Integrating the Healthcare Enterprise

IHE Pathology and Laboratory Medicine Technical Framework Supplement

Transfusion Medicine - Administration (TMA)

Rev. 2.1 – Trial Implementation

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Author: IHE PaLM Technical Committee

Email: PaLM@ihe.net

Please verify you have the most recent version of this document. See here for Trial Implementation and Final Text versions and here for Public Comment versions.

Foreword

This is a supplement to the IHE Pathology and Laboratory Medicine (PaLM) Technical Framework V10.0. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is published for trial implementation on October 22, 2019 and may be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results of testing. Following successful testing it will be incorporated into the Pathology and Laboratory Medicine Technical Framework. Comments are invited and may be submitted at http://ihe.net/PaLM_Public_Comments.

This supplement describes changes to the existing technical framework documents.

"Boxed" instructions like the sample below indicate to the Volume Editor how to integrate the relevant section(s) into the relevant Technical Framework volume.

Amend Section X.X by the following:

Where the amendment adds text, make the added text **bold underline**. Where the amendment removes text, make the removed text **~~bold strikethrough~~**. When entire new sections are added, introduce with editor's instructions to "add new text" or similar, which for readability are not bolded or underlined.

General information about IHE can be found at www.ihe.net.

Information about the IHE Pathology and Laboratory Medicine domain can be found at http://www.ihe.net/IHE_Domains.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at http://www.ihe.net/IHE_Process and http://www.ihe.net/Profiles.

The current version of IHE Pathology and Laboratory Medicine Technical Framework can be found at https://www.ihe.net/resources/technical_frameworks/.

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Introduction to this Supplement

The primary function of the full clinical transfusion medicine workflow is to ensure the appropriate matching & release of compatible blood products from an institutional supply to an individual patient recipient. Although there are shared elements with medical oncology/chemotherapy and genomic-based medicine, this particular function and the individualized precision it requires is largely unique within the current field of medicine aside from the closely related discipline of solid organ transplantation.

The Transfusion Medicine – Administration (TMA) supplement defines workflows and messaging transactions which focus on communicating the administration of and adverse reactions to blood products from an Electronic Medical Record (EMR) system to a Laboratory Information System (LIS), Incident Reporting System (IRS), or other interested observer of the transfusion process. These additions update the Technical Framework volumes 1 and 2.

Prior parts of the full clinical transfusion medicine workflow including patient testing and product ordering, as well as subsequent product dispensing and internal inventory/tracking, will be detailed in additional supplements. These are provisionally expected to be Transfusion Medicine – Ordering (TMO) and Transfusion Medicine – Dispense (TMD).

Open Issues and Questions

1. We have an expectation that two additional related profiles may be written in the future, to address upstream workflow considerations (tentatively to be titled Transfusion Medicine – Dispense [TMD] and Transfusion Medicine – Ordering [TMO]). This document will need to be amended when those are available with any changes to synchronize and cross-reference the whole family of profiles (at least including Section X.6 – TMA Cross Profile Considerations).
2. This profile does not extensively address the handling of transfusion reaction documentation, lab work-up, and reporting as the HL7®[1] specifications do not currently have enough capability to capture the necessary details. If future HL7 changes increase the capability to report reaction-related data, this profile will be updated to accommodate that as we believe that reaction-related integration *would* be IN SCOPE for this part of the workflow.
3. Scope of the TMA workflow does not include the receipt of the blood product unit. The scope of TMA shall start with the start of the transfusion.

   Check the Volume 2 3.Y.4.1.1 Trigger Events

[1] HL7 is the registered trademark of Health Level Seven International.

Closed Issues

1. Does the profile adequately differentiate between the blood products which are intended to be in scope for transfusion and various other derived products which are not (these are typically handled by a pharmacy workflow)?

   Based on committee review during the Nov 2017 face-to-face meeting in Cagliari, these in scope and out of scope product definitions appear as clear as we can make them until specific clarifications are requested by other readers.

   - In case of using PLASMA products, and the use of ISBT-128, it SHALL be required to communicate the full "ISBT-128 Donation Identification Number" which will include the FLAG-characters to have the product unit identifier unique. When this "ISBT-128 Donation Identification Number" is not unique, "ISBT-128 Product Code" shall be required too. See also Volume 1 "X.1.1.1 Blood Transfusion Documenter" : [the Blood Transfusion Documenter SHALL persist and return the unique product unit identifiers provided by the Blood Product Filler in issue/dispense steps of the workflow in order to be able to appropriately indicate the final disposition of each unit]
   - In Belgium: Blood Units provided by the Red Cross will always have "00" as FLAG.

2. We believe there may be a need for an additional workflow in which the Blood Transfusion Documenter queries the Blood Product Filler to confirm whether a specific unit of blood product is appropriate for a given patient, based on the results of blood type and antibody screen testing. Is this a real workflow that would be valuable to include in this profile? If so we invite more feedback on when & how it is performed.

   Based on research of real-world workflows either in use or requested by implementing organizations, we believe that there could be multiple times in the full transfusion medicine workflow at which a clinician might query for appropriateness. These could include steps earlier in the workflow than is in scope for TMA (e.g., in the dispensing process if a clinician takes a floor stock product from a general-use automated dispensing station (O-negative RBCs)

3. When does the workflow end in case of an interrupted transfusion? Will the documenter inform about the END of the transfusion, or can we consider the Interrupt as a sign to end the transfusion? See Volume 1 USE-CASE 2 (X.4.2.2 Use Case #2: Single Administration with interruption).

   Assume BTX-11=TI as Transfusion Ended with Interrupt

4. We believe that it will be necessary to request additions to HL7's Table 0513 (BLOOD PRODUCT TRANSFUSION/DISPOSITION STATUS) to include more granular statuses which may be documented during administration such as Start Transfusion, Stop Transfusion, etc. What kinds of status options might be helpful to include, from either a Documenter or Filler perspective?

a. At this time, we expect to include additional statuses of Unit Received, Begin Transfusion and Interrupt Transfusion and the interaction diagram in Section 3.Y.4 reflects some of the actions at these additional statuses.

b. Suggested values discussed during the Face-2-Face meeting 29-May-2019 :

1. TS : Transfusion Started
2. TI : Transfusion Interrupted
3. TX : Transfused
4. TR : Transfused with Reactions

5. What version of HL7 should we use for this profile – V2.5.1 or the latest (V2.8.2)?

   We chose HL7 V2.5.1 version, because the core profiles of the PaLM TF (including the LTW Profile, which conveys orders and results for blood bank tests) is based on V2.5.1. This same version is chosen for the TMA Profile.

General Introduction

Update the following Appendices to the General Introduction as indicated below. Note that these are not appendices to Volume 1.

Appendix A – Actor Summary Definitions

Add the following actors to the IHE Technical Frameworks General Introduction list of actors:

Actor	Definition
Blood Transfusion Documenter	Documents the administration of blood products to a patient and informs other systems of this process, given all requisites of prior testing, product cross-matching, and dispensing by other actors. This actor is typically used in a direct patient care setting.
Blood Product Filler	Issues specific units of blood product to specific patients, after all requisite prior testing & cross-matching, based on appropriate orders so that they may be acted upon. It, then, captures evens regarding the administration of these blood products. This actor is typically used in a blood bank setting.

Appendix B – Transaction Summary Definitions

Add the following transactions to the IHE Technical Frameworks General Introduction list of Transactions:

Transaction	Definition
Blood Administration Status [LAB-70]	This transaction provides the messages from a Blood Transfusion Documenter to a Blood Product Filler which indicate the status of a patient transfusion. It communicates events/statuses such as “complete”, “begin”, “suspend” and “resume”. The transaction may refer to one or more individual blood products.

Glossary

Add the following glossary terms to the IHE Technical Frameworks General Introduction Glossary:

Glossary Term	Definition
Blood product	Any component of the blood that is collected from a donor to be transfused to a recipient. It most commonly will be specific processed components such as red blood cells, blood plasma, platelets, or whole blood. Medications incorporating blood components are out of scope for laboratory profiles and should be considered under Pharmacy profiles.
Transfusion	The process of administering one or more prepared blood products to a patient.
Adverse transfusion reaction	Any undesirable and unintended patient condition change before, during or after transfusion of blood products that may be related to the administration of one or more individual product units.

Volume 1 – Profiles

Copyright Licenses

None

Add the following to the IHE Technical Frameworks General Introduction Copyright section:

Domain-specific additions

None

Add Section X

X Transfusion Medicine - Administration (TMA) Profile

The Transfusion Medicine - Administration (TMA) Profile provides specifications for clearly communicating the status and outcomes of workflows pertaining to administration of prepared blood products to a patient.

The TMA Profile represents the third and final portion of the full clinical transfusion medicine workflow. The first and second portions are ordering & testing, and product dispensing with inventory tracking. These prior workflow elements will be described in other profiles and together the three profiles will specify the full integration needs from the recipient's perspective in transfusion medicine.

Transfusion adverse reactions (suspected) documentation by the Blood Transfusion Documenter, as well as confirmatory testing in the Blood Product Filler or subsequent reporting to any other consumer of that information, are not covered by this version of the profile until further enhancement of the base standard, as explained in Open Issue #2.

Donor-perspective workflows are not currently defined.

X.1 TMA Actors, Transactions, and Content Modules

This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A at http://ihe.net/Technical_Frameworks.

Figure X.1-1 shows the actors directly involved in the TMA Profile and the relevant transactions between them. If needed for context, other actors that may be indirectly involved due to their participation in other related profiles are shown in dotted lines. Actors which have a mandatory grouping are shown in conjoined boxes.

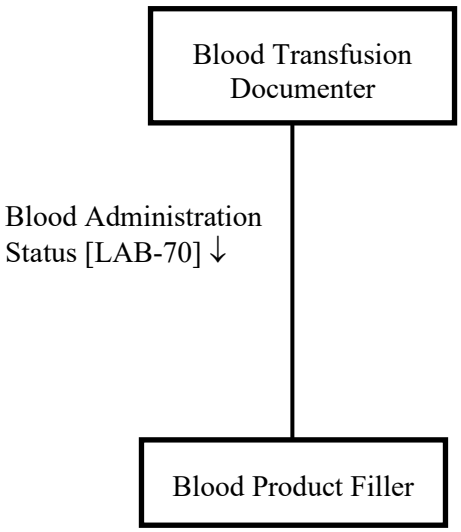

Figure X.1-1: TMA Actor Diagram

Table X.1-1 lists the transactions for each actor directly involved in the TMA Profile. To claim compliance with this profile, an actor shall support all required transactions (labeled "R") and may support the optional transactions (labeled "O").

Table X.1-1: TMA Profile - Actors and Transactions

Actors	Transactions	Optionality	Reference
Blood Transfusion Documenter	Blood Administration Status [LAB-70]	R	PaLM TF-2: 3.Y
Blood Product Filler	Blood Administration Status [LAB-70]	R	PaLM TF-2: 3.Y

X.1.1 Actor Descriptions and Actor Profile Requirements

Most requirements are documented in Transactions (Volume 2). This section documents any additional requirements on profile's actors.

X.1.1.1 Blood Transfusion Documenter

The Blood Transfusion Documenter represents the direct patient care system in which administrations of blood product are electronically documented. This role is typically fulfilled by an integrated EMR, dedicated nursing records system, or stand-alone transfusion administration system.

The Blood Transfusion Documenter must have information established in prior steps of the clinical transfusion medicine workflow to ensure that patient type and screen results are performed, and that individual product units are appropriately issued and dispensed to the patient. In some cases, this actor may have even been a primary participant in those prior workflow steps, such as when an integrated EMR is used for order placing as well as transfusion documentation.

In particular, the Blood Transfusion Documenter SHALL persist and return the unique product unit identifiers provided by the Blood Product Filler in issue/dispense steps of the workflow in order to be able to appropriately indicate the final disposition of each unit.

X.1.1.2 Blood Product Filler

The Blood Product Filler represents the information system of the organization responsible for performing crossmatch, issuance, potentially dispense, and closing the loop on final disposition of each prepared blood product in its inventory. This role is typically played by a blood bank laboratory information system..

Like the Blood Transfusion Documenter, the Blood Product Filler will have participated in previous steps of the clinical transfusion medicine workflow and assigned identifiers to each prepared blood product unit issued to a patient, as well has likely having managed the product cross-matching and dispensing processes.

X.2 TMA Actor Options

Options that may be selected for each actor in this profile, if any, are listed in Table X.2-1. Dependencies between options when applicable are specified in notes.

Table X.2-1: TMA - Actors and Options

Actor	Option Name	Reference
Blood Transfusion Documenter	No options defined	--
Blood Product Filler	No options defined	--

X.3 TMA Required Actor Groupings

Section not applicable.

X.4 TMA Overview

In the blood transfusion administration workflow, the actors will draw on results previously established in the full transfusion clinical workflow to establish the patient's ABO blood type and antibody screen results, then ordering and dispensing the necessary prepared product units for the specific clinical need (surgery, etc.). Based on these results the TMA Profile begins with assigned or general supply product units available to the clinician, at which point the clinician will perform final checks before patient will be transfused with the appropriate product units. The administration will then be documented electronically, and the patient will be observed post-transfusion to ensure no reactions occur to the given products.

X.4.1 Concepts

This profile relies on context including the use of the following concepts in transfusion medicine:

- Electronic crossmatch – a process for computerized review of patient-donor compatibility in ABO & antibody blood elements, which is subject to certain jurisdiction-specific constraints but generally includes applicability to only patients with a known blood sample on file with the lab and no "clinically significant" antibodies.

X.4.2 Use Cases

TMA Profile use cases assume that the appropriate prepared blood products have already been ordered, issued & dispensed, and are ready at the point of care.

X.4.2.1 Use Case #1: Single Administration

In this use case a single administration session of a prepared blood product is performed for the patient. The administration is documented in a single session informing about the start and end of the transfusion.

X.4.2.1.1 Use Case #1: Description

Patient transfusion of one unit begins, is documented with a start time [LAB-70] and proceeds normally. The person performing the beginning of this transfusion administration may be reported together with the person acting as the transfusion verifier.

Transfusion of the unit completes and is documented with an end time [LAB-70]. The person performing the end of this transfusion administration may be reported together with the person acting as the transfusion verifier.

X.4.2.1.2 Use Case #1: Workflow

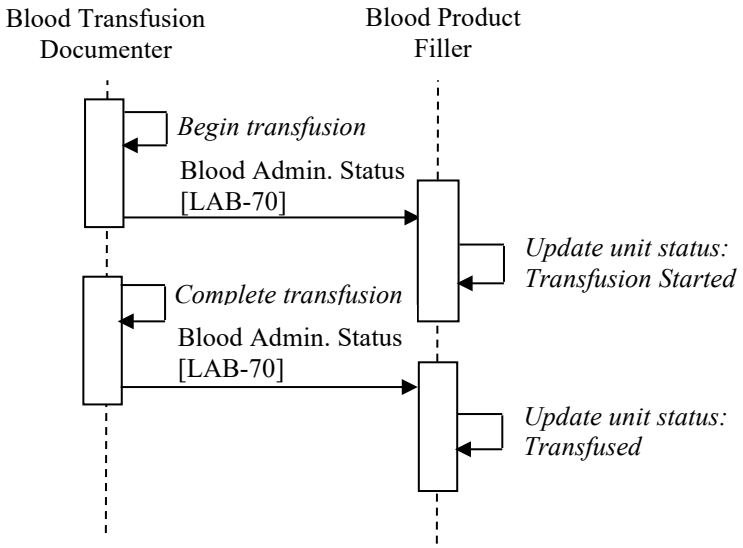

Figure X.4.2.1.2-1: Basic Process Flow in TMA Profile

X.4.2.2 Use Case #2: Single Administration with interruption

In this use case a single administration session of a prepared blood product is performed for the patient. The administration is documented in a single session. After having started the transfusion, a decision was taken to interrupt and cancel the transfusion.

X.4.2.2.1 Use Case #2: Description

Patient transfusion of one unit begins, is documented with a start time [LAB-70] and proceeds normally. The person performing the beginning of this transfusion administration may be reported together with the person acting as the transfusion verifier.

Transfusion of the unit requires to be interrupted and is documented with an end time and reason for interruption [LAB-70]. The person performing the interrupt of this transfusion administration may be reported together with the person acting as the transfusion verifier.

X.4.2.2.2 Use Case #2: Workflow

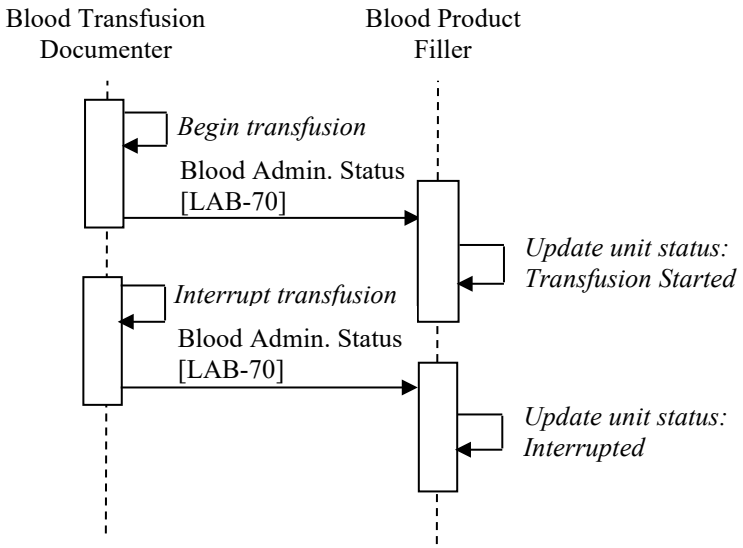

Figure X.4.2.2.2-1: Basic Process Flow in TMA Profile

X.4.2.3 Use Case #3: Single Administration with Reaction

In this use case a single administration session of prepared blood products is performed for the patient (may include more than one individual product unit, but it is expected that all units have been dispensed together and are on hand for the administering users). The administration is documented in a single session, but the patient has an adverse reaction to the administered products.

X.4.2.3.1 Single Administration with Reaction Use Case Description

The TMA Profile's use cases assume that the appropriate prepared blood products have already been ordered, issued & dispensed, and are ready at the point of care.

Patient transfusion of one unit begins, is documented with a start time [LAB-70] and proceeds normally. Transfusion of the unit completes and is documented with an end time [LAB-70]. After the administration is complete a caregiver observes that the patient vitals have taken a sharp adverse turn and documents a suspected transfusion reaction.

X.4.2.3.2 TMA Process Flow

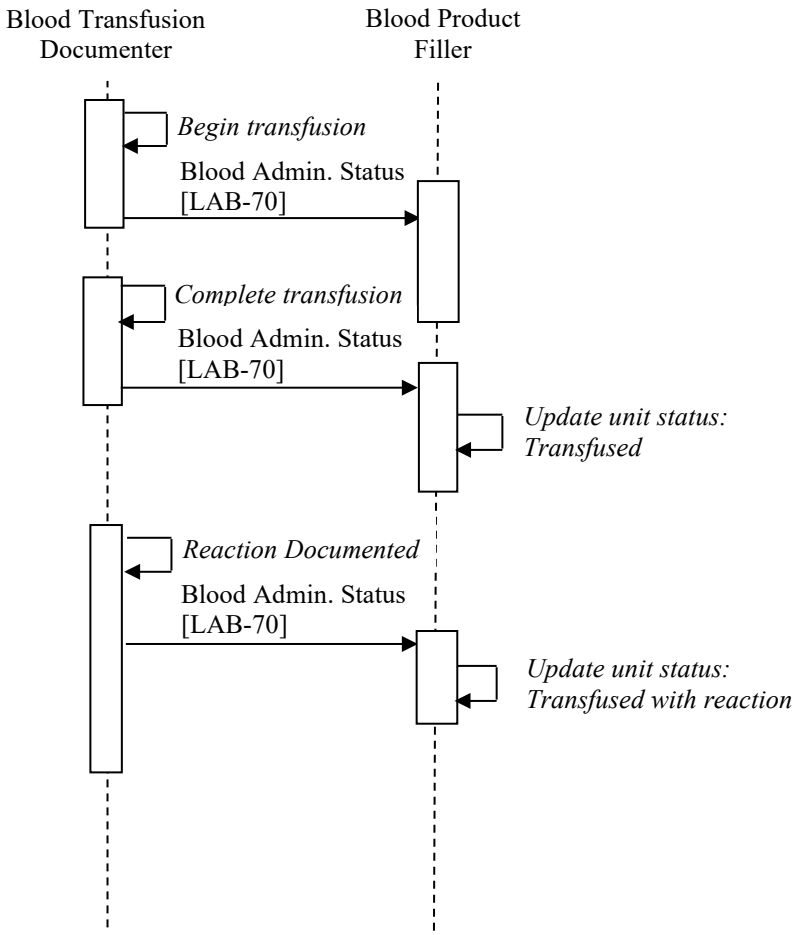

Figure X.4.2.3.2-1: Basic Process Flow in TMA Profile

X.5 TMA Security Considerations

X.5.1 Consistent Time (CT)

In order to address identified security risks, all actors in TMA SHOULD be grouped with the Consistent Time (CT) Profile - Time Client. This grouping will assure that all systems have a consistent time clock to assure a consistent timestamp for audit logging and form accuracy.

X.5.2 Audit Trail and Node Authentication (ATNA)

TMA will likely include clinical content related to the information subject. When it does, it is anticipated that transfers of Personal Health Information (PHI) will be protected. The IHE ITI Audit Trail and Node Authentication (ATNA) Profile SHOULD be implemented by all of the actors involved in the IHE transactions specified in this profile to protect node-to-node communication and to produce an audit trail of the PHI related actions when they exchange

messages, through other private security mechanisms MAY be used to secure content within enterprise managed systems.

X.5.3 Cross-Enterprise User Assertion (XUA)

For security and auditing purposes, when sending information between clinical documentation and laboratory systems it may be necessary to firmly establish the identity of the users performing each action. In this case the Cross-Enterprise User Assertion (XUA) Profile MAY be utilized to support this implementation.

Note that XUA is recommended over Internet User Authorization (IUA) as XUA is more applicable to known trusted partners and IUA is generally more applicable to Internet-facing applications in which users are less likely to be known to each other and OAuth-style authentication is necessary. TMA is expected to be used between systems owned by the same organization and on the same internal network, hence IUA in unnecessary.

X.6 TMA Cross Profile Considerations

Not applicable.

Appendices

None

Volume 2 – Transactions

Add Section 3.Y

3.Y Blood Administration Status [LAB-70]

This section corresponds to the transaction [LAB-70] of IHE Laboratory Technical Framework. The actors using this transaction are the Blood Transfusion Documenter and Blood Product Filler.

3.Y.1 Scope

This transaction is used to communicate status changes for individual blood products during the process of administering them.

3.Y.2 Actor Roles

Table 3.Y.2-1: Actor Roles

Actor:	Blood Transfusion Documenter
Role:	Documents the status of each unit of blood product it is using in a transfusion workflow, sends status messages to Blood Product Filler to keep the status of issued products in sync.
Actor:	Blood Product Filler
Role:	Receives status updates from the Blood Transfusion Documenter and updates the internal status for each product.

3.Y.3 Referenced Standards

HL7 version 2.5.1:

- Chapter 2: "Control" --> generic segments and data types
- Chapter 3: "ADT" --> PID and PV1 segments
- Chapter 4: "Order Entry" --> BTS and BRT messages, BPO and BPX segments

3.Y.4 Messages

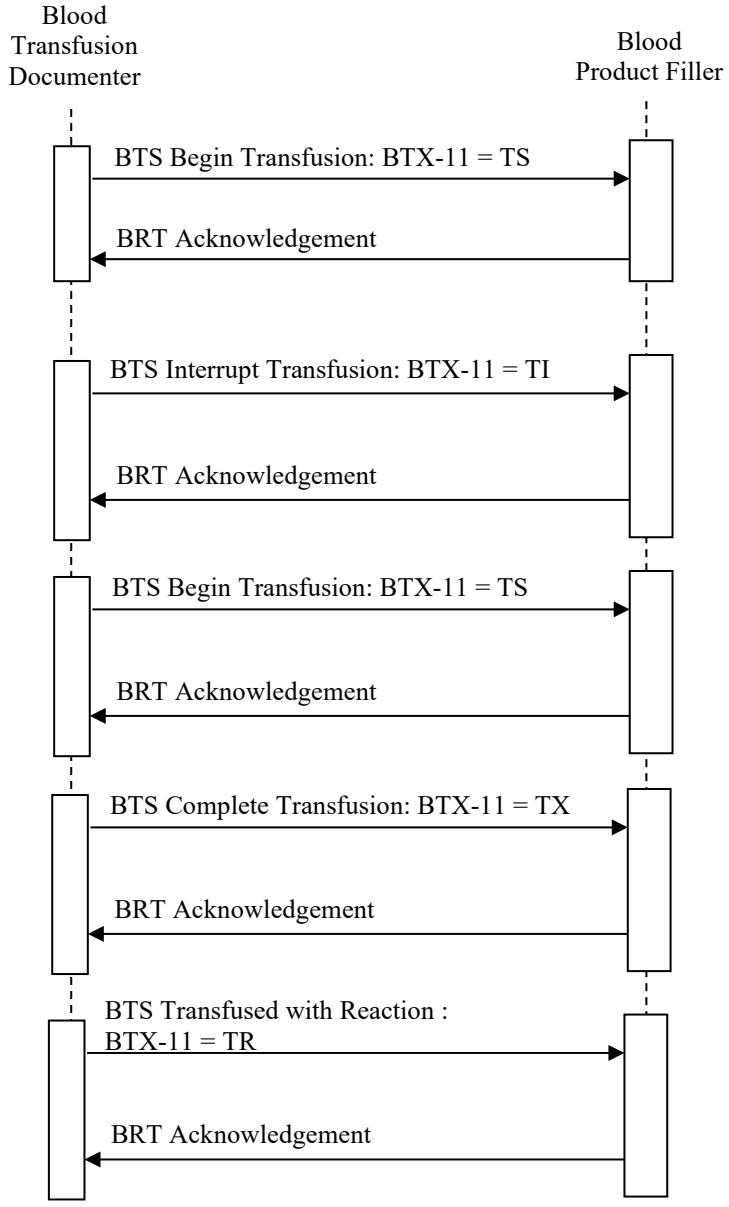

Figure 3.Y.4-1: Blood Administration Status Interactions

3.Y.4.1 Message BTS^O31 and its Acknowledgement BRT^O32

The transfusion status message contains a list of one or more individual blood products grouped under one or more product orders, all associated with the same patient and encounter. This

structure allows reporting on statuses of several individual blood product units in different statuses as well as multi-unit actions (such as massive transfusion protocols).

A Blood Product Documenter may send the BTS^O31 to multiple recipients interested in the disposition of products but the primary recipient is always the Blood Product Filler which issued the product. A Blood Product Filler may service multiple Blood Product Documenters in its organizational jurisdiction but only one Blood Product Documenter will be responsible for a given blood product unit and expected to provide that unit's status to the Blood Product Filler.

3.Y.4.1.1 Trigger Events

The BTS message is triggered by a change in the status of a blood product unit in a Blood Transfusion Documenter's system. The reception of a blood product unit is out of the scope of the TMA Profile and will be covered by the future Transfusion Medicine Dispense (TMD) Profile. Given that, a possible status progression for a single unit, which would trigger messages at each change, includes: Begin Transfusion, Interrupt Transfusion, Begin Transfusion [resume], End Transfusion and Document Transfusion with Reactions

Correction of information associated with a prior status (e.g., changing the time a unit is considered Received after it has already been advanced to Begin Transfusion) is out of scope for TMA as the relationship between BTX-11 and BTX-12 does not easily support this in all cases, particularly when the status event to be updated is more than one event prior in the sequence.

3.Y.4.1.2 Message Semantics

This message is an HL7 BTS^O31 (Blood Product Transfusion/Disposition) event.

3.Y.4.1.2.1 BTS^O31 Static Definition

Table 3.Y.4.1.2.1-1: BTS^O31

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message Header	R	[1..1]	2
[{ NTE }]	Notes and Comments (for Header)	O		
	--- PATIENT begin	R	[1..1]	
PID	Patient Identification	R	[1..1]	3
[PD1]	Additional Demographics	O	[0..1]	3
[{NTE}]	Notes and comments (for Patient)	O	[0..*]	2
	--- PATIENT_VISIT begin	R	[1..1]	
PV1	Patient Visit	R	[1..1]	3
[PV2]	Patient Visit – Additional Info	O	[0..1]	3
[{ PRT }]	Participation (for Patient Visit)	O	[0..*]	7
	--- PATIENT_VISIT end			
	--- PATIENT end			

Segment	Meaning	Usage	Card.	HL7 chapter
{	--- ORDER begin		[1..*]	
ORC	Common Order	R	[1..1]	4
[{	--- TIMING begin	O	[0..*]	
TQ1	Timing/Quantity	R	[1..1]	4
[{ TQ2 }]	Timing/Quantity Order Sequence	O	[0..*]	4
}]	--- TIMING end			
BPO	Blood Product Order	R	[1..1]	4
[{ NTE }]	Notes and comments (for BPO)	O	[0..*]	2
{	--- PRODUCT_STATUS begin	R	[1..*]	
BTX	Blood Product Transfusion/Disposition Status	R	[1..1]	4
[{ NTE }]	Notes and comments (for BTX)	O	[0..*]	2
}	--- PRODUCT_STATUS end			
}	--- ORDER end			

Field MSH-9 – Message Type SHALL have its three components valued as follows: BTS^O31^BTS_O31.

Segment PID – Patient Identification SHALL be included. (Note that this is not required in the base HL7 BTS^O31 message but is included here to help both sender and receiver clearly establish positive patient identification and clinical context for the workflow.)

Segment PV1 – Patient Visit SHALL be included. (Note that this is not required in the base HL7 BTS^O31 message but is included here to help both sender and receiver clearly establish positive patient identification and clinical context for the workflow.)

3.Y.4.1.2.2 BRT^O32 Static Definition

Table 3.Y.4.1.2.2-1: BRT^O32

Segment	Meaning	Usage	Cardinality	HL7 chapter
MSH	Message Header	R	[1..1]	2
MSA	Message Acknowledgement	R	[1..1]	2
[{ ERR }]	Error	O	[0..*]	2
[{ SFT }]	Software	O	[0..*]	2
[UAC]	User Authentication Credential	O	[0..1]	2
[{ NTE }]	Notes and Comments (for Header)	O	[0..*]	2
[	--- RESPONSE begin	O	[0..1]	
[PID]	Patient Identification	O	[0..1]	3
[{	--- ORDER begin	O	[0..*]	

Segment	Meaning	Usage	Cardinality	HL7 chapter
ORC	Common Order	R	[1..1]	4
[{	--- TIMING begin	O	[0..*]	
TQ1	Timing/Quantity	R	[1..1]	4
[{ TQ2 }]	Timing/Quantity Order Sequence	O	[0..*]	4
}]	--- TIMING end			
[BPO]	Blood Product Order	O	[0..1]	4
[{ BTX }]	Blood Product Transfusion/Disposition Status	O	[0..*]	4
}	--- ORDER end			
}	--- RESPONSE end			

3.Y.4.1.2.3 BPO Segment Static Definition

SEQ	LEN	DT	USAGE	Card.	TBL#	ITEM#	Element Name
1		SI	R	[1..1]		01700	Set Id – BPO
2	250	CWE	R	[1..1]		01701	BP Universal Service ID
3	250	CWE	O	[0..*]	0508	01702	BP Processing Requirements
4	5	NM	R	[1..1]		01703	BP Quantity
5	5	NM	O	[0..1]		01704	BP Amount
6	250	CE	O	[0..1]		01705	BP Units
7	26	TS	O	[0..1]		01706	BP Intended Use Date/Time
8	80	PL	X	[0..0]		01707	BP Intended Dispense From Location
9	250	XAD	X	[0..0]		01708	BP Intended Dispense From Address
10	26	TS	X	[0..0]		01709	BP Requested Dispense Date/Time
11	80	PL	X	[0..0]		01710	BP Requested Dispense To Location
12	250	XAD	X	[0..0]		01711	BP Intended Dispense To Address
13	250	CWE	O	[0..*]	0509	01712	BP Indication for Use
14	1	ID	O	[0..1]		01713	BP Informed Consent Indicator

This transaction relies on the base-standard segment field definitions. The fields documenting the order to dispense are not supported since the transaction is documenting the administration itself.3.Y.4.1.2.4 BTX Segment Static Definition

SEQ	LEN	DT	USAGE	Card.	TBL#	ITEM#	Element Name
1	4	SI	R	[1..1]		01735	Set Id - BTX
2		EI	R	[1..1]		01736	BC Donation Id
3		CNE	R	[1..1]	9999	01737	BC Component
4		CNE	RE	[0..1]	9999	01738	BC Blood Group

SEQ	LEN	DT	USAGE	Card.	TBL#	ITEM#	Element Name
5		CWE	X	[0..0]	0512	01739	CP Commercial Product
6		XON	X	[0..0]		01740	CP Manufacturer
7		EI	X	[0..0]		01741	CP Lot Number
8		NM	RE	[0..1]		01742	BP Quantity
9		NM	RE	[0..1]		01743	BP Amount
10		CWE	RE	[0..1]	9999	01744	BP Units
11		CWE	R	[1..1]	0513	01745	BP Transfusion/Disposition Status
12		ID	R	[1..1]	0511	01746	BP Message Status
13		DTM	R	[1..1]		01747	BP Date/Time Of Status
14		XCN	RE	[0..1]		01748	BP Transfusion Administrator
15		XCN	RE	[0..1]		01749	BP Transfusion Verifier
16		DTM	X	[0..1]		01750	BP Transfusion Start Date/Time Of Status
17		DTM	X	[0..1]		01751	BP Transfusion End Date/Time Of Status
18		CWE	O	[0..1]	0514	01752	BP Adverse Reaction Type
19		CWE	C(RE/X)	[0..1]	0515	01753	BP Transfusion Interrupted Reason

Explanations below are quoted from the base standard:

The BP prefix in the element name indicates that the attribute pertains to any type of blood product. A blood product is defined as any type of blood component or commercially prepared blood product that is prepared and dispensed from the transfusion service.

The BC prefix in the element name indicates that the attribute pertains only to blood components. A blood component is defined as any part or all of a whole blood donation. For example, from one whole blood donation, the unit of whole blood can be fractionated into red blood cells, plasma and platelets with each component contained in separate bags. These types of blood products are always assigned a unique donation identification number as well as a product code that indicates the type of component contained in the bag.

The CP prefix in the element name indicates that the attribute pertains only to Commercial Products. A commercial product is defined as a commercially manufactured product, such as blood derivatives (Rh Immune Globulin, Factor VIII Concentrate or Blood Recipient Sets or Filters). These types of products are tracked by manufacturer and lot number and are not necessarily assigned a unique donation number.

BTX-1 Set ID – BTX (SI)

HL7 Definition: This field contains the sequence number for the BTX segment under the related BPO segment. For the first product transfusion/disposition transmitted, the sequence number shall be 1; for the second product transfusion/disposition, it shall be 2; and so on.

BTX-2 BC Donation Id (EI)

HL7 Definition: The donation ID is the unique identification number assigned to a blood donation. The Donation ID depends upon the bar code labeling system used for the component. There are currently two blood component labeling standards: ABC CODABAR and ISBT 128. The preferred labeling system is ISBT 128. If using ISBT 128, the Donation ID is an internationally unique identifier consisting of the following 13 characters:

Country Code & Collection Facility - 5 characters

Donation Year - 2 characters

Serial Number - 6 characters

This is required for blood components and is not applicable for commercial product messages

IHE PaLM Definition :

When used with ISBT-128, the full Barcode Donation Identification Number, including the FLAG characters may be reported. This may result in 15 characters : 5 characters for the Facility ID Number + 2 characters for the Assignment Year + 6 characters for the Sequence Number + 2 characters for the FLAG characters

In case one Donation ID can deliver multiple components, the blood unit shall require the BTX-3 BC Component for unique identification of the blood unit.

BTX-3 BC Component (CNE)

HL7 Definition: The Blood Component field includes an identifier and description of the specific blood component.

The identifier consists of a numeric or alphanumeric product code that represents the type of blood component. The coding system will be determined by the bar code labeling system on the particular component of blood. The preferred coding system is ISBT 128.

If using ISBT 128 labeling standard, the product code will consist of an 8-character alphanumeric code, starting with an alpha character and including the component class, donation type/intended use and division indicator.

If using CODABAR product labeling standard, the product code is a 5-digit number.

This field is required for blood components and is not applicable for commercial product messages.

BTX-11 BP Transfusion/Disposition Status (CWE)

HL7 Definition: This field indicates the current status of the specified blood product as indicated by the placer. For example, the placer may return the blood product to the transfusion service unused because an IV could not be started. The blood component may have been entered, but the line was clogged and could not be used, in which case the component must be wasted. A final status would indicate that the product has actually been "transfused." Refer to HL7 Table 0513 - Blood Product Transfusion/Disposition Status for suggested values.

IHE Definition of HL70513:

Value	Description	Comment
TS	Transfusion Started	Extension of HL7 0513
TI	Transfusion Interrupted and consider being ended.	Extension of HL7 0513
TX	Transfusion Ended	Part of HL7 0513
TR	Transfusion Ended with Reactions	Part of HL7 0513

BTX-12 BP Message Status (ID)

HL7 Definition: The most commonly used message status values in a BTX will be preliminary and final. A status is considered preliminary until a blood product has reached a final disposition for the patient. For example, when the product is first cross-matched and a status message is sent, it would be considered preliminary. When the product is dispensed to the patient, that status would also be considered preliminary. However, once the product is transfused, the status would be considered final. The status of a blood product (BTX-11) can continue to change and the previous result should be overwritten until it reaches a final status (BTX-12). Refer to HL7 Table 0511 – BP Observation Status Codes Interpretation for valid entries.

HL70511 BP Observation Status Codes Interpretation

Value	Description	Comment
F	Final status; Can only be changed with a corrected status	

Fixed value: “F”

BTX-13 BP Date/Time Of Status (DTM)

HL7 Definition: This field indicates the date and time that the status of the blood component was changed. For example, if the blood component had a status of "TX" (Transfused), the date and time in this field would indicate the date and time the component was transfused by the placer system.

IHE PaLM Definition:

Example, if the blood component had a status of “TS” (Transfusion Started), the date and time of this field shall indicate the date and time the transfusion for this blood unit was documented.

BTX-14 BP Transfusion Administrator (XCN)

HL7 Definition: This field contains the identity of the individual who administers the transfusion of the blood product. If the code is sent as a local code, it should be unique and unambiguous. This field can be free text to permit capture without table update. In this case, the administrator's name must be recorded as the second through fourth components of the field.

BTX-15 BP Transfusion Verifier (XCN)

HL7 Definition: This field contains the identity of the individual who assists in the identification of the patient and verification of the product information prior to transfusion of the blood product. If the ID Number is sent as a local code, it should be unique and unambiguous. This field can be free text to permit capture without table update. In this case, the verifier's name must be recorded as the second through fourth components of the field.

BTX-16 BP Transfusion Start Date/Time Of Status (DTM)

HL7 Definition: This field indicates the date and time that the administrator started the transfusion of the blood component or commercial product.

IHE PaLM Definition:

This field BTX-16 is not supported since a specific transaction is expected for documenting the start of a transfusion.

With a BTX-11=|TS| the corresponding BTX-13 shall be filled with the transfusion start date

BTX-17 BP Transfusion End Date/Time Of Status (DTM)

HL7 Definition: This field indicates the date and time that the transfusion of the blood component or commercial product was completed or stopped.

IHE PaLM Definition:

This field BTX-17 is not supported since a specific transaction is expected for documenting the end of a transfusion.

With a BTX-11=|TX| or |TR| the corresponding BTX-13 shall be filled with the transfusion end date

BTX-18 BP Adverse Reaction Type (CWE)

HL7 Definition: This field contains the type of adverse reaction that the recipient of the blood product experienced

HL7 Definition: This field contains the reason that the transfusion of the blood product was interrupted. Refer to User-Defined Table 0514 - Transfusion Adverse Reaction for suggested values.

User-Defined Table 0514 – Transfusion Adverse Reaction

Value	Description	Comment
ABOINC	ABO Incompatible Transfusion Reaction	
ACUTHEHTR	Acute Hemolytic Transfusion Reaction	
ALLERGIC1	Allergic Reaction – First	
ALLERGIC2	Allergic Reaction – Recurrent	
ALLERGICR	Allergic Reaction – Repeating	
ANAPHYLAC	Anaphylactic Reaction	
BACTCONTAM	Reaction to Bacterial Contamination	
DELAYEDHTR	Delayed Hemolytic Transfusion Reaction	

Value	Description	Comment
DELAYEDSTR	Delayed Serological Transfusion Reaction	
GVHD	Graft vs Host Disease – Transfusion – Associated	
HYPOTENS	Non-hemolytic Hypotensive Reaction	
NONHTR1	Non-Hemolytic Fever Chill Transfusion Reaction – First	
NONHTR2	Non-Hemolytic Fever Chill Transfusion Reaction – Recurrent	
NONHTRREC	Non-Hemolytic Fever Chill Transfusion Reaction – Repeating	
NONIMMUNE	Non-Immune Hemolysis	
NONSPEC	Non-Specific, Non-Hemolytic Transfusion Reaction	
NORXN	No Evidence of Transfusion Reaction	
PTP	Posttransfusion Purpura	
VOLOVER	Symptoms most likely due to volume overload	

BTX-19 BP Transfusion Interrupted Reason (CWE)

HL7 Definition: This field contains the reason that the transfusion of the blood product was interrupted. The User-Defined Table 0515 - Transfusion Interrupted Reason has no suggested values.

IHE PaLM Definition:

Usage C(RE/X)

Condition predicate: When BTX-11=|TI| “Transfusion Interrupted” the blood transfusion documenter SHOULD inform about the reason for interruption. For all other values of BTX-11, the usage of BTX-19 is not supported.

3.Y.4.1.3 Expected Actions

Table 3.Y.4.1.3-1: Expected Actions by Responder in [LAB-70]

Event	Initiator	Responder	Expected action by the responder
Blood product status changed	Blood Transfusion Documenter	Blood Product Filler	Store the status to the appropriate product and acknowledge with OK.

3.Y.5 Security Considerations

The only security constraint is that both Order Result Tracker and Order Filler be grouped with a Consistent Time Client, as specified in PaLM TF-1, and that these two CT Clients be served by a common Consistent Time Server.

3.Y.5.1 Security Audit Considerations

Not applicable.

3.Y.5.1.1 <Actor> Specific Security Considerations

Not applicable.

Appendices

None

Volume 2 Namespace Additions

Add the following terms to the IHE Namespace

None

Volume 3 – Content Modules

Section not applicable.

5 Namespaces and Vocabularies

Add to Section 5 Namespaces and Vocabularies

None

Add to Section 5.1.1 IHE Format Codes

None

Add to Section 5.1.2 IHE ActCode Vocabulary

None

Add to Section 5.1.3 IHE RoleCode Vocabulary

None

Appendices

None

Volume 3 Namespace Additions

Add the following terms to the IHE Namespace:

None

Volume 4 – National Extensions

Add appropriate Country section

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None

