ProEmpower PCP conference

23 September 2020 10:00 – 11:30 CET

Questions and Answers

Q: Can you address the issue of data protection in the two solutions?

A: Privacy and data protection principles provided by the DM4all system were included to the system by the design process. GDPR by design of its variation data protection by design, is regarded as a multifaceted concept, involving various components. The main points that are covered in the system prototype of the DM4all system are: a) Data access: A Patient can access his/her data from local EHRs through appropriate web and Patient interfaces. b) Consent mechanism: A Patient can provide and revoke consent at any moment, while he/she can have a general overview of the activity logging data through the DM4all solution. c) Data portability: All information can be exported in CDA documents, CSV, and medical history is compliant to international patient summary standard. d) Right to be forgotten: A Patient can ask to delete his/her account, under regulatory and legal constraints.

A: DiaWatch hosts all patient's sensitive data in a cloud storage that implements hacking-proof data management and de-identification procedures such as Pseudonymization and Logical Separation of databases, as well as the robust encryption policy ensured by the Microsoft's Azure Cloud Service provider. At "human" level, we adopted secure authentication and strong password policy for doctor's access (minimum 8 characters, expiration every 3 months), as well as a no-credentials policy for user's login (direct QR code scan at the clinic: you can't lose or be robbed of something you don't possess). Robust and modern response tactics are also in use in the unlikely event of data breach. Compliance to all the GDPR regulations is solidly guaranteed in all compartments.

Q: How have you dealt with the challenges of testing the products during the COVID-19 pandemic?

A: The lockdown for the COVID-19 pandemic was an extraordinary chance to test/utilize the ProEmpower solutions. However, unfortunately, during this long period, technical issues requiring the presence of the patients in the Hospital could not be fixed, often resulting in the impossibility to keep using the solutions.

A: In fact, we did not have any difficulties during this period. On the contrary, following patients from their homes provided great convenience. In this way, the follow-up and treatment arrangements of the patients could be continued. All of the patients felt safe from being in this system during this special period.

A: Since all the DiaWatch kits were already totally up and running at patient's premises when the pandemic started, we did not have any major issues in managing the hardware situation. Software-wise, our local support teams have been keen and more than capable to help all patients that still needed to be accustomed to our system, simply by running their regular phone follow-up.

A: The piloting of the product was not interrupted during the pandemic. On the contrary, the solution has proven to be particularly useful during the pandemic since it allowed the patients to continue the treatment process (via following their treatment plans) and gave them the option of video-appointments with the physicians. This is also validated by the usage statistics where for some of the pilots even demonstrate peak usage during the pandemic. The challenge we faced was how to keep up with the physical trainings and follow-up meetings (with the physicians and the patients) that up to that time we had been organising regularly. Instead we were contacting the patients online and tried to answer any questions and resolve any issues they may had.

Q: In what concerns commercialisation (e.g. DiaWatch - standalone app), are you dealing with regulatory requirements for qualifying as a medical device? Are the devices defined as a “medical device”, and if so, what level/type?
A: For DiaWatch, the clinical platform software is certified as a medical device Class 2a under MDD. The certification of the App is in progress. **A:** For DM4All, we are working on getting the MDR certification as Class b. It is something that we have placed a high priority on.

Q: To what extent are the devices supported by a response system which is not purely ICT-based, for instance that responds to “critical alerts”?
A: The solution aims to assist and make more efficient the work of the HCP. It not meant to be used autonomously. Therefore, the condition of the patients is still monitored by the nurse or physicians using the traditional methods. **A:** In DiaWatch a doctor may have patients’ health conditions under their direct and constant monitoring. In addition, patients are able to promptly communicate in real time with their doctors and, eventually, with any other clinical staff member that is authenticated in our Clinical Platform. This is paramount in the detection and management of any critical event. Nonetheless, the use of the solution for critical alerts has to be agreed by health care providers formally. If the clinicians are not available for such use, DiaWatch relies on disclaimers that clarify the boundaries of use (e.g. “DiaWatch cannot be used for clinical emergencies, please refer to the local health care system).

Q: In the Campania and Murcia region, what was the average age of patients included?
A: As for Campania, we have a mean age of 61, but patients went from 35 to 81 years of age. So, it covered a wide range for the Type 2 Diabetes patients. **A:** For Murcia, the average age in Bº del Carmen (DM4all/Gnomon) was 61,53 years (rank 42-85), and in San Javier 59,51 years (rank 38-77 years).

Q: How was usability evaluated and at what stages? Was the data collection instrument for usability validated?
A: The usability questionnaire was administered at the end of the pilot duration. The questionnaire is based on the Questionnaire For User Interaction Satisfaction (QUIS7) instrument.

Q: What type of testing did you do with the patients, a real clinical study (validated by an ethical committee etc...) or a simpler testing phase? Have you had a control group to compare the results obtained?
A: I think the design was more of a technological trial. We do have, at least for Turkey, a retrospective control group and we are working hard to compare the data. We did not present the results today, but the results look promising and that the mHealth interventions were actually better in reducing the HbA1c levels, but we need further analysis, for each pilot. Because, as you can see, the social-demographic conditions of the patients are quite different, and we have to consider all of these elements together when making a comparison.

Q: From the procurers’ and suppliers’ perspectives, what are the plans regarding commercialisation and implementation of the solutions in real-live environments after the PCP?
A: We should sit down and evaluate the improvements which are being made and we should really assess, on the basis of the pilot and our experience, the feasibility in the present usage of the

solutions. Because we should not forget that the consortia are still improving their solution, so it's an ongoing process. At the same time, we should look at all the levels in national health service organisation, which should then support the usage of these tools.

A: About DM4All, indeed, we have a concrete commercialisation plan, so we are very much interested in commercialising the solution as we have seen very positive results so far by patients and the pilot experience. And we are utilising our extensive consortium business network in order to expand our activities geographically.

A: For Tech4Care, we are working on a new version implementing new features and going to the market. And there are some features already that we are launching to enlarge the solution, and we will do a study with the clinician society to evaluate and validate the system, not only from a clinical point of view, but also as a real tool to manage chronic diseases outside the hospital.

Q: Which difficulties do you foresee for the implementation of the solutions?

A: Both health care providers and patients need a good education to be able to use these technologies. Sometimes patients can use the system differently. They can constantly want to reach their doctor and disturb them. Therefore, the boundaries of the system must be defined correctly.

A: We are confident that the implementation of the solution can be rather swift, once certified also the App as MD Class 2a, especially as we consider DiaWatch to be very appealing for the current users of Meteda clinical platform.

A: The challenges we faced during the implementation and the piloting phase of DM4All can be summarised as follows:

1) Accurately capture the clinical pathways and protocol and translate them into functional requirements and features of the solution
2) Provide a friendly UI so that the solution can be used by less technologically competent individuals.

Set up and maintain seamless support and physical training sessions to make sure that both HCP and patients are aware of the functionality and stay engaged.

Q: From the procurers' point of view, what are the main strengths of the solutions?

A: I think some comments from the patients and professionals were common among the procurers, and that is the patient satisfaction. And the patient satisfaction was very much related to the automaticity, that means that they had an easier life with getting parameters and sending them to their doctors. I think this is the strength of the study. And the other one is that, with artificial intelligence and so on, we should be able to improve the empowerment of the patient towards the aim of the study. And there are some hints that this was also accomplished. But what has to come is that we need to take care of all these requests for education of the professional and the patient, and the right selection of the patient to be enrolled.

Q: Question for the Turkish diabetologist, can you clarify the issues related to metabolic impairment?

A: We define the metabolic control as HbA1c levels less than 7 according to our endocrinology guideline from the Turkish study group. And also, pre-prandial blood glucose, there was less than 130 and postprandial levels less than 160, or a difference in HbA1c of more than 1%.

Q: How relevant is using the FINDRISC score for people who already have diabetes?

A: The Diabetes Risk Score is a simple, fast, inexpensive, noninvasive, and reliable tool to identify individuals at high risk for type 2 diabetes. It is not reccomended for people who already have

diabetes. One of the goals at the beginning of the study was to screen patients at high risk for diabetes.

A: For people already diagnosed with diabetes, the FINDRISC is useless. In DiaWatch, we implemented the software module responsible for running the FINDRISC at the beginning of the trial phase, but only for undiagnosed patients.

A: In DM4All, we use FINDRISC only to undiagnosed at-risk people that are invited to the system by their GPs, or other HCPs.

Q: How do you see the role of the pharmacists as a contact point of diabetes patients and considering the current developments of online pharmacies and prescriptions?

A: We have been discussing very much with the pharmacists in Italy the opportunity to use a similar system, also demoing DiaWatch. Despite very much interest, we always lacked to finalise any concrete steps in this direction, probably due to a combination of economic and staffing reasons, so, basically the time that the pharmacists should dedicate. As the Turkish colleagues said, it's a telemedicine tool, so it takes a lot of responsibility if you start using it from a clinical point of view. So, for the time being, this is our experience, we got in the middle of the discussion and hope to move further, maybe with the future development of the sector.

A: Maybe I can express our side. So, in terms of requirements, we wanted to also get this type of stakeholder. The drug-to-drug interaction was also included in the system, so all users, patients and professionals could use this in order to test how the drugs that they use already interact with others, they might even buy it online before going to a physician. In terms of pharmacists as system users, yes, we had some initial contacts. However, this will take a little bit more time in order to demonstrate the system, get the actual user requirements, and also get it marketed and educate them in using the platform. So, it depends on the country, but in Greece we also wanted to include this type of stakeholder and user in the system.

Q: Can we use the two solutions for Type 1 Diabetes Mellitus?

A: In my opinion using these solutions for patients with Type 1 Diabetes Mellitus may work better. Because the patients in this group are both younger and more familiar with the use of mobile technologies.

A: DiaWatch is fully usable in all its main features by any kind patient (e.g. from undiagnosed patients that want just to develop a healthy monitoring habit or a behavioural change to Type 1 and Type 2 diabetic patients). Our platform allows to fully configure many aspects of Shared Care Plan, such as number and frequency of measurements, drug therapy, targets for health parameters, and so on, hence a Type 1 patient would not have any problem in using DiaWatch. We expect that the focus on the use of insulin will be more evident as well as the integration with a Continuous Blood glucose monitoring device.

A: Presently, it is not possible. For Type 1 Diabetes, the solutions should interact with all the different platforms concerning CGM and pump data.

A: Type 1 Diabetes is more demanding in several disease management aspects, but we are confident that the solution could be adapted to include it.

Q: In which extent can the technical infrastructure of the solutions be taken as a basis for the management of other chronic diseases?

A: The ProEmpower project included requirements that are indeed applicable to other chronic diseases as well, such as:

- Security and authentication

- Data Privacy
- Remote monitoring and video appointments
- Self-management
- Features for education and raising awareness of the disease.

Therefore, to a large extent, the technical infrastructure of the solution can be taken as a basis for the management of other chronic diseases.

A: We are confident that the overarching paradigms at the core of DiaWatch (e.g. remote monitoring, patients' empowerment and self-management etc.) can be to a large extent applied to different care scenarios, i.e. different chronic conditions.

A: The technical infrastructures seem to be adequate also for other chronic conditions. The critical issue may be the automaticity for condition-specific devices.