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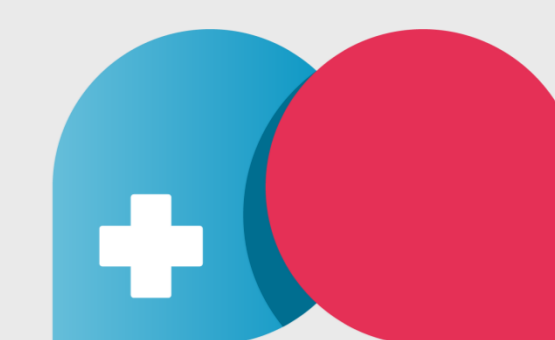
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# Making SDM a reality: Methods for large-scale production of evidence-based patient decision aids

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## Which of the methods in biometry, evidence-based medicine and health technology assessment can be applied to developing decision aids, and where do we have to develop new procedures?

### Background

Evidence-based patient decision aids (PDAs) should be available and affordable for many different medical decisions all over the world. Currently, PDAs are often developed as single-unit research projects. However, in order to make Shared Decision Making (SDM) an ubiquitous reality in hospital or ambulatory care, high-quality (evidence-based) PDAs must be developed simultaneously and updated regularly. Therefore, the focus should be on producing more PDAs in a more efficient way. This requires an effective and unified method, allowing the application of generic processes to different clinical contexts, languages and health care systems.

Within a German-Norwegian SDM project the evidence for relevant treatment options was searched systematically, appraised and synthesized in cooperation with Kleijnen Systematic Reviews (UK) and DynaMed (OptionGrid USA). Evidence was transferred to easily comprehensible patient-information within our web-based decision aid template by medical writers of our team.

As of June 2019, we have generated 30 different PDAs in 8 medical departments (3-4 evidence-based PDAs per month). We aim to complete 83 PDAs by September 2021.

### Aim

1. To share our experience of a 4-group international decision aid development team.
2. To encourage discussions about core methodological standards and processes for effective production of PDAs.
3. To establish an international network of developers.

### Results

The perspective of evidence-based PDAs often differs from those taken in other assessments in evidence-based medicine (EBM) such as systematic reviews, clinical guidelines, or health technology assessments. These often address specific research questions, for example by comparing the advantages and disadvantages of two different drugs.

In contrast, in SDM often involves a spectrum of questions regarding a range of options available to individual patients. This change in perspective needs to be considered in the evaluation of evidence and is often missing in tools and checklists currently available for the development of evidence-based PDAs.

### Information retrieval

We usually base our evidence synthesis on systematic reviews of randomized controlled trials (RCTs; "Review of reviews"-method). In addition, we search for good quality guidelines as doctors will rely on their professional organizations' advice.

### Evidence quality

To identify topics within their clinical area which are frequent, preference-sensitive and difficult to explain, medical doctors in the University Medical Center Schleswig-Holstein (UKSH) Kiel, a level III university hospital, were involved in the scoping process. For more than half of these topics, evidence for direct comparisons turned out to be scarce or of very low quality.

We therefore believe there is an urgent need for multiple high-quality RCTs comparing all relevant medical interventions in the largest medical fields.

### Presentation of numerical results

The International Patient Decision Aids Standards (IPDAS) criteria require event rates specifying the population and time period. In many cases, only indirect comparisons are possible, and studies have a high risk of bias. This raises the question whether it is still helpful to present numerical data in these situations. Sometimes presenting numerical data may give a false sense of security and be misleading.

## Possible Approaches to handle the problem of multiple comparisons

Primary studies often just compare one intervention to one comparator, whereas in SDM there is often a need to compare multiple interventions. We have used and present different approaches here:

Form of presentation	Advantages	Disadvantages
1. Narrative review of available evidence without attempt of direct comparison	<ul style="list-style-type: none"> <li>No need for assumptions</li> <li>Feasible irrespective of the kind of information available</li> </ul>	<ul style="list-style-type: none"> <li>Limits the usefulness of the information available to the patient for decision making</li> <li>Risk of being lengthy/ wordy</li> <li>Adequate representation of the evidence may be time-consuming</li> </ul>
2. Presentation of available evidence of direct comparisons – e.g. fact boxes	<ul style="list-style-type: none"> <li>Allows for methodologically correct presentation of available data</li> <li>High-quality data within each fact box if derived from high-quality RCTs</li> <li>Resources needed low, if adequate systematic reviews (SRs) available</li> </ul>	<ul style="list-style-type: none"> <li>Effect estimates may be heterogeneous for the same intervention in studies with different comparators leading to confusion, i.e. the effect estimates for intervention A may be different in the studies comparing it to intervention B to the effect estimates for intervention A in the studies comparing it to intervention C</li> <li>High risk that patients will start making indirect comparisons by comparing results from different fact boxes even if this is not appropriate, e.g. populations and baseline risks differ</li> </ul>
3. Present results of studies with same comparator side by side by estimating baseline risk	<ul style="list-style-type: none"> <li>Helps to present comparable data across a variety of interventions</li> <li>Amount of resources needed is moderate</li> </ul>	<ul style="list-style-type: none"> <li>Clinical expertise is necessary for realistic assumptions regarding baseline risks</li> <li>Comparison of older and newer studies with different comparators may be inappropriate because relative effects would be judged differently (e.g. changes in classification, (co-) interventions, patients included...)</li> <li>Rare to find that all the interventions of interest were compared to the same comparator</li> <li>It often requires the transformation of different outcome measures (odds ratio (OR), relative risk (RR), hazard ratio (HR)) to a common measure across all studies</li> </ul>
4. Network – Meta-Analysis (NMA)	<ul style="list-style-type: none"> <li>Allows comparisons even if not all interventions were compared to the same comparator</li> </ul>	<ul style="list-style-type: none"> <li>Most time consuming approach if no suitable Meta-Analysis available</li> <li>Mixes direct and indirect comparisons</li> <li>NMAs might be smaller, if only the relevant Interventions are included (e.g. no outdated interventions etc.)</li> <li>Issues related to option 3 apply as well</li> </ul>

## Acceptance with medical doctors

Results not meeting the expectations and practice of the clinicians might impact on the motivation to use the PDAs. The method of evidence generation is criticized for being out-of-date, too rigorous, and implying that the effects of treatment options do not differ when they actually do. In our experience, the best way to handle these obstacles is to involve medical doctors closely into the development process (which is another challenge in itself).

## Conclusion

Large-scale implementation of SDM demands a uniform and rigorous method of generating relevant information for evidence-based PDAs. Exchange and agreement on methods will enable to share PDAs across working groups and countries.

## Sample decision aids

Sample decision aid of our project in Norwegian and German language can be found at:

<https://demo.share-to-care.de>

Username: T01-demouser-0519

Password: GZYVKZ3z

or:

<https://helsenorge.no/samvalg>

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