A Clinical Practice Guideline

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52.1 Introduction

52.1.1 Why Clinical Practice Guidelines?

Within the past two decades, there has been a push toward evidence-based clinical practice guidelines (CPGs). These guidelines, unlike their opinion-based predecessors, would be designed to streamline health-care efficiency, improve health-care outcomes, and decrease practice variation [1]. In 2008, the US Congress mandated that the Institute of Medicine (IOM) develop standards for the evidence-based guidelines. In response, the IOM produced a rubric for well-organized and reproducible guideline development and evidence-based systematic review.

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52.1.2 A New System to Translate Best Evidence into Best Practice

Historically, clinical practice guidelines were largely based upon the consensus of physician expert opinion, specialist group recommendation, governments, payers, etc. [2]. Unfortunately, these unregulated recommendations frequently contradicted each other. The lack of a consistent and reproducible recommendation development process led to variations in patient care and questions about the validity and reliability of the guideline process. Other questions about the CPG process included concerns about the management of conflicts of interest (COI), as well as the ranking of relevant evidence [2]. Gaps in evidence, poor quality reviews, and biased recommendations based off of lower levels of research were all concerns relating to the guideline development [1]. Consensus/expert opinion-based guidelines left much to be desired by patients and caregivers alike and these concerns were sufficient to warrant a call to change from consensus-based to evidence-based guidelines.

Evidence-based clinical practice guidelines have been designed to replace the consensus-based guideline to increase health-care efficiency and patient care success.

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In 2001, the IOM Committee on Quality of Health Care in America completed an extensive analysis of the health-care system and concluded that there were four key quality problem areas:

- The growing complexity of science and technology.
- The increase in chronic conditions.
- A poorly organized delivery system.
- Constraints on exploiting the revolution in information technology.

These quality problem areas, along with questions raised regarding trustworthy and appropriate development of consensus−/recommendation-based guidelines, lead the IOM, along with other health-care agencies, to call for the increased use of evidence-based clinical practice guidelines (CPGs) in order to improve quality of care, decrease inefficiencies, and reduce practice variation within the health-care system in America [2, 3].

Although financial benefits are not the main focus of an evidence-based practice guideline, improved guidelines may also reduce costs [4].

52.1.3 Quality Problem Areas

52.1.3.1 Science and Technology

The rapid advancement of science and technology in health care creates challenges for improving the safe, effective, and efficient delivery of health care [5]. In addition, boundless medical research databases have led to challenges for physicians, patients, and payers, who desire access to timely, concise, relevant information to guide care. The volume of relevant scientific information provided by the extensive literature databases is overwhelming, and a process to select the highest-quality, lowest-bias research from these databases is critical to practice evidence-based practice.

> Over the past 30 years, the number of randomized clinical trials alone has increased from just over 100 to nearly 10,000 *annually*. The last 5 years alone account for nearly 50% of published articles in the medical literature, and there is no evidence the rate of publication is slowing [6].

There is no doubt the data organization and filter system of this information are in desperate need of a remodel. Rather than sorting through endless clinical trials to determine the best course of action, providers and patients should be able to turn to trustworthy evidence-based guidelines to efficiently determine the appropriate route of care [7].

52.1.3.2 Chronic Conditions

Chronic conditions, defined by the Centers for Disease Control and Prevention (CDC) as any illness lasting longer than 3 months and not self-limiting, were the leading cause of illness, disability, and death in America in 1996 [8]. According to a 2008 survey conducted by the CDC/National Center for Health Statistics, 85.6% of individuals 65 and older have *at least* one of the following chronic conditions: arthritis, asthma, cancer, cardiovascular disease, chronic obstructive pulmonary disease, and diabetes. In 2030, when the large baby boom cohort has entered old age, one in five persons is expected to be in this senior age group. With modern medicine and technological advances adding years to the average American life expectancy, now over 76 years of age, the incidence and prevalence of chronic conditions will only increase [3, 9]. According to the CDC, in 2012, almost half of all Americans (117 million people) were living with one or more chronic conditions [10], and in 2014, seven of the top ten leading causes of death were chronic diseases [10]. The treatment of chronic conditions accounted for 62% of health-care

spending in 2008 [10, 11], and in 2012, that number grew to 83%. Not to mention those with five or more chronic conditions had an average of almost 15 physician visits and filled over 50 prescriptions in a year. Osteoarthritis, a degenerative joint disease, affected 54 million Americans in 2014. According to the CDC, that number will rise to 67 million in the year 2025 [12].

The treatment of chronic conditions accounted for 62% of health-care spending in 2008 [10, 11], and in 2012, that number grew to 83%.

The demographic transformations that are projected to occur over the following years have important implications for the organization of the health-care delivery system. Self-management, family support services, committing to the treatment plan, and sustained follow-up visits are just as vital to patient recovery as initial diagnosis. Collaboration between the health-care provider, health-care provider team, patients, and patient's family adds an additional layer of complexity that must be considered when developing clinical guidelines [3]. It is yet another need for universally applied, clear, concise, and streamlined medical guidelines.

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52.1.3.3 Poorly Organized System

The current health-care delivery system is a labyrinth, a seemingly endless web of non-answers. Patients and families have described it as a "nightmare to navigate" [13]. Clinicians have reflected that it is an acute waste of time. The complex series of hand-offs between doctors, specialists, hospitals, insurance agencies, third parties, and other providers decreases the efficiency of patient care. While multiple hand-offs from specialty clinician to specialty clinician are vital when treating persons with multiple chronic conditions, the current mechanism of coordination is lacking and needs reconfiguring to increase efficiency and ensure safety and proper treatment. The ultimate goal is to help, not hinder a patient. It appears obvious that coordination should be as smooth and with the least number of hand-offs as possible to minimize time delay in health-care delivery.

52.1.3.4 Constraints on Information Technology

Information technology poses serious concerns for many health-care providers, the main concern being a patient's misunderstanding of proper medical treatment as they turn to web-based self-diagnosis and treatment rather than taking the time to see a trained medical professional. This may lead to serious illnesses being left poorly or inadequately treated.

However, when appropriately applied, the information technology is also a great tool to patients. E-mail allows for efficient communication between provider and patient. The web allows patients to self-educate and take more responsibility for and control of their recovery process. Online forums have been beneficial, especially for those struggling with rare diseases that may not have a community near them which they can lean on. Information technology has also the potential to increase the quality of health care through improving physician communication and removing communication barriers to health-care delivery.

These problems outlined by the IOM are simply additional reasons to update the health system and guideline development process.

52.2 What Is an Evidence-Based Clinical Practice Guideline?

CPGs, as defined by the CPG Development Manual, 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* [14].

These evidence-based recommendations are developed using a minimally biased, transparent,

and reproducible evaluation of published medical literature. Evidence-based CPGs are designed to withstand the type of scrutiny and review its "expert group/consensus-based" predecessor could not. They serve as an effective synthesis of an enormous literature database, providing a complete yet concise summary of available knowledge and a detailed treatment plan for a specific topic or condition. These "evidence-based guidelines" undergo a rigorous protocol to deliver the optimum care route for the patient [2]. Such a guideline should streamline patient care while ensuring patient safety and increasing outcome success. As with all information and technologies, CPGs are subject to regular updates as new research and clinical studies are published [3]. CPGs are beneficial in that they provide an efficient source of information for the best course of treatment while allowing for flexibility in a treatment pathway [3].

52.2.1 Trustworthy CPGs

The need for *trustworthy* guidelines is one of the main driving factors for the new guidelines. Guidelines must be developed by a qualified and diverse group of individuals. The development process critically analyzes the data, the source of the data, and those who conducted the study to ensure limited guideline bias. Bias and COIs can influence the efficacy of and impact published research findings have on a community [15–17]. Bias must be minimized in order to provide the public with the most trustworthy guideline. When bias and COIs are allowed to traverse the boundary line between good research and bad, the effect can be detrimental.

For instance, therapeutic drug research often is run more like a promotional campaign for pharmaceutical companies, rather than a clinical research study, intended to increase sales rather than improve drug performance [18]. In 2008 the *New England Journal of Medicine* published a study [19] which reviewed the selective publication process of antidepressant drugs and the effect those selected publications have on drug efficacy. The study found that of the 74 clinical trials conducted on one specific antidepressant, 38 produced positive results and 36 found the drug to have "questionable or no efficacy" [18]. However, only 8% of the "questionable or no efficacy" studies were published, while 94% of the positive studies were published. Moreover, 15% of the 8% "questionable or no efficacy" studies were published in such a way as to spin the results in a positive form [19]. As drug companies can cherry pick which data they wish to present, it is easy for physicians and medical providers to inadvertently develop a biased opinion about the drug. This can influence clinical practice and prescribing habits. Unsurprisingly, additional studies have found that industry-sponsored studies are significantly more likely to report favorable results and less likely to report unfavorable outcomes than their federally funded counterparts [15, 17]. This is troubling as many drugs are associated with serious adverse effects.

As such, it is vital that developers of CPGs look closely at the research evidence and develop CPGs in a trustworthy, reproducible, and transparent manner. Developers must consider not only the findings but also who sponsored the study. They must rigorously scrutinize if the results are reported truthfully. Only then can guideline development occur with minimal bias and maintain reliability.

52.3 Development of CPGs

In response to Congress and to develop trustworthy guidelines, the IOM has established eight standards of developing CPGs [1]:

1. Transparency.
2. Management of conflicts of interest (COI).
3. Development group diversity.
4. Systematic review.
5. Evidence and recommendation strength.
6. Articulation of recommendations.
7. External review.
8. Updating.

Each of these standards is intended to create the most well-researched, trustworthy, and clini-

cally relevant guideline possible. These standards, or "guidelines for the guidelines," are imperative in ensuring the reproducibility and clarity of the guideline development process—a factor the previous recommendation development process lacked.

52.3.1 Transparency

A transparent guideline serves two main purposes:

The first is to ensure unambiguous and reproducible guidelines. Transparency ensures the guideline is clear and easy to follow. The treatment pathway should be well articulated.

A transparent guideline also fully discloses author information, conflicts of interest (COIs), and guideline funding.

Transparency allows physicians and patients to evaluate for themselves the reliability of and potential biases within a guideline. Ideally, this translucent nature of the guideline development process will deter biases from crossing into the development process, further cementing the trustworthy quality of the guideline.

52.3.2 Management of Conflicts of Interest

Any association between a developer and the guideline in question serves as a potential for conflicting interests. These associations may include academic interests, professional gains, personal gains, or financial advancements. Biases may cause the guideline to be developed unduly—Intentionally or not. Therefore, COIs must be limited to maintain guideline credibility.

To manage COIs, each individual participating in guideline development must disclose interests and medical and financial associations relating to the guideline. Ideally, disclosures work to minimize the biases that may seep into the development process assuring that the guidelines were not developed to suit certain interests while harming others.

52.3.3 Development Group Diversity

A trustworthy CPG depends greatly on its team of developers. A diverse team—One that includes a member from every discipline or party associated with its implementation or consumption—Can provide a well-rounded guideline with the interest of all parties protected [4]. This team includes primary care physicians, specialists, nurses, other providers, and any other party who may utilize the guideline. Patients, or other proxies, who may advocate for patients, must be also present. Patients and other proxies need no prior medical experience with the guideline topic as their role is to provide a voice for patients.

Such a diverse group ensures that patients' needs are protected and concerns are respected.

52.3.4 Systematic Review

The systematic review (SR) process determines the inclusion and exclusion criteria for the literature search. During the SR process, articles are gathered, analyzed, and interpreted, and relevant data is summarized. The SR process begins with an all-inclusive search of the medical literature and ends with a preliminary draft of the guideline.

52.3.5 Evidence and Recommendation Strength

A ranking of the quality of evidence and the strength of research is conducted to apply appropriate weight to each guideline recommendation [20]. CPG developers focus on high-quality evidence to build their recommendation. Steering clear of overdependence on expert opinion is important as expert opinion may not be based upon well-rounded experience or complete information [4]. Basing guidelines on research with weak design or flawed methodology will result in biased or faulty guidelines. To ensure quality evidence, a quality assessment is performed for all research included in the guideline development.

Another factor the guideline team must consider while making recommendations is the fact that *a statistically significant finding may not be clinically relevant* [21]. To resolve this discrepancy, the America Academy of Orthopaedic Surgeons (AAOS) has applied the minimal clinically important improvement (MCII) method for determining clinical significance in research. This is similar to the minimally important difference (MID) or the smallest amount of change a patient may distinguish. Identifying clinical significance is important because a research finding that may be statistically significant to a researcher may not be relevant to patient treatment. Thus, certain research findings may not actually bear enough clinical weight to warrant a change in clinical treatment.

> *A statistically significant finding may not be clinically relevant* [21].

For example, a pharmaceutical company has two drugs, Drug A and Drug B, which both decrease anxiety. Drug A has a success rate of 95%, whereas Drug B has a success rate of 89%. Drug A costs five times as much as Drug B and has much more severe side effects than Drug B. Statistically, Drug A has a significantly greater success rate; however, clinically, Drug B is far more appealing in the eyes of the clinician and the patient. It saves the patient money and potentially harmful side effects and yields nearly the same treatment outcome. In this case, the statistically significant finding isn't applicable in the clinical setting as the patient wouldn't be able to distinguish a difference between the successes of both drugs.

Medical literature is analyzed and ranked by its quality of study design—the highest-quality evidence corresponds to the lowest risk of bias.

The AAOS has developed a reliable "Clinical Practice Guideline Strength of Recommendation" rubric (Table 52.1) [3] that has been proven to generate strong CPGs. The

Table 52.1 AAOS strength of recommendation description table [23]

Strength	Overall strength of evidence	Description of evidence strength	Strength visual
Strong	Strong	Evidence from two or more "high"-strength studies with consistent findings for recommending for or against the intervention	
Moderate	Moderate	Evidence from two or more "moderate"-strength studies with consistent findings or evidence from a single "high"-quality study for recommending for or against the intervention	
Limited	Low-strength evidence or conflicting evidence	Evidence from one or more "low"-strength studies with consistent findings or evidence from a single moderate-strength study for recommending for or against the intervention or diagnostic test or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention	
Consensus	No evidence	There is no supporting evidence. In the absence of reliable evidence, the work group is making a recommendation based on their clinical opinion. Consensus recommendations can only be created when not establishing a recommendation could have catastrophic consequences	

Table 52.2 AAOS recommendation language table

Guideline language	Strength of recommendation
Strong evidence supports that the practitioner should/should not do X, because…	Strong
Moderate evidence supports that the practitioner could/could not do X, because…	Moderate
Limited evidence supports that the practitioner might/might not do X, because…	Limited
In the absence of reliable evidence, it is the *opinion* of this work group that…	Consensus[a]

[a]Consensus-based recommendations are made according to specific criteria. These criteria can be found in Appendix VII

strength of a recommended treatment pathway in a CPG is based off the quality of its supporting evidence (Table 52.2) [3]. Evidence quality is based on the following hierarchy of study design [3]:

- High quality: <2 study design flaws.
- Moderate quality: ≥2 and <4 study design flaws.
- Low quality: ≥ 4 and <6 study design flaws.
- Very low quality: ≥6 study design flaws.

Two or more high-quality studies yield a strong recommendation. One high-quality study or two or more moderate-quality studies yield a moderate-strength recommendation. One moderate-quality study and/or two or more low-quality studies yield a limited-strength recommendation. If there is conflicting evidence, the recommendation is ranked as limited [3, 22]. If there is no evidence to support the recommendation and the development team produces a recommendation, it is labelled "consensus" and is published in a separate companion consensus statement document to ensure separation between evidence-based and consensus-based recommendations. A "consensus" recommendation is equivalent to the historic expert group-based recommendation.

The terminologies "strong," "moderate," "limited," and "consensus" are used to express the strength of recommendation within the guideline. After evidence analysis and recommendation ranking have occurred, the guideline is drafted.

In many cases, more than one recommendation may be presented. In instances such as these, care maps or flow diagrams may be the best way to convey information as they are concise and easy to read and understand even when multiple variables are present. Multiple recommendations are included in the guideline to account for the variances that may arise. No two clinical cases are the same; as such the guideline provides a myriad of recommendations, so the physician may alter treatment as needed.

52.3.6 Articulation of Recommendations

Recommendations must be clearly written. They must be presented in the standardized format that includes a detailed treatment pathway as well as circumstances in which each recommendation should be used. Particular language is used to properly express the strength of the recommendation as well as the level of confidence the development team has in the recommendation. This information is vital as it allows the reader to evaluate how closely the guideline should be followed.

52.3.7 External Review

After a guideline is developed by the work group, but before it is released, an external review is conducted by an independent peer review group [4]. The external review serves as an independent, non-biased evaluation of the guideline. The group consists of medical professionals in related areas, persons from medical societies, and persons from the community. Just as the development team members are required to disclose COIs, so are the external review group members.

Reviewers are asked to review the evidence and comment on the wording of the recommendations. The peer review group is responsible for ensuring three main qualities of the guideline: validity, reliability, and feasibility.

1. *Valid* guidelines clearly state the scientific evidence supporting their recommendation. Justifications are present where group consensus and expert opinion were needed to support recommendation.

2. *Reliable* guidelines are *reproducible*. They are guidelines in which a peer reviewer comes to the same conclusion as the focus group.
3. *Feasible* guidelines are easily understood by both patients and physicians and allow for both routine use and case-by-case modifications when necessary.

   The review team's written comments are collected into a single response form which is then reviewed and responded to by the chair of the guideline development team. Guideline development team members vote on all suggested revisions to recommendation language and are accepted with a majority vote [24]. The revision process is documented and reported in the guideline document until final guideline approval [24].

52.3.8 Updating

CPGs are subject to routine updates and amendments as new information presents itself or as time passes. Certain branches of medicine, such as the American Academy of Orthopaedic Surgeons and American Association of Otolaryngology-Head and Neck Surgery (AAO-HNS), update their guidelines at a minimum of 5 years after publication [21, 25]. Situations that warrant guideline updating may include but are not limited to [4, 26]:

- Changes/advancements in available treatment or intervention methods.
- New evidence that impacts current treatment.
- Changes in health-care availability, affordability, or access.

In addition to updates, CPGs may undergo amendments. There are three types of amendments:

1. Reaffirmations: This simply consists of a brief statement of the organization's agreement with the current guideline. This occurs when the guideline requires no significant alterations such as when time passes but treatment methods and research findings have not changed.
2. Minor revisions: A minor revision includes any alteration to the guideline that doesn't change the overarching treatment plan but changes minor steps. This may be due to new research findings.
3. Major revisions: A major revision is any revision that significantly alters the treatment plan, course of action, or main conclusion of guideline.

Updates and amendments undergo an independent review and majority vote and are then published and distributed with an alert that the guideline has been revised.

Each guideline is accompanied by its "profile." A short statement that discloses the entire decision-making process includes the development team's values, the evidence quality and harm-benefit assessments, and the level of confidence the team has in the evidence. Limitations of the guideline are also expressed such as intentional vagueness the team may have included [4]. CPGs will not always be correct, as they must be revised with new information as research is published, nor will they be entirely bias-free. The CPG process outlined by the IOM aims to limit the amount of bias that seeps into the recommendation development process, increase consistency within patient care, and streamline the health-care delivery process.

Often a brief disclaimer is added to the beginning of the guideline abstract, such as this one from the American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF) [4]:

> This clinical practice guideline is not intended as a sole source of guidance in managing [topic specified here]. Rather, it is designed to assist clinicians by providing an evidence-based framework for decision-making strategies. The guideline is not intended to replace clinical judgment or establish a protocol for all individuals with this condition, and may not provide the only appropriate approach to diagnosing the managing the problem.

AAOS includes similar language in the introduction to the guidelines:

> This guideline should not be construed as including all proper methods of care or excluding methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment must be made considering all circumstances presented by the patient and the needs and resources particular to the locality or institution.

52.3.9 Implementation

Guidelines are only as effective as those who implement them. The National Guideline Clearinghouse (NGC) is responsible for the announcement, promotion, and distribution of CPGs [14]. Once the guideline is ready for implementation, it is crucial that physicians and all health-care providers use the guideline to deliver the highest quality of care to the patient.

52.3.10 Outcomes Assessment

Outcomes assessments are important measures to determine whether or not treatment has been successful [14]. A CPG, like any treatment, undergoes an "outcome assessment." However, the organizations typically involved in outcome assessments, such as the National Quality Measures Clearinghouse (NQMC) and others, are not involved in the outcome assessment of CPGs. This is because the evaluation of outcomes is built into the CPG development process and expressed by the ranking of the recommendations. As such, the IOM Committee on Quality Health Care in America resolves that there is no need for the rating of quality measure of CPGs as it would be redundant. Moreover, an additional rating could create conflicts of interest as some CPG developers also develop related outcome assessment rubrics [14].

Clinical Vignette

Management of Anterior Cruciate Ligament Injuries:

As of 2017, the AAOS has completed 18 CPGs. In 2015, the AAOS published a guideline for the "Management of Anterior Cruciate Ligament Injuries" providing physicians with a detailed, outlined plan to aid in the prompt and accurate treatment of ACL injuries [27].

The topic was chosen for guideline development as some controversy existed over best treatment and management options, and this condition impacts a significant number of patients in the USA. The extensive literature had not yet been concisely accumulated to distinguish best treatment options for appropriate cases. A systematic review of the literature was conducted in adherence with the aforementioned guideline criteria. In the ranking of their guideline recommendations, the guidelines were assigned a star grade to easily distinguish strength of recommendation (4 stars for a strong recommendation, 3 stars for a moderate-strength recommendation, etc. in accordance with Table 52.1). The stars aligned the IOM's "strong," "moderate," "limited," and "consensus" rubric language terms.

Of the 20 recommendations put forth by this ACL injury management CPG, 5 had strong supporting evidence (4 stars), 6 had moderate supporting evidence (3 stars), 7 had limited supporting evidence (2 stars), and only 2 were consensus-based. This CPG shows not only great advancement in the strength of the orthopedic research being conducted but also great improvement in the guideline themselves. Only 6 years prior, in 2009, AAOS published its first CPG on diaphyseal femur fractures in pediatrics. This guideline, although much stronger than its consensus-based predecessor, only had 1 recommendation out of its 14 that would have received a 4-star ranking and only 2 that would have received 3 stars. The 2015 CPG on ACL injury management shows great advances from both an orthopedic research perspective and a clinical practice guideline and care management perspective.

The following are a few examples of the strongest recommendations from the ACL injury management CPG [27]:

1. "Strong evidence supports that the practitioner should obtain a relevant history and perform a musculoskeletal exami-

nation of the lower extremities, because these are effective diagnostic tools for ACL injury" (4-star/strong evidence recommendation).
2. "Strong evidence supports that the MRI can provide confirmation of ACL injury and assist in identifying concomitant knee pathology such as other ligament, meniscal, or articular cartilage injury" (4-star/strong evidence recommendation).
3. "When ACL reconstruction is indicated, moderate evidence supports reconstruction within five months of injury to protect the articular cartilage and menisci" (3-star/moderate evidence recommendation).

As the AAOS has gained more experience with the guideline process, and the overall quality of the orthopedic literature has improved, more recent guidelines include questions that follow patients through the path of care. The language for recommendations reflects the quality of evidence in research publications. The recent guidelines for management of elderly hip fractures and ACL injury are examples of high-level guideline recommendations.

The language for recommendations reflects the level of evidence in research publications. The recent guidelines for management of elderly hip fractures and ACL injury are examples of high-level guideline recommendations.

52.4 Turning CPGs into a Care Map

CPGs provide clinical guidance for a wide variety of topics and help manage specific conditions. CPGs may be used to support care maps, which can help local medical groups and health system and outline care pathways. Simple, easy-to-follow flow diagrams help providers quickly determine the best route of care for each specific clinical case.

The AAOS 2014 CPG for developmental dysplasia of the hip (DDH) was used to develop DDH Care Map for the St. Luke's Health System in Idaho [28]. The CPG summarized recent research and clinical treatment options for the evaluation of DDH, creating evidence-based treatment options for different clinical presentations of DDH. This guideline was turned into an easy-to-follow care map, providing practitioners with step-by-step instructions on how to best treat each specific case. The map includes treatment methods varying with patient age and degree of hip dysplasia. It also includes modifications to treatment for those clinics that may not have access to the ideal imaging machines. Moreover, it is easily accessed via smartphone, tablet, iPad, or other portable screens providing ease of access for providers and families.

The DDH Care Map (Fig. 52.1) continues to be used in clinical practice in the St. Luke's Health System, and this care map is continually reviewed and updated. Feedback from clinicians, as well recent publications, will lead to changes in the care map.

AAOS CPG program led to the development of other care maps for other health systems and practices, including those for carpal tunnel syndrome and for management of elderly hip fractures.

52.5 Limitations of CPGs

Many areas of medicine, like orthopedics, have massive medical literature databases. Sorting through the extensive databases for appropriate articles and ranking levels of evidence to develop CPGs requires considerable effort and expertise [3]. CPGs are beneficial for many reasons; however, some disadvantages include:

1. The process is time-consuming and expensive.
2. Patient feedback is ideal, but often not available from in the literature published.

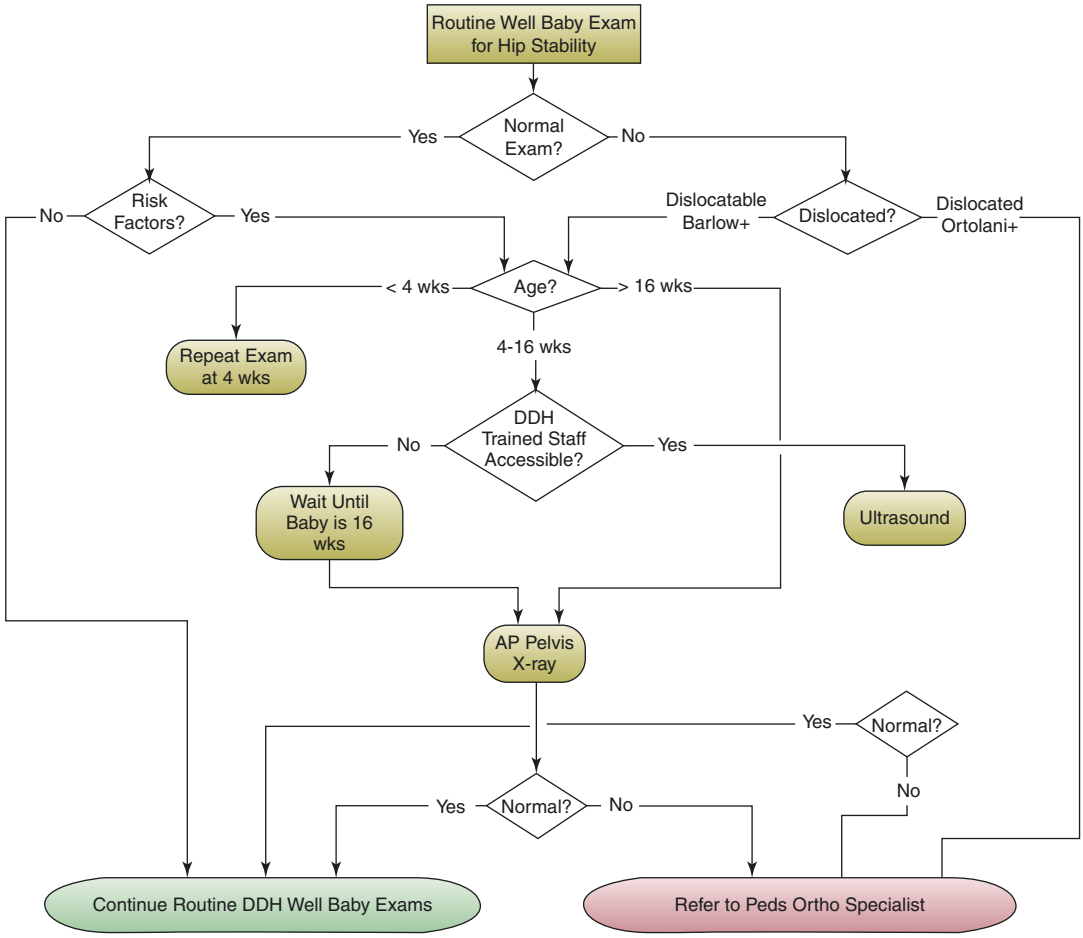

Fig. 52.1 Care map for DDH [29]

3. Guidelines are subject to misinterpretation.
4. Guidelines must be continuously updated, to reflect changes in the published literature.
5. Adequate literature is required to develop CPGs, so areas lacking in literature won't qualify for CPG development.
6. Guidelines are only as effective as those who implement and abide by them.
7. For less common conditions, adequate research literature may not support the development of a CPG.

For those guideline patient care questions that lack relevant research or have an insufficient database, members of the clinical practice guideline work groups are allowed to create a companion consensus statement [14]. These are statements based on expert opinion and are published separately from the CPGs to ensure separation of expert-opinion-based recommendations and evidence-based recommendations.

52.6 Future Studies

Although the guidelines have limitations, the guidelines are beneficial for many reasons. The guideline process identifies medical areas which

lack higher levels of research and highlight the direction for future research. A lack of evidence to develop strong evidenced-based CPGs is common in many medical specialties. A review article evaluating the strength of over 2700 recommendations put forward by the American College of Cardiology and the American Heart Association found that only 11% of those 2700 recommendations were based on Grade A, or "strong," evidence [3]. CPGs may not always be feasible to produce as certain topics lack sufficient data, but they do provide a service—highlighting important gaps in research and important clinical questions that must be answered in to provide optimal patient care.

Take-Home Message

- The IOM and others have called for a revision of the development of the highest standards of care in the American health system.
- Evidence-based clinical practice guidelines have been designed to replace the consensus-based guideline to increase health-care efficiency and patient care success.
- Guidelines have limitations, but they can have a positive impact on patient care.
- They are designed to streamline patient care—potentially aiding in the treatment of the anticipated increase of chronic conditions.
- As CPGs serve as a summary of scientific evidence available, those areas which lack adequate clinical research may become research priority.
- Through the extensive and deliberate analysis of high-quality medical literature, CPGs provide evidence-supported health-care plans for physicians and patients alike.
- Ultimately, these guidelines may reduce practice variation, improve quality of care, decrease inefficiencies, and withstand the scrutiny the previous guideline process could not.

52.7 Useful Websites

https://www.aaos.org/guidelines/?ssopc=1

http://www.orthoguidelines.org/topic?id=1018

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