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**SPECIAL REPORT**

Lexicon for guidance terminology in pediatric hematology/oncology: A White Paper

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Abstract

Terms used to label types of clinical recommendations and guidance are applied inconsistently and do not reflect the methods used to create each type. Here, the international Pediatric Oncology Supportive Care Guideline Network proposes a lexicon for types of recommendations and guidance documents. A lexicon describing three types of recommendations (clinical practice guideline-derived, good practice statement, and expert opinion statement) and two types of guidance documents (clinical practice guideline and expert opinion) is presented. Consistent use of this lexicon will allow pediatric oncology clinicians to readily appreciate the methods used to create clinical guidance.

KEYWORDS

clinical practice guideline, guidance, recommendation

1 | INTRODUCTION

A lexicon is defined as the vocabulary of a branch of knowledge.¹ Ideally, the lexicon used by a community of knowledge users is clearly understood by all members and supports knowledge advancement, uptake, and utilization. In contrast to the ideal scenario in which consistent language is used to describe similar products, the language used to describe the types of guidance offered to clinicians providing care to children with cancer varies considerably. Articles that provide

guidance typically incorporate one or more statements (or recommendations) within a single document (or guidance type). Today's guidance vernacular does not facilitate ready appreciation of the relative rigor of development of recommendation and guidance types.

The purpose of this paper is to frame a lexicon for types of recommendations and guidance documents to support clinical decision-making by the pediatric oncology community. This work was undertaken by the international Pediatric Oncology Supportive Care Guideline (iPOG) Network (<http://www.sickkids.ca/research/ipog/>), an international collaboration that aims to optimize the quality of life of all children receiving cancer treatment and undergoing bone marrow transplant by accelerating the development and incorporation of evidence into international standards of supportive care.

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; IOM, Institute of Medicine; iPOG Network, international Pediatric Oncology Supportive Care Guideline Network; NGC, National Guideline Clearinghouse.

2 | METHODS

2.1 | Environmental scan

A two-part approach was undertaken to identify terms used to describe types of recommendations and types of guidance documents and to understand the extent of variability in these terms. First, the findings of a previously published systematic review that aimed to identify current supportive care clinical practice guidelines relevant to the work of the Children's Oncology Group were utilized.² In brief, this systematic review was performed to identify English-language articles indexed between January 2012 and January 2018 that addressed a supportive care topic, were identified as a guideline by the authors of the paper, were based on a systematic review, and conformed to the Institute of Medicine³ (IOM) and National Guideline Clearinghouse⁴ (NGC) definitions of a clinical practice guideline. For the purpose of this environmental scan, the titles of the 133 articles that were excluded from the previously published systematic review were reviewed by one author (PDR) to abstract the terms used to categorize the nature of the guidance they provided. Second, websites of guideline methodology groups, large guideline development groups, particularly those focused on cancer, and key peer-review journals were searched to identify examples of the guidance terminology used.

2.2 | Consensus meeting

Seven members of the iPOG Network attended a one-and-a-half-day, face-to-face meeting in Toronto, Canada, in March 2019. An eighth member attended via video-conference. iPOG Network members who were leaders in clinical practice guideline development or methodology were specifically invited and funded to attend the face-to-face/virtual consensus meeting to develop the White Paper. Other members were also welcome to attend.

At this meeting, the results of the environmental scan were discussed. The definition and description of a clinical practice guideline³ and a good practice statement⁵ were reviewed and used as the basis of subsequent discussions. The guidance lexicon framework and the definitions of items included in the lexicon were developed by consensus and approved upon unanimous agreement of those present.

The draft lexicon framework was then circulated to all iPOG Network members (Supporting Information Table S1) and discussed at a teleconference. Revisions to the framework were made only after discussion and unanimous agreement.

3 | RESULTS

3.1 | Environmental scan

Across the 133 articles identified (Supporting Information S1), 43 different terms were used to describe the nature of the document (Table 1). The term "guideline," alone or in combination with other descriptors, was the most frequently used term (70/133; 53%). The second most commonly used term was "recommendation" alone or in

combination with other descriptors (28/133; 21%). The term "consensus" was also common (16/133; 12%).

Three general recommendation types were identified as being used by guidance developers and journals (Table 2): "clinical practice guideline-derived recommendations," "good practice statements," and "non-clinical practice guideline-derived (often termed consensus) recommendations." These recommendation types were included in four general types of documents to describe guidance documents: "Clinical practice guidelines," "Provisional clinical opinions," "Consensus statements," and "How I approach" (Table 2).

3.2 | Guidance lexicon development

The iPOG Network accepted the terms "clinical practice guideline" as defined by the IOM and NGC and "good practice statement" as conceived by the Grading of Recommendations Assessment, Development and Evaluation (GRADE) working group. These terms helped to frame the basis for distinguishing other forms of recommendation and guidance types in the proposed guidance lexicon (Tables 3 and 4).

"Clinical practice guideline-derived recommendations" flow directly from a systematic literature review and the link between them and the evidence is structured and explicit.⁶ "Good practice statements" arise where an attempt to obtain direct evidence would be considered preposterous and when there is an overwhelming and unanimous conclusion; for example, that patients with sepsis syndrome should be closely observed. They should not be "graded" in strength.⁷ An "expert opinion statement" is made when an indication of how to practice is desired on a topic where there is no evidence or on a topic for which no specific evidence summary was undertaken. Ideally, the creation of an "expert opinion statement" would be preceded by a systematic literature review that identifies no pertinent direct or indirect evidence to inform a clinical practice guideline. Unlike "good practice statements," "expert opinion statements" must be testable in the future. The rationale for the decision to develop an "expert opinion statement" must be stated, and the process used to develop it must be described. Because the guidance provided in this recommendation type is not supported by peer-reviewed evidence, the verb "suggest" or "recommend" should be avoided and "believe" or "feel" should be used instead.

Ordinarily, a "clinical practice guideline" should contain only "clinical practice guideline-derived recommendations" and, sparingly, "good practice statements." Inclusion of "expert opinion statements" in a "clinical practice guideline" would be unusual but possible. When a "clinical practice guideline" includes more than one recommendation type, each must be presented so that their distinction is obvious to readers. Similarly, an "expert opinion" document should include "expert opinion statements."

4 | DISCUSSION

We have found that many different terms are used to describe supportive care recommendations and guidance types. The variety of

TABLE 1 Terms used in titles of 133 pediatric oncology papers identified as providing recommendations that do not meet the definition of a clinical practice guideline as per the National Guideline Clearinghouse

Term used	Number of papers
Algorithm—Evidence-based	1
Clinical optimization	1
Clinical practice implications	1
Consensus agreement	1
Consensus report	2
Consensus statement	2
Considerations	1
Expert meeting—Indications	1
Expert meeting—Report	1
Guidance	2
Guideline and all subgroups	70
Guideline	40
Guideline—Clinical	4
Guideline—Clinical Practice	11
Guideline—Consensus	6
Guideline—Consensus report	1
Guideline—Consensus review	1
Guideline—Evidence-based clinical	1
Guideline—Evidence-based clinical practice	1
Guideline—Policy and practice	1
Guideline—Practical	1
Guideline—Practice	3
Management	1
Official position	1
Position paper	3
Practical approaches—Consensus	1
Principles of care	1
Recommendations and all subgroups	29
Recommendations	12
Recommendations—A systematic evidence-based practice review	1
Recommendations—Best practice	1
Recommendations—Clinical	2
Recommendations—Clinical practice	2
Recommendations—Consensus expert	1
Recommendations—Evidence-based	1
Recommendations—Evidence-based practice	3
Recommendations—From a consensus process	1
Recommendations—From a systematic literature review	1
Recommendations—From an expert meeting	1
Recommendations—From an expert panel	1
Recommendations—Practical	1
Recommendations—Practice	1

(Continues)

TABLE 1 (Continued)

Term used	Number of papers
Safe practices	1
Safety standard	1
Standard of care	7
None	5

these terms and the overuse of the terms “guideline” and “evidence” likely contribute to the uncertainty regarding the relative robustness and validity of guidance forms. Further, the common use of the term “consensus” to draw distinction between types of guidance is not helpful because building consensus is important to the development of both clinical practice guidelines and expert opinions.⁸ To improve clarity, we propose that guidance developers utilize the lexicon presented in Tables 3 and 4. Clear messaging will enhance the ability of clinicians to gauge the potential clinical utility of guidance.

Like GRADE, the iPOG Network appreciates that clinicians need guidance in the absence of peer-reviewed, published evidence. We also appreciate that the experience of experts may make useful contributions to the evidence base that informs guidance. Schönemann et al. have recently described a structure for incorporating expert experience into clinical practice guideline development while avoiding the incorporation of expert opinion.⁹ This structure involves the systematic gathering of expert experience and providing a summary of this experience to clinical practice guideline panels prior to panel deliberations.

“Expert opinion statements” fill the gap where insufficient evidence exists to inform a “clinical practice guideline” and yet clinicians must act. The decision to develop an “expert opinion statement” is often motivated by clinician discomfort with the *status quo*, the expected benefit of care standardization and available resources. One recent example was the need to control the pain experienced by many children receiving dinutuximab.¹⁰ “Expert opinion statements” cannot be perceived to be substitutes for “clinical practice guideline-derived recommendations.” Nevertheless, an “expert opinion statement” may serve as a pragmatic placeholder until studies are conducted. Indeed, evaluation of the outcomes of care provided according to an “expert opinion statement” may be included in the evidence base that informs a future “clinical practice guideline.”

All guidance should be clear and transparent with respect to the development process, values brought to bear on decision-making and potential bias. The AGREE-II instrument is a highly regarded method for systematically assessing the clarity and methodological rigor of clinical practice guideline development.¹¹ Expert Opinion Statements and Expert Opinions are inherently at high risk of bias and are less likely to be transparent and reproducible. We encourage authors of these forms of guidance to acknowledge this risk and to report their methods transparently. We also encourage readers of all guidance types, clinical practice guidelines, and expert opinion statements to critically evaluate the advice offered.

TABLE 2 Examples of organizational definitions of general classes of guidance documents and recommendation types identified in the environmental scan

Term	Organization	Description
Types of guidance document		
Clinical practice guideline (CPG)	Institute of Medicine ³	CPGs are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.
Provisional clinical opinion (PCO)	American Society of Clinical Oncology ¹² (ASCO)	The PCO is intended to offer timely clinical direction to the ASCO membership following the publication or presentation of potentially practice-changing data from major studies. The PCO may serve in some cases as interim direction to the membership pending the development or updating of an ASCO CPG.
Consensus statement (CS)	American Diabetes Association	A CS is a comprehensive analysis by a panel of experts of a medical issue. A CS is developed immediately after a consensus conference at which presentations are made on the issue under review. The statement represents the panel's collective analysis, evaluation, and opinion based, in part, on the conference proceedings. The need for a CS arises when clinicians desire guidance on a subject for which there is a relative deficiency of comprehensive evidence that might otherwise allow for a more definitive statement to be made.
How I approach	Pediatric Blood and Cancer ¹³ (PBC)	PBC publishes these articles, written by authorities in the field, which address approaches to diagnosis or treatment of pediatric blood disorders or cancers that lack sufficient high-quality data for a clinical practice guideline and do not have available consensus statements. The articles should incorporate the latest scientific and clinical basis for clinically relevant recommendations by an experienced and respected expert on the disease process, with one or two coauthors if necessary.
Type of recommendation		
CPG-derived recommendations	GRADE ¹⁴	Recommendations developed by a multidisciplinary panel of clinical experts and methodologists that are informed by a systematic review of the evidence. GRADE recommendations explicitly consider: <ul style="list-style-type: none"> • Balance between desirable and undesirable outcomes • Quality of evidence • Patient values and preferences • Resource use
Good practice statements	GRADE ⁵	Represent situations in which a large and compelling body of indirect evidence, made up of linked evidence including several indirect comparisons, strongly supports the net benefit of the recommended action. One strategy for recognizing a good practice statement is to ask: is the unstated alternative absurd or clearly not conforming to ethical norms?
Non-CPG-derived recommendations	ASCO National Institute for Health and Care Excellence (NICE)	If no or insufficient evidence is identified in a systematic review, ASCO and NICE develop consensus recommendations.

TABLE 3 Lexicon of recommendation types and their characteristics with examples

Recommendation type	Characteristics	Example
Clinical practice guideline-derived recommendation	<ul style="list-style-type: none"> • Meets the definition of the Institute of Medicine (see Table 2) • Based on a systematic literature review • Wording for strong recommendations: "We recommend..." or "Clinicians should..." • Wording for weak recommendations: "We suggest..." or "Clinicians might..." 	We recommend drug A be given for condition X. (strong recommendation) We suggest drug B be given for condition Y. (weak recommendation)
Good practice statement	<ul style="list-style-type: none"> • Meets the definition of GRADE (see Table 2) • To provide care other than as stated is considered preposterous or unethical. 	Patients with sepsis syndrome should be closely observed.
Expert opinion statement	<ul style="list-style-type: none"> • Does not meet the definition of a clinical practice guideline-derived recommendation or good practice statement • Reflects the consensus opinion of a panel of experts or the opinion of a single expert • Uses verb "feel" or "believe" 	We/I believe that drug A should be given for condition X.

TABLE 4 Lexicon of guidance document types and their characteristics

Guidance document type	Characteristics
Clinical practice guideline	<ul style="list-style-type: none"> Meets the Institute of Medicine's definition of a clinical practice guideline Includes clinical practice guideline-derived recommendations and good practice statements Rarely may include expert opinion statements
Expert opinion	<ul style="list-style-type: none"> Does not meet the definition of a clinical practice guideline Includes expert opinion statements

In conclusion, with the aim to communicate the nature of available forms of guidance more easily to knowledge users, the iPOG Network offers a lexicon for guidance. We expect and hope that, as our community becomes more familiar with the distinctions between guidance forms, the lexicon we have proposed will be refined and improved. We encourage pediatric oncology guidance developers to consider not only the terms we propose but also the characteristics of each when developing recommendations. iPOG Network members will use the proposed lexicon in the development of future supportive care clinical practice guidelines. We are hopeful that others will recognize the critical contribution of clear communication of guidance to informed clinical decision-making and will join the iPOG Network in adopting the proposed lexicon.

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CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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