Abstract

In this issue, Farias and colleagues describe how to develop a clinical care pathway by using a structured, continuous learning process embedded within the day-to-day delivery of care. Their method is called Standardized Clinical Assessment and Management Plans (SCAMPs). A care pathway, such as a SCAMP, includes multiple decision points and related recommendations. The SCAMP process can test the validity of each decision point if clinicians document patient data and record their reasoning when they deviate from the recommended action at a decision point. The unique feature of SCAMPs is that they encourage dissent, unlike clinical practice guidelines (CPGs), algorithms, and bundled electronic health record protocols, which are designed to be followed. If a clinician deviates from the recommended action at a decision point, an explanation is required. This feedback, which should explain why a patient does not precisely “fit” the logic of the care pathway, may lead the SCAMP developers to modify the decision point.

The authors of this Commentary argue that SCAMPs and CPGs, two approaches to developing clinical standards of care, are fundamentally equivalent. The key link between them is the recently described process of deconstructing a CPG into the many steps that are necessary to consistently apply it to clinical practice. The SCAMP process puts these steps to the test of daily practice.

The Commentary ends with a list of foundational principles for developing standards of clinical care. These principles should apply to care pathways, algorithms, practice guidelines, or SCAMPs.

Editor’s Note: This is a Commentary on Farias M, Friedman KG, Lock JE, Rathod RH. Gathering and learning from relevant clinical data: A new framework. Acad Med. XXXX;XX:XXX-XXX.

In this issue, Farias and colleagues describe improving clinical practices through a structured, continuous learning process embedded within the day-to-day delivery of care. This concept was first described almost a decade ago, and Farias and colleagues describe one way to operationalize it. The method extends work done 40 years ago on clinical algorithms for physician assistants in ambulatory practice, and later in empirical algorithms for common ambulatory care problems.

In the article by Farias and colleagues, the clinical setting is the pediatric cardiology clinic of a large urban hospital for children. They call their approach Standardized Clinical Assessment and Management Plans (SCAMPs). The authors define a SCAMP as “a care pathway designed around existing practice methods.” In their article, the authors emphasize the differences between SCAMPs and clinical practice guidelines (CPGs). We describe fundamental similarities between the two and examine how CPGs can be used to facilitate SCAMPs.

How Do SCAMPs Differ From CPGs?

Farias and colleagues describe the eight-step process that they, a group of pediatric cardiologists, used for developing a SCAMP. The first step, a literature review, parallels what CPG groups do, but the processes diverge thereafter, with empirical testing being a cardinal feature of the SCAMP development process but not of the CPG process. A care pathway, such as a SCAMP, includes multiple decision points leading to management recommendations. Some decision points are based on high-quality evidence, and others rely on consensus opinions. The logic of the care pathway may be represented by a clinical algorithm flow sheet.

The SCAMP process is a structured approach to testing the validity of the decision points in a care pathway. A data collection form displays the clinical data corresponding to the decision points. Clinicians record a patient’s data and their decisions. When a clinician disagrees with a specific action recommended by the care pathway, the clinician records his or her reasons for disagreeing. The data forms are collected and analyzed, with particular attention to deviations from the pathway and the accompanying rationale. This approach efficiently embeds the protocol for data collection and the testing of specific decision points into the routines of day-to-day care.

The SCAMP process is important because it seeks to learn from thoughtfully deliberated, well-documented decisions that deviate from care protocols. In contrast, other embedded protocols (algorithms, bundled computerized decision support, CPGs) are designed to be followed. With them, success is defined by less practice variation. In fact, learning...
from experience requires variation. If physicians are discouraged from taking alternative actions at decision points, how can developers fine-tune a care pathway to take account of circumstances that they did not anticipate? The leaders in the SCAMP network are taking the best evidence and expert opinion, developing an algorithm to embed this knowledge into their daily practice, looking at patient data, and deciding what works and what needs fixing. The SCAMP process can, therefore, be a practice-based test of the validity of current evidence and opinion.

The SCAMP process, therefore, contains an important conceptual advance: It encourages dissent. In so doing, it offers a way to accelerate the pace of improving health care.2,3 The SCAMP approach stands in contrast to the bundled computerized decision support systems that health systems currently use to reduce practice variation. Likewise, CPGs are designed to reduce practice variation. The SCAMP approach encourages practice variation in order to learn from it.

**Benefits and Challenges of Large-Scale Research Networks**

The network of pediatric cardiology clinics that participated in testing the SCAMPS illustrates an important trend in the study of clinical care: the use of large practice networks to extract clinical knowledge from daily practice. Although this approach is necessary for studying rare conditions, it is equally important for delving into the management of common conditions. As clinical questions become increasingly specific, the proportion of patients to which they pertain decreases, which means that a large-source population is required to meet the sample size requirements to study the affected subgroup. The best solution to this problem is multiple collaborating clinics.

Health care systems and networks of health care systems are ideally situated to accelerate this form of rapid learning. When individual practices or health care systems share an electronic health record and data infrastructure, clinical research on a very large scale becomes possible.

Of course, research involving networks of health care systems poses additional problems because health care systems typically do not use the same electronic health record. Even when several systems use the same electronic health record, they implement it differently. These methodological problems are now being addressed. For example, the HMO (health maintenance organization) Research Network includes 19 health system research centers.10 To analyze and interpret data across multiple data networks, individual research centers must map individual variables to a common standard definition and the data describing each variable to a common format.

To accelerate large-scale comparative effectiveness research, the Patient-Centered Outcomes Research Institute recently invested $93.5 million to support 29 national data networks (PCORnet).

**Remaining Questions About SCAMPS**

Farias and colleagues invite criticism on two points. The first is methodological. The last steps in the SCAMP process—analysis, learning, and iterative improvement—require traditional epidemiological and statistical methods. This article1 and another by the same authors11 do not adequately describe the statistical methods for these steps. The eight-step SCAMPS process is clear enough, but the authors will disappoint readers who want to replicate the SCAMP system. The authors do not address such critical questions as the inferential methods used to modify an algorithm based on the data collected by the pediatric cardiology network. The methods could rely on traditional research designs (e.g., randomized trials or quasi-experimental designs to measure the outcomes of using alternate forms of a decision point) or on the statistical features of quality improvement endeavors. Traditional study designs are being adapted for research in health systems12 and across multiple collaborating clinics (e.g., cluster randomized trials).13 If the SCAMP process becomes widely embedded in clinical practice, health care stakeholders will insist on knowing how the protocol developers used the clinical data from patients to shape a care pathway.

The second criticism is more fundamental. At first reading, the authors’ characterization of CPGs as static and “not knowledge building” seemed fair, but on further reflection, we feel it understates the critical role of CPGs in clinical research and discovery. The relationship between care pathways and CPGs is much closer than the authors imply—the two are at least complementary and perhaps even congruent. In the rest of this Commentary, we develop this idea into a unified approach to using evidence to formulate testable clinical standards of care.

**The Power of CPGs**

CPG programs began to appear in the mid-1980s, about 15 years after clinical algorithms were first used, and since then guidelines have flourished. CPGs, initially simply standards for clinical practice, have become a foundation for making insurance coverage decisions and developing practice-based quality measures. The best CPGs follow a rigorous methodology, are based on well-characterized evidence, transparently link the evidence to the recommendations, and use formal methods to rate the strength and quality of evidence for each recommendation. Methodological standards for “trustworthy” CPGs are the subject of an influential Institute of Medicine report14 and the AGREE standards.15 CPGs are now required to meet standards of trustworthiness before being accepted for posting on the U.S. Agency for Healthcare Research and Quality’s National Guidelines Clearinghouse. At its best, CPG production is a highly refined process.

Because guideline developers have carefully evaluated the evidence, researchers can use CPGs to identify critical evidence gaps. A recommendation rated as “insufficient evidence” should be a flag to researchers looking for good research topics. Moderate- to low-grade evidence is another flag. Recommendations based solely on consensus expose areas where the evidence needs strengthening. In their assessment of the evidence, guideline panels may note that a subgroup of randomized controlled trial participants responds especially well to a treatment (treatment response heterogeneity). Confirming this subgroup result would be another opportunity for research. In these ways, CPGs can influence the direction of clinical research.

CPGs are the end-product of a “knowledge building” process based largely on a systematic review of the literature, which aggregates knowledge into a body of evidence. A systematic
review uses a highly structured process to gather, summarize, and interpret evidence on the knowledge in a specific clinical domain. Because this process has become standardized, systematic reviews of the same topic should identify the same list of studies. Systematic reviews organize sporadic and disparate sources of evidence into knowledge.

**A Recipe for Improved Clinical Guidelines**

CPGs do complement SCAMPs. As noted earlier, the first step in developing a CPG—establishing the evidentiary foundation for sound clinical practice—parallels the first step in developing a CPG. SCAMP authors should use systematic reviews as the starting point for developing the evidence base for specific decision points in a care protocol. Likewise, SCAMP authors must explain the rationale for each decision point, whether it is evidence based or the consensus of clinical judgment.

Algorithms and care pathways describe a care process that has multiple decision points. A CPG focuses on a single decision point (e.g., the choice between screening tests for colon cancer). This difference seems fundamental, but it is illusory. A recommendation to screen for colon cancer may appear straightforward, but it implies a complex process of care that leads to successful execution of the screening recommendation. The process includes risk assessment, engaging the patient, timely scheduling of a screening test, and, eventually, interpretation of test results and communicating next steps to the patient. Deconstructing a CPG into its component processes of care is a relatively new development. The result can look like a SCAMP.

Tools are available to deconstruct a CPG into a set of decision points. Specific clinical decisions. For example, the Institute for Clinical Systems Improvement guidelines for management of low back pain can be expressed by 17 imperative and 50 conditional rules. Recommendations in the section "Home Self-Care Treatment Program" can be expressed by 4 conditional rules (e.g., "When a patient has not been previously evaluated, attempt to differentiate between untreated acute pain and ongoing chronic pain") and 3 mandatory rules. These 7 rules are further defined by 1 to 13 decision variables that describe the data needed, from either an existing source or directly from the patient or provider, to execute the rule. GEM Cutter is a software tool that translates guideline text to rules, variables, and grading of the evidence. These methods can take a single guideline (e.g., "screen 50- to 80-year-olds for colorectal cancer") and translate it into something that looks like a care pathway, algorithm, or SCAMP.

Think of a CPG recommendation as an item on a restaurant menu. A SCAMP or care pathway is the corresponding recipe. The special contribution of the SCAMP process is to foster thoughtful, documented, and testable deviations from the recipe and whether they improved the finished product.

**Foundational Principles for Developing Standards of Clinical Care**

Clinical algorithms (e.g., care pathways or SCAMPs) have been used for nearly a half century to describe the logic of clinical practice. Early algorithm systems anticipated the development of SCAMPs. They had three components: an algorithm for evaluating a clinical complaint, a problem-focused checklist of findings corresponding to the decision points in the algorithm, and a computer program to check adherence to the logic of the algorithm. The checklist became the clinical record of the patient care visit. Subsequently, algorithms have become widely used to display the logic of diagnosis and management, but they have not been taken seriously as a clinical practice standard. Now, as clinical algorithms are becoming embedded in EMRs, they will become a standard of practice. The SCAMP process is a way to generate practice-based evidence with which to fine-tune the process of care.

This discussion teaches us that a process for enabling rapid learning from clinical practice should include several key features: (1) a systematic review of the pertinent evidence; (2) recommendations for action that specify the necessary steps to assure consistent execution; (3) representation of the standard of practice in a form—such as an algorithm flow chart—that facilitates testing of each decision point; (4) using the clinical standard in daily practice while documenting patient data at each decision point; (5) encouraging clinicians to comment or take alternate actions but insisting on explanations; and (6) rigorous analysis of the data to advance and refine the care process.

Care pathways, algorithms, and CPGs are clinical standards that look different but are similar in every fundamental way, starting with their underlying structure, which consists of decision points linked to represent the logic and flow of clinical practice. Some decision points are buttressed by strong evidence. Most decision points—and their links to other decision points—are based on the consensus of experts. The SCAMPs process is an example of a rapid health care learning method for validating these theories of clinical practice and, uniquely to SCAMPs, discovering new theories.

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**References**

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