Multi-Stage CDA Validation

IHIC

May 2009

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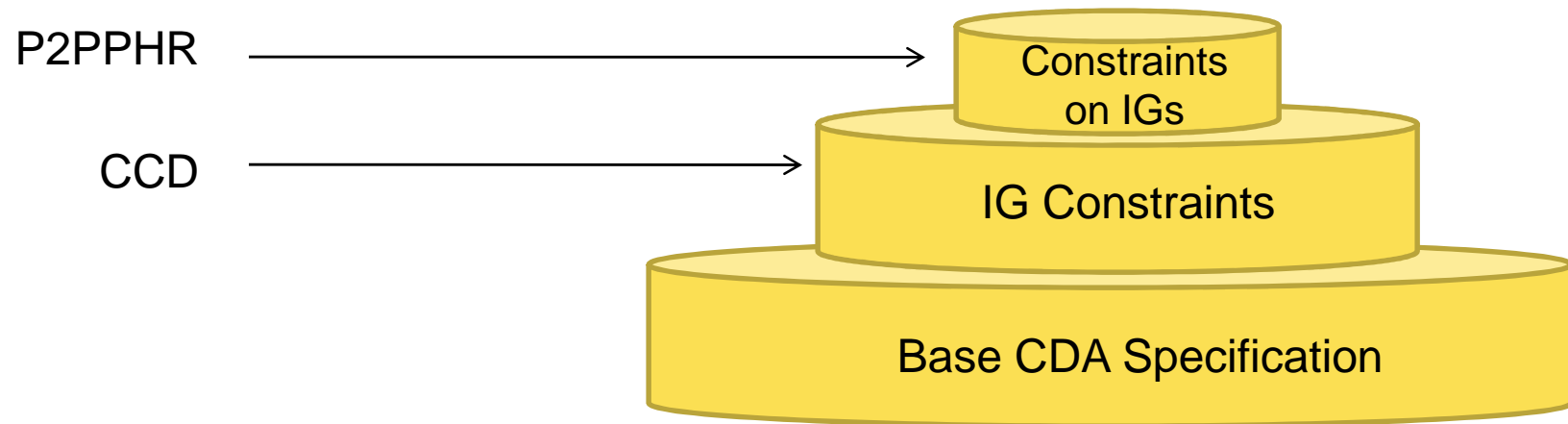www.alschulerassociates.com

CDA Conformance

- The base CDA specification defines the rules that apply to all CDA documents.
  - Example: A unique ClinicalDocument/code is required for all CDA documents.
- Implementation guides (IGs) constrain the base specification:
  - Example: CCD constrains ClinicalDocument/code to a single LOINC value: 34133-9, "Summarization of Episode Note".
  - Templates are used to group and identify a set of constraints
- IGs can also constrain other IGs.
- IGs typically do not restate inherited constraints.

Layered Constraints

Examples

P2PPHR $\longrightarrow$

CCD $\longrightarrow$

Constraints on IGs

IG Constraints

Base CDA Specification

Validation Options

- Create comprehensive schemas for each IG
  - Must validate both base CDA and IG specific constraints
  - Fails when documents dynamically assert templates from multiple IGs
- Mimic the layered nature of constraints
  - Use the base CDA schema as is
  - Provide additional schemas for IG constraints.

SDWG's Validation Approach

- All instances are valid CDA
  - maintain and validate multiple document types using single generic schema (CDA.xsd).

- Schematron/XPath statements
  - validate constraints specific to IG
  - validate constraints that can't be specified in W3C schema language
    - Example: A code element must contain either code and codeSystem attributes or a nullFlavor attribute.

What is Schematron?

- It is an XML schema language
  - Others are W3C XML Schema, RelaxNG, etc.
  - It is an ISO standard
  - See http://www.schematron.com for the specification

Reading Schematron

- <u>Schema</u> is a collection of <u>pattern</u>s.
- <u>Pattern</u>s contain one or more <u>rule</u>s with a <u>context</u>.
- <u>Rule</u>s <u>assert</u> that a <u>test</u> has passed.
- Failures may issue <u>diagnostic</u>s
- Now you can read the Schema

Schematron Example

Schema is a collection of patterns.

```
<schema xmlns="http://www.ascc.net/xml/schematron">
    <title>Sample Schematron schema</title>
    <ns prefix="cda" uri="urn:hl7 org:v3" />
```

Patterns contain one or more rules with a context.

```
<pattern name='ClinicalDocument' see='Sample.htm#ClinicalDocument'>
    <p>This schema applies to CDA Release 2.0 documents.</p>
    <rule id='cda root' context='/*'>
        <assert diagnostics="CNF 1" test='self::cda:ClinicalDocument'>
            The root of a Care Record Summary must be a ClinicalDocument
            element from  the <emph>urn:hl7 org v3</emph> namespace.
        </assert>
    </rule>
</pattern>
<diagnostics>
 <diagnostic id='CNF 1'>
    Ensure the appropriate namespace declaration exists.
    The root element must be ClinicalDocument.
 </diagnostic>
</diagnostics>
</schema>
```

Rules assert that a test has passed.

Failures may issue diagnostics.

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Running Schematron Validation

- The Schematron reference implementation compiles to an XSLT transformation.

  – Thus validation can be performed with any XSLT processor.

  – There are also native Schematron processors in existence.

- The output of schematron validation is an XML report on the validation status of the instance.

Example Validation Report

```xml
<?xml version="1.0" encoding="UTF-8" standalone="yes"?>
<schematron-output title="Schematron schema for validating conformance to CCD
    documents" schemaVersion="" phase="errors" xmlns:cda="urn:hl7-org:v3"
    xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
    xmlns:sch="http://www.ascc.net/xml/schematron">
<ns uri="urn:hl7-org:v3" prefix="cda"/>
<ns uri="http://www.w3.org/2001/XMLSchema-instance" prefix="xsi"/>
<active-pattern name="CCD v1.0 Templates Root - errors validation phase"/>
<fired-rule id=""
    context="*[cda:templateId/@root=&quot;2.16.840.1.113883.10.20.1&quot;]"
    role=""/>
<failed-assert id="" test="cda:code[@code='34133-
    9'][@codeSystem='2.16.840.1.113883.6.1']" role=""
    location="/@ClinicalDocument[1]">
<text>The ClinicalDocument/code element SHALL be present, and SHALL be valued
    with LOINC code 34133-9 (SUMMARIZATION OF EPISODE NOTE).</text>
</failed-assert>
...
</schematron-output>
```
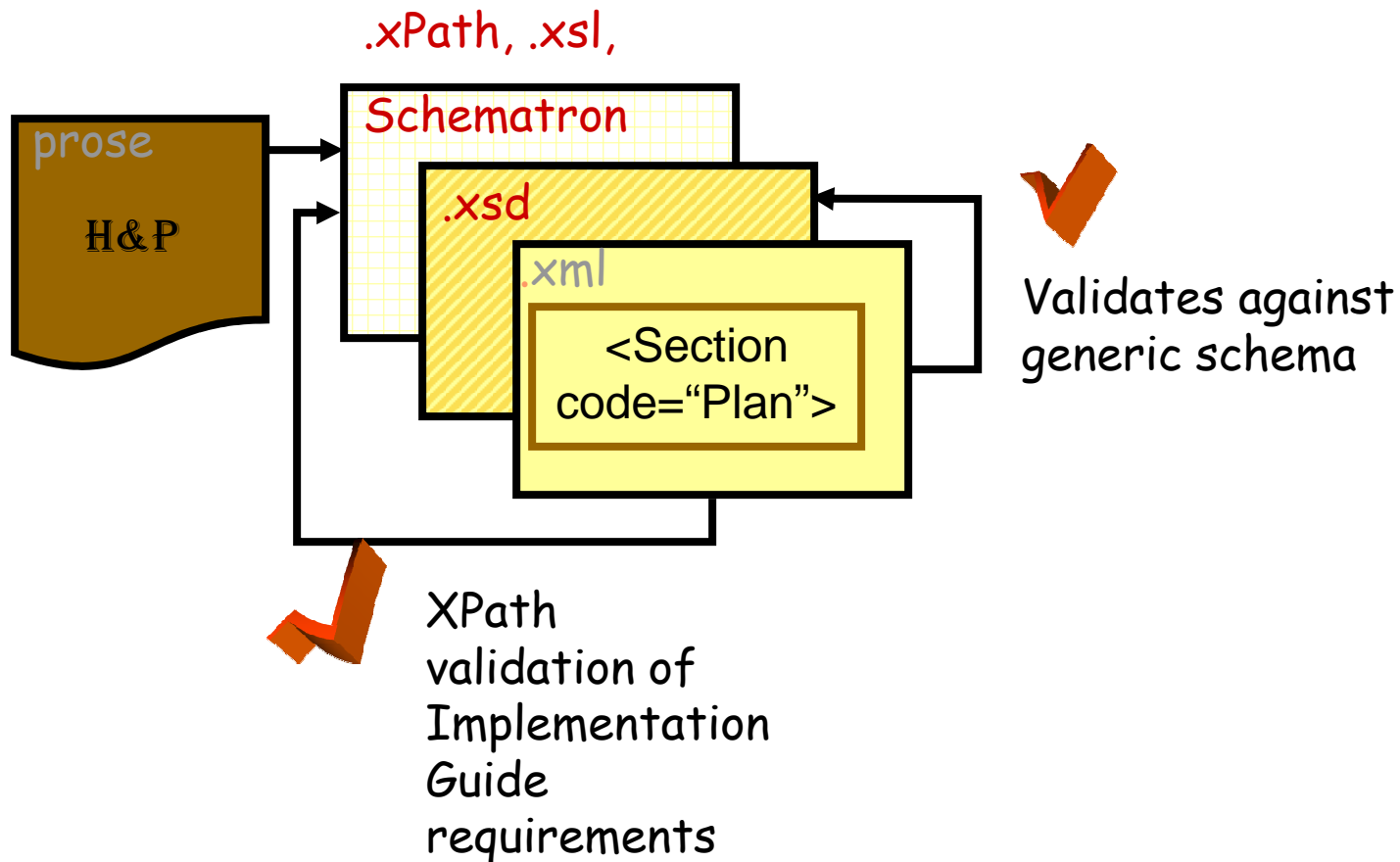
Multi-Stage Validation

- For each instance…
  - Validate it against the CDA.xsd schema.
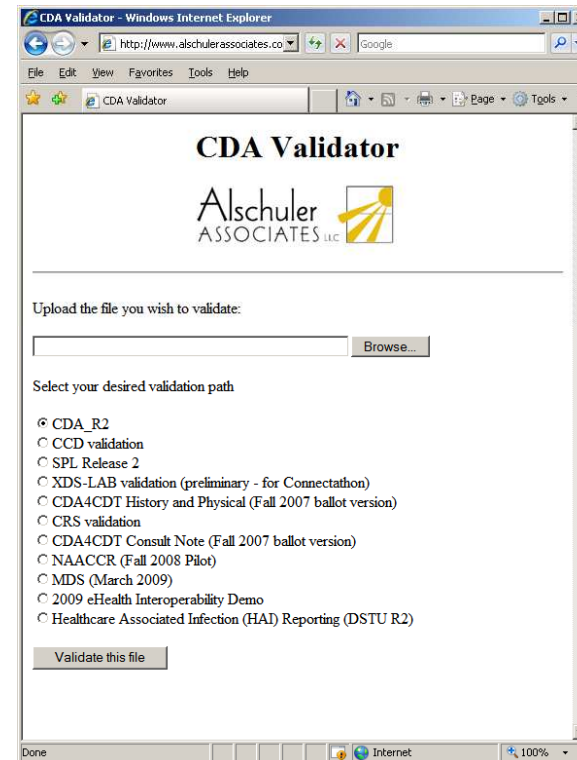 - Run zero or more secondary validation passes for any templates that are asserted by instance.

Multi-Stage Validation Illustration

.xPath, .xsl,

Schematron

prose

H&P

.xsd

.xml

<Section code="Plan">

Validates against generic schema

XPath validation of Implementation Guide requirements

Sample Implementation

- Online CDA Validator
  - Implements a basic multi-stage validation pipeline
  - Freely available for anyone to use
  - Provides validation for most SDWG-developed IGs

http://www.alschulerassociates.com/validator

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Examples

```xml
<?xml version="1.0"?>
<?xml-stylesheet type="text/xsl"
    href="CCD.xsl"?>
<ClinicalDocument xmlns="urn:hl7-org:v3"
    xmlns:voc="urn:hl7-org:v3/voc"
    xmlns:xsi="http://www.w3.org/2001/XMLSchema-
    instance" xsi:schemaLocation="urn:hl7-org:v3
    CDA.xsd">
<templateId root="2.16.840.1.113883.10.20.1"/>
<typeId root="2.16.840.1.113883.1.3"
    extension="POCD_HD000040"/>
<id root="db734647-fc99-424c-a864-
    7e3cda82e703"/>
<code code="34133-9x"
    codeSystem="2.16.840.1.113883.6.1"
    displayName="Summarization of episode
    note"/>
<title>Good Health Clinic Continuity of Care
    Document</title>
...
</ClinicalDocument>
```
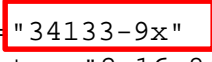
CCD Schematron Errors

CDA.xsd Errors

CDA Validator — Windows Internet Explorer

http://www.alschulerassociates.com/validator/upload.jsp;jsessionid=

CDA Validator

Processed file: *c:\documents and settings\rick geimer\workspaces\hands-on-training\validation\xml\badccd.xml*

Validator: *CCD validation*

Results: *The document is **not** valid*

Validate another file.

Validation Log:

Validating: **CDA XML Schema**

org.xml.sax.SAXParseException: cvc-complex-type.2.4.a: Invalid content was found starting with element 'templateId'. One of '{"urn:hl7-org:v3":realmCode, "urn:hl7-org:v3":typeId}' is expected.

Validating: **CCD Schematron Schema (Errors)**

CCD v1.0 Templates Root - errors validation phase

The ClinicalDocument/code element SHALL be present, and SHALL be valued with LOINC code 34133-9 (SUMMARIZATION OF EPISODE NOTE).

Location: */ClinicalDocument[1]*
Test: *cda:code[@code='34133-9'][@codeSystem='2.16.840.1.113883.6.1']*

Examples (cont)

```xml
<?xml version="1.0"?>
<?xml-stylesheet type="text/xsl"
    href="CCD.xsl"?>
<ClinicalDocument xmlns="urn:hl7-org:v3"
    xmlns:voc="urn:hl7-org:v3/voc"
    xmlns:xsi="http://www.w3.org/2001/XMLSchema-
    instance" xsi:schemaLocation="urn:hl7-org:v3
    CDA.xsd">
<typeId root="2.16.840.1.113883.1.3"
<templateId root="2.16.840.1.113883.10.20.1"/>
    extension="POCD_HD000040"/>
<id root="db734647-fc99-424c-a864-
    7e3cda82e703"/>
<code code="34133-9"
    codeSystem="2.16.840.1.113883.6.1"
    displayName="Summarization of episode
    note"/>
<title>Good Health Clinic Continuity of Care
    Document</title>
...
</ClinicalDocument>
```
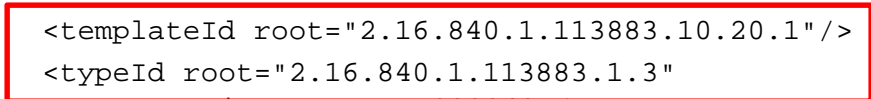
CDA Validator

Processed file: *c:\documents and settings\rick geimer\workspaces\hands-on-training\validation\xml\goodccd.xml*

Validator: *CCD validation*

Results: *The document is valid*

Validate another file.

Document validates!

Validation Log:

Validating: CDA XML Schema

  No issues found

Validating: CCD Schematron Schema (Errors)

  No issues found

Validating: CCD Schematron Schema (Warnings)

The following messages are not counted against the automated validation process, but may require attention.

Family history observation - warning validation phase

Drawbacks

- Implementers are often unfamiliar with Schematron
  - Can addressed by education
    - Explain in terms of XPath and XSLT
  - Lack of direct Schematron tool support remains as a minor issue.
- Performance
  - Running multiple XSLT transforms can be slow.
  - Partially addressed by pre-compiled XSLT transforms (translets, etc.)

Future Work

- "On demand" schematron generation
  - Process a CDA instance
  - Extract all asserted templates
  - Generate a "custom" schematron schema specific to that instance
  - Requires a template repository and schematron fragments for each template

References

- CDA Release 2.0 Normative Edition:
  - see HL7.org
- CCD
  - See HL7.org
- V3 Normative Edition
  - http://www.hl7.org/v3ballot/html/welcome/environment/index.htm
- XML
  - http://www.w3.org/TR/xml
- XSLT
  - http://www.w3.org/TR/xslt
- XPath
  - http://www.w3.org/TR/xpath
- Schematron
  - http://www.schematron.com/
  - http://xml.ascc.net/resource/schematron/schematron.html
- AlschulerAssociates.com
  - Quick Start Guides
  - CDA Validator
  - CDA Gallery
- rick@alschulerassociates.com

Thank you!
Questions?