Falls: assessment and prevention of falls in older people

NICE clinical guideline

Draft for consultation, January 2013

This clinical guideline provides recommendations on the assessment and prevention of falls in older people in both inpatient and community settings. This extends and replaces 'Falls: assessment and prevention of falls in older people' NICE clinical guideline 21 (2004), which provided recommendations for the community setting only.

This document includes all the recommendations, details of how they were developed and summaries of the evidence they were based on.

> You are invited to comment on the new recommendations (marked **[new 2013]**) and new content in this guideline only.
>
> Please do not comment on content from NICE clinical guideline 21. This content is greyed out and defined by a red box and/or labelled **[2004]**. Any comments made on this content will not be considered.
>
> Comments are invited for all appendices labelled 2013 but not for appendices labelled 2004.

This guideline has been developed following the methods and processes outlined in the 'NICE guidelines manual' (2009).

Contents

All appendices are in separate files.

Introduction

Falls and fall-related injuries are a common and serious problem for older people. People aged 65 and older have the highest risk of falling, with 30% of people older than 65 and 50% of people older than 80 falling at least once a year. This is estimated to cost the NHS more than £2.3 billion per year (College of Optometrists/British Geriatrics Society, 2011).

The human cost of falling includes distress, pain, injury, loss of confidence, loss of independence and mortality. Falling also affects the family members and carers of people who fall. Therefore falling has an impact on quality of life, health and healthcare costs.

This guideline provides recommendations for the assessment and prevention of falls in both inpatient and community settings. It is an extension to the remit of NICE clinical guideline 21 (published November 2004) to include falls in a hospital inpatient setting.

The 2 main parts of the guideline are as follows:

- Inpatient setting (section 3). New evidence has been reviewed and new recommendations have been made for the assessment and prevention of falls in the inpatient setting. This part was developed by the Internal Clinical Guidelines Programme in the Centre for Clinical Practice at NICE.
- Community setting (section 4). Evidence on the assessment and prevention of falls in the community setting has not been updated and the original 2004 recommendations remain unchanged (except for some minor wording changes for the purposes of clarification only). This part was originally developed by the National Collaborating Centre for Nursing and Supportive Care (now part of the National Clinical Guideline Centre) and published by the Royal College of Nursing.

Methods used to develop the guideline

The methods used to develop this guideline were different for different sections, because of the evolution of guideline development methodology. The ‘inpatient setting’ section (section 3) contains new evidence and

recommendations that were developed using The guidelines manual (2009). The 'community setting' section (section 4) comprises the previous 2004 guideline (CG21), which has been maintained as far as possible in its original structure and style (although it has been renumbered to maintain consistency throughout the entire guideline). This has inevitably led to inconsistencies in style. For example, GRADE methodology is used in section 3 to assess the quality and strength of the evidence and recommendations, whereas in section 4 the evidence and recommendations are graded using the old evidence hierarchy. In addition, in section 3 (developed in 2004) older people are defined as those aged 65 and older, but more recently the Department of Health has recognised that there are different interpretations of 'older people', some of which include people from the age of 50. Section 4 of the guideline reflects this, and some of the new recommendations also cover people aged 50 and above. The different sections of the guideline contain details of the methodology used at the time of development (see appendix J [2004] and appendix [2013]).

It is important to emphasise that although guideline methodology has changed over time, all of the 2004 recommendations are just as relevant and important now as they were when they were originally published.

Who this guideline is for

This document is for healthcare and other professionals and staff who care for older people who are at risk of falling.

Populations covered by this guideline

All people aged 65 or older are covered by all guideline recommendations. This is because people aged 65 and older have the highest risk of falling in both inpatient and community settings.

People aged 50 to 64 who are admitted to hospital and are identified by a clinician as being at risk of falling (for example, patients with a sensory impairment or dementia, and patients admitted to hospital with a fall, stroke, syncope, delirium or gait disturbances) are also covered by the guideline recommendations that relate to the inpatient setting.

Patient-centred care

This guideline offers best practice advice on the care of older people who are at risk of falling.

Patients and healthcare professionals have rights and responsibilities as set out in the NHS Constitution for England – all NICE guidance is written to reflect these. Treatment and care should take into account individual needs and preferences. Patients should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If someone does not have the capacity to make decisions, healthcare professionals should follow the Department of Health's advice on consent, the code of practice that accompanies the Mental Capacity Act and the supplementary code of practice on deprivation of liberty safeguards. In Wales, healthcare professionals should follow advice on consent from the Welsh Government.

NICE has produced guidance on the components of good patient experience in adult NHS services. All healthcare professionals should follow the recommendations in Patient experience in adult NHS services.

Strength of recommendations

Some recommendations can be made with more certainty than others. The Guideline Development Group makes a recommendation based on the trade-off between the benefits and harms of an intervention, taking into account the quality of the underpinning evidence. For some interventions, the Guideline Development Group is confident that, given the information it has looked at, most patients would choose the intervention. The wording used in the recommendations labelled **[new 2013]** in this guideline denotes the certainty with which the recommendation is made (the strength of the recommendation).

For all recommendations, NICE expects that there is discussion with the patient about the risks and benefits of the interventions, and their values and preferences. This discussion aims to help them to reach a fully informed decision (see also 'Patient-centred care').

Interventions that must (or must not) be used

We usually use 'must' or 'must not' only if there is a legal duty to apply the recommendation. Occasionally we use 'must' (or 'must not') if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

Interventions that should (or should not) be used – a 'strong' recommendation

We use 'offer' (and similar words such as 'refer' or 'advise') when we are confident that, for the vast majority of patients, an intervention will do more good than harm, and be cost effective. We use similar forms of words (for example, 'Do not offer…') when we are confident that an intervention will not be of benefit for most patients.

Interventions that could be used

We use 'consider' when we are confident that an intervention will do more good than harm for most patients, and be cost effective, but other options may be similarly cost effective. The choice of intervention, and whether or not to

have the intervention at all, is more likely to depend on the patient's values and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the patient.

Wording of 2004 recommendations

NICE began using this approach to denote the strength of recommendations in guidelines that started development after publication of the 2009 version of 'The guidelines manual' (January 2009). This does not apply to any recommendations shaded in grey and ending **[2004]** (see 'Labelling of recommendations' box below for details about how recommendations are labelled). In particular, for recommendations labelled **[2004]**, the word 'consider' may not necessarily be used to denote the strength of the recommendation.

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Labelling of recommendations

This guideline is an extension of NICE clinical guideline 21 (published November 2004) and will replace it.

New recommendations have been added about falls in the inpatient setting (labelled **[2013]**). You are invited to comment on these recommendations and the new content.

The original recommendations from NICE clinical guideline 21 about falls in the community setting are incorporated unchanged (except for minor wording changes shaded in yellow that have been made for the purposes of clarification only). These recommendations are shaded in grey and end **[2004]**. Please do not comment on these recommendations or on other content from NICE clinical guideline 21. This content is shaded in grey and defined by a red box. Any comments made on this content will not be considered.

Comments are invited for all appendices labelled 2013 but not for appendices labelled 2004.

2

3

Key priorities for implementation

The following recommendations have been identified as priorities for implementation.

Inpatient setting

- Regard the following groups of inpatients as being at risk of falling in hospital and manage their care according to recommendations 1.1.2.1 to 1.1.3.1:
  - all patients aged 65 years or older
  - patients aged 50 to 64 years who are identified by a clinician as being at higher risk of falling (for example, patients with a sensory impairment or dementia, and patients admitted to hospital with a fall, stroke, syncope, delirium or gait disturbances). **[new 2013] [1.1.1.1]**

- For patients at risk of falling in hospital (see recommendation 1.1.1.1), consider a multifactorial assessment[1] and multifactorial interventions[2]. **[new 2013] [1.1.2.2]**

- Ensure that any multifactorial assessment[1] identifies a patient's individual risk factors for falling in hospital that can be treated, improved or managed during their expected stay, including:
  - cognitive impairment
  - continence problems
  - falls history, including causes and consequences (such as injury and fear of falling)
  - footwear that is unsuitable or missing
  - health problems that may increase their risk of falling
  - medication
  - postural instability, mobility problems and/or balance problems
  - visual impairment. **[new 2013] [1.1.2.3]**

[1] An assessment with multiple components that aims to identify risk factors that can be treated, managed or improved.
[2] An intervention with multiple components that is linked to a person's multifactorial assessment.

Community setting

- Older people in contact with healthcare professionals should be asked routinely whether they have fallen in the past year and asked about the frequency, context and characteristics of the fall/s. **[2004] [1.2.1.1]**

- Older people who present for medical attention because of a fall, or report recurrent falls in the past year, or demonstrate abnormalities of gait and/or balance should be offered a multifactorial falls risk assessment. This assessment should be performed by a healthcare professional with appropriate skills and experience, normally in the setting of a specialist falls service. This assessment should be part of an individualised, multifactorial intervention. **[2004] [1.2.2.1]**

1 Recommendations

1.1 Inpatient setting

1.1.1 Predicting patients' risk of falling in hospital

1.1.1.1 Regard the following groups of inpatients as being at risk of falling in hospital and manage their care according to recommendations 1.1.2.1 to 1.1.3.1:

- all patients aged 65 years or older
- patients aged 50 to 64 years who are identified by a clinician as being at higher risk of falling (for example, patients with a sensory impairment or dementia, and patients admitted to hospital with a fall, stroke, syncope, delirium or gait disturbances). **[new 2013]**

1.1.1.2 Do not use numerical fall risk prediction tools to predict inpatients' risk of falling in hospital. **[new 2013]**

1.1.2 Assessment and interventions

1.1.2.1 Ensure that aspects of the inpatient environment that could affect patients' risk of falling (such as flooring, lighting and provision of hand holds) are systematically identified and addressed. **[new 2013]**

1.1.2.2 For patients at risk of falling in hospital (see recommendation 1.1.1.1), consider a multifactorial assessment[3] and multifactorial interventions[4]. **[new 2013]**

1.1.2.3 Ensure that any multifactorial assessment[3] identifies a patient's individual risk factors for falling in hospital that can be treated, improved or managed during their expected stay, including:

[3] An assessment with multiple components that aims to identify risk factors that can be treated, managed or improved.
[4] An intervention with multiple components that is linked to a person's multifactorial assessment.

- cognitive impairment
- continence problems
- falls history, including causes and consequences (such as injury and fear of falling)
- footwear that is unsuitable or missing
- health problems that may increase their risk of falling
- medication
- postural instability, mobility problems and/or balance problems
- visual impairment. **[new 2013]**

1.1.2.4 Ensure that any multifactorial interventions[5]:

- promptly address the patient's identified individual risk factors for falling in hospital **and**
- take into account whether the risk factors can be treated, improved or managed during the patient's expected stay. **[new 2013]**

1.1.2.5 Do not offer falls prevention interventions that are not tailored to address the patient's individual risk factors for falling. **[new 2013]**

1.1.3 Information and support

1.1.3.1 Provide relevant oral and written information and support for patients and their family members and carers, taking into account the patient's ability to understand and retain information. This should include:

- explaining about the patient's individual risk factors for falling in hospital
- showing the patient how to use the nurse call system and encouraging them to use it when they need help

[5] An intervention with multiple components that is linked to a person's multifactorial assessment.

- informing family members and carers about when and how to raise and lower bed rails
- providing consistent messages about when a patient should ask for help before getting up or moving about
- helping the patient to engage in any multifactorial interventions that are part of their care plan. **[new 2013]**

1.2 Community setting

1.2.1 Case/risk identification

1.2.1.1 Older people in contact with healthcare professionals should be asked routinely whether they have fallen in the past year and asked about the frequency, context and characteristics of the fall/s. **[2004]**

1.2.1.2 Older people reporting a fall or considered at risk of falling should be observed for balance and gait deficits and considered for their ability to benefit from interventions to improve strength and balance. (Tests of balance and gait commonly used in the UK are detailed in section 4.5.) **[2004]**

1.2.2 Multifactorial falls risk assessment

1.2.2.1 Older people who present for medical attention because of a fall, or report recurrent falls in the past year, or demonstrate abnormalities of gait and/or balance should be offered a multifactorial falls risk assessment. This assessment should be performed by a healthcare professional with appropriate skills and experience, normally in the setting of a specialist falls service. This assessment should be part of an individualised, multifactorial intervention. **[2004]**

1.2.2.2 Multifactorial assessment may include the following:

- identification of falls history
- assessment of gait, balance and mobility, and muscle weakness
- assessment of osteoporosis risk
- assessment of the older person's perceived functional ability and fear relating to falling
- assessment of visual impairment
- assessment of cognitive impairment and neurological examination
- assessment of urinary incontinence

- assessment of home hazards
- cardiovascular examination and medication review**. [2004]**

1.2.3 Multifactorial interventions

1.2.3.1 All older people with recurrent falls or assessed as being at increased risk of falling should be considered for an individualised multifactorial intervention. **[2004]**

In successful multifactorial intervention programmes the following specific components are common (against a background of the general diagnosis and management of causes and recognised risk factors):

- strength and balance training
- home hazard assessment and intervention
- vision assessment and referral
- medication review with modification/withdrawal. **[2004]**

1.2.3.2 Following treatment for an injurious fall, older people should be offered a multidisciplinary assessment to identify and address future risk and individualised intervention aimed at promoting independence and improving physical and psychological function. **[2004]**

1.2.4 Strength and balance training

1.2.4.1 Strength and balance training is recommended. Those most likely to benefit are older people living in the community with a history of recurrent falls and/or balance and gait deficit. A muscle-strengthening and balance programme should be offered. This should be individually prescribed and monitored by an appropriately trained professional. **[2004]**

1.2.5 Exercise in extended care settings

1.2.5.1 Multifactorial interventions with an exercise component are recommended for older people in extended care settings who are at risk of falling. **[2004]**

1.2.6 Home hazard and safety intervention

1.2.6.1 Older people who have received treatment in hospital following a fall should be offered a home hazard assessment and safety intervention/modifications by a suitably trained healthcare professional. Normally this should be part of discharge planning and be carried out within a timescale agreed by the patient or carer, and appropriate members of the health care team. **[2004]**

1.2.6.2 Home hazard assessment is shown to be effective only in conjunction with follow-up and intervention, not in isolation. **[2004]**

1.2.7 Psychotropic medications

1.2.7.1 Older people on psychotropic medications should have their medication reviewed, with specialist input if appropriate, and discontinued if possible to reduce their risk of falling. **[2004]**

1.2.8 Cardiac pacing

1.2.8.1 Cardiac pacing should be considered for older people with cardioinhibitory carotid sinus hypersensitivity who have experienced unexplained falls. **[2004]**

1.2.9 Encouraging the participation of older people in falls prevention programmes

1.2.9.1 To promote the participation of older people in falls prevention programmes the following should be considered.

- Healthcare professionals involved in the assessment and prevention of falls should discuss what changes a person is willing to make to prevent falls.

- Information should be relevant and available in languages other than English.
- Falls prevention programmes should also address potential barriers such as low self-efficacy and fear of falling, and encourage activity change as negotiated with the participant. **[2004]**

1.2.9.2 Practitioners who are involved in developing falls prevention programmes should ensure that such programmes are flexible enough to accommodate participants' different needs and preferences and should promote the social value of such programmes. **[2004]**

1.2.10 Education and information giving

1.2.10.1 All healthcare professionals dealing with patients known to be at risk of falling should develop and maintain basic professional competence in falls assessment and prevention. **[2004]**

1.2.10.2 Individuals at risk of falling, and their carers, should be offered information orally and in writing about:

- what measures they can take to prevent further falls
- how to stay motivated if referred for falls prevention strategies that include exercise or strength and balancing components
- the preventable nature of some falls
- the physical and psychological benefits of modifying falls risk
- where they can seek further advice and assistance
- how to cope if they have a fall, including how to summon help and how to avoid a long lie. **[2004]**

1.2.11 Interventions that cannot be recommended

1.2.11.1 **Brisk walking**. There is no evidence[6] that brisk walking reduces the risk of falling. One trial showed that an unsupervised brisk walking programme increased the risk of falling in postmenopausal women with an upper limb fracture in the previous year. However, there may be other health benefits of brisk walking by older people. **[2004]**

1.2.12 Interventions that cannot be recommended because of insufficient evidence

We do not recommend implementation of the following interventions at present. This is not because there is strong evidence against them, but because there is insufficient or conflicting evidence supporting them[6]. **[2004]**

1.2.12.1 **Low intensity exercise combined with incontinence programmes**. There is no evidence[6] that low intensity exercise interventions combined with continence promotion programmes reduce the incidence of falls in older people in extended care settings. **[2004]**

1.2.12.2 **Group exercise (untargeted).** Exercise in groups should not be discouraged as a means of health promotion, but there is little evidence[6] that exercise interventions that were not individually prescribed for older people living in the community are effective in falls prevention. **[2004]**

1.2.12.3 **Cognitive/behavioural interventions**. There is no evidence[6] that cognitive/behavioural interventions alone reduce the incidence of falls in older people living in the community who are of unknown risk status. Such interventions included risk assessment with feedback and counselling and individual education discussions. There is no evidence[6] that complex interventions in which group activities included education, a behaviour modification programme

[6] This refers to evidence reviewed in 2004.

aimed at moderating risk, advice and exercise interventions are effective in falls prevention with older people living in the community. **[2004]**

1.2.12.4 **Referral for correction of visual impairment.** There is no evidence[7] that referral for correction of vision as a single intervention for older people living in the community is effective in reducing the number of people falling. However, vision assessment and referral has been a component of successful multifactorial falls prevention programmes. **[2004]**

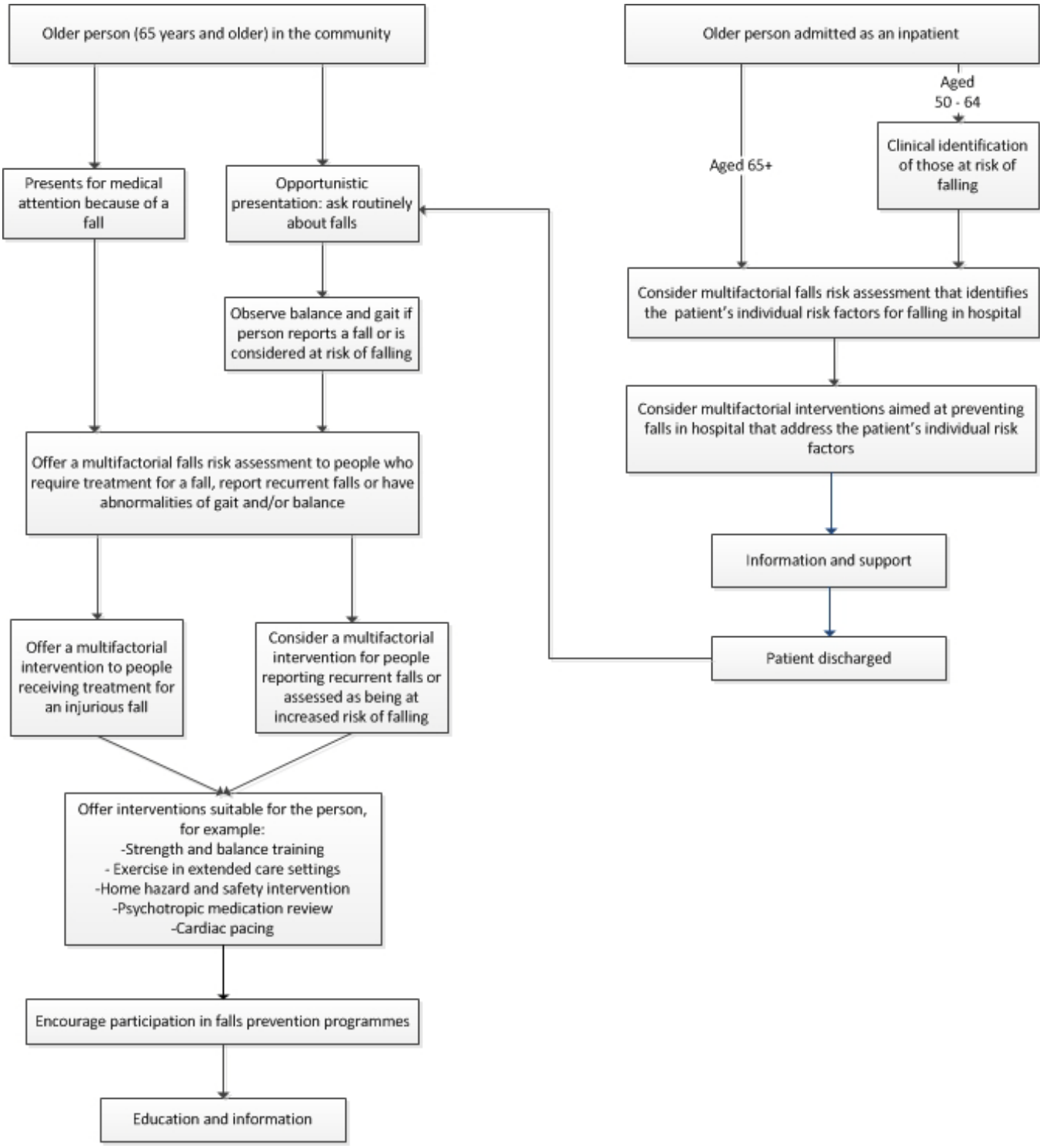
1.2.12.5 **Vitamin D.** There is evidence[7] that vitamin D deficiency and insufficiency are common among older people and that, when present, they impair muscle strength and possibly neuromuscular function, via CNS-mediated pathways. In addition, the use of combined calcium and vitamin D3 supplementation has been found to reduce fracture rates in older people in residential/nursing homes and sheltered accommodation. Although there is emerging evidence[7] that correction of vitamin D deficiency or insufficiency may reduce the propensity for falling, there is uncertainty about the relative contribution to fracture reduction via this mechanism (as opposed to bone mass) and about the dose and route of administration required. No firm recommendation can therefore currently be made on its use for this indication.[8] **[2004, amended 2013]**

1.2.12.6 **Hip protectors.** Reported trials that have used individual patient randomisation have provided no evidence[7] for the effectiveness of hip protectors to prevent fractures when offered to older people living in extended care settings or in their own homes. Data from cluster randomised trials provide some evidence[7] that hip

[7] This refers to evidence reviewed in 2004.
[8] The following text has been deleted from the 2004 recommendation: 'Guidance on the use of vitamin D for fracture prevention will be contained in the forthcoming NICE clinical practice guideline on osteoporosis, which is currently under development.' As yet there is no NICE guidance on the use of vitamin D for fracture prevention.

protectors are effective in the prevention of hip fractures in older people living in extended care settings who are considered at high risk. **[2004]**

2 Care pathway



All of section 3 is new and is open for consultation.

Please comment on section 3

3 Assessment and prevention of falls in older people: inpatient settings

3.1 Background

A scheduled review of NICE clinical guideline 21 identified that the inpatient setting should be included in the scope of that guideline to make the guideline more comprehensive, because effective interventions in community settings cannot simply be transferred to inpatient settings. Thus the Internal Clinical Guidelines Programme at NICE was commissioned to develop new recommendations on the assessment and prevention of falls in the inpatient setting.

Clinical need

Falls in hospitals are the most common patient safety incidents reported in hospital trusts in England, and treating inpatient falls alone costs the NHS more than £15 million per year (National Patient Safety Agency 2007).

Patients in hospital have a greater risk of falling than people in the community. This is partly because newly acquired risk factors (such as acute illness, delirium, cardiovascular disease, impaired mobility, medication and syncope) and unfamiliar surroundings can increase the risk of falling.

3.2 Methods used to develop this part of guideline

See appendix J for details of how this part of the guideline was developed.

3.3 Inpatient risk prediction : evidence review and recommendations

3.3.1 Review question

What risk prediction tool(s) or process(es) should be used to identify modifiable and non-modifiable risk factors for falling for patients in hospital? Does this method vary by inpatient setting?

3.3.2 Evidence review

This question focused on establishing which, if any, risk prediction tools should be used to predict which patients are at risk of falling in hospital and whether the risk prediction tool should vary depending on the inpatient setting. The Guideline Development Group (GDG) wanted to make it clear that they were specifically referring to risk prediction tools rather than assessment tools. This is because they felt that the term ‘assessment’ is often used interchangeably to refer to predicting or evaluating risk and to refer to a multifactorial risk assessment. In the context of falls, the GDG defined ‘risk prediction’ as a process applied to the entire inpatient population to predict which patients are at risk of falling during their hospital stay. The GDG defined ‘multifactorial assessment’ as a more in-depth and possibly on-going process of identifying falls risk factors that can be treated, managed or improved during the individual patient’s hospital stay, with the aim of reducing the patient’s risk of falling in hospital.

The initial search retrieved 1552 studies, and another 20 studies were identified through other sources. Studies were included in the review if they related to predicting which patients are at risk of experiencing a fall during their hospital stay. Only studies using a cross-sectional, cohort, case–control or randomised controlled trial design, and that were available in full text, were eligible for inclusion. Studies that did not relate to inpatient risk prediction tools, or that related to predicting fracture risk, were excluded. In addition, the GDG felt that further exclusion criteria should be applied. Published literature has suggested that fall risk prediction tools can be considered to be of high predictive value when they demonstrate sensitivities and specificities above

70% (Oliver et al. 2004; Perell et al. 2001; Scott et al. 2007). The GDG agreed with this, and only risk prediction tools or processes that demonstrated sensitivity and specificity values above 70% in at least one study were included. If a risk prediction tool or process met the threshold in one study, all studies regarding this tool/process were included in the analysis, even if they didn't achieve the threshold. This was done to ensure completeness in the evidence review. For a full list of excluded papers for this review question, see appendix G.

Thirteen full text articles met the eligibility criteria and were included in the final review. The quality of the included studies was assessed using appropriate NICE methodology checklists, and the GDG categorised each study according to the setting in which it was conducted (acute; non-acute; mixed or unclear).

GRADE (Grading of Recommendations Assessment, Development and Evaluation; see appendix J for details of the methods used) was applied to the studies using an approach developed by (Schunemann A. et al. 2008). In this approach prospective studies are regarded as high quality, and studies based on retrospective data as moderate quality. Any other design is considered low quality. Downgrading then takes place as appropriate with reference to study limitations, inconsistency, imprecision and indirectness as used in the standard GRADE approach, but with different criteria.

Meta-analysis was not conducted for this question, as the studies related to different risk prediction tools and it was not appropriate to combine the results. The summary table and the GRADE tables below present information for risk prediction tools or processes which demonstrated sensitivity values greater than 70% together with specificity values greater than 70% in at least one study. Appendix E (2013) contains the full summary and GRADE tables for the included studies.

Table 1 Summary of included studies for inpatient risk prediction

Study ID	Population	Risk prediction tool/process	Threshold
(Chu et al. 1999) Hong Kong	n=102 Mean age=77 years Medical inpatients	Clinical Judgement	Observation of lower limb weakness (<MRC grade 4) and Tandem walk 2 m (>2 errors)
(Eagle et al. 1999) Canada	n=98 Mean age=69 years (range 23-96). Rehabilitation and geriatric medical wards.	Clinical Judgement	NA
(Haines et al. 2006a) Australia	n=122 Mean age=79 years. Rehabilitation and aged care hospital.	Peter James Centre Falls Risk Assessment Tool (PJC-FRAT)	Recommendation of an alert card
	n=316 Mean age=80 years. Rehabilitation and aged care hospital.		
(Haines et al. 2009) Australia	n=1123 Mean age=75 years. Inpatient geriatric and rehabilitation units.	Clinical Judgement	NA
(Heinze et al. 2008) Germany	n=560 Mean age=82 years. Geriatric hospital	Hendrich Fall Risk Model	≥54
(Hendrich et al. 1995) USA	n=338 Mean age unclear. Patients admitted in one month in one teaching hospital.	Hendrich Fall Risk Model	≥3
(Maeda et al. 2009) Japan	n=72 Mean age=67.6 years Hemiplegic stroke patients	Berg Balance Scale	≥ 29
(Marschollek et al. 2009) Germany	n=110 Mean age=80 years (range 40-90). Inpatients in the department of geriatric medicine.	Clinical assessment (using Timed up and go, St Thomas's risk assessment tool in falling elderly inpatients, Barthel index, and sensory data)	Unclear
(Myers and Nikoletti 2003) Australia	n=226 Aged care and rehabilitation wards.	Clinical judgement	NA
(Nanda et al. 2011) USA	n=136 Mean age=80 years. Geriatric-psychiatric inpatients.	Fall Risk Assessment in Geriatric-Psychiatric Inpatients to Lower Events (FRAGILE)	≥0.05
(Rapport et al. 1993) USA	n=32 Participants were all Males (mean age=62 years, range=47-74) who were non-ambulatory and had sustained Right hemisphere stroke	Falls Assessment Questionnaire plus behavioural impulsivity measure.	≥0.55
(Vassallo et al. 2008) UK	n=200 Mean age=81 years Rehabilitation hospital	Clinical Judgement	Observation of wandering behaviour

Study ID	Population	Risk prediction tool/process	Threshold
(Walsh et al. 2011) Australia	n=130 Mean age=75 years (range 29-97). Acute medical and surgical wards.	Western Health Fall Risk Assessment (WHeFRA)	≥13

See Appendix E (2013) for summary tables for all included studies.

Table 2 GRADE table summary for inpatient risk prediction

2a) Acute setting

Studies	n	Index	TP	FP	FN	TN	Sens (95% CI)	Spec (95% CI)	Quality
Hendrich Fall Risk Model									
Threshold: ≥3									
1 Hendrich et al. (1995)	338	HFRM ≥3	79	67	23	169	77 (68-85)	72 (65-77)	V LOW
Western Health Falls Risk Assessment									
Score ≥10									
1 Walsh et al. (2010)	130	WHeFRA score ≥10	6	28	1	95	86 (42-100)	77 (69-84)	V LOW
Score ≥ 13									
1 Walsh et al. (2010)	130	WHeFRA score ≥13	6	10	1	113	86 (42-100)	92 (86-96)	V LOW
TP= True positive FP= False positive FN= False negative TN= True negative Sens= Sensitivity Spec= Specificity V LOW= Very low									

2b) Non-acute setting

Studies	n	Index	TP	FP	FN	TN	Sens (95% CI)	Spec (95% CI)	Quality
Berg Balance Scale									
Score ≤29									
1 Maeda et al. (2009)	72	Berg Balance Scale score 29	22	10	5	35	82 (65-98)	78 (65-91)	LOW
Falls Assessment Questionnaire									
Score >0.49									
1 Rapport et al. (1993)	32	Risk >0.49	15	7	0	10	100 (78-100)	59 (33-82)	LOW
Score >0.55									
1 Rapport et al. (1993)	32	FAQ plus behavioural impulsivity measure. Risk >0.55	12	3	3	14	80 (52-92)	82 (57-96)	LOW
Clinical Observation/Assessment									
Observation of wandering behaviour									
1 Vassallo et al. (2008)	200	Observation of wandering behaviours	22	14	29	135	43 (29-58)	91 (85-95)	LOW
1 Eagle et al. (1999)	98	Clinical judgement	22	35	7	34	76 (56-90)	49 (37-62)	V LOW
Peter James Centre Falls Risk Assessment Tool (PJC-FRAT)									
Recommendation of an Alert Card									
1 Haines et al. (2006)	122	Alert card	52	61	19	184	73 (61-83)	75 (69-80)	LOW
	316	Alert card	41	83	30	162	58 (45-68)	66 (60-71)	

TP= True positive
FP= False positive
FN= False negative
TN= True negative
Sens= Sensitivity
Spec= Specificity
V LOW= Very low

2c) Mixed or unclear setting

Studies	n	Index	TP	FP	FN	TN	Sens (95% CI)	Spec (95% CI)	Quality
Falls Risk Assessment in Geriatric-Psychiatric Inpatients to Lower Events (FRAGILE)									
Score≥0.05									
1 Nanda et al. (2011)	225	FRAGILE ≥0.05	125	15	11	74	92 (86-96)	83 (74-90)	LOW
Clinical Assessment/observation									
Clinical Judgement									
1 Myers and Nikoletti (2003)	226	Clinical judgement	30	142	4	50	88 (73-97)	26 (20-33)	LOW
1 Haines et al. (2009)	1123	Clinical judgement	125	161	81	756	61 (54-67)	82 (80-85)	LOW
Clinical assessment using TUG, STRATIFY and Barthel index									
1 Marsholleck et al. (2009)	110	Clinical assessment using TUG, STRATIFY and Barthel index	10	2	16	82	38 (20-59)	97 (92-100)	LOW
Clinical assessment and sensory measurement data									
1 Marscholleck et al. (2009)	110	Clinical assessment and sensory measurement data	15	0	11	84	58 (37-77)	100 (96-100)	LOW
Clinical risk factors									
Chu et al. (1999)	102	Clinical risk factors	25	5	26	46	49 (35-63)	90 (79-97)	V LOW
Clinical risk factors and functional performance									
Chu et al. (1999)	102	Clinical and functional performance	43	12	8	39	84 (71-93)	76 (65-88)	V LOW
Hendrich Falls Risk Model									
Score ≥3									
Heinze et al.(2008)	560	HFRM ≥3	61	449	2	48	97 (89-100)	10 (7-13)	LOW
Score >11									
Heinze et al. (2008)	560	HFRM ≥11	47	263	16	234	75 (62-85)	47 (43-52)	LOW

TP= True positive
FP= False positive
FN= False negative
TN= True negative
Sens= Sensitivity
Spec= Specificity
V LOW= Very low

See appendix E (2013) for the GRADE tables in full.

3.3.3 Evidence statements

For details of how the evidence is graded, see 'The guidelines manual (2009)'.

3.3.3.1 Although the falls risk prediction tools and processes examined in this question demonstrated sensitivities and specificities above the desired threshold (>70%), none of the tools or processes were adequately replicated in the relevant setting, meaning their validity and reliability are uncertain. The quality of this evidence was low or very low.

3.3.4 Health economic modelling

No existing literature was found to support this question (see section 3.4.4). In the economic plan, it was proposed that this question would be addressed using the same health economic model as for the question relating to inpatient fall prevention interventions (see section 3.4.4). However, based on the clinical effectiveness evidence, the GDG made a recommendation that fall risk prediction tools or processes should not be used, so no health economic modelling was undertaken for this question.

3.3.5 Evidence to recommendations

Relative value of different outcomes	The sensitivity and specificity of falls risk prediction tools and processes were the only outcome(s) considered in this review, because the GDG agreed that sensitivity and specificity are the most appropriate measures for prediction.
Trade-off between benefits and harms	The evidence review presented fall risk prediction tools and processes in terms of their sensitivity and specificity. Ideally, a perfect risk prediction tool would demonstrate 100% sensitivity (that is, all people who are at risk will test positive) and 100% specificity (that is, all people who are not at risk will test negative), but in reality most risk prediction tools have varying accuracies because of factors such as tool design, study design and biases. The GDG discussed the minimum acceptable level of accuracy to ensure benefit for patients and took guidance from published literature (Oliver et al. 2004; Perell et al. 2001; Scott et al. 2007). The GDG agreed that, in the context of falls, risk prediction tools should achieve minimum values of 70% for both sensitivity and specificity, as it felt that anything below this would not have acceptable accuracy and would not enable resources to be directed appropriately. The majority of risk prediction tools and processes that the GDG reviewed did not achieve this threshold. Those that did were from single studies that had not been replicated, so their validity and reliability are uncertain. Thus the GDG acknowledged that there is currently no way of accurately predicting the risk of falling for an older inpatient. Furthermore, risk prediction tools that provide a falls risk score or rating were felt to simplify the complex issues surrounding falls and were thought to potentially lead healthcare professionals to intervene with patients in a non-targeted and ineffective way. The GDG agreed that a 'do not do' recommendation was needed to prevent healthcare professionals from using and relying on the results of fall risk prediction tools. Instead, the GDG felt that all inpatients aged 65 and older, and all inpatients aged 50 to 64 years who are identified by a clinician as being at higher risk of falling, should have their care managed as if they are at risk of falling. This is because inpatients will often have newly acquired risk factors (such as acute illness, delirium, cardiovascular disease, impaired mobility, medication and syncope) and are exposed to unfamiliar surroundings, which puts them at increased risk of falling during their inpatient stay. The GDG felt that a good routine clinical assessment would highlight a patient's individual risk factors for falling that could be treated, managed or improved, and this assessment should be linked to related interventions to address the identified risk factors. Discussions around this were continued in a discussion of the evidence relating to inpatient fall prevention interventions (see section 3.4), where the GDG considered further evidence to enable it to elaborate on what this process should involve.
Economic considerations	Health economics were not considered for this review question.
Quality of evidence	Numerous fall risk prediction tools are available and used by healthcare professionals. However, most risk prediction tools were not validated for different data sets or study populations. From the systematic searches, 13 studies relating to 12 different risk prediction tools and processes were identified that met the inclusion criteria.

	These 13 studies were of low or very low quality and therefore needed cautious interpretation.
Other considerations	The GDG wanted to emphasise that all older people who are admitted to hospital should be considered for an individualised multifactorial risk assessment for their inpatient falls risk, and people living in the community who have risk factors for falls (see recommendations 1.2.1.1 and 1.2.1.2) should be considered for an individualised multifactorial falls risk assessment for their community based risk. Patients who have had a multifactorial risk assessment for their inpatient risk should still be considered for multifactorial falls risk assessment for their community based risk, if appropriate (see recommendation 1.2.1.2). The GDG also wanted to emphasise that all people aged 65 or older who attend hospital for any reason should be considered for a multifactorial falls risk assessment for their community based risk, in accordance with recommendation 1.2.1.1, regardless of whether they are admitted or not.

3.3.6 Recommendations and research recommendations for inpatient risk prediction

Recommendations

Recommendation 1.1.1.1

Regard the following groups of inpatients as being at risk of falling in hospital and manage their care according to recommendations 1.1.2 1 to 1.1.3.1:

- all patients aged 65 years or older
- patients aged 50 to 64 years who are identified by a clinician as being at higher risk of falling (for example, patients with a sensory impairment or dementia, and patients admitted to hospital with a fall, stroke, syncope, delirium or gait disturbances).

Recommendation 1.1.1.2

Do not use numerical fall risk prediction tools to predict inpatients' risk of falling in hospital.

Research recommendations

See section 3.6 for details of research recommendations.

3.4 Inpatient falls prevention interventions: evidence review and recommendations

3.4.1 Review question

What interventions reduce older patients' risk of falling and/or the severity of a fall in hospital, compared with usual care? Which interventions are the most effective? Does the intervention vary by inpatient setting?

3.4.2 Evidence review

This question focused on identifying the best interventions or strategies for reducing the risk and/or severity of a fall in hospital.

The search strategy for this question faced difficulties in using the term ‘falls’ as it is such a broad term. Using the term ‘falls’ on its own would mean the search would be too inclusive, as it would retrieve literature using the term fall in contexts that were not relevant to the research question, such as falls in glomerular filtration rates or falls in cancer rates. It would also have been difficult to comprehensively list all the possible terms for falls prevention interventions and capture them in the search strategy. Therefore after discussions with the GDG members it was decided to take the approach of combining the search terms for the ’falls’ concept with terms such as ’prevention’, ’reduction’, ’intervention’ and ’management’ for the intervention concept, instead of trying to list every intervention term that could be used to reduce inpatient falls. The performance of this strategy was also checked against the known relevant references to double-check the validity of this approach and it was found that most of the relevant references were being identified. It was hoped that searching in this way would capture the most relevant references needed to answer the review question. Using this approach 2880 studies were identified, and another 2 studies were identified through other sources. All studies were subject to screening, which led to the retrieval of 109 full texts which were considered in the review.

Studies were included in the review if they related to interventions which aimed to reduce the risk of a patient falling during their inpatient stay. Only comparative studies such as randomised controlled trials, cohort, case–control and before/after studies which were available in full text were eligible for inclusion. Studies that did not deliver the intervention in the inpatient setting, and studies that were non-comparative, were excluded. For a full list of excluded papers for this review question, see appendix G.

Thirty-seven full text articles met the eligibility criteria and were included in the final review. The quality of the 37 included studies was assessed using appropriate NICE methodology checklists, and the GDG categorised each study according to the setting in which it was conducted (acute; non-acute; mixed or unclear).

There was a lack of clarity in the terminology used to describe the type of intervention by the included studies, and so the ProFaNE (Prevention of falls network Europe) classification of falls prevention interventions (Lamb et al. 2005) was adopted to assist with synthesising the evidence. The system categorises interventions as follows:

- Single. Only one major subdomain of the intervention is provided to the participants.
- Multiple. Two or more subdomains of the intervention are given to every participant of the falls prevention programme
- Multifactorial. Two or more subdomains of the intervention can be given to participants, but the interventions are linked to each individual's risk profile and, unlike multiple interventions, not all participants receive the same combination of subdomains.

Using this system, some studies were placed in a different category to that described by the author. For example, the intervention in Haines et al. (2004) was described by the authors as a multi-intervention, but was classified as a multifactorial intervention for the purposes of this review, as participants received different combinations of two or more subdomains of the intervention.

Incidence rate ratios (IRRs) were calculated whenever it was possible to identify the number of falls from the number of occupied bed days. Relative risks (RRs) were calculated when it was only possible to identify the number of patients who fell from the total number of patients included. In studies in which data were provided for intervention and control groups for pre-implementation and post-implementation time points, a test of interaction (Altman and Bland 2003) was performed to compare the effect size for the pre-implementation period to the post-implementation period, giving a ratio of incidence rate ratio (RIRR) or ratio of relative risk (RRR). It was considered appropriate to combine IRR with RIRR, and RR with RRR, in subsequent meta-analysis.

Meta-analysis was conducted for multifactorial interventions only. The GDG had made an a priori decision to split the evidence according to the setting in which it was conducted, and so separate meta-analyses were performed for each setting (acute; non-acute; mixed or unclear). Several limitations were identified which could have an impact on the results of the meta-analyses. Firstly, multifactorial interventions are individually tailored to each patient's falls risk assessment and it was clear that there would be some clinical heterogeneity in the evidence, as different patients in a particular study could receive different components of the multifactorial intervention. Similarly, different studies used different types of multifactorial intervention depending on the resources available and the falls risk assessment that was used. Thus, the 'true' treatment effect may be different for different studies. Secondly, methodological heterogeneity was also present in the pool of evidence as different study designs were utilised. Different study designs suffer from different types and degrees of bias, which can lead to some studies over or under estimating intervention effects.

Meta-analyses performed when there is substantial clinical and methodological heterogeneity run the risk of obscuring important differences and providing misleadingly precise results. Thus the limitations associated with preforming a meta-analysis on heterogeneous evidence were discussed by the GDG and the technical team and it was debated whether it was

appropriate to perform meta-analysis at all. It was expected that clinical heterogeneity could not be significantly reduced by exploring the causes of it as there was limited available data on subgroups to perform the necessary analyses. The GDG considered methodological heterogeneity and whether data from non-randomised trials should be included in the meta-analysis or not, given that non-randomised trials are likely to over-estimate the intervention effect. The GDG agreed that only evidence from randomised studies should be used to drive recommendations, but it would be useful to examine the effects of non-randomised studies too. Thus, all study designs were included in the analysis, and the effects of randomised studies were examined separately from non-randomised studies by stratifying the analysis according to study design. This was done because exploring both randomised and non-randomised studies would provide the GDG with a comprehensive view of this complex and heterogeneous evidence base. The GDG acknowledged that progressing with a meta-analysis in this way would limit the results and may not be reflective of the actual effects that might be achieved in future inpatient multifactorial falls prevention interventions. After considering these limitations it was finally agreed that for this review question a meta-analysis with significant heterogeneity and limitations would be better than no meta-analysis at all. Rather than performing a narrative review or using the meta-analysis to identify the ‘true’ effect amongst the pool of studies, a random-effects model was used to estimate an average effect amongst this heterogeneous body of evidence.

GRADE was used to appraise the quality of the evidence, and the overall quality of the evidence was low. The tables below are the summary table and the summary GRADE tables. Appendix E (2013) contains the full summary and full GRADE tables for the included studies.

Table 3 Summary of included studies for inpatient interventions

Study	Participants	Mean Length of Stay	Intervention	Comparison
(Allen et al. 1986) USA	n=185 Aged >75 Patients admitted to all inpatient units other than intensive care	17 days	Geriatric consultation team recommendations	Usual Care
(Barry et al. 2001) Ireland	All inpatients Aged >65 Hospital providing long term services for older people	Unclear	Multifactorial	Pre intervention audit
(Bischoff et al. 2003) Switzerland	n=122 Mean Age=85 Long stay geriatric care	345 & 337 days	Vitamin D (800 iu cholecalciferol) +1,200 mg calcium carbonate once daily	1,200 mg calcium carbonate once daily
(Brandis 1999) Australia	n=550 Unclear age Acute general hospital inpatients	3.7 days	Multifactorial	Pre intervention audit
(Burleigh et al. 2007) Scotland	n=203 Aged 65> General assessment and rehabilitation ward in an acute geriatric unit	43 days	Vitamin D (800 iu cholecalciferol) +1,200 mg calcium carbonate once daily	1,200 mg calcium carbonate once daily
(Capan and Lynch 2007) USA	All admissions Unclear age Acute care hospital	Unclear	Multifactorial	Pre intervention audit
(Cumming et al. 2008) Australia	n=3999 Mean age=79 Elderly care wards in 12 hospitals	7 days	Multifactorial	Wards receiving usual care
(Donald et al. 2000) England	n=54 Mean age=81 Elderly care rehabilitation ward in a community hospital	23, 27, 32 & 36 days	Carpet floor + standard or enhanced physiotherapy	Vinyl floor + standard or enhanced physiotherapy
(Donoghue et al. 2005) Australia	n=unclear Age=unclear Aged care ward	Unclear	Companion observers	Pre intervention audit
(Dykes et al. 2010) USA	n=10,264 Age=Over 50% over 65 years Medical units	3 days	Multifactorial	Wards receiving usual care
(Fonda et al. 2006) Australia	All admissions Mean Age=82 Patients admitted to Aged Care Services	21 and 18 days	Multifactorial	Pre intervention audit
(Giles et al. 2006)	n=unclear	Unclear	Companion observers	Pre intervention

Australia	Age=unclear Geriatric wards			audit
(Haines et al. 2004) Australia	n=626 Mean age=80 Rehabilitation and care of the elderly wards	29 and 30 days	Multifactorial	Usual care
(Haines et al. 2006b) Australia	n=226 Mean age=82 Rehabilitation and care of the elderly wards (subgroup of Haines 2004)	Unclear	Patient education	Usual care
(Haines et al. 2007) Australia	n=173 Mean age=81 Rehabilitation and care of the elderly wards (subgroup of Haines 2004)	Unclear	Exercise	Usual care
(Haines et al. 2010) Australia	18 hospitals Mean age=unclear 18 hospitals who had not had access to low-low beds	Unclear	Low-Low beds	Usual care
(Haines et al. 2011) Australia	n=1,206 Mean age=74 Acute and geriatric rehab/assessment units	19, 20 and 23 days	Patient education +/- 1-1 follow up	Usual care
(Healey et al. 2004) England	All admissions Mean age=81 Care of the elderly wards	18 and 21 days	Multifactorial	Usual care
(Huda and Wise 1998) USA	All admission Age=unclear All admitted patients to a medical centre	Unclear	Multifactorial	Pre intervention audit
(Jeske et al. 2006) USA	n=unclear Age=unclear Acute care telemetry unit	Unclear	Educational Poster	Pre intervention audit
(Kato et al. 2008) Japan	n=52 Mean Age=84 Long term care facility	1 year	Multifactorial	Usual care
(Kilpack et al. 1991) USA	n=unclear Age=unclear Patients on unit with higher than the hospital average fall rate who had previously fallen in the hospital	Unclear	Multifactorial	Falls in rest of hospital
(Koh et al. 2009) Singapore	n=1122 Age=unclear Medical, surgical	>365 days	Multifactorial	Pre intervention audit + matched

	and geriatric patients from two acute care hospitals			control hospital fall rate
(Krauss et al. 2008) USA	n=unclear Mean age=65 General medicine floors of a tertiary care hospital	Unclear	Multifactorial	Usual care on control wards
(Lane 1999) USA	n=292 Age range=21-99 Patients from medical-surgical/critical care at a large community hospital	Unclear	Multifactorial	Pre intervention audit
(Lieu et al. 1997) Singapore	n=2106 Age=unclear Geriatric inpatients	Unclear	Multifactorial	Pre intervention audit
(Mayo et al. 1994) Canada	n=134 Mean age=70 Specialist physical rehabilitation hospital	Unclear	Risk identification bracelets	Usual hospital bracelet
(Mitchell and Jones 1996) Australia	n=58 Age range=38-92 Medical ward	Unclear	Multifactorial	Pre intervention audit
(Rainville 1984) USA	All admissions Age=unclear All inpatients admitted to a short term care facility on a unit with the highest rate of falls	Unclear	Multifactorial	Pre intervention audit
(Schwendimann et al. 2006a) Switzerland	n=34,972 Mean Age=67 All inpatients	12 days	Multifactorial	Pre intervention audit
(Schwendimann et al. 2006b) Switzerland	n=409 Mean age=71 Department of Internal Medicine	11 and 12 days	Multifactorial	Usual care
(Stenvall et al. 2007) Sweden	n=199 Age >70 Patients with fractured neck of femur	28 and 38 days	Specialist geriatric care	Conventional orthopaedic care
(Vassallo et al. 2004) England	n=825 Mean age=86 Elderly care wards in a community rehabilitation hospital	21 and 27 days	Proactive MDT approach	Usual care
(von Renteln-Kruse and Krause 2007) Germany	n=4272 Mean age=80 Geriatric clinic	21 and 19 days	Multifactorial	Pre intervention audit
(Wald et al.	n=217	3 days	Hospitalist run Acute Care of the	Usual Care

2011) USA	Mean age=80 Medical inpatients		Elderly Service (ACE)	
(Williams et al. 2007) Australia	n=1357 Median age=79 Tertiary teaching hospital	7 days	Multifactorial	Pre intervention audit

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Table 4 GRADE table summary for inpatient interventions

4a) Acute setting

No of studies	Design	Intervention	Comparison	Effect (95% CI)	Quality
Geriatric Consultation team compared with routine care					
Implementation of recommendations by staff (Mean difference)					
1 Allen et al. (1986)	Randomised trials	313/446 (70.4%)	102/377 (27.1%)	MD=2.59 (2.17 to 3.19)	MOD
Hospital Acute Care of the Elderly Service compared with Usual Care					
Falls (Incidence Rate Ratio- Number of falls as a proportion of occupied bed days)					
1 Wald et al. (2011)	Randomised trials	(4.8)	(6.4)	-	LOW
Companion observers in the rooms of high risk patients compared with no observers on the ward					
Falls in the intervention rooms and no intervention wards (Incidence Rate Ratio- Number of falls as a proportion of occupied bed days)					
2 Donoghue et al. (2005); Giles et al. (2006)	Non-randomised trials	111/8755 (12.68)	135/8770 (15.39)	IRR=0.75 (0.37 to 1.54)	V LOW
Falls in the intervention rooms only (Incidence Rate Ratio- Number of falls as a proportion of occupied bed days)					
1 Donoghue et al. (2005)	Non-randomised trials	2/3455 (0.57)	10/3972 (2.52)	IRR=0.22 (0.06 to 0.93)	V LOW
Educational Poster for patients/relatives, compared with no educational poster					
Falls (Incidence Rate Ratio- Number of falls as a proportion of occupied bed days)					
1 Jeske et al. (2006)	Non-randomised trials	(4.7)	(4.4)	-	V LOW
Multifactorial interventions, compared with no multifactorial interventions					
Falls (Incidence Rate Ratio- Number of falls as a proportion of occupied bed days)					
1 Huda and Wise (1998)	Non-randomised trials	(3.7)	(5.4)	-	V LOW
2 Cumming et al. (2008), Dykes et al. (2010),	Randomised trials	-	-	IRR=0.76 (0.40 to 1.44)	HIGH
1 Koh et al (2009)	Controlled pre/post			IRR= 0.79 (0.57 to 1.09)	V LOW
7 Brandis et al. (1999), Krauss et al. (2008), Lieu et al. (1997), Mitchell and Jones (1996), Rainville et al. (1984),	Non-randomised trials	-	-	IRR=0.76 (0.64 to 0.90)	V LOW

No of studies	Design	Intervention	Comparison	Effect (95% CI)	Quality
Geriatric Consultation team compared with routine care					
Implementation of recommendations by staff (Mean difference)					
Schwendimann et al. (2006b); Von Renteln-Kruse et al. (2007)					
Falls (Relative Risk- Number of inpatients who fell as a proportion of number of inpatients)					
1 Capan and Lynch (2007)	Non-randomised trials	3.20	4.50	-	V LOW
1 Kilpack et al. (1991)	Non-randomised trials	4.4	4.7	-	V LOW
1 Schwendimann et al. (2006a)	Non-randomised trials	8.9	9.1	-	V LOW
Any Injury (Incidence Rate Ratio- Number of falls resulting in any injury as a proportion of occupied bed days)					
1 Koh et al. (2009)	Controlled pre/post	-	-	RIRR= 0.64 (0.33 to1.27)	V LOW
3 Brandis et al. (1999), Schwendimann et al. (2006b), Von Renteln-Kruse et al. (2007)	Non-randomised trials	-	-	IRR=0.79 (0.68 to 0.92)	V LOW
Any Injury (Relative Risk- Number of inpatients who fell and sustained any injury as a proportion of number of inpatients)					
1 Dykes et al. (2010),	Randomised trials	7/2755	9/2509	RR=0.71 (0.26 to 1.90)	MOD
1 Schwendimann et al. (2006a)	Non-randomised trials	548/805	495/763	RR=1.05 (0.98 to 1.13)	V LOW
Severe Injury (Incidence Rate Ratio- Number of falls resulting in severe injury as a proportion of occupied bed days)					
3 Brandis et al. (1999), Schwendimann et al. (2006b), Von Renteln-Kruse et al. (2007)	Non-Randomised trials	-	-	IRR=0.64 (0.19 to 2.12)	V LOW
Severe Injury (Relative Risk- Number of inpatients who fell and sustained severe injury as a proportion of number of inpatients)					
1 Schwendimann et al. (2006a)	Non-randomised trials	31/805	19/763	RR=1.55 (0.88 to 2.71)	V LOW
Staff knowledge (Mean difference- Post intervention compared with pre intervention)					

No of studies	Design	Intervention	Comparison	Effect (95% CI)	Quality
Geriatric Consultation team compared with routine care					
Implementation of recommendations by staff (Mean difference)					
1 Krauss et al. (2008)	Non-randomised trials	90.7	71.3	MD=19 (16.70 to 21.73)	V LOW
RR= Relative Risk IRR= Incidence rate ratio MD= Mean difference V LOW= Very low					

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4b) Non-acute setting

No of studies	Design	Intervention	Comparison	Effect (95% CI)	Quality
Vitamin D plus calcium compared with calcium alone					
Falls (Relative Risk- Number of inpatients who fell as a proportion of number of inpatients)					
1 Bischoff et al. (2003)	Randomised trials	-	-	RR=0.75 (0.41-1.37)	LOW
Flooring- Carpet flooring compared with Vinyl flooring					
Falls (Relative Risk- Number of inpatients who fell as a proportion of number of inpatients)					
1 Donald et al. (2000)	Randomised trials	7/28 (25.0%)	1/26 (3.8%)	RR=6.50 (0.86 to 49.30)	V LOW
Physiotherapy- Enhanced (2x daily standard physiotherapy plus specific strengthening exercises) compared with Standard physiotherapy alone					
Falls (Relative Risk- Number of inpatients who fell as a proportion of number of inpatients)					
1 Donald et al. (2000)	Randomised trials	2/30 (6.7%)	6/24 (25.0%)	RR=0.27 (0.06 to 1.20)	V LOW
Education for patients (including 1:1 sessions) delivered in combination with another intervention, compared with no education					
Falls (Incidence Rate Ratio- Number of falls as a proportion of occupied bed days)					
1 Haines et al. (2006)	Randomised trials	26/3190 (8.2)	48/3007 (16.0)	IRR=0.51 (0.32 to 0.82)[10]	HIGH
		4/1026 (3.9)	9/652 (13.8)	IRR=0.28 (0.09 to 0.86)[11]	
		11/1964 (5.6)	24/2201 (10.9)	IRR=0.51 (0.26 to 1.03)[12]	
		15/1219 (12.3)	24/805 (8.9)	IRR=0.41 (0.22 to 0.78)[13]	
Exercise (45 min 3x per week) compared with no exercise					
Falls (Incidence Rate Ratio- Number of falls as a proportion of occupied bed days)					
1 Haines et al. (2007)	Randomised trials	26/2596 (10.0)	47/2215 (21.2)	IRR=0.47 (0.29 to 0.76)	HIGH
Bracelets worn by high risk patients, compared with no bracelet					
Falls (Relative Risk- Number of inpatients who fell as a proportion of number of inpatients)					
1 Mayo et al. (1994)	Randomised trials	27/65 (41.5%)	21/69 (30.4%)	RR=1.36 (0.86 to 2.16)	V LOW
Proactive MDT approach (Weekly assessment by all MDT members) compared with standard MDT approach					
Falls (Incidence Rate Ratio- Number of falls as a proportion of occupied bed days)					
1 Vassallo et al. (2004)	Non-randomised trials	72/5855 (12.3)	170/14791 (11.5)	IRR=1.07 (0.81 to 1.41)	V LOW
1.2.2 Multifactorial interventions compared with no multifactorial intervention					
Falls (Incidence Rate Ratio- Number of falls as a proportion of occupied bed days)					
2 Cumming et al. (2008), Haines	Randomised trials	-	-	IRR=0.78 (0.60 to 1.01)	MOD

No of studies	Design	Intervention	Comparison	Effect (95% CI)	Quality
et al. (2004),					
1 Kato et al. (2008)	Controlled pre/post	-	-	RIRR=0.75 (0.29 to 1.94)	V LOW
Falls (Relative Risk- Number of inpatients who fell as a proportion of number of inpatients)					
1 Barry et al. (2001)	Non-randomised trials	26/149	39/156	RR=0.70 (0.45 to 1.09)	LOW
Any Injury (Incidence Rate Ratio- Number of falls resulting in any injury as a proportion of occupied bed days)					
1 Haines et al. (2004)	Randomised trials	-	-	IRR=0.71 (0.42 to 1.20)	MOD
1 Kato et al. (2008)	Controlled pre/post	-	-	RIRR=0.24 (0.04 to 1.44)	V LOW
Any Injury (Relative Risk- Number of inpatients who fell and sustained any injury as a proportion of number of inpatients)					
1 Barry et al. (2001)	Non-randomised trials	4/149	27/156	RR=0.16 (0.05 to 0.43)	LOW
Severe Injury (Incidence Rate Ratio- Number of falls resulting in severe injury as a proportion of occupied bed days)					
1 Haines et al. (2004)	Randomised trials	2/9356	2/9239	IRR=0.99 (0.14 to 7.01)	LOW
Severe Injury (Relative Risk- Number of inpatients who fell and sustained severe injury as a proportion of number of inpatients)					
1 Barry et al. (2001)	Non-randomised trials	0/149	8/156	RR=0.06 (0.01 to 1.06)	LOW
RR=Relative Risk IRR=Incidence Rate Ratio RRR=Ratio of Relative Risk MOD= Moderate V LOW= Very low 10=Any participant recommended Education 11=Participants only recommended Education 12=Any participant recommended education with Mini Mental State Exam >23 13=Any participant recommended education with MMSE <23 (cognitively impaired)					

1

4c) Mixed or unclear setting

No of studies	Design	Intervention	Comparison	Effect (95% CI)	Quality
Education for patients (Model 1- including 1:1 sessions) compared with no education					
Falls (Incidence Rate Ratio- Number of falls as a proportion of occupied bed days)					
1 Haines et al. (2011)	Randomised trials	70/9174	81/8737	IRR=0.82 (0.60 to 1.13)[6]	LOW
		45/2941	35/3465	IRR=1.51 (0.97 to 2.36)[7]	
		25/6234	46/5275	IRR=0.45 (0.28 to 0.75)[8]	
Any injury (Incidence Rate Ratio- number of falls with any injury as a proportion of occupied bed days)					
1 Haines et al. (2011)	Randomised trials	32/9174	25/8737	IRR=1.22 (0.72 to 2.06)[6]	LOW
		22/2941	10/3465	IRR=2.59 (1.28 to 5.47)[7]	
		10/6234	15/5275	IRR=0.56 (0.25 to 1.26)[8]	
Severe injury (Incidence Rate Ratio- number of falls with severe injury as a proportion of occupied bed days)					
1 Haines et al. (2011)	Randomised trials	1/9174	2/8737	IRR=0.48 (0.04 to 5.25)[6]	LOW
		1/2941	0/3465	IRR=3.53 (0.14 to 86.76)[7]	
		0/6234	2/5275	IRR=0.17 (0.01 to 3.53)[8]	
Education for patients (Model 2- written materials only) compared with no education					
Falls (Incidence Rate Ratio- Number of falls as a proportion of occupied bed days)					
1 Haines et al. (2011)	Randomised trials	96/11149	81/8737	IRR=0.92 (0.69 to 1.25)[6]	LOW
		35/3695	35/3465	IRR=0.94 (0.59 to 1.50)[7]	
		61/7457	46/5275	IRR=0.94 (0.64 to 1.38)[8]	
Any injury (Incidence Rate Ratio- number of falls with any injury as a proportion of occupied bed days)					
1 Haines et al. (2011)	Randomised trials	40/11149	25/8737	IRR=0.39 (0.27 to 0.57)[6]	LOW
		15/3695	10/3465	IRR=1.04 (0.63 to 3.13)[7]	
		25/7457	16/5275	IRR=1.17 (0.62 to 2.24)[8]	
Severe injury (Incidence Rate Ratio- Number of falls with severe injury as a proportion of occupied bed days)					
1 Haines et al. (2011)	Randomised trials	2/11149	2/8737	IRR=0.78 (0.11, 5.56)[6]	LOW
		1/3695	0/3465	IRR=2.81 (0.11, 69.06)[7]	
		1/7457	2/5275	IRR=0.17 (0.01 to 3.53)[8]	
Education (Model 1- including 1:1 session) compared with education (Model 2- written materials only)					
Falls (Incidence Rate Ratio- Number of falls as a proportion of occupied bed days)					
1 Haines et al. (2011)	Randomised trials	70/9174 (7.36)	96/11149 (8.6)	IRR=0.89 (0.65 to 1.12)[6]	LOW
		45/2941	35/3465	IRR=1.62 (1.04 to 2.51)[7]	
		25/6234	61/7457	IRR=0.49 (0.30 to 0.78)[8]	
Any injury (Incidence Rate Ratio- Number of falls with any injury as a proportion of occupied bed days)					
1 Haines et al. (2011)	Randomised trials	32/9174	40/11149	IRR=0.97 (0.61 to 1.55)[6]	LOW
		22/2941	15/3695	IRR=1.84 (0.96 to 3.55)[7]	
		10/6234	25/7457	IRR=0.48 (0.23 to 1.00)[8]	
Severe injury (Incidence Rate Ratio- Number of falls with severe injury as a proportion of occupied bed days)					
1	Randomised	1/9174	2/11149	IRR=0.60 (0.06 to 6.70)[6]	LOW

No of studies	Design	Intervention	Comparison	Effect (95% CI)	Quality
Haines et al. 2011	trials	1/2941	1/3695	IRR=1.26 (0.07 to 20.08)[7]	
		0/6234	1/7457	IRR=0.40 (0.02 to 9.79)[8]	
Low-Low beds (1 for every 12 standard beds) compared with usual care					
Falls (Incidence Rate Ratio- Number of falls as a proportion of occupied bed days)					
1 Haines et al. (2010)	Randomised trials	186/35441 (5.25)	114/30228 (3.77)	RIRR=1.01 (0.74 to 1.37)	LOW
Any injury (Incidence Rate Ratio- Number of falls as a proportion of occupied bed days)					
1 Haines et al. (2010)	Randomised trials	85/35411 (2.4)	51/30228 (1.69)	RIRR=1.29 (0.80 to 2.07)	LOW
Severe injury (Incidence Rate Ratio- Number of falls with severe injury as a proportion of occupied bed days)					
1 Haines et al. (2010)	Randomised trials	3/35441 (0.08)	7/30228 (0.23)	RIRR=2.06 (0.36 to 11.70)	LOW
Vitamin D plus calcium compared with calcium alone (Number of inpatients who fell as a proportion of number of inpatients)					
Falls (Relative Risk- Number of inpatients who fell as a proportion of number of inpatients)					
1 Burleigh et al. (2007)	Randomised trials	36/100	45/103	RR=0.82 (0.59 to1.16)	MOD
Severe injury (Relative Risk- Number of inpatients who fell and sustained severe injury as a proportion of number of inpatients)					
1 Burleigh et al. (2007)	Randomised trials	1/100 (1.0%)	3/103 (2.91%)	RR=0.42 (0.05 to 3.84)	MOD
Adherence amongst all participants to drugs (Mean Difference)					
1 Burleigh et al. (2007)	Randomised trials	89/100 (89%)	87/103 (87%)	MD=1.05 (0.95 to 1.17)	MOD
Multifactorial Interventions					
Falls (Incidence Rate Ratio- Number of falls as a proportion of occupied bed days)					
1 Williams et al (2007)	Non-randomised trials	(8.0)	(9.5)	-	V LOW
2 Healey et al. (2004) Stenvall et al. (2007)	Randomised trials	-	-	IRR=0.42 (0.26 to 0.69)	HIGH
2 Fonda et al. (2006), Lane et al. (1997),	Non-randomised trials	-	-	IRR=1.17 (0.55 to 2.48)	V LOW
Any Injury (Incidence Rate Ratio- Number of falls resulting in any injury as a proportion of occupied bed days)					

No of studies	Design	Intervention	Comparison	Effect (95% CI)	Quality
1 Healey et al. (2004)	Randomised trials	(1.14)	(0.85)	IRR=1.34 (0.06 to 23.92)	MOD
Severe Injury (Incidence Rate Ratio- Number of falls resulting in severe injury as a proportion of occupied bed days)					
1 Fonda et al. (2006)	Non-Randomised trials	7/41013 (0.17)	27/37133 (0.73)	IRR=0.23 (0.10 to 0.53)	V LOW
RR=Relative Risk IRR=Incidence Rate Ratio RIRR=Ratio of Incidence Rate Ratio MD=Mean Difference MOD= Moderate V LOW= Very low 6=Analysis of all participants 7=Analysis of participants only with cognitive impairment 8 Analysis of participants who are cognitively intact					

See appendix E (2013) for the evidence tables in full.

3.4.3 Evidence statements

For details of how the evidence is graded, see 'The guidelines manual (2009)'.

Acute setting

3.4.3.1 For most of the single interventions included in the acute setting the evidence was low or very low in quality and there was uncertainty about whether the interventions actually reduced or increased fall rates. Moderate and low quality evidence from two single interventions (geriatric consultation team; companion observers) showed that these single interventions significantly reduced falls rates, but there was no further supporting evidence about these interventions.

3.4.3.2 For multifactorial interventions, high quality evidence from a subgroup of randomised trials indicated there was uncertainty about whether the multifactorial interventions reduced or increased falls. Additional very low quality evidence from non-randomised studies suggested that multifactorial interventions significantly

reduced falls rates. The results from non-randomised studies need interpreting with caution, since these results may be spurious.

Non-acute setting

3.4.3.3 *Again, most of the single interventions included in the non-acute setting had uncertainty about whether the interventions actually reduced or increased fall rates. High quality evidence on two single interventions (education in combination with another intervention; exercise) showed that the interventions significantly reduced falls rates, but there was no further supporting evidence about these interventions.*

3.4.3.4 *For multifactorial interventions, the meta-analysis results provided moderate quality evidence showing that, for the subgroup of randomised trials, there was uncertainty about whether the multifactorial interventions reduced or increased falls. Additional very low quality evidence from non-randomised studies also showed that there was uncertainty about whether the multifactorial interventions reduced or increased falls.*

Mixed or unclear setting

3.4.3.5 *Again, for single interventions included in the mixed or unclear setting there was uncertainty about whether the interventions actually reduced or increased fall rates. The only exception to this was low quality evidence from subgroup analysis of one study which showed that fall rates were lower for people who were cognitively intact and were offered written and video based educational materials with 1:1 follow up in comparison with those receiving materials only and the 'no intervention' control. There was no further supporting evidence about these interventions.*

3.4.3.6 *For multifactorial interventions, the meta-analysis results provided high quality evidence showing that, for the subgroup of randomised trials, multifactorial interventions significantly reduced the incidence of falls. Additional very low quality evidence from non-randomised*

studies showed that there was uncertainty about whether the multifactorial interventions reduced or increased falls.

3.4.4 Health economic modelling

This is a summary of the modelling carried out for this review question. See appendix K (2013) for full details of the modelling carried out for the guideline.

A search of published health economic analyses addressing the question of interest yielded a total of 1432 unique citations. Only one study (Haines et al., 2009) analysed both the costs and outcomes of measures to prevent inpatient falls but this study did not report outcomes in terms of QALYs. Therefore, in the absence of relevant published literature, an original health economic model was constructed.

Decision problem

The health economic analysis addressed one question from the guideline scope, based on GDG prioritisation:

- What is the cost effectiveness of multifactorial interventions to reduce the risk and/or severity of inpatient falls for patients aged 65+, compared with usual care (assumed to be no actions to prevent falls)?

The GDG recommended that single interventions should not be used to reduce the risk and/or severity of inpatient falls. Therefore, only multifactorial interventions were considered for health economic modelling.

De novo model: model structure and methods

The model was constructed in Microsoft Visual Basic for Applications, using Microsoft Excel 2010 as a 'front-end' in which parameters can be specified and results collected and analysed. Costs and benefits were discounted at 3.5% per annum each and all costs are based on 2010–11 financial year.

Model structure

The model used a discrete event (or individual patient) structure, capturing the costs and benefits associated with a series of events and discrete health states. A discrete event model was used to accurately model each patient's

falls history, variable lifespan and differing time in each state (for more details, see appendix K [2013]). Figure 1 illustrates the model structure.

A patient could be in one of five states in the model and a fall could occur in any state (apart from the dead state, the only absorbing state in the model). The model did not have a time cycle, but measured time continuously (in days).

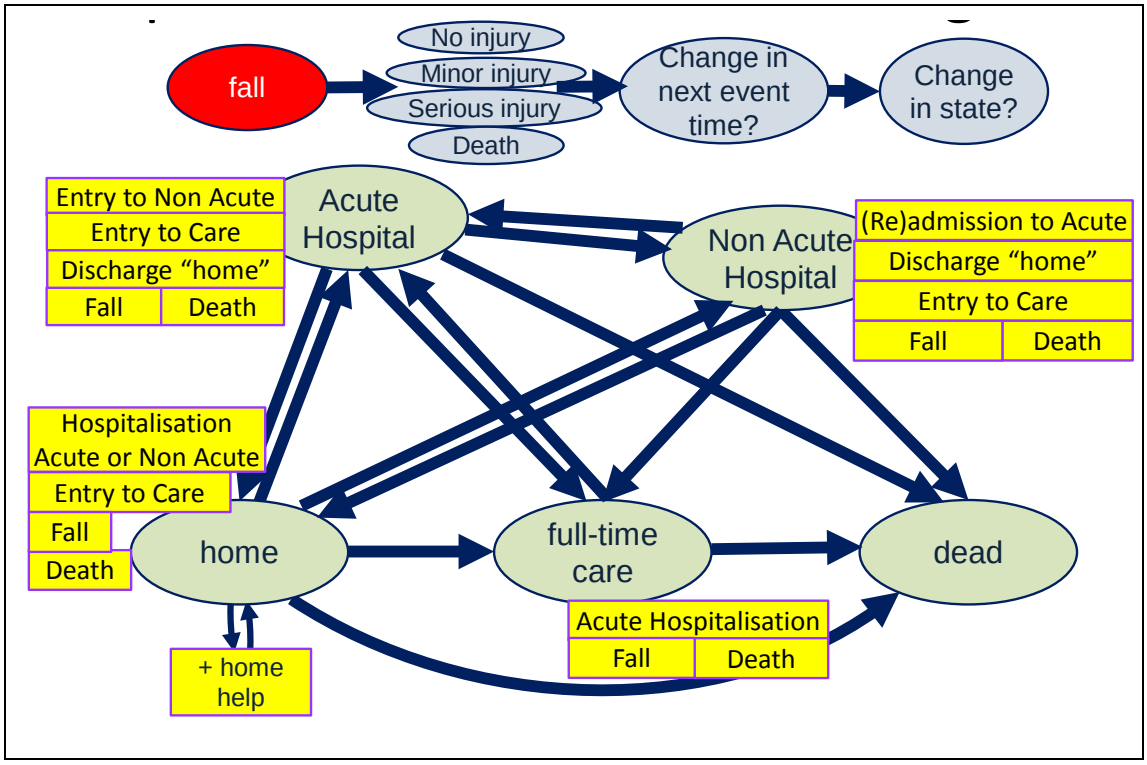


Figure 1: Inpatient falls prevention model structure

The GDG requested that the hospital state was split into acute and non-acute settings because the clinical evidence was split in this manner, because they felt that costs and resource use may differ between settings and because doing so allowed modelling of a number of scenarios or settings. The settings modelled were:

Acute: All patients start in the acute hospital setting but can be transferred to or admitted to acute or non-acute settings later in the model. Intervention is only ever applied in acute settings

Non-Acute: All patients start in the non-acute hospital setting but can be transferred to or admitted to acute or non-acute settings later in the model. Intervention is only ever applied in non-acute settings

The GDG agreed that the care state could be a generic state that represented any residential care facility (nursing or otherwise). The GDG also agreed to the simplifying assumptions that patients could not return home from the care state and patients cannot be directly admitted to the non-acute hospital setting from care (see appendix K [2013] for more details). The GDG discussed the complex array of social care arrangements available but no evidence was found to support any further division of the care process, apart from the addition of home help to those who fell in the home state or who fell in hospital and then returned to the home state.

Model transitions

All patients began the model in the hospital state (acute or non-acute), with their age, underlying residence (home or care), sex (all based on hospital episode statistics [HES] data, NHS Information Centre for Health and Social Care, 2012), falls history (falls within last 12 months, Vass et al., in print) and risk of death generated probabilistically. Times for each next possible event were generated based on these factors and the event with the soonest occurrence simulated, and the model updated.

Patients were then modelled for the remainder of their lives. Some patients may only have their initial hospitalisation and no falls, whilst others may have repeated falls in different settings and many hospitalisations. Whenever patients were simulated to experience a fall, their chances of injury were calculated and sampled probabilistically.

A patient only had a fall history for one year following a fall (in line with the source data) and, at one year, their risk and time of next events was recalculated.

The probability of hospital admission from home or care was taken from the Health Survey for England 2000 (Department of Health, 2002) and was split

by age, sex and underlying residence. The type of hospitalisation (acute or non-acute) was determined once a hospitalisation occurred, using an approximation calculated using NHS reference costs (Department of Health, 2011) and HES-online data for the rehabilitation specialty (specialty code 314, NHS Information Centre for Health and Social Care, 2012).

Hospital discharge time was determined by the length of stay, which was calculated on admission. A patient whose underlying residence was home could be discharged to care. In the acute setting, the probability of discharge to care reflected the age and gender of the simulated patient (NHS Information Centre for Health and Social Care, 2011); in addition, the likelihood of discharge to care was increased by the incidence of inpatient falls (Vass et al., in print). In the non-acute setting, this transition was dependent on the same age and gender rates, but a different odds ratio was applied to account for inpatient falls (Aditya et al., 2003).

The probability of transfer from acute to non-acute hospital settings was modelled separately for patients whose original admission was from home and care states. Different underlying rates were taken from HES data (NHS Information Centre for Health and Social Care, 2011). Rates for admissions from both settings were adjusted to take account of the increased risk associated with inpatient falls (Vass et al., in print). The only time when patients could transfer from non-acute to acute settings in the model was as a result of a serious injury fall in the non-acute setting.

The likelihood of entering care from home was calculated from a variety of sources (NHS Information Centre for Health and Social Care, 2011, Darton et al., 2006, Wang et al., 2001). As risk is linked to age, the risk of entering care is recalculated on every fifth birthday.

Patient mortality was calculated as predicted time of death, based on standard Office for National Statistics life tables for 2008-2010 (Office for National Statistics, 2011). Hazard ratios are applied for the increased risk of death when entering the care state (McCann et al., 2009) and for experiencing a

serious fall (in any setting, see appendix K (2013) for further discussion, Goldacre et al. 2002).

Inpatient fall consequences: the causal multiplier

A major challenge in modelling falls prevention interventions is accounting for the relationship between a fall and subsequent events. The GDG noted it would be misleading to assume that this relationship is directly causative; it will be confounded by a wide range of known and unknown patient characteristics. Consequently it is fallacious to assume that preventing an individual from falling will make the patient entirely immune from all consequences that are known to be associated with falls. On the other hand, preventing falls can be expected to result in some benefits in these areas. The unknown factor is the extent of these benefits.

To account for this uncertainty in the model, potential falls were simulated at the same rate in both the control and intervention arms but, whereas **all** potential falls were assumed to occur in the control arm, some potential falls were randomly selected to be averted in the intervention arms (with the proportion of averted falls derived from the incidence rate ratio defining the effectiveness of the intervention). The averted falls were then associated with **some** of the consequences of falls; the proportion of those consequences assumed to occur became known as the ‘causal multiplier’. A causal multiplier of 0 is equivalent to assuming that **none** of the consequences of falling occur when a fall is averted (that is, all post-fall negative events are directly ascribable to the fall). Setting the causal multiplier to 1 is equivalent to assuming that **all** of the consequences of falling occur, even when a fall is averted (that is, averting falls has no benefit in attenuating subsequent disadvantages). In the base case, this multiplier was assumed to be 0.5, and the impact of varying this assumption was tested in sensitivity analysis.

The causal multiplier is discussed in more detail in appendix K (2013) and was applied to the following consequences of having an inpatient fall:

- Increase in length of hospital stay observed in fallers
- Utility decrement seen in fallers

- Increase in mortality seen in those experiencing a hip fracture
- Days of home help received on discharge following a fall
- Increase in probability of discharge from acute to non-acute hospital
- Increase in probability of discharge from hospital to full-time care

Fall rates and severity

Hospital fall rates

The underlying rate of falls in hospital settings is taken from Healey et al. (2008), a comprehensive analysis of 12 months' data from the National Patient Safety Agency (NPSA). A rate of 6.7 falls per 1000 bed days was calculated for patients aged 65 and over. On GDG advice, this underlying rate was varied by age (Healey et al., 2008), sex (Healey et al., 2008) and falls history (falls within last 12 months, Vass et al. in print).

The same Healey et al. (2008) paper also reported on the severity of hospital falls, categorising them into five categories (see table 5). These probabilities were applied to all simulated inpatient falls in both acute and non-acute hospital settings.

Table 5: Inpatient fall severities (Healey et al., 2008)

Fall severity	Percent of Inpatient falls
No harm	65%
Low	31%
Moderate	4%
Severe	1%
Fatal	0.01%

The effectiveness of the modelled intervention was based on the meta-analysed evidence of multifactorial falls interventions discussed above (see table 4a and forest plots in Appendix E [2013]). In the acute setting, an incidence rate ratio of 0.76 was applied, implying multifactorial interventions have the capacity to reduce fall rates by 24%. A similar rate (0.76) was used for the non-acute setting These rates were the pooled means from the meta-analyses of all trial types (10 studies in the acute setting, 3 studies in the non-acute setting); rates from meta-analyses with alternative study groupings were

covered in the sensitivity analyses. Whilst these rates were very slightly different to the RCT-only rates, sensitivity analysis demonstrated that model results were trivially different if those rates were used instead (see below).

Home state fall rates

The fall rate for people living at home was taken from the Health Survey for England 2005 (NHS Information Centre for Health and Social Care, 2007). This gives a fall rate of 0.46 per person per year (split by age and sex). An incidence rate ratio of 2.6 for people with a history of falling (within last 12 months) was derived from O'Loughlin et al. (1993) and applied to the underlying rate.

Fall severities by age, sex and underlying residence were taken from Watson et al. (2009). Whilst based in Australia and on a slightly younger population, this study is one of the few to report non-injurious falls as well as injurious falls. In Watson et al., underlying falls incidence across all older people of both sexes is estimated at 0.27 per person per year, of which 28% result in injury.

Watson et al. only consider death from falls that result in an A&E attendance or hospitalisation (that is, moderate or severe injuries that lead to death). In order to treat mortality from a fall as a separate category, the probability of mortality from a fall leading to an A&E attendance or hospitalisation from Scuffham et al. (2003) was applied to moderate and serious injury rates from Watson et al. (2009).

Care state fall rates

The rate and severity of falls in care homes were based on pooled data from 3 UK-based studies (O'Halloran et al., 2004, Dyer et al., 2004, and McMurdo et al., 2000). These resulted in an overall fall rate of 3.9 falls per resident per year. An odds ratio was calculated from Delbaere et al. (2008) to reflect the increased risk of falling in those care home residents who had fallen within the past year. Delbaere's regression model found that age and sex were not significant predictors of falling, so care home fall rates were not adjusted for these factors. Fall severity probabilities were derived from the same sources as used for falls at home (see above).

Resource use and unit costs

State resource use and costs

The unit cost of a day in an acute hospital setting was based on the weighted average of all NHS reference cost elective and non-elective activity, including excess bed days (£524.01). The unit cost of a day in a non-acute hospital setting was based on all inpatient rehabilitation categories of NHS reference costs (£588.01, Department of Health, 2011). Length of acute hospital stay was based on data from Vass et al. (in print), because it was the only UK study available to us that provided details of length of stay relative to incidence and severity of falls. In this study, patients who did not experience a fall (n=[9]) had an average length of stay of [9] days (95%CI: [9], [9]); for people who had a non-injurious fall (n=[9]), the same figure was [9] days (95%CI: [9], [9]) and, for people who fell and were injured (n=[9]), the figure was [9] (95%CI: [9], [9]). Length of stay in non-acute hospital settings was based on HES data for those transferred to 'other NHS settings' (NHS Information Centre for Health and Social Care, 2012). Length of stay in non-acute hospital settings was split by age only as an inspection of the data showed length of stay did not vary by gender.

The length of each hospital stay was probabilistically sampled. When a fall occurred during the simulated patient's admission, the length of stay was adjusted by sampling an additional period reflecting the difference between a stay without falls and one in which a fall (non-injurious or injurious, as appropriate) occurred. This difference, calculated from Vass et al.'s data, was assumed to be the same for both acute and non-acute settings, in the absence of any source of data specific to the latter. Extended length of stay was calculated in exactly the same way for all averted falls, but was subject to the causal multiplier (see above). The change in length of stay was only applied to the first fall experienced in any given stay, as Vass et al. did not differentiate between single and repeat fallers.

[9] Academic-in-confidence material removed

The cost of a day in care was calculated from standard sources (PSSRU, 2011). Following the approach taken in previous NICE guidelines on delirium (CG103, National Clinical Guidelines Centre, 2010) and hip fracture (CG124, National Clinical Guidelines Centre, 2011) unit costs for different care home settings were weighted according to Netten et al. (1998). These combine to give a daily cost of being in care of £103.78 (see appendix K [2013] for details).

Resource use for patients receiving home help, stratified by fall severity, was agreed by the GDG. A fall leading to minor injury received 7 days' help, moderate injury 21 days' help and severe injury 42 days' help. The cost per day of receiving home help following a fall was estimated at £38.97 (PSSRU, 2011).

Not all residential care and home help is NHS/PSS funded. As in previous delirium (CG103) and hip fracture (CG124) guidelines and the Department of Health Fracture Plan (Department of Health, 2009) an assumption that 60% of such care is NHS/PSS funded was used.

Hospital fall resource use and costs

Inpatient fall resource use and costs are based on costs previously calculated by the NPSA (NPSA, 2007), uplifted from 2005–06 prices to 2010–11 prices (PSSRU, 2011). No evidence was found to assign different resource or costs by hospital setting, so the GDG agreed to assume that inpatient falls incurred the same cost, regardless of hospital setting (see table 6).

The GDG agreed to assume that fatal inpatient falls incurred no cost. Whilst this may not be true, the number of fatal inpatient falls that occurred in the model was so few that the costs will be negligible.

Table 6: Inpatient fall treatment costs by fall severity (based on NPSA, 2007)

Inpatient Fall Severity	Cost (2010–11)
No harm	£47.41
Low	£76.63
Moderate	£371.21
Severe	£2,290.94

Home and care fall resource use and costs

Watson et al. (2009) assumed levels of health service use following each fall severity, these were combined with GDG advice and assumptions about further likely follow up and transport resource use (see table 7). The unit cost of home and care falls were based on standard sources (PSSRU, 2011) for each activity. As with fatal inpatient falls, due to the small numbers of fatal falls at home or in care the GDG agreed to assume that these incurred no cost.

Table 7: Home and Care Fall Treatment Costs (PSSRU, 2011)

Fall severity	Resource use (unit cost)		Total cost per fall	
	Home	Care	Home	Care
No harm	No NHS/PSS resource use	No NHS/PSS resource use	£0	£0
Low	GP clinic attendance (£36)	GP home visit (£121)	£36	£121
Moderate	A&E attendance (£106) GP clinic follow up (£36)	A&E attendance (£106) via ambulance (£253) GP home visit follow up (£121)	£142	£480
Severe	A&E attendance(£147) via ambulance (£253), hospitalisation (simulated separately), outpatient follow up (T&O, £93)	A&E attendance(£147) via ambulance (£253), hospitalisation (simulated separately), outpatient follow up (T&O, £93)	£492.89	£492.89

Intervention resource use and costs

As no economic evaluations of inpatient falls prevention programmes currently exist (Davis, 2011), there were no examples of costed fall prevention interventions. One GDG member agreed to provide unpublished resource use estimates from a published trial that was included in the guideline meta-analysis and therefore the intervention costs are based on Healey et al. (2004). All the percentages and staff time requirements are assumptions and were varied in the sensitivity analysis.

The intervention first conducts a multifactorial assessment of a patient's risk factors. The assessment is assumed to be undertaken by a nurse and require 20 minutes' staff time. It is assumed the proportion of patients receiving the assessment will vary by setting (30% in acute; 80% in non-acute).

Depending on the outcome of the assessment, patients then receive the necessary components of the multifactorial intervention. Assumed proportions of patients receiving each intervention component and associated resource use (staff time and consumables) are shown in table 8.

Table 8: Components used to cost multifactorial intervention

Staff Member	Intervention Component	% of those assessed receiving component	Staff Time Required (mins)	Notes
Nurse	Eyesight - ophthalmology referral	3% (1/30)	30	More complex referral, hence staff time needed
	Medication - extra BP checks if CVD drugs changed	12% (20% of those having medication review (Dr))	35	Extra daily checks for 1 week
	Bed height alteration and bedrail removal	100%	5	Assess and remove if necessary
	Blood pressure check - referral to medical staff if high/low	Unknown	0	Referrals sticky label based, so no burden. No extra staff resource, just allowed prioritisation
	Mobility - physiotherapy referral	80%	0	Referrals sticky label based, so no burden
Healthcare Assistant	Urine test - send sample for analysis	25%	10	Also laboratory costs (estimated £1 per test, 2010-11 costs)
	Footwear check and advise relatives on replacements	10%	5	Phone call to relatives. Also 100 pairs slippers purchased (£4 each at 0102 costs, £5.35 at 1011 costs)
	Patient position in ward - move close to nurses	10%	10	2x HCA 5min each
	Call bell and hazard education (assumed grade)	100%	0	No additional cost, ought to happen as part of routine practice
Doctor	Medication review	60%	7	Review 2min, explanation 5min
Optician	Optician referral for glasses	Unknown	Unknown	Referral sticky label based, so no burden

The intervention cost is calculated as the cost per admitted patient. Given the different proportion of patients assessed, the acute cost per admitted patient is £7.83 and the non-acute cost per admitted patient is £21.81.

Utilities

State Utilities

Utility values for people in the home state were taken from the standard source for UK population norms (Kind et al., 1999). Polynomial (quadratic) regression was used to allow more accurate estimates of utility values in older age groups (75+). All subsequent changes to utility were applied as decrements to this baseline.

No published literature was found that detailed the utility decrement experienced as a result of being in hospital. Therefore, unpublished data from a falls prevention trial were used (Vass et al., in print) to estimate utility decrements of [redacted][10] for men (that is, the quality of life of men in hospital is, on average, [redacted]%[10] of that experienced by men of the same age at home) and [redacted][10] for women. The GDG agreed that utility decrements were unlikely to differ between acute and non-acute hospital settings.

No source of evidence was found that detailed the utility decrement experienced as a result of being in the care state. The GDG agreed to use an assumption of 0.8, which was a decrement compared with being at home, but less than that for being in hospital.

Fall utilities

Falls in any setting are assumed to have a detrimental impact on quality of life. A search for published studies containing utility values related to inpatient falls yielded a total of 3460 unique citations. 91 papers were retrieved at title and abstract search. However, none were found to meet the NICE reference case.

[10] Academic-in-confidence data removed.

Therefore, relative utility decrements for no, minor and moderate injury inpatient falls were taken from unpublished data (Vass et al., in print). This study reports EQ-5D-based utility estimates of [redacted][11] (95%CI: [redacted][11]) for people who did not fall during their hospitalisation (n=[redacted][11]), [redacted][11] . (95%CI: [redacted][11], [redacted][11]) for people who experienced a non-injurious fall during their hospitalisation (n=[redacted][11]) and [redacted][11] (95%CI: [redacted][11], [redacted][11]) for people who fell and were injured during their hospitalisation (n=[redacted][11]).

As Vass et al.'s data did not allow differentiation between different severities of injurious falls, the relative decrements for home/care injurious falls (see below) were applied to these data. Due to the small number of severe injuries sustained in Vass et al., utility decrements for inpatient falls resulting in severe injuries were assumed to be the same as those associated with a hip fracture (in any setting, see below).

The inpatient utility decrement was assumed to last until discharge, at which point the patient reverted to the relevant injury severity decrement for the home/care states for the remainder of the specified decrement duration.

Vass et al. did not differentiate between single and repeat fallers, so fall utility decrements could not be applied repeatedly. If more than one fall occurred whilst in hospital, the decrement associated with the most serious fall was applied. Once a patient was discharged, they reverted to the utility decrement associated with the same severity of fall in the home or care state.

Falls resulting in serious injury (in any setting) were assumed to be similar in utility loss and duration to hip fractures; falls resulting in moderate injury were assumed to be similar in utility loss and duration to wrist fractures (Peasgood et al., 2009). In line with Iglesias et al. (2009), falls resulting in minor injury were assumed to have half the impact on utility of moderate falls. Home and care falls resulting in no injury were assumed to have no impact on utility (see table 9).

[11] Academic-in-confidence data removed.

All fall utility decrements were assumed to last 1 year, within the exception of falls resulting in severe injury which were spread over 5 years, in accordance with Peasgood et al. (2009).

Fall utility decrements from multiple falls are applied multiplicatively in the home and care states. Finally, the causal multiplier was applied to utility decrements associated with averted falls in the inpatient setting.

Table 9: Utility decrement associated with falls by fall severity

Severity	Level of decrement		Duration of decrement
	Inpatient	At home / in care	
No injury	0.942	1	1 year
Minor	0.753	0.978	1 year
Moderate	0.736	0.956	1 year
Severe	0.700	0.7	1 year
	0.800	0.8	years 2–5

Model Assumptions

The health economic model of interventions to prevent inpatient falls relies on a number of assumptions. These assumptions tend to arise for two reasons – either to reduce the model complexity or because no data point could be found in the evidence base. All the assumptions were discussed with and agreed by the GDG and are listed in appendix K (2013) – the most important are considered in the discussion section. Where possible, a range of values for assumed inputs was tested in the sensitivity analyses.

Sensitivity Analysis

Sensitivity analysis was conducted to explore the various areas of uncertainty and their impact on the model, including one-way, two-way and threshold analyses (using point estimates of parameters only). Note that the use of a discrete event simulation model accounts for first order (patient level) uncertainty (O'Hagan et al., 2007),

Given the large number of inputs, it would be of benefit to perform probabilistic sensitivity analysis (PSA) to explore the effects of parameter uncertainty of model outputs. However, at the time of reporting, this has not been feasible

because of the additional computational burden introduced by the discrete event simulation approach.

Model outputs – results

In order to verify the face validity of the health economic model of multifactorial interventions to prevent inpatient falls, various model outputs were checked and presented to the GDG. All results are taken from a model run of 200,000 patients through an acute setting.

Patients were slightly more likely to be women (51.1%) than men, which was in line with the source data (HES, 51.5% women). The mean starting age of patients in the model was 77.2 years (range 65.0 to 109.3 years). Patients spent an average of 10.1 years in the model (range 0 to 43.5 years) and the average age at death was 87.3 years (range 65.2 to 111.0 years).

0.3% of patients started the model in full-time care (source data HES 0.2%) and another 23.1% of patients entered care at some point. Patients who started in or entered full-time care spent an average of 2.6 years in care.

Throughout their modelled lifetimes, patients had an average of 3.9 hospitalisations (including the first, which everyone incurs). 20.1% had no more hospitalisations whilst 10.5% had 8 or more hospitalisations.

The initial acute hospitalisation had a mean length of stay of 12.3 days (range 0.0 to 157.0 days). Subsequent non-acute hospitalisations had a mean length of stay of 20.4 days (range 0.0 to 244.7 days). Length of stay was higher for fallers and recurrent fallers than non-fallers.

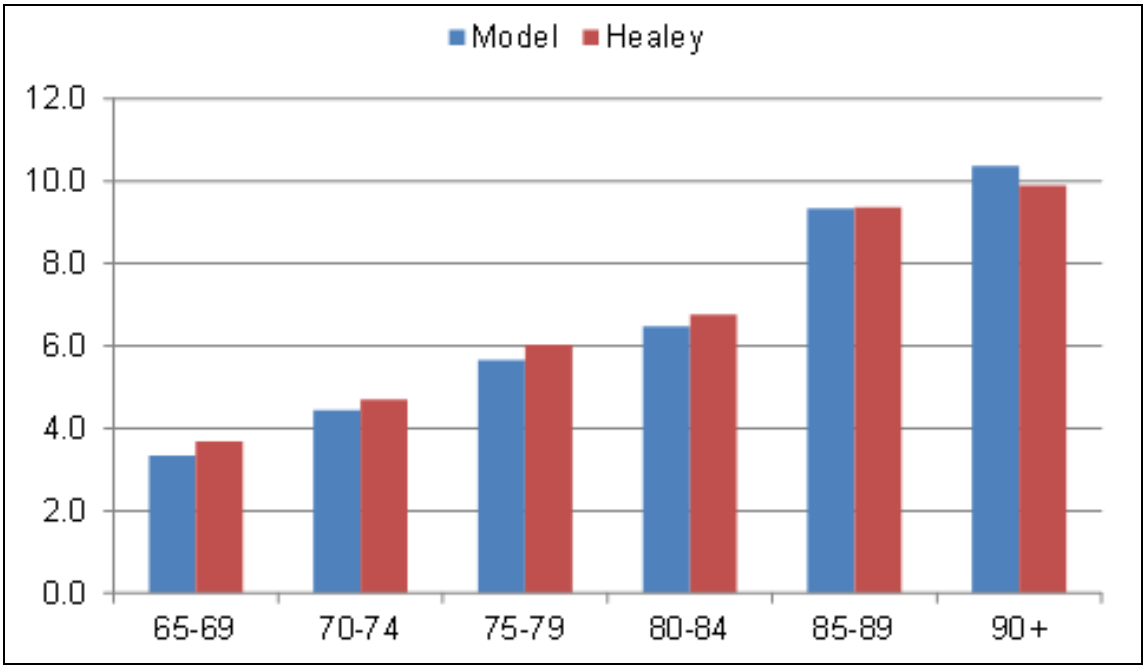


Figure 2: Inpatient fall rates per 1000 bed days

The model produced an overall average inpatient fall rate of 7.2 falls per 1000 bed days. This is higher than the input rate (6.6 falls per 1000 bed days, Healey et al. 2008), but this is to be expected, as the model is a cohort model in which simulated patients age and become subject to greater risks, whereas the source study is a cross-sectional 'snapshot' of the same population. As evidence of this, it can be seen that the fall rate varied by age in a similar manner to the source data (Healey et al., 2008, see figure 2). The majority (93.1%) of patients had no falls and very few (1.0% of patients) fell more than once during their hospital stay. Six patients fell six times and two patients fell seven times during a single hospital episode.

The severity of inpatient falls compared very closely with the source data (Healey et al. 2008), as this input was not related to age.

Patients had a mean of 1.0 falls per year at home and 4.8 falls per year in care. Injuries were more likely to occur in care, as in the source data.

Cost–utility results – base-case analysis

The health economic model to assess the cost effectiveness of a multifactorial inpatient fall prevention intervention (compared with no action) was run with 500,000 patients per arm. Results are tabulated in table 10.

Table 10: Base-case cost and QALY results (all costs and QALYs discounted at 3.5% per annum, 500,000 patients per arm)

Outcome	Arm	Acute	Non-acute
Lifetime costs	Control	£32,444	£36,852
	Intervention	£32,087	£36,651
	Difference	−£357	−£201
Lifetime QALYs	Control	5.447	5.421
	Intervention	5.448	5.424
	Difference	0.002	0.003
Cost per QALY (ICER)		Dominant	Dominant
Incremental net monetary benefit (£20k threshold)		£392	£260

Acute setting

In the acute setting, the multifactorial inpatient falls prevention intervention reduced costs and increased QALYs so is said to be dominant over the control arm.

The QALY difference (0.002 extra QALYs) generated was small – equivalent to less than 1 extra quality-adjusted day over the average 10-year lifetime of a patient in the model. The QALY gain arose from a small increase in time spent at home and a decrease in time spent in care.

In the acute setting, the cost difference was around 1% of lifetime costs. The difference in costs was largely generated by a saving in the hospital state (on average, £224 per patient over a lifetime). This comprises a slight reduction in length of stay (average 0.08 days shorter following the intervention) and reduced costs of treating falls. These savings are more than enough to offset the cost of implementing the intervention. There were also savings from a reduction in time spent in care (3.7 days per person, equating to an average lifetime saving of £147).

Non-acute setting

In the non-acute setting, the multifactorial inpatient falls prevention intervention also reduced costs and increased QALYs so is said to be dominant over the control arm.

The QALY difference (0.003 extra QALYs) was similar to the acute setting and was again driven by a slight increase in time spent at home. The cost difference was 0.5% of lifetime (discounted) costs and was due to a decrease in the average length of hospital stay.

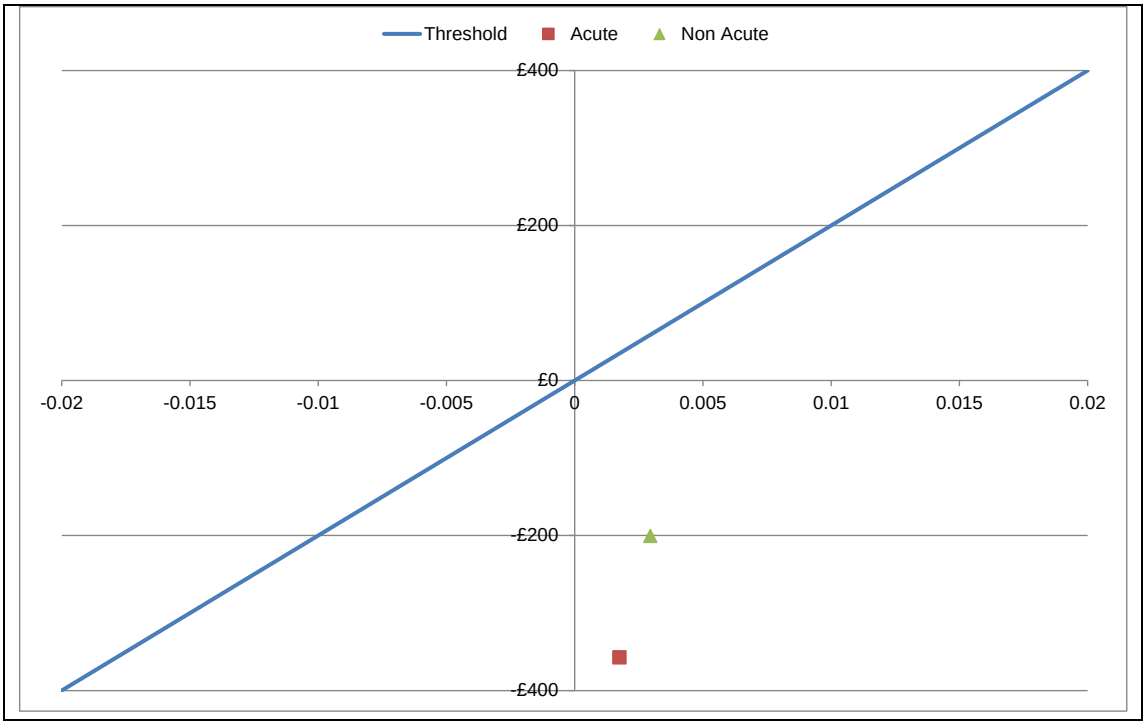


Figure 3: Cost Effectiveness Plane Showing Different Hospital Settings

Sensitivity analysis

Given the large number of inputs to this model, it is important to assess whether any inputs have a large influence on the outcomes generated. All deterministic sensitivity analyses were run in the acute setting with 500,000 patients using a fixed seed. Regression lines were fitted to the threshold analyses to minimise remaining sampling variation.

One-way sensitivity analysis

A number of input parameters had a noticeable impact on the cost effectiveness of the intervention (see appendix K (2013) for a tornado plot showing all input parameters varied).

The only parameter that impacted the cost effectiveness of the intervention to such an extent as to make the intervention not cost effective was the intervention effect (IRR for falls with intervention compared with control).

The cost of the intervention per patient was explored between £0 and £100 (base case £7.83 per patient) and the intervention remained cost effective; however it is inevitable that an even higher intervention cost would make the intervention not cost effective.

Varying individual parameters reflecting the costs and utilities associated with falls within plausible ranges did not affect the apparent cost effectiveness of the intervention.

Threshold Analysis

As it was the only parameter that appeared capable of influencing model results independently, the IRR associated with multifactorial inpatient falls prevention intervention was examined further in threshold analysis (see figure 4). This showed that, as long as some falls are prevented (IRR<1), the intervention is likely to be cost effective.

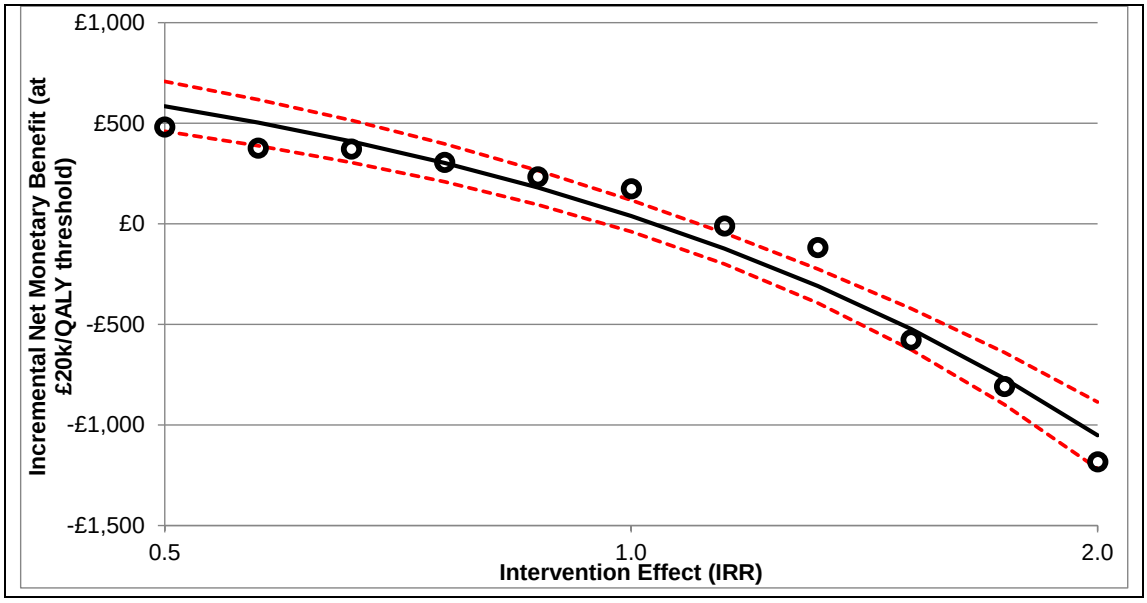


Figure 4: Threshold analysis of the incidence rate ratio for the multifactorial falls preventions intervention

Two-way sensitivity analysis

The GDG indicated it would be useful to consider the relationship between intervention effectiveness and cost. This two-way sensitivity analysis could either consider the cost worth paying for a known effectiveness, or the effectiveness required for a known cost.

The two-way sensitivity analysis suggests that, if the intervention effectiveness IRR is less than 0.85 (that is, if it reduces the incidence of inpatient falls by 15% or more), the intervention remains cost effective (at the £20,000 per QALY threshold) even when the intervention cost is £100 per admitted patient. The meta-analysis gave an IRR of 0.76, for which the two-way sensitivity analysis implies the intervention is cost effective even when the intervention costs £100 per admitted patient. Similarly, if the intervention is known to cost £7.83, then it remains cost effective as long as the IRR is less than 1.

Discussion

Principal findings

It would appear that, if inpatient falls can be prevented and/or their severity reduced, this is very likely to be a cost-effective course of action.

However, in both settings, the difference in QALYs is small, as can be seen in figure 3. The changes represent less than 0.06% of lifetime QALYs in the model. The cost differences are slightly bigger, but still less than 1.1% of an average patient's total lifetime costs.

A difference of 0.003 QALYs or less (1 quality-adjusted day or less) may be viewed as clinically not relevant over an average lifetime of ten years. However, the average experience of the simulated cohort contains a great heterogeneity of experience, and some simulated patients will have derived very appreciable benefit from having falls averted during their hospitalisation(s). Certainly, the 24% reduction in fall rates (taken from the meta-analysis) was thought to be clinically as well as statistically significant by the GDG. Cost differences were small but generally indicated savings in both settings. Therefore, the intervention can probably be said to be cost effective in the acute and non-acute settings, compared with no action to reduce the rate and/or severity of inpatient falls.

Strengths of the analysis

This is one of the first health economic analyses attempting to capture both the costs and benefits of interventions to prevent inpatient falls and is the first to consider outcomes in terms of QALYs (Davis et al., 2011). It was developed with a high degree of expert input from the GDG members that resulted in significant model changes.

The model structure reflects many of the complexities of the patient pathway, and is able to capture all important potential benefits of the intervention over a patient's lifetime. The discrete event approach enables a realistic simulation of a heterogeneous population, and allows the detailed exploration of the history of simulated patients and their likelihood of experiencing subsequent events.

Although the model contains a great many parameters, each of which is subject to a degree of uncertainty, conclusions are relatively robust when these values are varied within plausible ranges.

Limitations of the analysis

The model relies heavily on estimates of the cost of the intervention, the cost of treating inpatient falls and the ability of the multifactorial interventions to reduce fall rates – the true values of each remain unknown. The multifactorial intervention is deliberately generic but is costed based on informed estimates from one RCT and the estimated costs of treating inpatient falls are based on a number of assumptions about treatment received by each patient. Despite being based on a meta-analysis of reasonably powered RCTs, the intervention effect has relatively wide confidence intervals and, as discussed in section 3.4.2, using different groupings of evidence in meta-analyses produced different intervention effect sizes. However, the analysis suggests that the intervention as modelled is likely to be cost effective as long as (a) some reduction in falls is achieved and (b) the costs of the intervention do not outweigh this benefit.

The model relies on a linear combination of data on inpatient fall risk factors and is not able to account for the interactions that are likely to exist between these risk factors.

The splitting of hospital states into acute and non-acute is unlikely to reflect the complex array of arrangements that exist in the NHS. It was based on a simplifying decision by the GDG and is likely to be a source of structural uncertainty in the model. In some instances, the non-acute setting inputs were based on approximations to the true rates and, whilst they were shown not to impact the results, the parameters were not ideal. It is debatable whether splitting the hospital state into acute and non-acute settings increased the value of the health economic model or just increased the uncertainty within the model.

The causal multiplier was a necessary but limiting assumption. No evidence exists to quantify the causal relationship between an inpatient fall and

subsequent events. However, sensitivity analysis shows that the model is relatively robust to this uncertainty: as long as it can be assumed that some of the negative experiences associated with falls are avoided by averting the falls themselves, some value can be anticipated from the intervention.

Patients in the meta-analysis are unlikely to have received the inpatient falls intervention more than once. However, the model generates around four hospitalisations in each patient's lifetime and applies the intervention to each hospitalisation – the intervention may be more or less effective on subsequent applications and, accordingly, the model may under- or overestimate the value for money it provides.

The modelling of the social care process is a gross simplification of reality. The focus of the model was preventing falls during a patient's stay in hospital and, for this reason, the structure of the model was focused primarily on the hospital episode. However, the care state has a nontrivial influence on cost savings and QALY gains and therefore perhaps more modelling time should have been given to refining this state. This is set against the low quality of the evidence base and parameters on which to base the existing parameters – any further refinement of the care state would have probably introduced more uncertainty into the model.

The costs and benefits of interventions to prevent inpatient falls are likely to be borne by different parts of the NHS/PSS system and co-ordinated commissioning arrangements will be needed to implement them..

The intervention modelled only applies to the hospital setting. No costs or utilities associated with community falls prevention (CG21) are included within this model. The crossover between the previous falls prevention in the community guideline (CG21) and this guideline may be an area for potential future health economic research.

There remains a lack of direct evidence on the utility experienced by patients in hospital and the utility decrement and duration experienced following an inpatient fall. Similarly, the utility of people in care homes and the impact of falls therein were based on assumed values.

It is a significant weakness of this analysis that it has not proved computationally feasible to undertake full probabilistic sensitivity analysis, to explore the implications of parameter uncertainty for decision-making. A wide range of one-way sensitivity analyses was undertaken; this enables a fair degree of inference on the impact of such 'second-order' uncertainty and, in the light of these analyses, it is possible to state with some confidence that the intervention would be associated with a greater than 50% probability of cost effectiveness in a fully probabilistic analysis. However, it is not possible to quantify this probability accurately, nor to explore the potential value of further research, in the absence of such an analysis.

Finally, it is acknowledged that the model is extremely complex. A bigger model carries more structural uncertainty and requires more computational time. More sampling error than would be desired remains in the model, not least because inpatient falls are rare events, and inpatient falls with substantial consequences are rarer still. Therefore, it is necessary to simulate a very large number of patients to provide stable model results.

Conclusions

An innovative discrete event health economic model has been built that showed that, if it is possible to reduce inpatient fall rates, then this appears to be a cost effective course of action in the acute and non-acute hospital settings. However, the gains in QALYs and savings in costs were, for an average patient, small.

3.4.5 Evidence to recommendations

Relative value of different outcomes	Studies were grouped according to the setting in which they were conducted, because the GDG felt that there could be important differences between settings and that some interventions may be effective in some settings but not all. Thus the GDG categorised each study using their judgement based on the description of the hospital, type of patients and mean length of stay stated in each study. If this information was not available or was unclear, the GDG classified the study in the 'mixed or unclear' setting. Interventions were grouped using the fall prevention interventions classification system of single, multiple or multifactorial, developed by the Prevention of Falls Network Europe (ProFaNE).
Trade-off between benefits and harms	The GDG prioritised number or rate of falls as the outcome of interest, and this is what its deliberations were based on. Injuries were also considered to be important, because ideally a successful intervention should result in statistically significant reductions in both falls and injuries. However, the GDG acknowledged that injurious falls are relatively rare and most studies are underpowered to detect meaningful changes in injury rates. Thus falls were prioritised over injuries.
Economic considerations	An original cost–utility model was built to assess the cost effectiveness of multifactorial interventions to prevent or reduce the number and/or severity of inpatient falls, compared with no action. The model results suggested that, if falls can be prevented, then this is likely to be a cost-effective course of action. Although the changes in costs and quality-adjusted life years (QALYs) were small, this conclusion was robust under sensitivity analyses.
Quality of evidence	Most of the single interventions that were reviewed had evidence from only one study, and so meta-analysis was not conducted. In general the evidence was of low quality, and reported no statistically significant effects, meaning that there was uncertainty around whether the intervention actually worked or not. Some evidence did report statistically significant effects, but these results came from single studies so the GDG were not confident that the results could be replicated. Since there was no meta-analysis for the GDG to base their deliberations on, and the GDG were not confident in the results of single studies, they used their experience and expertise to develop recommendations. The GDG felt that most older inpatients will have multiple risk factors for falling, and so single interventions are unlikely to work in isolation. The GDG felt that healthcare professionals should not offer 'blanket interventions' to whole groups of patients in the hope that it will reduce risk of falls, as this may increase the likelihood that this type of intervention will be the only one used. Because of this, the GDG felt that single interventions that are not linked to an individual patient's multifactorial falls risk assessment should not be used, and so a 'do not do' recommendation was developed to reflect this. No evidence relating to multiple interventions was identified in this review. For multifactorial interventions, there were numerous studies, some of which provided high-quality evidence. Meta-analysis was conducted separately for each setting and the analyses were stratified by study

	design. Some significant heterogeneity remained in the analysis and the GDG debated whether it was appropriate to continue with the meta-analysis. It was agreed that in this case a meta-analysis with heterogeneity was better than no meta-analysis at all, as the GDG had no reason to identify a study or group of studies that were 'better' or more 'believable' than the others. So, rather than using the meta-analysis to identify the 'true' effect among the pool of studies, a random-effects model was used to estimate an average effect among this heterogeneous body of evidence. For acute and non-acute settings, the meta-analyses of randomised studies were non-significant indicating there is uncertainty about whether the intervention actually reduced or increased fall rates in these settings. For the mixed or unclear setting, the meta analysis of randomised studies were statistically significant and showed that multifactorial interventions reduced the rate of falls in this setting. The GDG discussed these results at length. The GDG felt that the a priori decision to separate studies depending on the setting in which it was conducted may not have been useful, as dividing the evidence up in this way may have contributed to a lack of statistical power in the meta analyses. On reflection the GDG felt that had all randomised studies been included in a single meta-analysis, the overall results were likely to have been statistically significant in support of multifactorial fall prevention interventions. The GDG felt that in reality most hospital wards in the UK will accommodate a mixture of acute and non-acute patients, and patients will have a mixture of acute and non-acute needs as their condition changes. The GDG felt that although the body of evidence is heterogeneous and lacking in statistical power, the mixed and unclear meta-analysis that most closely represents UK inpatient settings is supportive of multifactorial interventions in general, and evidence from non-randomised studies also supports this finding. Thus the GDG agreed that multifactorial fall prevention interventions could be recommended for all older inpatients. The GDG felt that there were two elements to most multifactorial interventions that were reviewed: general improvements to the inpatient environment (such as adequate lighting, handholds, etc.), and targeted multifactorial interventions that link to each patient's own multifactorial assessment. Thus the discussions linked back to those in section 3.3, where the GDG felt that a good multifactorial clinical assessment would highlight the patient's individual risk factors for falling that could be treated, managed or improved during their stay, and this assessment should be linked to related multifactorial interventions to address the identified factors. The group felt that it was not necessary to have a single assessment document for this; rather, the documentation could come from one or more existing assessments that are currently used. The GDG used their expertise and consensus to identify core elements that should be covered in the assessment as a minimum.
Other considerations	The GDG agreed that the aim of inpatient falls prevention interventions is to reduce the risk of the patient falling during their hospital stay, not to reduce their risk of falling once they leave hospital. This is because the risk factors in hospital are different from

	those in the community and require a different identification and assessment process. Recommendations for falls prevention when a patient returns to their normal place of residence already exist (see part B of this guideline). The GDG wanted to stress that staff should take into account the length of a patient's expected hospital stay when considering which interventions to offer, as short-stay patients may only benefit from short-term interventions, whereas longer-stay patients could benefit from more enduring interventions. The GDG felt that healthcare professionals are usually able to predict whether a patient will have a short or long inpatient stay, but acknowledged that this is not always possible. The GDG also felt that some interventions, such as the provision of appropriate walking aids, may only be available during Monday to Friday in some hospitals, with no provision over the weekend. The GDG felt that this was unacceptable; as potentially some patients admitted on Friday and discharged the following Monday may not have access to appropriate interventions. Thus the GDG wanted to stress that healthcare professionals should promptly address the patient's individual risk factors for falling that are identified.

1

3.4.6 Recommendations and research recommendations for inpatient fall prevention interventions

Recommendations

Recommendation 1.1.2.1

Ensure that aspects of the inpatient environment that could affect patients' risk of falling (such as flooring, lighting and provision of hand holds) are systematically identified and addressed.

Recommendation 1.1.2.2

For patients at risk of falling in hospital (see recommendation 1.1.1.1), consider a multifactorial assessment and multifactorial interventions.

Recommendation 1.1.2.3

Ensure that any multifactorial assessment identifies a patient's individual risk factors for falling in hospital that can be treated, improved or managed during their expected stay, including:

- cognitive impairment
- continence problems
- falls history, including causes and consequences (such as injury and fear of falling)
- footwear that is unsuitable or missing
- health problems that may increase their risk of falling
- medication
- postural instability, mobility problems and/or balance problems
- visual impairment.

Recommendation 1.1.2.4

Ensure that any multifactorial interventions:

- promptly address the patient's identified individual risk factors for falling in hospital **and**
- take into account whether the risk factors can be treated, improved or

managed during the patient's expected stay.

Recommendation 1.1.2.5

Do not offer generic interventions that fail to take into account the patient's individual risk factors for falling.

Research recommendations

See section 3.6 for details of research recommendations.

3.5 Inpatient information: evidence review and recommendations

3.5.1 Review question

What are the education and information needs of patients and their family members and carers after a hospital-based falls risk assessment, or a fall in hospital?

3.5.2 Evidence review

This question focused on identifying what information patients and their family members and carers should receive after a falls risk assessment or a fall in hospital. This review specifically did not address education and information that can be provided to patients with the aim of reducing their risk of falling, as this was considered to be a type of educational intervention for inclusion in section 3.4. Only information that aimed to enhance the patient experience was included in this question.

The initial search identified 2441 studies and all were subject to screening. This led to the retrieval of 13 full texts which were considered in the review.

Studies were included in the review if they related to patient or carer experience of the management of inpatient falls risk, or if they identified patient or carer needs for information during the management of inpatient falls risk. No restrictions on study design were imposed. Studies that sought patient experience of a fall that did not occur in the inpatient setting were excluded, as were studies that were not focused on patient or carer experience or needs. For a full list of excluded papers for this review question, see appendix G.

Three full text articles met the eligibility criteria and were included in the final review. The quality of the 3 included studies was assessed using appropriate NICE methodology checklists.

Quality assessment

The studies all had limitations, mainly because of inadequate reporting of the researcher's role and the impact this could have on participant responses, and a lack of reliability concerning the study findings. Indirect evidence from one quantitative study (Haines and McPhail 2011) provided some qualitative data for this review question (see table 15 and evidence tables in appendix E [2013] for further details).

Since GRADE is not currently developed for use with qualitative evidence, a key themes matrix was used to present the key themes from the included studies.

Table 15 Summary of included studies for inpatient information

Study	Participants	Mean Length of Stay	Method	Limitations
(Carroll et al. 2010) USA	9 participants who had fallen in hospital in the previous 48hrs Mean age=61.2 years, range=24 - 78 years	14 days	Interviews with patients	Lack of clear theoretical approach Lack of description of researcher role Unreliable methodology Lack of rich data
(Gallinagh et al. 2001) Ireland	9 relatives of 6 patients who had side rails up during their inpatient care Patient mean age=77 years	3 months	Interviews with relatives	Lack of description of researcher role Unreliable methodology
(Haines and McPhail 2011) Australia	125 inpatients from the geriatric assessment and rehabilitation unit, Mean age=79 years	Unclear	Cross sectional survey of patients willingness to pay for falls prevention interventions	Indirect evidence

Table 16 Key themes matrix for inpatient information

Reference	Awareness	Messages from staff	Memory	Discrepancies in knowledge/beliefs and behaviour	Preferences
(Carroll et al. 2010) USA	Patients were unaware of their own falls risk	Patients who were aware of their falls risk received inconsistent messages from their nurses	Patients often forgot that they were at risk of falling or to call for help, because of medication that clouded their memory or because they urgently needed to move.	Patients acknowledged the request to call nurses, but didn't want to bother or burden them	-
(Gallinagh et al. 2001) Ireland	Relatives/carers were unaware of rationale for using side rails	-	-	Carers accepted the use of side rails, but were aware they may also cause injury/harm	-
(Haines and McPhail 2011) Australia		Participants who were provided with visual cues about the intervention were less likely to misunderstand the intervention	-	-	Participants valued targeted multifactorial interventions the most, followed by falls consultation, exercise, and face to face education. Participants valued hip protectors, and booklet and video education the least.

3.5.3 Evidence statements

For details of how the evidence is graded, see 'The guidelines manual (2009)'.

Awareness

3.5.3.1 Evidence from 3 studies with some methodological limitations conducted in the USA, Ireland or Australia showed that:

- *There is a lack of awareness about falls risk and why interventions such as bed rails are being used.*
- *Patients receive inconsistent messages about their falls risk from staff.*

- *Visual cues about falls prevention interventions can reduce patients' misunderstanding of the intervention.*
- *Patients may forget they are at risk of falling, or may forget to ask for help when mobilising.*
- *Patients do not want to be a burden to staff by asking for help when mobilising.*
- *Some interventions such as bed rails can cause harm, even though they are meant to reduce harm.*
- *Multifactorial fall prevention interventions are valued the most by patients, and booklet/leaflet education is valued the least.*

3.5.4 Health economic modelling

Health economic modelling was not considered a priority for this review question.

3.5.5 Evidence to recommendations

Relative value of different outcomes	The GDG felt that one study (Simpson, 1995) should be removed from the analysis. This study examined whether patients at risk of falling wanted to, and could, be taught how to get up from the floor. The GDG stated that this study is in conflict with current NHS best practice, which states that all patients who are found on the floor should be provided with instructions about how to get up.
Trade-off between benefits and harms	The GDG discussed the need to provide information to patients and their family members and carers that is relevant and useful. However, it recognised that the ability of some patients (such as those with memory problems or cognitive impairment) to understand and retain information may be compromised. Qualitative evidence identified that patients and their families and carers are often unaware of the patient's fall risk, and that some patients who are aware of their increased falls risk feel they are burdening staff if they ask for help. The GDG felt that this was an accurate reflection of the inpatient experience and wanted to emphasise the need for healthcare professionals to provide consistent explanations about the patient's individual risk factors for falling and encourage them to ask for help when moving around the hospital. To do this, healthcare professionals also need to show the patient how to use the nurse call system. This also led to a discussion about bed rails, as some GDG members felt that family members and carers often do not know how to use them correctly. Since incorrect use can lead to patient injuries, the GDG wanted to make a recommendation about bed rails even though no evidence was found in relation to them.
Economic considerations	Health economics were not considered for this review question.
Quality of evidence	The evidence reviewed originated from two qualitative studies, both of which had limitations, and one quantitative study from which qualitative data were extracted. Thus the data can be considered to be of low quality. The GDG agreed that the themes identified were an accurate representation of the literature, and of the experiences of some patients and carers.
Other considerations	None

3.5.6 Recommendations and research recommendations for inpatient information

Recommendations

Recommendation 1.1.3.1

Provide relevant oral and written information and support for patients and their family members and carers, taking into account the patient's ability to understand and retain information. This should include:

- explaining about the patient's individual risk factors for falling in hospital
- showing the patient how to use the nurse call system and encouraging them to use it when they need help
- informing family members and carers about when and how to raise and lower bed rails.
- providing consistent messages about when a patient should ask for help before getting up or moving about
- helping the patient to engage in any multifactorial interventions that are part of their care plan.

Research recommendations

See section 3.6 for details of research recommendations.

3.6 List of research recommendations

The Guideline Development Group has made the following recommendation for research, based on its review of evidence, to improve NICE guidance and patient care in the future.

Adjustments to the ward environment aimed at reducing the risk of patients falling in hospital

What environmental adaptations can be made in existing inpatient units, and should be considered when inpatient units are built, to reduce the risk of inpatient falls?

Why this is important

Dementia, delirium, poor mobility and balance, urgent or frequent toilet needs or incontinence and visual impairment are common in older hospital patients. Several multifactorial studies have included adjustments to the ward environment that have plausible mechanisms for reducing falls in patients with these risk factors (such as improved lighting, changes to flooring, furniture, handholds, walking routes, lines of sight and signposting), but the impact of these changes has not been recorded. There is a need to understand what improvements to the inpatient environment are the most effective and cost-effective for preventing falls in hospital, and what factors architects should consider when designing new hospitals.

4 The assessment and prevention of falls in older people: community settings

All text in this chapter is taken directly from the 2004 guideline.

This work was undertaken by the National Collaborating Centre for Nursing and Supportive Care (NCC-NSC) and the Guideline Development Group (GDG) formed to develop this guideline. Funding was received from the National Institute for Clinical Excellence (NICE). The NCC-NSC consists of a partnership between: Centre for Evidence-Based Nursing; Centre for Statistics in Medicine; Clinical Effectiveness Forum for Allied Health Professionals, College of Health; Health Care Libraries (University of Oxford); Health Economics Research Centre, Royal College of Nursing and UK Cochrane Centre.

Disclaimer

As with any clinical guideline, recommendations may not be appropriate for use in all circumstances. A limitation of a guideline is that it simplifies clinical decision-making (Shiffman 1997). Decisions to adopt any particular recommendations must be made by the practitioners in the light of:

- available resources
- local services, policies and protocols
- the patient's circumstances and wishes
- available personnel and devices
- clinical experience of the practitioner
- knowledge of more recent research findings.

4.1 Executive summary

The National Institute for Clinical Excellence (NICE) commissioned the National Collaborating Centre for Nursing and Supportive Care (NCC-NSC) to develop guidelines on the assessment and prevention of falls in older people. This follows referral of the topic by the Department of Health and Welsh Assembly Government. This document describes the methods for developing the guidelines and presents the resulting recommendations. It is the source document for the NICE (abbreviated version for health professionals) and Information for the public (patient) versions of the guidelines that are published by NICE. A multidisciplinary Guideline Development Group produced the guidelines and the development process was undertaken by the NCC-NSC.

The main areas examined by the guideline were:

- The evidence for factors that increase the risk of falling.

- The most effective methods of assessment and identification of older people at risk of falling.
- The most clinically and cost effective interventions and preventative strategies for the prevention of falls.
- The clinical effectiveness of hip protectors for the prevention of hip fracture.
- The most clinically and cost effective interventions and rehabilitation programmes for the prevention of further falls.
- Older peoples' views and experiences of falls prevention strategies and programmes.

Recommendations for good practice based on the best available evidence of clinical and cost effectiveness are presented.

Evidence published after October 2003 was not considered.

Health care professionals should use their clinical judgement and consult with patients when applying the recommendations, which aim to reduce the negative physical, social and financial impact of falling.

4.1.1 Summary of recommendations (please refer to Sections 4.5.13 and 4.5.14 for system used to grade recommendations)

1.2.1 Case/risk identification

1.2.1.1 Older people in contact with healthcare professionals should be asked routinely whether they have fallen in the past year and asked about the frequency, context and characteristics of the fall/s. **[2004]**

1.2.1.2 Older people reporting a fall or considered at risk of falling should be observed for balance and gait deficits and considered for their ability to benefit from interventions to improve strength and balance. (Tests of balance and gait commonly used in the UK are detailed in section 4.5.) **[2004]**

1.2.2 Multifactorial falls risk assessment

1.2.2.1 Older people who present for medical attention because of a fall, or report recurrent falls in the past year, or demonstrate abnormalities of gait and/or balance should be offered a multifactorial falls risk assessment. This assessment should be performed by a healthcare professional with appropriate skills and experience, normally in the setting of a specialist falls service. This assessment should be part of an individualised, multifactorial intervention. **[2004]**

1.2.2.2 Multifactorial assessment may include the following:

- identification of falls history
- assessment of gait, balance and mobility, and muscle weakness
- assessment of osteoporosis risk
- assessment of the older person's perceived functional ability and fear relating to falling
- assessment of visual impairment
- assessment of cognitive impairment and neurological examination

- assessment of urinary incontinence
- assessment of home hazards
- cardiovascular examination and medication review**. [2004]**

1.2.3 Multifactorial interventions

1.2.3.1 All older people with recurrent falls or assessed as being at increased risk of falling should be considered for an individualised multifactorial intervention. **[2004]**

In successful multifactorial intervention programmes the following specific components are common (against a background of the general diagnosis and management of causes and recognised risk factors):

- strength and balance training
- home hazard assessment and intervention
- vision assessment and referral
- medication review with modification/withdrawal. **[2004]**

1.2.3.2 Following treatment for an injurious fall, older people should be offered a multidisciplinary assessment to identify and address future risk and individualised intervention aimed at promoting independence and improving physical and psychological function. **[2004]**

1.2.4 Strength and balance training

1.2.4.1 Strength and balance training is recommended. Those most likely to benefit are older people living in the community with a history of recurrent falls and/or balance and gait deficit. A muscle-strengthening and balance programme should be offered. This should be individually prescribed and monitored by an appropriately trained professional. **[2004]**

1.2.5 Exercise in extended care settings

1.2.5.1 Multifactorial interventions with an exercise component are recommended for older people in extended care settings who are at risk of falling. **[2004]**

1.2.6 Home hazard and safety intervention

1.2.6.1 Older people who have received treatment in hospital following a fall should be offered a home hazard assessment and safety intervention/modifications by a suitably trained healthcare professional. Normally this should be part of discharge planning and be carried out within a timescale agreed by the patient or carer, and appropriate members of the health care team. **[2004]**

1.2.6.2 Home hazard assessment is shown to be effective only in conjunction with follow-up and intervention, not in isolation. **[2004]**

1.2.7 Psychotropic medications

1.2.7.1 Older people on psychotropic medications should have their medication reviewed, with specialist input if appropriate, and discontinued if possible to reduce their risk of falling. **[2004]**

1.2.8 Cardiac pacing

1.2.8.1 Cardiac pacing should be considered for older people with cardioinhibitory carotid sinus hypersensitivity who have experienced unexplained falls. **[2004]**

1.2.9 Encouraging the participation of older people in falls prevention programmes

1.2.9.1 To promote the participation of older people in falls prevention programmes the following should be considered.

- Healthcare professionals involved in the assessment and prevention of falls should discuss what changes a person is willing to make to prevent falls.
- Information should be relevant and available in languages other than English.
- Falls prevention programmes should also address potential barriers such as low self-efficacy and fear of falling, and encourage activity change as negotiated with the participant. **[2004]**

1.2.9.2 Practitioners who are involved in developing falls prevention programmes should ensure that such programmes are flexible enough to accommodate participants' different needs and preferences and should promote the social value of such programmes. **[2004]**

1.2.10 Education and information giving

1.2.10.1 All healthcare professionals dealing with patients known to be at risk of falling should develop and maintain basic professional competence in falls assessment and prevention. **[2004]**

1.2.10.2 Individuals at risk of falling, and their carers, should be offered information orally and in writing about:

- what measures they can take to prevent further falls
- how to stay motivated if referred for falls prevention strategies that include exercise or strength and balancing components
- the preventable nature of some falls
- the physical and psychological benefits of modifying falls risk
- where they can seek further advice and assistance
- how to cope if they have a fall, including how to summon help and how to avoid a long lie. **[2004]**

1.2.11 Interventions that cannot be recommended

1.2.11.1 **Brisk walking**. There is no evidence[12] that brisk walking reduces the risk of falling. One trial showed that an unsupervised brisk walking programme increased the risk of falling in postmenopausal women with an upper limb fracture in the previous year. However, there may be other health benefits of brisk walking by older people. **[2004]**

12 This refers to evidence reviewed in 2004

1.2.12 Interventions that cannot be recommended because of insufficient evidence

We do not recommend implementation of the following interventions at present. This is not because there is strong evidence against them, but because there is insufficient or conflicting evidence supporting them[12]. **[2004]**

1.2.12.1 **Low intensity exercise combined with incontinence programmes**. There is no evidence[12] that low intensity exercise interventions combined with continence promotion programmes reduce the incidence of falls in older people in extended care settings. **[2004]**

1.2.12.2 **Group exercise (untargeted).** Exercise in groups should not be discouraged as a means of health promotion, but there is little evidence[13] that exercise interventions that were not individually prescribed for older people living in the community are effective in falls prevention. **[2004]**

1.2.12.3 **Cognitive/behavioural interventions**. There is no evidence[13] that cognitive/behavioural interventions alone reduce the incidence of falls in older people living in the community who are of unknown risk status. Such interventions included risk assessment with feedback and counselling and individual education discussions. There is no evidence[13] that complex interventions in which group activities included education, a behaviour modification programme aimed at moderating risk, advice and exercise interventions are effective in falls prevention with older people living in the community. **[2004]**

1.2.12.4 **Referral for correction of visual impairment.** There is no evidence[13] that referral for correction of vision as a single intervention for older people living in the community is effective in reducing the number of people falling. However, vision assessment and referral has been a component of successful multifactorial falls prevention programmes. **[2004]**

1.2.12.5 **Vitamin D.** There is evidence[13] that vitamin D deficiency and insufficiency are common among older people and that, when present, they

13 This refers to evidence reviewed in 2004

impair muscle strength and possibly neuromuscular function, via CNS-mediated pathways. In addition, the use of combined calcium and vitamin D3 supplementation has been found to reduce fracture rates in older people in residential/nursing homes and sheltered accommodation. Although there is emerging evidence[13] that correction of vitamin D deficiency or insufficiency may reduce the propensity for falling, there is uncertainty about the relative contribution to fracture reduction via this mechanism (as opposed to bone mass) and about the dose and route of administration required. No firm recommendation can therefore currently be made on its use for this indication.[14] **[2004, amended 2013]**

1.2.12.6 **Hip protectors.** Reported trials that have used individual patient randomisation have provided no evidence for the effectiveness of hip protectors to prevent fractures when offered to older people living in extended care settings or in their own homes. Data from cluster randomised trials provide some evidence that hip protectors are effective in the prevention of hip fractures in older people living in extended care settings who are considered at high risk. **[2004]**

[14] The following text has been deleted from the 2004 recommendation: 'Guidance on the use of vitamin D for fracture prevention will be contained in the forthcoming NICE clinical practice guideline on osteoporosis, which is currently under development.' As yet there is no NICE guidance on the use of vitamin D for fracture prevention.

4.2 Background

In March 2002, the National Collaborating Centre for Nursing and Supportive Care (NCC-NSC) was commissioned by NICE to develop clinical guideline on the assessment and prevention of falls in older people for use in the NHS in England and Wales. The remit from the DH and Welsh Assembly Government was as follows:

> To prepare clinical guidelines for the NHS in England and Wales for the assessment and prevention of falls, including recurrent falls in older people; with an associated clinical audit system.

Clinical need

Falls are a major cause of disability and the leading cause of mortality resulting from injury in people aged above 75 in the UK (Scuffham & Chaplin 2002). Furthermore, more than 400,000 older people in England attend accident and emergency departments following an accident, while up to 14,000 people die annually in the UK as a result of an osteoporotic hip fracture (National Service Framework for Older People 2001). It's clear that falling has an impact on quality of life, health and health care costs.

Falls are not an inevitable result of ageing, but they do pose a serious concern to many older people and to the health system. Older people have a higher risk of accidental injury that results in hospitalisation or death than any other age group (Cryer 2001). The Royal Society for the Prevention of Accidents (ROSPA) estimates that one in three people aged 65 years and over experience a fall at least once a year – rising to one in two among 80 year-olds and older. Although most falls result in no serious injury, approximately 5 per cent of older people in community-dwelling settings who fall in a given year experience a fracture or require hospitalisation (Rubenstein et al. 2001).

Incidence rates for falls in nursing homes and hospitals are two to three times greater than in the community and complication rates are also considerably higher. Ten to 25 per cent of institutional falls result in fracture, laceration or need for hospital care (Rubenstein 2001).

The key issue of concern is not simply the high incidence of falls in older people – since children and athletes have a very high incidence of falls – but rather the combination of a high incidence and a high susceptibility to injury (Rubenstein 2001). In 1999, there were 647,721 A&E attendances and 204,424 admissions to hospital for fall-related injuries in the UK population aged 60 years or over (Scuffham and Chaplin 2002). The associated cost of these falls to the NHS and PSS was £908.9 million and 63 per cent of these costs were incurred from falls in those aged 75 years and over (Scuffham and Chaplin 2002). In addition, 86, 000 hip fractures occur annually in the UK (Torgerson 2001) and 95 per cent of hip fractures are the result of a fall (Youm 1999). Although only 5 per cent of falls result in fracture (Tinetti 1988), the total annual cost of these fractures to the NHS has been calculated as £1.7 billion (Torgerson 2001) with many individuals losing independence and quality of life (Cooper 1993). Some older people have stated that they would rather die than fracture their hip and have to live in a nursing home (Salkeld 2000).

Although most falls do not result in serious injury, the consequences for an individual of falling or of not being able to get up after a fall can include:

- psychological problems, for example, a fear of falling and loss of confidence in being able to move about safely
- loss of mobility, leading to social isolation and depression
- increase in dependency and disability
- hypothermia
- pressure-related injury
- infection.

Falls have a multifactorial aetiology, with more than 400 separate risk factors described (Oliver 2000). The major risk factors for falling are diverse, and many of them – such as balance impairment, muscle weakness, polypharmacy and environmental hazards – are potentially modifiable. Since the risk of falling appears to increase with the number of risk factors, multifactorial interventions have been suggested as the most effective

strategy to reduce declines in function and independence and also to prevent the associated costs of complications (Gillespie et al. 2001).

Preventive programmes based on risk factors for falling include exercise programmes, education programmes, medication review, environmental modification in homes or institutions and nutritional or hormonal supplementation (Cummings et al. 2001).

Interventions need to target extrinsic factors such as hazards within the home environment and intrinsic risk factors, such as mobility, strength, gait, medicine use and sensory impairment (HDA 2002). Numerous interventions have been studied in the prevention of falls. Few trials have been carried out in the UK.

The prevention and management of falls in older people is a key Government target in reducing morbidity and mortality. This is outlined in the National Service Framework (NSF) for England, standard six for older people, which covers falls and specifically aims to:

> ‘reduce the number of falls which result in serious injury and ensure effective treatment and rehabilitation for those who have fallen’ (NSF 2001).

The NSF also outlines key changes needed to reduce the number of falls and their impact by:

a) prevention – including the prevention and treatment of osteoporosis

b) improving the diagnosis, care and treatment of those who have fallen

c) rehabilitation and long-term support

d) ensuring that older people who have fallen receive effective treatment and rehabilitation

e) ensuring that patients and their carers receive advice on prevention, through a specialised falls service.

In the light of the serious and costly impact of falls in the community and long-term care setting among older people, plus the potential of interventions to positively influence this problem, risk assessment and preventative interventions were selected as the focus for this NICE guideline.

These guidelines will support the implementation of standards two and six of the National Service Framework for Older People in England (2001).

4.3 Aims

- To evaluate and summarise the evidence for assessing and preventing falls in older people.
- To highlight gaps in the research evidence.
- To formulate evidence-based and, where possible, clinical practice recommendations on the assessment of older people and prevention of falls in older people based on the best evidence available to the GDG.
- To provide audit criteria to assist with the implementation of the recommendations.

4.3.1 Who the guideline is for

As detailed in the guideline scope, the guideline is of relevance to:

- those older people – aged 65 and above – who are vulnerable to or at risk of falling
- families and carers
- health care professionals who share in caring for those who are vulnerable or at risk of falling
- those responsible for service delivery.

4.3.2 Groups covered by the guideline

The recommendations made in the guideline cover the care of older people:

a) in the community or extended care, who are at risk of falling or who have fallen

b) who attend primary or secondary care settings, following a fall.

4.3.3 Groups not covered

The following groups are not covered by this guideline:

a) hospitalised patients who sustain a fall while in hospital or who may be at risk of falling during hospitalisation

b) people who are confined to bed for the long-term.

4.3.4 Health care setting

This guideline makes recommendations on the care given by health care professionals who have direct contact with and make decisions concerning the care of older people who have fallen or are at risk of falling.

It also makes recommendations on the care given by health care professionals or carers where applicable, involved in the care of older people who have been taken to hospital following a fall.

This is an NHS guideline, but also addresses the interface with other services, such as those provided by social services, secure settings, care homes and the voluntary sector. It does not include services exclusive to these sectors.

4.3.5 Interventions covered

The following interventions are covered:

- exercise, including balance training
- multifactorial interventions – packages of care, for example, exercise, education and home modifications
- vision assessment and correction of impaired vision
- home hazard assessment and modification
- patient and staff education
- medication review
- hip protectors
- rehabilitation strategies.

Podiatric interventions were in the scope of the guideline, however no controlled trials were identified with falls as an outcome.

Recommendations also take account of the psychosocial aspects of falling, including fear of falling and loss of confidence resulting from a fall.

4.3.6 Interventions not covered

- The prevention and treatment of osteoporosis (currently guidelines on this area are being developed by NICE).

- The management of hip and other fractures.
- The prevention of falls in acute settings.

4.3.7 Guideline Development Group

The guideline recommendations were developed by a multidisciplinary and lay GDG convened by the NICE-funded NCC-NSC, with membership approved by NICE. Members include representatives from:

- nursing
- general practice
- allied health
- NSF working party
- falls researchers
- falls clinicians
- patient groups.

A list of GDG members is attached (Appendix A). The GDG met eight times between September 2002 and December 2003.

All members of the GDG were required to make formal declarations of interest at the outset, which were recorded. GDG members were also asked to declare interests at the beginning of each GDG meeting. This information is recorded in the meeting minutes and kept on file at the NCC-NSC.

4.4 Methods

This section describes the systematic review methods used to inform the clinical questions. Results are presented that provided the basis for the evidence statements and recommendations, which are reported in Section 4.6.

4.4.1 Summary of development process

The methods used to develop this guideline are based on those outlined by Eccles and Mason (2001) and in the draft NICE technical manual. The structure of the recommendations section (Section 4.6) – that is recommendations; evidence statements, evidence narrative and GDG commentary – came from McIntosh et al. (2001).

The following sources of evidence were used to inform the guideline:

The Cochrane reviews: a) Interventions for the prevention of falls in older people (Gillespie et al. 2003) and b) Hip protectors for the prevention of hip fractures (Parker et al. 2003).

American Geriatric Society/British Geriatric Society (2001) clinical guidelines that were based on the systematic review Falls prevention interventions in the Medicare population (Shekelle et al. 2002).

Analysis of epidemiological data relating to risk factors (NCC-NSC).

Reviews of assessment processes, tools, tests and instruments for identifying those at risk (NCC-NSC).

Review of studies examining patients' views and experiences of falls prevention programmes and methods to maximise participation (NCC-NSC).

Reviews of studies on fear of falling and interventions to reduce the psychosocial consequences of falling (NCC¬NSC).

Reviews of the evidence on costs and economic evaluations (SCHARR).

Reviews of rehabilitation strategies (NCC-NSC).

The stages used to develop this guideline were as follows:

- develop scope of guideline
- convene multidisciplinary GDG
- review questions set
- identify sources of evidence
- retrieve potential evidence
- evaluate potential evidence
- utilise the updated Cochrane reviews – Interventions for preventing falls in older people (2003) and Hip protectors (2003)
- utilise the AGS/BGS clinical guidelines and Shekelle systematic review (2002)
- undertake systematic review on guideline areas not covered by either the Cochrane review, AGS/BGS guidelines and Shekelle review
- extract relevant data from studies meeting methodological and clinical criteria
- interpret each paper, taking into account the results including, where reported, the beneficial and adverse effects of the interventions; cost; acceptability to patients; level of evidence; quality of studies; size and precision of effect;and relevance and generalisability of included studies to the scope of the guideline
- prepare evidence reviews and tables that summarise and grade the body of evidence
- formulate conclusions about the body of available evidence, based on the evidence reviews, by taking into account the factors above
- agree final recommendations and apply recommendation gradings
- submit first drafts – short and full versions – of guidelines for feedback from NICE registered stakeholders
- GDC to consider stakeholders' comments, following first stage consultation
- submit final drafts of all guideline versions – including Information for the public version and algorithm – to NICE for second stage of consultation
- GDG to consider stakeholders' comments
- final copy submitted to NICE.

Questions addressed by the evidence reviews included:

- What is the best method of identifying those at highest risk of a first or subsequent fall? (Source of evidence: risk factor evidence review)
- What assessment tool or process should be used to identify modifiable risk factors for falling? (Source of evidence: assessment evidence review)
- What are the most clinically effective and cost effective methods for falls prevention? (Source of evidence: clinical and cost effectiveness reviews)
- What interventions are there to reduce the psychosocial consequences of falling? (Source of evidence: Cochrane review)
- What is the evidence for the effectiveness of hip protectors? (Cochrane review)
- What is the best method for maximising participation and compliance in falls prevention programmes and modification of specific risk factors, for example, medication withdrawal/review? (Source of evidence: patients' views and experiences)
- Are falls prevention programmes acceptable to patients? (Source of evidence: patients' views and experiences review)
- What is the best method of rehabilitation/intervention/process of care following a fall requiring treatment? (Source of evidence: rehabilitation review, hip protector review and Cochrane falls prevention review)

The methods and the main results for each review are reported in Sections 4.5.2 to 4.5.11. The detailed evidence summaries – including economic evidence, where relevant – evidence statements, GDG considerations and recommendations are in Section 4.6.

4.4.2 Risk factors for falling: review methods and results

4.4.2.1 Background

To identify those at risk of falling, it is necessary to review the evidence base for risk factors, looking at older people in both community dwelling and residential/extended care settings. Although some risk factors are intuitive, an examination of the empirical evidence provides a comprehensive and thorough overview, with information on the risk factors that should be considered for inclusion in screening/assessment tools and protocols.

Because the literature in this area is vast, the evidence statements and recommendations presented in the American and British Geriatric Society (AGS/BGS) 2001 guidelines, and an analytic review by Perell et al. (2001) formed the foundation for the current review. The Perell review provided information on the assessment of older people at risk and a summary of the risk factors predictive of falling.

This section reports the findings of these key documents and the review of evidence undertaken to update these documents.

Although risk factors for subsequent falls have 'face validity' (Colon-Emeric & Laing 2002), interpretation of the evidence base is often problematic. A variety of study designs have been employed to study this topic, with resulting issues of bias and confounding. This means that summarising such studies is challenging. Furthermore, there is no formal guidance on how best to review the risk factor evidence base.

The gold standard approach for researching risk factors is to carry out a prospective cohort study, in which predictors or risk factors are recorded at baseline, and participants are followed-up, with falls outcomes measured. Often study designs, such as case-control and cross-sectional, are used but these are more susceptible to confounding and other biases (Eggar et al. 2001).

Therefore, to build on the existing evidence base (provided by the AGS/BGS guidelines and the Perell review), we restricted the review to evidence from

prospective cohort studies. This decision was made following initial screening of search results, which indicated that many different study designs have been used to attempt to identify risk factors, and after consultation with methodological experts. The time and resources available to undertake an evidence review on this complex topic (and assessment tools – see Section 4.2) also provided further justification for restricting the study design criteria.

4.4.2.2 Objectives

The review sought to answer the following question:

What are the key risk factors that should be used to identify those at highest risk of a first or subsequent fall?

4.4.2.3 Selection criteria

Types of studies

Reviews of risk factors with preference given to systematic reviews.

Prospective cohort studies of risk factors of falls in older people who are either community-dwelling or living in extended care settings.

Types of participants

Older people aged 65 and over.

Types of outcome

Those studies that report falls as an outcome. Risk factors that were conceptually relevant. Explicit details of how risk factors were measured.

4.4.2.4 Search strategy

Twelve electronic databases were searched between 1998 and December 2002, using a sensitive search strategy – used for both the risk factor and risk assessment review questions. The bibliographies of all retrieved and relevant publications were searched for further studies.

Following guidance from NICE, we searched from the present, looking back over a five-year period, to assess the likely volume of papers that would

require eligibility assessment and critical appraisal. The volume of papers requiring screening and appraisal was considerable. As we were contributing to existing evidence bases (Perell 2001; AGS/BGS 2001), which would have captured the key studies prior to 1998, no further searching was carried out.

Hand searching was not undertaken following NICE advice that exhaustive searching on every guideline review topic is not practical and efficient (Mason et al. 2002). (Note: this applies to all reviews reported here, except for the Cochrane reviews summarised here).

Reference lists of articles were checked for articles of potential relevance (Note: this was done for all reviews reported in this guideline and will not be repeated in other methods sections).

The search strategies and the databases searched are presented in Appendix B. All searches were comprehensive and included a large number of databases.

4.4.2.5 Sifting process

Once articles were retrieved the following sifting process took place:

- First sift: for material that potentially meets eligibility criteria on basis of title/abstract by one reviewer.
- Second sift: full papers ordered that appear relevant and eligible and where relevance/eligibility not clear from the abstract.
- Third sift: one reviewer appraised full articles that met eligibility criteria. Time did not allow for an independent reviewer to identify and appraise studies.

(Note: this sifting process applies to all of the non-Cochrane reviews reported in this document and will not be repeated).

4.4.2.6 Data abstraction

Papers were screened for relevance and prospective cohort studies identified. Methodological quality was assessed using pre-defined principles as outlined

in 4.5.2.7 and epidemiological appraisal criteria, which were adapted for this review. Data were extracted by a single reviewer and evidence tables compiled.

The following information was extracted:

Author, setting,number of participants at baseline and follow-up, methods and details of baseline and outcome measurement, results including summary statistics and 95 per cent confidence intervals, and comments made on the methodological quality.

Masked assessment – whereby data extractors are blind to the details of journal, authors etc – was not undertaken because there is no evidence to support the claim that this minimises bias.

4.4.2.7 Appraisal of methodological quality

Each study was assessed against the following quality criteria:

Selection

Cohort of eligible older people with well defined demographic information.

High recruitment rate of participants equal to or greater than 80 per cent of those approached.

Identification of risk factors

Risk factors conceptually relevant.

Explicit details of how risk factor information is measured.

Confounding

Statistical adjustment carried out/ sensitivity analysis.

Analytic methods described.

Follow-up/outcomes

Method of measurement of outcome given.

Where quality was low, this is indicated in the evidence tables (Evidence table 1).

4.4.2.8 Data synthesis

No quantitative analysis was carried out for this review. Summary statistics and vote counting of statistical significance for each risk factor were reported in the evidence tables.

4.4.2.9 Details of studies included in the review

Results of the search and sift are shown in Table 1 below.

TABLE 1: SIFTING RESULTS FOR RISK FACTOR REVIEW

Initial search results	1396
N screened for relevance following sift	223
N identified as relevant	37
N included	28
N excluded	9

Participants and settings

Most studies reported findings from community-dwelling participants with varying sample sizes, method of recruitment, participation and follow-up rates. Three studies were conducted in an extended care setting. Baseline data collected ranged from detailed socio-demographic characteristics and full examination of health and functioning.

Methodological quality of studies

The quality of the identified studies that met the inclusion criteria was variable. Shortcomings included: self-reported data, low participation and follow-up rates; no details of how outcomes were ascertained; small sample sizes; no information on reliability and validity of outcome ascertainment. Often no justification was given for the selection of risk factors to study.

Outcome measurement

Methods of data collection included self-completed questionnaires, face-to-face interview and full medical examination. Measurement of baseline data

included self-report of falls history as a predictor, relying on the participants' recall of events. Other measurements, such as participants' perception of health status and functioning, were often recorded using self-reported rating scales, which are subjective and prone to bias. Outcome measurement also differed between studies and included: a final interview with a self-reported fall record during the follow-up period; falls diaries completed weekly by participants and posted monthly to researchers; and examination of medical and hospital admission records of fall events of the participants.

Statistical adjustment for confounding and/or sensitivity analysis was carried out in most of the studies and analytical methods described.

Characteristics of excluded studies are shown in Appendix G.

Table 2: STATISTICAL SUMMARIES OF RISK FACTORS FOR FALLS FROM PERELL (2001)

Risk factor	Mean RR/ OR (Range)
Muscle weakness	4.4 (1.5-10.3)
History of falls	3.0 (1.7-7.0)
Gait deficit	2.9 (1.3-5.6
Balance deficit	2.9 (1.6-5.4)
Use of assist devices	2.6 (1.2-4.6)
Visual deficit	2.5 (1.6-3.5)
Arthritis	2.4 (1.9-2.9)
Impaired activities of daily living	2.3 (1.5-3.1)
Depression	2.2 (1.7-2.5)
Cog impairment	1.8 (1.0-2.3)
Age → 80	1.7 (1.1-2.5

4.4.2.10 Summary of research evidence

A review of the empirical evidence relating to risk factors is provided by Perell et al. (2001). This review reported the mean relative risk (RR) or odds ratio (OR) and rank for each factor. However, no details were given of the study design of the included studies. These statistical summaries are reproduced in Table 2.

The included studies from the evidence update are presented in Evidence table 1 (Appendix E, 2004). Results of the studies are presented as either

relative risk or odds ratios. The risk factors reported in the evidence table of included studies are those that were reported as statistically significant.

Individual risk factors from the evidence update are summarised below. Table 3, column 3 reports the frequency that the risk factor was reported in the included studies. Heterogeneity between studies prohibited aggregation of results.

TABLE 3: FREQUENCY OF REPORTING OF RISK FACTOR IN INCLUDED STUDIES

Risk factor	RR/OR Range	Mean RR/OR (Range)
Falls history	OR = 2.4-2.6 RR = 1.9-2.4	11
Mobility impairment	OR = 2.0-3.0	8
Visual impairment	OR = 2.6-5.8 RR = 1.6	5
Balance deficit	OR =1.8-3.9 RR = 1.7	5
Gait deficit	OR = 1.8-2.2 RR = 2.2	4
Mental status	OR = 2.2-6.7 RR = 6.2	4
Functional dependence	OR = 1.7 RR = 5.6	4
Fear	OR = 1.7-2.8	3
Low body mass	OR = 1.8-4.1	3
Depression	OR = 1.5-2.2	3
Diabetes	OR = 3.8-4.1	2
Environmental hazards	OR = 2.3-2.5	2
Incontinence	OR = 1.8-2.3	2
Multiple medications	OR = 2.02-3.16	Meta-analysis: n=14 studies
Anti-arrhythmic	OR = 1.59	Meta-analysis: n=10 studies
Psychotropic drugs	OR = 1.66 (1.40-1.97)	Meta-analysis: n=11 studies

In addition to those risk factors shown in Table 3, other risk factors were reported as significant in single studies – that is those studies reporting on one risk factor – as follows:

- generalised pain

- reduced activity
- high alcohol consumption
- parkinson's disease
- arthritis
- diabetes
- stroke
- low body mass.

Whilst identification of single risk factors is informative, especially when planning interventions for prevention, it is also the interaction between multiple risk factors that needs to be considered (AGS/BGS 2001). Furthermore, within study analysis demonstrates association of different factors. Further details are reported in Evidence table 1 but a brief summary of such studies is presented below.

Covinsky et al. (2001) carried out regression analysis with significant risk factors and a final model (model 3) suggested that abnormal mobility, balance deficit and previous falls history were predictive of further falls. Stalenhoef et al. (2002) developed a risk model with postural sway, falls history, reduced grip strength and depression as significant predictors. Cwikel et al. (1998) developed a risk model (elderly falls screening test), which included: fall in last year, injurious fall in last year, frequent falls, slow walking speed, and unsteady gait. It is clear from the evidence that a previous fall and/or gait and balance disorders may be predictive of those at highest risk, but the presence of other less obvious factors should be considered in combination.

The results described above were obtained mainly from community-dwelling participants. The results from studies conducted with extended care participants were similar, in that a previous fall was predictive of a further fall. Medications also featured as important risk factors for both those in community and extended care settings – for example, benzodiazepines, antidepressants, neuroleptics and cardiotonic glycosides as single predictors, but also the use of multiple medications (Leipzig et al. 1999).

Analysis of multivariate studies of risk factors for falling

- of the included studies displayed in Evidence table 1, some reported adjusted summary statistics in which multivariate analysis had been carried out. Others had conducted bivariate analysis, with the reporting of unadjusted significant factors. Therefore, to assist with clarification of the risk factor evidence, the multivariate studies were analysed in depth. This section reports on:
- a detailed examination of studies in which multivariate analysis had been carried out
- further detailed examination of the quality of each multivariate study
- the results for each risk factor.

Methods

Multivariate analysis allows for the efficient estimate of measures of association, while controlling for a number of confounding factors simultaneously. Mathematical multivariate regression models include:

- linear regression when the dependant outcome variable is continuous data
- logistical regression for binary data.

While this information can be obtained from the studies included in our evidence review, there were several associated methodological issues that made data extraction and synthesis of the multivariate studies difficult. These included:

a) different methods of analysis are employed within each study

b) methods of conducting systematic reviews of prognostic studies are unclear.

The clinical interpretability of information from each study and risk factors is both complex and challenging due to the heterogeneity of the studies.

Methodological advice was sought on how to best appraise the studies and how to illustrate the results in a rigorous, but clinically relevant and meaningful way. We were advised to extract adjusted summary statistics and report

details of both the statistical methods and adjusted variables within each study. To aid interpretation, these results were presented in an evidence table (Evidence table 2, Appendix E) and a narrative summary was produced.

Study design inclusion criteria

Prospective cohort studies with multivariate statistical analysis, including those studies reporting statistical significance for the specified risk factor. Also included are studies reporting statistically non-significant results. This avoids introducing reporting bias.

Detailed quality assessment of risk factor studies

Studies were quality assessed using the following criteria. All studies had to fulfil the following criteria for inclusion:

- eligible cohort of participants
- high participation at baseline and follow-up > 70 per cent
- risk factors conceptually relevant
- baseline measurement of risk factors
- reporting of methods, explicit inclusion criteria and demographic information
- adequate length of follow-up > six months
- measurement of falls as outcome
- statistical methods detailed. Adequate reporting for data extraction. For methods of adjustment for confounding reported, see below.

Quality was then classified as follows:

High quality

- large sample >200
- high participation at baseline and follow-up > 80 per cent
- baseline measurement of risk factors: clear methods of measurement given. Balance between clinical tests and subjective measurement
- methods of outcome measurement clear. Falls diaries with frequent researcher follow-up. Minimal reliance on recall of fall events

- methods of adjustment: all factors adjusted and reported.

Medium quality

- large sample >200
- participation at baseline and follow-up 70-80 per cent
- baseline measurement of risk factors: unclear methods of measurement given. Subjective methods of measurement. or
- methods of outcome measurement clear. Inadequate measurement of outcome – that is relying on memory at follow-up alone
- methods of adjustment: Some adjustment and reporting.

Low quality

- small sample < 200
- low participation at baseline and follow-up < 70 per cent
- baseline measurement of risk factors: unclear methods of measurement given. Subjective methods of measurement. or
- methods of outcome measurement clear. Inadequate measurement of outcome – that is relying on memory at follow-up alone
- methods of adjustment: adjusted variables not reported.

Data abstraction

Evidence table 1 (Appendix E, 2004) from the previous review formed the basis of data extraction, but further details of statistical methods were extracted from the original paper. Studies were quality assessed using the criteria above.

For each risk factor, the following were extracted:

Study reference, risk factor, summary statistic and 95 per cent confidence intervals, adjustment variables and method of multivariate analysis, quality of study.

Results

Twenty-four of the 31 risk factor studies had conducted multivariate analysis. The studies were characterised by heterogeneity, for example:

- different summary statistics were reported
- different methods of measurement of baseline characteristic were used
- different aspects of particular risk factors were measured. While this is useful to describe factors within domains, it was more difficult to combine for graphical representation
- falls outcome measurement included single fallers, two or more falls and recurrent fallers.

Quality gradings of each study are shown in Evidence table 2 (Appendix E, 2004).

Heterogeneity between studies prohibited aggregation of results and, where stated, crude estimate of the range of both RR and OR is provided.

Evidence summary

Evidence table 2 (Appendix E, 2004) describes the included prospective cohort studies in which multivariate analysis had been conducted. The results are reported for each risk factor and include both the statistically significant and non-significant summary statistics following multivariate analysis. Non-significant results were reported to avoid introducing reporting bias. Each factor is also reported by setting. The following (Table 4) summarises Evidence table 2 and provides a frequency count of significant and non-significant results, based on the multivariate.

TABLE 4: FREQUENCY COUNT OF SIGNIFICANT AND NON-SIGNIFICANT RESULTS FOR MULTIVARIATE RISK FACTOR STUDIES

Risk factor	N = reporting statistical significance in multivariate analysis	N = reporting non statistically significant results in multivariate analysis
Falls history	10	7
Mobility impairment	2	4
Visual impairment	3	8
Balance deficit	4	8
Gait deficit	3	6
Cognitive impairment	3	9
Fear	3	1
Environmental hazards	2	
Muscle weakness		2
Incontinence	2	5

This further analysis indicated that the following factors were most predictive of falling and should be considered by clinicians responsible for assessing those at risk of falling:

Community-dwelling older people

Falls history

Gait deficit

Balance deficit

Mobility impairment

Fear

Visual impairment

Cognitive impairment

Urinary incontinence

Home hazards.

People cared for in extended care settings

Falls

history

Gait deficit

Balance deficit

Visual impairment

Cognitive impairment.

4.4.3 Assessment of those at high risk of falling: review methods and results

4.4.3.1 Background

The purpose of assessment is to identify those at risk of falling in order to target effective intervention(s). There are many falls assessment instruments that have been developed for specific purposes and settings. Many have been developed for use by specific health care professionals for community-dwelling individuals and those receiving care in residential/extended care settings. Other assessment instruments, functional observations and clinical tests have been developed and tested with older people in different settings and vary in their detail and administration.

Perell (2001) categorises such tools as follows:

- detailed medical examination and assessment of generic problems.
- nursing assessment by means of a scale with a scoring method. Low or high scores will trigger further investigation or planning of interventions.
- functional assessment or gait and balance limitation assessment to predict those likely to fall.

The aim of the current review was to provide information on the most well developed and pragmatic tools available for use in community and extended care settings.

Following methodological advice, key narrative reviews summarising assessment tools was used as a starting point for determining the scope of the review. These reviews suggested which tools were most advanced in their development and might be most useful for consideration in clinical practice. These tools were then profiled (see Evidence table 3, Appendix E, 2004), drawing on key primary studies with details provided of their development and properties.

A systematic review was not undertaken because of the size of the literature associated with each tool. However, a range of key tools was identified, reviewed and presented. GDG input then assessed the value and utility of

4.4.3.2 Objectives

The review sought to answer the following question:

What assessment tool (or process) should be used to identify modifiable risk factors for falling and those at high risk of falling?

4.4.3.3 Selection criteria

Types of studies

Narrative reviews were used as the principal source of evidence and further evidence was obtained from primary studies that described a particular tool.

- Narrative reviews were sought that provided information about currently available risk assessment instruments utilised in community dwelling and extended care settings.
- Primary studies describing the development of the most frequently cited risk assessment tools, the measurement properties and clinical utility of such tools were sought.

Exclusion criteria

- Individual, newly developed and less pragmatic tools were excluded but referred to in the table of excluded studies (Appendix G). Such tools include detailed analysis of gait requiring intensive training or specialist skills, and complex equipment for analysis. They are not useful as a generic tool for assessing and identifying risk.
- Inpatient assessment tools are excluded as this is beyond the scope of this section as it is covered in section 3.

4.4.3.4 Search strategy and sifting process

The search strategy, databases searched, dates and the sifting process are as for ‘risk’. See Sections 4.5.2.4 to 4.5.2.5.

4.4.3.5 Data abstraction

Data were extracted by a single reviewer and evidence tables compiled. The following information was extracted:

author, setting, population, objectives of tool, procedure, length of time to administer, training required, burden/acceptability to patients, measurement type, derivation of cut-off points for level of risk, further testing of the tool.

4.4.3.6 Appraisal of methodological quality

Narrative reviews and primary studies were included if they met the inclusion criteria. Where data were provided, this information was extracted. No clear quality criteria exist to appraise studies validating tools and tests for assessment. Whilst quality principles are defined for diagnostic studies (see Sackett 2000), these are not appropriate for assessing the quality of assessment tools or processes.

4.4.3.7 Data synthesis

No quantitative statistical analysis was conducted for this review.

4.4.3.8 Results of assessment evidence retrieval and appraisal

Table 5 details the sifting results and number of papers included.

TABLE 5: SIFTING RESULTS

Initial search results	1396
N screened for relevance following sift	223
N relevant	46
N included	17

Most of the evidence was extracted from identified narrative reviews (Evidence table 3, Appendix E, 2004). Supplementary evidence was obtained from included primary studies with large populations (greater than 50). Details are given of excluded studies (Appendix G). It was unrealistic to profile existing tools utilising all the original primary studies available on each tool.

This was beyond the search scope and time limits of this review and there reached a point where no further studies could be included.

Participants and settings

Studies were conducted with older people in both community-dwelling settings and extended care.

Assessment tools

The categories of tools identified included:

1. Tests of balance and gait used in both community dwelling and extended care settings.
2. Multifactorial assessment instruments/processes administered by health care professionals for all settings, including:

a) home hazard assessment instruments administered by health care professionals for community-dwelling people

b) multifactorial falls risk assessment processes.

3. Minimum data set (MDS) for home care and residential settings for comprehensive assessment.

1. Tests of balance and gait used in both community-dwelling and extended care settings

Table 6 illustrates the most frequently reported tools administered in community dwelling and extended care settings as identified by the review. For a full profile of each tool, readers should refer to the Evidence table 3, Appendix E.

TABLE 6: MOST FREQUENTLY USED TEST OF BALANCE AND GAIT

Timed up and go test
Turn 180º
Performance-oriented assessment of mobility problems (Tinetti scale)
Functional reach
Dynamic gait index
Berg balance scale

Methodological quality and type of studies

Many studies reporting the development of new tools were identified, in addition to studies that tested existing tools tested on small populations. Other tests/tools exist but have limited information regarding further testing with large populations and are considered to be less useful in a clinical context. Such tools include detailed balance and gait analysis, examination of footwear and in-depth assessment of visual factors. These processes are more useful for diagnostic purposes, rather than identifying those at risk in community and extended care settings. The quality of reviews identified was variable and most were narrative with brief methods reported.

Not all tests and instruments have undergone rigorous testing with large populations. Some studies use previous falls history as a reference frame and then examine whether the tool identifies the fallers from the non-fallers.

Comments on the quality of information is given in the evidence table. However, it was not possible to quality assess individual references relating to each tool cited in the narrative reviews.

Conclusion

It is unclear which tool or assessment instrument is the most predictive and therefore useful. Many tools have undergone testing and exploration of measurement properties and predictive ability. The clinical utility, feasibility for clinicians and acceptability to patients often guides the choice of tools, but some appear more useful than others. For example, the ‘timed up and go’ test (TUGT) – as referred to in the AGS/BGS guidelines – is both pragmatic and frequently cited, can be used in any setting, and its administration requires no special equipment. The ‘turn 180°’ test is of similar value and can be administered in any setting. However, both these tests rely on clinical judgement and the value of timed cut-off values for the TUGT and number of steps for the turn 180° test need to be considered, if recommending their use.

Other tests – such as the Berg balance test, Tinetti scale, functional reach and dynamic gait test – may offer more detailed assessment and be of diagnostic value, but take longer to administer and need both equipment and clinical

expertise. These tests cannot be recommended for use in all settings and may be more useful during a comprehensive assessment by a multidisciplinary team.

2 & 3. Multifactorial instruments and minimum dataset instruments administered by health care professionals (all settings)

There are many tools/instruments that can be administered by health care professionals. These can be categorised as follows:

a) Home hazard assessment instruments, administered by health care professionals for community-dwelling population.

b) Multifactorial falls risk assessment processes.

c) Minimum data set (MDS) home care and residential assessment instrument for comprehensive assessment.

a) Home hazard assessment instruments administered by health care professionals for community-dwelling population

Home hazard assessment instruments have been developed for use by community nursing personnel, occupational therapists, and physiotherapists to identify hazards in the home that may contribute to or increase the risk of falling. The content validity of these tools has been established.

Environmental hazards have been described as significant risk factors for selected individuals, but generalisability of the single most important risk factors for falling associated with home environment has not yet been established. The Perell (2001) review describes and details many nurse administered tools, but most are developed for use only in hospital settings.

The benefit of home hazard assessment for community-dwelling people is difficult to extrapolate from available studies, as most include some kind of intervention such as either referral or home modification. It appears that benefit is only achieved if followed by such referral.

The AGS/BGS (2001) guidelines recommended the following:

When older people at increased risk of falling are discharged from hospital, a facilitated home hazard assessment should be considered (B).

This is supported by level I evidence from a study by Cumming et al. (1999), which showed that a facilitated home/environmental hazard assessment and supervised modification programme after hospital discharge was effective in reducing falls: RR= 0.64(0.49-0.84). Sub-group analysis demonstrated a significant reduction in the number of participants falling in the group with a history of falling in the previous year: RR= 0.64(0.49-0.84), but not in those without a history of a previous fall RR=1.03(0.75-1.41). Five randomised controlled trials, reported in the AGS/BGS guidelines, demonstrated no benefit of home environment modification without other components of multifactorial interventions.

Many 'off the shelf ' home hazard assessment tools are available and are being developed at local level. Those administering the instrument should decide the choice of tool (Evidence table 4, Appendix E for further details).

b) Multifactorial falls risk assessment processes

Whilst the term 'multifactorial' is frequently referred to in relation to falls assessment, there is disparity between studies of what factors are included within this process. The AGS/BGS (2001) guidelines describe different levels of assessment determined by an older person's falls risk status. Consequently, a brief assessment for those at low risk of falling is suggested, with a more comprehensive and detailed assessment for high-risk groups. Referral to a geriatrician may be needed for such comprehensive assessment.

The Cochrane review (2001) on falls prevention reports that different details and levels of assessment are contained in the included studies. Components include:

- environmental, including home hazards
- medical
- functional

- psychosocial
- activities of daily living
- medication review.

The review by Shekelle (2002) reports similar differences between studies. The most common domains included in relation to risk assessment were:

- medication review
- vision
- environmental hazards
- orthostatic BP.

The results from Shekelle (2002) suggest that: “Although not proven, it makes clinical sense that comprehensive post fall and falls risk assessment should be targeted to persons at high risk as they have most to gain.”

The benefit of multifactorial assessment for older people is difficult to extract from available sources, as it appears that benefit is only achieved if followed by referral and therefore specific intervention.

The Shekelle review refers to randomised controlled trials in which multifactorial falls risk assessment and individually tailored follow-up and management programmes were most effective in preventing falls for community-dwelling older people. The pooled risk ratio of n=10 studies that included a multifactorial falls risk assessment and management programme was relative risk (RR) = 0.84 (0.73-0.97) for risk of falling and pooled incident ratio was 0.65 (0.49-0.85) for the number of falls (n=7 studies).

The Cochrane review on falls prevention reported that multidisciplinary, multifactorial, health/environmental risk factor screening/intervention programmes were effective for both unselected community-dwelling people: three trials pooled RR= 0.73 (0.63-0.86) and those with a history of falling / or known risk factors two trials= RR 0.79 (0.67-0.94) (Gillespie et al. 2003).

Nurse assessment, followed by physician referral for older people in extended care settings, was of no benefit in one study included in the Cochrane falls prevention review, RR= 0.97 (0.84-1.11) (Gillespie et al. 2003).

c) The minimum data set home care and residential assessment instrument for comprehensive assessment

Glossary
MDS: Minimum data set.
HC: Home care (community dwelling).
CAP: Client assessed protocol for home care.
RAI: Residential assessment instrument (extended care).
RAP: Residential assessed protocol for extended care.

While multifactorial assessment processes as described above are specific to falls, the implementation of the single assessment process (SAP) is driven by a holistic and individualistic approach to management and care of older people across a number of domains. MDS tools are referred to in the SAP and have been suggested as useful (DH 2001). Other tools are referred to in the DH single assessment process guidance (2002) and current existing tools are subject to accreditation. Details of such instruments are soon to be published on the SAP website (www.dh.gov.uk/scg/sap/).

The MDS assessment instruments have undergone testing for reliability and validity in community-dwelling and extended care settings but details are not reported here. There are currently two principal instruments with others being developed. The first instrument – MDS-RAI – is aimed at older people in residential settings, while the second – MDS-HC – is for community-dwelling older people receiving home care. There is an assessment data collection form and software is available, which is used in conjunction with the appropriate MDS assessment manual. The RAI and HC both have a standardised form that provides an initial assessment of minimum data taken at various stages along the service user's care pathway. The comprehensive design of the form will 'trigger' 1-30 care protocols. These protocols provide a more focused assessment leading to suggested care plans. The RAI is associated with the RAP – residential assessed protocol for extended care.

The MDS-HC is associated with CAP – a client-assessed protocol for home care.

The MDS is a standardised multidisciplinary assessment system for assessing care needs for older people within residential care. This instrument was originally developed in the USA to enable an accurate assessment of the older people leading to planned quality care. However, it is now being used in many other countries such as the UK, China, Japan, Italy and Norway.

The primary purpose of this tool is to provide a comprehensive assessment that is integrated with care planning. This includes identification and evaluation of potential problems; identification of requirements for rehabilitation; maintenance of client strengths and prevention of decline; and promotion of comprehensive well-being. It follows a pathway from identification and evaluation, to guidance on service provision and care planning. The instrument encompasses the following assessment domains: cognition, communication, activities of daily living, continence, social functioning, disease diagnosis, vision, physical functioning, health conditions and preventative health measures, informal supportive services, mood and behaviour, nutrition/hydration status, dental status, skin condition, environmental assessment, and service utilisation in the last seven days. The falls-related data are within different domains. Since 1997, it is compulsory for facilities in the US to complete this assessment instrument. This tool is suggested within Single assessment process: assessment tools and scales (DH 2002).

Detailed examination of the MDS

The content validity of the risk assessment of falls section of the MDS instrument was examined and information on the utility of the instrument in practice in relation to falls was also sought.

This was done to see if the MDS HC and RAI instruments provide adequate information to identify those at risk of falling, and whether all the important risk factors for falls are included.

Of particular interest was what factors within the associated protocols trigger either further assessment of falls or lead to targeted falls interventions.

As indicated by the risk factor review prospective cohort studies, in which multivariate analysis with adjustment for confounding was undertaken, the risk factors below were shown to be most significant by setting. These were compared with those risk factors listed in the CAP and RAP protocols.

Community-dwelling older people

Falls history, gait deficit, balance deficit, mobility impairment, fear, visual impairment, cognitive impairment, urinary incontinence and home hazards.

People cared for in extended care settings

Falls history, gait deficit, balance deficit, visual impairment and cognitive impairment.

The instruments (HC and RAI) contain falls-related data in various sections/domains and clear pathways exist for the trigger to the falls protocols.

Triggers for falls CAP: home care instrument

Within HC, the potential for repeated falls or risk of initial fall is suggested if one or more of the following factors below are present. This will lead to further detailed assessment and CAPs.

- Trigger factors for falls CAP
- Falls in the last 90 days
- Sudden change of mental functioning
- Being treated for dementia
- Being treated for Parkinsonism
- Has unsteady (abnormal) gait.

Triggers for Falls RAP: Residential care instrument

The potential for additional falls or risk of initial fall is suggested if one or more of the following factors outlined below are present. This will lead to further detailed assessment and the application of RAP (2000).

- Triggers for falls RAP
- Fall in the past month
- Fall in past one to six months
- Wandering
- Dizziness/vertigo
- Use of trunk restraint
- Anxiolytic drugs
- Antidepressants.

These tools provide relevant information about potential intrinsic and extrinsic risk factors, for which there are beneficial interventions. Of particular interest is the information relating to the assessment of balance and gait, which provides detailed aspects of balance and gait abnormalities, with possible diagnoses and rehabilitative or environmental interventions. There are also suggested care pathways relating to home hazard assessment.

However, although the instruments contain important risk factors for falling, no clear pathway exists to specifically identify patients at risk. In addition, the risk factors listed differ from those that emerged as significant in the risk factor evidence review. Each factor is within different domains and will lead to the falls care pathway. What is not clear is at what point an older person enters this process.

Evaluation of performance of MDS instrument

To see whether the MDS instrument improved the quality of care for older people at risk of falling, studies were sought evaluating its performance. Although as stated, this instrument is a comprehensive assessment tool that can provide information for the single assessment process, ‘falls’ represents one protocol within this document with an associated range of items to act as a trigger for further assessment. For the purpose of this review and scope of the guideline, only studies focusing on falls-related information were reviewed.

English language studies of the following designs: prospective cohort, quasi experimental/controlled before and after designs or pre and post were sought. In addition, these must have report fall-related information such as incidence rates, reduction in falls and the trigger of falls protocols.

Appraisal of methodological quality

The methodological quality of the studies was assessed using the following criteria:

- eligibility criteria stated
- appropriateness of design
- sampling method
- validation of measurements relevant to falls outcomes or the instrument's ability to perform in relation to falls
- response rate
- statistical techniques used
- bias and confounding addressed.

An overall subjective rating of quality was applied to each study as follows:

High: all of above criteria met

Medium: most of the criteria met

Low: insufficient information given.

Search strategy

Eight electronic databases were searched between 1995 and April 2003 using a sensitive search strategy. The bibliographies of all retrieved and relevant publications were searched for further studies. The lower limit was selected because this instrument is relatively new.

The major databases searched were MEDLINE, EMBASE, CINAHL, PSYCINFO, HMIC, AMED (Allied & Complementary Medicine Database), and BNI (British Nursing Index). The platform was Silver Platter Windows-based

WINSPIRS. The Web of Science and Cochrane Library databases were also searched, using just the first part of the search strategy found in Appendix B.

Data abstraction

The papers were screened for relevance and those papers that met the inclusion criteria were identified and quality appraised. Data were extracted by one reviewer and evidence tables compiled.

The following information was extracted:

Author and country of origin; aim and objective; population and setting; number of participants; study design and method; outcome measurements and summary statistics; and comments on methodological quality.

Results

An initial search strategy identifying UK only papers resulted in five papers, but they were not related to falls assessment or outcomes. The search was then broadened to include international papers. The following is the result of the search and sift for papers to meet the inclusion criteria. Table 7 provides information on the process of selecting papers for critical appraisal.

TABLE 7: SIFTING RESULTS FOR STUDIES EVALUATING MD

Initial search results	399
N screened for relevance	129
N relevant	3
N included	3

Methodological quality of studies

Three studies met the inclusion criteria. Two studies were conducted in the US and the third was a multi-centre, cross-cultural study of five countries.

The quality of the three included studies was medium. Two were prospective cohort and one a before/after study. Two were conducted with community-dwelling older people (HC) and one in extended care setting (RAI).

Evidence summary

The first study conducted by Fries et al. (1997) evaluated the effect of the implementation of the MDS:RAI system on selected conditions representing outcomes for nursing home residents. This was a simple before and after study design of medium quality. Measurements of the prevalence of falls 30 days prior to admission were taken at baseline and then at six months post intervention. The results were non-significant for prevalence of falls between pre and post administration of the RAI, although there was a slight increase in the percentage of residents who fell post-RAI (pre=10.5%, post=10.6%). The overall prevalence of falls was pre-RAI 6,597 and post-RAI 6,178.

The second study included was conducted by Ritchie et al. (2002). The aim of this study was to evaluate the establishment of a co-ordinated care programme for community-dwelling older people to receive assessments that lead to effective treatments, referral or care-plans. The sample was 99.6 per cent male of which 83.65 per cent were married, mean age=78. A thorough screening process was undertaken to locate those elders deemed as at risk. Follow-up measurements were taken at first and subsequent assessments using the MDS-HC instrument. A total of 158 protocols were triggered out of a possible 226. There were four typical response activities to falls triggered protocols that patients received. 38.4 per cent received falls prevention education, 5 per cent received prosthetics, 3.8 per cent received rehabilitation referral and 1.3 per cent received adult protective services. It is unclear as to whether there was overlap between these services. The most fundamental problem with this study is that the sample was 99.6 per cent male.

Finally, the third study (Morris et al. 1997) involved five volunteer countries: Australia, Canada, the Czech Republic, Japan and the US. The sample was randomly selected within facilities of community-dwelling people but did not represent a random sample within the population of the country. The study had two objectives, of which the one relevant to this review is reported. This examined the interaction between different client profiles measured by their cognitive performance – measured on the Folstein mini-mental examination – and the effect of these measurements on triggering the protocols. For a

sample size of 780, the average number of protocols triggered was nearly 12 of which the falls protocol represents 79 per cent. Those mentally intact triggered 82.5 per cent of the falls protocols, whereas 65 per cent at the lower of the cognitive scale triggered falls protocols. Those with severe cognitive impairment more frequently triggered bowel management, incontinence, and pressure ulcer protocols.

Further work needs to be done evaluating the impact of these instruments on patient care and outcomes. At this stage there is insufficient information to make recommendations regarding the use of these tools and protocols specifically for falls. This is a subject that should be reconsidered when the guidelines are updated.

4.4.4 Fear of falling as a risk factor and tools to measure fear of falling: methods and results

4.4.4.1 Background

Fear of falling is considered multifaceted in aetiology. While fear may result as a consequence of falling, anticipatory anxiety may also occur in those who have not fallen. Murphy et al. (1982) refers to the 'post fall syndrome' that recognises fear as a consequence of falling. Ptophobia – the phobic reaction to standing or walking – is a term introduced by Bhala et al. (1982).

Fear of falling has been further conceptualised as:

- encompassing activity limitation due to the residing fear
- fear resulting in loss of confidence in balance ability and
- low fall-related efficacy, which translates to low confidence at avoiding falls.

Fear of falling is not necessarily limited to those with a history of falling nor is fear predictive of a future fall. Fear may also compromise quality of life by limiting mobility and social interaction.

We conducted two evidence reviews on the area of fear of falling. Firstly, we reviewed the empirical evidence investigating associations of fear of falling

with future falling. Secondly, we reviewed methods available to measure fear and their usefulness for patients and clinicians.

4.4.4.2 Aim of review

The aim of this review was to:

1) identify studies in which fear has been examined as a predictor of falling and/or a consequence of falling

2) ascertain whether fear of falling should be included in risk assessment

3) assess methods and tools available to measure fear of falling and to ascertain their clinical utility.

4.4.4.3 Selection criteria

Types of studies

Prospective cohort studies, with fear and fall related data measured at baseline and follow-up, were preferred because we were interested in fear as a predictor of future or further falls.

Systematic/narrative reviews describing methods for measuring fear of falling.

Types of participants

Older people aged 65 and above.

Types of outcome

Those studies which report falls as an outcome.

Exclusion criteria

Individual studies examining the psychometric properties of instruments used to measure fear of falling and related constructs – this work was outside the resources available.

4.4.4.4 Search strategy

The searches for both fear of falling as a risk factor and tools to measure fear of falling were combined, as this was the most efficient way of searching. Please refer to Appendix B for details of the search strategy and databases searched.

Searches were confined to the period 1980 and December 2002/January 2003.The bibliographies of all retrieved and relevant publications were searched for further studies.

The databases searched were MEDLINE, EMBASE, CINAHL, PSYCINFO, HMIC, AMED (Allied & Complementary Medicine Database), ZETOC and BNI using the Silver Platter Windows-based WINSPIRS platform.

4.4.4.5 Data abstraction

The following data were extracted and evidence tables compiled:

Author, setting, number of participants at baseline and follow-up, methods and details of baseline and outcome measurement, results including summary statistics and 95 per cent confidence intervals, and comments on the quality of studies.

Once individual papers were retrieved, the articles were checked for methodological rigour – using quality checklists appropriate for each study design – applicability to the UK and clinical significance. Assessment of study quality concentrated on dimensions of internal validity and external validity. Information from each study that met the quality criteria was summarised and entered into evidence tables.

4.4.4.6 Appraisal of methodological quality

The methodological quality of each trial was assessed by one reviewer, using the principles of quality referred to in the risk factor review (Section 4.5.2.7).

4.4.4.7 Data synthesis

No quantitative analysis was carried out for this review. Summary statistics and reporting of statistical significance for each study are included in the evidence tables.

4.4.4.8 Details of studies included in the review

Sifting results

The number of studies included is shown in Table 8.

TABLE 8: SIFTING RESULTS ON DEAR OF FALLING

Initial search results	634
N considered for inclusion	50
N included	7 (inc. 2 reviews)

4.4.4.9 Methodological quality of the included studies

Generally, the quality of the prospective cohort studies on examining fear as a risk factor for falling and association of fear of falling with quality of life and health status was high. These studies were conducted on large samples of community-dwelling older people. No studies were identified that were specific to older people in extended care settings. Studies were excluded mainly because of small sample sizes.

The studies identified within the reviews on measurement of fear of falling and related constructs were categorised as follows:

- examination of the psychometric properties of available instruments
- development of new tools for the measurement of fear
- modification and testing of internationally developed instruments for use in the UK – for example, falls efficacy scale (FES).

Generally, the two identified reviews (Nakamara 1998 and Legters 2002) were of limited value. Both were narrative with no details of methods used to identify and appraise studies.

Characteristics of excluded studies are shown in Appendix G.

4.4.4.10 Evidence summary

Fear of falling

Three prospective cohort studies reported fear as a significant predictor of future falling (Arfken 1994; Cumming 2000; Friedman 2002). While it is clear that fear can be a predictor for falling and a consequence of falls, shared risk factors increase the likelihood of falling. Many studies examined specific factors that correlate with the fear of falling. Although such studies are not reviewed here, the literature refers to many correlates. For example: psychological indicators of balance confidence, (Powell 1995; Myers et al. 1996; Manning et al. 1997; and Parry 2000); lack of confidence leading to reduced activity and loss of independence, (Maki et al. 1991). Other correlates include chronic dizziness (Burker et al. 1995); fewer social contacts (Howland et al. 1998); lower quality of life (Lachman 1998), (see Evidence table 4, Appendix E for further details of included studies).

The findings from this review provided sufficient evidence that fear of falling is a significant predictor of future falling and should be considered in falls assessment of older people.

Measurement of fear of falling

Fear related to falling is an important consideration when assessing older people and planning interventions. How to elicit such information from older people has been the focus of much research.

In the discussion paper by Legters (2002), details are given of existing methods of measuring fear.Early research focused on simple questions to establish if fear was present. Examples given were responses to questions of ‘are you afraid of falling?’ in ‘yes/no’ or ‘fear/no fear’ format. Whilst this is a simple measure, it does not provide information of the degree of fear. Further development of such measures resulted in more sophisticated methods, such as verbal rating scales that provide ordinal levels of measurement of degrees

of fear. Examples of verbal rating scales include responses such as: not afraid; slightly afraid; somewhat afraid; very afraid.

Details of the study on the FES (Tinetti et al. 1990 USA), which appears to be the most widely used tool, are given in Evidence table 3, Appendix E. This tool was designed for the purpose of measuring fear in a research context. The conceptual framework underpinning the development of this instrument is related to asking individuals about their feelings, within a variety of specific situations or activity. Perceptions of capability are referred to as 'self-efficacy'. High efficacy relates to increased confidence. The FES measures the individual's degree of efficacy within a specific activity (Tinetti et al. 1991). Confidence in accomplishing each activity without falling is assessed on a 10-point scale, with a higher score equivalent to lower confidence or efficacy. The FES score is the sum of scores and possible scores range from 10-100. Other tools have been developed but none to the extent of FES.

In terms of clinical utility, it is suggested that the FES could be an effective screening tool to determine if further evaluation is needed, particularly concerning balance (Legters 2002; Nakamura 1998).

It is clear that fear of falling is related to future falling and this needs to be discussed with older people who are at risk of falling. However, whilst the FES does provide detailed information, this tool may, at this stage, only be useful for research purposes. What may be more important is that older people are asked if they are fearful of falling. If so, then the reason for this fear and the degree of fear should be assessed by an appropriate health care professional.

4.4.5 Interventions for the prevention of falls: review methods and results

4.4.5.1 Background

Many preventive intervention programmes aimed at recognised risk factors have been established and evaluated. These have included exercise programmes designed to improve strength or balance, education programmes, medication optimisation, environmental modification in homes or

institutions, and nutritional or hormonal supplementation. In some studies, interventions designed to reduce the impact of single risk factors have been evaluated. However, in the majority multiple interventions have been used. Interventions have been offered to older people at varying levels of fall risk, either as a standard package or individually tailored to target risk factors and impairments. Some are population-based approached programmes.

The best evidence for the efficacy of interventions to prevent falling should emerge from large, well-conducted randomised controlled trials, or from meta-analysis of smaller trials.

In July 2003, a Cochrane systematic review on Interventions for the prevention of falls in older people was updated (Gillespie et al. 2003). This was itself an update of a previous review (2001); has undergone peer review and is published in the Cochrane Library. This review has formed the basis for the evidence on effective interventions to prevent falls for this guideline.

The review methods and results are summarised below from the updated systematic review (full details are available on www.cochrane.co.uk).

4.4.5.2 Objectives

The review sought to present the best evidence for effectiveness of programmes designed to reduce the incidence of falls in both community-dwelling older people and those in extended care settings among those at risk of falling and known fallers. This review has also provided evidence for rehabilitation interventions for the secondary prevention of falls (see Section 4.5.9).

4.4.5.3 Selection criteria

Types of studies

RCTs, including those in which the method of allocation to treatment or control group was inadequately concealed – for example, trials in which patients were allocated using an open random number list or coin toss.

Subjects randomised to receive an intervention or group of interventions versus usual care to minimise the effect of, or exposure to, any risk factor for falling. Studies comparing two types of interventions were also included.

Types of participants

Older people of either sex, living in the community or extended care. Participant characteristics of interest included falling status at entry (for example, non-faller, single faller, multiple faller), residential status (for example,. community, extended care), and where appropriate, associated co-morbidity. While the review also included trials of interventions in hospital settings if the patients were elderly, those results are not reported here, as this is outside the scope of the guideline.

Types of intervention

Studies which evaluated the following interventions for falls prevention were included in the clinical effectiveness evidence review:

1 Exercise/physical therapy

2 Home hazard modification

3 Cognitive/behavioural interventions

4 Medication withdrawal/adjustment

5 Nutritional/vitamin supplementation

6 Hormonal and other pharmacological therapies

7 Referral for correction of visual deficiency

8 Cardiac pacemaker insertion for syncope associated falls

9 Exercise, visual correction and home safety

10 Multidisciplinary, multifactorial health/environmental risk factor screening and intervention (community-dwelling)

11 Multifactorial intervention in residential settings

12 Multidisciplinary, multifactorial health/environmental risk factor screening and intervention (community-dwelling)

13 Multifactorial intervention in residential settings.

Types of outcome

The main outcomes of interest were the number of fallers or falls, and severity of falls. Severity was assessed by the number of falls resulting in injury, medical attention, or fracture. Information was also sought on complications of the interventions employed, duration of effect of the interventions, and death during the study period.

Trials that focused on intermediate outcomes, such as improved balance or strength, and did not report fall rates or number of fallers, were excluded. An improvement in a surrogate outcome does not provide direct evidence that an intervention can impact on the clinical outcome of interest (Gotzsche 1996) – in this case, falls. Therefore only trials which reported falls or falling as an outcome were included.

4.4.5.4 Search strategy

The following databases were searched:

MEDLINE (1966 to February 2003)

EMBASE (1988 to 2003 Week 19)

CINAHL (1982 to April 2003)

The National Research Register, Issue 2, 2003

Current Controlled Trials (www.controlled-trials.com, accessed 11 July 2003) and reference lists of articles

PsycLIT and Social Sciences Citation Index to May 1997

No language restrictions were applied and further trials were identified by contact with researchers in the field.

The search strategies and the databases searched are presented in Appendix B. All searches were comprehensive and included a large number of databases. A combination of subject heading and free text searches was used for all areas. Free text terms were checked on the major databases to ensure that they captured descriptor terms and their exploded terms.

Further trials were identified by contact with researchers in the field.

4.4.5.5 Sifting process

From the title, abstract, or descriptors, two reviewers independently reviewed literature searches to identify potentially relevant trials for full review. Searches of bibliographies and texts were conducted to identify additional studies. From the full text, trials that met the selection criteria were quality assessed.

Once articles were retrieved the following sifting process took place:

- First sift: for material that potentially meets eligibility criteria on basis of title/abstract by two reviewers.
- Second sift: full papers ordered that appear relevant and eligible and where relevance/eligibility not clear from the abstract by two reviewers.
- Third sift: full articles are appraised that met eligibility criteria by two reviewers.

4.4.5.6 Appraisal of methodological quality and data extraction

The methodological quality of each trial was assessed by two researchers independently. The following quality criteria were used (Appendix C):

- description of inclusion and exclusion criteria used to derive the sample from the target population
- description of a priori sample size calculation
- evidence of allocation concealment at randomisation
- description of baseline comparability of treatment groups
- outcome assessment stated to be blinded
- outcome measurement

- clear description of main interventions.

The level of concealment of allocation at randomisation was assessed using the criteria in the Cochrane reviewers' handbook (Clarke 2003b). Studies were graded A if it appeared that the assigned treatment was adequately concealed prior to allocation, B if there was inadequate information to judge concealment, and C if the assigned treatment was clearly not concealed prior to allocation (see Appendix C for further details).

Data were independently extracted by pairs of reviewers using a data extraction form, which had been designed and tested prior to use. Consensus or third party adjudication resolved disagreement.

4.4.5.7 Data synthesis

Statistical analysis of individually randomised studies was carried out using MetaView in Review Manager (RevMan 2003). Raw data from cluster-randomised studies were not entered, as the units of randomisation and analysis differed. For dichotomous data, the individual and pooled statistics were calculated, using the fixed effects model, and were reported as relative risk (RR) with 95 per cent confidence intervals (95% CI). For continuous data (reporting mean and standard deviation or standard error of the mean), pooled weighted mean differences (WMD) with 95 per cent confidence intervals were calculated. Heterogeneity between pooled trials was tested using a standard chi-squared test and was considered to be significant when P< 0.1.

4.4.5.8 Details of studies included in the review

Included in the updated review were 62 trials reporting a variety of settings,participants, and interventions. Four studies reported results of prevention interventions in hospital settings and are excluded from this report, as this is not within the scope of the guideline. Details are therefore given of the remaining 58 studies.

Settings

Of the 58 studies, 47 reported the effect of interventions in participants living in the community.

Eight studies were set in long-term care facilities, including long-term care wards in hospital, or nursing homes.

A further three studies included participants with specific conditions from a range of residential settings.

Participants

In 16 studies, eligibility for inclusion included a history of falling, or of a postulated risk factor other than general frailty, residence in long-term care, or age.

General frailty, residence in long-term care, history of requiring admission to a rehabilitation facility for older people, use of home help services, or age at least 80 years defined eligibility in a further 14 studies.

In the remaining 28 studies, participants were recruited from seniors' centres, lists of older people, or through advertisement for volunteers.

The mean age of participants at enrolment exceeded 80 years in 13 studies and was less than 70 years in four studies.

In 10 studies, the participants were all women, and in one the participants were all men. The remaining studies recruited men and women in varying proportions. In most, the proportion of women was more than 70 per cent.

Interventions

Exercise/physical therapy interventions (22 studies)

Fourteen studies compared a physical exercise or physical therapy intervention alone with a social meeting or visit, education only, or no intervention. In one study, self-paced brisk walking was compared with upper limb exercises. Another study compared an enhanced exercise programme

that was offered to all other participants. The remaining six studies in this category examined complex interventions as follows:

- an exercise programme and a programme of medication withdrawal
- progressive resistance quadriceps exercises and the administration of oral vitamin D
- progressive strength training and conditioning with a Tai Chi programme, with a cognitive/behavioural component exercise programme and a cognitive intervention in a factorial design
- programme of exercise associated with management of urinary continence
- a cognitive/behavioural intervention either alone, or combined with: exercise, exercise and home safety screening, or exercise and home safety screening and medical assessment.

Home hazard modification (nine studies)

The following interventions were included in the studies:

- assessment of environmental hazards and supervision of home modifications by an experienced occupational therapist
- home safety assessment and facilitation of elimination of hazards
- comprehensive home visit that included assessment and modification of home hazards
- nurse-led home hazard assessment, free installation of safety devices, and an education programme
- exercise, correction of visual deficiency, and home hazard modification, each alone, and in combination.
- home hazard assessment as a component of two of four other intervention packages.

Three other studies evaluated home hazard modification in combination with other interventions, using a cognitive/behaviour modification approach.

Cognitive/behavioural interventions (seven studies)

The following interventions were included within this category:

- comparison of two risk assessment interviews and a feedback/counselling interview, with a single baseline assessment interview only
- comparison of a one-hour fall prevention education programme, delivered to a group or individually, with a control group receiving only general health promotion information
- the remaining five studies in this category were complex interventions and were also included in the previous two categories.

Medication withdrawal/adjustment (two studies)

- exercise programme and a placebo-controlled psychotropic medication withdrawal programme
- optimisation of medication along with home hazard modification
- medication withdrawal/adjustment was also included in the majority of the multifactorial intervention listed below.

Nutritional/vitamin supplementation (six studies)

Five studies were designed to evaluate the efficacy of vitamin D supplementation, either alone or with calcium co-supplementation, in fracture prevention. Each trial reported falls as a secondary outcome measure.

One other studied the efficacy of a 12-week period of high-energy, nutrient-dense dietary supplementation in older people with low body mass index, or recent weight loss.

Hormonal and other pharmacological therapies (two studies)

One reported incidence of falls as a secondary outcome after administration of hormone replacement therapy to calcium replete, post-menopausal women.

Another studied the effect of administering a vaso-active medication (raubasine-dihydroergocristine) to older people presenting to their medical practitioner with a history of a recent fall.

Referral for correction of visual deficiency (one study)

This study compared a control group with groups receiving exercise, correction of visual deficiency, and home hazard modification, each alone, and in combination.

Cardiac pacemaker insertion for syncope-associated falls (one study)

One trial reported the effectiveness of cardiac pacing in fallers who were found to have cardioinhibitory carotid sinus hypersensitivity following a visit to a hospital emergency department.

Exercise, visual correction and a home safety intervention (one study)

This study reported the effects of exercise, vision improvement, home hazard modification or no intervention in a factorial design.

Multidisciplinary, multifactorial, health / environmental risk factor screening and intervention (20 studies)

These were complex interventions that differed in the details of the assessment, referral, and treatment protocols. In most studies, a health professional – usually a nurse – or other trained person made the initial assessment, assessing the participants, providing advice and arranged referrals.

Multifactorial intervention in nursing home residents (one study)

One cluster randomised trial assessed the effectiveness of staff and resident education, including advice on environmental adaptations. In addition, residents were offered progressive balance and resistance training and hip protectors, and could choose any combination for any length of time.

4.4.5.9 Methodological quality of studies

A summary of the methodological quality of each study of the trials is shown in Appendix F.

The quality of studies was variable. In 19 studies, it appeared that the assigned treatment was adequately concealed prior to allocation. In three the

assigned treatment was not concealed prior to allocation. In the remaining 36, there was inadequate information to judge concealment.

Losses from groups resulted from, for example, withdrawal from the study or death.

In trials with community-dwelling subjects, the outcome of falling was self-reported and the subjects were often not blind to treatment assignment. Blinding was possible in four trials, by using placebos or identical tablets, when the intervention involved the administration of drugs.

A number of studies did not define a fall, and a variety of definitions were used in those that did. A fall was most frequently defined as 'unintentionally coming to rest on the ground, floor or other lower level; excludes coming to rest against furniture, wall, or other structure'.

Active registration of falling outcomes, or use of a diary, was clearly indicated in 31 studies. In the remaining 27 studies ascertainment of falling episodes was by participant recall, at intervals during the study or at its conclusion, or was not described.

TABLE 9: LENGTH OF FOLLOW-UP

Follow-up	n = trials
3 months	5
4 months	3
5 months	1
6 months	6
8 months	1
44 weeks	1
49 weeks	1
2 years	4
3 years	2
4 years	1
10 years	1

Duration of follow-up varied both between and within studies. It was for a minimum of one year in 38 studies. Table 9 reports the length of follow-up for other trials.

The period for which falls were recorded differed markedly between studies, and was not necessarily the same as the total period of follow-up described above.

The characteristics of excluded studies table (Appendix G) lists 97 studies, which fall into two categories. Thirty-five non-randomised studies reporting falls – or fall-related injuries – as an outcome were excluded on the basis of non-randomisation. Sixty-two randomised trials originally identified by the search strategy either reported intermediate outcomes of preventive strategies – for example, balance or muscle strength measures – or did not describe an intervention designed to reduce the risk of falling.

At the time of writing there were 14 trials waiting assessment and 29 ongoing trials identified.

4.4.5.10 Comparisons

Trials were included in which participants were randomised to receive an intervention or group of interventions, versus usual care to minimise the effect of, or exposure to, any risk factor for falling. Studies comparing two types of interventions were also included.

4.4.5.11 Summary of results

For full details of included studies see Evidence table 5, Appendix E.

The Cochrane review reports the following:

- Evidence for the effectiveness of home hazard management in people with a history of falling is somewhat strengthened by new data.
- Evidence for the effectiveness of exercise programmes and multifactorial assessment/ intervention programmes remains unchanged, despite the inclusion of a number of new trials.
- In a highly selected group of fallers with carotid sinus hypersensitivity, cardiac pacing is effective in reducing the frequency of syncope and falls.

Interventions likely to be beneficial:

- A programme of muscle strengthening and balance retraining, individually prescribed at home by a trained health professional (three trials, 566 participants, pooled relative risk (RR) 0.80, 95 per cent confidence interval (95%CI) 0.66 to 0.98).
- A 15-week Tai Chi group exercise intervention (one trial, 200 participants, risk ratio 0.51, 95%CI 0.36 to 0.73).
- Home hazard assessment and modification that is professionally prescribed for older people with a history of falling (three trials, 374 participants, RR 0.66, 95% CI 0.54 to 0.81).
- Withdrawal of psychotropic medication (one trial, 93 participants, relative hazard 0.34, 95%CI 0.16 to 0.74).
- Cardiac pacing for fallers with cardioinhibitory carotid sinus hypersensitivity (one trial, 175 participants, WMD -5.20, 95%CI -9.40 to -1.00).
- Multidisciplinary, multifactorial,health/environmental risk factor screening/intervention programmes in the community, both for unselected population of older people (four trials, 1651 participants, pooled RR 0.73, 95%CI 0.63 to 0.85), and for older people with a history of falling, or selected because of known risk factors (five trials, 1176 participants, pooled RR 0.86, 95%CI 0.76 to 0.98).
- Multidisciplinary assessment and intervention programme in residential care facilities (one trial, 439 participants, cluster-adjusted incidence rate ratio 0.60, 95%CI 0.50 to 0.73).

Interventions of unknown effectiveness:

- Group-delivered exercise interventions (nine trials, 1387 participants).
- Individual lower limb strength training (one trial, 222 participants).
- Nutritional supplementation (one trial, 46 participants).
- Vitamin D supplementation, with or without calcium (three trials, 461 participants).
- Home hazard modification in association with advice on optimising medication (one trial, 658 participants), or in association with an education package on exercise and reducing fall risk (one trial, 3182 participants).

- Pharmacological therapy (raubasine¬dihydroergocristine, one trial, 95 participants).
- Interventions using a cognitive/behavioural approach alone (two trials, 145 participants).
- Home hazard modification for older people without a history of falling (one trial, 530 participants).
- Hormone replacement therapy (one trial, 116 participants).
- Correction of visual deficiency (one trial, 276 participants).

Interventions unlikely to be beneficial:

- Brisk walking in women with an upper limb fracture in the previous two years (one trial, 165 participants).

The Cochrane review concluded the following:

- Prevention programmes that target an unselected group of older people with a health or environmental intervention on the basis of risk factors or age, are less likely to be effective than those that target known fallers.
- Even amongst known fallers, the risk reduction where significant is small, and the clinical significance remains less clear.
- Interventions that target multiple risk factors are marginally effective, as are targeted exercise interventions, home hazard modification and reducing psychotropic medications.
- Where important individual risk factors can be corrected, focused interventions may be more clearly effective.
- It appears that interventions with a focused intention may in fact be multifactorial.
- There is a lack of clarity about the optimum duration and intensity of interventions.
- Some interventions – for example, brisk walking – may increase the risk of falling.
- The outcome of interest – falling – was not always clearly defined in the studies and therefore the definition of falling used could alter the

significance of the results. In addition, methods used for recording falls also varied widely between studies.

The full summaries are included in Section 4.6. From these were derived evidence statements and recommendations.

4.4.6 Analysis of compliance with interventions for the prevention of falls

4.4.6.1 Background

Ideally, all participants in a trial should complete the study and follow the protocol in order to provide data on every outcome of interest at all time-points. However, in reality most trials have missing data. This may be because some of the participants drop out before the end of the trial; participants do not follow the protocol, either deliberately or accidentally; or some outcomes are not measured correctly, or cannot be measured at all, at one or more time-points. Regardless of the cause, inappropriate handling of the missing information can lead to bias. However, on occasions it is impossible to know the status of participants at the times when the missing information should have been collected. This could happen, for example, if participants move to different areas during the study or fail to contact the investigators for an unknown reason. Other reasons may include: inability to comply with the intervention, perhaps due to lack of motivation; the intervention being too difficult; or not acceptable to participants. Excluding these participants or specific outcome measurements from the final analysis can also lead to bias.

The only strategy that can be confidently assumed to eliminate bias in these circumstances is called ‘intention to treat’ analysis. This means that all the study participants are included in the analyses, as part of the groups to which they were randomised, regardless of whether they completed the study or not. This relies on the researcher having measurement of outcome, regardless of compliance to the intervention.

The purpose of this analysis was to examine the drop out rates and/or losses to follow-up for each trial included in the Cochrane review, where reported. This was done to shed light on the acceptability and sustainability of clinically effective interventions and prevention programmes.

4.4.6.2 Aim

The aim was to assess patient compliance with clinically effective interventions, as measured by drop-out rates/losses to follow-up.

4.4.6.3 Methods

Losses to follow-up rates and drop-out rates were extracted from those RCTs that reported clinically effective interventions and were included in the updated Cochrane review Interventions for the prevention of falls in elderly people (Gillespie et al. 2003). Reasons for drop-out/loss to follow-up were recorded where reported.

4.4.6.4 Results

The total number of studies reporting drop out rates/losses to follow-up was 19 out of 58 studies.

For each clinically effective intervention, where reported, details and reasons for drop out and losses to follow-up are presented in the table below. (Refer to Evidence table 6, for full details of the studies from which this information was extracted).

TABLE 10: LOSSES TO FOLLOW-UP AND DROP-OUT RATES IN THOSE STUDIES REPORTING POSITIVE RESULTS

Muscle strengthening and balance training		
Study	**Drop-out rates/ losses to follow-up**	**Comments**
Campbell (1997, 1999). Community-dwelling women aged 80 years and older, individually tailored intervention.	n = 622 invited to participate, n = 359 chose not to participate, n = 30 not eligible. n = 233 at randomisation Intervention (I) = 116 Control (C) = 117 At one year follow-up n = 213 (91%) I = 103 (88%), C = 110 (94%) n = 153 (71%) agreed to continue for a further year: I = 71 C = 81 At two year follow-up n = 103 (67%): I = 41(57%), C = 62 (76%) Total losses/ drop-out rates at two years Intervention = 75 (64%) Control = 55 (47%)	Falls were self-recorded using a calendar, which was posted monthly to researcher, for both groups. The intervention group also recorded if they had completed the prescribed exercises. Intention to treat analysis.
Robertson (2001). Community-dwelling aged 75 years and older, individually prescribed exercise programme.	n = 590 invited to participate n = 284 chose not to participate n = 6 not eligible n = 240 at randomisation Intervention (I) = 121 Control (C) = 119 n = 13 (10%) withdrew from exercise intervention Withdrew from trial: n = 8 (1) n = 21 (c) At one year follow-up, falls monitored n = 211 (87%), I = 113 (93%), C = 98 (82%) For the intervention group, 43% (49 of 113) carried out their exercise programme three or more times per week, 72% (n = 81) carried it out at least twice a week, 71% (n = 80) walked at least twice a week during the year's follow-up. Total losses/ drop-out rates: 10%	Self-reported postcards sent to researchers monthly. Intention to treat analysis.

Tai Chi		
Study	**Drop-out rates/ losses to follow-up**	**Comments**
Wolf (1996). Community dwelling untargeted people, mean age 76 years.	Total losses/ drop-out rates: 40 of 200 (20%) 20 months	Intention to treat analysis not possible.

Home hazard assessment and modification for those with a history of falling		
Study	**Drop-out rates/ losses to follow-up**	**Comment**
Nikolaus (2003). Older people (mean age 81) recruited from geriatric hospital and assigned to comprehensive assessment, followed by a diagnostic home visit and home intervention vs. recommendations and usual care.	n = 391 eligible n = 31 chose not participate n = 360 at randomisation Intervention (I) = 181 Control (C) = 179 At follow-up= I = 140 (77%) C = 139 (77%) Total losses/ drop-out rates 23% Compliance with intervention recommendations: Recommendation — Compliance rate N (/%) Shower seat — 23 (82) Emergency call — 14 (78) Garb bars — 27 (77) Night light (bed/ bathroom) — 20 (70) Anti-slip mat bath — 12 (66) Elevation of bed — 19 (63) Rollator — 37 (56) Elevation of toilet seat — 43 (54) Removal of rugs — 12 (41) Removal of obstructions in walkways — 15 (33) 12 months	
Day (2002). Untargeted community-dwelling 70 and over. Multi-faceted study including home hazard, exercise and vision referral interventions.	Total losses/ drop-out rates: 1.5% 18 months	Intention to treat analysis.
Pardessus (2002).	Total losses/ drop-out rates: 9 of 60 (15%)	Intention to treat analysis.

Home visit modification following hospital admission following a fall. Mean age 83 years.	One year	

Withdrawal of psychotropic medications		
Study	**Drop-out rates/ losses to follow-up**	**Comments**
Campbell (1999). Community-dwelling people aged 65 years and over. Gradual withdrawal of psychotropic medications vs. continuing to take medications.	n = 547 invited to participate n = 400 chose not to n = 54 not eligible n = 93 at randomisation Intervention (I) = 48 Control (C) = 45 Falls monitored for 24 months I = 33 (68%) C = 39 (86%) Total losses/ drop-out rates: I = 32% C = 14% Authors report that one month after completion of the study, 47% (8 of 17) of the participants from the medication withdrawal group who had taken capsules containing placebo only for the final 30 weeks had restarted taking psychotropic medication.	This study also included a group receiving exercise. Data here is combined to illustrate compliance with the psychotropic programme.

Cardiac pacing		
Study	**Drop-out rates/ losses to follow-up**	**Comment**
Kenny (2001). Older people presenting at A&E following a non-accidental fall, mean age 73. Pacemaker vs. no pacemaker.	Total losses/ drop-out rates: n = 16 of 175 (9%) On year	71,299 A&E attendees screened, n=1624 received carotid sinus massage, n=175 agreed to be randomised. Intention to treat analysis not possible.
Fabacher (1994). Community-dwelling people aged 70 years and over.	Total losses/ drop-out rates: 59 of 254 (23%) One year	Intention to treat analysis not possible.
Jitapunkel (1998). Community-dwelling people, mean age 76.	Total losses/ drop-out rates: 44 of 160 (28%) Three years	Not stated.
Newbury (2001). Community-dwelling, age range 75 – 91.	Total losses/ drop-out rates: 11 of 100 (111%) 12 months	Intention to treat analysis.
Wagner (1994). Community-dwelling, mean age 72 years.	Total losses/ drop-out rates: 89 of 1559 (6%) Two years	Intention to treat analysis not possible.

Targeted multidisciplinary interventions		
Study	**Drop-out rates/ losses to follow-up**	**Comment**
Tinetti (1994). Community-dwelling, mean age 77 years with at least one risk factor present.	Total losses/ drop-out rates: 10 of 301 (3%) One year	Intention to treat analysis not possible.
Close (1999). Community-dwelling older people, mean age 78, presenting at A&E following a fall.	Total losses/ drop-out rates: 93 of 397 (23%) One year	Intention to treat analysis not possible.
Hogan (2001). Community-dwelling, aged 65 years and over, with a falls history in the previous 3 months.	n = 163 at randomisation Intervention (I) = 79 Control (C) = 84 Completed trial: I = 66 (83%) C = 73 (86%) Total losses/ drop-out rates: I = 17%, C = 14% One year	Intention to treat analysis.
Kingston (2001). Community-dwelling, mean age 71 years, attending A&E following a fall.	Total losses/ drop-out rates: 17 of 109 (16%) 12 weeks	Intention to treat analysis not possible.
Lightbody (2002). Community-dwelling, median age 75, attending A&E following a fall.	Total losses/ drop-out rates: 34 of 348 (10%) Six months	Intention to treat analysis not possible.
Van Hastregt (2000). Community-dwelling, mean age	n = 392 met inclusion criteria n = 316 at randomisation Intervention (1) = 159 Control (C) = 157	Intention to treat analysis not possible.

77 years with a falls history.	N completed trial: I = 120 (75%) C = 115 (73%) Total losses/ drop-out rates: 81 of 316 (26%) 18 months	

Multidisciplinary: extended care		
Study	**Drop-out rates/ losses to follow-up**	**Comment**
Jensen (2002). Extended care residents aged 65 and over.	n = 439 residents (9 facilities) n = 402 assesses Intervention (I) = 194 (4 facilities) Control (C) = 208 (5 facilities) Follow-up and evaluation completed I = 157 (80%) C = 167 (80%) Total losses/ drop-out rates = 20% 8.5 months	Intention to treat analysis no tpossible.

4.4.6.5 Summary of results

Muscle strengthening and balance training: appears to be high participation with intervention at one-year follow-up. In one study, 57 per cent were carrying out the intervention at two years follow-up.

Tai Chi: 20 per cent dropout at seven to 20 month follow-up

Home hazard intervention: 2-28 per cent were not available at follow-up (one year-18 months).

Psychotropic medication withdrawal: 68 per cent at follow-up (24 months).

Cardiac pacing: 9 per cent were not available at follow-up (one year).

Untargeted, multidisciplinary interventions: 6-28 per cent drop-out (one to three years).

Targeted, multidisciplinary interventions: 3-26% drop-out (three to 18 months).

Extended care, multidisciplinary intervention: 80 per cent participation at follow-up (34 weeks).

Implications

The intention of this analysis was to shed light on the factors affecting likely patient compliance and adherence to intervention packages and on sustainability. However, insufficient information on reasons for patient drop-out was given in the studies. Drop-out/losses-to follow-up rates give a crude indication of possible participation rates. However, in everyday practice these could either be lower or higher. Factors influencing participation from the patient's perspective is given in Section.4.5.8.

4.4.7 Interventions to reduce the psychosocial consequences of falling: review methods and results

4.4.7.1 Methods

Aim of the review

To present findings on the effect of falls prevention interventions on psychosocial factors, such as confidence and fear of falling. No additional searching was conducted for this review as the source of results was extracted from those trials that reported effective falls prevention interventions and strategies in the Cochrane review (Gillespie et al. 2003).

The review sought to answer the following question:

Do effective falls prevention programmes also improve psychosocial factors related to fear of falling and the psychosocial consequences of falling?

4.4.7.2 Selection criteria

Study designs

RCTs from the Cochrane interventions for the prevention of falls systematic review that reported clinically effective interventions and that also investigated outcome in terms of psychosocial measures.

Patients

Older people, mainly more than 65 years of age but 60 acceptable.

Settings

All, including A&E; not relating to prevention of falls while a patient in hospital.

Interventions

Clinically effective prevention programmes/ interventions to reduce the incidence of falls that report psychosocial outcomes.

Outcomes

- Number of falls.
- Measurement of fear, confidence, quality of life and other aspects of psychosocial consequences of falling.
- Mean change or summary statistics were extracted, with significance levels where reported.

4.4.7.3 Data synthesis

Synthesis of results was not appropriate.

4.4.7.4 Evidence tables and summary

The number of studies providing information on psychosocial outcomes was two out of the 19 studies reporting clinical effectiveness.

The table below gives details of the psychosocial outcomes from the two studies.

TABLE 11

Unselected, multidisciplinary interventions: please refer to evidence table 1 for details of interventions			
Study	**Drop-out rates/ losses to follow-up**	**Mean change or relative risk (RR)**	**Comment**
Newbury (2001). Community-dwelling, aged 75 and over.	Self-rated health (n(%)) 'Very good' or 'good' for intervention group. Geriatric depression score (GDS).	Baseline = 22 (50%) Follow-up = 30 (68%) p = 0.032 Mean change from baseline to follow-up = 0.5 (3.95 to 2.95) p = 0.05	Participants were less depressed as measured by the (GDS) following the intervention

Muscle strengthening and balance training			
Study	**Drop-out rates/ losses to follow-up**	**Mean change of relative risk (RR)**	**Comment**
Campbell (1997, 1999). Community-dwelling women aged 80 years and older, individually tailored intervention.	Results reported for the intervention group, for those that continue with the study at one year and those who did not. Mean falls efficacy score. Results for those still exercising at two years and those not.	Mean (SD) falls efficacy score: Continued = 89.4 (12.8) Withdrew 83.3 (16.4) p = 0.009 Exercising = 93.3 (9.4) Not exercising = 86.8 (15.1) p = 0.03	Participants reported increased confidence and reduced fear of falling in the intervention group.

As can be seen above, secondary outcomes relating to psychosocial variables are not routinely measured in all of the included trials. It is therefore difficult to extrapolate from the available limited published evidence. While it is important to determine if falls prevention programmes are effective in reducing the incidence of falls, other outcomes – such as the reduction in fear of falling – that are important for patients should also be measured. It is not clear from the available evidence which component of a prevention programme acts on reducing the incidence of falling and increasing confidence and other quality of life measures.

These two trials, focused on those > 75 and 80 years of age, did show an improvement on psychosocial measures such as depression, confidence and fear of falling. However, in the absence of patient interviews it is difficult to know if it is the social benefits of participating in group programmes that exert a benefit, in addition to the benefit from reduction in falls.

4.4.8 Patient views and experiences: review methods and results

4.4.8.1 Background

Information on patients' views, compliance with and acceptability of falls prevention programmes is lacking within trials and systematic reviews. Accordingly, studies that investigated these factors were reviewed. Both this evidence and the evidence from the systematic review (Gillespie et al. 2003) are needed to enable the development of pragmatic recommendations on falls prevention.

Frequently within trials the only indicator of compliance is the drop-out/losses to follow-up rate, which includes reasons relating to morbidity and mortality (see Section 4.5.6 above).While these are useful measures, it is likely that compliance rates in trials of falls interventions may be lower than in actual clinical practice. This is because of the advantage within trials of dedicated resources – such as follow-up telephone calls etc – to maximise participation. Information of patients' views of the falls prevention trials in which they participated is similarly lacking.

Therefore, it was thought useful to review and summarise evidence that captures the patient perspective on the likely barriers to and facilitators of participation in falls prevention programmes. This may indicate successful methods to promote compliance/adherence and participation in falls prevention programmes.

Much of this evidence comes from studies conducted independently of trials of falls prevention, which therefore reflect a variety of designs, settings and participants. However, appraisal of this material enables a fuller consideration

of some of the issues associated with falls prevention programmes from the perspective of the intended target group.

All studies were quality assessed and the relevant data extracted and reported in evidence tables. The summarised results and conclusions were then condensed in a table on 'summary of barriers/facilitators relating to falls prevention programmes' to give the GDG a breakdown of the key points arising from these studies.

4.4.8.2 Methods

Objective

To review qualitative and quantitative studies published in the last 10 years, which examine older people's views of falls prevention strategies.

Inclusion criteria

Study designs: All (systematic review – qualitative). May include studies conducted concurrently with RCTs,

Publication status: Not theses, letters, editorials

Dates: 1990-May 2003

Language: English

Patients: Older people (mainly more than 65 years of age)

Settings: All, including A&E, except relating to preventing falls in hospital settings

Outcomes: Measures and/or self-report/clinician report of:

- barriers to and benefits of participation in falls prevention programmes
- participant views and experiences of falls prevention strategies
- compliance/adherence with falls prevention strategies or components of falls prevention strategies, such as exercise.

Exclusion criteria

Theses, letters, editorials, case studies.

Studies with a focus on hospital-based falls prevention programmes for patients who have fallen whilst a hospital inpatient.

4.4.8.3 Search strategy

The search strategy was devised to be very broad in order to pick up qualitative studies for this review. The search strategies and the databases searched are presented in Appendix B. All searches were comprehensive and included a large number of databases. All search strategies were adapted for smaller or simpler databases or for web-based sources, which did not allow complex strategies or multi-term searching. A combination of subject heading and free text searches was used for all areas. Free text terms were checked on the major databases to ensure that they captured descriptor terms and their exploded terms.

4.4.8.4 Data abstraction

Data from included trials were extracted by one reviewer into pre-prepared data extraction tables. The following data were extracted from each study:

Qualitative

Study, aim of study, methods, sample characteristics, setting, results, conclusions.

Quantitative

Study, objective, setting, population characteristics, methods, interventions, outcomes, results.

All data were extracted into evidence tables (Evidence table 6, Appendix E, 2004).

4.4.8.5 Appraisal of methodological quality

All studies were quality assessed by one person, using study design specific quality assessment checklists developed by the Centre for Statistics in

Medicine. The qualitative checklist was developed in-house, based on others, and then circulated to qualitative researchers for comment and refinement. See Appendix C for further details of quality for specific study designs.

4.4.8.6 Data synthesis

No quantitative analysis was undertaken. The data were presented in evidence tables and the main findings were qualitatively summarised. A table of barriers and facilitators was generated based on the findings of the studies.

4.4.8.7 Details of studies included in the review

Sifting results

The numbers of studies obtained are detailed in Table 12.

TABLE 12: RESULTS OF SEARCH/ SIFT FOR SUTDIES OF PATIENTS' VIEWS AND EXPERIENCES

Total number of hits	14576
Full articles ordered	31
Final number of articles included	24

Type of studies included

- Qualitative (two were unpublished) – 10
- Systematic review – one
- Narrative review – three
- Randomised controlled – three
- Before/after – three
- Cross-sectional – four.

Participants and settings

Qualitative

One study (Resnick 1999) investigated the views of nursing home residents. Three studies were conducted on hospital wards; one on people admitted to an orthopaedic trauma elderly care ward (Ballinger & Payne 2000); one on people admitted to an elder care ward after a fall sustained either in the community or hospital setting (Kong et al. 2002) and the other on patients

admitted to an acute elderly care medical ward (reasons not given) (Simpson et al. 2003). The remaining studies were conducted on community-dwelling residents.

Four studies examined the views of non-English speaking people (Aminzedah & Edwards 1998; Commonwealth of Australia 2000; Kong et al. 2002; Health Education Board 1999). Four studies were conducted in the UK.

Quantitative

All studies were based in the community, except Simpson (1995) who surveyed patients on a rehabilitation ward; and Wielandt (2002) and Culos-Reed (2000) who covered all settings. Most studies were conducted in the United Kingdom, USA or Australia.

Outcomes

Qualitative

All studies examined people's views or knowledge of falls prevention. Two examined perceptions, motivations and barriers to physical activity (Grossman et al. 2003; Stead et al. 1997). Outcomes were measured in various ways, including semi-structured interviews and focus groups. Commonly, the output from data collection was condensed into themes and categories.

Quantitative

These studies mainly measured or reviewed the following: predictors of increased exercise compliance, behaviour change, falls history, fear of falling, ability and confidence, self-efficacy, participation rates, or activity levels. Variables were categorical, ordinal or open-ended.

4.4.8.8 Methodological quality of studies

A summary of the methodological quality of each study is shown in Appendix F.

Qualitative

Ten qualitative studies of reasonable quality were found and reviewed. The results of the quality assessment are included in Appendix F. Respondent validation – where the analysis of the study is fed-back to the participants for validation – was the one criterion for which studies exhibited the most variable quality. However, the studies mainly scored well on other criteria and all were considered worthy of data extraction.

Qualitative methods used ranged from phenomenology – a qualitative method used to gain information on patients' experiences, in their own words – to discourse analysis – in which the output was subject to interpretation by the researcher. Many studies did not state a theoretical position. However, all papers appeared to be based on a similar framework, aiming to capture and analyse participant accounts and experiences of falls prevention or physical activity, using focus groups or unstructured/semi-structured interviews to collect data.

Quantitative

Overall the quality of the available studies was poor to fair. There were a limited number of review or summary papers and only one of these was done systematically (Hillsdon 1995). The conclusions authors drew and the recommendations they made very often did not flow from their own study results and/or from synthesising their results with previous work. None of the randomised trials had undertaken power calculations, so it is difficult to assess the reliability of these results. More details on the quality of each included study are included in the column 'comments/quality issues' of the Evidence table 7a and 7b, Appendix E.

Characteristics of excluded studies are shown in Appendix G.

4.4.8.9 Evidence summary

Studies focussed on patient views of either specific interventions, such as assistive/mobility aids (Aminzedah & Edwards 1998); or multiple separate interventions (Commonwealth of Australia 2000; Simpson et al. 2003) or a

single approach such as exercise (Health Education Board 1999; Stead et al. 1997; Grossman et al. 2003). There was no qualitative study that investigated older people's views on multifactorial packages. A number of studies also focussed on the likelihood of adopting preventative practices and need for information on falls prevention (Ballinger & Payne 2000; Kong et al. 2002; Porter 1999; Resnick 1999).

Table 13 summarises the facilitators to and barriers to falls prevention and physical activity from these studies.

Most of the studies investigating potential participants' views of falls prevention were conducted independently of trials of falls prevention. It is possible that if conducted concurrently as part of a trial the results may be different. Furthermore, it was not clear from many studies if any of the subjects had previously participated in falls prevention programmes. Nonetheless, important information is provided that requires consideration in addition to the clinical effectiveness evidence, when recommending which falls prevention programmes are suitable for whom and under what conditions.

TABLE 13: SUMMARY OF BARRIERS/ FACILITATORS RELATING TO FALLS PREVENTION PROGRAMMES

Community-dwelling older people	
Facilitators	**Barriers**
Information from a variety of sources (GP, mass media, community nurse, an published in different languages).	Lack of non-English speaking information.
Information that falls can be preventable rather than predictable.	The term 'fall prevention' is unfamiliar and the perceived relevance of falls prevention low until fall experienced.
Information that communicates life-enhancing aspects of falls prevention, such as maintaining independence, control.	Inaccessible and unappealing information.
Emphasis on social aspects of falls prevention programmes.	Social stigma attached to programmes targeting 'older people'.
Partnering with a peer who has successfully undertaken a falls prevention programme.	Low health expectation and low confidence in physical abilities.
Finding out which characteristics the person is willing to modify.	Differing agendas between older people and health professionals.
Countering the belief that nothing can be done for falls.	Pain, effort and age (in relation to exercise programmes).
Programmes with exercise which is of moderate intensity only. Addressing the following issues prior to participation in intervention strategies: activity avoidance, fear of falling, fear of injury, lack of perceived ability, fear of exertion.	Programmes with an emphasis on balance and strengthening.
Assistive mobility aids and home modification most readily accepted interventions.	Lack of transport to venues.
People may be more receptive to messages around prevention when they have actually had a fall or near fall.	No support from family.

Extended care settings	
Facilitators	**Barriers**
Reminders by staff to be active.	Fear of falling; reluctance to walk; pain, effort and age (in relation to exercise programmes).

4.4.9 Rehabilitation: review methods and results

4.4.9.1 Background

The focus of this review was on rehabilitation interventions following an injurious fall, which resulted in treatment within either primary or acute care. Rehabilitation involves a number of approaches from intensive training programmes – from multifactorial interventions to single more targeted interventions that focus on balance or strength exercise training. These interventions can be given through specialist care from therapists or via a multidisciplinary team. Therefore the aim of this review was to determine the effectiveness of these programmes for rehabilitation, following a fall that resulted in hospitalisation.

Definitions

The following explains the differences between primary prevention, secondary prevention and rehabilitation for the purposes of this review.Also defined is injurious fall.

- Primary prevention – interventions that are targeted at those at risk or high risk of a fall.
- Secondary intervention – interventions that are targeted at those with a history of falls.
- Rehabilitation – interventions that are targeted at those who have suffered an injurious fall.
- Injurious fall – fall resulting in a fracture or soft tissue damage that required treatment.

4.4.9.2 Objectives

The review sought to answer the following questions:

What are the most effective methods of rehabilitation/intervention/process of care, following an injurious fall?

4.4.9.3 Selection criteria

The Cochrane review on interventions for the prevention of falls was the principle source of evidence for this review, as this provided the most up-to-date evidence of falls prevention programmes, including some specific to rehabilitation strategies. Data from the RCTs included in this review that met the selection criteria were extracted.

A further search was conducted to ensure all relevant trials specific to rehabilitation had been identified.

In addition, key relevant published documents relating to rehabilitation, such as guidelines and systematic reviews nominated by the GDG, were reviewed.

Types of studies

For individual studies we selected RCTs, controlled clinical trials, controlled before and after studies, and interrupted time series analyses. Included were studies in the Cochrane review, which had been conducted on participants who were selected on the basis of an injurious fall, and were given rehabilitation in residential settings or in the home. This included studies examining early discharge programmes.

In addition, key documents such as clinical guidelines, health technology assessments, systematic reviews and other important policy documents relating to rehabilitation were sought.

Participants

Older people – mainly more than 65 years of age but 60 acceptable – who had sustained an injurious fall and received care/treatment from primary care, or acute care as an inpatient or outpatient.

Settings

Accident & Emergency, community-dwelling and extended care. Rehabilitation programmes implemented within inpatient discharge plans/programmes.

Interventions

Any intervention that is implemented for the purposes of rehabilitation following an injurious fall. For example:

- exercise/strength training
- nurse/therapist interventions
- balance training
- home modification
- early discharge vs. hospital rehabilitation
- education
- assistive devices
- multidisciplinary and community support.

Outcomes

Reduction in number of falls/injurious falls.

4.4.9.4 Search strategy

A search was conducted to ensure all relevant papers were gathered for this review, in addition to those identified in the Cochrane review, and to identify key documents relating to rehabilitation. The first search was conducted in October 2002, and it was updated on all selected databases in July 2003. Seven electronic databases were searched between 1980 and October 2002, using a sensitive search strategy.

The search strategies and the databases searched are presented in Appendix B. All searches were comprehensive and included a large number of databases. All search strategies were adapted for smaller or simpler databases or for web-based sources, which did not allow complex strategies or multi-term searching.

A combination of subject heading and free text searches was used for all areas. Free text terms were checked on the major databases to ensure that they captured descriptor terms and their exploded terms.

4.4.9.5 Data abstraction

The following data were extracted from each study:

Country of origin	Participant and setting details
Intervention and comparison	Sample sizes
Follow-up period	Losses to follow-up
Outcomes	RR and confidence intervals
Randomisation process	Quality assessment

No statistical analysis of inter-rater reliability of dual data extraction was performed. Differences were resolved by discussion.

4.4.9.6 Appraisal of methodological quality

Once individual papers were retrieved, the articles were checked for methodological rigour, using quality checklists appropriate for each study design (Appendix F), applicability to the UK and clinical significance. Assessment of study quality concentrated on dimensions of internal validity and external validity. Information from each study that met the quality criteria was summarised and entered into evidence tables.

Quality appraisal for this review was based on the Cochrane review criteria of assessment of methodological quality (Appendix F).The two papers excluded from the Cochrane review relevant to rehabilitation (Tinetti 1999 and Crotty 2002) included here were quality appraised using the Cochrane quality criteria.

4.4.9.7 Data synthesis

Individual study results were reported in evidence tables.

4.4.9.8 Details of studies included

As detailed below, nine studies were relevant and included from the Cochrane review.

There were nine trials from the Cochrane review relevant to rehabilitation (see table 14). Included studies were: Close et al. (1999); Crotty et al. (2002);

Ebrahim (1997); Kingston (2001); Lightbody (2001); Pardessus (2002); Rubenstein (1990); Shaw (2003); Tinetti (1999).

TABLE 14: INCLUDED STUDIES FOR REHABILITATION REVIEW

Cochrane review: included studies	58
Sifted relevant to this review	7 + 2 from the excluded 97 references related to review topic
Included	9

Two of these papers – Tinetti (1999) and Crotty (2002) – were excluded from the Cochrane review on the grounds that falls were only measured as adverse events, rather than as a primary outcome. However, they are relevant to this review as they evaluate rehabilitation programmes post-injurious fall. Data were extracted directly from the original paper and relative risks (RR) calculated.

Results of the supplementary search for additional trials and key documents are shown in the table below.

TABLE 15: RESULTS OF SUPPLEMENTARY RESEARCH

Total number of hits	1684
n screened	26
n relevant	9
Final number of articles included	1 trial 7 relevant documents

The supplementary search conducted for this review elicited one further RCT for inclusion (Crotty 2002), which had not been included in the Cochrane review. Many studies were identified that had examined the effects of rehabilitation on intermediate outcomes – for example: mobility, quality of life and psychosocial factors – but these studies did not measure subsequent falls as an outcome.

The key documents identified are listed below and summarised in Evidence table 9, Appendix E.

TABLE 16: REVIEWS AND GUIDELINES OF RELEVANCE TO REHABILITATION FOLLOWING A FALL

1. Cameron et al. (2000). Geriatric rehabilitation following fractures in older people: a systematic review. Health Technology Assessment 2000: 4 (2).
2. (2002) Prevention and management of hip fracture in older people, Scotland: Scottish Intercollegiate Guidelines Network.
3. (June 2000) Guidelines for the collaborative rehabilitative management of elderly people who have fallen, London: The Chartered Society of Physiotherapy and the College of Occupational Therapists.
4. Parker et al. (2002) Mobilisation strategies after hip fracture surgery in adults (Cochrane review) in The Cochrane Library, Issue 4 2002, Oxford.
5. Cameron et al. (2002). Co-ordinated multidisciplinary approaches for patient rehabilitation of older patients with proximal femoral fractures, (Cochrane review), in The Cochrane Library, Issue 3, Oxford.
6. Ward et al. (2003). Care home versus hospital and own home environments for rehabilitation of older people (Cochrane review), in The Cochrane Library, Issue 3.

Settings

Five trials reported the effect of interventions in A&E settings. In two trials, the intervention was initiated within a hospital setting and continued in the community. Two further trials included participants from an extended care setting and community-dwelling.

Participants

Three trials recruited participants presenting to A&E, following a fall, who were discharged home following treatment. One trial set in an A&E setting, recruited cognitively impaired participants with a recent fall requiring treatment. Two trials recruited participants in a hospital setting following surgical treatment of a hip fracture, and one other recruited those who had been hospitalised following a fall. Two trials recruited participants with a history of falls in an extended care setting and community-dwelling.

Interventions

Close (1999) compared a multifactorial intervention with usual care in community-dwelling individuals presenting at A&E following a fall. The intervention involved medical and occupational therapy assessments and targeted interventions; medical assessment to identify primary cause of fall and other risk factors; with an intervention or referral as required, and home visit by occupational therapist. Participants were at least 65 years old with a

history of falling, having presented at A&E with a subsequent fall. Falls data was obtained by a falls diary with four monthly follow-up for a period of one year.

Crotty (2002) compared accelerated discharge and home-based rehabilitation, including home modifications with conventional treatment in those admitted for surgical treatment for a hip fracture. The intervention included a home visit by a physiotherapist, an occupational therapist, a speech pathologist, a social worker and a therapy aid, who negotiated short-term goals with a participant and their carer. The sample size was small (n=66) but no losses to follow-up were reported.

Tinetti (1999) compared systematic multi-component rehabilitation with an 'aids to daily living' strategy, with usual care with limited activities, in non-demented older persons who underwent surgical repair of hip fracture and returned home within 100 days. This intervention included physical therapy involving assessment and exercise programmes individually tailored in strength, gait, balance, transfers and stair climbing. It also included functional therapy, based on principles of occupational therapy, to identify and improve performance of tasks of daily life. Both these programme elements involved tapered visits up to six months.

Ebrahim (1997) compared general advice on health and diet, and encouraging brisk walking for 40 minutes, three times per week, with general advice on health and diet with upper limb exercises. Participants were post-menopausal women identified from A&E and orthopaedic fracture clinic records who had a fractured upper limb in the last two years.

Kingston (2001) compared rapid health visitor intervention within five working days of index fall and multiple interventions, managed on an individual basis for 12 months, with usual post fall treatment in community-dwelling women attending A&E after a fall who were discharged directly home. The multiple interventions programme included pain control, getting up after a fall, education about risk factors, advice on diet and exercise to strengthen muscles and joints in an individualised programme.

Lightbody (2002) compared multifactorial assessment by a dedicated 'falls' nurse, with usual care in consecutive patients attending A&E following a fall. The intervention included one home visit for assessment of medication, vision, hearing, balance mobility, feet and environmental assessment, with referral to a range of other services as required. Advice was also given and education about home safety.

Pardessus (2002) compared a comprehensive two-hour home visit – with specialist health care professionals of multifactorial interventions – with usual care in those hospitalised with a recent fall, recruited in hospital. The intervention included assessment by specialist occupational therapist, rehabilitation doctor and physician prior to discharge. Environmental hazards were identified and modified and social support was given.

Rubinstein (1990) compared nurse practitioner assessment within seven days of a fall – with referral for intervention to physician for recommendations for action and referral for intervention – with usual care in men and women in long-term residential care.

Shaw (2003) compared multifactorial, multidisciplinary clinical assessment and intervention given for identified risk factors, with clinical assessment but no intervention in older people with cognitive impairment or dementia attending A&E after a fall. This intervention included medical, physiotherapy, occupational therapy and cardiovascular assessment with interventions for all identified risk factors.

4.4.9.9 Methodological quality of studies

A summary of the methodological quality of each study of the trials is shown in Appendix F.

In four studies, assignment of treatment was adequately concealed. (Crotty 2002; Ebrahim 1997; Rubinstein 1990; Shaw 2003). In the remaining five studies, information was inadequate to judge concealment. (Close 1999; Kingston 2001; Lightbody 2002; Pardessus 2002; Tinetti 1999). The overall quality scores were high-medium for two studies. (Crotty 2002; Shaw 2003).

They were medium in five studies. (Close 1999; Ebrahim 1997; Lightbody 2002; Pardessus 2002; Tinetti 1999). They were medium to low in one study (Rubinstein,1990) and low in one study (Kingston 2001).

Losses to follow-up ranged from 0 (or not stated), (Crotty 2002; Rubinstein 1990) to 41 per cent (Ebrahim 1997) mostly the studies fell within the 20 per cent quality cut-off or just outside at 23 per cent (Close 1999).

Five studies were based on intention to treat analysis (Crotty 2002; Pardessus 2002; Rubinstein 1990; Shaw 2003; Tinetti 1999) while for four studies, intention to treat analysis was not possible, as no outcome data were available (Close 1999; Ebrahim 1997; Kingston 2001; Lightbody 2002).

Active registration of falling outcomes or use of a diary was clearly indicated in five studies (Close 1999; Crotty 2002; Lightbody 2002; Rubenstein 1990; Shaw 2003) or was by participant recall, at intervals during the study or at its conclusion (Ebrahim 1997), or was not described in three studies (Kingston 2001; Pardessus 2002; Tinetti 1999).

Characteristics of excluded studies are shown in Appendix G.

4.4.9.10 Comparisons

Trials were included in which participants were randomised to receive an intervention or group of interventions versus usual care to minimise the effect of, or exposure to, any risk factor for falling. Studies comparing two types of interventions were also included.

4.4.9.11 Evidence summary

The studies reporting significant results suggest that a multifactorial approach, including multidisciplinary assessment and targeted interventions, could have some impact on reducing the incidence of falling as part of a rehabilitation programme, following a fall resulting in medical attention. It is less clear from this evidence of the impact of these complex interventions on other factors – such as confidence; quality of life and acceptability – as limited data were available. There perhaps also needs to be consideration of the planned

withdrawal of such programmes and the ability of these individuals to sustain the improvement shown.

It is less clear which specific mechanisms of this multifactorial approach to rehabilitation are effective, but the fundamental key to success may be through comprehensive discharge planning.

This evidence is supported by key documents, in particular the expected standards of care outlined in the NSF for older people (standard six).

4.4.10 The effectiveness of hip protectors: review methods and results

4.4.10.1 Background

Although hip protectors do not prevent falling, they do prevent one of the consequences of falling, that is hip fracture. Therefore, they can be considered as a secondary prevention/rehabilitation strategy in patients at risk of falling. The use of padding worn around the hip has been advocated as a measure of reducing the impact of the fall and thereby the chance of fracturing the hip. The fracture is usually the result of a fall. The fall usually occurs whilst standing or walking and the impact with the ground is usually on the side in the region of the hip (Hopkinson-W 1998). The rationale and development of such protectors has been summarised in Lauritzen (1977) and Lauritzen (1996).Various types of padded hip protectors have been developed. Most consist of plastic shields or foam pads, which are kept in place by pockets within specially designed underwear.

A Cochrane review on the effectiveness of hip protectors has recently been updated (Parker et al. 2003). The methods and results of the review are summarised below and are taken from Parker et al. (2003). The full details are available at the Cochrane Library.

4.4.10.2 Objectives

The review sought to answer the following question:

Do hip pads or protectors worn about the hip reduce the risk of fracturing the hip?.

4.4.10.3 Selection criteria

Types of studies

All randomised controlled trials comparing the incidence of hip fractures in those allocated to wearing hip protectors with the incidence in those not allocated to using protectors. Quasi-randomised trials were also considered for inclusion.

Types of participants

Older people of either gender living in the community or in institutional care.

Types of intervention

Allocation to wearing of hip protectors, or to not wearing hip protectors.

Types of outcome

- Incidence of hip fractures over the study period
- Incidence of pubic rami and other pelvic fractures
- Incidence of other fractures
- Incidence of reported fall
- Mortality
- Compliance with protectors
- Reported complications of use of protectors, including skin damage/breakdown
- Cost effectiveness of the protectors.

4.4.10.4 Search strategy

The following sources were searched:

- Cochrane Musculoskeletal Injuries Group's specialised register (April 2003)
- Cochrane Central Register of Controlled Trials (The Cochrane Library issue 1, 2003)
- MEDLINE (1966 to April 2003)

- EMBASE (1988 to 2003 Week 14)
- CINAHL (1982 to April 2003)
- reference lists of relevant articles
- trialists were contacted and ongoing trials identified in the National Research Register (http://www.update¬software.com/national/ accessed 20/01/03) and Current Controlled Trials (http://controlled-trials.com/ accessed 20/01/03).

The search strategies and the databases searched are presented in Appendix B. All searches were comprehensive and included a large number of databases. All search strategies were adapted for smaller or simpler databases or for web-based sources, which did not allow complex strategies or multi-term searching.

4.4.10.5 Sifting process

Once articles were retrieved the following sifting process took place:

- First sift: for material that potentially meets eligibility criteria on basis of title/abstract by two reviewers
- Second sift: full papers ordered that appear relevant and eligible and where relevance/eligibility not clear from the abstract by two reviewers
- Third sift: full articles are appraised that meet eligibility criteria by two reviewers.

4.4.10.6 Data abstraction

Data from included trials were extracted by two reviewers into pre-prepared data extraction tables. Discrepancies were discussed and resolved. The following data were extracted from each study:

  - patient inclusion/exclusion criteria
  - care setting
  - key baseline variables by group
  - description of the interventions and numbers of patients randomised to each intervention

- description of any co-interventions/standard care
- duration and extent of follow-up
- outcomes
- acceptability and reliability if reported. If data were missing from reports then attempts were made to contact the authors to complete the information necessary for the critical appraisal. If studies were published more than once, the most detailed report was used as the basis of the data extraction.

4.4.10.7 Appraisal of methodological quality

The methodological quality of each trial was assessed by two researchers independently using a 10-item scale, with a total score for each trial. Full details of the principles of quality used in this review are reported in Appendix C. The following quality criteria were used:

- description of inclusion and exclusion criteria used to derive the sample from the target population
- description of a priori sample size calculation
- evidence of allocation concealment at randomisation
- description of baseline comparability of treatment groups
- outcome assessment stated to be blinded
- clear description of main interventions
- intention to treat analysis
- timing of outcome measures
- reporting of loss to follow-up
- compliance of treatment.

4.4.10.8 Data synthesis

For each study, relative risk (RR)(fixed effect) and 95 per cent confidence limits (CI) were calculated for dichotomous outcomes. However, the authors of the review caution that the results must be considered as exploratory for the studies that used cluster randomisation. As cluster randomisation results in reduced effective sample size and statistical power, analysis using the

number of patients in each group gives inappropriately narrow confidence intervals (Parker et al. 2003). Results from individually randomised trials were pooled using the fixed effects model. Heterogeneity between comparable trials was tested using a standard chi-squared test. All statistical analysis was performed on Revman (v3.1.1) and conducted by the CWG.

4.4.10.9 Details of studies included in the review

Thirteen randomised controlled trials were included (seven in the previous review 1999).

Settings

The 13 included studies involved a total of 6,849 older people in residential settings or community dwelling. Within these, three studies were in a community-dwelling setting (one UK-based); the remaining 10 were conducted in a residential setting (one UK).

Participants

Mean age of participants in the individual studies, where reported, ranged from 80 to 86 years.

Interventions

Protective hip pads placed in the region of the greater trochanter were used in all trials. Ordinary underwear with no special fixation for the hip pad was used in Ekman (1997). The hip pads were fixed or sewn into special underwear in 12 studies (Birks 2003; Cameron 2001; Cameron 2003; Chan 2000; Harada 2001; Jantti 1996; Hubacher 2001; Meyer 2003; Kannus 2000; Lauritzen 1993; Van Schoor 2003; Villar 1998). All studies except two used an ‘energy shunting’ design. In Jantti (1996) ‘energy absorbing’ safety pants were used and for Chan (2000) the pads of local design for which it was not possible to say if they were energy absorbing or shunting.

Outcomes:

See Evidence table 11 (Appendix E, 2004) for details of other outcomes measured in the included trials.

4.4.10.10 Methodological quality of the studies

A summary of the methodological quality of each study of the trials is shown in Appendix F and principles of quality assessment in Appendix C.

Eight studies were randomised by participant (Birks 2003; Cameron 2001; Cameron 2003; Chan 2000; Janitti 1996; Hubacher 2001; Van Schoor 2003; Villar 1998). In Birks (2003), randomisation was carried out by a remote randomisation service accessed by telephone. Cameron (2001), Cameron (2003) and Janitti (1996) randomised the patients individually by sealed envelopes.Van Schoor (2003) used computer generated random numbers. Chan (2000) stated that the method of randomisation was by 'taking draws literally'. About half the participants in Hubacher (2001) were randomised by the head of the nursing home; the remainder were randomised by a computer. No details of the method of randomisation were provided by Villar (1998).

The remaining five studies were cluster randomised. The unit of randomisation in Lauritzen (1993) was the nursing home ward occupied by the participants, selected by an independent physician drawing the number of the 28 nursing home wards. In Ekman (1997), residents of one of four nursing homes were offered the hip protectors with the other three homes acting as controls. Kannus (2000) used an independent physician drawing sealed envelopes to randomise treatment units within 22 community based health care centres. Losses within treatment units during the study were replaced from a 'waiting list'. It is unclear how selection bias was avoided in this process. Harada (2001) used the even or odd digit of the patient's room number to allocate participants. Each room had up to four patients. The unit of randomisation in Meyer (2003) was a nursing home or independently working wards in large nursing homes. Forty-nine clusters were randomised by phone from an external central location using computer-generated lists.

Characteristics of excluded studies are shown in Appendix G.

4.4.10.11 Comparisons

The comparisons relevant to this guideline and able to be made on the basis of the included studies were: allocation to wearing of hip protectors, or to not wearing hip protectors.

4.4.10.12 Evidence summary

Parker et al. (2003) report the following:

- Five studies involving 4,316 participants were cluster randomised by care unit, nursing home or nursing home ward rather than by the individual. Individually, each of these studies reported a reduced incidence of hip fractures within those units allocated to receive the protectors.Because of the use of cluster randomisation, pooling of results of these studies was not undertaken.
- Pooling of data from five individually randomised trials conducted in nursing/residential care settings (1,426 participants) showed no significant reduction in hip fracture incidence (hip protectors 37/822, controls 40/604, RR 0.83, 95% CI 0.54 to 1.29).
- Two individually randomised trials of 966 community-dwelling participants, reported no reduction in hip fracture incidence with the hip protectors (RR 1.11, 95% CI 0.65 to 1.90). No important adverse effects of the hip protectors were reported but compliance, particularly in the long-term, was poor.

See Evidence table 10 and 11, Appendix E for further details of studies and outcomes.

Implications for practice (Parker et al. 2003)

- Reported studies that have used individual patient randomisation, have provided insufficient evidence for the effectiveness of hip protectors when offered to older people living in residential care or in their own home.
- Data from cluster randomised studies provide some evidence of effectiveness of hip protectors in reducing the risk of hip fractures in those living in nursing homes and considered to be a high risk of hip fractures.

- Reported adverse effects of hip protectors are skin irritation, abrasion and local discomfort.
- Compliance with wearing the protectors remains a problem.

Full evidence reviews are included under the relevant recommendations in Section 4.6, along with evidence statements.

4.4.11 Cost effectiveness review and modelling: methods and results

To fulfil the DH and Welsh Assembly Government remit, NICE requested that the cost effectiveness evidence of interventions for the assessment and prevention of falls in older people be assessed. In accordance with the objectives of the scope, cost effectiveness was addressed in the following way:

- a comparison of the cost and cost effectiveness of falls prevention interventions compared with usual care, other intentions or no intervention; and
- an investigation of which types of falls prevention programmes are the most cost effective.

The aim of the review was twofold. Firstly, to identify economic evaluations that had been conducted alongside trials and secondly, to identify evidence that could be used in cost effectiveness modelling.

Health economic evidence

The searches for economic evidence were designed to identify information about the resources used in providing the existing service, and any additional resource use associated with increased interventions and the benefits that could be attributed. The searches were not limited to RCTs or formal economic evaluations. The search strategy is shown below and the number of papers, sorted by intervention.

Identified titles and abstracts from the economics searches were reviewed by the health economist and full papers obtained as appropriate. The full papers

were critically appraised by the health economist. Consideration was given to each study design and the applicability of the results to the guideline context. Quality was assessed using the Drummond et al. (1999) economic evaluation checklist. An important issue in this respect is that much of the evidence on costs and benefits comes from health care systems outside a UK setting and are therefore of limited value to a UK guideline.

Searching for health economics evidence

The searching was carried out by an information scientist at the School of Health and Related Research (ScHARR), with guidance on the search terms from the health economist.

Search strategy

The search strategy used was as follows: Economic evaluations Fall or falls or falling or fallers

“Accidental-falls”/all subheadings old or older or senior* or elder* or aged or geriatric* explode “Aged”/all subheadings “Middle-Age”/all subheadings

1 economics/

2 exp “costs and cost analysis”/

3 economic value of life/

4 exp economics, hospital/

5 exp economics, medical/

6 economics, nursing/

7 economics, pharmaceutical/

8 exp models, economic/

9 exp “fees and charges”/

10 exp budgets/

11 ec.fs

12 (cost or costs or costed or costly or costing$).tw

13 (economic$ or pharmacoeconomic$ or price$ or pricing).tw

14 or/1-13

15 exp quality of life/

16 quality of life.tw

17 life quality.tw.

18 hql.tw

19. (sf 36 or sf36 or sf thirtysix or sf thirty six or short form 36

20. qol.tw.

21. (euroquol or eq5d or eq 5d).tw.

22. qaly$.tw

23. quality adjusted life year$.tw

24. hye$.tw

25. health$ year$ equivalent$.tw.

26. health utilitie$.tw.

27. hui.tw.

28. quality of well-being$.tw.

29. quality of well being.tw.

30. qwb.tw.

31. (qald$ or qale$ or qtime$). Tw.

32. or/15-31

32. from 32 keep 1

Searches were done from 1966 to the present (April 2003) and initially with no language restrictions. The following databases were searched

- Medline
- Embase
- NHS EED
- OHE HEED

Databases were searched in April 2003 and from these searches there were 2,354 hits.

In addition, reference lists from appraised papers were checked for further useful references. The systematic reviewer at the NCC also noted any potentially suitable references and passed them on to the health economist.

Inclusion criteria

The titles and, where available, the abstracts were screened to assess whether the study met the following inclusion criteria:

- Population: older people who had had a fall or were deemed at risk of a fall.
- Economic evidence: the study was an economic evaluation or included information on resources, costs or specific quality of life measures.
- Study design: no criteria for study design were imposed a priori.

Exclusion criteria

Papers were excluded if they did not contain cost effectiveness data, quality of life data or were simply a description of costs. An exception to this was made when examining papers that were of use in providing data on the costs of an intervention for any cost effectiveness modelling. Papers of this type needed to include a breakdown of resource use, unit costs, the source of the data, the year it was collected and the level of discounting applied.

Sifting was carried out by one assessor. Initially all papers that included the terms ‘cost effectiveness’,‘quality of life’ or ‘costs’ were selected. The abstracts were checked where possible and those papers that were descriptive or commentary were excluded.

Summary of results

After reviewing titles, abstracts and CRD/OHE HEED commentaries (where available), 106 potentially useful papers were included. A small number of these papers included background information and more detailed input about the interventions and issues involved. Six papers were in languages other than English and were not obtained.

Full papers were obtained and a significant number proved to be unhelpful. Papers had been ordered that contained at least one of the key words, costs, or quality of life and/or economics. On review, these papers were often found not to contain any data. This was particularly the case in papers that mentioned cost and quality of life in the title or abstract. This reduced the included papers to 14.Very few of these were good quality formal economic evaluations. Table 17 shows the areas directed by the GDG and the number of papers that were reviewed in each area.

TABLE 17: COST EFFECTIVENESS PAPERS REVIEWED

Area	Numbers of papers reviewed
Financial cost of falls to the NHS	1
Pharmaceutical interventions	2
Exercise programmes	4
Tai Chi	1
Home hazard assessment and modification	2
Multifactorial interventions	2
Hip protectors	2

Table 18 below details the papers included, the methodology used in the studies and the cost effectiveness results

TABLE 18

Author, year & country	Intervention	Client group age	Outcome measure	Method e.g RCT	Costs included	Cost per person	Cost effectiveness
Robertson 2001a NZ	Home-based exercise	≤ 80	Fall reduction	Yes	All costs associated with the intervention. Treatment costs.	NZ $432	NZ $1,803 per fall prevented
Robertson 2001b NZ	Home-based exercise	→80	Fall reduction	Yes	All costs associate with the intervention. Treatment costs.	NZ$418	NZ$1519 per fall prevented
Buchner 1997 USA	Centre-based exercise	68 - 65	Balance, gait, fall reduction	Yes	Not reported. Treatment costs.	N/A	N/A
Schnelle 2003 USA	Exercise and incontinence care	→80 in residential care	Overall health including falls	Yes	Not stated. Treatment costs.	N/A	N/A
Salkeld 2000 Aus.	Home hazard	→65 mean 74	Fall reduction	Yes	All costs associated with intervention. Treatment costs.	A$98	A$4986 per fall prevented
Smith 1998 Aus.	Home hazard model	→75	Fall reduction	Decision analytic model	All costs.	A$172	A$1721
Tinetti 1994 Rizzo 1996 USA	Multifactorial	→70	Fall reduction	Yes	Costs for intervention only. Treatment costs.	$891	$2150

Refer to Section 4.6 for recommendations and cost effectiveness details for each intervention.

In addition to the evidence reported in Section 4.6, the report by Scuffham et al. (2003) was also considered as it contains information on the incidence and costs of falls in the UK. The authors accessed the dataset from the Department of Trade and Industry (DTI) to examine the data collected in the year 2000 from the participating A&E departments.

They report the total cost of falls to the UK government as more than £1 billion. Just over half this cost was incurred by the NHS and rest by personal social services mainly in long-term care costs. They demonstrate the correlation between increasing age and less favourable outcomes after a fall.

Excluded studies

A study by Wilson and Datta (2001) Tai Chi for the prevention of fractures in a nursing home population: an economic analysis is a literature based cost-benefit analysis. This study was reviewed and has been excluded on the grounds that the data used to populate this model was inappropriate. The data on the relative risk of falls is not compatible with the risk of hip fracture.

In addition the GDG requested that we review the following studies. Two studies by Kenny were obtained and appraised. Neither of these studies met the inclusion criteria for economic evaluation. (Kenny 2001; Kenny 2002).

A further abstract from the PROFET study (Close 1999) was appraised. This reports on an economic evaluation however, as an abstract, there is insufficient information to allow a full crucial assessment.

Hip protectors

Hip protectors are considered as a secondary prevention/rehabilitation strategy in patients at risk of falling. The use of padding worn around the hip has been advocated as a measure of reducing the impact of the fall and thereby the chance of fracturing the hip. The recent updated evidence on clinical effectiveness is inconclusive (Parker et al. 2003). For an intervention to be cost effective, it must first be clinically effective.

Summary of the health economics evidence

Although clinical and cost effectiveness data exists for falls prevention, there are no UK studies. The quality of reporting in these studies is often patchy, as some costs and benefits are reported and not others. The above studies did not use the same costing methods or always report incremental costs or discounting.

Those from countries other than the UK have limited applicability as the health care systems are often very different. Even in the small number of studies included, few comparisons can be made between studies due to the differences in methodology.

Identifying those individuals who may benefit most from an intervention is not always reported.Who should be targeted for screening; when screening should take place; and at what intervals is an area of considerable uncertainty in terms of costs and benefits.

There is a lack of cost effectiveness evidence in this area and therefore, we would recommend further research.

The cost effectiveness of interventions to prevent falls in the elderly: modelling report

Introduction

Successive Government initiatives have identified falls in the elderly as a major cause of morbidity and mortality (DTI 2002). It has been estimated that between one-third and half of people above the age of 65 fall each year. Falls in the elderly result in extensive use of National Health Service resources. Scuffham and Chaplin report that in 2002, 400,000 A&E attendances per annum were attributable to accidents involving older people. There is also evidence of substantial mortality associated with such accidents.

Interventions that reduce the likelihood of falling or injury in the event of a fall have the potential to save NHS resources and improve the health of the UK's increasingly elderly population.

A systematic review of the published literature up to August 2003 found no published cost effectiveness analyses of strategies for falls prevention in the elderly. In this chapter we report cost effectiveness analyses of two falls prevention strategies; exercise programmes for at risk individuals dwelling in the community and multifactorial interventions for at risk individuals dwelling in the community. For results and discussion please refer to Section 4.6.

Methods

A simple life table model was constructed for people aged 60 and over. The model starts with a cohort of 100 people aged 60 and runs on an annual cycle until all the members of the cohort are dead.

In each year, each person faces a risk of death and a risk of experiencing a fall leading to a contact with local accident and emergency department. For each year of life there is a health related quality of life weight. This weight is on a scale between zero and one; where one is the value of full health and zero is the value given to a health state equivalent to being dead.

The risk of a fall is taken from the report by Scuffham and Chaplin. The risk of mortality is taken from the all cause mortality statistics published in Office of National Statistics Population Trends. The quality of life weight is taken from the population norms for the EQ-5D published by Kind et al. (1998).

Each fall incurs a cost of care and a reduction in quality of life. The cost of fall related injuries, except for hip fractures, is based upon the data reported by Scuffham and Chaplin. The cost reflects NHS and social service costs only – that is the cost effectiveness analysis is from the NHS perspective, not that of society as a whole. Using the data from Scuffham and Chaplin, it is assumed that the severity of the injury determines the NHS services received. Thus all events lead to an attendance at A&E with an ambulance journey. It was necessary to make assumptions about the relationship between event and subsequent treatment, as no data was available. The assumptions were:

- Ordinary fractures are assumed to be treated at A&E with an outpatient follow-up.

- Other fractures are assumed to be treated by hospital admission.
- Bruises, cuts, abrasions, and tenderness or swelling are assumed to be treated at A&E, with GP follow-up.
- Concussion and loss of consciousness are assumed to be treated by hospital admission.

The follow-up from hospital admissions was modelled on the basis of the data reported in Table 3.8 of Scuffham and Chaplin. Currently, the expected cost of each injury varies by age group, but not by injury site, with the exception of hip fracture. The unit costs of these events were obtained from the unit costs of health and social care report (Netton et al. 2003).

The direct cost of treating hip fractures is taken from a study by Parrot (2000), published by the UK Department of Trade and Industry. The utility reduction associated with injury was defined as a proportion of baseline utility, therefore it varied by age. The utility decrement for hip fracture was ranged from 0.166 (aged 60-69 years) to 0.146 (aged >=80 years) associated with hip. The utility decrement for all other fractures ranged from 0.074 (aged 60-69 years) to 0.065 (aged >=80 years). This model structure is used to estimate the total costs and QALYs accruing to treated and untreated cohorts for two interventions:

1. Exercise programme to prevent falls in at risk older people dwelling in the community; and

2. Multifactorial assessment and intervention programmes to prevent falls in at risk older people dwelling in the community.

The relative risk of falling associated with each intervention is taken from the meta-analyses reported in Appendix H of the clinical practice guideline. Detailed descriptions of these interventions are included in Section 4.5 of this guideline.

The cost of the exercise programme is taken from the work by Munro et al. (2002) and adjusted using the NHS Pay and Prices Indices to 2003 prices.

The cost of risk assessment for both interventions is taken from the work by Close et al. on the PROFET study. (Personal Communication J. Close).

All costs and quality adjusted life years (QALYs) are discounted at 3.5 per cent per annum. This is based upon the recommendations in the National Institute's Guideline development methods technical manual.

The incremental cost effectiveness of each of the interventions is calculated as the difference in the mean costs for the intervention and control cohorts, divided by the difference in the mean QALYs lived by each cohort.

In line with current best practice, we undertook probabilistic sensitivity analysis of the incremental cost effectiveness ratio. For this purpose, we defined probability distributions for the effectiveness of each of the interventions, representing our uncertainty as to the actual effectiveness of these interventions in practice. In addition to modelling the uncertainty on the effectiveness of the interventions, we considered the uncertainty relating to the costs of the intervention, the costs of treating injuries and the probability that a fall will lead to a hip fracture rather than any other injury.

Costs were assumed to have a log normal distribution – that is there is a small chance that the actual cost is much higher than the reported mean cost. This characteristic of cost data has been routinely reported in economic evaluations in many different areas of health care. The effectiveness of each intervention is described using a beta distribution. The beta distributions are characterised to reflect the 95 per cent confidence intervals reported in the guideline meta-analysis (Appendix H).

A Monte Carlo simulation, with 10,000 simulations, was then used to produce a probability distribution for the value of the mean costs and mean QALYs for an untreated cohort; a cohort receiving the exercise intervention; and a cohort receiving the multifactorial intervention. It is the mean value of the simulations that are used to estimate the incremental cost effectiveness ratios (ICERs). 95 per cent confidence intervals around the ICERs are then estimated using the bootstrap method.

The table on page 56 (Table 20) gives the parameter values used for the cost effectiveness analysis.

Results

The mean and incremental costs and QALYs and the ICERs for each of the interventions are given in Table 19.

TABLE 19: ICERS FOR MULTIFACTORIAL INTERVENTION IN THE AT RISK POPULATION AND THE EXERCISE PROGRAMME IN THE COMMUNITY POPULATION

Group	Mean costs (£)	Mean QALYs	Incremental costs	Incremental QALYs	Incremental cost effectiveness ratio, £'s per QALY
Control	14,431	8,766			
Multifactorial intervention	14,285	8,915	- 146	0.149	- 980
Exercise intervention	15,645	8,893	1,214	0.127	£9,559

Note: negative ICERs must be interpreted with great caution as they can be produced by negative costs and positive QALYs, or positive costs and negative QALYs. These outcomes are clearly not equivalent. The ICERs are highly labile; that is the small changes in the mean QALY gain will have a large impact upon the ICER.

Sensitivity analysis

The bootstrapped 95 per cent confidence interval for the exercise is -£184,828 to +£187,149. Figure 1 is a scatter plot of the incremental costs and incremental QALYs for the exercise intervention.

The bootstrapped 95 per cent confidence interval for the multifactorial intervention is -£19,533 to +£75,270. Figure 2 is a scatter plot of the incremental costs and incremental QALYs of the multifactorial intervention.

Discussion

The central estimates for the ICER for both the multifactorial and exercise intervention indicate that both interventions are cost effective, compared to

doing nothing. However, these results most be interpreted with great caution. The bootstrapped confidence intervals around the ICERS are large, reflecting the great uncertainty surrounding the evidence for the effect, and indeed the costs of providing the interventions and the costs of treating fall related injuries.

TABLE 20: PARAMETER VALUES USED IN THE COST EFFECTIVENESS MODEL

Parameter	Source	60 – 64 years	65 – 69 years	70 – 74 years	75+ years
Quality of life (QoL)	Kind et al.	0.8	0.8	0.75	0.75
QoL increment for injury	Assumption	- 0.05	- 0.075	- 0.1	- 0.12
Mortality	ONS	0.00914	0.01536	0.02429	0.03733
Baseline risk of injury	Scuffham and Chaplin	0.73	0.727	0.732	0.73
Hip fractures as a proportion of injuries from fall		0.0324	0.0324	0.0324	0.0324
Effectiveness of multi-model intervention	Guideline meta-analysis	0.86	0.86	0.86	0.86
Effectiveness exercise	Guideline meta-analysis	0.76	0.76	0.76	0.76
Cost ambulance	PSSRU	201	201	201	201
Cost of A&E contact	PSSRU	57	57	57	57
Cost of hospitalisation without follow-up	PSSRU	110	110	110	110
Cost of hospitalisation with outpatient follow-up	PSSRU	166	166	166	166
Cost of hospitalisation with long-term care	PSSRU	130	130	130	130
Cost of treating hip fracture	Parrot S	22,360	22,360	22,360	22,360
Cost of exercise intervention	Munro et al. PSSRU	25,425	25,425	25,425	25,425
Cost of multi-modal intervention	PROFET trail abstract	164	164	164	164
Discount rate	NICE Guideline Development Methods Guidance	6% pa	6% pa	6% pa	6% pa

Time horizon	NICE Guideline Development Methods Guidance	Lifetime	Lifetime	Lifetime	Lifetime

The ICERs are labile. The health gain from the interventions is small and small absolute variations in this gain lead to very large changes in the ICER. This is shown in Figures 1 and 2, which show that whilst there is no evidence that interventions will do any harm to the recipients (and are therefore better than many other health care interventions); the actual location of the intervention in the cost effectiveness plane is unclear. The intervention may save money and produce health or it may produce health at a substantial price.

More evidence is needed about almost all the parameters considered in the model; inter alia:

1. the quality of life impact of the full range of fall-related injuries
2. the cost of treating fall-related injuries and
3. the cost of the interventions.

Section 4.6 contains the full results under recommendations for multifactorial interventions and strength and balance.

Figure 1: Cost effectiveness of exercise intervention in falls prevention: plot on the cost effectiveness plane of 10,000 simulations

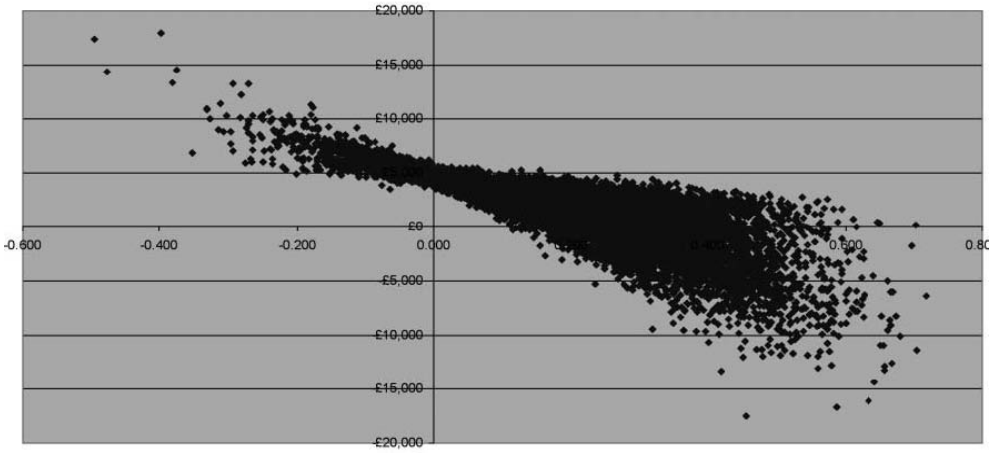
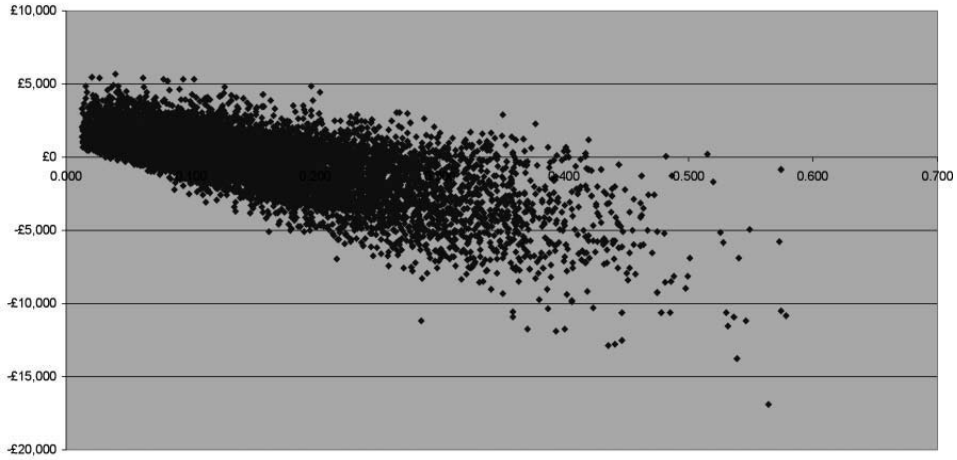


Figure 2: Cost effectiveness of multifactorial intervention in falls prevention: plot on the cost effectiveness plane of 10,000 simulations



4.4.12 Submission of evidence process

In December 2002, stakeholders registered with NICE (Appendix D) were invited to submit a list of evidence for consideration to ensure that relevant material to inform the evidence base was not missed.

The criteria for the evidence included:

- systematic reviews
- randomised controlled trials (RCTs) that examine clinical or cost effectiveness, and/or quality of life and economic analyses based on these findings
- representative epidemiological observational studies that have assessed the incidence of falls in the UK
- qualitative studies/surveys that examine patient/carer experiences of having fallen or fear of falling
- studies of any design which have attempted to formally assess the cost effectiveness of fall prevention programmes; assess the cost of falls or fall prevention programmes; assess quality of life in relation to falls.

Information not considered as evidence included:

- studies with ‘weak’ designs when better studies are available
- commercial ‘in confidence’ material
- unpublished secondary endpoint trial data,‘data-on¬file’ and economic modelling
- promotional literature
- papers, commentaries or editorials that interpret the results of a published study
- representations or experiences of individuals not collected as part of properly designed research.

Submissions were received from:

Abbott laboratories Limited (BASF/Knoll)
Alzheimers’s Society
Ambulance Service Association
British Geriatric Society
British Urological Institute
BUPA
Chartered Society of Physiotherapy
College of Occupational Therapists
Health Development Agency
Help the Aged (Department of Trade and Industry)
Limbless Association
Medtronic Limited
National Osteoporosis Society
Novartis Pharmaceuticals UK Ltd
Pfizer Limited
Roche Products Limited
Royal College of Physicians
Shire Pharmaceuticals Limited
Society of Chiropodists & Podiatrists

Submitted material received included notification of published, unpublished and ongoing research related to falls prevention.All references were screened for relevance and design criteria and those considered eligible were checked

with our databases to ensure our search had captured such studies. None of the submitted references provided relevant material additional to the studies we had already identified.

A list of registered stakeholders is included in Appendix D.

4.4.13 Evidence synthesis and grading

Evidence gradings were assigned to evidence statements that were derived from the evidence reviews. The evidence hierarchy used is shown below (Table 21) and was the hierarchy recommended at the time by NICE. (It should be noted that the hierarchy applies to questions of effectiveness, though it is used here to grade evidence other than clinical effectiveness).

TABLE 21: LEVELS OF EVIDENCE

I	**Evidence from meta-analysis of randomised controlled trials or at least one randomised controlled trial**
II	Evidence from at least one controlled trial without randomisation or at least one other type of quasi-experimental study
III	Evidence from non-experimental descriptive studies, such as comparative studies, correlation studies and case-control studies
IV	Evidence from expert committee reports or opinions and/ or clinical experience of respected authorities

Adapted from Eccles M, Mason J (2001) How to develop cost-conscious guidelines. Health Technology Assessment 5:16

The evidence tables and reviews were distributed to GDG members for comment and discussion.

4.4.14 Formulating and grading recommendations

In order for the GDG to formulate a clinically useful recommendation, it was agreed that the following factors be considered:

- the best evidence with preference given to empirical evidence over expert judgement where available, including:
- results of economic modelling

- effectiveness data, taking into account the strength of evidence – the level, quality, precision – as well as the size of effect and relevance of the evidence
- where reported, data regarding additional outcomes such as adverse events, patient acceptability and patient views
- a comparison between the outcomes for alternative interventions where possible
- the feasibility of interventions including, where available, the cost of the intervention, acceptability to clinicians, patients and carers and appropriateness of intervention
- the balancing of benefits against risks – including, where reported, all patient-relevant endpoints and the results of the economic modelling
- the applicability of the evidence to groups defined in the scope of the guideline, having considered the profile of patients recruited to the trials.

This information was presented to the group in the form of evidence tables, accompanying evidence summaries and evidence statements, with associated level of evidence grading. Interpretations of the evidence were discussed at GDG meetings. Where the GDG identified issues that impacted on considerations of the evidence and the ability to formulate implementable and pragmatic guideline recommendations, these have been summarised in the GDG commentary sections under each recommendation, though not all recommendations required a 'GDG commentary' section.

Issues relating to interpretation of the evidence and the wording of recommendations were discussed by the GDG, until there was agreement on the wording and grading of recommendations.

Where the GDG decided that hard evidence was essential before any recommendations could be considered, recommendations for future research were made using the NICE guidance on formulating recommendations.

The grading of the recommendations was agreed at the GDG meeting prior to first stage consultation using the scheme below.

Adapted from Eccles M, Mason J (2001) How to develop cost-conscious guidelines. Health Technology Assessment 5:16. .

TABLE 22: RECOMMENDATION GRADING

A	**Directly based on category I evidence**
B	Directly based on category II evidence or extrapolated recommendation from category I evidence
C	Directly based on category III evidence or extrapolated recommendation from category I or II evidence
D	Directly based on category IV evidence or extrapolated recommendation from category I, II or III evidence

The resulting recommendations with evidence statements, abbreviated evidence summaries and GDG commentary are presented in Section 4.6.

4.5 Guideline recommendations with supporting evidence reviews

Below are the recommendations agreed by the GDG, with associated evidence statements, evidence summaries and, where relevant, GDG commentaries on the consideration and interpretation of the evidence.

1.2.1 Case/risk identification (please see Sections 4.5.2 and 4.5.3 for evidence review methods)

1.2.1.1 Recommendation

Older people in contact with health care professionals should be asked routinely whether they have fallen in the past year and asked about the frequency, context and characteristics of the fall/s. [C]

Level of evidence	Evidence statement
Level III	Level III A previous fall is the most recently reported risk factor in prospective cohort studies, suggesting than an older person with a history of falling would be at high risk of a subsequent fall.

Evidence summary

Falls history

Falls history is a frequently reported significant risk factor and predictor of potential further falls. Ten studies reported falls history as statistical significant, among community-dwelling older people (Northridge 1996; Covinsky 2001;Tromp 2001; Friedman 2002; Stenbacka 2002; Wood 2002), and among residents of extended care facilities (Thapa 1996; Cavanillas 2000; Kallin 2002). For older people in community-dwelling settings, the range of summary statistics (OR/RR) reported was: 1.5-4.0. Three studies were of high quality; three of medium quality and one was low quality, with a reported OR of 4.0.

Studies conducted in extended care settings reported significant results, of which one high quality study reported a incident density ratio of 2.23 (1.4-4.37). Two other studies, of low quality, reported an odds ratio range of 1.9-

4.65. Seven studies reported falls history as significant in bivariate analysis but not in multivariate. Heterogeneity between these studies hinders interpretation of the clinical relevance of this finding.

GDG commentary

There is good evidence from cohort studies that an older person who has had a previous fall would be at risk of a subsequent fall. The group was keen to recommend that an older person be asked about their falls history based on this evidence. The purpose of obtaining this history would be to establish where possible, the frequency of falling; context and circumstances of the fall; and severity or injuries sustained from the fall. There was debate within the group of the best approach to identifying older people at risk, based on their previous falls history. Some were in favour of an annual review based on screening. Others considered that a case finding approach was more appropriate, asking an older person if they had fallen in the last year when seen by a health care professional. The group was in support of this being done yearly but did not want to reflect this in the recommendation.

1.2.1.2 Recommendation

Older people reporting a fall or considered at risk of falling should be observed for balance and gait deficits and considered for their ability to benefit from interventions to improve strength and balance. (Tests of balance and gait commonly used in the UK are detailed in Section 4.5.) [C]

Level of evidence	Evidence statements
Level III	- Mobility impairment, gait disorders and balance deficits have frequently been reported as significant risk factors in prospective cohort studies. - Many tests for the assessment of balance and gait are available to support clinical skill and the choice of such a tool should be determined at local level.
Level I	-Intervention trials focusing on gait and balance have shown a reduction in falls.

Evidence summary

Mobility impairment, gait disorders and balance deficits have frequently been reported as significant predictors of future falling in prospective cohort studies

(Bueno-Cavanillas 2000; Cesari 2002; Covinsky 2001; Northridge 1996; O'Loughlin 1993; Stalenhoef 2002).

Tests are available for the assessment of an older person's balance and gait that can inform clinical judgement. A detailed list of such tests is provided in Appendix E, Evidence table 3. These range from simple, pragmatic tests that require no special equipment, to those that require a trained health care professional with skill to administer.

GDG commentary

The group felt that assessment of older people who have fallen at least once should include observation for balance and gait deficits. This could be done on first contact by an appropriately trained health care professional in any setting. Clinical judgement should support the use of any test referred to in the clinical evidence and many other tests, developed by different disciplines, are likely to be available in trusts. However, a simple observation of a patient's ability to stand, turn and sit is considered adequate as a first level assessment.

Older people with observed gait or balance problems should be referred for targeted interventions. Identifying those most likely to benefit should also be considered.

The group was unable to recommend specific tests for use in practice, as there was a lack of robust validation studies. A profile of tools and tests identified in the assessment review is provided in Appendix E, Evidence table 3. The choice of tests should be determined at local level.

1.2.2 Multifactorial falls risk assessment

(please see Sections 4.5.2 and 4.5.3 for evidence review methods)

1.2.2.1 Recommendation

Older people who present for medical attention because of a fall, or report recurrent falls in the past year, or demonstrate abnormalities of gait and/or balance should be offered a multifactorial falls risk assessment. This assessment should be performed by a health care professional with

appropriate skills and experience, normally in the setting of a specialist falls service. This assessment should be part of an individualised, multifactorial intervention. [C]

1.2.2.2 Recommendation

Multifactorial assessment may include the following: [C]

- identification of falls history
- assessment of gait, balance and mobility, and muscle weakness
- assessment of osteoporosis risk
- assessment of the older person's perceived functional ability and fear relating to falling
- assessment of visual impairment
- assessment of cognitive impairment and neurological examination
- assessment of urinary incontinence
- assessment of home hazards
- cardiovascular examination and medication review.

Level of evidence	Evidence statements
Level III	Many individual risk factors have been proven to be predictive of a subsequent fall; therefore presence of more than one of the factors listed below increases the risk of falling: - falls history - gait deficit - balance deficit - mobility impairment - fear of falling - visual impairment - cognitive impairment - urinary incontinence - home hazards - number of medications - psychotropic and cardiovascular medications - muscle weakness.

Evidence summary

Gait deficit

Three community-dwelling studies reported this risk factor as statistically significant with a range of OR: 1.96-2.2 (Koski 1998; Cesari 2002; Northridge 1996). Four studies in community-dwelling settings reported non-significance in multivariate analysis (Northridge 1996; Stalenhoef 2002; Wood 2002; Tinetti 1995).

No studies in extended care settings reported gait deficit as significant (Cavanillas 2000; Kallin 2002) although one study carried out detailed gait analysis and found 'sitting down incorrectly' as significant in multivariate analysis significant (Cavanillas 2000).

In all of the above studies, the method of measuring gait and aspects of gait analysis differed between studies.

Balance deficit

Three studies conducted among community-dwelling participants, reported balance as statistically significant with a range of summary statistics of 1.83-3.9 (O'Loughlin 1993; Stalenhoef 2002; Covinsky 2001). However, each study measured different aspects of balance including dizziness, unbalanced and postural sway.

Eight studies did not find aspects of balance significant in multivariate analysis, two of which were conducted in extended care settings (Bueno-Cavanillas 2000; O'Loughlin 1993; Tinetti 1995; Northridge 1996; Koski 1998; Wood 2001; Stalenhoef 2002; Kallin 2002). Again, different aspects of balance were analysed.

Mobility impairment

Two community-dwelling studies reported statistical significance: In study one: trouble walking 400m: IRR=1.6(1.2-2.4); trouble bending down: IRR=1.4(1.0¬2.0) (O'Loughlin 1993). Study two conducted statistical modelling adjusting for different variables and reported the range for both multivariate models: OR=2.64-3.06 for mobility impairment (Covinsky 2001).

Four studies reported non-significance but as discussed earlier, different methods and aspects of mobility were measured (Bueno-Cavanillas 2000; Kallin 2002; Cesari 2002; Stalenhoef 2002).

Fear of falling

Three community-dwelling studies reported statistical significance of this factor, with a range of summary statistics 1.5 –3.2, although different methods of measuring fear were used (Arfken 1994; Cumming 2000; Friedman 2002). This included use of the falls efficacy scale (FES) to explore different cut-off values for determining risk and verbal rating scales to identify the degree of fear present. One study measured fear at baseline and reported non-significance in the results (Tromp 2001).

Friedman et al. (2002) carried out a prospective cohort study to examine the temporal relationship between falls and the fear of falling with n=2212 community-dwelling participants aged between 65 and 84 years. Fear was measured at baseline and at one-year follow-up with a simple yes/no answers to whether they were worried or afraid of falling, with a further question relating to their activity limitation when afraid of falling. This study was of high quality with a large sample and detailed baseline measurement. Logistical regression with adjustment for other variables in the model was performed on the data and results as follows. Fear of falling at baseline was significantly predictive of falling at follow-up with OR=1.78 (1.41-2.24), as well as fear at baseline predictive of fear at follow-up OR=5.40 (4.23-6.91). In addition to this, a fall at baseline was predictive of fear at follow-up

1.58 (1.24-2.01). Shared predictors of both falls and fear at follow-up include female gender and history of stroke. Cumming et al. (2000) carried out a prospective study to assess the impact of fear of falling with n=418 community-dwelling aged 65 and over. This study was of medium quality with a smaller sample size than others. The FES was administered at baseline with a total score of 100 indicating high fall related self-efficacy and 0 low fall related self-efficacy. Cut-off points were tested for predictive ability of falling in the analysis. Adjusted hazard ratio for all study participants with a FES score of <75 =

2.09 (1.31-3.33). Tromp et al. (2001) conducted a prospective study to examine all predictors for falls with n=1285 community-dwelling participants aged 65 years and more. This was a high quality study, with detailed baseline measurement and fall events measured with falls calendars. Fear was determined using a modified FES where answers were rated on a scale 0 (no confidence) to 3 (completely confident). Odds ratio for 1 fall and recurrent falls were significant in bivariate analysis but non-significant in logistic regression analysis.

Arfken et al. (1994) recruited patients from a prospective cohort study in which the purpose was to develop a screening tool for predicting falls in older people. The sample was 890 community-dwelling participants stratified in age groups ranging from 66 to 81+years. Baseline data were collected as part of the parent study and falls surveillance was conducted with participants reporting falls to a hotline plus monthly postcards reporting the incidence of falls.At one-year follow-up,the participants received a structured in-home assessment including demographics, health status, activity level, satisfaction with life, depressed mood and a brief physical assessment. Fear was determined with a three point verbal rating scale and dichotomised to summarise outcome as odds ratios: A= moderately fearful and not fearful, B= very fearful.Logistic regression models adjusted for gender and age. Results indicated that those who were moderately or not fearful predicted falling at least once: A= 1.52 (1.06-2.17) and very fearful participants: (B=

2.49 (1.48-4.20). Those experiencing frequent falls were more likely to be very fearful of falling: B=3.12 (1.61-6.06) than those moderately or not fearful A=1.71 (1.01-2.89).

Visual impairment

Two community-dwelling studies found that older people with a visual impairment were significantly at risk of falling, OR range=1.18-2.3 (Northridge 1996; Koski 1998). One extended care study of low quality reported OR =5.85 (Kallin 2002).

Eight studies reported non-significance in multivariate analysis, two of which were extended care setting studies (Tinetti 1995; Northridge 1996; Tromp 1998; Cesari 2002; Stalenhoef 2002; Wood 2002; Thapa 1996; Bueno-Cavanillas 2000).

Different aspects of vision were measured in these studies and included: visual impairment, visual acuity, depth perception and others.

Furthermore, there are a number of prospective cohort studies which we have been alerted to by stakeholders that demonstrate that visual impairment is an independent risk factor for falls and hip fractures (Felson et al. 1989;Cummings et al. 2003; Ivers et al. 2000 and 2004).

Cognitive impairment

Two studies in community-dwelling settings reported that older people with cognitive impairment were significantly at risk of falling OR=2.2-2.4 (Tinetti 1995; Van Schoor 2002). One low quality study in an extended care setting reported OR 6.2 (1.7-23.3) (Bueno-Cavanillas 2000).

However, nine studies did not find older people with cognitive impairment significantly at risk of falling in both settings (Tinetti 1995; Northridge 1996; Tromp 1998; Cesari 2002; Stalenhoef 2002; Van Schoor 2002; Thapa 1996; Kallin 2002; Wood 2002).

Urinary incontinence, including stress and urge incontinence

Two studies reported that older people suffering from urinary incontinence were at risk of falling with OR range=1.26-1.8 (Tromp 1998, 2001; Brown 2000). Additional studies that support incontinence as a significant risk factor include Luukinen 1996 and Tinetti 1995.

Five studies did not find incontinence a significant predictor of falling (Tinetti 1995;Koski 1998; Brown 2000; Cesari 2002; Thapa 1996).

Home hazards

Two studies reported that the presence of home hazards increased an older persons risk of falling, One study reported OR=1.51 (95% CI1.43-1.69)

(Cesari 2002). The other study (Gill 2000) carried out detailed analysis and reported that the following contributes to the risk of falls:

Loose rugs and mats: hazard ratio=5.87(95% CI 1.42¬24.2)

Carpet fold or tripping hazard: hazard ratio=3.45(95% CI 1.29-9.27).

Multiple medications

Seven studies were included in a systematic review and meta-analysis of cardiac and analgesic drugs (Leipzig et al. 1999a). All report that patients taking more than three to four medications were at risk of recurrent falls compared with patients taking fewer medications (range of results: OR 1.61 to 3.16). The studies included in this review were cohort, case control and cross sectional in design.

Anti-arrhythmic medications

In a meta-analysis of cohort, case control and cross-sectional studies (Leipzig 1999a), the following pooled results of 14 studies indicated that taking type 1A anti¬arrhythmic drugs increase the risk of falling (OR 1.22, 95% CI 1.05 to 1.42).

Psychotropic medications

In a systematic review and meta analysis of cohort, case control and cross-sectional studies examining psychotropic drugs and falls (Leipzig 1999b) the pooled results for the association between taking any psychotropic drug and risk of falling was 1.73 (1.52 to 1.97).

Muscle weakness

Muscle weakness has been reported as a significant risk factor (Perell 2001). Our updated review did not identify any studies reporting statistical significance of this factor. One study conducted in extended care and one in community-dwelling setting reported non-significance in multivariate analysis (Bueno-Cavanillas 2000; Koski 1998).

Discussion

We have reported here risk factors that are associated with falling. These results were statistically significant in multivariable analyses. The evidence

suggests that although each factor can be a predictor of falls, in some population groups or settings some risk factors may be more important than others. This is illustrated by studies that have carried out multivariate analysis and reported non-significance for each factor. However, there was substantial heterogeneity between studies and within each risk factor. Many different methods of measurement of risk factors are reported and no one study replicates another. An important example of this is those studies examining gait, balance and mobility problems. There is substantial overlap between each study's definition of each domain and method of measurement. The possible synergism between different risk factors should also be considered.

GDG commentary

Assessment of older people with a history of falling and the presence of other risk factors should be undertaken. The identification of older people at risk will enable practitioners to refer older people for effective interventions targeted at specific factors. Multifactorial assessment is an important process but must be linked to interventions. The grading of this recommendation reflects both the evidence on risk factors and level I evidence of assessment linked to intervention(s).

This multifactorial assessment should be done in the context of a comprehensive geriatric assessment where indicated.

1.2.3 Multifactorial interventions (please see Sections 4.5.5, 4.5.6, 4.5.9, 4.5.11 for evidence review methods)

1.2.3.1 Recommendation

All older people with recurrent falls, or assessed as being at increased risk of falling, should be considered for an individualised multifactorial intervention. [A]

In successful multifactorial intervention programmes the following specific components are common (against a background of the general diagnosis and management of causes and recognised risk factors): [A]

- strength and balance training

- home hazard assessment and intervention
- vision assessment and referral
- medication review with modification/withdrawal.

1.2.3.2 Recommendation

Following treatment for an injurious fall, older people should be offered a multidisciplinary assessment to identify and address future risk and individualised intervention, aimed at promoting independence and improving physical and psychological function. [A]

Level of evidence	Evidence statements
Level I	Multidisciplinary, multifactorial, tailored interventions are effective in reducing falls in the following population groups and settings: - community-dwelling older people - older people in extended care settings - older people presenting at A & E following a fall
Level I	Three trials suggest that multifactorial, multidisciplinary rehabilitation programmes are effective in reducing the incidence of further falling in older people who have suffered an injurious fall. This evidence is supported by key documents, in particular the expected standards of care outlined in the NSF for older people (standard six).

Evidence summary – multifactorial interventions

Community-dwelling, unselected (fallers and non-fallers in the population studied)

Of the eight studies that evaluated a multifactorial screening and intervention programme in community-dwelling older people, who were recruited on the grounds of age and domestic circumstances, without a requirement for the presence of known risk factors, data were pooled from four (Fabacher 1994; Jitapunkul 1998; Newbury 2001; Wagner 1994) involving 1,651 participants. The pooled data are homogeneous and show that the interventions are effective in reducing the proportion of fallers in the intervention group (pooled RR 0.73, 95%CI 0.63 to 0.85).

Data were not pooled from the other four studies in this category. In Carpenter (1990) (539 participants), which was cluster randomised by household, the

intervention involved an assessment by trained lay volunteers using a disability rating scale; an increase in disability score at a repeat visit was reported to the family medical practitioner. Only the total number of falls in each group in the month before the final interview was reported. The trialists reported significantly fewer falls in the experimental group during that period, but insufficient data were available to calculate an effect size. The fourth of the incremental interventions in Steinberg (2000) also cluster randomised, had a medical screen, home hazard assessment, and exercise. There was no significant difference in the incidence of falling between this group (59 participants) and the control group (63 participants) who received an information package alone. Van Rossum (580 participants) found no difference in the incidence of falls between the intervention and control groups,but no data were provided.Vetter (1992) (674 participants) was cluster randomised (by household). There were 95 of 350 fallers in the intervention group and 65 of 324 in the control group.

Community-dwelling, targeted (population studied are known fallers or have identified risk factors prior to enrolment)

Data from two studies in this category were not pooled as cluster randomisation was employed. Coleman (1999) (169 participants) reported that screening and intervention in a chronic care clinic provided no significant improvement in the incidence of falls at 12 or 24 months. Tinetti (1994) (301 participants) reported a significant reduction in the number of fallers in the intervention group, adjusting for age, sex, previous falls, and number of risk factors (adjusted incidence rate ratio 0.69, 95%CI 0.52 to 0.90). Data were pooled from the other five studies (Close 1999; Hogan 2001; Kingston 2001; Lightbody 2002; van Haastregt 2000). The pooled data show a significant reduction in the proportion of fallers in the intervention groups (pooled RR 0.86, 95%CI 0.76 to 0.98).

Exercise, visual correction, and home safety intervention

Day (2002), in a study of factorial design, examined the effect of exercise, visual correction and a home safety intervention. The impact of these three interventions combined was a significant reduction in the number of participants falling (RR 0.76, 95%CI 0.61 to 0.94). Further analysis was

carried out for the data for exercise plus vision correction (RR 0.76, 95%CI 0.62 to 0.95), and for exercise plus home hazard management (RR 0.84, 95%CI

0.69 to 1.03). These analyses are somewhat less favourable than the adjusted analyses presented by the authors in their original report.

Extended care

In Jensen (2002), a cluster randomised trial of an 11-week multidisciplinary programme, including general and resident-specific tailored strategies, reported a reduced incidence of falls in the intervention group (adjusted incidence rate ratio 0.60, 95%CI 0.50 to 0.73).

McMurdo (2000) (133 participants), also a cluster randomised study in an institutional setting, reported no significant difference between intervention and control groups in the percentage of participants falling in the six-month period after completion of the intervention. Ray (1997) (482 participants) was also cluster randomised. Data were reported on recurrent falls and injurious falls. The reporting of the data provides insufficient detail to confirm whether the reduction in recurrent falls experienced in the intervention group was significant. Rubenstein (1990) (160 participants) found no benefit from nurse practitioner assessment and physician referral within seven days of a fall (RR 0.97, 95%CI 0.84 to 1.11). Vassallo (2001) evaluated a multidisciplinary fall assessment in a cluster randomised trial in a geriatric rehabilitation setting, and reported fewer fallers (39/275) in the intervention group, compared with 111/550 in the control group.

Becker (2003), in a cluster randomised trial (N = 6) involving 981 long stay residents of community nursing homes, reported that the number of fallers was less in the intervention group (RR 0.75, 95%CI 0.57 to 0.98, trialists' analysis). The incidence density rate of falls per 1,000 resident years was also reduced in the intervention group (RR 0.55, 95%CI 0.41 to 0.73, trialists' analysis).

Cognitively impaired (any residence)

Shaw (2003), in a comparison of multifactorial assessment and intervention in 274 older people with cognitive impairment or dementia recruited from an A&E department following a fall, could not confirm the effectiveness of this intervention (RR 0.92, 95%CI 0.81 to 1.05). There is a lack of evidence of effective interventions for this group of older people. Many trials specifically excluded older people with a cognitive impairment.

Economic evidence

Tinetti et al. (1994) and Rizzo et al. (1996) both report on the same study. Tinetti reported on the clinical effectiveness. Rizzo undertook the cost effectiveness analysis. This study reported that the intervention package was cost effective in the high risk individuals. The high cost of the intervention was offset against the treatment costs of the high risk individuals. However, in this study not many of the control group had costly hospital admissions and the data was skewed. They undertook sensitivity analysis. There still remained a number of individuals in the intervention group who required costly treatment. The overall effect of this was to reduce the expected benefit in the intervention group. The analysis presented in the cost effectiveness analyses chapter (see Section 4.5.11) assumes that the at risk population can be reliably identified. Clearly the specificity and the sensitivity of the assessment tools will impact upon the cost effectiveness of the interventions.

The systematic review of assessment tools did not identify any information on the sensitivity and specificity of the existing assessment tools. In this context, there is even greater uncertainty about the true cost effectiveness of these interventions. The greater the ability of assessment tools to differentiate between those who are likely to fall without the intervention and the rest of the elderly population, the more cost effective the interventions will be. The figures presented in this chapter represent a best case, where the assessment is completely accurate. Nandy et al. (2004) report a high specificity (0.92) but a relatively low positive predictive value (0.57). Using this assessment tool, slightly more than 40 per cent of patients identified as being at high risk using this tool would not be expected to fall. This would have a significant upward impact upon the cost effectiveness results presented

above. This evidence became available too late in the process for it to be incorporated directly in cost effectiveness modelling.

The existing evidence base for judging the cost effectiveness of these interventions is poor. If the at risk population can be identified, our analysis indicates that the multifactorial intervention is likely to be cost effective compared to conventional thresholds, although there is a large degree of uncertainty around the actual incremental cost effectiveness ratio.

GDG commentary

The evidence above suggests that multifactorial interventions targeted to risk factors are effective in reducing falls in older people. However, it is difficult to make a definite recommendation of the key effective components for specific settings and populations. It is sensible therefore to refer a patient for intervention(s) that target known risk factors. Illustrative examples of good practice were nominated from trials by Close (1999), Jensen (2002) and Tinetti (1994).

Close (1999) identified older people living in the community who presented at A&E following a fall. The intervention included a detailed medical and occupational therapist assessment, with referral to relevant services for targeted interventions either by modification of risk factors where possible; referral to multidisciplinary team for further interventions; and drug medication review by the GP. Advice and education was given by the occupational therapist (OT) about safety in the home and modifications were made where appropriate. The OT supplied minor equipment or referral was made to social or hospital services as required.

Jensen (2002) recruited older people from extended care settings who received assessment by a physician and physiotherapist. This assessment included a full clinical examination and medication review. Targeted interventions included staff education, environmental modifications, exercise, supply or repair of aids, medication review and hip protectors.

Tinetti (1994) recruited older people living in the community with the presence of one of the following risk factors: postural hypotension; use of sedatives; use

of at least four medications; impairment in arm or leg strength or range of motion, balance, and ability to move safely from chair to bed. Assessment was conducted by a study nurse practitioner and physiotherapist. The intervention group was given either a combination of adjustment of their medications; or behavioural instructions and exercise programmes aimed at modifying their risk factors in the form of decision rules and intervention protocols for each risk factor.

These trials provide an example of approaches to providing effective multifactorial interventions, but the fundamental element is to prescribe or refer for targeted interventions.

Evidence summary: rehabilitation

Two trials reported a significant reduction in the incidence of further falling in those who had received attention for a previous fall (Close 1999; Crotty 2002). The intervention in the trial by Tinetti (1999) did not show an effect on the risk of falling, but there was a significant reduction in the incidence of individuals hospitalised. The key components of these studies included medical, physiotherapy and occupational therapy assessments with follow-up interventions, medical assessment to identify primary cause of fall and other risk factors with intervention or referral as required. Interventions may involve individually tailored exercise programmes aimed at improving strength, gait, balance, transfers and stair climbing. Social care and support were also part of some programmes.

The safety and efficacy of an exercise protocol designed to improve strength, mobility, and balance and to reduce subsequent falls in older patients with a history of injurious falls was examined in Hauer (2001). This RCT was a three-month intervention trial, with an additional three-month follow-up in an outpatient geriatric rehabilitation unit. The participants included 57 female patients, above the age of 75 years, admitted to acute care or inpatient rehabilitation, with a history of recurrent or injurious falls, including patients with acute fall-related fracture. Fall incidence was reduced non-significantly by 25 per cent in the intervention group, compared with the control group (RR: 0.753 CI: 0.455-1.245).

The studies reporting significant results suggest that a multifactorial approach, including multidisciplinary assessment and targeted interventions, could have some impact on reducing the incidence of falling as part of a rehabilitation programme following a fall resulting in medical attention. It is less clear from this evidence of the impact of these complex interventions on other factors – such as confidence;quality of life and acceptability – as limited data were available. Perhaps there also needs to be consideration of the planned withdrawal of such programmes and the ability of these individuals to sustain the improvement shown.

The evidence from geriatric hip fracture (GHFP) and early supported discharge (ESD) programmes suggest that they decrease the total length of hospital stay for older people who have suffered a hip fracture and inpatient treatment. In addition, these structured programmes of care achieve higher rates of return to previous residential status (Cameron et al. 2002). However, it is unclear what the effect these programmes have on reducing the incidence of a further fall. Furthermore, less is known about the impact on function, morbidity and quality of life for older people participating.

Two trials suggest that a multidisciplinary, multifactorial approach to management of older people, who have suffered an injurious fall and who have received treatment in a primary care or acute care setting, is an effective intervention package. Important components include assessment and a targeted intervention(s), underpinned by detailed discharge planning.

It is less clear which specific mechanisms of this multifactorial approach to rehabilitation are effective, but the fundamental key to success may be through comprehensive discharge planning.

In addition, the overall aim of these programmes for older people should be to regain confidence and subsequently prevent further falling. However, practitioners need to assess the extent to which the older person is likely to co¬operate with the intervention programme and the usefulness of the overall prevention strategies in the Cochrane review.

GDG commentary

There was substantial overlap between secondary prevention interventions and rehabilitation strategies. It was not possible to review the evidence of the effect of these interventions on important rehabilitation outcomes – such as improvement in function, mobility and psychosocial health – as these outcomes were outside the scope of the guideline. In this guideline, rehabilitation is considered as part of the secondary prevention of falls, but users of the guideline need to be aware of the potential for improvement in outcomes other than falls prevention.

1.2.4 Strength and balance training (please see Sections 4.5.5, 4.5.6, 4.5.9, 4.5.11 for evidence review methods)

1.2.4.1 Recommendation

Strength and balance training is recommended. Those most likely to benefit are older community-dwelling people with a history of recurrent falls and/or balance and gait deficit. A muscle strengthening and balance programme should be offered. This should be individually prescribed and monitored by an appropriately trained professional. [A]

Level of evidence	Evidence statement
Level I	A programme of muscle strengthening and balance training, individually prescribed at home by a trained health care professional is effective in reducing falls (pooled results from three trials).

Evidence summary

Exercise and/or physical therapy

Community-dwelling: targeted interventions

Pooled data from three studies from New Zealand, with a total of 566 participants (Campbell 1997; Campbell 1999; Robertson 2001a), using the same individually tailored programme of progressive muscle strengthening, balance retraining exercises and a walking plan, indicated that this intervention significantly reduced the number of individuals sustaining a fall over a one-year period (pooled RR 0.80, 95% CI 0.66 to 0.98). The number of people sustaining a fall resulting in injury was also significantly reduced

(pooled RR 0.67, 95%CI 0.51 to 0.89). Seventy-four per cent of participants in the control group and 69 per cent in the exercise group in Campbell (1997) continued for a second year.After two years,the rate of falls remained significantly lower in the exercise group (Campbell 1999a). The relative hazard for all falls in the exercise group was reported to be 0.69 (95%CI 0.47 to 0.97); the relative hazard for a fall resulting in a moderate or severe injury was 0.63 (95%CI 0.42 to 0.95).

These three studies involved older participants, but the components of the successful intervention suggest that balance retraining may be an important component of successful exercise programmes.

Economic evidence

The two papers by Robertson et al. (2001a, 2001b) report on the trials of the same home-based exercise programme in different centres carried out by different health care professionals. The programme delivered by the practice nurse was less costly than that delivered by the physiotherapist. However, the study undertaken with the practice nurse did not reduce hospital costs overall between the control and intervention groups.

The cost effectiveness analyses of exercise programmes for older people at risk of falling are reported. The exercise programme is likely to be cost effective but less cost effective than the multifactorial intervention. This said, exercise may produce other health benefits that have not been incorporated into the analysis presented in Section 4.5.11. However, in the absence of a sensitive and specific method for identifying those older people at high risk of falling, the cost effectiveness of exercise falls prevention strategies cannot be confirmed and any recommendation to implement such programmes should be treated with caution.

GDG commentary

The group agreed that strength and balance training should be administered by an appropriately trained professional. Although the evidence is relevant to community-dwelling older people with either a history of falls and/or a balance and gait deficit, this evidence could be generalised to other settings.At

present,individually prescribed exercise has been shown to be effective in falls prevention. Evidence of effectiveness of group exercise interventions is emerging and will be considered in the update of the guideline. In addition, the health benefits of exercise should be considered.

1.2.5 Exercise in extended care settings (please see Sections 4.5.5, 4.5.6, 4.5.11 for evidence review methods)

1.2.5.1 Recommendation

Multifactorial interventions with an exercise component are recommended for older people in extended care settings who are at risk of falling. [A]

Level of evidence	Evidence statement
Level I	The evidence suggests individually prescribed or group approached exercise interventions in extended care settings are not effective in reducing falls (pooled results from two trials and one single trial, non-significant). However, three trials report effectiveness of exercise as a component in multifactorial programmes.

Evidence summary

Nowalk (2001) in a study in long-term care facilities - ranging from independent living to skilled nursing care - reported no significant difference in number of falls between a control group and two untargeted exercise groups (resistance endurance training or Tai Chi).

Data were pooled from two studies. Donald (2000) studied the effect of a targeted physiotherapy programme in 54 patients in an elderly care rehabilitation ward. Mulrow (1994) studied elderly nursing home residents (194 participants), comparing a three times weekly exercise programme with a friendly visit of the same duration. The pooled data showed no evidence of effectiveness in this context (RR 1.02, 95%CI 0.74 to 1.41).

Schnelle (2003) compared a low intensity functionally oriented exercise and incontinence care programme with usual care in 190 incontinent nursing home residents. There was a non-significant trend towards a reduction in the number of fallers in this study, which may have been underpowered (RR 0.62, 95%CI 0.37 to 1.06).

GDG commentary

Whilst there is insufficient evidence to recommend exercise as a single intervention in extended care settings, multifactorial interventions in this setting with an exercise component have been shown to be effective. Please refer to page 66 for further details.

1.2.6 Home hazard and safety intervention

(please see Sections 4.5.5, 4.5.6, 4.5.11 for evidence review methods)

1.2.6.1 Recommendation

Older people who have received treatment in hospital following a fall should be offered a home hazard assessment and safety intervention/modifications by a suitably trained health care professional. Normally this should be part of discharge planning and carried out within a timescale agreed by the patient or carer, and appropriate members of the health care team. [A]

1.2.6.2 Recommendation

Home hazard assessment is shown to be effective only in conjunction with follow-up and intervention, not in isolation. [A]

Level of evidence	Evidence statements
Level I	Home safety interventions/ home hazard modifications have been shown to reduce the incidence of falls, especially in older people with a history of falling (pooled results from four trials).
Level I	There is no evidence for the effectiveness of home hazard modification in those without a history of falls in the previous year before enrolment (one trial, non-significant).

Evidence summary

Evidence for the effectiveness of home hazard management in people with a history of falling is somewhat strengthened by new data from the updated Cochrane review.

The association of domestic hazards with falls in the home has been controversial, despite its face validity (Clemson 1996; Gill 2000; McLean

1996; Northridge 1995; Parker 1996; Sattin 1998). However, six trials with a substantial home hazard modification component (Carter 1997; Cumming 1999; Day 2002; Hornbrook 1994; Nikolaus 2003; Pardessus 2002) have reported data that supports its effectiveness, particularly in those with a history of previous falls. Cumming (1999) cautioned that 'this effect is unlikely to be caused by home modifications alone' since the reduction in falls was not confined to falls inside the home. This is true also of the reduction in the number of participants reporting two or more falls in Carter (1997), where falls in the yard/ garden associated with the dwelling were also eligible, and in the study reported by Stevens (2001). Hornbrook (1994) also used a complex intervention. While the evidence supports interventions designed to reduce home hazards, the exact mechanism of the effect remains unclear.

Five studies evaluated home safety interventions alone (Cumming 1999; Day 2002; Nikolaus 2003; Pardessus 2002; Stevens 2001). Data for number of participants falling are available from four, (Cumming 1999; Day 2002; Nikolaus 2003; Pardessus 2002). Amongst those participants with a history of falling in the year prior to randomisation, there was a significant reduction in the number of participants sustaining two or more falls in the study period (RR 0.66,95%CI 0.54 to 0.81).An overall analysis including all participants, fallers and non-fallers prior to randomisation, showed a significant, but smaller, effect (RR 0.85, 95%CI 0.74 to 0.96).

In those without a history of falls in the previous year (Cumming 1999) there was no evidence for the effectiveness of home hazard modification (RR 1.03, 95% CI 0.75 to 1.41). In Cumming (1999) the rate of falls away from home was reduced by a similar extent to the reduction in falls at home.

Stevens (2001), in a population with mixed fall status, reported results of a cluster randomised study in which the individual household was the unit of randomisation. After one year there was no significant difference in the rate of falls (overall, and falls at home), the rate of fall injuries, or the proportion of fallers in the intervention group, compared with the control group.

Economic evidence

In a well-conducted cost effectiveness analysis, Salkeld et al. (2000) recruited patients during hospital admission, a number of whom had a history of falls. The intervention was implemented by an experienced occupational therapist. There was little improvement in the falls in the intervention group as a whole, but there was a statistically significant reduction in the number of falls in those with a previous history. The cost effectiveness relates to the high risk groups of older people.

Smith and Widiatmoko (1998) modelled the costs of fall with the costs of a home hazard intervention. Over the 10¬year period of the model, they demonstrated a cost saving of A$92 per person. However the various sources of the data used, and assumptions made, indicate that although useful, it is not necessarily a substitute for empirical evidence.

GDG commentary

It is clear from the evidence that providing a home hazard assessment with an intervention aimed at modification for older people with a history of falling is effective. It is not clear which component of this intervention has the most impact on preventing further falls. However, a combination of advice, education interventions aimed at increasing confidence, risk awareness and home modifications are effective. Cumming (1999) reported a significant reduction in two or more falls in older people with a history of falls. Assessment was carried out by an occupational therapist and recommendations for prevention supervised as necessary. This intervention not only reduced the incidence of falls within the home but also falls outside the home.

There was debate about who should carry out home hazard assessments. The GDG acknowledged that in practice this may not always be carried out by a health care professional, but by a suitably trained member of the health care team. The personnel involved in assessment within the studies reviewed were trained health care professionals – including a doctor, and occupational therapist (Pardessus 2002); nurses, physiotherapists, occupational therapists and social workers (Nikolaus 2003); occupational therapist (Cumming 1999); and a trained assessor (Day 2002).

1.2.7 Psychotropic medications (please see Sections 4.5.5, 4.5.6 for evidence review methods)

1.2.7.1 Recommendation

Older people on psychotropic medications should have their medication reviewed, with specialist input if appropriate, and discontinued if possible to reduce their risk of falling. [B]

Level of evidence	Evidence statement
Level II	One trial of older people above 65 years suggests that a psychotropic medication withdrawal programme, involving a gradual withdrawal of psychotropic medication over a 14-week period, is effective in reducing the risk of falls.

Evidence summary

Psychotropic drugs include neuroleptics, sedatives/hypnotics, antidepressants, and benzodiazepines. These can increase an older person's risk of falling, as can the use of multiple medications. Results of a systematic review and meta analysis to identify particular medications that may increase an older person's falls risk suggest that older people taking more than three to four medications were at risk of recurrent falls; and those taking psychotropic medications were also at risk of falling.

Campbell (1999) reported the results of a study of factorial design, in which the interventions were an individually tailored exercise programme of progressive muscle strengthening and balance retraining; a walking plan (also used in Campbell 1997 and Robertson 2001a); and a placebo-controlled psychotropic medication withdrawal programme. This was gradual withdrawal of psychotropic medication over a 14-week period. Inclusion criteria included those above the age of 65 years who were currently taking benzodiazepine, any hypnotic, antidepressant or major tranquilliser.

The analysis reported by the investigators, using a Cox proportional hazard regression model, showed that the overall risk of falls was lower for the medication withdrawal group (relative hazard 0.34, 95%CI 0.16 to 0.74).

Economic evidence

One Australian and one US study (Andrews et al. 2001 and Coleman & Fox 2002) looking at the contribution of medication use were also assessed. These involved pharmacy reviews of medication, which may have resulted in falls. Neither of these studies provides strong economic evidence, but they highlight the importance of assessment following a fall. The costs detailed in the paper by Andrews (2001) show the relationship between medication and the outcomes for patients. The study by Coleman illustrates some potential cost savings in reviewing medications.

GDG commentary

In addition to the evidence for psychotropic medication review, polypharmacy was identified as a risk factor for falling and medication review should be part of a multifactorial assessment, as described in recommendation 3.

1.2.8 Cardiac pacing (please see Sections 4.5.5, 4.5.6 for evidence review methods)

1.2.8.1 Recommendation

Cardiac pacing should be considered for older people with cardioinhibitory carotid sinus hypersensitivity who have experienced unexplained falls. [B]

Level of evidence	Evidence statement
Level II	Cardiac pacing in fallers with cardioinhibitory carotid sinus hypersensitivity is effective in reducing falls and syncope (one trial).

Evidence summary

Cardiac pacing in fallers with cardioinhibitory carotid sinus hypersensitivity (Kenny 2001) was associated with a statistically significant reduction in the number of participants who were not cognitively impaired, sustaining syncope (RR 0.48, 95%CI 0.32 to 0.73). In addition, the mean number of falls in 12 months in the intervention group was significantly reduced (WMD -5.2, 95%CI -1.0 to -9.4).

GDG commentary

This recommendation reflected the evidence for a stand¬alone intervention for older people who have cardioinhibitory carotid sinus hypersensitivity. The

evidence is also reflected in recommendation 3, which indicates that the GDG considered it necessary that a cardiovascular assessment should be carried out as part of a multifactorial assessment, where appropriate.

1.2.9 Encouraging the participation of older people in falls prevention (please see Sections 4.5.7, 4.5.8 for evidence review methods)

1.2.9.1 Recommendation

To promote the participation of older people in falls prevention programmes the following should be considered. [D]

- Health care professionals involved in the assessment and prevention of falls should discuss which changes a person is willing to make to prevent falls.
- Information should be relevant and available in languages other than English.
- Falls prevention programmes should also address potential barriers such as low self-efficacy and fear of falling, and encourage activity change, as negotiated with the participant.

1.2.9.2 Recommendation

Practitioners who are involved in developing falls prevention programmes should ensure that such programmes are flexible enough to accommodate participants' different needs and preferences, promoting the social value of such programmes. [D]

Level of evidence	Evidence statement
Level III-IV	People may be reluctant to participate in falls prevention programmes if they have not previously exercised, do not perceive a risk of falling or perceived poor functional ability or have not been adequately consulted about what changes they are willing to make.
Level IV	Much of the current information provision on falls prevention programmes may alienate rather than encourage participation by sterotyping older people, not being available in languages other than English, not emphasizing that many falls may be preventable and not promoting the social value of falls prevention programmes.

Evidence summary

The review of the quantitative and qualitative evidence on older people's views and experiences enabled the identification of factors that may promote the idea of falls prevention. Multiple barriers to participation in falls programmes were identified, the most significant of which are summarised in Table 16.

Some studies indicate that much of the information on falls prevention alienates rather than encourages participation by stereotyping older people (Aminzedah & Edwards 1998; Ballinger & Payne 2000); and by not producing information in languages other than English (Aminzedah & Edwards 1998; Kong et al. 2002). Other information needs include giving special advice to older people about the benefits of physical activity and falls prevention and how to stay motivated in the face of multiple barriers (Commonwealth of Australia 2000; King 1995).

Some studies also reported a mismatch between the strategies willingly accepted by older people – for example, walking aids, home modification, low intensity exercise – and those that are most effective (balance and strengthening training) (Commonwealth of Australia 2000; Health Education Board 1999; Stead et al. 1997; King 1998). Two studies pointed out that imposition of strategies thought most optimal by health professionals may alienate the target group (Simpson et al. 2003; Porter 1999) and that health professionals need to find out which characteristics people are willing to modify and what changes they are prepared to make (Porter 1999) before

suggesting strategies. This should be an ongoing process (Grossman et al. 2003).

Some of the individual factors that were shown to increase participation in falls prevention programmes or specific components of these programmes were: high exercise self-efficacy, past exercise history and general good health and functional ability (Rejeski 1997; King 1995; Oman 1998; Resnick 2000).Aspects of the format of falls prevention programmes that appeared to improve participation and maintenance included: home-based, telephone supervised, peer role models, low intensity exercise – for example, walking – moderate frequency – for example, two to three times per week – and be perceived as relevant, beneficial and fun for the participants. The social aspects of falls prevention programmes are probably their strongest selling point (Health Education Board 1999; Kong et al. 2002), particularly to older people without a history of physical activity.

Factors that appeared to be barriers to either initial participation or long-term maintenance of falls prevention programmes were mainly personal, rather than programme format issues. These included: low self-efficacy or lack of perceived ability to undertake components of the programme; fear of falling; fear of exertion; illness;denial or under-estimating personal risk of falling; embarrassment or increased inconvenience regarding use of assistive devices (Bruce 2003; King 1998; Yardley 2002).

In addition, the economic systematic review identified two studies that used quality of life measures (SF36) to look at the impact of fear of falling. The paper by Cumming et al. (2000) showed a link between fear of falling, SF36 measures and the admission to a long-term care institution. The study by Suzuki et al. 2002 showed that those subjects who expressed a great deal of fear of falling had SF36 scores, reflecting their increased anxiety and depression.

The most commonly occurring and consistent themes across all studies (observational and qualitative) were as follows:

Preferred strategies

- People may be reluctant to participate in falls prevention programmes that have an exercise-based component (including balance training), if they have not previously regularly exercised and in which the social value of participation is not promoted. This requires consideration in light of the Cochrane review findings that a) a programme of muscle strengthening and balance retraining, individually prescribed at home by a trained health professional and b) a 15¬week Tai Chi group exercise intervention are likely to be beneficial (Gillespie et al. 2003).
- Interventions not involving behaviour change, such as home modification and assistive aids, appear to be more readily accepted among potential participants. There was a fairly consistent finding across the reviewed studies that prevention programmes that were home-based, moderate or low intensity exercise with frequent professional contact were most acceptable and showed higher participation rates (Hillsdon 1995; King 1998; Oman 1998). Other single interventions reported as being beneficial in the Cochrane review (Gillespie et al. 2003) – such as cardiac pacing and withdrawal of medicines – similarly may be more acceptable to some people.

Individual factors

- Although trials of multifactorial packages have reported beneficial results (Gillespie et al. 2003), in clinical practice there may need to be more emphasis on finding out what characteristics a person is willing to modify and what changes are they prepared to make at what stage in their lives. This somewhat concurs with the finding that individually tailored interventions delivered by a health professional are more effective than standard or group delivered programmes (Gillespie et al. 2003).
- There was also evidence that the following factors are associated with activity avoidance: increasing age, being female, increasing anticipation of loss of function (Yardley 2002), not facing up to the risk of falling, (Simpson 1995) lack of perceived ability (King 1998), fear of falling (Bruce 2003) and fear of exertion (Grossman et al. 2003). However, fall prevention programmes that address self-efficacy and encourage activity change may result in increased uptake of falls prevention programmes (Cheal 2001;

Resnick 2002). This suggests that consideration of these factors is important when devising falls prevention programmes to ensure practical and appealing interventions are developed.

- Barriers need to be addressed prior to participation in a falls prevention programme to ensure commitment to the strategies.

Health promotion and information needs

- There is a need to inform and educate older people that many falls are preventable.
- Perceived relevance of falls prevention may be low until a fall has been experienced.
- The social value of falls prevention programmes, as well as the physical benefits, needs to be promoted to make them attractive to intended participants.
- Those from non-English speaking backgrounds may require targeted health promotion.

1.2.10 Education and information giving (please see Sections 4.5.8 for evidence review methods)

1.2.10.1 Recommendations

All health care professionals dealing with patients known to be at risk of falling should develop and maintain basic professional competence in falls assessment and prevention. [D]

1.2.10.2 Recommendations

Individuals at risk of falling, and their carers, should be offered information orally and in writing about: [D]

- what measures they can take to prevent further falls
- how to stay motivated if referred for falls prevention strategies that include exercise or strength and balancing components
- the preventable nature of some falls
- the physical and psychological benefits of modifying falls risk
- where they can seek further advice and assistance

- how to cope if they have a fall, including how to summon help and how to avoid a long lie.

Evidence summary

See evidence summary above associated with 'encouraging participation in falls prevention programmes'.

1.2.11 Interventions that cannot be recommended (please see Sections 4.5.5, 4.5.6 for evidence review methods)

1.2.11.1 Brisk walking

Level of evidence	Evidence statement
Level II	There is no evidence that brisk walking reduces the risk of falling. One trial showed that an unsupervised brisk walking programme increased the risk of falling in post-menopausal women with an upper limb fracture in the previous year. However, there may be other health benefits of brisk walking by older people.

Evidence summary

In one study (Ebrahim 1997), brisk walking in n=165 women with an upper limb fracture in the previous two years, reported RR 0.69,95% CI 0.12-4.03. This UK study included postmenopausal women identified from A&E and orthopaedic fracture clinic records, with a history of an upper limb fracture in the last two years. The intervention group received initial advice on general health/diet and then encouraged to build up to brisk walking 40 minutes, three times per week. The control group received initial advice on general health/diet and encouraged to perform upper limb exercises to improve post-fracture function. Falls events were greater in the intervention group.

GDG commentary

The group had reservations about this trial. It was a small trial with a specific group of older women. Although there was a significant increase of falls (I=52/81 vs. C=50/84 and fractures (I=2/81 vs. C=3/84) in the intervention group, the GDG recognise the limitations of the generalisability of these findings. For some other groups of older people, walking may have health benefits and should not be discouraged.

1.2.12 Interventions that cannot be recommended because of insufficient evidence (please see Sections 4.5.5, 4.5.6 for evidence review methods)

We do not recommend implementation of the following interventions at present. This is not because there is strong evidence against them, but because there is insufficient or conflicting evidence supporting them.

1.2.12.1 Low intensity exercise combined with incontinence programmes

Level of evidence	Evidence statement
Level I	There is no evidence that low intensity exercise interventions, combined with continence promotion programmes, reduces the incidence of falls in older people in extended care settings (one trial, non-significant).

Evidence summary

Schnelle (2003) compared a low intensity functionally oriented exercise and incontinence care programme with usual care in 190 incontinent nursing home residents. There was a non-significant trend towards a reduction in the number of fallers in this study, which may have been underpowered (RR 0.62, 95%CI 0.37 to 1.06).

Economic evidence

The study by Schnelle et al. (2003) made a number of assumptions that were not all reported in the paper. They acknowledge that this was an expensive and labour intensive intervention. They do not detail the costs but refer to them in the discussion. This intervention resulted in no significant difference between the control and intervention groups in the costs of assessing and treating acute conditions. The only statistically significant result was the stable fall rate in the intervention group. However, the authors recommend caution when interpreting these results, as this was a post hoc decision to analyse the data in this way.

1.2.12.2 Group exercise (untargeted)

Level of evidence	Evidence statement
Level I	Exercise groups should not be discouraged as a means of health promotion, but there is little evidence that exercise interventions that were not individually prescribed for community-dwelling older people are effective in falls prevention.

Evidence summary

Community-dwelling: untargeted interventions:

Using the FICSIT definition of falling, participants (n=200) exposed to the 15-week Tai Chi intervention had a lower rate of falling than controls in one trial (risk ratio 0.51, 95%CI 0.36 to 0.73) (Wolf 1996). Local advertisements and direct contact recruited the participants in this study. Inclusion criteria included ambulatory older people, above the age of 70 years, living in unsupervised environments.

Eleven studies, involving a total of 1,480 participants, reported the results of exercise interventions offered to groups of older community-dwelling people, where exercise interventions were not individually prescribed. Pooled data from nine studies (Buchner 1997; Cerny 1998; Cornillon 2002; Day 2002; Ebrahim 1997; Lord 1995; McMurdo 1997; Pereira 1998; Rubenstein 2000) does not confirm the effectiveness of untargeted exercise interventions in community-dwelling older people based on number of fallers (pooled RR 0.89, 95%CI 0.78 to 1.01). Data from Wolf (1996) were reported as adjusted estimates from a Cox proportional hazards analysis, and raw data to allow pooling were unavailable.

Carter (2002), in a comparison of a twice-weekly exercise class with no intervention, reported no difference between groups in the number of people falling. Means (1996) recruited 65 participants, with a history of falling, who all underwent a six-week supervised low to moderate intensity programme designed to improve balance and mobility. Thirty-one participants practised on an obstacle course, in addition to the exercise intervention, while 34 did not. No statistically significant difference in the mean number of falls was reported.

There were three complex intervention studies that included exercise. In a factorial design, Day (2002) compared group-based exercise, home hazard

modification and management of reduced vision. Although group based exercise alone was the most potent single intervention in this study RR 0.82 (0.70-0.97), falls were also reduced when exercise was combined with home hazard management, or reduced vision management, or both.

The remaining two trials were cluster randomised; their data could not be pooled. One (Reinsch 1992) evaluated the effectiveness of classes teaching exercise, relaxation and health and safety topics relating to fall prevention, and classes without the exercise component. Results did not demonstrate a statistically significant reduction in number of fallers for either intervention. The other (Steinberg 2000), using a cumulative intervention in which three out of four groups received a monthly one-hour exercise class and encouragement to exercise between classes, reported that the intervention strategies could achieve an 18 to 40 per cent reduction in the incidence of falling, but the hazard ratios were not significant.

Conclusion

The evidence for effectiveness of group exercise interventions remains limited, apart from the Tai Chi intervention of Wolf (1996) and Day (2002). However, the three trials from New Zealand (Campbell 1997; Campbell 1999; Robertson 2001a), which used an individually tailored exercise programme of progressive muscle strengthening, balance retraining and a walking plan, demonstrated effectiveness. These three studies involved older participants, but the components of the successful intervention suggest that balance retraining may be an important component of successful exercise programmes. However, there is no evidence of clinical effectiveness of other exercise interventions that was untargeted to specific older people at risk of falling.

GDG commentary

The GDG recognises the emerging positive evidence for group exercise with two studies published beyond the date of the literature review underpinning these guidelines (Lord et al. 2003; Barnett et al. 2003). This new evidence will need to be included in the guideline update. In addition the global health benefit of exercise needs to be emphasised.

Economic evidence

The study by Buchner et al. (1997) reported a relative risk for falls in the control group of 0.61. This study also measured quality of life using the SF36. They note that the hospital use between the two groups was very similar and the length of stay for the control group was likely to be longer resulting in additional costs.

1.2.12.3 Cognitive/behavioural interventions

Level of evidence	Evidence statement
Level I	There is no evidence of effect that cognitive/ behavioural interventions alone reduce the incidence of falls in community-dwelling older people of unknown risk status (two single trials, non-significant). Such interventions have included risk assessment with feedback and counselling and individual education discussions. There is no evidence that complex interventions - in which group activities included education, behaviour modification programme aimed at modifying risk, advice and exercise - are effective in falls prevention with community-dwelling older people(four single trials, non-significant).

Evidence summary

Cognitive/behavioural therapy alone

In Gallagher (1996) (100 participants), comparison of the two risk assessment interviews and a feedback/counselling interview, with a single baseline assessment interview, showed that the intervention had no statistically significant impact on the main outcome measures. In Ryan (1996) (45 participants), analysis of the number of fallers at three months showed no evidence that individual education sessions provided by a trained nurse were more effective than the one-hour group discussion of intrinsic and environmental risk factors.

Complex interventions including cognitive/behavioural intervention

Carter (1997) (658 participants) and Hornbrook (1994) (3182 participants) used a behavioural approach after carrying out an environmental safety assessment. Data have not been pooled from these studies, as Hornbrook (1994) is cluster randomised (by household). Both had co¬interventions. Hornbrook (1994) included group sessions designed to modify risk taking behaviour and an exercise component, and reported survival analyses for

sustaining any fall, injury fall, medical care fall, fracture fall, and fall causing hospitalisation. Unadjusted rates for all falls were significantly lower among intervention participants; for other categories of fall (injury falls, medical care falls) there were no statistically significant differences between groups. In Carter (1997) advice on optimising medication was given to the two intervention groups; a low intensity intervention in which advice alone was given on home safety, and a high intensity intervention that included professional formulation of an action plan. There was no evidence of a difference in the number of individuals falling between the control group and either intervention group. However, both interventions were associated with a significant reduction in the number sustaining two or more falls (low intensity intervention RR 0.27, 95%CI 0.08 to 0.95; high intensity intervention RR 0.22, 95%CI 0.05 to 0.98). In a cluster randomised trial, Reinsch (1992) evaluated the effectiveness of classes teaching exercise, relaxation and health and safety topics relating to fall prevention, and classes without the exercise component. The trial did not identify a statistically significant reduction in number of fallers. In another cluster randomised trial (Steinberg 2000), a cumulative intervention in which three out of four groups received encouragement to exercise and a monthly one-hour exercise class, the intervention strategies achieved an 18 to 40 per cent reduction in the incidence of falling, but the hazard ratios were not significant in any group.

1.2.12.4 Referral for correction of visual impairment

Level of evidence	Evidence statement
Level I	Exercise in groups should not be discouraged as a means of health promotion, but there is little evidence that exercise interventions that were not individually prescribed for community-dwelling older people are effective in falls prevention.

Evidence summary

In Day (2002) there was no evidence that referral for correction of vision in community-dwelling older people was effective in reducing the number of people falling (RR 0.88, 95%CI 0.54 to 1.43). This study, using a factorial design, compared a control group with groups receiving exercise, correction of visual impairment, and home hazard modification, each alone, and in

combination. Results above reflect analysis for the visual correction alone group.

GDG commentary

Whilst there is insufficient evidence that single interventions targeting vision impairment are effective in reducing falls, referral for visual correction as part of a multifactorial intervention has a significant impact on falls reduction.

Identifying older people with visual impairment and referral for intervention should be considered within a multifactorial intervention.

1.2.12.5 Vitamin D and oral supplementation

Level of evidence	Evidence statement
Level I	There is evidence that vitamin D deficiency and insufficiency are common amongst older people and that when present they impair muscle strength and possibly also neuromuscular function via CNS-mediated pathways. In addition, the use of combined calcium and vitamin D3 supplementation has been found to reduce fracture rates in older people in residential/ nursing homes and sheltered accommodation. Although there is emerging evidence that correction of vitamin D deficiency or insufficiency may reduce the propensity for falling, there is uncertainty about the relative contribution to fracture reduction via this mechanism (as against bone mass) and on the dose and route of administration required. No firm recommendation therefore can currently be made on its use for this indication.[15]

Evidence summary

There is no evidence from one small trial involving 50 participants (Gray-Donald 1995), for the effectiveness of a programme of oral nutritional supplementation – in this case, a high energy, nutrient-dense supplement – in preventing falls in a group of frail elderly women RR 0.10 (0.01 to 1.69).

Five studies (Bischoff 2003; Dawson-Hughes 1997; Latham 2003; Pfeifer 2000; Sato 1999) evaluated the effect of vitamin D on falling. Data were pooled from Bischoff (2003); Pfeifer (2000) and Latham (2003) (461

[15] The following text has been deleted from the 2004 guideline: 'Guidance on the use of vitamin D for fracture prevention will be contained in the forthcoming NICE clinical practice guideline on osteoporosis, which is currently under development.' As yet there is no NICE guidance on the use of vitamin D for fracture prevention.

participants). In these studies both intervention and control groups received calcium supplementation; the intervention group in each received oral vitamin D supplementation. Within this group of pooled studies, no evidence was produced of the effectiveness of vitamin D supplementation in reducing the number of people who fall amongst community-dwelling or hospitalised older people (RR 0.87, 95%CI 0.70 to 1.08). In Pfeifer (2000), the reduction in the number of falls resulting in fracture was not statistically significant (RR 0.48, 95%CI 0.02 to 11.84).

In Sato (1999) (86 participants), the administration of 1¬alpha-hydroxyvitamin D alone to people with Parkinson's disease (Hoehn and Yahr Stage <5) significantly reduced the number of fracture falls (RR 0.12, 95%CI 0.02 to 0.98), but did not reduce the mean number of falls in the intervention group (WMD 0.10, 95%CI -0.71 to 0.91).

In a placebo-controlled trial of administration of vitamin D and calcium supplementation to community-dwelling men and women over 65 years, Dawson-Hughes (1997) (445 participants) reported that the number of participants falling did not differ significantly between intervention and control groups. Data were not presented.

Vellas (1991) (95 participants) reported that administration of the vaso-active medication raubasine-dihydroergocristine to older people presenting to their medical practitioner with a history of a recent fall, significantly reduced the numbers of the intervention group who reported falls in the six months of therapy (RR 0.48, 95%CI 0.29 to 0.78).

A recent published meta-analysis of vitamin D supplementation suggests there is a reduction in falls (Bischoff-Ferrari, 2004). There results showed that vitamin D supplementation appears to reduce the risk of falls among ambulatory or institutionalised individuals with stable health by 20 per cent.

However, although there is emerging evidence that correction of vitamin D deficiency or insufficiency may reduce the propensity for falling, there is uncertainty about the relative contribution to fracture reduction via this mechanism (as against bone mass) and on the dose and route of

administration required. No firm recommendation therefore can currently be made on its use for this indication. Guidance on the use of vitamin D for fracture prevention will be contained in the forthcoming NICE clinical practice guideline on osteoporosis that is currently under development.

1.2.12.6 Hip protectors (please see Sections 4.5.10 and 4.5.11 for evidence review methods)

Level of evidence	Evidence statement
Level I	Reported trials that have used individual patient randomisation have provided no evidence for the effectiveness of hip protectors for the prevention of hip fractures when offered to older people living in extended care settings or in their own homes. Data from cluster randomised trials provides some evidence that hip protectors are effective in the prevention of hip fractures in older people living in extended care settings who are considered at high risk.

Evidence Summary

Incidence of hip fractures

Data from the five cluster randomised studies were not pooled with data from the individually randomised studies. Cluster randomisation methods were used in five studies (Ekman 1997; Harada 2001; Kannus 2000; Lauritzen 1993; Meyer 2003). However, an uncorrected exploratory analysis of the five cluster randomised studies was conducted by the trialists. In Kannus (2000), the exploratory analysis (RR 0.34, 95% CI 0.19 to 0.61) that uses the raw numbers of participants sustaining fracture in each group differs slightly from that in the primary report (relative hazard 0.4, 95% CI 0.2 to 0.8), which used Cox proportional hazards analysis adjusted for age, sex, body mass index, mental status, ability to walk, previous falls and previous fractures.

The cluster randomised trial by Ekman (1997) reports RR 0.34 (0.12-1.01) for the incidence of hip fractures, randomised by unit or nursing home. Harada (2001) reported the number of hip and other fractures, number of falls and compliance with hip protectors. Results for the incidence of hip fractures was RR 0.11 (0.01-0.84) and the incidence of other fractures RR 4.33 (0.21-88.74).

In the trial by Lauritzen (1993), the incidence of hip fractures, randomised by unit or nursing home, was RR 0.44 (0.20-0.93) and the incidence of pelvic fractures was RR 0.34(0.02-7.01).

The incidence of other fractures was RR 1.02 (0.55-1.89) in this trial.

Meyer (2003) reported the number of hip fractures, and other fractures; falls; mortality; compliance of wearing the hip protectors and the reasons for non-compliance. The incidence of hip fractures, randomised by unit or nursing home, was RR 0.53 (0.32-0.87) and the incidence of other fractures RR 1.14 (0.74-1.78).

Pooling of data from the seven trials in which randomisation was by individual showed no significant reduction in the incidence of hip fracture in those allocation to wearing hip pads (64/1306 (4.9%) versus 64/1086 (5.9%), RR 0.94, 95% CI 0.67 to 1.31).

Pooling of data from five individually randomised trials conducted in nursing/residential care settings (1,426 participants) (Cameron 2001; Chan 2000; Jantti 1996; Hubacher 2001; Van Schoor 2003) showed no statistically significant reduction in hip fracture incidence (hip protectors 37/822 (4.5%), controls 40/604 (6.6%), RR 0.83, 95% CI 0.54 to 1.24). The reviewers note that by the end of the one-year observation period, nearly half (16/36 versus 17/36) of the individuals in Jantti (1996) had been lost to follow-up through death or permanent hospitalisation.

Two individually randomised studies recruited community-dwelling older people (Birks 2003; Cameron 2003). These studies did not achieve a statistically significant reduction in the incidence of hip fractures (27/484 (5.6%) versus 24/482 (5.0%), RR 1.11, 95% CI 0.65 to 1.90).

Villar (1998) studied compliance with wearing hip pads in a study with a follow-up period of 12 weeks. As this study excluded mentally incapacitated patients, participants were at lower risk of hip fracture. No hip fractures occurred in either the 101 participants allocated to receive protectors or the 40

participants in the control group. Thus this study contributed no data to the meta-analysis.

Incidence of pubic ramus and other pelvic fractures

There is insufficient evidence to confirm whether the use of hip protectors significantly reduces the incidence of pelvic fractures. Data on the incidence of pubic ramus and other pelvic fracture were available in 10 studies. In the six studies that used individual randomisation there were 16/1266 (1.3%) in the protector group and 13/1055 (1.2%) in the control group (RR 1.15, 95% CI 0.58 to 2.31).

Incidence of other fractures/injuries

The use of hip protectors appears to have no effect on the incidence of other fall associated fractures. Data on the incidence of other fractures that occurred over the study periods were reported in 10 studies. Pooling of results from the individual randomised studies showed that 63/1266 (5.0%) occurred in the protector group and 56/1055 (5.3%) in the control group (RR 1.06, 95% CI 0.75-1.50).

Compliance

Amongst those who were assigned to their use, compliance with wearing of hip protectors was limited. It is not clear in some trials how compliance was measured, but for those that stated the method of measurement, the length of time wearing them was calculated.

Chan (2000) reported a compliance of 50.3 per cent, with dementia given as a reason for non-compliance. Ekman (1997) reported an average compliance of 44 per cent, although it is not clear how this was calculated. Harada (2001) reported that 17/88 (19 per cent) of those allocated to the protectors refused to wear them. Complete compliance estimated by hours worn was 70 per cent and partial compliance 17 per cent. Jantti (1996) stated that, of the 19 participants available at one year, 13 (68 per cent) were still using hip protectors. Of the subgroup of 45 individuals allocated to hip pads monitored in Lauritzen (1993), only 11 (24 per cent) wore the protectors regularly. In Kannus (2000), 31 per cent of those eligible declined to participate in the

study, while a further 71 of 446 patients discontinued use during the study. Compliance in those who agreed to participate in the study – assessed as the number of days the protector was worn as a percentage of all available follow-up days – was 48 per cent (±29%, range <1 to 100%).Van Schoor (2003) used random visits to assess compliance and found that, at one month, 39 per cent were not compliant with wearing the protectors. This figure had risen to 55 per cent at six months and 63 per cent at one year. Hubacher (2001) reported that for 384 allocated to the protector group, 138 were regular wearers, 124 discontinued wearing them and 122 refused to wear them. Even the 138 'regular wearers' only wore the pads

49.1 per cent of the time. Birks (2003) gave an overall compliance figure of 34 per cent. Cameron (2001) stated total compliance was 57 per cent. At the end of the study only 37 per cent were still regular wearers of the protectors. Meyer (2003) reported that the hip protectors were worn by 34 per cent of the intervention group participants. Cameron (2003) approached 1,807 potential subjects living in their own homes and 34 per cent of these agreed to participate. By two years, the end of this study, only 33-38 per cent of participants were wearing the protectors all the time. In Villar (1998), of the 288 individuals approached only 141 consented to participate. Of the 101 who received the protectors only 27 (27 per cent) wore them throughout the 12-week study period. In a breakdown of the reasons for non-compliance presented by Villar (1998), discomfort and poor fit were the most common reasons for discontinued use.

Other evidence reporting compliance problems is also worth summarising, as these sources of evidence also confirm many of the Cochrane review findings reported above.

A systematic review of the literature reported that the acceptance of, and compliance with, of hip protectors (Van Schoor 2002) ranged from 37 per cent to 72 per cent (median 68 per cent) for acceptance and 20 per cent and 92 per cent (median 56 per cent) for compliance. No details were given of specific settings or populations.

In a randomised controlled trial (Cameron 2000), the effect of hip protectors on fear of falling was examined in 131 women aged 75 and above who had two or more falls in the previous year. The results of this study report that hip protector users had greater improvement in falls self-efficacy at follow-up.

In a prevalence study (Villar 1998), which aimed to assess compliance with the use of hip protectors in a residential setting, only 27 per cent wore the hip protectors for the full 12-week study period and half of the women wore them for less than one week. The reasons for non-compliance were poor fit or discomfort.

Pakkari (1998) conducted a before and after study assessing the acceptability and compliance with hip protectors in 19 ambulatory residents in a nursing home. The small sample size for this study prevents generalisability, but results indicated that the tight fit of the hip protectors reduced the ability for independent toileting.

Complications (including skin damage/breakdown)

Ekman (1997) mentioned that the occurrence of skin irritation was used as a reason for non-compliance.Villar (1998) reported three individuals who were unable to tolerate the special undergarments during a heatwave and also mentioned discomfort as the prime reason for non-compliance. Kannus (2000) reported skin irritation or abrasion in 15 cases. In addition, one person reported the protector caused swelling of the legs and another that it caused bowel irritation. Hubacher (2001) reported that aches and pains and an uncomfortable feeling with wearing the protectors was given as a reason for non¬compliance. Minor skin irritation was reported in Cameron (2001), and Cameron (2003) reported minor skin irritation or infection caused by hip protectors in 16 users (5 per cent). Meyer (2003) reported five cases of skin irritation. In addition some of the care homes reported increased dependency of some of the residents at toileting, more difficulty in dressing and discomfort from wearing the protectors.

For the results of other outcomes measured in this review, see Evidence table 11 (Appendix E, 2004).

Summary

The cluster randomised studies, which formed the bulk of the evidence from the previous review (2001), supported a significant beneficial effect of hip protectors in reducing the incidence of hip fracture (Parker et al. 2003). However, this significant protective effect was not confirmed by pooling of data from studies using individual randomisation in the updated version (Parker et al. 2003). For those living in their own homes, the review authors suggest there is insufficient evidence from randomised trials to support any benefit of hip protectors. The authors note that in a number of the cluster randomised studies, although allocation was by institution, analysis was by individual, without allowing for the effect of clustering. This leads to an estimation of the treatment effect in which the confidence intervals are inappropriately narrow. Thus there is a risk that a statistically significant effect appears to exist, when in fact it may not. This may have encouraged inappropriate interpretation of the strength of the evidence.

The authors of the Cochrane review also noted other shortcomings – such as evidence of heterogeneity amongst the populations studied in respect of baseline risk of fracture; that most of the individually randomised studies were underpowered; that the use of protectors appears to have varied between trials and within trials; and that initial acceptance of, and later compliance with, wearing the hip protectors were reported as problems in all of the studies.

The reader is referred to the Cochrane report for full details.

Finally, the studies included in the Cochrane review (Parker et al. 2003) and additional studies on hip protectors involve the use of a number of different designs of hip protector. It is not possible to be sure that the different types of hip protector used had equal effectiveness. A variety of different types of hip protectors have now been produced and clinical studies will be required to see if these new designs of protector are equally effective in reducing the risk of hip fracture. In addition, the compliance may vary for the different types of hip protector.

Economic evidence

Two studies were identified as being relevant to the use of hip protectors. The first paper by Kumar and Parker (2000) looked at the cost effectiveness of hip protectors using the audit data from an English hospital and the Cochrane review of musculoskeletal injuries (Parker et al. 2001). The intervention was the wearing of hip protectors and the control was no intervention. The outcome measure was the number of hip fractures prevented.As the cost and benefit period was calculated over one year, discounting was not necessary. Direct costs only were used in the analysis and the number of protectors needed per person was obtained from previous studies and communication with the authors. The cost per item was obtained from the manufacturer. The authors use a previously published paper to estimate the average cost of a hip fracture the data updated to their cost year (1998).

The cost results showed that the three hip protectors required for each person cost £113 per year. The average cost of treating a hip fracture was £7,200. The results were presented by age group. The cost of fracture prevented in the 50 to 59 age group was £508,500. The cost per fracture prevented in the above 85 age group was £2,485. The authors conclude that the use of hip protectors in the above 85 age group appears to be cost effective.

However, there are a number of assumptions made in this study that may influence the results shown. The costs were calculated for those people who complied. They did not cost the supply of protectors to people who did not comply. They report a compliance rate of 36 per cent, which suggests that there is a problem. In addition, no sensitivity analysis was carried out on the price of the protectors. No indirect costs for hip fracture were included. The results of this study should be treated with caution.

The second study by Segui-Gomez, Keuffel and Frick (2002) was a state transition model. This models the movement of patients through the probability of sustaining a fall resulting in a hip fracture, not falling or dying from any cause. That is to say the patient is in one of three states: well, hip fracture or dead. Data for models are obtained from published literature, epidemiological data, quality of life data or utility data. The data driving the model was obtained from published literature of trials. The authors state that

they made some assumptions concerning the effectiveness of the protectors, which is normal when modelling. However, these assumptions need to be explicit in order to give validity to the model.

This model was populated by two hypothetical groups of 500,000 65-year-old men and women in the USA. The model was run for 35 years.

As with other studies it is difficult to generalise between health care systems. However, they did include a cost utility analysis. They obtained QALY data from expert opinion (a sample of gerontologists) and a sample of older people using a VAS scale. The authors do not give information about the sample other than it being one of convenience. There have been recent concerns about the use of VAS scales in deriving QALY data and this does raise some questions about their results (Brazier et al. 2003).

The authors showed that hip protectors are cost effective in the above 85 age group. The QALY data they collected showed that women gained QALYs overall, but with men there was a decrement. This is attributed to the inconvenience for men of wearing the protector.

There is considerable uncertainty about some of the sensitivity analysis. Compliance is an issue, as the authors state that hip protectors only result in cost savings when compliance is 70 per cent. The literature illustrates that there are problems with compliance and achieving 70 per cent would be difficult.

There are methodological questions with this model that make it difficult to use the results to inform practice.

Both of these studies have no intervention – that is doing nothing is the comparator. It is likely that this may not be the case in some areas where prescribed vitamin D and calcium or bisphosphonates may occur as part of a fracture prevention programme.
In view of recent effectiveness data, which show fewer benefits than previously anticipated, these two flawed cost effectiveness studies demand that their results be treated with caution.

GDG commentary

The GDG acknowledged that the evidence is less convincing of the effectiveness of hip protectors in the prevention of falls, following the update of the Cochrane systematic review on hip protectors. There was discussion about the benefit of hip protectors for high risk groups of older people. Older people at high risk might include those with the presence of multiple risk factors. However, the GDG felt that it was not possible, on the basis of the current clinical effectiveness evidence, to make a potentially expensive recommendation about their use until there are trials evaluating the newer types of hip protectors and national standards for their manufacture and safety are made.

4.6 Recommendations for research

The following research gaps were identified by the GDG. Following NICE requirements, the first five are those prioritised by the GDG.

- Further analysis of existing trial data to identify which components of multifactorial interventions are important in different settings and amongst different patient groups.
- Future trials designed and analysed with the intention of identifying cost effective components of multifactorial programmes for particular groups of older people in different settings.
- Evaluation of multi-agency falls prevention programmes to measure the impact of these programmes on reducing falls, injurious falls and fractures in older people.
- Falls prevention trials with a focus on injury reduction, such as fracture outcomes and fall related outcomes.
- Research on the optimal methods of risk assessment for falls in older people and evaluation of whether fall-prone individuals can be risk stratified, in terms of whom will most benefit from assessment and intervention.
- Trials investigating the most effective strategy for preventing falls in older people with cognitive impairment and dementia.
- UK-based cost effectiveness studies of falls prevention interventions.
- Trials to investigate the effectiveness of hip protectors compared with other fracture prevention interventions in older people at high risk of falling.

4.7 Validation

Section 4 of the guideline was validated through two stakeholder consultation processes. The first and second drafts were submitted to NICE in January and April 2004. They obtained and collated stakeholders' comments, which were considered by the GDG.

5 Further information

5.1 Guideline development group information

5.1.1 The Guideline Development Group, Internal Clinical Guidelines Team, and NICE project team 2013

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5.1.2 2004 Guideline Development Group membership and acknowledgements

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5.2 Notes on the scope of the guideline

NICE guidelines are developed in accordance with a scope that defines what the guideline will and will not cover.

- The scope of section 3 of this guideline (inpatient setting) is given in appendix I.
- The scope for section 4 of this guideline (community setting) is given in section 4.4.

5.3 Implementation

NICE has developed tools to help organisations implement this guidance.

5.4 Other versions of this guideline

5.4.1 NICE guideline

The NICE guideline contains all the recommendations, without the information on methods and evidence.

5.4.2 NICE pathway

The recommendations from this guideline have been incorporated into a NICE pathway.

5.4.3 Information for the public

A summary of the recommendations is available for the public (Information for the public).

We encourage NHS and voluntary sector organisations to use this text in their own information about falls.

5.5 Related NICE guidance

Published

- Osteoporosis. NICE clinical guideline 146 (2012)
- Patient experience in adult NHS services. NICE clinical guidance 138 (2012)
- Service user experience in adult mental health. NICE clinical guidance 136 (2011)
- Hip fracture. NICE clinical guideline 124 (2011)
- Delirium. NICE clinical guideline 103 (2010)
- Medicines adherence. NICE clinical guideline 76 (2009)
- Mental wellbeing and older people. NICE public health guidance 16 (2008)
- Stroke. NICE clinical guideline 68 (2008)
- Head injury. NICE clinical guideline 56 (2007)
- Dementia. NICE clinical guideline 42 (2006)
- Parkinson's disease. NICE clinical guideline 35 (2006)

Under development

NICE is developing the following guidance (details available from the NICE website):

Older people with multiple morbidities. NICE public health guidance. Publication expected September 2014

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5.7 Glossary and abbreviations

5.7.1 Glossary

Acute setting

The availability on site of the full range of diagnostic and therapeutic capability required for the diagnosis and treatment of acute physical illnesses

Assessment

An in-depth and possibly on-going process of identifying risk factors

Carer

Where the term ‘carer’ is used, this refers to unpaid carers as opposed to paid carers (for example, care workers).

Cognitive impairment

Defined as mini-mental state examination (MMSE)<24. (Folstein 1975).

Dementia

The diagnostic and statistical manual of mental disorders fourth version (DSM-IV, 1994) expresses the internationally prevailing view of the concept of dementia being a form of memory disturbance, with at least one of the following disturbances of aphasia, apraxia, agnosia and disturbance in executive functioning.

Extended care

A care facility, such as a nursing home or supported accommodation.

Fall

An event whereby an individual comes to rest on the ground or another lower level with or without loss of consciousness’ (AGS/BGS 2001).

Home hazard assessment

The assessment of an older person’s home environment and the identification of any hazards that may contribute to that person being at risk of falling.

Injurious fall

A fall resulting in a fracture or soft tissue damage that require treatment.

Multidisciplinary

More than one health care professional from different disciplines.

Multifactorial assessment /multifactorial falls risk assessment

An assessment with multiple components that aims to identify risk factors that can be treated, managed or improved

Multifactorial intervention

An intervention with multiple components that is linked to a person's multifactorial assessment.

Non-acute setting

Settings focused on recovery and rehabilitation, symptom control, or palliative care.

Older people living in the community

Older people living in their own homes or in extended care.

Older person

In section 3 'Inpatient setting', older people are people aged 50 years and older.

In section 4 'community setting', older people are people aged 65 years and older.

Primary prevention

Interventions that aim to prevent the first fall in a patient who is vulnerable to falling through, for example, unsteady gait, but has not yet fallen

Rehabilitation

Interventions that are targeted at those who have suffered an injurious fall.

Risk prediction tool

A tool that purports to calculate an individual patient's risk of falling, either in terms of at risk/not at risk, or in terms of low/medium/high risk, etc.

Secondary intervention

Interventions that are targeted at those with a history of falls.

Self-efficacy

An older person's perception of their capability. High self-efficacy relates to increased confidence. This term is referred to in relation to reducing the fear of falling.

Tailored

Intervention packages or programmes that are planned to meet the needs of patients.

Targeted

Interventions that are aimed at modifying a particular risk factor or factors.

Please see the NICE glossary for an explanation of terms not described above.

5.7.2 Abbreviations

ADL	activities of daily living
ARR	absolute relative risk
CAP	client assessed protocol
CI	confidence intervals
DH	Department of Health
FES	falls efficacy scale
GDG	Guideline Development Group
HC	home care
HTA	health technology assessment
IRR	Incidence rate ratio
MHRA	Medicines and Healthcare Products Regulatory Agency (formerly Medical Devices Agency)
NCC-NSC	National Collaborating Centre for Nursing and Supportive Care
NICE	National Institute for Clinical Excellence
NNT	number needed to treat
RAI	residential assessment instrument
RAP	resident assessed protocol
RCN	Royal College of Nursing
RCT	randomised controlled trial
RIRR	Ratio of incidence rate ratio
RR	Relative risk
RRR	Ratio of relative risk
SCHARR	School of Health and Related Research