



临床决策支持新进展与HL7

- 临床知识表达的架构、方法学和标准

李包罗 HL7 China

衷心感谢美国Partners/Harvard周丽博士和Lantana的李敬东先生提供的材料和帮助



术语解释

- Clinical Knowledge Resource: 临床知识资源
- CDS Intervention Representation: CDS干预表达
- Unsequenced Recommendation : 非顺序（模块结构）的临床规则
- CDS Interventions Type : CDS 干预类型
- Advancing CDS(ACDS): ONC支持项目
- Clinical Advices(Actions): 建议临床处置（活动）
- Clinical Scenarios: 临床场景
- CCD、CCDA: HL7 Continuity of Care Document Component, Consolidated CDA
- XML, XML Schema, XSD, XSL 与XML有关的文档类型
- Knowledge Engineer Style Sheet: 格式表
- CDS Consortium, Partners Healthcare , CDS联盟

CDS的定义

来自AMIA



Providing clinicians, patients or individuals with knowledge and person-specific or population information, intelligently filtered or presented at appropriate times, to foster better health processes, better individual patient care, and better population health.

In other words, providing the right information, to the right person, at the right time



CDS的定义 来自AMIA

为医务工作者、病人或任何个人提供知识、特定个体或人群信息，在恰当的时间，智能化的过滤和表达信息，为的是提供更好的健康、诊疗和公共卫生服务。

换句话说，就是在正确的时间，对正确的对象，提供正确的信息

有别于人工智能和专家系统



世界CQC和CDS的现状-1

- 没有广泛可接受的，标准的方法表述基于计算机的CDS干预和他们的结构化成分
- 各医院和各软件实现CDS的方法各不相同
- 因此计算机化的**CDS的广泛推广与实现几乎不可能**
- 为解决此难题，美国ONC组织了ACDS(Advancing Clinical Decision Support)项目， Led by RAND Corporation and Partners Health Care/Harvard Medical School

世界CQC和CDS的现状-2

• 哈佛团队（ RAND Corporation/Partner HealthCare ）的创新工作：

1. 比较HL7(Order set, Infobutton, vMR),ASTM GEM model, OpenEHR, OpenCDS, GELLO不同的表达方法，抽取出共性的元素
2. **标准的结构化的表达临床知识和CDS干预**
3. 提供共享知识服务（可重用组建）
4. 进行了实现验证，NQF项目，Meaningful Use 要求
5. 推广应用





需求分析的结果-1

CDS Intervention Type

1. Alerts and Reminders
2. Infobuttons
3. Order Sets
4. Documentation Templates and Forms
5. Relevant Data Presentation



需求分析的结果-2

Core Structural Elements Shared Across All Five Intervention Types

1. General Metadata
2. Applicable Clinical Scenarios
3. CDS Input
4. CDS Output
5. CDS Logic



知识表达的4个层次

four-layered knowledge representation framework (Boxwala, 2011)

- **Unstructured (L1):** human readable knowledge in any document format.
- **Semi-structured (L2):** knowledge is deconstructed as individual recommendations. A schema is developed, but Knowledge is not codified
- **Structured (L3):** specifies the **structure and semantics** of data elements and logic needed to make the knowledge **interpretable by computers**.
 - The knowledge is independent of implementation in a particular CDS tool or a particular clinical setting, to maximize its ability **to be shared**.
 - Unified Modeling Language (**UML**) models and **XML schemas** are developed for this layer.
 - Data elements are codified as necessary.
- **Executable (L4):** dependent on the specific CDS tool employed and clinical setting; implemented into specific **rule engines or clinical systems**.



通用定义和元数据的表达

General Metadata

- 各方所使用的定义和元数据十分类似
- General Definition 和Metadata可以涵盖所有的干预类型
- 定义提供了一个临床知识资源的总括的格式化描述：名字、介绍、标识
- Metadata包括了资源及该资源内的模块、建议处置的通用信息：UID, 作者，寻证基础，开发方法，知识类型，测试信息，文档版本和生命周期管理信息



适用临床场景的表达

Applicable Clinical Scenarios

- 场景的描述是临床知识表达的重要一环，干预的使用对象、条件与环境
- 包括单一逻辑条件 (Single Logical Condition) 或成组的逻辑条件
- 逻辑条件包括：标识，表达式，与病人数据模型的 Mapping
- 场景构件可以在临床规程 (Guideline) 、模块 (Module) 和特定临床规则 (Recommendation) 处置三个不同的层次使用



CDS Input 的表达

- CDS Input 的核心是病人数据
- CDS 建议病人数据模型采用HITSP的临床摘要，实际来自HL7的CCD（CCDA）组件
- 下一步方向是HL7的vMR标准



CDS Output 的表达

- 建议遵循 HITSP 认可的(约束的)HL7 CCD 临床表述模型 (Clinical Statement Model)
- 推荐的处置，可能是信息要求、事件要求、由行为构造器 (Action Organizer) 用逻辑关系互相连接的一组处置
- 例外的原因可以加到任何建议处置项目
- 其它与临床实践执行细节的描述 (优先级，前提，执行类别等)



CDS Logic 的表达

- CDS逻辑就是在特定的应用场景下成对地表达CDS输入模块和将封装在CDS输出模块中的推荐处置活动。
- CDS干预由 (1...n) 个模块 (Module) 构成
- 每个临床规则模块由特定元数据，模块化的特定场景（例如：过去12个月没血压）和 (0...n) 临床规则模块构成
- 每个临床规则模块又可以嵌套特定元数据、场景、建议处置
- 在给定的建议 (Advice) 内部又可以嵌套要表达在CDS Output 的活动 (Action)
- 总之，模块化的非顺序表达和灵活的嵌套是CDS规范表达的核心



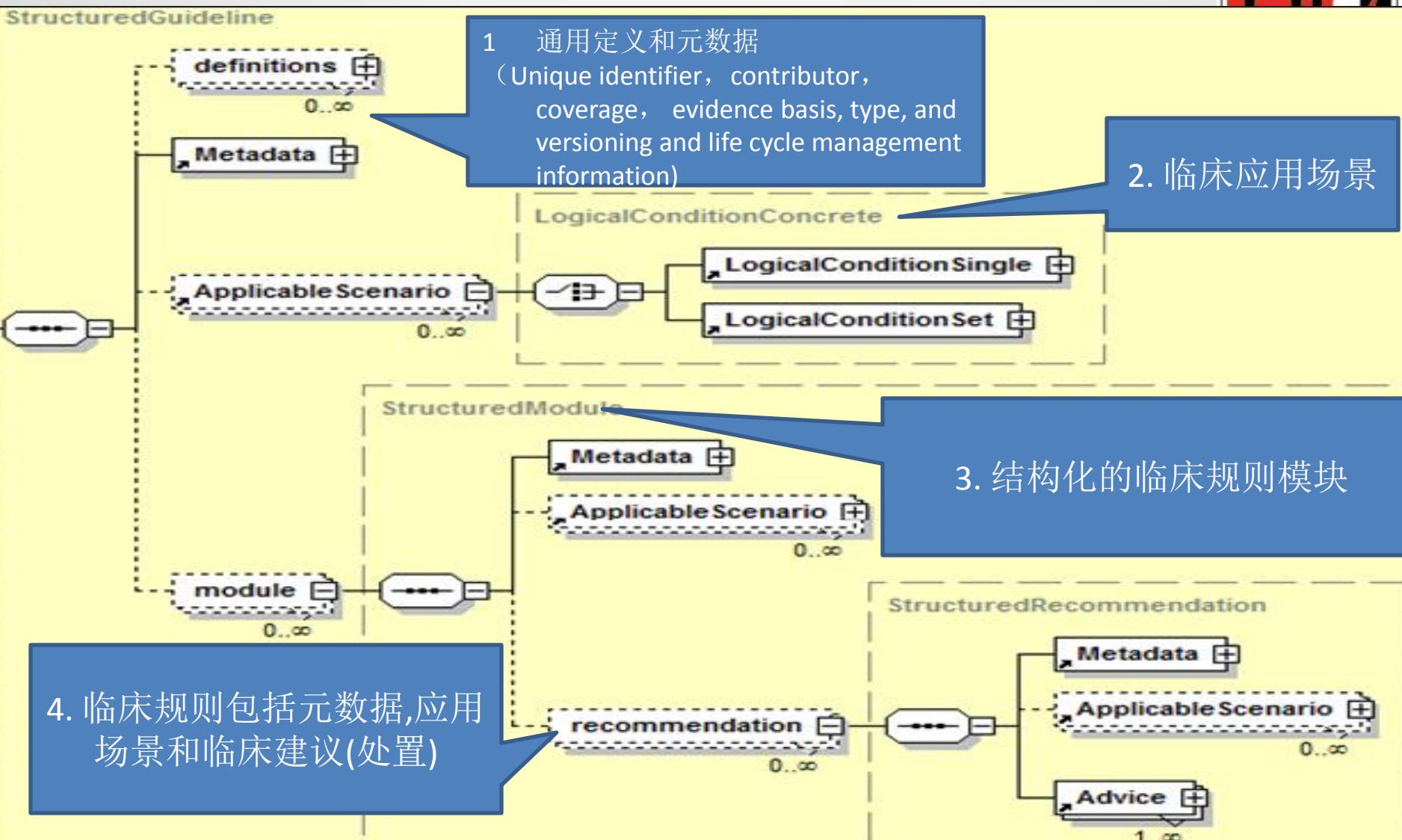
值域的表达

- 值域的统一表达涉及所有干预类型
- 有了值域的统一表达才可能有计算机对临床知识的理解, L3以上是必须的

例如，推荐用29个不同的SNOMED概念用于糖尿病人（8801005-Secondary diabetes mellitus）

- 已经开发了一个表达这些值域的模型
- 源码有一组属性，可以有进一步的约束和细化
- 可以和其他编码系统建立关系，例如 NQF eMeasures Value Sets.

方法学要素概要表达/L3 XML Schema





临床知识表达结构化模型

- Clinical Knowledge Resource as a collection of unsequenced recommendations
- The recommendations are organized into modules
- Each recommendation consists of metadata, applicable scenarios and clinical advices(actions)
- XML Schema Definition(XSD) and Extensible Stylesheet Language(XSL) files 下载地址：
<http://cdaportal.Partners/RelatedResources.aspx?pageId=3>

表格式表达（医学知识表达规范化L3 Stylesheet）的实例 -- 戒烟者的适用场景和处置建议

Applicable Scenario

AND	Patient is an adolescent or adult, i.e. age is greater than 12 years old Expression: CALCULATE_AGE_IN_YEARS(DoB)>=12	Status	Active (SNOMED Clinical Terms: 55561003)
	Patient is a tobacco user Expression: Social History: PATIENT_HAS_SOCIAL_HISTORY(tobaccoUser) Type Tobacco User SNOMED-CT Code List (American Medical Association: 2.16.840.1.113883.3.526.02.422)		
OR	Patient is a smoker Expression: Social History: PATIENT_HAS_SOCIAL_HISTORY(cdcSmokingRecodes) Type CDC Recodes Value Set (L3 spec) (Partners Healthcare System:)	Status	Active (SNOMED Clinical Terms: 55561003)

Reference eMeasure and CDC Value Sets for Smoking

Anti-Smoking Medications

- Substance Administration Request: Nicoderm-CQ 14mg 1 patch/day - Nicoderm-CQ (RxNorm: 351427)
- Substance Administration Request: Varenicline po 1mg 1tab / day - Varenicline (Chantix) (RxNorm: 637190)
- Substance Administration Request: Zyban ER po 150mg 1tab / day - Bupropion (RxNorm: 993956)

Referrals

- Encounter Request: Smoking cessation education (SNOMED Clinical Terms: 225323000)
- Encounter Request: Referral to smoking cessation advisor (SNOMED Clinical Terms: 395700008)
- Encounter Request: Referral to stop-smoking clinic (SNOMED Clinical Terms: 315232003)

Patient Education

- Knowledge Asset Request: Smoking Cessation Education Leaflet - Smoking cessation education (SNOMED Clinical Terms: 225323000) Target: Patient (SNOMED Clinical Terms: 116154003) <http://www.ahrq.gov/consumer/tobacco/helpsmokers.htm>

› 12岁的青少年或者成年人，吸烟史表达值域eMeasure、CDC二选一：Tobacco User or smoker
抗烟药物，转诊考虑，病人教育

Search Term:

Search

Clear Selection

Advanced Search Criteria**Specification Level:**

- Level 1 - Unstructured
- Level 2 - Semi-Structured
- Level 3 - Structured**

Contributing Entity:

- All Contributing Entities
- Advancing CDS
- CDS Consortium

Knowledge Type:

- Documentation Template/Form
- Order Refinement
- Order Set**

Care Setting:

- All Care Settings
- Acute Care
- Ambulatory Care

Intended Recipient Role:

- All Roles**
- Nurse
- Other Health Professions

Clinical Information System:

- All Clinical Info Systems
- GE
- Meditech

Patient Population:

- All Patient Population**
- Adolescent
- Adult

Quality Measure Target:

- All Quality Measures
- CMS PQRI Measures
- JCAHO Core Measures

Clinical Specialty:

- All Clinical Specialties**
- Aerospace Medicine
- Allergy and Immunology
- Anesthesiology
- Audiology
- Chiropractic Medicine
- Critical Care Medicine
- Dentistry
- Dermatology
- Emergency Medicine
- Family Medicine
- General Medicine
- Internal Medicine

Meaningful Use Stage:

- All Stages**
- Stage 1
- Stage 2



HL7 Infobutton

- The HL7 Context-Aware Knowledge Retrieval Standard provides a standard mechanism for EHR systems and knowledge resources to communicate, implementing infobutton capabilities.
- the Infobutton has been used to bring up decision support information for the clinician.
- This same HL7 standard can also be used to trigger relevant, helpful patient education orders or “information prescriptions”—for the patient.
- In an EHR, a clinician triggers a knowledge request to a content provider.



HL7 Infobutton Standard

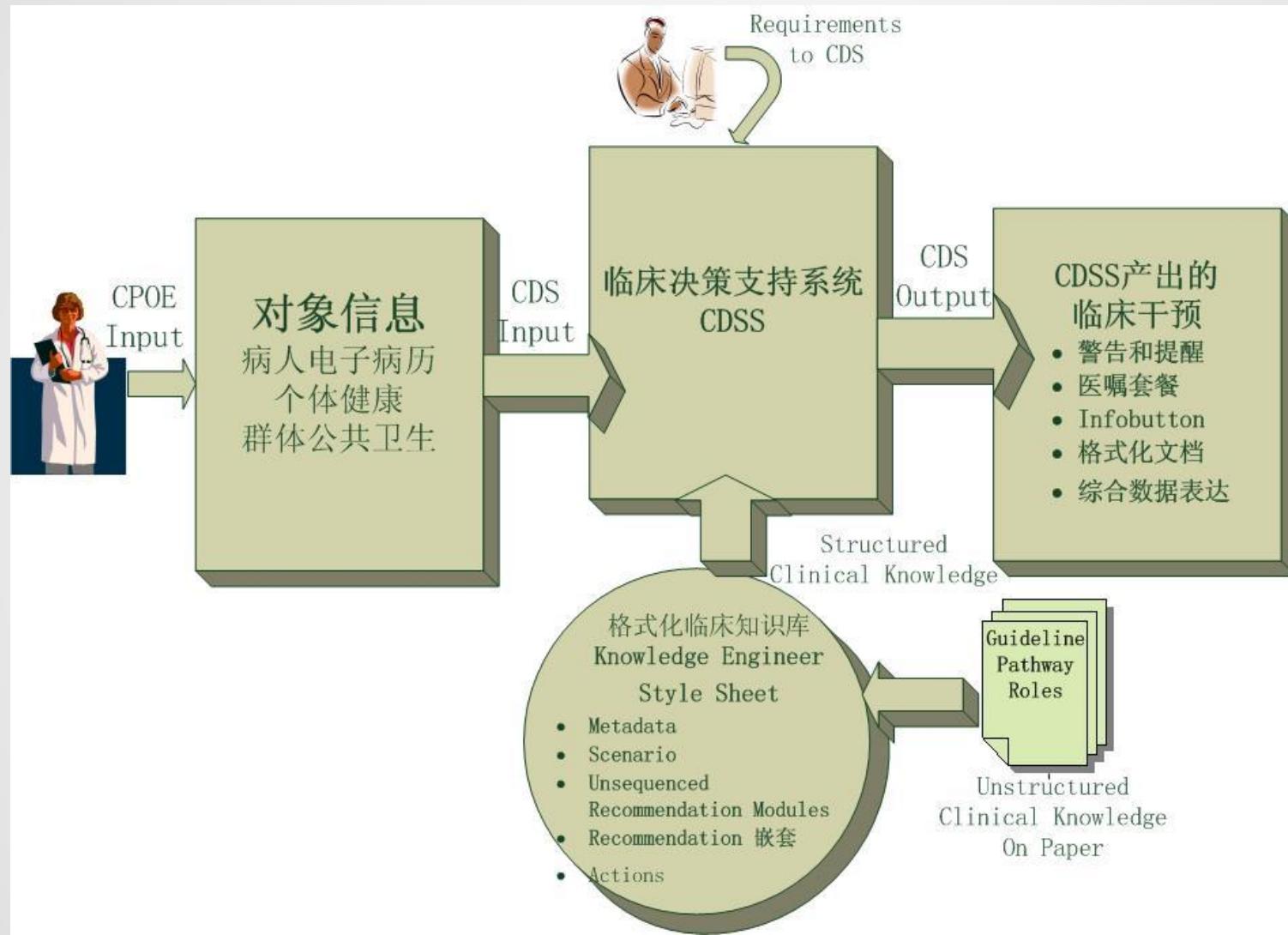
- [Context Aware Knowledge Retrieval Application \(“Infobutton”\), Knowledge Request](#) - normative specification that includes a domain analysis model and a message information model. By itself, this specification is not implementable.
- [URL-based implementation guide, Release 4](#) - specifies infobutton knowledge requests in a URL format
- [Infobutton Service-Oriented Architecture \(SOA\) Implementation Guide, Release 1](#) - RESTful specification and knowledge response in XML and JSON formats.



Infobutton Targets

- Clinical Information System Developers
- Clinical Knowledge Resource Publishers
- Clinical Decision Support Developers
- Healthcare Organizations

CDSS的功能体系架构

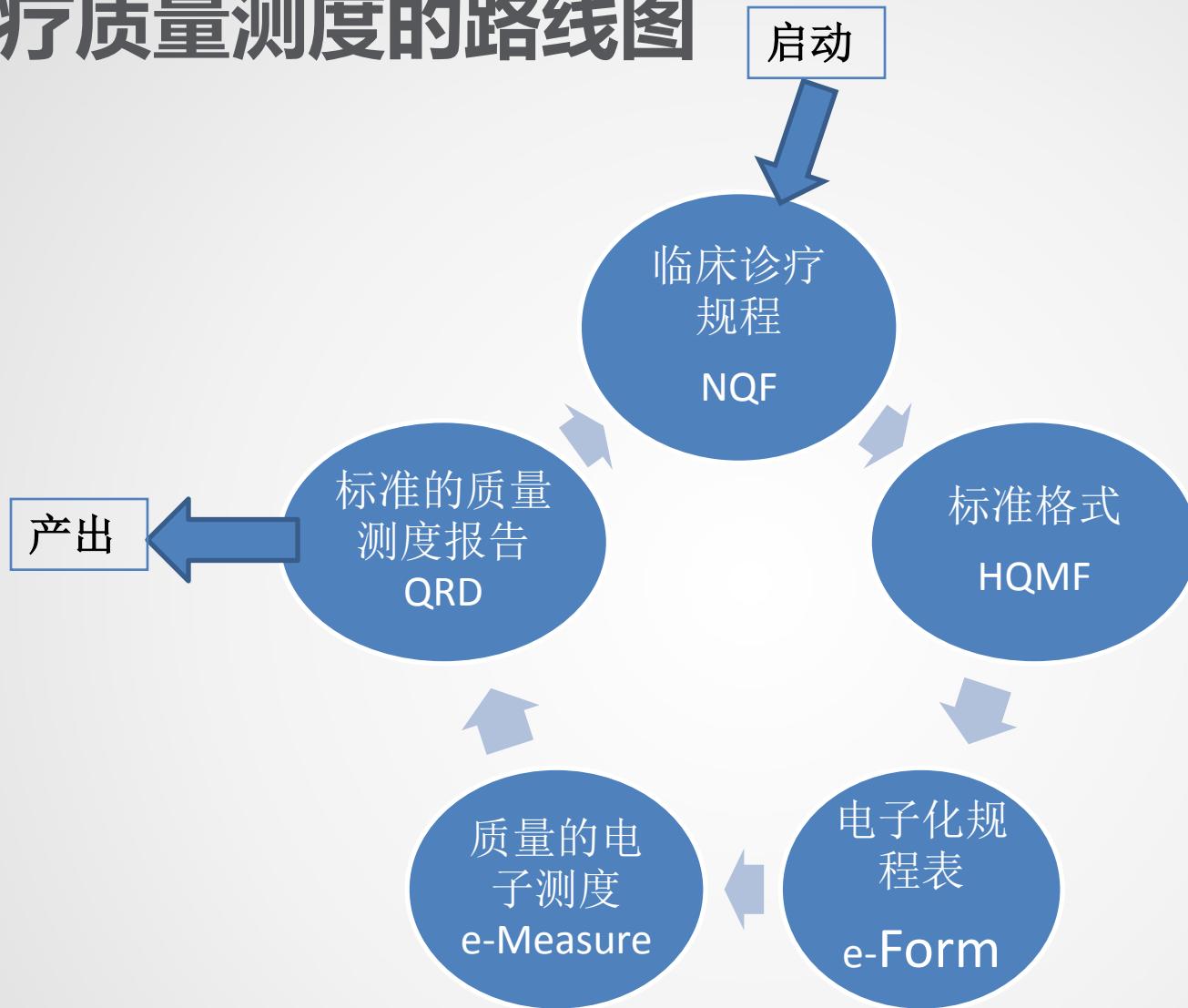




医疗质量测度的新进展

- 美国在此方面，已经走过了单纯的理论探讨和政策研究阶段
- 依托奥巴马总统的医改大潮，美国CMS牵头搞了一个测度管理系统 (The Measures Management System)
- 发展出了一个实现医疗质量测度的机制与步骤
- 其方法和路径，与信息技术、特别是信息标准化技术，包括HL7有密切的关系
- 尽管该系统最终运转的效果尚不得而知，但值得我们中国医改决策者借鉴是毫无疑问的

医疗质量测度的路线图





实现医疗质量测度的第一步

1.首先有医疗管理机构 (NQF) 公布一系列的临床诊疗规范 (Clinical guideline/Clinical Pathway)

Quality measures are often derived from **clinical guidelines** and are designed to determine whether the appropriate care has been provided given a set of **clinical criteria** and an **evidence base**



实现医疗质量测度的第二步

2. 制定一个可以表达这样规范的标准格式，这个格式应该是统一的（唯一性），完整地（可覆盖所有规范），可以电子化的（计算机能读懂）。

National Quality Forum (NQF) joined with HL7, AHIMA and consulting firm Alschuler Associates to develop a draft standard called Health Quality Measure Format (HQMF) which is a standard for representing a health quality measure as an electronic document



实现医疗质量测度的第三步

3. 把每个诊疗规范用统一的格式HQMF表达
NQF convert 113 NQF-endorsed measures
from a paper-based format to an electronic
"e-Measure" format.



实现医疗质量测度的第四步

4. 应用开发商根据质量测度的要求，从EHR/EMR中抽取必要的信息，即所谓e-Measure

Standardization of document structure (e.g. sections), metadata (e.g. author, verifier), and definitions (e.g. “numerator”, “initial patient population”) enables a wide range of measures, currently existing in a variety of formats, to achieve at least a minimal level of consistency and readability, even if not fully machine processable



实现医疗质量测度的第五步

5. 产生符合医疗管理部门要求的，标准化的质量测度报告，QRDA

The Quality Reporting Document Architecture (QRDA) project is developing a standard for communicating health care quality measurement information. The standard will conform to the requirements of the Health Level Seven (HL7) Clinical Document Architecture Release 2.0 (CDA)

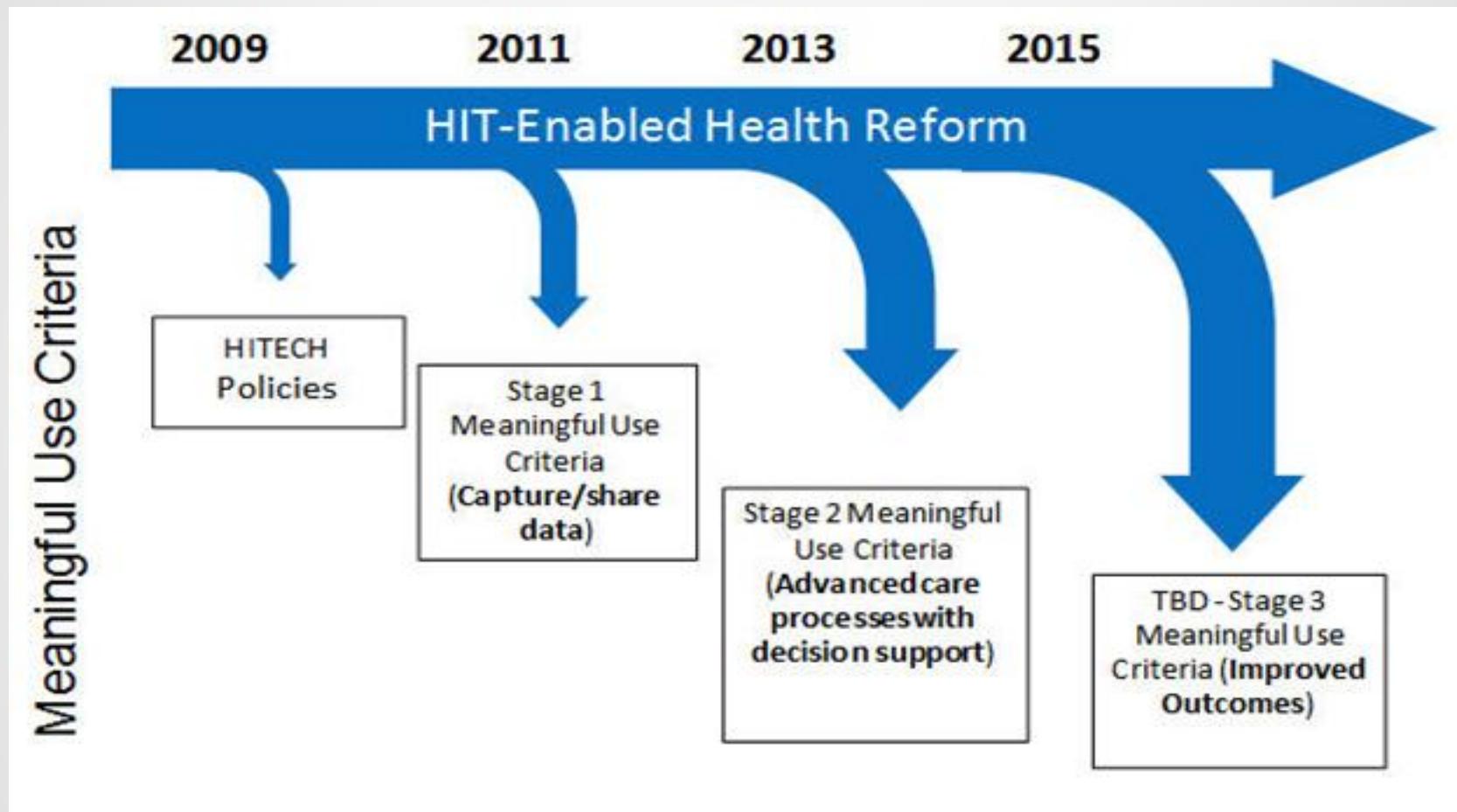
美国EMR实施的路线图

美国EMR/HER推广应用的直接动力是分阶段达到Meaningful Use所要求的资金激励计划和逾期达不到要求的惩罚条例。这些都是基于国会通过的法案。

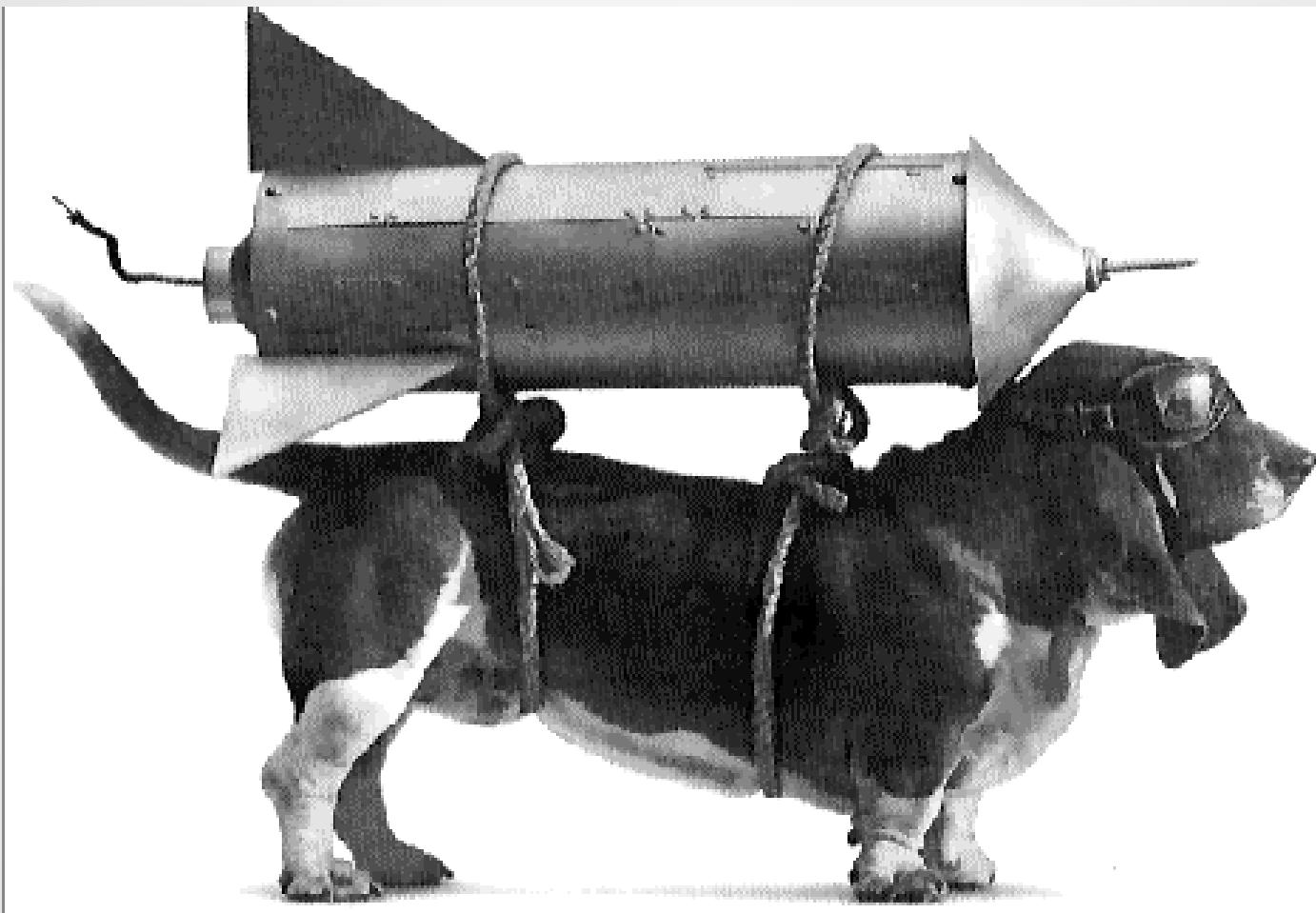
Measure Management System 将会成为达到 EMR Meaningful Use 条件的重要部分



MU Stages (有意义使用阶段)



解决方法学问题是达到目的必要条件





参考资料

- AMIA2009 Symposium Proceedings: A Methodology for the Design, Development, and Maintenance of Enterprise Clinical Decision Support Rules Page 1107
- MEDINFO 2013: Structured Representation for Core Elements of Common Clinical Decision Support Intervention to Facilitate Knowledge Sharing, doi:10.3233/978-I-61499-289-9-195
- A study of diverse clinical decision support rule authoring environments and requirements for integration BMC Medical Informatics and Decision Making 2012, 12:128
- Structured Representation for Core Elements of Common CDS Interventions to Facilitate Knowledge Sharing



衷心感谢Partners/Harvard周丽博士和Lantana公司的李敬东先生提供的材料和帮助

<http://cdsportal.Partner.org>

<http://www.rand.org/health/projects/clinical-decision-support.html>

Thank you!

<http://hl7china.org.cn>
liblpumch@gmail.com