

Evidence, experts, trustworthy guidelines and WikiRecs

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Clinical practice guidelines, based on the concept of evidence-based medicine, have positively impacted care of patients with cardiovascular disease, since their introduction over 30 years ago. Guidelines both 'guide' clinical practice and inform national and local healthcare policy. Now, a new definition for trustworthy guidelines—supported by explicit standards—is a major advance widely recognised by the guideline community, but largely unknown within the cardiology community.¹

CURRENT CARDIOLOGY GUIDELINES

Cardiology guidelines typically are developed and published by national and international professional organisations, most notably the European Society of Cardiology (ESC) and American College of Cardiology (ACC). Most cardiology guidelines address an entire disease process, such as heart failure, valvular heart disease or acute myocardial infarction, with numerous recommendations resulting in quite lengthy documents. Guideline development by organisations such as the ESC or ACC has relied on volunteer writing groups who are expected to review the published research, prepare evidence tables summarising these data, write recommendations with explanatory text and prepare clinical decision pathway flow charts.² An oversight committee sets standards for guideline development and directs this process. Committees usually include representation from partner societies to ensure clinical expertise in various aspects of clinical care, for example, cardiologists, cardiac surgeons, anaesthesiologists and imaging experts. After committee members reach a consensus on each recommendation, a rigorous process of internal and external reviews, with revision in response to each reviewer's comment, helps

ensure a robust document at the time of publication.

We all agree that these guidelines set a high standard of care for patients with cardiovascular disease and provide practical guidance for clinical cardiologists. However, the current process is no longer viable; we need a new approach. Clinical cardiology research is an actively expanding field, with more publications continuously adding to the existing evidence base. Current cardiology guideline development often falls short of meeting key standards of trustworthiness, is too slow and is not responsive to new practice-changing evidence. Many recommendations are based on expert consensus alone, given lack of evidence about a specific clinical issue. Others are based on incomplete literature searches, misinterpretations of published evidence or lack of integration of all evidence types, including epidemiological data, observational studies and clinical experience as well as randomised controlled clinical trials (RCTs). Further, committee members may bring unrecognised personal biases to the guideline-writing process. More importantly, the current process primarily includes only 'clinical content experts'—physicians who treat patients with cardiovascular disease.

GOALS FOR OPTIMAL GUIDELINE DEVELOPMENT

A more robust approach would include experts in health research methodology, who can prepare systematic reviews and meta-analyses to summarise the evidence for all patient-important outcomes. These experts would also aid the panel in moving from evidence to recommendations in a systematic and transparent way. Such an approach would also include editing professionals with expertise in writing and communication, who can ensure the wording and presentation of the final product are precise, unambiguous, concise, internally consistent and concordant with the overlapping guideline documents. Current cardiology guidelines use a complex system of classification (recommendation strength) and grading (evidence quality) that is confusing and differs from most other specialties; we should switch to the GRADE (Grading of Recommendations Assessment, Development and Evaluation) system.³

Finally, we need guidelines in a format compatible with the current practice of medicine. No one can remember all the individual recommendations in numerous guideline documents; an old-style published document, either on paper or in digital format, is useful only for archiving purposes. Even an 'app' for each set of guidelines is not enough; how many apps would we need and how will we know which one to look at? Recommendations need to be developed and presented in a modular digital format that allows periodic rapid updates, as needed to incorporate new evidence. Guideline content should be integrated into the electronic medical record (EMR), available quickly and easily at the point of care, and linked to decision support, management checklists and care plans.⁴

MAGIC AND WIKIRECS

Six years ago, current challenges within guideline development, dissemination and updating were recognised by an international team of methodologists, clinicians and researchers, initially focusing on updating authoritative guidelines for antithrombotic therapy.⁴ Their enthusiasm for trustworthy guideline standards and GRADE—coupled with the frustrating absence of solutions to numerous difficulties—resulted in a project called MAGIC: Making GRADE the Irresistible Choice (<http://www.magicproject.org>).⁵ MAGIC is a non-profit research and innovation programme set up to make evidence summaries and recommendations that work for clinicians at the point of care and to facilitate shared decision-making with patients. The web-based MAGIC authoring and publication platform (MAGICapp) is used by an increasing number of guideline organisations, because it provides a framework for use of digitally structured data combined with trustworthy guidelines development methods. This framework allows authoring, publication and dynamic updating of evidence summaries and recommendations, as well as consultation decision aids. All content is created and published in modular and digitally structured multilayered presentation formats, online and offline, 'anywhere, anytime on all devices', with these novel formats and tools being well received by clinicians.⁶ Content in MAGICapp is also set up for integration in structured EMRs as decision support systems and for more efficient adaptation to reduce duplication of guideline development.

Guideline developers continue to face organisational barriers with persistent challenges for decision-makers and clinicians in practice. This is perhaps

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particularly so for potentially practice-changing evidence, which is not transformed into guidance for clinicians speedily enough, leaving guideline recommendations and practice out of sync with the best current evidence. The MAGIC group has therefore moved on to create the WikiRecs project which represents a collaborative network of clinicians, patients, researchers and methodologists getting the work done quickly outside the restraints of organisational hurdles. In partnership with *the BMJ*, the WikiRecs group is seeking to improve the efficiency by which practice-changing evidence reaches patients. Faced with potentially practice-changing evidence, the goal is to rapidly create and disseminate trustworthy recommendations and evidence summaries in:

(1) a novel and user-friendly synopsis format published in *the BMJ*, (2) MAGICapp, together with consultation decision aids to facilitate shared decision-making and (3) other dissemination channels such as social media. This medical publication format is called *BMJ RapidRecs*.

BMJ RAPIDRECS FOR INTERMEDIATE RISK TAVI

The first WikiRecs to be published in collaboration with *the BMJ* concerns the use of transcatheter aortic valve implantation (TAVI) in patients with severe symptomatic aortic stenosis at low to intermediate surgical risk.⁷ Although data supporting TAVI in patients with aortic stenosis at high or prohibitive risk exist, data in patients with

lower surgical risk were limited until the publication of the PARTNERS 2A trial in late April 2016.⁸

Recognising the need for careful assessment of available data for this clinical question and the opportunity to provide early guidance based on this assessment to clinicians, a guideline panel consisting of methodologists, internists, cardiologists (including those with expertise in valvular disease), a cardiothoracic surgeon and two patient representatives was assembled. Another team of methodologists and clinicians from the WikiRecs group conducted a rapid and high-quality systematic review of available randomised clinical trials using GRADE methodology. This provided relative risks of TAVI versus surgical aortic valve replacement (SAVR) for all

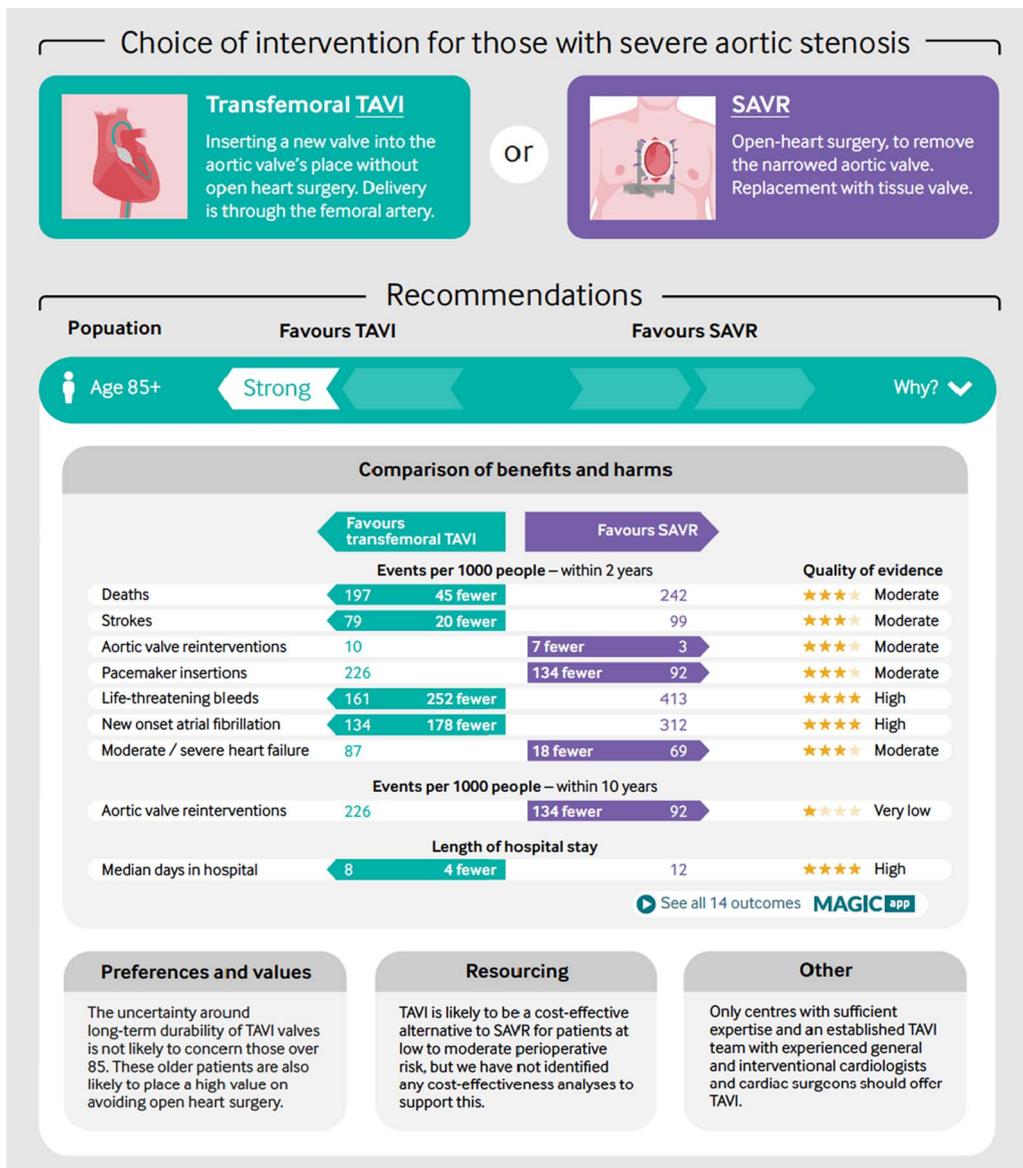


Figure 1 BMJ RapidRecs publication with Infographics, showing key information underlying the recommendation and link to MAGICapp (Making GRADE the Irresistible Choice authoring and publication platform). SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation. The infographics version of this figure can be found here <http://www.bmj.com/content/354/bmj.i5085>

identified patient-important outcomes. In addition, systematic reviews of observational studies and of values and preferences of patients undergoing SAVR were conducted.⁹ The observational review provided better estimates of baseline risk for key outcomes (including age-stratified risk), and through applying the relative risks, absolute risks and benefits of TAVI versus SAVR were estimated. Preplanned subgroup analyses were performed for patients undergoing transfemoral versus transapical TAVI. The quality of evidence for each outcome was assessed using GRADE methodology and rated as very low, low, moderate or high.

In brief, transfemoral TAVI was associated with a decrease in mortality, strokes and major bleeds but an increase in congestive heart failure, need for pacemakers and need for repeat aortic valve interventions compared with SAVR. Absolute benefits and risks of TAVI for some outcomes were smaller in younger patient age groups compared with older age groups given lower baseline risks. Another important concern was the lack of data regarding long-term durability of the TAVI prostheses with one recent presentation suggesting up to 50% valve degeneration at 8 years (low-quality evidence). Finally, available evidence suggested transapical TAVI was associated with excess harm (increased mortality, stroke, congestive heart failure, pacemakers and aortic valve reintervention) compared with SAVR.

The guideline panel then reviewed this evidence (individually and during two panel meetings). Based on careful assessment of the available evidence, five recommendations regarding the use of TAVI versus SAVR in low-to-intermediate

risk patients were drafted, peer reviewed for trustworthiness and published in the *BMJ* within 5 months of publication of the most recent RCT addressing this topic (figure 1). The goal for future guidelines is publication within 3 months following RCTs that have the potential to drive important changes in clinical practice.

WILL CARDIOLOGY TRANSITION TO TRUSTWORTHY GUIDELINES?

The question going forward is whether the cardiology community will embrace the explicit standards for development of trustworthy guidelines and make the transition from the historical (but outmoded) approach which brought us this far, to the modern approach which will take us into the future. The MAGIC programme, or something similar, has the potential to transform guideline development by adherence to rigorous standards for ensuring trustworthiness; inclusion of research methodology and communication experts, as well as clinical experts, in this process; and greater efficiency which will allow rapid periodic updates as new practice-changing research is published. Clinicians stand to gain from this transformation by having recommendations easily available in multiple formats 'anytime and anywhere', most importantly at the point of care, without needing to remember which guideline document is relevant, and when, where or how it was published. In addition, rather than simple guidelines, multilayered presentation formats will allow both physicians and patients to be better informed in the shared clinical decision-making process.

Competing interests CMO has participated in guideline-writing committees for the American College of Cardiology. POV is heading the non-profit MAGIC research and innovation programme. All three authors participated in the WikiRecs writing group for transcatheter aortic valve implantation in patients at intermediate surgical risk.

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