Interview summary

Interviewees: Carme Pratdepadua i Bufill; Carlos Mateu Lopez (TicSalut Foundation)
mHealth Practice: **the mConnecta platform**
Interviewers: Sonja Müller, Alexandra Prodan
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Topics

The mConnecta platform has a successfully approach on the following topics:

- Execution > Interoperability models
- Execution > Data security – legal framework; privacy

Summary of main interview ideas

Objectives of the mConnecta Platform

- Enabling the integration of data generated by patients through accredited applications, web applications, wearables, or medical devices into the mConnecta platform.

- mConnecta will be integrated into the Electronic Personal Health Record, where the data will be available for standard care on primary and hospital settings.

- Leveraging a patient-centred model between healthcare professionals and patients

- Integrating personal health data captured by mobile applications into electronic personal health records.

- Providing accreditation at usability, functionality, and evidence, technological, and security level.

- In the certification process, developers have the chance here to submit documents used in similar certification processes.

- The committee of experts is revised and adapted according to the needs of this very agile field.

- Everything is following the interoperability framework to guarantee the integration. Data is standardised by using for common syntax HL7 FHIR resources definition for clinical data. Semantic interoperability is ensured by using SNOMED and LOINC.

- The integration of the mobility data into the system does not require only interoperability and technological issues to be tackled, but also is important how the healthcare process will change; mConnecta is also considering change management processes.

- The mConnecta platform is using the cybersecurity norms that are working on the Information Systems of Catalonia, which are already provided.

- Both new apps and existing apps have the possibility to be integrated with mConnecta.

- Data storage and processing is a challenge, given the amount of data that comes into the system. The time and type of data is decided together with the providers, so all actors involved align.

- Not all data can be integrated in the EHR of the patient. mConnecta, as an intermediate platform, allows for filtering and selection of most important aspects required by the healthcare professionals.

- Involving practitioners in prescribing apps also requires the assessment of digital health literacy of the patient and it needs to be personalised. mConnecta is encouraging and allows for this aspect.

- Healthcare professionals are the "designers of the app" and can choose what type of data to see and what kind of algorithms to apply.

- The Executive Committee of mConnecta is also considering the need to train healthcare professionals to ensure full adoption by the care centres where it is implemented.

- The integration of mobility data makes sense if it follows an interoperability framework that guarantees the quality of the data and maintains its meaning. In addition, the change that this integration implies for the entire healthcare process must be managed.

- The architecture of the platform needs to guarantee scalability in terms of performance, this is a must in a system that have face the challenge to adapt to an unknown number of users, depending on the applications that are going to be aggregated in the future.

- Having a multidisciplinary team working in the certification process and in the definition of requirements of the mConnecta platform allows to have a complete vision of the project and helps in its definition and implementation.

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Topic 1: Security, privacy, and reliability

An important aspect of mHealth is the security, privacy and reliability of daily used apps. One of the issues TicSalutSocial approached was the creation a certification framework, which establishes a minimum set of criteria for apps that overcome this process. The guidelines and criteria are

published on the website as guidelines or recommendations for those who want to create an app in the health field.

Providing mHealth models into the healthcare system makes sense if there is trust and a secure environment. mConnecta uses this certification model as a first step in a series of many steps, although it is not a restrictive model as far as the integration solution is concerned. The model sets a baseline of criteria to be considered when developing an app. Obtaining the certification is a precondition for future integration in the system. It is necessary, but not a sufficient condition to integrate the app into the system as the body with executive power is the **mConnecta Execution Committee**, who will decide the areas to integrate and how the integration will look like and take place.

The project started at the beginning in 2016 with a series of objectives:

- define a set of criteria
- classify the apps depending on the risk
- define a workflow for the certification process
- constitute a committee of functional and technological experts
- create a technological architecture
- integrate mobility data into the system (using standards)

The certification process involves four steps:

1. **Apply for certification** – fill in technical and functional information about the app. **Developers have the chance here to submit documents used in similar certification processes**, for e.g. AppSalud in Andalusia. Or send us the CE mark, or a cybersecurity audit.

2. **Pre-validation and classification**. The app is assigned one of the three risk classes, depending on the risk for the patient. Level 1- lower risk, level 3 – higher risk. We use three important parameters:

   a. Number of people who potentially will use the app

   b. What kind of recommendations is the app providing (e.g. medical recommendations or general recommendations)?

   c. If the app processes sensitive data

   The classification of the app will define how strict will be the certification process. Which criteria will be compulsory, desirable or recommended.

   In the pre-validation process the app will be tested, and features such as registration and language will be checked. At the same time, the information provided by the developer is also assessed. This is an important part of the process as sometimes apps that could not perform these basic functions were identified.

3. **Criteria assessment by the experts**. The app is sent to the experts and they check the 120 criteria listed as a checklist, in four main categories:

   a. Design and usability

   b. Content and functionality

   c. Privacy and security

   d. Technological requirements

4. **Certification process**

Topic 2: Interoperability

mConnecta is a showcase for mobility components in healthcare, aimed to empower citizens in the self- management of their own health. In Catalonia there is a central repository for all the clinical data of the patients that is collected in the clinical care setting. The mConnecta platform is going to provide the solution for all mobility devices that collect data from the patients that is not collected Within the framework of formal healthcare service provision and documentation, that means data from mobile apps, wearables, and medical devices. All information is captured on the mConnecta platform through an interoperability layer.

The interoperability framework
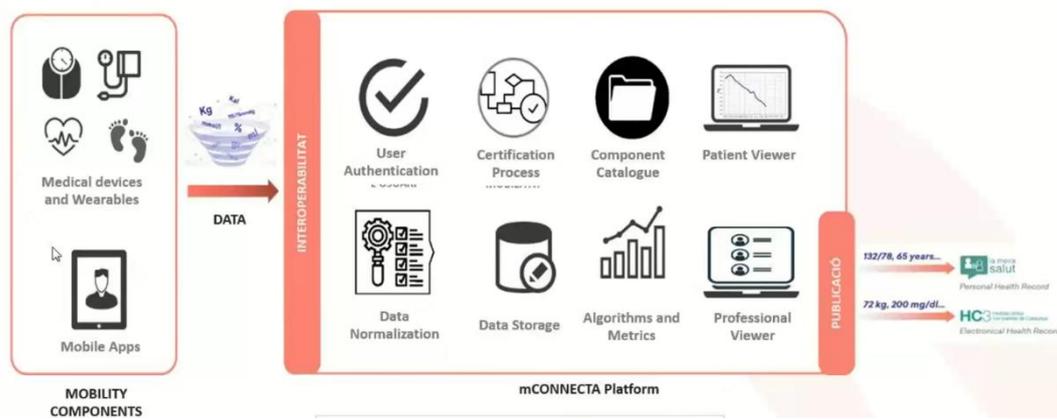
Inside the platform, authentication, certification process and algorithms that can extract information from the data are defined. The mConnecta has two view modes: one for patients, the so-called Patient Viewer and another one for healthcare professionals, the so-called Professional Viewer. Everything is following the **interoperability framework to guarantee the integration**. Data from apps but also all devices that provide mobility data in the system. It was also designed for monitoring patients at home if they own such a device. The monitoring can be implemented in mConnecta.

Internally, on the platform, there are a lot of services that need to be integrated. This is solved by microservices, working with docker systems architecture. All services must interact and have to be integrated to share the information. This is important for a platform that can grow and be scalable in performance. There are apps integrated that maybe don't need a lot of performance, but some other projects (diabetes).

The platform has, as mentioned above:
- Interface for the citizen
- Interface for practitioner
- Administration services

Data is standardised by using for common syntax HL7 FHIR resources definition for clinical data. Semantic interoperability is ensured by using SNOMED and LOINC.
The platform is integrated with third party services from other existent Catalonian Information Systems, that provide authentication services (LMS), the terminology server (all catalogues and info that we can use for the platform). mConnecta can also publish the data on the central repository, such as data important for physicians.

Crucial steps in implementation

The accreditation process started in 2016 and ended in 2018 with a pilot that rendered a list of improvements. The project name back then was AppSalut. AppSalut changed to mConnecta in the sense of having a global vision of the mobility data. The integration of the mobility data into the system does not require only interoperability and technological issues to be tackled, but also is important how the healthcare process will change; mConnecta is also considering change management processes.

The mConnecta will go live in approximately 2 months. Currently, the administration viewer is implemented, and the project is in the step of integrating it in the centres.

Committee of Experts

One of the objectives of the project was to create the Committee of Experts and to choose the right members. The Committee of Experts of mConnecta contains members from the following organisations:

- College of doctors
- Nursing school
- Association of Family and Community Nursing
- Catalan Family and Community Medical Society
- Catalan Psychologist Society
- Catalan physical activity and sports Society
- Pharmacy

Every year the possibility of incorporating new organisations in the Committee is considered. For example, two years ago the Catalan physical activity and sport Society was added because there are a lot of apps related to physical activity. The project maintains a flexible approach depending on what kind of apps must be certified, how many apps belong to certain categories, so the Committee of Experts is verified to check whether the right expertise is present. In the beginning the Committee was formed by four entities. After a short while it was realised this spectrum needs to be opened because otherwise it's difficult.

Challenges about cybersecurity

The mConnecta platform is using the cybersecurity norms that are working on the Information Systems of Catalonia, thus re-using and being aligned with the Xxx.

Data challenge

Data storage and processing is a challenge, given the kind of data that comes into the system. Wearables, medical devices are providing a lot of data, that, depending on the type of device, might be easier or harder to structure. The time and type of data is decided together with the providers, so all actors involved align.

Alignment with developers

New solutions: One way to align is having precommercial procurement projects (PCPs). Three important areas were identified: diabetes, mental health (bipolar disorder), and hospitalisation. For diabetes, the CatSalut will release the call for Tenders late 2020/early 2021. All companies can apply for the Tenders. In the end few will gain the process and will go through the test to be integrated. Before the procurement takes place, a consultation with a group of experts interested in the area is organised, in which the type of information and variables needed to be collected from the patients is discussed. In diabetes for example, the provider has a lot of variables. But at the end, the group of experts will decide the minimum variables that will be integrated in the EHR.

Existing solutions: After a solution has passed the certification process, they need to go through the integration process, which is ensured by the interoperability framework published and available. Afterwards, they go through a test with the mConnecta. Accreditation – then test validation to integrate the solution. The data needs to follow the two standards: SNOMED CT/ LOINC.
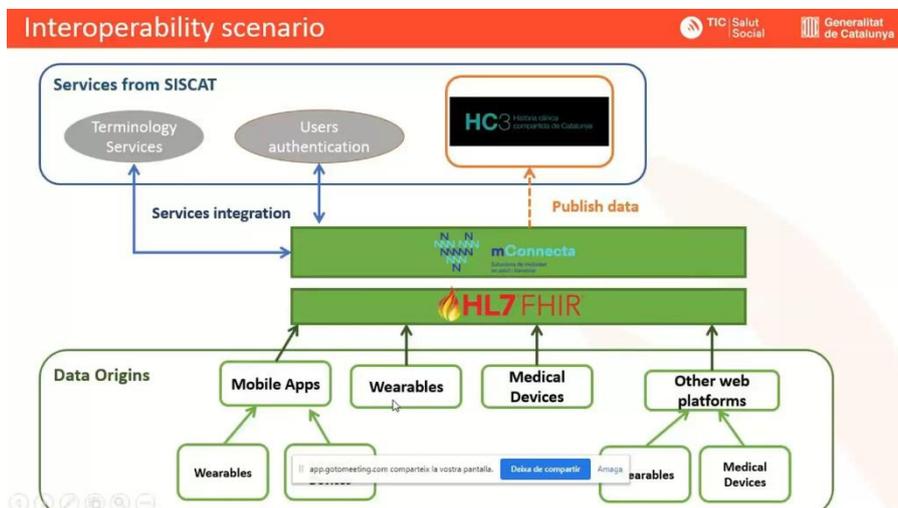
Privacy concerns

The informed consent is always signed previously. The Privacy Impact Assessment ("PIA") form needs to be implemented by the providers (or all entities that enrol a device)[1]. The PIA is not required for any processing of personal data, but only when there is a high risk to the rights and freedoms of individuals, by the nature of the processing, the scope and context, the purposes or use of new technologies. A lesson learned while carrying out interviews – how the solution works and how they guarantee the safety of data. **Sometimes even if they pass the security audits, but the informed consent is not there.** We are also doing these interviews because it is difficult to expect all entities to implement the form.

How do healthcare professionals interact with the platform?

Practitioners can choose what type of data to see in the practitioner's view. For each app, the platform asks the practitioners: what data you want to see, what kind of algorithms you want to apply on the data. Developers have more or less the same algorithms.

How do you ensure the adoption of the platform by the stakeholders?

The important body in this case is the executive committee, the personal healthcare expertise. There is a person responsible for what information is going to be sent to the citizen. This person is part of the executive committee. The committee decides the areas that need to be integrated. We identified these three areas mentioned above: diabetes, mental health (bipolar disorder), and hospitalisation. The major healthcare providers are who started to work with them to integrate them in the hospital. **In TicSalut Foundation we have a personal responsible to go to the centres, to do trainings with professionals, to help them understand how it works**. Having

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[1] template to fill in a PIA by any entity and a Guide with more information:
https://apdcat.gencat.cat/en/documentacio/guies_basiques/Guies-apdcat/Guia-sobre-la-evaluacion-de-impacto-relativa-a-la-proteccion-de-datos-en-el-RGPD/index.html

this executive committee is a key element to involve all actors into the system. Otherwise, TicSalut, it's hard that people have enough trust to adopt it and use it.

Currently, the platform is going to be integrated in 3-4 centres.

In the case of mental health, the committee published a previous report on the cost-benefit of how to implement mental health, where it has become clear that the bipolar disorder represented a good balance to implement it into the system (Benchmarking, what has been done).

Summary of key strengths

- In the certification process, developers have the chance here to submit documents used in similar certification processes.
- The committee of experts is revised and adapted according to the needs of this very agile field.
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- Not all data can be integrated in the EHR of the patient. mConnecta, as an intermediate platform, allows for filtering and selection of most important aspects required by the healthcare professionals.
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