Session 3 Conceptual Framework Underlying Ottawa Patient Decision Aids

This chapter describes the Ottawa Decision Support Framework that underpins the development of Ottawa Patient Decision Aids (PtDAs) and Ottawa Consult Decision Aids (OCDA). In this version of the document, an example is provided of how the concepts in the Framework are mapped onto elements in an Ottawa PtDA. This framework is a descriptive type of conceptual framework. Other classifications of frameworks and examples of frameworks used to develop PtDAs are described in Appendix A.

1.0 Deconstructing Elements of Ottawa PtDAs.

The Ottawa Decision Support Framework (see figure) is based on the construct of decisional conflict as well as theories from psychology, social psychology, economics, and social support.(1-11) Asserted in this framework is that the quality of decision-making can be adversely affected by unresolved decisional needs of patients and practitioners.(1, 12) Patients whose decisional needs are unresolved are more likely to delay decisions, feel regret, express dissatisfaction, and blame the practitioner for poor outcomes.(13, 14) However, decision support which is tailored to unresolved decisional needs can improve decision quality so that it is informed and based on personal values. Decision quality subsequently affects actions or behaviours (e.g. delay), health outcomes, emotions (satisfaction, regret, blame), and appropriate use and costs of services. This framework applies to all participants involved in decision making, including the individual, couple, or family and their health practitioner.



Figure: Ottawa Decision Support Framework

Unresolved decisional needs that adversely affect decision quality include: decisional conflict; knowledge deficits; unrealistic expectations; unclear values; inadequate support or resources; complex decision type; urgent timing; unreceptive stage of decision making; polarized leaning toward an option; and participant characteristics such as cognitive limitations, poverty, limited education, physical or emotional incapacitation.

Decision support in the form of clinical counselling, PtDAs and coaching can improve decision quality, by addressing unresolved needs. The combination and sequencing of decision support to address these unresolved decisional needs (professional counselling, PtDAs, coaching) depends on the type of decision and the usual decision support that is provided. Specific interventions include: clarifying the decision and the person's needs; providing facts and probabilities; clarifying values; guiding/coaching/supporting in deliberation and communication; and monitoring/facilitating progress. Health professionals tend to over-use factual information about options and under-use other strategies. Specific strategies tailored to each unresolved decisional needs are briefly described below.

Decisional conflict is personal uncertainty about the best course of action stemming from: a) inherent tradeoffs in the decision that make it; and b) modifiable factors contributing to uncertainty such as deficits in knowledge, values clarity, and support. Decisional conflict is addressed by tackling these modifiable factors.

Knowledge deficits are addressed by helping a person to access information on his/her health situation, the options available and the potential outcomes of the options. Both potential benefits and harms should be presented in sufficient detail for decision making. The information may be delivered by the practitioner or provided as written materials or multimedia presentations. The medium and pace with which the information is provided should be appropriate to the person's needs. It is important to assess the person's comprehension of the information after it is provided; the focus should be on information that is 'essential' for decision making.

Unrealistic expectations can be **re-aligned** in two ways. First, one can provide information on the probabilities of the outcomes for each option, observed in people with characteristics similar to the person facing the decision. Second, one can describe the outcomes in ways that make them easier to imagine and identify with.(6) In cases where a person over-estimates the chances of an outcome occurring, the practitioner should acknowledge the possibility, but then describe anecdotes in which the outcome <u>did not</u> happen. In cases where a person under-estimates the chances of an outcome occurring, the practitioner should acknowledge the possibility, but then describe (anecdotes) in which the outcomes <u>did happen</u>.

Unclear values are addressed by providing meaningful descriptions of outcomes so that patients can understand what it is like to experience their physical, emotional, and social consequences. Patients can also be asked to rate the personal importance of outcomes. Clinicians are not very good judges of patients' values, therefore, they need to obtain this information from patients.

Inadequate support, skills and resources can be addressed by providing structured guidance or coaching in the steps of deliberation and communication.

Unreceptive stage of decision making or predisposition towards options: patients need information and support at a time when they are actively deliberating about options; the Information Therapy (IT) movement (the right information, for the right patient, at the right time, as part of the process of care) is striving to find IT solutions to deliver information at definable moments in care (e.g. <u>http://www.healthwise.org/insights/information-therapy.aspx</u>). Others are developing care pathways to identify the appropriate time for decision support.

Failure to tailor decision support to personal and clinical characteristics including patients' physical, emotional, cognitive, and social functioning that interfere with the patients' capacities to participate in decision making; demographic characteristics that affect attitudes and capacities for participation in decision making (e.g. age, sex, ethnicity, language, education that affects literacy, numeracy, and learning style). The specific needs of diverse groups facing different decisions are beginning to be explored. For example, older patients and

those with less education are less likely to want to participate in decision making;(10) however, a strong minority do want to participate and therefore they need to be asked. Compared to men, women report more decisional conflict and also perceive risks differently than men.(11) Males from different ethnic groups also perceive risks differently.(11) Patients have different learning styles and health literacy.

2.0 Example of an Ottawa Patient Decision Aid (PtDA)

It is useful to review an example of a PtDA before deconstructing its conceptual elements. There are two types of decision aids based on the Ottawa Decision Support Framework – one that is intended for use either in preparation or during the consultation (PtDA) and another that is intended for use only within the consultation (Ottawa Consult Decision Aid).

The following example walks through the elements of a PtDA and links them to the elements of the Ottawa Decision Support Framework. For an interactive version of a PtDA, more detailed descriptions of highlighted information can be provided with a mouse click or mouse over.

Page 1: Introduce the Decision

The title introduces the question to be answered. Then the target audience is identified. There is a brief description about the condition that leads a person to consider the options. Outcome descriptions are described from the patient's point of view. The options are then explained so that a reader understands how they are involved. Because information cannot be tailored to an individual level, the reader is asked to identify personal factors that may affect the appropriateness of the options and the likelihood of benefits and risks. Finally, the reader is guided in the four steps in deliberation: understanding risks, clarifying values, identifying unresolved needs, and planning next steps.

Should I take etanercept (Enbrel®) for rheumatoid arthritis? A Cochrane decision aid to discuss options with your doctor

This decision aid is for you if:

- Your doctor says you have active rheumatoid arthritis
- You have tried methotrexate treatment and it is not working well enough.
- Your doctor has offered you etanercept (Enbrel®)

How is Rheumatoid Arthritis (RA) managed when methotrexate is not working? RA causes your immune system to attack and inflame the lining of your joints. Often starting in the hands and feet, they become hot, swollen, stiff and painful. Without treatment, inflammation permanently destroys the joints. Therefore early treatment with drugs such as methotrexate is important. If methotrexate is not controlling the inflammation, people are advised to take stronger 'biologic' treatments such as etanercept (Enbre®). It blocks a substance called TNF, which causes inflammation. There are several different biologic drugs which all work by blocking cells and substances in the body that contribute to the inflammation and joint damage.

What are your treatment options?

- Take etanercept (Enbrel®): Once or twice a week, you have an injection under the skin in different parts of the thigh or abdomen. A nurse or doctor teaches you how to do this. A family member or friend can also learn. You store the drug in a refrigerator and warm it to room temperature prior to use. Most people who fear self-injection are able to give these injections with mild or no discomfort.
- Decline etanercept (Enbrel®). You may wish to discuss other treatment options with your doctor.

What other factors may affect your choice?

Check ☑ any that apply and discuss your concerns with your doctor.

I have had a previous side effect to a biologic	I have a current infection
such as anakinra (Kineret®),abatacept	□ I have a history of recurring infections in the
certolizumab pegol (Cimzia®), etanercept	including shingles
Enbrel®), golimumab (Simponi®), infliximab Remicade®), rituximab (Rituxan®), tocilizumab	□ I or someone in my family has had multiple sclerosis (MS)
	I have cancer or used to have cancer

I am allergic to latex

L I have had TB

vaccine

I have the following drug allergies:

I have lived with someone who had TB

I have had a positive skin test for TB

I have been vaccinated for TB- BCG

- I have congestive heart failure
- l am pregnant or planning on becoming pregnant
- I am breast feeding
- I have recently had surgery or am planning to have it

Working through the 4 steps of this decision aid may help you consider the options.

Page 2: Describing Benefits, Risks, Probabilities

On page 2, the best available evidence regarding major benefits and risks is provided in a balanced way that allows for comparisons across options. Probabilities are provided with ratings using GRADE to indicate the strength of the evidence. For an interactive version, more detailed descriptions of highlighted outcomes can be provided with a mouse click or mouse over.



+Note: The options include 'estimates' of what happens to groups of people based on the available research. The quality of these estimates is rated summarized using the GRADE system as follows: ++++ High quality – further research is very unlikely to change the estimate. +++Moderate quality – further research may change the estimate. ++ Low quality – further research is used likely to change the estimate. +++Moderate quality – further research is very likely to change the estimate. +*NT stands for number needed to treat. It is a way of showing how many people must take a drug for one person to benefit. For example, 3 people would need to take Etanercept for one person to benefit (improved pain and dysfunction).

Page 3: Clarifying and Communicating Values

In the previous pages, outcomes were described so that it easier to judge their value. On this page, values for each benefit, risk, or side effect are elicited using an importance rating which is scaled from 0 to 5. Readers can add other reasons that are important to them. They are asked to consider which option has the reasons that matter most. Finally, readers indicate their preferred option.

	Step 2. What matters most to you?						
Co Ch '0'	mmon reasons to choose each option are listed below. eck ☑ how much each reason matters to you on a scale from (means it is not important to you. '5' means it is very important) to 5 to ye	i. Du.				
0	Reasons to take etanercept (Enbrel®)	Not Important 0 1 2			Very Important 3 4 5		
	How important is it to you to improve your symptoms of rheumatoid arthritis?						
	How important is it to you to reduce your chance of serious joint damage?						
	List other reasons to take etanercept (Enbrel®):						
<	Reasons to decline etanercept (Enbrel®)	Not Impo 0	ortan 1	1 ^t 2	lr 3	mpor 4	Very rtant 5
	How important is it to you to avoid injections?						
	How important is it to you to avoid the extra risk of tuberculosis?						
	List other reasons to decline etanercept (Enbrel®):						

Now, thinking about the reasons that are most important to you...

Which option do you prefer? Check ☑ one.

- □ I don't know
- Take etanercept (Enbrel®)
- Decline etanercept (Enbrel®)
- Discuss other treatment options

Page 4: Unresolved Needs and Next Steps

The readers' complete a knowledge test about their options and the SURE Test (15, 16). The SURE Test is the screening tool version of the Decisional Conflict Scale and includes modifiable factors contributing to decisional conflict (e.g. feeling uninformed, unclear values, unsupported). Both the knowledge test and SURE test are used to identify unresolved needs. Readers are then asked to consider next steps.

Page 4: Footer information

At the bottom of the page, additional information and disclosures are provided and/or hyperlinked. Addition information includes knowledge test answers, potential conflicts of interest, evidence used to inform the decision aid, dates (including commitment for updates), and disclosure of authors and funding sources. Reference to the original Ottawa Patient Decision Aid template is included.

Hyperlink for more detailed information

More detailed information can be hyperlinked. According to IPDAS certifying standards, reference to the scientific evidence needs to be provided. Other information that can be hyperlinked includes a description of the meaning of GRADE ratings, interpretation of the SURE test results, and more detailed information about the condition and options.

d to propose for desision mobile

	Check I the best answer.	Take etanercept (Enbrel®)	Decline etanercept (Enbrel®)	l don't know
1.	Which option <u>raises</u> your chance of improving pain, dysfunction, and the number of swollen joints?			
2.	Which option lowers your chance of serious joint damage?			
3.	Which option has a greater risk of skin reactions?			
4.	Which option has the lowest chance of tuberculosis?			
	Check	our answers	at the bolicim	of the pay
	Find out how comfortable you feel about deciding	r 1	Yes	No
~	Do you know enough on the benefits and harms of each of	ption to	_	
4	make a choice?			
A	Are you clear about which benefits and harms matter most to you?			
8	Do you have enough support and advice to make a choice	?		
4	Do you feel sure about the best choice for you?			

If you answered 'No' to any of these, discuss with your practitioner, (Adapted SURE Test III O'Connor & Légaré

Step 4: What are the next steps?

Check ☑ what you want to do next...

- Try etanercept (Enbrel®)
- Discuss other treatment options
- Other, please specify:

Step 3 answers: Questions 1, 2 and 3: Take etanercept (Enbrel®) Question 4. Dedline etanercept (Enbrel®)

This information is not intended to replace the advice of a health care provider

This decision aid was developed by Rader, T. Maxwell, L. Ghogomu, E. Tugwell, P. Welch, V. Conflict of interest disclosure available from trader@uottawa.ca. Funded in part by the Canadian Institutes of Health Research. Format based on the Ottawa Personal Decision Guide © 2000, A O'Connor, D Stacey, University of Ottawa, Canada. Last reviewed: July 2011. Acknowledgements: J. Karsh, MD, FRCPC provided scientific and clinical review of this aid. G. Wells converted Vanderheid-Sharp scores using Wells Calculator, References on outcomes from:1. Singh JA et al. Biologics for rheumatoid arthritis: an overview of Cohrane reviews. Cohrane Database of Systematic Reviews 2009, Issue 4. 2.Singh et at al. Adverse effects of biologics: a network meta-analysis and Cohrane overview. Cohrane Database of Systematic Reviews 2010, Issue 10.Art. No.: C0008794. DOI: 10.1002/14651858. CO008794. pub2. Information on clinical meaning of x-ray damage: Smolen JS, Aletaha D, Grisar JC, Stamm TA, Sharp JT. Estimation of a numerical value for joint damage-related physical disability in rheumatoid arthritis clinical trials. Ann Rheum Dis. 2010 Jun;89(6):1088-64. <u>http://creativecommons.org/licenses/by-nd/3.0/</u>



Appendix A: Types of Conceptual Frameworks Underlying Development of PtDAs

Several frameworks are available to guide PtDA development. These can be classified as: prescriptive, descriptive, and transactional.

Prescriptive frameworks use decision trees and expected utility maximisation principles to guide decision making.(17) Developers using this framework maintain that many decisions are too complex for unaided human processing. A more 'rational,' theoretically valid approach is to:

- a) create a decision tree describing options, outcomes, and their associated probabilities;
- b) elicit the patient's utilities or values for each outcome in the tree using techniques such as the standard gamble, time trade-off, or category rating; and
- c) calculate the expected utility of each option.

The *prescribed* or recommended option is the one with the highest expected utility. This recommendation is often the starting point for discussion with consumers about which option they prefer.(18) Stephen Pauker was the first to develop a PtDA using this model. The trials using prescriptive frameworks in the Cochrane systematic review are summarized in Appendix B.

Descriptive frameworks use decision trees only to structure the presentation of options. Developers use the underlying structure of the trees to *describe* options, outcomes, and probabilities so that patients are better able to judge the value of the benefits versus the harms. Their presentation of information conforms more closely to usual patient education approaches in clinical practice. 'Values clarification' is simpler than utility assessment, and placed in the context of the options being considered. Expected utilities are not calculated nor are options prescribed because expected utility maximisation does not conform to the way people make choices. Formal utility assessments are not used because they are complex, elicited outside the context of the choice, impractical in most practice settings, and fraught with their own measurement errors that often shift recommendations. Some descriptive frameworks also take into account determinants of decisions beyond perceived probabilities and values, for example, stage of decision making, the influence of others, personal and external resources, characteristics of participants, and socio-political influences. Common descriptive frameworks used for developing PtDAs were those of Mulley, O'Connor, and Rothert (1, 19, 20).

The third group of frameworks (21, 22) describe patient and professional transactional roles in a clinical encounter. They classify roles between practitioners and patients based on their level of mutuality and direction of exchange of information about options, outcomes, values and control over choices. These frameworks offer some insights into how PtDAs can facilitate patient participation in decision making. Many PtDAs based on these frameworks also stress the need to take into account patients' preferences for participation in decision making so that counselling can be tailored according to the preferred role. Examples in the patient decision aids based on Charles (21) and Degner (22) are in Appendix B.

There are two reviews that will provide more insight into conceptual underpinnings of PtDAs and shared decision making. One review discusses conceptual Frameworks that underpin PtDAs that were evaluated in randomized controlled trials.(23) The other review focuses on frameworks for shared decision making.(24) The tool used in this paper for appraising shared decision making frameworks will be applied in this etraining to the Ottawa Decision Support Framework.

Appendix B: Examples of Patient Decision Aids evaluated in randomized controlled trials and their link to conceptual frameworks

	Number of Enrollees in Intervention + Comparison: Options Considered	Comparison of Most and Least Intensive Intervention	Elements in DAs						
Source, Year, Location			Options & outcomes	Clinical problem	Outcome probability	Explicitly clarify values	Others' experiences	Guidance in steps of DM	
	PRESC	RIPTIVE FRAMEWORK	S						
Bekker 2004; UK	59 + 58 women: prenatal diagnostic screening for	Decision analysis plus consultation	X	X	X	Х		X	
Clancy 1988; US	753 + 263 physicians: Hepatitis B vaccine	Pamphlet + decision analysis PtDA	X X	X	X X	Х		Х	
Montgomery 2003;	52 + 55 + 51 + 59 adults:	Decision analysis PtDA	 X		 X	 X			
UK	hypertension treatment	Video and booklet PtDA	X	Х					
		Decision analysis, video & booklet PtDA	Х	Х	Х	Х			
		Standard care							
		DESCRIPTIVE							
Conceptual model of outc	omes research (Mulley et al,	, 1994)							
Barry 1997; US	104 + 123 men: benign prostate hypertrophy	Interactive videodisc PtDA	X	X	X		Х		
D	treatment	Usual care		X					
Bernstein 1998;	65 + 53 patients: ischemic	Video PtDA	X	X	X		X		
Deyo 2000; Phelan 2001; US	190 + 203 patients: herniated disc or spinal	Interactive videodisc PtDA	X	X	X		X		
	stenosis treatment	Simple PtDA pamphlet	X	Х					
Morgan 2000; CA	120 + 120 patients: ischemic heart disease	Interactive videodisc PtDA	X	Х	Х		Х		
	treatment	Usual care							
Volk 1999; US	80 + 80 men: prostate cancer screening	Video with pamphlet PtDA	X	X	X		X		
		Usual care							
Ottawa Decision Support	Framework (O'Connor et a	al., 1998)							
Chambers 2012; CA	74 + 77 healthcare	Web-based PtDA	X	X	X	Х		X	
	vaccine	Usual care							
Dodin 2001;	52 + 49 women: HRT	Audiotape booklet PtDA	X	Х	X	Х	X	Х	
CA		Simple PtDA pamphlet	X	Х					
Goel 2001; CA	86 + 50 women: breast cancer surgery	Audiotape and booklet PtDA	X	X	X	Х	Х	Х	
		Simple PtDA pamphlet	Х	Х					
Hunter 2005;	116 + 126 women:	Audiotape and booklet	X	X	X	X	X	X	
		Individual genetic counselling	X		X	Х			
Lalonde 2006;	13 + 13 patients:	Booklet PtDA	X	X	X	X	X	X	

			Elements in DAs						
Source, Year, Location	Number of Enrollees in Intervention + Comparison: Options Considered	Comparison of Most and Least Intensive Intervention	Options & outcomes	Clinical problem	Outcome probability	Explicitly clarify values	Others' experiences	Guidance in steps of DM	
СА	cardiovascular health treatment	Personal risk profile		Х	Х				
Laupacis 2006; CA	60 + 60 patients: pre- operative autologous	Audiotape and booklet PtDA	Х	Х	Х	Х		Х	
	blood donation	Usual care							
Legare 2003;	97 + 87 women: HRT	Audiotape booklet PtDA	X	X	Х	X	Х	X	
CA		Simple pamphlet PtDA	X	X	Х				
Man-Son-Hing 1999; CA	139 + 148 aspirin users in atrial fibrillation trial:	Audiotape and booklet PtDA	Х	Х	Х	Х	Х	Х	
	move to warfarin	Usual care							
McAlister 2005; CA	219 + 215 patients: antithrombotic therapy	Audiotape and booklet PtDA	X	X	Х	X	Х	Х	
		Usual care							
O'Connor 1998; CA	81 + 84 women: HRT	Audiotape and booklet PtDA	X	X	X	X	Х	X	
		Simple PtDA pamphlet	X	X					
O'Connor 1999; CA	101 +100 women: HRT	Audiotape and booklet PtDA	X	X	Х	Х	Х	Х	
		DA without explicit values clarification	X	X	Х		Х	X	
Shorten 2005;	85 + 84 pregnant women:	Booklet PtDA	X	X	Х	X		X	
AUS	birthing options after previous cesarean	Usual care							
Decision making process of	Decision making process of clinicians and patients (Rothert et al., 1987)								
Rothert 1997; Holmes- Rovner 1999; US	83 + 89 women: HRT	Lecture with personal decision exercise PtDA	X	X	Х	X	Х	X	
		Simple PtDA pamphlet	X	X					
TRANSACTIONAL									
Shared Decision Making Framework (Charles et al., 1999)									
Whelan 2003; CA	82 +93 women: breast cancer chemotherapy	Decision board PtDA and booklet	Х	Х	Х			Х	
		Usual care with booklet		X					
Whelan 2004;	94 + 107 women: breast	Decision board PtDA	X		Х			X	
CA	cancer surgery	Usual care							
Control Preferences Fram	Control Preferences Framework (Degner et al., 1988)								
Davison 1997; CA	30 + 30 men: prostate cancer treatment	Written materials PtDA and audiotape of consultation	X	Х	X		X		
		Usual care		X					

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