Impact of PGHD reliability on the usefulness of a clinical decision support system

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Abstract

Background. Using personal generated health data (PGHD) during medical consultations can be beneficial for both patients and clinicians: clinicians can get insights of the patients’ situation and patients can understand how their lifestyle impact their disease. However, multiple acceptance barriers such as time consuming and lack of PGHD reliability prevents a routine usage of this data during medical consultations. A clinical decision support system, called FullFlow, has been developed to address these acceptance barriers and facilitate the introduction of PGHD into medical consultations.

Objective. The objective of this study was to determine if the designed FullFlow system was useful during consultations for clinicians and to verify the hypothesis that the higher PGHD reliability, the more effective the system is.

Methods. The assessment of the objective relied on a medical pilot during which clinicians and patients with type 1 and type 2 diabetes used the FullFlow system during medical consultations. The data collection relied on a post-consultation questionnaire in addition to system logs. The qualitative data analysis relied on the participants, the PGHD reliability, the usage of the system and the correlation between the usage of the system and the PGHD reliability.

Results. This study showed that seven consultations took place during the medical pilot, involving three clinicians and six patients (T1D=2, T2D=4). The PGHD reliability was low or catastrophically low for an overwhelming majority of consultations (5/7). The information displayed was useful in half of the consultations according to the clinicians who answered the questionnaire (3/6). Despite this, the overwhelming majority of clinicians who answered the questionnaire (5/6) found that the designed FullFlow system permitted to gain insights of the patients’ situation. The study showed that a correlation exists between the PGHD reliability and the usefulness of the system (the higher the PGHD reliability is, the more useful the system is for clinicians).

Conclusion. PGHD usage in clinical settings can permit clinicians to gain valuable information regarding the situations of their patients. A clinical decision system can present useful information to clinicians. While the PGHD reliability is correlated to the usefulness of such system, it is not the only factor impacting it: clinicians and patients’ context such as novelty of usage and personal goals also plays a role in determining on how such system is useful for clinicians. However, due to a limited number of participants, a new medical pilot must be performed in order to confirm the results of this study.

Keywords: pghd, self-collected health data, diabetes, mHealth, decision support system

Introduction

Using self-collected health data, also referred as personal generated health data (PGHD), during medical consultations can be beneficial for both clinicians and patients [1, 2]: clinicians can get insights of their patients’ life while patients can understand their situation better and improve their self-management. However, a significant number of acceptance barriers preventing the wide usage of PGHD in medical context have been identified [3, 4]. Example of such barriers are the time consumption necessary to extract relevant information from this data and the lack of PGHD reliability for providing tailored medical services.

To address these barriers and facilitating the introduction of PGHD into medical consultations using diabetes as a case (type 1 and type 2), a clinical decision support system (CDSS), referenced as FullFlow henceforward, has been created. FullFlow has two main components. The first component is a context-aware knowledge-based module (KBM) in charge of analysing the PGHD, defining its data reliability and extracting relevant information [5]. The second component is a tailored dashboard focusing on displaying relevant data and information in an attempt to meet the clinicians’ information needs [6]. The dashboard includes the results of the KBM.

This article proposes to assess the usefulness of FullFlow system during medical consultations and to verify the hypothesis that more the data is reliable, more the system is useful for clinicians. The origin of this hypothesis emanates from previous studies pointing out that data quality can negatively impact services provided by CDSS [7] or healthcare services in general [8].

Methods

Protocol

The aim of this study was to evaluate if FullFlow was useful for the clinicians during medical consultation and to verify the hypothesis that more the PGHD is reliable, more the system is useful for clinicians. To perform this evaluation, a medical pilot involving clinicians and patients with diabetes was organised between November 2018 and December 2019. The FullFlow team recruited clinicians, who were in charge to recruit patients with diabetes. The FullFlow team expected between 14 and 28 clinicians and approximately 100 patients to participate, with a distribution of 70/30 to T2D/T1D.

The main study resolves around medical consultations in which patients share their PGHD using a combination of systems: 1) the Diabetes Diary, a mobile health application used for self-management [9], 2) the Diabetes Share Live, an extractor of the data stored in
the Diabetes Diary [10] and 3) FullFlow, a dashboard coupled with an artificial intelligence solution to extract and present relevant data to clinicians [5, 6]. The complete study protocol is available in a separate article [11].

Data collection:
The data collection relied on two methods: a survey and system logs. An invitation to fill up a custom online-based questionnaire after ending the medical consultation was shared with clinicians when they accessed the FullFlow system. LimeSurvey was used for managing the online questionnaires and collecting answers. While the questionnaire was inspired by standard questionnaires such as the Computer System Usability Questionnaire [12], we decided to use a custom questionnaire to focus on specific aspects of the intervention and to limit the time clinicians have to spend filling it up, considering they are already time-starved [3]. Table 1 describes the measurables included in the questionnaire. This study focuses exclusively on the usefulness of FullFlow for clinicians, and do not include other measurables such as patients’ blood pressure. These other measurables will be reported in other articles as specified in the study protocol [11].
The system logs contain information generated automatically by FullFlow when it receives patients’ self-collected health data. Table 2 describes these logs. This study only the logs related to the usage of the system. Other logs such as estimated HbA1c will be reported in other articles. The raw data of the logs and questionnaires are available in an appendix.

Table 1: Questionnaire questions, their descriptions and ID used in this article for reporting.

| Questions                                                                 | Description                                                                                           | ID               |
|--------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|------------------|
| Clinician ID                                                             | Unique identification number of the clinician. Has been anonymised in this article.                    | Clinician_id     |
| Was the information displayed by the system useful to you?               | Likert scale from 0 to 4. 0 indicates that the data was not useful at all and 4 that it was very useful. | Inf_useful       |
| Did the system helped you to provide specific recommendations to the patient, compared to without the system? | Likert scale from 0 to 4. 0 indicates that the system did not help in providing tailored services, while 4 indicates that it helped very much. | Inf_useful_no_system |
| After using the system, did you understand this patient's situation better? | Yes or no.                                                                                             | Gained_insights  |
| Did you use the overview in the system during consultation?              | Yes or no. The overview contains information regarding the data reliability and the data collected by the patients. | Overview         |
| Did you use the personal goals in the system?                           | Yes or no. The goals are the patients' personal goals written by the patients themselves in the Diabetes Diary. | Goals            |
| Did you use the noticeable events in the system?                        | Yes or no. The noticeable events are important events extracted by the system along their potential causes (e.g. hypoglycaemia event caused by too much insulin). | Events           |
| Did you use the graphs related to the noticeable events in the system?   | Yes or no. The system proposes graphs illustrating the trend of the noticeable events and their causes.  | Events_graphs    |
| Did you use the combined graph in the system?                           | Yes or no. The combined graph displays all the quantifiable data sent by the patients in combination with the calculated information for the whole period in a unique graph. | All_graph        |
| Did you use the time period in the system?                              | Yes or no. The Time Period displays the data for the whole period in multiple graphs (one graph per data type). | Time_period      |
| Did you use the daily distribution in the system?                       | Yes or no. The Daily Distribution distributes all quantifiable data per hour in multiple graphs (one graph per data type). | Daily_distribution |
| Did you use the daily evolution in the system?                          | Yes or no. The Daily Evolution summarizes the data per day in multiple graphs (one graph per data type). | Daily_evolution  |
| Did you use the data list in the system?                                | Yes or no. The data list lists the all the PGHD in a table.                                             | Data_list        |
| Did you use any other functionality in the system?                      | Open question. If the clinicians used anything else not specified in the previous questions.            | F_others         |
| What more would you like features and/or how would you change the system? | Open question. If the clinicians would like to change, add or remove a service in the system.            | F_new            |

Table 2: Data generated from the FullFlow system's logs and their description.

| ID                        | Description                                                                 |
|----------------------------|-----------------------------------------------------------------------------|
| Patient_id                 | Unique patient identification number generated by the Diabetes Diary and shared with the FullFlow system. |
| Is_td1                     | 1 if patient has type 1 diabetes, 0 otherwise. This information is extracted from the data collected by the Diabetes Diary. |
| Kbm_grade_reliability      | Data reliability grade determined by the context-aware knowledge-based module (KBM) of the FullFlow system. This module determines the reliability of the data by using an hypothesize-and-test strategy relying on rules (e.g. decrease reliability if [data_type] is erroneous or if the number of registrations deviates too much per day). The KBM and its rules are described in detail in a previous article [5]. Higher grade means higher data reliability (50 is the highest score possible). The logs also contains all issues leading to the calculated grade. |
| Kbm_reliability_group      | Group determined by the data reliability grade (previous entry). Four-steps scale: <15 = catastrophically low, [15,30] = low, [30,45] = acceptable, ≥ 45 = good. Different interpretation messages are displayed to the clinicians depending on the data reliability group (e.g. “the data is regularly acquired...” |
and seems reliable”, “the data quality is uncertain, multiple issues were identified”) in addition the list of issues, if identified. A previous article explains this process in detail [5].

GoalsDisplayed

Yes or no. Yes means that the FullFlow system displayed personal goals received from the Diabetes Diary. No means that no goal was received and therefore nothing was displayed.

EventsDisplayed

Yes or no. Yes means that the KBM identified noticeable events from the data (e.g. hypoglycaemia, lack of sleep) and displayed them to the clinicians. No means that the KBM has either not found noticeable events in the data or did not have the required data available to perform this task, and therefore nothing was displayed.

Data analysis:
The author performed a thematic data analysis based on four categories: the participants of the medical consultations, the reliability of the patients’ self-collected health data, the usefulness of the FullFlow system and the functionality usage. Finally, the relationship between the PGHD reliability and the usefulness of the system has been studied for answering the hypothesis explained in the beginning of this section. The feedback gained will be used for improving the FullFlow in the next iteration.

This study was guided by the Standards for Reporting Qualitative Research checklist to enhance its organization and its reporting [13].

Results

Consultations and participants

As shown in Table 3, FullFlow was used during seven (7) medical consultations. These consultations concerned six (6) patients (two (2) T1D and four (4) T2D) and three (3) or four (4) clinicians. The uncertainty regarding the number of clinicians who participated is linked to the absence of the clinician identification number in the questionnaire regarding the consultation number 0. Each patient consulted their clinician once, except one who consulted twice (consultations number 1 and 3).

Table 3: Consultations, participants, data reliability and usefulness of the FullFlow system. Each row represents one medical consultation. See Table 1 for legend. *: system-generated value. NaN: undefined.

| PatientId | is_tdi | ClinicianId | inf_useful | inf_useful_no_system | gained_insights | kbm_grade_reliability* | kbm_reliability_group* |
|-----------|--------|-------------|------------|----------------------|----------------|------------------------|------------------------|
| 0         | F3b07c7| 0           | NaN        | NaN                  | NaN            | -2.0                   | catastrophically low   |
| 1         | Fd26f0a| 0           | A          | 1.0                  | No             | 20.0                   | low                    |
| 2         | F4454b2| 1           | A          | 2.0                  | Yes            | 35.0                   | acceptable             |
| 3         | Fd26f0a| 0           | A          | 1.0                  | Yes            | 19.0                   | low                    |
| 4         | F1b84e4| 0           | B          | 4.0                  | Yes            | 15.0                   | low                    |
| 5         | Feac9e7| 1           | A          | 3.0                  | Yes            | 21.0                   | low                    |
| 6         | Fe00ba6| 0           | C          | 4.0                  | Yes            | 45.0                   | good                   |

PGHD reliability

The KBM is a service integrated in the FullFlow system in charge of analysing the self-collected health data to determine its reliability and extracting relevant information to present to clinicians. In summary, the KBM uses a four-steps scale for determining the data reliability: good (≥ 45), medium ([30,45[), low ([15,30[) and catastrophically low (<15). A good-grade data reliability permits precise and relevant medical and statistical calculations, while a catastrophically low grade renders these analyses uncertain. A separate article presents the functionality of the KBM and its approach for grading the self-collected health data [5].

The KBM determined that the data reliability was low or catastrophically low for an overwhelming majority of consultations (5/7) while the data was considered acceptable and good in only two cases (2/7). With an average value of 22 and a 50 percentile of 20, the distribution of the PGHD reliability grade is a multimodal and almost symmetrical distribution centred on the low reliability quality group, as shown in Figure 1.
Usefulness of the FullFlow System

Figure 2 illustrates the distribution of the Likert scale results of the questions ‘Did the system permitted you to provide specific recommendations and plans to your patient compare to without the system?’ and ‘Was the information displayed useful for you?’, omitting the empty questionnaire. Clinicians indicated in half of the consultations (3/6) that the system helped them providing specific recommendations to their patients compared to not using the system, while the system was not really useful for performing this task in two of the consultations and the usefulness was limited in one consultation. Similarly, clinicians indicated that the information displayed was useful from a large to very large degree in half of the consultations (3/6) while not really useful in two of the consultations and limited in one consultation.

However, the clinicians indicated that the system helped them gaining insights of the patients’ situations and understanding better in an overwhelming majority of the consultations (5/6).

Functionality usage

The usage of these functionalities is reported in Table 4.

| overview | goals_displayed | goals | events_displayed | events | events_graphs | all_graph | time_period | daily_distribution | daily_evolution | data_list |
|----------|-----------------|-------|------------------|--------|---------------|-----------|-------------|-------------------|-----------------|----------|
| 0        | NaN             | No    | NaN              | Yes    | NaN           | NaN       | NaN         | NaN               | NaN             | NaN      |
| 1        | Yes             | No    | No               | No     | Yes           | No        | No          | No                | Yes             | NaN      |
| 2        | Yes             | No    | No               | Yes    | No            | No        | No          | Yes               | No              | Yes      |
| 3        | Yes             | No    | No               | No     | Yes           | No        | No          | No                | No              | Yes      |
| 4        | Yes             | Yes   | No               | No     | Yes           | Yes       | Yes         | Yes               | No              | Yes      |
| 5        | Yes             | Yes   | No               | Yes    | Yes           | Yes       | Yes         | Yes               | No              | No       |
| 6        | Yes             | Yes   | No               | No     | Yes           | Yes       | No          | Yes               | No              | No       |

Omitting the instance without the filled-in questionnaire, clinicians used the overview section for all their consultations (6/6). The personal goals have not been used in any consultation (0/6). The noticeable events and the related graphs have only been used in one consultation (1/6). The clinicians reported erroneous data in consultations number 4 and 6, considering that FullFlow did not propose the noticeable events functionality during these consultations (illustrated in red in Table 4, see more details in discussion section). The time period graph displaying all data at once in a single graph has been used in four consultations (4/6). The daily distribution functionality and the combined graph have been used during half of the consultations (3/6) each, while the daily evolution was not used at all (0/6). The data list has been used in five out of six instances (5/6).

Table 5: Other functionalities used and new functionalities

| F_other | F_new |
|---------|-------|
| 0       | NaN   |
| 1       | NaN   |
| 2       | NaN   |
| 3       | NaN   |
| 4       | NaN   |
| 5       | NaN   |

As shown in Table 5, one clinician reported using continuous glucose monitor (CGM) data using an external application not integrated in FullFlow. While FullFlow is able to manage data collected CGM, the Diabetes Diary does not, and therefore no CGM data has been collected during this medical pilot (see the discussion section). The same clinician reported having difficulty navigating the combined data graph to browse day by day. The discussion section addresses this issue. Another clinician suggested to add an automatic exchange of data between patients’ applications (CGM and bolus calculator). However, this is an issue due to the Diabetes Diary and not the FullFlow.
Relationship between usefulness of the system and data reliability

![Graphs showing relationship between data reliability and usefulness of the system](image)

Figure 3: Relation between the data reliability grade and the usefulness of the information compare to without the system (left) and the relation between the data reliability grade and the usefulness of the displayed information (right) grouped by clinicians. The line of best fit (regression) and the confidence interval (80% confidence) are shown for both graphs. Data extracted from Table 3. The event involving catastrophically low data reliability is not included considering the concerned clinician did not filled up the questionnaire. An instance number represents a consultation number.

According to the line of best fit in Figure 3, the more the data is reliable, the more useful the system is for clinicians. However, due to a limited number of samples, the confidence interval is quite large and is expending on both ends of the spectrum for both graphs. Looking at individual events, the clinician C, who participated in only one consultation (number 6), ranked the usefulness of the system to the maximum (4) while the data reliability has been graded as good by the KBM (45). On the other side of the spectrum, the clinician B, who also participated in one consultation only (number 4), ranked the usefulness of the system to high (3 and 4) while the data reliability has been graded low by the KBM (15). For both instances, the clinicians indicated that the system permitted to understand their patients’ situation better (Table 3).

Clinician A, who participated in four consultations (numbers 1, 2, 3 and 5), ranked the system as not really useful twice (grade 1, consultations 3 and 1) for consultations involving low data reliability (19 and 20), involving the same patient (Fd26f0a) in both cases. In one of these instances, the clinician indicated that he did not understand the patient’s situation better (Table 1). For another instance, the clinician ranked the usefulness of the system as limited (2) when the data quality was acceptable (35), involving a different patient (F4454b2). However, the same clinician ranked the system as useful (3) for another consultation involving low data reliability (21), involving another patient (Feac9e7). In these two cases, the clinician indicated that the system permitted to understand the patients’ situation better (Table 1).

Based on these results, it is possible to say that while the data reliability grade plays a role in the usefulness of the system, it is not the only variable impacting it, considering that a clinician graded its usefulness as great while the data reliability was low. The discussion section addresses this.

Discussion

Presented results

This paper presented the results of the usage of the FullFlow by clinicians for consulting PGHD by diabetes patients during medical consultation. The paper showed that the FullFlow permitted clinicians to gain insights of the patients’ situation and helped them providing specific medical services in five out of six consultations. Clinicians reported that the information displayed by the system was really useful in 3 out of 6 cases and limited in 1 out of 6 cases. The most used functionality was the overview (6/6), following by the data list (5/6), the time period graph (4/6), the daily distribution and the combined graph (3/6 each) and the noticeable events (1/6). The daily evolution and the personal goals were not used at all.

In addition, the paper showed that the more the data is reliable, the most useful the system is.

Representativeness of the population

Regarding the representativeness of the population, only three clinicians (or four, assuming that another clinician did not filled up a questionnaire) and six patients (two T1D, four T2D) were involved in this medical trial. The participation was much less than anticipated: we estimated between 14 and 28 clinicians and 100 patients (73 T2D, 33 T1D) to participate in this study [11]. Unfortunately, the participants are not representative of the population. We suggest multiple factors leading to the failure of recruiting the targeted population:

1. Limiting the participation of the patients using the Diabetes Diary only. We knew that this application is not the optimum app for diabetes patients, as it lacks important features such as the insulin type, blood pressure, polypharmacy, and integration.
into glucometers and physical activity trackers for automatic data transmission, limiting the services FullFlow can offer, as stated in a previous article [6]. One activity tracker was integrated in June 2019 eight months after the start of the recruitment of the medical trial. In addition, the population using the Diabetes Diary is extremely limited compared to similar applications. For instance, MySugr has more than one million registered users while the Diabetes Diary has only one thousand. Therefore, this situation limits the possibility for clinicians to recruit patients due to resistance to change (i.e. difficulty to force patient using specific app while they are already using another one).

2. The complexity in usage of the Diabetes Share Live solution. “This platform requires eight steps to share the data: (1) patients open the Diabetes Diary, (2) patients wait for the application to give a unique identification code, (3) clinicians open an Internet Navigator, (4) patients give clinicians the unique code, (5) clinicians enter the code on the Webpage, (6) clinicians choose a time period, (7) patients acknowledge the time period given by the clinicians and select the data they want to share, and (8) clinicians consult the FullFlow” [6].

3. Non integrating the FullFlow into existing Electronic Health Records (EHRs), which is one of the main acceptance barriers limiting clinicians to use PGHD during consultation [7].

We believe that postponing the medical trial could have been a solution for avoiding this situation. It would have been possible to propose a better user experience by integrating multiple apps (such as MySugr or Glooko [15]) and proposing the integration in existing EHRs for example. Meanwhile, a more limited study, such as scenario-based laboratory tests supported by video-recording, could have been used to get more in depth results.

Unfortunately, the current study suffers the same problems that other eHealth research publications have: the limited number of participants and the non-representativeness of the population, which renders the efficiency limited [1]. In addition, due to the Diabetes Diary, the FullFlow was not used in its maximum potential (e.g. hazardous medical calculations due to the absence of insulin type). Therefore, another medical trial is necessary for confirming the results of this study.

Partial answers and erroneous reported data in questionnaires

Another point to address is the missing questionnaire and erroneous data reported by clinicians in two questionnaires concerning two variables. We think that the missing questionnaire is related to the catastrophically low reliability of the PGHD. In fact, the FullFlow displays firstly a message to clinicians informing them if the collected PGHD is worth their time or not, based on its reliability. In this case, the FullFlow clearly stated that the data is in fact so unreliable that a significant number of problems were identified limiting the usefulness of consulting the data. Therefore, we suppose that the clinician did not bother using the FullFlow and answering the questionnaire. The logs on LimeSurvey showed that the questionnaire was created by the FullFlow when the dashboard was accessed but was not open by the concerned clinician.

Regarding the erroneous data reported by clinicians claiming that they have used the noticeable events generated by the KBM (and the related graphs) while the FullFlow did not provide any for the concerned instances, we assume that the clinicians misunderstood which section was concerned by these questions considering that it was not displayed by the system. The concerned clinicians (B and C) only participated in one consultation each and did not meet the noticeable sections at all during these consultations. To avoid this type of erroneous reports in the future, we suggest displaying verbose messages such as “no noticeable events have been found” instead of hiding this section completely when no events are found.

Data reliability and usefulness of the system

Clinicians can perceive the system useful if it permits them to understand the situation of their patients better even if the data reliability is low and patients’ context (i.e. who they are, what are their goals, how do they self-manage) can also impact the usefulness of such system. In addition, the usage of the noticeable events and their potential causes may have helped the clinician A to grade one instance as highly useful (3) while having low data quality (21).

Future

One clinician reported having difficulty navigating day per day using the combined graph. Another possibility for navigating daily results was proposed in earlier design of the FullFlow (Figure 4). However, this approach was discarded considering that we were expecting patients to collect data for a long period of time, such as six or twelve months. In this situation, the proposed graph is not usable. However, for the next FullFlow version, this type of graph can be integrated as a separate tab in the menu if the data was collected during a period equal or shorter than one month.
This paper focused on the usefulness of the FullFlow system during consultation and future papers will focus on other measurables, such as feasibility of the system or change in the therapeutic relationship, patient empowerment and wellness, as described in the study protocol [11].

Conclusion

This paper showed that clinicians can get insights of the patients’ situation and provide specific medical services by consulting patients’ self-collected health data through a tailored dashboard. This paper also demonstrated that the usefulness of such system is impacted by the self-collected health data reliability (i.e. the more the data is reliable, the more useful the system is for the clinicians) and by patients and clinicians’ context. Diabetes type, medical specialty, self-management capabilities and personal goals are examples of such context. However, the medical pilot involved a limited number of participants, with only three clinicians and six patients. Unfortunately, the participants are not representative of the diabetes population and a new medical trial involving more participants should be organized to confirm the results.

Acknowledgements

This paper is one of the results of the Ph.D. of the author and of the FullFlow project. The qualitative analysis and this paper were written on the spare time of the author without financial support. The FullFlow project was supported by the Norwegian Research Council under the number 247974/070.

Conflicts of interest

None declared.

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