Trusted End-to-End Information Flows

A fundamental aspect of accountability and quality assurance is to ensure trusted end-to-end information flows, tracking flows from:

- Point of origination (point of service/care) to point of use (point of report);
- Source to consumer;
- Front-end to back-end to third party.

In the course of end-to-end flow, information may traverse one or more:

- Point(s) of interchange: e.g., interfaces between application systems or software components;
- Point(s) of translation: e.g., content translation between coding and classification schemes;
- Point(s) of convergence: e.g., aggregation, derivation, summarization functions.

The role of the HL7 SIGAQP is to address issues related to accountability and quality assurance in trusted end-to-end information flows and to form recommendations (to the HL7 TSC and TCs) related thereto. This document is an initial attempt to identify core principles and to forge a fulfillment strategy.

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Principles

1. Ensured Trust

Trust = confidence, surety.

Consider those constituent parties – individuals, organizations and business units – who have a trust stake in the veracity of the health record including its origination, amendment, stewardship and use and particularly with regard to:
1.1. Privacy and confidentiality;
1.2. Protection of individually identifiable information;
1.3. Protection in the course of interchange - "in transit".

To the greatest extent possible, it is the duty of HL7 to design its architectures and interchange methodologies to ensure trust in terms of the protection of health records to all constituent parties.

2. Trust and Accountability Constituency

See attached Appendix A, the SIQAQP Trust and Accountability Matrix.

There are an array of constituent parties to the health record and its content, each with definitive rights and obligations related thereto:

2.1. As subjects of the health record, e.g.:
.1 individual patients, health plan members,clients;
.2 individual practitioners/caregivers;
.3 individual originators of record content: authors, scribes and verifiers;
.4 organizations, including: providers, health plans;
.5 business units, including: departments, services, specialties;
.6 others, including: next of kin, emergency contacts, guarantors;

2.2. As parties participating in the provision, performance and completion of health(care) services and whose related actions are ascribed in the health record, e.g.:
.1 individual practitioners/caregivers;
.2 organizations;
.3 business units;

2.3. As parties participating in the origination, amendment, stewardship and use of the health record and whose related actions are ascribed therein, e.g.:
.1 individual practitioners/caregivers; in this context as
.2 individual authors, scribes and verifiers;
.3 organizations;
.4 business units.

Constituent parties, in terms of the health record and its content, are designated variously by legislation, regulation, standards of practice and custom, which are not the immediate authority or domain of HL7. To the greatest extent possible, it is the duty of HL7 to design its architectures and interchange methodologies to ensure the recognition and to protect the incumbent interests of these constituent parties.

3. Health Record Rights

Health record rights include information which complete and accurate and which is accessible to the record subject. Other crucial record rights include:
3.1. confidentiality and privacy protections, particularly with regard to access to, use and disclosure of:

.1 individually identifiable information;
.2 information subject to protection:
  .a by statute, regulation, standard of practice or custom; and/or
  .b by virtue of explicit disclosure grants and agreements;
.3 information made available by such grants and agreements:
  .a for purpose(s) intended;
  .b by those parties so authorized;
  .c for the period (of time) designated; and
  .d based on the principle of "need to know".

3.2. complete and accurate portrayal of health status and interventions;
3.3. complete and accurate portrayal of the provision, performance and completion of health services;
3.4. detailed audit logs tracking record access, use and disclosure.

Health record rights are designated variously by legislation, regulation, standards of practice and custom, which are not the immediate authority or domain of HL7. To the greatest extent possible, it is the duty of HL7 to design its architectures and interchange methodologies to ensure these crucial health record rights.

4. Health Record Obligations

Health record obligations include accountability for:
4.1. record content origination and amendment, as ascribed to authors, scribes and/or verifiers;
4.2. provision, performance and completion of health services, as documented in the health record and as ascribed to practitioners, caregivers;
4.3. accuracy, completeness of record content;
4.4. access to, and use of, record content;
4.5. duplication of record content;
4.6. disclosure, transmission and receipt of record content;
4.7. translation of record content (e.g., translation to alternate coding and classification schemes).

Health record obligations are designated variously by legislation, regulation, standards of practice and custom, which are not the immediate authority or domain of HL7. However to the greatest extent possible, it is the duty of HL7 to design its architectures and interchange methodologies to ensure these key health record obligations.

5. Health Record Components and Composition

In its fullest instantiation, the patient/member health record includes:
5.1. a longitudinal chronology of patient health status and interventions;
5.2. a chronicle of health service events corresponding to the provision, performance and completion of health(care) services;
5.3. a collection of discrete record instances (documents), often corresponding in a 1:1 relationship with health service events.

To the greatest extent possible, it is the duty of HL7 to design its architectures and interchange methodologies to fully represent these crucial health record components and composition.

6. Healthcare Parties and Their Accountable Actions

In this context, healthcare parties are those individuals, organizations and business units accountable for actions related to, and/or ascribed in, the health record, including:
6.1. origination or amendment of record content: as authors, scribes, verifiers;
6.2. provision, performance and/or completion of healthcare services, specifically health service events;
6.3. access to, and use of, health record content;

6.4. duplication of record content;
6.5. disclosure, transmission and/or receipt of record content;
6.6. translation of record content.

In many but not all cases, individuals as healthcare parties, act as agents/employees of and/or on behalf of organizations and business units.

To the greatest extent possible, it is the duty of HL7 to design its architectures and interchange methodologies to fully represent these healthcare parties and their accountable actions.

7. Healthcare Agents and Their Accountable Actions

In this context, healthcare agents are those medical devices (e.g., instruments, monitors) and software accountable for actions related to, and/or ascribed in, the health record, including:
7.1. origination of record content (typically pre-verification);
7.2. duplication of record content;
7.3. transmission and/or receipt of record content;
7.4. translation of record content.

Healthcare agents typically act within the domain, on behalf and under the immediate control of healthcare parties (as described above).

To the greatest extent possible, it is the duty of HL7 to design its architectures and interchange methodologies to fully represent these healthcare agents and their accountable actions.

8. Scope of Accountability, Unit of Accountability

Following from the above description of healthcare parties, healthcare agents and their accountable actions, it is necessary to designate a corresponding scope of accountability. Such scope includes (the domain of) health record content ascribed to:
8.1. healthcare parties in terms of their specific actions in the provision, performance and/or completion of health services;
8.2. healthcare parties and agents in terms of their specific actions in the origination, amendment, stewardship and use of the health record.

The scope of accountability resolves to a discrete unit of accountability, specifically the set of attributes (data elements):
8.3. describing the performance, provision and/or completion of a discrete health service event;
8.4. comprising a discrete record instance.

To the greatest extent possible, it is the duty of HL7 to design its architectures and interchange methodologies to fully represent healthcare parties and agents, their actions and corresponding scope of accountability.

9. Authentication, Attestation, Non-Repudiation, Digital Signature

Authentication is fundamental to trusted interchange of health information, which ensures the capability of a recipient to reliably ascertain parties to the origination, validation, transmittal and receipt of health records, in whole or in part. Specific authentication functions are crucial, including:
9.1. user authentication: evidence of individual identity;
9.2. source authentication: evidence of authorship, origination, amendment;
9.3. validation authentication: evidence of data verification, e.g.:
.1 of data originated by another party;
.2 of automated device input;
9.4. data interchange authentication: evidence of transmittal, receipt.

Other crucial aspects of authentication include:
9.5. non-repudiation (e.g., of authorship);
9.6. attestation;
9.7. digital signature;
9.8. public/private key infrastructure;
9.9. encrypted encapsulation: binding health record content to authenticated source.

To the greatest extent possible, it is the duty of HL7 to design its architectures and interchange methodologies to ensure and provide the full set of services for authentication, non-repudiation and digital signature.

10. Auditability

Intrinsic to full accountability is the instantiation of robust audit trails and audit tools sufficient to track healthcare parties and agents and their accountable actions (particularly as described in the preceding sections).

To the greatest extent possible, it is the duty of HL7 to design its architectures and interchange methodologies to promote full auditability of accountable parties and agents and their accountable actions.

11. Chain of Custody

As end-to-end information flows imply, there is an intrinsic need to track the chain of custody as health records transit points of interchange, points of translation and points of convergence.

To the greatest extent possible, it is the duty of HL7 to design its architectures and interchange methodologies to ensure chain of custody tracking in the course of information flow from point of origination to the point of use.

12. Faithfulness, Permanence, Persistence and Non-Alterability

Another key requisite is the need to ensure that health records are faithfully maintained in a permanent, fully persistent, non-altered form, from point of origination to point of use. This includes:
12.1. preservation of original content and context;
12.2. revision by (additive) amendment only;
12.3. preservation of discrete data states: original and for each amendment;
12.4. ability to reconstruct health records for any given historical date/time.

To the greatest extent possible, it is the duty of HL7 to design its architectures and interchange methodologies to ensure faithfulness, permanence, persistence and non-alterability of health record content.

13. Data Definition, Data Registry

Concise data definition is foundational to data integrity, including definitions of attributes (i.e., data elements) and data groups (e.g., minimum, core, reference datasets). Data registries, such as the U.S. Health Information Knowledgebase (USHIK), are a key method to ensure the formalization and harmonization of attribute/data group definitions across SDOs, accreditation and governance bodies, and others.

To the greatest extent possible, it is the duty of HL7 to design its architectures and interchange methodologies to ensure robust methods of data definition, including formalization and harmonization with recognized data registries.

14. Data Integrity

Key aspects of data integrity include accuracy, context, consistency, comparability, continuity, completeness and relevance. Data integrity is keyed on data definition, as described above, but also relies substantially on robust methods for information flow from the point of origination to the point of use.

To the greatest extent possible, it is the duty of HL7 to design its architectures and interchange methodologies to ensure key aspects of data integrity.

Key Contexts

Key contexts are intended to be conveyed from the point of origination (point of service/care) to the point of use (point of report) and are essential to trusted end-to-end information flows. These contexts are relevant to health record instances and their corresponding health service events. From an HL7 perspective, contexts may be represented in templates (as promulgated by the HL7 Vocabulary Technical Committee).

1. Accountability Context - Template

   This context describes the essential who, what, when, where and why aspects of the performance, provision and completion of health service events and the origination, amendment, stewardship and use of health records. It is designed to ensure the ascription of accountable parties and agents to their accountable actions.

2. Data Integrity Context - Template

   This context describes essential data integrity aspects relevant to the content of a health record instance and includes measures and indicators for (as applicable): accuracy, context, consistency, comparability, continuity, completeness and relevance.

3. Clinical Context - Template

   This context describes the essential clinical context relevant to a health service event and thus to the content of its corresponding health record instance and includes (as applicable):
   - 3.1. Rationale;
   - 3.2. Clinical parameters;
   - 3.3. Clinical context and conditions;
   - 3.4. Rules and measures to ensure:
     - .1 continuity and completeness;
     - .2 compliance: e.g., with standards of practice/care;
   - 3.5. Measures and indicators: e.g.,
     - .1 performance;
     - .2 quality;
     - .3 outcomes.

4. Operational Context - Template

   This context described the essential operational context relevant to a health service event and thus to the content of its corresponding health record instance and includes (as applicable):
   - 4.1. Allocation, deployment: e.g., of resources;
   - 4.2. Assigned responsibility: e.g., of healthcare parties;
   - 4.3. Parameters and measures: e.g.,
     - .1 resource utilization: staff, time, facilities, equipment, supplies;
     - .2 costs;
     - .3 productivity.

To the greatest extent possible, it is the duty of HL7 to design its architectures and interchange methodologies to ensure conveyance of these key contexts as a function of trusted end-to-end information flows, using templates as appropriate.

Roles and Relationships

1. Patients, Providers

   These roles instantiate the relationship between patients/health plan members/clients and their health care providers, practitioners and caregivers and include:
   - 1.1. Patient, health plan member;
   - 1.2. Provider, practitioners, caregivers, e.g.:
     - .1 Usual, primary physician;
     - .2 Admitting, attending physician;
     - .3 Consultant;
     - .4 Nurse;
     - .5 Therapist;
     - .6 Home caregiver;
   - 1.3. Others: next of kin, emergency contact(s), guarantor(s).

2. Health Services

   These roles instantiate the relationship of individuals to the provision, performance and completion of health services and include:
   - 2.1. performer of;
   - 2.2. observer of.

3. Health Record

   These roles instantiate the relationship of individuals, organizations and business units to the origination, amendment, stewardship and use of health records, including:
   - 3.1. origination, amendment of: author, scribe;
   - 3.2. verifier of: content authored by another, input from automated device;
   - 3.3. access to and use of;
   - 3.4. stewardship of;
   - 3.5. duplication of;
   - 3.6. disclosure, transmission and/or receipt of;
   - 3.7. translation of.

4. Individuals, Organizations, Business Units

   These roles instantiate the relationship among and between individuals, organizations and business units and include:
   - 4.1. business units as operational components of an organization: e.g., departments, services and specialties which are discretely managed, functional parts of a healthcare provider organization;
   - 4.2. individuals vis-à-vis an organization and/or business unit, acting:
     - .1 as an employee/agent of; and/or
     - .2 on behalf of.

5. Inter-Individual

   These roles instantiate the relationship among and between individual healthcare parties, including:
   - 5.1. chief to resident;
   - 5.2. preceptor, proctor, instructor to student;
   - 5.3. supervisor to staff.

To the greatest extent possible, it is the duty of HL7 to design its architectures and interchange methodologies to ensure the proper designation of these roles and relationships as a function of trusted end-to-end information flows.

Point of Definition

Data Registry

1. Attributes: definition of atomic data elements

   For each:
   1.1. Name, identifier
   1.2. Precise usage
   1.3. Data type, format
   1.4. Classification, coding scheme
   1.5. Range
   1.6. At the attribute level, measures and rules for: accuracy, consistency, comparability, continuity, completeness, relevance

2. Data Groups: definition of minimum/reference/core datasets (a.k.a., templates per HL7 Vocabulary TC)

   For each:
   2.1. Name, identifier
   2.2. Precise usage
   2.3. Aggregated attributes
   2.4. At the data group level, measures and rules for: contextual data (attribute) relationships, consistency, comparability, continuity, completeness, relevance

3. Context Sets - Templates

   Contexts sets are an instantiation of data groups pertaining to:
   3.1. Accountability Context - Template
   3.2. Data Integrity Context - Template
   3.3. Clinical Context - Template
   3.4. Operational Context - Template

Point of Service/Care – Health Service Event Instance

Accountability Context - Template

For each health service event instance, to ensure accountability for related actions, as applicable:

Service Event Instance ID
Who – Event subject
    Individual Patient/Member ID

Who – Accountable healthcare party(ies), as pertains to each:
    <Digital Signature>
    Organization ID/Descriptor, if applicable
    Business Unit ID/Descriptor, if applicable
    Individual Identifier
    Role, relative to organization/business unit: as employee/agent of, on behalf of
    Role, relative to patient/member: provider, practitioner, caregiver
    Role, relative to service event instance: performer, observer
    Role, relative to individual performer: chief of, preceptor/proctor/instructor of, supervisor of
    Scope of accountability: attributes ascribed to accountable party
    What – service event rendered (e.g., procedure)
    What – action: perform, observe
    What – event status: pending, in progress, complete, canceled
    What – related health record instance
    When – service event date/time, duration
    Where – physical location: point of service/care
    Where – network and/or device address
    Why – rationale, as applicable

Data Integrity Context - Template

Definitions, measures and indicators to ensure, as applicable:
    Data accuracy, context, consistency, comparability, continuity, completeness, relevance

Clinical Context - Template, as applicable:

Rationale
Clinical parameters
Clinical context, conditions
Definitions, rules and measures to ensure:
    Continuity, completeness
    Compliance: e.g., with standards of care/practice
Definitions, measures and indicators for:
    Performance
    Quality
    Outcomes

Operational Context - Template, as applicable:

Allocation, deployment
Assigned responsibility
Definitions, parameters and measures for:
    Resource utilization: staff, time, facilities, equipment, supplies
    Costs
    Productivity

Point of Origination or Amendment – Health Record Instance

If amendment, preserve original record content, append (create) new data state with amended content.

Accountability Context - Template

For each health record instance, for each action of record origination or amendment, to ensure accountability, as applicable:

Record Instance ID
File Name
Who – Record subject
    Individual Patient/Member ID

Who – Accountable healthcare party(ies), as pertains to each:
    <Digital Signature>
    Organization ID/Descriptor, if applicable
    Business Unit ID/Descriptor, if applicable
    Individual ID
    Role, relative to organization/business unit: as employee/agent of, on behalf of
    Role, relative to record instance: author, scribe, verifier
    Role, relative to individual author or verifier: chief of, preceptor/proctor/instructor of, supervisor of
    Scope of accountability: attributes ascribed to accountable party
    What – record instance (document) type
    What – action: author, scribe, verify
    What – record instance status: new, amended, verified
    What – record completion status: documented, dictated (pre-transcription), in progress, incomplete, pre-authenticated, authenticated, legally authenticated
    What – record confidentiality status
    What – record availability status
    What – record storage status
    What – reporting priority
    What – related health service event instance
    When – recording date/time, duration
    Where – physical location: point of recording
    Where – network and/or device address
    Why – rationale, as applicable
    How – content presentation: scanned image (SI), non-scanned image (NS), scanned document (SD), machine readable text document (TX), formatted text (FT), image data (IM), audio data (AU), other application or binary data (AP)

Who – Accountable healthcare agent(s), as pertains to each
    Device, application or software identifier
    Role, relative to record instance: originator
    Scope of accountability: attributes ascribed to accountable agent
    What – action: originate
    What – related health service event
    When – date/time
    Where –network address

Data Integrity Context - Template

Measures and indicators to ensure, as applicable:
    Data accuracy, context, consistency, comparability, continuity, completeness, relevance

Clinical and Operational Contexts - Templates

Encapsulated in corresponding health service event

Point of Interchange – Health Record Instance

Preserve original record content
Preserve as received:
- Accountability Context - Template
- Data Integrity Context - Template
- Clinical Context - Template
- Operational Context - Template

Append new atom to serialized chain of custody:

- Who – Accountable healthcare agent
  - <Digital Signature>
  - Device, application or software identifier
  - Role, relative to record instance: steward
  - Scope of accountability
  - What – action: transit point
  - When – date/time
  - Where – network address
- Who – Disclosed to: accountable healthcare party or agent

Point of Translation – Health Record Instance

Preserve original record content
Preserve as received:
- Accountability Context - Template
- Data Integrity Context - Template
- Clinical Context - Template
- Operational Context - Template

Append translated content:

- New atom for each translated attribute

- Who – Accountable healthcare agent
  - <Digital Signature>
  - Device, application or software identifier
  - Role, relative to record instance: mediator, translator
  - Scope of accountability
  - What – action: translate
  - When – date/time
  - Where – network address

Point of Aggregation, Derivation, Summarization – Health Record Instance

Preserve original record content
Preserve as received:
- Accountability Context - Template
- Data Integrity Context - Template
- Clinical Context - Template
- Operational Context - Template

Produce new record instance(s) containing specialized aggregations, derived data and/or summaries.
May or may not carry forward individually identifiable information.

Appendix A - Trust and Accountability Matrix

Trust Constituency: for health record content, including individually identifiable information	Individual	Organization	Business Unit	Subject of Record	Accountable Source, Author of Record Content	Accountable Verifier of Record Content	Accountable Scribe of Record Content	Accountable User of Record Content	Accountable Record Steward	Accountable Provider of Health Services as Documented in Record
Patient, Health Plan Member	X			Yes	Yes	A/A	N/A	A/A	No	No
Next of Kin, Emergency Contact, Guarantor	X			Yes	No	No	No	No	No	No
Practitioner, Caregiver	X			Yes	Yes	Yes	Yes	Yes	Yes	Yes
Transcriptionist	X			Yes	No	A/A	Yes	A/A	Yes	No
Department, Service, Specialty			X	Yes	N/A	N/A	N/A	Yes	Yes	Yes
Provider	X	X		Yes	N/A	N/A	N/A	Yes	Yes	Yes
Integrated Delivery Network (IDN)		X		Yes	N/A	N/A	N/A	Yes	Yes	Yes
Payer, Health Plan, HMO		X		A/A	No	No	No	Yes	Yes	No
Value Added Network (VAN)		X		No	No	No	No	Yes	Yes	No
Employer	X	X		A/A	No	No	No	Yes	A/A	No
Public Health Agency		X		No	No	No	No	Yes	A/A	No
Regulatory Agency		X		No	No	No	No	Yes	A/A	No
Accreditation Agency		X		No	No	No	No	Yes	A/A	No
Research	X	X		No	No	No	No	Yes	A/A	No
Clinical Education	X	X		No	No	No	No	Yes	A/A	No
Others										

N/A = Not applicable
A/A = As applicable