Department of Veterans Affairs
Veteran Health Administration
Knowledge Based Systems

Informatics Architecture Support Services

Analysis Normal Form and Patient Safety

Walter Sujansky
Sujansky & Associates, LLC

Veterans Health Administration, Office of Informatics & Analytics and Health Informatics Informatics Architecture Support Services Contract VA701-16-C-0039 CLIN 0012, 5.4.1A. Bi Weekly Web Based Workshops

June 12, 2018

www.BookZurman.com

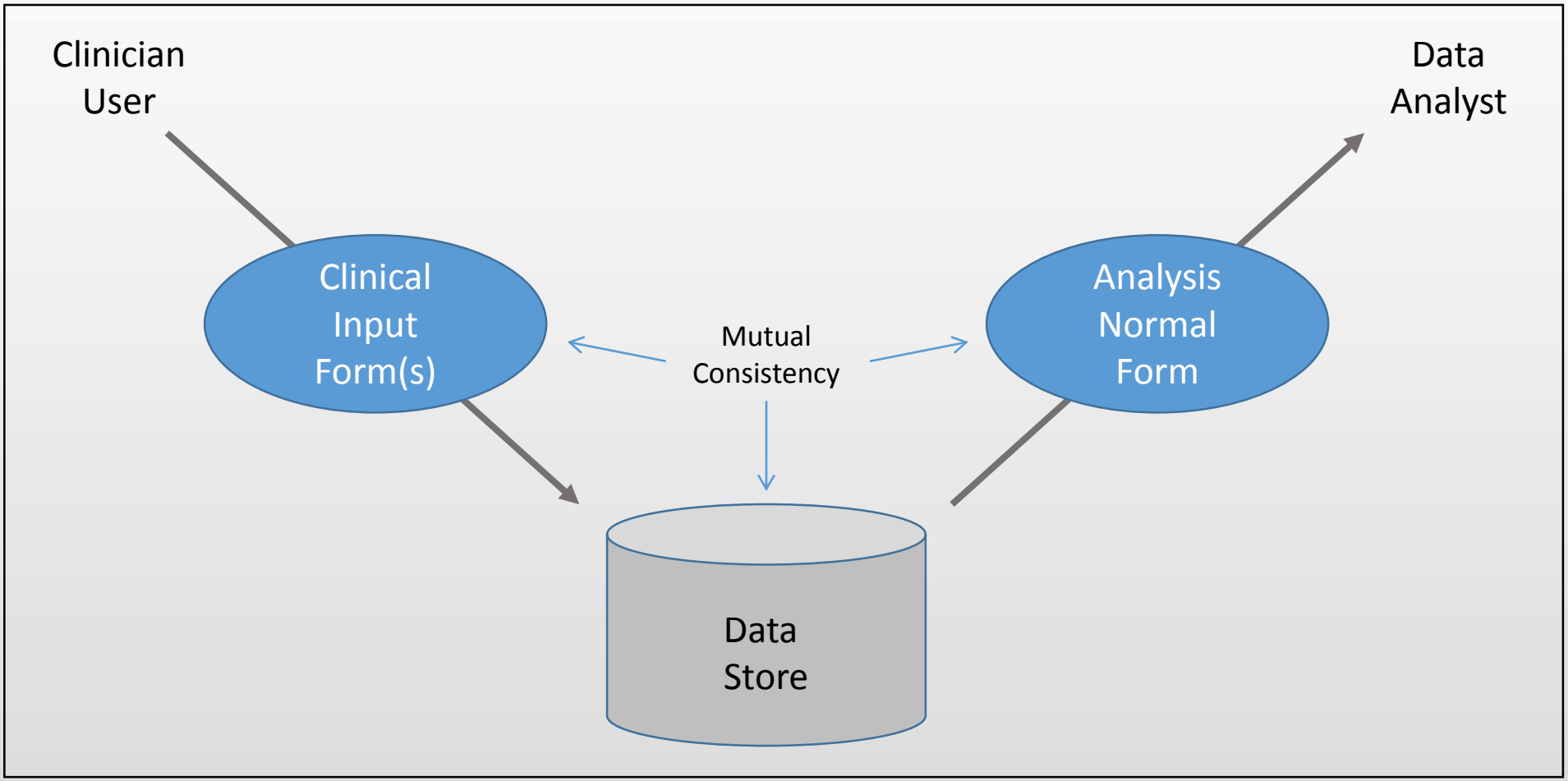
Outline

- Modeling Clinical Statements
  - Clinical Input Forms
  - Analysis Normal Form
- Example: Pressure ulcer
  - Representation
  - Querying
- Example: Family history of breast cancer
  - Representation
  - Querying
- Representational heterogeneity as threat to patient safety
  - Examples from FHIR profiles and C-CDA templates

Modeling a Clinical Statement

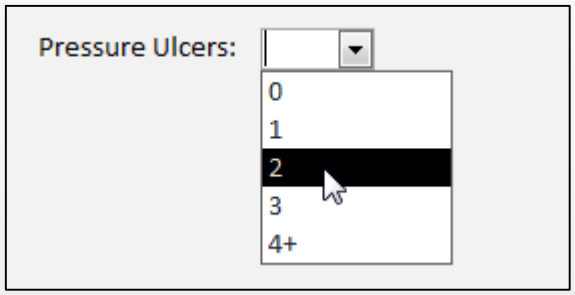
- Clinical Input Form(s)
  - Familiar to clinicians and convenient for *entering* clinical statements into EHRs
  - Multiple iso-semantic CIFs may exist for the same type of clinical statement, to support various preferences or contexts
- Analysis Normal Form
  - Normalized and semantically precise form for *retrieving and analyzing* clinical statements stored in EHRs
  - A unique canonical ANF should exist for each distinct type of clinical statement, regardless of the manner of data entry
- <u>Both forms are required to derive maximum benefit from EHRs</u>

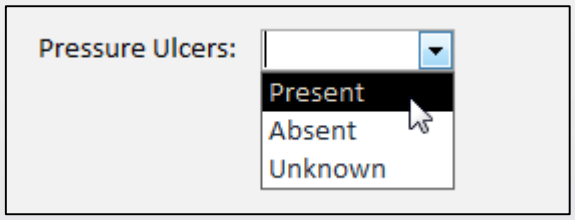
Modeling a Clinical Statement

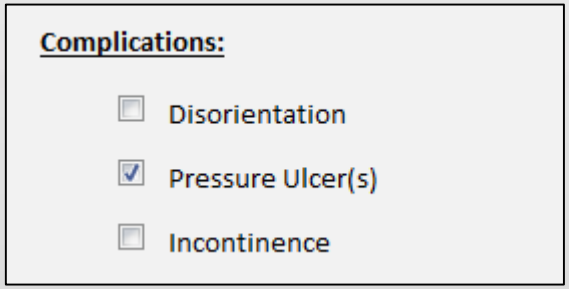


Example: Pressure Ulcer

Desired Data-Entry Method







Clinical Input Form

Topic: Pressure Ulcer

Value: {0, 1, 2, 3, 4+} [Required]

(Size, Severity, location, etc. [Optional])

Topic: Pressure Ulcer

Value: {Present, Absent, Unknown} [Required]

(Size, Severity, location, etc. [Optional])

Topic: Pressure Ulcer

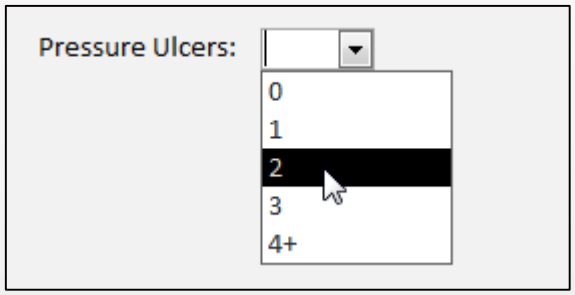
(Size, Severity, location, etc. [Optional])

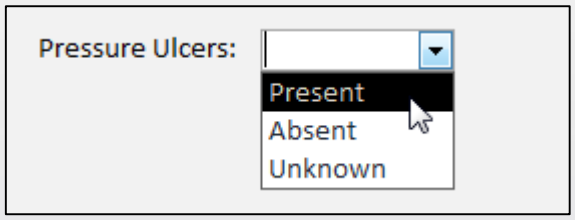
Example: Pressure Ulcer

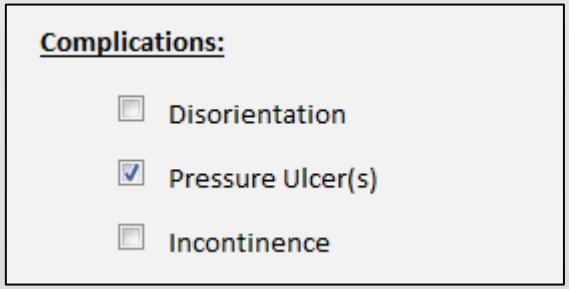
- Problems of CIFs for Data Analysis
  - Multiplicity of representations complicates queries
    - If EXISTS Observation WHERE Topic = PressureUlcers AND
      (Value > 0 OR
      Value = “Present” OR
      NOT EXISTS Value OR …)

Example: Pressure Ulcer

Desired Data-Entry Method







Clinical Input Form

Topic: Pressure Ulcer

Value: {0, 1, 2, 3, 4+} [Required]

(Size, Severity, location, etc. [Optional])

Topic: Pressure Ulcer

Value: {Present, Absent, Unknown} [Required]

(Size, Severity, location, etc. [Optional])

Topic: Pressure Ulcer

(Size, Severity, location, etc. [Optional])

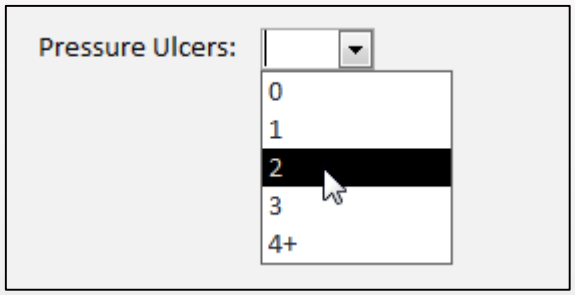
Example: Pressure Ulcer

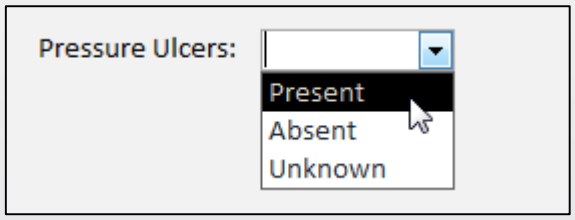
- Problems of CIFs for Data Analysis
  - Multiplicity of representations complicates queries
    - If EXISTS Observation WHERE Topic = PressureUlcers AND
      (Value > 0 OR
      Value = “Present” OR
      NOT EXISTS Value OR …)
  - Multiplicity of representations risks retrieval errors
    - If EXISTS Observation WHERE Topic = PressureUlcers AND
      Value = “Present”

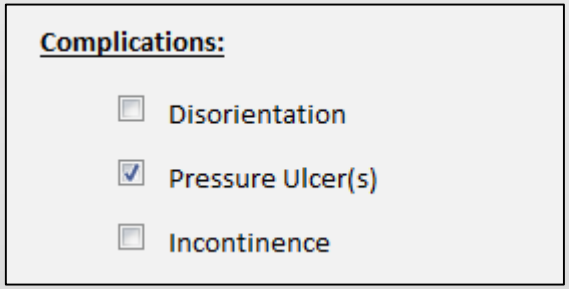
      $\Rightarrow$ Will miss instances where Value = 2 or where no Value is provided

Example: Pressure Ulcer

Desired Data-Entry Method







Clinical Input Form

Topic: Pressure Ulcer

Value: {0, 1, 2, 3, 4+} [Required]

(Size, Severity, location, etc. [Optional])

Topic: Pressure Ulcer

Value: {Present, Absent, Unknown} [Required]

(Size, Severity, location, etc. [Optional])

Topic: Pressure Ulcer

(Size, Severity, location, etc. [Optional])

Example: Pressure Ulcer

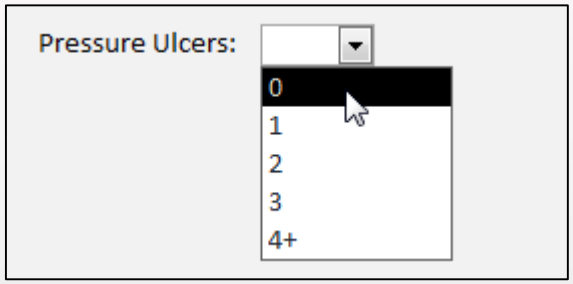
- Problems of CIFs for Data Analysis
  - Multiplicity of representations complicates queries
    - If EXISTS Observation WHERE Topic = PressureUlcers AND
      (Value > 0 OR
      Value = “Present” OR
      NOT EXISTS Value OR …)
  - Multiplicity of representations risks retrieval errors
    - If EXISTS Observation WHERE Topic = PressureUlcers AND
      Value = “Present”

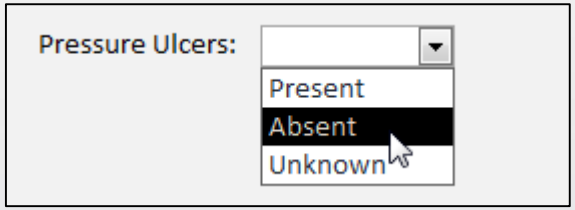
      ⇒ Will miss instances where Value = 2 or where no Value is provided
    - If EXISTS Observation WHERE Topic = PressureUlcers

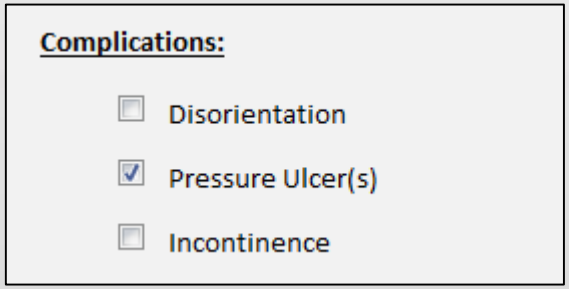
      ⇒ Will erroneously retrieve instances where Value = 0 or Value = Absent!

Example: Pressure Ulcer

Desired Data-Entry Method







Clinical Input Form

Topic: Pressure Ulcer

Value: {0, 1, 2, 3, 4+} [Required]

(Size, Severity, location, etc. [Optional])

Topic: Pressure Ulcer

Value: {Present, Absent, Unknown} [Required]

(Size, Severity, location, etc. [Optional])

Topic: Pressure Ulcer

(Size, Severity, location, etc. [Optional])

Example: Pressure Ulcer

- Problems of CIFs for Data Analysis (cont'd)
  - Query semantics may be poorly defined (e.g., negation)
    - "Find patients who have no pressure ulcers"
      - If NOT Exists Observation WHERE Topic = PressureUlcers AND Value > 0… (closed world assumption)

        vs.
      - If EXISTS Observation WHERE Topic = PressureUlcers AND Value = 0… (open world assumption)

The ANF Approach (Example)

Clinical Input Forms

Analysis Normal Form

Topic: Pressure Ulcer

Value: {0, 1, 2, 3, 4+} [Required]

(Size, Severity, etc. [Optional])

Topic: Pressure Ulcer

Value: {Present, Absent, Unknown} [Required]

(Size, Severity, etc. [Optional])

Topic: Pressure Ulcer

(Value, Size, Severity, etc. [Optional])

Topic: Pressure Ulcer

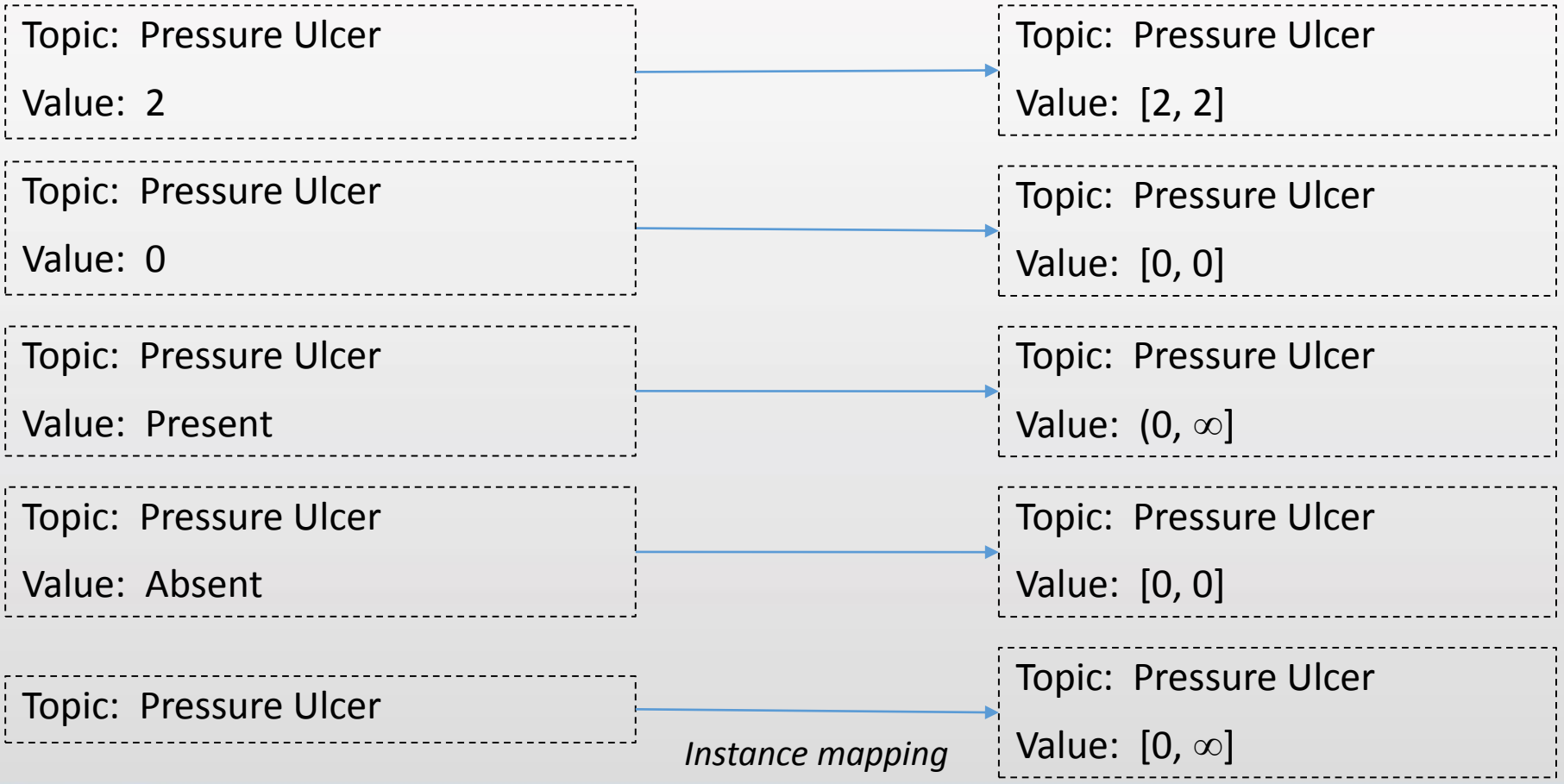
Value: [value-low, value-high] [Required]

(Size, Severity, etc. [Optional])

Mapping to a single normalized model

This form is used to retrieve patient data for CDS and analysis

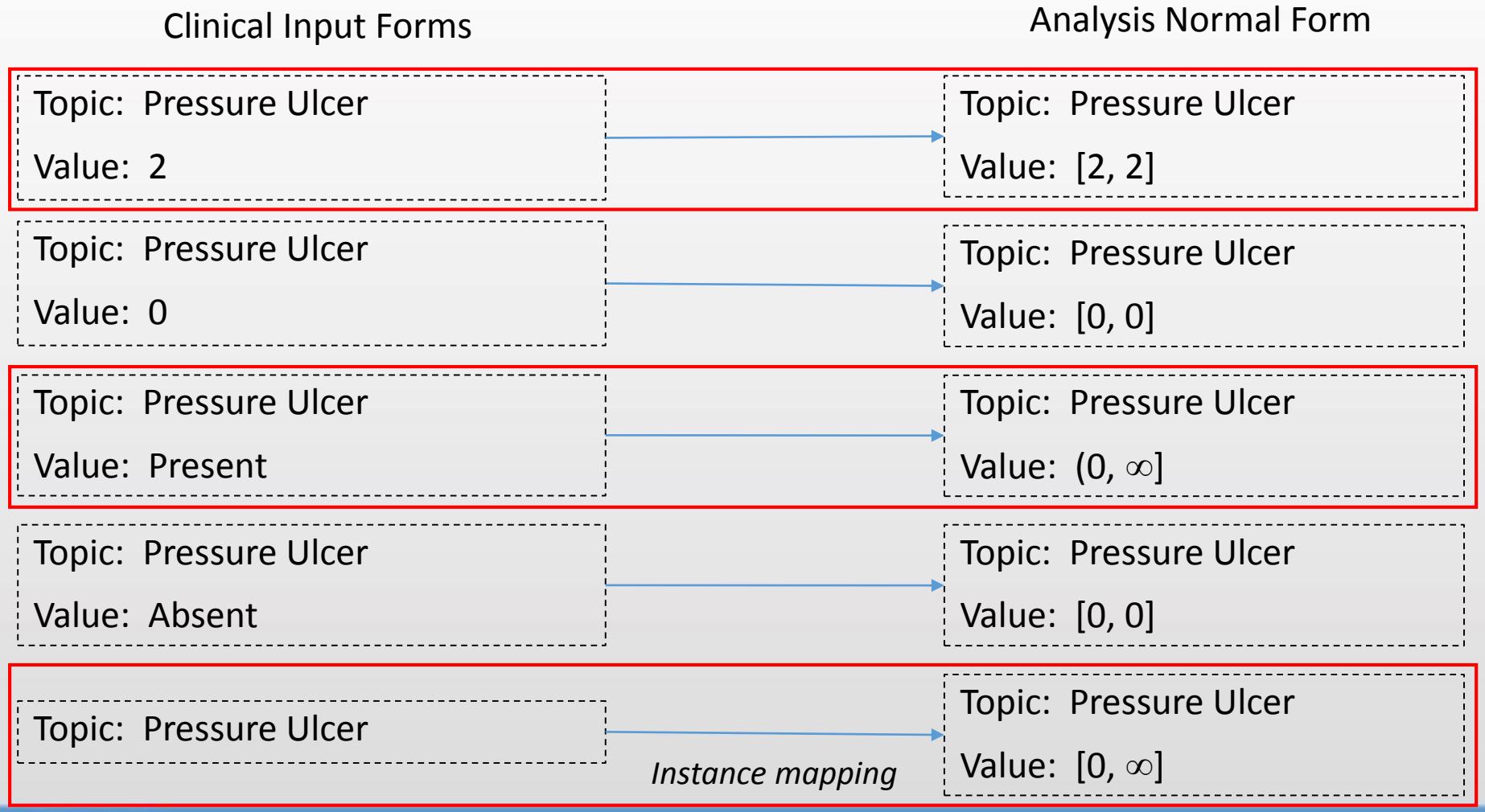
The ANF Approach (Example)



Querying Using the ANF

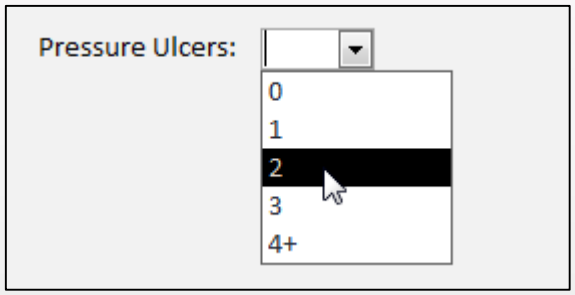
- Find Patients with pressure ulcers
  - If EXISTS Observation WHERE Topic = PressureUlcers AND IsWithin(Value, (0, ∞]) = TRUE)

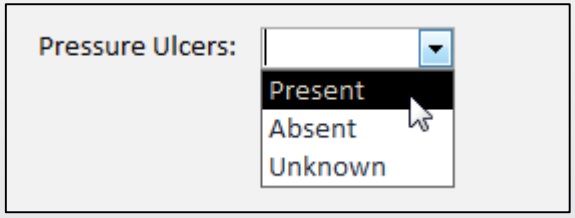
The ANF Approach (Example)

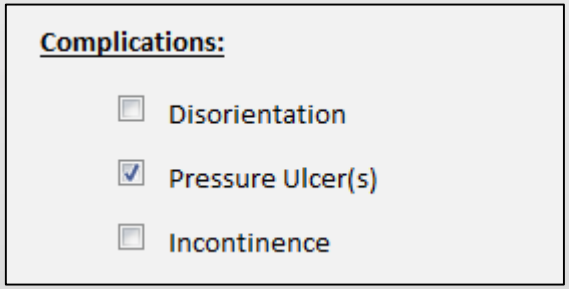


Example: Modeling a Clinical Statement

Desired Data-Entry Method







Clinical Input Form

Topic: Pressure Ulcer

Value: {0, 1, 2, 3, 4+} [Required]

(Size, Severity, etc. [Optional])

Topic: Pressure Ulcer

Value: {Present, Absent, Unknown} [Required]

(Size, Severity, etc. [Optional])

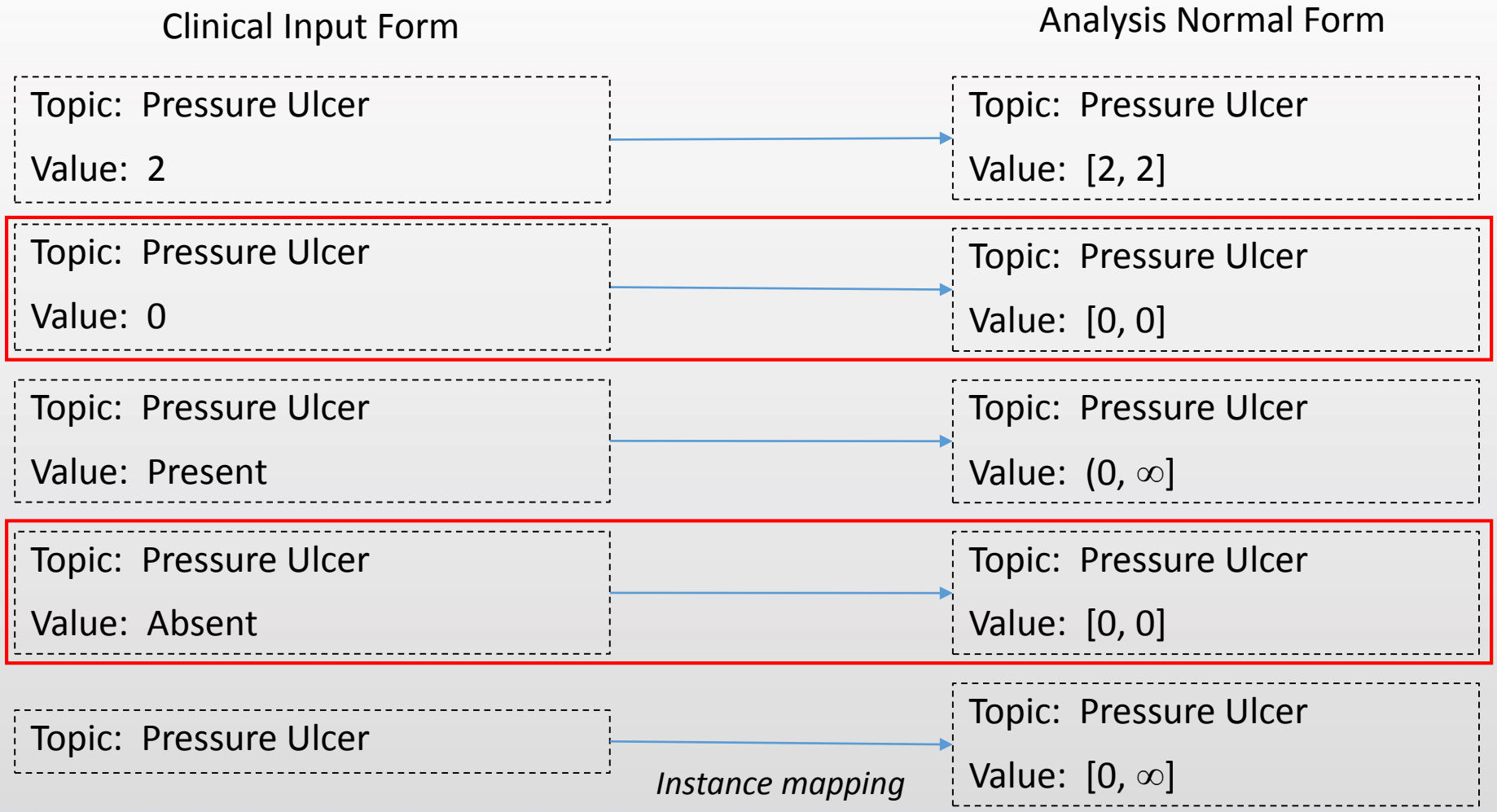
Topic: Pressure Ulcer

(Value, Size, Severity, etc. [Optional])

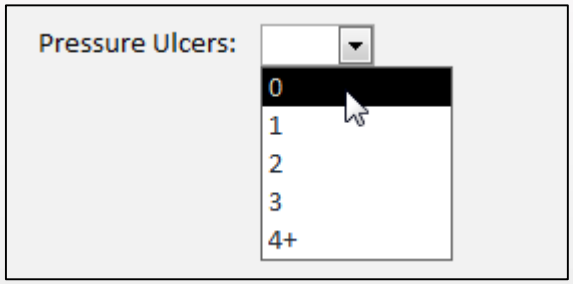
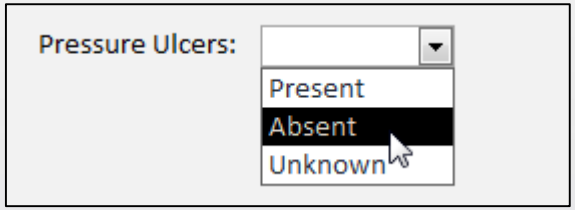
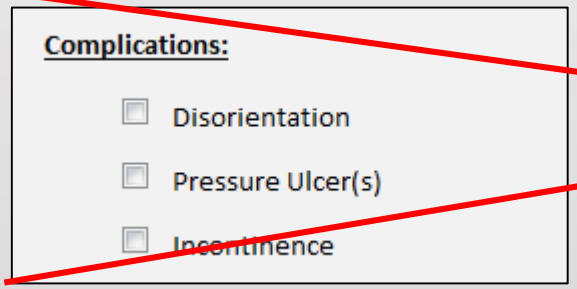
Querying Using the ANF

- Find Patients with pressure ulcers
  - If EXISTS Observation WHERE Topic = PressureUlcers AND IsWithin(Value, (0, ∞]) = TRUE)
- Find Patients without pressure ulcers
  - If EXISTS Observation WHERE Topic = PressureUlcers AND IsWithin(Value, [0, 0]) = TRUE)

The ANF Approach (Example)



Example: Modeling a Clinical Statement

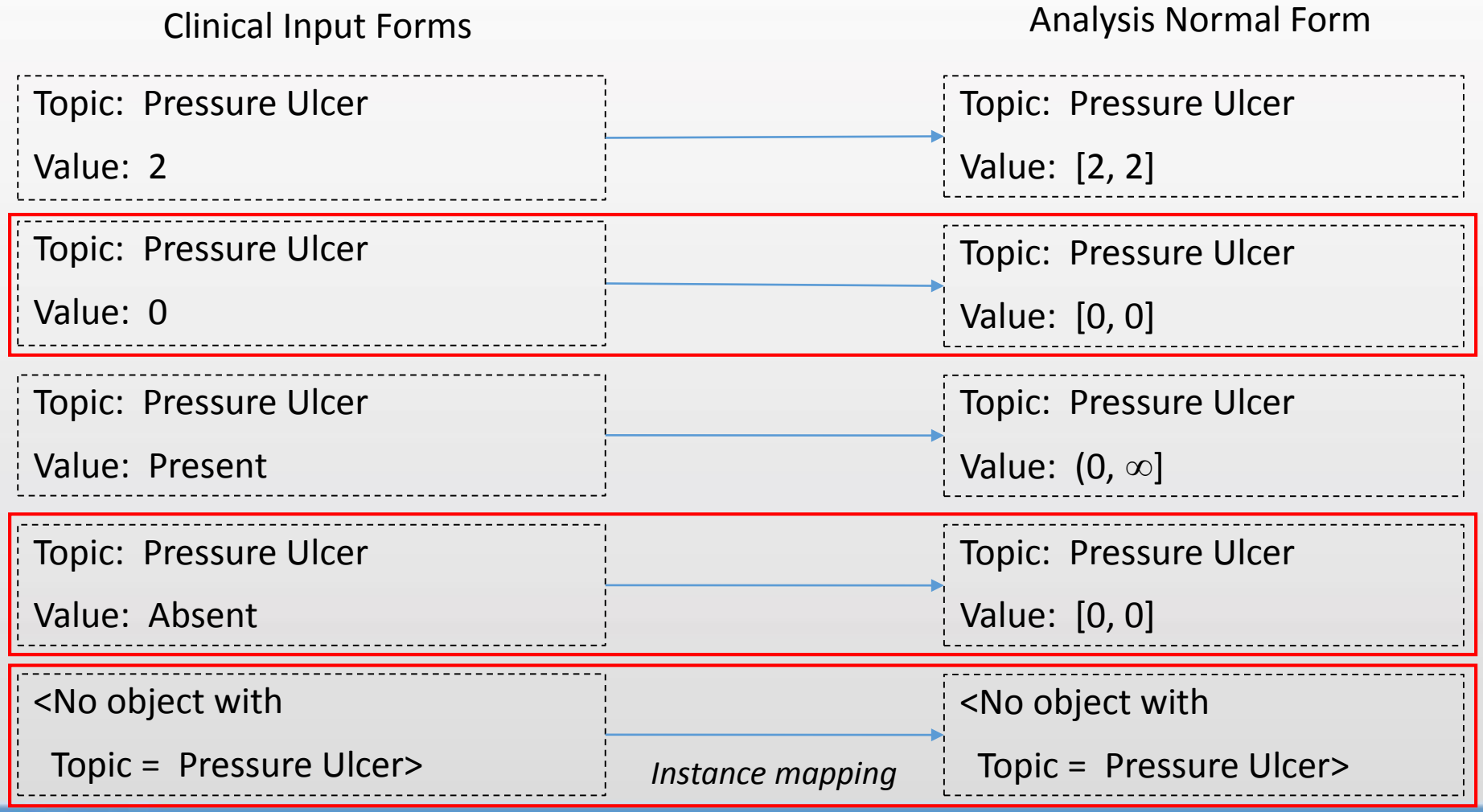
Desired Data-Entry Method	Clinical Input Form
	Topic: Pressure Ulcer Value: {0, 1, 2, 3, 4+} [Required] (Size, Severity, etc. [Optional])
	Topic: Pressure Ulcer Value: {Present, Absent, Unknown} [Required] (Size, Severity, etc. [Optional])
	Topic: Pressure Ulcer (Value, Size, Severity, etc. [Optional])

Querying Using the ANF

- Find Patients with pressure ulcers
  - If EXISTS Observation WHERE Topic = PressureUlcers AND IsWithin(Value, (0, ∞]) = TRUE)
- Find Patients without pressure ulcers
  - If EXISTS Observation WHERE Topic = PressureUlcers AND IsWithin(Value, [0, 0]) = TRUE)

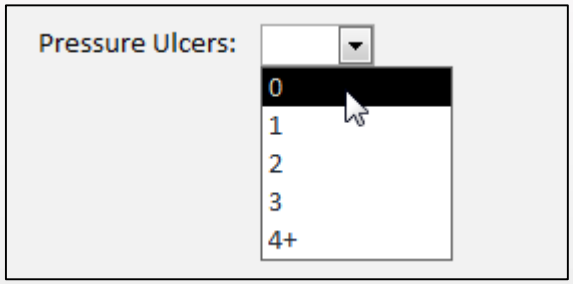
    OR
  - If NOT EXISTS Observation WHERE Topic = PressureUlcers AND IsWithin(Value, (0, ∞]) = TRUE)

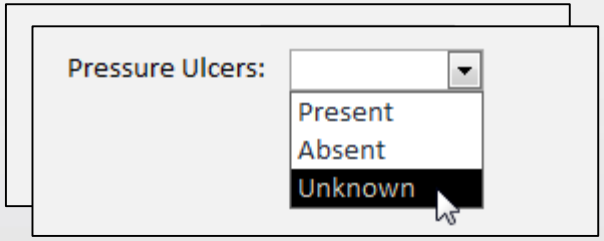
The ANF Approach (Example)

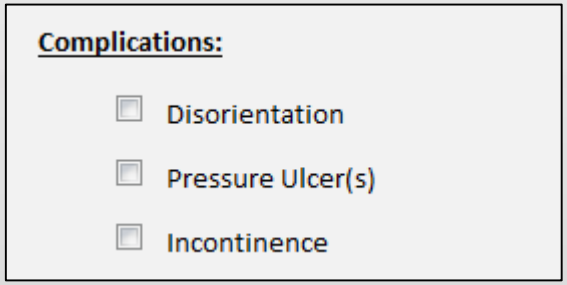


Example: Modeling a Clinical Statement

Desired Data-Entry Method







Clinical Input Form

Topic: Pressure Ulcer

Value: {0, 1, 2, 3, 4+} [Required]

(Size, Severity, etc. [Optional])

Topic: Pressure Ulcer

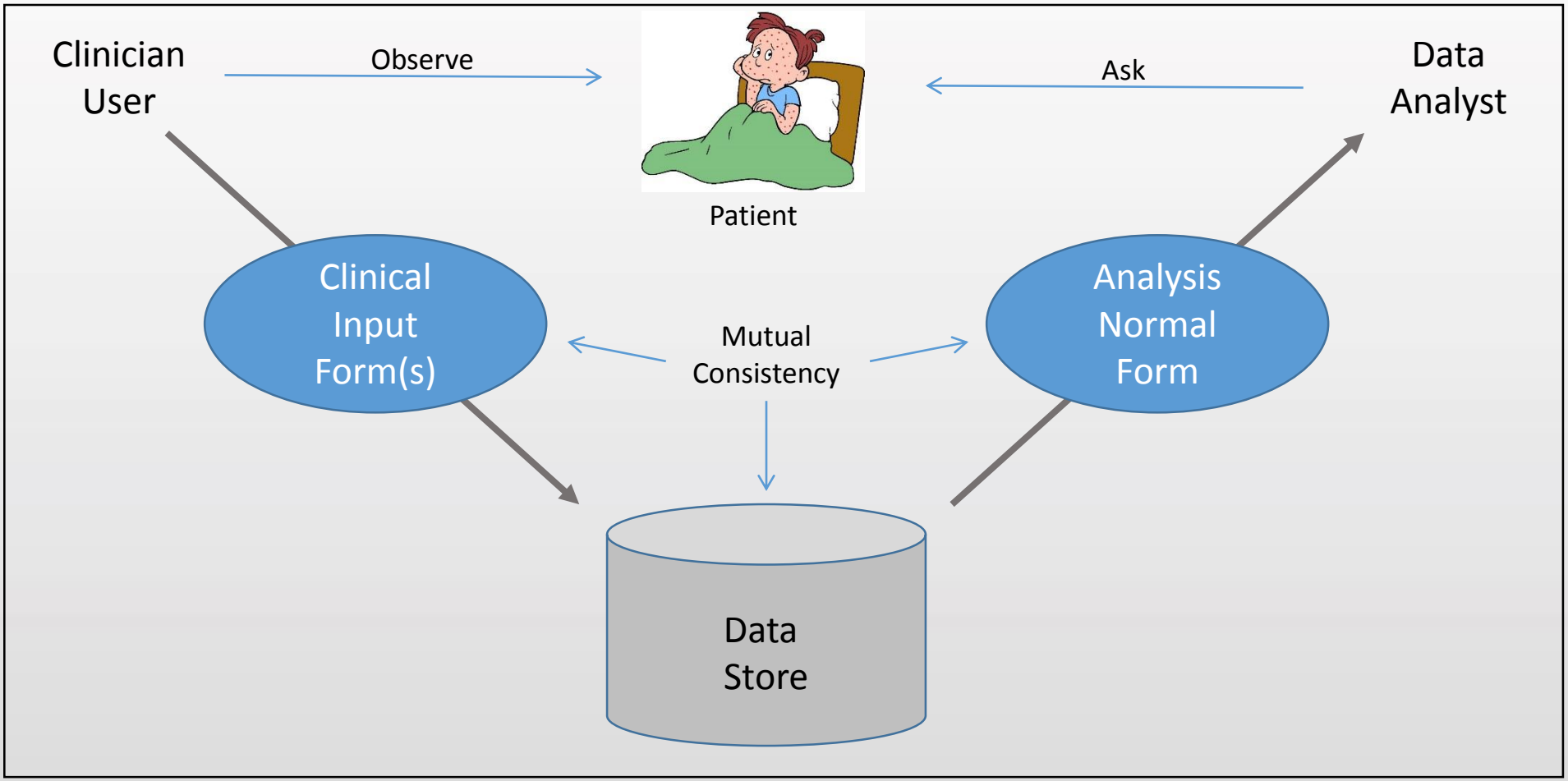
Value: {Present, Absent, Unknown} [Required]

(Size, Severity, etc. [Optional])

Topic: Pressure Ulcer

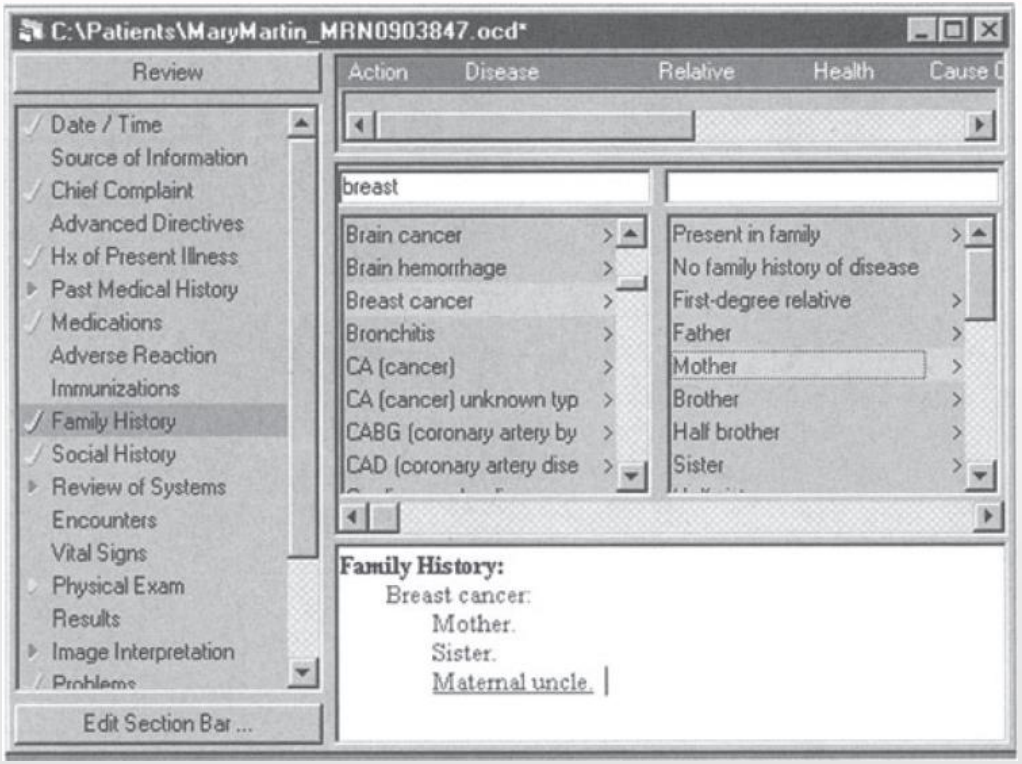
(Value, Size, Severity, etc. [Optional])

Modeling a Clinical Statement



Example 2: Family History

Desired Data-Entry Method



Clinical Input Form

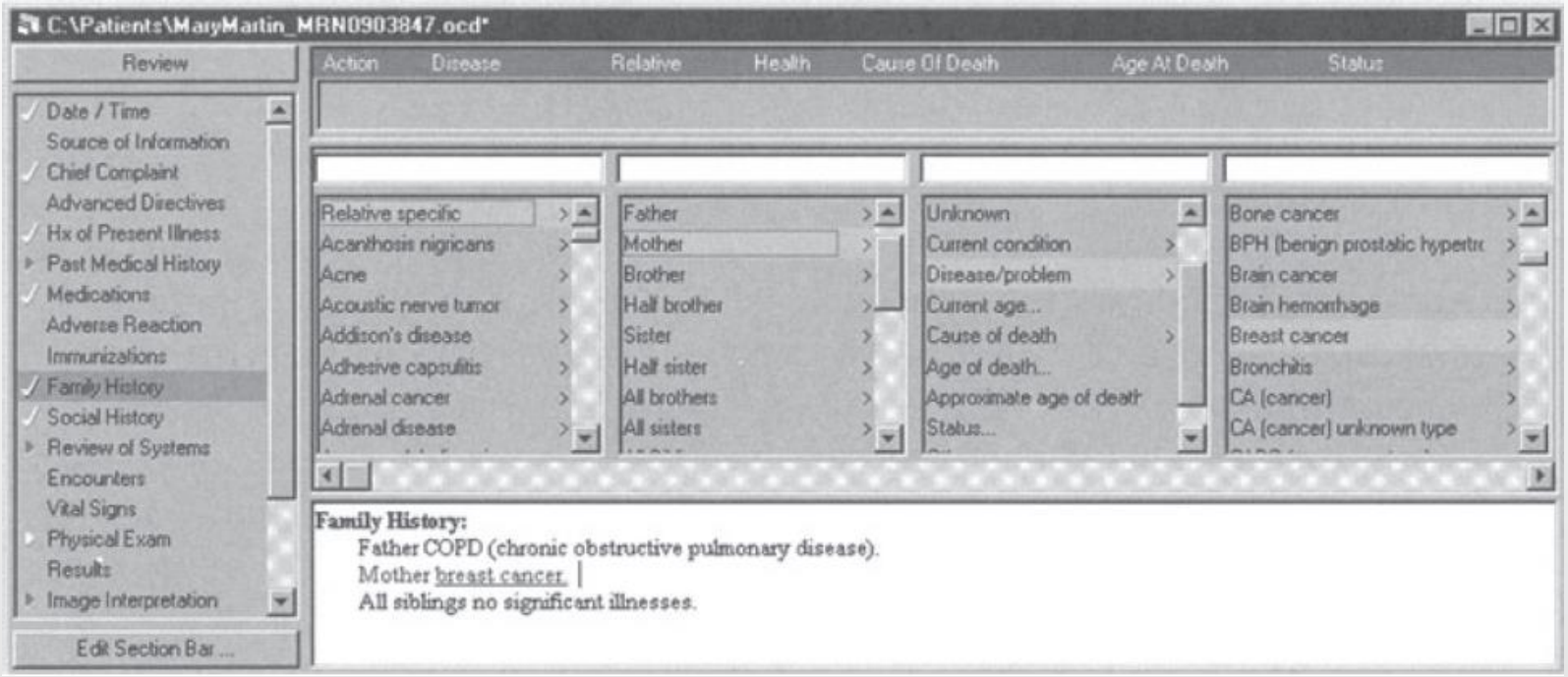
Topic: Family History of Breast Cancer

Value: {Present, Absent, Unknown} [Required]

Family Member: {Father, Mother, …} [Optional]

Example 2: Family History

Desired Data-Entry Method



Clinical Input Form

Topic: Mother's Family History

Disease: {Br. Cancer, M.I., … [Optional]

Age of Death: {<integer>} [Optional]

The ANF Approach (Example)

Clinical Input Forms

Topic: Family History of Breast Cancer

Value: {Present, Absent, Unknown} [Required]

Family Member: {Father, Mother, …} [Optional]

Topic: Mother's Family History

Disease: {Br. Cancer, M.I., … [Optional]

Age of Death: {<integer>} [Optional]

Analysis Normal Form

Topic: Family History

Family Member:
{Some family member,
Father, Mother, etc. }
[Required 1..1]

Family Dx: [Optional 0..*]

Dx Topic: {Br. Cancer, M.I., …}
[Required]

Dx Value: { [low, high] }
[Required]

Age of Death: {<integer>}
[Optional]

Querying Using the ANF

- Find Patients with family history of breast cancer
  - If EXISTS Observation WHERE Topic = FamilyHistory AND
    FamilyMember Is-A Some-Family-Member AND
    (EXISTS FamilyMember.FamilyDx
    WHERE DxTopic = Breast Cancer AND
    IsWithin(DxValue, (0, ∞]) = TRUE))
- Find Patients without maternal history of breast cancer
  - If NOT EXISTS Observation WHERE Topic = FamilyHistory AND
    FamilyMember = Mother AND
    (EXISTS FamilyMember.FamilyDx
    WHERE DxTopic = Breast Cancer AND
    IsWithin(DxValue, (0, ∞]) = TRUE))
  - If EXISTS Observation WHERE Topic = FamilyHistory AND FamilyMember = Mother AND
    (EXISTS FamilyMember.FamilyDx
    WHERE DxTopic = Breast Cancer AND
    IsWithin(DxValue, [0, 0]) = TRUE))

Representational heterogeneity as threat to patient safety

- Examples from FHIR profiles and C-CDA templates

FHIR US Core – Negation Issues

- Multiple ways to negate the same clinical statement

Name	Flags	Card.	Type	Description & Constraints
Condition	I		DomainResource	Detailed information about conditions, problems or diagnoses *+ If condition is abated, then clinicalStatus must be either inactive, resolved, or remission* *+ Condition.clinicalStatus SHALL be present if verificationStatus is not entered-in-error* Elements defined in Ancestors: id, meta, implicitRules, language, text, contained, extension, modifierExtension
identifier	Σ	0..*	Identifier	External Ids for this condition
clinicalStatus	?! Σ I	0..1	code	active | recurrence | inactive | remission | resolved Condition Clinical Status Codes (Required)
verificationStatus	?! Σ I	0..1	code	provisional | differential | confirmed | refuted | entered-in-error | unknown ConditionVerificationStatus (Required)
category		0..*	CodeableConcept	problem-list-item | encounter-diagnosis Condition Category Codes (Example)
severity		0..1	CodeableConcept	Subjective severity of condition Condition/Diagnosis Severity (Preferred)
code	Σ	0..1	CodeableConcept	Identification of the condition, problem or diagnosis Condition/Problem/Diagnosis Codes (Example)
bodySite	Σ	0..*	CodeableConcept	Anatomical location, if relevant SNOMED CT Body Structures (Example)
subject	Σ	1..1	Reference(Patient | Group)	Who has the condition?
context	Σ	0..1	Reference(Encounter | EpisodeOfCare)	Encounter or episode when condition first asserted
onset[x]	Σ	0..1		Estimated or actual date, date-time, or age

e.g., "No cardiovascular symptom"

FHIR US Core – Terminology Issues

- Overlapping Coding Systems/Value Sets
  - Condition resource profile allows patient problems to be represented using codes from either the SNOMED-CT “Clinical Finding” hierarchy or the SNOMED-CT “Situation-With-Explicit-Context” hierarchy (i.e., both hierarchies are included in the specified value set).
    - Finding: “Dizziness (finding)” [SCTID: 404640003]
    - Situation-with-Explicit-Context: “Dizziness present (situation)” [SCTID: 162260006]

FHIR US Core – Terminology Issues

- Optional Coding Systems/Value Sets
  - *Condition* resource profile specifies that implementers must use codes from a designated "Problem" value set when populating the "code" data element, but this terminology constraint is designated as "extensible".
    - FHIR specification: "The code populating this data element SHALL be from the specified value [SNOMED-CT] set if any of the codes within the value set can apply to the concept being communicated. If the value set does not cover the concept (based on human review), alternate codes (or text) may be included instead."
    - ICD-10: "Nodular lymphocyte predominant Hodgkin lymphoma, lymph nodes of inguinal region and lower limb" [ICD-10 C81.05]
    - SNOMED-CT: "Hodgkin lymphoma, nodular lymphocyte predominance" [SCTID 70600005])

Consolidated CDA – Unnecessary Complexity

- statusCode values of problem in *Problem Section* template

```
<section>  <!-- Problem Section template -->
  ...lines omitted...
  <act classCode="ACT" moodCode="EVN">  <!-- Problem Concern Act  template -->
      ...lines omitted...
      <statusCode code="active"/>  <!-- Means this is of ongoing concern to the provider -->
      <effectiveTime>
          <low value="200704141515-0800"/>  <!-- Concern was documented on Apr 14, 2007 -->
      </effectiveTime>
      <entryRelationship typeCode="SUBJ">
        <observation classCode="OBS" moodCode="EVN">  <!--  Problem Observation  template-->
          ...lines omitted...
          <code code="64572001" displayName="Condition" codeSystemName="SNOMED-CT" codeSystem="2.16.840.1.113883.6.96"/>
          <statusCode code="completed"/>  <!-- This statusCode reflects the status of the observation itself -->
          <effectiveTime>
            <low value="20070414"/>  <!-- The low value reflects the date of onset -->
                                     <!-- Absence of <high> element means the condition is not resolved -->
          </effectiveTime>
          <value xsi:type="CD" code="29857009" codeSystem="2.16.840.1.113883.6.96" displayName="Chest pain"/>
        </observation>
      </entryRelationship>
  </act>
<section>
```

Problem Section
- Problem Concern Act 1
  - Problem Observation 1
  - Problem Observation 2
  - …
- Problem Concern Act 2
  - Problem Observation 3
  - …

Is the chest pain currently active or resolved?

Consolidated CDA – Unnecessary Complexity

- statusCode values of problem in *Problem Section* template

```
<section>  <!-- Problem template -->
  ...lines omitted...
  <act classCode="ACT" moodCode="EVN">    <!-- Problem Concern Act  template -->
      lines omitted
      <statusCode code="active"/>  <!-- Means this is of ongoing concern to the provider -->
      <effectiveTime>
          <low value="200704141515-0800"/>   <!-- Concern was documented on Apr 14, 2007 -->
      </effectiveTime>
      <entryRelationship typeCode="SUBJ">
        <observation classCode="OBS" moodCode="EVN">  <!--  Problem Observation  template-->
          ...lines omitted...
          <code code="64572001" displayName="Condition" codeSystemName="SNOMED-CT" codeSystem="2.16.840.1.113883.6.96"/>
          <statusCode code="completed"/>  <!-- This statusCode reflects the status of the observation itself -->
          <effectiveTime>
            <low value="20070414"/>   <!-- The low value reflects the date of onset -->
            <high value="20070415"/>   <!-- Presence of <high> element means the condition is resolved -->
          </effectiveTime>
          <value xsi:type="CD" code="29857009" codeSystem="2.16.840.1.113883.6.96" displayName="Chest pain"/>
        </observation>
      </entryRelationship>
  </act>
<section>
```

Is the chest pain currently active or resolved?

Consolidated CDA – Unnecessary Complexity

- statusCode values of problem in *Problem Section* template

```
<section>  <!-- Problem template -->
  ...lines omitted...
  <act classCode="ACT" moodCode="EVN">    <!-- Problem Concern Act  template -->
      ...lines omitted...
      <statusCode code="active"/>  <!-- Means this is of ongoing concern to the provider -->
      <effectiveTime>
          <low value="200704141515-0800"/>   <!-- Concern was documented on Apr 14, 2007 -->
      </effectiveTime>
      <entryRelationship typeCode="SUBJ">
        <observation classCode="OBS" moodCode="EVN">  <!--  Problem Observation  template-->
          ...lines omitted...
          <code code="64572001" displayName="Condition" codeSystemName="SNOMED-CT" codeSystem="2.16.840.1.113883.6.96"/>
          <statusCode code="completed"/>  <!-- This statusCode reflects the status of the observation itself -->
          <effectiveTime>
            <low value="20070414"/>   <!-- The low value reflects the date of onset -->
            <high nullFlavor="UNK"/>   <!-- Presence of <high> element means the condition is resolved -->
          </effectiveTime>
          <value xsi:type="CD" code="29857009" codeSystem="2.16.840.1.113883.6.96" displayName="Chest pain"/>
        </observation>
      </entryRelationship>
  </act>
<section>
```

Is the chest pain currently active or resolved?

Consolidated CDA – Potentially Missing "Required" Values

- Example: *Medication Activity* template

```
<substanceAdministration classCode="SBADM" moodCode="EVN">   <!-- ** Medication Activity template ** -->
  ...lines omitted...
  <effectiveTime nullFlavor="NP"/>
  <doseQuantity nullFlavor="NP"/>
  <consumable>
    <manufacturedProduct classCode="MANU">   <!-- ** Medication Information template ** -->
      ...lines omitted...
      <manufacturedMaterial>
        <code code="1154379" displayName="Atenolol Tablet" codeSystem="2.16.840.1.113883.6.88" codeSystemName="RxNorm"/>
      </manufacturedMaterial>
    </manufacturedProduct>
  </consumable>
</substanceAdministration>
```

Consolidated CDA – Potentially Missing "Required" Values

- Other required fields that may have "nullFlavor" substitutes

Template Name	Data Element	DataType	Description
Vital Sign Observation	value	PQ	Value and unit of measure for the vital sign
Immunization Activity	effectiveTime	TS	Date/time at which immunization was given
Problem Observation	effectiveTime	TS	Date/time of problem onset and resolution
Medication Activity	doseQuantity	PQ	Dose of medication prescribed/administered
Medication Activity	effectiveTime	TS	Date/time when medication started and stopped

Consolidated CDA – Negation Issues

- Underspecification (redundancy) of negation methods in *Problem Observation* template

Representation 1:

```
<observation classCode="OBS" moodCode="EVN" negationInd="true"> <!-- ** Problem Observation template ** -->
  ...lines omitted...
  <effectiveTime>
    <low value="20130703"/>
    <high value="20130703"/>
  </effectiveTime>
  <value xsi:type="CD" code="88610006" codeSystem="2.16.840.1.113883.6.96" displayName="Heart murmur (finding)"/>
</observation>
```

Representation 2:

```
<observation classCode="OBS" moodCode="EVN">   <!-- ** Problem Observation template ** -->
  ...lines omitted...
  <effectiveTime>
    <low value="20130703"/>
    <high value="20130703"/>
  </effectiveTime>
  <value xsi:type="CD" code="301131000" codeSystem="2.16.840.1.113883.6.96" displayName="Heart murmur absent (situation)"/>
</observation>
```

Consolidated CDA – Terminology Issues

- Underspecification of Post-Coordinated Expressions in Problem Observations

```
<observation classCode="OBS" moodCode="EVN">   <!-- ** Problem Observation template ** -->
 ...lines omitted...
 <effectiveTime>
  <low value="20130703"/>
  <high value="20130814"/>
 </effectiveTime>
 <value xsi:type="CD" code="233604007" codeSystem="2.16.840.1.113883.6.96" displayName="Pneumonia">
  <qualifier>
   <code code="363698007" codeSystem="2.16.840.1.113883.6.96" displayName="Finding site"/>
   <code code="41224006" codeSystem="2.16.840.1.113883.6.96" displayName="Left lower lobe of lung"/>
  </qualifier>
 </value>
</observation>
```

The observation/value and all the qualifiers together (often referred to as a post-coordinated expression) make up one concept. Qualifiers constrain the meaning of the primary code, and cannot negate it or change its meaning. Qualifiers can only be used according to well-defined rules of post-coordination and only if the underlying code system defines the use of such qualifiers or if there is a third code system that specifies how other code systems may be combined.

Thank you

Questions?