Re-visiting the effects of decision aids on adherence: a secondary analysis of the Cochrane review of decision aids

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Keywords: patient compliance, medication adherence, decision support techniques

Abstract

Background: Adherence is critical to achieving the benefits of health services and decisions are critical to ensuring adherence success. However, it is unclear how decision aid (DA) studies align with taxonomies of adherence (i.e. theories, models, frameworks, or classifications with the express goal of identifying the full subset of factors affecting adherence).

Purpose: To understand the alignment of DAs with adherence taxonomies and their effects on outcomes.

Methods: This study is a secondary analysis of the 2024 Cochrane review of DAs, which examines the effects of randomized trials of DAs on outcomes, including adherence. A single reviewer reviewed DA studies from this review on two separate occasions over a month apart to identify the subset specifically designed to promote adherence in outpatient populations without special adherence needs. She then abstracted information for analysis with a later 2nd check. She used information to examine alignment with adherence taxonomies and examine the effects of DAs and supports on behavioral, decision making, collaborative, adherence, and health outcomes. She did not reappraise risk of bias.

Results: The Cochrane review included 5 studies that met inclusion criteria. Four used DAs alone; the 5th combined a DA with additional adherence supports. Overall alignment with taxonomies was limited. In-office DAs alone had few consistent effects. A single, longer, pre-visit DA accompanied by adherence supports improved a full set of outcomes.

Conclusions: Evidence of the effects of decision aids and supports on adherence is limited. Decision aids with additional adherence supports appear more likely to have success than DA alone.

Keywords: patient compliance, medication adherence, decision support techniques

Background

Adherence is critical to achieving the benefits of health services and supports and decisions are critical to ensuring adherence success. In national surveys as many as 41% of adults have some form of non-adherence. Two to 20% of patients sometimes or never filled their prescription (1-3) and 2-18% didn't take medicine as prescribed or stopped it early (2-4), in part because of decisions that medicines weren't worth it or they didn't have needed supports.

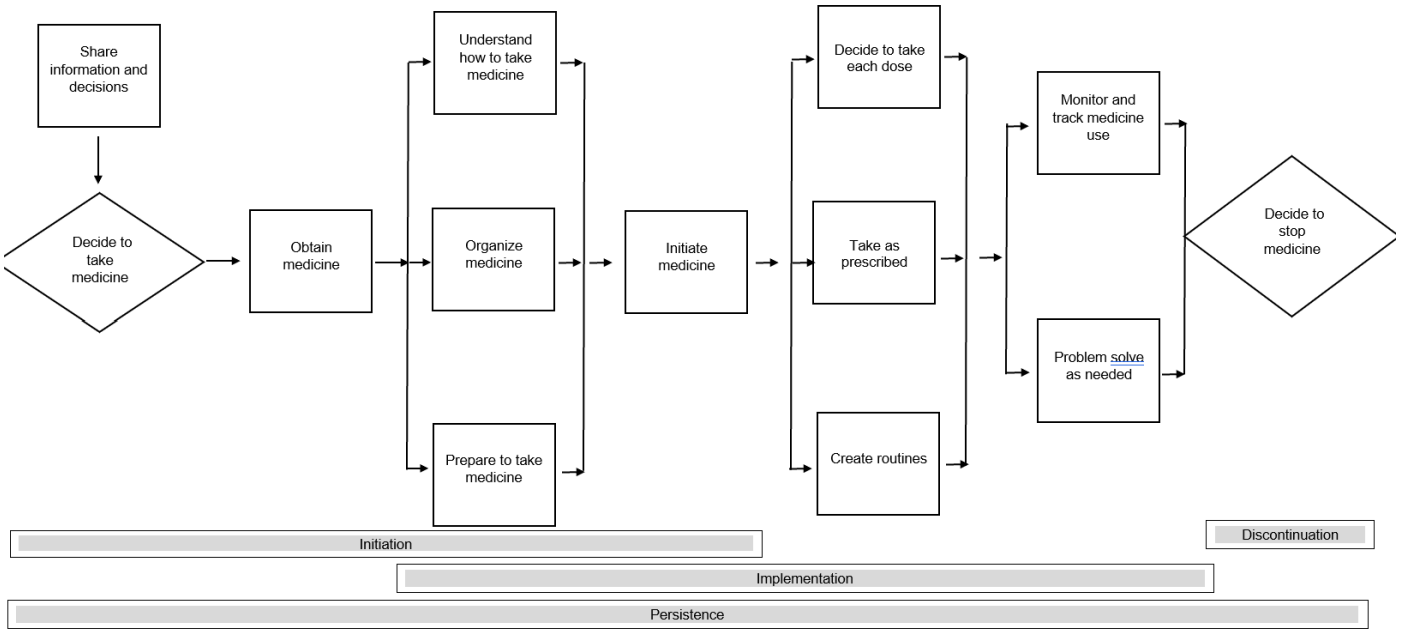
Recent taxonomies (i.e. classifications with the express goal of identifying the full subset of factors affecting adherence) summarize the definitions, processes, determinants, interventions, and communication elements that support adherence. When summarized and integrated, these taxonomies suggest (see Figures 1a-d) that, from the patient's perspective, adherence involves initiating medicine, taking it as prescribed, and persisting with it untold to stop (5). It includes a series of steps, including sharing information and decisions about medicine; obtaining medicine; understanding, organizing, and preparing to take medicine; initiating medicine; taking medicine as prescribed; creating routines; monitoring and tracking use; and problem solving as needed (6). Its success depends on a host of determinants (e.g. condition, treatment, patient, system, team, and socioeconomic factors) already linked to adherence (2, 3, 7-9) that need to be linked to appropriate interventions (10, 11) and communication to effect adherence (12, 13).

Decision aids are one option for improving decision making for adherence. Decision aids provide information, help clarify values, and facilitate a decision about the best option for any individual based on what matters most. However, their effect on adherence is still uncertain. A recent Cochrane review

(14) concluded that decision aids do not improve adherence. However, this review included adherence as one of many outcomes and it is unclear whether or not decision aids and their studies were specifically designed to promote adherence or were accompanied by the additional supports that are often needed to improve adherence (e.g. supports for obtaining medicine; understanding, organizing, and planning to take medicine; taking medicine as prescribed; and/or tracking and monitoring medicine).

Figure 1.

a. The process of adherence

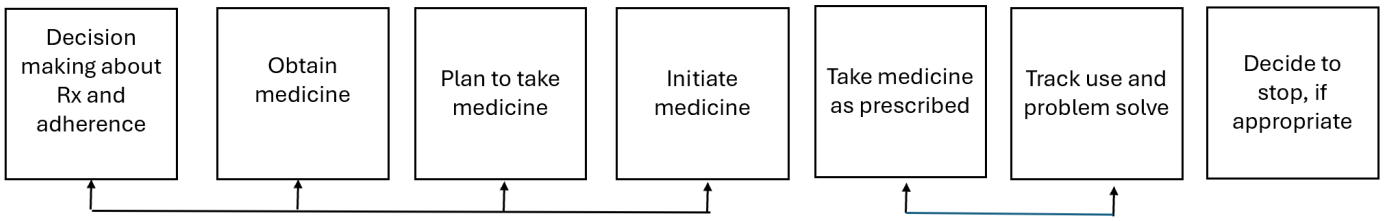


b. The determinants of adherence

Cross-cutting determinants:

- **Condition-related:** disease severity, symptoms/improvement, duration.
- **Treatment-related:** type of medicine, benefits, harms, patient-friendliness of regimen, # meds, complexity and duration of treatment, contraindications/tolerability, well-organized monitoring, left-over medicines.
- **Patient-related**: knowledge, beliefs, self-efficacy, preferences, decision, remembering, demographics, cognition, education, perceived control over health, goals, health, co-morbidities, trust in provider, accuracy of knowledge, personal resources (e.g. time, transport, housing), attitudes towards medicine, emotions (e.g. fear of meds) and concerns if any, "psychological" resources if needed, awareness of prescription, loss/transfer of prescription if any.
- **System and team resources:** Drug availability, prescription access to care, barriers to care (e.g. language, time, transportation), provider type, provider manner, patient-provider relationships, communication, shared decision making, interpreter services if needed, prescriptions, delivery route of prescription, drug supply, medication samples, information/education/counseling, sufficient follow-up/contact frequency, provider agreement, provider accountability, external (i.e. government) policies.
- **Socioeconomic factors:** medicine cost, prescription drug coverage, ability to pay, SES, employment, family and/or social support, social stigma if any, care-giver factors,

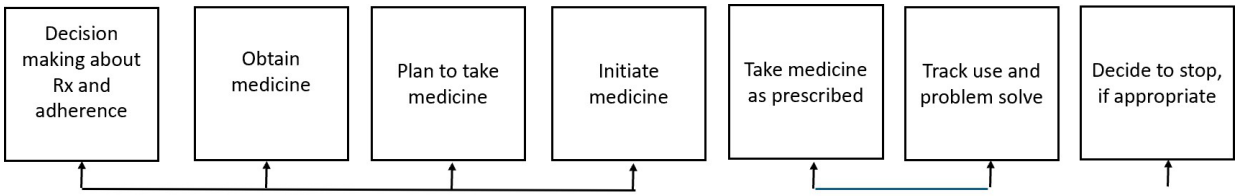
c. The possible interventions to address adherence



- Educational materials,
- Decision aids,
- Decision and communication training (incl. question lists),
- Training and counseling (incl action plans),
- Provider-guided medicine review
- Resources (e.g. alt. or simplified dosing, pre-packaged meds)

- Educational materials,
- Training/behavior counseling,
- Advice and reminders,
- Self-monitoring,
- Family, peer, group, other provider support.

d. The communication elements for adherence



- Current medicines,
- Medicine and allergy history,
- Name of new medicine,
- Purpose,
- Need for medicine,
- Encourage participation in discussion and decision,
- Efficacy (i.e. benefits),
- Safety (i.e. harms, side effects),
- Onset of effect,
- Cost/affordability,

- Prescription,
- Details of supplies

- Directions/routine (e.g. dose, frequency, route, duration, timing, start time),
- Special instructions (e.g. take with food)
- Onset of effect,
- Cost/affordability,
- Importance of adherence,
- Monitoring plans,
- Logistics of how to get medicine,
- Potential drug-drug interactions,
- Instructions (e.g. what to do with other medicines, how to use any equipment).

- Monitoring plans,
- Specifics of monitoring
- How to report side effects.

- Contingency plans (i.e. how to overcome barriers),
- Instructions on how to adjust medicines

- Not applicable

Purpose

The goal of this paper is to perform a secondary analysis of the 2024 Cochrane systematic review on decision aids to examine how decision aids align with taxonomies of adherence in populations without special adherence needs and how they effect outcomes compared with usual care or other comparators.

Methods

Data sources

To evaluate the alignment of decision aid studies with taxonomies of adherence, a single reviewer conducted a sub-analysis of a long-standing Cochrane review on decision aids (14).

Overview of Cochrane decision aid review from which studies are drawn

The Cochrane Decision Aid review, published in 2024, includes randomized trials and cluster randomized trials of decision aid studies that focus on the effects of screening and treatment decision aids on decision making and health outcomes, including adherence. They exclude studies that focus solely on promoting adherence without using decision aids. Trials are identified through systematic searches of multiple databases (e.g. Cochrane Central Register of Controlled Trials, Medline OVID, Embase OVID, PsychINFO Ovid, and CINAHL; all inception to 3-11-2022) and clinical trial registries (e.g. clinical trials.gov, WHO international clinical trials registry), and through handsearching of included articles. Identified studies are independently dual reviewed for inclusion using Covidence in a two-step process (e.g. titles and abstracts, full text articles). Then, data about basic methods, participants, interventions, and outcomes are independently abstracted into evidence tables. Investigators dually review risk of bias using standard Cochrane methods, which

evaluate and independently rate the risk of bias of items that represent several key categories of bias: selection bias (i.e. who gets in, is maintained within, and analyzed within the study); measurement bias (i.e. whether exposures and outcomes are accurately measured and rigorously reported); and "other bias" (e.g. confounding) that is identified by individual study investigators. Per Cochrane protocol, it does not specifically report an overall assessment of bias for individual studies. Data are meta-analyzed by key study outcomes using random effects models, excluding any articles considered at overall high risk of bias by investigators (n=1 in the 2024 review).

Using this process, the Cochrane review identified 25 studies of decision aids that measured adherence as an outcome. Studies may or may not have been designed specifically to promote adherence. The review placed no restrictions on study participants or study settings except that the age of the decision maker had to be 18+ years of age.

Study selection

A single reviewer reviewed adherence articles included in the Cochrane review (n=25) for inclusion on two occasions separated by over a month apart. She included all articles that measured medication adherence, stated they were specifically designed to promote adherence, and were conducted in primary care, specialty, or community settings in general populations of patients with any level of past adherence. She excluded studies that were not in English (or had non-English language decision aids), did not state an explicit goal of improving adherence, studied decisions with options other than medicines (e.g. devices, procedures), or were conducted in populations that had characteristics likely to differentially affect adherence (e.g. patients with depression, surrogate decision makers). As a quality check, she also reviewed articles excluded from the Cochrane review to determine whether any articles were excluded because they focused more broadly on adherence; none did.

Data extraction

A single investigator extracted data into tables with a check over a month later. Abstracted information included the basic details of the study, studied interventions and their components, study outcomes, and study results. Abstracted data expanded the information abstracted in the Cochrane review to allow an examination of the alignment of studies with adherence taxonomies and the process, interventions, and stages of adherence. It did not specifically examine intervention alignment with determinants or communication elements of adherence; few studies reported sufficient intervention detail. However, several key determinants (e.g. potential moderators) were noted as baseline characteristics of the populations studied. Specific study details included: study design, sample, sample characteristics, intervention, comparator, primary outcome, adherence outcome, and other outcomes. Possible interventions included: decisions aids, communication and decision training, medicine and adherence education, training/coaching (i.e. skill development), medicine review, advice and reminders, self-monitoring, support, and resources. Examined study outcomes included the major behavioral antecedents of adherence (e.g. knowledge, accuracy of risk perception, attitudes toward medicine, decision/intent to take medicine, knowledge for adherence, skills for adherence), stages of adherence (e.g. initiation, implementation, persistence), and health outcomes, if any. These outcomes were presented together to give an "at-a-glance" understanding of the impact of decision aids. Additional decision making and collaborative outcomes (e.g. shared decision making, decisional conflict, decision consistent with values, etc.) traditionally ascribed to decision aids were examined separately. Together these outcomes allow assessment of hypotheses about how decisions aids work to affect adherence, and whether or not they could be a necessary, if not sufficient component, for adherence. Finally, key sample characteristics that might moderate effect were noted. Abstractions were compared with those of the Cochrane review.

To facilitate understanding of results, studies were divided into those that studied decision aids only and those that studied decision aids in combination with other adherence supports.

Risk of bias

Included studies were of low or moderate risk of bias per Cochrane and were not re-appraised.

Data analysis

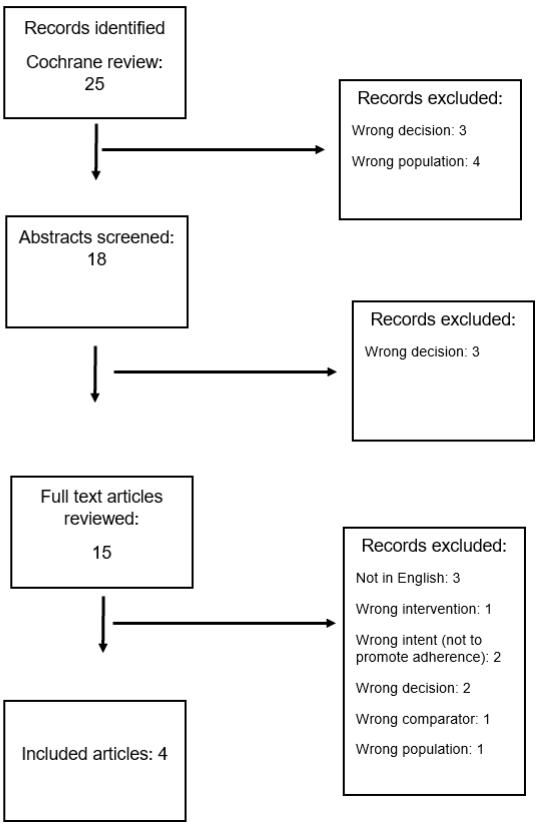
Data analysis focused on the alignment of decision aids with taxonomies of adherence and the effects of decision aids +/- other adherence interventions on outcomes including behavioral antecedents, decision making and collaborative outcomes, adherence, and distal outcomes. The primary outcomes of interest were the different stages of adherence, including initiation (i.e. starting medicine), implementation (i.e. taking medicine as prescribed), and persistence (i.e. taking medicine from the time it is prescribed until told to stop). However, analyses also focused on the effects of decision aids on behavioral, decision making, and collaborative outcomes and whether or not decision aids alone or in combination with other adherence supports improve adherence and distal outcomes. To examine these hypotheses, the reviewer analyzed data separately for studies that focused on decision aids alone versus decision aids plus other adherence interventions given that these were hypothesized to have differential effects. Effects were reported as in studies as changes in absolute risk (or sometimes as odds ratios).

Data synthesis (i.e. results)

Summarizing included studies

The Cochrane review included 5 studies of decision aids designed to promote adherence that met inclusion criteria (see Figure 2). Studies included one reported in two papers (15, 16).

Figure 2. Articles reviewed for inclusion/exclusion



Four studies used decision aids alone, while one used a decision aid with additional adherence supports (Tables 1)(15, 16). The 4 studies that used decision aids alone included 1 cluster randomized trial, 1 pilot randomized trial, 1 randomized trial, and 1 factorial randomized trial. All were low or moderate risk of bias per Cochrane. All were conducted in outpatient settings in patients who were eligible for treatment. Three used decision aids delivered during the clinical encounter. The factorial trial and a fourth trial (e.g. the pilot randomized trial) tested pre-visit delivery. Two decision aids were one-page decision aids and included information about medicine practicalities (e.g. routine and costs) in their discussion of the downsides of taking medicine. One used a tailored card-based design with 6-7 cards each addressing a single benefit, harm, or practicality (e.g. medicine routine, cost, or testing burden) for all options (18). Finally, one used a non-simultaneous, 2-week pre-visit workshop to introduce the decision aid that included an information booklet, audiocassette, and worksheet used to individualize decisions, clarify values, and state a preference. The single study that used a decision aid plus adherence supports was a randomized trial combining a pre-

visit, web-based, patient decision aid with tailored guidance, coaching for decision making and communication, tailored print messages for overcoming barriers to adherence, and provider training in cardiovascular risk reduction and adherence.

Most studies focused on decisions for new medications and none required participants to have prior non-adherence. Studies covered a wide range of clinical topics, including osteoporosis treatment (n=2), choice of diabetes medication in type 2 diabetes (n=1), whether or not to take statin for elevated lipids in diabetes (n=1), and the choice among various medicines to reduce the chances of primary atherosclerotic cardiovascular disease (n=1). Control groups included usual care in 2 studies and an information brochure in 2 studies. Most included older participants (mean age 55+ in all studies). Education levels varied with 2 studies having >90% of participants with at least a high school degree (15, 16, 19, 20). Most studies did not report insurance status or the availability of a prescription drug plan. Only two studies reported socioeconomic status with a mean income of $50,000/year (18, 19). Studies included a variety of adherence outcomes, including medicine initiation (n=2), medicine implementation (n=4), and medicine persistence (n=3). However, only three measured adherence as a primary outcome, ensuring adequate power to detect effects. All, except the pilot trial, measured at least some behavioral antecedents and some decision making and collaborative outcomes (e.g. informed/shared decision making; decisional conflict; decision consistent with values; satisfaction with process, decision, or conversation; patient-centeredness of discussion; trust in physician).

Table 1. Study detail

Study	Study design	Sample	Baseline adherence	Focus	Intervention	Comparator	Primary outcome	Adherence outcome	Other outcomes
Decision aid + adherence supports									
Sheridan, 2011 and 2014 (15, 16)	RCT	1 primary care practice in US 40 physicians 160 men and women, age 40-79, with no prior history of ASCVD Key adherence determinants: • Educ: 90% some college, • Health lit: NR, • Insurance: NR, • Prescription plan: 90%, • SES: NR, • Mean # meds: NR.	92%	ASCVD prevention	Pre-visit decision aid Decision and communication coaching, Tailored adherence counseling Provider education	Usual care	Not reported	Initiation (self-report) Use at 3 months (self-report)	• Knowledge, • Accuracy of risk perception, • Values clarity, • Decisional conflict, • Shared decision making, • Presence of patient-provider discussions, • Patient-centeredness of discussion, • Intent to start therapy, • Change in predicted risk, • ASCVD risk factors, • Tool use, • Feasibility of delivery.

Decision aids only									
Oakley, 2006 (21)	Pilot RCT	1 primary care practice in UK 33 post-menopausal women with osteoporosis or age 65 and radiologic evidence of fragility fracture Key adherence determinants: • Educ: NR • Health lit: NR, • Insurance: NR, • Prescription plan: NR, • SES: NR, • Mean # meds: NR.	91%	Osteoporosis treatment	Decision aid (pre-visit workshop)	Usual care	Not reported	Persistence at 4 months (via refill request) Implementation at 4 months (MARS scale)	• Satisfaction with information about medicine, • Decisional conflict scale (intervention group only) • Usefulness of the decision aid.
Montori, 2011 (19)	RCT	10 primary care practices in US 60 clinicians 100 women, 50+ y/o, with osteopenia or osteoporosis who were eligible for bisphosphonate	Not reported	Osteo-porosis treatment	Decision aid (in-visit)	Usual care + Brochure from National Osteoporosi s Foundation	Knowledge Adherence	Initiation Implementation (self-report single question) Persistence (% of days and >80% of days covered per pharmacy records)	For patient: • Knowledge, • Accuracy of risk perception, • Satisfaction with knowledge transfer, • Decisional conflict, • Involvement in decision making (Observer option scale), • Trust in physician, • Use of decision aid, • Fidelity of decision aid delivery.

		Key adherence determinants: • Educ: 96% some high school • Health lit: NR, • Insurance: NR • Prescription plan: NR, • SES: median income $50,000, • Mean # meds: NR							For physician: • Perceived decision quality • Satisfaction with knowledge transfer
Mullan, 2009 (18)	Cluster RCT	11 primary care practices in US 40 clinicians (physicians, NP, residents) 85 patients with diabetes and poor glycemic control (hgba1c 7-9.5%) on fewer than 3 medicines, no insulin Key adherence determinants: • Educ: 46% high school completion • Health lit: NR,	Not reported	Diabetes treatment with: -metformin -insulin, -glitazones, -exanatide, -sulfonyl-ureas.	Decision aid (in visit) Provider training in decision aid use only	Usual care + 12-page pamphlet on diabetes medicines	Helpfulness of inform-ation Shared decision making Adherence	Implementation (self-report at 6 months) Persistence at 6 months (# prescription days covered)	For patients • Knowledge, • Preferred involvement in decision making, • Involvement in decision making (Observer option scale), • Decisional conflict, • Trust in physician, • Hgba1c • Use of decision aid. For clinicians: • Decision, • Decision aid acceptability

		• Insurance: NR • Prescription plan: NR, • SES: median income $50,000, • Mean # meds: 6.							
Wey-miller, 2007 (20)	factorial RCT	1 metabolic clinic 21 clinicians in US 98 patients with diabetes and no contraindication s to statins. Key adherence determinants: • Educ: 93% high school completion, • Health lit: NR, • Insurance: NR • Prescription plan: NR, • SES: NR, • Mean # meds: 10.	Not reported	Statins, if diabetes	Decision aid (pre-visit)	Pamphlet on lipids, dietary guidelines, and risk reduction	Initiation of medicine	Initiation of medicine Use at 3 months (self-report) Implementation at 3-months (self-report, single question)	• Knowledge, • Accuracy of risk perception, • Decisional conflict, • Satisfaction with knowledge transfer, • Acceptability of decision aid.

ASCVD: atherosclerotic cardiovascular disease; BMI: body mass index; Educ: education; Health lit: health literacy; HgbA1c: hemoglobin A1c; MARS: medicine adherence reporting scale; meds: medicine; NR: not reported; RCT: randomized trial; SES: socioeconomic status; UK: United Kingdom; US: United States

Alignment with taxonomies (Appendix Table 1)

Overall, studies were only modestly aligned with taxonomies of adherence. While all addressed the process step of sharing information and decisions, only one addressed additional process steps including obtaining medicine, planning to take medicine, and taking medicine as prescribed. It used medicine education about costs, and planning and remembering to take medicine.

The effects of decision aids alone

Of the four studies that used decision aids alone, two examined a combination of behavioral antecedents, decision making and collaborative outcomes, and adherence (19, 20). One examined these plus health outcomes (18) and the pilot study measured only decision outcomes and adherence.

Effects on behavioral antecedents of adherence (Appendix Table 2)

Studies generally had mixed effects on behavioral antecedents. Three studies measured knowledge and two reported improvements in knowledge (1-2 points on 9 or 10 pt scales) (18, 19). Two measured accuracy of risk perception and reported improvements in the accuracy (+21% improvement in one study and OR 6.7, 95% CI 2.2 to 19.7, in the other) (19, 20); one of these reported that accuracy was not improved when the decision aid was used prior to the visit (20). None measured attitudes that taking and adhering to medicine is “worth it”. Only one reported on decisions/intent to take medicine, but didn’t report its significance to allow interpretation (18).

Effects on decision making and collaborative outcomes (Appendix Table 3)

Studies of in-visit decision aids measured a variety of decision making and/or collaborative outcomes, however, the number measuring each outcome was generally limited. None measured the presence of a discussion about medicine. Two of 4 measured involvement in informed and/or shared decision making using the observer option

scale and showed appreciable effects (+22-23 on 100 point scale with 95% confidence intervals ranging from 13 to 31) (18, 19). Four of 4 studies measured satisfaction with information/knowledge transfer and found mixed effects (18-20). Two studies measured trust in the physician and found no effect (18, 19). Three measured decisional conflict from feeling uninformed, unsupported, unclear on what's important, and/or unclear which choice is best (using the decisional conflict scale) (18-20); only one found significant improvement in this outcome (-10.6, 95% CI -15.4 to -5.9) (20).

The pilot study of a non-simultaneous, 2-week pre-visit decision aid measured decisional conflict in the intervention group only and found no effect of the decision aid on satisfaction with information (21).

Effects on adherence and health outcomes (Appendix Tables 2 and 3)

Studies using in-visit decision aids found mixed effects on adherence and no effect on distal outcomes. One study using in-visit decision aids alone (18, 19) found no effect on medicine initiation and two no effect on self-reported adherence) at 3-6 months; however, neither designated adherence as a primary outcome (18, 19). A third study found no effect on medicine use, but an effect on missing <1 dose of statin medicine in a week in those with diabetes: OR 3.4 (95% CI 1.5 to 7.5) (20). Two studies examined refill persistence (18, 19) with mixed effects. One examined distal health outcomes and found no effects (18).

The pilot study, which used a non-simultaneous, pre-visit workshop to deliver the decision aid, examined only self-reported medicine adherence and found no effects (21). This study did not examine health outcomes.

Studies using decision aids + adherence supports

The single study using a pre-visit decision aid + adherence supports (e.g. tailored guidance/coaching on decision making and communication, tailored messages on overcoming barriers to adherence, and provider training)

reported on a full complement of outcomes (15, 16). This study was unique in reporting an explicit values clarification exercise focused on ranking and rating the attributes of options that might affect adherence; facilitating a decision "committed to action"; and asking those who chose to do nothing to reflect on the potential downstream consequences of this decision. This study measured decision making, behavioral, collaborative, adherence, and health outcomes.

Effects on behavioral antecedents (Appendix Table 2)

It reported improvements in knowledge of effective options for CHD risk reduction (absolute difference: +28%, p< 0.0001), accuracy of risk perception (absolute difference: +33%, p<0.0001), and the intent to start any one of the effective options presented in the decision aid (absolute difference: +21%, 95% CI 5-37).

Effects on decision making and collaborative outcomes (Appendix Table 3)

It reported the presence of a discussion (absolute difference: +31%, 95% CI 15 to 45%), decisional conflict (absolute difference: -15.9 on 100 point scale, p=0.0001), and decisions consistent with values (absolute difference +15%, p=0.02). However, there was no effects on self-reported shared decisions and mixed effects on questions of the healthcare climate questionnaire, which addresses the patients perspective about whether the provider offered choices and options, understood how the patient sees things, expressed confidence in the patients' ability to make changes, provided encouragement to ask questions, and listened to and understood the patient perspective.

Effects on adherence (Appendix Tables 2 and 3)

The above improvements in understanding, decision making, and intent to start medicine resulted in improvements in self-reported initiation and use of chosen medicine at 3-months (absolute difference: +25%, p<0.01).

Effects on coronary heart disease events (Appendix Tables 2 and 3)

Further, these improvements resulted in improvements in CHD risk (absolute difference: -1.1%, 95% CI - 2% to -0.16%) with both intent to start medicine and self-reported adherence mediating the effect of the intervention on CHD risk in mediation analysis.

Discussion

This paper re-analyzed a recent Cochrane systematic review and meta-analysis of decision aids to a) determine the alignment of decision aids designed to promote adherence with recent taxonomies of adherence and b) to determine the effect of decision aids on behavioral, decision making, collaborative; adherence; and health outcomes. It showed that most decision aid studies used decision aids without additional supports to address medicine adherence. Further, in-office decision aids measured some, but not all relevant outcomes; seldomly measured the most proximate antecendents and stages of adherence (e.g. intent to adhere, initiation of medicine); and were often not powered to detect effects. A single, longer, pre-visit decision aid accompanied by adherence supports improved behavioral, decision making, collaborative, adherence, and health outcomes in a highly educated sample. Studies need to be further replicated to draw firm conclusions.

This review advances the work of previous reviews, including the Cochrane review of decision aids, an older narrative review of decision aids on adherence (22), and a systematic review of shared decision making tools for medicines (23) by focusing exclusively on tools designed to promote adherence and by providing a more comprehensive understanding of how studies address the process, determinants, and intervention components that support adherence. Within this framework, decision making is just one component of a much larger process of adherence and can be enhanced by providing supplementary

adherence supports. A host of interventions are available to support this process. (see Figure 1 c).

This review also advances the possibility that decision aids themselves can be improved to better facilitate adherence. For instance, the pre-visit decision aid accompanied by adherence supports included an explicit values clarification exercise that asked participants to rank and rate attributes of options that might affect adherence (e.g. benefits for other medical conditions, potential side effects, degree of difficulty for adherence, cost, and effect on others) and concluded by "asking participants which plan they intended to pursue, focusing on a commitment to action."(15, 16) Three studies of in-visit decision aids alone also facilitated consideration of attributes affecting adherence (e.g. side effects, costs, burden, routine)(18, 19); however, they relied on providers to facilitate consideration of importance. Other innovations included tailored, web-delivered, videotaped advice on how to overcome barriers to communication with the provider and tailored messages addressing reasons for choosing to do nothing (15, 16). It is an empirical question whether or not these types of innovations are important ingredients in facilitating adherence.

To further advance understanding of the effects of decision aids on adherence, it will be important for decision aid studies to broaden their goals to include adherence. Important additional content includes content that highlights the decisional goal of adherence, influences perceptions that medicine is "net beneficial" and "worth it", and highlights key practicalities that might affect adherence (e.g. medicine routine, cost, access). Many of these practicalities are highlighted as decisional needs in the Ottawa decision framework (25), but they could be more explicitly incorporated into decision aids (e.g. in education, values clarification exercises, and preference assessments) to promote adherence to chosen options. Decision aid studies might also strengthen their guidance on communication, collaboration, and shared decision making with providers given that all of these independently affect adherence outcomes (26, 27). Finally, and perhaps most importantly, decision aid studies need to provide additional supports for patient adherence.

To advance understanding, it will also be important for decision aids studies to make methodological

advances that will improve our understanding of the effects of decision aids on adherence. Such advances might include improvements in measurement and analyses. For instance, decision aid studies should measure and adequately power measures of adherence, particularly medicine initiation, which is the most proximate measure of adherence and one most likely to be affected by decision aids. They should also measure and adequately power intent to start therapy and decision making and collaborative outcomes. Reporting sample characteristics that might moderate the effect of decision aids on adherence would also help to understand effects; such characteristics include cognition, education/health literacy, socioeconomic status, insurance, ability to pay, and past adherence. Finally, decision aid studies should also test effects in representative settings and samples given that needed supports may vary by setting and sample characteristics.

Limitations

In considering this work, it is important for readers to understand the limitations of the work. First, this review is a sub-analysis of an existing systematic review and meta-analysis. The reviewer reviewed decision aid articles identified by that review. To the extent that their searches did not pick up relevant studies or their risk of bias assessments misclassified studies, this study might have made errant conclusions. Second, a single reviewer re-reviewed Cochrane studies for inclusion and re-abstracted articles for additional detail on two separate occasions over a month apart. It is possible results would be slightly different if checked by a second reviewer. Third, there are relatively few, small studies of decision aids alone and a single study testing decision aids and adherence supports. Additional studies are needed to draw firm conclusions. Fourth, many of the adherence analyses of the studies with decision aids alone were not powered to detect adherence. The lack of effect in outcomes could represent falsely negative findings. Finally, all of the included studies focus on decisions that either compare multiple net beneficial options or a single net beneficial option to usual care. It is as yet unclear whether or not promoting adherence to medicines with equipoise due to marginal net benefit or insufficient evidence should follow a similar process or would effect similar outcomes. (28, 29)

Conclusions

Despite minor limitations, we feel this review makes important advances. First, it provides a more rigorous framework for the evaluation of adherence than is possible in the Cochrane review of decision aids given its breadth. Second, it provides important insights on what works to promote adherence by juxtaposing all outcomes of individual studies. Third, it provides a foundation for future work to further explore the impact of decision aids and any accompanying adherence supports on adherence. It is entirely possible that decision aids are necessary to facilitate initiation of medicines (ensuring that patients intend to start medicine), but insufficient to support taking them as prescribed or persisting with them long-term.

Implications

Practice

Preliminary data suggest that practitioners should choose decision aids and supports that effect a full spectrum of outcomes, including behavioral, decision making, collaborative, adherence, and health outcomes.

Policy

Preliminary data suggests system level policymakers should offer decision aids that effect a full spectrum of outcomes. More data would be needed before mandating a broader approach to supporting adherence with decision aids.

Research

To adequately evaluate the effects of decision aids on adherence, studies need combine decision aids with other supports for adherence; measure intent to adhere, the different stages of adherence (e.g. initiation, implementation, and persistence), and key mediators and moderators; and test the independent effects of decision aids against decision aids with additional supports and usual care.

References

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Appendix 1. Alignment of decision aids with taxonomies of adherence

Stage of adherence	**Initiation of medicine**				**Implementation**		**Discontinuation**
Process of adherence	**Share information and decisions**	**Obtain medicine**	**Plan to take medicine**	**Initiate medicine**	**Take medicine as prescribed**	**Track use and solve problems**	**Decide to stop, if appropriate**
Interventions for adherence	**Decision aids**	**Medicine review, Simplified dosing, Medicine education and training**			**Reminders**	**Self-monitoring, Counseling, Self-management**	**Decision aids**
Decision aids + adherence supports							
Sheridan, 2011 and 2014	✓	✓	✓		✓		
Decision aids only							
Oakley, 2006	✓						
Montori, 2011	✓						
Mullan, 2009	✓						

Weymiller, 2007	✓						

Table 3a. Results of decision aid studies: adherence and its behavioral antecedents

Study	Knowledge for decision	Accuracy of risk perception (i.e. disease event probability, benefits and harms of medicine)	Attitudes toward medicine (i.e. perceived net benefit)	Decision and/or intent to take medicine	Knowledge for adherence	Skills for adherence	Adherence			Health outcomes
							Initiation	Implementation (i.e. take as prescribed)	Persistence (i.e. start and take until told to stop)	
Decision aid + adherence support										
Sheridan, 2011 and 2014	Knowledge of effective options for risk reduction: +28%, p<0.0001	Accurate perception of CHD risk: +33%, p<0.0001	Not measured	Intent to take any effective risk reducing strategy: +21% (95% CI: 5-37%)	Not measured	Not measured	Not reported	Not reported % with initiation and current use of chosen therapy at 3 months: +25%, P<0.01	Not measured	CHD risk: -1.1%, (95% CI -2.0% to -0.16%) SBP: -6.6 (95% CI -14.3 to 1.2) SBP, if reported adherence to new BP medicine: -8.6 mmHg, (95% CI -14.8 to -2.3) Total cholesterol: +8.0 (95% CI -12.0 to 28.1) Total cholesterol, if reported adherence to new cholesterol medicine: -45.6 mg/dL (95% CI -75.2 to -16.1)

Decision aid alone										
Oakley, 2006	Not measured	Not measured	Not measured	Not measured	Not measured	Not measured	Not measured	Medication Adherence Report Scale (self-report): +1%, sig. not reported	% total prescribing periods covered: +0%, p 0.80	Not measured
Montori, 2011.	Knowledge of information in decision aid: + 1.77 questions out of 9 (95% CI 0.77-2.77)	Accurate perception of fracture risk: +21%, sig. Accurate perception of benefits of medicine: +27%, sig.	Not measured	Not measured	Not measured	Not measured	+4%, p not reported	Self-reported 100% adherence: +2%, p=0.92	% total days of prescribing covered: +2%, P=0.09. Greater than 80% of days of medicine covered by pharmacy fills: +26%, P = 0.009	Not measured
Mullan, 2009	Knowledge of information in decision aid: + 1.10 (0.11 to 2.09) of 10 questions	Not measured	Not measured	Decision to take new diabetes medicine: +14, p not reported	Not measured	Not measured	Not measured	No difference at 6 months, p not reported	Total days of prescribing covered at 6 months: −11.8 (95% CI −21.0 to −2.67)	HgbA1c at 6 months: -0.01 (95% CI -0.50 to 0.49)
Weymiller, 2007	Knowledge about statins in diabetes (9 of 14 decision aid specific): +0.01 of 14 questions (95% CI –0.5 to 0.5)	Accurate heart attack risk perception: OR 6.7 (95% CI 2.2 to 19.7)	Not measured	Not measured	Not measured	Not measured	+7%, P not reported	Use of medicine at 3 months: +0%, p non-sig. Odds of adherence (missing <1 dose in 1 week): OR 3.4 (95% CI, 1.5-7.5)	Not measured	Not measured

	Differential effect by delivery: • During visit: +2.4 (95% CI 1.5 to 3.3) • Before visit: +0.8 (95% CI –0.3 to 1.9)	Differential effect by delivery: • During visit: 22.4 (95% CI 5.9 to 85.6) • Before visit: 2.8 (95% CI 0.9 to 8.5)								

*Adjusted to show effect of decision aid rather than usual care

Table 3b. Study results: decision making and collaborative outcomes

Relationship outcomes											
Study	**Presence of discussion**	**Informed/ shared decision making**	**Decisional conflict**	**Decision consistent with values**	**Satisfaction with process, decision, and/or conversation**	**Patient-centeredness of discussion**	**Trust in physician**	**Adherence**			**Health outcomes**
								Initiation	**Implementation** (i.e. take as prescribed)	**Persistence** (i.e. start and take until told to stop)	
Decision aid + adherence intervention											
Sheridan, 2011 and 2014 (15, 16)	+31% (95% CI +15 to +45%)	Patient-reported presence of shared decision: -9% (95% CI -27% to +10%)	Decisional conflict scale (adjusted to 100-point scale, lower better): -15.9, p<0.0001	+15%, p=0.02	Not measured	Provider offered choices and options: +15% (95% CI -0.1 to +31%) My provider understands how I see things: +9% (95% CI -7% to +25%) My provider conveyed confidence in my ability to make changes: +11%	Not measured	Not reported	Not reported % with initiation and current use of chosen therapy at 3 months: +25%, P<0.01	Not measured	CHD risk: -1.1%, (95% CI -2.0% to -0.16%) SBP: -6.6 (95% CI -14.3 to 1.2) SBP, if reported adherence to new BP medicine: -8.6 mmHg, (95% CI -14.8 to -2.3) Total cholesterol: +8.0 (95% CI -12.0 to 28.1)

						(95% CI -5% to +27%) My provider encouraged me to ask questions: +11% (95% CI -4 to +27%) My provider listened to how I'd like to do things: +21% (95% CI +6% to +37%) My provider tried to understand how I see things before making suggestions: +15% (95% CI -0.3% to 31%)					Total cholesterol, if reported adherence to new cholesterol medicine: -45.6 mg/dL (95% CI -75.2 to -16.1)
Decision aids alone											
Oakley, 2006 (20)	Not measured	Not measured	Not measured (intervention group only)	Not measured	Satisfaction with information scale: +0.3 on 17 pt scale, p 0.80	Not measured	Not measured	Not measured	Medication Adherence Report Scale (self-report): +1%, sig. not reported	% total prescribing periods covered: +0%, p 0.80	Not measured

Montori, 2011. (19)	Not measured	Observer-reported informed decision making (e.g. provider involvement of patient) via OPTION score (100-pt scale): +22.5 (95% CI +13.6 to +31.4)	Decisional conflict (100-point scale, lower better): -1.84 (95% CI -7.8 to +4.1)	Not measured	Satisfaction with knowledge transfer (7 point-scale): Amount of info: +0.22 (95% CI -0.28 to +0.73) Clarity of info: +0.36 (95% CI -0.22 to +0.96) Helpfulness of info: +0.22 (95% CI -0.36 to +0.8) Would want to other decisions aids: +0.37 (95% CI -0.25 to +0.98) Would recommend DAs to others: +0.18 (-0.28 to +0.65)	Not measured	Trust in physician (5-point scale, lower better) -0.45 (95% CI -3.2 to +2.30)	+4%, p not reported	Self-reported 100% adherence: +2%, p=0.92 Greater than 80% of days of medicine covered by pharmacy fills: +26%, P = 0.009	% total days of prescribing covered: +2%, P=0.09.	Not measured
Mullan, 2009 (18)	Not measured	Observer-reported informed decision making (i.e. provider involvement of patient) via OPTION score (100-pt scale): +21.8;	Decisional conflict (100-point scale): −0.89 (95% CI −5.37 to 3.59)	Not measured	Satisfaction with knowledge transfer (7 point-scale): Amount of info: −0.01 (95% CI −0.29 to +0.28)	Not measured	Trust in physician: (5-point scale, lower better) 2.06 (95% CI −1.78 to 5.89)	Not measured	No difference at 6 months, p not reported	Total days of prescribing covered at 6 months: −11.8 (95% CI −21.0 to −2.67)	HgbA1c at 6 months: -0.01 (95% CI -0.50 to 0.49)

		(95% CI +13.0 to +30.5)			Clarity of info: −0.01 (95% CI −0.38 to +0.36) Helpfulness of info: +0.38 (95% CI +0.04 to +0.72) Would recommend to others: +0.38 (95% CI −0.28 to 1.05) Would want to use for other decisions: +0.34 (95% CI −0.39 to +1.08)						
Weymiller, 2007 (20)	Not measured	Not measured	Decisional conflict post visit (100-pt scale, lower better) –10.6 (95% CI –15.4 to –5.9)	Not measured	Satisfaction with knowledge transfer (7 point-scale): Amount of info: +3.4 (95% CI +1.7 to +6.7) Clarity of info:	Not measured	Not measured	+7%, P not reported	Use of medicine at 3 months: +0%, p non-sig. Odds of adherence (missing <1 dose of medicine): OR 3.4 (95% CI, 1.5-7.5)	Not measured	Not measured

					+1.6 (95% CI +0.8 to +3.2) Helpfulness of info: +2.3 (95% CI +1.4 to +3.8) Would want to other decisions aids: +1.5 (95% CI +0.6 to +3.8) Would recommend DA to others: +2.6 (95% CI +0.8 to +8.0)						

*Adjusted to show effect of decision aid, rather than usual care, which is what is reported in the paper