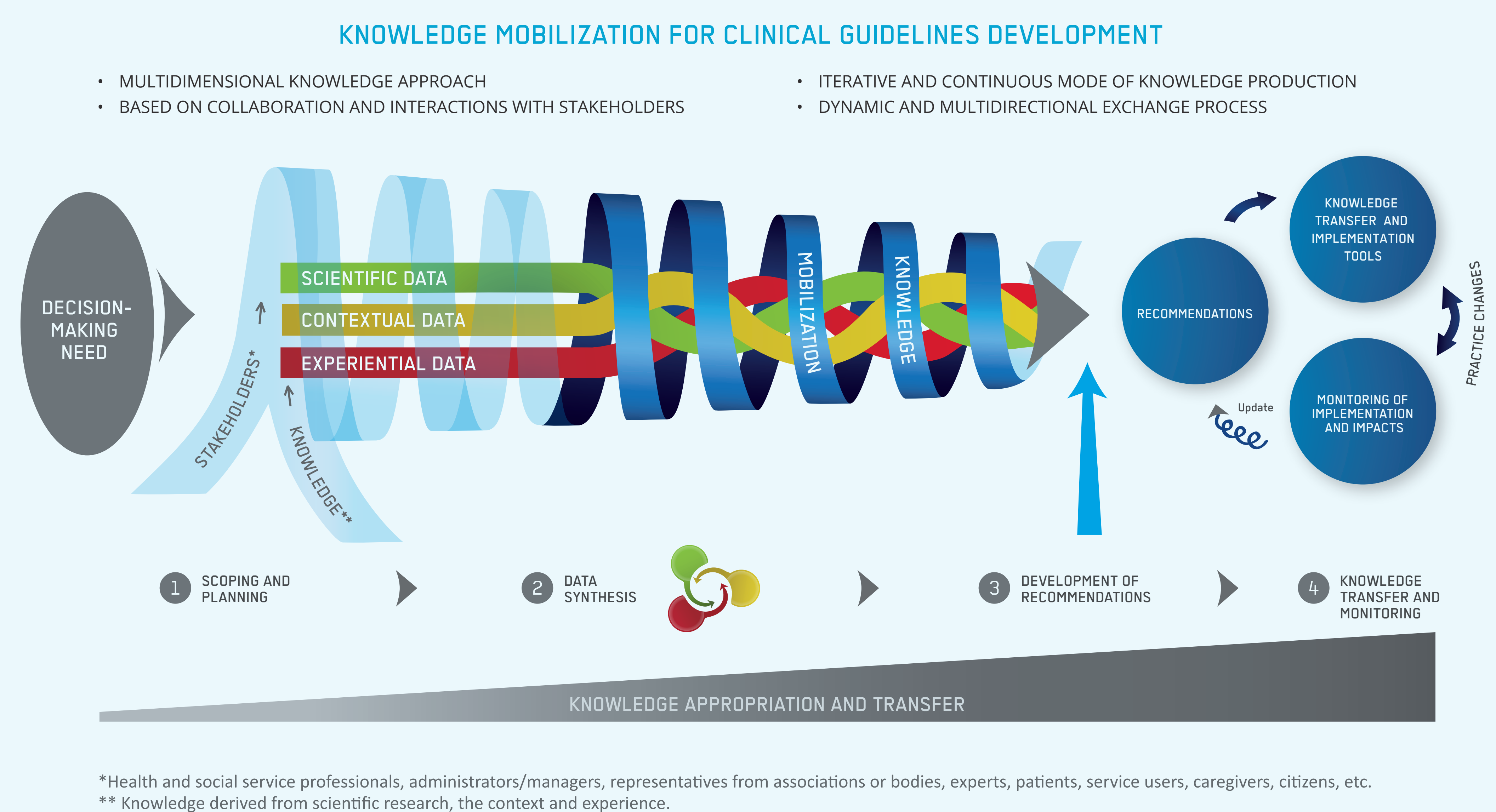


BACKGROUND

To increase the sense of ownership and empowerment of clinical guideline end-users, it is necessary to go beyond scientific data gathered from the literature. Quebec's HTA organization (INESSS) proposes an integrated and systematic approach to grading the evidence level and strength of clinical guideline recommendations through a deliberative process. This approach is based on the knowledge mobilization framework for clinical guidelines development, which considers **the evidence** (i.e., scientific, contextual and experiential data) and interactions with stakeholders (e.g., patients and caregivers) to be the key components required in order to meet the needs and contexts of all the actors concerned by the recommendations.

INESSS's approach was developed through a literature review of different process and methods for guidelines development and through consultations with methodologists and clinical guideline producers and users.



1 SCIENTIFIC EVIDENCE APPRAISAL

Evidence appraisal involves assessing the evidence according to criteria in order to determine the extent to which the data presented help establish a link between a given intervention and the outcomes achieved. Each criterion is rated on a 3-point scale.

Appraisal criteria	Appraisal
Methodological limitations of the studies <ul style="list-style-type: none"> The number of studies included in the data synthesis. The optimal study design for answering the assessment question. The risk of bias/compliance with methodological criteria. Precision (optimal sample size and statistical power). 	Minor limitations Moderate limitations Serious limitations
Consistency/Dependability <ul style="list-style-type: none"> Consistency in the intervention's effect, considering the comparability of the populations, methods and measurement instruments. The complementarity and diversity of the methods and measures. 	Consistent Inconsistent Not applicable
Clinical or organizational impact/Credibility <ul style="list-style-type: none"> Clinical/organizational/social relevance of the effect. The achievement of the intervention's objectives. 	High impact Moderate impact No impact
Generalizability/Transferability. <ul style="list-style-type: none"> Similarity between the populations and between the study contexts and the target contexts. The possibility of adapting the intervention. 	Generalizable/transferable Adaptable Not generalizable/not transferable

2 LEVEL OF THE SCIENTIFIC EVIDENCE

Appraising scientific evidence according to predetermined criteria leads to an overall appraisal of the level of this evidence for each assessment question or for each outcome of interest.

Level of evidence	Definition
High ■■■■■	<ul style="list-style-type: none"> All the criteria are appraised positively. The evaluators are highly confident that the estimate of effect is comparable to the intervention's objectives. It is unlikely that the conclusion drawn from the scientific data will be strongly affected by the results of future studies.
Moderate ■■■■	<ul style="list-style-type: none"> Most of the criteria are appraised positively. The evaluators are moderately confident that the estimate of effect is comparable to the intervention's objectives. It is fairly unlikely that the conclusion drawn from these data will be affected by the results of future studies.
Low ■■■	<ul style="list-style-type: none"> Most or all of the criteria are appraised negatively. The evaluators are weakly confident that the estimate of effect is comparable to the intervention's objectives. It is very likely that the conclusion drawn from these data will be strongly affected by the results of future studies.
Insufficient ■■■	<ul style="list-style-type: none"> The available evidence is insufficient. The evaluators have no confidence in the link between the estimate of effect and the intervention's objectives or cannot draw any conclusions from the presented evidence.

3 «THE EVIDENCE» APPRAISAL

The integration of the three types of evidence (scientific, contextual and experiential), respecting the contribution of each, is made through a deliberative process involving a variety of stakeholders, including patients, and is intended to facilitate the implementation of the recommendations. The deliberation enables the working group to make judgments leading to the development of recommendations reached by consensus.

Decision-making criteria	
Statement and level of scientific evidence	<ul style="list-style-type: none"> Evidence statement from the analysis of the scientific data.
Clinical/epidemiological/organizational aspects	<ul style="list-style-type: none"> The natural history of the disease or condition, the seriousness of the disease or condition, its prevalence, the availability of alternate treatment options considered effective, etc.
Applicability (implementation)	<ul style="list-style-type: none"> Assessment of the relevance of the findings from the scientific evidence for the health-care system or the clinical context in which the recommendations will be implemented. Assessment of the possibility of applying the proposed intervention (obstacles and facilitators). Assessment of the feasibility of the proposed intervention (available resources). Compliance with societal values and standards and laws and regulations.
Acceptability	<ul style="list-style-type: none"> Accessibility of the proposed intervention (geographical, organizational, economic, sociocultural). Convenience of delivering the proposed intervention. Expectations, preferences and values of patients, users or the families of users regarding the effects, risks and costs of the intervention. Preferences and values of professionals in the health and social services system regarding the clinical and practice modalities for delivering the intervention.
Potential impact of implementation	<ul style="list-style-type: none"> Impact of implementing interventions on the target population, practices, the organization of care and services, and resources.
Consensual decision	<ul style="list-style-type: none"> Consensual decision by the working group regarding the balance between the intervention's benefits and drawbacks in light of all the criteria mentioned above.

4 STRENGTH OF RECOMMENDATIONS

The recommendations resulting from the deliberative process supported by the evidence are formulated and graded as to strength according to the confidence (consensus) expressed by the members of the working group regarding the effects of the intervention and the expected level of uptake by decision-makers.

Strength of the recommendations	Level of consensus based on all the evidence	Interpretation of the recommendations
Strong recommendation	The working group believes, with a high level of confidence, that for the vast majority of patients , users or caregivers:	The recommendation can be applied to most patients, users or caregivers in most situations with no restrictions.
	The benefits outweigh the drawbacks. OR The drawbacks outweigh the benefits.	OR The recommendation cannot, under any circumstances, be applied to most patients, users or caregivers in most situations.
Recommendation with some restrictions	The working group believes, with a moderate level of confidence, that for certain patients , users or caregivers:	The recommendation can be applied to certain patients, users or caregivers in certain situations.
	The benefits outweigh the drawbacks. OR The drawbacks outweigh the benefits	OR The recommendation cannot be applied to certain patients, users or caregivers in certain situations. The other available intervention options should be considered. The recommendation should be applied with caution. The best course of action to be taken may differ according to the circumstances, the patient's, user's or caregiver's preferences, or the organizational context.
Good practice recommendation	The working group believes, with a fairly high level of confidence, that the experiential data are sufficient for developing a good practice recommendation applicable to most patients, users or caregivers.	No scientific evidence has been established. However, the experiential data suggest that the recommendation could be applied to certain patients, users or caregivers in certain conditions.

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FUTURE DEVELOPMENTS

The proposed approach is currently in the process of being validated. Adjustments may therefore be made to it. The validated version of the tool for appraising the level of evidence and the strength of recommendations will be available on INESSS's website or by contacting the authors.