

Università degli Studi di Trieste

Corso di Laurea Magistrale in
INGEGNERIA CLINICA

LINEE GUIDA IN MEDICINA

Corso di Informatica Medica

Docente Sara Renata Francesca MARCEGLIA



Dipartimento di Ingegneria e Architettura



UNIVERSITÀ
DEGLI STUDI DI TRIESTE

Evidence based medicine



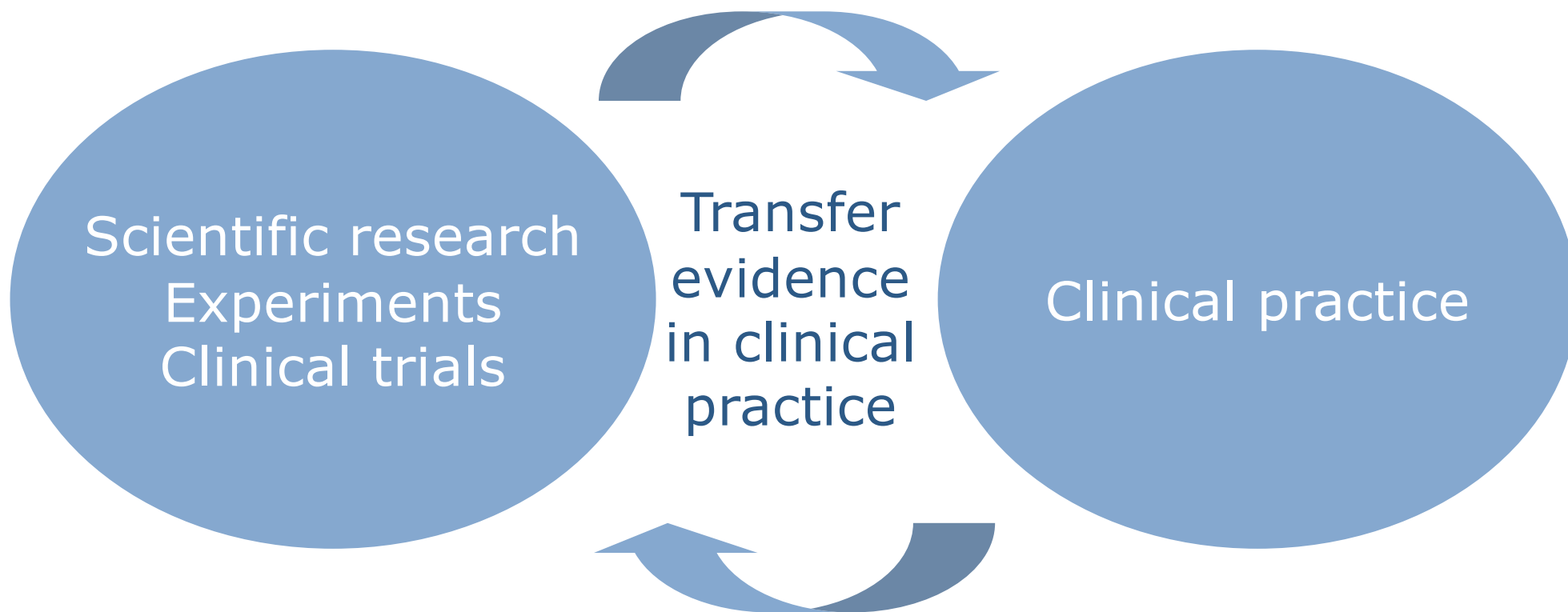
UNIVERSITÀ
DEGLI STUDI DI TRIESTE

EVIDENCE BASED MEDICINE *INTEGRATE* INDIVIDUAL CLINICAL

EXPERTISE WITH THE BEST AVAILABLE EXTERNAL CLINICAL

EVIDENCE FROM SYSTEMATIC RESEARCH

Transfer evidence into practice – MEDICINE





PROTOCOLS

GIVEN
CONSTRAINTS

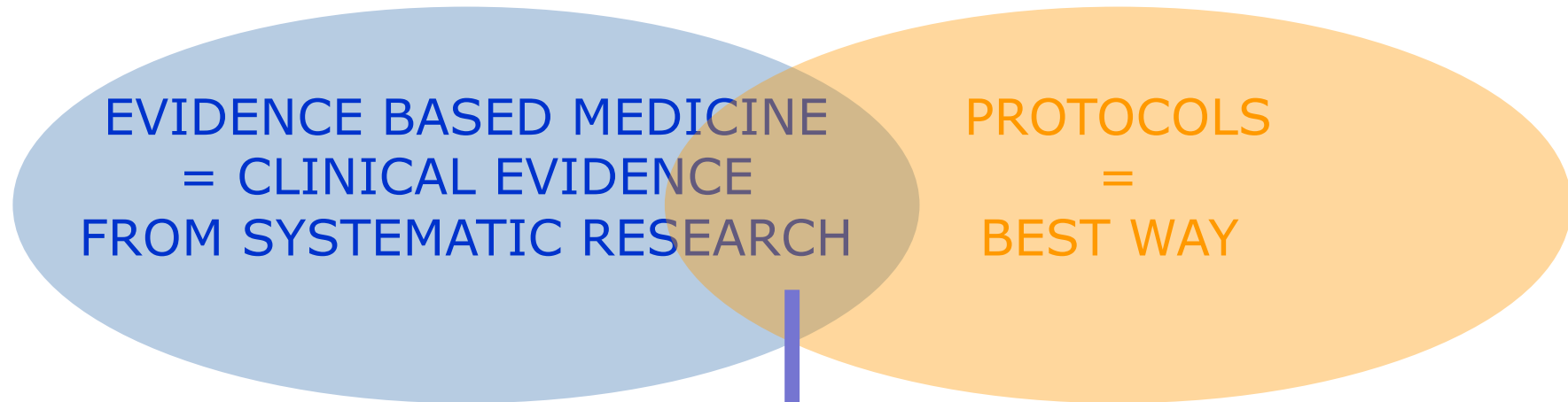
PROVED
BY USE

OTHER WAYS
ALREADY CHECKED

SET OF PREDEFINED
ACTIONS THAT PROVIDE
THE BEST WAY TO DO
SOMETHING

PROTOCOL

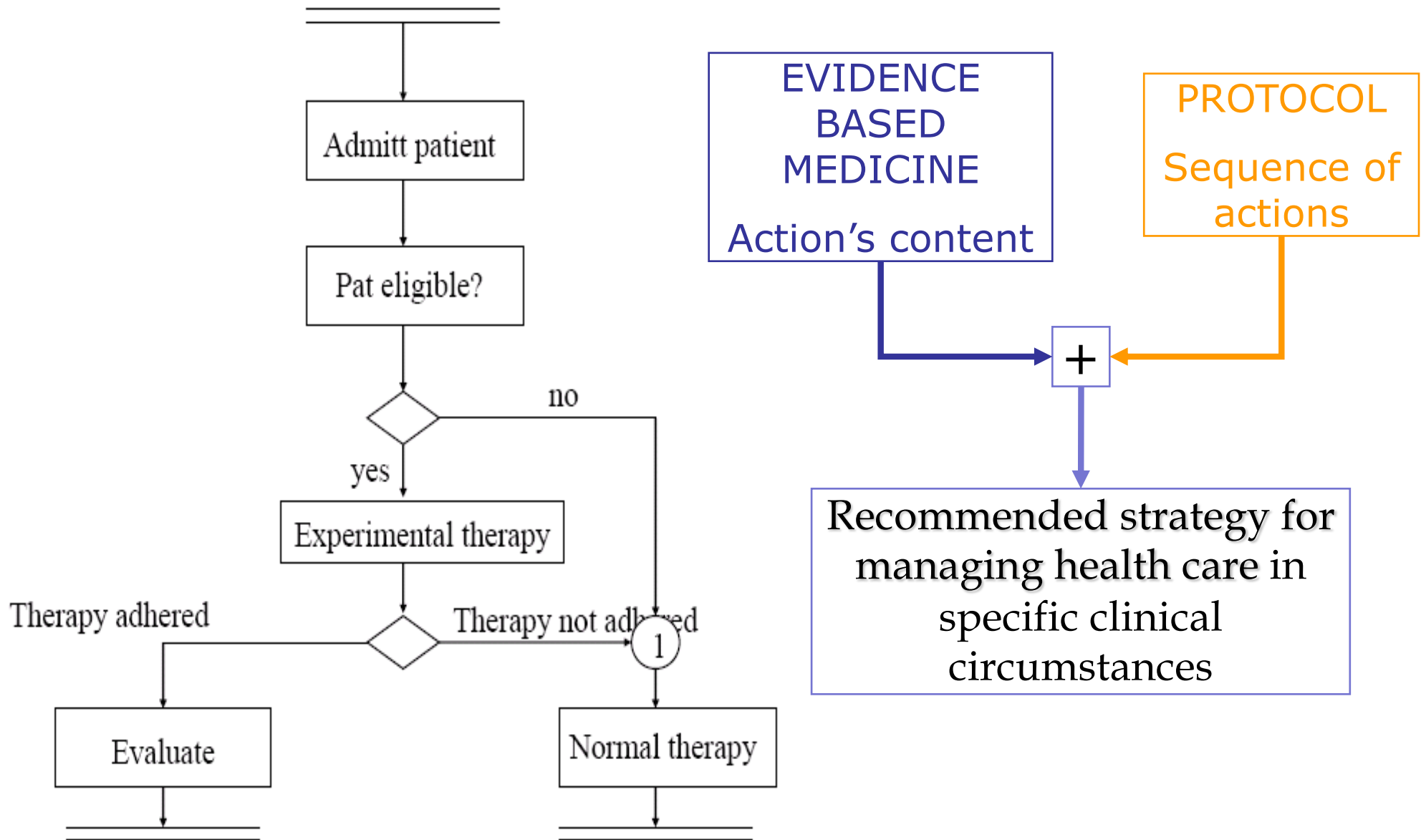
PROTOCOLS AND EVIDENCE BASED MEDICINE



STANDARDIZED AND CONTROLLED
MEDICINE TO OPTIMIZE THE
TREATMENT OF THE PATIENT

EACH PATIENT IS TREATED IN THE
SAME WAY GIVEN THE EVIDENCE
OF HIS/HER STATE

EXAMPLE



DEFINITIONS

ALGORITHM



- A set of instructions to carry out some task programmatically
- Can involve some form of numerical calculation

PROTOCOL



- Describes all the steps in the management of a clinical condition (from diagnosis to treatment)
- Deviations from protocol result in the exclusion of the patient

GUIDELINE



- Synonymous of protocol (often)
- Emphasizes the idea of recommendation instead of duty

CARE PATHWAY



- Used in nursing
- Describe the steps to be followed and also the expected course of patient's state

PRACTICE PARAMETERS



- Evidence-based clinical guidelines
- They set the acceptable boundaries of safe patient care

CLINICAL GUIDELINES: applications - NCG



Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

Evidence-based guideline database

Visit: [National Quality Measures Clearinghouse](#) | [AHRQ Home](#)

[Sign In](#)



National Guideline Clearinghouse

[Help](#) | [Videos](#) | [RSS](#) | [Subscribe to weekly e-mail](#) | [Site map](#) | [Contact us](#) | [For web developers](#)

T- T+

Home

Guidelines

Expert Commentaries

Guideline Syntheses

Guideline Matrix

Guideline Resources

Compare Guidelines

FAQ

Submit Guidelines

About

My NGC

NGC is a public resource for evidence-based clinical practice guidelines.

Search the site:

[Search Tips](#) | [Advanced Search](#) | [About Search](#)

[▶ Show Advanced Search filters](#)

New This Week

May 04, 2015

Guideline Summaries

- New American Society of Clinical Oncology (ASCO)
- New Society of Interventional Radiology (SIR)

[View All](#)

Announcements

Conference News

The **Guidelines International Network (G-I-N)** 12th annual conference will take place from **October 7–10, 2015** in Amsterdam. The theme is "Engaging all stakeholders. Guidelines from a societal perspective." To register and book a pre-conference course, visit the [G-I-N Conference Web site](#).

[More...](#)

Sign In to My NGC

Save your favorite guideline summaries and organizations, and create custom e-mail alerts.

E-mail:

Password:

Remember Me

[Forgot your password?](#)

New User? [Create a free account](#)



Technical Assistance Videos

NATIONAL GUIDELINE CLEARINGHOUSE BROWSER



National Guideline Clearinghouse

Help | Videos | RSS | Subscribe to weekly e-mail | Site map | Contact us | For web developers

Search Search Tips Advanced Search About Search T- T+

Home

Guidelines

Browse

- **By Topic**
- By Organization
- Guidelines in Progress
- Guideline Index
- Guideline Archive
- Related NQMC Measures

Expert Commentaries

Guidelines by Topic

Browse topics to find guidelines represented in NGC that are linked to a particular term derived from the U.S. National Library of Medicine's (NLM) [Medical Subject Headings \(MeSH\)](#), a controlled vocabulary for disease/condition, treatment/intervention, and health services administration. MeSH is one of the controlled vocabularies included within the Unified Medical Language System (UMLS) ([what's this?](#))

MeSH terms are arranged hierarchically ranging from broad headings to more narrow concepts. For example, the general concept "Nervous System Diseases" can be followed through the MeSH hierarchy down to the concept "Myasthenia Gravis, Neonatal;" the broad concept "Diagnostic Techniques, Digestive System" can be followed through "Endoscopy, Gastrointestinal" to the narrow concept "Sigmoidoscopy."

Create Topic E-mail Alerts

Visit: [National Quality Measures Clearinghouse](#) | [AHRQ Home](#)

[Sign In](#)

National Guideline Clearinghouse

Help | Videos | RSS | Subscribe to weekly e-mail | Site map | Contact us | For web developers

Search Search Tips Advanced Search About Search T- T+

Home

Guidelines

Browse

- By Topic
- **By Organization**
- Guidelines in Progress
- Guideline Index
- Guideline Archive
- Related NQMC Measures

Expert Commentaries

Guideline Syntheses

Guideline Matrix

Guidelines by Organization

Browse Organization to find guidelines represented in NGC that are linked to a specific guideline developer or issuing organization.

[A](#) [B](#) [C](#) [D](#) [E](#) [F](#) [G](#) [H](#) [I](#) [J](#) [K](#) [M](#) [N](#) [O](#) [P](#) [Q](#) [R](#) [S](#) [T](#) [U](#) [V](#) [W](#) [A](#) [I](#) [L](#)

- Academy for Chiropractic Education** (1) ☆
- Academy of Breastfeeding Medicine** (10) ☆
- Academy of Medicine, Singapore** (1) ☆
- Academy of Nutrition and Dietetics** (11) ☆
- Advanced Research Techniques in the Health Services** (1) ☆
- Agency for Health Quality and Assessment of Catalonia (AQuAS)** (5) ☆
- AIM Specialty Health** (10) ☆
- Alberta Health Services, Cancer Care see [CancerControl Alberta](#)** (67) ☆

NCA: guidelines by topic

Disease/Condition

- ▶ **Anatomy** (17)
- ▶ **Organisms** (37)
- ▶ **Diseases** (2225)
- ▶ **Chemicals and Drugs** (22)
- ▶ **Analytical, Diagnostic and Therapeutic Techniques and Equipment** (137)
- ▶ **Psychiatry and Psychology** (405)
- ▶ **Phenomena and Processes** (531)
- ▶ **Anthropology, Education, Sociology and Social Phenomena** (72)
- ▶ **Technology, Industry, Agriculture** (2)
- ▶ **Humanities** (1)
- ▶ **Information Science** (5)
- ▶ **Named Groups** (88)
- ▶ **Health Care** (198)

Treatment/Intervention

- ▶ **Anatomy** (80)
- ▶ **Organisms** (49)
- ▶ **Diseases** (150)
- ▶ **Chemicals and Drugs** (1661)
- ▶ **Analytical, Diagnostic and Therapeutic Techniques and Equipment** (2282)
- ▶ **Psychiatry and Psychology** (771)
- ▶ **Phenomena and Processes** (851)
- ▶ **Disciplines and Occupations** (358)
- ▶ **Anthropology, Education, Sociology and Social Phenomena** (733)
- ▶ **Technology, Industry, Agriculture** (264)
- ▶ **Humanities** (59)
- ▶ **Information Science** (246)
- ▶ **Named Groups** (24)
- ▶ **Health Care** (1680)
- ▶ **Publication Characteristics** (18)

Health Services Administration

- ▶ **Chemicals and Drugs** (4)
- ▶ **Analytical, Diagnostic and Therapeutic Techniques and Equipment** (131)
- ▶ **Psychiatry and Psychology** (80)
- ▶ **Phenomena and Processes** (47)
- ▶ **Disciplines and Occupations** (139)
- ▶ **Anthropology, Education, Sociology and Social Phenomena** (203)
- ▶ **Technology, Industry, Agriculture** (29)
- ▶ **Humanities** (11)
- ▶ **Information Science** (192)
- ▶ **Named Groups** (35)
- ▶ **Health Care** (418)
- ▶ **Publication Characteristics** (2)
- ▶ **Geographicals** (17)

NCA: guideline summary



The screenshot displays the National Guideline Clearinghouse website interface. At the top, there is a navigation bar with links for Help, Videos, RSS, and a subscription option for weekly e-mails. A search bar is prominently featured, along with search tips and advanced search options. The main content area is titled "Guideline Summary" and includes a "Guideline Title" section with the text: "Systemic therapy in men with metastatic castration-resistant prostate cancer: American Society of Clinical Oncology and Cancer Care Ontario clinical practice guideline." Below this, the "Bibliographic Source(s)" section lists the authors and the journal reference: "J Clin Oncol. 2014 Oct 20;32(30):3436-48. [65 references] PubMed". The "Guideline Status" section notes that this is the current release and meets the 2013 inclusion criteria. A "Jump To" section provides a list of links for various parts of the guideline, such as Scope, Methodology, Recommendations, and Qualifying Statements.

Home | [Print](#) | [Download: PDF \(Adobe Reader\)](#) | [Word](#) | [HTML](#) | [XML](#) | [Export to Citation Manager](#) | [Save to Favorites](#)

Guideline Summary

Guideline Title

Systemic therapy in men with metastatic castration-resistant prostate cancer: American Society of Clinical Oncology and Cancer Care Ontario clinical practice guideline.

Bibliographic Source(s)

Basch E, Loblaw DA, Oliver TK, Carducci M, Chen RC, Frame JN, Garrels K, Hotte S, Kattan MW, Raghavan D, Saad F, Taplin ME, Walker-Dilks C, Williams J, Winquist E, Bennett CL, Wootton T, Rumble RB, Dusetzina SB, Virgo KS. Systemic therapy in men with metastatic castration-resistant prostate cancer: American Society of Clinical Oncology and Cancer Care Ontario clinical practice guideline. *J Clin Oncol.* 2014 Oct 20;32(30):3436-48. [65 references] [PubMed](#)

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Jump To

- [Scope](#)
- [Methodology](#)
- [Recommendations](#)
- [Evidence Supporting the Recommendations](#)
- [Benefits/Harms of Implementing the Guideline Recommendations](#)
- [Qualifying Statements](#)
- [Implementation of the Guideline](#)
- [Institute of Medicine \(IOM\) National Healthcare Quality Report Categories](#)
- [Identifying Information and Availability](#)
- [Disclaimer](#)

GUIDELINES DEFINITION: strength of evidence



Guidelines are based on evidence that is collected in the literature and in randomized controlled trials (RCTs)

Rating Scheme for the Strength of the Evidence

Guide for Rating Strength of Evidence

Rating for Strength of Evidence	Definition
High	High confidence that the available evidence reflects the true magnitude and direction of the net effect (i.e., balance of benefits versus harms) and that further research is very unlikely to change either the magnitude or direction of this net effect.
Intermediate	Moderate confidence that the available evidence reflects the true magnitude and direction of the net effect. Further research is unlikely to alter the direction of the net effect; however, it might alter the magnitude of the net effect.
Low	Low confidence that the available evidence reflects the true magnitude and direction of the net effect. Further research may change either the magnitude and/or direction this net effect.
Insufficient	Evidence is insufficient to discern the true magnitude and direction of the net effect. Further research may better inform the topic. The use of the consensus opinion of experts is reasonable to inform outcomes related to the topic.

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

GUIDELINES DEFINITION: methods to formulate the recommendations



Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Panel Composition

The American Society of Clinical Oncology (ASCO) Clinical Practice Guidelines Committee and Cancer Care Ontario (CCO) Program in Evidence-Based Care convened an expert panel with multidisciplinary representation in medical oncology, urologic oncology, radiation oncology, community oncology, patient advocacy, health services, implementation research, and guideline methodology. Members of the expert panel are listed in Appendix Table A1 of the original guideline document.

Guideline Development Process

The expert panel met on several occasions and corresponded frequently through e-mail; work on the guideline was completed primarily through the writing group, along with ASCO staff. The purpose of the panel meetings was for members to contribute content, provide critical review, and finalize the guideline recommendations, including an assessment of benefits and harms associated with treatments based on consideration of the evidence. All members of the expert panel participated in preparation of the draft guideline document, which was then disseminated for external review and submitted to *Journal of Clinical Oncology (JCO)* for peer review.

Development of Recommendations

The guideline recommendations were crafted, in part, using the GuideLines Into DEcision Support (GLIDES) methodology and accompanying BRIDGE-Wiz software™. This method helps guideline panels systematically develop clear, translatable, and implementable recommendations using natural language, based on the evidence and assessment of its quality to increase usability for end users. The process incorporates distilling the actions involved, identifying who will carry them out, to whom, under what circumstances, and clarifying if and how end users can carry out the actions consistently. This process helps the Panel focus the discussion, avoid using unnecessary and/or ambiguous language, and clearly state its intentions.

GUIDELINES DEFINITION: types of recommendations



Guide for Types of Recommendations

Type of Recommendation	Definition
Evidence based	There was sufficient evidence from published studies to inform a recommendation to guide clinical practice.
Formal consensus	The available evidence was deemed insufficient to inform a recommendation to guide clinical practice. Therefore, the Expert Panel used a formal consensus process to reach this recommendation, which is considered the best current guidance for practice. The Panel may choose to provide a rating for the strength of the recommendation (i.e., "strong," "moderate," or "weak"). The results of the formal consensus process are summarized in the guideline and reported in the Data Supplement (see the "Availability of Companion Documents" field).
Informal consensus	The available evidence was deemed insufficient to inform a recommendation to guide clinical practice. The recommendation is considered the best current guidance for practice, based on informal consensus of the Expert Panel. The Panel agreed that a formal consensus process was not necessary for reasons described in the literature review and discussion. The Panel may choose to provide a rating for the strength of the recommendation (i.e., "strong," "moderate," or "weak").
No recommendation	There is insufficient evidence, confidence, or agreement to provide a recommendation to guide clinical practice at this time. The Panel deemed the available evidence as insufficient and concluded it was unlikely that a formal consensus process would achieve the level of agreement needed for a recommendation.

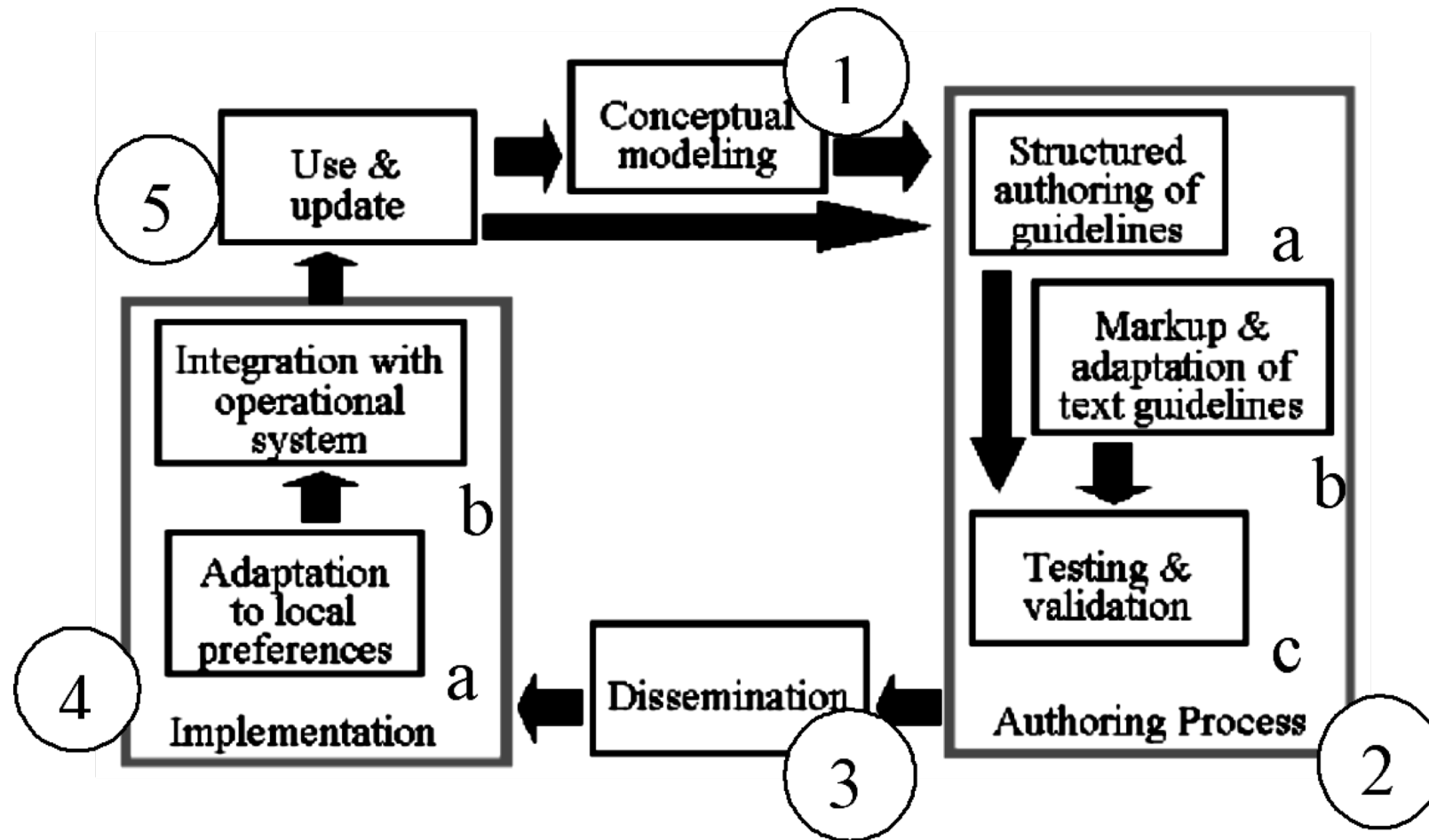
GUIDELINES DEFINITION: strength of recommendations



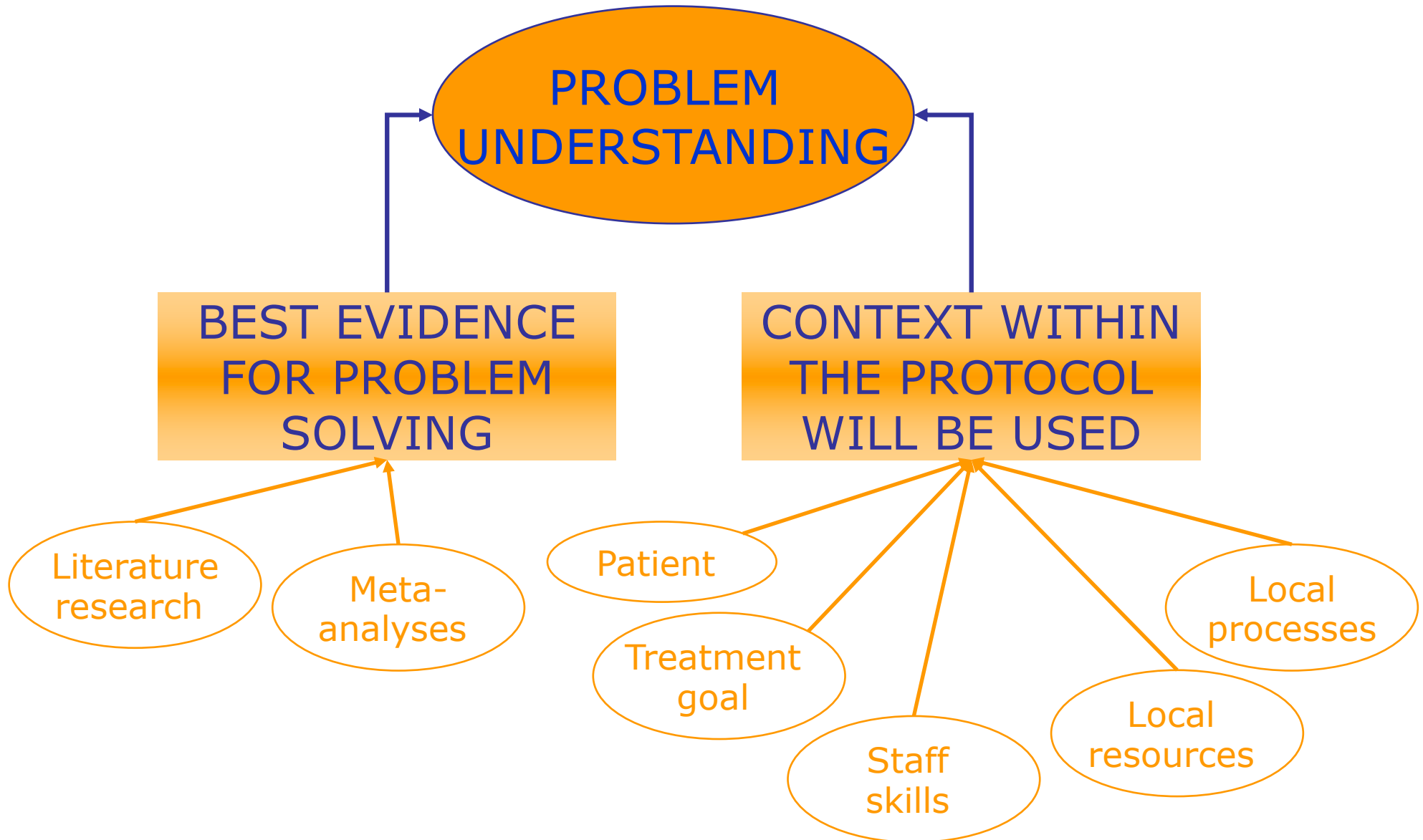
Guide for Strength of Recommendations

Rating for Strength of Recommendation	Definition
Strong	There is high confidence that the recommendation reflects best practice. This is based on (1) strong evidence for a true net effect (e.g., benefits exceed harms); (2) consistent results, with no or minor exceptions; (3) minor or no concerns about study quality; and/or (4) the extent of panelists' agreement. Other compelling considerations (discussed in the guideline's literature review and analyses) may also warrant a strong recommendation.
Moderate	There is moderate confidence that the recommendation reflects best practice. This is based on (1) good evidence for a true net effect (e.g., benefits exceed harms); (2) consistent results, with minor and/or few exceptions; (3) minor and/or few concerns about study quality; and/or (4) the extent of panelists' agreement. Other compelling considerations (discussed in the guideline's literature review and analyses) may also warrant a moderate recommendation.
Weak	There is some confidence that the recommendation offers the best current guidance for practice. This is based on (1) limited evidence for a true net effect (e.g., benefits exceed harms); (2) consistent results, but with important exceptions; (3) concerns about study quality; and/or (4) the extent of panelists' agreement. Other considerations (discussed in the guideline's literature review and analyses) may also warrant a weak recommendation.

MEDICAL GUIDELINE LIFECYCLE



PROCESS MODELING FOR GUIDELINE CONCEPTUALIZATION



PROTOCOL/GUIDELINES DISSEMINATION



1. Easy access to evidence on best practice (and supporting evidence)
 - Cochrane collaboration
 - Internet → tool for publishing and distributing protocols
 - Provides immediate access
 - Problem of quality
2. Even if guidelines are available, they are not used
3. Evidence based practice is an information product, and clinicians are consumers
4. Level of acceptance → depends on the costs vs benefits balance (perceived by the clinician)
5. The impact factor of a guideline depends not only on its scientific value but also on the medium used for dissemination



IMPROVING GUIDELINE UPTAKE

- Increase the value for the clinician, making benefits for him more evident (time, amount of work, quality, ...)
- Decrease the costs of evidence-based practice, not in financial terms but in terms of time and mental efforts
- Optimize the protocol to suit the clinical context
- Strong educational strategies
 - Overcome socio-technical barriers
 - Share the use with all the levels of the system