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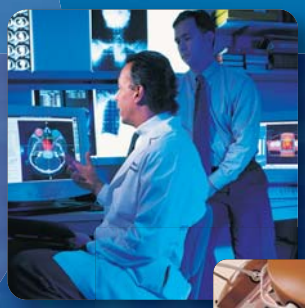
HTA

May 2008

Hip Protectors in Long-Term Care: A Clinical and Cost-Effectiveness Review and Primary Economic Evaluation



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Hip Protectors in Long-Term Care: A Clinical and Cost-Effectiveness Review and Primary Economic Evaluation

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May 2008

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Canadian Agency for Drugs and Technologies in Health

HTA

HEALTH TECHNOLOGY INQUIRY SERVICE (HTIS)

Health technology assessment (HTA) agencies face the challenge of providing quality assessments of medical technologies in a timely manner to support decision making. Ideally, all important deliberations would be supported by comprehensive health technology assessment reports, but the urgency of some decisions often requires a more immediate response.

The Health Technology Inquiry Service (HTIS) provides Canadian health care decision makers with health technology assessment information, based on the best available evidence, in a quick and efficient manner. Inquiries related to the assessment of health care technologies (drugs, devices, diagnostic tests, and surgical procedures) are accepted by the service. Information provided by the HTIS is tailored to meet the needs of decision makers, taking into account the urgency, importance, and potential impact of the request.

Consultations with the requestor of this HTIS assessment indicated that a review of the literature would be beneficial. The research question and selection criteria were developed in consultation with the requestor. The literature search was carried out by an information specialist using a standardized search strategy. The review of evidence was conducted by one internal HTIS reviewer. The draft report was internally reviewed and externally peer-reviewed by two or more peer reviewers. All comments were reviewed internally to ensure that they were addressed appropriately.

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ABBREVIATIONS

CAOT	Canadian Association of Occupational Therapists
CI	confidence interval
CRI	credibility interval
CRT	cluster randomized trial
HTA	health technology assessment
ICER	incremental cost-effectiveness ratio
LTC	long-term care
NICE	National Institute for Health and Clinical Excellence
OR	odds ratio
QALY	quality-adjusted life year
RR	relative risk
RTC	randomized controlled trial

EXECUTIVE SUMMARY

Title: Hip Protectors in Long-Term Care: A Clinical and Cost-Effectiveness Review and Primary Economic Evaluation

Date: May 2, 2008

Context and Policy Issues

Over 300,000 Canadians reside in long-term care (LTC) facilities. Hip injuries in these residents are a health concern. Each year approximately 50% of them fall at least once, and 5% to 10% of these falls will result in fractures. The one-year mortality rate following a hip fracture is about 20%. The societal cost in the first year following a hip fracture is about $34,000 per LTC facility resident (in 1997 Canadian dollars).

One approach to prevention of hip fractures is the use of an external hip protector. Hip protectors consist of an underwear-type garment with pockets in which protective pads (hard-shelled or soft-shelled) are inserted on each side over the greater trochanter. In the event of a fall, the shell disperses the force away from the hip and into the surrounding tissue.

Research Questions

1. What is the clinical effectiveness of hip protectors to prevent hip fractures for residents of LTC and assisted or supervised care facilities?
2. What is the cost-effectiveness of hip protectors to prevent hip fractures for residents of LTC and assisted or supervised care facilities?
3. What are the guidelines and criteria for patient selection for use of hip protectors?

Methods

Published literature was obtained by cross-searching MEDLINE, EMBASE, and CINAHL databases on the OVID search system between 2003 and March 2008. Parallel searches were performed on PubMed and the Cochrane Library (Issue 1, 2008) databases. Web sites of regulatory agencies and health technology assessment (HTA) and related agencies were also searched, as were specialized databases such as those of the University of York Centre for Reviews and Dissemination. The Google search engine was used to search for a variety of information on the Internet. These searches were supplemented by hand searching the bibliographies of selected papers.

Included clinical studies needed to meet the following criteria: study design — HTA, systematic review, randomized controlled trial (RCT) or observational study; population — patients in LTC or assisted or supervised care facilities (but not home care or community use); intervention — hip protectors (both hard- and soft-shelled); comparator — not specified a priori (could be usual care, drug therapy, etc.); outcomes — hip injuries or fractures. Criteria for the economic evaluations were similar except that the study design was a full economic evaluation and the outcome was a summary measure of the trade-off between additional cost and additional benefit. Guidelines relating to hip protector use were also reviewed. Evidence on compliance with hip protector use, as well as evidence on who might best benefit from hip protectors, was compiled.

The primary economic evaluation was a cost-utility analysis developed within a Microsoft Excel spreadsheet using a Markov model with a one-year cycle length and a lifetime horizon. The perspective was that of a provincial ministry of health. The economic model allowed the evaluation of hip protector use in LTC facilities versus no treatment, treatment with alendronate, and the combination of hip protectors plus alendronate for the prevention of hip fractures.

Summary of Findings

Five systematic reviews on the effectiveness of hip protectors were retrieved. They all found hip protectors had a protective effect on hip fractures for the elderly in residential care. The relative risk (RR) varied between the systematic reviews, largely because the individual studies included in the meta-analyses differed. One RCT published subsequent to the systematic reviews

was included. It did not find a protective effect for hip protectors, but the trial did not employ the recommended use for hip protectors. One observational study, described in two separate articles, was also included. Using the same group of patients in a pre-test/post-test design, it found hip protectors reduced the incidence of hip fracture and resulted in an odds ratio of 0.31 for hip protector wearers versus non-wearers.

Six clinical practice guidelines covering hip fractures were retrieved. Four of the six recommended the use of hip protectors, with varying grades of evidence. The National Institute for Health and Clinical Excellence (NICE) guideline did not recommend their use. It made an overall recommendation, not made specifically for LTC- or community-living individuals, which may explain its discordance with the other guidelines reviewed.

Eight economic evaluations were retrieved for review. With one exception, all of the economic evaluations found results favourable for hip protectors. For the three economic evaluations done in Canadian settings, all found hip protectors likely to be cost-saving.

For the primary economic evaluation, the base-case results found that, for the prevention of hip fractures, the incremental cost per quality-adjusted life-year (QALY) for hip protectors versus no intervention was $14,000. For the hip protector versus alendronate comparison, alendronate dominated (less costly and more effective). For the hip protector plus alendronate combination versus alendronate alone, the ICER was $40,000. The results were sensitive to changes in the compliance rate with hip protectors, the number of new hip protectors required annually, the relative risk reduction, and age.

Compliance has been recognized as an important issue in hip protector research and implementation. Compliance can be described as the percentage of time the hip protector is worn correctly, and it appears to be about 25%. Factors that make patients reluctant to use hip protectors include discomfort, appearance and distortion of body image, cost, skin irritation, dressing and toileting difficulties, and inadequate patient instruction and orientation on use. In terms of overcoming barriers to compliance with hip protectors, caregiver motivation and involvement appear to be crucial. In terms of those most likely to benefit from hip protectors, decision makers may consider targeting LTC facility residents with these risk factors: hypertension, incontinence, a previous history of falls and fractures, cognitive impairment, stroke (especially hemiplegia), dementia, disorders of gait and balance, Parkinson's disease, peripheral neuropathy, lower extremity weakness or sensory loss, lower body mass indexes, and substantial vision loss.

Conclusions and Implications for Decision or Policy Making

Hip protectors appear to be effective at reducing the risk of hip fractures in LTC facility residents, with a relative risk of 0.77. Our primary economic evaluation suggests that if the available options are hip protectors, alendronate, alendronate plus hip protectors, and no treatment, a combination of alendronate and hip protectors causes the greatest reduction in disease burden and would be considered cost-effective compared to alendronate if a decision-maker is willing to pay up to $50,000 for a quality-adjusted life-year in women between 75 and 89 with a previous fracture. Compared to no intervention, hip protectors are a cost-effective treatment option (based on a willingness to pay of $50,000/QALY) for women over 70 years of age living in LTC facilities.

1 CONTEXT AND POLICY ISSUES

Hip injuries in residents of long-term care (LTC) and assisted or supervised care facilities are a health concern in Canada and are likely to increase in importance as current demographic trends in ageing continue. In 2007 there were approximately 4.4 million people in Canada aged 65 and older.[1] Of these, 7.4% (or 325,600) were living in health care facilities.[2] Each year approximately 50% of residents of LTC facilities fall at least once, and 40% fall twice or more.[3] Around 10% to 25% of these falls are associated with serious injuries requiring medical treatment, and 5% to 10% will result in fractures, most commonly of the hip, wrist, or vertebrae.[2-4]

In 2005/2006 there were 28,200 hospitalizations for hip fractures in Canada.[5] Hip fractures reduce quality of life,[5,6] cause health problems such as chronic pain, and affect the ability to perform daily activities.[6] In 2005/2006, approximately 7% of seniors admitted to hospital for a hip fracture died within 30 days. The one-year mortality rate following hip fracture is about 20%.[7]

In Canada, the average societal cost in the first year following a hip fracture is, overall, about $27,000 (in 1997 Canadian dollars) per patient and $34,000 per LTC facility resident.[8] The total annual economic costs of hip fractures from a societal perspective are estimated at $650 million and are expected to rise to $2.4 billion by 2041.[8]

The prevention of hip fractures among older people usually consists of (i) prevention and treatment of osteoporosis, (ii) prevention of falling (it has been estimated that 90% of hip fractures are caused by falls[6]), and (iii) prevention of fractures with injury-site protection.[9] The majority of hip fractures are caused by a sideways fall with direct impact on the greater trochanter of the proximal femur.[9]

One approach to injury-site protection is the use of an external hip protector. This takes the form of an underwear-type garment in which protective pads are inserted on each side. In the event of a fall, the impacting force and energy are first weakened by the padding and then diverted away from the greater trochanter to a wider area.[9] Each patient will need more than one hip protector, because of the need to launder them and replace them after falls have occurred. There are compliance issues with wearing the hip protector. Some patients find them to be unsightly or uncomfortable.

The Canadian Association of Occupational Therapists (CAOT) lists the manufacturers and prices of hip protectors. The price ranges from C$48 to C$110 for hard-shelled hip protectors and C$55 to C$79 for soft-shelled hip protectors.[10] The pricing from the manufacturers of hip protectors in Canada is listed in Table 1.

A review of the evidence regarding the clinical and cost-effectiveness of hip protectors is necessary to help decision makers determine whether hip protectors should be purchased for residents of LTC and supervised care facilities and whether there is a clinical benefit with the use of hip protectors. A new primary economic evaluation was also feasible, based on an update of an existing model.[13]

Table 1: Hip protectors available in Canada

Manufacturer	Type	Price* ($ Canadian)
HipSaver Canada[11]	Hard-shelled	N/A
	Soft-shelled	$59.99 to $73.99
Impactwear[12]	Hard-shelled	N/A
	Soft-shelled	$132.25

*These are published retail prices. Volume discounts may be obtainable. The price is for the set of undergarment(s) plus protective pads.

2 RESEARCH QUESTIONS

1. What is the clinical effectiveness of hip protectors to prevent hip fractures for residents of LTC and assisted or supervised care facilities?
2. What is the cost-effectiveness of hip protectors to prevent hip fractures for residents of LTC and assisted or supervised care facilities?
3. What are the guidelines and criteria for patient selection for use of hip protectors?

3 METHODS

The report includes a review of evidence on clinical effectiveness, a review of economic evaluations, and a cost-utility analysis.

3.1 Literature Search

Published literature was obtained by cross-searching MEDLINE, EMBASE, and CINAHL databases on the OVID search system. Regular alerts were established on MEDLINE, EMBASE, and CINAHL, and information retrieved via alerts is current to March 31, 2008. Parallel searches were performed on PubMed and the Cochrane Library (Issue 1, 2008) databases. Results from these searches were limited to articles published between 2003 and March 2008 and to English language publications only. No filters were applied to limit the retrieval by study type in the main search of hip protectors in LTC facilities. However, filters were used to limit the retrieval to economic and clinical guidelines in a general search on hip protectors.

Web sites of regulatory agencies and health technology assessment (HTA) and related agencies were also searched, as were specialized databases such as those of the University of York Centre for Reviews and Dissemination. The Google search engine was used to search for a variety of information on the Internet. These searches were supplemented by hand searching the bibliographies of selected papers.

3.2 Study Selection

Papers for the clinical and economic reviews were selected by two reviewers (AB and KC). Conflicts were resolved by discussion and consensus. Only the most recent report published by the same site or study group was incorporated.

Included clinical studies needed to meet the following criteria:

- Study design: HTA, systematic review, randomized controlled trial (RCT) or observational study
- Population: patients in LTC or assisted or supervised care facilities (but not home care or community use)
- Intervention: hip protectors (both hard-shelled and soft-shelled)
- Comparator: not specified a priori (could be usual care, drug therapy, etc.)
- Outcomes: hip injuries or fractures.

Criteria for the economic evaluations were similar except that the study design was a full economic evaluation (cost-utility analysis, cost-effectiveness analysis, cost-benefit analysis, or cost-minimization if effectiveness was equivalent) and the outcome was a summary measure of the trade-off between additional cost and additional benefit [i.e., cost per fall avoided, cost per quality-adjusted life year (QALY) gained].

3.3 Primary Economic Evaluation

The cost-utility analysis employed the same decision analytic model for osteoporosis adopted in a previous CADTH report, which was updated with 2007 cost data for a recent HTIS report.[14,15] An earlier version of this model was used in a previous evaluation of hip protectors in the Canadian context.[13] A more extensive description of the model design and the parameters used to populate the model is contained in the original CADTH reports.[14,15]

Briefly, the model reflects the natural history of women with osteoporosis, incorporating the sequelae associated with osteoporosis (e.g., fracture) and also the transition of women in terms of the development of osteoporosis, history of fracture, and residential status (Appendix 1). The model used the most recently available data relevant to the Canadian population. Given the chronic nature of osteoporosis, a Markov model with a one-year cycle length with a lifetime horizon was used and was developed within a Microsoft Excel spreadsheet. The model provides estimates of the lifetime cost, lifetime QALY, and life expectancy.

In the model, the probability of a woman experiencing a hip, wrist, or vertebral fracture was assumed to be dependent on three factors: age, osteoporotic status, and previous history of osteoporotic fractures.[16-18] Both hip and vertebral fractures are associated with excess mortality.[16,19,20] In addition, the probability of hip fracture and the probability of mortality post-hip fracture increases if a woman resides within a LTC facility after controlling for age and co-morbidities.[21] The model was populated with relevant transition probabilities and estimates of the costs and utilities associated with each health state. To allow evaluation of hip protectors, three additional variables were required: the annual cost of hip protectors, the relative risk (RR) reduction in hip fractures associated with the use of hip protectors, and the compliance with hip protectors. Adverse events were not modelled directly, but we modelled compliance, which can be affected by skin rashes, discomfort, and other complications.

The annual cost of hip protectors was estimated based on the acquisition cost of the Nursing Home brand of HipSaver®, a hip protector commonly used in Canada.[11] The cost per hip protector was $59.99, and it was assumed that a supply of seven hip protectors is required per individual per year.[11,13] The relative risk of hip fracture (0.77) was taken from the recent meta-analysis by Parker (see Table 2).[22] The meta-analysis adopted an intention-to-treat analysis — the relative risk already incorporates the lack of compliance with hip protectors, albeit within a trial setting rather than an everyday health care setting. Thus, in the base-case analysis, the effectiveness of hip protectors was not adjusted further for compliance. A recent review of studies looking at compliance with hip protectors found a median compliance rate of 56% with a range from 24% to 92%.[23] The upper and lower bounds of the range were used in the sensitivity analysis.

The model allowed the conduct of a cost-utility analysis, with outcomes expressed in terms of QALYs. The analysis was presented in terms of the incremental cost per QALY gained and was conducted from the perspective of a provincial ministry of health or equivalent.[24] Costs and benefits were discounted at 5% per annum.[24]

The base-case analysis was conducted for women aged 80 to 84 years with a previous osteoporotic fracture, living in LTC facilities assuming a compliance rate of 56% and a relative risk of hip fracture of 0.77. Further analysis was conducted for women of different ages (70 to 74, 75 to 79, and 85 to 89) and for women without previous fracture. Additional sensitivity analysis was conducted relating to the compliance with therapy (24% and 92% — the range from the recent review[23]), the number of hip protectors required (4 and 14), and the relative risk of hip fracture (0.86 — the relative risk from the recent meta-analysis by Parker *et al.*[22] excluding cluster trials).

Currently there is no standard practice in Canada with respect to the use of hip protectors, either as sole therapy or in combination with other therapies. The analysis assessed the cost-effectiveness of hip protectors both as an adjunct to osteoporotic drug therapy and without drug therapy. Drug therapy was assumed to be generic alendronate which, in a previous HTIS report, appeared to be the optimal drug therapy for osteoporosis.[15] For hip protectors with no drug therapy, comparators were no intervention and alendronate. For hip protectors in combination with alendronate, the comparator was alendronate alone.

4 SUMMARY OF FINDINGS

4.1 Health Technology Assessments

No HTAs on hip protectors were identified.

4.2 Systematic Reviews and Meta-analyses

Five systematic reviews on the effectiveness of hip protectors were retrieved and are summarized in Table 2. They all found hip protectors had a protective effect on hip fractures for the elderly in residential care (e.g., chronic care facilities, nursing homes, homes for the aged).

4.3 Randomized Controlled Trials

We considered the Parker *et al.*[22] systematic review (published March 2006) as a reliable and conservative estimate of the effectiveness of hip protectors (see the "Limitations" section). We retrieved one RCT published subsequent to it. In an RCT by Kiel *et al.*,[29] 1,042 nursing home residents were randomly assigned to wear a hip protector (the HIP PRO) on either the left or right hip. The outcome was the occurrence of hip fractures on the padded versus the unpadded hips. The incidence of hip fracture on protected versus unprotected hips did not differ (3.1%; 95% CI: 1.8% to 4.4% versus 2.5%; 95% CI: 1.3% to 3.7%; p=0.70). Hip protectors are typically worn bilaterally, so the trial design does not reflect the recommended use. This is a possible limitation of this study.

4.4 Observational Studies

One experimental observational study, described in two articles (Forsen *et al.*, 2003,[30] and Forsen *et al.*, 2004[31]), was included. The Forsen *et al.*, 2003[30] study described a non-randomized pre-test/post-test observational design involving 17 nursing homes in Norway. The pre-intervention (control) and intervention periods each lasted 18 months. During the intervention period, all 965 residents were offered free use of hip protectors. The intervention period showed a 39% reduction in hip fracture incidence (p=0.003) compared with the pre-intervention period. The percentage of daily users of the protector varied from 35% during the first months to 22% at the end of the study. The study concluded hip protectors considerably reduced the incidence of hip fracture; higher compliance and greater reduction in hip fractures could be achieved if manufacturers would increase the comfort of the protector without reducing its effect. Furthermore, it was concluded that it is important for health workers to encourage more individuals at high risk (e.g., elderly LTC facility residents, or those with a previous hip fracture) to use hip protectors.

In the second article on this study (Forsen, 2004[31]), the authors reported the OR of suffering a hip fracture was 0.31 (95% CI: 0.13 to 0.75) for hip protector wearers compared with non-wearers, adjusted for age, gender, and whether they were registered users or not. Registered users were offered a hip protector (underwear and protection pads) every morning and also new ones during the day if necessary. Each time a new resident moved into the nursing home, they were offered hip protectors and registered as a user or non-user of hip protectors.

4.5 Guidelines

Six clinical practice guidelines covering the use of hip protectors were retrieved.

The *Falls Assessment Working Group* report[32] (May 2006) by Nova Scotia Health recommended that "should the Department of Health pursue the development of policies related to the use of hip protectors, more in-depth study and consultation, particularly in relation to the Cost of Care initiative, will be required." The strategy of the working group was to establish and develop a standardized risk and fall assessment framework for use within LTC, acute care, and home care across Nova Scotia. Their recommendations were based on a thorough literature review and synthesis.

Table 2: Systematic reviews and meta-analyses of hip protectors		
Study	**Number of Trials and Patients**	**Objective and Key Results or Conclusions**
Sawka *et al.*, 2007[25]	4 trials (3 CRTs) 1,922 patients	To design a Bayesian random effects model to pool data from CRTs and RCTs and determine if hip protectors decrease the risk of hip fracture in elderly nursing home residents. Hip protectors decreased the risk of hip fractures in elderly nursing home residents. The pooled OR of sustaining one or more hip fractures was 0.40 (95% CRI: 0.25 to 0.61).
Oliver *et al.*, 2006[26]	11 trials	To assess strategies to prevent falls or fractures in residents in care homes and hospital inpatients and investigate the effect of dementia and cognitive impairment. Included a subgroup analysis on effectiveness of hip protectors in care homes. For hip protectors in care homes, the rate ratio* for hip fractures was 0.67 (95% CI: 0.46 to 0.98).
Parker *et al.*, 2006[22]	11 trials (6 CRTs) 8,433 patients	To present updated results of a systematic review of the effectiveness of hip protectors from randomized trials (RCTs and CRTs) and explore the evolution of that evidence. Pooling of trials carried out in nursing or residential care settings showed evidence of a marginally statistically significant reduction in incidence of hip fracture. The RR was 0.77 (95% CI: 0.62 to 0.97).
Sawka *et al.*, 2005[27]	3 trials 1,188 patients	To systematically review trials of hip protectors to determine if they reduce hip fractures in the elderly. Separate analyses for community and residential (including nursing homes, residential group homes, and seniors' hostels) patients. There is little evidence to support the use of hip protectors outside the nursing home setting. In three trials with institutionalized elderly, the RR was 0.56 (95% CI: 0.31 to 1.01). In a subgroup analysis of two trials of 1,014 nursing home residents, the RR was 0.50 (95% CI: 0.28 to 0.91).
Cowling, 2004[28]	9 trials	To determine if hip protectors reduce risk of hip fracture and to determine patient compliance to wearing the hip protectors. Of the nine included articles, six found hip protectors to be effective in preventing hip fractures in selective populations. Poor compliance rates were found in all reviewed trials. Future research should focus on improving compliance rates.

CI=confidence interval; CRI=credibility interval†; CRT=cluster randomized trial; OR=odds ratio; RCT=randomized controlled trial; RR=relative risk.
*The rate ratio is similar but not identical to the relative risk. It is the ratio of the number of fractures occuring in the control and intervention groups, allowing for multiple fractures per person.
†"Credibility interval" is a term used in Bayesian analysis and is analagous to a confidence interval.

The *Prevention of falls and fall injuries in the older adult* nursing best practice guideline[33] (March 2005) by the Registered Nurses Association of Ontario recommended that "nurses could consider the use of hip protectors to reduce hip fractures among those clients considered at high risk of fractures associated with falls; however, there is no evidence to support universal use of hip protectors among the elderly in health care settings." The level of evidence was rated as Ib (evidence obtained from at least one randomized controlled trial) and the grade of recommendation was B (there is fair evidence to recommend the clinical preventive action). The 2005 publication is an update to the 2002 version of the guidelines and was reviewed and revised to reflect current evidence.

In the *Clinical practice guideline for the assessment and prevention of falls in older people*[34] by NICE in the UK (November 2004), hip protectors were listed under "interventions that cannot be recommended." This appears to be an overall recommendation, not made specifically for LTC facility or community-living individuals, which may explain its discordance with the other guidelines reviewed. However, the NICE guidelines also stated that "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."[34] NICE uses a systematic review process for developing their guidelines.

The *Fall prevention for older adults* guideline[35] by the University of Iowa Gerontological Nursing Interventions Research Center (February 2004) found there was "strong evidence to support the ability of hip protectors to prevent hip fractures in persons 65 years of age and older, in nonhospitalized settings, who fall." However they noted that widespread acceptance of hip protectors by nursing home residents has been low. The recommendation was given evidence grade B [evidence from well-designed controlled trials, both randomized and nonrandomized, with results that consistently support a specific action (e.g., assessment, intervention or treatment)]. The evidence was reviewed by two experts using a common critique format.

The *Prevention of Falls and Injuries Among the Elderly* report[36] (January 2004) by the British Columbia Ministry of Health Planning from the Office of the Provincial Health Officer listed the use of hip protectors to cushion the hip from the impact of a fall as an evidence-based strategy "effective in reducing the incidence and prevalence of falls and fractures." The report included an extensive review of the clinical and economic evidence.

The recommendation of the *Prevention of hip fracture amongst people aged 65 years and over* best practice evidence-based guideline[37] (June 2003) by the New Zealand Guidelines Group was that "hip protectors appear to reduce the incidence of hip fractures in older people in institutional care provided that compliance/adherence is achieved." The recommendation was given grade A (at least one meta-analysis, systematic review, or RCT rated 1++, and directly applicable to the target population; or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results). The hip fracture guideline development team was commissioned by the New Zealand Guidelines Group and funded by the Ministry of Health to develop an evidence-based guideline on the prevention of hip fracture among people aged 65 years and older. A mutidisciplinary group was convened with members representing stakeholder professional groups and consumers.

4.6 Economic Studies

Eight economic evaluations were retrieved for review. The study by Waldegger *et al.*, 2003[13] was done in a Canadian setting. It included a meta-analysis that indicated hip protectors resulted in an relative risk of hip fracture of 0.40 (95% CI: 0.23 to 0.70). The cost-utility analysis had a societal perspective, and found that the use of hip protectors is expected to be both effective and cost-saving — in other words, it dominates the no-therapy alternative. Results were robust to a range of analyses examining the uncertainty of input parameters. The study concluded that there was

sufficient clinical and economic evidence to support the use of hip protectors for the institution-dwelling elderly.

The study by Colon-Emeric *et al.*, 2003[38] was done in a US setting. The objective was to evaluate the economic impact of hip protectors for nursing facility residents. A societal perspective with an 18-month time horizon was used. The study found hip protectors were cost-saving and effective over a wide range of cost and utility assumptions. They saved approximately US$300 per patient and added 0.01 QALYs over 18 months.

The study by Singh *et al.*, 2004[39] was done in a Canadian setting and modelled the cost-effectiveness of hip protectors in the prevention of osteoporosis-related hip fractures in elderly nursing home residents. It took a societal perspective with a lifetime horizon. Hip protectors were found to be dominant (lower cost and higher effectiveness) compared with both no treatment and to calcium and vitamin D supplements. The study concluded hip protectors could save money while preventing hip fractures and improving quality of life in nursing home residents.

The study by Fleurence, 2004[40] was done in a UK setting. The objective was to assess the cost-effectiveness of vitamin D and calcium and hip protectors in patients over 70 years of age at high risk and general risk of fracture. In the general-risk female and male groups, the incremental cost per QALY relative to no treatment was US$11,722 and US$47,426, respectively, for hip protectors. In the male high-risk group, the incremental cost per QALY was $17,017 for hip protectors. In the female high-risk group, hip protectors were cost-saving. Vitamin D and calcium were dominated by hip protectors in all four subgroups (i.e., hip protectors had lower cost and higher effectiveness). The study concluded that, at a willingness to pay of $20,000 per QALY, hip protectors were cost-effective in the general female population and high-risk male population (elderly LTC facility residents or those with a previous hip fracture) and cost-saving in the high-risk female population (elderly LTC facility residents or those with a previous hip fracture), despite low compliance rates.

The study by van Schoor *et al.*, 2004[41] was done in the Netherlands. The economic analysis was done alongside an RCT assessing the effectiveness of hip protectors in the prevention of hip fractures in the frail institutionalized elderly. Since hip protectors were not found to be effective in preventing hip fractures in the RCT, the objective of the economic analysis was to examine whether the use of hip protectors results in lower average costs per participant. The use of hip protectors was not found to be associated with lower costs. The average costs per patient, including costs of the intervention, was 913 Euros in the hip protector intervention group and 502 Euros in the control group.

The study by Honkanen *et al.*, 2005[42] was done in a US setting. The objective was to assess a program of hip protectors in nursing homes from a US Medicare perspective. The study concluded that hip protectors were cost-saving in the nursing home when the relative risk of fracture with hip protectors was less than or equal to 0.65. In that case, Medicare could save $136 million in the first year of a hip protector reimbursement program. The base-case relative risk in the analysis was 0.43.

The study by Meyer *et al.*, 2005[43] was done in Germany and was "piggy-backed" onto a cluster RCT. The intervention was education sessions for nurses, who subsequently educated residents, and the provision of three hip protectors per patient. The comparator group did not receive hip protectors, but got a demonstration and some information about them. The study found the cost per additional hip fracture avoided was US$1,234. Sensitivity analysis led to incremental cost-effectiveness ratios (ICERs) ranging from US$439 to US$1,693. Lowering the price of hip protectors could result in a cost-saving situation. The break-even price for a cost-saving result was US$22 per hip protector.

The economic analysis by Sawka *et al.*, 2007[44] was, strictly speaking, not an economic evaluation, because it looked only at costs and not the health benefit of outcomes. However, it is included here because it may be useful as a cost analysis from the Ontario Health Ministry perspective. The objective was to determine whether the provision

of hip protectors to all Ontario nursing home residents aged 65 and older could result in cost savings due to reductions in initial hospitalizations for hip fracture. The study found that providing hip protectors to all 60,775 elderly Ontario nursing home residents could result in a mean cost savings of $6 million Canadian dollars in one year (95% credibility interval: -26.4 million to +39.7 million). This assumes no additional labour expenditures.

To summarize, all of the economic evaluations found results favourable to hip protectors except for van Schoor *et al.*.[41] For the three economic evaluations done in Canadian settings (Waldegger *et al.*,[13] Singh *et al.*,[39] Sawka *et al.*[44]), all found hip protectors likely to be cost-saving. Additional details of the Canadian studies are provided in Appendix 2.

4.7 Primary Economic Evaluation

Full details of the results of the cost-utility analysis are provided in Table 3. Baseline results are for an 80- to 84-year-old osteoporotic woman living in LTC with a previous osteoporotic fracture, assuming a compliance rate of 56% and an relative risk of hip fracture of 0.77.

For the cost-utility analysis carried out for this report, if alendronate is available as a stand-alone treatment only, both the no-therapy strategy (no hip protectors or drug therapy) and the use of hip protectors alone are dominated by alendronate in that they are more expensive and less effective. The incremental cost per QALY for hip protectors compared with no therapy is $14,000 (Table 4).

Table 3: Summary results of economic analysis

	Lifetime Costs	Lifetime QALYs	Life Expectancy
No intervention	$8,448	3.469	5.793
Alendronate	$8,099	3.501	5.832
Hip protectors	$8,625	3.482	5.809
Hip protectors and alendronate	$8,381	3.508	5.841

QALYs=quality-adjusted life years.

Results were sensitive to changes in the compliance rate with hip protectors, the number of new hip protectors required annually, the relative risk reduction, and the woman's age (Table 4).

Table 4: Sensitivity analysis

	Incremental Cost per QALY		
	Hip Protectors versus No Intervention	Hip Protectors versus Alendronate	Hip Protectors and Alendronate versus Alendronate
Base case	$14,000	Dominated	$40,000
70 to 74 years old with previous fracture	$31,000	Dominated	$67,000
75 to 79 years old with previous fracture	$19,000	Dominated	$49,000
85 to 89 years old with previous fracture	$11,000	Dominated	$34,000
80 to 84 years old with no previous fracture	$22,000	Dominated	$53,000
RR of hip fracture=0.86	$35,000	Dominated	$77,000
Compliance of 20%	$36,000	Dominated	$79,000
Compliance of 92%	$15,000	Dominated	$42,000
4 hip protectors required per annum	Dominant	Dominated	$14,000
14 hip protectors required per annum	$47,000	Dominated	$98,000

QALY=quality-adjusted life year; RR=relative risk.

For the hip protectors versus no hip protectors comparison, hip protectors were cost-effective at a willingness to pay of $50,000 per QALY under all scenarios in the sensitivity analysis, except for one where it was dominant (more effective and less costly) (see Table 4).

If the combination of alendronate plus hip protectors is available, this combination is more costly and more effective than alendronate alone. The incremental cost per QALY gained for hip protectors and alendronate compared with alendronate alone is $40,000.

5 LIMITATIONS

For the review of clinical evidence, we did not conduct a new meta-analysis but relied on a review of published systematic reviews, RCTs since the last included systematic review, and observational studies.

Regarding the quality of the included systematic reviews, the study by Parker *et al.*[22] was the most comprehensive. It had the largest number of hip protector trials (11) and patients (8,433). It was an update by the same group of authors that has previously published Cochrane reviews on hip protectors in 2005[45] and 1999.[46] The Sawka *et al.*[25] study (2007) was limited to nursing home residents. The Oliver *et al.*[26] study covered hip protectors in care homes only as a subgroup analysis — it also included falls prevention, multifaceted interventions, and hospital patients. Sawka *et al.*[27] (2005) included only three trials. The Cowling[28] study had only one author and therefore might not be considered "systematic." No attempt was made to pool the trial results — they were compared and critically appraised. A general criticism of many of the systematic reviews could be their use of cluster randomized trials (CRTs). In CRTs, the institution, rather that the patient, is randomly allocated to the intervention or comparator. Researchers in methodology have argued that cluster trials may produce a biased estimate of effect.[47] The included RCT by Kiel *et al.*[29] published subsequent to the Parker *et al.*[22] systematic review was not able to detect a protective effect on the risk of hip fracture, although the hip protector analyzed (HIP PRO) is not commercially available in Canada. Also, in this trial hip protectors were not used as recommended (i.e., bilaterally). Thus, it is unclear if the results of this study are relevant.

The included observational study (described in Forsen *et al.*, 2003,[30] and Forsen *et al.*, 2004[31]) found a protective effect for hip protectors. However, this study would probably have a lower internal validity compared with the designs involving RCTs. In addition, observational studies do not control for selection bias.

Regarding the economic evaluations included for review, the article by Waldegger *et al.*[13] has been reviewed by Birks *et al*.[48] The new cost-utility analysis undertaken in this report takes an approach similar to Waldegger *et al.* but updates the parameters and takes the more conservative estimate of effectiveness developed by Parker *et al.*[22] Similar to the study by Waldegger *et al.*, the study by Singh *et al.*[39] used trials for relative risk available at the time, which have proved to be more favourable to hip protectors than more recent trials. The study by Fleurence[40] looked at populations over age 70 that were at high risk or general risk of fracture, but did not specify that they were LTC facility residents. The study by van Schoor *et al.*[41] was based on effectiveness measures from a single RCT, which is not as generalizable as a case where the effectiveness measure is derived from a meta-analysis. The study by Honkanen *et al.*[42] may have used an overly optimistic relative risk of hip fracture for hip protectors for a cost-saving result (RR ≤0.65). Meyer *et al.*[43] could be criticized for being based on a single CRT, with the limitation of basing the effectiveness measure on a single study, as well as limitations to the CRT methodology. The Sawka *et al.*[44] study assumed no additional labour costs due to hip protectors, but it is generally recognized that they result in increased laundry costs and can require support from nursing aids to apply the hip protectors.

There is a number of limitations with the primary cost-utility analysis. The analysis does not involve a probabilistic analysis, which would more fully allow for the uncertainty within all the input parameters in the model — especially

the effectiveness of hip protectors. A more complete health technology assessment would incorporate a detailed probabilistic analysis as well as a more thorough stratified analysis, which would allow for more complete recommendations on what would be the most cost-effective option for various patient groups. A further limitation is that the analysis employs the estimate of effectiveness from the Parker *et al.* meta-analysis without a specific re-analysis for this study. A more complete analysis would involve a revised meta-analysis that would allow consideration of the effects of compliance, concomitant medications, age, and fracture history as well as a full critique of the methodological quality of these studies. The latter is of particular concern given the large number of CRTs and their relative contribution to the effectiveness estimate. The analysis was limited to women, given the lack of Canadian data on the hip fracture risk for men. A Dutch study suggests that the incidence of hip fracture in men is the same as for women after adjusting for bone mineral density.[49] This suggests that the conclusions may be similar for osteoporotic men with previous fracture.

6 COMPLIANCE

Compliance has been recognized as a very important issue in hip protector research and implementation.[50] Low compliance also compromises the power of RCTs to detect a real effect.[51] The way compliance is defined and measured can vary between studies. Kurrle *et al.*[52] have proposed a standard definition: compliance is the wearing of hip protectors in accordance with recommended use, and it is measured as the amount of time hip protectors are worn. Compliance estimates within study settings have been as low as 25% after 11 months. This is lower than estimated compliance with pharmaceuticals interventions, which typically is about 50%.[13] Some studies have suggested the relative risk for protected falls (falls in which hip protectors are actually worn) is as low as 0.04 (95% CI: 0.01 to 0.16).[13] This suggests the potential to reduce hip fractures would be significant if compliance could be improved.

Cryer *et al.*[51] note that hip protectors cannot work if they are not worn. Potential barriers to compliance that have been cited include discomfort, appearance and distortion of body image, cost, skin irritation, dressing and toileting difficulties, and inadequate patient instruction and orientation on use.[9,53,54] Some suggestions for reducing the barriers to compliance have been made. Burl *et al.*[55] found evidence that education and promotion of hip protectors by geriatric and rehabilitation staff to nursing home staff, residents, and their families resulted in high compliance rates. Other suggestions to make acceptance and compliance more likely include efforts by manufacturers to improve comfort, design, and appearance while maintaining safety and efficacy;[51,56] inclusion of nursing assistants in hip protector education and decision making;[56] and provision of free hip protectors.[57]

7 WHO IS MOST LIKELY TO BENEFIT FROM HIP PROTECTORS?

Cryer *et al.*[51] studied factors associated with hip protector compliance among older people in residential care. Increased hip protector compliance was observed in patients with hypertension, incontinence, and a previous history of falls and fractures and in patients who lived in a residential care setting with a history of hip fractures. Decreased compliance was associated with arthritis of the lower limbs and dizziness on rising. Variation in compliance between the residential care settings in the study was almost completely explained by the above factors. In a similar study, O'Halloran *et al.*[58] recommended targeting residents with cognitive impairment if a policy of hip protectors was implemented in nursing homes. The study found that these residents were at greater risk of hip fracture and appeared to be more likely to continue wearing hip protectors.

Bast and Greenwald[59] describe a strong relationship between prior stroke and the

development of hip fracture, especially in patients with hemiplegia (paralysis of one side of the body). Thurman *et al.*[60] identified that an increased risk of falls is established in persons diagnosed with stroke, dementia, or disorders of gait and balance and is probable in persons diagnosed with Parkinson's disease, peripheral neuropathy, lower extremity weakness or sensory loss, and substantial vision loss. Willig *et al.*[61] found that patients who sustained a hip fracture after a fall on the hip versus those who did not were more likely to be women, live in long-term institutional care, use neuroleptics, be dependent in activities in daily living, have a history of previous stroke with hemiparesis or Parkinsonism, and have lower body mass indexes.

8 CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING

Based on the most recent update by the authors of the Cochrane reviews on this topic (Parker *et al.*[22]), it appears that hip protectors are effective at reducing the risk of hip fractures in LTC patients (RR 0.77, 95% CI: 0.62 to 0.97). The authors described this as "a marginally statistically significant reduction in incidence of hip fracture," although this protective effect is comparable to that of many drug therapies deemed to be effective. The other included meta-analyses also found hip protectors to be effective, with a stronger protective effect than that found by Parker *et al.*.

Of the guidelines discussed in this report, four were supportive of the use of hip protectors for our patient group,[33,35-37] one suggested more research is needed,[32] and one did not recommend their use (although this last recommendation related to older patients in general and not specifically to those in LTC facilities).[34]

The economic evaluations retrieved for this report were, overall, supportive of hip protectors for LTC patients. All but one study from the Netherlands[41] predicted that they would be cost-effective or cost-saving.

The cost-utility analysis undertaken for this report is an update to previous work in that it used the same model design with updated input parameters.[13-15] This analysis finds that hip protectors are less cost-effective than previously suggested,[13] primarily due to the recent evidence from RCTs suggesting that hip protectors are less favourable, as well as the availability of cheaper forms of effective drug therapy. If available options are hip protectors, alendronate, alendronate plus hip protectors, and no treatment, and if a decision-maker was willing to pay $50,000 per QALY gained, the analysis found that the combination of alendronate and hip protectors would be the most cost-effective option for women older than 75 years of age with a previous fracture. For osteoporotic women younger than 75 years of age, treatment with alendronate alone would be the most cost-effective option. However, if a decision-maker was willing to pay up to $100,000 per QALY gained, then the combination of alendronate and hip protectors would be the most cost-effective option for all osteoporotic women older than 70 years of age living in LTC. Therefore, under these conditions, our primary economic evaluation suggests that a combination of alendronate and hip protectors should be used for the more elderly women with osteoporosis living in LTC. For younger osteoporotic women, alendronate therapy alone will be optimal.

If the choice is between hip protector use and no hip protectors, based on a willingness to pay of $50,000, our primary economic evaluation suggests hip protectors are a cost-effective treatment option for women older than 70 years of age living in LTC.

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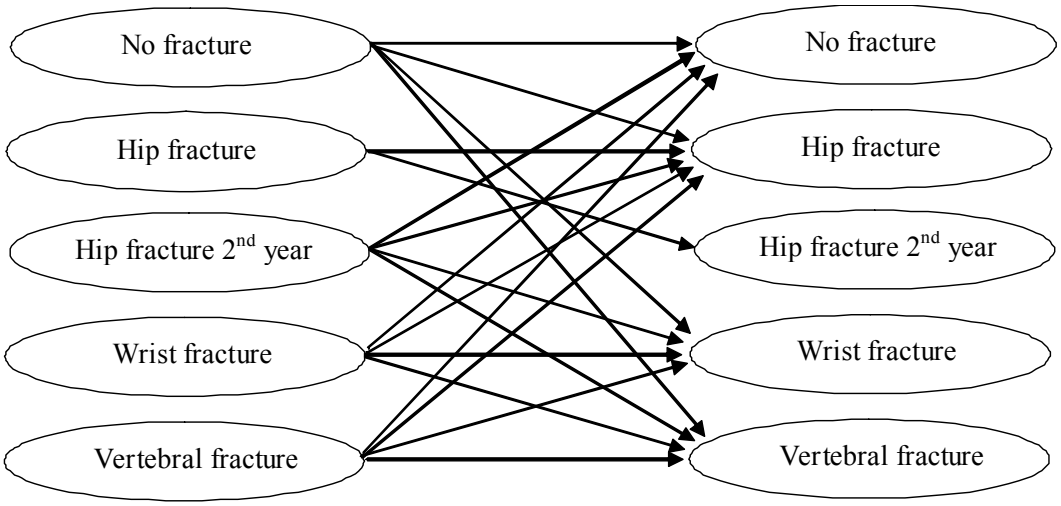
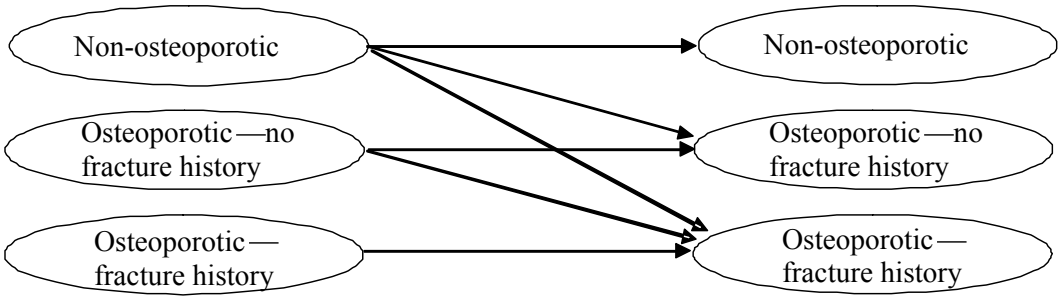
APPENDIX 1: DESIGN OF DECISION MODEL

a. Fractures



b. Osteoporotic status



APPENDIX 2: DETAILS OF INCLUDED CANADIAN ECONOMIC ANALYSES OF HIP PROTECTORS

	Type of Analysis	Population	RR of Hip Fracture	Details on Hip Protector Analyzed	Model and Assumptions
Waldegger *et al.*, 2003[13]	Cost-utility analysis, societal perspective, lifetime horizon	Elderly (82 years of age base case), living in institutions	0.40 (95% CI: 0.23 to 0.70) (hip protectors relative to no treatment)	HipSaver® hip protector (rationale: the most widely available model in Canada and appears to most closely estimate the models used in the clinical trials). Seven hip protectors required per person per year (based on laundry time, loss, wear and tear). $46 per hip protector, $322 per patient for hip protectors per year.	Markov process with cycle length of one year. Utility values from a sample of osteoporotic women treated at the Ottawa Hospital. Compliance for hip protector use 25%. Cost per patient of a hip fracture: $19,685 (most costs for treatment of fractures assumed to occur in the first year post-fracture). Costs and benefits discounted at 5% per year. Base analysis assumed a threshold value of a quality-adjusted life year of C$50,000 with further analysis assuming a range from zero to C$100,000. Adverse events were not modelled. Univariate sensitivity analysis on base-case clinical and economic assumptions. Probabilistic sensitivity analysis using Monte Carlo simulation (stochastic variables included RR, probability of death following hip fracture, cost of fracture, and utility in fracture states).
Singh *et al.*, 2004[39]	Incremental cost-effectiveness analysis, societal perspective, dual time horizon (lifetime for QALYs gained, one year for costs)	Nursing home residents (85 years of age base case)	0.37 (95% CI: 0.24 to 0.56) (hip protectors relative to no treatment) 0.73 (calcium and vitamin D supplements relative to no treatment)	Impact® hip protector. One hip protector per person per year (each set comes with three pairs of underwear for easier laundering). $150 per hip protector set, $150 per patient for hip protectors per year.	Authors describe the model as an incremental cost-effectiveness analysis, with decision analytic methods, using standard methodology, but costs were modelled for only one year and there is no mention of a Markov process. Microsoft Excel used for all data analysis. Utility values obtained from the literature. Data on costs and effectiveness from the literature and from Peace Arch Hospital (a community hospital in White Rock British Columbia — used as source for cost of treating a hip fracture). Compliance in real life assumed to be similar to

	Type of Analysis	Population	RR of Hip Fracture	Details on Hip Protector Analyzed	Model and Assumptions
					compliance in the RCTs (24% to 48%). Costs reported in 2001 Canadian dollars. Cost per patient of acute hospital treatment of a hip fracture: $16,250. QALYs were discounted at 3% per year (lifetime horizon). Costs were not discounted, since they were only calculated over the first year of the model. Adverse events from treatment options in the trials required no treatment; therefore they were not included in the analysis. One-way and two-way sensitivity analyses on base-case clinical and economic assumptions. Probabilistic sensitivity analysis (stochastic variables included RR, cost of acute hospital treatment of hip fracture, baseline incidence of hip fracture).
Sawka *et al.*, 2007[44]	Cost analysis, third-party-payer perspective (Ontario Ministry of Health and Long-Term Care), one-year time horizon (rationale for time horizon — the trials were generally one year in duration and mortality rates in nursing homes are high so the benefit of any fracture	All Ontario nursing home residents 65 years of age and older	0.29 (95% CRI: 0.2 to 0.38) (strategy of hip protectors relative to no hip protector strategy)	Safehip® hip protector. Three sets of hip protectors per person per year. (Rationale: this number and brand were most commonly used in the RCTs.) $85 per hip protector, $255 per patient for hip protectors per year.	Cost analysis at a macro level analyzing potential cost implications of a strategy of providing hip protectors to all Ontario nursing home residents aged 65 and older. Data on costs were from the Ontario Case Costing project. Compliance and duration of daily wear of hip protectors assumed to be similar to that of the RCTs. Assumed annual incidence of hip fracture for nursing home residents =4.3% (note: this is several times higher than for community-dwelling population of similar age). Assumed a maximum of one hip fracture prevented per individual. Costs reported in 2003 Canadian dollars, except hip protectors (2006). Assumed 2003 and 2006 price of hip protectors the same, giving a conservative estimate of potential cost savings. Costs restricted to those of acute initial

	Type of Analysis	Population	RR of Hip Fracture	Details on Hip Protector Analyzed	Model and Assumptions
	prevention strategy should ideally be observed within a short time frame).				hospitalization [direct and indirect (overhead)] and physician billing for acute fracture care. Rationale for not including costs after initial acute hospitalization: these costs are not as clearly defined, generally they are not tracked by federal or provincial agencies, and they are sometimes privately funded. Cost per patient of acute treatment of a hip fracture: $11,160 (comprised of $10,193 for hospitalization and $967 for physician fees). No discounting, since one-year time horizon. Sensitivity analysis on the price of the hip protectors was done. Assumed hip protectors are generally applied by staff in nursing homes. Base-case analysis assumed no additional labour expenditures for application of hip protectors. However, when an additional labour cost for application of hip protectors was modelled it was unlikely that cost savings would be realized. Cost of help from nursing aid for one year for application and removal of hip protector: $413 (included for sensitivity analysis in the event this could not be accomplished by existing staff during the work day).

CI=confidence interval; QALYs=quality-adjusted life years; RCTs=randomized-controlled trials; RR=relative risk.