Domain: Deliberations and Contextualizations

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<td>Deliberations &amp; Contextualizations</td>
<td>Scientific evidence is only one of many factors that influence the translation of research findings to the context of use. The process of considered judgment is essential in guideline development and often requires extensive discussions and consensus among experts. Availability of services, resources, cost-effectiveness are important considerations (1). Clinical problems that recommendations target involve complex trade-offs between competing benefits, harms, and costs, usually under conditions of uncertainty (uncertainty in the evidence). As such, disagreement and ambivalence among developers is common (2).</td>
<td>How-to:</td>
<td>Medicine</td>
<td>• If the underlying evidence is weak, no matter what degree of consensus or peer review, the clinicians’ confidence in the validity of the guideline will be limited (2).</td>
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<td>Synonyms: Decision making Negotiating clinical benefits and harms</td>
<td>Recommendations based solely on clinical judgment and experience (in this case it means expert opinion) are likely to be more susceptible to bias and self-interest. A method should be used to collect and assess expert opinion. There is currently no optimal method for this, but whatever you do needs to be made as explicit as possible. Opinion will be used to interpret evidence and also to derive recommendations in the absence of evidence; particularly important for assessing issues of generalizability (3).</td>
<td>• Explicit strategies documenting, describing, and dealing with dissent among judges, or frank reports of the degree of consensus attained can help clinicians decide whether to adopt or adapt a recommendation (2). If the underlying evidence is weak, no matter what degree of consensus or peer review, the clinicians’ confidence in the validity of the guideline will be limited (2). • Decision Analytical Framework- by using a decision analytical framework approach when developing guidelines, professionally held values that might affect the formulation of recommendations would be made explicit. Using this approach will also help to identify gaps where additional evidence, or, in the absence of evidence, professional judgments are required (4). • Heuristic-based- guidelines developed through consideration of heuristics may have a better chance of being used than those that rely exclusively on decision analytic theory; most problems- computational, physical, biologic, and social- have more than one solution. The possible solutions are not equivalent; this is usually some trade-off between efficiency and precision (5). • Common Sense Approach –approach used to assess consultant’s counsel, which can be applied to CPGs (2). • The presence of a large proportion of recommendations with no supporting data from RCTs requires careful judgment by guideline authors. In such circumstances, the potential for authors’ conflicts of interest may be important. Recommendations based only on expert opinion may be prone to conflicts of interest because just as clinical trialists have conflicts of interest, expert clinicians are also those who are likely to receive honoraria, speakers bureau, consulting fees, or research support from industry (6, 7). The level of evidence classification combines an objective description of the existence and the types of studies supporting the recommendation and expert consensus. The classes of recommendation designation indicates the strength of a recommendation and requires guideline writers not only to make a judgment about the relative strengths and weaknesses of the study but also to make a value judgment about the relative importance of the risk and benefits identified by the</td>
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• Health administrators should realize there is limited evidence that PG have reduced costs except in situations where the misuse of a procedure or medication is widespread (12).
Guidelines are not orders or protocols - The clinical and patient must be guided by the best clinical judgment and exercise of prudence.

Guidelines may satisfy the needs of health regulators and administrators more than that of individual patients -- recommended clinical practices that help to control healthcare costs and decrease practice variations may be suboptimal for patient care.

Negotiating clinical benefits and harms is a key stage in moving from evidence to recommendations is balancing the benefits and harms of an intervention. This may be done qualitatively (for example, 'the evidence of a reduction in mortality outweighed a small increase in side effects'), or quantitatively using a decision model.

Examples:

- Heuristics - the role of heuristics - the balancing efficiency and precision - is commonly underplayed by guideline developers. In addition, people, including health care providers, do what they do because a status quo choice has already proved economically feasible and remains cognitively less taxing than all other alternatives.

- Common Sense Approach - we are impressed when a consultant explains her suggestions clearly, discusses alternatives, and acknowledges potential biases and extenuating circumstances. This same approach can be used to assess, the validity, importance, and applicability of CPGs.

Formulation of recommendations

Standards on the formulation of recommendations, including values, patient preferences, flexibility, and strength of evidence. The guideline panel formulated a recommendation if the members thought it was appropriate not for all but for a significant majority of patients. Recommendations were graded as option if the panel determined that the health outcomes were not sufficiently well known and no clear patient preferences were apparent (Point 1).

Examples:

- The 279 guidelines evaluated adhered poorly to methodological standards on the formulation of recommendations with overall compliance of 46%.

Medicine

- None.
### CODEBOOK – Deliberations and Contextualizations

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#### Concept

**Clinical Applicability**

**Synonyms:**
- Appropriateness?
- Relevance
- Applicability
- Clinical Relevance

**CODEBOOK DEFINITION**

Guidelines reflect the ideal patients and may not apply to everyone since they are difficult to use effectively with specific patients (15, 16). Different situations need different approaches - doctors feel that most recommendations in guidelines are not suitable for every situation and that the sequence advocated by the recommendations is often not appropriate for a particular consultation - they feel that guidelines do not afford them sufficient flexibility to achieve efficient and effective communication (17). How applicable recommendations are in clinical practice (18) and whether a guideline responds to patient variability (19). Applicability is an important attribute that contributes to the effects of practice guidelines (20). The lack of applicability with guideline recommendations (21).

**OPERATIONALIZATION – “How-to”**

**Examples:**
- Shekelle et al. evaluate the effect of different levels of specificity of recommendations on clinicians' test ordering behaviour using clinical vignettes. They found that clinicians ordered fewer indicated tests for appropriate indications than physicians who received specific recommendations. The authors concluded that the clarity and **clinical applicability** of a guideline are important attributes that contribute to the effects of practice guidelines (14).
- Both GPs and internists perceived guidelines as useful memory aids but found them difficult to apply to their non-ideal patients (study results) (15).
- The barrier (applicability) was specifically mentioned when participants explained why they didn't adhere to communication guidelines (17).
- 27% of physicians responded that practice guidelines can address patient variability, 25% responded negatively, and 49% responded “not sure” (19).

**CONTEXT**

Medicine (14, 16-19, 21-23)

Medical Informatics (15)

**RELATIONSHIP WITH UPTAKE**

- Applicability significantly predicted increased knowledge resource use. However, authors note a lack of clinically applicable information in the research literature and in knowledge resources/tools used (or supposed to be used) by clinicians (23).
- GPs disagreed with a recommendation if they felt that a recommendation was not applicable to a specific group of patients. Other studies have demonstrated that lack of applicability is an important barrier to guideline adherence, particularly to patients with co-morbidity (22).
- Study participants felt that using the complete guideline was not helpful or that the guideline was of no use at all in many situations: “Well, what I wanted to say here is that the problem here is that it's a very general schema and it is also bristling with assumptions. And because of that funny enough again it's not a general schema. And a lot of the problems you see in general practice they just don't fit into the schema” (study participant) (17).
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<td>Clinical relevance</td>
<td>The recommendation is concerned with a relevant aspect of care in daily practice (24) and is concerned with a common clinical issue or a decision important in daily care (25). The relative frequency that the topic of the resource focuses on questions that arise in clinical practice (23). Good guidelines focus on key clinical decisions and emphasize the priority of the clinical topic (26). Guidelines with assumption flaws (they) are somewhat artificial and reflect(ing) assumptions with little relevance to day-to-day practice (17). Recommendations are not relevant to their practice or were inaccessible or out of the scope or GPs' practice (27). Guidelines less useful in daily clinical practices (28). One GP stated that the guidelines were useful for research and audit purposes but not in daily clinical practices (study results) (28). GP saw consultations with real patients as more complicated than their portrayal in the guidelines (29-40). Lack of fit between GPs own experiences and the guideline recommendations (41). Also, guidelines exist for relatively few guideline scenarios (42). Patients and physicians recognize that a particular intervention might be useless for the general population but useful to an individual (30). CPGs can generate conclusions, make recommendations based on benefits that are statistically significant, but not clinically significant (Chou, 2008). For information to be of value or used, information which will lead to a decision other than the decision resulting from no information has a reasonably high probability of occurring (43). Central vs. peripheral - the degree to which the innovation concerns the major day-to-day work of the organization and involves activities critical to organizational performance (44).</td>
<td>How-to:</td>
<td>Medical (9, 17, 23-28, 30, 41, 45, 47)</td>
<td>(Knowledge) Resources focused on frequently questioned topics have a higher likelihood of being considered for use, independent of quality or accessibility characteristics, than resources that offer less coverage of such issues (study results). For instance, the reported high priority for information on drugs (49).</td>
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<td>Relevance of evidence</td>
<td>Skeptical about the evidence based for guidelines (41). Guidelines should apply to patient populations defined in accordance with scientific evidence or best clinical judgment (50). Some GPs feel that the evidence in the literature, based on RCTs, presents an artificial situation. They feel the conclusions from the research trials may not be relevant to everyday practice (study results) (51). A common reason for downgrading RCT-based recommendations is based on concerns of the clinical relevance of the RCT (e.g., RCT reported surrogate outcomes only rather than patient-centered outcomes (52).</td>
<td>None.</td>
<td>Medicine (41, 51-54)</td>
<td>Applicability of recommendations is at least as relevant as their support with evidence to guarantee adherence to guidelines; The most important barriers to the application of recommendations are concerned with the need for new skills and the complexity of the recommendations (53).</td>
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**Patient relevance**

Applicability to the practice population (22). Does the patient characteristics fit the intended target audience of the guideline (14). In addition to clinical evidence, recommendations reflect the applicability of the evidence to the population of interest; economic considerations; guideline developers' awareness of practical issues; and guideline developers' societal values (55). Concerns expressed by GPs about the applicability of trial data to their own patients, who were more "difficult" or to whom the protocols simply do not apply (31). Contextual or supplementary clinical information is provided by which to interpret and apply the recommendations for individual patients, clinicians value guidance on how to blend experience with evidence when applying the recommendations to individual patients and engage patients in shared decision making (56). Guidelines need to be interpreted as to their appropriateness for individual patients. Guidelines do not take into account the individual differences seen in response to treatment (57). The purpose, rationale, patient population and provider population for whom CPG is directed or should use (58). Generalizability or external validity. Even when CPGs appear valid, findings and recommendations may not be applicable to all patients (47). Belief that recommendation is not applicable to patient population. Belief that benefits do not outweigh patients' discomfort (59). Many guidelines emphasize the state of scientific knowledge rather than being written for practicing physicians (60). How applicable to a specific population or clinical setting (10). The recommendation is too rigid to apply to individual patients (61). One weakness in PG is to include patients more representative of clinical practice in randomized controlled trials (16). To be really useful, guidelines should describe interventions well enough for their exact duplication. Clinicians must determine whether their patients are the intended target of the particular guideline (62). GPs perceived some recommendations not being applicable due to heterogeneity of patient populations. Other studies also demonstrated that lack of applicability is an important barrier to guideline adherence, particularly to patients with co morbidity (21). Whether a recommendation is suitable for the patients who it is intended for (61).

**How-to:**

- **Elements within Applicability (63).**
- Individualization (Clinical information (indications, criteria, risk factors, drug dosing) that facilitates application of the recommendations explicitly highlighted as tips or practical issues using subtitles or text boxes, or summarized in table and referred to in recommendations or narrative contextualizing recommendations.
- Practice guidelines should be as inclusive of appropriately defined patient populations as evidence and expert judgment permit, and they should explicitly state the population(s) to which statements apply (50).

**Examples:**

- GPs' argued that population based trials were not necessarily applicable to individual patients; "guidelines were often viewed as having been developed by enthusiasts outlining "ideal" practice which did not always translate to typical patients within practices with difference demographics" (31); uncertainty about the evidence base in the face of changes over time and controversies (30, 39, 40); GPs' concerns about the generalizability of trial results is an issue that has long been recognized and needs to be addressed by the scientific community (64); GP also pointed out that the use of narrow inclusion criteria could weaken the applicability of the evidence (31).
- Unless the scope and purpose of the guideline are clearly stated, users can only guess whether and when its pertinent. Lack of applicability is in part due to guidelines being based on studies designed to evaluate efficacy (whether intervention works) rather than effectiveness (whether it works in real world settings); For example: Results of SR of a European formulation of glucosamine are less applicable in the US where it is not regulated as a drug and the content and purity varies substantially in over-the-counter formulations (47).
- Guidelines are often viewed as having been developed by enthusiasts, outlining "ideal" practice which did not always translate to typical patients within practices with differing demographics: "The trial data are always derived from relatively fit health people, all the 'grottos' (sic) are excluded...so your typical trial patient is not necessarily the typical patient we see in general practice" (study participant).
- If the patient has a different prevalence of disease or risk factors, the guideline may not apply (14).
- The realities of "real life" were cited with often

**Medicine**

(10, 14, 16, 19, 21, 22, 31, 47, 50, 51, 56-59, 61)

**Health Policy**

(55)

**Physicians believing that a specific guideline does not apply to their patients are one of the most fundamental of the "unfavorable attributes" of CPGs (16).**
interfering with strict adherence to the guidelines (study participant) (31).

- GPs were aware of the guidelines and used them to frame the problem in general but found it difficult to be consistent at the level of different categories of patients [study results]; nearly all GPs in the study provided examples of divergence from guideline recommendations; It has been argued that clinicians feel that research evidence is robust at the level of general or trial populations but that it does not necessarily resolve their dilemma of how this evidence would affect individual patient care (57).

- In the context of this study, lack of applicability related to the population was as a result of local patterns of bacterial resistance. Concern with benefits vs. discomfort related to the time needed to wait for results of the dipslide, particularly in the case of serious complaints (59).

- Such specificity should be expressed explicitly in the CPG or in an addendum. One should not assume that guidelines developed in a particular country would be applicable to another population. Morimoto et al. (2004) demonstrated this in their study that showed the benefit-risk ration for the use of aspirin is different for American and Japanese populations (10).

- After validity and reliability, clarity and applicability are the other two most important attributes. A guideline that is ambiguous is less likely to be followed and a guideline that is not applicable to for a specific population group or clinical setting will have poor adherence (10).

- Some GPs believed that recommendations were not applicable due to the heterogeneity of patient populations (22).

- The most cited reason for those not using PG in private individual practice, group outpatient practice and community mental health practice was that the PG applied poorly to the patients seen in the particular practice; Those who did not use PG were most likely to feel that such PG did not apply to the patient population in their clinical practice. This belief is an important finding as it may help those who formulate PG in attempting to address such populations; Failure to include patients more representative of clinical practice in randomized controlled trials has been investigated before and found to be a weakness of current evidence-based medicine (65); Results suggest that more attention to subpopulations, including co morbidities and ranges of severity for example may be worthwhile in future PG (16).
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<td>Applicability emphasizes the need to take into account implementation during the development process so that guidelines have an influence on clinical practice (66, 67). Describe anticipated barriers to application of the recommendations (68).</td>
<td>Provide reference to an auxiliary document for providers or patients that are intended to facilitate implementation; Suggest review criteria for measuring changes in care when the guideline is implemented (68). Authors suggest the lack of applicability should be a more prominent category in framework of barriers to implementation (22), including different reasons such as the benefits and harms or patients who require special attention (21). Factors to consider when judging clinical significance include (47): Magnitude of treatment benefits whether patient-centered clinical outcomes were assessed. Whether validated and standardized methods were used to measure outcomes. Whether all important potential outcomes (beneficial and harmful) were considered; For example, CPGs that focus on surrogate outcomes such as physiologic imaging or laboratory results can be misleading because they often do not correlate well with patient-centered outcomes such as pain, functional status, or ability to work.</td>
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Examples:
- Most guidelines assessed in this study did not include information on barriers to implementation or costs implications. This may be because guidelines are often translated into protocols for local implementation and use (69).
- The criteria for applicability specify that, to improve uptake, guidelines should include information about anticipated organizational barriers, costs associated with adoption, and measures for audit and monitoring. GLIA states that guidelines should explicitly identify the anticipated impact of adoption on individuals and organizations, and include measures by which performance of the recommended medical interventions or services can be evaluated (70). Endorsement of and intent to use guidelines are predicted by this attribute (71).
- Lack of consistency in the recommended practice also can be a barrier to implementation (72). |

Medicine (21, 47, 68, 72, 73)
| Acceptability (an outcome of applicability) | Whether providers experience in caring for the disease/disorder that is the focus of the CPG, believe the guideline applied to common clinical situations (18); Note: the author thought of this as an element of clinical acceptability). Acceptability describes whether the recommendation should be put into practice (74) and providers’ views about how useful each guideline would be in clinical practice (18). Absence of controversy (30). Acceptability is predicted by the endorsement and intent to use a guideline (75). | How-to: | Acceptability is evaluated based on: (1) perceived comprehensiveness and (2) perceived validity (18). Acceptability of recommendations may be strongly related to the quality assessments so that quality beliefs add little above acceptability beliefs (61). | Examples: | Comprehensive in this study meant that panelists believed that the guidelines addressed appropriateness or quantity for most workers with the condition who might be considered candidates for the therapy (18). | Panelists frequently felt that the guidelines discussed therapies without defining appropriateness or quantity of care for most workers with the condition. Panelists judged all five guidelines to be of intermediate comprehensiveness overall (18). | \begin{itemize} \item When ACCEPTABILITY IS applied, the recommendation will produce more benefits for patients than harms (61). \item The lack of guidelines for clinical scenarios is one of the factors that hinders clinician acceptance and utilization of guidelines (77-80) \end{itemize} |
**CODEBOOK – Deliberations and Contextualizations**

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Clinicians assessing guidelines should look for information about who was explicitly involved in assigning values to outcomes, or who, by influencing recommendations, was implicitly involved in assigning values. Reporting the methods used to develop consensus is important to include in a guideline (2).

Examples:

- Clinical practice guidelines may evaluate similar evidence and report comparable results, but reach discordant conclusions about how clinicians should act on those findings. This can occur because of differences in how outcomes are prioritized or valued (47).
- The American Heart Association recommend short-term opioid analgesics over NSAIDs as first-line for musculoskeletal symptoms in patients with known cardiovascular disease because of increased risk of MI - recommendations that are likely informed by the high priority of the association to prevent MI. In other guidelines, opioids remain a second-line agent because side effects and long-term risks of opioids. Weighing of outcomes involved in assessing the balance of benefits and harms almost always involves subjective judgments. However, clinicians evaluating discordant guidelines should consider whether the values placed on different outcomes are congruent with the importance they (and their patients) would assign to them (47).
- When making a decision on treatment options for the prevention of osteoporotic fractures, some experts may formulate recommendations in favor of treatment with teriparatide for women at high fracture risk - One woman may share values and preferences in keeping with this recommendation, whereas another woman in the same situation may find the injection or its cost unacceptable and would thus prefer not to take it. With weak recommendations, the clinician will need to have a more detailed and deliberate discussion with the patient, reviewing several reasonable options, particularly when clinicians and patients find their own values and preferences at odds with those the guideline panel considered in making its recommendations - the use of decision aids is a promising tool to overcome these challenges (82).
- Only 6.1% of the guidelines discussed the values used by the developers to judge the desirability of alternative practice and outcomes and to make recommendations. (13).
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| Provider Values         | The degree to which an innovation is perceived as consistent with the existing values, past experiences, and needs of potential adopters (86). Compatible with existing norms and values in practice; when the recommendations are... | How-to:  
- Trying desired changes to existing norms helps people understand and adopt practices (5).                                                                 | Clinical Epidemiology (25)                                                                 | • Compliance was lower if recommendations were vaguely worded, incompatible with clinician norms and values, and disruptive to routine practice (24). |
| Syonyms:                | • Compatible with norms and values; conflict between guideline aims and GP motivation; consumer resistance to innovation; traditions and norms; personal relevance. | Examples:  
- Pain is often inadequately managed because “as needed” often requires that a patient admit their discomfort and causes disruption of other routine nursing tasks to receive information. Designating pain as “the fifth vital sign” obligates the caregiver to routinely assess the patient, solicit the patient’s subjective assessment, and deliver relief as part of routine, not outside routine. This practice is now widely embraced by nurses and mandated by regulatory agencies (5).  
- If guideline recommendations implied rationing services, the importance of preserving a good doctor-patient relationship was sometimes cited as more important than following the guidelines (30, 31, 34, 36, 40). Rationing was perceived as both unpleasant and in conflict with the ideals of patient-centered medicine and the economic incentives of competition for patients (41).  
- Both physicians and patients expressed the opinion that experts place economic considerations ahead of scientific concerns when they judge the value of screening activities. Many felt that experts do not take into account the limits of current knowledge and they may not recommend performing a test that could prove to be effective in the future (30). | Economic Psychology (89)                                                                 | • Whether a recommendation was controversial and incompatible with existing values in the target group and whether it was clearly defined were particularly important. Compatibility is one of three attributes (the others are vague and routine changes) contributed most to the explanation of variance. These attributes mainly had an independent effect on the compliance rate in practice. They explained 17% of the variance (study results) (24). |
|                         |                                                                                                                                                    |                                                                                               | Marketing (114)                                                        | • Herbig and Day (1992) suggest that culture and society create so-called diffusion thresholds and that when innovations go beyond these thresholds they will be resisted; Hirschman (1987) suggests that innovations that are closer to traditional norms are more acceptable where as innovations that deviate from these ideas are resisted at first; Ram and Sheth (1989) suggest a negative relationship between societal disapproval and resistance. Expected to be particularly present for eating customs, as they are strongly culturally embedded (89). |
|                         |                                                                                                                                                    |                                                                                               | Medicine (5, 24, 30, 41, 88, 113)                                      | • If the product does not stimulate much interest, consumers do not give much attention to it; high involvement indicates more personal relevance or importance; in general, consumer acquisition of low involvement products is often done without carefully examining brand and product information, this lack of commitment suggests that information on the package would carry relatively less value in such cases; on the other hand, more highly involved consumers evaluate message information more carefully, relying on the message to from their attitudes and purchase intentions (115). |
|                         |                                                                                                                                                    |                                                                                               |                                                                                        | • Doctors may be more likely to change their clinical practice when they perceive new norms for professional behaviour rather than when they simply receive new information (116). |
Guidelines were viewed as not being flexible enough to take into account the complexity of individual circumstances (e.g., multiple diagnoses, painful side-effects, and patient preferences) (41). Guideline flexibility allows users to individualize recommendations or justify departure from the recommendations altogether (14). Guidelines can and should give users greater flexibility of action (optionality of adherence) (117). PG should be flexible enough to apply to individual patients (118). The degree to which a recommendation permits interpretation and allows for alternatives in its execution (GLIA) (70, 83). Whether a guideline is flexible enough to use with all patients (37). A common reservation for participants about guidelines was their perceived need for flexibility to take into account the individuality of each patient (28). Flexibility in the application of the CPG, or situations in which CPGs may not apply (58). One-for-all guidelines that are designed for a specific population do not account for differences between patients' characteristics and preferences, suggesting a need for flexible guidelines that enable and facilitate patient involvement in medical decision making (119). "The main goal of guidelines is to assist physicians and to improve patient care, which implies that they should be developed and considered as a support for practitioners with space for flexibility, rather than a set of constrained rules” (120).

Guidelines that are applicable in many situations and that have proven effectiveness for the settings in which they are to be used (17). Note: this seems different from the other definitions and we’re not sure if we agree with it.

How-to:
- Flexibility in the recommendations is specified (13).
- The flexibility of the guideline may be indicated by the patient or practice characteristics that require individualizing recommendations or that justify departure form the recommendations (62).
- CPGs should be designed so that they are both flexible enough to be applicable in the real world across different levels of expertise, and sufficiently explicit to ensure that correct inferences are made in most cases (121).
- Guidelines should identify exceptions to their recommendations and indicate how patient preferences are to be incorporated in decision making (50).
- Practice guidelines should identify the specifically known or generally expected exceptions to their recommendations and discuss how patient preferences are to be identified and considered (50).
- Exceptions to the recommendations should be specified especially if they are supported by good scientific evidence or reliable clinical experience. CPGs should also take into the importance of patient perceptions and preferences, and articulate ways to adopt a more patient-centered approach to decision-making (10).
- …guidelines need to remain flexible enough to permit a degree of patient-specific departures from specified prevention, diagnostic and treatment protocols (122).

Example:
- The risk stratification of clinically localized prostate cancer into low, intermediate and high risk categories is an example of differing recommendations for different prognostic groups (14).
- Some interviewees argued PG were not flexible enough to apply to individual patients (123). While PG expected GP to think in certain ways, patient expectations were different. PG were most useful where the clinical problem had not much variation. In practice many conditions were complicated (118).
- GPs were asked if depression guidelines were sufficiently flexible to use with all their patients in managing depression. Many GPs thought the guidelines were not flexible. There were different worries with lack of flexibility: -legal cases - concern with malpractice lawsuits - guidelines should not be used in all situations because they vary so much.
- Guidelines make invalid assumptions about patients presenting with only one illness -- not useful for patients with certain illness combinations. Some participants suggested that you can't use the guideline with every patient because there will always be certain patients to whom guidelines do not apply. (study participants) (37).
- For example, it would allow for specific work orders prepared on-site from one day to the next; A framework with built-in flexibility is indispensable, given the ways in which the functions recommended in guideline texts are specified and assigned, if we are to build workflow systems which will be accepted by the medical community (46).
- Does the recommendation specify patient or practice characteristics (clinical and non-clinical) that require (or permit) individualization (70).
- Boilerplate schemes are classification schemes and algorithms. These are technically correct, but clinically incorrect. They allow doctors to become so wedded to generic profiles that they ignore the individual characteristics of the patient (124).
## Elements of Provider Values: Clinical Flexibility; Clinical judgment

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| Clinical flexibility | Clinical freedom is the space provided to doctors to enable individual flair and innovation (128). Clinical freedom is the resistance to following codified instructions and the threat to medical autonomy and tacit knowledge and skill (57); (129). The exercise of clinical freedom should have one aim -- to benefit the patient. Misplaced professional pride has no place: “Granting physicians clinical autonomy is justified by reference to the patient’s interests, not the physician’s” (9). The need for professional discretion in use and adaptation of guidelines (19). The user should feel he/she is in control of the system (not the reverse) (130). Clinical freedom can also be used to mask inappropriate and inefficient practice (128). Patients should have the security of knowing that whatever doctor they consult, he or she will provide them with a certain minimum standard of cost-effective care (128). One of the erroneous assumptions about doctors - Doctors need to be in charge sometimes. The guidelines are patient-centered. Doctors sometimes feel as a result that they do not have sufficient opportunity to structure consultations when patients' stories are very long-winded and unstructured, support anxious or inductive patients, or set boundaries when patients' behave inappropriately (17). Blind obedience is showing undue deference to authority or technology (131). | How-to:  
- Freedom is facilitated by the provision of (1) clearly marked exits; (2) Support undo and redo transactions; (3) Make it difficult to perform irreversible actions - There should always be a way for users to back out of current actions and they should not perceive that they are controlled or irreversibly locked into actions or procedures by the system (130).  
- Each treatment should be analyzed and examined on its own merits, including its bounds of uncertainty (55).  
- Guidelines can help define this standard but also need to reflect honestly the areas of uncertainty that exist at any given time, in order to avoid stifling healthy innovative practices (128).  

Examples:  
- The key issue from this study was the need to define the appropriate balance between the consistency of management approaches and allowing professional discretion (57).  
- 87% of respondents scored 7 or above (1=low value, 10=high value) when asked to rate the value of the freedom to modify the guideline as appropriate under specific clinical circumstances - thus, respondents indicated a desired to adapt guidelines to clinical circumstances when necessary; This finding is similar to Tunis et al., in which 24% of respondents indicated that practice guidelines were too rigid to apply to individual patients, and 21% perceived guidelines as a challenge to physician autonomy (19).  
- Endocrinologists involved in this study found the guideline to be very useful, although neither one felt that it adds much to their clinical practice - One ENDO said that he would skip or change a recommendation if his clinical experience indicated that this would be a reasonable step. Reasons for any groups included in this study (GPs, internist, Endos) to depart from the guideline were based on practical clinical experience (15).  
- Clinical autonomy is one of the factors that hinders clinician acceptance and utilization of guidelines (77-80). Comments from clinicians on the modified guideline generally requested a reduction in the guideline expectations prior to their agreement with them. However, a few clinicians did request more rigorous standards for some items (42). | Medicine (9, 10, 17, 19, 57, 60, 78, 129, 132, 133)  
Biomedical Informatics, Cognitive science (130)  
Cognitive Ergonomics (42)  
Health policy (55)  
Medical Informatics, Cognitive science (15)  
Psychology (131) | • GPs feel that the move towards collecting information about guideline adherence means there is less trust in professional discretion in decision making, resulting in a culture of suspicion (57).  
• Some guidelines fail to take into account clinical freedom in recommendations (Tan, 2006).  
• Doctors are finding it more difficult to exercise clinical freedom and to deviate from PG, which are becoming more like “rules” than “guidelines” (10).  
• Interventions that decrease physicians’ decision-making authority, are more likely to fail (134).  
• Listed as a problem with guidelines: Affect autonomy for 5% of respondents (n=509) (126).  
• Physicians are concerned about guidelines because they see them as a threat to clinical autonomy (132, 133). |
<table>
<thead>
<tr>
<th>Clinical Judgment</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Synonyms:</strong></td>
<td><strong>(83, 128, 135, 137, 138, 140, 141)</strong></td>
</tr>
<tr>
<td>Clinical discretion</td>
<td>Often, guidelines seek to convey clinical judgment decisions about the individual patient with subtle language distinctions (*&quot;X may be useful&quot;) (135).</td>
</tr>
<tr>
<td>Autonomy (note – autonomy is used both in the context of Clinical Freedom and Clinical Judgment)</td>
<td>100% adherence to CPG recommendations is likely to reflect poor clinical practice - not appropriate in all circumstances (136).</td>
</tr>
<tr>
<td>How-to:</td>
<td>&quot;...reasons for nonuse...those most often mentioned were cookbook medicine/do not allow for clinical judgment (41%)...&quot; (126).</td>
</tr>
<tr>
<td>Practitioners and patients should use their clinical judgment to decide if the circumstances of the patient and point of the therapy are such that the guideline recommendations are appropriate (136).</td>
<td>PG should recognize the importance of professional judgment and discretion and do not unnecessarily or inappropriately limit the practitioner (141).</td>
</tr>
<tr>
<td>As guidelines are increasingly being used to measure quality or guide reimbursement, they will need to distinguish those measures for which (135).</td>
<td>Guidelines do not rely on diagnostic technology results (and under-appreciation of technology’s limitations) may be akin to blind obedience, which leads people to stop thinking when confronted with an apparent authority that may be human (for example, an assertive colleague) or technological (for example, an objective lab result) (131).</td>
</tr>
<tr>
<td>There is clear and compelling evidence of important benefits (e.g., childhood vaccinations),</td>
<td>The apparent over-reliance on diagnostic technology results (and under-appreciation of technology’s limitations) may be akin to blind obedience, which leads people to stop thinking when confronted with an apparent authority that may be human (for example, an assertive colleague) or technological (for example, an objective lab result) (131).</td>
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<tr>
<td>Measures that should be encouraged but not required (e.g., sigmoidoscopy),</td>
<td>Descriptive and rigid guidelines are not useful (146).</td>
</tr>
<tr>
<td>Interventions for which the best strategy depends on clinical judgment and patient preference (e.g., hormone replacement therapy)</td>
<td>Cookbook medicine works against the principle of shared decision-making in an ideal doctor-patient relationship (19).</td>
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<tr>
<td>Flexibility in the recommendations should be specified (13).</td>
<td>Those PG that provide blanket recommendations may ignore special needs</td>
</tr>
<tr>
<td>Examples:</td>
<td>Guidelines offer physicians a means for permanently recording their reasons for noncompliance; The perception that guidelines reduce the role of clinical judgment poses a barrier to wider acceptance by clinicians (135). Treatment must always be individualized, taking into account co morbid conditions and other complicating factors. The patient's own values and the physicians’ clinical judgment must always come into play (138).</td>
</tr>
<tr>
<td>For example, a woman eligible for a Pap smear might refuse it or be menstruating: A man with metastatic lung cancer would not be a candidate for fecal occult blood screening; Treatment recommendations in guidelines generally emphasize evidence of effectiveness, but clinicians must also consider other factors such as patient preferences, costs, competing health priorities, and the magnitude of the benefit when dealing with individual patients (135).</td>
<td>Cookbook medicine works against the principle of shared decision-making in an ideal doctor-patient relationship (19).</td>
</tr>
<tr>
<td>Guideline can replace the role of clinical judgment (135). The balance of the desire to create guidelines that are forthright and unambiguous with the recognition that no guideline can replace the role of clinical judgment about the individual patient (135). Guidelines are not intended to supersede professional judgment - rather, they may be viewed as a relative constraint on individual clinical discretion in a particular clinical circumstance (83). Guidelines are designed to assist practitioners and patients in making complex clinical judgments, and not to replace the judgment process (136). Guidelines do not usurp physician autonomy when it comes to clinical expertise and judgment. Guidelines are a guide, not a command or standard that must be met on every occasion (137). Clinicians should always act and decide in a way that they believe will best serve their patients’ interests and needs, regardless of guideline recommendation (83). It is critical to recognize that not all guideline rules will be followed and that this &quot;noncompliance&quot; will often be appropriate. In fact, medicolegal risk will be lessened if systems to invoke guidelines offer physicians a means for permanently recording their reasons for noncompliance; The perception that guidelines reduce the role of clinical judgment poses a barrier to wider acceptance by clinicians (135). Treatment must always be individualized, taking into account co morbid conditions and other complicating factors. The patient's own values and the physicians’ clinical judgment must always come into play (138).</td>
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<table>
<thead>
<tr>
<th>Cookbook</th>
<th>Medicine</th>
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<tbody>
<tr>
<td><strong>Synonyms:</strong></td>
<td><strong>(10, 17, 19, 22, 41, 126, 132, 133, 135, 138, 142-144, 146)</strong></td>
</tr>
<tr>
<td>Prescriptive, Rigid, Standardized, simplying decision making</td>
<td>Prescriptive and rigid guidelines are not useful (146).</td>
</tr>
<tr>
<td>CPGs have been regarded by many doctors as leading to the practice of &quot;cookbook&quot; medicine (10). Too rigid to apply (132); (142); (133), cookbook medicine biases synthesis, challenge autonomy, not practical (22). Guidelines are viewed by some as efforts by sub-specialty groups to protect their turf or attempts by cost-cutters to cram homogenized &quot;cookbook&quot; medicine down their throats of formerly independent practitioners (138).</td>
<td>Cookbook medicine works against the principle of shared decision-making in an ideal doctor-patient relationship (19).</td>
</tr>
<tr>
<td>How-to:</td>
<td>Those PG that provide blanket recommendations may ignore special needs</td>
</tr>
<tr>
<td>In the prescriptive studies authors focus on the difficulties GPs experience when attempting to adapt recommendations to the circumstances of the individual patient and to the practical constraints of the consultation (41).</td>
<td>Prescriptive and rigid guidelines are not useful (146).</td>
</tr>
<tr>
<td>In the prescriptive studies the focus is on the dilemmas of combining the role of gatekeeper and the role of</td>
<td>Cookbook medicine works against the principle of shared decision-making in an ideal doctor-patient relationship (19).</td>
</tr>
<tr>
<td></td>
<td>Those PG that provide blanket recommendations may ignore special needs</td>
</tr>
<tr>
<td>Antonyms:</td>
<td>The use of PG in clinical practice implies, to a greater or less extent, the standardization (143). The extent to which guidelines suggest or prescribe that a physician does something (19). Guidelines are oversimplified (133). Prescriptive guidelines encourage a certain type of behaviour or treatment (41). Proscriptive guidelines discourage certain treatment or behavior (41). Rigidity makes guideline usage inefficient and time consuming (17). Criteria presented in guidelines are too stringent (144).</td>
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| patient advocate; such studies refer to GPs' concerns that rationing may harm the doctor-patient relationship or even lead to litigation (41). Clinicians balance their own preferences, those of patients and caregivers, the benefits, side effects, and safety of treatment and, to varying extents (depending on the mode of reimbursement), cost in reaching decisions (55). Over-precision should be challenged and all uncertainties should be explored, which are appropriate to the data or expressed in the group (Mason, 1999). Occam's razor is a familiar heuristic: choose the simplest hypothesis that explains the most findings (135). In a time-sensitive situation in which the alternatives are clear-cut, guidelines may be very effective. When a stereotyped yet medically appropriate response to a small number of yes-no variables can be implemented in seconds by a relatively unsophisticated practitioner, such as an emergency medical technician, a rapid "cookbook" solution is preferred. For instance, when a patient has a cardiac arrest, simple low-level algorithmic approaches, such as the Advanced Cardiac Life Support guidelines, are universally acknowledged to be effective instruments (142). Examples: | Physiotherapy (145) | or preferences of individual patients (10). The positive side of standardization is the reduced variation in care practices; the potential negative effects may be a reduction in patients' influence of care or providers who experience diminishing professional freedom (143). Blindly following general rules will obscure valid individual differences and result in poor care (135). “...reasons for nonuse...those often mentioned were cookbook medicine (126, 132). |
## Attribute: Feasibility

<table>
<thead>
<tr>
<th>Concept</th>
<th>CODEBOOK DEFINITION</th>
<th>OPERATIONALIZATION – “How-to”</th>
<th>CONTEXT</th>
<th>RELATIONSHIP WITH UPTAKE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feasibility</td>
<td>Feasibility: Feasible guidelines are clearly written, are user friendly, allow for flexibility in individual clinical decisions, and are suitable for routine use in intended settings (83). Feasible guidelines are in agreement with users’ opinions, skills, and practice routines (17). Policy and administrative implications of using the guideline (referring to the feasibility of implementation) (147). PG should be feasible and as clear, understandable and unambiguous as possible, given current healthcare practices (148). The ease of adopting a practice (5).</td>
<td>How-to:</td>
<td>Medicine (3, 5, 17, 83, 126, 133, 147, 148, 150)</td>
<td>• None.</td>
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<td>Political acceptability</td>
<td>Feasibility is directly influenced by the existing conditions for the delivery of preventive services; difficulties in changing practice routines (150).</td>
<td>Sociology (149)</td>
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<td>Ease of use</td>
<td>The guideline should include: time, staff, equipment necessary to carry out recommendations and the ability of systems of care and patients to implement them (3).</td>
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<td>Political acceptability: Political acceptability: The acceptability of a statement is evaluated by discussing how it might affect what members see as the relevant distributions of power in the institutions in which the guideline is going to be implemented. The repertoire of politics has to do with the collaborative evaluation of the political sensibility of evidence statements and recommendations inscribed in the guideline. The worth of a statement is evaluated by a) the distributions and the force of positions and accountabilities within health care institutions, b) whether or not a statement might interfere with such distributions, and c) how such change might be justified in the light of a different version of just distribution of power (149).</td>
<td>Examples:</td>
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<td>• Question: &quot;What would make you most likely to follow practice guidelines?&quot; (n = 513). Pediatricians’ responses (12%): Feasible/practical for my practice (126).</td>
<td>Medicine (3, 5, 17, 83, 126, 133, 147, 148, 150)</td>
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<td>• 30% of negative comments about guidelines from physicians focused on lack of feasibility (133).</td>
<td>Sociology (149)</td>
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<td>• Most important in terms of treatment feasibility was &quot;to have a stepped therapy schema&quot; and to increase self-confidence; for example, &quot;the feeling to do the right thing and not alone&quot;, &quot;to find their own treatment approach supported by others&quot; and &quot;to become more self-confident in the medical care of PD patients&quot; were cited as important factors (133).</td>
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<td>Political Acceptability Example:</td>
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<td>• A consultant from the CPG development group questions the extent to which the group’s recommendation about restricting the intake of a particular nutrient is going to be effective. The controlled intake of a given nutrient is seen as an effective way of lowering the specific health measurement within which a guideline is concerned. However, it is argued that similar positions have been met with problems in the past. Such problems were associated with the political history of the debates about the inclusion of this nutrient in processed foods (145).</td>
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### Concept: Local Applicability

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<th>Sub-attribute: Local Applicability</th>
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#### CODEBOOK DEFINITION

**Adaptability**: the ability to refine, elaborate, and modify a guideline according to the needs and objectives of the implementer (48), or applicable values (81).

#### OPERATIONALIZATION – “How-to”

**How-to:**

- Guidelines can be adapted to different users or purposes (56), and to respond to local circumstances, objectives and constraints (151).
- It involves reformulating the recommendations in terms of measurable criteria and targets for quality improvement (152).
- Carefully developed PG should set bounds on adaptation by offering accepted options of practice (151).
- **Context adaptation**: involves taking into account the resources requirements associated with each action in a guideline (153). Only those actions whose resource requirements can be satisfied in the given context can be executed. The context adaptation process can prune all non-executable actions from general guidelines (153).
- Through **Accommodation**: Costs, resources, competencies, and training, technical specifications and anticipated impact required to accommodate use are identified (56).

**Examples:**

- Elements within Accommodation: Objective (Explicitly state purpose of guidelines (clinical decision making, education, policy, quality improvement); Users (who would deliver/enable delivery of recommendations (individuals, teams, departments, institutions, managers), who would receive the services (patients/caregivers); User needs/values (identification of stakeholder needs, perspectives interests, values); Technical (equipment or technology needed, or the way services should be organized to deliver recommendations); Regulatory (industrial standards for equipment or technology or policy regarding their use); Human Resources (type and number of health professionals needed to deliver recommended services); Professional (education, training or competencies needed by clinicians/staff to deliver recommendations); Costs (Direct or productivity costs incurred as a result of acquiring resources or training needed to accommodate recommendations, or as a result or service reduction during transition from old to new processes; Research suggests that individual clinicians value details about competency and training requirements (18, 24, 56, 81, 118, 151, 152, 155)); Less than a third included tailoring the PG to suit local circumstances.

#### CONTEXT

- **Medicine**: (18, 24, 56, 81, 118, 151, 152, 155)
- **Sociology**: (48)
- **Medical Informatics**: (153)

#### RELATIONSHIP WITH UPTAKE

- **None.**
• The Canadian Best Practice Recommendations for Stroke Care have a section for each guideline topic outlining the system implications. For example, for their blood pressure management recommendations, they have listed the following under “System Implications”:
  o Coordinated hypertension awareness programs at the provincial and community levels that involve community groups, pharmacists, primary care providers and other relevant partners.
  o Stroke prevention, including routine blood pressure monitoring, offered by primary care providers in the community as part of comprehensive patient management.
  o Increased availability and access to education programs for healthcare providers across the continuum of care on hypertension diagnosis and management for adults and children.
  o Increased programs for patients and families on home monitoring of blood pressure and blood pressure self-management programs.
<table>
<thead>
<tr>
<th>Attribute</th>
<th>CODEBOOK DEFINITION</th>
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<th>CONTEXT</th>
<th>RELATIONSHIP WITH UPTAKE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local Adaptation</td>
<td>Local Adaptation: PG may be developed at a national level and contain intentionally broad statements aimed at providing general advice (156). This local adaptation enhances implementation and evaluation (157). Adaptation for a local setting and tailoring evidence-based implementation strategies to local factors (45). &quot;...adapt the guideline as needed&quot; - identifies this as responsibility of a formal guideline leadership team. (158).</td>
<td>How-to:</td>
<td>Medicine</td>
<td>Only the people involved in the developing procedure are likely to use them (45).</td>
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<tr>
<td>Synonyms:</td>
<td></td>
<td>• In order to reflect local service provision, it is recommended that nationally produced PGs are then adapted to contain more specific detail (156).</td>
<td>(45, 70, 71, 84, 117, 156-159)</td>
<td>Context: Locally developed PG may be less valid (tradeoff) (45).</td>
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<td>• Explicit consideration of context during adaptation to ensure relevance for local practice (71).</td>
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<td>• Recommendations should be non-controversial and aiming for minimal change, taking into consideration the local facilities and resources (159).</td>
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<td>• Does the recommendation specify patient or practice characteristics (clinical and non-clinical) that require (or permit) individualization? For example, immediate angioplasty and MR imaging may not be available in all settings (70).</td>
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<td>• Recommendations may need to be adapted to specific settings, can only be implemented in specific settings, and their impact can only be assessed in specific settings (84).</td>
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<td>Examples:</td>
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<td>Examples:</td>
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<td>• Locally developed PG are less likely to go through the appropriate development process to ensure their validity, and only the people involved in the developing procedure are likely to use them (45).</td>
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<td>• Nationally developed PGs are often dismissed by clinicians as &quot;cookbook medicine&quot;, which they believe lowers their practice to a lower common denominator. On the other hand, CPGs developed locally by multidisciplinary teams seem to be received more readily (160). It is questionable, however, how local PGs will reduce practice variability. Although reinventing the wheel is seldom justified, standardized outcome measures are a necessity if CPGs are to be &quot;borrowed&quot; from other jurisdictions (161).</td>
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<td>• International guidelines should be more non-prescriptive, whereas local guidelines should be more prescriptive as they can easily allow for specific country issues and differences (117).</td>
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**Elements of Local Applicability: Application tools and strategies**

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<tr>
<th>Attribute</th>
<th>CODEBOOK DEFINITION</th>
<th>OPERATIONALIZATION – “How-to”</th>
<th>CONTEXT</th>
<th>RELATIONSHIP WITH UPTAKE</th>
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<tbody>
<tr>
<td><strong>APPLICATION Tools and Strategies</strong></td>
<td>Strategies to implement the guideline. One item of implementation dimension (147). Guidelines should contain implementation and dissemination strategies and monitoring (162). Strategies for identifying barriers for use and selecting, planning, and applying promotional strategies are described; Including implementability information within guidelines to help users apply the recommendations represents a less-threatening, practice-relevant approach to guideline implementation compared with complex, costly inconsistently effective implementation strategies often viewed negatively by guideline users (56). Anticipated barriers to implementation, auxiliary materials, review criteria (68, 83). Implementable: Whether guidelines successfully equate to practical bedside action statements, or whether guidelines have to be translated into clinical pathways, nurse-driven protocols, or physician orders to be effective (163). Elements within implementation: Barriers/facilitators (individual, organizational or system barriers that are associated with adoption); Tools (instructions, tools or templates to tailor guideline/recommendations for local context; point of care templates/forms); Strategies (Possible mechanisms by which to implement guideline/recommendations); research suggests that including information within PG to assist users with implementation of the recommendations may promote greater understanding of how users are to accommodate the recommendations, which may stimulate confidence in capacity to practice the recommended behavior, leading to greater intent to use PG and possibly actual use (56, 63).</td>
<td>Examples: For example: &quot;implementation may be supported by a variety of activities including continuing education and training, and clinical audit; Less than a third included templates such as order forms or assessment checklists (30.0%) and fewer than this offered cursory instructions for identifying barriers of use (15.0%); Our findings simply suggest that more PG could be modified to include implementability content, but it remains unclear how various implementability features might influence PG use; Our findings simply suggest that more PG could be modified to include implementability content, but it remains unclear how various implementability features might influence PG use (56). Introduction of a daily goal sheet and daily multidisciplinary rounds, which helped to remind the ICU team of the guidelines and generated discussion of nutrition support (164).</td>
<td>Medicine (11, 27, 52, 56, 137, 147, 162)</td>
<td>Including implementability information within PG to help users apply the recommendations represents a less-threatening, practice-relevant approach to PG implementation compared with complex, costly, inconsistently effective implementation strategies often viewed negatively by PG users (41); while 45.0% mentioned the need to actively promote PG use, none thoroughly described how to undertake or evaluate this process (56). A well-crafted guideline includes a plan for how the recommendations will be implemented, and anticipates obstacles to implementation (83).</td>
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the NHS as a whole. The number of recommendations prioritized in this way will vary depending on the guideline, and should normally be between five and ten. These recommendations are the ones for which NICE provides clinical audit support, promotional slide sets and other tools to aid implementation (see chapter 13). Many different criteria can be used to select the key priorities for implementation, but key priorities should always be recommendations likely to do at least one of the following: (a) have a high impact on outcomes that are important to patients (b) have a high impact on reducing variation in care and outcomes (c) lead to more efficient use of NHS resources (d) promote patient choice (e) promote equality (11).

- The GDG should attempt to identify recommendations that are particularly likely to benefit from support from NICE’s Implementation Support Team. Criteria include whether a recommendation: (a) relates to an intervention that is not part of routine care; (b) requires changes in service delivery; (c) requires retraining of staff or the development of new skills and competencies; (d) highlights the need for practice to change; (e) affects and needs to be implemented across a number of agencies or settings (complex interactions); (f) may be viewed as potentially contentious, or difficult to implement for other reasons. There should be a clear record of which criteria were considered particularly important by the GDG for each key priority. This should be reported in a short paragraph in the full guideline (11).

- Users of PG may require a set of specific, clinically attractive tools to facilitate the improvements implied by the recommendations. Such tools may include a variety of strategies and means for changing practices, such as flow charts (137).

<table>
<thead>
<tr>
<th>Performance Measures (All a HOW-TO of Implementability)</th>
<th>Performance measures for audit or monitoring (56). Guideline-related behavior should be measurable (166). Evaluating guidelines will test them in practice, which will help prove their effectiveness. This is good because lack of proof of effectiveness in general practices impedes CPG use (17). Elements within Evaluation: monitoring compliance, audit tools, performance measures/quality indicators (56).</th>
<th>Practice guidelines should be accompanied by estimates of the health and cost outcomes expected from the interventions in question, compared to alternative practices. Assessments of relevant health outcomes will consider patient perceptions and preferences (50). How to: Measurability: The degree to which the guideline identifies markers or endpoints to track the effects of implementation of this recommendation (70, 83). Data and values: the practice must have access to sufficient data and sufficiently specified rules (135). The guideline presents monitoring and/or auditing criteria; The guideline presents key review criteria for monitoring and/or audit purposes (165).</th>
<th>Medicine (17, 50, 56, 70, 83, 135, 165-168)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synonyms:</td>
<td>Performance Measures</td>
<td>Measurability</td>
<td>Links with audit</td>
</tr>
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</table>
Links with audit: Development, dissemination and implementation of a guideline should be monitored and evaluated through clinical audit. During the development of the guideline, the development group identifies key points for audit. These should allow the implementation of the guideline recommendations and the impact of these on the processes and, where possible, the outcomes of care to be measured objectively. Often these process and outcome indicators are presented in the form of a minimum data set. SIGN has recently been collaborating with the Information and Statistics Division (ISD) and the Scottish Government to produce national datasets specific to guideline topics (167).

Examples:
The Canadian Stroke Network’s (2012) Canadian Best Practice Recommendations for Stroke Care has a section on performance measures for each set of guidelines. For example, in the Blood Pressure Management section, the “Performance Measures” section indicates:

1. Proportion of persons at risk for stroke who had their blood pressure measured at their last healthcare encounter.
2. Proportion of the population who have diagnosed elevated blood pressure (hypertension).
3. Proportion of the population who are aware of hypertension and the risks of high blood pressure.
4. Proportion of the population who report having hypertension.
5. Percentage of the population with known hypertension who are on blood pressure lowering therapy.
6. Proportion of the population with hypertension who are being treated and have achieved control of their blood pressure within defined targets (as per Canadian Hypertension Education Program guidelines).
7. Proportion of stroke and transient ischemic attack patients who have received a prescription for blood pressure lowering agents on the discharge from acute care.
8. Proportion of stroke and transient ischemic attack patients who have received a prescription for blood pressure lowering agents after assessment in a secondary prevention clinic.

Measurement Notes
Performance measures 1 through 4: data may be available through the Canadian Hypertension Education Program database, the Canadian Community Health Survey, and other provincial and local health surveys and patient self-reports.
Performance measures 5 and 6: data may be available through audit of primary care physician charts. Prescription information may also be available through provincial drug plan databases, although these may have limitations with respect to the age of those covered by the plans, and there is variation across provinces and territories.

Performance measures 7 and 8: prescriptions for blood pressure lowering agents may be given during the inpatient stay or during a secondary prevention assessment and follow-up. When tracking these performance rates, it is important to record the setting where this therapy is initiated. Data sources may include physician order sheets, physicians’ or nurses’ notes, discharge summaries or copies of prescriptions given to patients.

Prescriptions given to a patient do not imply compliance.

Algorithms to identify incidence and prevalence of hypertension from administrative databases have been validated in Canada and should be used for consistency in measurement when possible.
### Concept: Resources

**CODEBOOK DEFINITION**
Resources required to deliver recommended care (75). Local parameters including the level of resources available in a healthcare system and cultural and organizational factors may play a significant role in promoting or inhibiting implementation of CPGs (117). Costs are a function of resources expended and the cost per unit of resource (169). Lack of resources can include: lack of facilities (144), lack of access to treatment options (170), lack of third party reimbursement (171). PG should take into account economic considerations (such as lack of resources) as it heavily influences implementation of the PG (171). Cost implications of fully applying the guideline (9) and different alternatives (55) should be included.

Some recommendations are made to help control costs (113), but this should not be the goal of recommendations, but rather to produce optimal health outcomes, minimize harm, and reduce inappropriate variation in clinical care (83).

Aspects of health care likely to reap the most benefit from the application of practice guidelines are those for which there is demonstrable variation in costs (135).

**OPERATIONALIZATION – “How-to”**

**How-to:**

Guideline developers should:
- Document best estimates of resource use not best estimate of costs (169).
- Be cognizant of the time and resources required to implement guidelines in practice (164).
- Costs should be included in the evidence profile (13, 83, 172).
- Use costing and discounting methods that accord with standard guidelines for economic evaluation (173).
- Be prepared to say “we just don’t know yet” in a recommendation about cost-effectiveness of treatment and that more precise data is required (55).
- Take into account local factors that may affect cost effectiveness (93).
- Consider the potential resource implications of applying the recommendations (168).

**Examples:**
- Some recommendations are made to help control costs (113), but this should not be the goal of recommendations, but rather to produce optimal health outcomes, minimize harm, and reduce inappropriate variation in clinical care (83).
- The recommendation to provide gastro protection to high-risk patients was observed to be a barrier, particularly among patients who are treated in environments with restrictive formularies, or for patients who have financial constraints (174).
- When guidance is issued, the increased costs related to outbreak control measures are not considered (175).
- The presence of a full-time dietician was highlighted as fundamental to implementing the Canadian Nutrition Support CPGs. Another identified enabler corresponded with the general innovative approach observed at this site, such as bedside decision support guides and instant communication using a handheld electronic device (164).
- “Economics also plays a part… because it can take… half an hour to explain to a patient why you don’t want to do something. It can take 2 minutes to do it” (participant) (39).
- In most guidelines, there is no mention of costs of illness or cost effectiveness of treatment (26).

**CONTEXT**

**Communicable Diseases** (175)
**Engineering Management** (134)
**Health Policy** (55)
**Medical** (3, 11, 13, 18, 26, 39, 55, 63, 75, 83, 93, 113, 117, 135, 144, 146, 159, 168-173, 176, 177)
**Nutrition** (164)

**RELATIONSHIP WITH UPTAKE**

Not considering resources reduces uptake

If the proposed new practice will cost more to implement and follow and this has not been considered, the change in practice will again fail (159).

Where the benefits of diagnostic procedures and treatments are partial or unclear, it may prove difficult to set these against the costs of implementation (55).

Lack of funding and/or resources is a barrier to guideline implementation (63).

Resources and costs have no impact on uptake

The cost of innovation does not actually influence adoption, although it is assumed to (134).
Example (taken in verbatim from the International Diabetes Federation 2012 Clinical Guidelines Task Force – Global Diabetes Guideline)

Levels of care

All people with diabetes should have access to cost-effective evidence-based care. It is recognized that in many parts of the world the implementation of particular standards of care is limited by lack of resources. This guideline provides a practical approach to promote the implementation of cost-effective evidence-based care in settings between which resources vary widely.

The approach adopted has been to advise on three levels of care:

- **Recommended care** is evidence-based care which is cost-effective in most nations with a well developed service base, and with health-care funding systems consuming a significant part of national wealth.

- **Limited care** is the lowest level of care that anyone with diabetes should receive. It acknowledges that standard medical resources and fully-trained health professionals are often unavailable in poorly funded health-care systems.

- **Comprehensive care** includes the most up-to-date and complete range of health technologies that can be offered to people with diabetes, with the aim of achieving best possible outcomes. However the evidence-base supporting the use of some of these expensive or new technologies is relatively weak.
### Elements of Resources: Economic evaluation, Availability of resources

<table>
<thead>
<tr>
<th>Concept</th>
<th>CODEBOOK DEFINITION</th>
<th>OPERATIONALIZATION – “How-to”</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Economic evaluation</td>
<td><strong>Economic Outcomes:</strong> Practitioners interested in using resources efficiently must also mind economic outcomes. Whether developers examine economic outcomes at all - and if they do, whether they look at costs from the patients’, insurers’, or the healthcare system perspective, or consider broader issues such as the consequences of time lost from work - can strongly influence final recommendations (2).</td>
<td>Example: Particularly high-tech innovations often require high investments (in money and in learning new technology) which makes consumers reluctant to spend such amounts of money as they worried about how well spent this money really is on a long-term basis. This type of risk is expected to be especially relevant for technology-related innovation (89). Consumers’ reluctance to buy genetically modified food decreases when price decreases. Consumers postpone adoption until they feel they can afford the innovation (89).</td>
<td><strong>Medical</strong> (2, 3, 14, 18, 93, 146, 177, 178)</td>
<td>Some researchers suggest a negative relationship between economic risk and resistance (89). Others suggest that financial risk leads to rejection (89). If clinicians believe that recommendations do not appear cost effective, they are less likely to adopt them (18). Consumers will speculate about future lower prices, which lead to postponement (89). Including cost effectiveness is controversial. Only including evidence of costs and cost-effectiveness may make the application of CPGs more problematic (136). Attitudes differ as to whether costs should influence doctor’s decisions about treating individual patients; healthcare cost may vary widely among and even within jurisdictions and quickly change over time (168). Emphasizing cost reduction in a guideline is not useful (146). Although the health care intervention (the use of which is recommended in an evidence-based guideline) may be cost-effective, it does not follow that implementation strategies designed to increase utilization will themselves be cost effective (176).</td>
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<td></td>
<td><strong>Economic Risks:</strong> Concern that the innovation will be a waste of economic resources (89).</td>
<td>How-to: The majority of guidelines do not include formal cost analyses. Those that do, use a variety of analytic techniques that makes this information hard to apply to individual practice settings. Practitioners can gain a better understanding of the potential importance by seeing if the economic projections involve a sensitivity analysis. This allows you to gauge how recommendations might change if assumptions about costs change (2). When economic outcomes are taken into account it is important to realize which perspective was chosen, such as that of the patient, insurer or health care systems overall, and whether broader issues such as the consequences of time lost from work were included which can have a major impact on the final recommendations (14).</td>
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<td><strong>Cost Effective</strong> Scientifically supportable practices that center on the best cost-benefit balance for the patient in both the short and long term (178). Judgments about whether the costs of tests or treatments are reasonable depend on how cost effectiveness is defined and calculated, on the perspective taken and on the resources constraints of the healthcare system (3). Guidelines that ignore the issue of cost-effectiveness (most) might recommend practices resulting in large increases in cost for little corresponding improvement in health (93). Comparison of costs and health consequences (176).</td>
<td>Cost effective analysis: Cost effectiveness analysis is useful in guideline development for: (1) quantifying the differences between two or more effective services for the same condition, (2) illustrating the impact of delivering a given intervention at different intervals, different ages, or to different risk groups, (3) evaluating the potential role of new technologies, (4) identifying key conditions that must be met to achieve the intended benefit of an intervention, (5) incorporating preferences for intervention outcomes, (6) developing a ranking of services in order of their costs and expected benefits (177). If there are net health benefits from an intervention, there should be an explanation of how the implications of resource use were considered in determining cost effectiveness. This may be informal, or may be more</td>
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formal and include the use of economic modeling.

(11).

- Although the healthcare intervention (the use of which is recommended in an evidence-based guideline) may be cost-effective, it does not follow that implementation strategies designed to increase utilization will themselves be cost effective (176).
- The role of CPGs is not to derive a cost per QALY, but to help clinicians to explore the attributes of treatments and aggregate these to develop well-informed social preferences - Such a process still requires the costs and benefits of treatment to be methodologically sound but stops at the point where guideline members have enough information to proceed with the formulation of recommendations. It recognizes that assumptions required to extrapolate from the results of trials in an effort to identify an overall answer (such as a QALY) may introduce more and greater uncertainties. Each condition and treatment should be explored to the extent merit by available data. The novel aspect is the dynamic use of economic data (rather than static published studies) alongside traditional clinical inputs, in the development of clinical evaluation of treatments and consequent recommendations (55).

<table>
<thead>
<tr>
<th>Availability of Resources (Data Availability; Treatment Availability)</th>
<th>Treatment Availability: It is apparent that this core set of recommended therapies must reflect the availability of treatments (179).</th>
<th>Examples: • Topical NSAIDs and avocado soybean unsaponifiables are available in Europe but not in the USA (179).</th>
<th>Medicine (135, 179) • The less than universal recommendation for some modalities of therapy may have been a consequence of them not being universally available (179). • Lack of access to treatment options is a structural barrier to guidelines which prevent guideline-concordant patient management (170).</th>
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<td>Data availability: the practice must have access to sufficient data and sufficiently specified rules (135).</td>
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Availability of Resources: Data Availability; Treatment Availability

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Medicine (135, 179)

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- Lack of access to treatment options is a structural barrier to guidelines which prevent guideline-concordant patient management (170).
### Concept: Novelty

#### Synonyms:
- Adoptability - Newness of information
- Magnitude
- Radicalness
- Extent of Change Required
- Gap with usual care
- Controversial

#### Antonyms:
- Familiar: previously seen (180)
- Consistent with current trends
- Consumer Resistance to an Innovation

#### Novelty

**Definition:** Degree to which the recommendation proposes behaviors considered unconventional by clinicians or patients (70, 83). People prefer familiar stimuli because they are considered safer, at least in the absence of negative memories (180). The degree of displacement of existing organizational states that the innovation implies. Organizational states that may be affected by an innovation include structural arrangements, personnel, and financial resources (181). Radicalness is the extent to which an innovation represents technological changes and thus implies new behaviours for organizational sub-systems and/or members (44, 166, 182-185) or the gap between proposed care and usual care (166). While some guidelines are widely respected and standardize the care with diminution of variations and improved health outcomes, others are developed with economic goals in mind and are controversial (140).

- **Consumer Resistance to an Innovation:** The resistance offered by consumers to an innovation, either because it poses potential changes from a satisfactory status quo (not appropriate to conclude that resistance is simply the obverse of adoption) (89).
- **Mechanisms:**
  - Resistance to change: Research in nonmedical settings suggests that experts are particularly prone to persevere with their initial ideas and to change their minds less frequently than would be ideal. Changing one's mind is unpleasant because it implies that the original thinking was incorrect. Changing one's mind in medicine is even more troublesome because of the need to explain the switch to patients, families, colleagues and others (186).
  - Intrinsic load: The ease that an individual has in processing novel information that is part of a learning task itself. For example, information related to completing the steps in a new procedure will be experienced as cognitive load, depending upon that learner's relevant prior knowledge. Various types of scaffolding can assist in managing intrinsic load (187).
  - Anchoring: The value we place on something or the initial impression of something can be influenced by arbitrary initial anchors. For example, if the coffee we get every day is $1, we think that coffee should be $1. It would be difficult to sell us another kind of coffee for $2, unless the marketers of that coffee convince you that the two coffees are not comparable. Anchors help us assess the value of things (188).

#### Context

- Economic Psychology (89)
- Educational Psychology (187)
- Information Systems (189)
- Management (43)
- Medicine (83, 140, 166, 190)
- Psychology (180, 186, 188)
- Sociology (48, 149)

#### Relationship with Uptake
- **Novelty is a barrier to uptake**
  - Familiar material is easier to process than novel material. As such, people erroneously infer that that which is easy to process is familiar (180).
  - Understanding is increased by task familiarity (189).

- **Novelty enhances uptake**
  - When things are perceived as "new" they are more likely to be adopted (43).
  - Information adoption is facilitated when consumers are persuaded that information exists which is contrary to their expectations, and that information is available to allow confirmation or rejection by the consumer (43).
### Elements of Novelty: Compatibility, Knowledge and skills

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<tr>
<td>Compatibility</td>
<td>• Compatibility: The degree to which an innovation is perceived as being consistent with the existing values, needs, and past experiences of potential adopters (25, 48, 98, 134, 191-194). Compatibility refers to how much different the innovation is from older ways of doing the job (134). It is about consistency of the practice guideline recommendations with existing practices and values, past experiences, and needs (72). Practice guidelines take into account current policy and clearly acknowledge that federal and state laws supersede the practice guidelines (141). PG should be clear, easy to use in practice and compatible with usual routines (53). • Compatible with existing norms and values in practice: When the recommendations are easy to follow and compatible with norms and values, the application of the recommendations will be facilitated; For diagnostic recommendations, the ease of applying them in practice seems to be more important than for therapeutic recommendations (53). The recommendation is not compatible with existing norms and values in practice—it is revolutionary and provokes discussion (54, 91-112). • Social Norms: Social norms include the friendly requests that people make of one another. They are usually warm and fuzzy. Instant paybacks are not required (188). • Consistent with current trends: the doctor perceives a change required by a guideline is consistent with current trends in the field (195).</td>
<td>How-to: • Supported by the system: Change is supported by the system; the necessary technology, resources and training are available to implement the change recommended by a guideline (195). • Remedy would be to adapt recommendation to current practice by not recommending tests that are not available in out of hours services or other contexts (59). Examples Guidelines could be extremely controversial when developed by governmental agencies. Guidelines could be controversial for numerous reasons including the type of recommendations and the restrictions on practice patterns. A prime example is the demise of the AHCPR in 1995 following the development of acute low back pain guidelines (35), which issued 19 guidelines between 1992 and 1996 at a cost of $750 million. Guidelines have been questioned on various fronts based on pharmaceutical and medical device company sponsorship (140). The support of the recommendation with a discussion of &quot;benefits and harms&quot; was only positively associated with high compliance rates for therapeutic recommendations (53). Whether a recommendation was controversial and incompatible with existing values in the target group and whether it was clearly defined were particularly important. Three attributes contributed most to the explanation of variance: (1) controversial and not compatible; (2) vague; and (3) routine changes. These attributes mainly had an independent effect on the compliance rate in practice. They explained 17% of the variance (study results) (24). All practice guidelines must be consistent with the current APA Ethics Code. A statement is needed concerning consistency with the current APA Ethics Code. Guidance developers are also encouraged to consider and comment on guidelines adopted by other organizations for the same or related areas (141).</td>
<td>Clinical Epidemiology (25) Economic Psychology (89) Engineering Management (134) IT/Marketing (191) IT (192) Management (196) Medicine (5, 24, 53, 59, 72, 75, 83, 94, 102, 141, 142, 190, 193-195, 197) Nutrition (164) Psychology (188) Sociology (48, 98, 149)</td>
<td>Compatibility with social norms increases uptake • Doctors think that it is necessary that a guideline is consistent with current trends to ensure adoption (195). • People will do more if you invoke social norms, versus market norms (188). There is conflicting opinion regarding the influence of compatibility on uptake • There is strong evidence to suggest that the stronger the compatibility, the more likely the adoption (194, 197). • Compatibility was negatively associated with behavior change despite being positively associated with compliance. Therefore, recommendations less compatible with clinicians’ norms and values were associated with greater improvements in clinical practice, and recommendations that are compatible may have ceiling effects - limited scope for further improvement.</td>
</tr>
<tr>
<td>Disruptive to routine practice</td>
<td>• Disruptive to routine practice: guidelines that are disruptive to routine practice require a change in existing practice routines or habits (24, 25, 59) or how care is organized (25, 75, 89), organization of care (24), workflows (83, 190), or additional provider time, staff, equipment, etc. or changes to what is seen as common practice in the target group (24). They are also How-to: • “Often part of the change process is getting the increased cost approved by the clinic” (195). • Identification of practice changes required to accommodate these recommendations (75). • In order to evaluate the ‘practice’ worth of a statement,</td>
<td>Clinical Epidemiology (25) Economic Psychology (89) Management</td>
<td>Disruption to Routine Practice Decreases Uptake • The more recommendations required changes to routines, the lower the compliance (25). • Requires organizational change was positively associated with behaviour change despite being negatively</td>
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**Synonyms:**
- **Compatible**
- **Compatible with existing norms and values in practice**
- **Social Norms**
- **Consistent with current trends**
- **Disruptive to routine practice**
  - **Innovation decision-set compatibility**
Routine Changes

Antonyms:
- Job Fit
- Explicit consideration of day to day realities
- Fit
- Scope of practice
- Do not require change

inconvenient (59). The application of the recommendation demands changes in the organization requires changes in existing routines and habits (53).

Explicit Considerations of Day to Day Realities: Guidelines are often designed and disseminated without explicit consideration of the day-to-day realities of practice environment (5).

Job Fit (Thompson 1991): Perceived job fit measures the extent to which an individual believes that using an innovation can enhance the performance of his or her job (e.g. obtaining better information for decision making) if innovation is compatible with individuals' job responsibilities. Performance factor and system/work fit - facilitating accomplishment of core tasks, improving individual job productivity, improving quality of work output. Perceived usefulness - user's subjective probability that using a specific system will increase his or her job performance. Correspondence between job tasks and the capabilities of the information system to support the tasks.

Innovation decision-set compatibility: The innovation's compatibility with the pattern of medical staff specialization (196).

members of the CPG development team estimate whether or not the statement proposes a change to the dominant health care practices of the moment. Such evaluation is thus grounded in the rendering of the contexts in which it the statement might be used (149).

Examples:
A clinical audit of general practitioners in the Netherlands found that guideline recommendations were followed on average 61% of the time, but recommendations that required changing existing practice routines were followed 44% of the time (142).

Motivation: Due to inertia of previous practice, habit, and routines. Physicians may not be able to overcome the inertia of previous practice, or they may not have the motivation to change. (22).

Uptake increases if the recommendations within the user's scope of practice or current practice
- Guidelines are more successful when the recommendations are within the audience's scope of practice (164).
- The compatibility (i.e. compatible with all aspects of the role of perioperative nurse) was one attribute most strongly related to the implementation of smoke evacuation recommendations (72).
- Adherence to guidelines depends upon the fit between the standards and the goals and demands upon the individual physicians (149).

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Medicine (5, 24, 53, 59, 75, 83, 190)
<table>
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<tr>
<th>Knowledge and skills</th>
<th>Requires new knowledge and skills: recommendation demands the acquisition of new competence (knowledge and skills) (24, 25, 196). Degree of manual skill or specialized training required to use an innovation (196).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synonyms:</td>
<td>Pervasiveness Motivation High Complexity</td>
</tr>
<tr>
<td>Antonyms:</td>
<td>Easy to do</td>
</tr>
<tr>
<td>Pervasiveness:</td>
<td>Low to high - the proportion of total behaviours occurring within an organization that are expected to be affected by the innovation; pervasiveness is a function of how many organizational members are expected to change their behaviours due to the innovation and how much of the time these involved people will be behaving in new ways (48).</td>
</tr>
<tr>
<td>High Complexity:</td>
<td>High complexity is when a practitioner with usual training and skills working in an average setting, perceives it to be difficult to acquire the skills for or to understand; or has no direct control over any resource changes required for implementation (94).</td>
</tr>
<tr>
<td>How easy the...</td>
<td>How-to:</td>
</tr>
<tr>
<td></td>
<td>Can the recommendation by performed by the guidelines’ intended users without acquisition of new competencies (190)?</td>
</tr>
<tr>
<td>Examples:</td>
<td>Recommendation can be followed only when a doctor has specific knowledge and skills (24).</td>
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<td>The application of the recommendation requires new skills… (53).</td>
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<td>The most important barriers to the application of recommendations are concerned with the need for new skills and the complexity of the recommendations; (53).</td>
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<td>The use of radiotherapy for cancer patients was considered high on complexity, not only because of the uncertain impact of its application, but also because of the need to integrate the availability of radiotherapy facilities with the treatment decision (94).</td>
</tr>
<tr>
<td>Clinical Epidemiology</td>
<td>(22, 25, 53)</td>
</tr>
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<td>Medicine</td>
<td>(24, 53, 94)</td>
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<td>(48)</td>
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<tr>
<td>Management</td>
<td>(196, 198)</td>
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<td></td>
<td>Expected negative relationship with organizational uptake (196). Those innovations that required little skill to use were more likely to be adopted (196).</td>
</tr>
<tr>
<td></td>
<td>More recent graduates are more likely to adopt an innovation because it requires less skill/work for them (196).</td>
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</tbody>
</table>
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