

Practical Organization of Clinical Practice Recommendations (SOP*)



Type and quality of a new guideline

- The potential benefits of practice guidelines are only as good as the quality of the practice guidelines themselves.
- High level of quality & strength (usually based on large RCTs) → Guidelines
- Fair / poor level of quality & strength → Clinical Practice Recommendations (CPR) or Consensus Papers
- Poor guideline development process → Poor Guideline or Recommendation

*This SOP will be followed by ESPN, IPNA and ERKNet

Practical Organization of Clinical Practice Recommendations (SOP)



Methodology

- Pragmatic & standardized approach (SOP available online)
- Focus on clinical usefulness
- Suggestions will be made where there is no RCT to guide evidence based practice
- Use the **GRADE** method (e.g. define **PICO** questions) & follow the recommendations of the **Right Statement** (checklist)
- Set a schedule & adapt it during the process
- Goal: finish guideline within 1 year (otherwise it is outdated by the time of publication)

Practical Organization of Clinical Practice Recommendations (SOP)



RESEARCH AND REPORTING METHODS **Annals of Internal Medicine**

A Reporting Tool for Practice Guidelines in Health Care: The RIGHT Statement

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The quality of reporting practice guidelines is often poor, and there is no widely accepted guidance or standards for such reporting in health care. The international RIGHT (Reporting Items for practice Guidelines in HealThcare) Working Group was established to address this gap. The group followed an existing framework for developing guidelines for health research reporting and the EQUATOR (Enhancing the QUALity and Transparency Of health Research) Network approach. It developed a checklist and an explanation and elaboration statement. The RIGHT checklist includes 22 items that are considered essential for good reporting of practice guidelines: basic information (items 1 to 4), background (items 5 to 9), evidence (items 10 to 12), recommendations (items 13 to 15), review and quality assur-

ance (items 16 and 17), funding and declaration and management of interests (items 18 and 19), and other information (items 20 to 22). The RIGHT checklist can assist developers in reporting guidelines, support journal editors and peer reviewers when considering guideline reports, and help health care practitioners understand and implement a guideline.

Ann Intern Med. 2017;166:128-132. doi:10.7326/M16-1565 www.annals.org
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This article was published at www.annals.org on 22 November 2016.

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† Members of the RIGHT Working Group are listed in **Appendix 1** (available at www.annals.org); their contributions are listed in **Appendix 2** (available at www.annals.org).

Table. RIGHT Checklist

Evidence		
Health care questions	10a	State the key questions that were the basis for the recommendations in PICO (population, intervention, comparator, and outcome) or other format as appropriate.
	10b	Indicate how the outcomes were selected and sorted.
Systematic reviews	11a	Indicate whether the guideline is based on new systematic reviews done specifically for this guideline or whether existing systematic reviews were used.
	11b	If the guideline developers used existing systematic reviews, reference these and describe how those reviews were identified and assessed (provide the search strategies and the selection criteria, and describe how the risk of bias was evaluated) and whether they were updated.
Assessment of the certainty of the body of evidence	12	Describe the approach used to assess the certainty of the body of evidence.
Recommendations		
Recommendations	13a	Provide clear, precise, and actionable recommendations.
	13b	Present separate recommendations for important subgroups if the evidence suggests that there are important differences in factors influencing recommendations, particularly the balance of benefits and harms across subgroups.
	13c	Indicate the strength of recommendations and the certainty of the supporting evidence.
Rationale/explanation for recommendations	14a	Describe whether values and preferences of the target population(s) were considered in the formulation of each recommendation. If yes, describe the approaches and methods used to elicit or identify these values and preferences. If values and preferences were not considered, provide an explanation.
	14b	Describe whether cost and resource implications were considered in the formulation of recommendations. If yes, describe the specific approaches and methods used (such as cost-effectiveness analysis) and summarize the results. If resource issues were not considered, provide an explanation.
	14c	Describe other factors taken into consideration when formulating the recommendations, such as equity, feasibility, and acceptability.
Evidence to decision processes	15	Describe the processes and approaches used by the guideline development group to make decisions, particularly the formulation of recommendations (such as how consensus was defined and achieved and whether voting was used).
Review and quality assurance		
External review	16	Indicate whether the draft guideline underwent independent review and, if so, how this was executed and the comments considered and addressed.

Table–Continued

Section/Topic	Number	Item
Funding and declaration and management of interests		
Funding source(s) and role(s) of the funder	18a	Describe the specific sources of funding for all stages of guideline development. Describe the role of funder(s) in the different stages of guideline development and in the dissemination and implementation of the recommendations.
	18b	
Declaration and management of interests	19a	Describe what types of conflicts (financial and nonfinancial) were relevant to guideline development. Describe how conflicts of interest were evaluated and managed and how users of the guideline can access the declarations.
	19b	
Other information		
Access	20	Describe where the guideline, its appendices, and other related documents can be accessed.
Suggestions for further research	21	Describe the gaps in the evidence and/or provide suggestions for future research.
Limitations of the guideline	22	Describe any limitations in the guideline development process (such as the development groups were not multidisciplinary or patients' values and preferences were not sought), and indicate how these limitations might have affected the validity of the recommendations.

RIGHT = Reporting Items for practice Guidelines in HealthCare.

American Academy of Pediatrics grading system

Aggregate Evidence Quality	Strength of Recommendation	
	Benefit or Harm Predominates	Benefit and Harm Balanced
<p>Level A Intervention: Well-designed and conducted trials, meta-analyses on applicable populations Diagnosis: Independent gold standard studies of applicable populations</p>	<p>Strong Recommendation</p>	<p>Weak Recommendation (based on balance of benefit and harm)</p>
<p>Level B Trials or diagnostic studies with minor limitations; consistent findings from multiple observational studies</p>	<p>Moderate Recommendation</p>	
<p>Level C Single or few observational studies or multiple studies with inconsistent findings or major limitations.</p>	<p>Weak Recommendation (based on low quality evidence)</p>	<p>No recommendation may be made</p>
<p>Level D Expert opinion, case reports, reasoning from first principles</p>		
<p>Level X Exceptional situations where validating studies cannot be performed and benefit or harm clearly predominates</p>	<p>Strong Recommendation</p> <p>Moderate Recommendation</p>	

12 Steps in guideline development

1. Select the topic & define the population covered (1 coordinator)
 - e.g. Children with CKD stage 2-5 with high BP
2. Define type of guideline: consensus paper – CPR – (guideline)
3. Define working groups for guideline preparation:
 - Core group: approx. 10-12 members; the WG will choose them according to clinical experience and publication record with this topic
 - include all specialities needed, include a patient representative
 - External expert group: preferentially from European Networks or Societies
 - Voting group: ESPN WGs and other WGs (ERKNet)
4. Ask the right questions – selecting the right outcomes
 - Define PICO questions
 - Each question gets allocated to a subgroup of 2-4 core group members

Steps 1-4 may be done within a 2-3 hour face to face meeting

Questions & Outcomes – Why?

Are speeding cameras good?

Depends on what is meant by good...

Speeding tickets can be good for

- reducing traffic accidents
- reducing damage from accidents
- reducing human damage from accidents
- increase tax income

→ Not everyone values these outcomes the same way...



PICO Questions: Example

- **P**atient (or Population) to whom the recommendation will apply:
short children with CKD stage 3-5D and after KTx
- **I**ntervention being considered: **GH treatment**
- **C**omparison (which may be “no action” or an alternative intervention): **no GH treatment**
- **O**utcomes affected by the intervention:
increase in standardized height

12 Steps in guideline development

5. Systematic literature review (RCTs, non-controlled / observational studies)
 - Prepare evidence tables
 - Check for risk of bias for an outcome in individual studies
 - Check for quality of evidence for each outcome across studies
 - Inclusion of an epidemiologist may be helpful
6. Plan a one day face to face meeting (basic financial support of the WGs from ESPN (2,000€ per year) may be used to finance travel costs)
 - Half day meeting may be fine for consensus papers

Before the meeting: subgroups are requested to prepare a preliminary answer & evidence text for each PICO question

This should be as concise and brief as possible (<1 page)
7. At the meeting:
 - Formulate recommendations & evidence text
 - During this process new (sub)questions may arise
 - Grade recommendations (AAP system)

12 Steps in guideline development

9. Editing of draft by core group (within 3 months)
10. Draft sent out to external experts & voting group (4 week deadline)
 - Delphi process for grading and changes
11. Consider to endorse the guideline by ERNs or Societies before submission
12. Publication 😊
13. The ESPN council will give an incentive of 2,000 € for each published guideline to the WG if the guideline was mainly developed by an ESPN WG

Thereafter: Distribution & Implementation