A FRAMEWORK FOR CONDUCTING ECONOMIC EVALUATIONS WHEN USING PATIENT DECISION AIDS IN HEALTH CARE DECISION MAKING

2015
Report 049

Authors: Ara R\textsuperscript{1}, Brazier JE\textsuperscript{1}, Sculpher M\textsuperscript{2}, Manca A\textsuperscript{2}, Bjoke L\textsuperscript{2}, Preston L\textsuperscript{1}, Basarir H\textsuperscript{3}

\textsuperscript{1} ScHARR, The University of Sheffield
\textsuperscript{2} Centre for Health Economics, University of York
\textsuperscript{3} Health Economics Unit, University of Birmingham
The Policy Research Unit in Economic Evaluation of Health and Care interventions is funded by the Department of Health Policy Research Programme. It is a collaboration between researchers from the University of Sheffield and the University of York.

The Department of Health’s Policy Research Unit in Economic Evaluation of Health and Care Interventions is a 5 year programme of work that started in January 2011. The unit is led by Professor John Brazier (Director, University of Sheffield) and Professor Mark Sculpher (Deputy Director, University of York) with the aim of assisting policy makers in the Department of Health to improve the allocation of resources in health and social care.

This is an independent report commissioned and funded by the Policy Research Programme in the Department of Health. The views expressed are not necessarily those of the Department.
EXECUTIVE SUMMARY

Objective
The objective of the research described in this report was to develop a framework to evaluate the economics associated with the use of patient decision aids (PDA) used within a shared decision making (SDM) process.

Methods
A systematic review of existing economic evaluations of PDAs, and a literature review of systematic reviews of PDAs were undertaken. Studies identified were summarised, outcomes extracted and tabulated, and a thematic analysis was conducted to identify main patterns and themes that emerged from the data extracted from the reviews. Input and opinions of specialist experts in the field of PDAs and SDM were obtained during an interactive workshop. The results generated from these three pieces of work were used to inform and develop a conceptual framework for economic evaluations of PDAs used in a SDM process.

Results
Literature reviews: Just five existing economic evaluations of PDAs were identified. The PDAs evaluated were used in a variety of conditions covering either primary or secondary care, with 4 evaluations set in the UK and 1 in Finland. The main limitations of the existing evaluations were the short time horizons (maximum 2 years), the outcomes reported (only one presented a formal incremental cost per quality adjusted life year (QALY)), and the restricted focus within the evaluation (i.e. the effects of patient satisfaction or preferences on health related quality of life were not incorporated).

A review (2014) including 115 studies of RCTs of PDAs (compared to usual care and/or alternative interventions) was used as the basis for the second review. The main outcomes assessed included the attributes of choices made and the attributes of the decision-making process. Secondary outcomes included behavioural, health outcomes, and health-system effects. The RCTs covered decisions ranging from screening through treatment and surgery, and predominantly related to prostate cancer screening (n=15), colon cancer screening (n=10), or hormone replacement therapy (n=10). In summary, comparing the use of PDAs to usual care, PDAs improved people’s knowledge of the options available, reduced decisional conflict relating to feeling uninformed, and reduced the proportion of people who were unclear about their personal values. PDAs stimulated people to take a more active role in decision making and improved congruence between patient’s values and the
option chosen. PDAs had a more variable effect on the consultation time and the choice of intervention, and did not appear to have any adverse effect on either health outcomes or satisfaction. However, there was insufficient evidence to determine the effects of PDAs on patient-practitioner communication, adherence with the chosen option or the costs and resource use.

Workshop: The main messages emerging from the workshop suggested the following concepts were worthy of consideration: the ‘quality’ of the treatment decision; both health and non-health benefits of PDAs; the potential inability of a single generic measure capturing all benefits; process outcomes and non-tangible effects (increase in dignity, or increase in anxiety); the similarity of SDM and a basic standard of care; conflicts with the QALY maximisation model in terms of individual’s preferences; and finally, the possible reduction in efficiency and potential trading of non-health benefits and QALYs to utilise the current standard framework.

Conceptual framework: PDAs may impact on processes, outcomes and costs. While the reviews provided clear evidence on improvements of patients’ knowledge of the outcomes of alternative interventions, and providers’ understanding of the preferences and values of patients, the evidence was more mixed for patient satisfaction, health outcomes, resource use and cost impact. The literature suggested little or no health benefits from PDAs with the main benefits likely to arise from non-health effects such as reduced decisional conflict and satisfaction with the decision making process. These require quantifying in terms of equivalent lost benefits from displaced activities in the NHS due to any additional costs imposed by PDAs. In addition to non-health effects, the current QALY model makes assumptions about people’s preferences for health over time and uncertainty, and health states are usually valued using general population valuation preferences rather than patients. Any deviations in patient preferences from these assumptions may result in patients making choices that are not considered cost-effective under the QALY framework.

Conclusion/Summation: The implications for economic evaluations of PDAs within SDM is that the framework needs to be extended beyond health to better incorporate what matters to patients, but this raises important normative concerns and conflicts with the current aim of cost-effectiveness analysis to maximise health measured through the QALY. We have provided a framework for extending economic evaluation and the types of data to be collected, but further research is required in order develop methods for putting it into practice.
## CONTENTS

Executive Summary

1. Introduction  
   6

2. Objective  
   7

3. Economic Evaluation  
   8
   3.1 Current approach  
   8
   3.2 Challenges of conducting economic evaluations of PDAs  
   9

4. Systematic Review of Economic Evaluations of PDAs  
   9
   4.1 Search methodology for economic evaluations of PDAs  
   10
   4.2 Inclusion criteria for economic evaluations of PDAs  
   10
   4.3 Data extraction for economic evaluations of PDAs  
   10
   4.4 Characteristics of studies of economic evaluations of PDAs  
   10
   4.5 Synopsis of studies of economic evaluations of PDAs  
   11
   4.6 Reported outcomes and resource use in studies of economic evaluations of PDAs  
   13
   4.7 Reported results in studies of economic evaluations of PDAs  
   14
   4.8 Limitations of economic evaluations of PDAs used in SDM process  
   16

5. Literature Review of Systematic Reviews of PDAs  
   17
   5.1 Search methods  
   17
   5.2 Studies included  
   17
   5.3 Types of outcomes assessed or reviewed  
   17
   5.4 Results of the Cochrane Review  
   18
   5.5 Author’s conclusions from the Cochrane Review  
   21

6. Workshop Involving Experts in the Field of PDAs and SDM  
   26
   6.1 Structure of workshop  
   26
   6.2 Main themes emerging from workshop  
   26

7. A Conceptual Framework for Economic Evaluations of PDAs used in SDM  
   27
   7.1 A pathway of the impact of PDAs  
   27
   7.2 Normative issues  
   28
   7.3 Valuing non-health benefits  
   29

8. Implications for the Design of Economic Evaluations of PDAs  
   30

9. Conclusions  
   31
TABLES
Table 1  Main characteristics of the five studies for economic evaluations of PDAs  12
Table 2  Outcomes and resource use collected and reported for economic evaluations of PDAs  13
Table 3  Main results reported in the economic evaluations of PDAs  15
Table 4  The impact of PDAs  31

FIGURES
Figure 1  Impact of PDAs  28

ACRONYMS
AQuA  Advanced Quality Alliance
DSI  Decision support interventions
HRQoL  Health related quality of life
ICER  Incremental cost-effectiveness ratio
NICE  National Institute for Health and Care Excellence
OR  Odds ratio
PDA  Patient decision aid
QALY  Quality adjusted life year
RCT  Randomised controlled trial
RR  Relative risk
SDM  Shared decision making
1. INTRODUCTION

There has been a concern that medical decision making has not sufficiently incorporated the individual circumstances and concerns of patients. This has led to the development over the last 20 years of a shared approach to decision making that involves both the clinician and the patient equally. The process of Shared Decision Making (SDM) has been defined as:

‘...a process in which clinicians and patients work together to select tests, treatments, management or support packages, based on clinical evidence and the patient’s informed preferences. It involves the provision of evidence-based information about options, outcomes and uncertainties, together with decision support counselling and a system for recording and implementing patients’ informed preferences.’[6]

Patient Decision Aids (PDA) are a technology designed to promote the SDM process and to help patients make more informed choices and decisions relating to treatment options which are appropriate for them. They help patients bring aspects of their own circumstances and values that may otherwise be overlooked by a centralised (or clinician led) decision making process with a consequent potential for improvement in the outcomes of care. PDAs are defined as:

‘interventions designed to help people make specific, deliberative choices by providing information about the options and outcomes that are relevant to a patient’s health status and by clarifying personal values. They are intended as adjuncts to counselling.’[6]

There is currently a strong Government commitment to SDM in the UK, with a move away from the standard paternalistic approach to healthcare and a move towards a paradigm whereby there is ‘no decision about me, without me’. [8] Recent initiatives in this area includes the development of a programme to develop 37 PDAs for both treatment and screening decisions in a broad range of clinical areas including: cardiovascular, dermatology, diabetics, gynaecology, mental health, obstetrics, oncology, ophthalmology, orthopaedics, nephrology, respiratory, rheumatology, and urology.[18] Furthermore, almost three quarters (14/20) of the National Institute for Health and Care Excellence (NICE) clinical guidelines published in the previous 12 months (May 2012 to June 2013), had at least one explicit recommendation relating to patient (family or carer) involvement in the treatment decision making process, or SDM was inferred through recommendations such as
‘take account of patient’s preferences’. In addition, the current NICE quality standard on patient experience in adult NHS services in England includes the quality statement:

‘Patients are actively involved in shared decision making and supported by healthcare professionals to make fully informed choices about investigations, treatment and care that reflect what is important to them.’[19;20]

While preliminary results of initial evaluations of PDAs are beginning to emerge,[5;21] there is limited evidence describing the associated potential benefits and costs of SDM. Recommendations proposed by CAPITA to support the use of SDM in mainstream clinical practice included the suggestion of using existing national surveys (such as the Inpatient, Outpatient, and GP patient survey) and surveys of PDA users and PROMS to explore reactions to PDAs, and to collect outcomes such as patients’ reactions (feelings of involvement and satisfaction) to SDM, the impact and costs relating to treatment uptake and adherence, and clinicians’ perceptions, levels of involvement and training needs.[4] However, there has been no formal economic evaluation of the new PDA programme. In the current economic climate, given the budgetary constraints and ever increasing demands on healthcare resources, SDM can only be considered good value if its benefits are greater than those forgone due to services being displaced in response to any additional resources required to provide SDM. The aim of the project reported here was to examine the challenges in evaluating the cost-effectiveness of PDAs used in SDM and to develop a conceptual framework for evaluation. It is acknowledged that the concept of SDM is broader than the use of PDAs, however, for the context of the current research, the remit is limited to the effects of PDAs within the SDM process as dictated by the policy question being addressed.

2. OBJECTIVE

This project was commissioned by the DH under the EEPRU programme of work with the objective of developing a conceptual framework for economic evaluations of PDAs used in a SDM process to inform a number of case studies. The research conducted to inform the framework consists of:

a) a systematic review of economic evaluations of PDAs
b) a literature review of systematic reviews of PDAs or SDM
c) a workshop involving experts in the field of PDAs and SDM

1 Three of the guidelines which did not include a recommendation were in indications where a SDM process was not applicable due to the need for immediate or emergency clinical decisions and actions.
The report is organised as follows. Section 3 provides an overview of the current approaches to economic evaluation and some of the challenges of conducting economic evaluations of PDAs. Sections 4 and 5 describe the methods and results of the systematic review of economic evaluations of PDAs and the literature review of systematic reviews of PDAs or SDM, respectively. Section 6 describes the outcomes generated from the workshop involving experts in the field of PDAs and SDM, and Section 7 provides the proposed conceptual framework. The final section examines the implications for the design of economic evaluations of PDAs.

3. ECONOMIC EVALUATION

3.1 Current Approach

In publicly funded budget constrained healthcare systems, the standard cost-effective framework seeks to determine if the benefits gained from a new health care intervention are greater than the benefits foregone from the interventions displaced to make way for any additional costs for the new intervention. Health Technology Assessments (HTA) commonly use a standard health maximisation criterion that describes the ‘benefits’ as ‘health’ hence examines if the health gained from the new intervention is greater than the health foregone from the interventions displaced.

In the UK, for example, NICE use the quality adjusted life year (QALY) maximisation criterion to assess new interventions. QALYs are a measure of health that combine duration and health related quality of life, by assigning a value anchored on a scale where 1 is full health and zero is for states as bad as being dead. Under QALY maximisation, interventions are deemed to be cost-effective if they fall below NICE’s threshold of £20,000-£30,000 per QALY, which represents the loss in QALYs from services displaced in the NHS where additional costs are imposed on the budget. In this framework, ‘health’ is quantified in terms of both the quality and quantity of life gained and foregone by the new and displaced treatments. The use of the QALY is advocated by NICE as this metric facilitates comparison across disparate health conditions and interventions.

The preferred measure of health by NICE is currently the EQ-5D. The EQ-5D is a generic quality of life instrument which asks patients if they have any problems with the following dimensions of health: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each of the five questions has three possible responses leading to a total of 243 (3^5) possible health states. The ‘tariff’ of preference weights for the 243 health states was based on valuations for a subset of 42
health states, where the weights were elicited using the time trade-off method from a random sample (n=2997) of the UK general population. The application of the tariff to the responses to the five questions produces an overall mean index of preference-weighted health state utility values which can be used to weight the quality of survival in economic evaluations.

3.2 Challenges of Conducting Economic Evaluations of PDAs

Assessments of the cost-effectiveness of numerous interventions including therapeutics, diagnostics, care, service and delivery are typically based on average outcomes and costs for a given group of patients using QALYs to estimate the benefit. While it is theoretically possible to use this framework to evaluate the cost-effectiveness of PDAs used in SDM, there are a number of challenges including the use of societal valuation of health and the QALY model of preferences. Patients have been shown in many situations to have different preferences for health to the public across the dimensions of health and health related quality of life and survival (see Section 5). Furthermore, patients have been shown to have preferences over profiles of health that differ from the QALY model of preferences.

The use of QALYs will also ignore the potential non-health ‘benefits’ which are advocated as fundamental components of SDM. For example, one of the core principles of SDM is to help informed patients express their preferences and views on their choice of treatment with the objective of respecting “what matters most” to the individual patient.[10] This is in direct opposition with the current QALY maximisation model which favours the use of societal preference to value health benefits, rather than the individual patient preferences. Treatment options are informed by NICE Guidance based on the incremental cost-effectiveness ratio (ICER) threshold which maximises societal net health benefit, and treatment decisions (within the treatments deemed cost effective) are made by clinical judgement (informed by clinical assessment of a patient’s characteristics with minimal input from the patient). The use of PDAs and SDM has the potential to move treatment decisions closer towards maximising patients’ perceived benefits (i.e. beyond the QALY), although the realisation of this potential may require some fundamental changes to the normative framework underpinning the use of health economic evaluation for resource allocation decisions. The next section in this report examines how previous economic evaluations of PDAs have dealt with these challenges (if at all).
4. SYSTEMATIC REVIEW OF ECONOMIC EVALUATIONS OF PDAs

The main objective of this review was to examine how economic evaluations of PDAs have dealt with the challenges identified above. It does not formally assess the quality of the studies and the specific results are of secondary importance for this review.

4.1 Search Methodology for Economic Evaluations of PDAs

In order to identify references for this review in a timely and efficient manner, an iterative search was undertaken. Rather than assuming that an initial database search is the most efficient way to identify evidence, this approach allows the systematic reviewer and information specialist to work together to develop an understanding of the topic area. This feature helps to ensure that searches are relevant and specific to identify key evidence for the review.

A number of small and targeted searches were undertaken in order to develop our understanding of economic evaluations of PDAs. Methods adopted included searches of key websites, including the Department of Health, Capita, the NHS, and focussed Google searches. Liaison with topic experts had identified two key systematic reviews,[7;25] as well as several individual articles. These reviews and articles were examined in order to identify specific papers relating to economic evaluations of PDAs and also to harvest terms to develop database searches for economic evaluations of PDAs. As a result of these initial searches, a focussed database search was undertaken in Medline and Embase (see Appendix 1). Citation searches of all relevant papers identified were undertaken in Web of Science and this was a key element of the search process.

4.2 Inclusion Criteria for Economic Evaluations of PDAs

Studies were included if they assessed both the costs and benefits associated with any SDM process involving PDAs in any indication or setting. Studies were excluded if they reported just the costs or just the effects associated with the SDM process. Studies which specifically looked at heterogeneity in patient preferences related to quality of life measures, without a SDM process involving a PDA, were excluded.

4.3 Data Extraction for Economic Evaluations of PDAs

A tailored data extraction form was developed to summarise the key variables of interest. Of particular methodological interest were any deviations from (or similarities with) variables or methods used in standard cost-effectiveness evaluations.
4.4 Characteristics of Studies of Economic Evaluations of PDAs

Of the 679 initial hits, six studies satisfied the inclusion criteria and reported both costs and benefits associated with a PDA used in the context of SDM. As two of the six studies described results from the same clinical trial,[14;15] only the latest publication, which reported a formal ICER,[14] was included in this review. All five studies were conducted alongside randomized clinical trials examining the effects of PDAs, with just one presenting results in terms of the incremental cost per QALY.[14] Four were set in the UK and took a NHS perspective;[13;14;16;17], the fifth was set in Finland and included direct healthcare costs, costs to the patient, and productivity losses.[26] Two of the studies examined the effects of PDAs for primary care treatment decisions (prostatic hypertrophy,[16] hormone replacement therapy,[17] while three examined the effects of PDAs for secondary care treatment decisions (uncomplicated menorrhagia,[14;26] or mode of delivery after previous Caesarean section[13]).

4.5 Synopsis of Studies of Economic Evaluations of PDAs

All five studies examined the effects of SDM using a condition specific PDA compared to usual care (Table 1). The PDAs were delivered using a variety of mediums ranging from a 25 page booklet posted prior to the initial consultation,[26] to a booklet and complementary video program supplemented with a face to face home consultation to elicit preferences.[14] All PDAs provided details of possible treatment options with corresponding benefits and risks.
Table 1: Main characteristics of the five studies for economic evaluations of PDAs

<table>
<thead>
<tr>
<th>Study</th>
<th>Setting (Perspective)</th>
<th>Indication</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Treatment options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Murray (2001a)[16], RCT</td>
<td>UK, general practice (NHS)</td>
<td>Men with benign prostatic hypertrophy</td>
<td>PDA - interactive multimedia programme with booklet and printed summary</td>
<td>Normal care</td>
<td>Surgery (prostatectomy or transurethral prostatectomy), balloon dilation of the prostate, drugs ($\alpha_1$ blockers, $S\alpha$ reductase inhibitors), watchful waiting</td>
</tr>
<tr>
<td>Murray (2001b)[17], RCT</td>
<td>UK, general practice (NHS)</td>
<td>Perimenopausal or menopausal women considering hormone replacement therapy</td>
<td>PDA - interactive multimedia programme with booklet and printed summary</td>
<td>Normal care</td>
<td>Start, stop or continue hormone replacement therapy</td>
</tr>
<tr>
<td>Kennedy (2003)[14], RCT</td>
<td>UK, hospitals (NHS)</td>
<td>Women with non-urgent, uncomplicated menorrhagia</td>
<td>a) Information - a booklet and complementary videotape. b) Interview - a booklet and complementary videotape, plus interview (immediately before consultation to clarify and elicit their preferences)</td>
<td>Normal care</td>
<td>Advice and reassurance, address possible iatrogenic cases, drug therapy, referral to gynaecologist for hysterectomy or endometrial destruction</td>
</tr>
<tr>
<td>Vourma (2004)[26], RCT</td>
<td>Finland, hospitals (Societal)</td>
<td>Women aged 35-54 with menorrhagia or fibroids</td>
<td>PDA - mailed 25 page information booklet on menorrhagia and treatment options with benefits and risks for each</td>
<td>Usual care</td>
<td>Active observation, non-hormonal medical treatment, hormonal medical treatment, hormonal intrauterine system, removal of copper intrauterine device and progestin capsules, minor surgery (destruction of endometrial lining and/or fibroid, hysterectomy)</td>
</tr>
<tr>
<td>Hollinghurst (2010)[13], RCT</td>
<td>UK, hospitals (NHS)</td>
<td>Women with a previous Caesarean Section</td>
<td>a) Usual care plus Information program consisting of home visit by a researcher with a computerised more complex DA plus access to a password protected website for information in the future if required, b) usual care plus decision analysis program (DAP) consisting of home visit by a researcher with computerised DA</td>
<td>Usual care</td>
<td>Mode of delivery: normal, assisted, Caesarean section</td>
</tr>
</tbody>
</table>
4.6 Reported Outcomes and Resource Use in Studies of Economic Evaluations of PDAs

All five studies collected both costs and benefits associated with the interventions (Table 2), comparing the interventions in terms of mean total costs, uptake rates of the alternative treatment options, and measures such as decisional conflict or health related quality of life (HRQoL). Outcomes included both primary and secondary care health resources and associated costs, rates for the alternative treatment options, HRQoL scores, measures of decisional conflict and condition specific symptoms. Costs of the interventions under evaluation and any associated clinicians’ time were also reported.

Table 2: Outcomes and resource use collected and reported for economic evaluations of PDAs

<table>
<thead>
<tr>
<th>Study</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Murray (2001a)</td>
<td>Decisional Conflict Scale, GPs’ and patients’ perceptions of who made the decision, Anxiety, Prostatic symptoms, EQ-5D, SF36</td>
</tr>
<tr>
<td>Murray (2001b)</td>
<td>Decisional Conflict Scale, GPs’ and patients’ perceptions of who made the decision, Menopausal symptoms, Anxiety, EQ-5D, SF36, Treatment persistence</td>
</tr>
<tr>
<td>Vourma (2004)</td>
<td>Treatment outcome satisfaction, SF36, VAS Anxiety, McCoy sex scale, Menstrual symptoms,</td>
</tr>
<tr>
<td>Hollinghurst</td>
<td>Decision Conflict Scale, Mode of delivery</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study</th>
<th>PDA cost/resource</th>
</tr>
</thead>
<tbody>
<tr>
<td>Murray (2001a)</td>
<td>Production of intervention and software, Equipment associated with video sessions, Staff time associated with Interactive decision aid session</td>
</tr>
<tr>
<td>Murray (2001b)</td>
<td>Cost of intervention (video costs, nurse time, accommodation), Interactive session</td>
</tr>
<tr>
<td>Kennedy (2003)</td>
<td>Development and production of intervention, Duration of nurse time for interview</td>
</tr>
<tr>
<td>Vourma (2004)</td>
<td>Intervention booklet</td>
</tr>
<tr>
<td>Hollinghurst</td>
<td>Provision of intervention</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study</th>
<th>Additional resource use reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Murray (2001a)</td>
<td>Generic consultation with doctor, Number and duration of GP and urology consultations, Tests (urine, prostatic specific antigen, ultrasound, cytoscopy, urinary flow, biopsy) Transurethral prostatectomy drugs</td>
</tr>
<tr>
<td>Murray (2001b)</td>
<td>Generic consultation with doctor, specialist referral from doctor, 3 month supply of Prempaci-C (and related drugs)</td>
</tr>
<tr>
<td>Kennedy (2003)</td>
<td>Inpatient days (any reason), Outpatient and GP visits (any reason), Therapeutic and diagnostic procedures, Medications for menorrhagia</td>
</tr>
<tr>
<td>Vourma (2004)</td>
<td>GP visits, Hospitalisation and readmittance, Outpatient visits, Diagnostic procedures, surgery/treatment procedures including medical treatments, Women’s own costs (travel, sanitary pads), Productivity loss</td>
</tr>
<tr>
<td>Hollinghurst</td>
<td>Clinicians time, Out of hours with GP or health visitor, Inpatient stays (mother and baby), Outpatient appointments, Cost of delivery</td>
</tr>
</tbody>
</table>

* cost pro-rata assuming 3 year effective life for intervention, and all women in England and Wales aged 25-52 years referred from primary to secondary care for uncomplicated menorrhagia. Although reported in the initial publication,[15] cost of the intervention was not included in the formal economic evaluation.[14]
4.7 Reported Results in Studies of Economic Evaluations of PDAs

In general, authors reported PDA users had lower decision conflict,[13;16;17] higher satisfaction with the decision making process,[14] and that the PDAs helped the majority of users.[16;17] However, one study reported the satisfaction associated with the decision making process was only improved when information packs were supplemented with a structured interview.[14] Comparing the PDA groups with the controls, increases in the SF36 role physical dimension,[15] and the role emotional functioning dimension were greater in the PDA groups.[26] Conversely, other authors reported no difference between arms for either the EQ-5D preference-based index,[16;17] or the SF-36 physical functioning.[16;17]

Rates for surgical treatment options were reported to be lower: Caesarean deliveries,[13] hysterectomy rates,[14] uterus saving surgeries,[26] with increases in rates for pharmaceutical therapies in the latter two.[14;26] Conversely, no difference was observed on average resource use in men with prostatic hypertrophy,[16] or women considering hormone replacement therapy.[17]

In terms of costs, the results differed widely with two studies reporting mean total costs were higher for PDA users,[16;17] two reporting they were lower,[14;26] and one reporting no difference.[13] However, these findings are not directly comparable due to the differences in resource use items and length of follow-up etc. that were used in the calculations. While one study suggested potential cost savings due to changes in mode of PDA deliver,[17] another reported the PDA cost was insignificant compared to other costs. Just one of the studies presented results in terms of a formal incremental cost-effectiveness analysis (Table 3) and all studies limited costs and benefits to those observed within the RCT horizons (Table 1).
Table 3: Main results reported in the economic evaluations of PDAs

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>PDA users had lower decisional conflict at 3 month (maintained at 9 month)</td>
<td>PDA users had lower decisional conflict at 3 month (maintained at 9 month)</td>
<td>PDA appeared to increase patients’ participation in decision making</td>
<td>Interview group had higher satisfaction levels for the decision making process (p&lt;0.01) and the treatment outcome (p&lt;0.05)</td>
<td>At 12 months there was no significant difference for satisfaction with treatment</td>
<td>Decision aids reduced decisional conflict</td>
</tr>
<tr>
<td>PDA users were perceived to make treatment decisions by both GPs and patients</td>
<td>PDA seemed to make a more definite choice (fewer ‘undecided’, more not taking HRT at 3 month)</td>
<td>Differences for satisfaction levels between information and control groups was smaller (p not reported)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PDA helped in 46/50 patients, made no difference for 3/50 and hindered 1/50</td>
<td>PDA helped 61/73, made no difference for 11 and hindered 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No significant differences across groups for health status outcomes (SF36, EQ-5D)</td>
<td>No significant difference across arms for health status outcomes</td>
<td>Comparing Interview and control groups there was a significant difference on the SF36 Role Physical (p&lt;0.05) but not for other dimensions[Kennedy 2002]</td>
<td>There was an overall improvement in all health outcomes with the exception of sexual life</td>
<td>Despite no large difference in health outcomes at 1 year follow-up between the study arms, there was an overall improvement in all health outcomes with the exception of sexual life</td>
<td></td>
</tr>
<tr>
<td>PDA unlikely to reduce the UK rates of prostatectomies and did not reduce costs</td>
<td>PDA made no difference to the uptake rate of hormone replacement therapy or the use of health services resources</td>
<td>Interview group had reductions in hysterectomy rates compared to control (p&lt;0.05) and information groups (p&lt;0.01) with no difference between control and information groups (p=0.53)</td>
<td>The intervention group had a lower rate of diagnostic procedures (p=0.07), uterus saving surgeries (p=0.08) and higher rate of medical treatments episodes (p=0.06)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Including costs of video sessions, mean costs £306 vs. £91</td>
<td>No significant difference detected for mean costs when the cost of trial technology was excluded</td>
<td>Intervention groups more likely to have drug therapy than the control group (p=0.17 and p=0.11)</td>
<td>The PDA did not affect total healthcare costs despite some differences in treatment courses (p=0.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Delivering the PDA via the internet would reduce the intervention costs from £177 to £5</td>
<td>The information and interview recipients had lower inpatient and outpatient costs</td>
<td>The information and interview recipients had lower inpatient and outpatient costs</td>
<td>There was no difference in meant total costs when including or excluding productivity costs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Both intervention groups showed large mean total cost savings compared to control group</td>
<td>Both intervention groups showed large mean total cost savings compared to control group</td>
<td>Excluding unrelated inpatient costs, the interview group retained lowest mean total costs</td>
<td>The cost of the decision aid was insignificant compared to other costs</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4.8 Limitations of economic evaluations of PDAs used in SDM process

The results of the review show that very little evidence exists from economic evaluations of PDAs over recent years. The studies identified and included in the review are limited in terms of both the types of costs and benefits evaluated and the time horizons covered by the follow-up periods in the relatively short-term RCTs. Consequently, the longer-term implications of the treatment decisions are not taken into account. Current treatment decisions could have implications in terms of future treatment options and treatment decisions, and the outcomes and costs associated with these.

It is possible that, for some health conditions, several treatment decisions are required at different points along the clinical pathway. An economic evaluation relating to a decision at one point in time in the clinical pathway, which does not explore the consequences of that decision further down the clinical pathway, will fail to capture the full health effects and costs associated with the isolated treatment decision. One example might be renal disease where progression rates differ by individual patient and treatment decisions are revised and reconsidered over a number of years. A delay in a surgical procedure in some conditions could either just offset the costs and resource implications to a future time point, or could have substantial implications in terms of recovery rates, surgical mortality rates, adverse events, length of stay and even whether the probability of surgery is still a viable treatment option. These factors will all have long-term effects for healthcare resource use and associated costs.

Although some of the studies included in the review measured patient satisfaction for the decision making process, and captured patient preferences in terms of HRQoL measures, no attempt was made to include these measures formally in the economic evaluations. Several studies known to the authors have examined potential methods of incorporating these variables in economic evaluations of SDM, for example: evaluating the effect of including patient preferences for treatment allocation in gynaecology;[22] discussing methods of incorporating individual patient preferences where general population preferences are used;[2] the need to reflect the existence of clinical subgroups;[23] the development of a framework to evaluate and understand the value of incorporating heterogeneity resulting from individualised care.[11] As mentioned earlier, only one of the studies presented a formal incremental cost-effectiveness ratio in terms of cost per QALY which could be
used to examine opportunity costs associated with the interventions. For this reason a more general review of evaluations of PDAs has been undertaken in the next section.

5. LITERATURE REVIEW OF SYSTEMATIC REVIEWS OF PDAs

The objective of the second review was to examine the evidence on the impact of PDAs in promoting SDM to help inform the consequences that need to be taken into account in an economic evaluation. A Cochrane review of this particular literature was published in January 2014.[24] The objective of the Cochrane review was to assess the effects of PDAs for people facing either treatment or screening decisions. Decision aids were defined to be ‘interventions designed to help people make specific and deliberate choices amongst options (including status quo), by making the decision explicit and by providing (at the minimum) a) information on the options and outcomes relevant to a person’s health status and b) implicit methods to clarify values.’ As this matched with the objective of the current study the methodology and results of the review are summarised below. Full details of the searches, selection criteria and the detailed methodology are available in the original article.[24]

5.1 Search methods

As this was an update of an existing Cochrane review, the searches were limited to the period 2009 to June 2012, with periods prior to this covered in the earlier review. Databases searched included MEDLINE, CENTRAL, EMBASE, PsycINFO, and grey literature.

5.2 Studies included

Articles describing randomised controlled trials (RCT) evaluating PDAs compared to usual care and/or alternative interventions were included in the review.

5.3 Types of outcomes assessed or reviewed

The main outcomes examined within the Cochrane review may be sub-grouped as follows:

A. Attributes of ‘choice made’ including: outcomes such as knowledge, accurate risk perceptions, and chosen decision option congruent with the patient’s values (i.e. the features that matter the most to the patient).

B. Attributes of the ‘decision-making process’ including: whether the PDA helps people: recognise a decision needs to be made, know the available options and corresponding
features, be clear about which option features matter most to them; understand that values affect the decision, and to discuss said values with their practitioner.

Additional attributes of the ‘decision-making process’ including: decisional conflict, the proportion undecided, patient-practitioner communication, participation in decision making and satisfaction.

C. Secondary outcomes including: behavioural (choice implemented and adhered to), health outcomes (generic or condition specific quality of life, anxiety or depression, emotional distress, regret, confidence), health-system effects (costs, cost-effectiveness, consultation length, litigation rates).

The results of the individual studies were pooled using random-effects models where possible, with pooled results reported as mean differences (MD) and relative risks (RR).

5.4 Results of Cochrane Review

5.4.1 Overview of studies included in the Cochrane review
A total of 142 citations involving 115 studies of RCTs (total participants = 34,444) were included in the review. The RCTs were predominantly conducted in the US (n=53), Canada (n=21), Australia (n=15), or the UK (n=14). There were a total of 46 different decisions ranging from screening through treatment and surgery. The most common intervention decisions related to: prostate cancer screening (n=15), colon cancer screening (n=10), or hormone replacement therapy (n=10).

A total of 88 of the 115 studies reported on at least one of the outcomes examined:

A) Attributes of ‘choice made’; 76 studies reported knowledge scores, 25 reported accurate risk perceptions and 20 reported informed value-based choice.

B) Attributes of ‘decision-making process’; 34 studies examined whether patients felt informed, and 29 studies examined whether patients felt clear about values.

5.4.2 Attributes of ‘choice made’

Knowledge: Defining knowledge to be the proportion of accurate responses to information contained within the PDA (0: no knowledge; 100: perfect knowledge), compared to usual care, people using a PDA had higher average knowledge scores (42 studies; 10,842 participants; MD 13.34; 95% CI 11.17 to 15.51). In addition, when comparing detailed PDAs with simple decision aids, there was a statistically significant relative improvement in knowledge (19 studies; 3,531 participants; MD 5.52; 95% CI 3.90 to 7.15) for those using the detailed PDA.
**Accurate risk perception:** Based on the accuracy of patients’ perceived probabilities of outcomes, patients using a PDA which included descriptions of the outcome probabilities were more likely to have accurate risk perceptions than those who used PDAs that did not have outcome probabilities (19 studies; 5,868 participants; RR 1.82; 95% CI 1.52 to 2.16).

**Chosen option congruent with values of patient:** Compared to usual care patients using a PDA were more likely to chose an option congruent with their personal values (13 studies; 4,670 participants; RR 1.51; 95% CI 1.17 to 1.96).

**Decisional conflict:** Compared to usual care, the use of PDAs resulted in less people feeling uninformed (22 studies; 4,343 participants; MD -7.26 on scale 0-100; 95% CI -9.73 to -4.78); less people feeling unclear about personal values (18 studies; 3,704 participants; MD -6.09 on scale 0-100; 95% CI -8.50 to -3.67). Similarly, the use of PDAs resulted in a reduced proportion of people being passive in the decision making (14 studies; 3,234 participants; RR 0.66; 95% CI 0.53 to 0.81), and a reduced proportion of people remaining undecided (18 studies; 4,753 participants; RR 0.59; 95% CI 0.47 to 0.72) after the intervention.

**Communication** between the patient and practitioner appeared to improve when using PDAs (9 studies; 687 participants; unpooled data).

**Satisfaction:** Patients were either more satisfied or there was no difference when examining: satisfaction with the decision (8 studies, 834 participants; unpooled data), the decision-making process (17 studies, 834 participants; unpooled data) or preparation for decision making (3 studies; 322 participants; unpooled data).

### 5.4.3 Secondary outcomes

**Behaviour:** Due to the large differences in the health conditions for the participants in the individual RCTs, the outcomes reported which related to patients’ behaviours covered a substantial range of options including the patients’ choice or preferences for surgery, tests, medical treatments and screening. In summary, compared to usual care the use of PDAs reduced the number of people electing to have major invasive surgery in favour of more conservative options (15 studies; 3,553 participants; RR 0.79; 95% CI 0.68 to 0.93); reduced the number of people having prostate-specific antigen screening (9 studies; 3,565 participants; RR 0.87; 95% CI 0.77 to 0.98). When comparing
detailed PDAs to simple decision aids, fewer people elected for menopausal hormone therapy (3 studies; 357 participants; RR 0.73; 95% CI 0.55 to 0.98). However, for other decisions there was a variable effect on choices (for example screening for colorectal cancer (10 studies; 4,529 participants; RR 1.12; 95% CI 0.95 to 1.31).

**Health care system effects:** The effect of the use of PDAs on the time of consultation ranged from 8 minutes shorter than usual care (p=0.03), to 23 minutes longer (p=0.001), with a media of 2.55 minutes longer, and six of the nine studies reporting this outcome finding no difference in the consultation length. There was also no difference observed in terms of anxiety (30 studies; 6,725 participants; unpooled data), general health outcomes (11 studies; 2,246 participants; unpooled data), or condition-specific health outcomes (11 studies; 2,706 participants; unpooled data). The evidence relating to adherence to the decision/intervention, and the cost and resource use was inconclusive.

**5.5 Author’s conclusions from the Cochrane review**
The authors concluded that when comparing the use of PDAs to usual care, there was high-quality evidence that PDAs improved people’s knowledge of options available, reduced people’s decisional conflict relating to feeling uninformed, and the proportion of people who were unclear about their personal values. In addition, there was moderate-quality evidence that compared to usual care, PDAs stimulated people to take a more active role in decision making. There was low-quality evidence that PDAs improved congruence between the patient’s values and the option chosen. While PDAs have a more variable effect on the length of consultation and the choice of intervention, they do not appear to have any adverse effect on either health outcomes or satisfaction. There were insufficient studies to determine the effects of PDAs on patient-practitioner communication, persistence with the chosen option, the costs and resource use.
6 WORKSHOP INVOLVING EXPERTS IN THE FIELD OF PDAs AND SDM

6.1 Structure of Workshop
A workshop was held with a range of experts in the field of SDM and PDAs on the 24th June 2013. The purpose of the workshop was to obtain experts’ views on concepts and issues that could potentially be relevant to future economic evaluations of PDAs being introduced in the NHS.

The morning session began with presentations describing the conventional approach to economic evaluations, the existing economic evaluations of PDAs within SDM, and a proposed draft framework for capturing the benefits of PDAs used to inform SDM (slides provided in Appendix 2). These were followed by presentations describing current use of PDAs and SDM within renal services in England and an overview of interim results from an applied project conducted by AQuA (Advanced Quality Alliance) analysing the potential benefits of SDM in several conditions. Question and answer sessions were held after each presentation.

The afternoon session comprised of small group breakout discussions focussing on five key questions identified from the preparatory research and the background reading material circulated to attendees prior to the meeting. The concepts discussed included: identifying consequences of SDM in terms of processes and health outcomes; patient preferences over health outcomes and their relevance to decision makers such as NICE; the trade-off between health and non-health benefits and the implications of this; whose preferences should be used (e.g. the patient, doctor or commissioner); and an open question aimed to identify potential challenges for economic evaluations of PDAs/SDM.

Details of the agenda, the questions presented in the breakout discussions and a synopsis of the key themes raised during the discussion groups is provided in Appendix 2.

6.2 Main Themes Emerging from Workshop
In summary, the main messages that emerged from the workshop include:

- The ‘quality’ of the treatment decision (defined to be either a ‘better’ or ‘correct’ decision for the individual patient) made under the SDM process is an important consideration.
- The potential benefits of SDM include both process and non-process outcomes and not all benefits are likely to be captured in a generic health related quality of life instrument such as the EQ-5D.
• Process outcomes should be considered when quantifying benefits of SDM - the SDM process itself could have non-tangible beneficial (increase in dignity) or detrimental (increase in anxiety) effects.

• SDM may be considered to be part of a basic standard of care like privacy. Although any additional costs of implementing SDM may result in some types of patients forgoing improved health, this may be considered morally justified.

• While there is a risk that relying on patients’ choice may reduce the efficiency of healthcare programmes in terms of the QALY maximisation model, non-health benefits could potentially be traded for QALYs to adjust for potential benefits within the same framework.

The current framework for economic evaluation is limited to a focus on health and uses the preferences of members of the general public, and the individual’s preferences and personal trade-offs do not sit well within this generic framework. In the next section we try address this challenge.

7. A FRAMEWORK FOR ECONOMIC EVALUATIONS OF PDAs USED IN SDM

7.1 A Pathway of the Impacts of PDAs

A summary of the way PDAs may impact on decision making process, the decisions made, the outcomes of those decisions and costs is provided in Figure 1 and this can be linked to the evidence reviewed above as follows. PDAs are designed to improve the decision making process in terms of patients’ knowledge of the outcomes of different interventions and the understanding of health care professionals (HCPs) of the preferences and values of patients. PDAs should also improve the communication between patient and HCPs. Our review identified clear evidence for these effects.

The consequences of improved decision making should be better satisfaction with the decision and reduced decision conflict and anxiety, however here the evidence was more mixed, though the majority of studies did report an improvement. It could be argued that anxiety in some cases may be increased, since being better informed about the choices and the outcomes from those choices could increase or reduce anxiety. PDAs may impact on the treatment choice through providing more relevant information on outcomes and risks to patients for the different options. There is no consistent pattern in the evidence on treatment choice and uptake which are likely to be dependent on the context. There is little support for differences in health outcomes, but some evidence for differences in resource use, though the impact is mixed. Although the evidence is limited, the
overall cost impact is composed of the cost of the PDA itself (e.g. provision of software), longer consultation, choice of treatment and compliance, and longer term consequences of the treatment.

7.2 Normative Issues

Conventional economic theory usually takes a ‘welfarist’ normative stance, which assumes that individuals are the best judge of their own welfare as expressed in terms of individual utility. This implies that the benefits of one course of action over another (e.g. the introduction of a PDA), are simply the sum of the individual utilities. For a health care system with a fixed budget this would require combining the utility changes in those who benefit from the PDA with any losses from displacing some other activity. However, this ‘welfarist’ approach is rarely used in health economics, which normally takes a ‘non-welfarist’ approach that uses the idea of social good determined by the general public or decision makers taking the decisions on their behalf. Economic evaluation in health care has usually assumed social good to be a function of total population health and this is measured by the QALY. The standard (NICE-defined) framework for economic evaluation of health technologies, for example, is to examine the incremental costs and health benefits measured in terms of QALYs using EQ-5D compared to a cost per QALY threshold range reflecting how else the resources could be used in the NHS. As we have seen there are a number of reasons for thinking this focus on societies’ valuation of health through the QALY is too narrow in the context of evaluating PDAs and SDM more generally.

The scope of an economic evaluation of PDAs needs to be extended beyond the health related QALY and this reflects recent interest in taking account of the wider societal benefits of health services.
Figure 1 represents the pathway of impact of PDAs and shows that it would be important to take account of non-health benefits such as improved communication, reduced decisional conflict and and better satisfaction with the decision making process, but these effects must be accounted for in the estimation of the lost benefits from displaced activities in the NHS. One solution discussed in the workshop is to find ways of expressing non-health benefits in terms of QALYs (see next section).

Another concern arises from the use of general population values to value health and the use of the QALY model of preferences. Aside from the exclusion of non-health effects, the conventional QALY model makes assumptions about people’s preferences over health. It assumes, for example, that patients are risk neutral (e.g. 10 years for certain is worth the same as a 50% chance of living for 20 years or 50% chance of death). There is a large body of evidence suggesting this is not the case with patients tending to be risk averse. QALYs also assume that individuals trade-off life-years at the same rate regardless of life expectancy, and also that the value of a health state is the same regardless of what went before it or what is expected after it (e.g. there is no allowance for the impact of disappointment or regret). Added to these, QALYs use mean general population values for health states. As for risk, there is evidence that individuals’ own preferences violate these assumptions. [2] In as much as PDAs result in providers taking greater account of the preferences of patients, then this may result in choices that do not maximise societal QALYs which raise important normative issues within the current non-welfarist approach that focuses on QALY maximisation.

One solution would be to limit the choice of interventions to those that have been found to be cost effective (for example by NICE). However, this may result in cheaper treatments not being made available to patients since, according to societal preferences, they are not cost-effective compared to alternatives due to the potential difference in health gains.[2] The cheaper option in some circumstances may be preferred by some patients (e.g. where the alternative is less invasive) and a health care system may decide to make these cheaper options available to patients. Both these options give primacy to the cost per QALY using societal values.

Authors on this topic in the past have suggested more direct ways of incorporating patient values explicitly. These may involve asking patients to provide values for health states and incorporate these into a decision analytical model,[9] or inviting patients to value the whole profile of benefits in terms of QALYs (e.g. using a measure called healthy year equivalents.[12] This would create a large measurement burden in the form of eliciting preferences from patients using techniques such as time trade-off and discrete choice experiments (DCE). Furthermore, it has implications for the
consistency of decisions between patients and would be a major departure from the current position of NICE and similar agencies around the world who in most cases recommend the use of general population values. However, recent years has seen commentators and policy makers in the UK reconsider the current dependence on cost per health related QALY though currently there are no plans to change methods.[3]

7.3 Valuing Non-Health Benefits
This section briefly considers some of the ways that non-health benefits could be incorporated into economic evaluations of PDAs and other ways of promoting SDM. Interventions that aim to change human interactions are often complex, and PDAs and SDM are no exception. The actual process of using a PDA and taking part in the SDM process could have a value in its own right. The reviews presented in this report have found evidence in some studies of an impact on patient knowledge, level of involvement in decision making, satisfaction with the decision making process, satisfaction with the decision and decision conflict. This will require studies to collect data from patients with and without the use of a PDA in a SDM context. It also implies the need to be able to trade-off between health and these non-health benefits, since in as much as PDAs increase costs any gains in non-health benefits need to be compared to the reductions in health for other individuals from resources diverted from elsewhere.

Expressing non-health in terms of health benefits like QALYs requires a preference elicitation technique such as discrete choice experiments or matching. A DCE involves describing the benefits of PDAs in terms of their impact on different health and non-health attributes. Each attribute will have a number of levels, and combining levels across the attributes results in the generation of profiles. In one form of DCE respondents are asked to compare pairs of profiles that vary in terms of the attributes. This will allows one attribute to be expressed in terms of another one. In order to be able to express the attributes on the zero to one scale used to calculate QALYs or QALY equivalents, it is necessary to append an attribute for duration,[1] or where there is interest in a more welfarist approach, then a cost attribute can obtain a willingness to pay in money.

Matching involves asking people to state the number of outcomes of one kind they consider to be ‘just as good’ as a specified number of outcomes of another kind.(43) The technique is an established method in health economic evaluation, where it has commonly been referred to as the person trade-off (PTO) technique.(44) It was used to derive the quality of life weights for disability adjusted life years (DALYs) in the World Health Organisation’s Global Burden of Disease Study.(45)
There may also be interest in understanding the extent to which patient preferences for health outcome differ from the QALY assumptions. This would help explain likely patient choices between alternative interventions and any likely conflict with societal preferences.

As discussed earlier, this leaves the key problem of who should value health and non-health benefits. Patients using PDAs would best reflect their views, but this would not be compatible with the way other technologies are evaluated and would raises concerns about comparability across patient groups. However, it will be important to have both in order to better understand the differences between the general population and patients.

8. IMPLICATIONS FOR THE DESIGN OF ECONOMIC EVALUATIONS OF PDAs

The literature reviews and the workshop helped to identify the costs and benefits of PDAs that need to be considered in an economic evaluation. The perspective of an economic evaluation is a normative issue, but here it is assumed that there will be interest in more than just the health service costs and health effects, since the literature suggests there are little or no health benefits from PDAs. The main benefits are likely to arise from non-health effects (see Table 4).

It will be important to collect data in a controlled study in order to estimate the effects of the PDA. The precise nature of the control group is a matter for detailed design, but it could be from a randomised controlled trial (where the patient, clinician or provider is randomised), a prospective before and after study of introducing PDA, or a comparison of providers with and without the PDA.

PDAs vary considerably even for the same patient group and it is often not possible to generalise from one to another. At the same time, a given PDA is well defined but the precise way the PDA is used in a consultation varies widely. Consequently, the way PDAs are used in the clinical consultation must be fully understood and thus an economic evaluation should be undertaken alongside a broader mixed methods evaluation.

The costs and consequences of PDAs are listed in Table 4. The costs of developing, updating and providing the PDA can be obtained outside of any prospective study. All other consequences of a PDA will require data to be collected in a controlled study including: clinical consultation time, treatment choice, uptake and compliance, clinical and intermediate outcomes, survival (where
relevant), health related quality of life, patient experience and satisfaction with the decision making process, and resource use (resultant from any changes in treatment choice and uptake). There are a range of existing validated instruments which can be used to assess decision quality including patients’ understanding of the options and outcomes, the extent to which patients receive treatment which is concordant with their values, and the extent to which patients are involved in the decision making process.[#ref Sepucha] It may be possible to model the longer term consequences for resource use and outcomes from the treatment decision and clinical outcomes (e.g. the consequences of an increase take-up in home dialysis can be modelled using estimates from the literature).

Finally the range of outcomes requires a method for aggregation. This would require a study into patient or general population preferences across the different benefits of PDAs, and their expression in terms of QALYs using preference elicitation methods such as those described in the last section.

<table>
<thead>
<tr>
<th>Component</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impact on treatment and uptake</td>
<td>The use of a PDA in SDM may (or may not) change the intervention provided to the patient and their uptake of it</td>
</tr>
<tr>
<td>Resources</td>
<td>Cost of developing, updating and providing PDA</td>
</tr>
<tr>
<td></td>
<td>Consequences of using PDAs for consultation time with clinicians</td>
</tr>
<tr>
<td></td>
<td>Changes in treatment choice will have consequences for the resources used (e.g. where fewer patient choose surgery)</td>
</tr>
<tr>
<td></td>
<td>Changes in uptake or compliance with treatment</td>
</tr>
<tr>
<td></td>
<td>Changes in health outcome (see below) will have consequences for resources used (e.g. from better control of blood sugar reducing complications)</td>
</tr>
<tr>
<td>Benefits</td>
<td>Changes in health the health outcomes of survival and health related quality of life</td>
</tr>
<tr>
<td></td>
<td>Changes in intermediate clinical outcomes – like blood glucose – that impact health outcomes (and resources)</td>
</tr>
<tr>
<td></td>
<td>Changes in non-health benefits – such as satisfaction with the decision making process, degree of decision conflict and anxiety about the decision</td>
</tr>
<tr>
<td>Preferences over health and non-health outcomes</td>
<td>Patient preferences for health outcomes differ from the QALY assumptions</td>
</tr>
<tr>
<td></td>
<td>Patient and general population values on the trade-off between health and non-health outcomes</td>
</tr>
</tbody>
</table>

8.1 Policy Implications
There are three key areas that may have policy implications: the choice of treatments offered via the SDM process, the non-health benefits, and the cost of resources associated with the PDAs and SDM process. There is currently no rationale for SDM providing access to treatments that the current system considers not cost-effective using standard methods. As things stand, the system does not typically define just one treatment per patient since more than one may be cost-effective and patients may select lower cost (e.g. less invasive) interventions, so choice is generally available. This becomes the choice set for SDM. However, the benefits of PDAs extend beyond health through processes of care themselves (e.g. satisfaction with decisions).

Identifying the net cost implications of SDM, (taking development, consultation and treatments into consideration), is a priority. If the net cost implications of SDM is cost saving, or marginally additional (displacement is negligible), then formal economic evaluations may not be necessary. In many cases it may be possible to determine the effect through existing data. However, in indications where the net cost is markedly higher, then primary studies would be required to estimate overall costs, health effects and non-health benefits of PDAs by condition.

9. CONCLUDING STATEMENTS

The implications for economic evaluations of PDAs within SDM is that the framework needs to be extended beyond health to better incorporate what matters to patients, but this raises important normative concerns and conflicts with the current aim of cost-effectiveness analysis to maximise health measured through the QALY. We have provided a framework for extending economic evaluation and the types of data to be collected, but further research is required in order develop methods for putting it into practice.
APPENDIX 1: Search strategy used in the literature reviews

Iteration One
1. (decision aid* or shared decision making or treatment decision* or decision model).ti.
2. (cost* or randomi?ed or trial* or study or studies or outcome).ti,ab.
3. 1 and 2

Iteration Two
1. ((patient* or parent* or consumer*) adj (decision* or empowerment* or involvement* or choice* or preference* or communicat* or participat* or centre* or center* or informed or collaborat*)).ti.
2. (Treatment adj (choice or preference)).ti.
3. decision aid*.ti.
4. decision making.ti.
5. decision model*.ti.
6. 1 or 2 or 3 or 4 or 5
7. (Systematic adj review*).tw.
8. (Data adj synthesis).tw.
9. (Published adj studies).ab.
10. (Data adj extraction).ab.
11. Meta analysis/
13. 7 or 8 or 9 or 10 or 11 or 12
14. 6 and 13
15. limit 14 to (english language and humans and yr="2003 -Current")
APPENDIX 2: Workshop involving external experts in PDAs and SDM

A2.1 Experts involved in SDM workshop

Professor John Brazier, Professor of Health Economics, EEPRU, University of Sheffield
Dr Laura Bojke, Senior Research Fellow, EEPRU, University of York
Ms Rebecca Smith, Managing Consultant, Capita Group
Dr Alan Glanz, Research & Development, Department of Health
Dr Emma Walker, Programme Lead, Shared Decision Making, Salford Royal NHS Foundation Trust
Professor Vikki Entwistle, Professor of Health Services Research & Ethics, University of Aberdeen
Professor Mark Sculpher, Professor of Health Economics, EEPRU, University of York
Dr Hasan Basarir, Research Associate, University of Sheffield
Mr Simon Palfreyman, Research Nurse, University of Sheffield
Dr Alastair Bradley, Academic Training Fellow, University of Sheffield
Mr Santiago Calvo Ramos, Economic Adviser, NHS England/Department of Health
Professor Donal O’Donoghue, Consultant Renal Physician, Salford Royal NHS Foundation Trust
Ms Roberta Ara, Senior Research Fellow, EEPRU, University of Sheffield
Professor Andrea Manca, Professor of Health Economics, EEPRU, University of York
Dr Phil Shackley, Senior Lecturer in Health Economics, University of Sheffield
Dr Eldon Spackman, Research Fellow, University of York
Dr Hilary Bekker, Senior Lecturer in Behavioural Sciences, University of Leeds
Prof Nigel Mathers, Professor of Primary Medical Care, University of Sheffield
Conceptual Framework for Economic Evaluations in Shared Decision Making

AGENDA

9:30-10:00 Coffee

Morning session chaired by Professor John Brazier

10:00-10:15 Introduction (JB)
10:15-10:30 Framework Policy: Normative (MS)
10:30-10:45 Framework: Practicalities (JB)
10:45-11:00 Literature Reviews (LB)
11:00-11:15 Renal SDM - Guest presentation (Donal o'Donoghue)
11:15-11:30 AQuA results – Guest presentation (Hilary Bekker)
11:30-12:00 Renal SDM response potential issues & open discussion

12:00-12:30 LUNCH BREAK

Afternoon session chaired by Professor Mark Sculpher

12:30-13:15 Breakout group sessions
13:20-14:00 Plenary/next steps

Contact: Liz Metham tel: 0114 222 0671
A2.3  PowerPoint slides used in SDM Workshop

01/10/2013

Conceptual Framework for Economic Evaluations in Shared Decision Making Workshop
Policy Research Unit in Economic Evaluation of Health and Care Interventions (EERRU)

Introduction

Working definition reminders
- SDM process is defined as:
  A process in which clinicians and patients work together to select, appraise, manage and share risky options, select appropriate health and care treatments, and permissions - involves the provision of information, advice, education, support, and understanding, together with decision support tools and systems, to explore mutual concerns and to promote shared decision making and informed preference (Glasier 2009)

Working definition reminders
- PDAs are defined as:
  Information designed to help people make specific decisions, either by providing information about the options and outcomes, or by helping them learn about and understand their health issues and by clarifying personal values, and are intended to support shared decision making (Glasier 2009)

DH funded PDA programme
- DEFGI funded a programme to develop PDA - a decision aid
- target clinical pathways - included in the development
- PDA developed an evaluation framework suggesting costs of reaching the PDA and PDA success, levels of PDAs and PDAs, and levels of PDAs and PDAs for evaluation
- developed a framework for evaluation
- 1. To develop a framework for evaluation
- 2. To develop a framework for evaluation

Conceptual Framework for Economic Evaluations in Shared Decision Making
Normative Issues

Mark Sculpher, PhD
Professor of Health Economics
Centre for Health Economics
University of York, UK
Types of economic evaluation

- Cost-effectiveness analysis: Interventions compared in terms of cost per unit of clinical outcome.
- Cost-utility analysis: Quality-adjusted life years (QALY) of new interventions compared to a threshold (e.g., £20,000 per QALY).
- Cost-benefit analysis: All costs and benefits are valued in monetary terms and compared where B/C ratio is proposed.
- Cost-consequence analysis: Where all costs and benefits are assessed, but conclusions are based on policy maker.

Main differences between techniques

Prospective
- QALY and QUA are linked to QALY and QUA but estimated in different ways (e.g., QALYs estimated as a weighted average of utilities of states).
- Cost-benefit analysis, QUA, and QUA can be valued in terms of costs and benefits.
- Costs and benefits can be valued using different discount rates.
- Differential costs and benefits are assessed.

Key components of economic evaluation

- Impact on intervention
- Resource use — hence costs
- Outcomes
- Values and preferences over health outcomes
- Values and preferences for non-health outcomes and processes

KEY COMPONENTS OF IMPACT

Component | Impact | Implication/Fact
--- | --- | ---
Health outcomes | Measured in QALYs | Health outcomes improve
Costs | Measured in monetary terms | Costs increase
Environmental impacts | Measured in QALYs | Environmental impacts improve
Application of framework to case studies

- Renal services
- Musculoskeletal
- Others?

Review (1)

Objective
To identify any published literature describing economic evaluations of a SDM process involving a PDA.

Inclusion criteria
Articles that assessed the costs and benefits associated with any SDM process involving PDA in any indication or setting.
Review of existing systematic reviews involving PDAs and/or SDM

- To identify, develop, and review existing SRs of SDM and/or PDAs
- To inform the conceptual framework for economic evaluations in SDM
- To include, extend, or project systematic analysis of PDAs or SDM for any selection or indication
- Evaluation criteria: any article describing the development of a PDA or individual application of PDAs or SDM

Outcomes reported for PDA cohorts

- Lower decisional conflict
- Higher satisfaction with decision making process
- No significant difference in quality of life scores
- Surgical treatment options lower (3)

No formal incremental analyses
No downstream costs or benefits

Objectives

- To identify, develop, and review existing SRs of SDM and/or PDAs
- To inform the conceptual framework for economic evaluations in SDM
- To include, extend, or project systematic analysis of PDAs or SDM for any selection or indication
- Evaluation criteria: any article describing the development of a PDA or individual application of PDAs or SDM

Review (1)

- 51 total hits
- 6 satisfied inclusion criteria
  - 2 in primary care (psoriasis, diabetes, small test)
  - 2 in secondary care (vascular, menorrhagia)
  - 4 in UK, 1 in Finland

Results

- 21 reviews involving 2 to 115 individual studies
  - Predominantly PDAs (not SDM)
  - Mixed range of indications & settings
  - Mixed conditions, etiologies, both primary & secondary care, time of publication
  - Extraction template: outcomes reported in the SR
  - Thematic analysis
  - Impact on patient, physician, experience, satisfaction, attitudes, treatment & resource implications

Contributors/Investors in SDM

| Consumer | Family/ Care | Health Care/ Providers | Decision
| --- | --- | --- | ---
| Experiences & preferences | Knowledge & resources | Clinical expertise & outcomes | Economic considerations & upstream actions

01/10/2013
Patient outcomes (1)

- Knowledge
- Patient-reported symptoms
- Patient's concern about survival
- Treatment recommendations
- Treatment-related adverse events
- Treatment-related costs
- Treatment-related quality of life

2 reviews involving 17 individual studies

Family/carer outcomes

2 reviews involving 17 individual studies

Patient outcomes (2)

- Anxiety
- Pain
- Patient's perception of the benefit
- Patient's perceived control
- Patient's physical and psychological functioning
- Patient's decision to continue treatment

3 reviews involving 97 individual studies

Provider outcomes

- Effectiveness of treatment
- Side effects
- Contraindications
- Complications
- Reactions

5 reviews involving 210 individual studies

Payer outcomes

- Cost effectiveness of treatment
- Cost effectiveness of procedure
- Cost effectiveness of intervention
- Cost effectiveness of treatment

5 reviews involving 210 individual studies

Summary

- Various outcomes reported
- Emphasis on 'non-existing' or process outcomes
- Concepts considered to be important area
- Knowledge, experience, satisfaction, anxiety, treatment, quality, clinical outcomes & resource implications
- Literature places more emphasis on patient experience & little on other 3 contributors
What do you consider to be the challenges for economic evaluations of SDM/PDAs?

Initial thoughts
Application to guest presentations

Renal SDM

Professor Donal O’Donoghue
Consultant Renal Physician
Working for Better Kidney Care

Demand for renal replacement therapy continues to increase but incident rates have reached a plateau.

The mean eGFR at initiation of RRT is rising.

Kidney transplants in the UK
SHARE: A patient experience of shared decision making.

Hilary Blyth: Senior Lecturer
Emma Nye: NHS AQUA Programme Lead
Aidan Nye: NHS AQUA Clinical Lead

- NHS AQUA implementing shared decision making (Nye, Emma)
- Patient decision aids to enable informed patient decisions (Nye, 2012, Nye, 2013)
- Shared decision making theory and evidence of practice
  (Blyth, Nye, Van der Straat, and Guelfi, 2014)
- Rating scales, audit, feedback
- The future of EDM measures
Evidence-based information resources to help people make informed decisions between treatments.

An informed decision is one made with and based on:
- a patient evaluation of accurate information about the advantages and disadvantages of all options and their consequences
- in accordance with their beliefs and
- before trade-offs between these evaluations.

(Sommers et al. 1989, 2005, 2010)

An interactive process in which patients and professionals collaborate to choose health care. (Round et al. 2010)
- Exchange information, knowledge and treatment.
- Express preferences about treatments
- Explicit reasoning about treatment choices
- Agree and implement choice

Patient decision aids may facilitate shared decision making:
- Before consultation; helps the patient become decision literate and able to engage in the consultation conversation.
- During consultation: helps structure the consultation and enable shared conversation.
- After consultation: support informed decision making but only shared if multiple encounters prior to decision making.
- PCA Utilisation: patient and professional relation

Assess aspects of communication and/or decision outcome.
- Shared decision making process:
  - Patient engagement, involvement, activation (Donoghue, 2016)
  - Informed patient decision making (BHR, 2016)
  - Doctors' communication skills (EDM2, 2016)
  - Patients' perception of doctors' communication skills

Assess impact of EDM professional skills training on patient outcomes.
- Evaluate variations in quality of EDM across services;
- Items to be used after every consultation completion.

Best patient-reported outcome measure of EDM:
- Decisional Conflict Scale (O'Connor et al. 1995)
- BURE (O'Connor and Legare, 2001) – 10-item decisional conflict screening tool for usual care consultations.

<table>
<thead>
<tr>
<th>Item</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item 1</td>
<td>Score 1</td>
</tr>
<tr>
<td>Item 2</td>
<td>Score 2</td>
</tr>
<tr>
<td>Item 3</td>
<td>Score 3</td>
</tr>
<tr>
<td>Item 4</td>
<td>Score 4</td>
</tr>
<tr>
<td>Item 5</td>
<td>Score 5</td>
</tr>
<tr>
<td>Item 6</td>
<td>Score 6</td>
</tr>
<tr>
<td>Item 7</td>
<td>Score 7</td>
</tr>
<tr>
<td>Item 8</td>
<td>Score 8</td>
</tr>
<tr>
<td>Item 9</td>
<td>Score 9</td>
</tr>
<tr>
<td>Item 10</td>
<td>Score 10</td>
</tr>
</tbody>
</table>

If patient raises any new decisional conflict present, an item primary care consultations have been done with 10% for usual care consultations.

01/10/2013
November components of shared decision making process
Need for more sensitive measures?

Retail registry pilot 1 (n=10)
- SHARED: Dutch Decision Instrument Knowledge options, obesity, male, demographics.
Retail registry pilot 2
- modified questionnaire testing and data collection point
Dutch study cancer choices (n=26)
- Dutch test-recording consultations and completion
SHARED
Psychometric testing
A2.4 Questions and themes emerging from the group discussions in the SDM workshop

The text below outlines the questions discussed and a summary of the themes that emerged from the small group discussions.

**Question 1: Identify consequences of SDM (Do process/non process outcomes form part of health or are these a separate set of outcomes? Are these outcomes part of a wider definition of well-being?)**

- It was suggested that: “making a decision in a good way is a process, whereas making a ‘better’ decision is an outcome”. However, the definition of a ‘better’ decision could be dependent on the perspective.
- It was noted that outcomes such as wellbeing, happiness, decisional conflict or satisfaction, knowledge and skills to navigate health services etc were attributes distinct from health and that a generic health related quality of life questionnaire such as the EQ-5D would not capture these components.
- There was some discussion relating to measuring and quantifying the ‘effectiveness’ (and conversely any potential harm) of PDAs and SDM and how best to determine if their use has informed or influenced a ‘better’ decision, a ‘more-informed’ decision, or the ‘correct’ decision. It was also noted that while PDAs may not achieve a better SDM process they could still be beneficial (e.g. might be dignity of patient, autonomy of patient etc). Conversely, the process may impact indirectly on patient experience by increasing individual’s anxiety.
- One group noted that if process aspects were considered ‘important’ they should be treated as separate outcomes to health and they should be valued in a similar way to health – potentially through trading off QALYs. It was thought the EQ-5D was unlikely to capture process outcomes.
- One group talked in terms of human rights and basic standards of care not being tradable (see question 3)
- There was some emphasis on the importance of quantifying the long-term benefits and implications of using PDAs/SDM. It was noted that a) studies with longer follow-up could potentially provide information on activities displaced and both healthcare and wider social costs and b) while SDM is unlikely to be cost-neutral, the effectiveness will differ depending on the specific condition and associated interventions offered.
Question 2: Patient preferences over health outcomes

- It was noted that PDAs now sit within NICE Clinical Guidelines and that SDM is encouraged and included in the formal recommendations, thus outcomes will be relevant to decision makers.
- One group noted that as decision makers such as NICE currently make recommendations using societal values, incorporating patients’ preferences (i.e. in SDM, patients express their preferences through their choice of treatment) could be problematic. It was suggested that preferences could be obtained from large groups of patients but as preferences are transient in nature this adds to the complexity. There was also some discussion relating to the effect of the inclusion of different preferences on the data used in future NICE appraisals.

Question 3: Health non-health benefit trade-off (Do we have to trade-off some health outcomes for non-health outcomes and what are the implications of this? Who should make these trade-offs?)

- One group talked in terms of human rights and suggested that basic standards of care were not tradable. Another group voiced the opinion that it was not appropriate to ‘trade’ health and non-health outcomes as all patients should be treated respectfully.
- Others suggested that trade-offs were inevitable, for example if a basic level of care was not provided, then non-health outcomes could be traded to improve the standard of care provided, and if the SDM process resulted in an increase in consultation time and one less appointment a day, this has a cost implication which requires balancing against potential health (or non-health) benefits.
- One group questioned whether society would accept an increase in costs caused by providing patients with a choice in treatment options, which again suggests there would need to be a trade-off. However, another group noted that any potential trade-off would depend on the particular implications and which specific groups were affected by the non-health outcomes.
- It was noted that any trade-offs would need to be quantified and there were questions whether the current cost-effectiveness framework was fit for purpose in terms of evaluating SDM and quantifying any potential trade-offs. It was also emphasised that there would be different implications for different patients and systems and it was questionable whether people should trade-off their own health/non health outcomes with others’ health/non health outcomes.
- One group suggested that there was a risk that patients may reduce the efficiency of healthcare programmes by choosing less effective interventions via their trade-off between
health and non-health benefits, and it may be possible to quantify this effect using an equivalent to the QALY measure.

• One group discussed whether clinicians’ preferences should be included in trade-offs, and what if any value there was to the clinicians with regard to helping patients make trade-offs.

**Question 4: Whose preferences (patient, doctor, commissioner)?** *(Whose preferences count when it comes to the valuation of health outcomes?)*

• One group noted that by limiting the alternative treatment options to interventions which were deemed cost-effective, the public perspective/preferences were already taken into account

• It was suggested that it is difficult to defend public preferences in cases where patients chose interventions which were less effective.

• After noting that both patients and clinicians were involved in making a joint decision, both their preferences were relevant. However, the process could introduce a dilemma for clinicians when patients had a preference for non-health outcomes and chose an intervention which would provide less health benefit, and this would then introduce a conflict with clinicians’ preferences or their duties as defined by the Hippocratic Oath. The possibility of aggregating the three different options (patient, doctor, commissioner) was discussed but no consensus was reached.

**Question 5: Identifying challenges** *(circulated with background reading material prior to the workshop, attendees were asked to consider the challenges for economic evaluations of PDAs/SDM)*

**Research definition boundaries and future investment prioritisation**

• There was some discussion regarding the remit of the research in terms of the definitions of PDAs included and the possibility of widening the scope beyond the PDAs developed under the DH programme. There are now multiple PDAs used in clinical practice; some of which have been developed independently for personal use by a single clinician.

• It was suggested that financial investment could be targeted to conditions where decisions were difficult or complex and thus decisional conflict was extremely high, patient involvement was low, there was poor satisfaction with decisions, or in as investment in these areas could potentially yield greater benefits. Said benefits could potentially include empowering the patients to become more valued and valuable citizens.
• Inequity was highlighted as a potential problem and it was suggested that more articulate, affluent patients may get better outcomes than disadvantaged/marginalised groups. However, it was also noted that if language barriers and cultural heterogeneity were overcome SDM could increase equity as it gives all a chance to participate.

• On a similar theme, clarification was sought with regards to the specific areas of use of the PDAs as these were not deemed appropriate for use in routine monitoring appointments.

• Concern was expressed that results of evaluations might indicate that SDM was not a good use of resources which could potentially lead to a disinvestment in the area.
Reference List


