

6-17-2014

# Clinical decision-making tools: how effective are they in improving the quality of health care?

Lyndal Trevana  
*University of Sydney*

Kirsten McCaffery  
*University of Sydney*

Glenn Salkeld  
*University of Sydney*

Paul Glasziou  
*Bond University, paul\_glasziou@bond.edu.au*

Chris del Mar  
*Bond University, chris\_del\_mar@bond.edu.au*

*See next page for additional authors*

Follow this and additional works at: [http://epublications.bond.edu.au/hsm\\_pubs](http://epublications.bond.edu.au/hsm_pubs)

 Part of the [Medicine and Health Sciences Commons](#)

---

## Recommended Citation

Trevana, Lyndal; McCaffery, Kirsten; Salkeld, Glenn; Glasziou, Paul; del Mar, Chris; Doust, Jenny A.; and Hoffmann, Tammy, "Clinical decision-making tools: how effective are they in improving the quality of health care?" (2014). *Faculty of Health Sciences & Medicine Publications*. Paper 861.  
[http://epublications.bond.edu.au/hsm\\_pubs/861](http://epublications.bond.edu.au/hsm_pubs/861)

This Research Report is brought to you by the Faculty of Health Sciences & Medicine at ePublications@bond. It has been accepted for inclusion in Faculty of Health Sciences & Medicine Publications by an authorized administrator of ePublications@bond. For more information, please contact Bond University's Repository Coordinator.

---

**Authors**

Lyndal Trevana, Kirsten McCaffery, Glenn Salkeld, Paul Glasziou, Chris del Mar, Jenny A. Doust, and Tammy Hoffmann

no: NLCG-2

date: 17/06/14

**title** Clinical decision-making tools: how effective are they in improving the quality of health care?

**authors** Associate Professor Lyndal Trevena  
Associate Professor Kirsten McCaffery  
Professor Glenn Salkeld

Sydney School of Public Health  
University of Sydney

Professor Paul Glasziou  
Professor Chris Del Mar  
Professor Jenny Doust  
Associate Professor Tammy Hoffman

Centre for Research in Evidence-Based Practice  
Bond University

**contact** **Dr Anne-marie Boxall**  
Director  
Deeble Institute for Health Policy Research  
Australian Healthcare and Hospitals Association  
Email: [aboxall@ahha.asn.au](mailto:aboxall@ahha.asn.au)  
Twitter: [@DeebleInstitute](https://twitter.com/DeebleInstitute)

**National Lead Clinicians Group**  
*Enhancing clinical leadership and engagement in the Australian health system*

This issues brief was commissioned by the Australian Government National Lead Clinicians Group

© Australian Healthcare and Hospital Association, 2014. All rights reserved.

## Contents

Executive summary .....	1
How effective are clinical decision-making tools in improving the quality of health care?: A short overview .....	2
What are clinical decision-making tools? .....	4
What types of clinical decision-making support tools are commonly used in Australia?.....	7
What does the national and international evidence say on the effectiveness of various clinical decision-making tools? .....	11
<i>Promoting evidence-based practice</i> .....	11
<i>Reducing unnecessary variation in the quality of care</i> .....	13
<i>Improving patient outcomes</i> .....	14
Are clinical decision-making support tools a recommended means of achieving the above objectives?.....	18
What is the quality of evidence?.....	18
What are the implications for policy and practice? .....	19
What are the cost implications for health care providers and the health system of increasing the uptake of clinical decision-making tools? .....	19
References.....	21

### Executive summary

- Clinical decision-making tools can be considered in two broad categories – those designed to be used by clinicians and those designed to promote shared decision making with the clinician and patient together.
- The potential effect of computerised clinical decision support systems (CDSS) on variations in practice is not well understood, and CDSS are currently not a recommended means of improving evidence-based practice, or patient outcomes, since the mechanisms of success and failure are not well defined and the potential impact on workflows and adverse events are poorly evaluated.
- Despite numerous randomised controlled trials, there is poor quality evidence for the effect of CDSS on processes of care and patient outcomes.
- There is moderate-high quality evidence for the role of patient decision aids in preference-sensitive and shared decision making contexts.
- Recommendations for Commonwealth action:
  - (i) Develop and implement CDSS standards, and ensure they align with evidence-based guidelines.
  - (ii) Exercise caution over broader implementation of CDSS until their strengths and weaknesses are better understood.
  - (iii) Encourage the development and implementation of shared decision-making tools for preference-sensitive decisions.
  - (iv) Show leadership in the development of provider and consumer awareness and training, which should be developed alongside the tools themselves.

## How effective are clinical decision-making tools in improving the quality of health care?: A short overview

Clinical decision-making tools can be considered in two broad categories: those designed to be used by clinicians, and those designed to promote shared decision making with the clinician and patient together.

There are many forms of evidence summaries and clinical risk prediction tools currently available to Australian clinicians. Their quality varies, and the way they are used at the point of clinical decision-making is ad hoc and not well defined. When components of them have been included in broader decision support systems (usually computerised) these are referred to as computerised clinical decision support systems (CDSS).

In a recent series of systematic reviews of the evidence on CDSSs, which summarised over one hundred randomised controlled trials, experts found that they had variable effects on processes of care, and limited impact on patient outcomes.<sup>(1)</sup> Despite all these studies, experts point out that there is very little evidence on the mechanisms underpinning the success and failure of CDSS, their impact on workflow and provider concentration levels, and the possibility of adverse events occurring.<sup>(2, 3)</sup>

With the increasing computerisation of Australian clinical practice, numerous versions of CDSS are currently available through proprietary software programs. Standards Australia has established an e-health sub-committee to develop standards in this area.<sup>(13)</sup> In the absence of standards, an evaluation of seven prescribing systems in Australian general practice reported poor linkage to evidence-based guidelines, poor quality and the potential to increase prescribing errors.<sup>(4)</sup>

Clinical decision-making tools designed to facilitate shared decision-making between the clinician and their patients are mostly used where:

- evidence is uncertain;
- there are multiple options to be weighed up; and
- the patients' preferences are important.

These are sometimes called preference-sensitive decisions and many would argue that they comprise a large percentage of clinical decisions in daily practice, exemplifying the true definition of ‘evidence-based practice’.

The standards for evidence-based patient decision aids (International Patient Decision Aid Standards) have recently been updated <sup>(5)</sup>, and they provide a useful framework for developing clinical decision-making tools. We already know, however, that patient decision aids help patients make more informed decisions that are more likely to be consistent with their preferences or ‘values’.<sup>(6)</sup> At an individual-patient-level, patient decision aids are also ethical and beneficial with no documented evidence of harms.<sup>(6, 7)</sup> They tend to result in patients choosing more conservative management options (such as reduced PSA testing and reduction in elective surgery for some conditions), but caution is needed in extrapolating early evidence that they result in system-wide cost savings.<sup>(8)</sup> They should be recommended for improving evidence-based practice, patient outcomes and variations in preference-sensitive care.

Australia lags behind countries, such as the UK, in developing policies that facilitate shared decision-making for preference-sensitive decisions. However, the existing evidence on clinical decision-making tools suggests that there is an urgent need to develop and implement standards for CDSS before rolling them out more broadly because their strengths and weaknesses are not well understood.

We recommend the development of a broader policy on clinical decision-making tools with an initial focus on tools to facilitate shared decision-making, since these have been shown to be effective and there has been no evidence of harms. The role of decision-making tools in decisions about effective care (i.e. where the evidence is clear that the benefits outweigh the harms) remains an issue of dissemination of evidence and we would urge any policy in this field to be considered in the broader context of organisation of care and effective strategies to improve quality.

## What are clinical decision-making tools?

Decision-making tools are electronic or paper-based supports to assist clinicians and their patients make decisions. They commonly assist the patient (and clinician) to go through several necessary steps: listing the options available; quantifying the benefits and harms of each; and then ensuring that the patient's preferences are articulated, and then incorporated, into the final decision. They can be clinician-mediated, shared, or patient-mediated.

### **Clinical decision-making tools primarily designed to be used by clinicians**

These are decision tools aimed at clinicians, to help provide them with information required for shared decision making. They include the summary of findings tables in systematic reviews; risk prediction charts (such as for cardiovascular risk, fracture risk, and breast cancer risk); and a large number of clinical prediction tools and algorithms. Some are paper-based, and others electronic.

There are also many types of what are known as computerised decision-support systems (CDSSs) that may include (or link to) some of the above tool types. CDSSs have been defined as 'information systems for improving clinical decision-making'. They may include some or all of the following components: a mechanism for healthcare staff or patients to enter patient characteristics, or alternatively, electronic medical records may be queried to retrieve these; individual patient data may be matched to a knowledge base (e.g. clinical practice guidelines) and software algorithms then produce patient-specific assessments and/or recommendations. <sup>(1)</sup>

### **Clinical decision-making tools designed to be used by patients or by clinicians and patients together**

For many clinical decisions, the clinician should not be the sole decision maker, but rather the clinician and patient should, in partnership, make the decision after an informed discussion about the relevant issues. This consultation process is referred to as "shared decision making" and is where clinicians and patients jointly participate in making a health decision, having discussed the options, their benefits and harms, and considered the patient's values, preferences, and circumstances. <sup>(9)</sup> It is a process that can be used to guide decision making about many health decisions, such as screening, tests, and treatments. It can also be thought of as a mechanism for

applying evidence with an individual patient through personalising the clinical decision. Shared decision making is seen internationally as a hallmark of good clinical practice, an ethical imperative, <sup>(7)</sup> and a way of enhancing patient engagement and activation. <sup>(10)</sup> It is increasingly being advocated for in clinical guidelines and healthcare policies.

The types of decision-making tools described in the above section, while useful for helping clinicians to be aware of the evidence and make decisions about options, do not typically map well onto decision points in a consultation, nor do they promote patient interaction and discussion. <sup>(2)</sup> Shared decision making can be particularly useful in the following clinical decision-making contexts:

- (i) where the evidence is uncertain;
- (ii) where there is not one option that is clearly superior to all others (i.e. the majority of clinical decisions); and
- (iii) where benefits and harms need to be weighed up with patient preferences and clinical contexts to individualise decisions. <sup>(11)</sup>

Specifically-developed decision-support tools can help to operationalise the evidence into clinical decisions and encourage clinicians to share the decision-making process with their patients. This category of decision-support tools take a number of formats, with some examples listed in Table 1 (see next page). Some are explicitly designed to facilitate shared decision making (e.g. decision aids). Others provide some of the information needed for some components of the shared decision-making process referred to above (clinician-focussed decision aids), or provide ways of initiating or structuring conversations about health decisions (e.g. communication frameworks, question prompt lists). These decision-support tools can be used in various ways: during the consultation; as 'homework tools' (where the patient is invited to use them either in the waiting room or at home, before or after the consultation); and either with or without assistance.

Decision-support tool use is not always straightforward: they may not fit the patient's clinical or personal circumstances; clinicians and patients need to be willing to use them; they require clinicians to have some skills in how to use them; and there may need to be support for their use

and delivery. Decision support tools alone are not the answer, and providing them does not guarantee that shared decision making will occur. Barriers and facilitators to implementation often lie at the individual clinician level with lack of knowledge/skills, poor clinician-patient relationships, and lack of time and/or motivation. However, many system-level barriers also need to be addressed, particularly in the multidisciplinary setting where poor communication, lack of trust between disciplines and lack of visibility/accessibility to tools exist. <sup>(12)</sup>

**Table 1: Examples of types of decision support tools that can be used to facilitate shared decision-making**

Type of tool	Brief description	Examples
<b>Condition-specific tools</b>		
Decision aids	Describe the options, the benefits and harms of each option, along with a values clarification exercise and sometimes a guide to decision-making.  [For information about assessing the quality of decision aids, see <a href="http://ipdas.ohri.ca/">http://ipdas.ohri.ca/</a> ]	Ottawa Hospital Research Institute Inventory of Decision Aids ( <a href="http://decisionaid.ohri.ca/AZinvent.php">decisionaid.ohri.ca/AZinvent.php</a> )
Decision (fact) Boxes	Short summary of the benefits and harms of an intervention, often presented in two columns.	Drug fact box ( <a href="http://dartmed.dartmouth.edu/spring08/html/disc_drugs_we.php">dartmed.dartmouth.edu/spring08/html/disc_drugs_we.php</a> )  Decision box ( <a href="http://decisionbox.ulaval.ca/index.php?id=810&amp;L=2">decisionbox.ulaval.ca/index.php?id=810&amp;L=2</a> )
Option Grids	A one-page summary of the evidence about the possible options, addressing patient-centred outcomes and questions/concerns frequently asked by patients. Can be useful within the consultation for a patient to highlight what is important to them.	Option Collaboration ( <a href="http://optiongrid.org">optiongrid.org</a> )
Question prompt lists	A pre-defined list of condition-specific questions for patients to consider using in a consultation.	Question prompt lists for cancer patients ( <a href="http://cancerinstitute.org.au/patient-support/what-i-need-to-ask">cancerinstitute.org.au/patient-support/what-i-need-to-ask</a> )
Evidence summaries	Clinical practice guidelines and other summaries of the body of evidence.	Clinical Evidence ( <a href="http://clinicalevidence.bmj.com">clinicalevidence.bmj.com</a> )  Up-To-Date ( <a href="http://uptodate.com">uptodate.com</a> )
<b>Generic tools</b>		
Communication frameworks	Provide a generic set of questions or scripts and a structure for clinicians and patients to use during decision-making.	Ask, Share, Know ( <a href="http://askshareknow.com.au">askshareknow.com.au</a> )  Ottawa Personal Decision Guide ( <a href="http://decisionaid.ohri.ca/decguide.html">decisionaid.ohri.ca/decguide.html</a> )

### What types of clinical decision-making support tools are commonly used in Australia?

There is currently no systematic way of determining what types of clinical decision-making support tools are used in Australia, or how commonly they are used by clinicians and their patients.

## Clinical decision-making tools designed for clinicians

CDSSs are probably more common in Australia as a result of computerisation of clinical practice and medical records in both hospital-based and general practice settings in recent years. For example, Standards Australia has established a Clinical Decision Support Sub-Committee to 'coordinate, develop, disseminate and promote standards for Clinical Decision Support (CDS) information technology in Australia and contribute to the development and harmonisation of international CDS standards'.<sup>(13)</sup> They claim that there is a readiness and partial uptake of CDS in Australia, particularly around medication management. However they note that there are numerous third party add-ons from vendors and organisations such as the RACGP without adequate guarantees of applicability across products, and no nationally agreed governance or responsibility to maintain and update these.

In general practice, a limited evaluation of seven clinical software programs in Australia showed that CDS features for safe prescribing were not well implemented in these programs. This evaluation by a collaboration between the National Prescribing Service (NPS), La Trobe and Monash Universities, the Medical Software Industry Association and the Royal Australian College of General Practitioners in 2008, audited the seven most commonly used general practice programs for 50 features previously rated as having high impact on quality and safety in healthcare. They found that 34-62% of features were fully implemented, 18-26% were partially implemented and 18-40% were not implemented. In particular, linkage to evidence-based drug and therapeutic information was limited, as were patients' resources and medicine lists, which were described as sub-optimal. During prescribing there was potential for medicine mis-selection in some systems and linking a medicine with its indication was optional.<sup>(14)</sup> The seven programs evaluated (Best Practice™, Genie™, Medical Director 2™, Medical Director 3™, MedTech32™, Practix™, and Profile™) account for 90% of prescribing software in Australian general practice. The results of this evaluation were fed back to the industry but we could not find a subsequent evaluation of the impact of this activity.

Most of these programs include prescribing components that link to the Monthly Index of Medical Specialties (MIMS), Therapeutic Guidelines (TG) and/or the Australian Medicines Handbook

(AMH). Some also included risk calculators such as absolute cardiovascular risk but are not linked to guidelines or recommendations. A qualitative study of 27 GPs in 2008 found that the integration of MIMS, TG and AMH were valued and used but that cost was an issue and subscriptions and licences were not always up to date. Participants in this study also highlighted the danger of drug and allergy ‘alert-fatigue’ with the risk of clicking through or even turning off warnings and alert systems. <sup>(4)</sup>

It has also been suggested that many existing CDSSs in Australian general practice may actually be distracting and potentially harmful through poor design. <sup>(15)</sup> The authors of this paper recommend a minimum set of safety features be included in all software programs including ‘alerts for contraindicated drugs, drug dosage support, (e.g. paediatric dosage, dosage if renal impairment, warnings for potentially harmful doses), and timely warnings about newly identified medicine safety issues. These and other types of decision-support should be underpinned by high quality, up-to-date information, and be implemented in such a way that they fit with work flow and are easy to use.’

The Victorian government is exploring policies around CDSS (mainly for hospital settings) with an underpinning assumption that CDSS will ‘improve patient care and reduce errors’, although they admit a lack of clear standards and governance on this matter. <sup>(16)</sup> These proposed developments include improved diagnostic algorithms and prescribing systems. The NSW Health Department’s Clinical Information Access Portal (CIAP) provides state-employed health-workers with access to evidence-based databases, journals, clinical practice guidelines and protocols. The Western Australian Government’s e-Health program is also being phased in and is planned to include CDSS for cardiology, gastroenterology and nephrology. We could not find any evaluation of these.

There is also a range of decision-support tools best described as ‘clinical reference tools’ available to Australian clinicians but most require subscription for access. Many of these are high quality, regularly updated and evidence-based but information about Australian subscribers and rates of utilisation are not publicly available. It is likely that some individual clinicians and their employers have subscriptions to these tools. Such decision-support tools include *Best Practice (BMJ)*, *Up-to-date*, *DynaMed* and others. They are designed to be evidence-based point-of-care reference tools

that can be accessed from a computer or hand-held mobile device. There are also a number of clinical risk prediction tools available free on the websites of organisations such as the absolute cardiovascular risk calculator on the National Heart Foundation site, and Breast and Ovarian Cancer Risk tool on Cancer Australia's website, and there are numerous others nationally and internationally. To what extent clinicians know about these tools, access them or use them, remains unknown.

### **Clinical decision-making tools designed for clinicians & patients to use together**

These are widely available on the Internet and it is difficult to know to what extent Australians are using them. There is a fairly comprehensive inventory of patient decision aids online at the Ottawa Health Research Institute (<https://decisionaid.ohri.ca/AZinvent.php>) most of which have been evaluated against the International Patient Decision Aid Standards (IPDAS) and some of these developed and evaluated by Australian researchers.

Although Australian researchers have been leaders in the research field of shared decision making, it is only recently that this work has started to reach policy and possible implementation in Australia.<sup>(17)</sup> The UK on the other hand, already has a comprehensive and advanced policy and programs of implementation in this field ([www.patient.co.uk](http://www.patient.co.uk)).<sup>(18)</sup> Recently however, the Australian Commission on Safety and Quality in Healthcare has commenced some programs in Shared Decision-Making as part of its commitment to supporting patient-centred care and to complement their work on reducing unwarranted variations in medical practice and ensuring appropriateness of care (<http://www.safetyandquality.gov.au/our-work/shared-decision-making/>).

From personal communication, we know that one patient decision aid developed for the NHMRC, to assist women deciding whether to take hormone replacement therapy for menopausal symptom control, had over 75,000 copies printed and distributed between 2004-2006, and has since been available online (number of downloads not known by the authors).<sup>(19)</sup> Anecdotally we also know that an Australian-developed online decision aid for parents with concerns about the safety of MMR vaccination has been well received and widely used by Australian immunisation

providers and their patients. <sup>(20, 21)</sup> A more comprehensive evaluation of uptake and use of patient decision-support tools in Australia has not been completed.

## What does the national and international evidence say on the effectiveness of various clinical decision-making tools?

### *Promoting evidence-based practice*

#### **Clinical decision-making tools designed for clinicians**

There was a comprehensive systematic review of more than one hundred randomised controlled trials of CDSSs completed and published in 2011. <sup>(1)</sup> The authors looked at the effects of CDSSs in six different clinical decision contexts resulting in a six-article series of papers with the following results on 'process of care'.

- *Primary preventive care* (41 RCTs) <sup>(22)</sup>: There was some evidence that CDSS improved the screening of appropriate patients for cardiovascular risk factors and the implementation of evidence-based guidelines for CVD risk reduction by clinicians. All nine trials showed an increase in targeted CVD assessment and three showed improved management of hyperlipidaemia. However there were mixed results for cancer screening (five out of ten trials showed an increase in appropriate referral to screening), mental health screening and management (two out of six trials showed an increase in discussion of domestic violence), immunisation and other preventive care evidence (six out of ten trials showed improved ordering of vaccinations, prophylactic aspirin and heparin prescriptions etc). See the following section for their effect on patient outcomes and therefore caution about recommending their use at this stage.
- *Chronic disease management* (55 RCTs) <sup>(23)</sup>: Twenty five of the 55 included trials improved processes of care such as measurement of HbA1c, BP, BMI, foot surveillance, smoking and exercise status at specified times, prescription of antiplatelet medication, lipid measurement, pneumococcal and influenza vaccination in diabetics and, to some extent for CVD risk reduction. However this effect was not replicated for processes of care in asthma, chronic obstructive pulmonary disease (COPD), rheumatoid arthritis, cardiac care,

cancer and others. The mechanisms behind systems' success or failure are understudied and make it difficult to clearly recommend their use at this stage.

- *Therapeutic drug monitoring and dosing* (33 RCTs)<sup>(24)</sup>: There was some evidence that insulin dosing and vitamin K antagonists dosing were improved by CDSS but the longer-term sustainability of this is unknown. Systems need to be evaluated against costs and workflow and no specific system can be recommended at this stage.
- *Acute care management* (36 RCTs)<sup>(25)</sup>: Once again, just over half of the studies showed an improvement in processes of care particularly through the use of medication dosing assistants, management assistants with alerts and reminders, management assistants using guidelines and algorithms and diagnostic assistants. These reduced inappropriate medication for elderly patients in ED, improved accurate administration of insulin in critically ill patients, improved intraoperative antibiotic re-dosing, prescriptions consistent with evidence-based recommendation in children with upper respiratory tract infections in outpatients, appropriate antibiotic treatment in hospital patients generally, improved documentation of diagnosis of patients admitted to orthopaedics ward, timely measurement of blood glucose according to protocols. Although processes of care may have improved in some acute care situations, patient outcomes were less likely to be measured and far less likely to show positive results (see below).
- *Drug prescribing and management* (65 RCTs)<sup>(26)</sup>: Once again CDSS improved processes of care in more than half of the studies but seldom impacted on patient outcomes. There are potentially negative impacts on workflow with these systems as some trials reporting clinically inappropriate reminders and one trial stopped early because of a 40% error rate.
- *Diagnostic test ordering behaviour* (35 RCTs)<sup>(27)</sup>: Just over half of the studies improved test ordering behaviour and four systems designed to reduce unnecessary test ordering achieved that. As with other applications of CDSSs, it is unclear what determines success or failure of these systems and there is only minimal data on adverse events, user satisfaction and impacts on workflow.

Other types of clinical decision-making tools designed for use by clinicians such as clinical prediction rules and clinical reference tools have not been rigorously evaluated for their impact on processes of care. <sup>(28, 29)</sup>

### **Clinical decision-making tools designed for use by clinicians & patients together**

The latest update of the Cochrane review of the effect of patient decision aids for screening and treatment decisions now includes 115 RCTs. <sup>(6)</sup> When considering their effect on evidence-based practice, many would argue that shared decision making exemplifies evidence-based practice as it was originally defined – integrating the best available evidence with clinical expertise and patients preferences and values. <sup>(30)</sup> With this definition in mind, patient decision aids do increase evidence-based practice as they significantly increase patient knowledge, improve accuracy of risk perception, and result in a higher proportion of patients choosing an option that is congruent with their values. <sup>(6)</sup>

### ***Reducing unnecessary variation in the quality of care***

Arguably the world's leading expert on variations in medical practice is John Wennberg, the US epidemiologist who developed the Dartmouth Atlas. He has spent his career highlighting and studying how we might reduce unwarranted variations in clinical practice. He describes the importance of considering clinical care in three categories (see below) when evaluating practice variation and considering the implications for clinicians, patients and policymakers.

*Effective care is defined as interventions for which the benefits far outweigh the risks; in this case the "right" rate of treatment is 100% of patients defined by evidence-based guidelines to be in need, and unwarranted variation is generally a matter of underuse.*

Wennberg proposes that the most effective way to reduce most of this kind of variation is to have stronger primary care systems and better care coordination. <sup>(31)</sup>

*Preference sensitive care is when more than one generally accepted treatment option is available, such as elective surgery; here, the right rate should depend on informed patient choice, but treatment rates can vary extensively because of differences in professional opinion.*

The best approach to reducing this type of variation is through shared decision making. Clinical decision-making tools such as patient decision aids generally result in patients choosing a more conservative option, such as less back surgery and less PSA screening for prostate cancer once they are better informed. <sup>(6, 31)</sup>

*Supply sensitive care comprises clinical activities such as doctor visits, diagnostic tests, and hospital admissions, for which the frequency of use relates to the capacity of the local healthcare system.*

Once again, Wennberg proposes that better care coordination and stronger integration between primary and secondary care within organized health systems holds the key to reducing this kind of variation. <sup>(31)</sup>

### *Improving patient outcomes*

#### **Clinical decision-making tools designed for clinicians**

In most of the 100+ trials of CDSSs, patient-relevant outcomes were rarely assessed. Of the studies that did measure patient outcomes, many showed no impact, despite some improvement in processes of care. <sup>(22, 24-27)</sup> The most promising improvement in patient outcomes, however, came from CDSS use in diabetic patients where there was some component of patient feedback or coaching, combined with physician reminders and recommendations. This was not replicated in other chronic conditions such as asthma and chronic obstructive pulmonary disease (COPD), but those CDSS systems did not include an active patient component. <sup>(23)</sup>

The potential harms of CDSS to patients is understudied and under-reported, although a small number of studies have shown an increase in prescribing errors with CDSS compared with usual care. <sup>(26)</sup> A meta-regression of these studies found that systems presenting advice in electronic

charting or order entry system interfaces were less likely to be effective (OR 0.37, 95% CI 0.17 to 0.80).<sup>(32)</sup> Systems were more likely to succeed if they:

- a) provided advice for patients in addition to practitioners (OR 2.77, 95% CI 1.07 to 7.17);
- b) required practitioners to supply a reason for over-riding advice (OR 11.23, 95% CI 1.98 to 63.72); or
- c) were evaluated by their developers (OR 4.35, 95% CI 1.66 to 11.44).<sup>(32)</sup>

### **Clinical decision-making tools designed for clinicians & patients to use together**

As outlined earlier, tools in this category have generally been developed for decisions where the evidence is uncertain, where several options are available and/or where the patients' preferences and values need to be considered. Many would argue this applies to the majority of clinical decisions made. The greatest body of evidence is for the effect of patient decision aids,<sup>(6)</sup> but other tools such as option grids, decision boxes etc. often contain similar components and have an overlapping purpose, albeit slightly different formats.

The international research community in this field has developed a set of standards: the International Patient Decision Aid Standards (IPDAS). These have drawn on the body of scientific knowledge about decision-making theory, cognitive psychology, human design and technology, evidence-based medicine and implementation science. The purpose of the standards is to improve the quality of patient decision aid development and design.

A recent paper has shown a correlation between tools with higher IPDAS ratings and a positive impact on patient knowledge of outcome probabilities – i.e. a more informed decision.<sup>(33)</sup> A recent update on the evidence behind these standards has resulted in a series of articles within a special supplement (see Table 2).<sup>(5)</sup>

**Table 2: Topics covered in the recent IPDAS update series**

Systematic development process
Disclosure of conflicts of interest
Providing information about options
Basing information on comprehensive, critically appraised, and up-to-date synthesis of the scientific evidence
Balancing the presentation of information and options
Presenting qualitative information about decision outcomes
Clarifying values
Addressing health literacy
Coaching and guidance
A critical review of the role of patient stories
Delivering patient decision aids on the Internet
Establishing effectiveness: key constructs and measurement instruments
Implementation

The IPDAS collaboration was established in 2003 to ‘enhance the quality and effectiveness of patient decision aids by establishing an evidence-informed framework their content, development, implementation and evaluation.’ Over the past decade, this group has established background documents on 12 core dimensions, originally established by a Delphi process and the development of the IPDAS checklist (74 items), the IPDAS qualifying (6 items), certifying (6 items+ 4 for screening) and quality criteria (28 items).<sup>(5)</sup>

The recently updated Cochrane review of patient decision aids for treatment and screening decisions now includes 115 RCTs. The summary of findings table for this review using GRADE shows:

- high quality evidence that *patient decision aids increase knowledge* compared with usual care (Mean 13.5, 95% CI 11.2-15.5);
- moderate quality evidence that *accuracy of risk perception is improved* (RR 1.82 95% CI 1.17-1.97)

- low quality evidence of congruence between the chosen option and patient values (RR 1.51 95% CI 1.17-1.97)
- high quality evidence of *reduced decisional conflict* on the uninformed subscale – i.e. patients felt more informed (Mean 7.26 95% CI 9.73-4.78)
- high quality evidence of reduced decisional conflict on the unclear values subscale – i.e. patient felt clearer about their values (Mean 6.09 95% CI 8.50-3.67)
- moderate quality evidence of increased involvement in decision making (RR 0.66 95% CI 0.53-0.81).

Understandably, decision aids have a variable effect on choice, but the Cochrane review also showed that generally people are more likely to choose conservative options, such as less discretionary surgery and less PSA screening for prostate cancer. There are no apparent adverse effects on health outcomes or patient satisfaction. They significantly increase patient-provider communication. Eight trials have measured the impact on health using the Short Form Health Survey (SF-36) with three showing an improvement in physical and emotional domains in the decision aid groups. There was no effect on mental or social domain scores.

It has also been shown that patient decision aids have a greater effect on patients with lower baseline knowledge levels, and there is increasing interest in their potential role in improving health literacy.<sup>(33)</sup>

Thus, there is good quality evidence that patient decision aids improve informed decision-making and patient involvement in clinical decisions. This is particularly important given the findings that CDSS for clinicians had limited impact on clinical outcomes unless active patient components were included. There is a picture emerging within this body of evidence that the clinician-patient partnership is crucial to the effectiveness of clinical decision-making tools. Targeting one side of this partnership alone will have limited impact on health outcomes.<sup>(34)</sup>

## Are clinical decision-making support tools a recommended means of achieving the above objectives?

CDSS is currently not a recommended means of improving evidence-based practice or patient outcomes since the mechanisms of success and failure are not well defined and the potential impact on workflows and adverse events are poorly evaluated. The potential effect of CDSS on variations in practice is not well understood. Where they do have an impact on clinical outcomes, it is generally only when an active patient component is included.

There are many tools designed for clinicians to assist with clinical risk prediction and point-of-care access to evidence summaries that have the potential to improve evidence-based practice, patient outcomes and reduce variations in effective care practices. Access to these often remains restricted for Australian clinicians by subscriptions, and those which are free of charge are not systematically collated or rated for quality, making it difficult for clinicians to 'trust' to 'access' and to 'use' them.

If evidence-based practice is defined as the 'integration of best available evidence with clinical expertise and patient preferences' then good quality patient decision aids are a recommended means of increasing evidence-based practice and patient outcomes for some clinical decision contexts, through improving patients' knowledge about the evidence and facilitating choices that are more likely to be congruent with their preferences or 'values'. They are also recommended as a means for reducing preference-sensitive variations in clinical practice. However, more broadly, the implementation of shared decision making has proved challenging with a recent systematic review showing that clinicians barriers, such as workflow challenges, and most commonly 'indifference', were problematic in many models that relied on them referring patients to these resources. <sup>(35)</sup>

## What is the quality of evidence?

Despite numerous randomised controlled trials of CDSSs, there is poor quality evidence for their effect on processes of care and patient outcomes. It remains uncertain what components of these systems lead to success, and which lead to failure.

There is moderate-high quality evidence for the role of patient decision aids in preference-sensitive and shared decision making contexts. The evidence for effective implementation of these tools is less clear.

### **What are the implications for policy and practice?**

Given the rapid computerisation of clinical practice, and the ad hoc implementation of various CDSSs in Australia, the development of standards for this field and closer alignment and linkage with evidence-based guidelines is an important policy issue.

Improving the uptake of resources that can inform clinicians' decision-making, such as clinical prediction and risk tools and point-of-care evidence summaries, is unlikely to occur through clinical decision-making tools alone. The extensive work of the Cochrane Effective Practice and Organisation of Care (EPOC) group has shown that broader strategies also need to be deployed through activities such as audit and feedback, continuing education and so on. Any policy on the role of clinical decision-making tools for the Australian system should consider this broader context.

Clinical decision-making tools, particularly shared decision-making tools that incorporate components of the IPDAS criteria, should be more readily accessible and implemented in Australian clinical practice for preference-sensitive decisions. The UK approach to developing a policy and program for implementation of shared decision-making and relevant high quality patient decision aids should be considered for the Australia setting. However, it is important to realise some of the potential barriers from organisations and providers through unfamiliarity and 'indifference'. Provider and consumer awareness and training in the use and appraisal of these tools should be developed alongside the tools themselves. There needs to be a sustainable approach to maintaining and updating these tools to ensure their ongoing safety and use.

### **What are the cost implications for health care providers and the health system of increasing the uptake of clinical decision-making tools?**

Some of the CDSS studies reported the financial costs as part of their results. In summary the effect of these systems was mixed, with some resulting in savings, some having no effect, and

some increasing costs. As mentioned earlier, there has been very little research on the impact of such tools on workflow and provider concentration/levels of distraction, which is an important issue to address.

Similarly the financial costs of patient decision aids have only been measured in a small number of studies and the impact on costs has been variable. <sup>(6, 8)</sup> A recent sub-analysis of economic analyses of the Cochrane review of patient decisions <sup>(6)</sup> included seven studies. <sup>(8)</sup> It found that four out of the seven analyses predicted system-wide savings with the predicted savings ranging from USD8 to USD3058 per patient. However, the authors note that the quality of these studies was low-moderate and the risk of bias high. Mixed methodologies were used with evaluations over short periods only and an absence of incremental cost-effectiveness ratios. They concluded that:

*“Although there is evidence to show that patients choose more conservative approaches when they become better informed, there is insufficient evidence, as yet, to be confident that the implementation of patient decision support interventions leads to system-wide savings’.* (8)

## References

1. Haynes R, Wilczynski N, Team CCDSSSR. Effects of computerized clinical decision support systems on practitioner performance and patient outcomes: methods of a decision-maker-researcher partnership systematic review. *Implement Sci.* 2010;5:12.
2. Greenhalgh T, Howick J, Maskrey N. Evidence based medicine: a movement in crisis? *BMJ.* 2014;348.
3. Swinglehurst D, Greenhalgh T, Roberts C. Computer templates in chronic disease management: ethnographic case study in general practice. *BMJ Open.* 2012;2(6).
4. Robertson J, Moxey A, Newby D, Gillies M, Williamson M, Pearson S-A. Electronic information and clinical decision support for prescribing: state of play in Australian general practice. *Family Practice.* 2011;28:93-101.
5. Volk R, Llewellyn-Thomas H, Stacey D, Elwyn G. Ten years of the International Patient Decision Aid Standards Collaboration: evolution of the core dimensions for assessing the quality of patient decision aids. *BMC Medical Informatics and Decision Making.* 2013;13(Suppl 2):S1.
6. Stacey D, Légaré F, F CN, L BC, J BM, B EK, et al.: Decision aids for people facing health treatment or screening decisions. : *Cochrane Database of Systematic Reviews.*
7. Elwyn G, Tilburt J, Montori V. The ethical imperative for shared decision-making. *European Journal for Person Centered Healthcare* 2013;1:129–131. *Healthcare.* 2013;1:129-31.
8. Walsh T, Barr PJ, Thompson R, Ozanne E, O'Neill C, Elwyn G. Undetermined impact of patient decision support interventions on healthcare costs and savings: systematic review. *BMJ.* 2014;348.
9. Hoffmann T, Légaré F, Simmons M, Mc Namara K, McCaffery K, Trevena L, et al. Shared decision making: what do clinicians need to know and why should they bother? *MJA.* *MJA.* 2014(July).
10. Stiggelbout AM, Weijden TVd, Wit MPTD, Frosch D, Légaré F, Montori VM, et al. Shared decision making: really putting patients at the centre of healthcare. *BMJ.* 2012;344.
11. Müller-Engelmann M, Donner-Banzhoff N, Keller H, Rosinger L, Sauer C, Rehfeldt K, et al. When Decisions Should Be Shared: A Study of Social Norms in Medical Decision Making Using a Factorial Survey Approach. *Medical Decision Making.* 2013;33(1):37-47.
12. Hofstede S, Marang-van de Mheen P, Wentink M, Stiggelbout A, Vleggeert-Lankamp C, Vliet Vlieland T, et al. Barriers and facilitators to implement shared decision making in multidisciplinary sciatica care: a qualitative study. *Implementation Science.* 2013;8(1):95.
13. Australia S. E-health: Clinical Decision Support [2 May 2014]. Available from: <http://www.e-healthstandards.org.au/IT014SubjectAreas/ClinicalDecisionSupport.aspx>.
14. Sweidan M, Williamson M, Reeve J, Harvey K, O'Neill J, Schattner P, et al. Evaluation of features to support safety and quality in general practice clinical software. *BMC Medical Informatics and Decision Making.* 2011;11(1):27.
15. Sweidan M, Reeve J, Dartnell J, Phillips S. Improving clinical decision support tools Challenges and a way forward. *Australian Family Physician.* 2011;40:561-2.
16. Government V. Health Design Authority: Health Design Forum - Clinical Decision Support 2013 [cited 2014]. Available from: <http://www.health.vic.gov.au/designauthority/forum-session4.htm>.
17. McCaffery KJ, Smith S Fau - Shepherd HL, Shepherd HI Fau - Sze M, Sze M Fau - Dhillon H, Dhillon H Fau - Jansen J, Jansen J Fau - Juraskova I, et al. Shared decision making in Australia in 2011. (1865-9217 (Print)).

18. Foundation H. Implementing Shared Decisiion-Making in the UK. 2010.
19. NHMRC. Making Decisions: Should I take hormone replacement therapy? [2 May 2014]. Available from: <http://www.nhmrc.gov.au/files/nhmrc/publications/attachments/wh37.pdf>.
20. Wallace C, Leask J, Trevena LJ. Effects of a web based decision aid on parental attitudes to MMR vaccination: a before and after study. *BMJ*. 2006;332(7534):146-9.
21. Shourie S, Jackson C, Cheater FM, Bekker HL, Edlin R, Tubeuf S, et al. A cluster randomised controlled trial of a web based decision aid to support parents' decisions about their child's Measles Mumps and Rubella (MMR) vaccination. *Vaccine*. 2013;31(50):6003-10.
22. Souza N, Sebaldt R, Mackay J, Prorok J, Weise-Kelly L, Navarro T, et al. Computerized clinical decision support systems for primary preventive care: A decision-maker-researcher partnership systematic review of effects on process of care and patient outcomes. *Implementation Science*. 2011;6(1):87.
23. Roshanov P, Misra S, Gerstein H, Garg A, Sebaldt R, Mackay J, et al. Computerized clinical decision support systems for chronic disease management: A decision-maker-researcher partnership systematic review. *Implementation Science*. 2011;6(1):92.
24. Nieuwlaat R, Connolly S, Mackay J, Weise-Kelly L, Navarro T, Wilczynski N, et al. Computerized clinical decision support systems for therapeutic drug monitoring and dosing: A decision-maker-researcher partnership systematic review. *Implementation Science*. 2011;6(1):90.
25. Sahota N, Lloyd R, Ramakrishna A, Mackay J, Prorok J, Weise-Kelly L, et al. Computerized clinical decision support systems for acute care management: A decision-maker-researcher partnership systematic review of effects on process of care and patient outcomes. *Implementation Science*. 2011;6(1):91.
26. Hemens B, Holbrook A, Tonkin M, Mackay J, Weise-Kelly L, Navarro T, et al. Computerized clinical decision support systems for drug prescribing and management: A decision-maker-researcher partnership systematic review. *Implementation Science*. 2011;6(1):89.
27. Roshanov P, You J, Dhaliwal J, Koff D, Mackay J, Weise-Kelly L, et al. Can computerized clinical decision support systems improve practitioners' diagnostic test ordering behavior? A decision-maker-researcher partnership systematic review. *Implementation Science*. 2011;6(1):88.
28. Maguire JL, Kulik Dm Fau - Laupacis A, Laupacis A Fau - Kuppermann N, Kuppermann N Fau - Uleryk EM, Uleryk Em Fau - Parkin PC, Parkin PC. Clinical prediction rules for children: a systematic review. (1098-4275 (Electronic)).
29. Stanton TR, Hancock Mj Fau - Maher CG, Maher Cg Fau - Koes BW, Koes BW. Critical appraisal of clinical prediction rules that aim to optimize treatment selection for musculoskeletal conditions. (1538-6724 (Electronic)).
30. Sackett DL, Rosenberg WMC, Gray JAM, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. *BMJ*. 1996;312(7023):71-2.
31. Wennberg JE. Time to tackle unwarranted variations in practice. *BMJ*. 2011;342.
32. Roshanov PS, Fernandes N, Wilczynski JM, Hemens BJ, You JJ, Handler SM, et al. Features of effective computerised clinical decision support systems: meta-regression of 162 randomised trials. *Bmj*. 2013;346:f657.
33. Gentles S, Stacey D, Bennett C, Alshurafa M, Walter S. Factors explaining the heterogeneity of effects of patient decision aids on knowledge of outcome probabilities: a systematic review sub-analysis. *Systematic Reviews*. 2013;2(1):95.
34. Legare F, Guerrier M, Nadeau C, Rheaume C, Turcotte S, Labrecque M. Impact of DECISION + 2 on patient and physician assessment of shared decision making implementation in the context of antibiotics use for acute respiratory infections. *Implement Sci*. 2013;8:144.

35. Elwyn G, Scholl I, Tietbohl C, Mann M, Edwards A, Clay C, et al. "Many miles to go ...": a systematic review of the implementation of patient decision support interventions into routine clinical practice. BMC Medical Informatics and Decision Making. 2013;13(Suppl 2):S14.