

FROM PATIENTS' NEEDS TO HOSPITAL PHARMACY MANAGEMENT: AN HOLISTIC APPROACH TO THE PROCESS MODELLING

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ABSTRACT

Materials management is a great issue for healthcare systems because it influences performances of structures in terms of clinical and financial outcomes. Enhancements can be done by means of an appropriate management of data related to these materials coming from all processes in which they are involved. This paper presents an integrated and detailed description and model of the hospital materials management process, able to tackle information from patient requirements to materials usage, according to traceability and streamlined processes perspectives. The holistic approach adopted, based on hospital cases analysis, literature review and international guidelines, tends to look at all actors, materials and processes involved, with the attempt to provide academicals and practitioners with a useful guide to the various technology-related, management and business issues that can arise during the design or reengineering of this business process and the associated information system.

Keywords: hospital materials management,-healthcare process modelling,-drug inventory management, healthcare logistics

1. INTRODUCTION

Materials management is a great issue for healthcare systems because it influences performances of structures in terms of clinical (service level offered to patients, quality, timeliness, etc.) and financial outcomes (expenditures on warehousing, handling, deterioration, etc.). Enhancements can be done by means of an appropriate management of data related to these materials coming from all processes in which they are involved.

Apart from the managerial choices to take, indeed, the description and analysis of physical and information integrated flows as they may, should or have to happen, is useful to achieve medical risk reduction and materials and information traceability.

Moreover, before selecting, adapting and implementing leading or optimized practices, it is necessary to develop a good understanding of processes and activities in place (Landry and Philippe 2004) in order to lay the foundations of an efficient

reengineering of supply chain that reduces healthcare costs without affecting the quality of care (Jarrett 1998).

In literature, many collateral references on how the materials management works are reported but it is really difficult to find a detailed, integrated and exhaustive hospital materials management workflow analysis and description. The aim of this paper is to develop such a process model with an holistic approach to the system, describing actors, tasks and information needed to manage materials from their acceptance to utilization.

2. PROCESS ELEMENTS

The first step to conduct the hospital pharmacy “micro-world” reengineering process towards optimization is to identify the behaviour of this system, such as what to manage in terms of materials, actors and processes, taking into account information and legal constraints. In the remainder of this paper, a detailed description of actors, materials and macro-processes is carried out, followed by a thorough explanation of all processes and sub-processes involved.

2.1. Actors

First of all, it is fundamental to profile all the actors that take part to materials management processes, distinguishing by the level at which they participate to them, that is:

- Medical Unit actors: together with patient needing for care, physician (who delivers the care), nurse (who dispenses the care) and nurse manger (who supervisions the dispense of care) are basically the other actors involved at the medical unit materials management stage;
- Pharmacy Unit actors: international health care standards require a central pharmacy unit in hospitals that maintains and provides the inpatient pharmacy needs (Joint Commission International 2011). The pharmacy unit is usually composed by hospital pharmacists, storekeepers and transporters;
- Other organizational functions: the Medical Director, the Superintendence and Treasure's Office, the Accounting Office take part to the process.

2.2. Materials

Management of materials in healthcare involves two kinds of items' clusters, that is drugs (or medicines) and medical devices, subjected to different regulations harmonized by countries according to international guidelines.

The properties of medicines in a hospital information system may be mandatory or optional depending on the contextual workflow (IHE 2010). A fundamental "identifier" is the ATC, Anatomic – Therapeutic – Chemical classification, internationally accepted and maintained by the World Health Organization. In addition to commercial drugs, drug administrations can also refer to galenics, such as personalized medicines prepared as a "mixture" of commercialized products at the bedside, in hospital pharmacy or in another defined medical unit. In parallel, medical devices can be required as surgical kit and apparatus compounded by many of them, that can be managed as single items by pharmacists or directly supplied as a pack.

The item list (in other words, the set of medicines or medical devices that can be administered/dispensed or implanted to patient in a healthcare system) changes from hospital to hospital, depending not only on healthcare services managed, but also on physician's expertise and preferences and following pharmacoeconomics principles.

2.3. Processes

Irani et al. in Vergidis et al. (2008) sustain that businesses should not be analysed in terms of the functions in which they can be decomposed to or in terms of the output they produce, but taking into account the key processes they perform.

The hospital medication workflow is triggered by patient needing drugs and medical devices. In this perspective the Technical Framework, developed for the pharmacy domain by the initiative Integrating the Healthcare Enterprise (IHE), was born to stimulate the integration of healthcare information systems operating with different standards (such as DICOM, HL7, etc.). In the proposed pharmacy interoperability model (IHE 2011), the care path (clinical perspective) described is orthogonally combined with the supply path (logistical perspective) in the phase of distribution but - as explicitly stated - supply chain of ordering/delivering medication and stock management are out of IHE scope.

According to the Irani et al. opinion, we adopt and refine the IHE pharmacy interoperability model as an "information track" to classify and describe all the elements depending on logistics decisions in the hospital medication workflow. We readapt that model to define in more detail different care paths, distinguishing among the type of medicine or medical device employed; moreover, we explore the management area, depicting all the processes involved.

Analysing some hospital cases, literature review and international guidelines and considering the clinical/logistical perspective, we define the hospital materials management as to be composed by the main following macro-processes, that are fully described, together with their sub-processes (reported in Figure 1) in the next sections:

- a) Patient Management
- b) Medical Unit inventory Management
- c) Centralized inventory Management

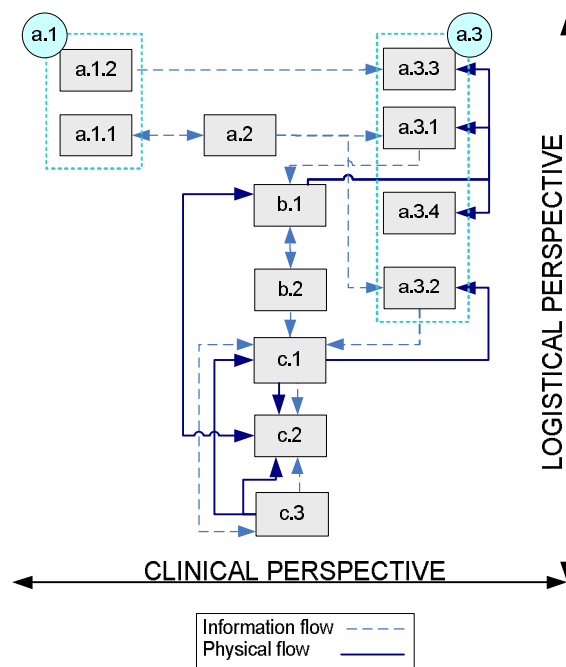


Figure 1: Process Framework of Materials Management in a Hospital (the notation used is explained later in the next sections)

3. PATIENT MANAGEMENT PROCESS (a)

The first macro-process is the patient management, since the need for care (and then the hospital medication workflow) triggers materials requirements.

When it comes to a patient admission (in emergency or outpatient department), a physician states a diagnostic hypothesis, attributing (with or without a confirmation) one or more diseases to the patient.

Depending on resources availability (beds, laboratories capacity, etc.) and urgency, (s)he also assigns a diagnostic and/or therapeutic pathway to be followed in the hospital or at home.

The hospitalisation in a medical unit can be immediate or delayed according to a queue list (for Inpatient access, Day Hospital, Day Surgery, etc.); hospitalisation or not, a patient anamnesis and a previous and current therapies recording are always required to know if they are compatibles with the pathway to perform.

The patient management process is composed by 3 sub-processes:

- a.1) Prescription
- a.2) Pharmacy prescription validation
- a.3) Materials delivery to patient

3.1. Prescription (a.1)

A prescription is the outcome of a clinical decision, is issued by a physician for one patient and may be the input of pharmaceutical validation and dispense. Sometimes, there can be a medication dispensed or administered outside the context of a prescription (for example, in case of urgency in the Emergency Department). They are considered as attached to an order session, which can be associated with a prescription.

We distinguish between two kind of prescriptions that are related to materials consumption:

- a.1.1) Drug Prescription or surgical intervention plan
- a.1.2) Exam prescription

3.1.1. Drug Prescription or surgical intervention plan (a.1.1)

In addition to pharmaceutical validation, a drug prescription is also the input of nurses' instructions to administer the drug for hospitalized patient or, in case of outside dispense, for patient home care. Variations in the content of prescriptions can occur, being dependent on country regulation, responsibilities and standard developed but, on the basis of regulations, IHE statements (2010) and interviews, the medical prescription data set is compounded, among others, by actors (Patient and Physician) Id, reason for prescribing, number of refills (for dispense), active substance and brand, dosage, frequency of intake and quantity. Alerts about prescribing restrictions and potential Intolerance, Contra-indication and Allergies (ICA) should be easily consulted.

The active substance(s), as stated before, is usually a key element because it can permit evaluations about pharmaco-economics and availability (for example, to distribute the cheapest brand name stored in satellite or central pharmacy or to prescribe what is stored in the local warehouse), but clinical consideration can imply a more rigid selection. The active substance(s), together with the pharmaceutical form, may allow to entry the medicine database and look for the most frequent disease for which it is adopted, ICA, maximum dosage per administration, frequency and times of standard intake depending on patient age, gender or weight. Physicians and pharmacists have to take into account all these data and combine them with patient characteristics to assure the best choice and to prevent mistakes.

In case of surgical intervention, some materials have to be explicitly prescribed (for example, an orthopaedic prosthesis and its size or surgical kit).

3.1.2. Exam prescription (a.1.2)

The physician can prescribes some diagnostic examinations to patients, such as laboratory exams (e.g. blood, RX) or other activities that require materials.

3.2. Pharmacy Prescription Validation (a.2)

After a prescription act, prescription information may be made available to pharmacists as a pharmacy validation can be delivered. It can be advisable but not mandatory, so that many organizations tend to jump this step. This implies no double reviews and, hence, no possibility of medical error reduction.

A detected problem can be a supply issue (suspended medication, out-of-stock., etc.), a legal issue (medication recalled or not allowed under certain conditions), or a medical issue (redundancy, interaction, contra-indication, etc. as an ICA).

3.3. Materials delivery to patient (a.3)

The diagnostic or therapeutic pathway involve materials requirements that can be indirectly related to patient because it is not convenient to address their usage to a specified activity performed ("General" goods usage") or directly related to it, as the case of "drug prescription or surgical intervention plan". Exam prescription triggering materials usage can fall in both of these classes. In more detail, four events can imply materials delivery to patient (see Figure 1) which are described in the following paragraphs:

- a.3.1) Preparation, administration or implant (inside dispense)
- a.3.2) Dispense to patient (outside dispense)
- a.3.3) Exam accomplishment
- a.3.4) "General" goods usage

3.3.1. Preparation, administration or implant (a.3.1)

When it's time to administer a medication (depending on the prescription), a message is sent to the nurse in charge and a preparation may take place. However, many hospitals do not have such an information tool or do not have an information system at all, so nurses are in charge of transcribing prescriptions on provided diaries, checking them to know when to administer. This implies risk of errors in transcription and administration execution (right time, person, etc.).

Preparation is the phase in which nurses take drugs from the stock and prepare them to be administered to patients. Some hospitals manage patient unit dose packed by robots or nurses at hospital pharmacy or medical unit warehouse, while others manage the most part of materials in the original package up to the patient bed.

Galenics (that are, as said before, extemporaneous composition of commercial drugs), are a special case because the preparation, depending on type and organization, may involve pharmacists and requires an appropriate recording of all actions and items used (information about drug id, lot number, quantity used, etc.) for traceability reasons. While an intravenous

injection of cortisone diluted in 0.9% sodium chloride solution can be prepared at patient bed, oncological galenics are usually made in a dedicated medical unit and later transported. Labelling with patient and galenic Id is the right way to reduce clinical risk while assuring traceability.

According to IHE suggestions, the assignment of a medication unit to a specific patient means a “dispense”; a galenics dispense can be considered as the instant in which labelling occurs.

All the medication are usually collected in a trolley or an already filled trolley is used, with a number of drawers containing the most frequently used drugs and other drawers destined to specific patients’ needs (this is the case described in Augusto and Xie 2009). Moreover, some medical devices such as syringes, gloves, roller bandages etc. have to be added to the trolley.

Inventory updated information are crucial, because previous checks should be done in order to assure that each patient has his own medication available at the time indicated in the prescription (naturally, this check is easy if an integrated information system is used). Together with quantity availability at the due date, expiration date control has to be done and the package with the closest expiration date should be drawn and disposed.

Administration follows. Nurse goes to patient bed and does the 7 “rights” checks (right patient, right drug, right dose, right route, right time, with the right information and documentation), administers the medication and records all the connected information, according to traceability and medical risk reduction objectives. Moreover, dispense (if done) or administration coincide with the recording of the consumption of medicine used (unit dose for commercial drugs or components for galenics and protocol – following the related bill of materials) from medical unit virtual stock so that warehouse management system is always up to date.

In case of surgical intervention, medical devices, kits or apparatus have to be used. After it, information about these materials has to be recorded as indicated before for drug administered, in order to satisfy clinical, traceability and inventory management requirements.

3.3.2. Dispense to patient (a.3.2)

In some healthcare organizations, hospital pharmacy can be charged also of materials dispense for home care (from outpatient departments or discharged patient). These materials are almost overlapping to that used by inpatients.

Outside dispense can be liken to medical unit dispense, because prescription is checked, material is taken from warehouse, recorded and given to the patient. In particular, a dispensation, among others, is composed by the refill number and the dispensing period.

3.3.3. Exam accomplishment (a.3.3)

Differently from “general goods usage” explained later, some medical devices can be directly attributable to one patient needs because a bill of materials may exist for each examination belonging to the deliverable service list of one hospital. Inventory levels are usually updated when examination is performed (back-flushing method) because examination duration is not so long to require single picking item recording.

3.3.4. “General” goods usage (a.3.4)

This process concerns medical devices utilisation not planned nor directly attributable to one patient care. This distinction is trivial because it is always possible to record each activity performed for one patient and its requirements in terms of materials, but most of the accountability/information systems does not elaborate on this function. For this reason, the medical devices belonging to this process are considered “general goods” for hospitals (examples are gloves to handle test-tube, elastic bandages).

4. MEDICAL UNIT INVENTORY MANAGEMENT PROCESS (b)

The second macro-process identified deals with the material management at medical unit level. Before going into deep of this process, we give some insight about places and policies concerning it.

First of all, regarding to places of materials management and dispensing, it is possible to distinguish between clinical and managerial perspectives. From a clinical point of view, the usefulness of having centralised patient-oriented pharmacy services to deliver professional services to patient (Carroll and Gagnon 1984) has been recognised. From a managerial perspective, many authors state the possibility to reduce logistics costs using a satellite pharmacy systems (Poley et al. 2004); numerous studies, finally, suggested the benefits of having central inventory control – rather than allowing department or region to deal with suppliers individually (O’Hagan 1995 cited in Jarrett 2006) – particularly in terms of drug waste reduction (Poley et al. 2004). In addition to a centralised point of distribution, however, it is necessary to have a decentralised materials management warehouse close to the point of delivery (Little and Coughlan 2008) to allow nurses to quickly reach stocks in the proximity of places (beds) where services (administrations) are delivered. The same holds good for medical devices, particularly in case of vendor managed inventory for surgical interventions. For these reasons, the inventory system is typically characterised by centralised and decentralised stores (de Vries 2010), with two types of warehouses: medical unit and hospital pharmacy. The first one has to deliver materials to the patients of the facility, the second one is in charge of managing items for inside (to medical unit) and outside dispense (to patients).

For what concerns policies of materials management, literature and practical cases are full of

different approaches. Going to the bottom of the issue, the two fields of intervention which need to be globally optimised are medical unit supplies and pharmacy supplies. Look-back (for example Re-Order Level, Re-Order Cycle, Just in Time), look-ahead (for instance Material Requirements Planning) or mixed (for example Vendor Managed Inventory) approaches can be used. All these approaches can be adopted inside the same healthcare system depending on the item typology (ordering prices, inventory costs, shelf life, demand mean and deviation, etc.). Cluster analysis has to be performed in order to group items that can be similarly managed. For example, galenics may have little or no stock, their components may be managed in lots. Look back approach is more popular than the other ones but it is characterised by higher inventory levels. Moreover, forecasts on aggregate data about consumptions recorded by pharmacy are influenced by medical unit materials management. Look-ahead techniques, instead, need for careful and punctual information about requirements forecast.

In what follows, the description of the two activities compounding the Medical Unit Inventory management process is reported:

- b.1) Medical unit stock management and re-ordination
- b.2) Pharmacy order assessment

4.1. Medical unit stock management and re-ordination (b.1)

Medical and surgical supplies close to the point of delivery (i.e. ward, theatre or laboratories) are usually managed by medical units, who are in charge of:

- handling incoming and materials to dispose;
- keeping warehouse management system up-to-date;
- dispensing and recording the dispense of materials triggered by a validated prescription (for preparation and administration or implant), materials for exam accomplishment, "General" goods usage;
- controlling stock levels and determining that a warehouse replenishment is needed.

A medical unit order (that is a replenishment request to hospital pharmacy) can be delivered for different motivations, depending on materials typology:

- the no-stock policy is adopted, as happens in Wong et. al (2003), where a medication ordering-dispensing and administration process triggered by patient needs is evaluated;
- there is a warehouse but a stock is not provided for this material, rarely prescribed;
- it is an out-of-stock item (also the security stock is consumed).

The order can be transmitted in form of a list to be sent to the hospital pharmacy, as a Kanban (in case of Just In Time method), as a requirement for each patient or, as happened in Augusto and Xie (2009), in the form of a mobile medicine closet to be partially refilled.

The typical materials' list, headed with list Id, date and requesting medical unit, contains items Id and quantity for each one, being comprehensive of raw materials belonging to galenics' bill of materials. According to the policy applied, in case of drugs, the item Id can refer to the brand name or the general name.

As Nicholson et al. (2004) claim, the most traditional servicing approach is the periodic review par level (or order-up to level), that requires to set the review interval and the optimal security stock (base stock level). While the second depends on therapeutic and medical constraints set by taking into account demand variability, the first has to be defined according to resources involved.

Indeed, implementing an inventory control tool which links prescription and consumption through an computerized prescriber order-entry system (considered the first step to adopt look-ahead techniques by Awaya et al. (2005)), could allow to deal with the complex and stochastic nature of demand adopting information about materials requirements of patients. Data coming from Electronic Patient Records, such as requirements and administrations concerning prescriptions for inpatients and outpatients, together with forecasts about incoming or belonging to waiting lists' patients, may be merged to develop an optimized supply and delivery planning.

Some examples of re-ordination strategies come from Kalmeijer et al. (2003), who promote the extensive use of Information Systems to manage requirements considering the default medication database as the local stock. Non-stock items are automatically ordered from pharmacy, instead.

4.2. Pharmacy order assessment (b.2)

If medical units are in charge of inventory management, pharmacists usually have to control re-orders' adequacy in terms of frequency and quantity for each material, real requirements and stock availability. Here, clarifications and changes can be made. The process ends with the release of the orders.

5. CENTRALIZED INVENTORY MANAGEMENT (c)

The final process is the centralized inventory management one, that links the internal requirements to the external supply chain. The sub-processes involved are:

- c.1) Pharmacy stock management, order disposition and supplying activities
- c.2) Internal distribution
- c.3) Materials Admission and Quality control and Payment

5.1. Pharmacy stock management, order dispositions and supplying activities (c.1)

After pharmacist order assessment, the stock management and supplying activities take place. Operationally speaking, the tasks to carry out are:

- handling of incoming order and expiration materials;
- keeping warehouse management system up-to-date;
- budget reconciliation assessment. Each cost centre/medical unit typically has its own budget to manage for each expenditure class, and the same for materials belonging to tenders, that have their specification budget. Materials have to be transferred according to them, otherwise a budget integration has to be requested - to Superintendence and Treasurer office - reporting quantities and extra-fund amount needed);
- stock levels control and authorization to dispense;
- supplying activity.

As happened to medical unit stock management, different inventory management policies can be implemented in order to take frequency/quantity supplying decisions.

The order is e-transmitted to the supplier or to a “Central of Purchasing”, whose task is to sort orders to the supplier and sends feedback information such as order acceptance or delivery due date.

An exception case is the out-of-stock of life-saving drugs or medical devices. Provided that hospital pharmacy has its own fund, a supplier different from the tender winners or more expensive than the usual ones can be contacted if provisioning lead time are supposed to be shorter.

5.2. Internal distribution (c.2)

This process is carried out starting from pharmacists authorization triggered by medical unit replenishments, eventually fulfilled by supply order (also transient materials).

Inside hospital pharmacy delivery systems have a key role in hospital's service quality (Yurtkuran and Emel 2008). The diffusion of multi-echelon inventory problem opposed to scheduling oriented ones (Lapierre and Ruiz 2007) has often coped with in literature, and different transportation solutions or search for optimized routing problems (for example, see Augusto and Xie 2009) are presented, in which transportation costs and resources (both personnel and physical resources like means of transports etc.) are some of the main variables taken into account. The reason is the pervasiveness of satellite pharmacies and hub and spoke models in which geographical distances among medical units to be served can be great. Another issue is resource sizing that depends, inter alia, on frequency

and quantity of transport from pharmacy to medical units, quantity to handle due to arrivals, characteristics of material handling equipment.

The order preparation, performed by storekeepers, consists in printing (also virtually) the materials list released by pharmacists for a medical unit (if the list exists and no refilling method is applied), labelling and filling a bag/receptacle with all materials listed. FIFO logic should be adopted, considering materials expiration date.

The second task, that is the delivery to medical unit, can be carried out immediately or according to a schedule by transporters (that can belong to pharmacy personnel or medical units' nurses staff).

Materials are considered as booked for medical unit till the drawing occurs, when it is subtracted from pharmacy inventory records and registered as “incoming” in medical unit warehouse system. In the end, it is virtually added to medical unit warehouse stock. This operation can be immediate or delayed depending on the information system, the traceability features involved and the other tools available for technicians.

5.3. Materials Admission and Quality control and Payment (c.3)

When the order is dispatched and the incoming materials are delivered, pharmacy personnel has to:

- Check the correspondence in type and quantity between and delivered goods;
- Accept with reserve the goods;
- Verify label conformity, item code, quantity, batch number, physical integrity;
- Transmit the definitive acceptance to the Accounting Office to perform the payment (through a Central of Purchasing or directly).

If the item is managed by pharmacy, products are handled and stored in the dedicated warehouses (chilled or not), otherwise (in case of “transient” material or belonging to a urgent order), it has to be transported (internal distribution is activated). Quantity and Lot Number are registered where materials are firstly handled.

For transient materials kept in consignment stock, the consumption corresponds to an invoice and a replenishment order release.

6. CONCLUSIONS

This study is the result of literature review, interviews and the analysis of international guidelines, presenting a new holistic approach to the hospital materials management issue, defining all materials, actors and processes involved and focusing on the coherence, traceability and integration of information and physical flows. In doing so, it attempts to provide academics and practitioners with a useful guide to the various technology-related, management and business issues

that can arise during the design or reengineering of this business process and the related information system.

The description and formalization of all tasks and processes involved in the hospital materials management - enabling data sharing and, at the same time, traceability - have a double scope. First, in the clinical perspective, it allows to enhance patient safety through medical risk reductions (for example, suggesting mandatory matching between drug prescribed and to be administered, or avoiding transcriptions), to be ready in case of recall and to efficiently manage drug shelf life and expiration dates; second, from the logistical point of view, it lays the foundations for optimising the materials management because an exhaustive, robust and flexible basis of information can permit to collect data - from materials prescriptions to their delivery, from orders to fulfillment lead times -, identify key performance indicators and compare them in different management techniques scenarios, carrying out performance evaluations.

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