

Colombia

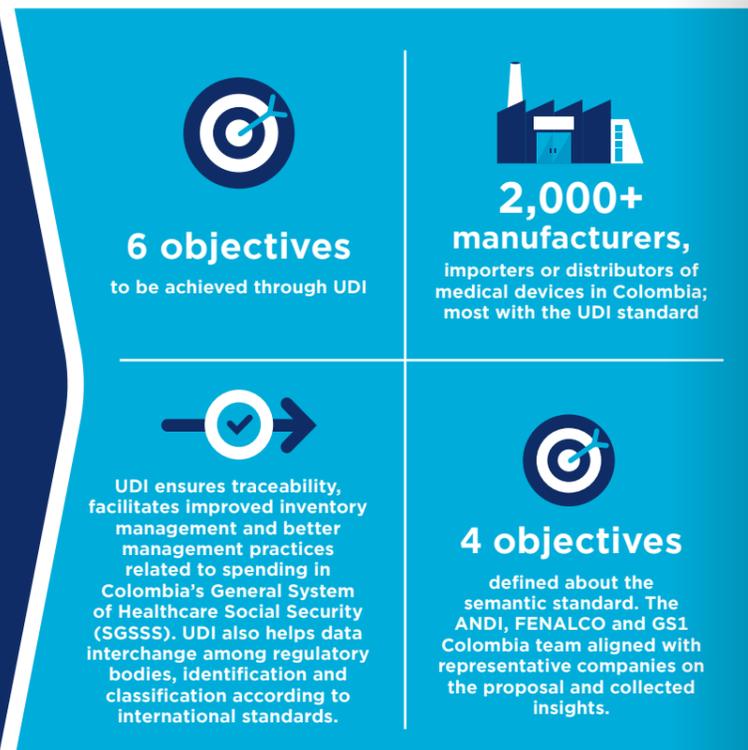
UDI pilot proposal with Ministry of Health and Social Protection

Challenge

It was a challenge to validate the endorsement and approval of the Ministry of Health and Social Protection to carry out a pilot test and make use of the Unique Device Identification (UDI) device identifier (DI) to identify medical devices in Colombia, as well as align healthcare providers with the proposal.

Approach

A public consultation was held to review the draft resolution of the proposed semantic standard for UDI. Representatives from GS1 Colombia, the National Association of Businessmen of Colombia (ANDI) and National Federation of Merchants (FENALCO) started meeting with Colombia's Ministry of Health and Social Protection (MoH) to identify key points about why and how it would implement UDI, according to the needs of the government and healthcare industry.



Resolution 2535 of 2013, Article 3 states by semantic standard the process of continuously standardising and updating data related to health technologies in categories associated with procedures, medicines, inputs and medical devices. With diagnostics, these technologies align with the provisioning of services, whether individual or collective, as an essential source of the healthcare information system.

The MoH reference proposal aims to structure and implement the semantic standard and coding for medical devices for human use in the country. Its scope includes all medical devices, including biomedical equipment, in vitro diagnostic medical devices (IVDs) and medical devices (MDs), and vital biomedical equipment.

From the MoH's public consultation of the draft resolution of the semantic standard for MDs, "through which the semantic standard and coding for MDs for human use in Colombia is structured and implemented," the opportunity was identified to implement the UDI standard at

the national level. Regulated by the MoH, a pilot test was needed to demonstrate the benefits and solution points for the healthcare sector that align with the purpose of the semantic standard. This would become part of the regulation that all stakeholders in the healthcare value network would make use of this standard to identify their devices.

More than 47 stakeholders were nominated for the initiative, working in conjunction with the national government, MoH, ANDI, FENALCO and the Colombia National Food and Drug Surveillance Institute (INVIMA) for the planning, execution and monitoring the UDI pilot test, addressing government and industry needs.

This pilot test of the UDI standard was developed based on the needs in the draft resolution of the semantic standard of medical devices (Resolution 2535 of 2013), highlighting the need for alignment with international standards as outlined in Article 4, Number 6 of that resolution, "Facilitate identification

and classification according to international standards of medical inputs and devices."

The main objectives were to:

- Validate the application and functionality of the UDI-DI against the MoH's required semantic standard for medical devices.
- Perform a comparative analysis with medical device identification (IDM), for medical device identification.

The specific objectives were:

1. Facilitate the exchange of information and interoperability between actors and regulatory entities with the use of UDI-DI as a common identifier and language, including issuing an electronic Invoice).
2. Optimise the supply management and inventory control of medical devices for expense and consumption reports.
3. Strengthen mechanisms for traceability records along the value chain, in the final use and disposal of products, and strengthen patient safety processes.
4. Analyse the conceptual and structure definitions of UDI-DI compared to the local IDM, according to the guidelines of the semantic standard of medical devices.



Methodology

The methodology used for the development of the pilot consisted of evidence-based, concurrent mixed research. A field project and evaluation process of the current use state of the UDI standard were implemented, as well as the application and functionality against the semantic standard for MDs. In addition, the pilot compared this code with the local IDM, built by the MoH.

A series of interviews were conducted, evaluating the management of MDs using the UDI standard. This was done in order to validate its compliance with the specific objectives of the pilot.

At the end, compliance indicators were generated for each specific objective. This resulted in a comparative analysis of the international UDI standard versus the local IDM code. The project was divided into four phases: sensitisation, alignment, field project and results measurement.



Objective: Validate the application and functionality of UDI-DI against the requirement of a semantic standard for medical devices of the MoH. Perform a comparative analysis with local IDM for medical device identification.

The pilot test's scope was defined as the implementation of the UDI standard within a period of eight weeks. During this time, it was evaluated as part of the flow of the product and information (including electronic invoicing) of medical risk classification devices I, II, IIA, IIB and III—from their coding at source to their delivery in the main warehouse, to the respective business partners.

For this part of the process, it was defined to require a minimum of:

- 3 local MD manufacturers
- 3 international MD manufacturers
- 3 healthcare service providers (IPS)
- 1 healthcare service promoter (EPS)
- 2 distributors of medical devices

The MoH suggested prioritising the following types of medical devices:

- Infusion pumps
- Pacemakers
- Syringes
- IVDs (e.g., Troponin)
- Anesthesia

Participants

For the development of the pilot, different stakeholders—manufacturers, distributors/pharmaceutical managers, IPS and EPS—were identified. Interactions between them were defined, specifically the flow of products throughout the hospital value network. (See Figure 1.)

Participant roles: Manufacturers, Distributors, IPS and EPS.

Participant profiles: Project leaders, inventory leaders, staff in charge of tasks such as master data management, product marking and identification, internal logistics, distribution or related.

UDI pilot test

The stages in the pilot included:

Sensitisation: The objective of this stage was the call, planning and kickoff of the pilot with the participants. A communication plan, roadmap and an initial work schedule were put in place.

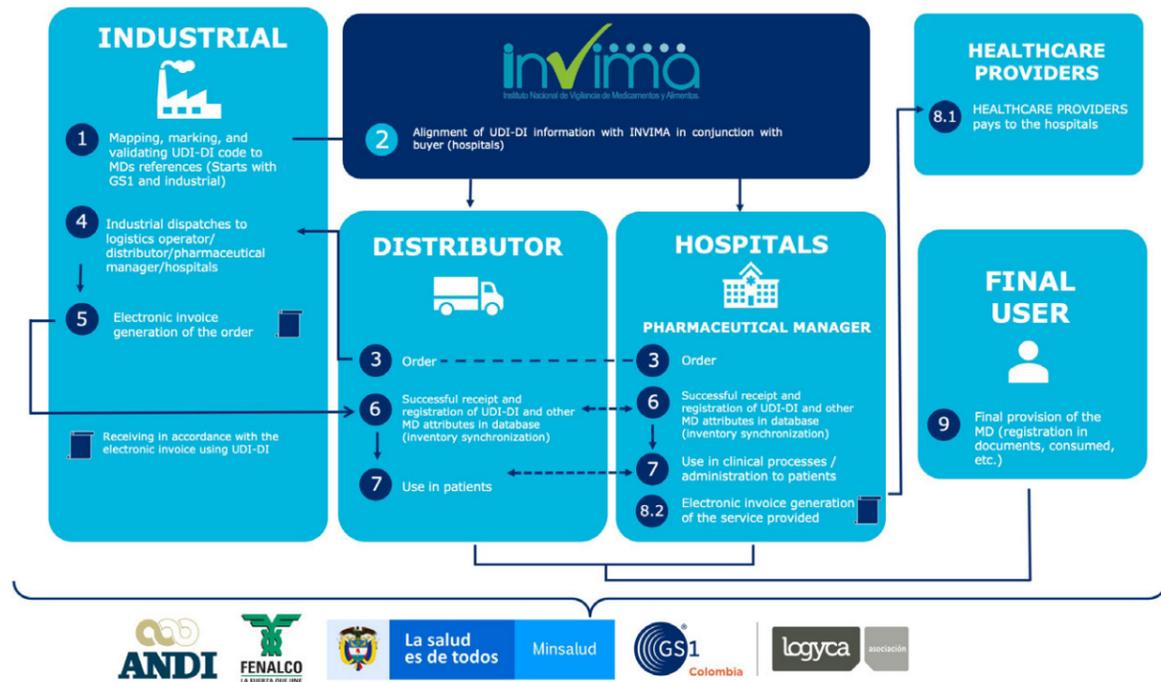


Figure 1: The flow of products across the healthcare sector value network

“It is a unique opportunity that has been given to the industry for the construction of public policies around the healthcare sector.”

Marisol Sánchez González,
Director of the Sectorial Chamber of Medical Devices and Health Supplies, ANDI

At this stage, a call/presentation of the pilot test was conducted during which the step-by-step roadmap was defined by each stakeholder in the value network. Timelines were considered and mandatory participation requirements were determined.

Alignment: The objective of this stage was to understand any gaps in the sector and focus the work on creating joint improvements. Closing the gaps in the identification of MDs

would be achieved through evaluation and training in international standards and best practices. As a deliverable of this process, 16 hours of training, session learnings and technical evaluation were provided regarding the UDI standard.

During this stage, a series of technical trainings were conducted about standards and best logistics practices. They were divided by modules: identification, capture, and exchange and use. This was designed to align and educate all participating companies about the UDI standard. The training sessions were virtual. Therefore, it was essential that the participants had enough time to attend (2-4 hours / week), with a computer and quality network connection that enabled learning.

Participants of the sessions included leaders in inventory, master data management, product marking and identification, internal logistics, distribution and related.

Field project: The field project stage focused on the current process by participants. It was designed for the monitoring or implementation of UDI (according to each stakeholder) via a process review checklist (e.g., coding, dispatch, receiving, and more). Documentation was also considered along with the step-by-step process according to the stakeholder’s need.

The objective was to deliver a report of results and general documentation.

At this stage, multiple interviews were conducted with each company to create the necessary information survey to validate the compliance indicators aligned with specific objectives of the pilot.

3rd stage: field project

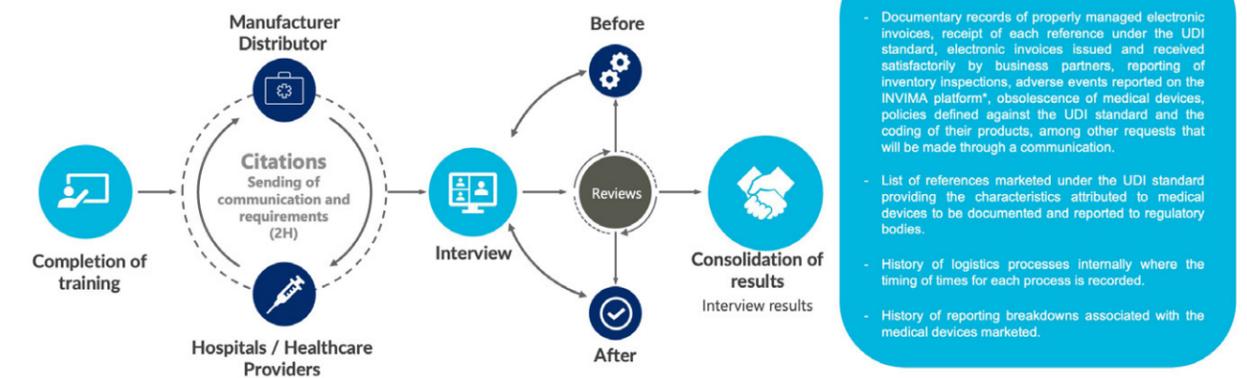


Figure 2: Interview flow for companies participating in the UDI pilot

Results measurement: The objective of this stage was to validate the fulfillment of the specific and general objectives of the pilot, and analyse their alignment with objectives 1, 2, 3, 5 and 6 of Resolution 2535/13. In addition, the qualitative and quantitative results of the pilot were measured. To do this, a compliance indicator was used for each specific objective along with the development of a tailored outreach plan. A results report, guide, manuals, infographics and outreach support were generated as deliverables of this process.

In this final stage, all participants received the results that were analysed quantitatively and qualitatively. Corresponding conclusions were made, and a final report was generated. All results and information was socialised with all stakeholders involved in the healthcare value network during a closing meeting.

UDI pilot test results

Following the official launch of the pilot on 17 December 2020, the industry expressed various doubts and suggestions regarding the pilot. That’s why the rest of the phase was focused

on resolving doubts, making adjustments and re-defining the roles of the participants.

During this period (December 2020 to March 2021), the mandatory requirements for participation in the pilot were socialised, an assessment was carried out to select participating companies and observer companies, which would make up the pilot monitoring committee. More than 27 meetings with participants during which an estimated 100 hours of joint alignment were invested. Six work tables were held that focused exclusively on each of the medical devices that were prioritised by the MoH with the participation of approximately 150 people. As a result of this entire process, manufacturers from the following participants were defined: B. Braun, Baxter International, Mindray Medical International, GBarco, Abbott Laboratories, St. Jude Medical, Innomed, Medical Industries Sampedro, Stryker Corporation, Amarey Group, Roche Products, Cardinal Health, Medtronic, Siemens, Becton Dickinson, Alfa Trading, Rymco Medical and Ortho Clinical. These 18 participants were asked to read and sign an act of commitment for the development of the processes ahead.

Next steps

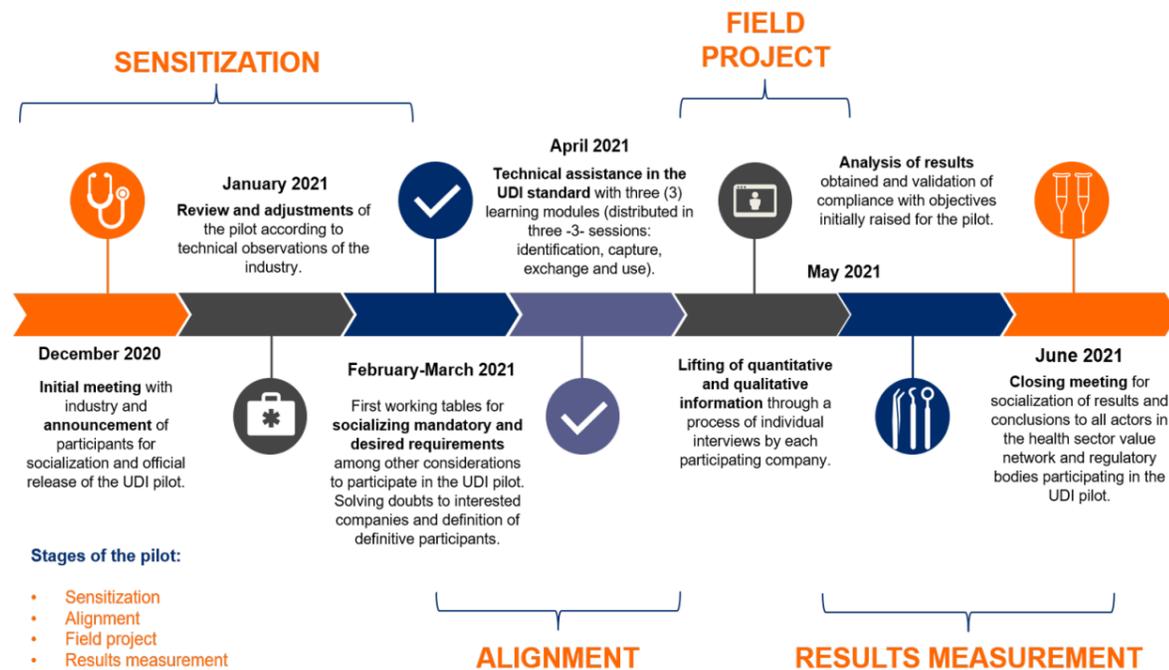


Figure 3: Timeline of progress made and next steps of the UDI pilot

Benefits

The following benefits from the UDI pilot proposal were defined associated with the complete adoption of the UDI standard in Colombia, to include:

- Increased participation by GS1 Colombia in the healthcare sector
- Facilitation of the exchange of information and interoperability between stakeholders and regulatory entities with the use of UDI-DI as a common identifier and language
- Issuance of electronic invoices
- Optimisation of supply management and inventory control of medical devices as inputs for expense and consumption reports
- Improved mechanisms for traceability records along the value chain, in final use and disposal
- Stronger patient safety processes

Conclusions

The pilot has been well-received by the healthcare sector, which exceeded initial expectations. An example of this success was increasing the number of manufacturers participation from 6 to 18 companies.

At the clinical level, each medical device has different characteristics, components, risks

and functions. Due to these differences, they must have specific protocols, classifications and management for each within the health factors. However, it is important to remember that at the level of identification, regardless of the type of medical device being marketed and the management of master data, it is essential that all products require an identifier as “key” to have the necessary information for decision-making. For this reason, it is possible to extrapolate the UDI standard and the associated information for all medical devices at the identification level.

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Leonel Pava Casilimas has extensive experience in the design and implementation of collaboration programs in sectors such as Mass Consumption, Health, HORECA, Transportation and Logistics, among others. These programs include projects related to the implementation between collaborative platform business partners that handle large volumes of data, such as: Sales and Inventory Data, Master Data Synchronisation, Traceability, Exhausted, Service Level, etc. He currently serves as Director of Community Development at LOGYCA.



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About the organisations

ANDI is a non-profit organisation, which aims to divulgate and promote political, economic and social principles for a healthy system of free enterprise. It consists in a significant percentage of companies belonging to sectors such as industrial, financial, agro-industrial, food, commercial and services, among others.
www.andi.com.co

FENALCO is the guild that represents and defends the interests of trading; contributes to its sustainable development and continued growth through ongoing accompaniment and the provision of innovative services, which drive business competitiveness and innovation.
www.andi.com.co

GS1 Colombia is a GS1 Member Organisation of the global GS1 network. It is a meeting point where different economic sectors coordinate and achieve common technological solutions, in the face of the needs imposed by the market. Thanks to the effort, responsibility and desire to involve greater performance and efficiency in all processes of the value network, the management of technology and the possibility of sharing internationally, the results have become possible.
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