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Software Engineering and Traceability of Medical Devices in Supply Chain Management Surgical Materials

Software Engineering and Medical Device Traceability in Surgical Supply Chain Management

Software Engineering and Processing of Medical Devices in the Management of the Cadena de Surgical Supplies

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Summary

Medical device management involves information that flows through suppliers, hospitals, and administrative teams, the continuity of which is necessary to reconstruct the path of surgical materials. This article analyzes the contribution of software engineering to the traceability of orthoses, prostheses, and special materials, considering system architecture, data integration, document reconciliation, and operational control. The approach consists of a narrative literature review and conceptual analysis of institutional documents on unique device identification and the deployment of health technologies. The development examines the difference between registration identity and movement history, the representation of events and exceptions, interoperability requirements, and the preservation of digital evidence. Indicators for evaluating the completeness, timeliness, and investigative capacity of records are discussed. The analysis argues that traceability depends on the articulation between data models, business rules, and work responsibilities. Standardized identification is a necessary resource in certain contexts, but its operational use requires integration and validation. The study presents an analytical proposal for organizing the systems. Its application and its possible financial and healthcare effects require subsequent empirical evaluation.

Keywords: Software engineering. Traceability. Medical devices. Medical devices. Interoperability.

Abstract

Medical device management involves information shared across suppliers, hospitals, and administrative teams. Continuity between these records is necessary to reconstruct the movement of surgical supplies. This article analyzes the contribution of software engineering to the traceability of orthotics, prosthetics, and special materials, considering system architecture, data integration, documentary reconciliation, and operational control. The approach combines a narrative literature review with a conceptual analysis of institutional documents on unique device identification and health technology implementation. The discussion examines the distinction between master-data identity and movement history, the representation of events and exceptions, interoperability requirements, and the preservation of digital evidence. Indicators are discussed to assess record completeness, timeliness, and investigative capability. The analysis argues that traceability depends on the coordination of data models, business rules, and workflow responsibilities. Standardized identification is necessary in certain contexts, but its operational use requires integration and validation. The study offers an analytical proposal for organizing information systems. Its practical application and financial and healthcare effects require subsequent empirical evaluation.
Keywords: Software engineering. Traceability. Medical devices. Surgical supplies. Interoperability.

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Introduction

The movement of a medical device produces different records along its path.
The manufacturer identifies the product, the distributor registers its entry, and the hospital requests materials for...
A procedure is in place, and the responsible teams document receipt and use. Billing...
It adds another perspective by relating the materials to authorization and billing documents.
Although these records refer to the same operation, their production in different environments may...
to make reconstructing the route more difficult.
In the segment of orthotics, prosthetics, and special materials, known as OPME, the inventory position
It only offers part of that information. Knowing the quantity available does not clarify which ones.
Units were reserved, delivered, or used in a specific surgery. To answer these
Questions, the system needs to preserve relationships between the identity of the materials, the events
which modify their situation and the documents that support each step.
The problem also involves the interpretation of the data. An item delivered to the hospital does not equate to
an item consumed, as well as a quantity pending return, does not represent
necessarily a loss. When systems treat these conditions as synonymous or fail to
To record their differences, the conference requires further investigation. Traceability may be
understood, in this context, as an informational capacity to reconstruct relationships, and not
only as the presence of codes on the packaging.
The unique identifier for medical devices, UDI, provides a reference for recognizing
products. The Food and Drug Administration documentation distinguishes the model identity from the
Production information, such as batch and serial number. In Brazil, Anvisa describes the standard as...
an instrument for unequivocal identification and support for post-market monitoring (United States,
[n.d.]; National Health Surveillance Agency, [n.d.]). These references establish a basis
for registration, but the trajectory of each material still depends on the records of the organizations that...
They move.
The aim of this article is to discuss how software engineering can structure this continuity in
Surgical materials supply chain. The analysis covers architecture, integration, validation rules, and usage.
data management. Their contribution consists of making explicit the modeling decisions that make the
A verifiable process that allows for the evaluation of the quality of the information produced.

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Methodology

The study is theoretical in nature and uses narrative literature review and document analysis. They were...
Institutional documents regarding unique device identification and security were examined.
Information, in addition to scientific articles on the implementation of technologies in healthcare. The focus
considers the continuity of records in the circulation of surgical materials and the decisions of
engineering necessary to preserve it.
The selection was guided by relevance to issues of identification, continuity of records and
implementation. The set includes documents from Anvisa and the FDA, works by Wilson and
Contributors on UDI, the Sittig and Singh model, and the NIST cybersecurity framework.
The sources were organized into analytical axes, from which the propositions about [the subject matter] are developed.
Architecture and operational evaluation. The method does not constitute a systematic review nor does it intend to be exhaustive.
the available literature.
No patient data or internal company databases were collected. Operational examples
The hypothetical situations presented are used to examine relationships between records and decisions.
The proposals for integration and indicators constitute conceptual contributions of the article, without
Benefit estimates or causal demonstration of results.

Chapter 1 Device Identification and Continuity of Operational Information

The first modeling decision involves defining what is being identified. Product
commercial unit, physical unit, packaging, and set of materials are related entities, but
different. A registration that only represents the commercial description does not allow distinguishing between two.
units of the same model when the investigation requires production information. Conversely,
Registering a batch without correctly identifying the product also leaves the evidence incomplete.
the material.
The FDA differentiates the fixed component of the UDI, associated with the labeling authority and the version or
to the model, of the variable production component. Its GUDID database gathers registration data from
device and does not contain production identifiers or data on who used each item (United
States, [n.d.]). This distinction leads to a consequence for engineering: a cadastral consultation.
This does not replace local records of circulation and use.
In Brazil, Anvisa reports that SIUD has been operational since March 2026. The existence of the database
It expands the identification infrastructure, while hospitals and suppliers remain responsible.
by organizing information from their own processes (National Health Surveillance Agency,

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[sd]). For the operating system, the standardized identifier must be associated with the references.
used in inventory and documents, without erasing the origin of each correspondence.
These correspondences need to allow for changes in catalog and presentation. An internal code.
It can be replaced, and a description can be corrected. If the change is applied
By retroactively applying this information to all records, the institution may lose the ability to understand how...
The material was identified when the movement occurred. It is proposed that the identification be preserved.
Valid at the time of the event, along with the registration change history.
The unit of measurement requires similar attention. Box, set, and unit are not interchangeable.
An input of two boxes with five items each cannot be directly compared to an output.
of two units. The application must specify the authorized conversions and indicate when the opening
The way packaging is modified changes the control method. This helps prevent quantity discrepancies.
produced solely by the representation of the data.
Finally, identity and trajectory must be linked to an operational context. A material can
to be reserved for a procedure, in transit between organizations, or at a conference after
return. These situations require relationships between entities that cannot be resolved by simply updating.
from a balance. The quality of traceability depends on the ability to explain the current state from
of the recorded events.

Chapter 2 Software Architecture and Interoperability Between Organizations

An architecture for traceability should separate product registration from event tracking.
movement and reference documents, while maintaining links between them. This separation favors
The evolution of applications because changing a billing rule doesn't necessarily mean modifying the...
The meaning of a delivery that has already been made. The design should allow each piece of information to be consulted.
in the context in which it was produced.
Integration between organizations presents additional challenges. Supplier and hospital may
Using different codes, units, and states. Message exchange via an API solves this.
Data transmission is possible, but it doesn't guarantee that participants will interpret the content in the same way.
Operational interoperability requires agreement on the concepts represented and on the conditions.
at which point a record can be considered confirmed.
For a received message, for example, the integration contract should indicate whether it...
It represents physical verification, document acceptance, or simply arrival registration. It also needs
To clarify whether the confirmation covers the entire shipment or part of it. These definitions affect the next step.

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The following should be included in the interface documentation, with version control and assigned users.
change.

Temporary communication failures require processing rules. When the sender does not receive
In response, you can resend a previously transmitted confirmation. The receiving system must recognize this.
Repetition is used to avoid duplicate effects, such as a second stock decrease. It is proposed to assign
to assign identity to events and adopt idempotent processing, whereby the same information is received again.
The operation does not modify a situation that has already been correctly recorded.

There may also be delays in the order of arrival. A message regarding usage may reach the
application before confirmation of receipt, especially when records pass through channels.
different. Instead of discarding the information or automatically completing the missing step, the
The architecture must anticipate pending issues, reconciliation, and investigation. The decision regarding the status of the process.
You need to distinguish between the order of transmission and the actual sequence of events.

The observability of the integrations completes this design. Correlation identifiers allow
to monitor an operation between applications, while technical logs report errors of
transmission and processing. This data must be associated with the operational context without exposing
Unnecessary sensitive content. A flaw identified only through technical code may be
Insufficient for the team that needs to know which shipment is pending.

The choice between a centralized application and distributed services depends on scale and capacity.
Maintenance and integration conditions. Technical fragmentation is not an end in itself. For
In organizations with small teams, excessive division of components can increase the workload.
of support. The proposed criterion is to maintain clear boundaries between responsibilities and ensure that the
The route should remain verifiable, regardless of the architecture chosen.

Chapter 3 Surgical workflow modeling and handling of exceptions

The flow of materials can include requisition, authorization analysis, reservation, picking, shipping,
receipt, confirmation of use, return, and invoicing. This sequence offers a
Reference, but does not represent all possible events. Cancellations, remittances
Additional additions and authorized replacements make it necessary to model alternative routes.

The application must preserve the difference between states and events. A state describes a condition,
as material in transit; the event records the occurrence that produced it, such as an expedition.
When architecture retains only its most recent condition, it loses some of its capacity to explain.
how it was achieved. The historical record should allow for an examination of the relevant changes and documents.
which justified them.

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Consider a shipment of three units, of which two have been used. The third can wait.

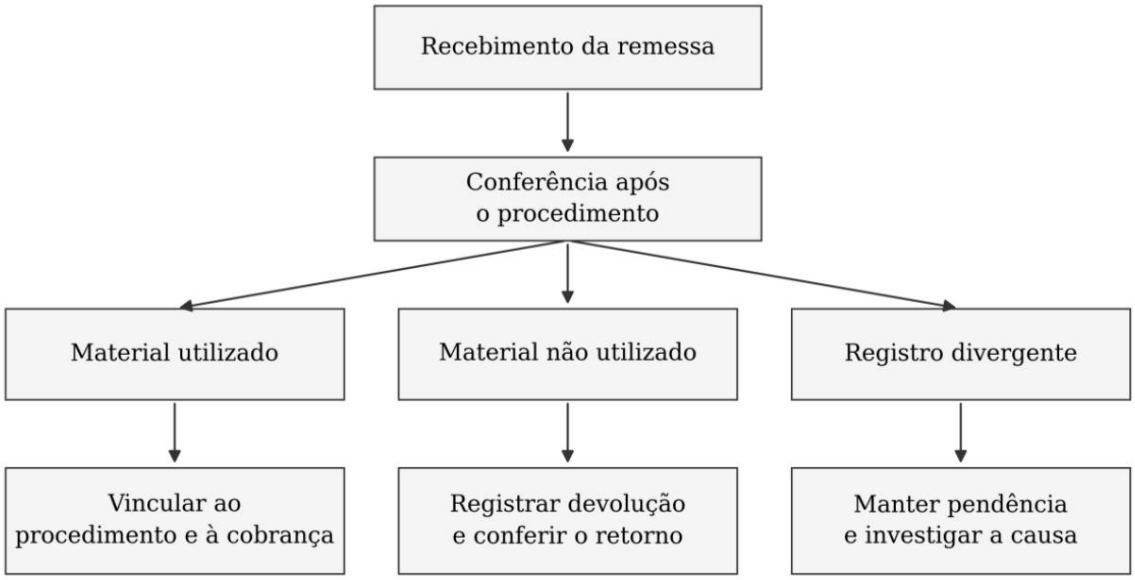
The return will remain the responsibility of the hospital. The record must indicate this situation.

distinguishing it from a unit returned and checked by the supplier. The difference between consumption and

Delivery, in this case, does not necessarily imply inconsistency; it represents an ongoing process.

not completed.

Figure 1 Treatment of materials after the procedure



Source: author's own elaboration. Conceptual framework, without empirical data.

Figure 1 distinguishes between consumption, return, and documentary discrepancy. The diagram summarizes the conditions.

The principles discussed in this chapter do not represent the protocol of any specific institution nor do they replace the...

Confirmation of the documents for each transaction.

An authorized replacement requires a different form of registration. The originally requested material must...

It should remain identifiable, as well as the item that replaced it and the documentary reference for the change.

Deleting the initial request can make it difficult to understand the authorization or charge.

The representation must preserve both the original plan and the permitted alteration, with an indication of

Your time and your responsibility.

Document reconciliation compares evidence for different purposes. Request, authorization,

Delivery, consumption, and billing do not express the same fact. A validation mechanism can...

To signal the absence of a usage record, but the decision regarding the pending issue requires verifying whether the

The document is overdue if there has been a change in procedure or if there is an actual discrepancy.

Automation is most useful when it directs the investigation toward identifiable causes.

The glosses need to be examined within this distinction. Documentary inconsistencies may

contribute to payment denials, while contractual and coverage criteria also

interfere. Evaluating a solution requires classifying the causes of refusals to understand which ones.

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These issues are amenable to technological intervention. Reducing a category of pending issues does not authorize... to conclude that all financial losses have been resolved.

A well-defined workflow should allow the operation to be completed or explicitly state what prevents it from being completed. its conclusion. This capability depends on transition rules that reflect the actual work, with Participation of logistics and administration teams. Exceptions recorded no longer depend on Individual memory and can be examined as part of the process.

Chapter 4 Integrity of records and information security

The usefulness of a traceability trail depends on trust in the records. Integrity involves Preserve the content and make its changes verifiable. Correct a quantity or associate a Submitting material to another procedure may be necessary, but the correction must maintain authorship and justification. and its relation to the previous release.

Access permissions must match job functions. Receiving a shipment, changing Registering a profile and approving a reconciliation are different decisions. When the same profile can... Performing all of them and clearing the history makes the investigation dependent on evidence. controlled by the person responsible for the operation. The segregation of permissions must be proportional. to the context and accompanied by review in cases where small teams concentrate functions.

The NIST CSF 2.0 organizes cybersecurity risk management outcomes and can guide the discussion. regarding institutional responsibilities and priorities. Its structure does not determine a single set. of controls for all organizations (Pascoe; Quinn; Scarfone, 2024). In the context of this article, It helps to situate security as part of the planning, while the selection of measures should Consider the information and consequences of an interruption.

The link to a surgical procedure can bring data from informational materials closer together. personal. Architecture should examine which relationships are necessary for each task and limit the exhibition. A team responsible for the logistics conference may need the identifier of The procedure does not allow access to the entire medical record. Authorization to view information must be granted. This will depend on the operational purpose and applicable requirements.

Continuity also affects integrity. After an interruption, restoring files does not guarantee integrity. that all events are reconciled. Records made using alternative procedures. These need to be incorporated, and pending messages should be checked. The recovery plan It should clarify how to resume the operation without creating duplicates or omitting any previous actions. during the downtime.

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Restoration tests need to examine the consistency between registration, inventory, and history. A database that opens correctly may contain incomplete relationships, and a restored integration may to continue transmitting old messages. It is proposed to evaluate the recovery with situations representative operational tasks, verifying if the team can reconstruct a route and identify the remaining pending issues.

Chapter 5 Traceability Indicators and Operational Performance Analysis

Evaluating traceability requires indicators related to the questions the system intends to answer. The number of records stored, in isolation, does not indicate whether a shipment can answer. to be reconstructed or whether the documentation supports the conference. The indicators must be defined to starting from the process and accompanied by accuracy checks.

Completeness can be measured by the proportion of procedures that have records. Required for its effective implementation. Inapplicable steps, such as use in a cancelled surgery, They need to be handled according to documented rules. Therefore, the denominator represents Comparable operations allow one to distinguish between the absence of evidence and a legitimate flow condition.

Timeliness refers to the interval between an event and the availability of information for the next step. It is necessary to distinguish between the date of the transaction and the date of synchronization.

The median and upper percentiles may offer a more informative reading than the average. especially when a few prolonged delays concentrate the operational difficulty.

Documentary discrepancies should be calculated using a classification of causes. Registration error, Unreconciled quantity, overdue document, and authorized change without electronic link require different interventions. Grouping all these situations into a single index makes evaluation difficult. what changed after implementation and what still requires manual work.

Another measure is the time required to reconstruct the path of a unit or batch. An exercise An audit can verify whether the located records are sufficient and consistent, including Returns and corrections. The speed of the consultation should be interpreted in conjunction with the quality of the... Evidence: Quickly finding incorrect information does not represent an improvement in traceability.

The financial effects require separate analysis. Less conference time can free up capacity. Work without producing an immediate reduction in expenses. The recovery of a previously existing value.

The rejection needs to be associated with the reason for the rejection and the changes during the period. Comparisons should Consider volume, procedure composition, and contractual changes to avoid assignments. improper.

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During implementation, identifying more discrepancies may result from increased detection capabilities. Therefore, time series should be examined with stable criteria and with information about the method of data collection. The proposed evaluation prioritizes the explanation of the indicator and its verification. independent of some of the records, allowing us to distinguish apparent performance from improvement. sustained.

Chapter 6: System Implementation and Knowledge Transfer

Wilson et al. (2021) present the implementation of point-of-care IDUs as a process. organizational. In a subsequent publication, they discuss barriers and strategies for its adoption in health systems (Wilson et al., 2022). These studies help to understand why the The availability of an identifier needs to be accompanied by effective capture conditions and use.

The Sittig and Singh (2010) model recognizes the interdependence between technical and social dimensions. of health information systems. Applied to the problem discussed here, this perspective guides An analysis of the relationships between interface, record content, responsibilities, and work. A rule. The validation process may be technically correct and yet be inadequate at the time when... The team manages to obtain the information.

Implementation can begin with a defined workflow, selecting common situations and... Relevant exceptions. A pilot consisting only of simple operations offers little information. Regarding returns, cancellations, and integration failures. Expansion should depend on the capacity to... to treat these conditions and to maintain consistent evidence during the transition.

Training needs to combine task execution and record interpretation. The user must Understanding what constitutes receiving, using, and closing a business, as well as knowing how to record it. A pending issue. The ability to recognize outdated data or a repeated message. It is also important when the application receives information from other organizations.

Knowledge transfer requires documentation of the rules and the rationale behind them. Without this record, changes in staff or supplier can silently alter the... Data interpretation. Maintaining an operational dictionary and exception examples. It contributes to preserving an understanding of the process throughout the system's evolution.

Final Considerations

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Software engineering contributes to the traceability of surgical materials by organizing relationships between identity, events, and documents. The analysis developed shows that the position of Inventory, the presence of an identifier, and operational history answer distinct questions. Its articulation allows for the reconstruction of routes and the examination of pending issues with greater precision. informational.

The proposed design relies on controlled registration matches, states clearly Defined and integrated solutions capable of handling repetition, delay, and exceptions. Preservation of the history of Changes and the definition of permissions support the reliability of the evidence. These decisions They need to consider the teams' routines and the conditions for data flow between organizations. The indicators discussed offer criteria for evaluating completeness, timeliness, and capability. of investigation. Its application must be accompanied by accuracy verification and analysis of the Conditions of the period. Measuring financial or welfare benefits requires studies. specific and does not automatically result from the implementation of a platform. The study has limitations regarding the narrative selection of sources and the lack of validation in field. Further research could examine the feasibility of the model in hospitals and providers. with different structures, in addition to their maintenance costs and the workload required to Record capture. This investigation will allow us to assess the conditions under which data integration can occur. It produces effectively usable traceability.

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