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Building a simple model of a complex intervention: using preliminary data to assess the likely effect of an intervention to reduce falls related injuries in older people

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Abstract

Interest in the evaluation of complex health care interventions is growing. We used quantitative modelling to examine the effectiveness, cost-effectiveness, strengths and weaknesses of a complex intervention designed to prevent injuries from falls amongst older people. The first model estimated the probability of falling over a 12-month period based on a decision tree analysis; the second model used a Markov simulation to look the impact of the programme over time. The model indicated that our intervention would reduce the proportion falling by only 3.8% over a 12-month period. The major reason for this small effect was that less than 13% of high risk of falling were assessed using our screening tool. Even if policy makers were willing to spend £25,000 per quality adjusted life year gained there was only a 12.9% chance that the intervention would be cost effective. Sensitivity analyses showed that the only scenarios which produce a substantial increase in the effect of the intervention were those in which all older people are assessed. The intervention is unlikely to be either effective or cost-effective due to its inability to reach those at high risk of falling. This information can be used to re-design the intervention, although in this case there were other reasons why the trial was no longer viable. This model building approach is useful when designing similar trials and in situations when a trial is not possible. If inability to reach the target group is a weakness common to other interventions, this suggests an area for further research.

Introduction

The effectiveness of interventions to improve the quality of health care and patient outcomes has been tested in randomised controlled trials of varying complexity [1; 2; 6], which have often been cluster randomised[1; 2; 5; 6]. It has been shown that the introduction of guidelines and various changes in organisation can bring positive benefits [8]. Results from some trials, however, have shown that the positive benefits of some interventions, particularly those aiming to affect whole communities, have been marginal[1]. It is important to understand why this may be so[11] and how trials, and the interventions tested in trials might be improved as a result.

We planned a pragmatic cluster randomised trial to test the implementation of an intervention at Primary Care Trust (PCT) level to prevent injuries from falls amongst older people[5]. The intervention involved the introduction of a facilitator into intervention PCTs to introduce a programme of falls risk assessment and referral. This involved enhancing existing referral systems, the establishment of a falls clinic if there was not one previously and the introduction of a specially designed tool for assessing older peoples for the risk of falling. Preliminary work for the trial was carried out in a single PCT. We use a model based on data from this preliminary work to look at the possible effects of the intervention we designed.

Modelling using the results of a trial, or qualitative work alongside a trial[2] have been used to improve understanding of the components of complex interventions. In recent years there has been increasing recognition that quantitative modelling work in advance of a trial can be used to inform the design of the trial itself (Campbell et al, 2000). The construction of a model can, for example,

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throw light on how effective different stages of the intervention might be, identifying weaker parts of the intervention and highlighting areas in which the intervention could be improved. The effectiveness of the trial intervention can be increased and ultimately patient outcomes can be improved. This is essential for implementation trials, such as ours, where the intervention is aimed at increasing the uptake of treatments or preventive measures with proven effectiveness; knowledge about ways of altering parts of the intervention to increase uptake is useful. Sensitivity analyses can also be performed to assess the effect of changing model parameters to reflect changes in the effectiveness of different stages of the intervention.

Increasingly, assessing the cost-effectiveness alongside the effectiveness of an intervention is an integral part of trials. A further reason for modelling prior to undertaking a trial is related to assessing cost- effectiveness. This assessment requires the building of a model based on data from the trial. Micro-level data on costs and transitions at each stage of the model are needed. Building a preliminary model in advance of a trial clarifies the data required for the model in the trial. In particular, it allows a consideration of the main elements which are driving the overall result, and how worthwhile it is to obtain more detailed information on different elements[3; 7]

In our case there was an additional reason for using data from our preliminary work to model our intervention effect. The National Service Framework (NSF) for older people was published shortly after we applied for funding. Some features that our trial was intended to test were contained in the framework. As a result it would have been virtually impossible to find an uncontaminated control group for our trial. Partly because of this, our trial was not funded. Without the main trial, our model provides the only estimates of the possible effectiveness and cost-effectiveness of our intervention. In the circumstances, it may also provide estimates of the effectiveness of some features of the NSF.

Using our preliminary models we therefore aimed to assess:

1) the effectiveness of different stages of implementation of the intervention
2) the likely over all effect of our intervention
3) the likely over all cost-effectiveness of the intervention and the main elements driving the overall result
4) how effective a range of interventions are predicted to be

In addition, we hoped that a description of the way in which we built our model might be a useful example for others thinking about trial design in similar circumstances. This paper therefore describes the construction of the model in some detail, as well as the results relevant to our four aims.

Method

The trial intervention

Our intervention was designed to reduce falling amongst older people. The focus of the intervention was on those at high risk of falling. We planned the intervention to last a year in the main trial, but only 6 months in the preliminary work. The main elements of the intervention were:

- A specially designed 2-page assessment tool (FRAT) which was designed to be used by a range of health professionals in a variety of settings ranging from GP surgeries to A&E departments and residential homes. This tool:

(a) assessed older people to be at high or low risk of falling using a number of criteria shown to be related to the risk of falling.
(b) made suggestions and recommendations for referral to various agencies including a falls clinic which was to be set up with the help of the facilitator where none existed.

- Appropriate referral or treatment was recommended for all those at high risk of falling who had risk factors that were modifiable. These factors were: history of falling in the previous year, four or more medications per day, balance and gait problems, postural hypertension, and vision problems.
- Enhanced referral systems set up or encouraged by the facilitator. Referrals could be made to a number of different services including a falls clinic, which was set up as part of the intervention. Alternatively the individual could be treated by the assessing service. Figure 1 shows the implementation strategy for falls prevention guidelines.

The models

Two separate but interrelated models were constructed. The first estimated the effectiveness of the intervention using a simple probability tree with transition probabilities. The second used Markov chain modelling to incorporate the estimated effectiveness of the intervention from model 1 into a full cost-effectiveness model which considered the likelihood of older people moving between various health states. This model used data on fractured femurs given these were the most likely and costly injuries attributed to falls and considered the long-term effect of the intervention. The second model links a number of states that older people can find themselves in, it cannot be represented in a linear form because individuals can move both ways between many of the states. This model was fitted with and without allowing for the effect of the intervention, and differences were taken between the two simulations to calculate the net benefit of the intervention.

Model 1- Probability tree for effectiveness of the intervention:
The model of intervention effectiveness was conceptualised as 5 stages corresponding to 5 transitions, starting with all older people and finishing with their chance of falling as shown in figure 2. Stages 1, 2 and 3 represent the major focus of our proposed trial intervention: the assessment of older people (age>65), the identification of those at high risk, and referral. Stage 4 represents the chance of being treated dependent on being assessed and/or referral, and stage 5 the effect of any treatment on the probability of falling in the next 12 months.

In order to build model 1 we ideally required:

- transitional probabilities for each stage of the model,
- an estimate of the numbers of those referred and treated following use of the FRAT who would have been referred and treated without our intervention

Model 2 – Markov model of long-term effectiveness and cost effectiveness of the intervention:
A Markov model is used to estimate long-term impact of the intervention for a hypothetical cohort of 1000 older people until their death. The model is used to estimate the different situations that older people are likely to find themselves each year. These situations are called Markov states and include whether an older person is at risk of falling, termed a faller, or if they have recently fallen and fractured etc. There are nine Markov states in the model that are used to capture key costs and utilities (see figure 3 and the assumptions in table 1). The states are assigned utilities based on the work by Salkeld et al (2000). Salkeld et al (2000) derives a utility for those at risk of falling and who have a fear of falling (0.67), a 'bad' hip fracture that results in the admission to a nursing home (0.05) and a 'good' hip fracture that results in the patient maintaining their independence and living in the community (0.31). Each year, there is a chance that an older person remains in the same state or moves to another state, determined by the Markov transitional probabilities. The

assumption is that the probability of transition from one state to another is independent of all previous states that an individual has been in. The arrows show the direction in which an older person can move between the states. The intervention affects two of the Markov transitional probabilities, which are shown by the dashed lines in figure 3. For instance, it reduces the risk of a faller in the community falling, with onward implications for the rate of fractures. The intervention also affects the assessment and referral costs. The model also captures the increasing chance that a person falls or dies as they age (Lord et al, 2001).

In order to build model 2 we ideally required:

- Markov transitional probabilities
- costs of assessment, referral and treatment
- quality of life of patients, termed utilities here.

Model outcomes:

The cost-effectiveness is estimated using a relatively new measure. The change in the costs and effects is usually estimated by the incremental cost effective ratio calculated as a change in the costs, ΔC, to the effects, ΔE. The intervention goes ahead if the ratio of the costs to the effects is lower than the cut off money that the government is willing to spend to achieve a given improvement in health, R, i.e. the intervention will go ahead if:

$$R > \frac{\Delta C}{\Delta E}$$

We use instead the net benefit measure, which based on a rearrangement of the cost effectiveness ratio, by setting R at a particular level. The intervention goes ahead if there are net benefits to implementation:

$$R\Delta E - \Delta C > 0$$

The net benefit measure is recommended instead of the cost effectiveness ratio since the interpretation of negative values of cost effectiveness ratios can be problematic in models[10].

Sensitivity analyses:

We also present summary results of sensitivity analyses that assess the effect of changing various transitional probabilities on the effectiveness of the intervention. Full cost-effectiveness models are not fitted for these analyses.

Data and assumptions

Data:

The data used in the models come from various sources. We conducted surveys amongst older people in the single PCT in which we carried out the preliminary work. The surveys included data on the numbers who had fallen in the past year, and the numbers categorised as high risk and low risk by the FRAT. At a service provider level, service use data were also collected on the number of assessments, duration of assessments and referrals made by different agencies, and whether the assessments resulted in individuals being categorised as high or low risk. The falls clinic accounts were part of this data, and collected start up costs, print costs and the cost of providing the falls clinic. Routine data on fracture rates were obtained from the public health common data set. Death rates, inclusive and exclusive of deaths attributable to accidental falls, were calculated using 2000 data provided by the Office of National Statistics. The number of older people in the PCT was obtained from the appropriate Health Authority. Routine data on wage costs of staff making the assessments were obtained from the Department of Health[9] and the wages of the fall facilitator were recorded in the project accounts. Falls literature provided us with estimates of the proportion

of good and bad hip fractures, the costs of fractures that arise from falls and the utilities associated with the different health states.

The sources of data for the various stages of the model are summarised in table 1. Tables 2 and 3 shows the data used to inform model 2 and records whether the uncertainty surrounding cost or treatment data is represented by values following a normal or log normal distribution.

Assumptions:
Also shown in table 1 are the assumptions that we used in the modelling. Some parts of the model rest much more heavily on assumptions than other parts. For, example, stage 4 of model 1 rests entirely on assumptions. There were no data available from our preliminary work to support or to counter these assumptions. In stages 1,2,3 we make assumptions about the completeness and accuracy of the data available to us, and extrapolate from it. Although differential rates of transition for different groups of individuals between some of the states seemed likely, where there was no clear evidence of these differential transitional probabilities we assumed that the probabilities were constant across different groups.

Most of the assumptions made in relation to model 1 are best case scenario assumptions. Altering these assumptions will result in the estimate of intervention effect being reduced. The exceptions are the assumptions that 50% of those assessed but not referred were treated, and that the intervention did not affect individuals that were not assessed. Sensitivity analyses were performed to assess the impact of changing some of these assumptions.

In the Markov model each cycle of the model is for one year (so we assess the impact of the FRAT at one year intervals) and the benefit arising in each year is calculating by counting those remaining in each state at the end of each year. To reflect the impact of time in the Markov model we have added the additional assumptions:

- transitions between the states occur halfway through each year. The aim of this assumption is to minimise measurement error since in reality transition between states occurs throughout the year. Sonnenberg and Beck (1993) referred to this adjustment as a half-cycle correction.
- costs and benefits arising in the future are given less weight to those occurring today. This reflects the notion that society would prefer to enjoy the savings and benefits now as opposed to later because they can benefit from these in the interim. The rate at which costs and benefits are discounted each year is 6% for costs and 2% for benefits (Gravelle et al, 2000).

Results

Figure 4 illustrates the impact that the intervention was shown to have upon the different 5 stages of model 1. The coloured boxes show the pathways for those where the falls rate is affected by the FRAT tool, and the corresponding transitional probabilities. Those in white boxes are unaffected. A striking feature of the model is that relatively few high or low risk fallers are assessed by the FRAT. This suggests that a weakness of the intervention was its inability to assess enough fallers. This was a community level intervention. At the inception we were concerned with the duplication of assessment that the FRAT might create, and we have assumed the best case scenario, where each assessment is for a unique faller. Despite this, service data show that the breadth of coverage was low.

The model was also used to predict the impact that the FRAT had upon the proportion of older people falling in a one-year period. The model predicted that the FRAT reduced falls from 25% to 24.04%. The proportionate reduction in falls is 3.8% (1-(24.04/25)). Given the lack of data

available on the relationship between falls and fractures, our model predicts the same proportionate fall in fractures.

The incremental net benefit was calculated by comparing the net benefit of the intervention against the net benefit where no intervention is used. For this calculation it is necessary to assign a cut-off value that policy makers are willing to spend per quality adjusted life year. Figure 5 shows the probability that the incremental net benefit is positive for different cut-off values. This shows that even if policy makers were willing to spend £25,000 per quality adjusted life year gained the probability that the falls programme was cost effective would be only 0.129.

Because the effect of our intervention appeared extremely small we restricted our sensitivity analyses to consider only scenarios where the impact of the intervention was enhanced. Three possibilities were considered:

- an increase in the numbers of older people being assessed
- an increase in the proportion of older people (identified as high risk) being treated
- an increase in both the numbers being assessed and the proportion being treated

We considered both moderate increases in the numbers being assessed and treated and the maximum possible increase to 100% of older people being assessed and 100% of those identified as high risk being treated. Thus 8 sensitivity analyses were performed. The sensitivity analysis showed that, given the tool that we used to assess, the only scenarios which produce a substantial increase in the effect of the intervention are those in which all older people are assessed.

Discussion

Previous evaluation of falls assessment tools has demonstrated a much larger reduction in the risk of falls compared to the 3.8% reduction in falls found here. For instance, the Cochrane Evaluation meta-analysis of screening/intervention programmes found these reduced falls by 27% (Gillespie et al, 2002). The likely explanation for the difference is that the intervention was implemented at a community level, whereas the others were not, and the effectiveness of falls assessment tools are likely to be diluted in a community setting. In addition, though the tool is relatively quite cheap to administer, cost effectiveness analysis has showed that the intervention is also unlikely to be cost effective in its present form. The need to reach a greater number of older people suggests the effectiveness could be improved if the interventions includes a health promotion campaign to encourage older people to self refer for assessment. The NSF guidelines given greater emphasis to health promotion, and this is likely to affect the ability to reach high risk groups.

One of the strengths of the modelling exercise was that we had sufficient data to assess the impact and cost effectiveness of the pilot. Much of the data was obtained directly from the preliminary work. This included a community survey, which was designed initially to provide information on service use, quality of life, and fear of falling. In this survey we also included the FRAT tool, which allowed us to measure the number of high and low risk fallers that the FRAT would identify in the community. Observing the number of high risk and low risk fallers in the survey allowed us to link this data with the number of high and low risk that were assessed and referred in the routine data. In addition, the survey made observations upon the same individuals over time, to create a panel data set, to mimic the notion of cohort analysis. The study was therefore able to observe *changes* in the use of services and quality of life from the same individuals for the economic evaluation[4]. Preliminary analysis provided some data on the referral pathways, to allow us to begin to identify the weakest links in the referral chain e.g. between falls and fractures. Finally, an attempt was made to model the variation in cost and effect data in the Markov model by creating a

distribution of values around key variables based on the standard deviation reported in the falls literature or assumptions about the relative size of this standard deviation.

Nevertheless we are aware that the data had limitations. The study contained no control group and so could not give an accurate estimate of change. As a consequence, we do not know if the intervention simply substituted for existing services, rather than enhancing service. Although this is a problem in the pilot, it could also be problem in a study with a control because it is hard to monitor micro level cost data in control sites from routine sources. This suggests the usefulness of baseline data from referral services as a pseudo-control in the piloting stages, and the need to think carefully about systems to record process data in the control sites by small observational studies. The study also did not collect detailed disaggregated assessment and referral data. If we were to repeat the exercise, we would aim to get more detailed data on the numbers assessed and referred from different providers, like district nurses, and the falls clinic itself. In addition, we would aim to link the primary outcome (fractures) with the intervention, i.e. the link between high risk fallers and fractures, by collecting fracture data in the community survey. The study was also restricted by the time interval used in the data collection. In our study, the main data collection was over a 6 months period, since the community surveys were six months apart. Though a shorter or longer period could be used in the Markov model, the conclusions that can be drawn from this are restricted to some degree since the estimates of effectiveness are based on this 6 months period. In our case, the Markov model considered annual costs and benefits because this was the average recovery period after a hip fracture, and most of the literature reported annual data. Though there were felt to be no need to consider differential assessment or referral rates over the life of the intervention in this study, this may become more important to assess if the programme includes health promotion campaigns whose effects diminish over time. The other limitations of the study relate to the sub hypotheses that would be useful to consider in further falls studies. For instance, it would have been useful to focus upon easily identifiable high risk groups, e.g. those living in homes, to evaluate why the assessment of high risk groups was low. Finally, we do not have data on whether those that were not assessed were affected. The model could be expanded to consider these indirect impacts, but one of the challenges would be to measure these indirect effects accurately.

It would have been useful to conceptualise the model at an even earlier stage to help inform the types of data that would be required to evaluate the programme. We spent some time thinking about patterns of care at the beginning, mainly to think about implementation rather than evaluation. A model would have provided a framework for the evaluation by monitoring where data is likely to be obtained and by assessing the likely data quality up front, as we do in table 1. This exercise would also provide a check of the validity of referral impact that the FRAT assumed and the possible sources of uncertainty. This process would have helped to identify at an early stage that most studies looked at the impact on falls, without questioning the impact that falls reduction has on fracture reduction. In addition, the uncertainty surrounding the number of risk factors that define a high risk faller could have been more closely checked in the routine data. The community survey results showed that the sensitivity of the FRAT could be increased from 0.42 to 0.59 (and specificity would fall from 0.92 to 0.79) by changing the definition of high risk groups to those with 2 or more risk factors. However, the impact that this would have on the number of those that were assessed and referred was not monitored in the service use data.

The paper has demonstrated the usefulness of modelling techniques in the early stages of developing a complex intervention. If as the model suggested, a particular weakness of community programmes is their ability to reach target groups, an early realisation of this would inform the design the intervention and its assessment strategy. In our case, incorporating a health promotion campaign or monitoring the effect of changing the sensitivity and specificity of the FRAT tool.

There is the potential for these methods to influence the design of future trials in other ways. For example, future trials could be used to focus upon process measures alone, if the impact of these process measures on final outcomes is known from the literature and can be captured by a model. The methods outlined here could also avoid the need to conduct a trial in some situations, if the basic relationships remain the same, but the baseline figures have changed.

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Sonnenberg F.A., Beck, J.R. Markov models in medical decision making: a practical guide. *Medical Decision Making* 1993; 13:322-338.

Figure 1. Implementation strategy for falls prevention guidelines

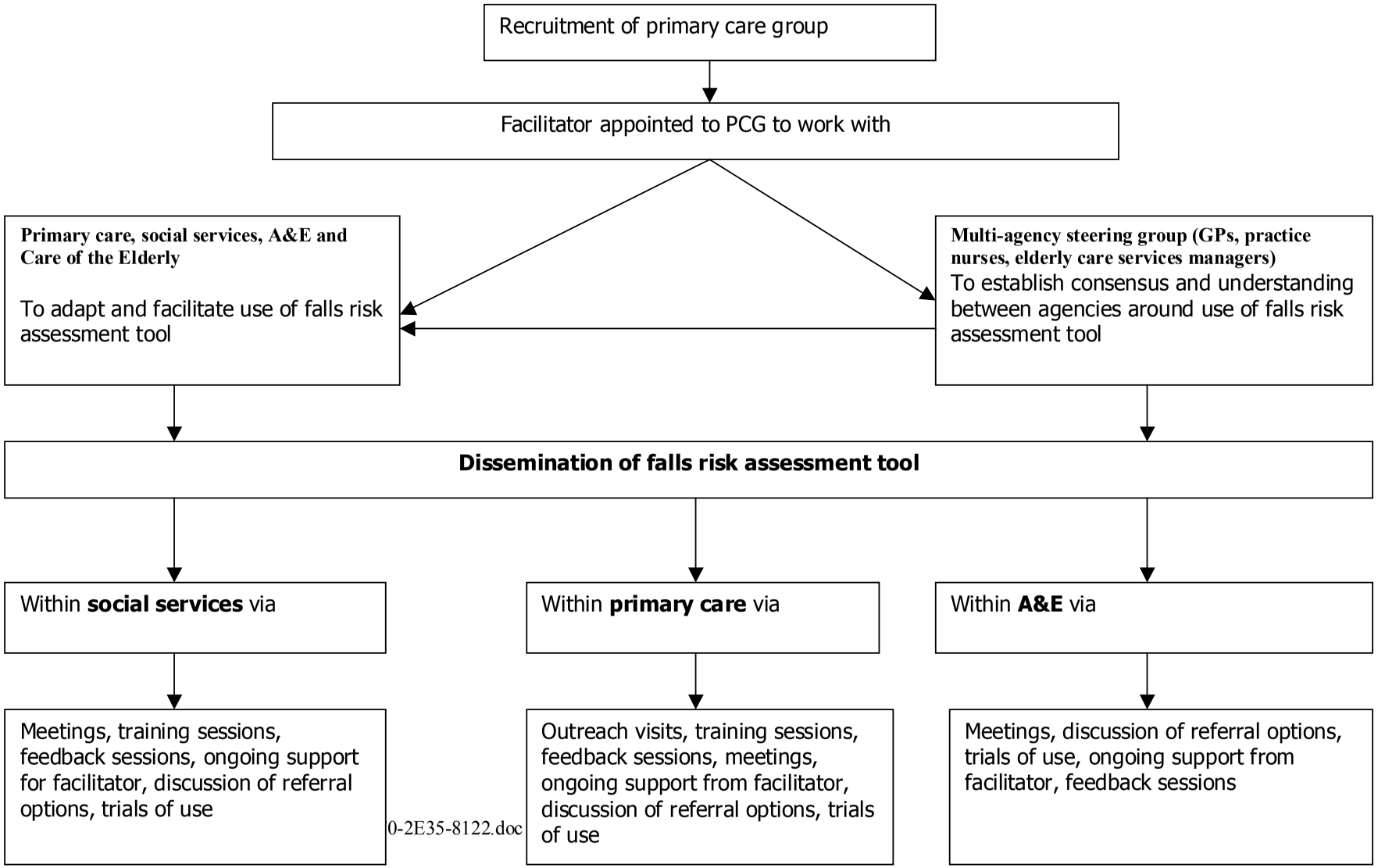

Figure 2. Overview of model 1

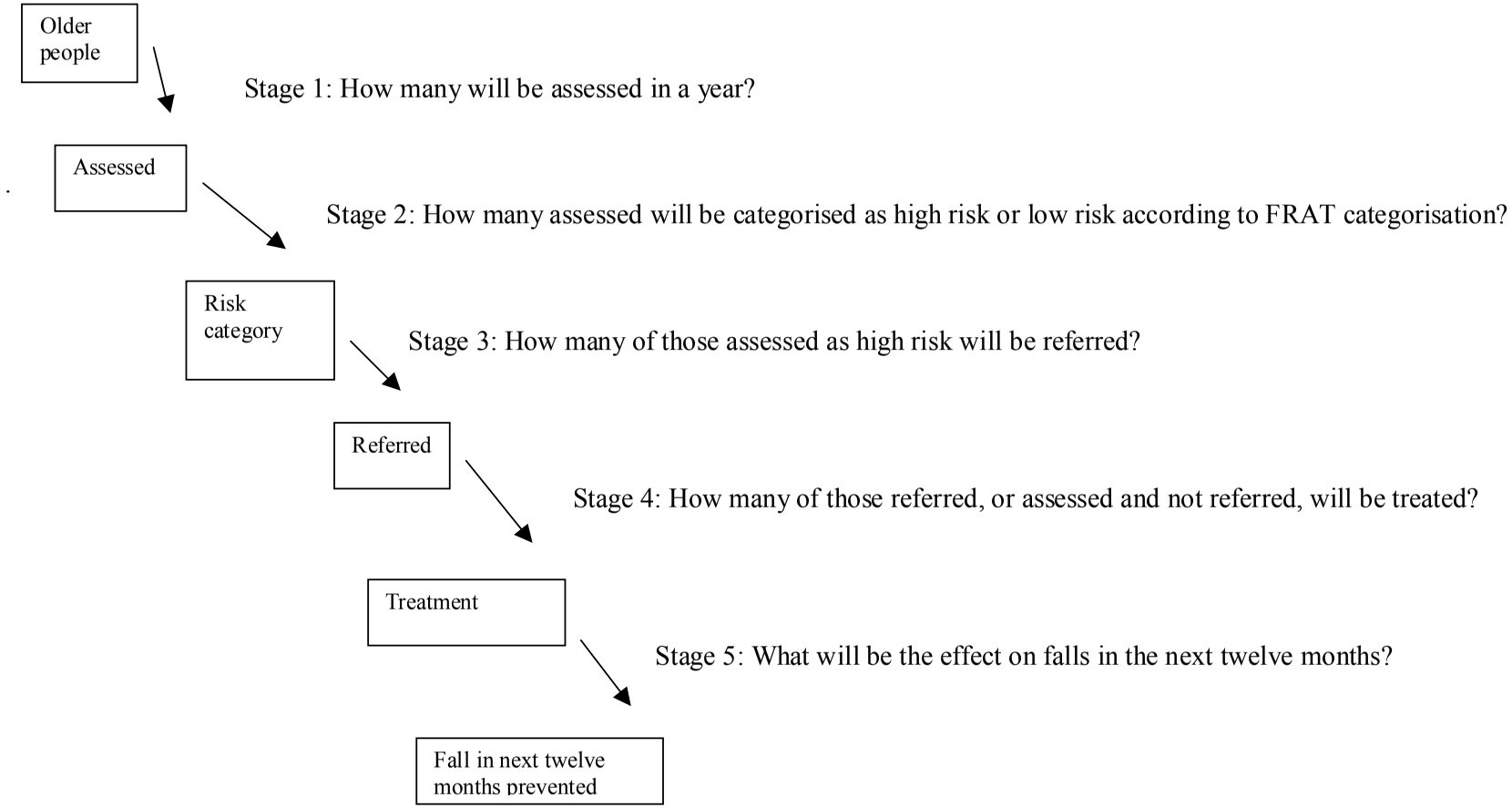

Figure 3. Overview of model 2

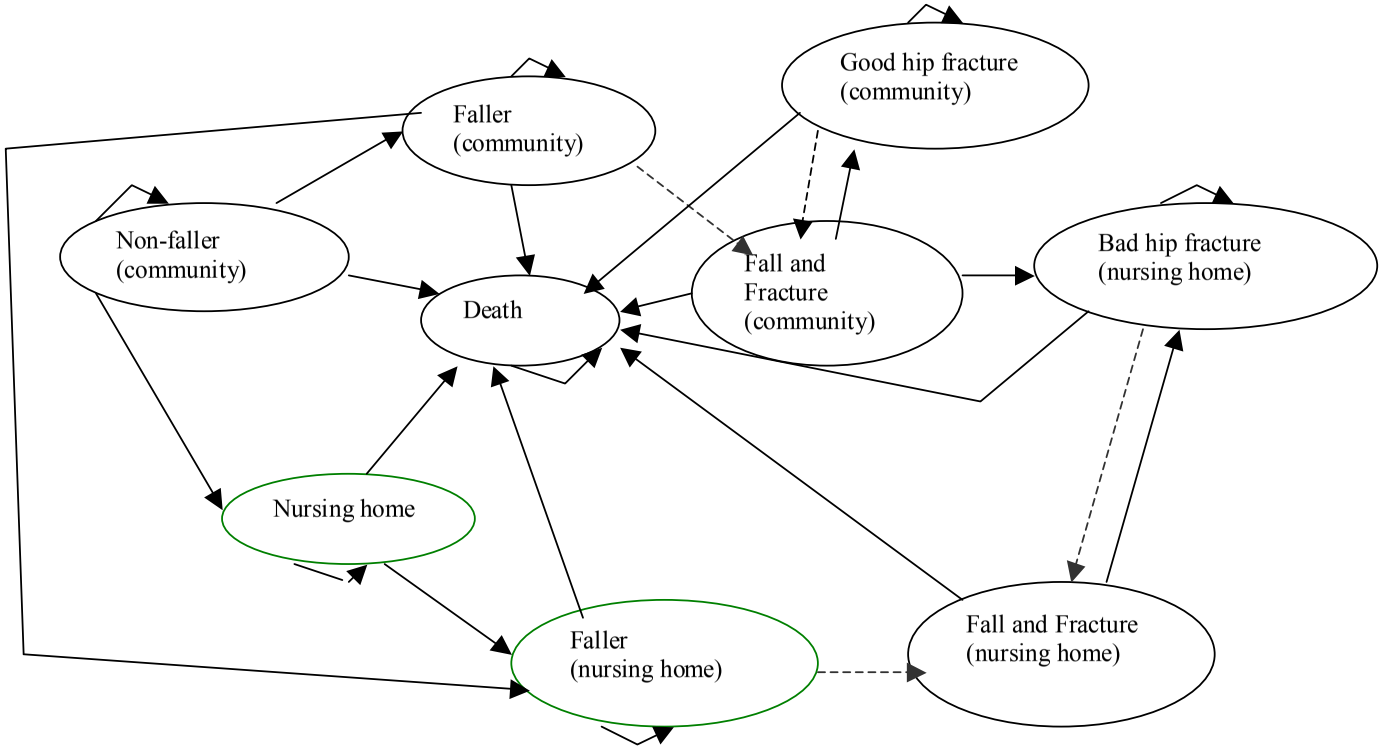

Figure 5. Cost effectiveness results

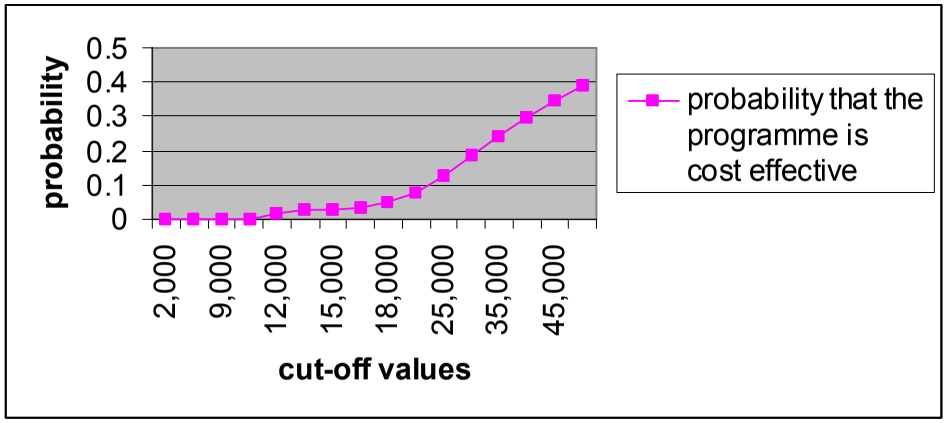

Table1: Data and assumptions

	Literature review	Survey	Service use data	Routine data	Assumptions
Model 1, stage 1,2,3: assessment, risk categorisation, referral			X	X	- twice as many people would be assessed in a year as in 6 months - none of those assessed, referred and treated using the FRAT would have been treated otherwise - each assessment/ referral made was on a separate individual - the effect of the intervention outside the FRAT was negligible i.e. that, for example, the intervention did not make GPs more likely to treat older individuals that were not assessed - only high risk patients are referred
Model 1, stage 4: treatment					- all those referred on from the assessing service received treatment - 50% of those not referred on from the assessing service received treatment
Model 1, stage 5: fall in next twelve months	X	X			- the effect of treatment is to reduce risk of falling on average by 38% during the subsequent year
Model 2, transition to and from fractures	X			X	- the transitional probability that a person will fall and fracture is the same for people living in the community and nursing home, and for people who have experienced a good or bad fracture - the transitional probability from non-faller to nursing home is assumed to be 0.01, with a standard deviation of 0.02. - the transitional probability from faller in the community to faller in a nursing home is assumed to be 0.022. - the standard deviations for the treatment effect of the FRAT and the transitional probability from non-faller to faller are 1/2 the mean values
Model 2, costs	X		X	X	- the costs of treating a fracture are for one year only, with subsequent costs dependent upon whether the fracture is classified as a good or bad hip fracture - the assessment costs are proportional to the numbers assessed and are the same for those residing in the community or nursing home - the referral costs include the falls clinic costs and 10% of an occupational therapists whole time equivalent - the direct medical costs and community care costs have standard deviations that are 3/4 the mean values
Model 2, utilities	X				- the utility assigned to the fear of falling and fracture is based on the study by Salkeld et al (2000). A utility of 1 is assigned to non-fallers and those living in nursing homes; 0.67 to a fallers in the community and fallers in the nursing home; 0.31 for an initial fracture in the community and a good hip fracture; 0.05 for an initial fracture in the nursing home and a bad hip fracture. Death is assigned a utility of zero.

Table 2

Cost	Value		Distribution	Standard Deviation
Direct Medical costs				
fracture		£13,000	Log-Normal	£9,750
Community care cost				
Cost of well		£0		
Cost of fall and fear falling		£53	Log-Normal	£39
Cost of nursing home		£20,000	Log-Normal	£15,000
Costs of FRAT				
Start up costs, first year only		£660		
Facilitator		£23,979		
Printing		£108		
Falls clinic		£34,764		
Occupational therapist		£3,335		
Total fixed costs FRAT per year		£62,187		
Cost of a good fracture		£5,000		
Cost of a bad fracture		£6,000		
Assessment costs	*time in min*		cost min	cost per staff
GP		*2*	£2.18	£4.36
Practice Nurse		*2*	£0.59	£1.18
District Nurse		10	£0.59	£5.90
A&E staff		2	£0.59	£1.18
			average	£3.16

Utilities

(source: Salkeld et al, BMJ 2000)

State	Value		Distribution	Standard Deviation
Well		1	Normal	0.2
Fall and fear falling		0.67	Normal	0.2
Good hip fracture		0.31	Normal	0.2
Bad hip fracture		0.05	Normal	0.2

Other parameters

Parameter	Value			Standard Deviation
Treatment effect risk reduction		0.038	Normal	0.19
Annual discount rate - costs (%)		6%		
Annual discount rate - benefits (%)		2%		

Table 3

Markov transition probabilities	ages				
	65-74	75-84	85+	Distribution	Standard Deviation
non-faller to non-faller	*0.945*	*0.918*	*0.833*		
non-faller to faller	0.022	0.0133	0.0133	normal	0.011, 0.006, 0.006
non-faller to nursing home	0.01	0.01	0.01	normal	0.02
non-faller to death	0.023	0.059	0.144		
faller to faller	*0.905*	*0.869*	*0.784*		
faller to faller nursing home	0.022	0.022	0.022		
faller to fracture	0.04	0.04	0.04		
faller to death	0.033	0.069	0.154		
fracture to good fracture	*0.547*	*0.511*	*0.426*		
fracture to bad fracture	0.26	0.26	0.26		
fracture to death	0.193	0.229	0.314		
Good fracture to good fracture	*0.955*	*0.919*	*0.834*		
Good fracture to fall & fracture in community	0.022	0.022	0.022		
Good fracture to death	0.023	0.059	0.144		
Bad fracture to bad fracture	*0.955*	*0.919*	*0.834*		
Bad fracture to fall & frat in nursing home	0.022	0.022	0.022		
Bad fracture to death	0.023	0.059	0.144		
fracture nursing home to bad fracture	*0.807*	*0.771*	*0.686*		
fracture nursing home to death	0.193	0.229	0.314		
faller nursing home to fracture nursing home	0.022	0.022	0.022		
faller nursing home to faller nursing home	*0.955*	*0.919*	*0.834*		
faller nursing home to death	0.023	0.059	0.144		
nursing home to faller nursing home	0.200	0.200	0.200		
nursing home to nursing home	*0.777*	*0.741*	*0.656*		
nursing home to death	0.023	0.059	0.144		
death to death	1	1	1		

Figure 4. Model 1