

## RESEARCH REPORT

### A Framework for Conducting Economic Evaluations when using Patient Decision Aids in Health Care Decision Making

Ara R, Brazier JE, Sculpher M, Manca A, Bjoke L,  
Preston L, Basarir H

Correspondence to: Roberta Ara, HEDS,  
SCHARR, University of Sheffield, Regent Court,  
30 Regent Street, Sheffield, S1 4DA

RR0049

2015

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’.<sup>1</sup> 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 EEPUR 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

---

<sup>1</sup> 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.[20] 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.[20] 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**

<b>Study [horizon]</b>	<b>Setting (Perspective)</b>	<b>Indication</b>	<b>Intervention</b>	<b>Comparator</b>	<b>Treatment options</b>
Murray (2001a)[16], RCT (n= 112) [9 month]	UK, general practice (NHS)	Men with benign prostatic hypertrophy	PDA - interactive multimedia programme with booklet and printed summary	Normal care	Surgery (prostatectomy or transurethral prostatectomy), balloon dilation of the prostate, drugs ( $\alpha_2$ blockers , $5\alpha$ reductase inhibitors), watchful waiting
Murray (2001b)[17], RCT (n= 205) [10 month]	UK, general practice (NHS)	Perimenopausal or menopausal women considering hormone replacement therapy	PDA - interactive multimedia programme with booklet and printed summary	Normal care	Start, stop or continue hormone replacement therapy
Kennedy (2003)[14], RCT (n= 627) [24 month]	UK, hospitals (NHS)	Women with non-urgent, uncomplicated menorrhagia	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)	Normal care	Advice and reassurance, address possible iatrogenic cases, drug therapy, referral to gynaecologist for hysterectomy or endometrial destruction
Vourma (2004)[26], RCT (n= 569) [12 month]	Finland, hospitals (Societal)	Women aged 35-54 with menorrhagia or fibroids	PDA - mailed 25 page information booklet on menorrhagia and treatment options with benefits and risks for each	Usual care	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
Hollinghurst (2010)[13], RCT (n= 742) [12 month]	UK, hospitals (NHS)	Women with a previous Caesarean Section	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	Usual care	Mode of delivery: normal, assisted, Caesarean section

#### 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**

Study	Outcomes
Murray (2001a)[16]	Decisional Conflict Scale, GPs' and patients' perceptions of who made the decision, Anxiety, Prostatic symptoms, EQ-5D, SF36
Murray (2001b) [17]	Decisional Conflict Scale, GPs' and patients' perceptions of who made the decision, Menopausal symptoms, Anxiety, EQ-5D, SF36, Treatment persistence
Kennedy (2003)[14]	Patient satisfaction, SF36, EQ-5D, Severity of menorrhagia
Vourma (2004)[26]	Treatment outcome satisfaction, SF36, VAS Anxiety, McCoy sex scale, Menstrual symptoms,
Hollingshurst (2010)[13]	Decision Conflict Scale, Mode of delivery
<b>PDA cost/resource</b>	
Murray (2001)[16]	Production of intervention and software, Equipment associated with video sessions Staff time associated with Interactive decision aid session
Murray (2001)[17]	Cost of intervention (video costs, nurse time, accommodation), Interactive session
Kennedy (2003)[14]	Development and production of intervention <sup>a</sup> , Duration of nurse time for interview
Vourma (2004)[26]	Intervention booklet
Hollingshurst (2010)[13]	Provision of intervention
<b>Additional resource use reported</b>	
Murray (2001)[16]	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
Murray (2001) [17]	Generic consultation with doctor, specialist referral from doctor 3 month supply of Prempacl-C (and related drugs)
Kennedy (2003)[14]	Inpatient days (any reason) Outpatient and GP visits (any reason) Therapeutic and diagnostic procedures Medications for menorrhagia
Vourma (2004)[26]	GP visits Hospitalisation and readmittance, Outpatient visits Diagnostic procedures, surgery/treatment procedures including medical treatments Women's own costs (travel, sanitary pads) Productivity loss
Hollingshurst (2010)[13]	Clinicians time, Out of hours with GP or health visitor Inpatient stays (mother and baby) Outpatient appointments Cost of delivery

<sup>a</sup> 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**

<b>Results PDA effects</b>	
Murray (2001a)[16]	PDA users had lower decisional conflict at 3 month (maintained at 9 month) PDA users were perceived to make treatment decisions by both GPs and patients PDA helped in 46/50 patients, made no difference for 3/50 and hindered 1/50
Murray (2001b)[17]	PDA users had lower decisional conflict at 3 month (maintained at 9 month) PDA appeared to increase patients' participation in decision making PDA seemed to make a more definite choice (fewer 'undecided', more not taking HRT at 3 month) PDA helped 61/73, made no difference for 11 and hindered 1
Kennedy (2003)[14]	Interview group had higher satisfaction levels for the decision making process ( $p < 0.01$ ) and the treatment outcome ( $p < 0.05$ ) Differences for satisfaction levels between information and control groups was smaller ( $p$ not reported)
Vourma (2004)[26]	At 12 months there was no significant difference for satisfaction with treatment
Hollinghurst (2010)[13]	Decision aids reduced decisional conflict
<b>Results health outcomes</b>	
Murray (2001)[16]	No significant differences across groups for health status outcomes (SF36, EQ-5D)
Murray (2001)P[17]	No significant difference across arms for health status outcomes
Kennedy (2003)[14]	Comparing Interview and control groups there was a significant difference on the SF36 Role Physical ( $p < 0.05$ ) but not for other dimensions[Kennedy 2002] Over 24 month period, QALY gain (measured at 6 monthly intervals using EQ-5D) for Information only intervention was slightly smaller than for control[Kennedy 2003] The effect of the PDA is likely to be less important than the effects of treatments (neither intervention had a major effect on health status) Providing women with evidence alone (just information) did not affect health outcomes
Vourma (2004)[26]	There was an overall improvement in all health outcomes with the exception of sexual life There was a statistically significant positive effect for intervention group for the SF36 dimension emotional role functioning ( $p < 0.01$ ) but not for the other SF36 dimensions, VAS, psychological, or menstrual health outcomes At 12 months there was no statistically sig difference in psychological, menstrual health outcomes
Hollinghurst (2010)[13]	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
<b>Results resource use and costs</b>	
Murray (2001)[16]	PDA unlikely to reduce the UK rates of prostatectomies and did not reduce costs
Murray (2001)[17]	PDA made no difference to the uptake rate of hormone replacement therapy or the use of health services resources Including costs of video sessions, mean costs £306 vs. £91 No significant difference detected for mean costs when the cost of trial technology was excluded Delivering the PDA via the internet would reduce the intervention costs from £177 to £5
Kennedy (2003)[14]	Interview group had reductions in hysterectomy rates compared to control ( $p < 0.05$ ) and information groups ( $p < 0.01$ ) with no difference between control and information groups ( $p = 0.53$ ) Intervention groups more likely to have drug therapy than the control group ( $p = 0.17$ and $p = 0.11$ ) The information and interview recipients had lower inpatient and outpatient costs Both intervention groups showed large mean total cost savings compared to control group Interview group showed a reduction in mean total costs compared to the information group Excluding unrelated inpatient costs, the interview group retained lowest mean total costs
Vourma (2004)[26]	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 ( $p = 0.06$ ) The PDA did not affect total healthcare costs despite some differences in treatment courses ( $p = 0.1$ ) There was no difference in mean total costs when including or excluding productivity costs The cost of the decision aid was insignificant compared to other costs



Hollinghurst (2010)[13]	Women using the PDA had fewest Caesarean deliveries No increase or decrease in antenatal or postnatal services The mode of delivery was most important determinant of cost differences (cost of delivery represented 84% of total cost) The information program could be implemented at no additional cost to NHS
----------------------------	--

---

#### 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 24<sup>th</sup> 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**

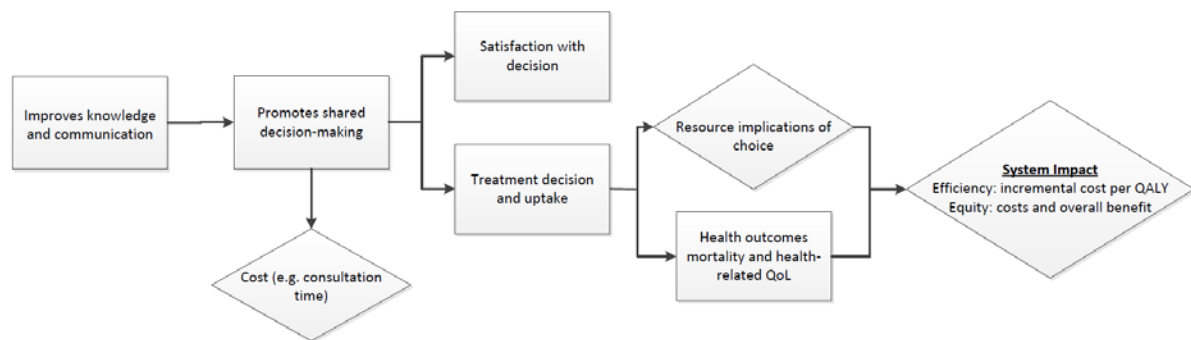
### **7.1 A Pathway of the Impacts of PDAs**

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.

**Figure 1: Impact of PDAs**



## 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 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 raise 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 4: The impact of PDAs**

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

## 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/
12. Meta-analysis.ti.
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

## A2.2 SDM AGENDA

Monday 24<sup>th</sup> June, Pemberton Room, ScHARR, University of Sheffield



*School of  
Health  
And  
Related  
Research*



THE UNIVERSITY *of* York

# 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 (EEPRU)

Monday 01-10-2013, 10:00 AM - 12:00 PM, The University of York

### Introduction

### Working definition reminders

- SDM process is 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 (Coultar 2009)

### Working definition reminders

- PDA's 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 (Coultar 2009)

### DH funded PDA programme

Strong Government commitment to shared decision making: no decision about me, without me

- Steve Leiner led a programme to develop PDAs in 37 conditions (with Capita)
- Capita undertook work to embed the PDAs - but currently piecemeal and varies between conditions
- Capita developed an evaluation framework suggesting use of national IQWiP and GP surveys, surveys of PDA users and PROs


DH approached EEPRU to consider the economics of SDM and PDAs. EEPRU has agreed:

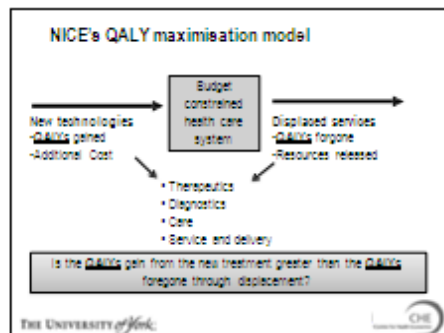
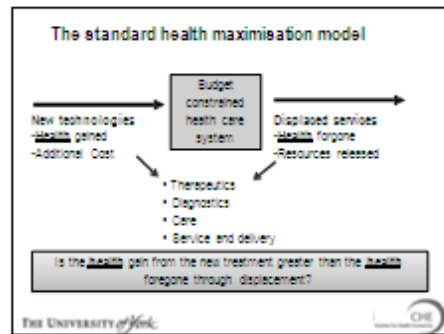
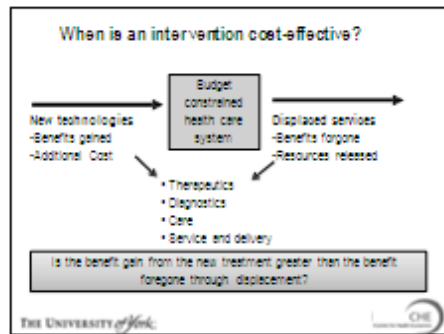
- to develop a framework for evaluation,
- to conduct evaluations in a number of case studies - where possible.

### 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

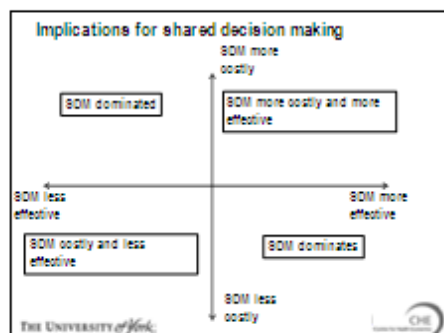




### Health outcomes - EQ-5D

Statement	0 1 2 3
<b>Mobility</b>	
I have no problems in walking about	0 1 2 3
I have some problems in walking about	0 1 2 3
I am confined to bed	0 1 2 3
<b>Self-Care</b>	
I have no problems with self-care	0 1 2 3
I have some problems with self-care (washing or dressing myself)	0 1 2 3
I am unable to perform my usual activities	0 1 2 3
<b>Usual Activities (e.g. work, study, household, family or leisure activities)</b>	
I have no problems with performing my usual activities	0 1 2 3
I have some problems with performing my usual activities	0 1 2 3
I am unable to perform my usual activities	0 1 2 3
<b>Pain/Discomfort</b>	
I have no pain or discomfort	0 1 2 3
I have moderate pain or discomfort	0 1 2 3
I have severe pain or discomfort	0 1 2 3
<b>Anxiety/Depression</b>	
I am not anxious or depressed	0 1 2 3
I am moderately anxious or depressed	0 1 2 3
I am severely anxious or depressed	0 1 2 3

THE UNIVERSITY of York



### Quantifying the benefits of SDM – conceptual issues

What can SDM achieve?	Analytical response
SDM can improve health outcomes	Can be evaluated with standard methods
SDM can improve a more broadly defined set of health outcomes	• Are these legitimate? • Extend health classification and quantify trade-offs
SDM improves non-health outcomes	• Are these legitimate? • Extend health classification and quantify trade-offs

THE UNIVERSITY of York

**Conceptual Framework**  
**PRACTICAL ISSUES**

- Types of economic evaluation**
- **Cost-effectiveness analysis:** interventions compared in terms of cost per achievement of natural units of outcome
  - **Cost-utility analysis:** cost per quality adjusted life years (QALY) of new intervention compared to a threshold (20-30K for NICE)
  - **Cost-benefit analysis:** all costs and benefits are valued in monetary terms and compared; where B>C then proceed
  - **Cost-consequences analysis:** where all costs and benefits are assessed, but not combined and decision left to policy maker

- Main differences between techniques**
- Perspective:**
- CBA and CUA tend to be limited to health care perspective - so only count NHS (and PSS) costs (though under Value Based Pricing looking at methods for extending it to include WSS)
- Measure of benefit:**
- CBA uses natural units, CUA/QALYs, CBA/Bs and CCA does not try to value all outcomes in a common unit.
- Decision rule:**
- CBA/CUA should have a threshold to represent opportunity costs
  - CBA uses net benefit
  - Policy maker undertakes a judgement (perhaps using NICE)

- 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	Implications for study design
Impact on intervention	CCU with PCA may (or may not) change the intervention provided to the patient	Requires data on choice of treatment with and without PCA

**KEY COMPONENTS OF IMPACT**

Component	Impact	Implications for study design
Resources	Cost of providing PCA, training of staff and time of clinicians	Micro-costing
	Change in treatment choice will have consequences for resources used (e.g. fewer patients choose surgery)	Collect data on treatment choices with and without PCA and model consequences for resources
	Changes in health outcomes (see below) will have consequences for resources used (e.g. from better control of blood sugar reducing complications)	Collect data on outcomes – immediate or final; collect resource use data and/or model cost consequences

## KEY COMPONENTS OF IMPACT

Component	Impact	Implication for study design
Outcomes	Improved outcomes through better compliance, greater confidence in decision and closer alignment of decision and preferences  Intermediate outcomes like blood glucose  Health Outcomes- survival and health related quality of life to estimate QALYs	Collect data on intermediate outcome and model impact on health outcomes  Collect data health outcomes (e.g. QOD through PPDVIG)

## KEY COMPONENTS OF IMPACT

Component	Impact	Implication for study design
Preferences over health outcomes	Economic evaluation typically capture outcomes using QALYs  QALY assumptions about the nature of preferences over health outcomes that are violated: Value of health to patients depends on how long it lasts (e.g. maximal endurable time) (The value of states depends on context of overall profile (e.g. people preferring ending on a high)  (Risk neutrality – people are usually risk averse about their health  (Implies patient choice may not conform to QALY model)	Collect data on choices  Compare choices with those predicted by QALYs  Value benefits to patient using preference studies (e.g. Ask patients to rate whole health profiles?)

## KEY COMPONENTS OF IMPACT

Component	Impact	Implication for study design
Preferences over non-health outcomes and processes	Decisional conflict, confidence, satisfaction with decision and so forth	Data collected in studies using questionnaires  Conduct patient preference studies of non-health to health benefits – such as DDD or matching?

## Application of framework to case studies

- Renal services
- Musculoskeletal
- Others?

Literature reviews of economic evaluations of SDM/PDAs

## 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 PDAs in any indication or setting.

### Review(1)

670 initial hits,  
 5 satisfied inclusion criteria  
 (EE alongside RCT, PDA vs. 'standard care')  
 2 in primary care (prostatic hypertrophy, HRT)  
 3 in secondary care (uncomplicated  
 menorrhagia (2), mode of delivery following  
 C-section)  
 4 in UK, 1 in Finland

### 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

### Review of existing systematic reviews involving PDAs and/or SDM

### Objectives

- To identify and review existing SRs of SDM and/or PDAs
- To help inform the conceptual framework for economic evaluations in SDM
- Inclusion criteria: any systematic review of PDAs or SDM in any setting or indication
- Exclusion criteria: any article describing the development of a PDA/any individual application of PDA or SDM

### Results

- 21 reviews involving 2 to 115 individual studies
- Predominantly PDAs (not SDM)
- Broad range of indications & settings
  - Cancer: mixed conditions, ethnic groups, both primary & secondary care, time of publication
- Extraction template: outcomes reported in the SRs
- Thematic analyses:
  - Impact on knowledge, experience, satisfaction, anxiety, treatment uptake, clinical outcomes & resource implications

### Contributors/Investors in SDM



### Patient outcomes (1)

- Knowledge
  - 14 reviews involving 124 individual studies
  - Many reported an improvement in knowledge
  - Understanding of risks improved
  - Those with lower baseline had biggest improvement
- Decision
  - 7 reviews involving 188 individual studies
  - Mixed results regarding satisfaction with consultation
  - One review showed a 70% positive effect on communication
- Satisfaction
  - 12 reviews involving 229 individual studies
  - Increase satisfaction with decision making process
  - Improvement in satisfaction with care received
  - Decisional conflict reduced in the majority

### Patient outcomes (2)

- Anxiety
  - 14 reviews involving 124 individual studies
  - Majority reported a reduction in anxiety
  - Differences in emotional wellbeing but no difference in functional wellbeing
- Treatment decisions
  - 10 reviews involving 105 individual studies
  - No consistent effect on preferred choice of treatment
  - Patients may be willing to accept more toxic treatments
- Health outcomes
  - 8 reviews involving 29 individual studies
  - No difference in outcomes including mortality

### Family/carer outcomes

2 reviews involving 17 individual studies

### Provider outcomes

3 reviews involving 97 individual studies

### Payer outcomes

6 reviews involving 210 individual studies

### Summary

- Various outcomes reported
  - Emphasis on 'non-health' or process outcomes
- Concepts considered to be important are:
  - Knowledge, experience, satisfaction, anxiety, treatment uptake, 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

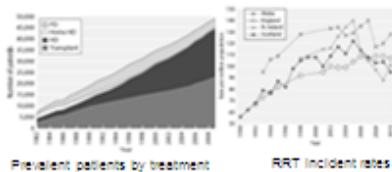
Professor Donal O'Donoghue  
Consultant Renal Physician

*Working for Better Kidney Care*

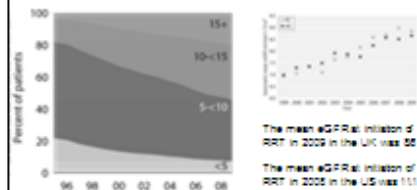
Conceptual Framework for Economic Evaluation in Health Care Decision Making  
University of Exeter  
31 June 2013

**Demand for renal replacement therapy continues to increase**

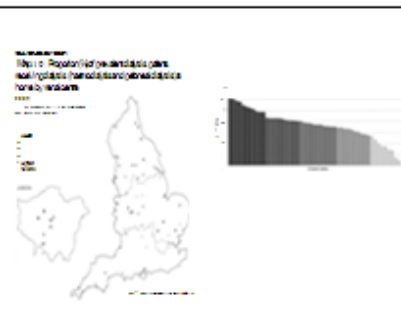
but incident rates have reached a plateau



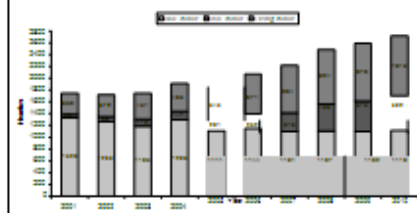
**The mean eGFR at initiation of RRT is rising**

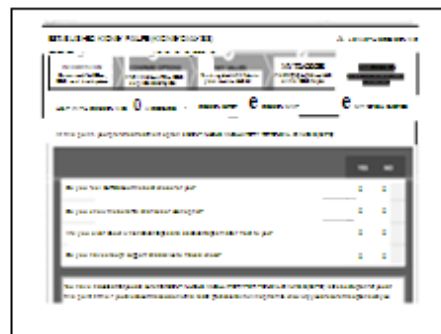
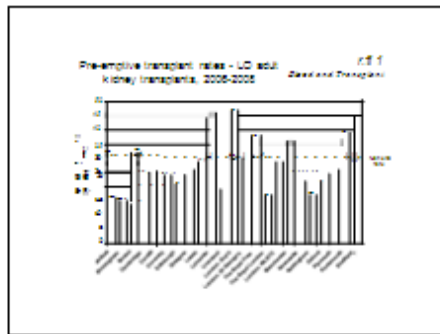


Percent distribution at initiation by eGFR



**Kidney transplants in the UK**





Leeds Institute of Health Sciences  
 Faculty of Medicine & Health Sciences  
 UNIVERSITY OF LEEDS

SHARED:  
 A patient experience of shared decision making measures.

Hilary Bekker, Senior Lecturer

Emma Walker, NHS AQUA Programme Lead  
 Alan Nye, NHS AQUA Clinical Lead

AQUA

UNIVERSITY OF LEEDS

- NHS AQUA implementing staff training (Alan Nye, Emma Walker)
- Patient decision aids to enable informed patient decisions (Bekker, 1999+, O'Connor, 1995+)
- Shared decision making theory and reviews of practice (Sladey, Legerik, Makoul and Dayman, Toivola and Goodwin)
- Reviews of shared decision making measures (Kasper et al, 2011; Cople, 2012)
- Piloting SURE, SURE+, SHARED
- The future for SDM measures



UNIVERSITY OF LEEDS

Evidence-based information resources to help people make informed decisions between treatments.

An informed decision is one made well and based on:

- a person's evaluations of accurate information about the advantages and disadvantages of all options and their consequences
- in accordance with their beliefs, and
- personal trade-offs between these evaluations.

(Zakeri et al. 1999, 2003, 2010)

UNIVERSITY OF LEEDS

"an interactive process in which patients and professionals collaborate to choose healthcare" (Chen et al. 1997)

Consultation conversation where patient and professional (Stacey et al. 2010):

- Exchange information/knowledge about treatments
- Express preference/values about treatments
- Explicit reasoning about treatment choices
- Agree and implement choice

UNIVERSITY OF LEEDS

Patient decision aids might facilitate shared decision making:

- Before consultation: helps 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
- PDA Utilisation: patient and professional variation

UNIVERSITY OF LEEDS

Assess aspects of communication and/or decision outcome, not shared decision making process:

- Patient engagement, involvement activation (Degner, BDMQ)
- Informed patient decision making (DCB, SURE)
- Doctors' communication skills (BDMQ 5: option)
- Patients' perception doctors' communication skills

UNIVERSITY OF LEEDS

- Assess impact SDM professional skills training on patient outcomes.
- Evaluate variations in quality of SDM across services.
- Brief tool to be used after every consultation/decision.

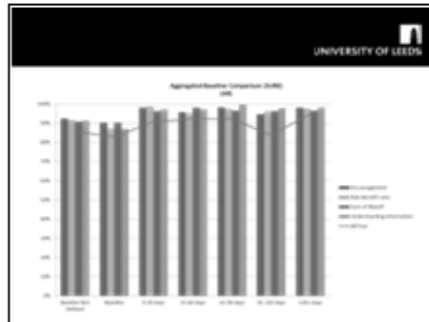
Best patient reported outcome measure of IDM:

- Decisional Conflict Scale (O'Connor et al., 1998):
- SURE (O'Connor and Legare, 2008) – 4 item decisional conflict screening tool for usual care consultations.

UNIVERSITY OF LEEDS

SURE:	Items	Yes/No
Sure of myself	Do you feel sure about the best choice for you?	Yes/No
Understand the options	Do you know the benefits and risks of each option?	Yes/No
Risks/benefits trade-off	Are you clear about which advantages and disadvantages of each option matter most to you?	Yes/No
Encouragement	Do you have enough support and advice to make a choice?	Yes/No

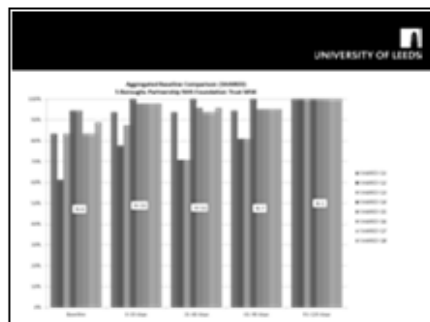
If patient answers 'no' to any then decisional conflict present.  
Around 5% primary care consultations have decisional conflict, 15% for difficult topics.



Not targeting components of shared decision making process.

Need for more sensitive measures?

Q/R	Question	Yes	No
Q/R	Do you feel sure about the best choice for you?	84	16
Q/R	Do you know the benefits and risks of each option?	84	16
Q/R	Did you hear about the advantages and disadvantages of each option from the doctor?	84	16
Q/R	Do you have enough suggestions and advice to make a choice?	84	16
Q/R	Did the health professional talk about other treatment options for the health problem than the one you chose?	84	16
Q/R	Were you able to tell the health professional what was important about your choice?	84	16
Q/R	Did you understand the risks of not having the one option that was medically better than another?	84	16
Q/R	Did you feel it should be OK to choose an option that was different from the health professional's choice?	84	16



		SHARED	SHARED	SHARED	SHARED	SHARED
1	The health professional asked about other options for me and my choice					
2	The health professional asked about other options and then asked me what I chose for my health problem					
3	The professional gave me information about the options					
4	The health professional asked for my choice about the options					
5	I asked about the risks and benefits of the other treatment options					
6	I asked about the risks and benefits of the other treatment options					
7	I asked about the risks and benefits of the options for me and my health					
8	It felt I could be OK to choose an option that was different from the health professional's choice					
9	It felt the decision made was the best one for me					
10	It felt the health professional and I agreed on which option was the best one for me					

Renal registry pilot 1 (n=330)  
 SHARED; BURE; Decision Involvement; knowledge options; choice made; demographics;

Renal registry pilot 2  
 modified questionnaire rating and data collection point.

Dutch study cancer choices (n=20)  
 audio tape-recording consultations and completion SHARED

Psychometric testing

UNIVERSITY OF LEEDS

- What value is informed and/or shared decision making to patients?
- What is the relationship between use of PDAs and SDM with clinical practice outcomes?
- What does economic evaluation want to capture, decisions made effectively by patients or services delivering shared decision making?
- When is it best to measure informed and/or shared decision making: before, during or after decision outcome?
- How do you capture good practices in contexts with multiple professionals and information points (e.g. chronic condition)?
- Does it matter that a good decision making process and service practices may not lead to clinically effective choices?

AQUA

WIS

UNIVERSITY OF LEEDS

- Bekker H, Thomson JG, Gray CM, Cornally G, Haxton J, Lilleyman J, et al. Informed decision making: an annotated bibliography and a practical review. *J Gen Intern Med* 2009; 34: 100-109.
- Bekker HJ, Haxton J, Thomson JG. Understanding why decision aids work: linking process and outcome. *Patient Education and Counseling* 2009; 76: 103-109.
- Bekker HJ. The loss of choice in patient decision aid research: do checklist enhance the validity of informed choice when informed? *Patient Education and Counseling* 2010; 79: 227-244.
- Bekker HJ, Nya J, Walker S, Lopez R. SHARED: Patient Experience of Shared Decision Making Measure (2012). <http://www.leeds.ac.uk/leedsresearch/leedsresearch/leedsresearch/>
- Nya J on behalf of the NHS Advancing Quality Alliance. Your Health, Your Decision. A report on the creating a receptive culture shared decision making project. *Right Care NHS 2011-12*. <http://www.nhs.uk/ourwork/yourhealthyourdecision/>
- Our Shared Decision Making Programme in partnership with Celia Gray, RCU. *Measuring Shared Decision Making: a review of research* (2011). [www.rcu.ac.uk/leeds/](http://www.rcu.ac.uk/leeds/)

#### **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

- [1] N. Bansback, J. Brazier, A. Tsuchiya, A. Anis, Using a discrete choice experiment to estimate health state utility values. *J.Health Econ.* 31 (2012) 306-318.
- [2] Brazier J, Dixon S, Ratcliffe J, The role of patient preferences in cost-effectiveness analysis. *Pharmacoeconomics* 27 (2009) 705-712.
- [3] Brazier J, A. Tsuchiya, Improving cross-sector comparisons: going beyond the health related QALY. *Applied Health Economics and Health Policy* 13 (2015) 557-565.
- [4] Capita A. Shared Decision Making Programme An Evaluation Approach: Evidence Baseline & Research Framework. 2013.
- [5] Capita B. Shared Decision Making Programme Use of Patient Decision Aids in Herts Valley - implementation case study. 2013.
- [6] A. Coulter. Implementing shared decision making in the UK, a report for the Health Foundation 2009. 2009.
- [7] da Silva D. Evidence: Helping people share decision making: A review of evidence considering whether shared decision making is worthwhile. The Health Foundation. 2012.
- [8] Department of Health. Liberating the NHS: No decision about me without me. 2013. 2013.
- [9] J. Dowie, Towards the equitably efficient and transparently decidable use of public funds in the deep blue millennium. *Health Economics* 7 (1998) 93-103.
- [10] G. Elwyn, D. Frosch, R. Thomson, N. Joseph-Williams, A. Lloyd, P. Kinnersley, E. Cording, D. Tomson, C. Dodd, S. Rollnick, A. Edwards, M. Barry, Shared Decision Making: A Model for Clinical Practice. *Journal of General Internal Medicine* 27 (2012) 1361-1367.
- [11] M. Espinoza, A. Manca, M. Sculpher, K. Claxton, Individual Decisions and Social Value: A Conceptual Framework to Explore Alternative Decision Making Approaches and the Value of Heterogeneity in the Era of Individualized Care. *Value in Health* 15 (2012) A2.
- [12] A. Gafni, Birch S, Mehrez A, Economics, health and health economics: HYE (healthy-years equivalent) versus QALYs (quality-adjusted life-years). *Journal of Health Economics* 12 (1993) 325-339.
- [13] S. Hollinghurst, C. Emmett, T.J. Peters, H. Watson, T. Fahey, D.J. Murphy, A. Montgomery, Economic Evaluation of the DiAMOND Randomized Trial: Cost and Outcomes of 2 Decision Aids for Mode of Delivery among Women with a Previous Caesarean Section. *Medical Decision Making* 30 (2010) 453-463.
- [14] A.D.M. Kennedy, M. Sculpher, A. Coulter, N. Dwyer, M. Rees, S. Horsley, et al, A multicentre randomised controlled trial assessing the costs and benefits of using structured information and analysis of women's preferences in the management of menorrhagia. *Health Technology Assessment* 7 (2003).



- [15] A.D.M. Kennedy, M.J. Sculpher, A. Coulter, N. Dwyer, M. Rees, K.R. Abrams, S. Horsley, D. Cowley, C. Kidson, C. Kirwin, C. Naish, G. Stirrat, Effects of decision aids for menorrhagia on treatment choices, health outcomes, and costs - A randomized controlled trial. *Jama-Journal of the American Medical Association* 288 (2002) 2701-2708.
- [16] E. Murray, H. Davis, S.S. Tai, A. Coulter, A. Gray, A. Haines, Randomised controlled trial of an interactive multimedia decision aid on benign prostatic hypertrophy in primary care. *British Medical Journal* 323 (2001) 493-496A.
- [17] E. Murray, H. Davis, S.S. Tai, A. Coulter, A. Gray, A. Haines, Randomized controlled trial of an interactive multimedia decision aid on hormone replacement therapy in primary care. *BMJ* 323 (2001) 490-493.
- [18] NHS. Shared Decision Making Decision Aids. Rightcare . 2013.
- [19] NICE. Patient experience in adult NHS services: improving the experience of care for people using adult NHS services. CG138. 2012. 1-6-0013.
- [20] NICE. NICE Quality Standards. NICE . 2013. 1-6-2013.
- [21] Rightcare. AQuA: Your Health - Your Decision. Evaluation & Output Report of the AQuA Workstream within the National Shared Decision Making Programme. Rightcare . 2013. 1-7-2013.
- [22] M. Sculpher, The cost-effectiveness of preference-based treatment allocation: The case of hysterectomy versus endometrial resection in the treatment of menorrhagia. *Health Economics* 7 (1998) 129-142.
- [23] M. Sculpher, Reflecting Heterogeneity in Patient Benefits: The Role of Subgroup Analysis with Comparative Effectiveness. *Value in Health* 13 (2010) S18-S21.
- [24] D. Stacey, F. Legare, N.F. Col, C.L. Bennett, M.J. Barry, K.B. Eden, M. Holmes-Rovner, H. Llewellyn-Thomas, A. Lyddiatt, R. Thomson, L. Trevena, J.H. Wu, Decision aids for people facing health treatment or screening decisions. *Cochrane.Database.Syst.Rev.*2014) CD001431.
- [25] D. Stacey, C.L. Bennett, M.J. Barry, N.F. Col, K.B. Eden, M. Holmes-Rovner, H. Llewellyn-Thomas, A. Lyddiatt, F. Legare, R. Thomson, Decision aids for people facing health treatment or screening decisions. *Cochrane Database of Systematic Reviews*2011).
- [26] S. Vuorma, J. Teperi, A.M. Aalto, R. Hurskainen, E. Kujansuu, P. Rissanen, A randomized trial among women with heavy menstruation - impact of a decision aid on treatment outcomes and costs. *Health Expectations* 7 (2004) 327-337.