



Building Better Recommendations

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Overview

- Essential background
 - Rationale: Why software?
 - Ideal recommendation
 - Action-types
 - Level of obligation
- Building recommendations with BRIDGE-Wiz

Rationale

- Key Action Statements (“recommendations”) differentiate guidelines from other publications
 - What to DO!
- Shortcomings lead to difficulties in implementation
 - Often vague, underspecified, ambiguous
 - Unclear linkage of recommendation to supporting evidence
 - Expected level of adherence not explicit
- Many panel members are unfamiliar with recommendation building
- BRIDGE-Wiz program offers a systematic and replicable approach

Authors Should Be Explicit About

- **WHEN** {under what circumstances} **Denominator**
- **WHO** {in the Intended Audience} **Numerator**
- **Ought to** {with what level of obligation}
- **DO WHAT**
- **{To WHOM}** {which members of the target population}
- **HOW**
- **WHY**

Establishing Evidence Foundations for and Rating Strength of Recommendations

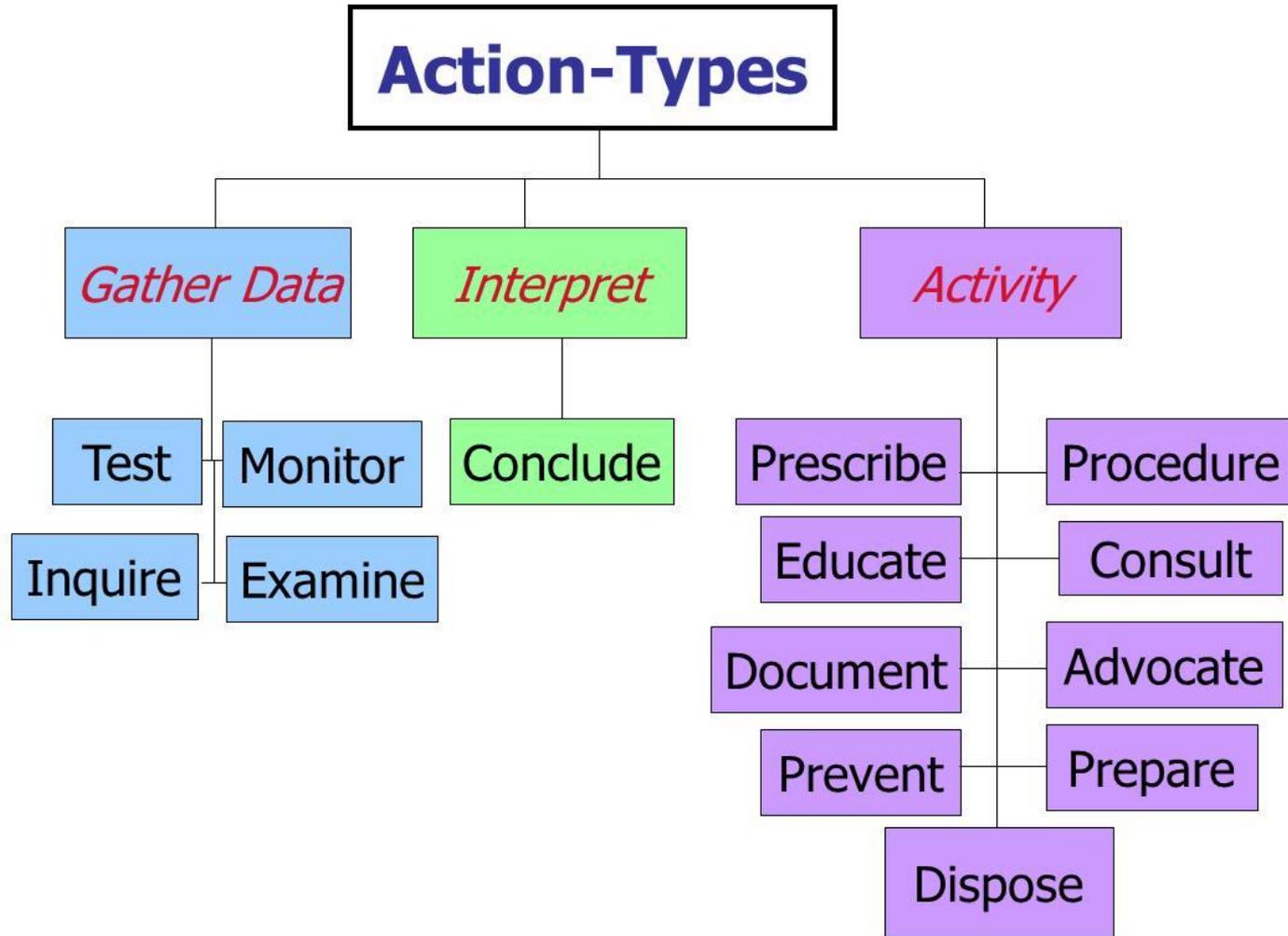
5.1 For each recommendation, the following should be provided:

- An explanation of the reasoning underlying the recommendation, including:
 - A clear description of potential benefits and harms.
 - A summary of relevant available evidence (and evidentiary gaps), description of the quality (including applicability), quantity (including completeness), and consistency of the aggregate available evidence.
 - An explanation of the part played by values, opinion, theory, and clinical experience in deriving the recommendation.
- A rating of the level of confidence in (certainty regarding) the evidence underpinning the recommendation.
- A rating of the strength of the recommendation in light of the preceding bullets.
- A description and explanation of any differences of opinion regarding the recommendation.

Articulation of Recommendations

- 6.1 Recommendations should be articulated in a standardized form detailing precisely what the recommended action is, and under what circumstances it should be performed.
- 6.2 Strong recommendations should be worded so that compliance with the recommendation(s) can be evaluated.

Action Types

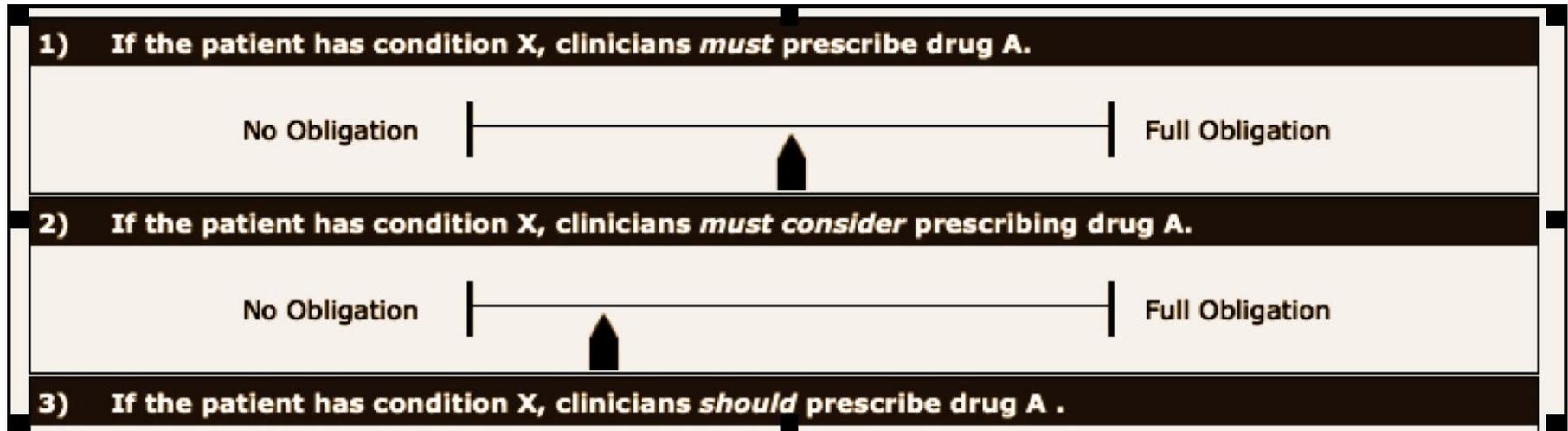


Examples of Recommendations

Statement	Topic
is not contraindicated	Single dose of PCV-7 for high risk children of any age
may benefit from	RSV prophylaxis for infants 32 weeks' gestation or less
may be beneficial	Meningococcal polysaccharide vaccine for travelers
will benefit from	RSV monoclonal antibody for children 24 months of age or less with hemodynamically significant congenital heart disease
may be helpful	Testing for asymptomatic seroconversion after varicella exposure and receipt of VZIG
most experts recommend	RSV prophylaxis for infants 32 to 35 weeks' gestation with risk factors
some experts recommend	Pertussis vaccine for children who have had natural pertussis
some experts suggest	Duration of face-to-face contact that qualifies for significant varicella exposure
some experts prefer	Serologic testing for anti-HBsAg antibody after primary vaccine series in perinatally exposed infants
some experts consider	Safety of influenza vaccine during early pregnancy
experts differ in opinion	HBIG for the incompletely immunized child exposed to a discarded needle in the community
the manufacturer recommends	Avoidance of salicylates after varicella vaccine

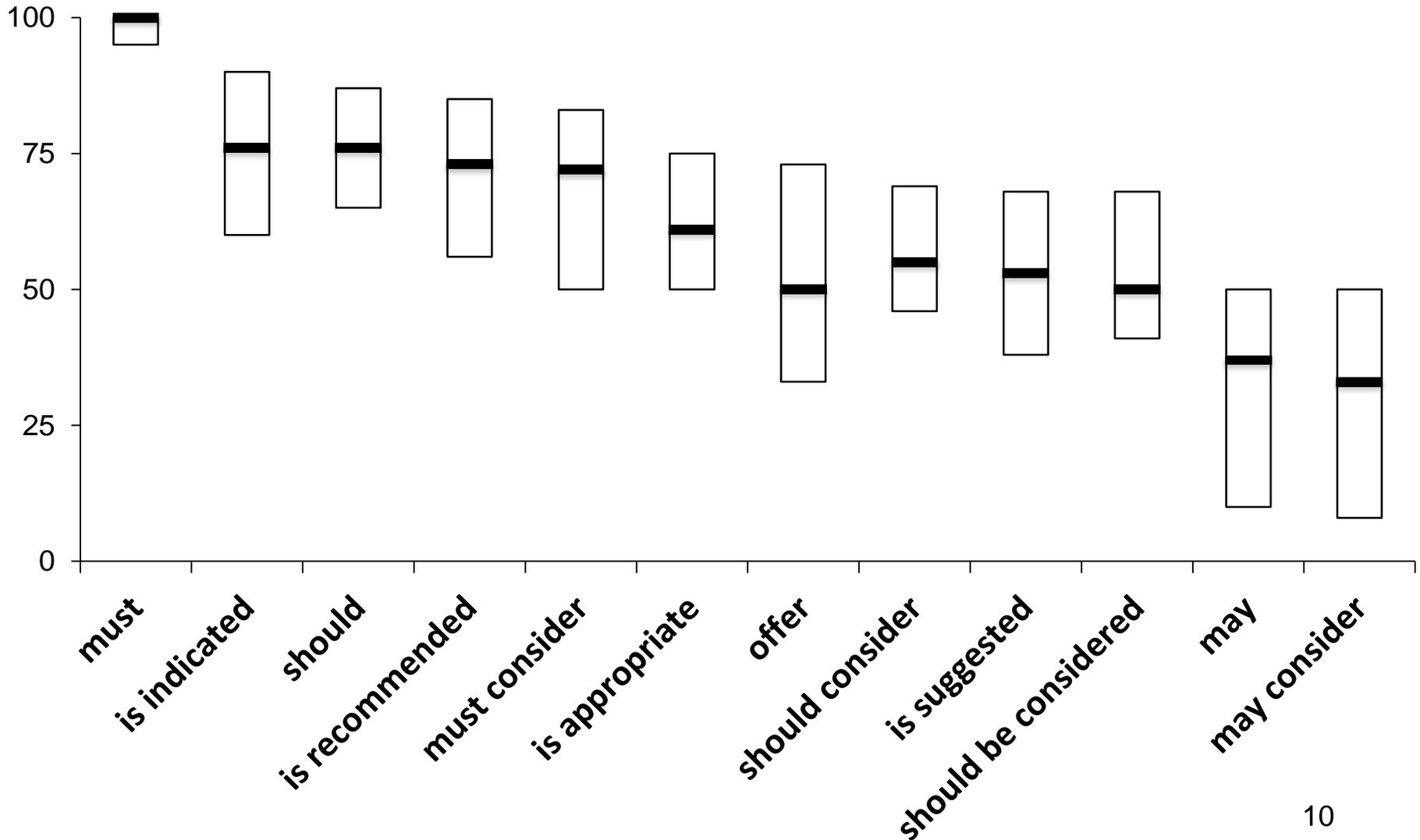
How “Should” We Write Guideline Recommendations

- Web-based survey of 1332 registrants to AHRQ Annual Meeting
- Presented 12 statements:

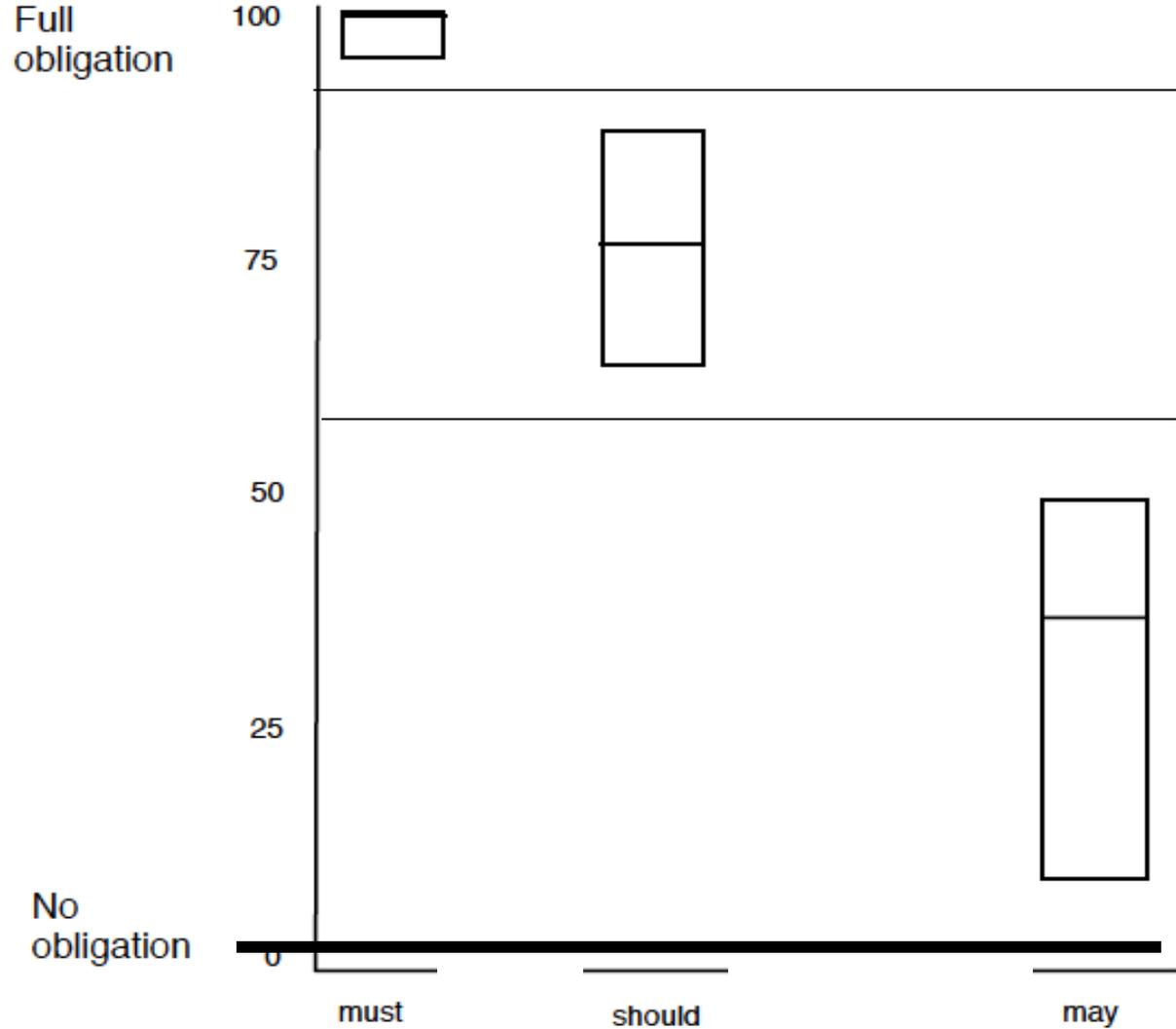


- Participants indicated the level of obligation they believed guideline authors intended using a slider from No obligation to Full obligation (0 to 100)

Level of Obligation



Level of Obligation (Slide 2)



“Musts” (19/1250 – 1.5%)

- Narcotic use **must** be carefully titrated and supervised.
- Clinicians working in juvenile justice settings **must** be vigilant for personal safety and security issues and aware of actions that may compromise their safety and/or the safety and containment of the incarcerated youth
- Nurses working with individuals with asthma **must** have the appropriate knowledge and skills to identify the level of asthma control, provide basic asthma education, conduct appropriate referrals to physician and community resources
- Treatment of duodenal adenomas depends on adenoma size and the presence of severe dysplasia. Small tubular adenomas with mild dysplasia can be kept under surveillance, but adenomas with severe dysplasia **must** be removed



Bridge the Gap Between Authors and Implementers With BRIDGE-Wiz

(Building Recommendations In a Developer' s Guideline Editor)

BRIDGE-Wiz



Example Guideline



Metformin should be first-line treatment for kids with newly diagnosed type 2 diabetes along with diet and exercise.

Complete COGS Checklist or Create a Recommendation

Welcome

Welcome to Bridgewiz

BridgeWiz aims to assist guideline authors to write more comprehensive guidelines and clearer, more actionable recommendations. BridgeWiz incorporates a number of features that are designed to safeguard against creating vague and underspecified recommendations.

The end-products of BridgeWiz include:

- A completed template that provides information required to be compliant with a guideline quality checklist, the COGS appraisal
- One or more skeleton IF-THEN statements that are expected to facilitate implementation in a computer-based decision support system
- A partially populated Evidence Profile for each Key Action Statement.

Begin by selecting an activity described below:

Create COGS Statement

Create Key Action Statement

Notes

Guideline Quality Appraisal

Guideline Quality Appraisal	
Focus	<i>Describe the primary disease/condition and intervention/ service/technology that the guideline addresses. Indicate any alternative preventive, diagnostic or therapeutic interventions that were considered during development.</i>
▣	▣
Goal	<i>Describe the goal that following the guideline is expected to achieve, including the rationale for development of a guideline on this topic.</i>
▣	▣
Users/Setting	<i>Describe the intended users of the guideline (e.g., provider types, patients) and the settings in which the guideline is intended to be used.</i>
▣	▣
Target population	<i>Describe the patient population eligible for guideline recommendations and list any exclusion criteria.</i>
▣	▣
Developer	<i>Identify the organization(s) responsible for guideline development and the names/credentials/potential conflicts of interest of individuals involved in the guideline's development.</i>
▣	▣
Funding source/sponsor	<i>Identify the funding source/sponsor and describe its role in developing, and/or reporting the guideline. Disclose potential conflict of interest.</i>
Source of Funding	▣
Conflict Of Interest	▣
Evidence collection	<i>Describe the methods used to search the scientific literature, including the range of dates and databases searched, and criteria applied to filter the retrieved evidence.</i>
▣	▣

Choose Action-Type

RULE EDITOR

What

What type of activity do you propose?

NOT

Definition

Notes

Back

Next

Restart

Action-Types

What

What type of activity do you propose?

▾

- GATHER DATA**
- INQUIRE
- EXAMINE
- TEST
- MONITOR
- DRAW CONCLUSION**
- CONCLUDE
- ACTIVITY**
- ADVOCATE
- DISPOSE
- DOCUMENT
- EDUCATE/COUNSEL
- PERFORM
- PREPARE
- PRESCRIBE
- PREVENT
- REFER/CONSULT

NOT

Select Prescribe

What

What type of activity do you propose?

PRESCRIBE

NOT

Based on the PRESCRIBE action type,
select a verb:

ADD

Select a “Prescribe-related” Verb

What

What type of activity do you propose?

PRESCRIBE ▼

NOT

Based on the PRESCRIBE action type,
select a verb:

- ▼
- reduce
- repeat
- replace
- reserve
- restart
- review
- start
- suggest
- supplement
- taper
- titrate
- treat
- use
- utilize
- warrant
- ▼

ADD

“Start” WHAT?

What

What type of activity do you propose?

PRESCRIBE

NOT

Based on the PRESCRIBE action type,
select a verb:

start

ADD

Start what?

VERB

WHAT

start

AND

OR

DEL

Action

What

What type of activity do you propose? NOT

Based on the PRESCRIBE action type, select a verb:

Start what?

VERB	WHAT
<input type="text" value="start"/>	<input type="text" value="metformin as first-line treatment"/>

Another Action

What

What type of activity do you propose?

NOT

ADD

VERB

WHAT

start

metformin as first-line treatment

AND

AND

OR

DEL

AND

OR

DEL

Add Another Action

What

What type of activity do you propose?

EDUCATE/COUNSEL

NOT

Based on the EDUCATE/COUNSEL action type,
select a verb:

recommend

ADD

Recommend what?

diet and exercise

VERB

WHAT

	start	metformin as first-line treatment	AND	OR	DEL
AND	recommend	diet and exercise	AND	OR	DEL

Check Executability

Executability

Is each recommended action(s) (what to do) stated specifically and unambiguously? That is, would members of the intended audience execute each action in a consistent way? If not, rewrite the action.

Recommended Action

start	metformin as first-line treatment
recommend	diet and exercise

Add Conditions

When

Under what conditions will **start metformin as first-line treatment AND recommend diet and exercise** be performed?

Under What Conditions

newly diagnosed with type 2 diabetes

AND

OR

DEL

Check Decidability

Decidability

Would the guideline's intended audience consistently determine whether each condition has been satisfied? If not, rewrite the condition.

Condition

newly diagnosed with type 2 diabetes

Modify Condition to Clarify (if needed)

Decidable

Would the guideline's intended audience consistently determine whether each condition has been satisfied? If not, rewrite the condition.

Condition

newly diagnosed with type 2 diabetes, i.e., not previously treated

Describe Benefits

Benefits

What are the anticipated Benefits of
start metformin as first-line treatment AND recommend diet and
exercise

IF

newly diagnosed with type 2 diabetes, i.e., not previously treated

Lower Hgb A1c
Target A1c sustained longer
Less early deterioration of blood glucose
Lower chance of weight gain
Improved insulin sensitivity
Improved lipid profile

Risks, Harms, Costs

What are the anticipated Risks, Harms, and Costs of

start metformin as first-line treatment AND recommend diet and exercise

IF

newly diagnosed with type 2 diabetes, i.e., not previously treated

GI side effects

Potential for lactic acidosis/B12 deficiency

Cost of medication and administration

SMBG

Possible metabolic deterioration if Type 1 is misdiagnosed and treated as type 2

Potential risk of lactic acidosis in setting of ketosis or significant dehydration

Judge Benefit-Harms Balance

Balance

Is there Equilibrium or a preponderance of Benefits or Risks, Harms, and Costs?



- Equilibrium
- Preponderance of Risks, Harms, Costs
- Preponderance of Benefit

Benefits

- Lower Hgb A1c
- Target A1c sustained longer
- Less early deterioration of blood glucose
- Lower chance of weight gain
- Improved insulin

SMBG

- Possible metabolic deterioration if Type 1 is misdiagnosed and treated as type 2
- Potential risk of lactic acidosis in setting of ketosis or significant dehydration

Select Aggregate Evidence Quality

Evidence Quality

What aggregate evidence quality supports these benefits, risks, harms, and costs?
start metformin as first-line treatment AND recommend diet and exercise

IF
newly diagnosed with type 2 diabetes, i.e., not previously treated

Evidence Quality

- A Well-designed, well-conducted randomized, controlled trials or diagnostic studies performed on a population similar to the guideline's target population
- B Randomized, controlled trials with "nonfatal flaws" or methodologic limitations; overwhelmingly consistent evidence from observational studies
- C Observational studies (case control or cohort design)
- D Expert opinion, case reports, reasoning from first principles
- X Exceptional situations where validating studies cannot be performed and there is a clear preponderance of harm or benefit

Resources

Quality Appraisal

Aggregate

RCT-Consort

RCT-Casp

Observation

MetaAnalysis

Diagnostic

Notes

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Restart

Recommendation Strength

RULE EDITOR

Deontic

Evidence Quality	Preponderance of Benefit or Harm	Balance of Benefit and Harm
A. Well designed RCTs or diagnostic studies on relevant population	Strong	Option
B. RCTs or diagnostic studies with minor limitations;overwhelmingly consistent evidence from observational studies	Rec	
C. Observational studies (case-control and cohort design)	Option	
D. Expert opinion, case reports, reasoning from first principles	Option	No Rec
X. Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit or harm	Strong Rec	

Based on the Quality of Evidence **Grade C** and **Preponderance of Benefit**

this key action statement can have a Recommendation Strength of **Recommendation**

Based on this, the level of obligation should be **Should**

Guideline Statement Types

Guideline Statement Types	Imbalance	Balance
A (well-constructed RCTs or extremely strong and consistent observational studies)	STANDARD	OPTION
B (RCTs with weaknesses of procedures or applicability or moderately strong and consistent observational studies)	STANDARD	OPTION
C (observational studies yielding inconsistent findings or that have other problems)	RECOMMENDATION	OPTION
Very Widely Agreed (may/may not be evidence)	CLINICAL PRINCIPLE	CLINICAL PRINCIPLE
Panel Consensus (training, experience, knowledge, and judgment for which there is <u>no</u> evidence)	EXPERT OPINION	EXPERT OPINION

Key Action Statement Editor

KEY ACTION STATEMENT EDITOR

Completed 11 of 11 St

ClassifyEvidenceQuality

What aggregate evidence quality supports these benefits, risks, harms, and costs?

IF

- A Well-constructed RCTs or extremely strong and consistent observational studies
- B RCTs with weaknesses of procedures or applicability or moderately strong and consistent observational studies
- C Observational studies yielding inconsistent findings or that have other problems
- Very Widely Agreed may or may not be evidence
- Panel Consensus training, experience, knowledge, and judgment for which there is no evidence

Key Action Statement Editor (Slide 2)

Deontic

Evidence Quality	Imbalance	Balance
A (Well-constructed RCTs or extremely strong and consistent observational studies)	STANDARD	OPTION
B (RCTs with weaknesses of procedures or applicability or moderately strong and consistent observational studies)	STANDARD	OPTION
C (Observational studies yielding inconsistent findings or that have other problems)	RECOMMENDATION	OPTION
Very Widely Agreed (may/may not be evidence)	CLINICAL PRINCIPLE	
Panel Consensus (training, experience, knowledge, and judgment for which there is <u>no</u> evidence)	EXPERT OPINION	

Based on the Quality of Evidence GRADE Q and <BALANCE>

this key action statement can have a Recommendation Strength of

<REC STR>

The level of obligation should be

May Should

Define the “Actor”

Who

WHO is to start metformin as first-line treatment AND recommend diet and exercise IF newly diagnosed with type 2 diabetes, i.e., not previously treated?

Clinicians

Choose a Recommendation Style

If
newly-diagnosed with type 2 diabetes (i.e., not previously treated)
Then
Clinicians should start metformin as first-line treatment AND
recommend diet and exercise

Select

Clinicians should start metformin as first-line treatment AND
recommend diet and exercise
if/when/whenever
newly-diagnosed with type 2 diabetes (i.e., not previously treated)

Select

The *{developer}* recommends that if
newly-diagnosed with type 2 diabetes (i.e., not previously treated)
Then
Clinicians should start metformin as first-line treatment AND
recommend diet and exercise

Select

The *{developer}* recommends that
Clinicians should start metformin as first-line treatment AND
recommend diet and exercise
if/when/whenever
newly-diagnosed with type 2 diabetes (i.e., not previously treated)

Select

Key Action Profile

Evidence Profile Summary

☐
☐
☐
☐
☐

Date: 9/7/2009

Key Action Statement:

If newly-diagnosed with type 2 diabetes (i.e., not previously treated)
Then Clinicians should start metformin as first-line treatment AND recommend diet and exercise

Aggregate Evidence Quality:

Grade C

Benefit:

Lower A1c; target A1c sustained longer; less early deterioration of blood glucose; lower chance of weight gain; improved insulin sensitivity; improved lipid profile

Risk, Harm, Cost:

GI side-effects; potential for lactic acidosis; B12 deficiency; cost of medication; cost to administer; additional teaching about med; SMBG; possible metabolic deterioration if type 1 is misdiagnosed; potential risk of lactic acidosis with ketosis or significant dehydration

Benefit-Harm Assessment:

Preponderance of Benefit

Value Judgments:

☐
☐

Intentional Vagueness:

☐
☐

Role Of Patient Preferences:

☐
☐

Exclusions:

☐
☐

BRIDGE-Wiz



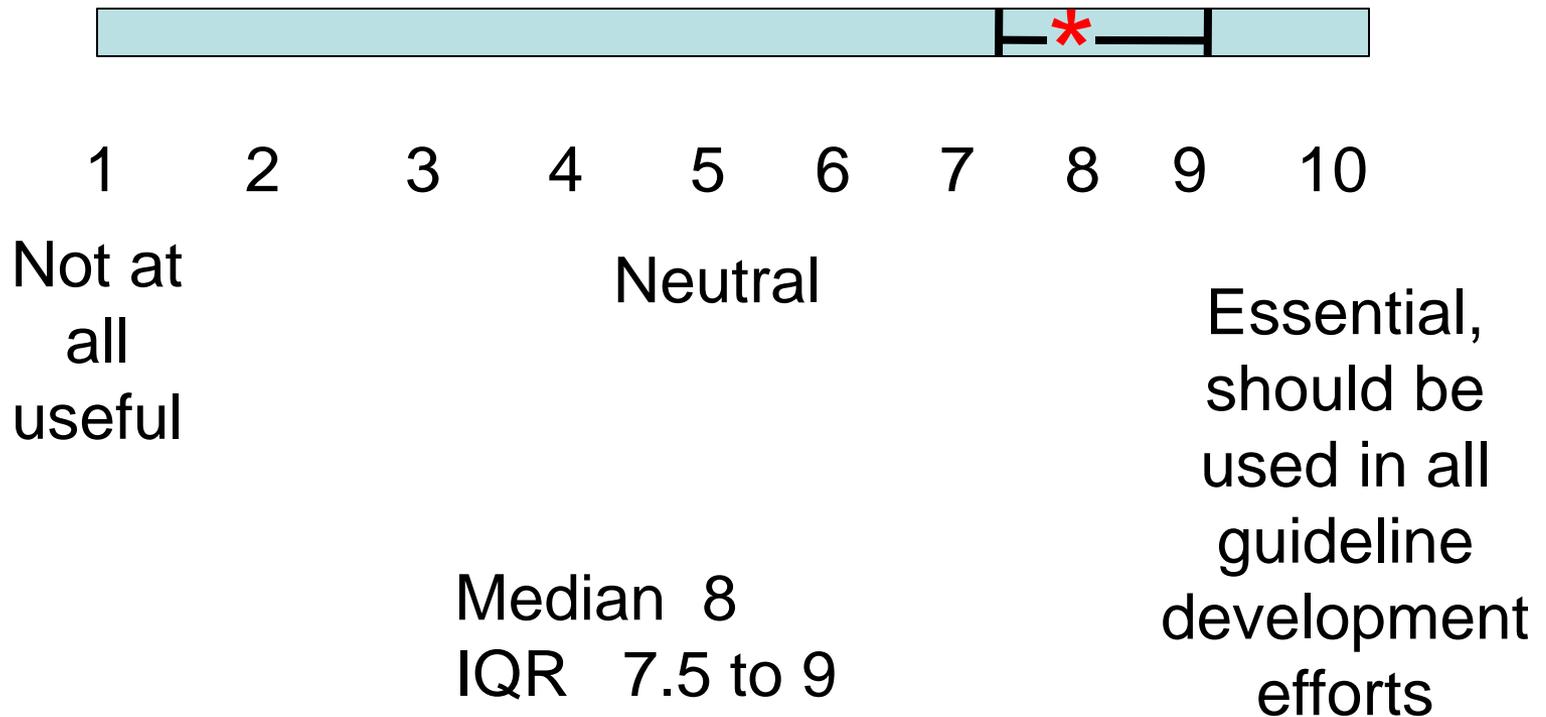
Building Recommendations in a Developer's Guideline Editor

- Formalizes a process for writing implementable recommendations
- Focuses discussion
- Incorporates prompts based on COGS to improve guideline quality
- Controlled natural language
 - Offers verb choices based on action-type
 - Traps and disallows use of “consider”
 - Discourages “statement of fact” masquerading as recommendation
 - Limits boolean connectors to all ANDs or ORs in a statement
- Incorporates decidability and executability checks
- Requires systematic appraisal of evidence quality and benefit-harms
 - Suggests appropriate obligation term (deontic modal)
- Output includes a high-level “rule” and an evidence profile

Organizations & BRIDGE-Wiz

- *American Academy of Pediatrics
- *American Academy of Otolaryngology-Head and Neck Surgery
- *American Urological Association
- *American Society for Clinical Oncology
- American Society for Parenteral and Enteral Nutrition
- Columbia University Ctr for Behavioral Health
- American Physical Therapy Association
- Children's Mercy Hospital
- Cancer Care Ontario

Overall Usefulness (N = 69)



Usefulness Survey Summary

QUALITY

Use of the COGS framework improves the overall quality of the guideline.

CLARITY

The listing of verb choices based on action types is useful.

I found using BRIDGE-Wiz to limit ANDs and ORs to be useful.

I found that asking the question "Would the guideline's intended audience consistently determine whether this condition has been satisfied?" to be valuable.

I found that asking the question "Is each recommended action (what to do) stated specifically and unambiguously, ie would members of the intended audience execute each action in a consistent way?" to be valuable.

TRANSPARENCY

BRIDGE-Wiz simplifies the process of devising quality of evidence ratings.

BRIDGE-Wiz simplifies the process of devising recommendation strength ratings.

I found the process of defining benefits, risks, harms, and costs to be useful.

IMPLEMENTABILITY

Use of BRIDGE-Wiz discourages the use of the term "consider" in key action statements.

BRIDGE-Wiz' suggestion of appropriate obligation term is useful.

Use of BRIDGE-Wiz discourages writing statements of fact as key action statements.

On average, recommendations written using BRIDGE-Wiz are more easily implemented than recommendations constructed in a conventional manner.

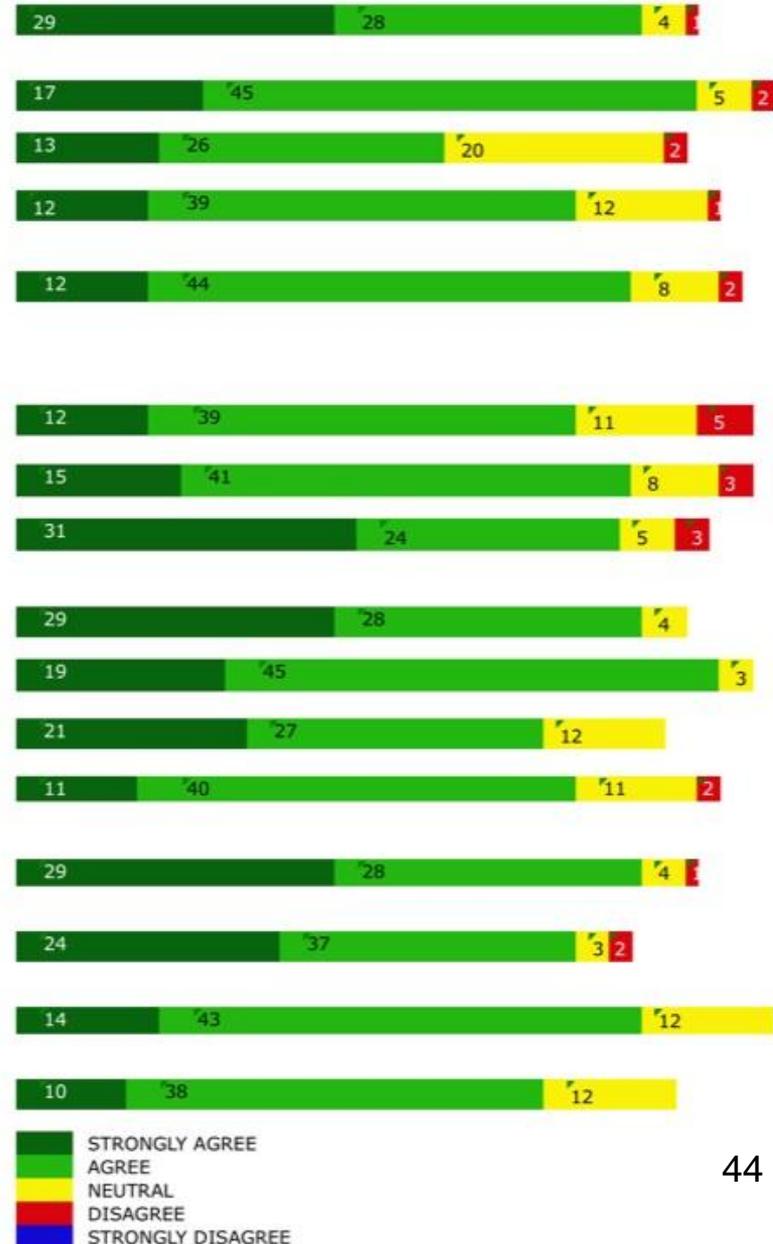
DEVELOPMENT PROCESS

Use of the BRIDGE-Wiz program helps to formalize a process for writing guideline recommendations.

Using the BRIDGE-Wz program helps to focus the discussion while authoring key action statements.

The committee was able to define the action-types of proposed key action statements before defining the statements.

The process of describing WHAT the guideline proposes can be determined BEFORE defining the circumstances under which it is to be done.



Thank you!

Recommendations

...

3a. Magnetic resonance imaging (MRI) is a non-invasive imaging test that produces high-quality and detailed images of the brain without the use of radiation.

3b. MRI (or other imaging modality) should be considered and neurological consultation requested for patients with new onset seizures when localizing signs are present on neurologic examination and CT scan is negative or headaches have been problematic.

...

Recommendations (Slide 2)

- S: patients with new onset seizures
 - AND
- L: localizing signs are present on neurologic examination
 - AND
 - C: CT scan is negative
 - OR
- H: headaches have been problematic

S AND (L AND C) OR H
(S AND L) AND (C OR H)