

EHR Vendor Support for Meaningful Use Stage 2 Certification and Implementation

Direct Basics & Transitions of Care

February 19, 2013 2:00 PM EST



Initial Curriculum Topics



Today's Session is focused on: Direct 101, TOC Requirements, touching all 4 domains:

Domain **Topic** Domain **Topic** Direct 101 Real world Cross-vendor exchange TOC and VDT **Basic Requirements** Standards and implementation Trust Bundle Exchange & **Specifications** Optional Direct + XDR/XDM Scalable Trust for Direct Blue Button Plus and Direct Optional SOAP + XDR/XDM **HISP Services** C-CDA Info for end-users (Working with RECs, approach, considerations, cost, timing, Acceptable testing scenarios pilot lessons) TOC and VDT regulatory Counting numerators & Test procedures Certification interpretation denominators of MU Measures testing Test tools TOC via exchange option (formerly NwHIN)

Objectives and Agenda



- Review the basic Direct transport standard for MU Stage 2, how it supports Transitions of Care (TOC) requirements, and testing procedures and tools
- Begin a discussion of key considerations for Direct implementations in the real world (beyond testing)
- Today's agenda and speakers include:
 - Why transitions of care + measures and objectives (Travis Broome)
 - Direct overview and deep dive (John Hall)
 - Acceptable certification testing scenarios (Paul Tuten)
 - Certification testing procedures and tools (Asara Clark)
 - Open discussion (All)



Transition of Care Measures and Objectives

Travis Broome

Centers for Medicare and Medicaid Services

(CMS)

Meaningful Use & Certification Relationship "Transitions of Care" (ToC) Objective



Meaningful Use

- When looked across both Stages 1 & 2, the ToC objective includes 3 measures:
 - Measure #1 requires the provision of a summary of care record for more than 50% of transitions of care and referrals.

Stage 1 only

Stage 2

- Measure #2 requires that the provision of a summary of care record using electronic transmission through CEHRT or eHealth Exchange participant for more than 10% of transitions of care and referrals Stage 2
- Measure #3 requires at least one summary care record electronically transmitted to recipient with different EHR vendor or to CMS test EHR Stage 2

Exclusion:

Eligible professionals who have less than 100 transitions of care and referrals in the reporting period do not have to meet these measures

Note: For any of these measures it is important to remember that the recipient does NOT also have to have Certified EHR Technology.

2014 Edition Certification

- Two 2014 Edition EHR certification criteria
- 170.314(b)(1): Transitions of care receive, display, and incorporate transition of care/referral summaries
- 170.314(b)(2): Transitions of care create and transmit transition of care/referral summaries.

Feature Focus: ToC Measure #2 & 170.314(b)(2)



ToC Measure #2

- The eligible provider, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 10% of such transitions and referrals either:
 - (a) electronically transmitted using CEHRT to a recipient; or
 - (b) where the recipient receives the summary of care record via exchange facilitated by an organization that is a NwHIN Exchange participant or in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network.

170.314(b)(2)

- Transitions of care—create and transmit transition of care/referral summaries.
 - (i) Enable a user to electronically create a transition of care/referral summary formatted according to the Consolidated CDA with, at a minimum, the data specified by CMS for meaningful use.
 - (ii) Enable a user to electronically transmit CCDA in accordance with:
 - "Direct" (required)
 - "Direct" +XDR/XDM (optional, not alternative)
 - SOAP + XDR/XDM (optional, not alternative)



Direct Overview and Deep-Dive

John Hall Coordinator, Direct Project

What is the Direct Project?



A project to create the set of **standards** and services that, with a policy framework, enable simple, directed, routed, scalable transport over the Internet to be used for secure and meaningful exchange between known participants in support of meaningful use.



Direct: Secure Directed Exchange via the Internet







b.wells@direct.aclinic.org

h.elthie@direct.ahospital.org

- Simple. Connects healthcare stakeholders through universal addressing using simple push of information.
- Secure. Users can easily verify messages are complete and not tampered with en route.
- **Scalable.** Enables Internet scale with no need for central network authority that must provide sophisticated services such as EMPI, distributed query/retrieve, or data storage.
- **Standards-based**. Built on well-established Internet standards, commonly used for secure e-mail communication; i.e.,. SMTP for transport, S/MIME & X.509 certificates for encryption and integrity protection

Key Concepts in Direct



- Direct enables push-based transport a sender pushes information to one or more recipients
- Direct Messages act as containers of health information
- Direct Addresses are used to route Direct Messages
- Digital certificates are used to protect Direct Messages in transit and to express trust relationships
- SMTP is used to transport Direct Messages
- Security/Trust Agents (STAs) such as Health Information Service Providers (HISPs) are responsible for providing the services necessary for exchange using Direct

Direct Messages



- Direct Messages are like secure email messages
 - Comply with RFC 5322
 - Headers
 - Contents text plus attachments
 - Security information signatures, certificate information as applicable
- Contents can be structured or unstructured
 - Text and other human-readable representations
 - Consolidated CDA (CCDA), CCD, CCR
 - PDF, TIFF
 - Office documents
 - HL7 lab results
 - IHE XDM specifications

Direct Addresses



- Direct Addresses are used to route information
 - Look like email addresses
 - Used <u>only</u> for health information exchange



- Direct Addresses may route to an inbox of a person, a task or workflow queue handled by one or more people, a data repository or registry, or other types of endpoints
- A person may have multiple Direct Addresses, one or more for each organizational affiliation

Direct & Digital Certificates



- Each Direct Address must have at least one X.509v3 digital certificate associated with it
 - Address-bound certificate certificate bound to a specific Direct Address
 - Organizationally-bound certificate certificate bound to the Domain that is part of a Direct Address and tied to the organization exchanging information using Direct
- Digital certificates are used within Direct to express trust relationships and to secure Direct Messages in transit by encrypting and signing information.
- Direct certificates are discovered using DNS+LDAP
 - First search DNS for address-bound certificates, moving to organizationallybound if none are found
 - Repeat with LDAP if no certificates are found in DNS
 - Note that, to support universal discovery, certificates can be published using either DNS or LDAP, but do not have to be published with both

Digital Certificate Issuance

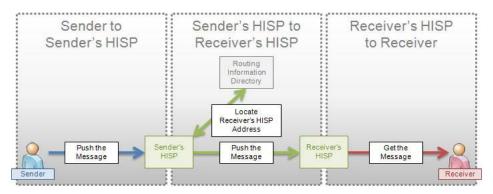


- Registration Authority (RA)
 - Collects information for the purpose of verifying the identity of an individual or organization (i.e., identity proofing)
 - Produces certificate requests based on gathered attributes
- Certificate Authority (CA)
 - Digitally signs certificate requests
 - Issues digital certificate that ties a public key to the gathered attributes

STAs and HISPs



- Security/Trust Agents (STAs) are responsible for securing, routing, and processing Direct Messages
 - STA may be a system under the direct control of an exchange participant
 - STA may be a service offered by an intermediary, known as a Health Information Service Provider (HISP), acting on behalf of an exchange participant
- STAs and HISPs are responsible for performing a number of services required for the exchange of health information as defined by the Direct Project
 - Provide Direct Addresses
 - Publish and find digital certificates
 - Secure health information in transit using S/MIME and certificates
 - Route and transport Direct Messages using Direct Addresses and SMTP
 - Depending on implementation model (e.g., web portal), possibly store Direct Messages



How do HISPs relate to RAs and CAs?



HISPs can relate to RAs and CAs in a number of ways.

A HISP may ...

Act as RA and CA. HISP identity proofs during enrollment and issues certificates as appropriate.

Act as RA only. HISP identity proofs during enrollment, passing necessary information to an independent CA. CA provides certificate to HISP upon issuance.

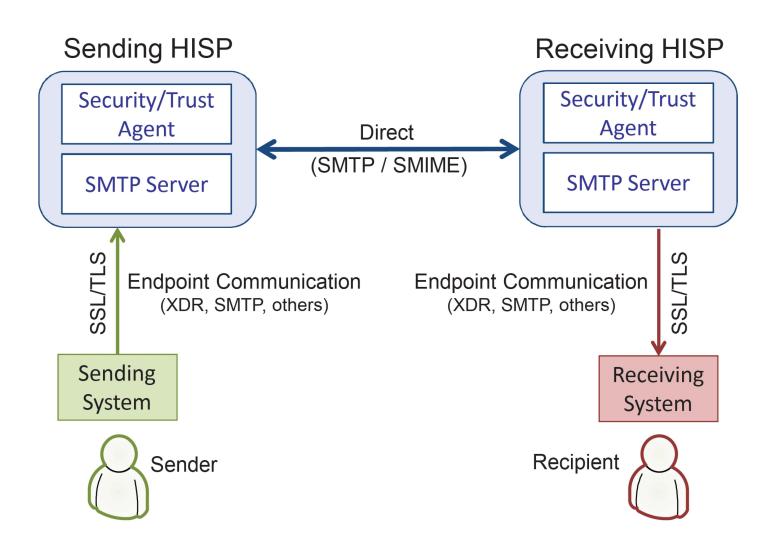
Act as CA only. Independent RA identity proofs during enrollment in HISP, passing necessary information to HISP, which issues certificates as appropriate.

Act as neither CA nor RA. Independent RA identity proofs during enrollment in HISP, passing necessary information to independent CA, which provides certificate to HISP upon issuance.

Source: Direct Implementation WorkGroup – John Hall – July 03, 2011

An Example Direct Scenario





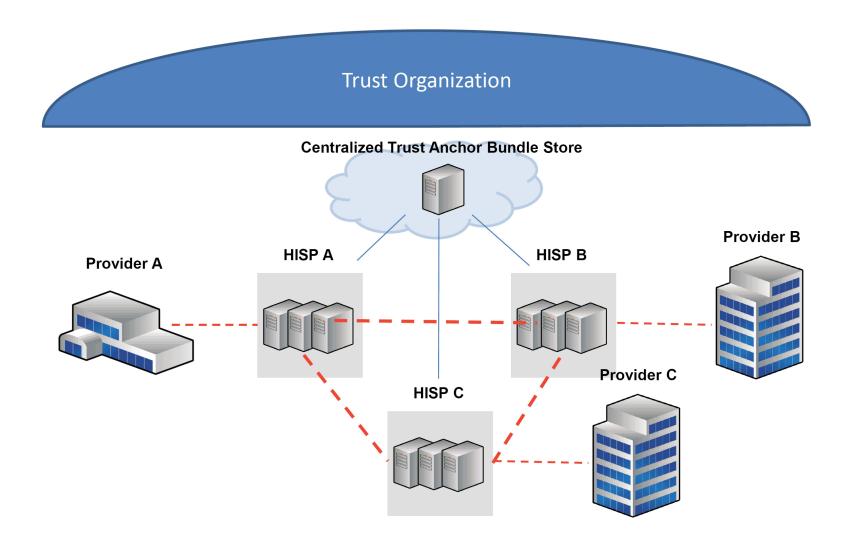
Direct and Trust



- Communication using Direct can only occur between trusted parties.
 - Sender and recipient may each individually manage trust relationships.
 - STAs/HISPs may manage trust relationships on behalf of their participants.
 - Both of the above may be true in a given environment.
- Trust relationships are expressed using digital certificates. A party may choose to trust a specific certificate, as well as any certificate that cryptographically chains to a trust anchor.
- Certificates are issued only to parties that agree to abide by specified trust policies. These policies often cover:
 - Certificate applicability (i.e., purposes for which certificates are issued)
 - Identity proofing and registration of parties
 - Security requirements of parties
- Setting trust policy is <u>outside</u> the domain of the Direct Project.
 - For health information exchange, policy originates with the HITPC and ONC
 - Trust communities have emerged to address these issues, urge adoption of solutions across participants and avoid the need for peer-to-peer exchange agreements

Direct and Trust Communities







Certification Options

Paul Tuten
State HIE Program

3 Valid Certification Options for EHR Technology

(to meet minimum certification requirement)



www.HealthIT.gov

45 CFR 170.314(b)(2)

- Create CCDA with requisite data specified for MU
- Enable a user to electronically transmit ToC in accordance with "Direct" (or "Direct" +XDR/XDM; or SOAP + XDR/XDM)

Option 1

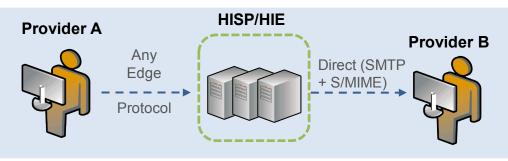
1.EHR generates CCDA 2.EHR performs as STA and sends Direct msg



STA/HISP function integrated into EHRs; no separate certification testing for HISP.

Option 2

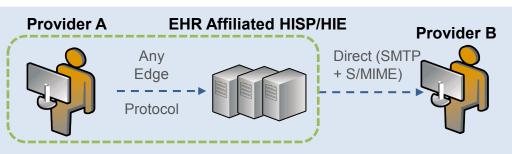
1.EHR sends "data" to HISP 2.HISP generates CCDA 3.HISP performs as STA and sends Direct msg



HISP/HIE certified on its own.

Option 3

1.EHR generates CCDA 2.EHR sends CCDA to HISP 3.HISP performs as STA and sends Direct msg



HISP/HIE certified as "relied upon software" with the EHR. Certification given to the pair, not separately to EHR and HISP.

To be, or not to be a HISP, that is the question



- HISP = Health Information Service Provider, and being a service provider means ongoing responsibilities that often include:
 - Developing, maintaining, and enforcing participation agreements
 - Providing online and phone support for onboarding, connectivity issues and outages, and other service needs
 - Assigning and managing (directly or through delegation) Direct domains and addresses
 - Provisioning, managing, and publishing certificates using DNS or LDAP
 - Maintaining trust relationships, possibly entailing joining a trust community and fulfilling its accreditation and other membership requirements
 - Ensuring Direct Security/Trust Agent (STA), certificate publication, and other customersupporting services are available and perform to the needs of customers
- Partnering with a HISP can an alternative to being a HISP
 - EHR would certify in combination with one or more HISPs ("relied-upon software")
 - EHR could also additionally certify to SOAP+XDR, enabling connectivity with any HISP that supported that connection mechanism
 - In the field, each partner can then focus on the responsibilities and functions within their core competencies



Certification Testing Procedures and Tools

Asara K. Clark

Office of Certification

Office of the National Coordinator for Health IT (ONC)

ONC resources for 2014 Testing and Certification



- Latest version of Test Method (Test Procedures, Test Data, and Test tools) posted on Healthit.gov
- Version Overview matrix for summary of all test procedure versions and dates revised

http://www.healthit.gov/policy-researchers-implementers/2014edition-final-test-method

2014 Standards and Certification Criteria Direct Testing



The 2014 Standards and Certification Program employs three test procedures to test a Complete EHR's ability to send or receive messages via Direct:

- 1. 170.314(b)(1) Transitions of Care Receive, Display and Incorporate Transitions of Care/Referral Summaries (Ambulatory and Inpatient Settings)
- 2. 170.314(b)(2) Transitions of Care Create and Transmit Summary Care Records (Ambulatory and Inpatient Settings)
- 3. 170.314(e)(1) View, Download, Transmit to 3rd Party (Ambulatory and Inpatient Settings)

Note:

The current published version of this test procedure includes strikethrough text to indicate capabilities that were not available in the Transport Testing Tool prior to February 15th.

An updated version of the Transport Testing Tool was released on February 15th, and the test procedures and corresponding strikethrough text will be updated to reflect capabilities currently available in the tool.

2014 Standards and Certification Criteria Testing Tools for Direct



The Transitions of Care (ToC) Test Procedures use the **Transport Testing Tool (TTT)** and the **Direct Certificate Discovery Tool (DCDT)** to verify successful transmission and packaging of health information according to document architecture and transport standards

- The Transport Testing Tool (TTT) (developed by the National Institute of Standards and Technology (NIST)) supports certification through testing of the following capabilities:
 - Sending Messages
 - Direct with S/MIME
 - Simple Object Access Protocol (SOAP) with C-CDA Attachments
 - Direct with XDM Attachment Messages
 - Receiving Messages
 - Direct with S/MIME
 - Direct with XDM Attachment Messages
 - SOAP
 - Document Validation
 - C-CDA-based content (MDHT validation)
- The Direct Certificate Discovery Tool (DCDT) (developed by ONC) tests the ability of an EHR technology to correctly discover and host address-bound and domain-bound certificates

Direct Certificate Discovery Tool



The Direct Certificate Discovery Tool (DCDT) was created to support automated testing of systems implementing the Certificate Discovery for Direct Project Implementation Guide. This IG ensures systems conform to the requirements for MU2 (Applicability Statement for Secure Health Transport).

DCDT tests the infrastructure that stores and utilizes the certificates required for secure Direct communication. This infrastructure typically includes DNS and LDAP servers that contain certificates and trust anchors.

A DCDT instance is used in conjunction with the "System Under Test" (SUT) to determine if the SUT correctly performs the 5 Hosting Tests and the 11 Discovery Tests.

DCDT - Components



In addition to the tool itself, there are a suite of utilities that are available to aid in the testing process. The DCDT instance also utilizes a Java Direct RI. The utility suite consists of:

- Configuration Generator (configgen) generates deployment-specific versions of the property files used by the web application portion of the Direct Certificate Discovery Tool.
- Data Generator (datagen) generates deployment-specific private keys, certificates, and keystores as needed by the web application portion of the Direct Certificate Discovery Tool.
- Data Loader (dataloader) loads deployment-specific certificates, keystores,
 DNS entries, and Agent settings into a specified Direct Java RI Configuration Service.
- LDAP Loader (Idaploader) creates and (optionally) loads deployment-specific
 LDAP Data Interchange Format (LDIF) files.

DCDT Discovery Flow



The basic discovery flow checks for certificates in the following order:

- 1) Address-bound DNS CERT Resource Record
- 2) Domain-bound DNS CERT Resource Record
- 3) Address-bound entry in an LDAP Server
- 4) Domain-bound entry in an LDAP Server

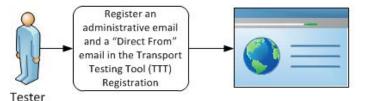
170.314(b)(2) ToC – create and transmit summary care records



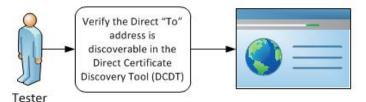
- Required: Create and transmit a Summary of Care record (C-CDA) using Direct
- Optional: Transmit using Direct with XDM attachments or transmit using SOAP with C-CDA attachments
- Test Procedure Steps involving the Direct Transport Specification
 - Create
 - Transmit
 - EHR can discover certificates from other parties in DNS CERT records and LDAP servers
 - EHR is able to create and store a listing of Direct recipients
 - Transmit C-CDA to the Transport Testing Tool using the Direct (with S/MIME) transport specification
 - Validation report indicates success of transmission, success of decryption, and C-CDA XML output
 - Visual inspection of report required to validate C-CDA content

170.314(b)(2) ToC – create and transmit summary care records

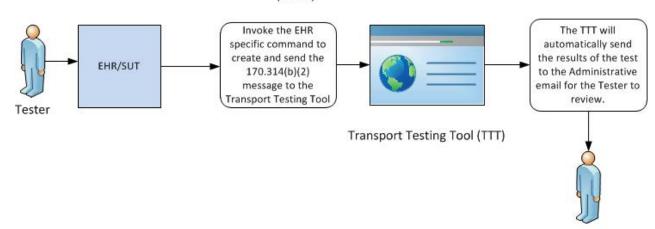


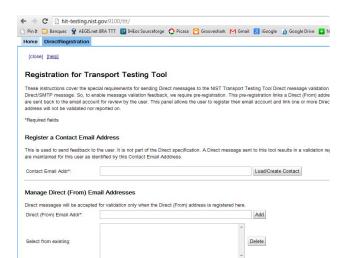


Transport Testing Tool (TTT)



Direct Certificate Discovery Tool (DCDT)





Validation Results

Valiation from Fri Feb 15 19:54:59 UTC 2013

Summary: Errors were found Time of validation: Client IP Address: 0.0.0.0

Detail

Message Validator

The file was recognized as a DIRECT message.

Encrypted Message

- ----Orig-Date: Fri, 15 Feb 2013 19:54:51 -0000
- ----From: test1user1@directtest1.com
- ----To: direct-clinical-summary@ttt.transport-testing.org
- -----Message-Id: <7fbe9f8f182ed6c86f1172ba62aa2dce.squirrel@localhost>
- -----MIME-Version: 1.0
- ----Received:

Tester

- ----Reply-To: test1user1@directtest1.com
- ----Content_tyne: annlication/nkcs7-mime: name=smime n7m: smime_tyne=er

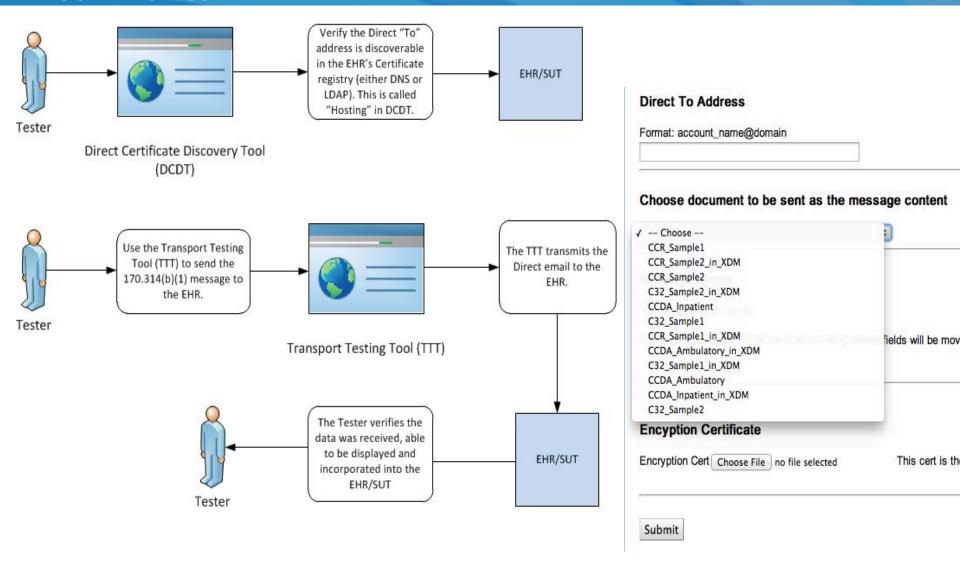
170.314(b)(1) ToC – Receive, Display, and Incorporate Transition of Care/Referral Summaries



- Required: Receive a Summary of Care record (C-CDA) using Direct
- Optional: Receive using Direct with XDM attachments or transmit using SOAP with C-CDA attachments
- Test Procedure Steps Involving the Direct Transport Specification
 - Receive
 - Verifies the EHR hosted certificates in either DNS CERT records or LDAP servers that are discoverable by others
 - Send C-CDA, CCR, C/32 documents using Direct from the Transport Testing Tool to the EHR Tests both RFC-5751 wrapped and unwrapped messages, based upon vendor capabilities
 - Negative tests:
 - Invalid trust anchor
 - Invalid certificate
 - Expired certificate
 - Revoked certificate
 - Certificate with invalid trust relationship
 - The Tester verifies successful receipt of the health information by the EHR, and that the health information can be successfully decrypted and that a Message Delivery Notification (MDN) is sent by the EHR to the Transport Testing Tool
 - Display (C-CDA, CCR, C/32) and Incorporate (C-CDA only)

170.314(b)(1) ToC – Receive, Display, and Incorporate Transition of Care/Referral Summaries



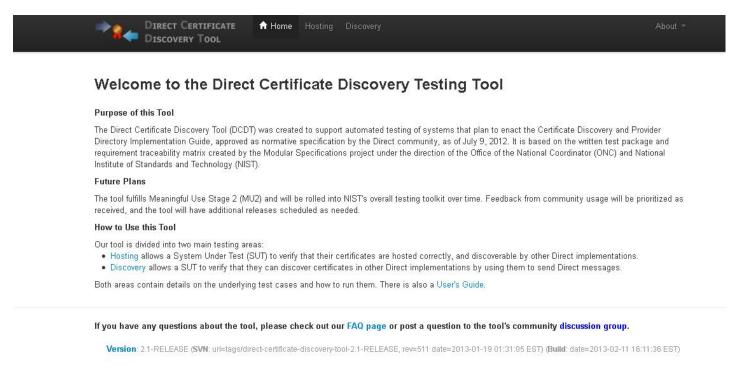


DCDT Resources



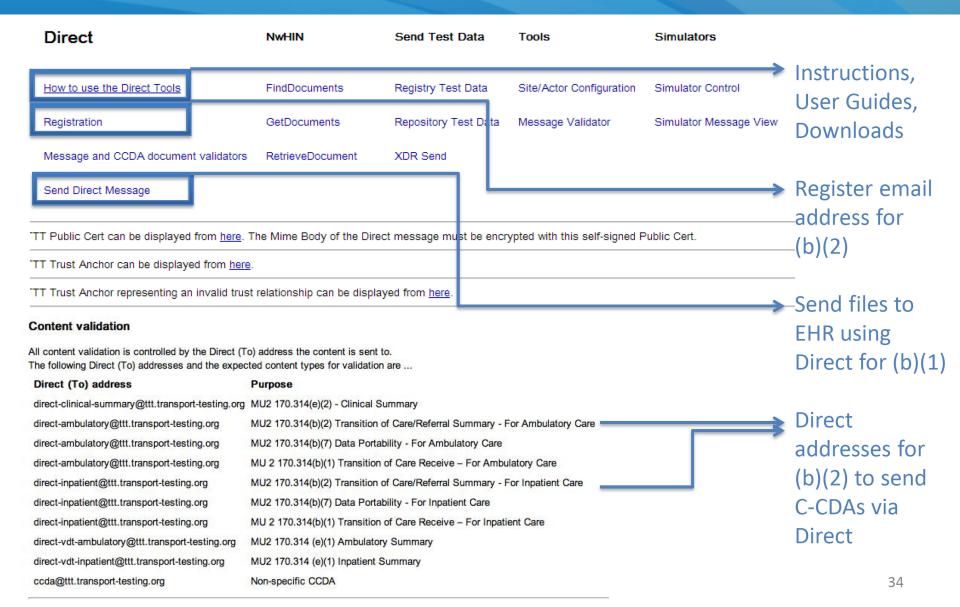
The source code, user's guide, and a support forum are available at http://code.google.com/p/direct-certificate-discovery-tool/

A working instance of the tool is available at <u>direct-test.com</u> (snapshot below)



Transport Testing Tool Homepage





Transport Testing Tool Support & User Guide



Table of Contents

- Online version available at http://transport-testing.nist.gov
- User guides, local installation information available at: http://healthcare.nist.gov/ttt
 .html

OVE	RVIE	w		3					
	Role	of NIST		3					
			ing Tool						
	Purpose								
	Access								
	Testing Overview.								
1.0	REGISTRATION								
		1.1.1	Registering a DIRECT web address	8					
			Registering a SOAP web address						
			Diagram for Send/Receive by MU Objective						
2.0	SENDING C-CDA MESSAGES TO THE TRANSPORT TESTING TOOL								
	2.1	Send a I	Direct Message to the TTT	11					
	2.2 Send a Direct + XDM message to the TTT								
	2.3 Send a SOAP message to the TTT								
3.0	SEN	SENDING MESSAGES FROM THE TRANSPORT TESTING TOOL TO A SYSTEM UNDER TEST 16							
	3.1	3.1 Send a Direct message to a System Under Test							
	3.2								
	3.3 Send a SOAP message to a System Under Test								
4.0	MAI	NUALLY	VALIDATING C-CDA	21					
5.0	APPENDIX								
	5.1	170.314	(b)(2) Transitions of Care (Ambulatory)	23					
	5.2		(b)(2) Transitions of Care (Inpatient)						
	5.3		(b)(7) Data Portability (Ambulatory)						
	5.4	170.314	(b)(7) Data Portability (Inpatient)	29					
	5.5	170.314	(e)(1) View, Download, Transmit to 3rd Party (Ambulatory)	31					
	5.6		(e)(1) View, Download, Transmit to 3rd Party (Inpatient)						
	5.7 170.314(b)(2) Clinical Summary								

Resources



- Modular Specification more information and tooling to support Direct Specifications
 - Description of RTM requirements tractability matrix
 - Test implementation and test tools wiki
 - Test Implementation/ Demos and Pilots
 - http://modularspecs.siframework.org/Directed+Exchange+Artifacts
- Transport Test Tool (TTT)
 - Hosted on NIST website: http://transport-testing.nist.gov
 - Local Tool Installation: http://healthcare.nist.gov/ttt.html
 - User Guide: http://healthcare.nist.gov/docs/TransportTestingTool--User Guide.pdf
 - Release Notes: http://transport-testing.nist.gov/ttt/doc/release_notes.html
 - If you have any questions or issues with using the TTT, please submit them to the Transport Testing Tool Google Group: https://groups.google.com/d/forum/transport-testing-tool
- Direct Certificate Discovery Tool (DCDT)
 - DCDT Version 2.1: https://direct-certificate-discovery-tool.googlecode.com/svn/tags/direct-certificate-discovery-tool-2.1-
 RELEASE
 - User Guide: http://code.google.com/p/direct-certificate-discovery-tool/wiki/User Guide 2 1
 - Release Notes: http://code.google.com/p/direct-certificate-discovery-tool/wiki/Release Notes 2 1
 - If you have any questions or issues with using DCDT, please log issues at the Direct Certificate Discovery Tool Google Group: https://groups.google.com/forum/?fromgroups#!forum/directtesttool
- Direct Project Implementation Geographies Work Group
 - Direct implementers meet weekly to review and discuss implementation challenges and issues
 - http://wiki.directproject.org/Implementation+Geographies

Upcoming HIMSS Sessions of Interest



Tentative Title	Session #	Day	Start Time	End Time	Speakers
The Ins and Outs of Meaningful Use: Understanding Stage 1 Changes & Stage 2 Requirements	4	Monday, March 4	9:45am	10:45am	 Robert Anthony, Policy Analyst, Health IT Group, Office of E-Health Standards and Services, CMS Steve Posnack, Director, Federal Policy Division, Office of the National Coordinator for Health IT
Stage 1: CMS EHR Incentive Programs	23	Monday, March 4	11:00am	12:00pm	 Elizabeth Holland, Director, Health IT Group, Office of E-Health Standards and Services, CMS Robert Anthony, Policy Analyst, Health IT Group, Office of E-Health Standards and Services, CMS Jason McNamara, Technical Director for Health IT, CMS
Stage 2: CMS EHR Incentive Programs	62	Tuesday, March 5	9:45am	10:45am	 Elizabeth Holland, Director, Health IT Group, Office of E-Health Standards and Services, CMS Travis Broome, Policy Analyst, Health IT Group, Office of E-Health Standards and Services, CMS Jason McNamara, Technical Director for Health IT, CMS Steven Posnack, Director, Federal Policy Division, Office of the National Coordinator for Health IT
CMS Town Hall: CMS and eHealth: Building the Future	81	Tuesday, March 5	1:00pm	2:00pm	 Robert Tagalicod, Director, Office of E-Health Standards and Services, CMS Elizabeth Holland, Director, Health IT Group, Office of E-Health Standards and Services, CMS Christine Stahlecker, Director, Administrative Simplification Group, Office of E-Health Standards and Services, CMS Maribel Franey, Director, Privacy Policy Compliance Group, Office of E-Health Standards and Services, CMS
Making MU Stage 2 Exchange Requirements work in the Real World	Not listed in brochure – room 293	Tuesday, March 5	3:30pm	5:30pm	More info coming soon

	HIMSS C	Cont.		Putting the I in Health IT		
	Tentative Title	Session #	Day	Start Time	End Time	Speakers
	ICD-10 and Administrative Simplification	138	Wednesday, March 6	9:45am	10:45am	 Christine Stahlecker, Director, Administrative Simplification Group, Office of E-Health Standards and Services, CMS Matthew Albright, Lead Health Insurance Specialist, Administrative Simplification Group, Office of E-Health Standards and Services, CMS Kari Gaare, Health Insurance Specialist, Administrative Simplification Group, Office of E-Health Standards and Services, CMS Denesecia Green, Health Insurance Specialist, Administrative Simplification Group, Office of E-Health Standards and Services, CMS
	Direct & Scalable Trust	Interop Showcase Edu Theater B	Wednesday, March 6	3:30pm	4:00pm	 Paul Tuten, Senior Advisor, HHS Office of the National Coordinator for Health IT
	ONC Health IT Certification Program: Multi Agency Panel Discussion	159	Thursday, March 7	10:00am	11:00am	 Judy Murphy, Deputy National Coordinator for Programs and Policy, Office of the National Coordinator for Health IT Carol Bean, Director, Office of Certification and Testing, Office of the National Coordinator for Health IT
	CMS Quality Measurement	178	Thursday, March 7	11:15am	12:15pm	 Maria Michaels, Quality Measures & Health Assessment Group, Office of Clinical Standards and Quality, CMS Deborah Kraus, Quality Measures & Health Assessment Group, Office of Clinical Standards and Quality, CMS Maria Harr, Quality Measures & Health Assessment Group, Office of Clinical Standards and Quality, CMS
ONC HIE Town Hall		191	Thursday, March 7	11:15am	12:15pm	 Farzad Mostashari, National Coordinator for Health Information Technology Claudia Williams, Director State HIE Program, ONC Douglas B. Fridsma, Director Office of Science and Technology, ONC Steven Posnack, Director Federal Policy Division Office of Policy and Planning, ONC

Wrap-Up



- Thank you for joining!
- We welcome your feedback regarding today's session. Please continue to share pain points and need for information in ongoing manner through this WG
- Please e-mail <u>Julie.Crouse@hhs.gov</u>