



Enhancing Imm Messaging

New Release of National IG
and Support for Transition

Agenda

- **Why and How We are Updating the National IG**
- **Release 2.0: Summary of Key Updates**
- **Introductions to HTI-2 and Our IG**
- **Transition planning**
 - Validation Tools Development & Compliance Review
 - Regulatory Assistance & Support Resources
- **Conclusion**
- **Additional Insights and Information**

Why we are updating the National IG?

The HL7 v2.5.1 Implementation Guide for Immunization Messaging, Release 1.5 (National IG) is widely used, but **it has not been comprehensively updated since 2015.**

While an addendum was added in 2015, **new challenges have emerged, requiring updated guidance.**

Gaps identified by:

- Community feedback (CDC, AIRA, IIS community, NIST, ASTP)
- EHR system updates and interoperability needs
- Standardization efforts to align with national data exchange practices

The goal is to **enhance clarity, reduce ambiguity, apply newer conformance methodology, and ensure consistency** across IISs and providers.

Purpose of the Implementation Guide Expert Group (IGEG)

The Immunization Implementation Guide Expert Group (IGEG) was formed to update and maintain the National IG.

The National IG ensures consistent, accurate immunization data exchange between healthcare providers, Immunization Information Systems (IISs), and other stakeholders.

Purpose of the Implementation Guide Expert Group (IGEG)

IGEG's goal is to identify gaps, clarify existing guidance, and improve data quality to align with current healthcare practices and interoperability standards.

IGEG is a collaboration among CDC, AIRA, IIS community members, EHR vendors, and public health agencies to ensure the next release meets community needs.

The Process – How We Are Updating the Guide



Gap Identification & Prioritization

We gathered over **100 gaps** in the current National IG.

These gaps range from editorial clarifications (71%) to HL7 structure updates (24%) and new functionality (5%).



Definition Review & Approval

IGEG reviews proposed updates, incorporating community feedback.

We refine changes to ensure usability, clarity, and alignment with standards.



Voting & Consensus Process

IGEG members vote on finalized language and structure.

We incorporate approved updates into the next version of the guide.



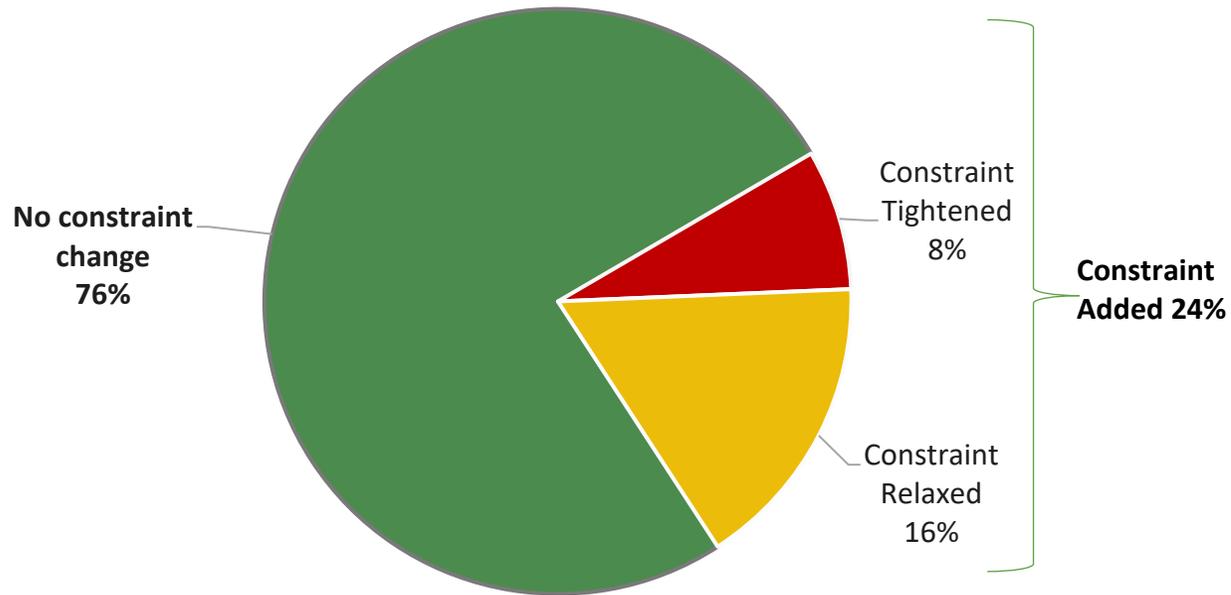
Finalization & Publication

The revised guide goes through the AIRA SISC review, HL7 ballot process, and ASTP's SVAP process.

Upon approval, we officially publish Release 2.0 of the HL7 v2.5.1 Implementation Guide (Release 2.0).

Release 2.0: Summary of Key Updates

Approved Work Items by Constraint Change
(N=103)



Most Common Work Item Categories

Work Item Category	Number of Items
RSP Guidance	9
General - Conformance	8
RXA Vaccine Code Guidance	8
PID Name Guidance	7
ACK and Error Guidance	6
General	6
OBX Guidance	6
Address and Tel Guidance	5
General - Coded Values	4
General - New Functions	4
PID Medical Record Number and State Registry Guidance	4
RXA Information Source Guidance	4

Introduction to HTI-2 and Our IG

- HITECH Act Title II (HTI-2) promotes health information technology adoption in the U.S.
- Advances HTI-1 objectives by emphasizing interoperability, data exchange standards, data quality, and public health reporting.



<https://blog.pocp.com/hubfs/HTI-2%20blog%20image.png>

Introduction to HTI-2 and Our IG

- HTI-2 emphasizes the National IG's crucial role in facilitating the sharing of vital immunization information between healthcare providers and public health
- HTI-2 also acknowledges IGEG's work towards Release 2.0
- Release 2.0 seeks to clarify guidance for implementers to ensure interoperability between EHR vendors and Immunization Information Systems (IIS)

Validation Tools Development & Compliance Review

- A public validation tool will be developed for Release 2.0 to help implementers ensure compliance with updated guidelines
- A validation tool will be developed using NIST's GVT to allow implementers to test HL7 message compliance before Release 2.0 regulation

The image shows a screenshot of the NIST GVT 1.2.0 website and a flow diagram of the tool architecture.

NIST GVT 1.2.0
NIST HL7 V2 General Validation Tool

Navigation: Home, Context-free, Context-based, Documentation, About

Welcome to the NIST General Validation Tool

Supporting

The General Validation Tool (GVT) is part of the **NIST HL7 v2 Standards Development and Testing Platform**. It utilizes artifacts developed in the NIST Implementation Guide Authoring and Management Tool (IGAMT) and Test Case Authoring and Management Tool (TCAMT), including validation services provided by the Testing Infrastructure and Framework, to allow users to develop conformance testing tools.

GVT is available to the public for conducting conformance testing of HL7 v2 messages. No User Account is needed for accessing the GVT test tools for executing conformance testing. Users must create an Account in order to use GVT for Tool Development purposes.

Have a Question?

A Google Group (HL7 v2 General Validation Tool) has been established for discussion/questions about the testing tool and testing issues. No membership is required. A Google account is required for posting.

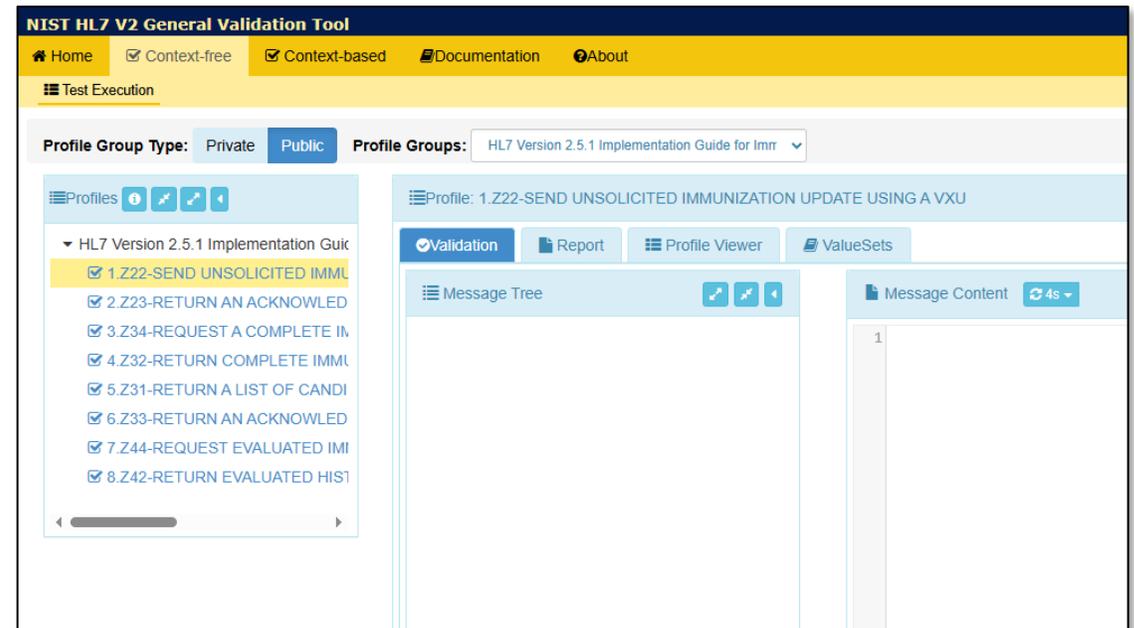
- Site: <https://groups.google.com/forum/#forum/nist-gvt>
- Email: nist-gvt@googlegroups.com

Flow Diagram:

The diagram illustrates the workflow of the NIST GVT. It starts with a user (represented by a person icon) interacting with the **IGAMT** (Implementation Guide Authoring and Management Tool). The IGAMT outputs HL7 messages (represented by document icons) to the **TCAMT** (Test Case Authoring and Management Tool). The TCAMT then outputs these messages to the **GVT (Context-Free & Context-Based Testing)** tool.

Validation Tools Development & Compliance Review

- This tool will help implementers verify correct application of new constraints in the upcoming release
- It will test logic related to constraints like usage and cardinality, helping identify potential issues early in implementation
- Implementers must also review the IG's narrative sections to ensure full compliance with all guidance



Regulatory Assistance & Support Resources

- Plans are in place to incorporate Release 2.0 into regulation, though it is not automatically entering
- **To assist EHRs and IIS:**
 - Additional guidance on the differences between current and new releases will be provided
 - Presentations and learning opportunities for implementers will occur
 - Other resources will be developed as the need arises

Conclusion

- Release 2.0 will clarify ambiguous guidance in the National IG, enhancing interoperability
- IGEG's work highlights the commitment to incorporating diverse stakeholder feedback, ensuring Release 2.0 meets all users' needs
- Release 2.0 will improve the National IG's accessibility and specifications, laying the groundwork for validation tools that ensure compliance and seamless data exchange between IISs and EHR systems

Conclusion

- Upon Release 2.0 publication, implementers will receive support through resources, training, and collaboration for a smooth transition and successful adoption.
- We encourage stakeholder engagement throughout this process—your insights are essential for creating an accessible and relevant IG for everyone!

Thank you!!

- **CDC**
 - Ciarra Nelson
 - Fikru Mekonnen
 - Stuart Myerburg
- **AIRA**
 - Nathan Bunker
 - Erin Roche
- **Implementation Guide Expert Group**

Additional Insights and Information

- **CDC is operating under communication restrictions**
 - May join online standards meetings to listen
 - Cannot contribute to standards work in these meetings
 - Cannot answer questions in these meetings
 - Can still work on projects internally
 - Can meet with partners individually
- **Impact on IGEG work**
 - Public work on hiatus since January
 - AIRA will work with CDC to restart in June

Questions?