Clinical Practice Guidelines: Closing the Gap Between Theory and Practice

A White Paper by Joint Commission International
Foreword

Health care providers throughout the world share a common goal—safe, high-quality care for every patient, every time. Implementing proven, consistent processes is central to the effort toward achieving this goal. Clinical practice guidelines (CPGs) are part of the foundation for these processes and have contributed to the continuous improvements in safety and patient care seen across the globe.

We have a way to go however. To reach the maximum potential, CPGs must be both well developed and effectively introduced into clinical practice. The core focus at Joint Commission International (JCI) is patient safety and quality, and our standards require that CPGs are used in all accreditation programs. With this requirement, we see growing evidence of improved patient safety and quality care throughout our accredited organizations.

This white paper describes the role and value of CPGs, examining ways to help ensure the successful adoption in a health care organization. It provides a definition of clinical pathways and guidelines and covers the importance of accessing credible, evidence-based data when selecting and implementing practice guidelines.

JCI hopes you find this white paper helpful and informative. We share your commitment to protecting your patients, your staff, and your organization.

Paula Wilson
President/CEO, Joint Commission International
BACKGROUND

The Value of Clinical Practice Guidelines

Clinical practice guidelines (CPGs) are one of the major tools used to improve the value (quality and cost) of health care. CPGs are central to the practice of evidence-based medicine (part of the foundation of high-value care delivery), transforming solid evidence into impactful patient care. CPGs also support quality metrics, including performance measures, which are used for care accountability. A recent study estimated that if clinicians in the United States followed six heart failure guideline recommendations, nearly 68,000 deaths a year could be prevented.¹

In addition, a recent report from the United States’ Agency for Healthcare Research and Quality (AHRQ) states that the chances of a patient receiving safer care when entering a hospital are increasing.² For example, between 2010 and 2014, an estimated 87,000 fewer patients died from hospital-acquired conditions (HACs). The final report concludes that the overall incidence of health care-acquired conditions (HACs) has been reduced by 2.1 million. Not only does this represent a major improvement in patient safety, such a reduction resulted in an estimated savings of $19.8 billion U.S. dollars. This hard-won progress is the result of concerted national attention by everyone from front-line staff to nurses to physicians and hospital administrators. But according to AHRQ, the hard work of reducing and sustaining declines in HACs requires additional, ongoing involvement of the public and private sector, including the provision of Medicare payment incentives, widespread use of hospital-based electronic health records, provider and patient education and outreach, and evidence-based tools through which to implement best practices.

Much of the literature on clinical guidelines comes from the field of medicine. There are reviews of clinical guidelines in nursing, including analyses of the effectiveness of such guidelines in changing the behavior of nurses, midwives, and other non-physician health professionals. Examples of clinical areas for which guidelines have been evaluated include urinary catheter care, hypertension, pressure ulcers, dietary counseling, and suicide risk awareness. The evidence demonstrates that guideline-based care can positively affect nursing practice and patient outcomes.

It is clear that integration and coordination of care by all care disciplines play an essential role in achieving success. Joint Commission International (JCI) standards require that

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<td>Systematically developed statements to assist with practitioner and patient decisions for specific clinical circumstances</td>
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<td><strong>Clinical pathways</strong></td>
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<td>Multidisciplinary management tools based on evidence-based practice for a specific group of patients with a predictable clinical course</td>
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<td><strong>Clinical protocols</strong></td>
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<td>Plans for carrying out a patient's treatment regimen founded on evidence-based strategies and consensus statements by peers in the field</td>
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<td><strong>Clinical bundle</strong></td>
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<td>Structured way of improving the processes of care and patient outcomes; a small, straightforward set of evidence-based practice</td>
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the patient care team work collaboratively to achieve and maintain quality outcomes and patient safety to support this overall effort.

The Gap between Theory and Practice

While the potential of CPGs to support implementation of evidence has been demonstrated, they are not currently achieving anything close to their maximum potential. CPGs are sometimes poorly developed, and many are ineffectively implemented. To improve clinical practice and health outcomes, CPGs must be both well developed and effectively introduced into clinical practice.

Guideline development processes vary substantially, and many guidelines do not meet basic evidence-based quality criteria. Uniform standards for guideline development can help organizations ensure that recommendations are evidence-based and identify truly high-quality guidelines for users.

CPGs serve as a reference point for clinical decision making and performance improvement. Yet tough questions about guidelines persist:

- Is there enough evidence for recommendations?
- How prescriptive should they be?
- How should we apply recommendations to individual patients?
- And, given their wide availability over many years, why does health care remain troubled by gaps in guideline-focused care, variations in quality, and unsustainable costs?

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**Figure 1.** Example of how scientific evidence/information can be used as a process in the future and to assist others in adapting evidence-based guidelines.
What are Clinical Practice Guidelines?
JCI standards use the terms together for clarification: Standard GLD.11.2 states, “Department/service leaders select and implement clinical practice guidelines, and related clinical pathways, and/or clinical protocols, to guide clinical care.” JCI has accreditation standards for hospitals, ambulatory care, clinical care programs, clinical laboratories, home care, long term care, medical transport, and primary care. In all these programs, the standards require the use of clinical practice guidelines, pathways, or protocols, and they must be evidence-based or assessed for their scientific evidence and endorsed by an authoritative source. JCI, the author of this paper, also relies on evidence-based practice (EBP) as the basis for its standards to accredit health care organizations.

The focus of this paper is to support EBP to achieve the effectiveness of better patient outcomes and safe care. By “effective,” we mean delivering health care that adheres to an evidence-based practice topic and results in improved health outcomes for individuals and communities, based on need. By “safe,” we mean delivering health care which minimizes risks and harm to service users. The focus of this paper is not on an individual term.

EVIDENCE-BASED PRACTICE

Definition of Evidence-Based Practice
Evidence-based medicine (EBM) is the standard of clinical practice taught to all new clinicians and is increasingly used to measure quality of care. However, inability to quickly access the latest evidence, along with ambiguity and contradiction from many “credible” sources, make the application of EBM to decision-making challenging. Decision-making in health care has evolved from opinion-based decisions (guided solely by experience and learning, the practitioner selects the approach to patient care) to care decisions based on sound scientific evidence (EBM), Clinical Decision Support Systems (CDSS) that combine an evidence-based database with a smart search engine tool can allow clinicians to more rapidly survey the evidence and determine how to apply the information to their patient.

Multiple models of EBP are available and have been used in a variety of clinical settings. Common elements of these models include the following:

- Selection of a practice topic;
- Critique and syntheses of evidence;
- Implementation;
- Evaluation of the impact on patient care and provider performance; and
- Consideration of the setting in which the practice is implemented.

The translation of research into clinical practice provides valuable information to further improve the process in the future and to assist others in adapting the evidence-based guideline and/or implementation strategies.

A recent conceptual framework for maximizing and accelerating the transfer of research results in clinical practice comes from the Patient Safety Research Coordinating Committee of the AHRQ. This model is a synthesis of concepts from scientific information on knowledge transfer, social marketing, social and organizational innovation, and behavior change.

Evidence-Based CPGs
Evidence-based CPGs follow a rigorous developmental process and are based on the highest-quality scientific evidence. Evidence-based CPGs can also be defined as documents that support clinical decision-making and contain systematically developed recommendations, processes, and timeframes for managing specific medical conditions or interventions, based on a search and review of available credible literature. CPGs have been implemented worldwide.

Guidelines typically consider different clinical questions including the following:

- The risk factors for conditions;
- The diagnostic criteria for conditions;
- The prognostic factors with and without treatment;
- The benefits and harms of different treatment options;
- The resources associated with different diagnostic or treatment options; and
- Patients’ experiences with health care interventions.

Evidence-based CPGs to support EBP are available for a number of clinical conditions. However, these guidelines are not always implemented in care delivery, and variation in practices abound. Traditionally, patient safety research has focused on data analyses to identify patient safety issues and to demonstrate that a new practice will lead to improved quality and patient safety. Much less research attention has been paid to how to implement practices. Only by putting
into practice what is learned from research will care be safer. Implementing evidence-based safety practices is difficult and requires strategies that address the complexity of systems of care, individual practitioners, senior leadership, and—ultimately—changing health care cultures to evidence-based safety practice environments.

At its best, EBP is the conscientious and judicious use of current best evidence in conjunction with clinical expertise and patient values to guide health care decisions. When enough is available, research evidence should guide practice, in conjunction with clinical expertise and patient values. In some cases, however, a sufficient research base may not be available, and health care decision-making is derived principally from non-research evidence sources, such as expert opinion and scientific principles. As more research is done in a specific area, the research evidence must be incorporated into the EBP.

IMPLEMENTATION CHALLENGES

Factors Contributing to the Challenges of Implementing CPGs
Translating CPGs into practice is complex and arduous. Changing practice takes considerable effort at both the individual and organizational level to successfully apply evidence-based information and products in a particular clinical context.

Challenges on a Global Level
A major challenge to implementing CPGs falls at an organizational level. Many groups charged with guideline development have voiced that such lengthy standards lists, while aspirational, are not feasible to follow in their entirety. In recent years, many countries have gained experience in developing, appraising, and implementing CPGs at professional, institutional, regional, and national levels, recognizing that guidelines are key to improving quality and appropriateness of health services. Organizations such as the United States’ Institute of Medicine and the United Kingdom’s National Institute for Health and Clinical Excellence have developed standards for defining trustworthy guidelines within their locales.

A number of national agencies, institutions, experts, and health care providers specializing in the guideline field across the globe are also involved in supra-national networks. In Europe, such activities have resulted in a Recommendation of the Council of Europe on Guidelines Methodology and in a generic methodology for guideline appraisal (AGREE Instrument). The United States established the U.S. National Guideline Clearinghouse. In Australia and New Zealand, as well as in Asia and Africa, activities aiming at the use of quality CPGs have been funded.

Despite these initiatives around the world, there has been no established forum for those involved in such development, appraisal, and implementation of CPGs to communicate with one another. Consequently, financial and human resources and time have been wasted as different countries duplicate efforts to develop similar strategies aimed at achieving similar goals.

Challenges on a Local Level
Medical literature has identified the most important factors that could limit a physician’s failure to adhere to CPGs. Included are educational programs and compliance incentives, which may be perceived by practitioners as barriers to CPG implementation; and routine use. However, other studies note that for guideline recommendations to have a real influence on patient outcomes, CPGs must have an impact on a physician’s knowledge, attitude, and practice behavior. Although behavior can change even without significant changes in knowledge and attitude, behavioral changes influenced by new knowledge and attitudes are more permanent compared with indirect manipulation of the behavior alone.

In summary, knowledge modification can be impeded by the following factors:

1. Lack of awareness about guidelines availability. Physicians must be made aware of available guidelines in order to apply them properly and critically in clinical practice. Furthermore, CPGs are often presented as lengthy narratives rather than as actionable, synoptic content, thus making it challenging for physicians to rapidly determine the critical steps that lead to the desired outcomes.

2. Lack of familiarity with guidelines. Although physicians know recommendations for particular diseases exist, this does not guarantee ready familiarity with the CPG information at the time and location of care delivery.

Attitude modification can be influenced by the following factors:
1. **Lack of agreement about guidelines.** Physicians may not accept a particular guideline or even the basic concept of CPGs. Some fail to accept CPGs because they believe guidelines to be oversimplifications that are not clinically useful and/or created by specialists with insufficient credibility. Moreover, many physicians consider CPGs as inhibiting their professional autonomy and flexibility, as well as depersonalizing the physician-patient relationship.

2. **Lack of auto-effectiveness.** Physicians may not trust their ability to implement the CPGs because of burn-out, stress, or difficulties in updating due to time and resources available. Physicians may focus only on a single patient, therefore considering population-based CPGs of little help.

3. **Lack of success expectations.** If physicians are not convinced that CPGs will improve clinical outcomes, they are unlikely to follow them.

4. **Lack of motivation and consolidation of habits in clinical practice.** Without incentives (or disincentives), physicians may not implement CPGs, resorting to well-established habits in providing care.

Behavioral modification can be affected by a variety of factors. Knowledge pertinence, together with a positive attitude toward change and quality improvement, is necessary but not sufficient to guarantee CPG adherence. Physicians can deviate from CPGs due to external factors (including concerns with the guidelines themselves) as well as environmental challenges (organizational dysfunction, lack of resources, economic aspects) and specifics of the individual patient situation. Other factors include the following:

- Payment and cost issues are often the most cited obstacles to successful CPG implementation.
- Physicians may not follow CPGs if they think that they are founded in opinion, based on poor evidence, or do not consider patients’ values and preferences. Moreover, the sheer volume of CPGs means that most physicians do not have time to read and memorize the full details of all guidance documents.
- Legal issues and lack of local resources are also identified barriers to guidelines implementation.
- Organizational factors, such as physician and patient turnover or lack of coordination among the different hospital departments, also are common barriers to CPG adherence.

**IMPLEMENTATION STRATEGY**

**Steps Taken to Tackle Challenges on a Global Level**

A major stimulus in recent years to international cooperation in CPGs development has been the AGREE Collaboration, which was formed in 1998 to develop a common guideline appraisal instrument. Although the AGREE project was funded by the European Union, from the outset, it involved guideline developers and researchers from Canada and soon expanded to include the United States and New Zealand, along with fourteen European countries. The AGREE project highlighted the increasing harmonization of the methodologies used by guideline agencies and programs around the world, and the Collaboration itself provided a forum for guideline developers, researchers, and implementers to meet and share ideas.

After the initial AGREE project, in 2001, results of a survey conducted with 36 institutions in 18 countries were discussed during the International Guideline Conference of the German Agency for Quality in Medicine (ÄZQ) in June 2002, which formed the framework for a position paper presenting the background and objectives of a new organization. The Guidelines International Network (GIN) was subsequently founded in November 2002.

**Approach to Tackling Challenges on a Local Level**

Today, technology and clinical decision support solutions are readily available to help transform research into practice and recommendations. These solutions take clinically-approved best practice guidelines and match them with each patient to provide a recommended and customized care pathway for optimal outcomes. They can also be configured to meet the needs of each organization, taking into consideration local needs and practices.

One way to incent the use of CPGs is to consider the guidance from Joint Commission International (JCI) in its hospital standards, which require that department/service leaders select and implement CPGs and related clinical pathways and/or clinical protocols to guide clinical care (Standard GLD.11.2. *Joint Commission International Accreditation Standards for Hospitals*, 5th Edition). This standard requires that department/service leaders work together annually to determine at least five hospital-wide priority areas on which
to focus the use of CPGs. In addition, department/service leaders follow a specific process to select and implement CPGs, which include the following:

- Select CPGs from among those applicable to the services and patients of the hospital (mandatory national guidelines, if available, are included in this process);
- Evaluate CPGs for their relevance to identified patient populations;
- Adapt CPGs when needed to the technology, drugs, and other resources of the hospital or to accepted national professional norms;
- Assess CPGs for their scientific evidence and endorsement by an authoritative source;
- Formally have the hospital approve or adopt the selected CPGs;
- Implement selected CPGs and measure for consistent use and effectiveness;
- Support CPGs by training clinical staff to apply the guidelines or pathways; and
- Periodically update CPGs based on changes in the evidence and evaluation of processes and outcomes.

The department/service leaders must then implement CPGs and any associated clinical pathways or clinical protocols for each identified priority area as relevant to the department/service and demonstrate how the use of CPGs, clinical pathways, and/or clinical protocols has reduced variation in processes and outcomes.

Another way to ensure the success of CPG implementation in a hospital is to use the eight key “S” factors as part of an environmental scan prior to CPG implementation:

### Standardized Practice Leads to Improved PICU CLABSI Rates

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**Key**

CLABSI = central line associated blood stream infection
PICU = pediatric intensive care unit

**Figure 2.** How central line-associated blood stream infections can be reduced in a pediatric intensive care unit by using a standardized process.
Clinical Practice Guidelines: Closing the Gap Between Theory and Practice

1. Significance
2. Stakeholders
3. Systems and structure
4. Social factors
5. Skills, and support
6. Surveillance
7. Seminar, educational tool kits, enablers, and mentors
8. Sharing implementation stories

Also, care provided in accordance with CPGs has the potential to be not only clinically but also cost effective. Achieving quality and financial goals depends on many factors, specifically the following:
- Access to good-quality CPGs;
- Collection and synthesis of comprehensive, reliable, and valid information about patients and their preferences;
- Accurate diagnostic reasoning, including strategies that explicitly share decision-making between practitioners and patients;
- Clinical actions based on the guidelines;
- Evaluation of the efficacy and acceptability of the guidelines; and
- Mechanisms by which each of these activities feeds back into a research and development agenda.

Implementation Example
In discussions, a number of accredited U.S. and international hospitals identified this basic CPG implementation process, which has resulted in sustained improvements:
- Define the clinical problem.
- Assemble a multidisciplinary team.
- Identify, assess, and synthesize evidence.
- Produce a systematic review report.

Unfortunately, in some organizations, this is where the process ends. While this ultimately produces a well-designed and evidence-based CPGs report, it is usually many pages long, and most physicians do not have the time nor inclination to read and process all the information, let alone integrate that information into clinical practice. Successful implementation with better documented outcomes would more likely occur if the above implementation process steps were followed by additional activities performed by the multidisciplinary team (or through the addition of an implementation team):
1. Review the systematic review report, along with experts’ opinions and patient preferences and characteristics.
2. Achieve consensus with potential users.
3. Produce a CPGs medical record form, which focuses on the following criteria for establishing diagnosis in order to place a patient on the guideline:
   - Assessments and interventions
   - Medications and treatments
   - Consults
   - Mobility, nutrition, and so on
   - Patient and family education
4. Place the medical record form in the patient’s record (can be used as an order form).
5. Use the completed form when the patient is discharged as the data collection tool to evaluate the following:
   - Compliance to the guideline
   - Patient outcome based on guideline (if evident)

What We Have Learned
Clinicians must balance the risks and benefits of any guideline recommendation for an individual patient and consider that patient’s preferences. If the patient does not adhere to care recommendations, health benefits will not be maximized or perhaps even realized. Clinical decisions should be based on guideline recommendations, but all decisions must be individualized according to a patient’s risk-benefit ratio, incorporating patient preferences through shared decision-making. Clinician leadership in quality improvement efforts and administrative support are key drivers of quality and safety improvement and include care-integrated tools and aligned incentives aimed at achieving meaningful guideline implementation.

If guideline recommendations are not applied in clinical practice, gaps between diagnostic and therapeutic advances and improved health outcomes will persist. To narrow these gaps, we must focus on several areas:
1. Patients must be empowered as partners in their health care.
2. We must leverage implementation science and robust quality improvement practices.
3. We must focus on value in health care delivery.
CONCLUSION

Patient safety is the cornerstone of high-quality, cost-efficient health care. Evidence demonstrates that CPGs are truly major and effective tools for uniformly and sustainably delivering optimal, quality-focused, patient-centric, safe care. In every country, there is opportunity to improve the quality, cost-efficiency, and performance of the health care system. Advanced technology (in the form of clinical decision support solutions and systems) has played a transforming role in easing and encouraging consistent CPG implementation to raise the standards of clinical care. Leaders are critical in meeting the challenges of CPG implementation across their organizations and in managing the change process required for patients to receive sustainable safe, high-quality care. CPGs provide an effective and efficient way to begin.

References
