

The Value, Role & Limitation of Clinical Practice Guidelines

Some Background

When I first took on responsibilities for reviewing & discussing various drug therapy areas, I would stumble across a recent guideline and think "YES, someone has already done all the work for me!!!" This was a balloon soon began to deflate. A variety of events forced me to dig much deeper on therapeutic decision making, and the role of guidelines. Here are a few of them ...

- 1) a hypertension decision point for which I soon found out it depended "which guideline group you followed", as there were different groups who were at odds
- 2) working through a project on HRT recommendations and getting a phone call from a clinician regarding "does this 72 yo women really still need to be on estrogen/progesterone?" Delving into evidence before and after WHI gave me an appreciation for factors that affected the interplay of evidence and guidelines.
- 3) participating in a guideline committee, and finding no one else on the committee was delving into the evidence but rather working with their assumptions and a pre-packaged synopsis of information
- 4) hearing a controversial speaker address commonly accepted guideline recommendations, take some flak for the position, but see all 4 messages substantiated in evidence and guidelines within 1-6 years (glucose targets/outcomes, HRT, coxibs, docusate)
- 5) participating in a national guideline process and seeing how the discussion and voting process works
- 6) taking in a Cochrane Conference where one of the topics was "how many guidelines, meet the guidelines for guidelines?" The number from an analysis at that time was ~ 17%
- 7) the number of guideline statements that change dramatically over time

Over time, I moved to value guidelines for what expertise and insight they brought, and for the effect they had on impacting standards of care. I also grew to discover and recognize their many limitations.

In terms of evidence, three observations

- 1) when evidence is scarce and/or weak, this is often, though not always, acknowledged. One usually realizes recommendations as being lower grade - characterized by less certainty and more opinion.
- 2) when there is substantial evidence, the potential for stronger recommendations and greater certainty is there; however, even then, there is always the need to extrapolate, interpret and contextualize. This often requires working with theoretical models, and these models are themselves subject to beliefs, assumptions, perspectives and thus bias. So, even when evidence seems more robust, its application to various populations and individuals can be left with a fair bit of uncertainty. While good outcome evidence often holds up, the model by which one may apply its findings to various patients may change with time, as we become aware of subtle complexities. This is often a valid consideration for recommendations around surrogate outcomes and targets, and unique populations.
- 3) Some guideline groups take evidence and efforts to remove bias much more seriously than others!!!

How does one make sense of all this?

1. Be aware of the varying strength of evidence behind various guidelines and guideline recommendations.
2. Be cautious around recommendations based on low quality evidence or extrapolations of evidence beyond the treatment type or patient type studied (e.g. application to very low risk; application to geriatric population).
3. Value the expertise represented in the guideline process for what it is, and look for the discussion, often in the detailed text noting varying points of view and important caveats.
4. Look at the makeup of the guideline committee. Did they have conflicts of interest? Were they all from one "party" or perspective? Where did guideline funding come from?
5. Allow for evidence to inform your take on a guideline statement. Conversely, allow insight in the guideline to speak to possible ways to interpret and apply the evidence.
6. Where possible, check out a few different guidelines on the same therapy area. Note any differences which often speak to *holes in the evidence*.
7. Let the guideline serve the patient, not the patient the guideline!
8. Incorporate patient values and shared decision making where appropriate.
9. Remember that a clinical guideline that excludes any significant cost considerations, by default ends up abdicating that component of decision making to a policy committee.
10. Discuss therapeutic options with the patient or the substitute decision maker as appropriate.
11. If making a therapy decision that differs from a guideline recommendation, document your reason for doing so.

I still really like to look at and use a good guideline in therapeutic decision making. However, I also remember that *the truth is out there*, and not necessarily in every guideline.

And...one more thing...

- In order to increase the chance of a behaviour change, a guideline recommendation is often crafted to be clear and actionable, without being too "wishy-washy". The more I delve into evidence, the more I appreciate how things are often more complex with subtleties and uncertainties. So as Alfred North Whitehead said, "Seek simplicity, and mistrust it!"

Ah, the art of bringing evidence, experience and an appreciation for the unknowns to drug therapy decision making! No one said it would be easy!!!

Keep thinking!!!

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