Integrating the Healthcare Enterprise

IHE Pathology and Laboratory Medicine Technical Framework Supplement

Transfusion Medicine - Administration (TMA)

Rev. 2.0 – Draft for Public Comment

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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 V8.0. 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 on April 27, 2018 for public comment. Comments are invited and can be submitted at http://ihe.net/PaLM_Public_Comments. In order to be considered in development of the trial implementation version of the supplement, comments must be received by May 27, 2018.

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 http://www.ihe.net/Technical_Frameworks.

CONTENTS

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 believe that it will be necessary to request additions to HL7®[1]'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.
2. 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).
3. This profile does not extensively address the handling of transfusion reaction documentation, lab work-up, and reporting as the HL7 specifications do not currently have enough capability to capture the necessary details. If future HL7 changes grow the capability to report reaction-related data, this profile should be updated to accommodate that as we believe that reaction-related integration *would* be IN SCOPE for this part of the workflow.

[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.

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)

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 (Blood Product Filler, Adverse Event Consumer) of this process, given all of the requisite prior testing, product cross-matching, and dispensing by other actors. This actor is typically used in a direct patient care setting and is involved in the TMA Profile.
Blood Product Filler	Issues specific units of blood product to specific patients, after all requisite prior testing & cross-matching, based on appropriate orders from an Order Placer so that they may be acted upon by a Blood Transfusion Documenter. It also receives updates from a Blood Transfusion Documenter. This actor is typically used in a blood bank setting and is involved in the TMA Profile.

Appendix B – Transaction Summary Definitions

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

Transaction	Definition
[LAB-70] Blood Administration Status	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”, “suspect” 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:

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Glossary Term	Definition
Blood product	Any component of the blood which 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 which 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 testing & ordering, 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 of 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 #3.

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.

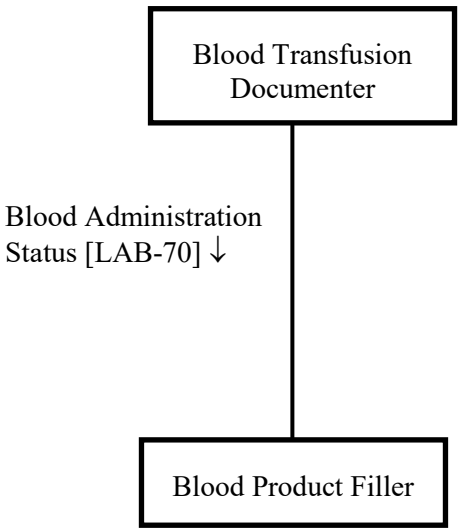


Figure X.1-1: TMA Actor Diagram

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) and Content Modules (Volume 3). 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 laboratory information system 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 fulfilled by a blood bank laboratory information system, though may be either integrated with the main clinical pathology LIS or a standalone application.

Like the Blood Transfusion Documenter, the Blood Product Filler will have participated in previous steps of the clinical transfusion medicine workflow and assigned identifiers for each

prepared 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 the 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

X.4.2.1 Use Case #1: Single Administration with Reaction

In this use case a single administration session of prepared blood products is performed for the patient (may include 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.4.2.1.1 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 as sharp adverse turn and documents a suspected transfusion reaction.

X.4.2.1.2 TMA Process Flow

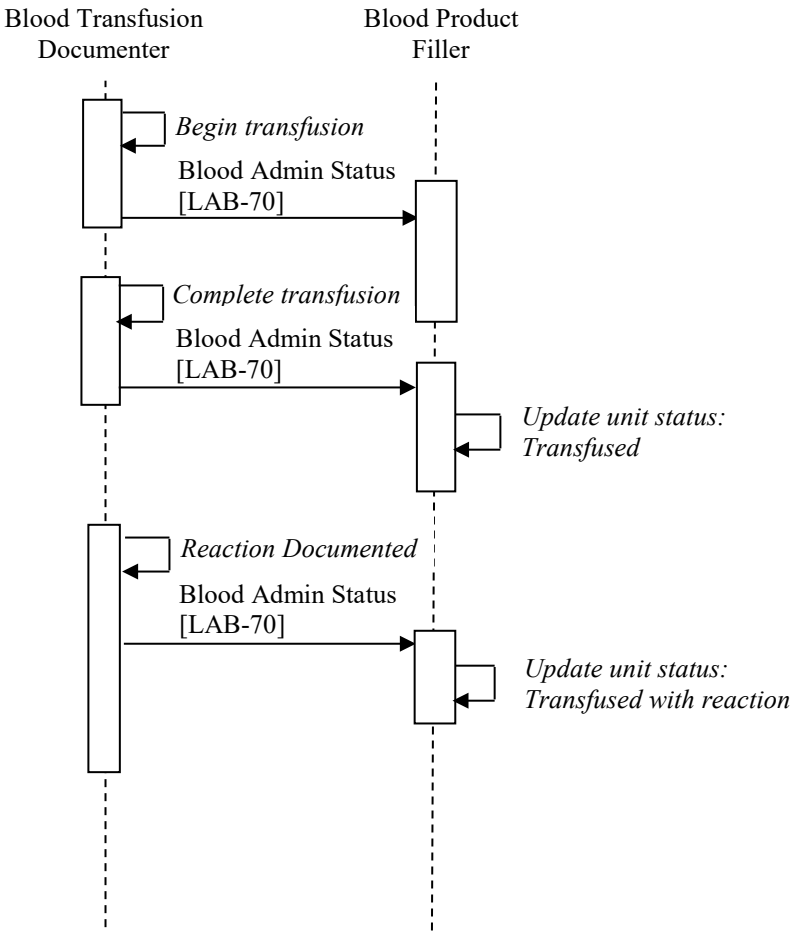


Figure X.4.2.1.2-1: Basic Process Flow in TMA ProfileX.5 TMA Security Considerations

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 Consistent Time (CT) Profile - Time Client Actor. 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

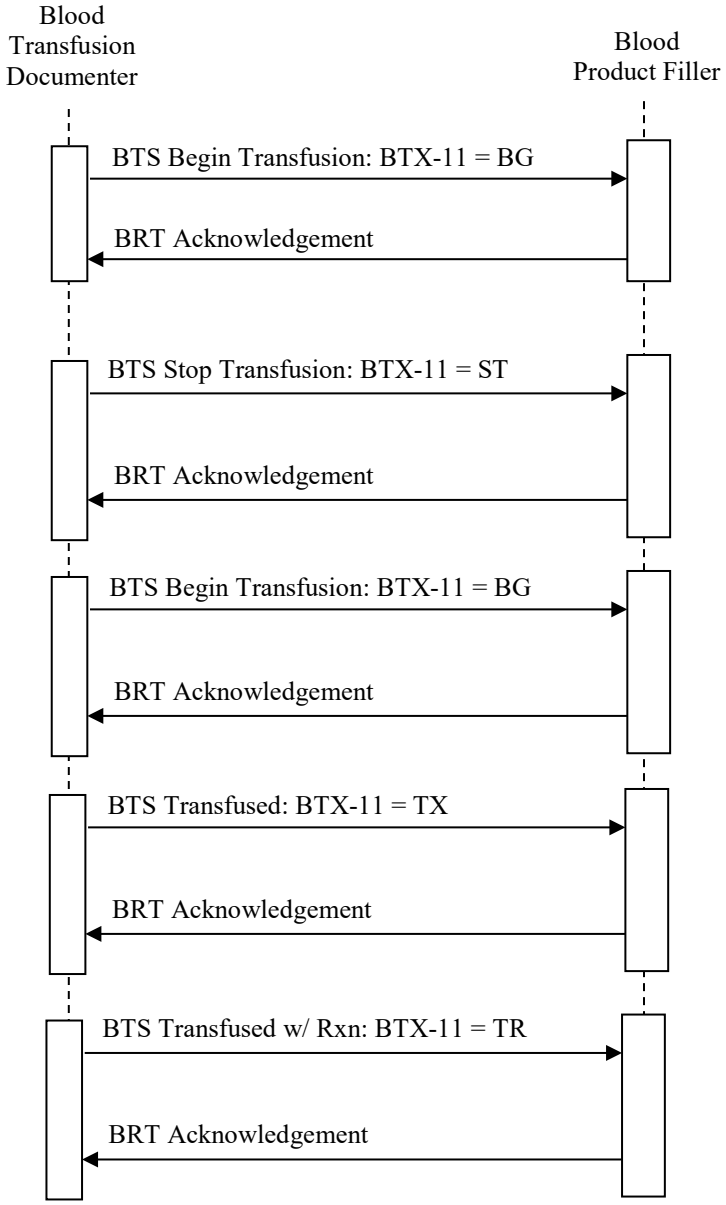
Actor:	Blood Transfusion Documenter
Role:	Documents the status of each unit of blood product it is using in a transfusion workflow, sends status messages to Blood Product Filler to keep statuses of issued products in sync.
Actor:	Blood Product Filler
Role:	Receives status updates from the Blood Transfusion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

3.Y.3 Referenced Standards

HL7 version 2.8.2:

- 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 Interaction Diagram



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 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 any given 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. A possible status progression for a single unit, which would trigger messages at each change, includes: Unit Received, Begin Transfusion, Interrupt Transfusion, Begin Transfusion [resume], and Transfused.

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
[{ SFT }]	Software	O	[0..*]	2
[UAC]	User Authentication Credential	O	[0..1]	2
[{ NTE }]	Notes and Comments (for Header)	O	[0..*]	2
	--- PATIENT begin		[1..1]	
PID	Patient Identification	R	[1..1]	3
[PD1]	Additional Demographics	O	[0..1]	3
[{ PRT }]	Participation (for Patient)	O	[0..*]	7
[{NTE}]	Notes and comments (for Patient)	O	[0..*]	2
	--- PATIENT_VISIT begin		[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			
{	--- ORDER begin		[1..*]	

Segment	Meaning	Usage	Card.	HL7 chapter
ORC	Common Order		[1..1]	4
[{ PRT }]	Participation (for Order)	O	[0..*]	2
[{	--- TIMING begin		[0..*]	
TQ1	Timing/Quantity		[1..1]	4
[{ TQ2 }]	Timing/Quantity Order Sequence		[0..*]	4
}]	--- TIMING end			
BPO	Blood Product Order		[1..1]	4
[{ NTE }]	Notes and comments (for BPO)		[0..*]	2
{	--- PRODUCT_STATUS begin		[1..*]	
BTX	Blood Product Transfusion/Disposition Status		[1..1]	4
[{ NTE }]	Notes and comments (for BTX)		[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 received 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 received 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		[0..1]	
[PID]	Patient Identification	O	[0..1]	3
[{ ARV }]	Access Restrictions	O	[0..*]	3

Segment	Meaning	Usage	Cardinality	HL7 chapter
[{	--- ORDER begin		[0..*]	
ORC	Common Order		[1..1]	4
[{ PRT }]	Participation (for Order)	O	[0..*]	2
[{	--- TIMING begin		[0..*]	
TQ1	Timing/Quantity		[1..1]	4
[{ TQ2 }]	Timing/Quantity Order Sequence		[0..*]	4
}]	--- TIMING end			
[BPO]	Blood Product Order		[0..1]	4
[{ BTX }]	Blood Product Transfusion/Disposition Status		[0..*]	4
}	--- ORDER end			
}	--- RESPONSE end			

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.

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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.

375 #### 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

4 National Extensions

None

