

Contents

Part I Healthcare Information Technology

1	Introduction	3
1.1	The Case for Common Understanding	5
1.1.1	The Need for Consistency	6
1.2	Information Cycle	7
1.3	Motivation for Cooperation	8
1.4	Definition of Key Terms and Concepts	9
1.4.1	Conformance	9
1.4.2	Interoperability	10
1.5	Interoperability Levels	12
1.6	Standards Development Life-Cycle	13
1.7	ISO/OSI Stack	15
1.8	Reference Model for Open Distributed Processing (RM-ODP)	17
1.9	Concept Relationships	19
1.10	Approaches to Standards Development	20
1.11	Testing	22
1.12	Scope and Purpose	23
1.13	Commonly Used Terms and Definitions	25
1.14	Intended Audience	27
1.15	Keywords for Use	28
1.16	Summary	28
	References	29
2	Architecture	31
2.1	Interface	31
2.1.1	Types of Interfaces	32
2.1.2	Communication Paradigms	35
2.1.3	Protocol Layer	36
2.1.4	Levels for Interoperability	36

2.2	Interfacing.	37
2.2.1	Impact on Interfaces	38
2.3	Serving Interfaces with Data.	39
2.3.1	General “Capability” of a System	39
2.3.2	Relevance for Interfaces.	41
2.4	Dynamic Behavior	42
2.4.1	Message Pairs	42
2.4.2	Timing.	43
2.4.3	Message Identification	43
2.4.4	Routing to Multiple Destinations.	45
2.4.5	Responsibility of a System	46
2.4.6	Event Handling	47
2.4.7	Delayed Message Handling (Sender).	48
2.4.8	Handling of Outdated Data (Receiver).	49
2.5	Intermediate Message Handling	50
2.6	Message Population	51
2.7	Information Transmission	52
2.8	Delete Indication.	53
2.8.1	Legal Requirements for Data Persistence.	56
2.8.2	Receiver Responsibility	56
2.8.3	Data Granularity	57
2.8.4	Impact of Order of Messages.	57
2.8.5	Sender Responsibility: Impact to System Design.	58
2.9	Null Flavors	59
2.10	Snapshot Mode Versus Update Mode.	61
2.11	Considerations in Application Development.	64
2.11.1	Introducing Functional Requirements.	64
2.11.2	Conformance Discussion	69
2.12	Summary	72
	References.	73
3	Healthcare Standards Landscape.	75
3.1	Introduction	75
3.2	Standards Developing Organizations.	76
3.2.1	UNECE.	76
3.2.2	ASC (US)	77
3.2.3	ASTM (US).	78
3.2.4	HL7.	78
3.2.5	DICOM.	79
3.2.6	KBV, ZI and QMS (Germany)	80
3.2.7	KV-Telematik (Germany)	80
3.2.8	NCPDP (USA)	81
3.2.9	OASIS.	82

3.3	Profile Development Organizations	83
3.3.1	IHE	83
3.3.2	ELGA (Austria)	86
3.3.3	eHealth Suisse (Switzerland)	87
3.3.4	HITSP (US)	88
3.3.5	S&I Framework (US)	89
3.3.6	Standards Collaborative (Canada)	90
3.3.7	Interop'Santé (France)	91
3.3.8	ASIP Santé (France)	92
3.3.9	Phast (France)	92
3.3.10	eSanté (Luxembourg)	93
3.3.11	Interoperability Forum (Germany)	93
3.3.12	NHS (UK)	95
3.3.13	SMART Health IT on FHIR® (US)	96
3.4	Overview of Widely Used Standards	97
3.4.1	HL7	97
3.4.2	Other Standards	100
3.5	Summary	101
	References	101
4	Healthcare Data Exchange Standards	105
4.1	Introduction	106
4.2	HL7 Version 2.X	106
4.2.1	Versions	107
4.2.2	Information Model	109
4.2.3	Message Structure	109
4.2.4	Optionality	111
4.2.5	Encoding	112
4.2.6	Delimiters	114
4.2.7	Delete Requests	114
4.2.8	Null-Flavors	115
4.2.9	Data Types	115
4.2.10	Events	117
4.2.11	Dynamic Behavior	119
4.2.12	Transmission Protocols	121
4.2.13	Tables and Table Values	121
4.2.14	Conformance Methodology	123
4.3	FHIR (HL7)	123
4.3.1	Introduction and Overview	123
4.3.2	Element Hierarchy	126
4.3.3	References	128
4.3.4	Bundling	129
4.3.5	Retrieval and Queries	129
4.3.6	Extensibility	130
4.3.7	Use of Vocabulary	130

4.3.8	Data Types	131
4.3.9	Representation/Encoding	133
4.3.10	Maturity Model	133
4.3.11	Versions.	134
4.3.12	Profiling by “Slicing”	135
4.3.13	Conformance	135
4.3.14	Conformance Methodology	139
4.4	UN/EDIFACT.	140
4.4.1	Introduction and Overview	140
4.4.2	Message Structure	140
4.4.3	Delimiter	141
4.4.4	Data Types Format Notation	143
4.4.5	Tables	144
4.4.6	Conformance Methodology	145
4.5	ebXML.	145
4.5.1	ebRIM.	145
4.5.2	Data Types	146
4.5.3	Classes and Attributes	147
4.5.4	Methods.	147
4.5.5	Conformance Methodology	148
4.6	CTS2 (HL7)	148
4.6.1	Information Model.	149
4.6.2	Conformance Methodology	150
4.7	ClaML (ISO)	150
4.7.1	Information Model.	150
4.7.2	Conformance Methodology	151
4.8	Technical Compatibility Matrix	152
4.9	Summary	152
	References.	155

Part II Conformance (and Tools)

5	Conformance Constructs.	159
5.1	Overview	159
5.1.1	Conformance Constructs Overview	160
5.1.2	Related Conformance Concepts.	163
5.1.3	Example Specifications	164
5.1.4	Summary.	165
5.2	Data Structures and Data Types	166
5.2.1	Binding to Elements	166
5.2.2	Atomic Versus Complex Information	167
5.2.3	Representation/Formats	168
5.2.4	Precision in Representation	169

5.2.5	Precision in Meaning	170
5.2.6	Collections of Data Types	170
5.2.7	Promotion/Demotion (in HL7 V3).	171
5.3	Usage (Optionality).	172
5.3.1	Example Application Discussion	173
5.3.2	Support for an Element	175
5.3.3	Implementation Support Versus Presence in Instances	176
5.3.4	Conditional Usage	177
5.3.5	Case Study: HL7 v2.x Conditional Usage	178
5.3.6	“Required” Versus “Mandatory”	179
5.3.7	Binding of Elements	181
5.3.8	Interface Design Choices	181
5.3.9	Sender and Receiver Perspectives	182
5.4	Cardinality	182
5.4.1	Limitations.	183
5.4.2	Delimiters	184
5.4.3	Alternate Terms for Cardinality	184
5.4.4	Notation for Cardinality	184
5.4.5	Use of Cardinality	184
5.4.6	Relationship of Optionality and Cardinality	185
5.5	Length	186
5.5.1	Sender/Receiver Role.	187
5.5.2	Truncation	187
5.5.3	Padding	188
5.5.4	Conformance Length	189
5.6	Content	189
5.6.1	Vocabulary	190
5.6.2	Null Flavors (Values)	201
5.6.3	Fixed Value (Constant)	202
5.6.4	Default Values	203
5.6.5	Placeholder Values	204
5.7	Conformance Statements	204
5.8	Data Semantics	205
5.8.1	Models	205
5.9	Encoding	205
5.9.1	Display-Oriented Encoding Concepts	206
5.9.2	Presence/Absence of an Element	213
5.9.3	Parsing	216
5.10	Summary	220
	References	220
6	Principles of Specifying Conformance	223
6.1	Introduction	223
6.2	Overloaded Terms	225

6.2.1	Declaring Requirements and Conformance	225
6.2.2	Requirement Documents	226
6.3	Conformance Keywords	226
6.3.1	Impact of Keywords on Requirements.	228
6.3.2	Nested Requirements	229
6.3.3	Normative and Informative Statements	230
6.4	Conformance Clause.	230
6.4.1	Conformance Claim.	231
6.5	Specifying Conformance Requirements.	232
6.5.1	Implicit Definitions with Conformance Constructs	232
6.5.2	Explicit Definition with Normative Statements	236
6.5.3	Principles for Writing Conformance Requirements.	236
6.6	Scope of Conformance Specifications.	239
6.7	Summary	241
	References.	241
7	Principles of Effective Profiling	243
7.1	Introduction	243
7.2	Profiling: Definition of Terms.	244
7.2.1	Profile Components	249
7.2.2	Annotations	249
7.3	Refinement of a Standard	250
7.3.1	Profiling Methodology Summary.	251
7.3.2	Constraints.	251
7.3.3	Allowable Constraints	257
7.3.4	Extensions	257
7.3.5	Conformance Approaches: Constraints Versus Extensions	258
7.4	Profile Hierarchy.	258
7.4.1	Profile Hierarchy in Use	260
7.4.2	Profile Hierarchies for Standard Specifications	261
7.4.3	Non-compliant Profiles	263
7.5	Profiling Case Study: HL7 v2.	264
7.5.1	HL7 v2.x Profiles: Background and Motivation.	264
7.5.2	HL7 v2 Conformance Profile Defined	266
7.5.3	Message Profile Components Defined	267
7.6	Vocabulary Profiling.	269
7.6.1	Vocabulary Binding and Profiling	270
7.6.2	Use of Extensibility and Stability	273
7.6.3	Profiling at the Code Level	275
7.6.4	Summary	283

7.7	Vocabulary Management	283
7.7.1	Managing Code Systems	284
7.7.2	Value Set Definition and Expansion	285
7.7.3	Managing Dynamic Value Sets	286
7.8	Uses of Conformance Profiles.	288
7.9	Profile Design and Management	289
7.9.1	Profile Identification Management	292
7.9.2	Publishing the Specification.	292
7.10	Pairing Sender and Receiver Profiles for Use	293
7.10.1	One-to-One Profile Pairing	294
7.10.2	One-to-Many Profile Pairing	294
7.10.3	Many-to-One Profile Pairing	296
7.10.4	Design Considerations: Profiling Pairing	299
7.11	Case Studies	299
7.11.1	Localization Using Profile Components	299
7.11.2	IHE Integration Profile.	301
7.11.3	Laboratory Orders, Results, and Public Health	301
7.11.4	HL7 v2.x Message Profiles (in Germany)	304
7.12	Documenting Interfaces	306
7.12.1	Profile and Implementation Relationships	307
7.12.2	Documentation Quality	310
7.13	Summary	310
	References.	312
8	Profile Relationships	315
8.1	Introduction	315
8.2	Specialization of Profiles.	319
8.2.1	Usage (Optionality) Compliance Rules	320
8.2.2	Cardinality Compliance Rules	324
8.2.3	Length Compliance Rules	325
8.2.4	Vocabulary Compliance Rules.	327
8.3	Versioning of Profiles.	328
8.3.1	Example.	330
8.4	Creating New Profiles.	332
8.5	Compatibility of (Sender and Receiver) Profiles	332
8.5.1	Usage.	333
8.5.2	Cardinality.	335
8.5.3	Length.	335
8.5.4	Vocabulary	336
8.6	Summary	337
	References.	338
9	Conformance Profiling Tools	339
9.1	Introduction	339
9.2	Messaging Workbench	340

9.3	IGAMT.	343
9.4	MDHT.	345
9.5	ART-DECOR.	346
9.6	Lantana Template Repository: Trifolia.	352
9.7	Forge.	358
9.8	Summary.	360
	References.	360

Part III Testing (and Tools)

10	Testing Models.	365
10.1	Introduction.	365
10.2	Testing Objectives.	366
10.3	Definition of Terms.	367
10.4	Test Organization Hierarchy.	368
10.5	Test Evaluation Types.	372
10.6	Testing Models.	374
10.6.1	Data Instance Testing Model.	375
10.6.2	Isolated System Testing Model.	376
10.6.3	Peer-to-Peer System Testing Model.	378
10.7	Additional Testing Considerations.	379
10.8	Summary.	380
	References.	381
11	Principles of Conformance Testing.	383
11.1	Overview.	383
11.2	Conformance and Interoperability Testing.	384
11.2.1	Conformance Testing.	384
11.2.2	Interoperability Testing.	384
11.2.3	Conformance and Interoperability Testing Relationship.	385
11.2.4	Periodic Testing.	387
11.2.5	Conformance Testing in Operational Environments.	387
11.3	Standards Development Life-Cycle.	388
11.4	Test Methodology Framework.	390
11.4.1	System-Under-Test (SUT).	392
11.4.2	Anatomy of a Test Suite.	392
11.4.3	Anatomy of a Test Plan.	392
11.4.4	Anatomy of a Test Case.	393
11.4.5	Anatomy of a Test Step.	393
11.4.6	Test Data.	394
11.4.7	Test Script.	394
11.4.8	Inspection Documents.	395
11.4.9	Test Artifact.	395

11.4.10	Test Assertion	396
11.4.11	Test Tool	396
11.4.12	Configuration Information	396
11.4.13	Test Report	397
11.5	Testing in Practice	397
11.5.1	Testing Sending Applications	397
11.5.2	Case Study: Laboratory Results	401
11.5.3	Testing Receiving Applications	407
11.5.4	Case Study: Incorporation of Laboratory Results	413
11.6	Context-Based Test Data Categorizations	418
11.6.1	Data Content Conformity Assessment Examples	424
11.6.2	Testing Cardinality and Other Conformance Constructs	426
11.7	Strategies and Best Practices for Test Case Development	426
11.8	Capability, Site, and Interoperability Testing	430
11.9	Negative Testing	432
11.9.1	Message and Document Incorporation	433
11.9.2	Boundary Testing	435
11.9.3	False Positive and False Negative Test Results	435
11.10	Other Types of Testing	436
11.10.1	Smoke Testing	437
11.10.2	Communication Testing	437
11.10.3	Application Functional Testing	438
11.10.4	Data Quality Testing	439
11.10.5	Usability Testing	440
11.10.6	Load Testing	441
11.11	Summary	441
	References	443
12	Conformity Assessment	445
12.1	Overview	445
12.2	Processing Aspects (for Receiving Applications)	448
12.3	Usage/Optionality	448
12.3.1	Sender Usage Conformity Assessments	449
12.3.2	Receiver Usage Conformity Assessment	451
12.4	Cardinality	457
12.4.1	Sender Cardinality Conformity Assessment	458
12.4.2	Receiver Cardinality Conformance Assessment	464
12.5	Vocabulary Conformance and Assessment	475
12.5.1	Vocabulary Conformance	475
12.5.2	Vocabulary Conformity Assessment	477
12.6	Summary	480
	References	480

13	Testing Architectures	481
13.1	Introduction	481
13.2	Testing Infrastructure	482
13.2.1	Key Objectives of a Testing Infrastructure	485
13.2.2	Resource Repository	485
13.2.3	Test Harness	486
13.2.4	Services	487
13.2.5	Infrastructure Components	496
13.2.6	Testing Infrastructure—A Broader Context	496
13.2.7	Testing Infrastructure Observations	499
13.3	A Test Scenario	499
13.4	Testing Frameworks	503
13.4.1	Data Instance Test Framework	503
13.4.2	Isolated System Test Framework	505
13.4.3	Peer-to-Peer Testing Framework	506
13.5	Instantiation of Test Tools	508
13.5.1	Data Instance Testing Test Tool	508
13.5.2	Isolated System Testing Test Tool	509
13.5.3	Interoperability Test Bed	513
13.6	Summary	523
	References	523
14	Testing Tools	525
14.1	Introduction	525
14.2	NIST HL7 v2.x Test Tools	526
14.2.1	NIST Immunization Test Suite	527
14.2.2	Testing Functional Requirements with the Tool	534
14.2.3	NIST HL7 v2.x Testing Web Services API	536
14.3	Message Workbench (MWB)	536
14.3.1	Message Instance Validation	536
14.3.2	Message Validation via a Proxy-Server	537
14.3.3	MWB Validation Server	537
14.4	CDC Message Quality Framework	539
14.5	AHML-Australian Healthcare Messaging Laboratory	540
14.5.1	Message Testing Process	541
14.5.2	Reporting	543
14.6	CDA Test Tools	543
14.6.1	ART-DECOR	543
14.6.2	Lantana Trifolia	544
14.6.3	NIST CDA Testing	545
14.6.4	eHealth Suisse	547
14.6.5	IHE Gazelle Object Checker	548
14.7	IHE Conformance and Interoperability Test Tools	548

14.8	e-Prescribing (e-Rx) Tools	550
14.8.1	NIST e-Prescribing Test Tool	551
14.9	DVTk—DICOM Validation Toolkit	552
14.9.1	History.	552
14.9.2	Functionality	552
14.10	Related Tools	554
14.10.1	HAPI.	554
14.10.2	MDHT.	555
14.10.3	IPF (by Open eHealth Foundation)	556
14.10.4	eHealth Connector (by eHealth Suisse)	556
14.11	Table of Tools and Access Points.	557
14.12	Summary	557
	References.	557
15	Testing and Certification Programs	559
15.1	Introduction	559
15.2	Certification Perspectives	560
15.3	IHE Testing Programs.	562
15.3.1	IHE Technical Framework Overview.	562
15.3.2	IHE Testing Process	562
15.3.3	IHE Product Registry.	566
15.3.4	Gazelle	567
15.4	EHR Certification and Meaningful Use Programs.	568
15.4.1	Patient Safety and Federal EHR Technology Programs	568
15.4.2	The Federal HIT Certification Program	569
15.4.3	The Role of NIST	574
15.4.4	Reaction in the Market to the Federal EHR Programs.	577
15.4.5	The Interoperability Factor	582
15.4.6	Summary and Conclusions	583
15.5	Other Programs.	584
15.5.1	Surescripts.	584
15.5.2	Certification in Australia	584
15.5.3	Certification in Germany	585
15.6	Scope of Certification Testing.	586
15.7	Summary	588
	References.	588
	Appendix A: Additional Healthcare Data Exchange Standards.	591
	Appendix B: Trademark Information	649
	Index	651

<http://www.springer.com/978-3-319-44837-4>

Healthcare Interoperability Standards Compliance
Handbook
Conformance and Testing of Healthcare Data Exchange
Standards
Oemig, F.; Snelick, R.
2016, XLVI, 662 p. 292 illus., 289 illus. in color.,
Hardcover
ISBN: 978-3-319-44837-4