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

EVIDENCE BASED MEDICINE *INTEGRATE* INDIVIDUAL

CLINICAL EXPERTISE WITH THE BEST AVAILABLE

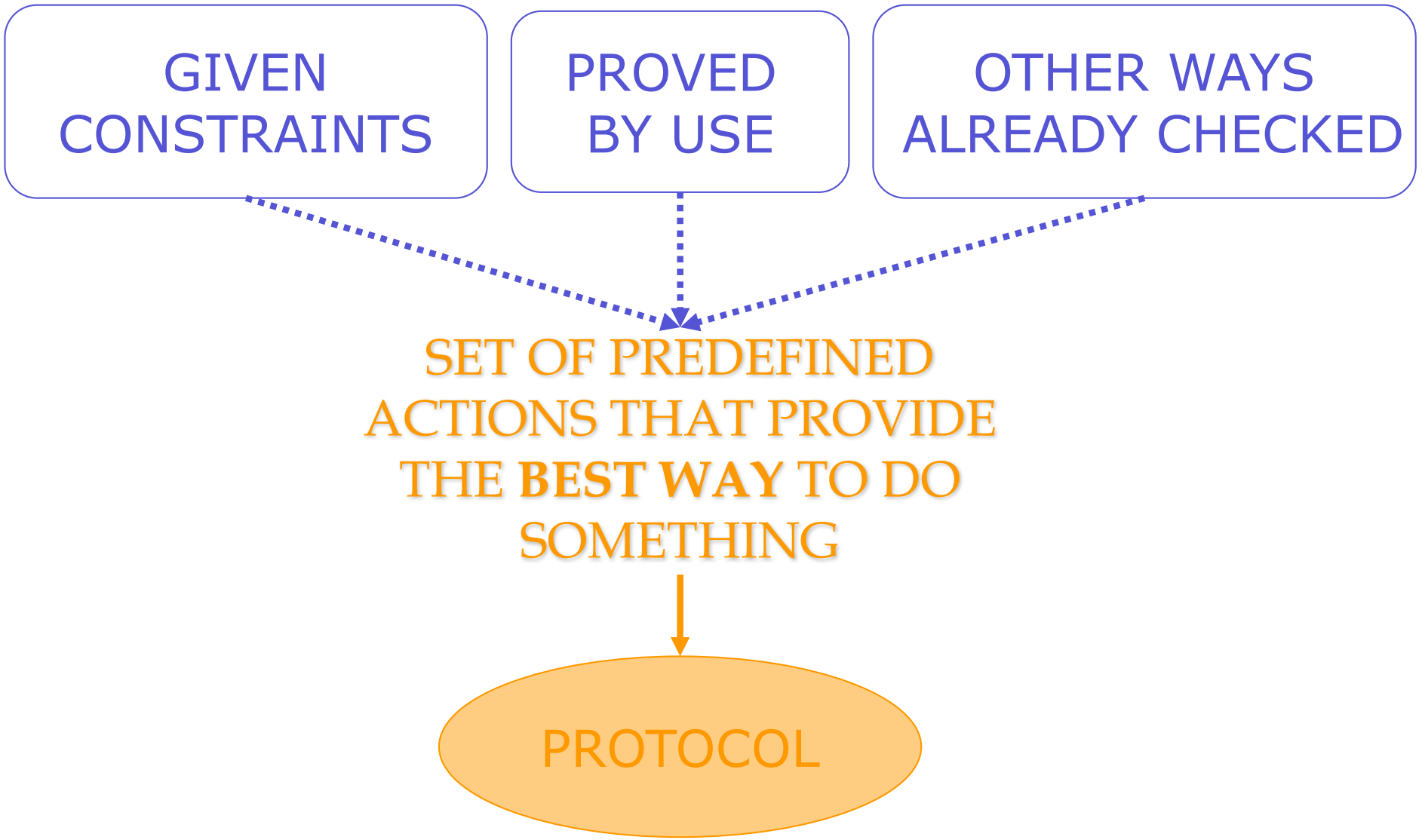
EXTERNAL CLINICAL EVIDENCE FROM SYSTEMATIC

RESEARCH

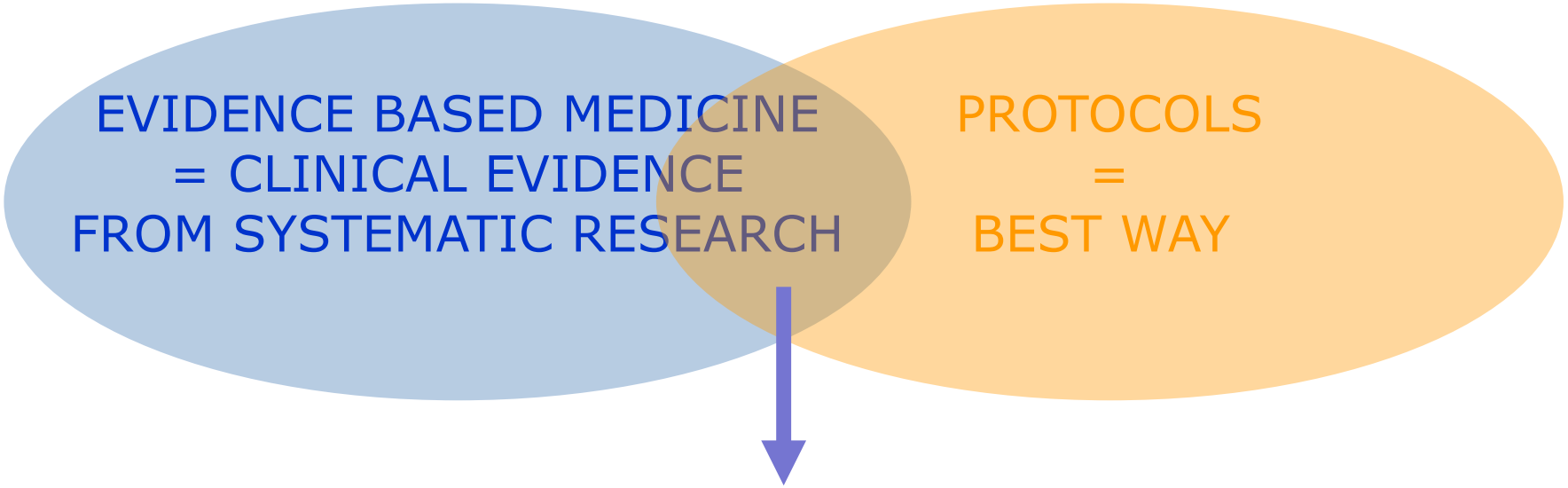
Transfer evidence into practice – MEDICINE

UNIVERSITÀ
DEGLI STUDI DI TRIESTE

PROTOCOLS


GIVEN CONSTRAINTS
PROVED BY USE
OTHER WAYS ALREADY CHECKED
SET OF PREDEFINED ACTIONS THAT PROVIDE THE **BEST WAY** TO DO SOMETHING
PROTOCOL

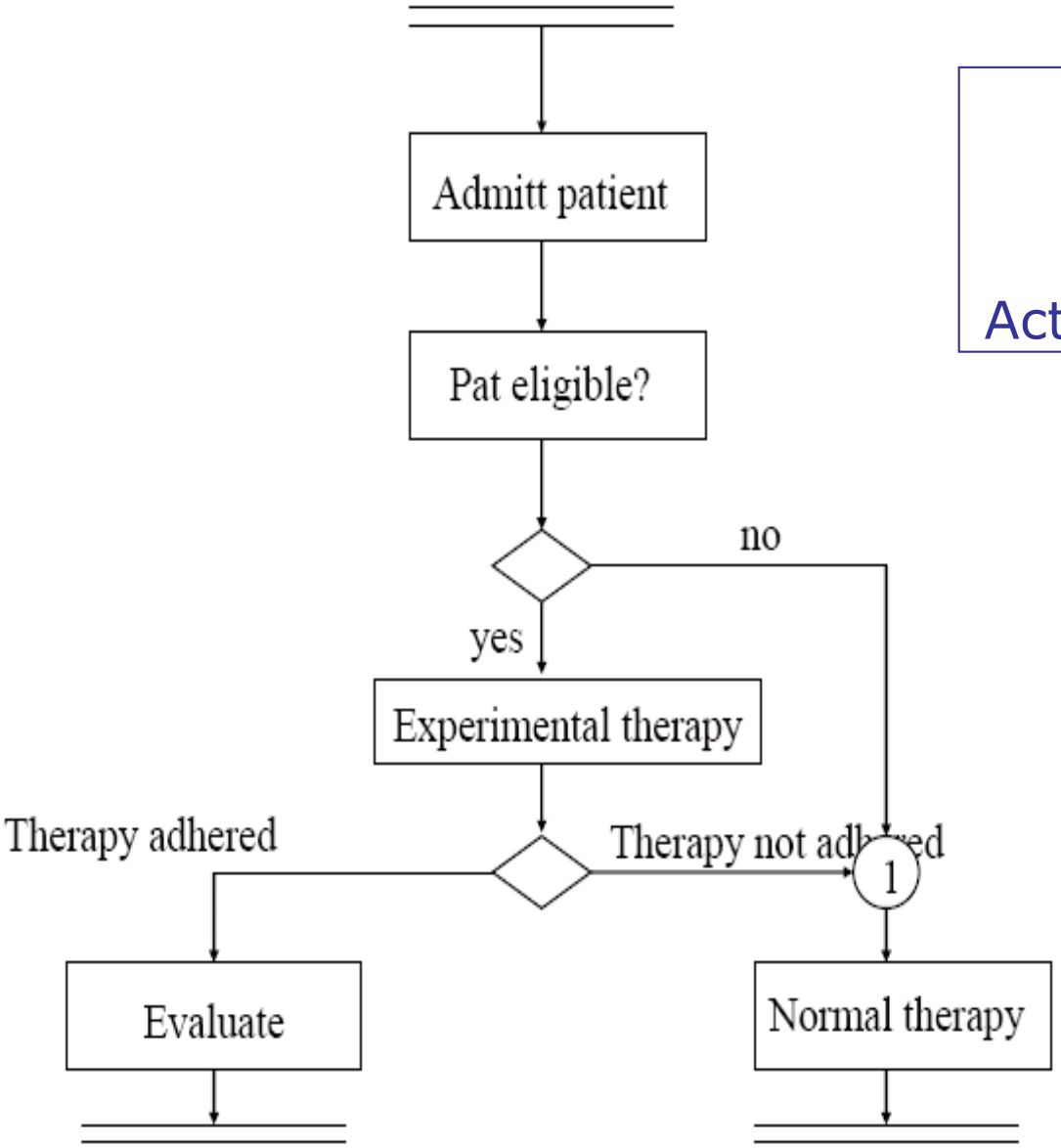
PROTOCOLS AND EVIDENCE BASED MEDICINE



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



EVIDENCE BASED MEDICINE

Action's content

PROTOCOL

Sequence of actions

+

Recommended strategy for managing health care in specific clinical circumstances

DEFINITIONS

UNIVERSITÀ
DEGLI STUDI DI TRIESTE

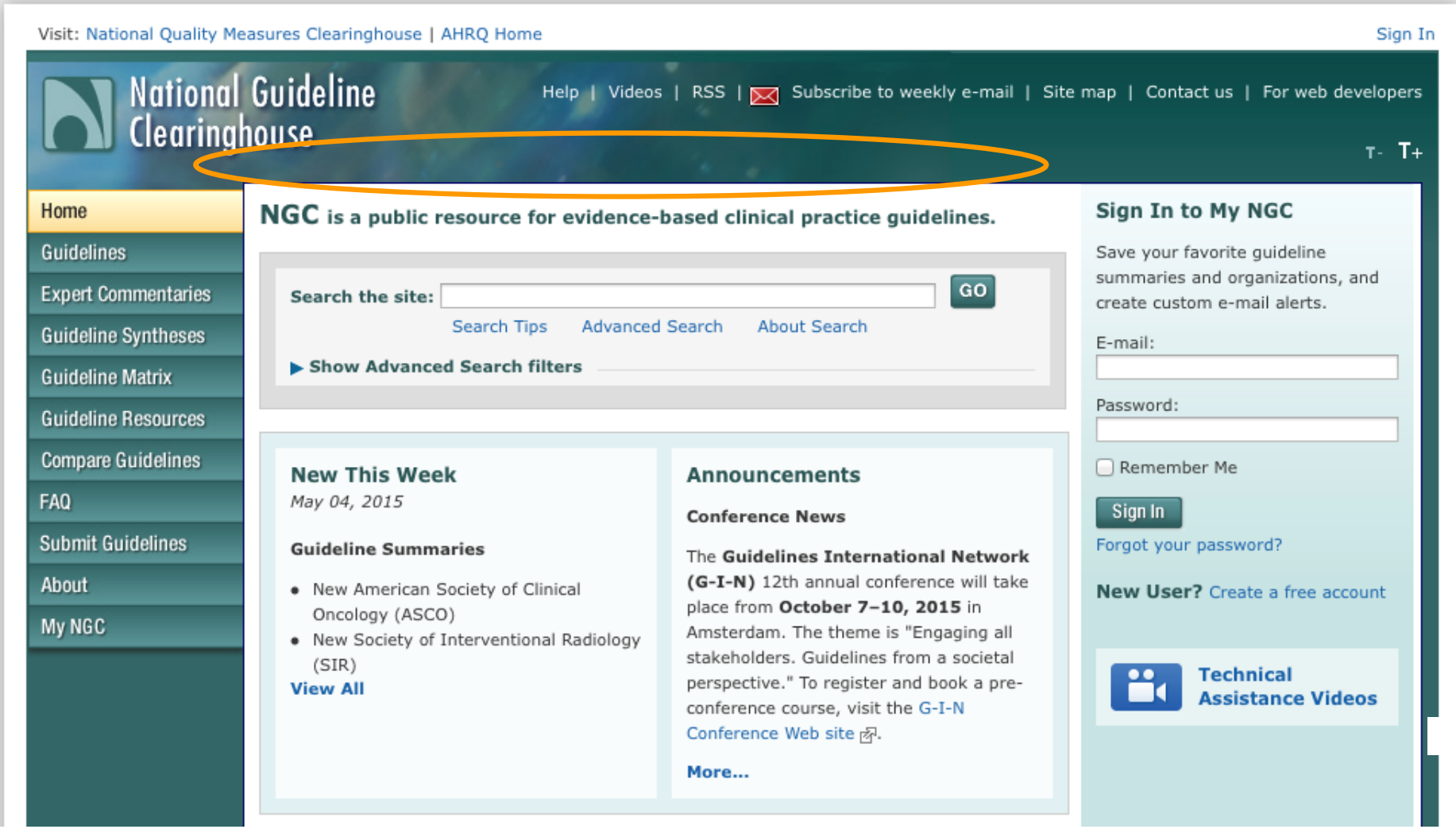
ALGORITHM →	•A set of instructions to carry out some task programmatically •Can involve some form of numerical calculation
PROTOCOL →	•Describes all the steps in the managment of a clinical condition (from diagnosis to treatment) •Deviations from protocol result in the exclusion of the patient
GUIDELINE →	•Synonimous of protocol (often) •Emphasizes the idea of reccomendation 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

UNIVERSITÀ DEGLI STUDI DI TRIESTE

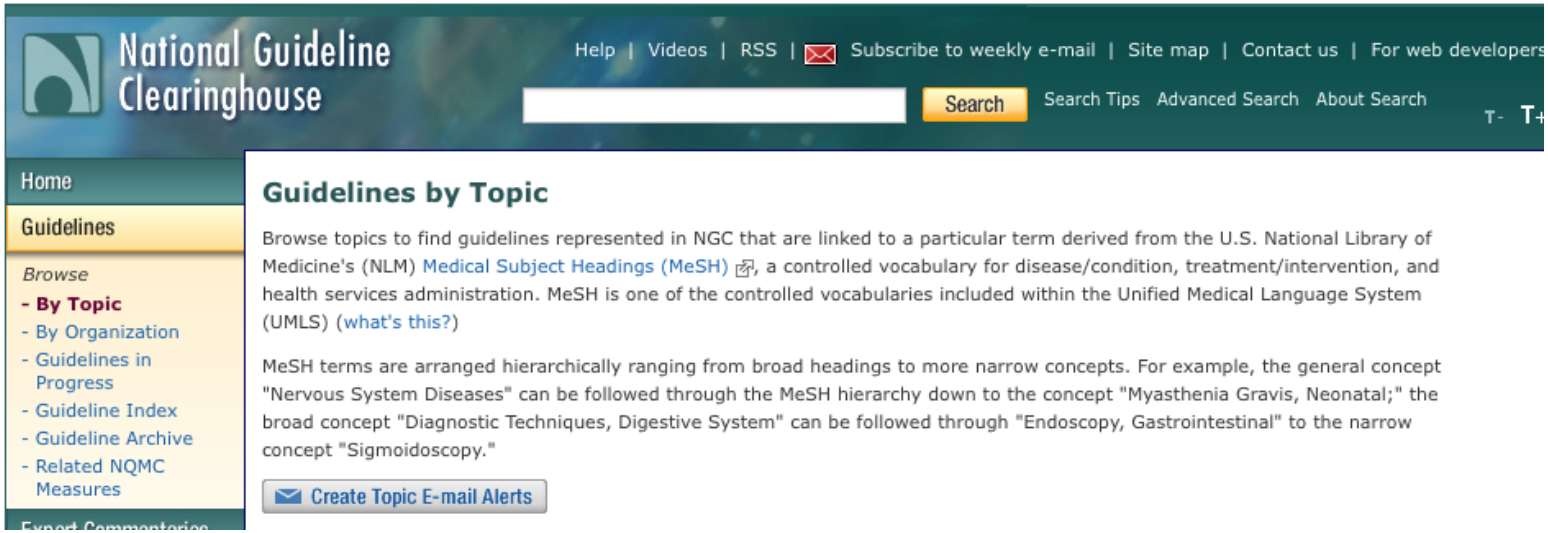
Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

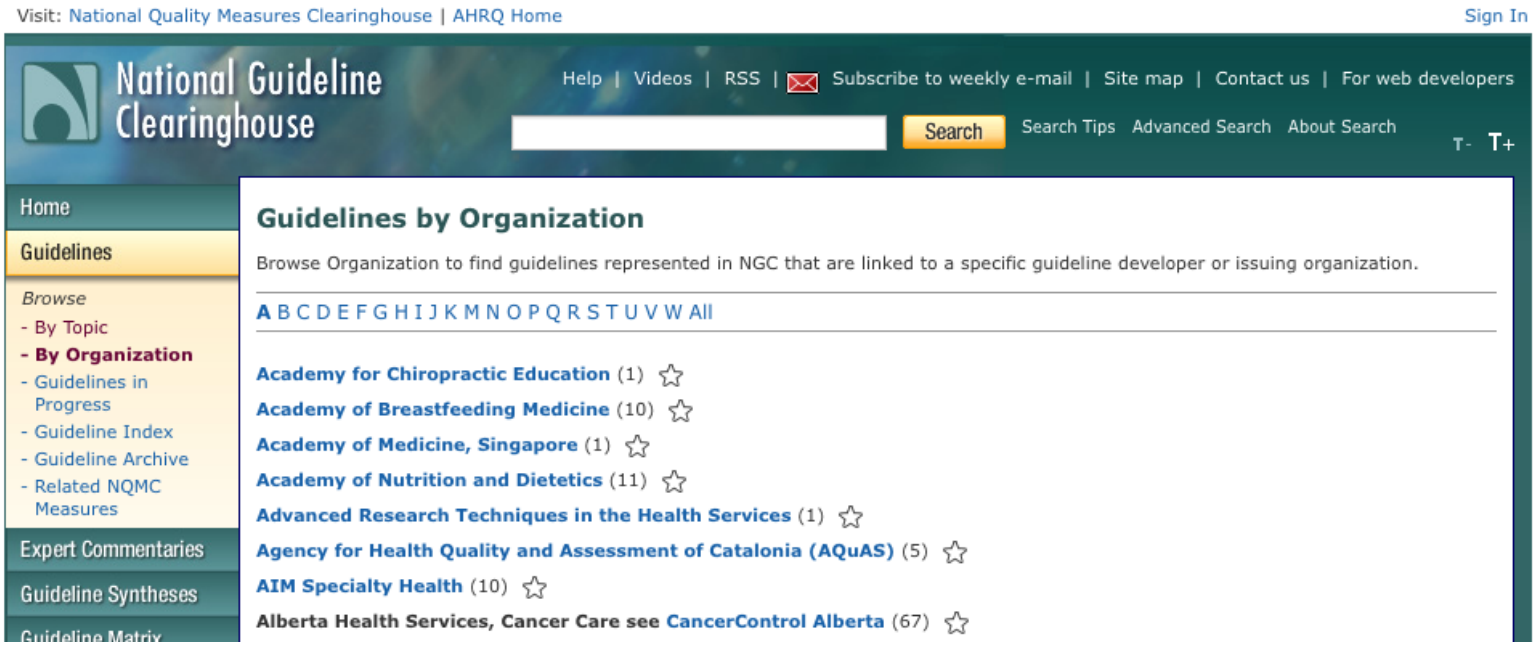
Evidence-based guideline database



NATIONAL GUIDELINE CLEARINGHOUSE BROWSER

UNIVERSITÀ DEGLI STUDI DI TRIESTE





NCA: guidelines by topic

UNIVERSITÀ
DEGLI STUDI DI TRIESTE

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

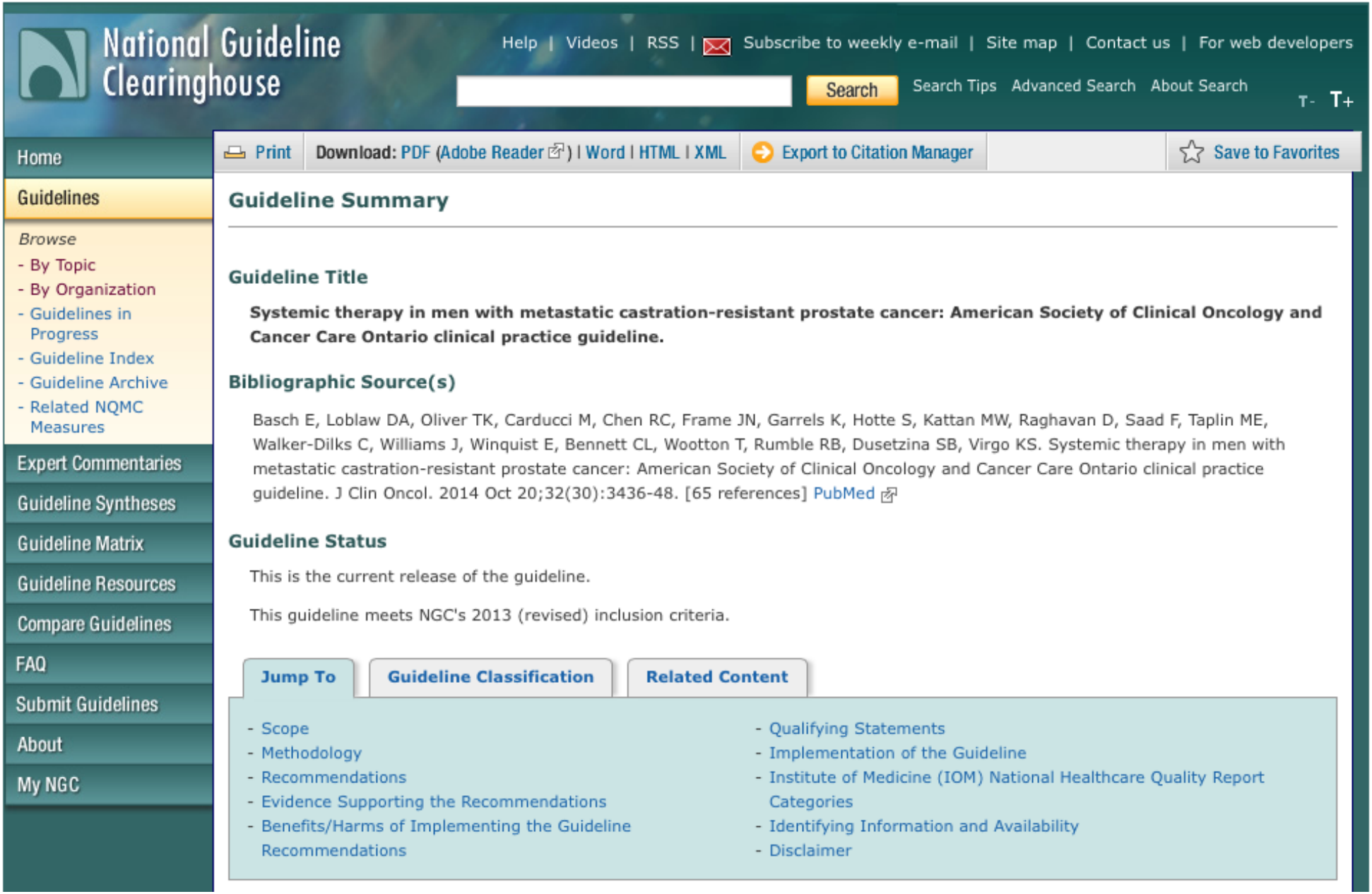
- **Anatomy** (80)
- **Organisms** (49)
- **Diseases** (150)
- **Chemicals and Drugs** (1661)
- **Analytical, Diagnostic and Therapeutic Techniques and Equipment** (2282)
- **Psychiatry and Psychology** (771)
- **Phenomena and Processes** (851)
- **Disciplines and Occupations** (358)
- **Anthropology, 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

UNIVERSITÀ
DEGLI STUDI DI TRIESTE



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
Guideline Resources
Compare Guidelines
FAQ
Submit Guidelines
About
My NGC

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 | Guideline Classification | Related Content

- 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

UNIVERSITÀ DEGLI STUDI DI TRIESTE

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

UNIVERSITÀ
DEGLI STUDI DI TRIESTE

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

UNIVERSITÀ
DEGLI STUDI DI TRIESTE

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.

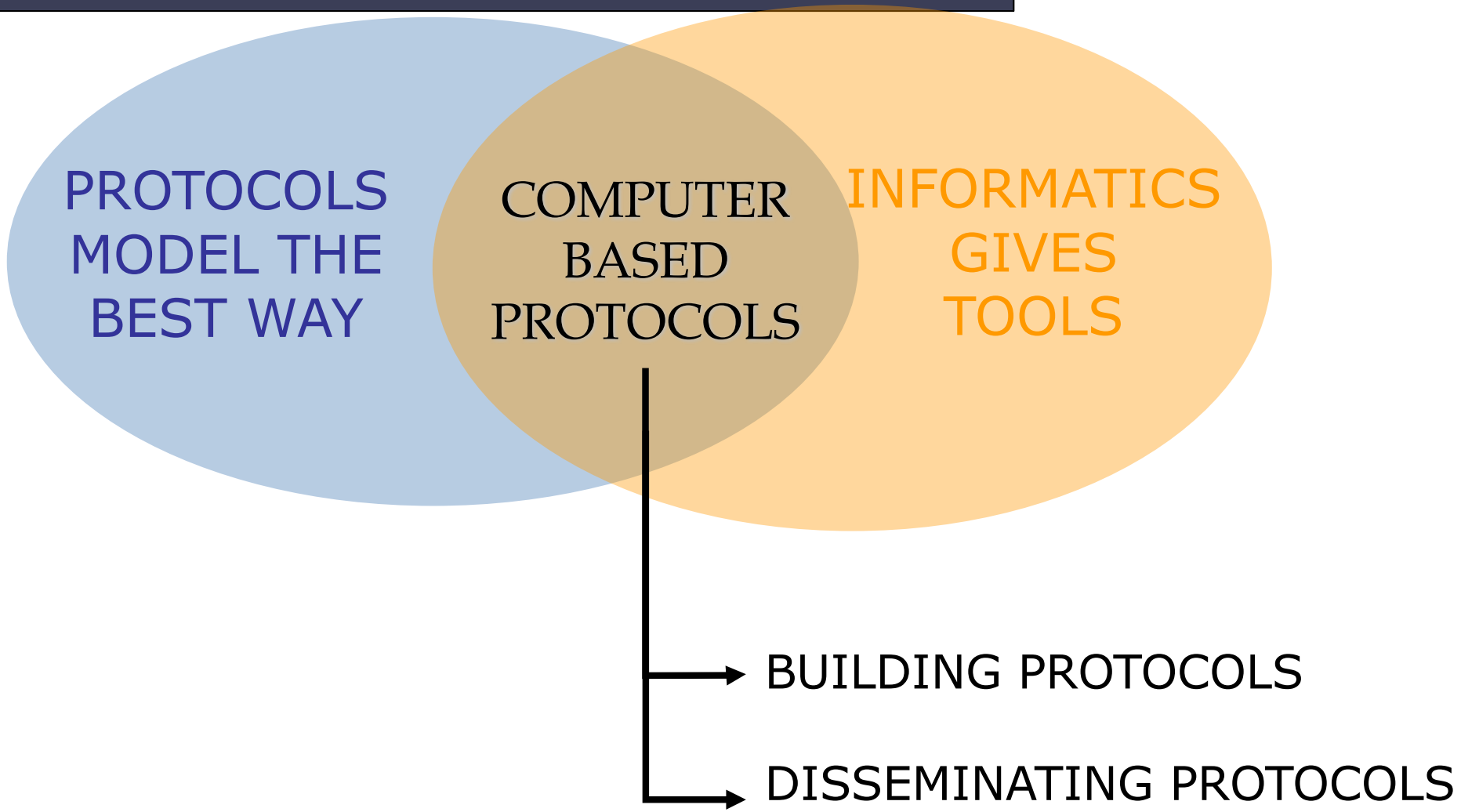
GUIDELINES DEFINITION: strength of recommendations

UNIVERSITÀ
DEGLI STUDI DI TRIESTE

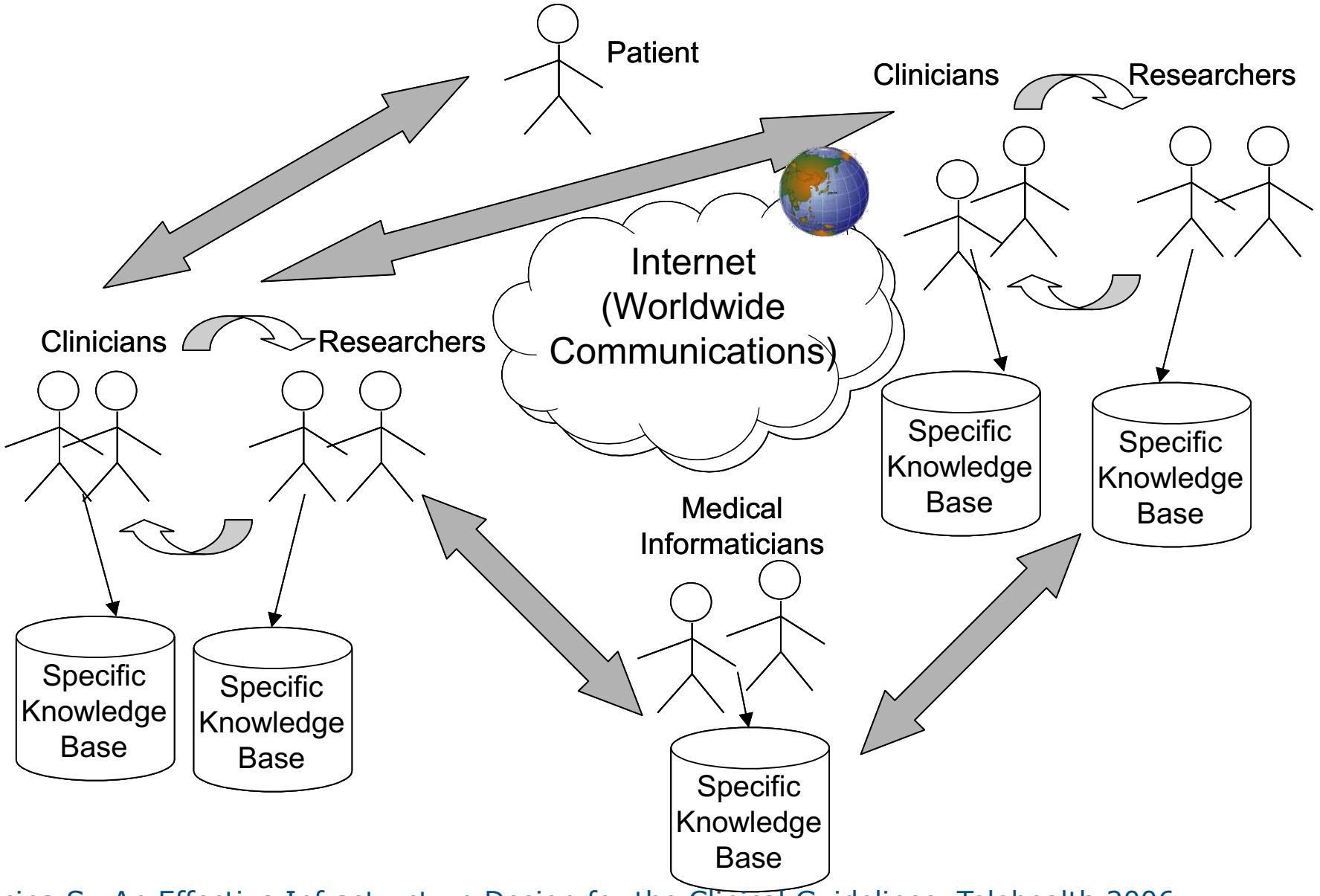
Guide for Strength of Recommendations

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.

COMPUTER-BASED PROTOCOLS

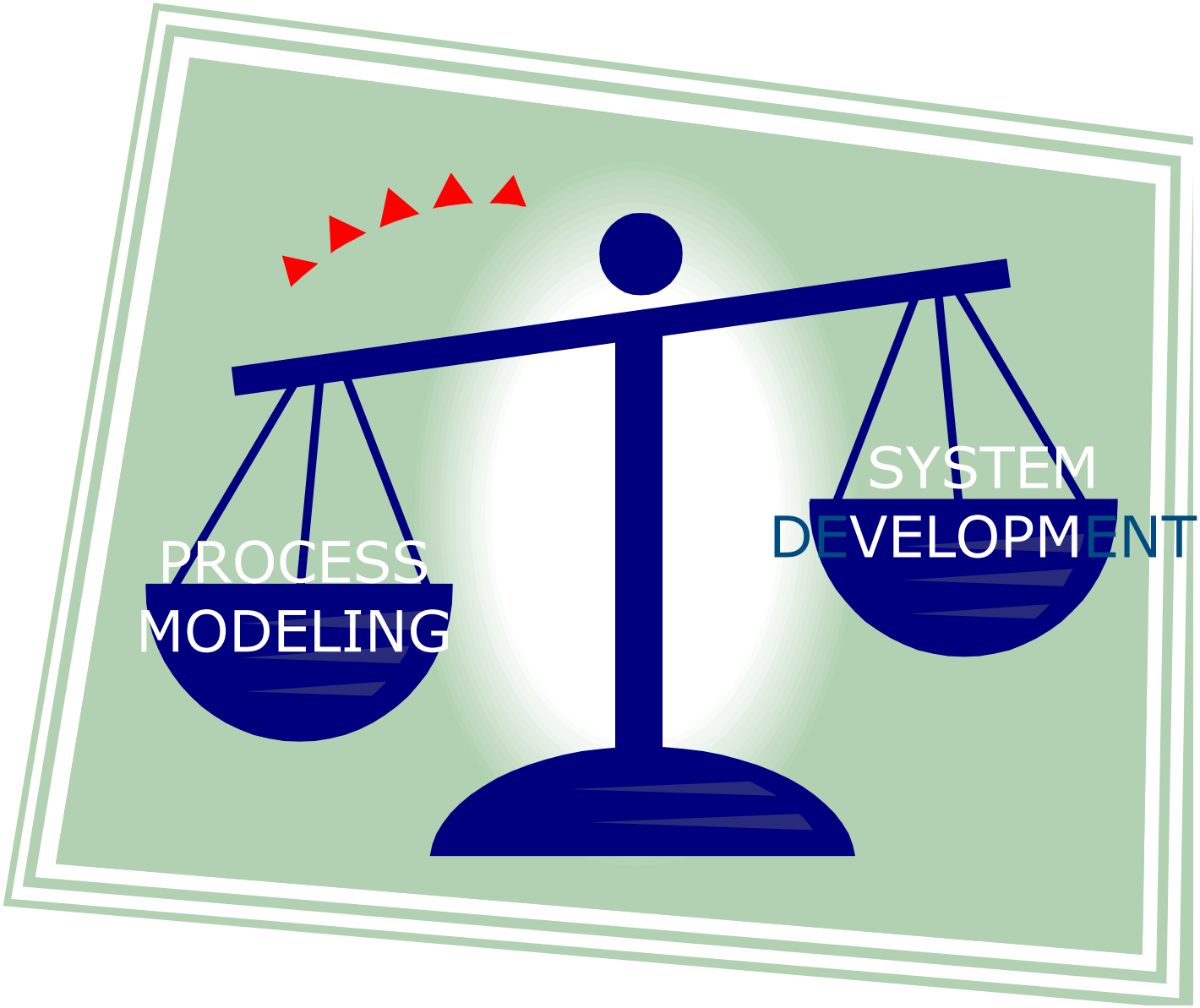


COMPUTER-BASED PROTOCOLS/GUIDELINES: ACTORS

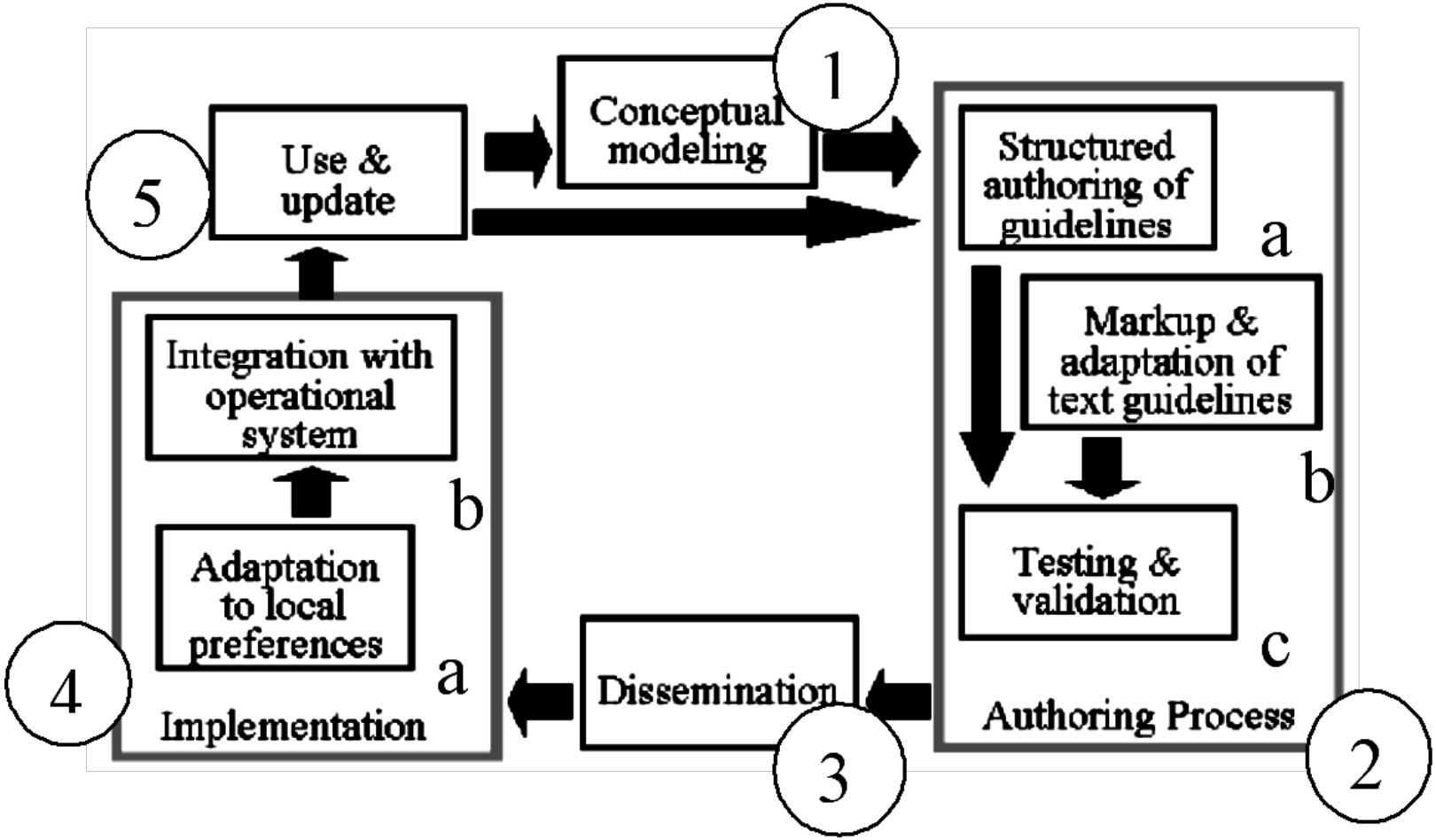


Bonacina S., An Effective Infrastructure Design for the Clinical Guidelines, Telehealth 2006

DESIGNING PROTOCOLS



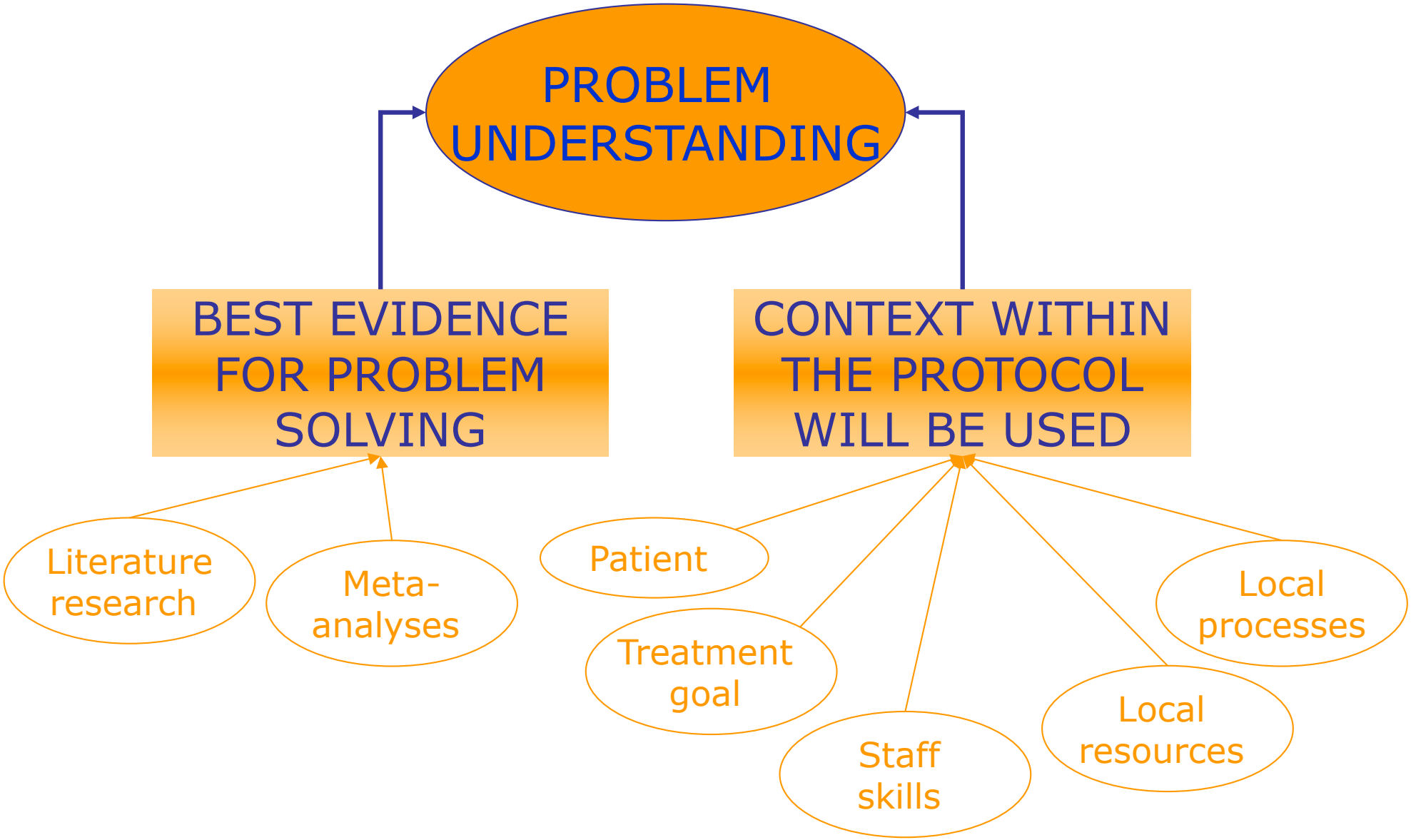
MEDICAL GUIDELINE LIFECYCLE



Greenes RA et al., 2001

PROCESS MODELING FOR GUIDELINE CONCEPTUALIZATION

UNIVERSITÀ DEGLI STUDI DI TRIESTE



SYSTEM DEVELOPMENT: designing principles

- The model defined is not static → improved by new evidence, protocol application outcomes, protocol deviations, …
- The protocol should not seem to be rigid or static or difficult to use
- Any assumption about the context of use should be explicit
- The protocol should not be more specific than it is necessary to achieve the goal
- Protocol design should reflect the skill level and circumstances of users
- Protocols should be constantly reviewed

PASSIVE vs ACTIVE SYSTEMS

UNIVERSITÀ
DEGLI STUDI DI TRIESTE

PASSIVE SYSTEMS

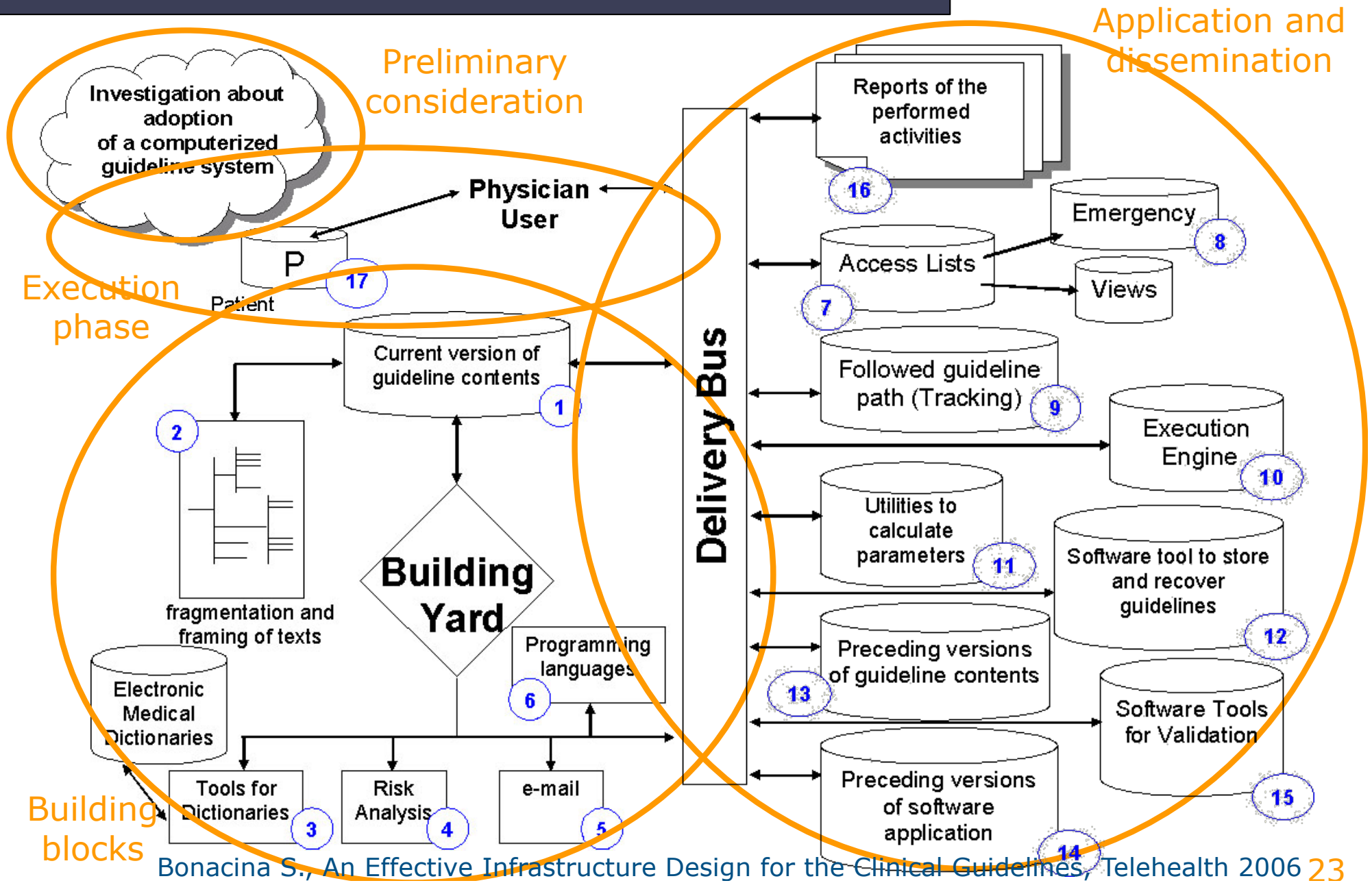
- Not intrinsecally incorporated in the healthcare system
- Clinicians are free to choose whether or not consulting the protocol
- Protocols are like "reference materials"
- Not integrated with the EHR

ACTIVE SYSTEMS

- Integrated with the system (EHR, laboratory reports, pharmacy)
- Clinicians' actions are fully guided by protocols
- Data entry in the EHR is facilitated (predefined steps, the system automatically generates the description→ ↑quality, ↓error rate, ↓time)

DESIGN INFRASTRUCTURE

UNIVERSITÀ
DEGLI STUDI DI TRIESTE



INFRASTRUCTURE: preliminary consideration

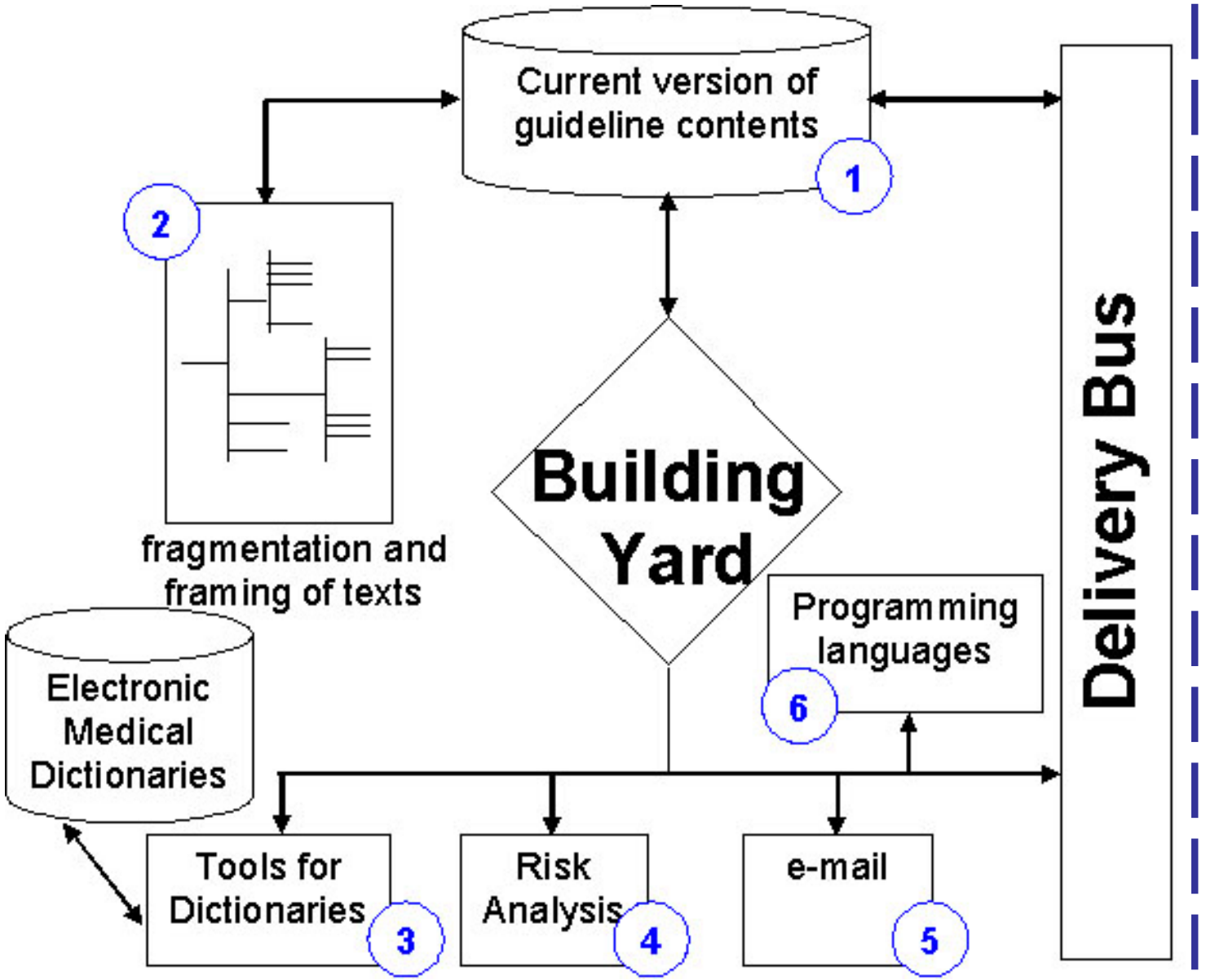
Verify:

- available instrumentations
- health information systems

in the light of embedded guidelines

INFRASTRUCTURE: "building yard" (1)

UNIVERSITÀ DEGLI STUDI DI TRIESTE



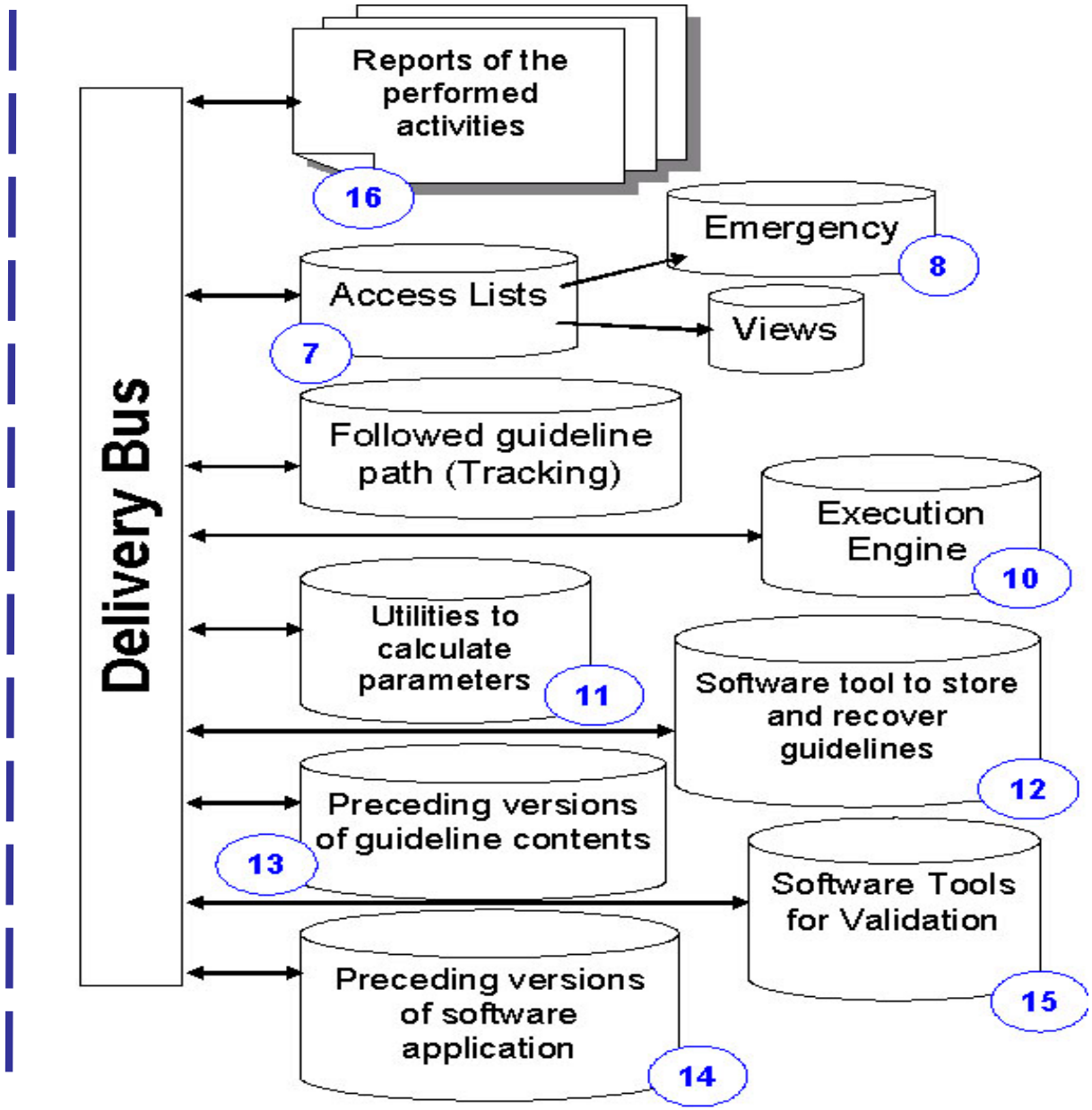
Bonacina S., An Effective Infrastructure Design for the Clinical Guidelines, Telehealth 2006

INFRASTRUCTURE: "building yard" (2)

1. Current version of guideline contents
   - Text format or executable format
   - Also guidelines in intermediate state (between text and executable)
2. Text fragmentation and framing
   - Translation text → exe
   - Representation of the textual form of the protocol in a specific language (UML – Unified Modelling Language)
   - XML format can be used
3. Tools for dictionaries
   - Standardized medical terms
   - Do not need concept "translation"
4. Risk analysis
   - Minimize recovery time
   - Analyze all the possible risk situations
5. E-mail
   - Communication systems to reach medical expertises (cooperative systems)
6. Programming languages
   - Guidelines implementation
   - Examples: Arden Syntax, Protegè

INFRASTRUCTURE: "application tools" (1)

UNIVERSITÀ DEGLI STUDI DI TRIESTE



INFRASTRUCTURE: "application tools" (2)

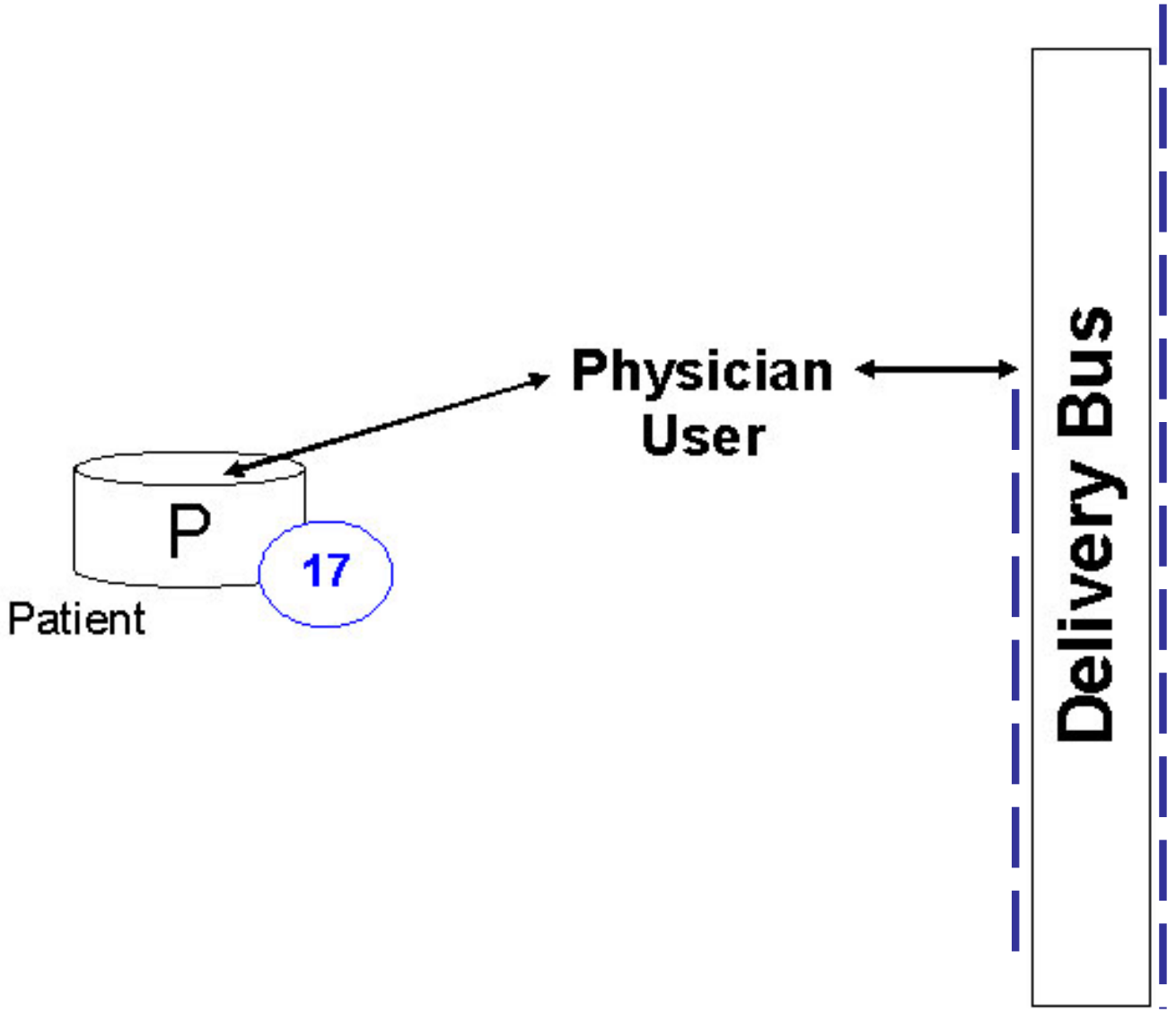
UNIVERSITÀ DEGLI STUDI DI TRIESTE

7. Access list
   - System protection
   - Different responsibilities → user's view
   - Electronic sign, audit trail, timestamps, …
   - Specific set of actions/operations/views for each kind of user
8. Emergency
   - Guideline path can change in the case of emergency (inclusion criteria in normal situation or in the case of natural disaster)
   - In the emergency case also the access politics can change
9. Followed guideline path tracking
   - Tracking system (action, time, data, …)
   - Used for medical intervention evaluation and for outcome measure
10. Execution engine
    - The implemented guideline is executed through the execution engine
11. Parameters calculation
    - Particular situations (chemotherapy)

INFRASTRUCTURE: "application tools" (3)

12. Software tool (storage and recovery)
    - Save/recover a certain guidelines in the system
    - Recall and execute
13. Preceding version of guideline contents
    - In a certain time frame a certain version of the guideline is used → you have several patients treated in that particular way
14. Preceding version of software application
    - Problem of version updating
    - Not all the old features are supported/compatible with the new version
15. Software tools for validation
    - Needed in every system
    - More important in the medical field (every error is paid by the patient)

INFRASTRUCTURE: execution phase



LANGUAGES: Arden syntax

- AIM → structuring and sharing knowledge

- STANDARD LANGUAGE →

  1994 – American Society for Testing Materials (ASTM)

  now – American National Standard Association (ANSA)

- USE→
  - Implementation of medical knowledge bases
  - Alarms and alerts generation
  - Diagnosis interpretation
  - Clinical studies screening
  - Message delivery managment

ARDEN SYNTAX: medical logic modules

UNIVERSITÀ DEGLI STUDI DI TRIESTE

DB managment

MAINTENANCE

File identification

LIBRARY

File content description

Real guideline

KNOWLEDGE

Decision rules and actions

- Three modules structure
- ASCII files (textual description)

```
maintenance:
     title: _____;;    (some brief description)
     filename: _____;;    (a unique name for the MLM)
     version: 1.00;;    (always start with 1.00)
     institution: _____;;    (your affiliation)
     author: _____;;    (your name)
     specialist: ;;    (always blank to start)
     date: _____;;    (today's date, like 1993-10-31)
     validation: testing;;    (start with testing)
library:
     purpose:    (why would you use the MLM)
          _____
          _____;;
     explanation:    (how does the MLM work)
          _____
          _____
          _____
          _____;;
     keywords:    (words or phrases that describe the MLM)
          _____;    _____;    _____;;
knowledge:
     type: data-driven;;    (always data-driven)
     data:    (define the event used in the evoke slot, and read data for the logic slot)
          _____
          _____
          _____
          _____
          _____;;
     evoke: _____;;    (what event should trigger this MLM)
     logic:    (create the logic necessary to carry out the task and conclude true when
          you want to write a message)
          _____
          _____
          _____
          _____
          _____;;
     action:    (write a message, combining narrative text and calculated values)
          _____
          _____
          _____;;
end:
```

ARDEN SYNTAX: example


```
maintenance:
      title: Alert on low hematocrit;;
      filename: low_hematocrit;;
      version: 1.00;;
      institution: CPMC;;
      author: George Hripcsak, M.D. (hripcsa@cucis.columbia.edu);;
      specialist: ;;
      date: 1993-10-31;;
      validation: testing;;

library:
      purpose: Warn provider of new or worsening anemia.;;
      explanation: Whenever a blood count result is obtained, the
            hematocrit is checked to see whether it is below 30 or
            at least 5 points below the previous value.;;
      keywords: anemia; hematocrit;;

knowledge:
      type: data-driven;;
      data:
            blood_count_storage := event
                  {'complete blood count'};
            hematocrit := read last
                  {'hematocrit'};
            previous_hct := read last (
                  {'hematocrit'}
                  where it occurred before the
                  time of hematocrit);;
      evoke: blood_count_storage;;
      logic:
            if hematocrit is not number then
                  conclude false;
            elseif hematocrit <= previous_hct - 5
              or hematocrit < 30 then
                  conclude true;
            endif;;
      action:
            write "The patient's hematocrit ("|| hematocrit ||") is
                  low or falling rapidly.";;

end:
```

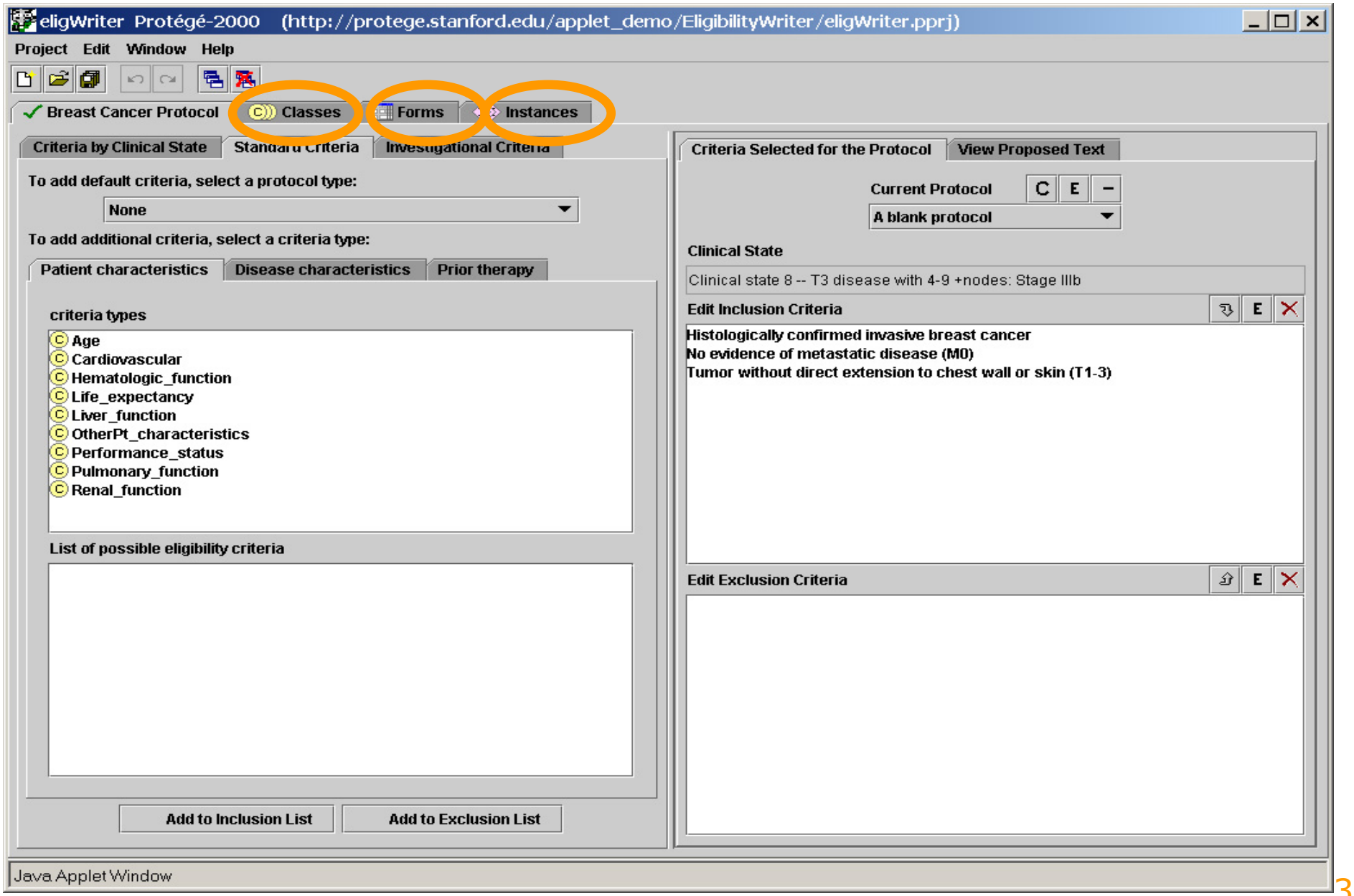
ALERT ON LOW HEMATOCRIT

LANGUAGES: Protegè

- AIM → Ontologies and knowledge-base editor
- Free software, based on Java
- USED TO →
  - Build personalized ontologies
  - Create personalized data entry forms
  - Insert data
- INCLUDES →
  - Tables
  - Graphs
  - Images
  - Sounds
  - Other multimedia files

PROTÉGÉ': example

UNIVERSITÀ DEGLI STUDI DI TRIESTE



SYSTEM IMPLEMENTATION TOOLS: GEM

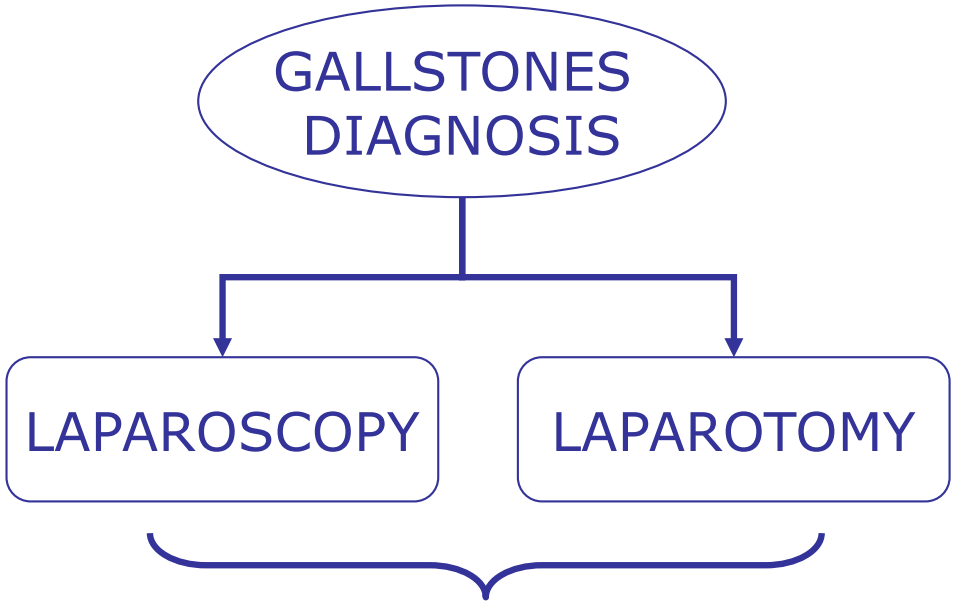
- Guideline Elements Model
- Based on XML
- Developed by the Yale university
- AIM → create a model for guideline documents
- Facilitates the translation

  text → structured format
- Towards computer implementation

SYSTEM IMPLEMENTATION TOOLS : GLARE

- GuideLine Acquisition, Representation & Execution
- Guideline implementation system
- AIM → support of the decision making process
- FEATURE → "what if" service →

Alternative choices are developed and virtually followed to evaluate possible time, costs, resources,…



Waiting times, costs, patient's outcome, …

→ Choose the best way in each particular case

SYSTEM IMPLEMENTATION TOOLS: GLIF

- GuideLine Interchange Format
- Developed by Columbia, Stanford e Harvard Universities (Intermed Collaboratory)
- AIM → tool for guideline implementation in different/shared informative systems (integration)
- Model language: Arden Syntax
- Medical Data Model: HL7 Reference Information Model
- GLIF3 guidelines can be implemented using Protegè

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