

Medicine Tracing System: validating a model at the Largest Hospital Complex in Brazil

Elcio B. da Silva, Maria L. R. P. Dias, Eduardo M. Dias, Sergio L. Pereira, Vidal A. Z. Melo

Abstract—This paper presents models of medicines track and trace systems adopted over the world, focusing on the Brazilian model, the National Medicines Control System (SNCM), its requirements and peculiarities. Considering the necessity of tracing medicines in compliance with that, the present work proposes a pilot project for the implementation of SNCM in the largest Public Hospital complex in Brazil, Hospital das Clínicas (HC). First, it introduces the background of Brazilian track and trace regulation and its impact. Then, it presents models of medicines track and trace systems in five other countries. After that, specific features and challenges of the Brazilian law are presented, leading to a comparison of experiences. After that a pilot project for HC is proposed, highlighting the benefits that will result for the participants, between them compliance and patient security.

Keywords—Medicines track and trace, SNCM, RDC54/2013, patient security, public hospital.

I. INTRODUCTION

The quality of the medicine is a key factor to its efficacy. This is why it is extremely important to adopt measures to verify and guarantee its quality through the whole supply chain. A medicine leaves the factory and can follow a long path to reach the patient; nevertheless, it has to be as effective as it was when produced. If it is not, it cannot reach the patient. In that sense, it is fair to state that tracing is an important tool to control the medicine's supply chain and, consequently, to improve patient's security.

The Brazilian government trying to improve patient's security established medicines traceability across the pharmaceutical chain with the National Medicines Control System (SNCM), by passing Law 11.903 on January 14,

2009 [1]. Law 11.903 was systematized by the Brazilian National Health Surveillance Agency (ANVISA), through a Board Resolution, Resolução da Diretoria Colegiada (RDC) n.º 54 in 2013 [2], detailed by norms contained in Instrução Normativa (IN) n.º 6 in 2014 [3], and clarified by a technical note, Nota Técnica (NT) n.º 1, in 2015 [4].

According to these rules, the holder of the medicine register, which is done by ANVISA, is responsible to form, generate and affix a Medicine Unique Identifier (IUM) on the package of the medicine (art. 5º, [2]). The IUM contains, necessarily: its register number (provided by ANVISA), serial number, expiration date (format MM/YY), and batch number (art. 6º, I to IV, [2]). This information is the base of the SNCM. It is what makes possible to track and trace that specific medicine along the whole supply chain.

The SNCM aims to prevent simultaneously the three main irregularities in medication use: use of medicines without certified origin, sales of medications without therapeutic equivalence and elimination of unsafe practices of transportation and storage of medicines. With this aim, ANVISA conceived a unique logic model to regulate the operation dynamics of medicine distribution [5][6].

As stated on [2], art. 10, the technology to capture, store and electronically transmit the data required by SNCM is the Datamatrix. It must be affixed on the package of the smaller unit commercialized and must contain, at least the elements that compound the IUM (its register number (provided by ANVISA), serial number, expiration date and batch number) (art. 13, I to IV, [2]). Fig. 1 is a representation of a Datamatrix affixed on a medicine package and its IUM.

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The presented paper is an extended version of "Implementation of Track and Trace System for Medication in the Largest Hospital Complex in Brazil", Elcio B. da Silva, Maria L. R. P. Dias, Eduardo M. Dias and Sergio L. Pereira, presented at CSCC2015.

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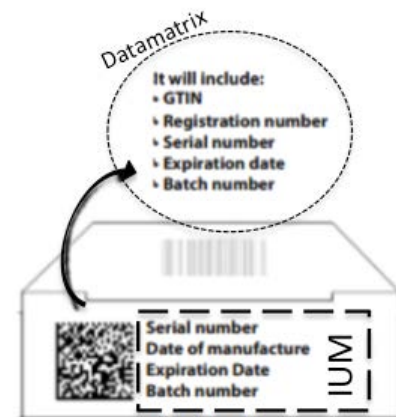


Fig. 1 - Representation of the Datamatrix affixed on a medicine package and its IUM. Adapted of GS1BR [7]

Hospital das Clínicas of the Medicine School of the University of São Paulo (HC/FMUSP) is the largest public hospital complex in Brazil, with a capacity of 2,200 beds. The HC, as an important agent in the Brazilian health system, must have its operations comply with the demands made by Law n.º 11.903/2009 within the deadlines specified by RDC n.º 54/2013. By December of 2015, companies holding medicine registration shall make available to ANVISA the complete trace data of three lots from the affixation of the Datamatrix until the dispensing units. And, by December of 2016, all medicinal products marketed and distributed in the country must be in compliance with SNCM (art. 23, I and II, [2]).

Those deadlines are extremely close, so questions have been raised regarding the capability to attend and the necessity to change them. Besides, there have been debates over the laws, requirements and ways to comply with ANVISA goods more efficiently [8].

Brazilian model of medicines track and trace is the SNCM, however other models can be applied. In that sense, it is very useful to compare those models. Taking into account the pioneer aspect of the logic model proposed by ANVISA, the lack of empirical proof of the effectiveness of available technological solutions and the extent of operations of HC, implementation of SNCM becomes a highly complex activity, which must be carried out without adding costs for the patients or the institution.

As there is no possible confirmation of a mapping of risks, their probabilities, effectiveness of risk-mitigation mechanisms, as well as strategies of reaction to them, this paper proposes, theoretically, a scope of execution of a pilot project for implementation of SNCM in HC. The results of this pilot project could provide material to base the discussions over the regulation.

The execution of a pilot project in HC, supported by a holistic view and scientific rigor, is a valuable tool to accelerate the process of implementation of SNCM in this institution. The pilot project for HC has moreover the potential of collaborating to answer questions about the implementation of SNCM in the public sector, which is one of the main factors of doubt as to the feasibility of compliance with the regulations in the specified deadlines [8].

The present paper is divided in six items. Item I ("Introduction") briefly presents the situation of SNCM, Brazilian official model of medicines track and trace. Item II ("Global experiences in the implementation of medicines traceability") presents five implementation experiences of systems to track and trace medicines (Turkey, Argentina, China, Europe, and the United States), which are pioneer projects and represent significant improvements in global health care and security of the patient. Item III ("Medicines traceability in Brazil") presents the requirements defined by ANVISA for the Brazilian model and a discussion of what this Brazilian model implies for the health system as a whole, for HC, and for the patients. Item IV ("Comparison

between medicines track and trace models") consolidates a comparative analysis of the models adopted globally. Item V ("Proposal of SNCM pilot project for Hospital das Clínicas - Scope") presents characteristics of HC in terms of business, operational and technology processes. Based on that, are presented HC scenario and the proposal of scope for the pilot project. Item VI ("Conclusions") presents conclusions and proposals for future studies.

II. GLOBAL EXPERIENCES IN THE IMPLEMENTATION OF MEDICINES TRACEABILITY

There are different models of tracing medicines through its supply chain. Brazilian model is one of them. It is valuable to analyze models that are considered pioneers and/or improvements in global health care and security of the patient. This is why the present item is dedicated to the study of the traceability models adopted in Turkey, Argentina, China, Europe, and the United States.

A. Medicines Traceability in Turkey.

The Turkish medicines track and trace system is called ITS (abbreviation of *İlaç Takip Sistemi* which in Turkish means "Medicines Traceability System"). Bearing in mind that the ITS has been operating since 2010, it can be considered a pioneer implementation. Medicines traceability in Turkey covers all medication commercialized in the country, which receive a single mark at item level, i.e., on the medication's secondary package [6][9]. The marking on the secondary package is made by a datamatrix two-dimensional code.

Traceability in the pharmaceutical chain in Turkey comprises manufacturers, distributors, hospitals, pharmacies, assistance organizations that need reimbursement with medication expenses, and the country's health surveillance agency, "Turkish Medicines and Medical Devices Agency", which plays a crucial role in the process, as illustrated on Fig. 2.

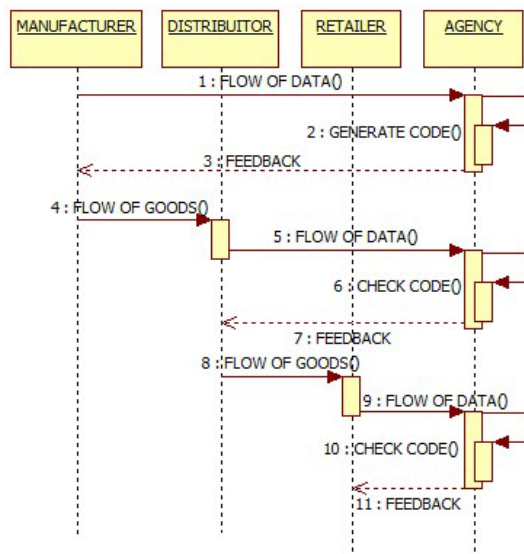


Fig. 2: Physical and logical flow of serialized medicines distribution in Turkey.

In the Turkish model medicines traceability control consists of two layers:

- a. Corporate layer: In this layer the organizations which participate in the manufacturing and distribution of medicines have a system architecture dedicated to control: the receipt of valid serial numbers (in the case of manufacturers), the medicines movements within the organization to identify medicines with serial numbers, the permissions from the government layer to transfer the possession of medicines to another organization and, lastly, the report of internal movements considered critical by the surveillance agency.
- b. Government layer: The government layer is responsible for controlling serial numbers liberation for medicine identification, for validation of transfers of possession among organizations that belong to the chain, for registration of movements, and for storage of track and trace data of medicines commercialized in the country.

B. Medicines Traceability in China.

A "China Food and Drug Administration" (CFDA), the Chinese health surveillance agency, determined the implementation of medicines traceability in China in waves. The first wave, which started operation in 2013, covered serialization of the pharmaceutical chain of medicines listed on the "National Essential Drug Lists" (NEDL) of 2009. After the first wave there followed a series of partial implementations, aiming at total completion of track and trace implementation in December 2015, with serialization and control by CFDA of all the products commercialized in the country [10].

In terms of control structure the Chinese model is similar to the Turkish model, in so far as both consist of two layers.

The significant differences dwell basically:

- a. In the way in which manufacturers obtain permission to serialize medicines in the CFDA,
- b. In the set of movements that are controlled by CFDA in each link of the chain, and
- c. In the strategy of implementation adopted.

Besides the differences mentioned above, the method used for marking medicines is also a peculiar feature of the Chinese system. In this system bar coding is the technology adopted instead of datamatrix technology [10].

C. Medicines Traceability in Argentina.

In Argentina implementation of medicines traceability began with the publication of Resolution n.º 435 in 2011 by the Health Ministry [11], which was later detailed by "Administración Nacional de Medicamentos y Tecnología Médica" (ANMAT) through Regulamentation n.º 3683, also in 2011 [12]. The track and trace scope follows the same line of the other nations, aiming at covering traceability of all medications commercialized in the country, by means of implementing the system in waves, the first of which has the goal of controlling traceability of products regarded as critical.

Again, in terms of control the structure adopted is similar to the one in the Turkish model. Both consist of two layers and a surveillance agency, which centralizes the control of critical movements within and among organizations.

The main difference between the systems is their building. In the Argentinian system, the ANMAT formally adopted several components of the standard proposed by EPCGlobal¹. Based on this fact it might be concluded that from ANMAT's point of view the adoption of a global standard is a facilitating factor in the implementation of the system.

D. Medicines Traceability in Europe.

In Europe the implementation of medicines traceability was a public-private initiative began with a pilot in Sweden. The operational phase of the pilot lasted from September 2009 to February 2010. Its scope was reduced, for it only included 14 manufacturers, 25 products, and 25 pharmacies.

The implementation of medicines traceability in Sweden was the result of a joint effort made by the *European Federation of Pharmaceutical Industries and Associations* (EFPIA), the *European Association of Euro-Pharmaceutical Companies* (EAEPCC), the *Groupement International de la Repartition Pharmaceutique* (GIRP), and the *Pharmaceutical Group of the European Union* (PGEU) [13].

The aim of the project in Sweden was to gather information to support the development of regulations on medicines traceability in the European Union (EU). Based on that the *European Falsified Medicines Directive* (EU-FMD) was published. It defines December 2017 as the final

¹ www.g1.com

deadline for the implementation of the traceability system to be concluded. A further development of this effort was the creation of the *European Medicines Verification Organisation* (EMVO), a non-profit organization, kept by the medication registration holders, with the goal of providing the system, called *European Medicines Verification System* (EMVS), for tracking medicines in the EU member states [14].

Instead of two layers (corporate layer and government layer), the control model of the EMVS system consists of three layers: the corporate layer, the national layer, and the regional layer. The corporate layer is responsible for controlling the traceability events that take place within organizations. A regional HUB is fed by data from the registration holders, answering for the distribution of data about medicines to the national layer. The national layer in its turn is responsible for answering the information queries of pharmacies and distributors.

It is important to point out that in the EMVS verification model of the medicine serial number in its regional layer is mandatory for the pharmacies prior to sale of the medicine and optional for the distributor.

Two characteristics that differentiate the European model from the others are:

- a. the optional query of the medicine traceability in the distributor, and
- b. the transfer of responsibility for traceability to a non-profit organization.

The non-mandatory feature of traceability in the

distributor does not imply a greater difficulty of relating problems with medicine quality due to deviations from the good practices of medication storage and distribution. And the participation of a non-profit organization in the process may mean that, in comparison with other models, the traceability here could be implemented with less need of public investment.

However, in spite of the fact that EMVO is a non-profit organization, in case the estimate made as to the prices charged for similar services by private companies in the United States and Brazil is really confirmed, the costs of association to the organization are significantly higher. This might eventually make it impossible for small manufacturers to become associated in EMVO, what can be actually understood as a deviation of its purpose in the sense of creating a commercial barrier to newcomers to the European market.

E. Medicines Traceability in the United States.

In the United States medicines traceability is a long-time demand, which began in California in 2004, when the bases for the concept of e-pedigree were established in order to prove authenticity of medicines by means of electronic documents concerning their movements in the chain [15].

Fig. 3 presents an end-to-end verification system *versus* a e-pedigree system.

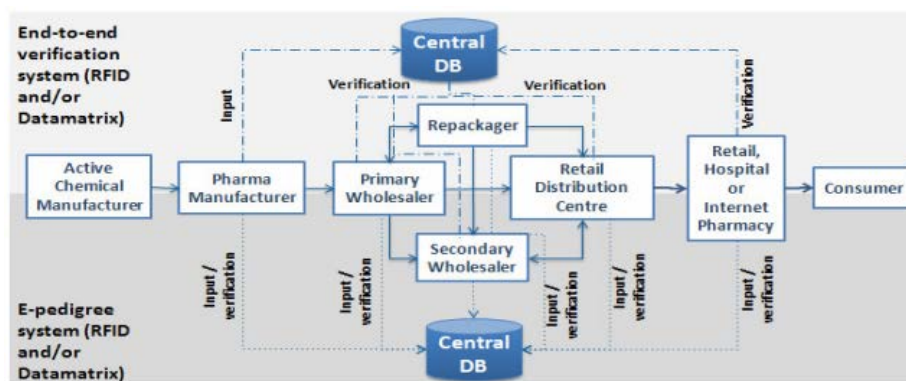


Fig. 3 - End-to-end verification system vs. e-pedigree. Source [16]

In 2013, when the *Drug Quality and Security Act* (DQSA; Law 113 – 54) was published, it was defined that medicines traceability would have national reach and that, similar to what had happened in other nations, the implementation process would happen in three waves [17]:

- a. In the first wave, with deadline set for 2015, traceability will occur at batch level, with verification and storage of movements;
- b. In the second wave, with its beginning set for 2017 and its end in 2020, traceability will come to occur at the level of serialized items and boxes, again

with verification and storage of movements;

- c. In the third wave, set for 2023, traceability will become mandatory at item level.

It is interesting to point out that e-pedigree was based on radiofrequency identification (RFID), while DQSA model bases tracing on two-dimensional barcode datamatrix technology. [16, 18 and 19]

The control structure of the traceability system in the United States, unlike what happens in the other countries analyzed, has only one layer. In the American model only the organizations that participate in the pharmaceutical chain are responsible for building medicines traceability.

The logic used in the model is one of transferring the data necessary to building a track and trace point-to-point system among the organizations and towards the patient. From this perspective, Fig. 3 presents the physical and logical flow of serialized medicines distribution in the USA.

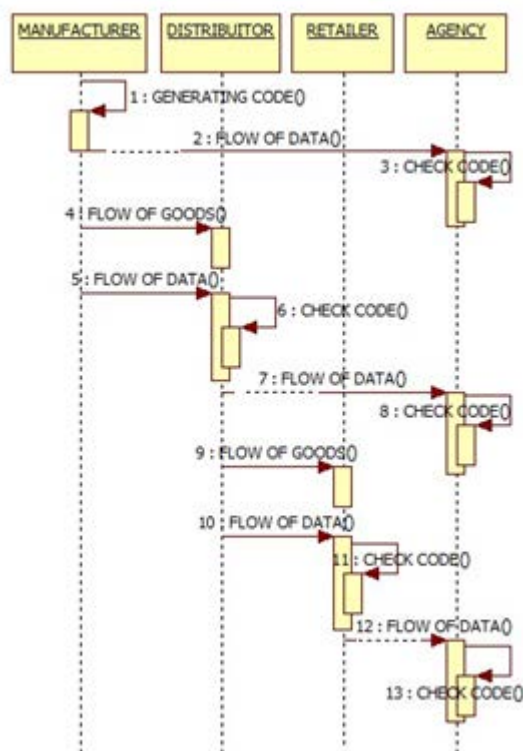


Fig. 3: Physical and logical flow of serialized medicines distribution in the United States.

With the point-to-point transfer it is possible to recover the whole record of movements that took the medicine to the observation point, in any organization belonging to the chain. Furthermore, in this model terms, the agency can check such a record at any time.

The American model strategy has a progressive feature of improvement of control over the authenticity of medications. In the first phase of implementation the consumer is able to retrieve data at batch level, i.e., retrieve data which confirm that a certain batch was sent to the link of the chain where the query is being made. In the second phase the consumer is able to confirm that the batch was sent to the link where the query is being made, as well as confirm that the serial number of the medication belongs to the set of numbers associated to the batch under scrutiny. In the third phase the consumer can check that the batch was sent to the link, that the serial number belongs to the set associated with that batch, and that it is expected that the serial number under scrutiny is in the link where its authenticity is being investigated.

Another feature that differentiates the American strategy from those of other countries is that it allows the organizations themselves freedom to define the best way of establishing communications control among the links of the

chain. This flexibility of the model, which had already been recommended in the Californian law in 2004, brought about new elements to be considered in designing a track and trace solution [20] [21] [22]. Within the scope of this paper four aspects are pointed out:

- Volume of data: The concern with the volume of data stored and in transit among the links;
- Technological partnership: The feasibility of having a technology partner responsible for operating data exchange among the links;
- Governance: The definition of roles and responsibilities of organizations (manufacturers, distributors, retailers, technology partners, and surveillance agency) in view of flaws in the building of track and trace data;
- Standardization: The standardization of the architecture of systems, processes, data models, message layouts, and other elements necessary to building a track and trace system solution.

III. MEDICINES TRACEABILITY IN BRAZIL

The implementation of SNCM will happen in two phases. In the first, called pilot, the holder will have to prove the efficiency of his track and trace systems in three batches of medicines, from manufacturing to dispensation point. This phase is expected to end in 2015. In the second phase, which is supposed to end in 2016, the holder will have to expand the capacity of his systems to track all his products.

In Brazil, similarly to what happens in the United States, the organizations which take part in the pharmaceutical chain are also responsible for the control of the SNCM. However, aiming to fulfill the goal set by the Brazilian State of employing medicines traceability to fight the use of medicines whose source is not certified, the commercialization of medicines with no therapeutical equivalence, and to eliminate transportation and storage practices that endanger the quality of medications, the Brazilian model differs from the American in the way control is made.

In this aspect, the basic difference of the Brazilian model is that the medicine registration holder, manufacturer or importer, plays a relevant role in the process, answering to ANVISA for:

- controlling the movements of medicines within their operations;
- controlling the movements of medicines among the organizations that participate in the pharmaceutical chain;
- replying to ANVISA's queries concerning the current positions of medicines commercialized by the company, as well as the sequence of movements which took the medicines to the observation position;
- monitoring the chain and notifying deviations in the process.

For this to happen a point to point communications

connection between the registration holder and the other links in the chain is supposed to exist, making the registration holder the center of track and trace control of his medications. Fig. 4 presents the physical and logical flow of serialized medicines distribution in Brazil.

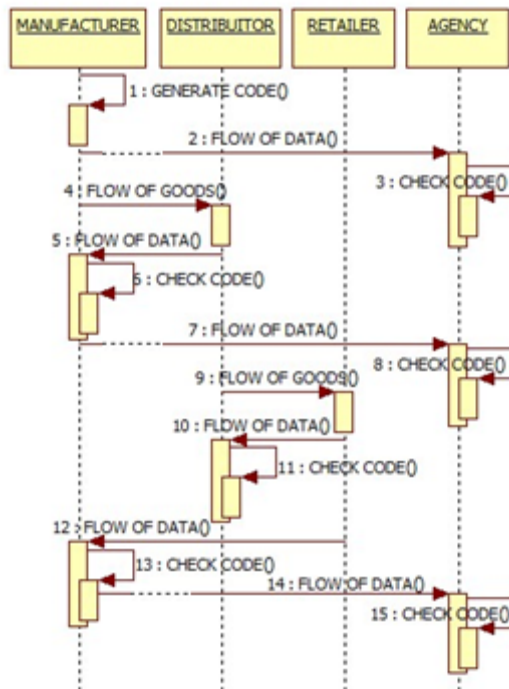


Fig. 4: Physical and logical flow of serialized medicines distribution in Brazil.

In practice the SNCM nominates the registration holder leader in the process. Thus it is natural to expect the registration holder to be even more selective when it comes to choosing his direct and indirect business partners. Giving priority to better-structured partners theoretically means having partners more capable of following good manufacturing practices (in terms of storage and distribution of medicines) and less subject to improper commercial proposals, such as bonus sales.

Considering the number of agents in the pharmaceutical chain, a point-to-point connection among partners is not technically feasible. To solve this problem, there is the understanding that having a technological partner is essential in order to mediate communications among the links. This partner would have to:

- execute transactions of data transfer about possession of the medications among the organizations;
- make the exchange of messages generated in different standards possible ;
- validate the effectiveness of transactions;
- storage track and trace data about the medications;
- report queries of the agencies.

IV. COMPARISON BETWEEN MEDICINES TRACK AND TRACE MODELS

As can be seen by the presentation of the medicine tracing models adopted by Brazil, Turkey, Argentina, China, Europe and United States, models can have very different structures. In terms of business model and data, Brazil establishes that the register holder has all data, while the retailer will have it in the US, the entities will have it in the Europe and the Government will have it in Turkey. This is closely related to the responsibility for implementing the tracing system: private sector (Brazil and US), public sector (Turkey) or both (Europe); and, costs. As costs can be analyzed capital expenditure (CAPEX) and operational expenditure (OPEX). In Brazil and US we have high CAPEX, and private OPEX regulated by market, little public OPEX, which is different of Turkey, where there was a massive government financing and there is a high public OPEX.

Based on the convergence of issues raised during the analysis of the global models studied in this paper, a set of points was prepared about the SNCM implementation, organized into five dimensions which can influence the implementation itself:

- Business model:** The adoption of a technology partner is practically mandatory in the Brazilian model. Today the business model of technology partners consists of service fees based on the volume of medicines commercialized by the registration holders. These partners should be approved by private associations, in order to assure they have technical and financial conditions. The business model of technology partners, the authority of associations to give their approval to them, as well as the criteria for approval of technology companies, are not consensual among the participants of the chain who fear that such an approval process might result in implementation of a commercial barrier to new companies wishing to take part in the pharmaceutical chain.
- Confidentiality:** One of the factors that can jeopardize the implementation of the system is the obligation that the downstream links of the chain share data with the registration holder. Sharing such data has an impact on the usual information asymmetry among the links in the chain. Information about storage levels might be used in commercial dealings in a way that is disadvantageous to the downstream links. Nevertheless, this is not the only negative factor. The level of data sharing with the technology suppliers is also sensitive for the organizations, which can resist doing that since the partner is able to store the record of several commercial transactions among manufacturers and other links of the chain, and this information can be liable to leaking.

- c. Standardization: Traceability of medicines is a global demand, and several nations tend to adopt open standards like the one of GS1. In cases in which no government recommendation exists, as in the USA, the market must come to an agreement. Coming to an agreement can take long and prove to be even impossible. That results, therefore, in at least three scenarios:
1. a delay in the implementation of the SNCM;
 2. an implementation based on the convergence of organizations to a market standard that is established in view of its efficiency;
 3. a revision of position by ANVISA, in relation to defining a standard.
- d. Operational efficiency: The implementation of the SNCM implies significant changes in operation. It increases the number of tasks on plant-floor, storage, and dispensation points, something which might demand a manpower increase in operation. Because of that, selection and training processes might be necessary, something which may also tamper with deadlines for compliance with the regulations.
- e. Technical feasibility: The uniqueness of the Brazilian model demands different levels of development and customization, even when one considers solutions used in other countries as platforms, because prior solutions can prove useless when SNCM implementation reaches full operational level.

register holder and it will end when the secondary package is open, "killing the IUM". In other words, for the purpose of the SNCM, the supply chain will usually begin at the pharma manufacturer (register holder) and end when it gets to the pharmacy or hospital.

Considering that a hospital have an internal pharmacy, in terms of processes, it is fair to conclude that by studying the impact of the SNCM at the hospital's pharmacy it is possible to foreseen the impacts over pharmacies in general. In that sense, to study the supply chain of medicines acquired by hospitals (processes and technologies explored) allows to study the impacts of the SNCM over links of the supply chain. Nevertheless, for more precise results it is necessary to test the system at that particular environment. Fig. 4 presents the scope of HC pilot project.

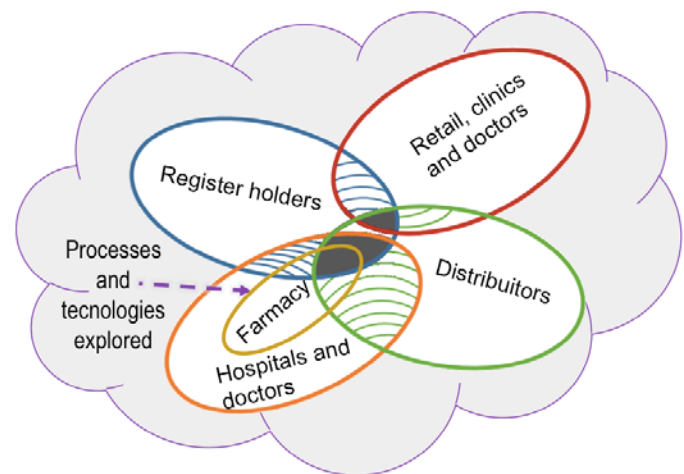


Fig. 4 - Scope of HC pilot project

V. PROPOSAL OF SNCM PILOT PROJECT FOR HOSPITAL DAS CLÍNICAS - SCOPE

Considering all the open questions related to SNCM, it is necessary, in order to guarantee patient's security, to verify the effectiveness and efficiency of implementation of a track and trace solution from the point of view of operation, processes, and technology. In these terms, the Hospital das Clínicas (HC) pilot project has as its objective to map out the risks for the patient and the institution, besides preparing the organization to react to those risks.

The supply chain starts with the active chemical manufacturer, passes through pharma manufacturer, wholesaler, retail distribution center, retail, hospital, Internet pharmacy, until it ends when consumed by the consumer/patient. In terms of the SNCM this supply chain begins with the creation and affixation of the IUM by the

The relevance and importance of HC for such a purpose derives from its size, caring for 5 million patients a year, with a volume of 100 million reais in purchases of medicines delivered by over 200 suppliers.

Building data about medicines traceability in Hospital das Clínicas (HC) is an operation that begins in its distribution center (DC). The center is responsible for the distribution of about 1,200 medicines, provided by a chain of more than 200 suppliers. These medicines are distributed to 11 institutes, which have approximately 250 points of dispensation. Fig. 5 presents the main stages in the distribution logistics inside the DC and HC, together with the several events of interest for the SNCM, which must be collected in each of the stages of the medicines movements.

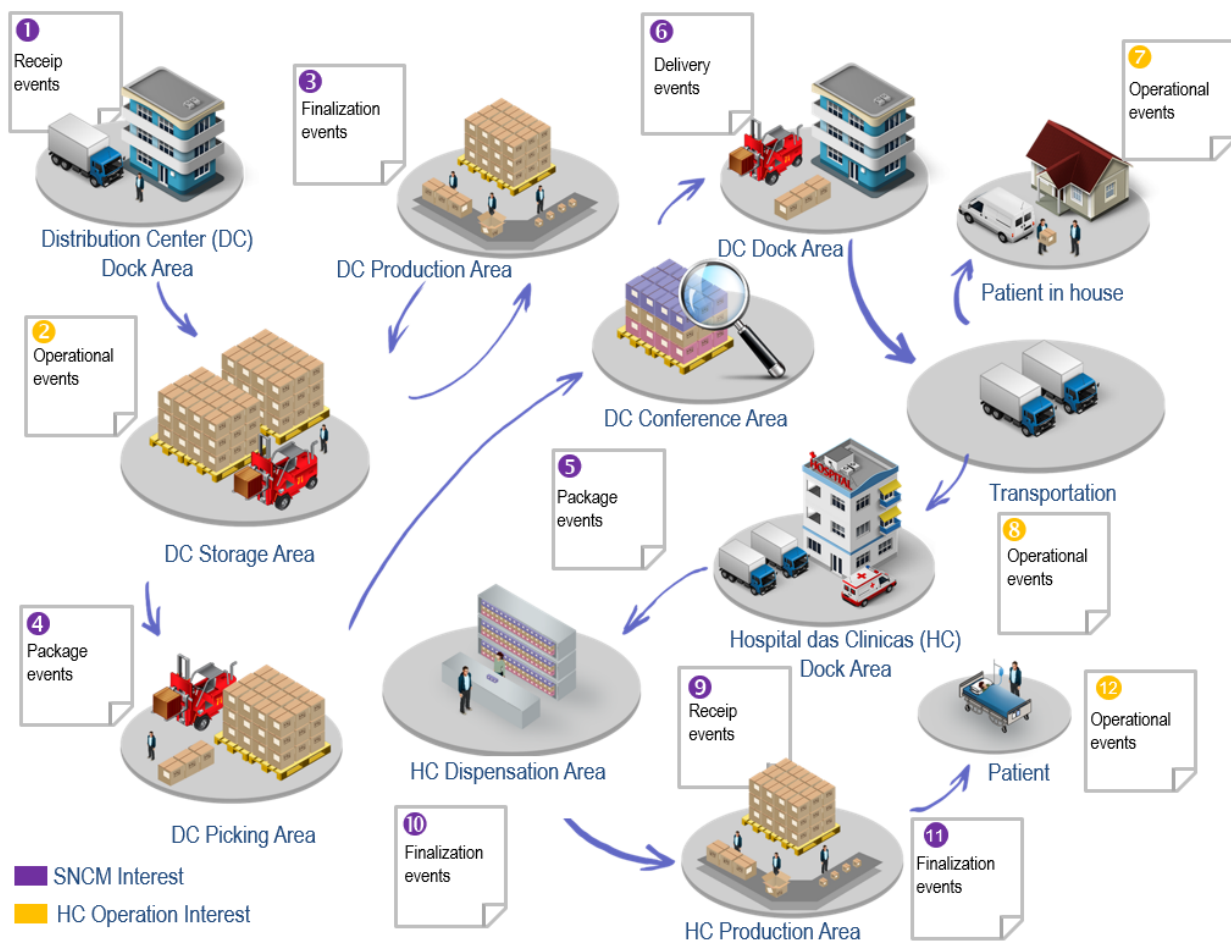


Fig. 5 - SNCM process flow of events inside HC

In terms of operation it is proposed that the pilot control medicines traceability of ten business partners within the center of distribution of the Hospital, as well as their distribution in one of its institutes. This approach will allow observation of some operational difficulties in the handling of the medicines from different suppliers in the center of distribution, as well as the dispensation of medicines in different types of dispensation points in one of the institutes of HC.

In terms of processes the pilot will make possible a better understanding of the impacted processes, and also of the needs to create new mechanisms to make the gradual introduction of medicines, institutes, and dispensation points feasible.

From the point of view of technology the pilot with ten business partners will allow verification of the challenges of communication with several business partners, possibly involving the need of communication with several technology partners.

As HC is a hospital with high medication consumption, the pilot will also contribute for the registration holders participating in it at one site to assess the readiness of their processes and systems to control the collection of events of dispensation of medicines, in compliance with IN6/2014, at a

high volume.

Carrying out a pilot project as comprehensive as the one proposed means having the potential to offer a significant tool for the surveillance agency, which can use the amount of data from the pilot as a basis to validate premises assumed in regulation, as well as eventually provoke the reassessment of requirements of RDC54/2013, IN6/2014, and NT1/2015, before the beginning of the second phase of SNCM implementation, as stated by RDC54/2013.

Execution of the pilot project will allow:

- a clear understanding of the risks for patient and institution,
- definition of probability of effectiveness of risk, associated severity, reinforcement or development of mitigation mechanisms, as well as
- formulation and selection of proposals of reaction to risks.

Also, it would be able to deliver:

- implanted traceability in HC to meet the pilot phase of the regulation RDC54/2013;
- a gateway application to internal hospital operations - which controls the events in hospital operations and distributes the information to the

materials management, bedside traceability and SNCM systems;

- c. a methodology to certify technological solutions;
- d. a methodology to certify traceability processes in manufacturing, distribution and pharmacies.

By doing so, this pilot project allows:

- a. HC to adequate their processes to SNCM (compliance);
- b. Pharma manufacturer to use the pilot to create a process to meet regulations more effectively and at lower cost, to materialize traceability and ensure progress towards implementation of SNCM; to prepare for the approval of ANVISA;
- c. HC's Institute of Scientific Technology (ICT) to receive royalties of the gateway application that will be sold to public and private hospitals and, as accreditation entity, of certifying companies responsible for auditing technologies and processes adopted by link agents, users of the methodologies created.

Thus, carrying out a pilot project in HC is an essential step for the compliance of the institution with the regulation and very possibly a relevant contribution for the agency and the society in terms of an empirical experiment.

VI. CONCLUSIONS

When presenting in this paper a proposal of scope for a pilot project of implementation of the National Medicines Control System (SNCM) in Hospital das Clínicas (HC), we have considered several important aspects. First, the history of the Brazilian regulation with the challenges it presents to the largest hospital complex in Latin America. Second, the pioneer experiences of track and trace implementation in other countries and how they compare with one another. Third, we have shown the characteristics of the Brazilian law which regulates medicines traceability and, in view of implementation experiences of similar laws in the countries discussed and compared in the previous section, we have raised some still controversial issues, whose impacts on the effectiveness of the system must be taken into account. Finally, the pilot project for HC aims at implementing a medicines track and trace system which allows observation and comprehension of possible risks for patients and institution, resulting from flaws in the system.

The implementation of a project such as the one here presented benefits all parties involved in the process. As it implements medicines traceability in one part of its operations, HC will take an important step in the compliance with the law that regulates SNCM, both batch and total traceability phases. Additionally, by executing the pilot project, HC can develop a gateway to guarantee the communication between SNCM and internal hospital's operation systems, and a methodology to

certify technological solutions and traceability processes in manufacturing, distribution and pharmacies.

Not only HC is expected to benefit from implementing this pilot project, so are pharma manufactures and HC ICT. As explained before, pharma manufacturer will be able to use the pilot to create a process to meet regulations more effectively and at lower cost, to materialize traceability and ensure progress towards implementation of SNCM; to prepare for the approval of ANVISA. And, HC's ICT can receive royalties of the gateway application that will be sold to public and private hospitals and, as accreditation entity, of certifying companies responsible for auditing technologies and processes adopted by link agents, users of the methodologies created.

Moreover, it is essential to underline the need for such a pilot so that there is a mensuration of the operational risks involved, as well as a safe evaluation of the practical feasibility of the terms demanded by the law. The more empirical results are obtained in the scale of this proposal, the more feasible will it be to evaluate and improve the system. Considering the direct and indirect motives for the implementation of SNCM, there is no denying that it is in society's best interest that the system should become operational as soon as possible. On the other hand, the impact of a non-adequate implementation of SNCM can be drastic, and this reinforces the importance that studies such as this one be carried out in multiple links of the chain, employing different perspectives, with scientific rigor, seeking a solid level of knowledge in phase with the timetable of SNCM implementation.

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