Traceability Based Description of Clinical Processes: Extension of IHE Guidelines for Phlebotomy Workflows

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Abstract

The increasing diffusion of data acquisition systems paves the way to traceability based process management and definition. In the clinical context, IHE formalizes the reference guidelines, periodically enhanced to reflect processes evolution.
In this work we describe how we have modeled the phlebotomy process following the IHE references and best-practices to obtain a fully traceable workflow. The work has resulted in two new transactions for the IHE LBL profile, describing samples containers production and samples collection. The complete workflow has been implemented and successfully tested in real clinical environments. The traceability data acquired have then been studied using Process Mining techniques to compare the production model with idealized workflow and guide further developments.

Keywords

Traceability; IHE; HL7; Interoperability; Process Mining

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1 Introduction

The management of a healthcare process depends on many factors, coming from the clinical domain, the nature of the process, the fundamental actions and their collateral effects, the main stakeholders and their respective interactions, the relationships between patients, operators and devices supporting the considered clinical pathway. The ever-increasing penetration of digital acquisition systems brings the promise of a more systematic clinical processes management approach based on process traceability and quantitative description.

In this paper we report on how we modeled – within the context of international guidelines and best-practices, in particular IHE (Integrating Healthcare Enterprise) [1] – a clinical process with the goal of a fully traceable and quantitative description of its running. Specifically, we considered the phlebotomy process in clinical laboratories. From the analysis of the traceability requirements, we developed two new IHE transactions which have been actualized in a commercial product [2] thus demonstrating the feasibility of this approach in a production context.

Traceability data provide useful information about what activities were performed, by whom, and when. Together, they allow reconstructing the actions that brought about a specific result. With this information the process can be analyzed and improved, with potential benefits to safety and quality of care.

The IHE is the reference institution for the interoperability of systems in the healthcare environment; the consortium is divided into clinical domains and, for each one of them, it periodically publishes a specific Technical Framework. Technical Frameworks describe the domains processes in the form of use cases, workflows and transactions that can be mapped to significant events. They form an ideal basis for a traceability system to monitor the process. There are at least two reasons to follow the IHE's guidelines when modeling a clinical process: they are defined, starting from a process-oriented point of view, by a wide number of experts in the field and they can provide useful information about correctness and completeness of

the process chain. Furthermore, an IHE-based process solution ensures a high level of reliability and repeatability. However, not all clinical processes are completely covered by IHE guidelines; the initiative iteratively improves them with the collaboration of clinical experts and software vendors. It is possible to submit Supplements and Change Proposals to the Technical Committees should uncovered aspects of a clinical process be found; after a period of evaluation and testing, the extensions can be included into the official guidelines. Our work shows that traceability can be a powerful tool to extend IHE coverage.

The remainder of the paper is structured as follows. Section 2, provides a brief overview of the clinical context (laboratory medicine) and its IHE profile coverage, followed by the definition of the process from a traceability perspective. Section 3 describes the transactions we proposed as an extension to the IHE Laboratory guidelines, their implementation in a commercial device and how they fit in a specific process mining use case. Section 4 analyzes the effect of the work. Finally, Section 5 draws conclusions and describes future work.

2 Methods

In this section, after a general description of laboratory medicine workflow, we will target the phlebotomy process and we will contrast its steps with the existing IHE profiles and transactions. We will then analyze the issues of the IHE guidelines for this sector and introduce our contribution to fill the missing segments.

2.1 Laboratory Workflow and Errors

Laboratory is a crucial part of the clinical practice and an error in its process can bring serious consequences in the rest of the patient care [3].

As shown in Figure 1, traditionally the laboratory workflow is divided into three main subprocesses:

- **pre-analytical**: it consists of tests ordering, patient identification, sample collection and transportation to the laboratory and sample preparation for analysis (i.e., sorting and routing, aliquoting, centrifugation, etc.);
- **analytical**: it includes all the steps to perform the requested analysis on the samples;
- **post-analytical**: it consists in reporting and distribution of test results.

In the past decades the most error affected phase was the analytical one, but "automation, improved laboratory technology, assay standardization, well-defined rules for internal quality control, effective quality assurance schemes and better trained staff" [4] have made it the most affordable part of the overall process [5]. The improvement is highlighted in many studies showing how after this evolution the majority of errors have moved to the pre-analytical and post-analytical phases [4] [5] [6]: in particular the first one [7] [8] can be considered the most error-prone segment of the whole Laboratory process.

In this paper we focus on the part of the pre-analytical phase that concern phlebotomy, whose central aspects are patient identification and sample collection. The most common errors in this subprocess are patient misidentification, use of inappropriate containers for specimen collection and wrong tube filling [7]. Automated systems and devices, combined with the adherence to best-practices and guidelines, can help in avoiding a wide number of these errors, guiding the operators in the correct execution of secure phlebotomy and automatically tracing the main events that enable the analysis of the process, in order to iteratively improve it.

2.2 IHE Coverage for Phlebotomy

Phlebotomy main steps are identification and sample collection, which can be respectively mapped to IHE PDQ (Patient Demographics Query) [9] and LBL (Laboratory Specimen Barcode Labeling) [10] profiles. All transactions for both profiles are based on HL7 messages.

PDQ profile describes two transactions, ITI-21 and ITI-22 [11], which are two of the most supported by vendors. They allow a Patient Demographics Consumer (PDC) to query a Patient Demographic Supplier (PDS) for patients information. They match the patient identification step of the process, as they cover the information exchange needed to retrieve and check patient identity.

Sample collection, in a venipuncture process supported by automation, can be associated to the LBL integration profile, whose use cases cover the robotized labeling of specimen containers and involve two actors:

- **LIP (Label Information Provider)**: it is the actor that provides the information about the labels;
- **LB (Label Broker)**: it is the actor responsible for the labeling of the containers according to the information provided by the LIP.

The main information needed for the labeling are embedded in the HL7 messages exchanged between the actors and they are: patient data, drawn specimens with their unique id, tests to be performed on every specimen and type of container to use. This information is very useful for traceability purpose.

The profile provides two different use cases according to the actor that initiates the transaction: in case of LAB-61 (Request Mode) the LIP sends a labeling request to the LB; on the other hand, in LAB-62 (Query Mode) the LB queries the LIP to retrieve the information needed [12].

2.3 Phlebotomy Process in a Traceability Perspective

In order to create a traceable system in the field of laboratory pre-analytical phase based on IHE transactions,

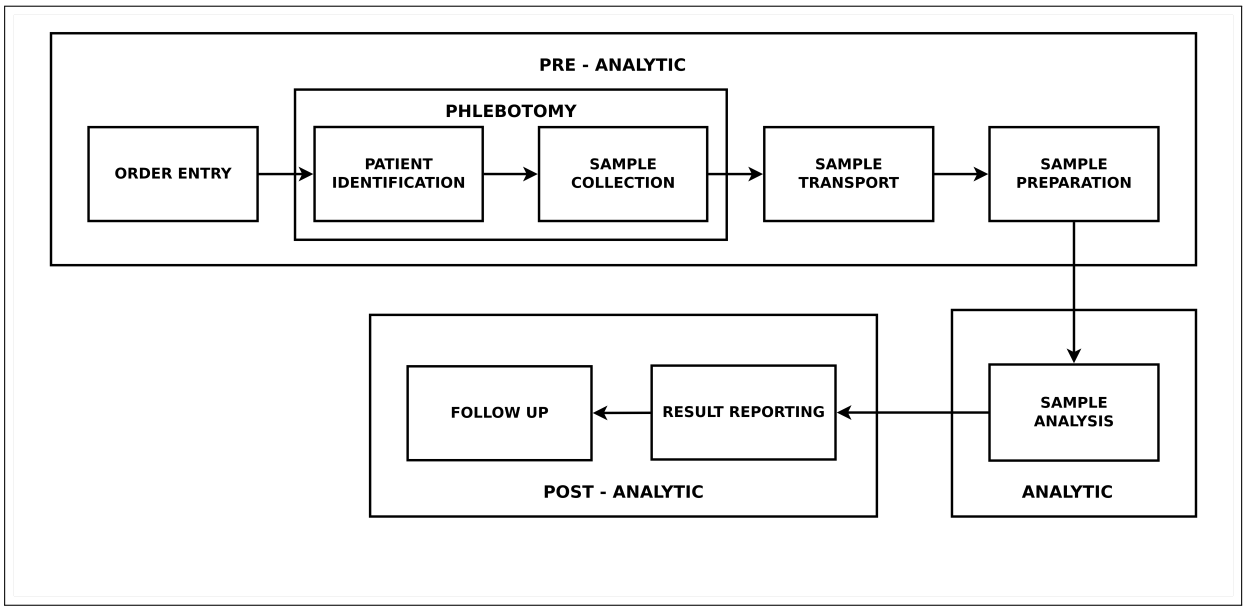

Figure 1: The laboratory workflow.

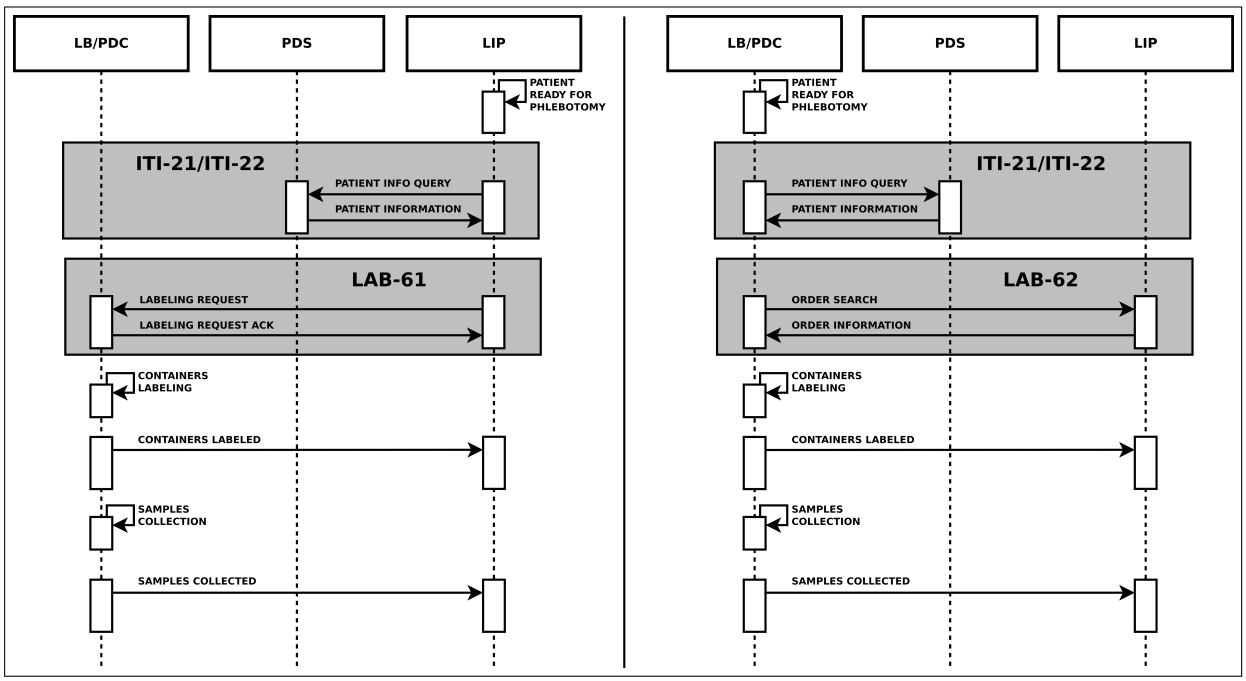

Figure 2: The sample collection process and its IHE coverage in case of Request Mode and Query Mode

we formalized the phlebotomy process supported by automation as illustrated in Figure 2. The figure delineates two possible scenarios, one for each LBL's use case, and highlights how the IHE transactions maps the steps of the process.

In case of Request Mode the main steps are:

1. **Patient ready for phlebotomy**: the patient needs to perform some tests that have been requested before;
2. **Patient Identification**: the LIP queries the PDS for patient data using a unique id. In this way the phlebotomist is sure of the patient identity;
3. **Labeling requests from the LIP**: the LIP sends the labeling request to the LB/PDC with all the necessary information; the LB/PDC responds with an ack message;
4. **Containers Labeling**: the LB/PDC prints the labels and attaches them to the correct containers;

5. **Containers Labeled**: the LB/PDC sends a message to the LIP to acknowledge the containers production;
6. **Sample Collection**: the phlebotomist draws the specimens;
7. **Sample Collected**: the LB/PDC sends a message to the LIP to acknowledge the collection has ended.

In case of Query Mode the main steps are:

1. **Patient ready for phlebotomy**: the patient needs to perform some tests that have been requested before;
2. **Patient Identification**: the LB/PDC queries the PDS for the patient information using a unique id. In this way the phlebotomist is sure of the patient identity;
3. **Order Search**: the LB/PDC queries the LIP for orders related to the patient. The LIP responds with information about the tests to be performed, the labels and the containers to use;
4. **Containers Labeling**: the LB/PDC prints the labels and attaches them to the correct containers;
5. **Containers Labeled**: LB/PDC sends a message to the LIP to acknowledge the containers production;
6. **Sample Collection**: the phlebotomist draws the specimens;
7. **Sample Collected**: the LB/PDC sends a message to the LIP to acknowledge the collection has ended.

As we said, it is important to trace these main steps in order to reconstruct the actions that brought to a specific result. We can map the actions to the following sets of traceability events.

In the case of Request Mode the events are:

- **RE1**: the LIP queried the PDS for patient information;
- **RE2**: the PDS responded with the patient information;
- **RE3**: the LIP sent a labeling request to the LB/PDC;
- **RE4**: the LB/PDC labeled the containers with the correct information and notifies the LIP that the containers have been labeled;
- **RE5**: the phlebotomist performed the samples collection and notified the LIP of the completion.

In the case of Query Mode the events are:

- **QE1**: the LB/PDC queried the PDS for patient information;
- **QE2**: the PDS responded with the patient information;
- **QE3**: the LB/PDC queried the LIP for order information (tests and containers);
- **QE4**: the LIP responded with the orders information;
- **QE5**: the LB/PDC labeled the containers with the correct information and notifies the LIP that the containers have been labeled;
- **QE6**: the phlebotomist performed the samples collection and notified the LIP of the completion.

Building the traceability environment, emerged that two issues prevent from reconstructing, from a traceability point of view, the complete process with IHE transactions:

- once the LB has finished to produce the labeled containers, no message is sent to the LIP to notify it about the success or failure of this operation;
- when the phlebotomist has completed the samples collection, no notification is sent to the LIP about the effective production of the specimens and their delivering to the laboratory.

This motivated our proposal of two new transactions that complete the process which are LAB-63 and LAB-64. Figure 3 shows how the two new transactions fill the missing steps of the whole Phlebotomy. In section 3 we describe the two new transactions in detail.

3 Results

The extension for the IHE LBL profile we proposed consists of two new transactions:

- **LAB-63 (Labeled Containers Production Confirmation)**: this transaction is sent by the LB immediately after that the robotic device has finished to produce the labeled containers, to notify the LIP about the effective completion of this operation;
- **LAB-64 (Specimens Collection Confirmation)**, sent by the LB immediately after that the phlebotomist has performed the specimens collection.

Figure 4 shows the interaction diagrams for the actors in the two transactions. Basically, they provide HL7 message exchanges between LB and LIP: the LB sends a message with the information about the completed actions and the LIP responds with an acknowledgment to confirm the reception of the message. The actions that trigger them are *CONTAINERS LABELED* for LAB-63 and *SAMPLE COLLECTED* for LAB-64. For the LAB-63 the message carries the data about the labeled containers which are, for every labeled container, patient identifier,

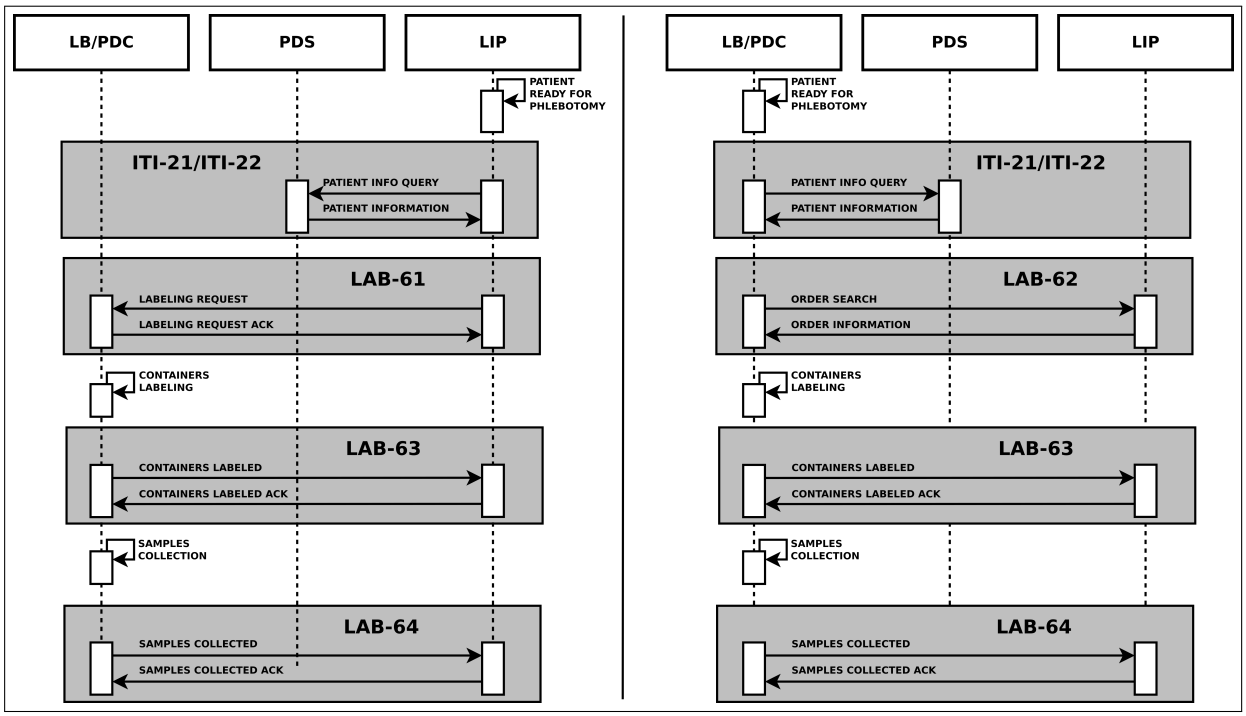

Figure 3: The mapping of the IHE new transactions to the specimens collection process

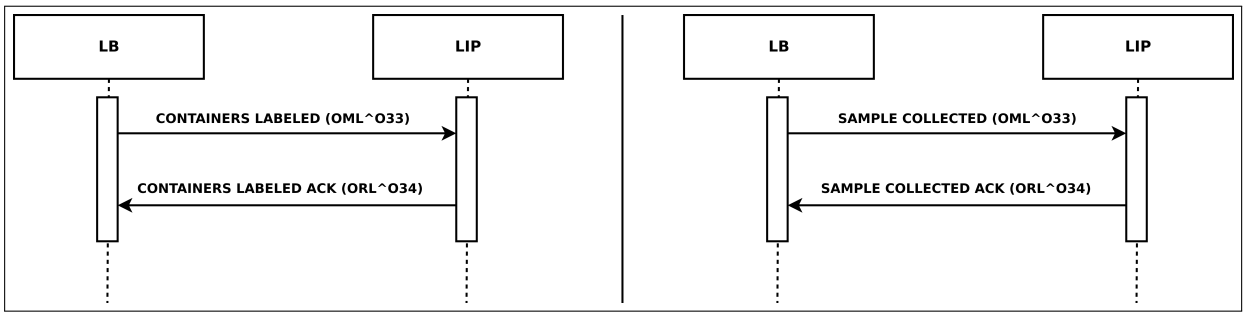

Figure 4: The integration diagrams of the LAB-63 and LAB-64 transactions

type of the container to use, barcode identifier and related tests. For LAB-64 the message carries the same information but in this case they refer to the specimens that have been collected. It is important to note that in both cases the data are a subset of the specimens issued by the previous transactions of the workflow (LAB-61 or LAB-62) and they can coincide with the whole required batch or not. Indeed it can happen that not all the containers had been actually prepared (LAB-63) or filled (LAB-64).

The choice of the proper HL7 message is very important, as its structure must carry all the needed traceability information. According to the prerequisites specified before, the most suitable message for both transactions has been identified in the OMLˆO33 (Laboratory Order Message), since its specimen-centric structure perfectly fits with our needs: as a matter of fact, it provides for each specimen a list of containers and a list of order batteries. Notice that this message is also the reference one for the LAB-61 transaction.

Table 1 reports the segments and blocks structure of OMLˆO33 message. Concerning the segment blocks carrying the information about specimens and orders, OMLˆO33 message is very similar to the homologous message used for the LAB-62 RSPˆK11. The OMLˆO33 message is structured as follows:

- PID and PV1 segments contain patient and visit information;
- every SPM segment carries the related specimen information. An OMLˆO33 message must have at least one SPM segment. This segment begins a block structure; it means that until another SPM segment is found in the message, all segments following refer to the same SPM block;
- ORC, OBR, TQ1, OBX can appear more than once for the same SPM segment. They carry all details about tests that will be executed on the specimen they refer to. Every SPM segment must be followed

by at least one block of these segments (notice that only ORC and OBR segments are always mandatory).

Table 1: OMLˆO33 message structure

Segment	Description	Card.
MSH	Message Header	R, [1..1]
[	— PATIENT begin	R, [1..1]
PID	Patient Identification	R,[1..1]
[PV1]	Patient Visit	RE, [0..1]
]	— PATIENT end	
{	— SPECIMEN begin	R, [1..*]
SPM	Specimen	R, [1..1]
[SAC]	Specimen Container	O, 0..*]
{	— ORDER begin	R, [1..*]
ORC	Common Order	R, [1..1]
[{TQ1}]	Timing Quantity	RE, [0..1]
[	— OBS. REQ. begin	O, [O..1]
OBR	Observation Request	R, [1..1]
[TCD]	Test Code Details	O, [0..1]
[{OBX}]	Obs. Result	O, [0..*]
]	— OBS. REQ. end	
}	— ORDER end	
}	— SPECIMEN end	

The most important traceability fields of the message are:

- PID-3 (Patient Identifier): it is the patient identifier;
- SPM-2 (Specimen ID): it contains the barcode identifier of the label applied to containers in LAB-63 and of the filled specimen in LAB-64;
- SPM-4 (Specimen Type): it is the specimen's type that the printed tube will contain (LAB-63) and of the specimens to draw (LAB-64). For example, B for Blood, U for Urin;
- SPM-27 (Container Type): it provides, for both transactions, a code referred to the specific container that will be printed or filled. Internally, the LB can associate this code to the specific tube model and manufacturer used;
- OBR-4 (Universal service ID): it reports, in both cases, the code of the test that will be performed on the referred specimen (e.g., LDL Cholesterol).

According to HL7 standard, the acknowledge message is the ORLˆO34. Its structure, shown in Table 2, is similar to the OMLˆO33 one, except for the MSA acknowledge segment and for the fact that patient, specimens and orders segments are optional.

As we can infer from the transactions details above, our extensions for the LBL profile completely address the issues discussed in the previous section.

According to IHE roadmap for new proposals, we submitted a Supplement to the Committee for public discussion in July, 2011. The first version has been debated during the IHE Laboratory Technical Committee face-to-face meeting held in Tokyo in September 2011. The LAB-63 transaction has been reviewed and accepted, with the name *Labels and Containers Delivered*. The work on the LAB-64 has been postponed because the confirmation of specimens collection goes beyond the scope of the LBL profile, involving various actors of other profiles.

Table 2: ORLˆO34 message structure

Segment	Description	Card.
MSH	Message header	R, [1..1]
MSA	Message Ack	R,[1..1]
[{ERR}]	Error	C, [0..*]
[	— RESPONSE begin	O, [0..1]
[PID]	Patient Identification	O, [0..1]
{	— SPECIMEN begin	O, [0..*]
SPM	Specimen	R,[1..1]
[{SAC}]	Specimen Container	O, [0..*]
[{	— ORDER begin	O, [0..*]
ORC	Common Order	R, [1..1]
[{TQ1}]	Timing/Quantity	RE, [0..1]
[OBR]	Observation Request	R, [1..1]
}]	— ORDER end	
}	— SPECIMEN end	
]	— RESPONSE end	

Since 2012, the Supplement is available at the IHE website [13], and the LAB-63 transaction has been featured in the set of Connectathon tests for the Laboratory LBL profile.

3.1 Application of LAB-63 in a commercial device: Inpeco ProTube System

The LAB-63 implementation has been included in the prototype of an IHE compliant device supporting fully traceable sample collection. The prototype is one of the outcomes of the collaboration between our center and the Inpeco [14], a company specialized in laboratory automation, in the context of a project focused on traceable laboratory solutions following international standards and best-practices for clinical guidelines and health informatics. The prototype has been developed by following the philosophy that error rates in the sample collection process could be decreased by supporting operators through the use of automated systems.

The main components of the system are two:

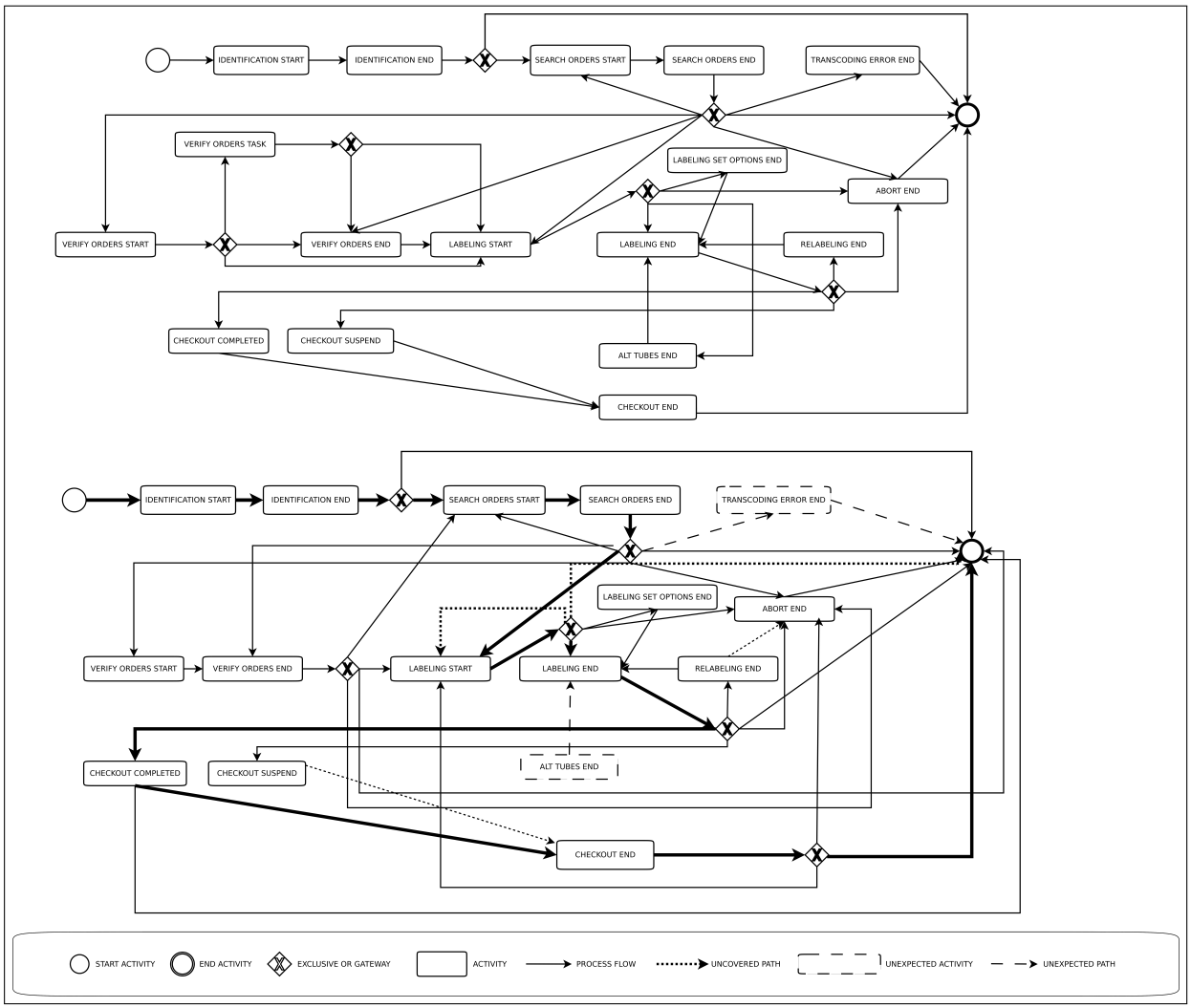

Figure 5: Comparison between the BPMN sample collection process theoretical model and the one inferred through Process Mining. Most covered paths are depicted in bold.

- **Labeling Device**: it is a machine, produced by Inpeco, able to print label and attach them to the tubes. The tube is inserted into the labeler which can recognize its cap color and length, ensuring that the correct container is used;
- **HUB**: it is a server that communicates with clinical Information Systems to retrieve information about patients and their related laboratory requests. It also collects the traceability events of the entire process.

The workflow of the system follows the query mode steps described in 2.3. From an IHE transactions perspective, the Labeling Device is the LB/PDC actor, while the HUB represents the LIP/PDS. The system ensures that all main operations performed along the process are traced by generating the related event logs, with the aim to optimize performance and reduce error rates. The prototype has been industrialized and commercialized by Inpeco, with the name of ProTube, and successively tested in some real clinical environments. Piva et al. in 2015 observed the benefits of the system in the University Hospital of Padua [15]

3.2 Application of LAB-63 for process analysis: traceability data and Process Mining

Traceability data play an essential role for the logging, monitoring, control and improvement of a clinical process: at every point of a process chain, events must be collected and recorded, and they should carry all relevant information about the performed actions: when it happened; who was the operator; and the systems involved.

Process Mining is a young discipline, placed in the middle between Business Intelligence and Business Process Management, and useful to bridge the gap between them: classical data mining concepts are enriched with a process driven approach.

Different types of Process Mining [16] can be used to analyse a workflow:

- **discovery** aims to infer a process model from traceability data, without a-priori information;
- **conformance** compares an existing model (inferred or theoretical) with actual traceability data, checking the conformance between reality and the model itself;
- **enhancement** improves, extends or repairs the a-priori model, using traceability data to infer a model better conform to reality, taking into consideration some new aspects and points of view.

Figure 5 shows the result of Process Mining algorithms applied to traceability data coming from a real clinical site, using a ProTube prototype for the phlebotomy process [17]. It shows a comparison between the theoretical model and the one inferred from traceability data through the use of Discovery Process Mining techniques. Both models have been depicted adopting the Business Process Model and Notation (BPMN) specifications. [18]. Concerning the theoretical model, the following macro activities have been identified:

- **IDENTIFICATION**: query and retrieve of patients information;
- **SEARCH ORDERS**: query and retrieve of patient orders;
- **TRANSCODING ERROR**: atomic activity indicating that an error occurred while computing the required tubes for the retrieved orders;
- **VERIFY ORDERS**: this activity is performed if some orders have to be filtered (according to the site configuration) or have some peculiarities (i.e., timed repetitions)
- **LABELING**: production of the labels;
- **LABELING SET OPTIONS**: configurations for the labeling;
- **RELABELING**: sample relabeling;
- **ALT TUBE**: choice of different tube types;
- **CHECKOUT**: confirmation that all tubes or part of them are filled and ready for transport;
- **ABORT**: interruption of the process caused by the operator

Notice that not all these activities strictly refer to the IHE transactions for the phlebotomy process; some of them are strictly related to specific features of the prototype (e.g., labeling abort, transcoding errors). The CHECKOUT activity in the model is related to the new LAB-63 transaction.

4 Discussion

The new two transactions that we proposed, LAB-63 and LAB-64, complete the description of the phlebotomy process. The first describes the preparation of the specimen container, while the latter covers specimen collection. From an IHE point of view, LAB-63 is completely within the LBL profile scope, while LAB-64 involves other IHE Laboratory domain profiles.

The availability of traceability data enables the application of Process Mining techniques to analyze, reconstruct, monitor or discover a process, enabling the comparison of the real behaviour of a system with its theoretical model. Figure 5 compares theoretical and mined BPMN models obtained applying Discovery [16] algorithms to ProTube prototype traceability data collected in a clinical experimentation site. The figure highlights that there are some activities and paths belonging to the theoretical model that are not covered by the mined one; on the other hand, the inferred model also shows some activities and paths that are not present in the theoretical one. These results can be used to improve the theoretical model, by adding the missing activities and paths, and also to detect errors and exceptions which have to be handled by directly acting on the process components – e.g., actors and procedures. Process Mining analysis also measures the overall process performance through a study of the most covered paths and relevant key performance indicators, such as turnaround time and lead time [19].

In [20] and [21] there are two examples of the use of Process Mining for the analysis of IHE workflows, based on the implementation of the *Audit Trail and Node Authentication* (ATNA) profile and the *Audit Record Repository* actor (ARR). The ATNA profile controls the access to protected health information – for instance, demographic data and clinical documents – logging every access into the ARR. The authors use log information as an input for the Process Mining algorithm to discover patient pathways. This approach, however, presents some difficulties to identify the traces (intended as the set of event logs belonging to the same process instance) and thus perform process reconstruction.

5 Conclusions

Our work demonstrates the benefits that the application of IHE workflow formalizations, traceability-oriented analysis and process mining techniques can bring to health process management. The two new transactions (LAB-63 and LAB-64) we presented to the IHE Laboratory Committee fully covered the traceability of two events critical for the phlebotomy process – i.e., specimen container preparation and sample collection.

LAB-63 was accepted by the IHE and, after a brief revision work, allowed for Trial Implementation. It was successfully tested at the 2013 European Connectathon by two vendors and, according to IHE roadmap, only another

Connectathon testing session is needed before the transaction can be definitively included in the Technical Framework [22]. In 2015, the LAB-63 was further improved to handle additional specimen descriptions and usage specification [23].

LAB-64 instead needs additional discussion, as its scope involves not only the LBL profile, but also external profiles. This transaction has been the starting point for the development of a new IHE Laboratory Profile, called SET (Specimen Event Tracking), whose first version is in the agenda of the Technical Committee for the 2016-2017 period.

The extended IHE workflow also served as the basis to formalize the phlebotomy processes from a process mining perspective: starting from the main IHE transactions, we identified a set of events to trace the process' behaviour and to compare it to the real one.

In the future, the most important priorities are the definitive inclusion of LAB-63 in the Technical Framework and the development of the SET profile. Moreover, the methodology described in this paper, for creating an IHE-compliant traceability system, will be extended to different clinical processes related to other IHE domains and profiles.

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