Score (AMTS)³⁵ presented in Table I, the median postoperative AMTS was 9 (IQR 7 to 10) and the proportion of patients with AMTS of less than seven (which suggests cognitive impairment) was 22.3% (n = 934). The most common type of fracture was a displaced intracapsular fracture (46.1%, n = 1,928), treated with a hemiarthroplasty (38.3%, n = 1,602) (Table II).

Completion rate. Completion rates per question varied between 75% and 89% for the pre-injury health resource section, and between 96% and nearly 100% at four months (Table III). Completion rate at four months is higher than at baseline because the completion of the baseline health resource section was not mandatory, unlike baseline clinical information. The high completion rate suggests that enough useful information could be extracted from the patients' responses in order to estimate the utilization rate and mean cost of health resources per patient during pre- and post-injury periods.

Utilization rate of health resource. Table IV reports the noticeable increase in utilization of part-time home care (from 12.0% (n = 501) pre-injury to 23.6% (n = 832) post-injury) and informal care (17.7% (n = 739) pre-injury and 35.2% (n = 1,242) post-injury) after a hip fracture. Among 2,288 patients who returned to their own home by four months post-injury, 1,630 (71.2%) had formal or informal care while 1,142 (49.9%) had at least one form of home adaptation. The utilization rate of NHS or private physiotherapy between discharge from their index hospital and four months post-injury among patients who returned to their own home was 54.9% (n = 1,256).

Mean cost per patient. In the base case analysis, the main cost driver pre-injury was formal care; this changed

Table II. Baseline characteristics of patients from the World Hip Trauma Evaluation cohort between May 2017 and April 2018

Characteristic	WHITE cohort (n = 4,183)*
Mean age, yrs (SD)	82.8 (8.6)
Sex, n (%)	
Female	2,913 (69.6)
Male	1,270 (30.4)
Diabetes, n (%)	
No	3,108 (74.3)
Yes	591 (14.1)
Unknown	484 (11.6)
Smoker, n (%)	
No	3,310 (79.1)
Yes	374 (8.9)
Unknown	499 (11.9)
Renal failure, n (%)	
No	3,389 (81.0)
Yes	295 (7.1)
Unknown	499 (11.9)
Median preoperative AMTS (IQR)	9 (7 to 10)
Median postoperative AMTS (IQR)	9 (7 to 10)
Pre-injury mobility, n (%)	
Freely mobile without aids	36 (0.9)
Mobile outdoors with one aid	1,602 (38.3)
Mobile outdoors with two aids or frame	944 (22.6)
Some indoor mobility	665 (15.9)
No functional mobility	785 (18.8)
Unknown	151 (3.6)
ASA physical status grade, n (%)	
I	84 (2.0)
II	907 (21.7)
III	2,238 (53.5)
IV	592 (14.2)
V	15 (0.4)
Unknown	347 (8.3)
Fracture classification, n (%)	
Intertrochanteric	1,748 (41.8)
Intracapsular (undisplaced)	238 (5.7)
Intracapsular (displaced)	1,928 (46.1)
Subtrochanteric	141 (3.4)
Unknown	128 (3.1)
Operation type, n (%)	
Hemiarthroplasty	1,602 (38.3)
Total hip arthroplasty	378 (9.0)
Screw fixation	85 (2.0)
Intramedullary nail fixation	537 (12.8)
Sliding hip screw fixation	1,429 (34.2)
Other	26 (0.6)
Unknown	126 (3.0)

*Due to rounding off errors, the percentages may not always add up to 100%. AMTS, abbreviated mental test score; ASA, American Society of Anesthesiologists; IQR, interquartile range; WHITE, World Hip Trauma Evaluation.

Table III. Completion rate (%) of health resource items during pre- and post-injury

Resource item	Pre-injury (n = 4,183)	Post-injury (n = 3,524)
Formal care		
Residential care facilities	3,705 (88.6)	3,516 (99.8)
Full-time home	3,543 (84.7)	3,461 (98.2)
Part-time home	3,497 (83.6)	3,451 (97.9)
Informal care	3,149 (75.3)	3,420 (97.0)
Home adaptation	N/A	3,490 (99.0)
Physiotherapy		
NHS	N/A	3,375 (95.8)
Private	N/A	3,381 (95.9)

N/A, not applicable.

to informal care in the post-injury phase (Figure 1). However, in the sensitivity analysis, where informal care was capped, the main cost driver was formal care, both before and after the injury.

Only 75 (8.2%) patients reported that informal carers were providing over 155 hours of care per week (or approximately 22 to 24 hours per day) before their injury. This rose to 511 (34.8%) in the four months post-injury (Figure 2). Applying the limit of 17.2 hours per day (or 120.4 hours per week) for informal care would drastically decrease the mean cost of informal care from £1,761 (SD 7,297) to £361 (SD 819) in the four months prior to the injury and from £6,613 (SD 15,146) to £660 (SD 1,040) in the four months after the injury (Table V). This in turn resulted in a decrease in the total mean cost in the sensitivity analysis, where the overall cost decreased from £3,659 (SD 7,992) to £2,470 (SD 4,669) during the pre-injury time frame and was almost halved from £9,969 (SD 15,173) to £4,189 (SD 5,426) during the post-injury time frame. However, if median cost and its IQR were considered, median cost of informal care pre-injury remained unchanged due to its positive skewness while the IQR became narrower (from £0 to £2,064, to £0 to £1,827) when the number of hours of informal care was capped. Estimated mean costs for home adaptations and physiotherapy were £706 (SD 1,706; median £0, IQR 0 to 100) and £9 (SD 33; median 0, IQR 0 to 8), respectively.

Discussion

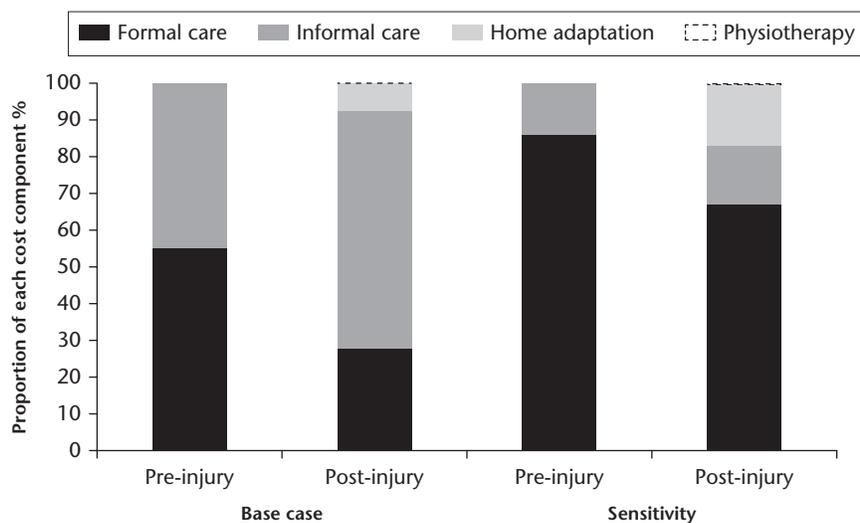
This feasibility study found that there is considerable variation in the interpretation of informal care, which might explain informal care being the main cost driver for patients over the age of 60 years following a hip fracture but formal care being the main cost driver after the informal care hours were capped at 17.2 hours per day. The high levels of informal care reported could be due to some patients signalling the care availability instead of the time-use of care as patients in this study had found it difficult to assess the time and intensity of informal care, particularly when carers live at the same address as the patient. However, since the mode of administration and content of the resource use section was the same before and after the injury, any measurement error can be assumed to be the same for both. Therefore, while the magnitude of the use of informal care may be subject to interpretation, there is a clear increase in the need for informal care following a hip fracture.

Based on a study conducted by Leal et al,³⁶ the mean cost of hospital treatment in the 12 months following a hip fracture in the UK was approximately £8,613 (in 2012/2013 prices). This would amount to around £8,813 in 2017/2018 prices after adjusting for inflation using the HCHS index. If the amount of formal and informal care recorded in this study were assumed to remain constant between four and 12 months, the mean cost

Table IV. Utilization rate of health resources and estimated cost per patient over four months for pre- and post-injury periods (in 2017/18 £)

Resource item	Pre-injury (n = 4,183)			Post-injury (n = 3,524)		
	No. of patients (%)	Mean cost, £ (SD)	Median cost, £ (IQR)	No. of patients (%)	Mean cost, £ (SD)	Median cost, £ (IQR)
Formal care						
Residential care facilities						
Residential home	292 (7.0)	1,135 (3,880)	0 (0 to 0)	265 (7.5)	1,085 (3,802)	0 (0 to 0)
Nursing home	188 (4.5)	603 (2,608)	0 (0 to 0)	326 (9.3)	1,101 (3,446)	0 (0 to 0)
Full-time home	107 (2.6)	21 (122)	0 (0 to 0)	39 (1.1)	8 (75)	0 (0 to 0)
Part-time home	501 (12.0)	435 (1,774)	0 (0 to 0)	832 (23.6)	669 (3,016)	0 (0 to 0)
Informal care	739 (17.7)	1,761 (7,297)	0 (0 to 0)	1,242 (35.2)	6,613 (15,146)	0 (0 to 0)
Home adaptation						
Bathroom	N/A	N/A	N/A	407 (11.5)	532 (1,465)	0 (0 to 0)
Bedroom	N/A	N/A	N/A	13 (0.4)	0.44 (7.19)	0 (0 to 0)
Fixed hoist	N/A	N/A	N/A	11 (0.3)	10 (179)	0 (0 to 0)
Grab rail	N/A	N/A	N/A	584 (16.6)	17 (37)	0 (0 to 0)
Level-access shower	N/A	N/A	N/A	34 (1.0)	49 (499)	0 (0 to 0)
Outdoor rail	N/A	N/A	N/A	92 (2.6)	2.53 (15)	0 (0 to 0)
Ramp	N/A	N/A	N/A	27 (0.8)	7.01 (79)	0 (0 to 0)
Stair lift	N/A	N/A	N/A	135 (3.8)	79 (395)	0 (0 to 0)
Steps	N/A	N/A	N/A	15 (0.4)	3.78 (58)	0 (0 to 0)
Toilet	N/A	N/A	N/A	7 (0.2)	5.08 (113)	0 (0 to 0)
Physiotherapy						
NHS	N/A	N/A	N/A	1,206 (34.2)	8.22 (33)	0 (0 to 6.94)
Private	N/A	N/A	N/A	87 (2.5)	0.74 (6.76)	0 (0 to 0)

IQR, interquartile range; N/A, not applicable.

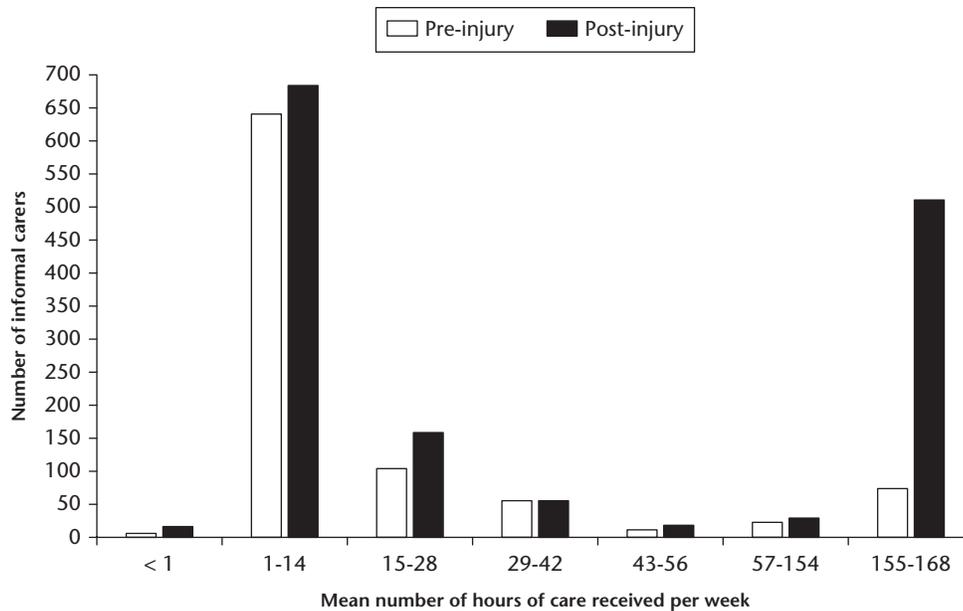
**Fig. 1**

Mean cost of each cost component during pre- and post-injury for base case and sensitivity analysis.

of formal care after a hip fracture would be similar at around £8,529, and mean cost of informal care would be about £1,980 over 12 months, using the conservative estimate of informal care from our sensitivity analysis. Given that the majority of the patients reported a need for formal or informal care following their injury, these costs clearly need to be included when examining the 'true' economical burden of hip fractures in older patients. We found that informal care plays a significant role in the care of older patients in the UK. Around 85% of the 2.3 million elderly with functional disabilities

living in private households in England received informal care³⁷ and, according to the National Audit Office, the value of informal care provided in 2015/16 is comparable to the national spending on healthcare and significantly outweighs that of formal care provided by local government and the NHS.³⁸

There is a desire of the majority of older people to live independently in their own homes for as long as possible and home adaptations have been shown to improve older and disabled people's quality of life by enabling such independence.^{39,40} This is reflected in our


Fig. 2

Frequency of the mean number of hours of informal care received per week during pre- and post-injury.

Table V. Estimated cost of the main cost components per patient over four months in base case and sensitivity analyses (in 2017/18 £)

Analysis	Pre-injury (n = 4,183)		Post-injury (n = 3,524)	
	Mean cost, £ (SD)	Median cost, £ (IQR)	Mean cost, £ (SD)	Median cost, £ (IQR)
Base case				
Formal care	2,164 (4,684)	0 (0 to 710)	2,843 (5,467)	0 (0 to 2,241)
Informal care	1,761 (7,297)	0 (0 to 0)	6,613 (15,146)	0 (0 to 2,064)
Home adaptation	N/A	N/A	706 (1,706)	0 (0 to 100)
Physiotherapy	N/A	N/A	9 (33)	0 (0 to 8)
Total	3,659 (7,992)	0 (0 to 3,137)	9,969 (15,173)	3,620 (0 to 11,880)
Sensitivity				
Informal care	361 (819)	0 (0 to 0)	660 (1,040)	0 (0 to 1,827)
Total	2,470 (4,669)	0 (0 to 1,827)	4,189 (5,426)	1,846 (0 to 6,499)

IQR, interquartile range; N/A, not applicable.

preliminary results where 981 (85.9%) patients who lived in their homes and made at least one home adaptation were patients with limited mobility (i.e. needed at least one aid or help to move around). Although almost half of the patients who live in their homes reported not having physiotherapy within 120 days since discharge, it remains unknown if this was due to patient's choice or the logistics of receiving rehabilitation after leaving the hospital. According to the Physiotherapy Hip Fracture Sprint Audit, the wait for physiotherapy after a hip fracture was 15 days on average but could be as high as 80 days.⁴¹

To our knowledge, this is the first study that estimates the cost of informal care as a result of a hip fracture in the UK. However, it is not without its limitations. In order to keep the length of the questionnaire short to reduce respondent fatigue and increase completion rate of health resource use in a frail elderly cohort, assumptions that could underestimate/overestimate the cost of the

examined health resources were made. Patients who had died before the completion of the four-month questionnaire were treated as non-response (n = 38, or 0.9% of the baseline population) instead of assuming that they had not incurred any cost. These patients were likely to require more care before they died and hence the actual cost of care may be underestimated in this study. Patients who reported to be living in residential care facilities at four months were assumed to have stayed there since discharge from the acute hospital, although patients could potentially have been discharged home and then moved to a care facility. Hence, the cost of residential care could be overestimated and the cost of formal home care, informal care, home adaptation, or physiotherapy could in turn be underestimated. Likewise, we assumed that patients living in residential care facilities/hospitals or those who had formal full-time care would not have any physiotherapy. While it seems unlikely that patients

received much physiotherapy in these contexts, this could lead to an underestimate of the physiotherapy costs. We did not collect detailed information on the home care companies which patients used or how much the patient paid out-of-pocket versus how much was subsidized by the local government agency in order to reduce the length of the questionnaire to prevent respondent fatigue. We used the UK Home Care Association's estimation of the minimum price that homecare providers need to receive from councils as a conservative estimate of the cost of full-time home care.

Another key limitation is the difficulty patients had in reporting their use of informal care. Although we sought to account for this in our sensitivity analysis, those results may still overestimate informal care as the carer was assumed to be providing care except when he/she was sleeping. The challenges when measuring the amount of informal care using surveys are not unique to this study; similar concerns were reported in the English Longitudinal Study of Ageing.³¹ These challenges, nonetheless, must be borne in mind when designing, conducting, and interpreting results from these types of studies.

Based on findings from this feasibility study, the health resource section used in the WHiTE cohort and embedded randomized trials will be refined, with emphasis on capturing the time-use of informal care by patients in order to obtain more accurate cost estimates. We will include a definition of informal care with an emphasis on stating the time taken to perform specific tasks. This is consistent with the practice used in validated questionnaires on productivity loss and informal care.⁴²

In conclusion, formal and informal care are the major drivers of costs for patients after they leave hospital following a hip fracture and should be included in economic analyses where an accurate measure of overall costs is necessary. Informal costs in particular can be challenging to collect but understanding the complexities of these data can help design questionnaires that produce reliable estimates. Once more reliable estimates can be obtained, future work could include subgroup analysis of formal and informal care by, for example, patients with cognitive impairment versus those without.

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- M. E. Png: Analyzed the data, Wrote the manuscript.
- X. L. Griffin: Designed the study, Critically reviewed the manuscript.
- M. L. Costa: Designed the study, Critically reviewed the manuscript.
- J. Achten: Critically reviewed the manuscript.
- R. Pinedo-Villanueva: Critically reviewed the manuscript.

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Conflict of interest statement

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Ethical review statement

- The World Hip Trauma Evaluation (WHiTE) cohort study has NHS Research Ethics Committee (REC) Approval (on 18 August 2011 by London-Camberwell St Giles REC; ref. 11/LO/0927) and approval from the Research and Development Department at each recruiting hospital. The study is registered with the National Institute for Health Research Portfolio (UKCRN ID 12351) and the ISRCTN registry (ISRCTN63982700).

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