THE EXPANDED USE OF CLINICAL PRACTICE GUIDELINES FOR ARIZONA'S WORKERS' COMPENSATION SYSTEM

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The Industrial Commission of Arizona is considering expanding the use of the Work Loss Data Institute's Official Disability Guidelines (ODG) for treating injured workers within the state's workers' compensation system. Arizona currently uses the ODG for the management of chronic pain and opioids. The expanded use of the ODG would encompass all applicable medical treatment decisions of injured Arizona workers.

The Industrial Commission seeks to answer the following questions prior to implementing a change: 1) Will adoption of the Official Disability Guidelines improve medical treatment for injured workers? 2) Do the Official Disability Guidelines adequately cover the body parts or conditions encountered in the Arizona workers' compensation system? and 3) Will adoption of the Official Disability Guidelines make treatment and claims processing more efficient and cost effective?

Will adoption of the ODG improve medical treatment for injured workers?

MAXIMUS has experience performing independent medical review in multiple states and utilizes numerous clinical practice guidelines. The use of a specific guideline or set of guidelines is typically set by the governing body of the state where it is used. Although we have a great deal of experience using CPGs, MAXIMUS cannot recommend any specific clinical practice guideline or comment on whether guidelines improve medical treatment for injured workers. However, a body of research has emerged that attempts to clarify the effect of guidelines in the practice of medicine.

To answer the question of whether adopting a clinical practice guideline will improve medical treatment for Arizona's injured workers, two additional questions should be addressed. First, what factors must be present in a credible set of clinical practice guidelines (CPGs) that yield quality treatment for workers? And second, will providers use CPGs when treating injured workers?

The development of reliable treatment guidelines has long been debated, but practical guiding principles were established in 2011. The Institute of Medicine published an extensive report in that year entitled, Standards for Developing Trustworthy Clinical Practice Guidelines. (1) The report attempted to clarify how medical evidence, published research, and expert consensus should be utilized to develop a set of clinical practice guidelines. The Institute of Medicine recommended CPGs be developed using the following criteria:

- The methods by which a CPG is developed and funded should be detailed explicitly and publicly accessible.
- Transparency exists averting conflicts of interest, bias, and funding from within the panel of CPG developers.
- The panel contains a multidisciplinary mix of clinicians, experts, and other stakeholders expected to be affected by the CPGs, such as patients and consumer groups.

- A rigorous review of all available evidence
- Clear summaries of the evidence detailing the potential benefits or dangers in following a recommendation of a CPG.
- An explanation of the evidentiary parts that were used in deriving a recommendation.
- A rating of the quality and strength of the evidence for a recommendation.
- Rigorous external peer review.
- A process of re-evaluation and revision of recommendations as new evidence is published.

Although opinion still differs and controversy persists regarding the use and implementation of CPGs, it has been generally established that a credible set of treatment guidelines effectively improves the quality of healthcare in a population of patients. In addition, CPGs have been found to reduce medical errors due to clinical practice variation among providers. (2)

Providers' use of CPGs in treating injured workers when directed to do so in the past, has shown a limited effect on provider practice behavior. (3) However, when coupled with an effective utilization review system and provider education, this practice can be optimized. There may be an amount of resistance by experienced medical providers who are unaccustomed to using guidelines in their practice. It is true that guidelines cannot replace years of clinical practice experience, however, they can improve the quality of clinical decisions and offer recommendations for clinicians who are uncertain about a treatment pathway. In addition, CPGs may call the provider's attention to obsolete treatments and provide recommendations that change treatment habits and lead to improved patient care. (3) Although established providers may be initially resistant to using CPGs, they become more comfortable with CPG use over time. More recently trained providers offer less resistance to adopting practice guidelines, presumably due to the increased utilization of CPGs in training programs. (4)

The medical literature seems to suggest that the implementation of clinical practice guidelines that follow standards of The Institute of Medicine should improve medical care and management for Arizona's injured workers. This implies that CPG treatment recommendations ought to ultimately improve patient outcomes and discourage overutilization of ineffective or unproven treatments.

Do the ODG adequately cover the body parts or conditions encountered in the Arizona workers' compensation system?

No set of clinical practice guidelines covers every conceivable treatment, injury, or medical condition. In addition, medical evidence is not always available from research, and studies are not always conclusive. Most effective CPGs cover a wide range of work-related conditions and treatments. But because no set

of guidelines covers all conditions, an alternate pathway should be accessible for the review of medical evidence. A clearly defined methodology for evaluating medical evidence should be available to determine the hierarchy of evidence supporting a recommendation.

For example, the State of California applies a set of regulations, the Medical Treatment Utilization Schedule (MTUS) as the primary CPG guiding treatment decisions. The medical evidence search sequence is:

1. MTUS
2. ACOEM Guidelines or ODG
3. Consult other evidenced-based guidelines
4. Consult other scientifically-based studies
5. Expert Medical Consensus

In our medical-necessity review experience, the majority of treatment decisions can be handled when utilizing a hierarchy of evidence.

Will adoption of the Official Disability Guidelines make treatment and claims processing more efficient and cost effective?

Adopting and integrating new rules and procedures into the complex environment of workers' compensation and medicine always poses a degree of difficulty due to the numerous stakeholders competing for consideration. Even with an effective plan to integrate a set of clinical practice guidelines into the workers' compensation system, it will likely take time to implement. However, CPGs are emerging and evolving in the administration of treatment for not only injured workers, but for healthcare in all medical systems in the United States. (5) Eventually, it is likely that all treatment will be guided, at least in part, by evidence-based medicine.

Those states that have adopted CPGs as a tool for evaluating the treatment provided to their injured workers have not necessarily found treatment and claims processing more efficient (6). This is due to the additional time and effort that is required to review and evaluate disputed treatments. However, treatment requests known to be within the guidelines typically move through the system unimpeded. Based on the regulations and resulting system edits and claim suspension for medical review, claims administrators become familiar with which treatments are recommended by the CPG and providers learn which treatments to request that will be approved.

Regarding cost effectiveness, nearly all states that have adopted CPGs report a decrease in the cost of providing medical treatment to the injured workers in their state.

Conclusion

Although much of the discussion surrounding the use of CPGs is centered on whether clinical practice guidelines save money and help patients obtain proper care, there is also a consideration of the perceived quality of each specific CPG. Competition is driving various groups or stakeholders that support adoption of a specific set of guidelines. CPG proponents may claim their guidelines possess the most up-to-date and accurate recommendations, or provide better patient safety, or prevent utilization of unnecessary treatments. CPGs developed by specialty associations have been criticized as being too narrow in focus containing recommendations more favorable to the use of procedures used primarily in that specialty. As payment models in healthcare move from volume based to value based, it is likely to see treatment recommendations evolve based on cost utilization analyses. Finally, various stakeholders such as attorney groups representing injured workers may have differing opinions regarding CPGs depending upon that group's role in the workers' compensation system. Regardless, in states where CPGs have been adopted, guidelines seem to bring most stakeholders to common ground.

The currently available research indicates that the conscientious and judicious use of clinical practice guidelines would help provide current, evidence-based medical treatment to Arizona's injured workers, while helping decrease unnecessary or ineffective treatments. Any state adopting clinical practice guidelines, however, needs to be aware that a set of clinical practice guidelines is simply a tool that may help guide treatment and medical decision-making toward the best practice in medicine; but even the most credible CPGs may not be applicable to every individual patient. Choosing a process or set of guidelines that address the majority of conditions and treatments with a protocol for coverage of any gaps will likely lead to an effective and successful model. However, an effective appeal system will also contribute to the success of the program.

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Why Don't Physicians Follow Clinical Practice Guidelines?

A Framework for Improvement

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Context Despite wide promulgation, clinical practice guidelines have had limited effect on changing physician behavior. Little is known about the process and factors involved in changing physician practices in response to guidelines.

Objective To review barriers to physician adherence to clinical practice guidelines.

Data Sources We searched the MEDLINE, Educational Resources Information Center (ERIC), and HealthSTAR databases (January 1966 to January 1998); bibliographies; textbooks on health behavior or public health; and references supplied by experts to find English-language article titles that describe barriers to guideline adherence.

Study Selection Of 5658 articles initially identified, we selected 76 published studies describing at least 1 barrier to adherence to clinical practice guidelines, practice parameters, clinical policies, or national consensus statements. One investigator screened titles to identify candidate articles, then 2 investigators independently reviewed the texts to exclude articles that did not match the criteria. Differences were resolved by consensus with a third investigator.

Data Extraction Two investigators organized barriers to adherence into a framework according to their effect on physician knowledge, attitudes, or behavior. This organization was validated by 3 additional investigators.

Data Synthesis The 76 articles included 120 different surveys investigating 293 potential barriers to physician guideline adherence, including awareness (n = 46), familiarity (n = 31), agreement (n = 33), self-efficacy (n = 19), outcome expectancy (n = 8), ability to overcome the inertia of previous practice (n = 14), and absence of external barriers to perform recommendations (n = 34). The majority of surveys (70 [58%] of 120) examined only 1 type of barrier.

Conclusions Studies on improving physician guideline adherence may not be generalizable, since barriers in one setting may not be present in another. Our review offers a differential diagnosis for why physicians do not follow practice guidelines, as well as a rational approach toward improving guideline adherence and a framework for future research.

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CLINICAL PRACTICE GUIDELINES are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."[1] Their successful implementation should improve quality of care by decreasing inappropriate variation and expediting the application of effective advances to everyday practice.[2,3]

Despite wide promulgation, guidelines have had limited effect on changing physician behavior.[4-7] In general, little is known about the process and factors responsible for how physicians change their practice methods when they become aware of a guideline.[8,9] Physician adherence to guidelines may be hindered by a variety of barriers. A theoretical approach can help explain these barriers and possibly help target interventions to specific barriers.

In this article, we review barriers to physician adherence to practice guidelines. Such knowledge can help developers of guidelines, practice directors, and health care services researchers design effective interventions to change physician practice.

METHODS

Data Sources

We conducted a systematic review of the literature to identify barriers to guideline adherence. We searched all articles, limited to the English language and human subjects, published from January 1966 to January 1998

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using the MEDLINE, Educational Resources Information Center (ERIC), and HealthSTAR databases. To find candidate titles that describe barriers to adherence, we included titles that appeared in 2 searches. The first used medical subject heading (MeSH) descriptors *clinical practice guidelines* or *physicians' practice patterns*. The second used the descriptors *behavior, knowledge, attitudes*, and *practice, attitude of health personnel, guideline adherence*, or the text words *behavior change*. We also examined candidate titles of papers describing theories of physician behavior change to find constructs useful in describing barriers. We used candidate titles with the MeSH descriptor or text words *behavior* and 1 of the following terms: "*model, organizational*," "*model, theoretical*," "*model, psychological*," or "*model, educational*." We identified additional candidate articles by reviewing the bibliographies of articles from the search; contacting experts in psychology, management, and sociology; and reviewing bibliographies of textbooks of health behavior and public health.

Data Selection

We included articles that focused on clinical practice guidelines, practice parameters, clinical policies, national recommendations or consensus statements, and that examined at least 1 barrier to adherence. A *barrier* was defined as any factor that limits or restricts complete physician adherence to a guideline. We focused on barriers that could be changed by an intervention. As a result, we did not consider age, sex, ethnic background, or specialty of the physician as barriers. In many of the articles, respondents indicated barriers via responses to survey questions. For qualitative studies, major themes from focus groups or interviews identified barriers.

One investigator (M.D.C.) screened titles and/or full bibliographic citations to identify candidate articles. Two investigators (M.D.C. and P.-A.C.A.) then independently reviewed the full text to exclude articles that did not fulfill our criteria. Differences were resolved by consensus with a third investigator (H.R.R.).

Data Extraction

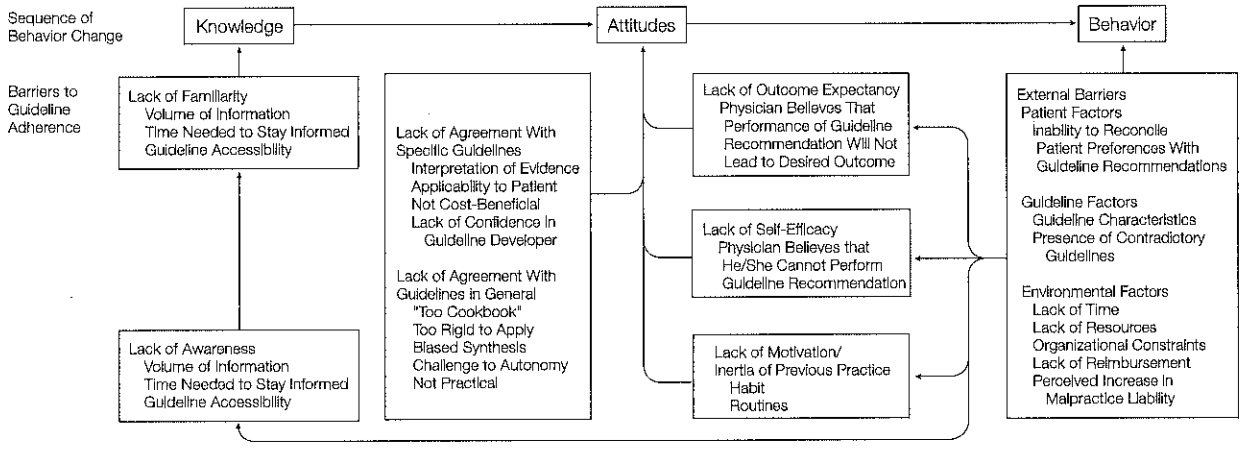
Two investigators (M.D.C. and P.-A.C.A.) then abstracted the following information from each article: description of barrier, description of the guideline, the percentage of respondents describing the barrier, demographics of the respondents, and study characteristics. If possible, we calculated the percentage of respondents affected by a barrier as the difference between 100% and the sum of the percentage with no opinion and those not affected.

All barriers abstracted from the articles were grouped into common themes, then further organized into groups based on whether they affected physician knowledge, attitude, or behavior. The organization of these categories was validated by 3 additional investigators (A.W.W., N.R.P., and C.S.R.) and was based on a model that describes an ideal, general mechanism of action for guidelines, the knowledge, attitudes, behavior framework[6] (FIGURE). Before a practice guideline can affect patient outcomes, it first affects physician knowledge, then attitudes, and finally behavior. Although behavior can be modified without knowledge or attitude being affected, behavior change based on influencing knowledge and attitudes is probably more sustainable than indirect manipulation of behavior alone.

Factors limiting adherence through a cognitive component were considered barriers affecting knowledge, through an affective component were considered barriers affecting attitude, and through a restriction of physician ability were considered barriers affecting behavior.

Based on previous work by Davis and Taylor-Vaisey,[10] the following terms were used: *adoption* refers to a provid-

Figure. Barriers to Physician Adherence to Practice Guidelines in Relation to Behavior Change



er's commitment and decision to change practice, *diffusion* is the distribution of information and the unaided adoption of recommendations, *dissemination* is more active than diffusion and is the communication of information to improve knowledge or skills, and *implementation* refers to active dissemination, involving strategies to overcome barriers.

Lack of familiarity included the inability of a physician to correctly answer questions about guideline content, as well as self-reported lack of familiarity. When studies reported the percentage of physicians answering questions incorrectly, the highest percentage of incorrect answers was used to measure lack of familiarity. Lack of awareness was the inability to correctly acknowledge a guideline's existence.

RESULTS

Search Yield

We found 5658 candidate titles possibly examining barriers to adherence. We excluded 5235 titles after examination of the bibliographic citation. After examining the full text of 423 articles or chapters, 76 articles fulfilled our criteria. The κ to measure interrater reliability for article selection was 0.93.

The 76 accepted articles included 5 qualitative studies and 120 different surveys asking a total of 293 questions addressed to physicians regarding possible barriers to guideline adherence. A survey was defined as at least 1 question to a group of physicians about barriers to adherence for a unique guideline recommendation.

Type of Barriers

After classifying possible barriers into common themes, we found that the 293 questions about barriers included 7 general categories of barriers (Figure). The barriers affected physician knowledge (lack of awareness or lack of familiarity), attitudes (lack of agreement, lack of self-efficacy, lack of outcome expectancy, or the inertia of previous practice), or behavior (external barriers).

Comprehensiveness of Surveys

We examined how often surveys considered the full variety of barriers to physician adherence. Theoretically, a survey could examine up to 7 different types of barriers to adherence. Of the 120 surveys, 70 (58%) examined only 1 type of barrier, and the average number examined was 1.67 (median, 2). Of the remaining surveys, 30 (25%) examined 2, 11 (9%) examined 3, 8 (7%) examined 4 , and 1 (0.8%) examined 5. None examined 6 or more types of barriers.

Characteristics of Physician Surveys

The number and characteristics of the surveys examining each barrier are listed in Table 1, which is not included in the print version of this article but is available at http://www.jama.com. We found that the surveys used a heterogeneous variety of physician populations (based on specialty or location of practice) and investigated guidelines on a variety of subjects (immunization, preventive care, or treatment). The surveys also displayed a wide range of the percentage of respondents reporting each barrier. A description of each category of barriers and the surveys that investigated these barriers, which are not included in the print version of this article but are available online, are listed in Tables 2 through 11 and are discussed below. Table 2 is available at http://www.jama.com and Tables 3 through 11 are available at http://www.ped.med.umed.edu/RESEARCH/cabana/tables.htm or on request from the authors.

Adherence Barriers Identified by Studies

Lack of Awareness. Forty-six surveys[5,11-40] measured lack of awareness as a possible barrier (Table 2). Sample size ranged from 69 to 2860 (median, 392), and the response rate ranged from 26% to 95% (median, 54.5%). The sample size and response rate were not reported in 1 of the studies.[19] The percentage of respondents identifying lack of awareness as a barrier was as high as 84% (United States Preventive Services Task Force [USPSTF] guidelines[16]) and as low as 1% (asthma guidelines[30] and measles immunization guidelines[40]) with a median of 54.5%. In 36 (78%) of the 46 surveys, at least 10% of the respondents were not aware of the guideline.

Lack of Familiarity. Thirty-one surveys[12-15,41-50] measured lack of familiarity as a possible barrier. Sample size ranged from 69 to 1513 (median, 326), and the response rate ranged from 49% to 98% (median, 60%). The percentage of respondents suggesting lack of familiarity as a barrier was as high as 89% (American College of Physicians exercise stress testing guidelines[41]) and as low as 0% (asthma guidelines[46]) with a median of 56.5%. In 28 (90%) of the 31 surveys, at least 10% of the respondents were not familiar with guideline recommendations.

Lack of Agreement. Thirty-three surveys[15,16,28,38,40,41,43,48,51-64] investigated 47 possible reasons for lack of agreement as a barrier to adherence to specific guidelines. At least 10% of the respondents disagreed with a guideline due to differences in interpretation of the evidence (2/2 cases), the belief that the benefits were not worth patient risk, discomfort, or cost (9/11 cases), applicability to the practice population (5/7 cases), that guidelines were oversimplified or "cookbook" (5/5 cases), or that guidelines reduced autonomy (1/1 case). In 18 cases, a reason for disagreement was not specified. In 8 of these cases, disagreement was reported by at least 10% of the respondents. Finally, 2 surveys investigated disagreement due to lack of credibility by guideline authors and 1 investigated the perception that the authors were biased. In all 3 cases, disagreement was less than 10%.

The percentage of respondents identifying lack of agreement as a barrier for a specific guideline was as high as 91% (American Academy of Pediatrics ribavirin recommendations[57]) and as low as 1% (American Cancer Society Clinical Breast Examination[53] and USPSTF

counseling of fat and cholesterol intake[56]). In 29 (62%) of the 47 cases, at least 10% of the respondents reported lack of agreement.

Fifteen surveys[5,15,17,20,41,65-74] investigated 43 possible examples of lack of agreement as a barrier to adherence to guidelines in general. At least 10% of the respondents disagreed with a guideline due to the perception that guidelines were oversimplified or "cookbook" (9/9 cases), would reduce autonomy (10/12 cases), were not practical (3/3 cases), were biased (4/4 cases), would decrease physicians' self-respect (1/1 case), were not applicable to a practice population (3/3 cases), would decrease flexibility (7/7 cases), lacked credible authors (1/1 case), or would make the patient-physician relationship impersonal (1/1 case). Thirty-eight percent of respondents reported a lack of agreement in 1 case for which a reason for disagreement was not specified.

The percentage of respondents identifying lack of agreement as a barrier to adherence for guidelines in general was as high as 85% (lack of credibility) and as low as 7% (perceived reduction in autonomy). In 41 (95%) of the 43 cases, at least 10% of respondents reported lack of agreement as a barrier to adherence to guidelines in general.

Lack of Self-efficacy. Nineteen surveys[18,21,51,62,63,75-77] measured lack of physician self-efficacy as a possible barrier. Sample size ranged from 23 to 941 (median, 633), and the response rate ranged from 53% to 85% (median, 63%). The response rate was not reported in 3 studies. The percentage of respondents identifying this barrier was as high as 65% (nutrition education[18]) and as low as 1% (general exercise counseling[76]) with a median of 13%. In 15 (79%) of the 19 surveys, at least 10% of the respondents reported a lack of self-efficacy.

Lack of Outcome Expectancy. Eight surveys[48,51,58,59,62,63,75,78] measured lack of outcome expectancy as a possible barrier. Sample size ranged from 97 to 480 (median, 237), and the response rate ranged from 47% to 85% (median, 69.5%). The percentage of respondents identifying this barrier to adherence was as high as 90% (alcohol abuse prevention[66]) and as low as 8% (clinical breast examination[51]) with a median of 26%. In 7 (88%) of the 8 surveys, at least 10% of the respondents reported a lack of outcome expectancy.

Inertia of Previous Practice. Fourteen surveys[38,40,62,79] measured the inertia of previous practice as a possible barrier. Sample size ranged from 141 to 1421 (median, 745), and the response rate ranged from 66% to 81% (median, 67%). The percentage of respondents identifying this barrier was as high as 66% (infant sleeping position[38]) and as low as 23% (immunizations[40]) with a median of 42%. In all the surveys more than 10% of the respondents reported the inertia of previous practice as a barrier.

External Barriers. Thirty-four surveys* investigated 85 possible external barriers that affect the ability to perform a guideline recommendation. External barriers fell into 3 categories: guideline related (n = 23), patient related (n = 17), and environmental (n = 45). At least 10% of respondents described guidelines as not easy to use (1/2 cases), not convenient (6/11 cases), cumbersome (2/4 cases), and confusing (2/6 cases). In all surveys of patient-related factors, at least 10% of the respondents indicated that the factor was a barrier. In all surveys about environmental factors, at least 10% of respondents indicated that the environmental factors were barriers to adherence, except for lack of time (only 11/17 cases) and insufficient staff or consultant support (3/4 cases).

Qualitative Studies

Five qualitative studies[84-88] investigated barriers adherence. Four[84,85,87,88] of the 5 studies emphasized external barriers (patient characteristics or time constraints) as barriers to adherence. Lack of optimism in the success of counseling, which suggests poor outcome expectancy, was a major barrier for Agency for Health Care Policy and Research smoking cessation guidelines.[86]

*References 16-18, 23, 28, 29, 32, 36, 38, 40, 41, 43, 47, 48, 50, 51, 54, 58, 61-63, 68, 70, 72, 75, 78, 80-83.

COMMENT

Physician adherence is critical in translating recommendations into improved outcomes. However, a variety of barriers undermine this process. Lack of awareness and lack of familiarity affect physician knowledge of a guideline. In terms of physician attitudes, lack of agreement, self-efficacy, outcome expectancy, and the inertia of previous practice are also potential barriers. Despite adequate knowledge and attitudes, external barriers can affect a physician's ability to execute recommendations.

Barriers to Physician Adherence

Lack of Awareness. The expanding body of research makes it difficult for any physician to be aware of every applicable guideline and critically apply it to practice.[89,90] Although many guidelines have achieved wide awareness (ie, immunization guidelines, recommendations for infant sleeping position), for 78% of the guidelines, more than 10% of physicians are not aware of their existence.

Lack of Familiarity. Casual awareness does not guarantee familiarity of guideline recommendations and the ability to apply them correctly. Of 74 surveys that measured guideline awareness or familiarity, only 3 (4%) also measured both.[12-14] In all cases, lack of familiarity was more common than lack of awareness.

Lack of Agreement. Physicians may not agree with a specific guideline or the concept of guidelines in general. Although physicians commonly indicate a lack of agreement when asked about guidelines in theory, from this analysis and others, when asked about specific guidelines, physician lack of agreement is less common.[15] The results of studies that examine physician attitudes to guidelines in general should be interpreted with caution when applied to specific guidelines.

Lack of Self-efficacy. Self-efficacy is the belief that one can actually perform a behavior. It influences whether a behavior will be initiated and sustained despite poor outcomes.[91] For example, higher self-efficacy in prescribing cholesterol-lowering medications was associated with physicians initiating therapy consistent with national guidelines.[92] Low self-efficacy due to a lack of confidence in ability or a lack of preparation may lead to poor adherence. Sixty-eight percent of the surveys that reported this barrier involved preventive health education and counseling, which suggests that poor self-efficacy may be a common barrier to adherence for such guidelines.

Lack of Outcome Expectancy. Outcome expectancy is the expectation that a given behavior will lead to a particular consequence.[91] If a physician believes that a recommendation will not lead to an improved outcome, the physician will be less likely to adhere. For example, the USPSTF recommends that physicians provide smoking cessation counseling.[93] Although most physicians are aware of and agree with the recommendation,[94] many smokers are not counseled to quit during a physician visit.[95,96] An important reason for physician nonadherence is a belief that the physician will not succeed.[97,98]

Although counseling may increase a population's quit rate from 3% to only 5%,[99] given smoking prevalence even this small change is enormously beneficial.[100] However, since physicians see patients individually, they may not discern success at the population level. Overlooking population-level successes can negatively influence outcome expectancy and lead to nonadherence. Seventy-five percent of surveys reporting lack of outcome expectancy, such as those reporting lack of self-efficacy, involved preventive health counseling and education guidelines.

Inertia of Previous Practice. Physicians may not be able to overcome the inertia of previous practice, or they may not have the motivation to change. Although this barrier has not been investigated as widely as others, for all 14 surveys that examined this barrier, more than 20% of respondents indicated that it was a barrier to adherence.

The readiness for change model, developed by Prochaska and DiClemente,[101] describes behavior change as a continuum of steps that include precontemplation, contemplation, preparation, action, and maintenance[101] and was applied to physician attitudes toward cancer screening guidelines. The results suggest that close to half of physicians surveyed were in a precontemplation stage and not ready to change behavior (ie, adopt guideline recommendations).[79] The change process model described by Geertsma et al[102] and the theory of learning and change model described by Fox et al[103] also suggest similar constructs, ie, a priming phase and the need for an initial force for change, professional, personal, and/or social.

External Barriers. Appropriate knowledge and attitudes are necessary but not sufficient for adherence.[80] A physician may still encounter barriers that limit his/her ability to perform the recommended behavior due to patient, guideline, or environmental factors.

External barriers that limit the ability to perform a recommended behavior are distinct from lack of self-efficacy. For example, well-trained physicians confident about their counseling skills can still be affected by external barriers (time limitations, lack of a reminder system) that prevent them from adhering to a counseling guideline. However, the persistence of these barriers may also eventually affect physicians' self-efficacy, outcome expectancy, or motivation (Figure).

Guideline-Related Barriers. Physicians were more likely to describe guidelines as not easy to use or not convenient when asked about guidelines in theory. When physicians were asked about barriers for specific guidelines, a significant percentage (more than 10% of respondents) described them as inconvenient or difficult to use in only 6 (38%) of 16 cases.

Other guideline characteristics may also affect adherence. Guidelines recommending elimination of an established behavior may be more difficult to follow than guidelines that recommend adding a new behavior.[104] Trialability of a guideline and its complexity are also described as significant predictors of adoption.[105] *Trialability* is "the degree to which an innovation may be experimented with on a limited basis."[106]

Patient-Related Barriers. The inability to reconcile patient preferences with guideline recommendations is a barrier to adherence.[107] Patients may be resistant or perceive no need for guideline recommendations. In addition, a patient may perceive the recommendation as offensive or embarrassing. In all the surveys that included patient-related factors, more than 10% of physicians indicated them as a barrier to adherence.

Environmental-Related Barriers. Adherence to practice guidelines[108] "may require changes not under physician control, such as acquisition of new resources or facilities."[108,109] For example, unavailability of an anesthesiologist 24 hours a day may interfere with physician ability to adhere to guidelines aimed at decreasing the rate of elective cesarean deliveries.[109] Many factors described as barriers by more than 10% of respondents, such as lack of a reminder system, lack of counseling materials, insufficient staff or consultant support, poor reimbursement, increased practice costs, and increased liability, may also be factors beyond physician control.

With adequate resources or referral privileges, physicians may be able to compensate for other external barriers. Although lack of time is commonly described as a barrier to adherence by more than 10% of respondents (11/17 cases), time limitations were not a barrier for mammography referral or breast examination guidelines (4 surveys), management of fever (1 survey), and hyperbilirubinemia (1 survey).

Limitations

Because this review only includes published articles, it is susceptible to pub-

lication bias.[110] All included articles, except 5 qualitative studies[84-88] were surveys using closed-ended questions, and the barriers examined were dependent on investigator selection. For example, physician discomfort with uncertainty, a compulsion to treat (despite the lack of effective interventions), opinion leaders who may have nonevidence-based opinions, pharmaceutical representatives, and fear of standing out may all be additional barriers but were not specifically investigated in the included studies.

In addition, surveys of barriers depend on physicians' perceptions of them. The perceptions may not accurately reflect how problematic the barrier actually is. Whether the problem is actual or perceived may also affect the type of intervention needed to overcome the barrier.

Finally, barriers to adherence in different situations may facilitate adherence. For example, although patient pressure may be a barrier to adherence in some cases, patient requests for mammograms may improve physician adherence to mammography referral guidelines.[51]

Implications

Our results suggest several implications for guideline implementation and research. This analysis offers a differential diagnosis of why physicians may not follow clinical practice guidelines. There are a variety of barriers to guideline adherence, which include lack of awareness, lack of familiarity, lack of agreement, lack of self-efficacy, lack of outcome expectancy, the inertia of previous practice, and external barriers.

Few studies consider the variety of barriers that must be overcome to achieve adherence. Although we found 76 articles that included 120 surveys investigating possible barriers to guideline adherence, 70 (58%) of the 120 surveys examined only 1 type of barrier. By not considering the variety of barriers, interventions to improve adherence are less likely to address these factors and are less likely to be successful.

In addition, the interpretation of successful interventions to improve physician adherence should be reviewed carefully. Strategies successful in one setting (in which a single external barrier exists—eg, lack of a reminder system) may be less useful in a setting where barriers differ (eg, poor physician knowledge and attitudes in addition to the lack of a reminder system). This framework might be useful to standardize the reporting of barriers to adherence. Just as clinical trials report baseline patient comorbidities in treatment and control groups, interventions to improve adherence should report baseline barriers to adherence. The effectiveness of interventions to improve adherence is dependent not only on the intervention itself but also on the existence and intensity of baseline barriers.

It is difficult to compare any framework with other similar frameworks or checklists.[41,42] However, this framework is based on a comprehensive review, which is specific to physician guideline adherence. In addition, it incorporates different behavioral constructs. Unlike the awareness to adherence model, which is based on immunization guideline adherence, this framework incorporates self-efficacy and outcome expectancy, which are important considerations in improving adherence to other preventive health guidelines, besides immunizations.[40] Focusing on barriers to adherence may also be more direct in improving physician behavior, instead of investigating predisposing factors, which may be too broad in helping select possible interventions.[111]

In summary, this review offers a differential diagnosis for why physicians do not follow practice guidelines. Few studies consider this diversity of barriers that we describe. By not entertaining the full spectrum of barriers, important interventions to improve physician behavior might not be investigated or implemented. This framework may also be useful to help document the generalizability of studies used to improve guideline adherence.

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The beauty and genius of a work of art may be reconceived, though its first material expression be destroyed; a vanished harmony may yet again inspire the composer; but when the last individual of a race of living things breathes no more, another heaven and another earth must pass before such a one can be again.
—Charles William Beebe (1877-1962)

Table 1. Surveys of Barriers to Adherence: Types of Guidelines Studied, Characteristics, and Percentage of Respondents Reporting Barrier*

Barrier Examined	Total No. of Studies	By Author			By Subject				% of Surveys That Include Primary Care Physicians	% of Surveys That Include Physicians in United States	% of Respondents Reporting Barrier (Median) Range
		Government	Professional Organization	Other	Immunization	Screening Prevention Tests	Treatment	Other Combination			
Lack of awareness	46	16	9	19	7	10	19	10	0.8	0.63	54.5 (1-84)
Lack of familiarity	31	6	14	11	3	13	12	3	0.77	0.77	66.5 (9-89)
Lack of agreement (with specific guideline)											
No reason specified	30	7	0	23	7	23	0	0	1.00	1.00	8 (1-48)
Interpretation of evidence	2	0	2	9	0	1	1	0	0.50	1.00	68 (45-91)
Benefits not worth patient risk, discomfort, or cost	11	1	1	9	1	8	2	0	0.82	0.82	6 (2-62)
Not applicable to practice population	7	3	1	3	0	2	5	0	0.56	0.71	10 (4-59)
Credibility of authors questioned	2	0	1	1	0	0	2	0	0.00	0.50	7.5 (6-9)
Guideline authors biased	1	0	1	0	0	0	1	0	0.00	1.00	– (6)
Oversimplified cookbook	5	2	1	2	0	1	4	0	0.80	0.80	25 (15-33)
Reduces autonomy	1	0	0	1	0	1	0	0	1.00	0.00	– (13)
Lack of agreement (guidelines in general)											
No reason specified	1	...	...	...	...	...	...	...	1.00	0.00	... (38)
Oversimplified cookbook	9	...	...	...	...	...	...	...	0.89	0.44	22 (14-43)
Not applicable to practice population	3	...	...	...	...	...	...	...	0.67	0.33	20 (12-26)
Reduces autonomy	13	...	...	...	...	...	...	...	0.92	0.54	21 (7-60)
Biased synthesis	4	...	...	...	...	...	...	...	1.00	0.25	39.5 (16-66)
Decreases physician's self-respect	1	...	...	...	...	...	...	...	0.00	0.00	... (22)
Decreases flexibility	7	...	...	...	...	...	...	...	0.86	0.57	24 (10-60)
Credibility of authors questioned	1	...	...	...	...	...	...	...	1.00	0.00	... (15)
Not practical	3	...	...	...	...	...	...	...	1.00	0.33	49 (13-70)
Makes patient-physician relationship impersonal	1	...	...	...	...	...	...	...	0.00	0.00	... (13)
Lack of self-efficacy	19	12	1	6	0	13	5	1	0.89	0.63	13 (1-65)
Lack of outcome expectancy	8	4	0	4	0	6	2	0	1	0.63	26 (8-90)
Inertia of previous practice	14	11	1	2	1	12	1	0	1	0.93	42 (23-66)
External barriers (guideline-related)											
Not easy to use	2	0	0	2	0	0	1	1	0.5	0.5	17 (7-27)
Not convenient	11	2	1	8	0	1	4	6	0.91	0.55	11 (2-72)
Cumbersome	4	2	1	1	0	1	3	0	1	1	10 (4-16)
Confusing	6	3	1	2	1	2	3	0	1	1	4.5 (3-80)
External barriers (patient-related)											
Patient resistance/noncoherance	11	4	2	5	3	6	2	0	1	0.66	28 (12-70)
Patient does not perceive need	3	0	0	3	2	1	0	0	1	0.66	70 (45-84)
Perceived to be offensive to patient	1	1	0	0	0	1	0	0	1	1	16
Causes patient embarrassment	2	1	0	1	0	1	1	0	1	1	22 (18-26)
External barriers (related to practice setting)											
Lack of reminder system	1	0	0	1	0	1	0	0	1	0	45
Lack of educational materials	1	1	0	0	0	1	0	0	1	0	48
Cost to patient	7	0	1	6	2	4	1	0	1	0.86	31 (14-80)
Lack of insurance coverage	3	0	0	3	0	3	0	0	1	1	30 (29-65)
Cost to practice	2	0	0	2	2	0	0	0	1	1	39 (26-52)
Insufficient staff or consultant support	4	0	1	3	0	3	1	0	1	1	21 (7-25)
Lack of time	17	5	1	10	1	11	5	0	0.94	0.71	20 (2-73)
Lack of reimbursement	8	3	1	2	0	4	2	0	1	0.5	41 (15-52)
Not compatible with practice home setting	2	1	1	0	0	1	1	0	1	0.5	30 (12-48)
Increased malpractice liability	2	1	0	1	1	1	0	0	1	1	13 (12-14)

*Government indicates number of surveys that studied guidelines authored by a government agency; Professional Organization, number of surveys that studied guidelines authored by a professional organization; Other, number of surveys that studied guidelines by a combination of authors or a nongovernment and nonprofessional organization; Immunization, the number of surveys that studied guidelines whose subject matter was immunizations; Screening Prevention, the number of surveys that studied guidelines whose subject matter was the use of screening tests or prevention, except immunizations; Treatment, the number of surveys that studied guidelines whose subject matter was treatment or management of a disease; Other Combination, the number of surveys that studied guidelines whose subject matter was a combination of Immunizations; Screening/Prevention and/or Treatment.

Table 2. Physician Surveys That Investigate Lack of Awareness as a Possible Barrier to Guideline Adherence

Guideline Author*	Subject of Guideline†	Specialty‡	Practice Location	Study Date§	No. (%)‖	% Not Aware of Guideline
USPSTF	Preventive care	P	US, national	. . .	300 (54)	84
. . .	Practice guidelines (general)	A, P, S, I, O, G, E	United Kingdom	1993-1994	268 (66)	79
BFNE	Obesity treatment	GP	the Netherlands	1992	633 (63)	77
RCP	Urinary tract infections	GP	Great Britain	1995	NR	74
AHCPR	Incontinence	FP	US, New York	1994	519 (53)	70
AHCPR	Pressure ulcers (treatment)	FP	US, Minnesota	1995	155 (53)	70
AHCPR	Pressure ulcers	FP	US, New York	1994	519 (53)	70
AHCPR	Pressure ulcers (prevention)	FP	US, Minnesota	1995	155 (53)	67
AHCPR	Depression	FP	US, New York	1994	519 (53)	66
NHLBI	Asthma management	EDD	US, national	1992	373 (68)	54
Italian National Task Force	Ovarian cancer treatment	ON	Italy	1986	770 (41)	54
Italian National Task Force	Colorectal cancer treatment	ON	Italy	1986	770 (41)	53
ACEP	Chest pain	E	US, national	1993	338 (62)	52
CDC	Hepatitis B immunization	FP	US, North Carolina	1992	153 (78)	52
AHCPR	Otitis media	P	US, national	. . .	300 (54)	50
USPSTF	Preventive care	FP	US, Ohio	1990	898 (50)	44
Italian National Task Force	Breast cancer treatment	ON	Italy	1986	770 (41)	40
NIH	Hypertension	FP, GP, I	US, Maryland	1984	262 (44)	38
. . .	Management of fever	P	US, national	. . .	300 (54)	36
AAP	Hyperbilirubinemia	P	US, national	. . .	300 (54)	34
NIH	Consensus development program	GP, FP, I, S, O	US, national	1984	1453 (72)	34
AAP	Tuberculosis	P, FP	US, mid-Atlantic	1994	762 (66)	25
USPSTF	Preventive care	FP	US, national	1992	263 (55)	24
NHMRC	Breast cancer	S, ON	Australia	1996	69 (77)	20
CDC	Hepatitis B immunization	P	US, North Carolina	1992	542 (78)	18
CDC	Lead poisoning	P	US, national	1993	826 (52)	17
RCR	Use of radiology department	GP	Great Britain	1995	300 (54)	17
NCEP	Elevated cholesterol level	FP, GP, O, I, P	US, Florida	1989	1909 (26)	17
NIH	Breast cancer screening	PC	US, North Carolina	1994	545 (42)	17
AAP, ACIP	*Haemophilus influenza* b vaccination	P, FP, GP	US, New Mexico	1985	369 (95)	15
CPSO	Deep venous thrombosis	I	Canada	1988	392 (26)	15
MFR & SPRI	Swedish consensus conference (7 topics)	O, P, S, I, E	Sweden	1985	2860 (86)	6-14
Canadian Consensus Conf.	Cesarean delivery	O	Canada	1988	160 (80)	13
OMA	Thrombolytic drugs	I	Canada	1988	392 (26)	12
DCGP	Cervical cancer screening	GP	the Netherlands	1993	293 (79)	11
AAP, ACIP, CDC	Pertussis vaccination	FP, P	US, national	1993	1421 (66)	10
DCGP	Cholesterol management	GP	the Netherlands	1992	633 (63)	9
. . .	Practice guidelines (general)	FP	US, national	. . .	205 (51)	8
NCEP	Elevated cholesterol level	GP, FP, I, C	US, national	1990	1604 (54)	8
Canadian Consensus Conference	Cesarean delivery	O	Canada	1986	160 (80)	6
AAP	Infant sleeping position	P	US, New York	1994	121 (61)	2
AAGBI	Anesthesia monitoring	A	United Kingdom	. . .	202 (69)	2
AAP, ACIP, CDC	*H influenza* b vaccination	FP, P	US, national	1993	1421 (66)	2
AAP, ACIP, CDC	Hepatitis B vaccination	FP, P	US, national	1993	1421 (66)	2
AAP, ACIP, CDC	Measles vaccination	FP, P	US, national	1993	1421 (66)	1
British Thoracic Society	Asthma	GP	Great Britain	1995	300 (54)	1

*Guideline authors (listed alphabetically): AAFP indicates American Academy of Family Practice; AAP, American Academy of Pediatrics; ACEP, American College of Emergency Physicians; ACIP, Advisory Committee on Immunization Practices; ACOG, American College of Obstetricians and Gynecologists; ACP, American College of Physicians; ACS, American Cancer Society; ACSM, American College of Sports Medicine; AHCPR, Agency for Health Care Policy and Research; BAAEP, British Association for Accident and Emergency Physicians; BFNE, Bureau of Food and Nutrition Education; BTS, British Thoracic Society; CDC, Centers for Disease Control and Prevention; CPSO, College of Physicians and Surgeons of Ontario, Canada; CTF, Canadian Task Force; CTFPHE, Canadian Task Force on Periodic Health Examination; DCGP, Danish College of General Practitioners; HCFA, Health Care Financing Administration; JNC, Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure; MFR, Swedish Medical Research Council; NCI, National Cancer Institute; NHG, Netherlands Huisartsen Genootschap; NHMRC, National Health and Medical Research Council, Australia; NCEP, National Cholesterol Education Program; NIA, National Institute on Aging; NIH, National Institutes of Health; OMA, Ontario Medical Association, Canada; RCP, Royal College of Physicians, Great Britain; RCR, Royal College of Radiologists, Great Britain; SPRI, Swedish Planning and Rationalization Institute for the Health and Social Sciences; UK Toxicology Group, United Kingdom Toxicology Group Expert Workshop; and USPSTF, US Preventive Services Task Force.

†Subject of Guideline abbreviations: GBS indicates group B Streptococcus; DTP, diphtheria tetanus pertussis.

‡Specialty abbreviations (alphabetically): A indicates anesthesiology; C, cardiology; E, emergency medicine; EDD, emergency department directors; FP, family practice; G, gynecology; GP, general practice; I, internal medicine; ID infectious disease; O, obstetrics; ON, oncology; P, pediatrics; PC, primary care; PIC, pediatric intensive care; R, radiology; S, surgery; and U, urology.

§Study Date refers to the year that data collection was started. Ellipses indicates study date not reported.

‖Number in parentheses indicates overall response rate.

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Clinical guidelines
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Potential benefits, limitations, and harms of clinical guidelines

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This is the first in a series of four articles on issues in the development and use of clinical guidelines

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Over the past decade, clinical guidelines have increasingly become a familiar part of clinical practice. Every day, clinical decisions at the bedside, rules of operation at hospitals and clinics, and health spending by governments and insurers are being influenced by guidelines. As defined by the Institute of Medicine, clinical guidelines are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."[1] They may offer concise instructions on which diagnostic or screening tests to order, how to provide medical or surgical services, how long patients should stay in hospital, or other details of clinical practice.

The broad interest in clinical guidelines that is stretching across Europe, North America, Australia, New Zealand, and Africa (box) has its origin in issues that most healthcare systems face: rising healthcare costs, fueled by increased demand for care, more expensive technologies, and an ageing population; variations in service delivery among providers, hospitals, and geographical regions and the presumption that at least some of this variation stems from inappropriate care, either overuse or underuse of services; and the intrinsic desire of healthcare professionals to offer, and of patients to receive, the best care possible. Clinicians, policy makers, and payers see guidelines as a tool for making care more consistent and efficient and for closing the gap between what clinicians do and what scientific evidence supports.

As guidelines diffuse into medicine, there are important lessons to learn from the firsthand experience of those who develop, evaluate, and use them.[3] This article, the first of a four part series to reflect on these lessons, examines the potential benefits, limitations, and harms of clinical guidelines. Future articles will review lessons learned about their development,[4] legal and emotional ramifications,[5] and finally their implementation.[6]

Summary points

- Clinical guidelines are an increasingly familiar part of clinical practice
- They have potential benefits and harms
- Rigorously developed evidence based guidelines minimise the potential harms
- Clinical guidelines are only one option for improving the quality of care

Potential benefits of clinical practice guidelines

Go to:

The principal benefit of guidelines is to improve the quality of care received by patients. Although it has been shown in rigorous evaluations that clinical practice guidelines can improve the quality of care,[7,8] whether they achieve this in daily practice is less clear. This is partly because patients, doctors, payers, and managers define quality differently and because current evidence about the effectiveness of guidelines is incomplete.

Potential benefits for patients For patients (and almost everyone else in health care), the greatest benefit that could be achieved by guidelines is to improve health outcomes. Guidelines that promote interventions of proved benefit and discourage ineffective ones have the potential to reduce morbidity and mortality and improve quality of life, at least for some conditions. Guidelines can also improve the consistency of care; studies around the world show that the frequency with which procedures are performed varies dramatically among doctors, specialties, and geographical regions, even after case mix is controlled for.[9] Patients with

identical clinical problems receive different care depending on their clinician, hospital, or location. Guidelines offer a remedy, making it more likely that patients will be cared for in the same manner regardless of where or by whom they are treated.

Overview of international activity on guidelines

More details in the form of a full paper are available on the *BMJ*'s website.	*Germany, Italy, and Spain*—Guidelines are on the rise in Germany and Italy, where a guidelines database is being developed to support national healthcare reform. In Spain, the Catalan Agency for Health Technology Assessment has begun preparing guidelines and teaches methods of guideline development. Consensus guidelines figure prominently in Catalonian healthcare reform.
Europe	**North America**
United Kingdom—Guidelines have existed in England for decades; recent years have heightened interest in guidelines as a tool for implementing health care based on proof of effectiveness. Professional bodies, encouraged by the NHS, are producing guidelines for use by providers to improve care and by purchasers to guide contracting and commissioning decisions. The NHS is now using a critical appraisal instrument to determine which guidelines to commend to health authorities. Although historically most British guidelines have derived from consensus conferences or expert opinion, there is growing interest in using explicit methods to develop evidence based guidelines. The Scottish Intercollegiate Guideline Network uses a systematic multidisciplinary approach to prepare evidence based guidelines. National guidelines are converted at the local level into formats that encourage adoption in practice.	Guidelines, protocols, and care pathways developed by professional societies and other groups are common in American hospitals and health plans, where they are used for quality improvement and cost control. Although some evidence based guidelines produced by government panels and medical societies have received prominent attention, many healthcare organisations purchase commercially produced guidelines that emphasise shortened lengths of stay and other resource savings. Canadian health care is largely state funded, but a similar proportion of organisations as in the United States use guidelines. The massive guideline industry in America has created special problems such as information overload. Directories and newsletters have become necessary to monitor the hundreds of guideline topics and sponsoring organisations. Americans have articulated evidence based methods in manuals and other reports. This expertise has not always found its way into actual guidelines—most of which remain rooted in consensus or opinion.
The Netherlands—In the Netherlands, the Dutch College of General Practitioners has produced guidelines since 1987, issuing more than 70 guidelines at a rate of 8-10 topics per year. A rigorous procedure involves an analysis of the scientific literature, combined with consensus discussions among ordinary general practitioners and content experts. A systematic implementation programme follows guideline development. Updating of the guidelines has recently begun. Guidelines figure prominently in Dutch health policy.	**Australia and New Zealand**
Finland and Sweden—In Finland, national and local bodies have issued more than 700 guidelines since 1989. A programme for evidence based guideline development has been started recently. Guidelines in Sweden appear in reports by the Swedish Council on Technology Assessment in Health Care, an internationally consulted technology assessment agency, and in recommendations from other government bodies.	Guidelines in Australia date to the late 1970s, when the state health authority began endorsing guideline booklets,[2] and they continue on a large scale today. There is an increasing emphasis on the need for evidence based methods.
France—In France, the Agence Nationale de l'Accréditation et d'Évaluation en Santé has published over 100 guidelines based on consensus conferences or modified guidelines from other countries. It has also developed more than 140 références médicales, guidelines on procedural indications for use in setting coverage policy. The guidelines are disseminated through networks of general practitioners, and their effectiveness is evaluated through local audits.	Guidelines in New Zealand emanate directly from national health policy. New Zealand's choosing to restrict services at the point of service through guidelines received international attention in debates about rationing. One guideline on hypertension and a subsequent cholesterol guideline from the New Zealand National Heart Foundation broke new ground methodologically by linking recommendations to patients' absolute risk probabilities rather than to generic treatment criteria .

Clinical guidelines offer patients other benefits. Those accompanied by "consumer" versions (leaflets, audiotapes, or videos in lay language) or publicised in magazines, news reports, and internet sites inform patients and the public about what their clinicians should be doing. Increasingly, lay guidelines summarise the benefits and harms of available options, along with estimates of the probability or magnitude of potential outcomes.[10] Such guidelines empower patients to make more informed healthcare choices and to consider their personal needs and preferences in selecting the best option. Indeed, clinicians may first learn about new guidelines (or be reminded of oversights) when patients ask about recommendations or treatment options.

Finally, clinical guidelines can help patients by influencing public policy. Guidelines call attention to underrecognised health problems, clinical services, and preventive interventions and to neglected patient populations and high risk groups. Services that were not previously offered to patients may be made available as a response to newly released guidelines. Clinical guidelines developed with attention to the public good can promote distributive justice, advocating better delivery of services to those in need. In a cash limited healthcare system, guidelines that improve the efficiency of health care free up resources needed for other (more equitably distributed) healthcare services.

Potential benefits for healthcare professionals Clinical guidelines can improve the quality of clinical decisions. They offer explicit recommendations for clinicians who are uncertain about how to proceed, overturn the beliefs of doctors accustomed to outdated practices, improve the consistency of care, and provide authoritative recommendations that reassure practitioners about the appropriateness of their treatment policies. Guidelines based on a critical appraisal of scientific evidence (evidence based guidelines) clarify which interventions are of proved benefit and document the quality of the supporting data. They alert clinicians to interventions unsupported by good science, reinforce the importance and methods of critical appraisal, and call attention to ineffective, dangerous, and wasteful practices.

Clinical guidelines can support quality improvement activities. The first step in designing quality assessment tools (standing orders, reminder systems, critical care pathways, algorithms, audits, etc) is to reach agreement on how patients should be treated, often by developing a guideline. Guidelines are a common point of reference for prospective and retrospective audits of clinicians' or hospitals' practices: the tests, treatments, and treatment goals recommended in guidelines provide ready process measures (review criteria) for rating compliance with best care practices.[11]

Medical researchers benefit from the spotlight that evidence based guidelines shine on gaps in the evidence. The methods of guideline development that emphasise systematic reviews focus attention on key research questions that must be answered to establish the effectiveness of an intervention[12] and highlight gaps in the known literature. Critical appraisal of the evidence identifies design flaws in existing studies. Recognising the presence and absence of evidence can redirect the work of investigators and encourage funding agencies to support studies that fulfill this effectiveness based agenda.

Finally, some uses of clinical guidelines straddle the boundary between benefits and harms. Clinicians may seek secular (and even self serving) benefits from guidelines. In some healthcare systems, guidelines prompt government or private payers to provide coverage or to reimburse doctors for services. Specialties engaged in "turf wars" to gain ownership over specific procedures or treatments may publish a guideline to affirm their role. Clinicians may turn to guidelines for medicolegal protection or to reinforce their position in dealing with administrators who disagree with their practice policies.

Potential benefits for healthcare systems Healthcare systems that provide services, and government bodies and private insurers that pay for them, have found that clinical guidelines may be effective in improving efficiency (often by standardising care) and optimising value for money.[13] Implementation of certain guidelines reduces outlays for hospitalisation, prescription drugs, surgery, and other procedures. Publicising adherence to guidelines may also improve public image, sending messages of commitment to excellence and quality. Such messages can promote good will, political support, and (in some healthcare systems) revenue. Many believe that the economic motive behind clinical guidelines is the principal reason for their popularity.

Potential limitations and harms of guidelines

The most important limitation of guidelines is that the recommendations may be wrong (or at least wrong for individual patients). Apart from human considerations such as inadvertent oversights by busy or weary members of the guideline group, guideline developers may err in determining what is best for patients for three important reasons.

Firstly, scientific evidence about what to recommend is often lacking, misleading, or misinterpreted. Only a small subset of what is done in medicine has been tested in appropriate, well designed studies. Where studies do exist, the findings may be misleading because of design flaws which contribute to bias or poor generalisability. Guideline development groups often lack the time, resources, and skills to gather and scrutinise every last piece of evidence. Even when the data are certain, recommendations for or against interventions will involve subjective value judgments when the benefits are weighed against the harms. The value judgment made by a guideline development group may be the wrong choice for individual patients.

Secondly, recommendations are influenced by the opinions and clinical experience and composition of the guideline development group. Tests and treatments that experts believe are good for patients may in practice be inferior to other options, ineffective, or even harmful. The beliefs to which experts subscribe, often in the face of conflicting data, can be based on misconceptions and personal recollections that misrepresent population norms.[14]

Thirdly, patients' needs may not be the only priority in making recommendations. Practices that are suboptimal from the patient's perspective may be recommended to help control costs, serve societal needs, or protect special interests (those of doctors, risk managers, or politicians, for example).

The promotion of flawed guidelines by practices, payers, or healthcare systems can encourage, if not institutionalise, the delivery of ineffective, harmful, or wasteful interventions. The same parties that stand to benefit from guidelines—patients, healthcare professionals, the healthcare system—may all be harmed.

Potential harms to patients The greatest danger of flawed clinical guidelines is to patients. Recommendations that do not take due account of the evidence can result in suboptimal, ineffective, or harmful practices. Guidelines that are inflexible can harm by leaving insufficient room for clinicians to tailor care to patients' personal circumstances and medical history. What is best for patients overall, as recommended in guidelines, may be inappropriate for individuals; blanket recommendations, rather than a menu of options or recommendations for shared decision making, ignore patients' preferences.[15] Thus the frequently touted benefit of clinical guidelines—more consistent practice patterns and reduced variation—may come at the expense of reducing individualised care for patients with special needs. Lay versions of guidelines, if improperly constructed and worded, may mislead or confuse patients and disrupt the doctor-patient relationship.

Clinical guidelines can adversely affect public policy for patients. Recommendations against an intervention may lead providers to drop access to or coverage for services. Imprudent recommendations for costly interventions may displace limited resources that are needed for other services of greater value to patients. The tendency of guidelines to focus attention on specific health issues is subject to misuse by proponents and advocacy groups, giving the public (and health professionals) the wrong impression about the relative importance of diseases and the effectiveness of interventions.

Potential harms to healthcare professionals Flawed clinical guidelines harm practitioners by providing inaccurate scientific information and clinical advice, thereby compromising the quality of care. They may encourage ineffective, harmful, or wasteful interventions. Even when guidelines are correct, clinicians often find them inconvenient and time consuming to use. Conflicting guidelines from different professional bodies can also confuse and frustrate practitioners.[16] Outdated recommendations may perpetuate outmoded practices and technologies.

Clinical guidelines can also hurt clinicians professionally. Auditors and managers may unfairly judge the quality of care based on criteria from invalid guidelines. The well intentioned effort to make guidelines explicit and practical encourages the injudicious use of certain words ("should" instead of "may," for example), arbitrary numbers (such as months of treatment, intervals between screening tests), and simplistic algorithms when supporting evidence may be lacking. Algorithms that reduce

patient care into a sequence of binary (yes/no) decisions often do injustice to the complexity of medicine and the parallel and iterative thought processes inherent in clinical judgment. Words, numbers, and simplistic algorithms can be used by those who judge clinicians to repudiate unfairly those who, for legitimate reasons, follow different practice policies. Guidelines are also potentially harmful to doctors as citable evidence for malpractice litigation and because of their economic implications. Referral guidelines can shift patients from one specialty to another. A negative (or neutral) recommendation may prompt providers to withdraw availability or coverage. A theoretical concern is that clinicians may be sued for not adhering to guidelines although, as discussed in the third paper in this series,[5] this has not yet become an important reality.

Guidelines can harm medical investigators and scientific progress if further research is inappropriately discouraged. Guidelines that conclude that a procedure or treatment lacks evidence of benefit may be misinterpreted by funding bodies as grounds for not investing in further research and for not supporting efforts to refine previously ineffective technologies.

Potential harms to healthcare systems Healthcare systems and payers may be harmed by guidelines if following them escalates utilisation, compromises operating efficiency, or wastes limited resources. Some clinical guidelines, especially those developed by medical and other groups unconcerned about financing, may advocate costly interventions that are unaffordable or that cut into resources needed for more effective services.

Conclusion

Go to:

In the face of these mixed consequences, attitudes about whether clinical guidelines are good or bad for medicine vary from one group to another. Guidelines produced by governments or payers to control spiraling costs may constitute responsible public policy but may be resented by clinicians and patients as an invasion of personal autonomy. Guidelines developed by specialists may seem self serving, biased, and threatening to generalists. To specialists, guidelines developed without their input do not contain adequate expertise. Inflexible guidelines with rigid rules about what is appropriate are popular with managers, quality auditors, and lawyers but are decried as "cookbook medicine" by doctors faced with non-uniform clinical problems and as invalid by those who cite the lack of supporting data.

These disparate sentiments and the growing awareness of their limitations and harms have done little to stem the rapid promulgation of guidelines around the world (see box). The unbridled enthusiasm for guidelines, and the unrealistic expectations about what they will accomplish, frequently betrays inexperience and unfamiliarity with their limitations and potential hazards. Naive consumers of guidelines accept official recommendations on face value, especially when they carry the imprimatur of prominent professional groups or government bodies.

More discerning users of clinical guidelines scrutinise the methods by which they have been developed.[4] Moreover, a more fundamental problem is that guidelines may do little to change practice behaviour.[6]

Clinical guidelines are only one option for improving the quality of care. Too often, advocates view guidelines as a "magic bullet" for healthcare problems and ignore more effective solutions. Clinical guidelines make sense when practitioners are unclear about appropriate practice and when scientific evidence can provide an answer. They are a poor remedy in other settings. When clinicians already know the information contained in guidelines, those concerned with improving quality should redirect their efforts to identify the specific barriers, beyond knowledge, that stand in the way of behaviour change.

Supplementary Material

Go to:

[extra: Clinical guidelines]

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Footnotes

Go to:

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website *extra*: An additional article—an international overview—is available on our website, as is a longer version of this article **www.bmj.com**

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an affordable cost (some estimates suggest approximately $66 million). This goal is surely one to aspire to, given the human cost of maintaining the status quo.

Eliminating cholera transmission in Haiti with a combined, integrated approach at the population level would be a major achievement for the government and people of Haiti. It would also have broad implications for the control of cholera in other affected populations around the world. The time for ambitious action on cholera control and elimination in Haiti is now.

An audio interview with Dr. Ivers is available at NEJM.org

Disclosure forms provided by the author are available at NEJM.org.

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Care for the Vulnerable vs. Cash for the Powerful — Trump's Pick for HHS

Sherry A. Glied, Ph.D., and Richard G. Frank, Ph.D.

Representative Tom Price of Georgia, an orthopedic surgeon, will be President-elect Donald Trump's nominee for secretary of health and human services (HHS). In the 63-year history of the HHS Department and its predecessor, the Department of Health, Education, and Welfare, only two previous secretaries have been physicians. Otis Bowen, President Ronald Reagan's second HHS secretary, engineered the first major expansion of Medicare, championed comparative effectiveness research and, with Surgeon General C. Everett Koop, led the fight against HIV–AIDS.[1] Louis Sullivan, HHS secretary under President George H.W. Bush, focused his attention on care for vulnerable populations, campaigned against tobacco use, led the development of federally sponsored clinical guidelines,[2] and introduced President Bush's health insurance plan, which incorporated income-related tax credits[3] and a system of risk adjustment. In their work at HHS, both men, serving in Republican administrations, drew on a long tradition of physicians as advocates for the most vulnerable, defenders of public health, and enthusiastic proponents of scientific approaches to clinical care.

Tom Price represents a different tradition. Ostensibly, he emphasizes the importance of making our health care system "more responsive and affordable to meet the needs of America's patients and those who care for them."[4] But as compared with his predecessors' actions, Price's record demonstrates less concern for the sick, the poor, and the health of the public and much greater concern for the economic well-being of their physician caregivers.

Price has sponsored legislation that supports making armor-piercing bullets more accessible and opposing regulations on cigars, and he has voted against regulating tobacco as a drug. His voting record shows long-standing opposition to policies aimed at improving access to care for the most vulnerable Americans. In 2007–2008, during the presidency of George W. Bush, he was one of only 47 representatives to vote

against the Domenici–Wellstone Mental Health Parity and Addiction Equity Act, which improved coverage for mental health care in private insurance plans. He also voted against funding for combating AIDS, malaria, and tuberculosis; against expansion of the State Children's Health Insurance Program; and in favor of allowing hospitals to turn away Medicaid and Medicare patients seeking nonemergency care if they could not afford copayments.

Price favors converting Medicare to a premium-support system and changing the structure of Medicaid to a block grant — policy options that shift financial risk from the federal government to vulnerable populations. He also opposed reauthorization of the Violence Against Women Act and has voted against legislation prohibiting job discrimination against lesbian, gay, bisexual, and transgender (LGBT) people and against enforcement of laws against anti-LGBT hate crimes. He favors amending the Constitution to outlaw same-sex marriage.

In addition, he has been inconsistent in supporting investments in biomedical science. He opposes stem-cell research and voted against expanding the National Institutes of Health budget and against the recently enacted 21st Century Cures Act, showing particular animus toward the Cancer Moonshot.

Price has also been a vociferous opponent of the Affordable Care Act (ACA) and a leader of the repeal-and-replace movement. His proposal for replacing the ACA is H.R. 2300, the Empowering Patients First Act,[5] which would eliminate the ACA's Medicaid expansion and replace its subsidies with flat tax credits based on age, not income ($1,200 per year for someone 18 to 35 years of age; $3,000 for someone 50 or older, with an additional one-time credit of $1,000 toward a health savings account). Price's plan is regressive: it offers much greater subsidies relative to income for purchasers with high incomes and much more meager subsidies for those with low incomes. In today's market, these credits would pay only about one third of the premium of a low-cost plan, leaving a 30-year-old with a premium bill for $2,532, and a 60-year-old with a bill for $5,916 — along with a potential out-of-pocket liability of as much as $7,000. By contrast, subsidies under the ACA are based on income and the price of health insurance. Today, a low-income person (with an income of 200% of the federal poverty level) pays, on average, a premium of $1,528 per year (regardless of age) for a plan with an out-of-pocket maximum of $2,350, and that payment does not change even if health insurance premiums rise.

To put the plan's subsidies into perspective, consider that in 1992, when per capita health expenditures were just one third of what they are today, President Bush and HHS Secretary Sullivan proposed a slightly larger individual tax credit ($1,250) for the purchase of insurance than Price proposes today. Even in 1992, analysts reported that the credit would be insufficient to induce most people to buy coverage.

The Price plan would eliminate the guaranteed-issue and community-rating requirements in the ACA and create anemic substitutes for these commitments to access to comprehensive coverage for Americans with preexisting conditions. These replacements include an extension to the nongroup market of the continuous-coverage rules that have long existed in the group market with little benefit; penalties on reentering the market for anyone who has had a break in coverage; and a very limited offer of funding for states to establish high-risk pools. In combination with relatively small tax credits, these provisions are likely to lead low-income and even middle-class healthy people to forgo seeking coverage until a serious health problem develops. Without the income- and premium-based subsidies in the ACA acting as market stabilizers, Price's provisions would erode the nongroup health insurance market.

Price's plan would withdraw almost all the ACA's federal consumer-protection regulations, including limits on insurer profits and requirements that plans cover essential health benefits. By allowing the sale of health insurance across state lines, the plan would also effectively eliminate all state regulation of health insurance plans, encouraging a race to the bottom among insurance carriers. Finally, Price would fund his plan by capping the tax exclusion for employer-sponsored health insurance at $8,000 per individual or $20,000 per family. These caps are well below those legislated through the Cadillac tax in the ACA, a provision that Price himself has voted to repeal.

In sum, Price's replacement proposal would make it much more difficult for low-income Americans to afford health insurance. It would divert federal tax dollars to people who can already buy individual coverage

without subsidies and substantially reduce protections for those with preexisting conditions. The end result would be a shaky market dominated by health plans that offer limited coverage and high cost sharing.

Whereas Price's actions to date have not reflected the tradition of the physician as advocate for the poor and vulnerable, they do harken back to an earlier tradition in American medicine: the physician advocate as protector of the guild. His Empowering Patients First Act would directly advance physicians' economic interests by permitting them to bill Medicare patients for amounts above those covered by the Medicare fee schedule and allowing them to join together and negotiate with insurance carriers without violating antitrust statutes. Both these provisions would increase physicians' incomes at the expense of patients. Price has consistently fought strategies for value-based purchasing and guideline development, opposing the use of bundled payments for lower-extremity joint replacements and proposing that physician specialty societies hold veto power over the release of comparative effectiveness findings. These positions reduce regulatory burdens on physicians at the cost of increased inefficiency and reduced quality of care — and reflect a striking departure from the ethos of his physician predecessors, Secretaries Bowen and Sullivan.

The HHS Department oversees a broad set of health programs that touch about half of all Americans. Over five decades and the administrations of nine presidents, both Democratic and Republican secretaries have used these programs to protect the most vulnerable Americans. The proposed nomination of Tom Price to HHS highlights a sharp contrast between this tradition of compassionate leadership and the priorities of the incoming administration.

Disclosure forms provided by the authors are available at NEJM.org.

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Patient-Reported Outcomes — Harnessing Patients' Voices to Improve Clinical Care

Ethan Basch, M.D.

Symptom management is a cornerstone of clinical care, particularly for patients with chronic conditions. Yet patients' symptoms and physical impairments go undetected by health care providers as much as half the time, particularly between clinic visits.[1] As a result, we miss opportunities to intervene and alleviate suffering. Moreover, incomplete documentation of this information in the electronic health record (EHR) limits our ability to understand key patient outcomes when we aggregate EHR data for comparative effectiveness research or quality-of-care assessments.[2]

Recent advances in technology and survey methods provide a potential solution in the form of patient-reported outcomes (PROs) recorded electronically — using simple but methodologically robust questionnaires, completed by patients at or between visits over the Internet or on a smart device, with data transmitted into the EHR.[3] Clinicians can receive automated notifications about worrisome symptoms or functional issues, such as severe dyspnea or reduced physical activity in an outpatient with heart failure. They can review longitudinal PRO reports at visits and import that information into their EHR notes as a part of the review of systems. There is evidence that this approach can improve patients' quality of life, enhance patient–clinician communication, reduce emergency de-

2015 State of the Line—Analysis of Workers Compensation Results

By Kathy Antonello, FCAS, FSA, MAAA, Chief Actuary, National Council on Compensation Insurance, Inc.

In some ways, workers compensation insurance is unique as a line of business because it endeavors to balance the interests of numerous system stakeholders—including injured employees and their families, employers, insurance companies, medical providers, regulators, and states—in their efforts to protect and retain jobs. Understanding the detailed interactions and dependencies among the various system participants allows an in-depth appreciation of the shared social and economic implications innate to this line of insurance.

Throughout its history, these interdependencies have contributed to several significant transformations in our industry. Workers compensation claim frequency has dropped more than 50% over the last 20 years, underscored by dramatic improvements in workplace safety. Insurers have formed medical networks that are designed to leverage the skills of doctors who specialize in occupational injuries—emphasizing the fact that a significant majority of workers who suffer physical injuries are seen within a few days of their injury, many on the same day.

Today's environment demands a different emphasis than in the past. Construction and manufacturing employment totals are still well below their prerecession levels. Weak demand for new single-family housing has hampered recovery in the construction sector, while the manufacturing industry continues to suffer from reduced overseas demand as a result of a weak global economy and a strong US dollar. This is significant for the workers compensation industry because these two sectors accounted for approximately 40% of the industry's prerecession premium volume.

In addition, the extended period of record-low new money yields is forcing workers compensation insurers to take a fresh look at how they conduct business. Adapting to today's economy by putting more emphasis on underwriting, loss prevention, medical cost containment, and return-to-work programs has become a vital component of success.

These actuarial- and economic-related realities highlight the importance of a collective effort among system stakeholders to both accurately and judiciously address these topics.

The following sections highlight the most recent industry results and include key related observations.

Property/Casualty (P/C) Industry Results

The P/C industry had a strong year in 2014—posting an overall combined ratio of 97%. This is the second year in a row with an underwriting gain for an industry that experienced underwriting losses from 2008 through 2012 (Exhibit 1). Interestingly, the average combined ratios by underwriting cycle emphasize the fact that the most recent cycle has been quite different from the preceding one. The average combined ratio for Calendar Years 1993 through 2001 was 108%, compared with the notably lower average of 101% from 2002 to 2013.

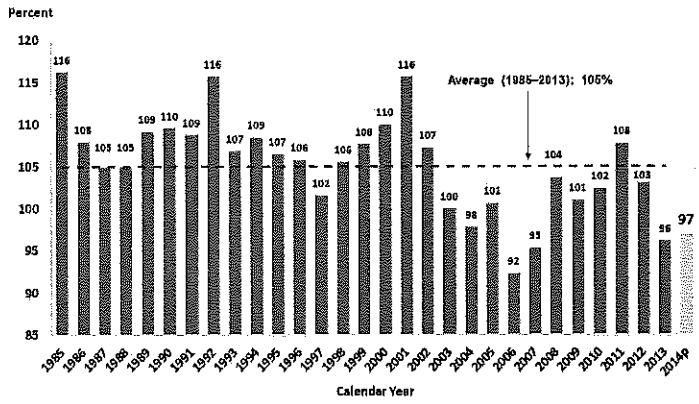
The combined ratio results differ by line of business, with only workers compensation and commercial auto showing improvement between Calendar Years 2013 and 2014 (Exhibit 2). While the homeowners, commercial multiple peril, and fire and allied lines posted combined ratios of less than 100% in 2014, they all experienced increases versus 2013, in part due to the occurrence of relatively more catastrophic losses.

In 2014, the industry's net written premium volume grew 4.1%, with the largest percentage increases in the commercial auto and homeowners lines of business (Exhibit 3). Although 2014 marks the fifth consecutive year in which industry premiums have risen, this year's change falls short of the rates of growth observed in 2012 (4.3%) and 2013 (4.5%).

A similar observation can be made for the workers compensation line of business. While workers compensation private carrier premium grew by 4.6% in 2014, this increase was comparatively less than the corresponding growth rates observed in 2012 (8.8%) and 2013 (5.1%).

Exhibit 1

P/C Industry Net Combined Ratios
Private Carriers



p Preliminary
Sources: 1985–2007, 2012–2014p, Annual Statement data
2008–2011, ISO

Exhibit 2

P/C Industry Net Combined Ratio
Overall Underwriting Gain
Private Carriers

Line of Business	Calendar Year 2012	2013	2014p
Personal Auto	102%	102%	102%
Homeowners	104%	90%	92%
Other Liability (Incl Prod Liab)	104%	100%	102%
Workers Compensation	**109%**	**102%**	**98%**
Commercial Multiple Peril	107%	98%	99%
Fire & Allied Lines (Incl EQ)	103%	84%	87%
Commercial Auto	107%	107%	103%
All Other Lines	98%	83%	84%
Total P/C Industry	**103%**	**96%**	**97%**

p Preliminary
Source: Annual Statement data for individual carriers prior to consolidation of affiliated carriers
Includes carrier data available as of 4/16/2015

Exhibit 3

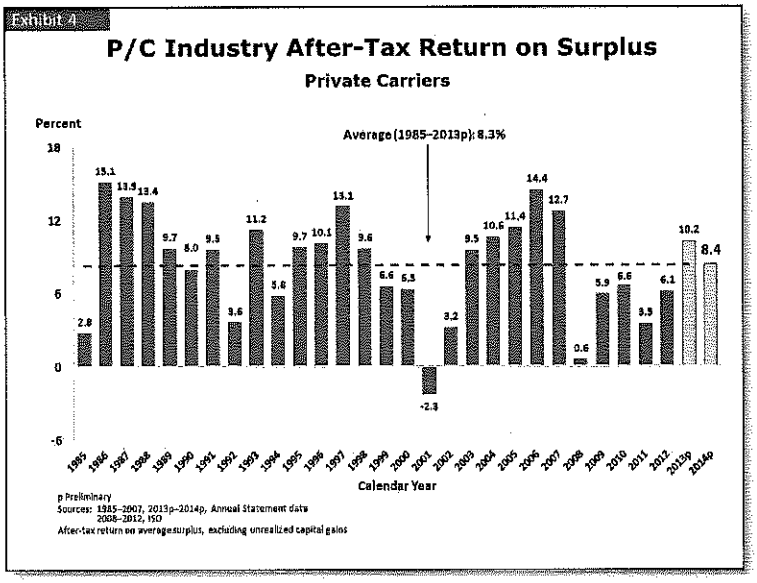
P/C Industry Net Written Premium
All Major Lines Increased
Private Carriers

Line of Business	Calendar Year ($ Billions) 2012	2013	2014p	Change (%) 2013–2014p
Personal Auto	$ 168.0	$ 174.9	$ 183.2	4.7%
Homeowners	$ 66.9	$ 71.9	$ 76.9	6.9%
Other Liability (Incl Prod Liab)	$ 41.7	$ 45.6	$ 47.6	4.3%
Workers Compensation	**$ 35.1**	**$ 36.9**	**$ 38.5**	**4.6%**
Commercial Multiple Peril	$ 31.4	$ 33.2	$ 34.3	3.4%
Fire & Allied Lines (Incl EQ)	$ 25.9	$ 27.0	$ 27.1	0.5%
Commercial Auto	$ 22.1	$ 23.9	$ 25.6	7.1%
All Other Lines	$ 65.8	$ 63.9	$ 63.6	-0.5%
Total P/C Industry	**$ 456.8**	**$ 477.3**	**$ 496.9**	**4.1%**

p Preliminary
Source: Annual Statement data for individual carriers prior to consolidation of affiliated carriers
Includes carrier data available as of 4/16/2015

The industry earned an 8.4% after-tax return on surplus in 2014 (Exhibit 4). After earning returns between 0.6% and 6.6% between 2008 and 2012, 2014 marks the second consecutive year in which the industry's return has exceeded the 8.3% long-term average.

Exhibit 4



The investment gain ratio decreased from 12.5% in 2013 to 11.5% in 2014, primarily driven by the continued decline in the net investment income component. The long-term average net investment income of 14.1% for 1986 through 2001 dropped to 11.0% for 2002 through 2014—with consistent declines of approximately 0.6% observed in each of the three most recent years. While net investment income has declined, net realized capital gains have remained strong—averaging 2.0% since 2012.

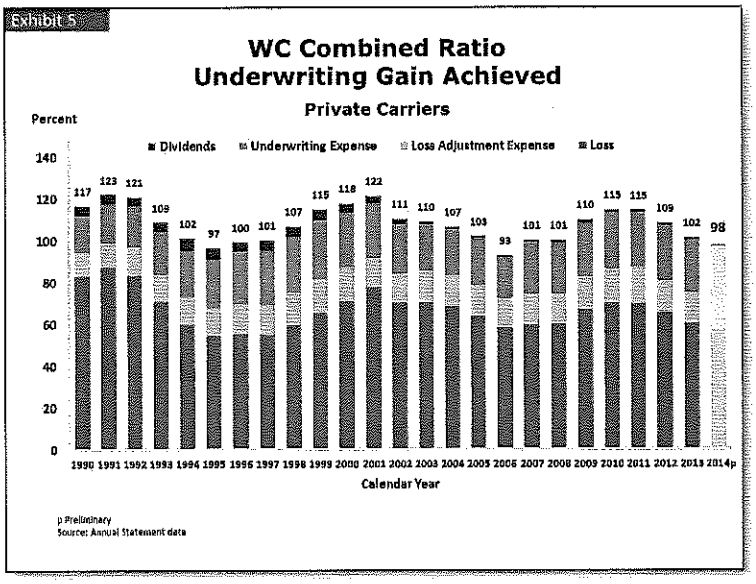
Total industry surplus grew to $675 billion in 2014 and the industry's premium-to-surplus ratio (0.74:1) remained stable, the latter as a result of the observed calendar year increases in both surplus and premium. The industry remains extremely well capitalized.

Workers Compensation Results

Calendar Year Combined Ratio

Based on NCCI's preliminary analysis, a 98% workers compensation combined ratio is estimated for 2014. Underwriting gains are relatively infrequent for the workers compensation line of business—only occurring twice between 1990 and 2013 (Exhibit 5). The 2014 combined ratio represents a 4-point improvement over that for 2013 and a 17-point drop from the peak of the last underwriting cycle in 2011.

Exhibit 5



The combined ratio decline in 2014 is primarily driven by an improvement in the underlying loss ratio. The changes by component are as follows:

- The loss ratio fell by three points, from approximately 61% to 58%
- The loss adjustment expense ratio to premium remained slightly higher than 14%
- The underwriting expense ratio dropped about one point, from 25% to 24%
- The dividend ratio stayed just above 1%

The 2014 preliminary estimate for the investment gain on workers compensation insurance transactions is 12%. This is the lowest this figure has been in the last five years and is below the long-term average of 14.2% (Exhibit 6). Mirroring the P/C industry's declining net investment income figures, a general downward trend in the workers compensation investment gain percentages has been observed since 2010. This trend is not surprising; it is likely associated with the observed decline in the industry's bond portfolio embedded yields in the years following the Great Recession.

A 14% pretax operating gain for 2014 results after combining the year's underwriting and investment gains (Exhibit 7). While the results for 2013 and 2014 are a welcome change versus those from the prior four-year period, the year-to-year volatility in these figures underscores the unwavering importance of insurance industry underwriting.

Reserve Position

NCCI's estimate of the reserve position for the private carriers as of Year-End 2014 is a deficiency of $10 billion (Exhibit 8). This is $1 billion lower than NCCI's estimate as of Year-End 2013 and the second consecutive year that the estimated countrywide reserve deficiency has fallen.

After allowing for the permissible discounting of indemnity reserves for lifetime pension cases, the currently estimated remaining inadequacy still exceeds $5 billion—which represents about 4.3% of the $121 billion in carried reserves. It is estimated that approximately 40% of the total deficiency is associated with accident years prior to 2005, with further notable contributions associated with several accident years in the 2007 through 2011 time period. NCCI estimates some redundancy in the Accident Year 2014 reserves at first report.

Exhibit 6

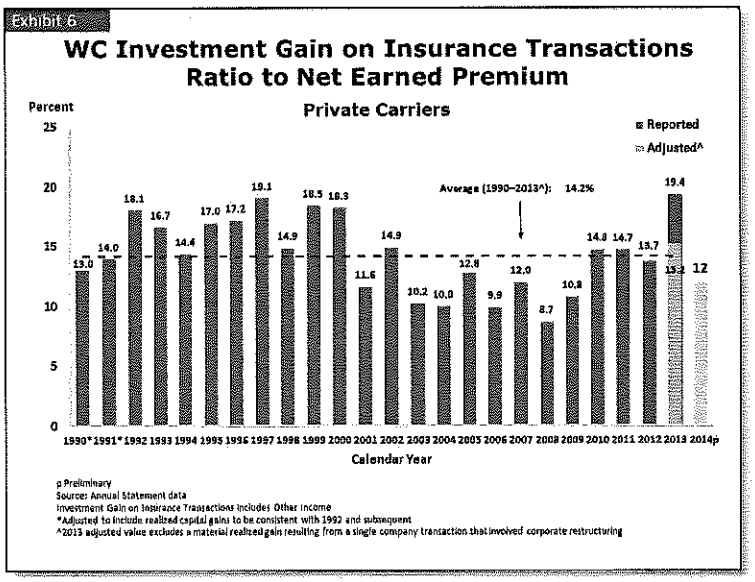


Exhibit 7

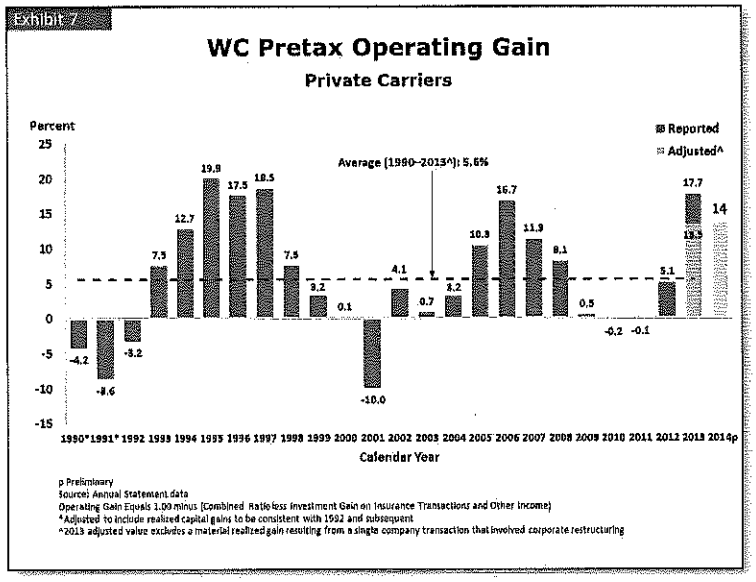
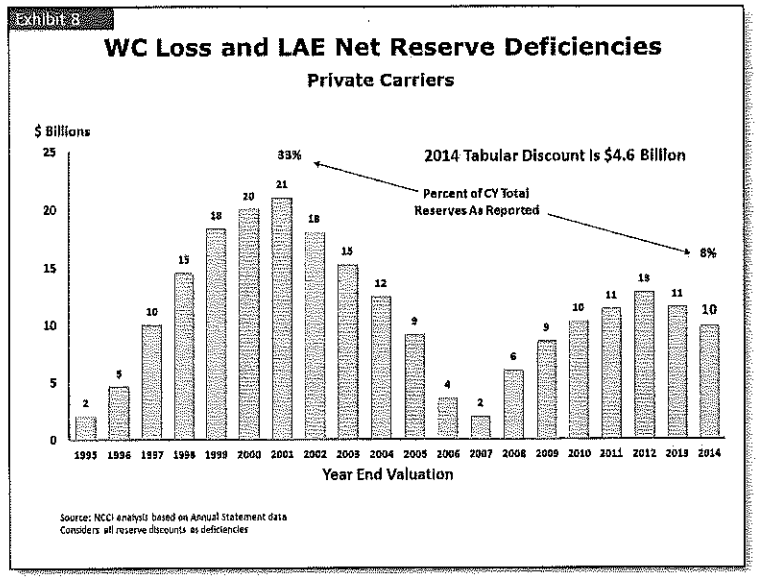


Exhibit 8



Accident Year Results

It is also helpful to analyze workers compensation experience on an accident year basis—because it may provide additional insight into the underlying performance of this "long-tailed" line of insurance without the distortions of prior-year reserve adjustments.

Consistent with the recent calendar year results, workers compensation accident year combined ratios have also improved. Over the last five years, the accident year combined ratio dropped from 118% in 2010 to a preliminary estimate of 95% in 2014 (Exhibit 9). Time will tell if the industry has reached its peak of combined ratio improvement or if 2015 will bring more favorable news to system stakeholders.

Workers Compensation Net Written Premium

Calendar Year 2014 marks the fourth consecutive year of workers compensation net written premium growth—with year-over-year increases observed for both private carriers and state funds (Exhibit 10). It is estimated that the 2014 total workers compensation net written volume exceeds $44 billion. This is more than a 5.5% increase versus that for Calendar Year 2013.

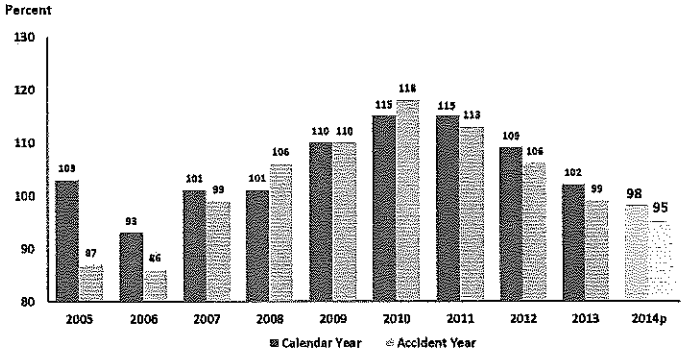
Payroll growth was once again the primary factor underlying the most recent year's increase in premium volume (Exhibit 11). Payroll growth of 4.7%, along with changes in carrier discounting and other factors, more than offset 2014's decline in the average bureau loss cost level.

Bureau Premium Level Changes

Countrywide average approved premium level changes were quite modest in 2014—whether viewed on an "all-states" basis (+0.5%) or restricted to only those jurisdictions for which NCCI provides ratemaking services (–1.4%). The changes approved thus far with effective dates in

Exhibit 9

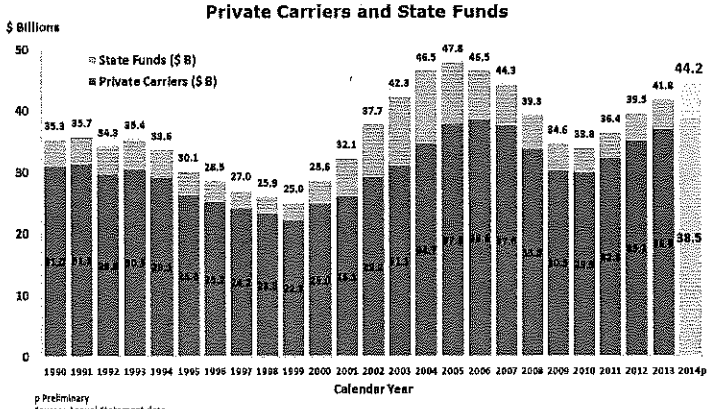
WC Net Combined Ratios
Calendar Year vs. Ultimate Accident Year
Private Carriers



p Preliminary
Source: NCCI analysis based on Annual Statement data
Accident year data is evaluated as of 12/31/2014 and developed to ultimate
Includes dividends to policyholders

Exhibit 10

WC Net Written Premium
Growth Continued
Private Carriers and State Funds



p Preliminary
Source: Annual Statement data
Includes state insurance fund data for the following states: AZ, CA, CO, HI, ID, KY, LA, MD, MO, MT, NM, OK, OR, RI, TX, and UT
Each calendar year total for state funds includes all funds operating as a state fund in that year

Exhibit 11

WC
Components of Written Premium Change
Private Carriers

Written Premium Change From 2013 to 2014	
Net Written Premium—Countrywide	**+4.6%**
Direct Written Premium (DWP)—Countrywide	**+4.6%**
Direct Written Premium (DWP)—NCCI States	**+4.5%**
Components of DWP Change for NCCI States:	
Change in Carrier Estimated Payroll	**+4.7%**
Change in Bureau Loss Costs and Mix	**–1.4%**
Change in Carrier Discounting	**+0.4%**
Change in Other Factors	**+0.8%**
Combined Effect:	**+4.5%**

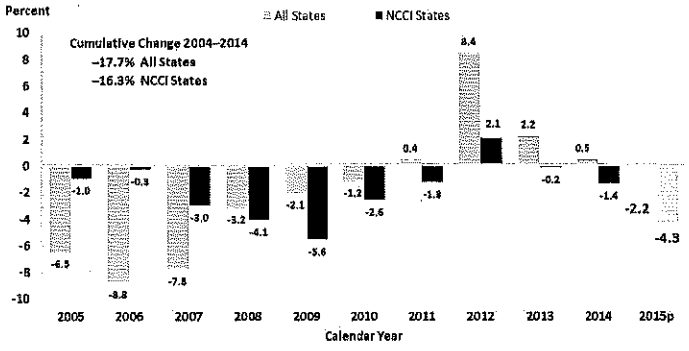
Sources: Countrywide: Annual Statement data
NCCI States: Annual Statement Statutory Page 14 for all states where NCCI provides ratemaking services
Components: NCCI Policy data

2015 support further average declines relative to the respective 2014 values (Exhibit 12).

The magnitude of historical premium level changes have varied over time and were likely influenced by factors including the impact of system reforms, the economic environment, and changes in claim frequency and severity. Since 2004, the magnitude of the cumulative approved premium level change across all states has been consistent with that observed in the NCCI jurisdictions—with the average changes in the NCCI states exhibiting smaller year-to-year fluctuations.

Exhibit 12

WC Approved Changes in Bureau Premium Level
By Effective Date for Total Market

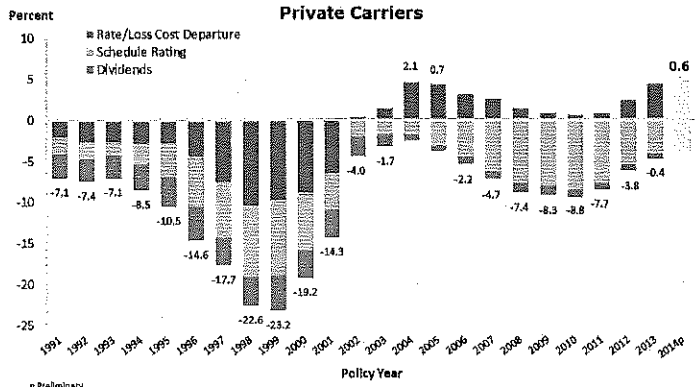


p Preliminary
Bureau premium level changes are countrywide approved changes in advisory rates, loss costs, assigned risk rates, and rating values, as of 4/14/2015, as filed by the applicable rating organization, relative to those previously approved

Carrier discounting from bureau rates/loss costs has declined in NCCI states for the fourth consecutive year. The declines in both 2013 and 2014 were primarily driven by the change in rate/loss cost departures (Exhibit 13). The long-term patterns observed pre- and post-2002 generally seem to mirror each other, with the more recent period exhibiting a relatively smaller range of annual impacts.

Exhibit 13

WC Impact of Discounting on Premium
NCCI States
Private Carriers



p Preliminary
Sources: Annual Statement Statutory Page 14 and NCCI Financial Call data
Dividend ratios are based on calendar year statistics
NCCI benchmark level does not include an underwriting contingency provision
Based on data through 12/31/2014 for all states where NCCI provides ratemaking services, excluding TX

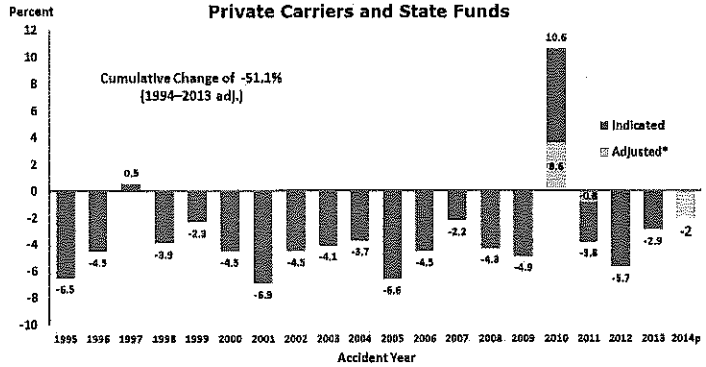
Claim Frequency

NCCI estimates that workers compensation lost-time claim frequency per $1 million of pure premium declined 2% in 2014—marking the 18th annual claim frequency decline in the last 20 years (Exhibit 14). The familiar pattern of claim frequency changes observed prior to the Great Recession (i.e., a relatively large decrease in frequency followed by several years of smaller decreases) seems to have continued in 2012.

A review of the underlying mix of lost-time claims by size also suggests a return to pre-recessionary patterns. As the recession deepened in 2008 and 2009, the frequency of small claims dropped more rapidly than that for larger claims. This trend reversed itself coincidentally with the economic recovery. NCCI

Exhibit 14

WC Lost-Time Claim Frequency
Change in Lost-Time Claims per $1M Pure Premium
Private Carriers and State Funds



*Adjustments primarily due to significant changes in audit activity
p Preliminary based on data valued as of 12/31/2014
Source: NCCI Financial Call data, developed to ultimate and adjusted to current wage and voluntary loss cost levels; excludes high deductible policies; 1994–2013: based on data through 12/31/2013
For all states where NCCI provides ratemaking services, excluding WY

research has shown that, over the last few years, annual changes in frequency for small-versus-large lost-time claims have been consistent with each other (Exhibit 15).

Indemnity and Medical Average Claim Costs

The countrywide average cost of the indemnity portion of a workers compensation lost-time claim in 2014 is estimated to be $23,600 (Exhibit 16). This represents a 4% increase over the corresponding value for 2013—slightly outpacing the 3% increase in wages over this same time period.

Similarly, the countrywide average cost of the medical portion of a lost-time claim is estimated to have also increased by 4% to $29,400 (Exhibit 17). Based on data submitted to NCCI, countrywide average medical benefits per lost-time claim have increased in each of the last 20 years—more than tripling the medical average cost per claim since 1995.

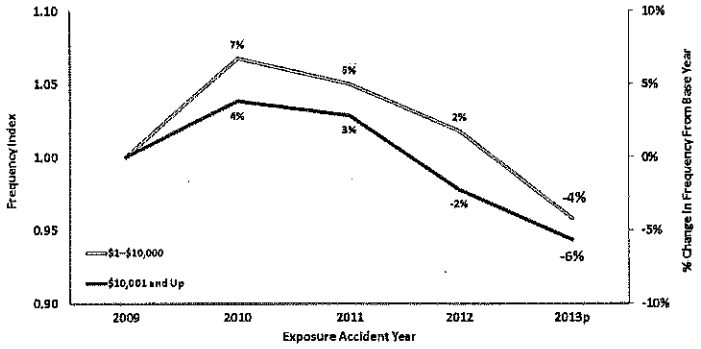
As with all countrywide averages, values by individual jurisdiction may vary.

While continued declines in claim frequency serve to partially offset increases in claim severity, continued diligence is needed by all workers compensation stakeholders to ensure that the system remains strong and competitive.

Exhibit 15

WC Lost-Time Claim Frequency Changes by Total Size of Loss

Index: Exposure Accident Year 2009 = 1.00

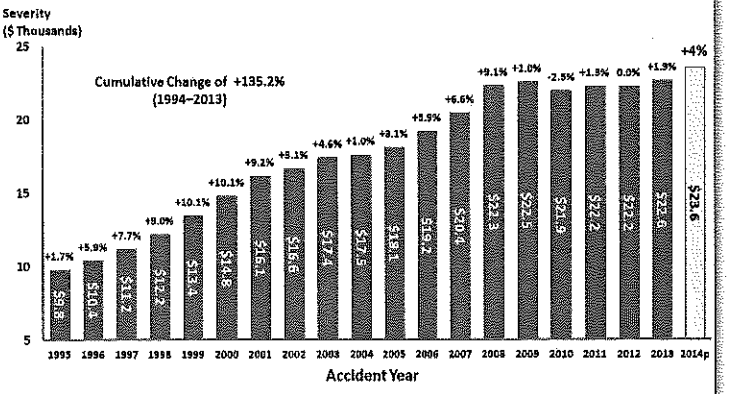


p Preliminary
Source: NCCI Unit Statistical Plan data
Frequency is the number of lost-time claims at 1st report per $1M premium at current wage and average carrier rate level
Prior to assigning individual claims to size of loss groupings, reported loss amounts are adjusted for inflation through 2013
For all states where NCCI provides ratemaking services

Exhibit 16

WC Average Indemnity Cost per Lost-Time Claim

Private Carriers and State Funds

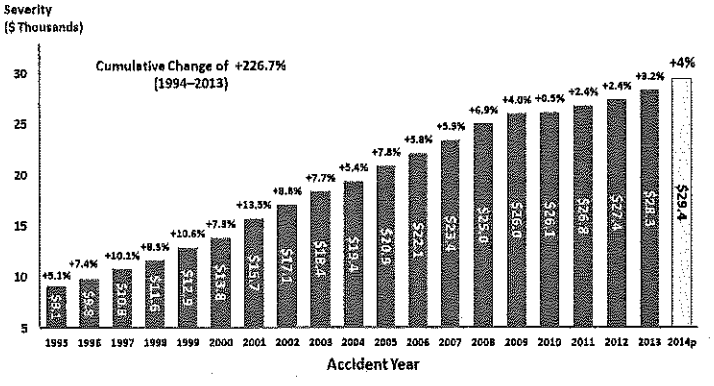


p Preliminary based on data valued as of 12/31/2014
Source: NCCI Financial Call data, developed to ultimate; excludes high deductible policies
1994–2013: Based on data through 12/31/2013
For all states where NCCI provides ratemaking services, excluding WV

Exhibit 17

WC Average Medical Cost per Lost-Time Claim

Private Carriers and State Funds



p Preliminary based on data valued as of 12/31/2014
Source: NCCI Financial Call data, developed to ultimate; excludes high deductible policies
1994–2013: Based on data through 12/31/2013
For all states where NCCI provides ratemaking services, excluding WV

Residual Market Update

It is estimated that residual market premium increased in 2014 by approximately $75 million to $1.2 billion in total (Exhibit 18). This increase is notably less than the $250+ million increases observed in both 2012 and 2013. The residual market share for states in which Pools are serviced by NCCI held steady at a manageable 8% between 2013 and 2014.

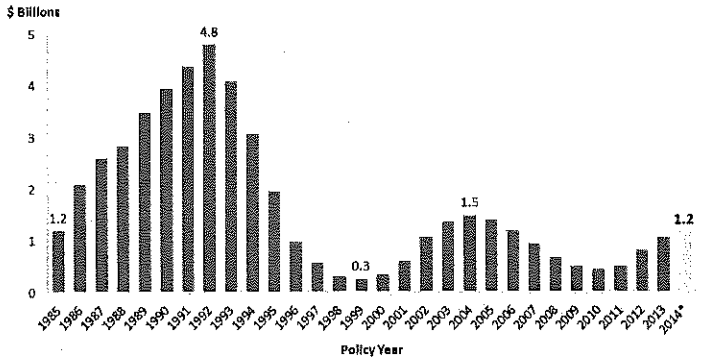
The 2014 residual market combined ratio has also remained stable at 106%. Primarily driven by the increase in premium, this represents an 8% combined ratio improvement since 2011 (Exhibit 19). The current policy year underwriting loss is estimated to have risen to about $74 million from the $64 million estimate for 2013 (Exhibit 20).

In the first quarter of 2015, residual market premium volume declined versus that from a year prior in three policy-size categories greater than $10,000. This may indicate that residual market growth has begun to subside. NCCI will remain vigilant in maintaining programs to help manage the residual market growth and, to whatever extent possible, prevent significant erosion of the residual market operating results.

Exhibit 18

WC Residual Market Premium

NCCI-Serviced WC Residual Market Pools

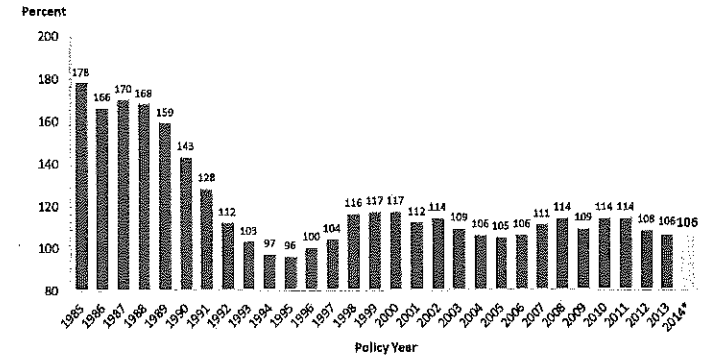


*Incomplete policy year projected to ultimate
Includes pool data as of 12/31/2014 for all NCCI-serviced WC residual market pool states
Source: NCCI, *Residual Market Quarterly Results*

Exhibit 19

WC Residual Market Combined Ratio

NCCI-Serviced WC Residual Market Pools

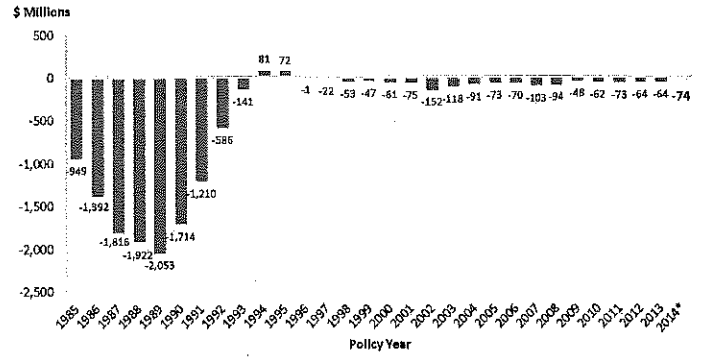


*Incomplete policy year projected to ultimate
Includes pool data as of 12/31/2014 for all NCCI-serviced WC residual market pool states
Source: NCCI, *Residual Market Quarterly Results*

Exhibit 20

WC Residual Market Underwriting Results

NCCI-Serviced WC Residual Market Pools



*Incomplete policy year projected to ultimate
Includes pool data as of 12/31/2014 for all NCCI-serviced WC residual market pool states
Source: NCCI, *Residual Market Quarterly Results*

In Conclusion

Overall, 2014 was a good year for both the P/C industry and the workers compensation line of business. More specifically:

- The workers compensation line posted its first underwriting gain since 2006
- Workers compensation lost-time claim frequency continued its long-term decline, partially offsetting the observed modest increases in claim severities
- The P/C industry remains well capitalized and likely comforted by the recent renewal of the Terrorism Risk Insurance Act

Challenges to the line also remain, including:

- A continuing low-interest-rate environment threatens investment results over the long term
- While workers compensation premium volumes continue to increase, construction and manufacturing employment totals remain well below prerecession levels—restraining even higher premium growth rates

NCCI will continue to work with all workers compensation system stakeholders to help maintain adequate rate/loss cost levels, provide unbiased impact analyses of proposed legislative reforms, and strive for self-funded residual markets. By providing timely in-person and online educational opportunities, along with the production of relevant, forward-looking research, NCCI will continue to assist all interested parties in understanding both current and emerging trends impacting workers compensation.

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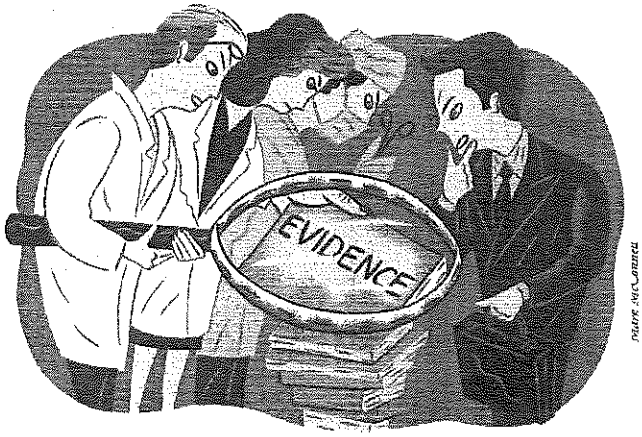
Developing clinical guidelines

The methods of guideline development should ensure that treating patients according to guidelines will achieve the outcomes that are desired. This article presents a combination of the literature about guideline development and the results of our combined experience in guideline development in North America and Britain. It considers the 5 steps in the initial development of an evidence-based guideline.



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Identifying and refining the subject area of a guideline

Prioritizing topics

Guidelines can be developed for a wide range of subjects. Clinical areas can be concerned with conditions (abnormal uterine bleeding, coronary artery disease) or procedures (hysterectomy, coronary artery bypass surgery). Given the large number of potential areas, some priority setting is needed to select an area for guideline development. Potential areas can emerge from an assessment of the major causes of morbidity and mortality for a given population, uncertainty about the appropriateness of health care processes or evidence that they are effective in improving patient outcomes, or the need to conserve resources in providing care.

Refining the subject area

The topic for guideline development will usually need to be refined before the evidence can be assessed in order to answer exact questions. The usual way of refining the topic is through dialogue among clinicians, patients, and the potential users or evaluators of the guideline. Discussions about the scope of the guideline will also take place within the guideline development panel.

If the topic is not refined, the clinical condition or question may be too broad in scope. For example, a guideline on the management of diabetes could cover primary, secondary, and tertiary care elements of management and also multiple aspects of management, such as screening, diagnosis, dietary management, drug treatment, risk factor management, or indications for referral to a specialist. Though all of these legitimately could be dealt with in a guideline, the task of developing such a guideline would be considerable; therefore, a group to develop guidelines needs to be clear which areas are and are not within the scope of their activities. It is possible to develop guidelines that are both broad in scope and evidence-based; but to do so usually requires considerable time and money, both of which are frequently underestimated by inexperienced developers of evidence-based clinical practice guidelines.

One method of defining the clinical question of interest and also identifying the processes for which evidence needs to be collected and assessed is the construction of models or causal pathways.[1] A causal pathway is a diagram that illustrates the links between interventions of interest and the intermediate, surrogate, and health outcomes that the interventions are thought to influence. In designing the pathway, guideline developers make explicit the premises on which their assumptions of effectiveness are based and the outcomes (benefits and harms) that they consider important. This identifies the specific questions that must be answered by the evidence to justify conclusions of effectiveness and highlights gaps in the evidence for which future research is needed.

Summary Points

- Identifying and refining the subject area is the first step in developing a guideline
- Convening and running guideline development groups is the next step
- On the basis of systematic reviews, the group assesses the evidence about the clinical question or condition
- This evidence is then translated into a recommendation within a clinical practice guideline
- The last step in guideline development is external review of the guideline

Running guideline development groups

Setting up a guideline development project

To successfully develop a guideline, it may be necessary to convene more than 1 group. A project or management team could undertake the day-to-day running of the work, such as the identification, synthesis, and interpretation of relevant evidence; the convening and running of the guideline development groups; and the production of the resulting guidelines. An additional guideline development group would produce recommendations in light of the evidence or of its absence.

Group membership and roles

Group members—Identifying stakeholders involves identifying all of the groups whose activities would be covered by the guideline or who have other legitimate reasons for having input in the process. This is important to ensure adequate discussion of the evidence (or its absence) when developing the recommendations in the guideline. When presented with the same evidence, a single specialty group will reach different conclusions than a multidisciplinary group—the specialty group will be systematically biased in favor of performing procedures in which it has a vested interest.[2,3] For example, a group of vascular surgeons favored the use of carotid endarterectomy more than a mixed group of surgeons and medical specialists.[4] Individuals' biases may be better balanced in multidisciplinary groups, and such balance may produce more valid guidelines. Ideally, the group should have at least 6 but no more than 12 to 15 members; too few members limit adequate discussion and too many members make effective functioning of the group difficult. Under certain circumstances (for example, in guidelines for broad clinical areas), it may be necessary to trade off full representation against the requirement of having a functional group.

Roles—Roles required within guideline development groups are those of group member, group leader, specialist resource, technical support, and administrative support. Group members are invited to participate as individuals working in their field; their role is to develop recommendations for practice based on the available evidence and their knowledge of the practicalities of clinical practice.

Skills needed for guideline development

- Literature searching and retrieval
- Epidemiology
- Biostatistics
- Health services research
- Clinical experts
- Group process experts
- Writing and editing

The role of the group leader is to ensure that the group both functions effectively (the group process) and achieves its aims (the group task). The process is best moderated by someone who is familiar with (though not necessarily an expert in) the management of the clinical condition and the scientific literature yet is not an advocate. He or she stimulates discussion and allows the group to identify where true agreement exists but does not inject his or her own opinions in the process. This requires someone with both clinical skills and group process skills. Using formal group processes rather than informal ones in group meetings produces different and possibly better outcomes.[5-7]

Identifying and assessing the evidence

Identifying and assessing the evidence is best done by performing a systematic review. The purpose of a systematic review is to collect all available evidence, assess its potential applicability to the clinical question under consideration, inspect the evidence for susceptibility to bias, and extract and summarize the findings.

What sort of evidence?

Identifying the clinical questions of interest will help set the boundaries for admissible evidence (types of study design, year of publication, etc.). For example, questions of the efficacy of interventions usually mean that randomized, controlled trials should be sought, while questions of risk usually mean that prospective cohort studies should be sought.

Where to look for evidence?

The first step in gathering the evidence is to see if a suitable, recent systematic review has already been published. Searching the *Cochrane Library* will also identify relevant Cochrane review groups, which should also be contacted to see if a review is in progress.

If a current systematic review is not available, a computer search of Medline and EMBASE is the usual starting point, using search strategies tailored to appropriate types of studies (though such strategies have been validated only for randomized, controlled trials.[8] For example, randomized, controlled trials provide the best evidence to answer questions about the effectiveness of treatments, whereas prospective cohort studies generally provide the best evidence for questions about risk. The Cochrane Controlled Trials Register (part of the *Cochrane Library*) contains references to over 218,000 clinical trials that have been identified through database and hand searching; it should be examined early on in any review process. Checking the references in articles will show additional relevant articles not identified by the computer search, and having experts in the field examine the list of articles helps ensure that there are no obvious omissions. Additional

search strategies, including searches for articles published in languages other than English,[9-11] computer searches of specialized databases, hand searching of relevant journals, and searching for unpublished material will often yield additional studies, but the resources needed for such activities are considerable. The cost-effectiveness of various search strategies has not been established. It is best to match the scope of the search strategy to the available resources.

Assessing studies for relevance

Once studies have been identified, they are assessed for relevance to the clinical questions of interest and for bias.[12, 13] Screening for relevance is often possible from the abstract; it narrows the set of studies to those needing a more detailed assessment. Using explicit rather than implicit criteria should improve the reliability of the process.

Summarizing evidence

Data are extracted from the relevant studies on the benefits, the harms, and (where applicable) the costs of the interventions being considered. These data are usually presented in a form that allows the designs and results of studies to be compared. Where appropriate, meta-analysis can be used to summarize the results of multiple studies.

Categorizing evidence

Summarized evidence is categorized to reflect its susceptibility to bias. This is a shorthand method of conveying specific aspects of the evidence to a reader of the guideline. A number of such "strength of evidence" classification schemes exist, but empirical evidence exists only for schemes that categorize effectiveness studies by study design.[14, 15] The box shows a simple scheme for classifying the evidence that supports statements in practice guidelines and the strength of the recommendations. Guideline developers should use a limited number of explicit criteria, incorporating criteria for which there is explicit evidence.

Classification Schemes

Category of evidence:

- IA evidence for meta-analysis of randomized, controlled trials
- IB evidence from at least one randomized, controlled trial
- IIA evidence from at least one controlled study without randomization
- IIB evidence from at least one other type of quasi-experimental study
- III evidence from nonexperimental descriptive studies, such as comparative studies, correlation studies, and case-control studies
- IV evidence from expert committee reports or opinions or clinical experience of respected authorities, or both

Strength of recommendation:

- A directly based on category I evidence
- B directly based on category II evidence or extrapolated recommendation from category I evidence
- C directly based on category III evidence or extrapolated recommendation from category I or II evidence
- D directly based on category IV evidence or extrapolated recommendation from category I, II, or III evidence

Factors contributing to the process of deriving recommendations

- The nature of the evidence (for example, its susceptibility to bias)
- The applicability of the evidence to the population of interest (its generalizability)
- Costs
- Knowledge of the health care system
- Beliefs and values of the panel

Translating evidence into a clinical practice guideline

The evidence, once gathered, needs to be interpreted (see box). Since conclusive evidence exists for relatively few health care procedures, deriving recommendations solely from such examples would lead to developing a guideline of limited scope or applicability.[16] This could be sufficient if, for example, the guideline is to recommend the most strongly supported treatments for a given illness. More commonly, however, the evidence needs to be interpreted into a clinical, public health, policy, or payment context. Therefore, within the guideline development process, a decision should be made about how opinion will be both used and gathered.

Using and gathering opinion

Opinion will be used to interpret evidence and also to derive recommendations in the absence of evidence. When evidence is being interpreted, opinion is needed to assess issues such as the generalizability of the evidence—for example, to what degree evidence from small, randomized clinical trials or controlled observational studies may be generalized or to what degree results from a study in one population can be extrapolated to the population of interest in the guideline (for example, extrapolating a study from a tertiary, academic medical center to the community population of interest to potential users of the guideline).

Recommendations based solely on clinical judgment and experience are likely to be more susceptible to bias and self-interest. Therefore, after deciding what role expert opinion is to play, the next step is deciding how to collect and assess expert opinion. There is currently no optimal method for this, but the process needs to be made as explicit as possible.

Resource implications and feasibility

In addition to scientific evidence and the opinions of expert clinicians, practice guidelines must often take

into account the resource implications and feasibility of interventions.

Judgments about whether the costs of tests or treatments are reasonable depend on how cost effectiveness is defined and calculated, on the perspective taken (for example, clinicians often view cost implications differently than payers or society at large), and on the resource constraints of the health care system (for example, cash-limited public systems versus private insurance-based systems). Feasibility issues worth considering include the time, skills, staff, and equipment necessary for the provider to carry out the recommendations and the ability of patients and systems of care to implement them.

Grading recommendations

It is common to grade each recommendation in the guideline. Such information provides the user with an indication of the guideline development group's confidence that following the guideline will produce the desired health outcome. "Strength of recommendation" classification schemes (such as the one in the box) range from simple to complex: no one scheme has been shown to be superior. Given the factors that contribute to a recommendation, strong evidence does not always produce a strong recommendation, and the classification should allow for this. The classification is probably best done by the group panel, using a democratic voting process after group discussion of the strength of the evidence.

Reviewing and updating guidelines

Guidelines should receive external review to ensure content validity, clarity, and applicability. External reviewers should cover three areas: people with expertise in clinical content who can review the guideline to verify the completeness of the literature review and ensure clinical sensibility; experts in systematic reviews, guideline development, or both, who can review the method by which the guideline was developed; and potential users of the guideline, who can judge its usefulness.

The guideline can be updated as soon as each piece of relevant new evidence is published, but it is better to specify a date for updating the systematic review that underpins the guideline.

Conclusions

New advances in understanding the science of systematic reviews, the workings of groups of experts, and the relation between guideline development and implementation are all likely in the next 3 to 5 years.

We believe that 3 principles will remain basic to the development of valid and usable guidelines:

- The development of guidelines requires sufficient resources in terms of financial support and people with a wide range of skills, including expert clinicians, health services researchers, and group process leaders;
- A systematic review of the evidence should be at the heart of every guideline; and
- The group assembled to translate the evidence into a guideline should be multidisciplinary.

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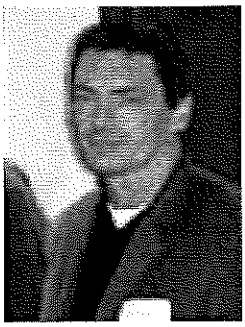

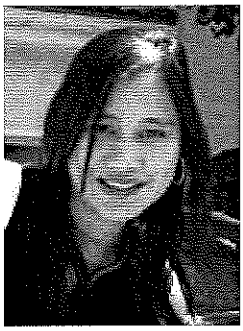

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Quality assessment of clinical practice guidelines

'Implementing the findings of evidence-based guidelines is a quality-improvement process that provides accountability through the monitoring of the reliability of practices to models that have been demonstrated by research to be effective.'

Expert Rev. Pharmacoeconomics Outcomes Res. 6(1), 1–4 (2006)

Overview of evidence-based medicine

Fundamentally, evidence-based medicine (EBM) represents an effort to improve the quality of information about benefits of healthcare services and their related effectiveness [1]. One of the most important contributions of EBM is to draw attention to gaps in the scientific evidence upon which healthcare decisions are made, thereby helping to shape a research agenda that focuses on answering the questions important to medicine. Clinical practice guidelines (CPGs) take the next step, helping to translate science into policy for practitioners and administrative decision-makers. The EBM movement has given rise to evidence-based practice guidelines, which offer clinical guidance as well as documentation of the quality of evidence or opinion supporting practice recommendations. CPGs are used increasingly by government agencies and professional organizations around the world to improve patient care [2,3]. There is a pressing need for recognized criteria to assess guidelines that are valid, clear, cost-efficient, usable and reliable [4,5,101].

EBM has been recognized as an effective mechanism for not only improving healthcare quality, but also for reducing medical errors precipitated in part by clinical practice variation [1]. It provides for an integration and translation of evidence, experience and values into clinical and policy decision-making. EBM provides an organized structure to explicitly link clinical and public health policy to a systematic examination of the quality of supporting scientific evidence [6]. EBM can be a tool to assess the effectiveness of a new technology and its benefits, thereby informing decisions related to health policy and access to new technologies [1,5,6]. An important application of EBM is in the development of CPGs.

Clinical practice guidelines

The Institute of Medicine (IOM) defined CPGs as systematically developed statements to assist practitioners' and patients' decisions about appropriate healthcare for specific clinical conditions and/or circumstances [5]. These statements should be based on the best available scientific evidence and practical knowledge. However, an increasing number of CPGs and variations in their recommendations have stimulated discussion about their value.

Why is a quality assessment of clinical practice guidelines important?

Over the past two decades, CPGs have become an increasingly popular tool for the implementation of scientifically based clinical information to improve the quality of healthcare [6,7,8]. They are intended to present a synthesis of current evidence and recommendations performed by expert clinicians and may affect the practice of large numbers of physicians. Therefore, there must be agreement as to how the guidance is generated and how the

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evidence is interpreted [10]. Guideline developers attempt to identify, appraise and collate the best evidence to ensure that the highest quality information is available for clinicians and patients. It would also be beneficial if guideline developers could follow a common standard of reporting similar to that used by consolidated standards of reporting trials (CONSORT) for randomized controlled trials [9,11]. The resulting quality assessments should be made available to practitioners, policy-makers and the public to facilitate informed decision-making about the quality and usefulness of particular guidelines. Coleman indicated that published sources of evidence-based guidance were used in clinical practice, but there were clear differences in knowledge, use and perceived influence of different sources of guidance among the professionals based in different healthcare settings [12]. Those responsible for health policy were much more likely to believe that evidence-based guidance had influenced their practice than doctors who provided clinical care in hospitals or primary care. Their study showed that awareness, use and perceived impact of evidence-based guidance was much greater among those involved in health policy and administration, responsible for determining patient access issues or purchasing healthcare products and services, than among consultants in hospitals or primary care physicians.

'Conflicts or variations in guidelines from different professional bodies can lead to confusion and frustration among practitioners wanting to utilize CPGs.'

Is there doubt about the quality of published CPGs?

CPGs are now a common feature of clinical practice [3,13]. They are expected to facilitate more consistent, effective and efficient medical practice. In principle, a good guideline is one that eventually leads to improved patient outcomes. However, applying guidelines to individual care is likely to require the exercise of professional judgment, even when recommendations are properly linked to evidence. Cranney assessed the quality of osteoporosis guidelines produced in the 1998–2001 period [14]. The Appraisal Instrument for Clinical Guidelines (version 1, 1999) was used to assess the quality of guidelines. It consists of 37 items in three dimensions with yes, no and not sure format. This instrument was used widely in the UK and Canada during that period. It had shown acceptable reliability and criterion validity. They found the methodological quality of current osteoporosis guidelines was low, although their scores for clinical content were high and no guidelines covered the dissemination issue. Choudhry concluded that any influence that CPG authors experience from their interactions with pharmaceutical companies may be transmitted to the CPG readers [15]. If CPG authors have relationships that pose a potential conflict of interest, readers may wish to know about them to evaluate the merit to those guidelines. Thus, a systematic assessment of the process used in CPG development can provide users of these recommendations a means to mitigate potential biases.

Potential explanation for why recommendations are different among CPGs

Over the past 20 years, guidelines have been developed to bridge the gap between research and practice. There has been a concerted effort to base clinical decisions on research evidence and to make this evidence available globally [9,101]. Since bibliographic databases (e.g. Medline) are readily available, one might expect that this would lead to international consensus on the evidence chosen to support recommendations for clinical care and a consequent convergence of recommendations made in guidelines. Nevertheless, clinical recommendations often differ in guidelines on the same topic [16,17]. Investigators suggest that differences are due to cultural factors, such as differing expectations of apparent risks and benefits, socio-economic factors, varied characteristics of healthcare systems, insufficient evidence, differing interpretations of evidence, the influence of professional bodies and unsystematic guideline development methods.

What factors might influence the quality of CPGs?

Some guidelines published in the peer-reviewed medical literature during the past decade do not adhere well to methodological standards. While all areas of guideline development may benefit, the greatest improvement is needed in the areas of identification, evaluation and synthesis of the scientific evidence. There is evidence that guidelines can improve clinical practice, but their successful utilization is dependent on many factors, including the clinical context, methods of development, dissemination and implementation [101,102]. Successfully addressing all of these issues in routine practice can prove difficult, but is necessary if CPGs are to improve the quality of healthcare.

There are numerous potential barriers to the development of good clinical guidelines [8,101]. Some CPGs may not have been developed by a fully multidisciplinary group that is representative of those clinicians who will use them or patients affected by them, with the result that there is a lack of ownership. Value judgements made by a guideline group may not accurately reflect those of the patients. The CPGs may include recommendations that do not comprehensively take into account the scientific evidence, potentially leading to suboptimal or ineffective practice. There can be insufficient, misleading or misinterpretations of the scientific evidence about what to recommend. Guideline development groups may lack the time, resources and skill to gather and scrutinize evidence in detail. Recommendations may be biased by the opinions, clinical experience and composition of the guideline group. Conflicts or variations in guidelines from different professional bodies can lead to confusion and frustration among practitioners wanting to utilize CPGs.

Literature on quality assessment of CPGs

Despite improvement over time, the quality of practice guidelines developed by specialty societies may be unsatisfactory in some cases [18]. Increasing concern is related to the number of

guidelines of low quality and guidelines that contain conflicting recommendations [5,15,16]. A properly performed evaluation of the scientific evidence is critical in ensuring the scientific validity of a guideline. An important goal for guideline use is to increase the efficiency in the utilization of healthcare resources. According to Shaneyfelt, almost 60% of guidelines reviewed did not mention costs and only 14% provided any quantitative cost estimates [5]. Clearly, if guidelines are to improve the cost-efficiency of healthcare, greater attention must be given to economic analysis. Graham concluded that the quality of all CPGs in Canada should be assessed in a systematic fashion by an independent body using a standardized appraisal instrument [21].

The AGREE Collaboration published the international appraisal instrument for CPGs, the 'AGREE' instrument [18]. It was tested on 100 guidelines selected from 11 participating countries by 194 independent appraisers. The median time for appraising a guideline was 1.5 h, including reading of the guideline and completing the appraisal instrument [8]. This adoption of a common standard has the potential for improving the consistency and quality of the reporting of guideline development worldwide and provides a framework to encourage international comparison of CPGs based on the quality of their development.

The AGREE instrument identifies criteria for the development of high-quality CPGs [8]. CPGs should contain a specific statement about the overall objective(s), clinical questions and descriptions of the target population. They should provide information about the composition, discipline and relevant expertise of the guideline development group, and they should involve patients in their development. They should also clearly define the target users, with pilot testing among them prior to CPG publication. CPGs should provide detailed information on the search strategy, the inclusion and exclusion criteria for selecting the evidence and the methods used to formulate the recommendations. Recommendations should be linked explicitly to the supporting evidence, with a discussion of the health benefits, side effects and risks. There should be an external review before publication, with detailed information about the procedure for updating the guideline. CPGs should contain specific recommendations on appropriate patient care and consider different possible options. Key recommendations should be found easily, as well as a summary document and patient information. We would expect to see a discussion regarding the organizational changes and cost implications of applying the recommendations, and a presentation of review criteria for monitoring the use of the guidelines. There should be an explicit statement regarding the nature of involvement of the funding body in the CPG development process, to ensure that they have not unduly influenced the final recommendations. Also, members of the guideline development group should declare possible conflicts of interest.

Benefits of quality assessment of CPGs

A properly performed evaluation of the scientific evidence is critical in ensuring the scientific validity of a guideline. Quality assessment tools can be helpful for clinical practice in two ways: to help clinicians appraise, then adopt recommendations from different sources; as an information support to be used more confidently in the continued quality improvement of medical practice [8,102].

Conclusions

Concern about the quality of healthcare, uncertainty and variability in decision making, as well as rising costs, have stimulated a marked growth over the past 5 years in the development and use of CPGs [20,21]. Clinicians, policymakers and payers may see CPGs as a tool to facilitate more consistent and efficient decision-making, useful in closing the gap between what clinicians do and what the scientific evidence supports. Implementing the findings of evidence-based guidelines is a quality-improvement process that provides accountability through the monitoring of the reliability of practices to models that have been demonstrated by research to be effective. Using this framework, policy makers can approach payers with greater confidence. They can argue for resources to implement evidence-based guidelines with a greater assurance of accountability and value for money. The achievement of consistently positive outcomes is at the heart of an evidence-based practice. Providers, both clinicians and administrators, must understand new clinical practice options and their utility before they can be expected to adopt them.

An increasing concern is the number of disease-specific guidelines that offer inconsistent recommendations. Many reasons have been put forward to explain this variability, ranging from lack (or differing interpretation) of underlying research findings, different values given to anticipated outcome (for example clinical versus economic), questioning the achievement of consensus and possible bias introduced through conflicts of interest [15]. Several approaches could be used to improve the quality of CPGs. Guideline developers should become more familiar with CPG development standards and strive to incorporate them into their efforts [8,101].

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