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Obstructive Sleep Apnea compliance: verifications and validations of personalized interventions for PAP therapy

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Abstract— **The Positive Airway Pressure (PAP) therapy is the most capable therapy against Obstruction Sleep Apnea (OSA). PAP therapy prevents the narrowing and collapsing of the soft tissues of the upper airway. A patient diagnosed with OSA is expected to use their CPAP machines every night for at least more than 4h for experiencing any clinical improvement. However, for the last two decades, trials were carried out to improve compliance and understand factors impacting compliance, but there were not enough conclusive results. With the advent of big data analytic and real-time monitoring, new opportunities open up to tackle this compliance issue. This paper's significant contribution is a novel framework that blends multiple external verification and validation carried out by different healthcare stakeholders. We provide a systematic verification and validation process to push towards explainable data analytic and automatic learning processes. We also present a complete mHealth solution that includes two mobile applications. The first application is for delivering tailored interventions directly to the patients. The second application is bound to different healthcare stakeholders for the verification and validation process.**

Keywords— **Obstructive Sleep Apnea, homecare, validation, verifications, compliance, PAP therapy**

I. INTRODUCTION

Obstructive Sleep Apnea (OSA) is a sleeping disorder where the patients suffer from a partial or complete collapse of the upper airway during sleep. This disorder causes either cortical arousal or a fall in blood oxygen saturation (SpO_2) [1]. Consequences of OSA are: daytime sleepiness [2], depression [3], and cardiovascular disease [4].

The primary treatment for OSA is Positive airway pressure (PAP), indifferent to the severity. The PAP consists of a mask connected to a pressurized circuit. This pressure maintains the upper airway open when wearing the mask, consequently maintaining the respiratory system open [5]. The PAP therapy regulates the sleeping condition of 90% of patients with a sufficient compliance level [6].

For the effectiveness of the therapy, the patient must respect its conformity. The minimum adherence level to experience an improvement in the health condition is four h/night [7]. Nevertheless, PAP therapy is a very constraining therapy. It has one of the lowest adherence when compared to other therapy. Furthermore, this adherence level has been sluggish over the last 20 years [8]. Nevertheless, new opportunities open up to tackle this identified problem in PAP therapy. One of the opportunities is the emergence of big data [9]. The data monitoring and analytics in homecare allow a detailed patient characterization to deliver personalized intervention [10], [11].

This research project aims at developing, delivering, and monitoring tailored interventions for homecare patients suffering from OSA. To achieve this goal, we collect monitoring data from the PAP device and analyze them to build multiple data models. This comprehensive project's expected results are: firstly, a system that can adapt itself based on feedback from the different users, and secondly, maximize the adherence for the PAP therapy. We use the Information Systems Research (ISR) approach in our overall research to develop our methodology [12]. The Information System Research brings together the business needs (environment analysis) and the rigor of a knowledge base composed of foundations and methodology. We used the ISR methodology to define different research topics and an approach to tackle multiple issues.

In figure 1, we present the project's overall research approach to achieve our goals. The research approach is entirely driven by multiple data sources and focuses on the PAP therapy's initial phase since it is the most crucial phase [13]. There are two primary sources of data. The first one is the PAP monitoring data, i.e., data directly related to the OSA treatment progression, and the second one is the interventions monitoring data, i.e., the patient consumption and perception of the delivered interventions.

Before building and delivering personalized interventions, we need to characterize the patients to understand their needs in the PAP therapy (figure 1.1). We firstly build multiple patient profiles and pathways throughout the therapy based on the PAP monitoring data. We already developed this patient profiling and characterization in a previous paper [14]. With this patient characterization, there is a patient vulnerabilities detection system. In this work we focus on the vulnerabilities to comply with PAP therapy during the initial phase. The vulnerabilities allow the system to select the most appropriate intervention in a consolidated interventions repository.

While developing this vulnerability detection system and intervention repository, we perform various verification procedures that benefit from the knowledge of the experts in PAP therapy. The sleep experts, homecare experts, and

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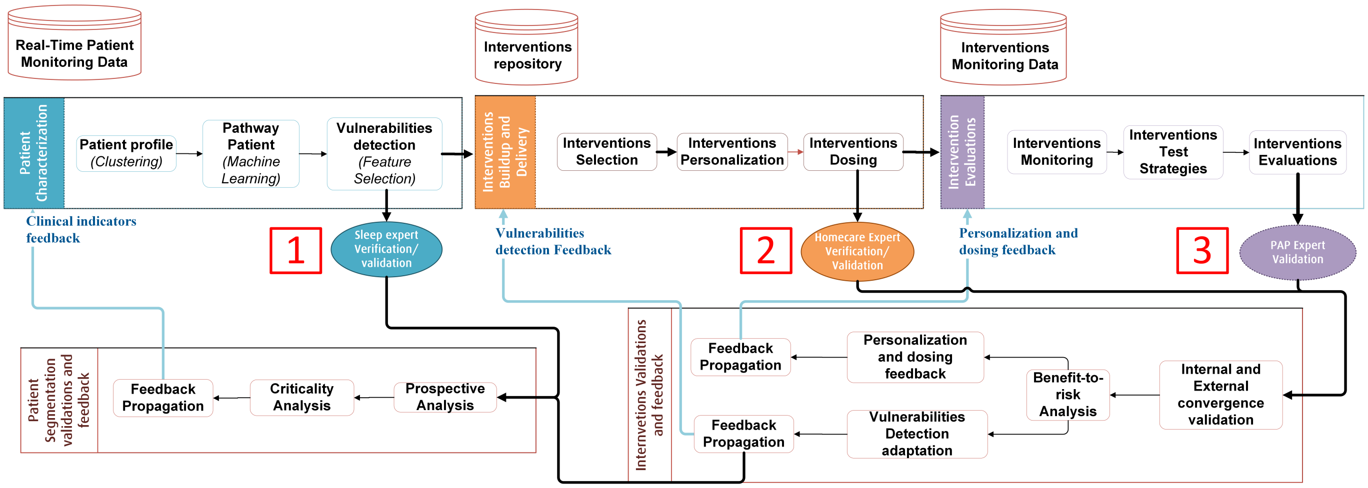


Fig. 1: Research Approach

PAP experts contribute to making the interventions in our system, and the homecare experts supply guidelines for the intervention schedule.

To go deeper in the patient-centric approach, we add a personalization level to each selected intervention to get the most practical interventions for each patient and answer everyone's needs (figure 1.2). Before delivering the interventions, a homecare expert verifies the interventions' personalizing level. We then deliver the interventions to the patients through a personalized mHealth solution called Sleep.Py.

Lastly, the system monitors the intervention's consumption and the patient's perception of the interventions (figure 1.3). When the patient finalizes the intervention's consumption, three experts validate the intervention efficiency on different criteria. This validation mechanism allows the system to collect multiple feedbacks from the different stakeholders. The system propagates on the feedback according to the different decision support models. Consequently, our iterative approach regularly integrates experts' feedback to improve each personalized intervention's overall expected results.

In this paper, we focus on the interventions' monitoring, assessments, verifications, and validations. Nonetheless, these concepts raise several questions: firstly, how to monitor the consumption of the intervention using mHealth solution and combining quantitative and qualitative data. As a result, the second issue is how to analyze these intervention monitoring data to calculate the interventions' efficiency without inducing a bias. The intervention delivery varies according to the patient, and this is challenging to have a test for each intervention. Consequently, our proposed framework needs to blend multiple tests to get a reliable test protocol to evaluate the interventions.

Finally, the last issue involves multiple experts at various levels to improve our self-learning system. We collect the validations from different sources, and we need to compare the validation results to the analytic results of the decision support model. This comparison is complex as we compare data based on human experience with results from a data model.

In Section II, the paper provides an overview of the related works and the limits around different topics on monitoring, evaluating, and validating personalized interventions in a mHealth solution. Section III develops the proposed framework to respond to the different issues we addressed in this paper. Section IV details the implementation of this framework and the results obtained. Section V discusses the limitations and perspectives of this work.

II. RELATED WORKS

This section describes the most relevant works according to the three issues presented previously. i.e., collecting qualitative data on the interventions, computing the efficiency of the interventions, and finally validating these interventions after the patients' consumption. We carried systematic research-based for these issues using the keywords close to the topic.

We extracted 1951 papers in Web Of Science Core Collection, Scopus, and PubMed. We performed a systematic analysis of these 1951 papers to get the complete scope of the most relevant works in these fields. We found 239 papers closely related to our topics, and then we perform an in-depth investigation of these works to select papers focusing on the OSA therapy or homecare patient.

As recurrent topics, we identified the perspective of personalized interventions and the ever-growing of data harvesting and analytic in homecare. We mainly focus on papers with proven results whether at a prototype level or complete implementations.

A. Personalized interventions for PAP therapy

Recently, PAP therapy makes most of the monitoring by collecting data recorded by the PAP device only. *Schwab et al.*. present these three data, namely the adherence level, the residual apnea events, and mask leakage [15]. This monitoring offers new possibilities to provide adaptive interventions based on the patient phenotype [16].

In 2007, *Stepnowsky et al.* set up the Sleep Apnea Self-Management Program (SASMP), which consists of empowering patients in his PAP therapy through multiple informative sessions on the PAP therapy[17]. *Weaver et al.* presented a review of different personalized interventions to increase compliance in OSA. Already in 2010, they conclude there was no one to fit all intervention for the PAP therapy [18].

In 2017, *Lim et al.* provided the P4 approach to the OSA. The P4 approach consists of Predicting patient suffering from OSA disease, Preventing possible problems, Personalizing the PAP therapy, and make the patient participate in his therapy[19]. In a recent study, *Pepin et al.* brought together the data science approach to provide novel interventions for treating the OSA [9],

B. Intervention and patients' perception monitoring

The PAP device provides multiple monitoring data as presented in the previous section. However, these monitoring data do not include the patients' perceptions. The Epworth Sleepiness Scale (ESS) is a widely used tool that has been validated as a measure of sleepiness [20]. The ESS consists of 8 situations that the patient has to answer according to a scale. The sum of all the answers gives the ESS score.

The Pittsburgh Sleep Quality Index(PSQI) [21] is another questionnaire that measures sleep quality. The PSQI consists of 19 self-reporting questions and 5 questions reported by the patient's bed-partner. *Ye et al.* proves that including the partner in the PAP therapy increase the compliance level [22]. Hence, the PSQI is a valuable questionnaire as it measures the partner's role in therapy.

The questionnaire that directly assesses PAP therapy's perception is the Continuous Positive Airway Pressure Fear, and Avoidance Scale (CPAP-FAAS) [23]. *Chasens et al.* modified the FAAS questionnaire [24] to includes six items assessing agoraphobia and five items assessing claustrophobia. To monitor the OSA's perception, *Micoulaud-Franchi et al.* proposed the Self-Efficacy Measure for Sleep Apnea (SEMSA) [25]. This SEMSA also assesses PAP therapy's beneficial effects and the patient's engagement level in the therapy.

C. Intervention test strategies

To use the monitoring data, we need to determine a test strategy to determine the PAP therapy changes. The Randomized Control Trial (RCT) is the most used test strategies to measure the direct change of the clinic conditions [26]. The most straightforward RCT setup is determining two cohorts of patients, and then only one cohort receives the new interventions while the other received the standard intervention. To detect any changes, we analyze in detail the differences between the two groups. However, to get relevant results, the RCT sometimes needs to be carried out over several years.

The Multiphase Optimization Strategy (MOST) [27] and the Continuous Evaluation of Evolving Interventions (CEEI) [28] are two test strategies that address shortcomings of the RCT. MOST add a screening phase to RCT. This phase builds the best possible intervention before the trials. However, like RCT, the intervention cannot be changed during the trial; hence MOST is not flexible. On the other hand, CEEI offers a continuous evaluation of the interventions for greater flexibility. *Mohr et al.* designs the CEEI for evaluating mobile and web-based interventions.

D. Validation mechanisms in healthcare

The validation of the interventions is essential in healthcare, mainly when the data analytic selects the internvetions. *Angehrn et al.* reviewed different case studies that applied artificial intelligence and machine learning in the healthcare system [29]. They reviewed different regulatory requirements to validate these algorithms for deployment in Point of Care. This review highlights the importance of external validation, and this validation needs to be carried out by an expert in the corresponding fields.

Kumar et al. summarized the results gathered from the workshop for mHealth evaluation [30]. They present multiple validations methods based on the data analysis. The predictive validation using the machine learning algorithm opens up new opportunities to validate interventions without carrying out trials on a large cohort of patients. Furthermore, mHealth enables to take multiple monitoring. Consequently, concurrent validations can easily be implemented by comparing data having the same topology,

E. Discussions

We presented the evolution of the interventions in PAP therapy for better patient management. The advent of real-time monitoring data brings up new tailored solutions for the patient suffering from OSA. We fill these opportunities with our data analytic approach [13] to characterize the patients [14] for delivering tailored interventions.

To monitor the intervention and patients' perception, there are multiple questionnaires. However, none of the questionnaires covers all the indicators on which the interventions have an impact. We propose to use multiple types of questionnaires during the intervention monitoring. We will dynamically select relevant and already validated questionnaires according to the patient's vulnerabilities. To get the complete scope of multiple intervention consumption to evaluate their efficacy, we presented multiple test protocols and healthcare strategies. However, we propose adaptive interventions that evolve according to every patient's needs. The CEEI adapts partially to our problem; improved results can be obtained by combining the CEEI and the MOST strategies. In other words, before delivering the interventions, we perform a screening phase via multiple validation levels to guarantee the delivery of the best possible interventions.

There is a pressing need to include external stakeholders in healthcare to validate the results and go towards explainable data analytic. Therefore, we propose combining this validation carried out by experts with data analytic to offer two validation levels. This method offers validations that do not solely rely on expert experience or statistical reasoning but a combination of both. We did not find noteworthy papers which explicitly explain this combination of these two types of validations.

III. PROPOSED FRAMEWORK

This section presents our proposed framework to verify and validate personalized interventions delivered to the patient suffering from OSA. Fig. 2, summarizes the processes present in the framework. In this framework, multiple stakeholders play a crucial role in OSA patient management.

A. Stakeholders

*1) **patient**:* the patient who is already diagnosed with OSA and is prescribed a PAP therapy by a sleep expert. During the installation of the PAP device, the patient receives the mHealth solution.

*2) **Analytic layer**:* the analytic layer of the framework relies on multiple data analytics models to automatically process a large volume of data. There are two primary sources of data, the PAP telemonitoring data and the intervention monitoring data. We will discuss these processes further down in this section.

*3) **Sleep expert**:* the sleep expert physician has two main tasks. Firstly, verifying the intervention selection and scheduling made by the analytic layer. Secondly, validating the intervention's efficiency on the patient's vulnerabilities. The intervention test strategy validates this efficiency. Beforehand, the sleep expert also performs the OSA screening of the patient.

*4) **PAP expert**:* the PAP expert is a homecare technician specialized in PAP therapy. The PAP expert validates the direct impact of the interventions on the PAP therapy only. He is in charge of setting up the PAP device at the patient place. Moreover, he delivers the in-person interventions throughout the therapy. For example, the PAP expert delivers essential information on the PAP device and adjusts the mask correctly during the initial phase.

*5) **Homecare expert**:* the homecare expert is a multi-therapy expert who manages different homecare patients. This expert has an overview of a large number of patients with different phenotypes. Furthermore, the expert schedule and monitor the delivered interventions. Consequently, the homecare expert verifies the intervention scheduling and validates the interventions' consumption based on the intervention monitoring data. There are 3 main functionalities in this framework, namely intervention selection, intervention consumption, and intervention validation and feedback.

B. Intervention Selection

Before selecting the appropriate interventions, the PAP expert needs to set up the PAP device at the patient's home. Afterward, the patient starts to use the PAP device, and at the same time, we collect the PAP expert's feedback. With these first data collections, the analytic can build the patient profile to detect the patient's vulnerabilities.

We presented the detailed implementation of this patient profiling in a previous paper [14]. The analytic selects the most appropriate intervention from a repository of predefined of interventions. All three different (sleep, PAP, and homecare) experts contributed to building this repository. We associate each intervention present in the repository with a vulnerability to compliance.

Henceforth, with the patient profiling's vulnerabilities, the system matches with the interventions that solved these vulnerabilities. These vulnerabilities use the patient's health record, for example, the comorbidities, type of Apnea, residual Apnea–hypopnea index and etc Consequently, the sleep expert (physician) is the most appropriate person to verify this intervention selection. This expert has an overview of the patient's health condition apart from PAP therapy.

C. Intervention Consumption

After verifying the interventions, the analytic layer adds a personalization level to each intervention according to the patient profile. The intervention repository contains only standard interventions, and these interventions might not fit all patients. The analytic model customizes the intervention by adapting the configurable section of the intervention. Consequently, the patients have a completely personalized intervention consumption model.

Before delivering the interventions to the patient, there is a verification process. The homecare expert verifies the personalization level applied by the analytic model. We combine this verification process based on the expert's experience on homecare intervention consumption with the analytic model's decision support tool.

Finally, the patient receives the intervention through the mHealth solution, which allows him to consume the intervention. During the consumption, we monitor the intervention at different points in time using the different tools presented in section II-B. We collect and store all these data for the validation and feedback process.

D. Intervention Validation and Feedback

To validate the interventions and the different data analytic models, we have to calculate each interventions' efficiency or set of interventions' efficiency. Firstly, the analytic layer retrieves the intervention monitoring data as well as the PAP telemonitoring data. Secondly, we applied the appropriate intervention test strategy accordingly. As a result, the analytic layer automatically deduces the efficiency of the intervention. Finally, we compute the variety of data and data quality to calculate the reliability of the previous results.

The different experts use this reliability as decision support to validate the interventions at different levels. The sleep expert validates the impact of the interventions on the vulnerabilities detected by the patient profile. In other words, it validates any improvement in the health condition of the patient attributed to the interventions.

The PAP expert performs the second level of validation. This step incorporates the validation of the impact on the PAP therapy. The PAP expert uses three different telemonitoring data defined in section II-A, i.e., the adherence level, the residual apnea events, and mask leakage.

Lastly, the homecare expert validates the intervention consumption by the patient. This step is significant; it validates

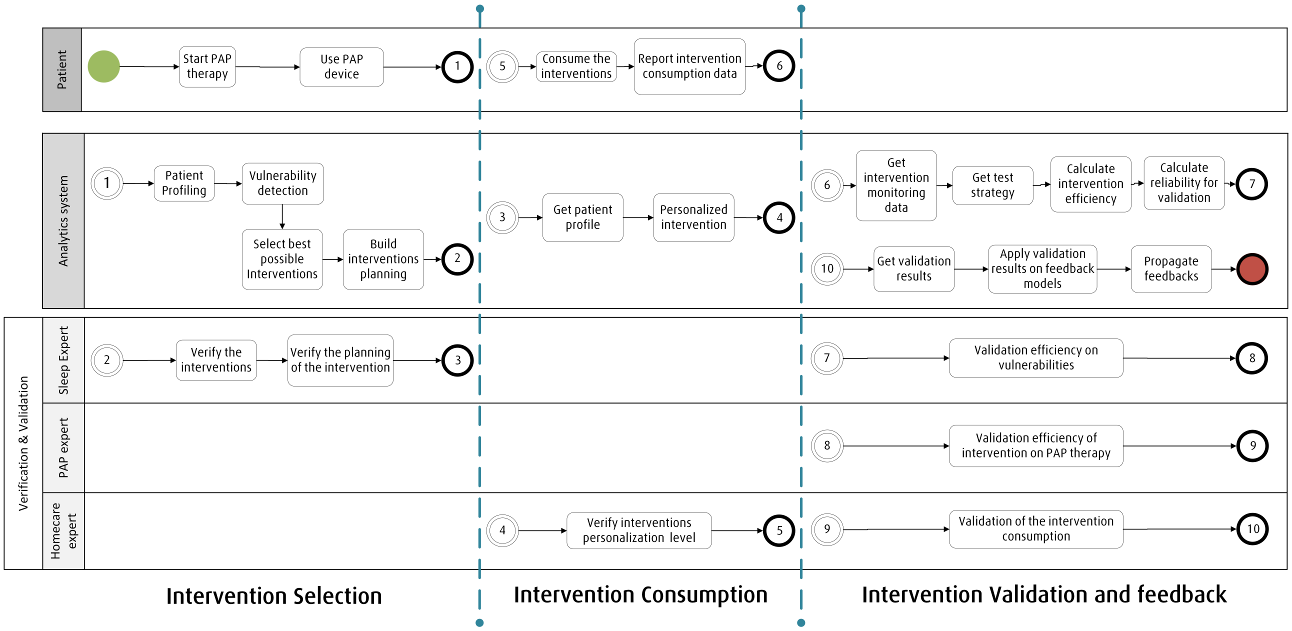


Fig. 2: Proposed framework for selecting, monitoring and validating homecare interventions for PAP therapy

the compliance of the patient to the interventions only. The expert uses the intervention completion percentage and compared patients in the same profile to validate this intervention consumption. Consequently, we deduce the efficiency of the personalization for the patient.

The analytic level collects all the validations results from the different experts and uses these validations for feedback. A feedback model confronts the experts' validation with the validation carried out by the analytic layer. Based on these results, the framework will propagate the feedback to the different data models present in the analytic layer to improve the models' accuracy. To implement this propagation, we infer the models' feedback directly by adding weighted variables in the dataset and adjusting the thresholds of the decision support tools. Consequently, increase the efficiency of the personalized interventions to tackle the patients' vulnerabilities.

The presented framework integrates the recent advances in data analytic to validate different healthcare stakeholders. As a result, the framework supply multiple decision support tools to the stakeholders at critical moments in the PAP therapy, and this decision uses the feedback for continuous improvement. The framework can deliver a personalized patient follow-up to a large number of patients.

IV. IMPLEMENTATION

This section presents the implementations of the framework presented previously (section III). We implement two different mobile applications. The main application (Sleep.Py Patient) delivers the personalized interventions to the patients. The second application (Sleep.Py Expert) collects the verification and validations of the different experts. We implement these 2 applications employing the cross-platform Flutter framework. For the analytic data layer, we use the

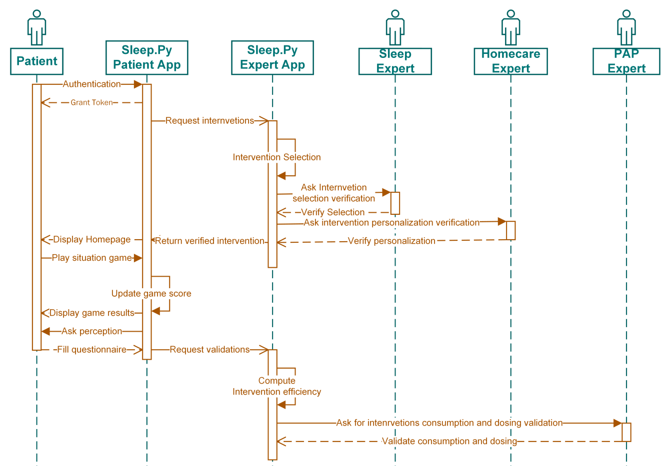


Fig. 3: The Sleep.Py patient and expert apps sequence diagram

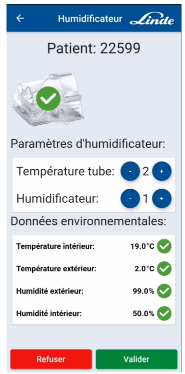
Python language.

On figure 3, we detailed the Sleep.Py Patient and Expert applications' functioning. This sequence diagram exposes the interactions between the main stakeholders with the mHealth solution. In this section, the implementation we present focuses on verifying the sleep expert's intervention selection and the intervention's efficiency validation by the PAP expert.

*1) **Patient and Expert Authentications**:* Before accessing the Sleep.Py applications,there is an authentication process. We use the OAuth 2.0 [31] protocol for this authentication. Multiple health monitoring devices use this protocol for easy interoperability of the systems. Hence, aside from authentication, this OAuth 2.0 implementation allows our system to collect data from different systems while having the patient's consent.

(a) Patient app: Situation Game

(b) Patient app: Questionnaire



(c) Expert app: Humidifier decision support tool

Fig. 4: Sleep.Py app

*2) **Intervention Selection Verification**:* While the analytic layer selects the most appropriate interventions, the sleep expert receives a notification on the Sleep.Py expert to verify this selection. To help the sleep expert in this verification process, we provide to the latter multiple indicators. Figure 4c illustrates this decision support tool. In this example, the analytic layer decides to supply a humidifier to the patient, and the sleep expert verifies this decision based on the patient's environmental data.

*3) **Intervention Delivery**:* To deliver the personalized interventions, we built a serious game that focuses on sleep and PAP therapy. Figure 4a shows an example of a situation that highlights the need to wear the mask all night. According to the patient's vulnerability, we will push the most appropriate situation game after the verification process.

For each situation, the patient will have 2 possible answers, and according to the answer selected by the patient, the app will display the appropriate information. Moreover, the patient can receive gaming points when he completes the situations game.

*4) **Intervention monitoring**:* The Sleep.Py Patient app has an adaptive module to manage multiple questionnaires to assess the patient and the intervention consumption. According to our approach and framework, this module is critical as there are different types of assessments and, hence, different types of questionnaires. This module displays the questionnaire on an intuitive page like on fig. 4b.

For this module to display the questionnaire, the latter is transcripted into the JSON format. A software engineer was in charge of this transcription. When the patient fills out the questionnaire, the results are stored in a database. The different data models and experts use these results to improve the decision support tools and validate the interventions.

For monitoring the intervention consumption, the Sleep.Py Patient app also logs all the pages visited each time the patient uses the application. Furthermore, for the questionnaires, we log the time spent by each patient answering each question. The data model again uses the logged data to build the consumption profile of the patient based on unsupervised learning methods. For this specific clustering, we use the KMeans algorithm.

*5) **Intervention Validation**:* As expressed in section III, the PAP experts validate the interventions' efficiency. In this implementation, we mainly focus on improving the PAP adherence level and reducing the residual apnea event. Consequently, to measure the intervention's efficiency, we apply the test strategy on the PAP monitoring data [15].

To help the PAP expert in the validation process, we provide multiple charts in the Sleep.Py Expert app. We implement 3 charts to track the evolution of the adherence level, residual apnea event, and mask leakage. Based on these time-series charts, the PAP expert can perform validation with unbiased data.

V. Discussions

The vulnerability detection system that selects the intervention relies significantly on the patient profile. The system uses only three types of PAP telemonitoring data; thus, there is a little variety of patient data. A complete set of sensors can be installed at the patients' homes to collect more information on the patients and their environment to solve this issue.

In our proposed framework, different stakeholders verify and validate the results used as feedback in the different models. However, we never questioned this verification or validation results even though the experts may give a wrong verification or validation. In other words, we directly include these results in the feedback. We can compare the results coming from the stakeholders with the results coming from the data model. When there is a substantial divergence between the two results, we can investigate more in detail the diverging results instead of directly using the expert results as feedback.

For the intervention monitoring, the patient self-reports the different assessment questionnaire. In some cases, the data quality and reliability of this self-reporting can be problematic. One solution to this issue is setting up a dedicated validation mechanism to ensure that the data's reliability is high.

VI. Conclusion & Future Work

We presented a novel framework to provide a multi-level verification and validation of personalized intervention for patients suffering from OSA who received PAP therapy. The framework includes three main stakeholders that perform the verifications and validations based on each stakeholder's expertise. We supply various decision support tools to help the stakeholders in the verifications and validation processes. The proposed framework also uses these decisions' results as feedback, a continuous improvement mechanism for various decision support tools like suggesting the optimal PAP configuration and parameters. These are included in a the Sleep.Py expert application

This paper also presented another mobile application that delivers multiple personalized interventions directly to the patients. The application includes a situation game that delivers multiple information to the patient in an interactive interface. Finally, this app also monitors the intervention consumption and the perceptions of the interventions by the patient himself.

In future work, we planned to complete the Sleep.Py Patient app by including more interactive games. Consequently, there will be more interventions in the interventions repository. Hence, we will be able to tackle a wider variety of vulnerabilities. Finally, we are expecting to test the Sleep.Py app on OSA patients recruited by Linde Homecare France.

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