From Non-Formal Clinical Information Constructs
to
open**EHR** Clinical Models
to
Software

Endoscopy as an example domain

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Agenda

- Importance of 'common understanding'
- Endoscopy domain ....
- MST – a very good initiative
- Formal (openEHR) Modelling
- GastrOS Project
- Interim results on software maintainability
- Interoperability & domain knowledge governance aspects

Common Understanding

- E
- T
- I
- I
- H

"Corr   osis"

tka

— arou I Saw That   I Heard That   I'm Gonna Tell

Letters to the Editor

How often is large smaller than small?

P. W. Moorman[b], P. D. Siersema[a], M. A. J. de Ridder[a] and A. M. van Ginneken[a]
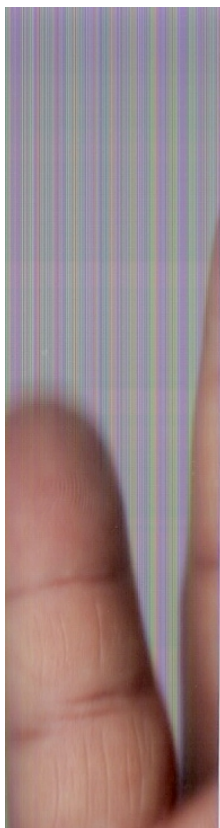
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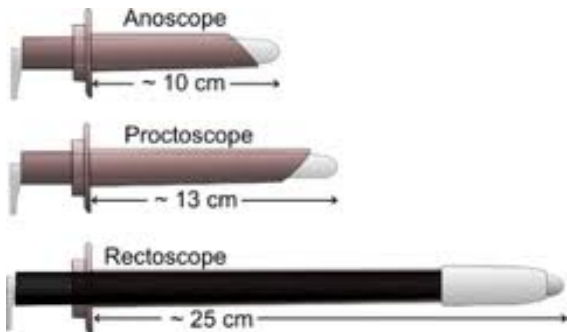
How Often is Large Smaller than Small?

Abstract

In endoscopy reports, one third of the sizes of gastric ulcers are described using a non-numerical expression only. To study in which extent such expressions of size form a source of ambiguity, we sent a questionnaire to 222 Dutch physicians who perform endoscopies. They were asked to make the expressions 'small', 'medium', and 'large', when used to describe the size of a gastric ulcer, explicit on a numerical scale. Response rate was 71.2%. Overlap in the range of terms was large. In 31.1% 'large' did not exceed 'small'. As this may have clinical consequences, we recommend the use of numerical size estimates.

Endoscopy
A Not So Pleasant Experience!

Anoscope
~ 10 cm

Proctoscope
~ 13 cm

Rectoscope
~ 25 cm

What if all the pain and humiliation were for nothing?

Pub**Med**.gov

U.S. National Library of Medicine
National Institutes of Health

Search: PubMed ▾

Limits   Advanced search   Help

Display Settings: ☑ Abstract

Send to: ☑

Are referring physicians satisfied with endoscopy reports?

Moorman PW, Siersema PD, van Ginneken AM, van Blankenstein M.

Department of Medical Informatics, Erasmus University, Rotterdam, The Netherlands.

Abstract

To assess the opinions of referring physicians on the contents of endoscopy reports, 150 consecutive endoscopy reports were accompanied by a questionnaire. Of these, 102 reports were returned: response was 68%. Almost half of the reports were considered not fully satisfactory. However, endoscopy reports may be improved by including information such as indication, therapy plan and follow-up plan on a more regular basis, and add clarity whether findings may account for complaints of the patient. To tailor endoscopy reports to the needs of individual referring physicians, more explicit information of referring physicians is required. If endoscopists are responsible for the information they provide to the referrer, it is also their task to facilitate the explicit formulation of preferences by the referrer.
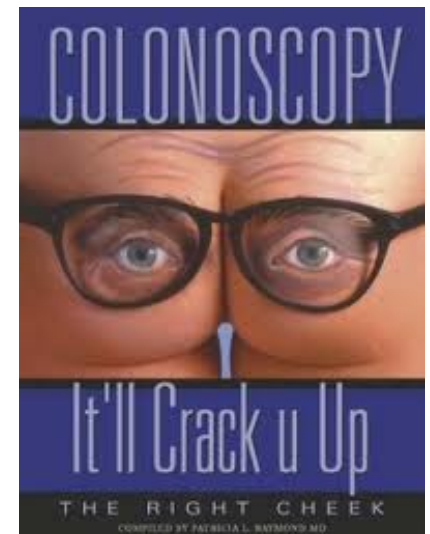
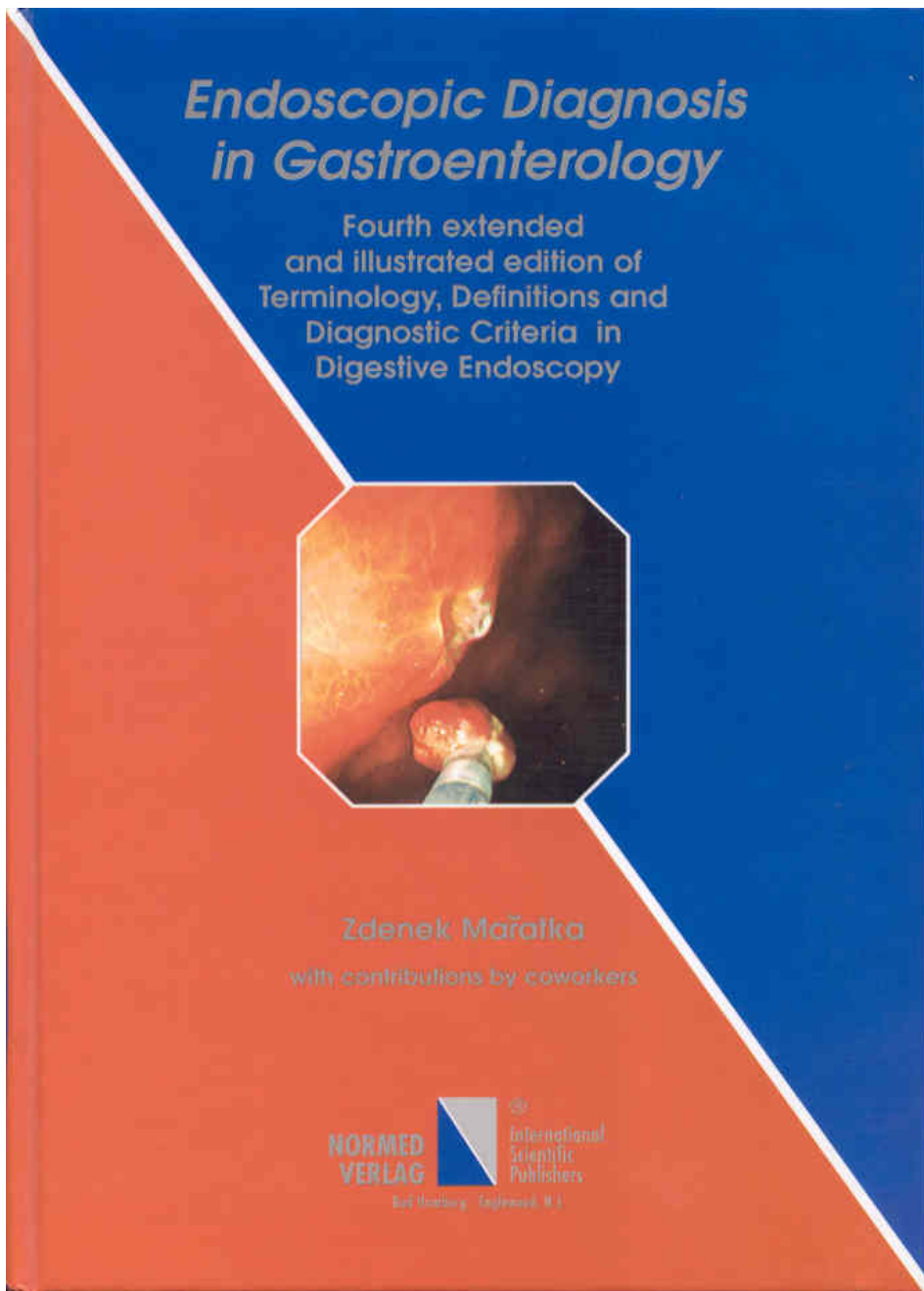# Research Domain

Gastroenterologic Endoscopy

- A small and manageable (niche) domain
- Visualisation of the gastrointestinal tract for both diagnostic and therapeutic purposes
- Quite invasive procedure ➜ results need to be reliable, complete and unambiguous
- Good level of common medical language
- Worldwide accepted terminology
- Request from a top-tier University Hospital Endoscopy Unit

Terminology Standardization in Endoscopy

Endoscopic Diagnosis in Gastroenterology

Fourth extended and illustrated edition of Terminology, Definitions and Diagnostic Criteria in Digestive Endoscopy

Zdenek Mařatka
with contributions by coworkers

NORMED VERLAG
International Scientific Publishers

Section 4 - Findings

Section 4.1 - Findings for Upper Gastro-intestinal Endoscopy.

Table 10. Findings for Esophagus

| Term	Attribute / Attribute value	Definition
Normal		This term describes the situation of the organ in the absence of any lesion. The lumen is tubular; the surface is smooth with a whitish pink mucosa.
	Z line	A circular, sometimes irregular, border demarcating the interface between the whitish esophageal mucosa and redder gastric mucosa.
	cm. from incisors	Location of the Z-line, defined as the number of cm, measured on the endoscope shaft, the tip of it being set at the level of the Z-line.
Lumen		Inside space of the examined organ and the wall delimiting it.
Dilated		Increase in the caliber of the lumen.
Stenosis		Decrease in caliber of the lumen or of a sphincter, that seems permanent.
	Upper limit	Defines the upper limit of the stenosed segment of the organ.
	cm from incisors	Location of the upper limit of a stenosis, defined as the number of cm, measured on the endoscope shaft, the tip of it being set at the level of the stenosis.
	Appearance	Endoscopic aspect of the narrowing that may indicate its probable origin.
	Extrinsic	Narrowing of the lumen, resulting from a process external to the lumen.
	Benign intrinsic	Narrowing of the lumen, resulting from a process that involves the wall and appears to be benign.
	Malignant intrinsic	Narrowing of the lumen, resulting from a process that involves the wall and appears to be malignant.
	Length (cm)	Length of the narrowed segment, expressed in cm, measured as the difference in distance from

38

Minimal Standard Terminology for Digestive Endoscopy (MST)

- Initiated by the European Society for Gastrointestinal Endoscopy (ESGE) in 1990, now official terminology for World Society of Gastro-intestinal Endoscopy (OMED)
- A "minimal" list of terms for use in computer system used to record the results of a gastrointestinal endoscopy
- Validation in EU project – GASTER and an US project
- Already integrated with the NLM's Unified Medical Language System (UMLS)
- Eleven language translations
- Research prototype GST is based on Turkish translation, being used since 2000 at Başkent University Hospital in Ankara

MST Organization
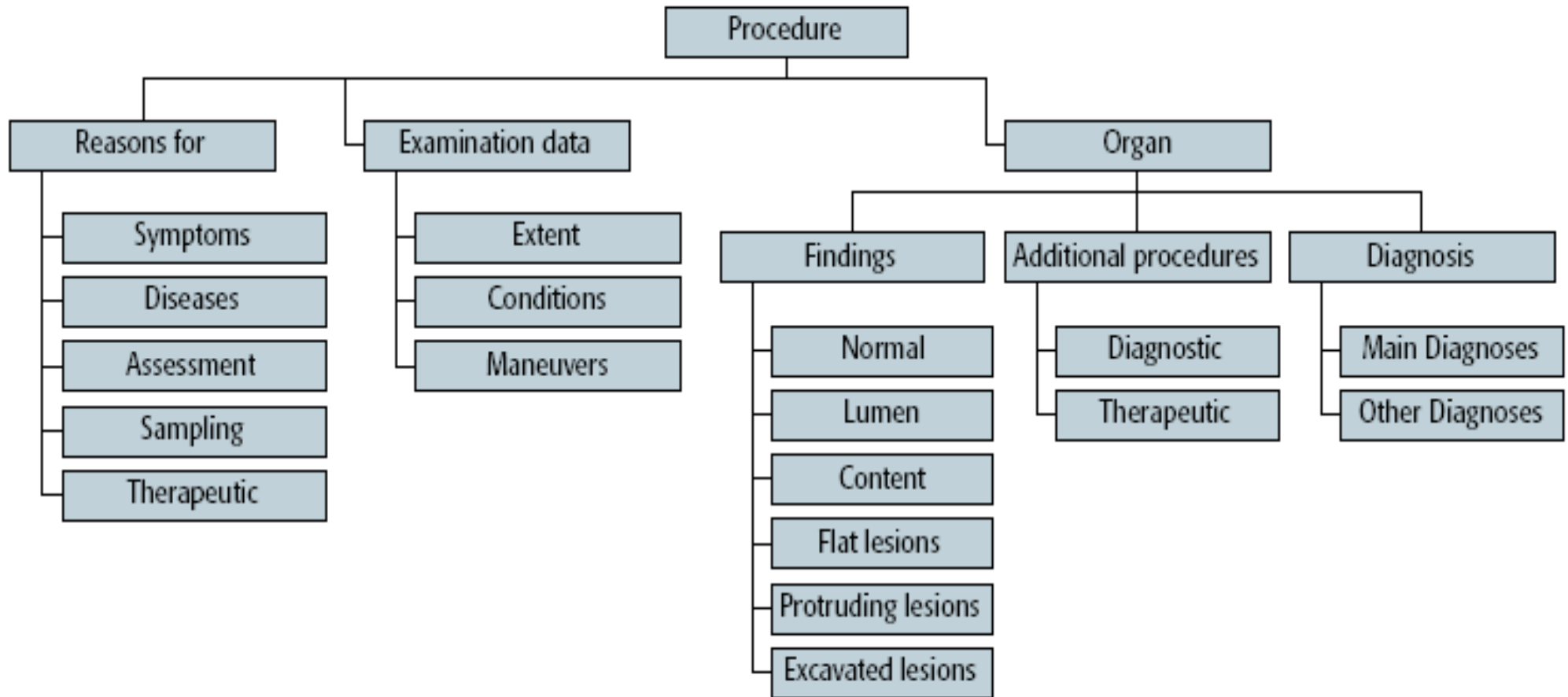
MINIMAL STANDARD TERMINOLOGY© FOR DATA PROCESSING IN DIGESTIVE ENDOSCOPY

M. Delvaux MD,PhD; L.Y. Korman MD;

M. Crespi MD; O. Cass MD; F.M. Zwiebel

GASTROİNTESTİNAL ENDOSKOPİDE VERİ İŞLEMLERİ İÇİN MİNİMAL STANDART TERMİNOLOJİ©

M. Delvaux MD,PhD; L.Y. Korman MD;

M. Crespi MD; O. Cass MD; F.M. Zwiebel

4.1 List of terms for esophago-gastro-duodenoscopy.

The following terms shall be used to describe observations made during examination of the upper gastrointestinal tract. At the end of each section, the term "other" should be displayed and should open to a free text block allowing the description of rare findings, not present as a term in the list.
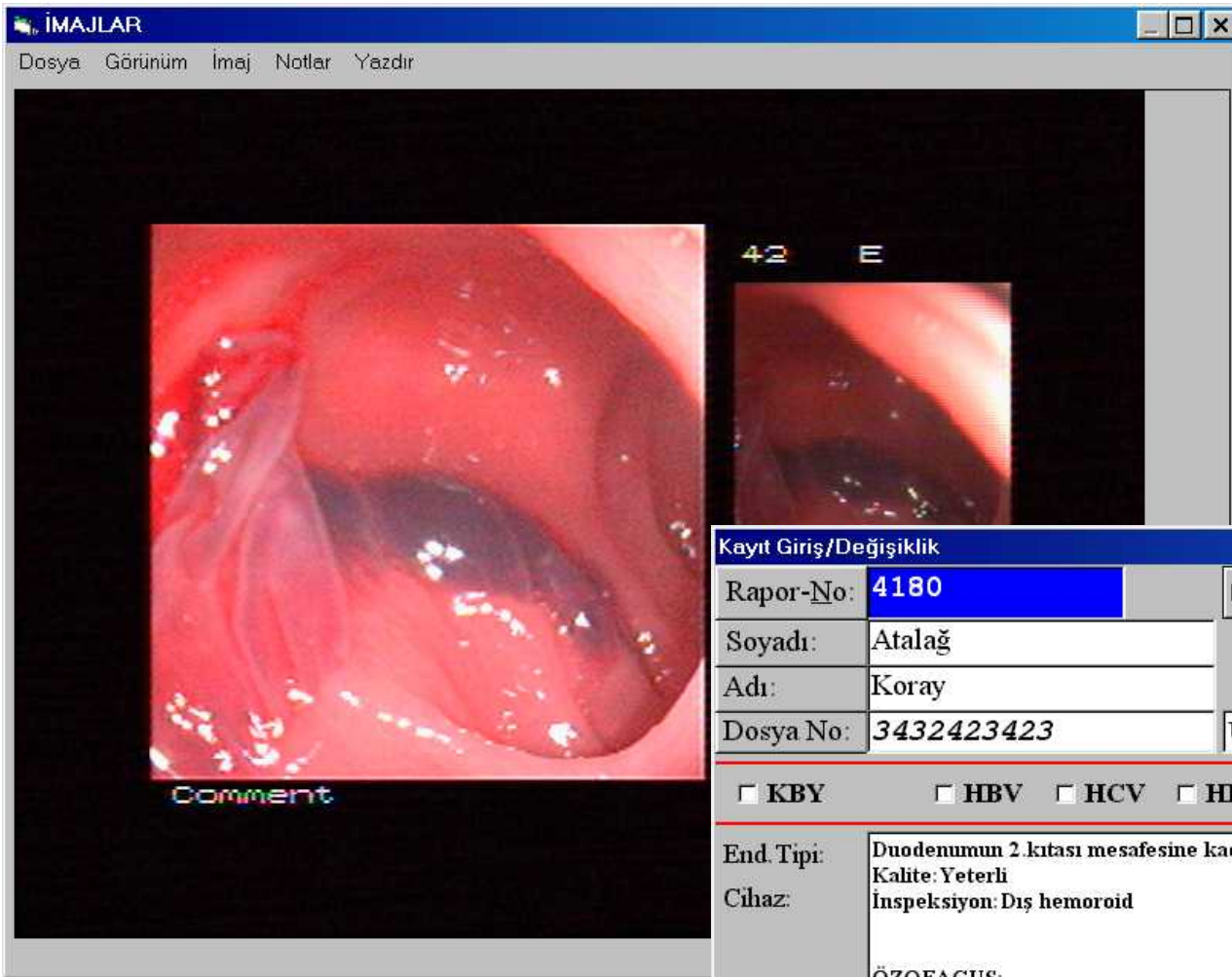
4.1.1 List of terms for the esophagus

The following terms shall be used to describe observations made during examination of the esophagus.

Table 6. Terms for the esophagus.

HEADINGS	TERMS	ATTRIBUTES	ATTRIBUTE VALUES	SITES
Normal	**Normal**	Z line	Distance in cm	cm from incisors
Lumen				
	Dilated			Site(s)
	Stenosis	Appearance	Extrinsic	cm from incisors
			Benign intrinsic	
			Malignant intrinsic	
		Length (cm)		
		Traversed	Yes	
			After dilatation	
			No	
	Extrinsic Impression[4]	Size	Small	Site(s)
			Large	
	Web			Site(s)
	Ring (iincludes Schatzki Ring)			Site(s)
	Hiatus Hernia	Size / Volume	Small	
			Medium	
			Large	
		Site of Z-line	cm from incisors	
		Site of Hiatal Narrowing	cm from incisors	
	Lower Esophageal Sphincter[5]	Tone	Gaping	
			Hypertonic	

Past Experience

- Developing HIS since 1995

- Own company, employee, academician, freelance consultant and contractor

- Problem➜maintenance/evolution of CIS

- Case study: Endoscopy Reporting Application
  - Started 1999 as commercial project
  - Went well initially but then….
  - Became academic and served as PhD prototype
  - I have collated all CR over its usage
  - Motivation for my research (make it future-proof!)

Research Prototype

GST

(Turkish GUI)

Automatic report generation

Why Change?

Extensions & problems with domain knowledge

- Addition of new anatomical sites, new terms, attributes and attribute values for describing findings and interventions.
- Introduction of a whole new section
- Semantic problems eliminated in initial model
- Translation errors were corrected

Extensions & problems with structure

- Identification of a significant structural problem in MST hierarchy
- Extended the hierarchy by first splitting *observation* & *interventions* and then linked *anatomic sites* directly to *terms* describing findings and interventions

A Semantic Problem in MST
Inconsistent use of attribute and attribute values

MST-Table 7 Terms for Stomach		
Evidence of previous surgery	**Type** Anastomosis	Billroth I **anastomosis** Billroth II **anastomosis** Gastroenterostomy Pyloroplasty Anti-reflux surgery Banded gastroplasty
MST-Table 9 Terms for colon		
Evidence of previous surgery	**Type**	Colo-colonic **anastomosis** Ileo-colonic **anastomosis** Colo-anal **anastomosis** Ileo-anal **anastomosis** Colostomy

Extension of MST Structure

Original MST Hierarchy

Endoscopic Observation — Malignant Appearing Stenosis of the Antrum of the Stomach

Class — Lumen

Term — Stenosis

Attribute — Appearance

Value — Malignant Intrinsic

Site — Stomach Antrum

Intervention — Biopsy Cold

Modified MST Hierarchy

Endoscopic Observation — Malignant Appearing Stenosis of the Antrum of the Stomach

Class — Lumen

Term — Stenosis

Site — Stomach Antrum

Attribute — Appearance

Value — Malignant Intrinsic

Endoscopic Intervention — Cold Biopsy at the Antrum of the Stomach

Class — Diagnostic Procedures

Term — Biopsy

Site — Stomach Antrum

Attribute — Method

Value — Cold

Clinical Validation of MST

Data collected in Başkent University Hospital Endoscopy Unit by research prototype (aka GST or old app)

15,638 valid records analyzed (2000-2003)

Overall MST usage:

Findings: 93.98%

Examination characteristics: 85%

Reasons for endoscopy: 2.21%

Diagnostic and therapeutic procedures: 19%

Total MST diagnoses: 42,550 (>1 Dx/exam)
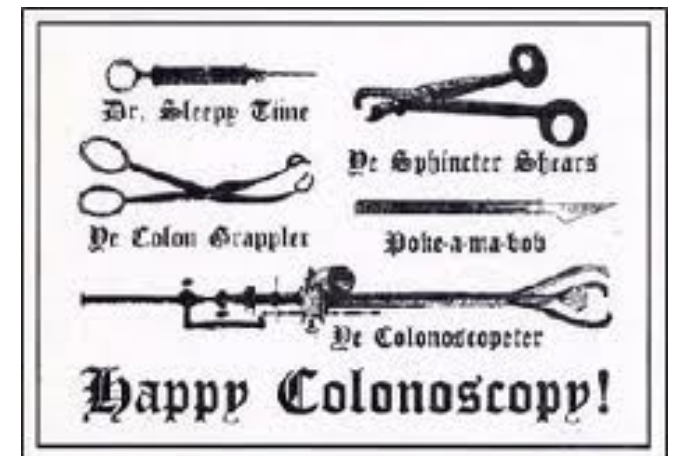
Paper published in *The Turkish Journal of Gastroenterology*

What Have We Learned?

- ✓ MST content is not sufficient alone for software ➡️ additional domain knowledge is needed

- ✓ MST structure is not appropriate for modeling

- ✓ However MST terms are highly accepted & valuable

- ✓ Hardcoding domain knowledge in software code & DB schema is not acceptable – changes ➡️ nightmare

- ✓ Need computationally usable means to capture more knowledge and express consistently

- ✓ Need a powerful modelling and development methodology

- ✓ The new methodology should also address interoperability and multilinguality issues

Maintenance/Evolution of HIS

- Constitutes the majority of development costs
- Degrades overall quality / longevity / satisfaction

Source of problem➜ change in domain related requirements (mostly functional)

How?

- Incomplete / wrong req. at outset
- New / no longer valid requirements

Why?

- Essential + handover
- Volatility of domain concepts & processes

An Important "bottleneck"

- **Cognitive friction /limits to human communication**
- **Unknown requirements**
- **Wrong requirements**
- ➔ **Changing requirements?**

© Thomas Beale
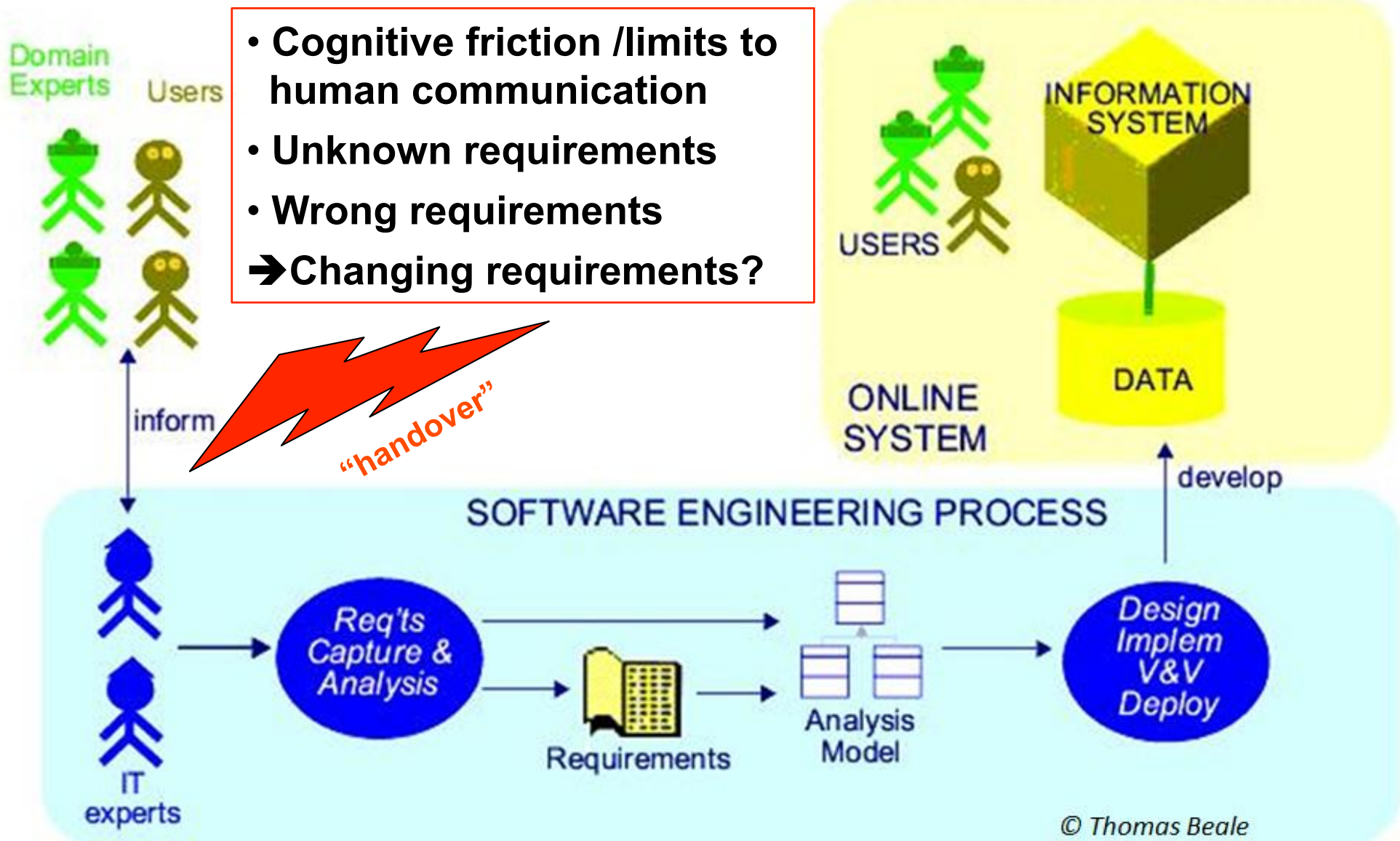
The Modeling Paradigm

Why modeling?

- Sufficient level of abstraction for handling complexities of healthcare and IS
- Ability to generate code + GUI
- More efficient, productive, effective and easily repeatable development process
- Efficient communication tool among clinicians, technical people, managers etc

How to model formally?

- Many alternatives: OO/OR w/ UML, openEHR, HL7v3, openSDE, SGML/XML, OMG IDL & Z, Object Z, B, …

Mainstream Modelling Methods

HL7 v3 and openEHR/13606 standards

HL7 uses RIM + data types + vocabulary domains

- successively refine a general model

- CDA very popular for document structuring

openEHR more holistic and an 'EHR' standard

- Has Reference Models; i.e. data structures, types, EHR structure, security, identifiers etc.

- Additional level of modelling on RM: Archetypes constraint based domain models (OCL + DDL)

- Can be specialised without breaking semantics

- Native query language; very important for DSS

openEHR Multi-Level Modelling

ONTOLOGIES | MODELS | SYSTEMS

TEMPLATES — Presentation/GUI

USER SCREENS
Blood Pressure
Protocol — ☑ Sitting
Free text
OK

Ontology

Terminology

Coding and Classification

ARCHETYPES — Business Logic

REFERENCE MODEL — Persistence

DATABASE
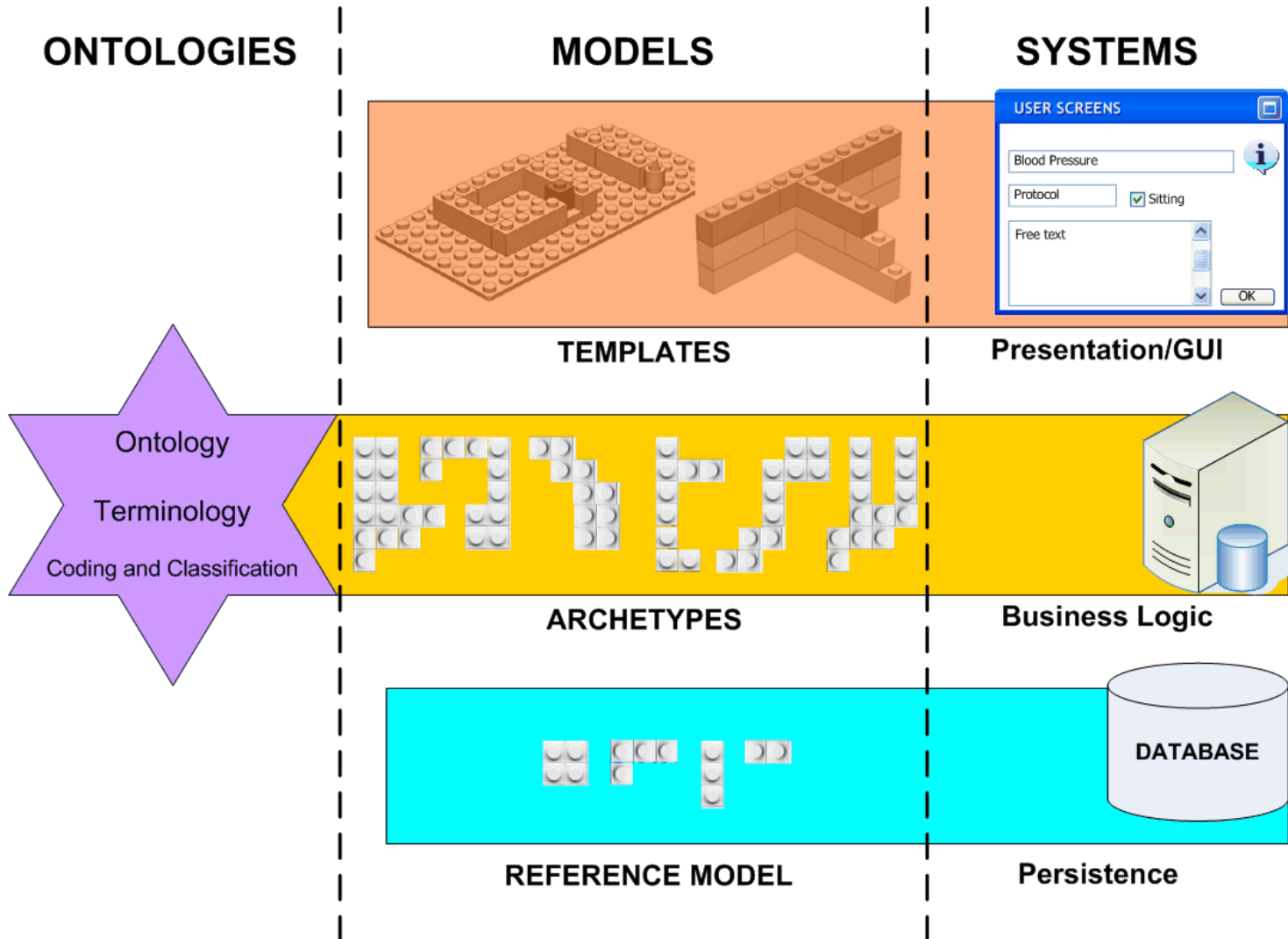
Specialisation of MST Archetypes

ALL BACKWARD COMPATIBLE
➔ *semantic interoperability!*

Findings Stomach (normative)

Published version

Findings Stomach (fixes+extensions)

Intl. Update
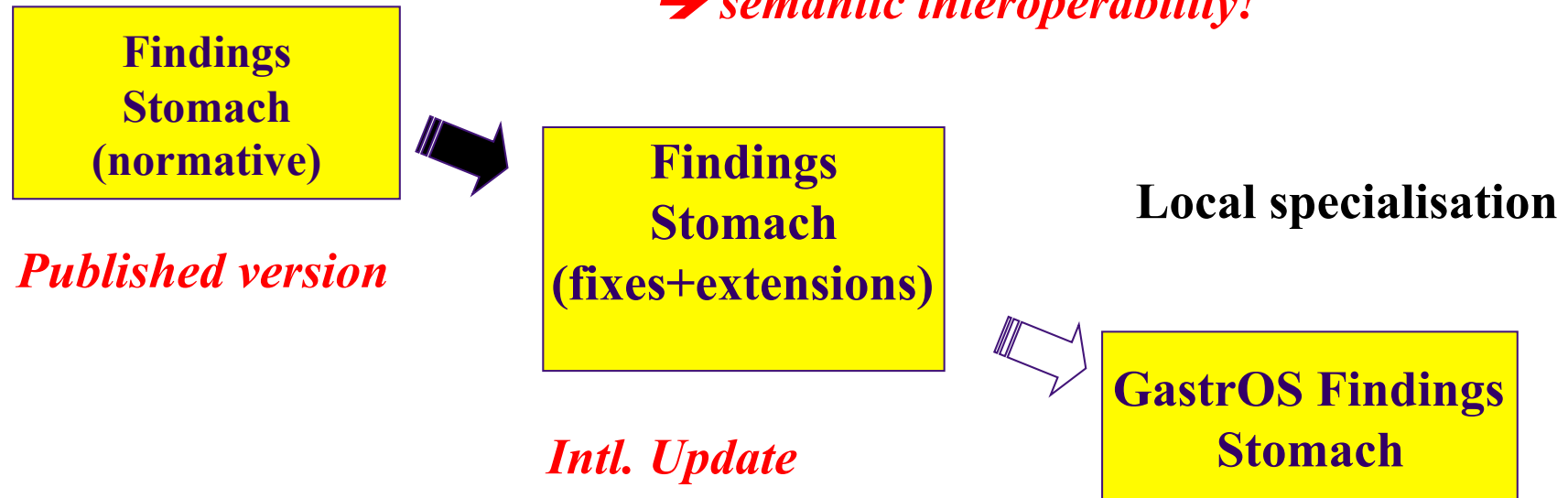
- Rapid Urease
- Rectal exam (free text)
- Etc.

Local specialisation

GastrOS Findings Stomach

Extensions+Translation
+
- *Rectal exam (coded text)*
  - Method
  - Result
  - etc

Modelling: The 'Standard' Endoscopy Report
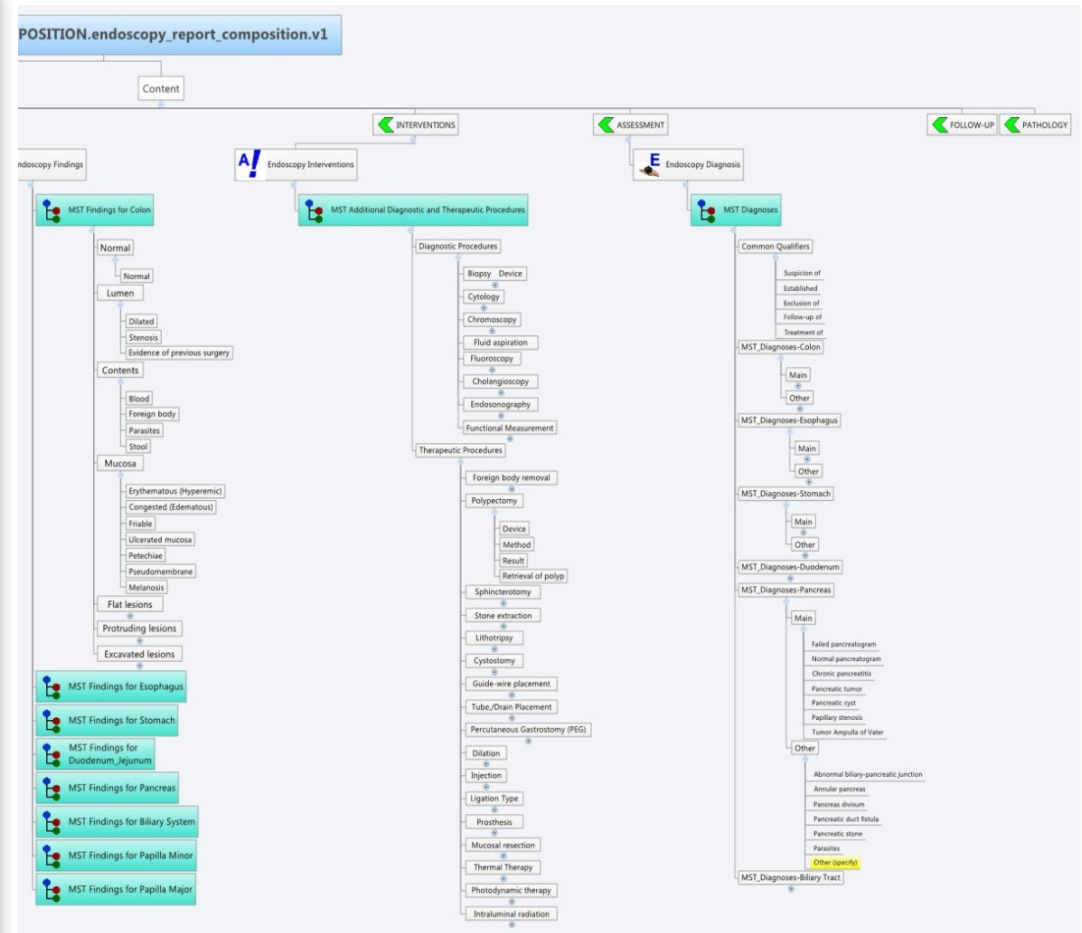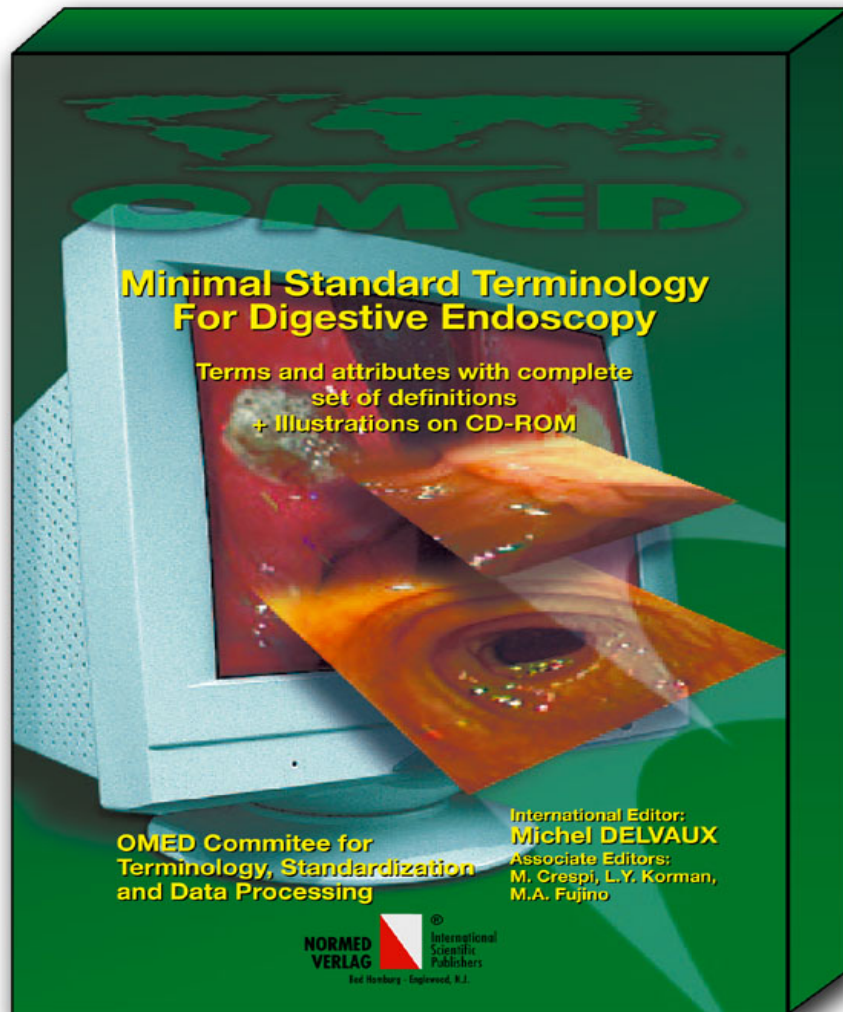
Modeling of MST via openEHR RM & Archetypes

Modeling work started in 2003

- Specifications were quite immature by then
- No tools were present ☹
- Problem w/ non-unicode chars

Decided upon how different parts of MST fall into EHR structure (i.e. Observation, Action, Evaluation …)

Decided upon where to start➔Entry:Observation – MST Colon

Each findings Archetype **>3,000** lines

Alternative MST Models

Possible/Useful MST Hierarchy (Site Oriented by Heading)
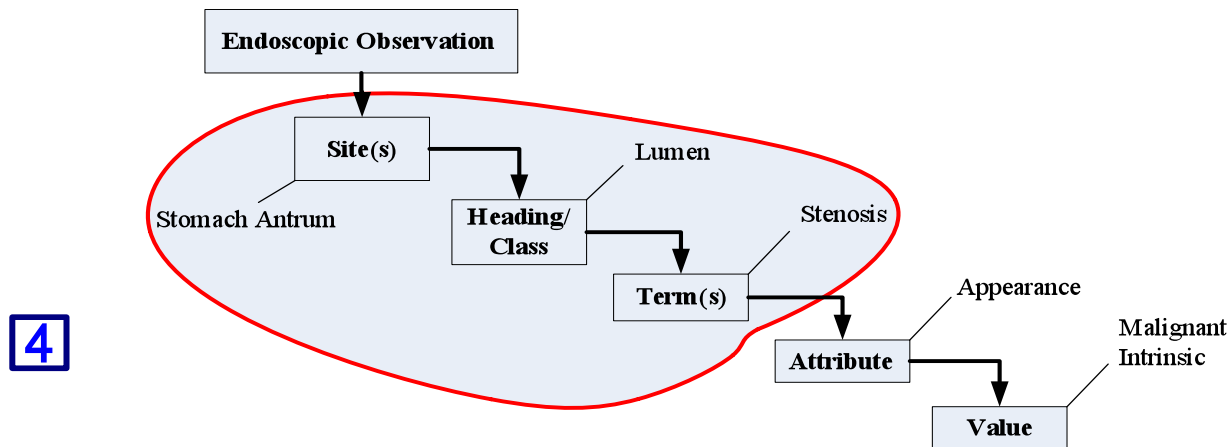
Model 3: "Lumen at stomach antrum has stenosis having appearance of malignant intrinsic"
Model 4: "At stomach antrum lumen has stenosis having appearance of malignant intrinsic"

Current Research Framework

Stage-1:

- SRS based on previous app (GST)
- Develop GastrOS based on openEHR

Stage-2:

- Select Change Requests (CR) from past usage of GST
- Implement in GastrOS + check (repeat for some) in GST
- Determine metrics & measure (presented @ HIC'10)

Stage-3:

- New CR
- Implement changes in both applications
- Measurement

Results & Evaluation

➡ **Look at ease with which GastrOS can be changed/maintained**

Development: GastrOS

- .Net and C# WinForms Application

- openEhrV1 .Net C# Reference Model Library (from Ocean Informatics) + extended it

- MST Archetypes & Templates

- Introduced 'GUI Directives' for GUI generator

- Wrapper + SDE Component= GST functionality

- Destined to be Open Source (depends on Ocean C# Library!)

- Commercial friendly license: plugged into any HIS

GUI Directives

➔ 10 of them; all generic ☺ with some parameters

isOrganiser (g): when this is set then it will be shown as a group which will contain all its children (i.e. as a frame, form etc.). A container object will simply be ignored when this is not set.

isCoreConcept (g): This is an abstract concept; but we can say that Core Concepts are real-world entities which we can talk about their absence (i.e. a clinical finding, a disease but not tumour grade or physical examination). The directive depicts whether a node with all its children (if any) shall be handled and repeated as a whole in an archetype (i.e. makes sense together such as a clinical finding with other attributes defining its nature). When the node and/or its children are selected, its presence information is stored in the corresponding ELEMENT node which records this (i.e. in MST Findings archetypes [Present?] node).

GUI Directives (cont.)

showAs (form|splash, modal|modeless|smart) (g): Determines the behaviour when node's values or children are displayed. The node's label is shown as a reference (i.e. link, button or similar) and the contents will be shown on another modal form - (**form**) or on a pop-up form (**splash**). (**smart**) is a special type of modeless form which closes when loses focus).

- If this is a leaf node (i.e. ELEMENT) then its values will be listed to be selected (depending on the cardinality and occurrences allowed in the archetype single or multiple selection will be possible.
- If this is not a leaf node then the node and all its children will be displayed using regular display options.

break (next|parent|tab) (g): causes the node and rest of the model to appear in the next column but within the same organiser (**next**); in the next column within a separate organiser which is semantically the continuation of current one (**parent**); in a new tab within the same form (**tab**).

A Look at GastrOS GUI

Ocean Template Designer - 2.6

File   View   Tools   Help

GastrOS Repository

[MST_v2-UpperGIS.oet]

Archetypes   MST

Template Properties
Endoscopy Report
  context
  PATIENT
  VISIT
  CLINICAL
  EXAMINATION
    Endoscopy Examination
      data
        Any event
          data
            MST ExamCharSlot
              MST Examination Characteristics | GastrOS
            MST ReasonsSlot
              MST Reasons for Endoscopy
            MST ComplicationsSlot
              T MST Complications
            T Description
      protocol
  FINDINGS
    Endoscopy Findings
      data
        Any event
          data
            MST Findings
              MST Findings for Esophagus | GastrOS   Δ [0..*] to [0..1],
              MST Findings for Stomach | GastrOS   Δ [0..*] to [0..1],
              MST Findings for Duodenum   Δ [0..*] to [0..1],
              MST Findings for Colon| GastrOS
              MST Findings for Papilla Major
              MST Findings for Papilla Minor
              MST Findings for Pancreas
              MST Findings for Biliary System
            T Description
  ASSESSMENT
    Endoscopy Diagnosis
      data
        MST Diagnoses Slot
          MST Diagnoses | GastrOS
        T Description
  INTERVENTIONS
    Endoscopy Interventions
      description
        Slot for MST Interventions
          MST Additional Diagnostic and Therapeutic Procedures | GastrOS
        T Description
  FOLLOWUP
  PATHOLOGY

structure
cluster
  MST Additional Diagnostic and Therapeutic Procedures   (v1)
  MST Additional Diagnostic and Therapeutic Procedures | Gast
  MST Anatomic Sites   (v1)
  MST Anatomic Sites!   (v1)
  MST Diagnoses   (v1)
  MST Diagnoses | GastrOS   (v1)
  MST Examination Characteristics   (v1)
  MST Examination Characteristics | GastrOS   (v1)
  MST Findings for Biliary System   (v1)
  MST Findings for Colon   (v1)
  MST Findings for Colon| GastrOS   (v1)
  MST Findings for Duodenum   (v1)
  MST Findings for Esophagus   (v1)
  MST Findings for Esophagus | GastrOS   (v1)
  MST Findings for Pancreas   (v1)
  MST Findings for Papilla Major   (v1)
  MST Findings for Papilla Minor   (v1)
  MST Findings for Stomach   (v1)
  MST Findings for Stomach | GastrOS   (v1)
  MST Reasons for Endoscopy   (v1)
element
  MST Complications   (v1)

Template Node Properties

Constraints
  Occurrences   optional, repeating - no limit [0..*]
DataSubject
  DataSubjects   not set
Information
  Annotation   formAspects(width=750,height=380)
  Conditional
  Description   Generic archetype which contains slots for M
Name
  Name
Technical
  Archetype node   True
  Class   Observation
  Path   [openEHR-EHR-OBSERVATION.endoscopy_e

Name
The name for this instance of the node as a string

Ocean Template Designer - 2.5 Alpha

File   View   Tools   Help

[MST_v2.oet]

Template Properties
Endoscopy Report
  context
  PATIENT
  VISIT
  CLINICAL
  EXAMINATION
    Endoscopy Examination
      data
        Any event
          data
            MST ExamCh
              MST Exa
            MST Reasons
              MST Rea
            MST Complic
              T MST Con
            Description
      protocol
  FINDINGS
    Endoscopy Findings
      data
        Any event
          data
            MST Findings
              MST Find
            MST Findings
              MST Find
                NORM
                LUME
                  Di
                  St
                  Ev
                CONT
                MUCO
                FLAT
                PROT
                EXCAV
            MST Findings
            Description

Maintainability Assessment

- Maintenance vs. maintainability

- ISO/IEC 9216 and 25000 Software Quality std.

- External Quality➔Maintainability characteristic; Changeability Subcharacteristic

- Two metrics: (mainly look at maintenance tasks)

  - Change cycle efficiency (CCE)➔time from initial request to resolution of the problem

  - Modification complexity (MC)➔sum of time spent on each change per size of software change divided by total number of changes

- 10 CR – real ones from GST usage

- SVN + JIRA tools for documentation + measure

Stage-2 Results

No	Type	Description	Time (min)		Changed LOC	
			GST	GastrOS	GST	GastrOS
1	Fix	MST: Anatomic site (colon): add site **anal canal**	3	10	1	83
2	Ext	MST: Findings (stomach): add term **rapid urease test** | add attribute **result** | add attribute values **positive** and **negative**	30	5	45	37
3	Fix	MST: Findings (stomach and colon>protruding lesions>tumor/mass): add attribute: **Diameter** | change attribute value **diameter in mm. ➔ in mm.**	50	13	92	2
4	Ext	MST: Findings (colon>protruding lesions>hemorrhoids): add new attribute **type** and add attribute values **Internal** and **External**	30	7	46	23
5	Fix	MST: Therapeutic procedures (Sphincterotomy>Precut): add attribute value **No**	6	5	1	4
6	Ext	MST: Therapeutic procedures (Thermal therapy>Device): add attribute value **Heat-probe**	11	5	1	4
7	Ext	MST: Diagnoses (stomach): add main diagnoses **Antral superficial, Pangastritis, Atrophic, Alkaline reflux** and **Somatitis**	6	8	4	20
8	Ext	MST: Diagnoses: Add free text description for each organ	50	10	60	20
9	New	Other: Split **lower gastrointestinal examination** type into **colonoscopy** and **rectoscopy**. Bind both types to **Findings for colon**	30	10	6	2
10	New	Other: Localise MST Findings for Stomach form to English	1116	70	722	499
		TOTAL	**1332**	**143**	**978**	**694**

Metric	GST	GastrOS
CCE	133.20	14.30
MC	0.14	0.02

CCE➔ 9 times less effort overall to modify GastrOS
MC➔ the changes were on average 7 times less complex

Bottomline with openEHR Modelling

Identified separation of domain knowledge from software code and DB schema as the ultimate area of improvement in this study to alleviate problems and tackle challenges in CIS development

Solution: openEHR Multi-level Modeling

Archetype modeling of domain knowledge:

- Manage complexity & changeability of domain concepts
- Computationally usable in HIS development
- Extensible during maintenance & change management
- Provide means for interoperability & multilinguality

True separation of information vs knowledge by Multi-level modeling

Development based on small & stable RM

All models map onto standardized EHR architecture

Uses external terminologies & other ontologies

Next Steps with Modelling

- Next generation MST will be published as openEHR clinical models
(collab. With MST editor Dr. Louis Korman)

- openEHR CKM will be pivotal – this IS how you make terminology work!

- Maximal vs. Minimum Data Set??

  - Archetypes as max data set

  - Minimum: something which may grow!

  - MST Archetypes represent the 'minimum' structured content which fits nicely into 'maximal' scheme

Questions?