Clinical Practice Guidelines: Choosing Wisely

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Learning Objectives
• To understand the process of developing guidelines
• To understand the process of critically reviewing guidelines
• To understand how/which guidelines should be implemented

2.1 Introduction

As Paediatric Urologists or in fact as clinicians in any discipline, we come across a vast array of guidelines from which to choose. The ultimate aim of clinical guidelines is to offer the clinicians an evidence based patient focused resource to improve patient outcomes, maintain patient safety and provide the most cost effective treatments. Guidelines can be found nationally, regionally or locally. Most local guidelines are adopted from existing guidelines but tailored for local use. With the vast array of guidelines available it can be a daunting task to determine which guidelines to choose from for patient management as not all guidelines are consistent and may differ widely in their content and recommendations. This chapter will focus on how guidelines are developed and how end users—the clinicians can determine which guidelines have been developed in a robust fashion to use with the highest level of evidence.

2.1.1 Clinical Guideline Development

There are several key steps when developing guidelines. These are:

1. Identify an area in which to develop the guidelines
2. Establish a core guideline developmental group
3. Agree on guideline appraisal process
4. Assess existing guidelines for quality and clinical content
5. Decision to adopt or adapt guideline
6. External peer review of the guideline
7. Endorsement and ratification at local level
8. Local adoption
9. Periodic Review of the guideline

2.2 Identifying an Area in Which to Develop Guidelines

The key consideration is to develop a guideline for areas which may be prevalent in the local population or which will have improved outcomes for a maximum number of patients. This could be areas such as urinary tract infections in children, congenital obstructive uropathies, urinary tract calculi, nocturnal enuresis to name a few.

2.3 Establish a Core Guideline Developmental Group

Once an area has been established, all stakeholders including patients/carers should be involved in the guideline development process. For urinary tract infections this may include pediatricians, Paediatric urologists, general practitioners, nursing staff, microbiologists, parents of infants and young children and older children. In essence any stakeholder who may provide a clinical service for or who may benefit from the area that the guideline is designed for should be included.

2.4 Agree on a Guideline Appraisal Process

How can one determine whether a guideline is sufficiently rigorously developed to adopt? The guideline development group therefore needs to agree on how the guidelines will be appraised. The AGREE instrument is one such appraisal methodology and is shown below.

2.5 Assessing Existing Guidelines

The initial chapters on Evidence Based Medicine already highlights the levels of evidence and the hierarchy of evidence. As clinical guidelines are outcome focused and are aimed to be cost effective, the following levels of evidence and their implication for clinical decision making may be used to assess existing guidelines. A strategy to retrieve guidelines has to be agreed eg. Search terms, language/s, databases etc.
Levels of evidence for therapeutic studies

| Level | Type of evidence |
|-------|------------------|
| 1A    | Systematic review (with homogeneity) of RCTs |
| 1B    | Individual RCT (with narrow confidence intervals) |
| 1C    | All or none study |
| 2A    | Systematic review (with homogeneity) of cohort studies |
| 2B    | Individual Cohort study (including low quality RCT, e.g. <80% follow-up) |
| 2C    | “Outcomes” research; Ecological studies |
| 3A    | Systematic review (with homogeneity) of case-control studies |
| 3B    | Individual Case-control study |
| 4     | Case series (and poor quality cohort and case-control study) |
| 5     | Expert opinion without explicit critical appraisal or based on physiology bench research or “first principles” |

*From the Centre for Evidence-Based Medicine, [http://www.cebm.net](http://www.cebm.net)*

**Grade practice recommendations**

| Grade | Descriptor | Qualifying evidence | Implications for practice |
|-------|------------|---------------------|---------------------------|
| A     | Strong recommendation | Level I evidence or consistent findings from multiple studies of levels II, III, or IV | Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present |
| B     | Recommendation | Levels II, III, or IV evidence and findings are generally consistent | Generally, clinicians should follow a recommendation but should remain alert to new information and sensitive to patient preferences |
| C     | Option | Levels II, III, or IV evidence, but findings are inconsistent | Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role |
| D     | Option | Level V evidence: little or no systematic empirical evidence | Clinicians should consider all options in their decision making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role |

*From the American Society of Plastic Surgeons. Evidence-based clinical practice guidelines. Available at: [http://www.plasticsurgery.org/Medical_Professionals/Health_Policy_and_Advocacy/Health_Policy_Resources/Evidence-based_GuidelinesPractice_Parameters/Description_and_Development_of_Evidence](http://www.plasticsurgery.org/Medical_Professionals/Health_Policy_and_Advocacy/Health_Policy_Resources/Evidence-based_GuidelinesPractice_Parameters/Description_and_Development_of_Evidence)*

While the agree criteria may be used to determine the quality of the guideline, a quick screening process that has been advocated is to determine the rigor of development (number 7 of the AGREE criteria). Furthermore, the guideline should be current. The content of the guideline also must be considered. Where more than one guideline is being considered, a comparison between guidelines, recommendations
and levels of evidence may result in evolution of a guideline incorporating recommendations from more than one guideline.

### 2.6 Decision to Adapt or Adopt a Guideline

Once the process above is completed, a decision must be made by the guideline development group as to the robustness of the guideline for local use. The guideline may be used unmodified or may need to be adapted for local use but maintaining the key principles within the guideline.

### 2.7 External Peer Review

If a decision is made to adopt a guideline, the guideline should be sent to a specialist in that field for peer review of the applicability of the guideline for local use. In some instances when local guidelines are being developed without reference to national/international guidelines, the peer reviewer may be a senior clinician within the speciality. For example, a guideline on the management of Transanal irrigation or on insertion of catheters may be developed by specialist urology nurses and reviewed by a Paediatric Urologist.

#### 2.7.1 Endorsement and Ratification at Local Level

Once peer reviewed, the guideline has to pass through a formal process of ratification usually via a committee that approves the guideline for local use. In the authors’ institution, this is the Clinical Audit and Effectiveness Committee. Guidelines for approval are sent out in advance of the meeting and discussed in the meeting prior to approval.

### 2.8 Local Adoption

Once approved, the guidelines are adopted for local use. Guidelines are reviewed at periodic intervals of 2–3 years with updates.

### 2.9 Conformity to Guideline Adherence

While the process above describes best practice in developing guidelines and how to determine which guidelines are robust, getting clinicians to adhere to the guidelines can be a different matter. In the past, surgical training was more paternalistic in that the ‘doctor was always right’ and training was more experience based rather
than evidence based. In such scenarios, changing mindset of individuals can be a daunting task. So imagine a scenario where a guideline is developed in a robust fashion using the AGREE tool and the surgeon does not adhere to the guideline. How can that be reversed?

In many organisations and indeed nationally there are specific standards that need to be met in terms of guideline adherence. In England for example the National Institute for Health and Clinical Excellence (NICE) publishes monthly requests for information regarding guidelines adherence and new technology appraisals. Individual organisations are expected to provide a baseline assessment of adherence to the guideline (Urinary tract infection is a good example) or provide deviation statements with rationale for the deviation from the guideline. These baseline assessments are required to be updated every 2 years. In many instances individual organisations may face a financial penalty for not providing these reports. As a result at local level, organisations have mechanisms in place led by clinicians to ensure this information is collected in a prompt manner.

Guidelines are developed to ensure standardised care and best possible clinical outcomes. Hence audit of outcomes are also important in ensuring adherence to guidelines. If outcomes are poorer than expected than a review of the guideline or adherence to the same by clinicians should be triggered.

### 2.10 Conclusion

It is important for clinicians to understand the process of guideline development. Wherever possible guidelines that are developed using the highest level of evidence should be considered for local use. These guidelines may be tailored for local use and must be reviewed periodically to incorporate any new evidence that may be available. Regulatory oversight and audit of outcomes are useful tools to ensure guidelines are being followed.

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### Appendix: Domains of AGREE II Appraisal Instrument

**Scope and purpose**

1. The overall objective(s) of the guideline is (are) specifically described
2. The health question(s) covered by the guideline is (are) specifically described
3. The population (patients and public) to whom the guideline is meant to apply is specifically described

**Stakeholder involvement**

4. The guideline development group includes individuals from all the relevant professional groups
5. The views and preferences of the target population (patients, public, etc.) have been sought
6. The target users of the guideline are clearly defined
Rigor of development
7. Systematic methods were used to search for evidence
8. The criteria for selecting the evidence are clearly described
9. The strengths and limitations of the body of evidence are clearly described
10. The methods for formulating the recommendations are clearly described
11. The health benefits, side effects, and risks have been considered in formulating the recommendations
12. There is an explicit link between the recommendations and the supporting evidence
13. The guideline has been externally reviewed by experts before its publication
14. A procedure for updating the guideline is provided

Clarity of presentation
15. The recommendations are specific and unambiguous
16. The different options for management of the condition or health issue are clearly presented
17. Key recommendations are easily identifiable

Applicability
18. The guideline describes facilitators and barriers to its application
19. The guideline provides advice and/or tools on how the recommendations can be put into practice
20. The potential resource implications of applying the recommendations have been considered

Editorial independence
22. The views of the funding body have not influenced the content of the guideline
23. Competing interests of guideline development group members have been recorded and addressed

AGREE appraisal of guidelines research and evaluation