Reliable Blood Pressure Self-measurement in the Obstetric Waiting Room

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Keywords
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Summary

Background: Patients often fail to adhere to clinical recommendations when using current blood pressure self-measurement (BPSM) methods and equipment. As existing BPSM equipment is not able to detect non-adherent behavior, this could result in misdiagnosis and treatment error. To overcome this problem, we suggest introducing an alternative method for achieving reliable BPSM by measuring additional context meta-data for validating patient adherence. To facilitate this, we have developed ValidAid, a context-aware system for determining patient adherence levels during BPSM.

Objectives: The aim of this study was to validate this new reliable BPSM method based on ValidAid in the clinical setting. Specifically, we wanted to evaluate ValidAid’s ability to accurately detect and model patient adherence levels during BPSM in the clinic.

Methods: The validation was done by asking 41 pregnant diabetic patients scheduled for self-measuring their blood pressure (BP) in the waiting room at an obstetrics department’s outpatient clinic to perform an additional BPSM using ValidAid. We then compared the automatically measured and classified values from ValidAid with our manual observations.

Results: We found that a) the pregnant diabetics did not adhere to given instructions when performing BPSM in the waiting room, and that b) the ValidAid system was able to accurately classify patient adherence to the modeled recommendations.

Conclusions: A new method for ensuring reliable BPSM based on the ValidAid system was validated. Results indicate that context-aware technology is useful for accurately modeling important aspects of non-adherent patient behavior. This may be used to identify patients in need of additional training, or to design better aids to actively assist the patients during measurements. ValidAid is also applicable to other self-measurement environments including the home setting and outpatient clinics in remote or underserved areas as it is built using telemedicine technology and thus well-suited for remote monitoring and diagnosis.

1. Introduction

Obtaining reliable BP measurements is essential in the diagnosis and monitoring of hypertensive pregnant women suffering from diabetes as well as for other patient groups [1–3]. Hypertension occurs in more than 10% of pregnant women in most populations and may lead to several complications during pregnancy and at delivery [4].

In the waiting room at the obstetrics department, Aarhus University Hospital, the pregnant diabetic patients are required to self-measure their BP before consultation. The BPSM process requires the patient to follow a range of recommendations to be valid [5]. As existing state-of-the-art BP devices are not capable of sensing incorrect usage [6] and only measurements following the recommendations are considered reliable [1–3], this could lead to potential misdiagnosis and possibly result in medication errors and other treatment errors [7, 8].

Previously, we have suggested designing adherence models for sensing and modeling patient adherence during BPSM [9–12] utilizing context-aware technology [13, 14] as a novel method for achieving reliable BPSM. To facilitate this, we have constructed ValidAid, an automatic context-aware system for capturing BPSM data combined with relevant contextual metadata relating to the BPSM procedure and recommendations. The measured context is used to model the adherence of the patient to the BPSM healthcare process. ValidAid has previously been validated in the laboratory but not in a clinical setting [9, 15].
The aim of this study was to validate this new reliable BPSM method based on ValidAid in the clinical setting. Specifically, we wanted to evaluate ValidAid’s ability to accurately detect and model patient adherence levels during BPSM in the clinic.

2. Background

Some pregnant women need to visit the obstetric outpatient clinic up to 19 times during a pregnancy to self-measure their BP, weight, urine-protein-levels, blood sugar, and perform a fetal CTG [6]. Pregnant women suffering from diabetes or hypertension hold an increased risk of harm to their fetus due to the complications experienced during pregnancy.

In addition, fetal and maternal morbidity and mortality rates are higher than normal when pregnant women have a diastolic pressure of 110 mm Hg or higher during the first trimester [16]. Other potential maternal complications related to pregnant diabetics include development or worsening of a range of conditions including diabetic retinopathy, nephropathy, pre-eclampsia, and several cardiovascular diseases [17].

3. Methods

3.1 Participants and Setting

The Department of Obstetrics, Aarhus University Hospital delivers around 5,000 babies each year. A minority of women suffers from complications in their pregnancy leading to around 8,000 visits to the obstetric outpatient clinic per year for medical consultations. This includes pregnant women suffering from diabetes, hypertension, pre-eclampsia, and other complications.

Every Thursday is diabetes day at the obstetrics outpatient clinic. In the waiting room, the women are required to self-measure their BP before attending one or more consultations. In the waiting room, two automatic BP devices are provided for the women to perform their self-measurements. Usually, only one measurement is taken which is then written down by the patient in her personal log book and brought to the ensuing consultation as reference. During their first visit at the outpatient clinic, patients are instructed in the correct BPSM procedure after which they are expected to act autonomously and self-directed, performing all succeeding measurements in the waiting room unsupervised.

3.2 Study Design

Following a participatory design approach [18, 19] based on the adherence strategy engineering framework (ASEF) [20], we arranged a series of interviews with healthcare staff on current BPSM interventions used in the waiting room including questions on instruction and training provided to the pregnant women on how to self-measure in the waiting room, and on what equipment was available for self-measuring. Also, during field studies over a four week period, we observed patients self-measuring in the special context of the waiting room in order to provide an understanding of current practice.

We adapted the existing ValidAid system [9] according to the findings from the participatory design process and ASEF design guidelines. This included designing an information model of the BPSM healthcare process and identifying relevant sensors for measuring patient adherence [20]. ValidAid is an automatic context-aware system for capturing BP data using telemedicine equipment combined with relevant contextual meta-data that can be used to model patient adherence to recommendations that may have an impact on BP. The contextual parameters supported by ValidAid include “time seated” before measurement, “talking” during measurement, and whether the patient has “legs crossed” [9]. These three contextual parameters were chosen based on recommendations from the Danish Hypertension Society (DaHS), American Heart Association (AHA), and the European Society of Hypertension (ESH) [4]. Other contextual parameters were considered, including correct cuff size and mounting, back supported, as well as arm rested [7, 8]. While these contextual parameters are likewise important for obtaining valid blood pressure measurements, and thus relevant to measure, they were not technically feasible to model with currently available technology.

3.3 Data Collection

We evaluated ValidAid’s ability to model patient behavior by asking 41 pregnant diabetic patients to perform an additional BPSM using ValidAid after having self-measured their BP as usual with one of the existing BP devices in the waiting room. Data was obtained during a two week field study in the waiting room after having provided the patients with sufficient information on the background and purpose of the study and having them sign an informed consent form following national ethical regulations. The participants were instructed to perform the measurement exactly as they would usually self-measure their BP in the waiting room or at home. For each participant, we observed and registered their ability to follow the guidelines before and during measurement. Meanwhile, the system autonomously collected data on patient behavior using context sensors as well as the resulting BP measurements. We registered patient performance for a total of six recommendations, three of which were supported by the ValidAid prototype.

3.4 Data Analysis

We compared the observed behavior data of the 41 participants with the data that was automatically collected by the ValidAid system as part of the adherence model, including the calculated adherence level. This provided us with a measure of the accuracy of the ValidAid system; specifically with regard to its ability to model non-adherent behavior of the patients using the designed adherence model.

4. System Design

The ValidAid system consists of several conceptual and technical components. These include an adherence model that defines the tasks and rules of the healthcare process, a range of physical context sensors and healthcare devices, as well as the ValidAid application as the integrating compo-
The ValidAid application implements the adherence model, provides a user interface for the test facilitator, data processing and communication facilities, as well as facilitating audio context classification. These components are presented in the following sections.

### 4.1 Adherence Model Design

An adherence model (AM) is used to model and describe a healthcare process, such as performing BPSM in the waiting room, which patients will need to follow in order to adhere to the associated rules and guidelines. It reduces the healthcare process into a series of elements that are “measurable, quantifiable, and feasible to transform into a data-model” [20]. This facilitates identifying and integrating the various components of the system, such as healthcare and context sensors, as well as relevant program logic and algorithms in order to transform the abstract conceptual model of the healthcare process into an operational information system.

The adherence model is central to supporting the development of adherence engineering strategy based systems such as ValidAid and may be modeled using a dedicated modeling language called the "Adherence Model Markup Language" (AMML) which is based on extensible markup language (XML) and Schema technology [21]. AMML provides designers with an ontology-based analysis and design aid [22]. Alternatively, it is possible to use a text-based description of the model instead, implementing the rules directly in the application as programming logic [20]. We chose to implement the adherence model in AMML, later integrating it with the physical context sensors and other hardware components using a general purpose programming language [23]. Also, we used web service technology [24] for implementing a web based clinical decision support system for providing data access to staff and researchers.

Following the ASEF framework guidelines [20], we analyzed the BPSM healthcare process and designed an adherence model of the BPSM healthcare process in the waiting room as well as an adherence strategy for how to use the data. This allowed us to implement the ValidAid system for measuring and quantifying current adherence levels, and it provided us with a basis for improving patient adherence through “adherence aids” for supporting patients during self-measurements.

From the participatory design analysis phase we found that the diabetics are instructed to follow a subset of the recommendations from the DaHS on how to perform reliable BPSM [25]. Instructions include: to rest at least 5 minutes prior to measurement, not move or talk during measurement, sit with back-supported, keep feet flat on the ground and legs not crossed, as well as no talking during measurements. Also, the arm should be supported, the patient should use the correct cuff size, and the cuff should be mounted at heart level. While the DaHS recommendations also suggest taking three consecutive measurements as part of the procedure for valid self-measurements, this is not part of the procedure in the waiting room where only a single measurement is performed. Based on the above input, we designed an adherence model that models the relevant contextual information and provides the means for using context-aware information technology for registering and assessing whether the patient is adhering to these guidelines. As it is not feasible to model all relevant aspects of the measurement process, we created a reduced adherence model [20] focusing on patient rest time before measurement, patient talking during measurement, and whether legs are crossed.

### 4.2 Adherence Strategy

An adherence strategy is defined as “the means, measures, and interventions used to facilitate patient adherence during a healthcare process as part of the overall disease management” [20]. For the waiting room, the main aim was to investigate whether patients would adhere to the DaHS recommendations for performing BPSM or not as modeled by the reduced adherence model. Thus, an adherence strategy was defined consisting of three adherence verifiers to update the adherence model. This included adherence verifiers for measuring: patient rest time, whether patient is talking during measurement, as well as detecting whether legs are crossed during measurement. Adherence verifiers are defined as: “elements that quantify the adherence levels of a given healthcare process and the resulting data quality of the healthcare process” [20] and are often implemented as context-aware sensors.

The chosen adherence strategy combines the data from the three verifiers and uses these data to classify a measurement as being either adherent or non-adherent. Thus, the developed adherence strategy does not aim at improving the adherence of the patient by exerting direct influence on the patient during the BPSM process, but rather at providing an assessment of the level of adherence of the patient as a clinical decision support tool. This assessment may then be used to identify patients in need of additional instruction and training.

### 4.3 ValidAid System Overview

The ValidAid system consists of a clinically approved BP device as used in current clinical practice, a sensor seat implementing two adherence verifiers for registering legs-crossed and rest-time respectively, as well as a tablet computer that integrates the BP device and sensor seat components, provides a user interface for the test facilitator, and performs audio classification of the data obtained (Figure 1).

Also, all BP measurement data and contextual meta-data are collected in a structured format using XML, and all audio data are stored as raw Pulse-code modulation (PCM) files for later review [26]. Data and meta-data are accessible for clinicians using a web solution, the Clinical Decision Support System (Figure 2).

We utilize the sensor seat and associated software components in order to register test-subjects getting seated and later standing up. This is used to determine when to start recording audio data and when a measurement session should be considered complete. Also, the sensor seat will provide information on patient rest time and whether legs were crossed during measurement.

For overall system architecture, we rely on the "Reliable Evaluation Infrastructure" (RELEI) framework [27] which provides us...
with additional tools for adherence engineering, patient adherence evaluation, as well as a reliable execution environment for the ValidAid application. RELEI was designed as a toolkit for facilitating research into patient self-care activities in the unsupervised setting supporting systems such as ValidAid.

4.4 Components used

The tablet computer device (ASUS Eee Slate EP121, Asus Computer Inc., Taiwan) [28] is running the ValidAid application (Figure 1) that communicates with the BP and sensor seat devices, and it provides audio context classification capabilities. The audio classification algorithm is based on the artificial neural network classifier [29]. The method of using an audio classification algorithm for detecting talk during measurement has previously been validated in a laboratory study [9, 15].

The BP device is based on the widely used A&D BP device (A&D Digital BP Monitor UA-767PBT, A&D Company Limited, Japan) [30] which can communicate wirelessly using Bluetooth. This device is specifically developed for telemedicine purposes and has previously been used for telemedicine studies involving BP self-measurement [31].

The sensor seat is based on the TinyOS platform (Shimmer Wireless Sensor, Shimmer Research, Ireland [32]) using two external piezoresistive sensors (FlexiForce, Tekscan Inc., US) [33] for sensing leg placement and for registering time seated through the strain applied to the sensor in terms of the weight of the legs. Also, for improved accuracy of the leg sensors, a pressure mat sensor was used to allow for sensor fusion (Defender PM1/PK, Farnell Ltd [34]).

4.5 Audio Classification Method

The standard approach to audio classification is feature extraction followed by classification with a classifier such as an Artificial Neural Network (ANN) or Hidden Markov Model (HMM) classifier [29].

Feature extraction for audio classification is often based on the spectral (or cepstral) content over short-time windows such as 50 milliseconds windows. Other features include short-time energy or zero-
crossing ratio [35]. In our work, we used the Mel-Frequency Cepstral Coefficients (MFCCs) which have previously been used to represent both music and speech successfully [36]. For each 50-millisecond window, 13 MFCCs are extracted using a dedicated Matlab library [37].

We used a hopsize of 20 milliseconds between windows such that 50 13-dimensional feature vectors are extracted each second. We chose the Artificial Neural Network classifier (ANN) which has been implemented in Matlab [38]. One of the advantages of the ANN as compared to more advanced classifiers is the low computational demands to classify new data once training is complete.

The ANN classifier is a 2-layer, feed-forward ANN (i.e. a single layer of hidden units) and uses the so-called Softmax function as output function. A regularization term was added to the classifier cost function to avoid over-fitting. We trained the classifier to discriminate between the classes "background noise" and "speech" and evaluated it in the laboratory setting.

The output from the ANN classifier is an estimate of the probability that the current 50-millisecond time window will belong to a given class. Instead, we would like to reach decisions on a 2-second time window since this time window is more appropriate in our application. To achieve this, hard assignment is performed on the short-time windows and is combined with majority voting. Thus, each short-time window is assigned to exactly one class, and each 2-second time window is assigned to the class with the majority of short-time "votes". A hop-size of 1 second is used between the 2-second windows to get 60 classifications per minute.

The algorithm was developed and trained using Matlab and then linked into the ValidAid application as an assembly dynamic link library [23].

5. Results
In Table 1, we present the results from the self-measurement process with regard to patient adherence to the individual recommendations, expressed as a percentage of patients adhering to the individual recommendations.

In Table 2, we present the percentage of modeled adherence as measured and calculated by the ValidAid system vs. the observed patient behavior. The "difference" is calculated as the "measured" subtracted from the "observed". This provides an objective measure of the accuracy of the ValidAid system's ability to detect and classify adherent and non-adherent behavior.

We found that none of the patients (0%) followed all of the recommendations while self-measuring using the ValidAid research prototype. A quarter of the patients adhered to five recommendations. Around half of the 41 patients (48%) adhered to four out of six of the recommendations while 25% followed three recommendations. Only a minor group followed one or two recommendations (15%) while all patients followed at least one recommendation.

The ValidAid system registered that the 41 patients had rested around 60 seconds on average before taking the BP measurement, ranging from 30 seconds for the least rested to 118 seconds for the most rested. The context parameters "talking" and "legs crossed" were negligible. Detailed results can be found in Table 3.

6. Discussion
In the present study, we have validated a new method for reliable BPSM based on the ValidAid system. Furthermore, we found that the current BPSM method used in the waiting room is challenged by several factors and is inadequate for providing accurate diagnoses. In the following, we discuss the findings from the validation process as well as identified challenges to existing BPSM method and equipment, their causes, and possible solutions, providing specific suggestions to the clinic.

6.1 Method Validation
By comparing the ValidAid measured adherence data with the manual observations, we found that the three adherence verifiers had provided the same results that could be manually observed. As presented in Table 2, a minor difference of 2%, corresponding to one out of the 41 patients, was found. This difference was due to a manually observed and registered incident of a single patient as "talking" which was not modeled as talking by ValidAid. In fact, the adherence model had captured three incidences of patients or others in the waiting room talking, but they were all below the 10% offset limit defined in the adherence model to be classified as non-adherent behavior. Adjusting for this, we found a 100% correlation between the adherence model and the manually observed data. Thus, we found that the adherence model used in the ValidAid system was able to accurately detect and model patient adherence during BPSM. Thus, the suggested new method for reliable BPSM using the ValidAid system was validated.

6.2 Insufficient Number of Measurements
We found that patients are instructed by the department nurses to follow a subset of

### Table 1
The observed adherence levels of the patients during self-measurements using the ValidAid system

<table>
<thead>
<tr>
<th>Recommendation adhered to</th>
<th>Patients adhering, percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not talking</td>
<td>98%</td>
</tr>
<tr>
<td>Legs not crossed</td>
<td>100%</td>
</tr>
<tr>
<td>Rest time (5 min.)</td>
<td>0%</td>
</tr>
<tr>
<td>Correct cuff size</td>
<td>88%</td>
</tr>
<tr>
<td>Arm supported</td>
<td>66%</td>
</tr>
<tr>
<td>Back supported</td>
<td>39%</td>
</tr>
</tbody>
</table>

### Table 2
The percentage of patient adherence as measured by the ValidAid system vs. the observed

<table>
<thead>
<tr>
<th>Adherence to recommendation</th>
<th>Measured</th>
<th>Observed</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not talking</td>
<td>100%</td>
<td>98%</td>
<td>2%</td>
</tr>
<tr>
<td>Legs not crossed</td>
<td>100%</td>
<td>100%</td>
<td>0%</td>
</tr>
<tr>
<td>Rest time (5 min.)</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>
the recommendations from the DaHS with the exception of only performing a single BP measurement. Disregarding any patient related adherence issues, this could be a serious challenge to the data quality of the measurements as relying on a single measurement does not secure reliable data sufficiently [25, 39].

6.3 Low Patient Adherence to the Recommendations

None of the patients followed all of the recommendations while self-measuring in the waiting room while only a minority (around a quarter) of the participants followed five out of six recommendations. Deviating from only one of the recommendations is sufficient to cause critical bias to the measurement and could lead to misdiagnosis and treatment errors [4, 5].

Also, we found that none of the patients adhered to the recommended rest time of 5 minutes. Instead, they had only rested around 60 seconds on average before taking the measurement, ranging from 30 seconds for the least rested to 118 seconds for the most rested. This might be attributed to the fact that several of the included patients had already been in the waiting room for some time before measuring and thus might have felt that they were sufficiently rested. However, even standing up and walking through the waiting room require the patient to rest another 5 minutes before measurement according to protocol. This highlights a general challenge when utilizing context-aware technology to model human activities. The ValidAid adherence verifier can only rely on what it is able to sense during the healthcare process of which it is part and cannot take the individual patient’s actual situation into account.

6.4 Suggestions for the Clinic

Findings indicate that current BPSM methods and equipment are inadequate for securing valid BP measurements in the unsupervised setting. Therefore, we suggest that further training or guidance should be provided to achieve a higher degree of patient self-measurement adherence. Such extended training would most likely strain staff resources and would still not allow the staff to identify non-adherent patients. Also, increased quality control could be achieved by letting trained staff supervise the measurements. However, while such increased supervision appears to be the “gold standard”, this would also increase staff costs and might cause white coat bias in some patients due to the presence of healthcare professionals during measurements [5].

As an alternative to training and supervision, we suggest using context-aware technology to detect and classify non-adherent patient behavior as demonstrated in this study. ValidAid is capable of identifying individual patients using a small radio identification card or biometric parameters provided as part of the RELIEF framework [27]. While these features were not used in the current study, they would allow ValidAid to automatically associate patients with specific measurements enabling context tagging of the BP data [20]. This would alert the treating physician or nurse to specific patients who have not adhered to the recommendations, thus identifying them for additional training and instructions using a suitable interface for the healthcare professionals such as the Clinical Decision Support System (Figure 1 and Figure 2). BP and contextual data could be presented to the treating physician or nurse during consultation on existing client devices such as the consultation room computer or a mobile device depending on the setting. This would allow healthcare staff to take the necessary steps on an informed basis.

In addition, we suggest introducing increased tool support in the waiting room to improve guidance to patients while self-measuring, e.g. correcting any non-adherent patient behavior in real time rather than retrospectively. These objectives could be achieved by basing such a system on the adherence verifiers created for the ValidAid system and extending these with proper adherence aids for guiding the user to avoid operating errors. Adherence aids can be considered “the gold standard” for improving patient adherence, and it could be argued that adherence aids should be prioritized in adherence strategy engineering projects [20]. However, adherence aids have proven to be more complex to design and implement than adherence verifiers and may appear as much more intrusive in the healthcare process. Relying e.g. on an audio based guiding system might be disturbing in the waiting room. Adherence aids also risk causing additional “observer bias” during BPSM, potentially leading to adverse effects not unlike the white coat effect as the increased computer presence may induce additional anxiety and increase the BP accordingly [6]. While this has not been adequately investigated so far, such challenges should be investigated further before designing new intervention methods based on novel adherence aids. In this perspective, the adherence verifier may appear as the most straightforward solution, not running the risk of introducing additional bias while at the same time providing healthcare staff with an evaluation of the data quality of the measurements.

6.5 Additional Recommendations

The ValidAid adherence model focuses on three context parameters: “talking”, “legs crossed”, and “rest time” besides the BP measurements themselves. A further context parameter is the “time of day” parameter. This parameter is provided by the BP device used when it reports the measured BP data to the ValidAid system and is considered trivial to obtain. However, previous studies have underlined the relevance of the time-of-measurement due to the circadian variability of the BP during the day meaning that blood pressure levels change during the day, typically being

<table>
<thead>
<tr>
<th>Table 3</th>
<th>BP and context data as measured by ValidAid. Values are presented as average and standard deviation or stated otherwise.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measured Parameter</td>
<td>Measured Value</td>
</tr>
<tr>
<td>Systolic BP</td>
<td>130 ± 17 mmHg</td>
</tr>
<tr>
<td>Diastolic BP</td>
<td>84 ± 11 mmHg</td>
</tr>
<tr>
<td>Pulse/heart rate</td>
<td>84 ± 11 bpm</td>
</tr>
<tr>
<td>Time seated</td>
<td>60 ± 19 s</td>
</tr>
<tr>
<td>Time seated, minimum</td>
<td>30 s</td>
</tr>
<tr>
<td>Time seated, maximum</td>
<td>118 s</td>
</tr>
<tr>
<td>Talk detected, percentage</td>
<td>0.4 ± 1.6%</td>
</tr>
<tr>
<td>Legs crossed, percentage</td>
<td>0%</td>
</tr>
</tbody>
</table>
lowest in the morning before waking up and highest in the evening [40]. The three other context parameters are implemented as adherence verifiers based on context-aware sensors, and for these three the adherence model also provides a calculated adherence level (adhered/not adhered) as well as an overall adherence level for the entire measurement.

However, the ValidAid system can only model a subset of the recommendations relying on a coarse grained resolution only. If a patient fails to adhere to any of the remaining recommendations, which cannot be detected by the system, the resulting measurement may still not be valid despite ValidAid having classified it as such based on its limited model of reality. To be able to model all relevant aspects of adherence is not likely to be achievable. Thus, it is not possible to guarantee the validity of an unsupervised measurement. Although, by using adherence verifiers in the clinic, we would be able to reduce the number of potential sources of bias and perhaps limit the impact on the resulting measurement. Also, adherence verifiers facilitate the identification of patients that should be targeted for staff supervised measurements rather than BPSM. Therefore, introducing more adherence aids might not be the best solution to pursue as actively guiding the patient to avoid the bias we are able to detect could result in a false sense of confidence in the data quality due to aspects we cannot detect. Rather, we should consider only context tagging the BP data, marking the measurement as unfit for diagnostic use, and informing the healthcare staff of the invalid measurement.

6.6 Related Work

Several studies have investigated patients’ ability to correctly self-report home measurements [41–43]. These include three related studies in which a total of 98 participants were equipped with BP devices for four days of home BPSM. The participants were not told that the devices had memory for storing the self-measured BP values. After a period of self-measuring, paper records and BP values from device memory were compared. In total, more than half the patients had either omitted or fabricated readings indicating unacceptable levels of reporting bias. In a later study, Santamore et al. investigated 161 patients’ ability to accurately report self-measured BP data using a web solution interface and a home BP device [44]. The study compared the self-reported data from the web with the data stored in the device memory. The authors found that around 16% of the reported data deviated from the actual data stored in the memory. Results from the four studies thus indicate a challenge with BPSM when used in the unsupervised setting with regard to participants’ ability to accurately report self-measured data. However, none of the four studies investigated the participants’ adherence to the recommendations.

In a recent study, our group investigated current clinical practice and patient understanding of the guidelines for BPSM [6]. Results from the field studies and interviews at two general practitioners’ clinics and at two hospital departments combined with a questionnaire study including 201 members of the Danish Heart Association indicated low patient-awareness of the recommendations for self-measurement of BP, and of the importance of this in order to obtain valid and reliable measurements. The interviewed healthcare professionals acknowledged the identified challenges and the importance of following the recommendations but reported being unable to validate self-measured data with current state-of-the-art technology [6]. In a follow-up study, through anonymous and unobtrusive observations of 81 patients self-measuring in the waiting room, we found further indications that current methods and equipment employed at the obstetrics outpatient clinic were not sufficiently robust to allow for reliable measurements [61]. The follow-up study found that none of the 81 participants adhered to all six investigated recommendations. Around a quarter (26%) adhered to five out of six of the recommendations. Around a third followed four recommendations (37%), a fifth followed three (21%), 12% followed two, and 3% followed only one recommendation. These numbers are comparable to the results of the present study, as presented in Table 1, with the exception of two notable deviations: First, none of the 41 patients in the current study had their legs crossed, as compared to 65% in the referenced follow-up study [61]. Second, none of the 41 patients in the current study observed the full 5 minutes rest time, as compared to 17% in the referenced follow-up study [61]. These differences could be explained by the presence of the ValidAid equipment and a test facilitator in the present study, which could have affected patient behavior during the experiment. Thus, as the referenced follow-up study [61] was purely observational and unobtrusive, and the patients were using the usual waiting room blood pressure equipment and methods, these findings are likely to be less biased than the present study’s findings.

Few studies have investigated the potential for using context-aware sensors for measuring the adherence level and guiding patients. Copetti et al. used smart home sensor technologies for sensing user activities during ambulatory BP measurement (ABPM) to build a context-aware telemonitoring system [45]. D’Angelo et al. [46] present a system for motion-aware ABPM. They focus on measurement errors occurring due to movement artifacts, wrong posture during the measurement, or absence of proper rest time prior to the measurement.

Several commercial telemonitoring platforms feature patient guidance during measurements. This includes the Intel Health Guide which has been used in several telemedicine studies [47, 48]. The Intel Health Guide also features BPSM support from Continua Certified BP devices [49]. This feature allows the patient to take the recommended three successive measurements and automatically calculates the average while the patient is being instructed via audio and video. The Intel Health Guide has the capability of enforcing a one minute wait between the three measurements as recommended in most guidelines. Using this system, the patient will have an adherence aid helping her comply with the rest time. However, the remaining recommendations are not supported and rest time cannot be verified retrospectively. The system is not able to detect whether the patient has actually rested adequately or was correctly seated...
during measurements. Related commercial systems include the Tunstall mymedic [50] and the Bosch Health Buddy [51].

Work in related fields includes medication adherence, rehabilitation adherence, and measurement adherence using other medical device types in the unsupervised setting. In a review of 139 studies on medical adherence, Osterberg and Blaschke report adherence rates as low as 43% among patients receiving treatment for chronic conditions including hypertension [52]. Several projects have suggested solutions for improving medication adherence using adherence or compliance aids [53–56]. Alternative approaches include persuasive technologies, relying on technology to further engage the users through adding motivating incentives to improve adherence [53, 57]. Strategies for measuring and improving rehabilitation adherence include using technology for aiding the patients through their exercises, e.g. with regard to Vestibular and Pulmonary rehabilitation [58–60]. Measurement adherence strategies have also been investigated for other medical device types such as oximeters frequently used in self-care programs for COPD patients [31, 60].

6.7 Future Work

Although our results provide a good indication of the challenges facing BPSM in the waiting room and the potential of meeting these challenges with the new reliable BPSM method based on ValidAid, it would be beneficial to obtain more data on actual use in the current clinical practice, e.g. by creating a permanent and ubiquitous installation of the ValidAid system in the outpatient clinic for a longer period acquiring data from a larger patient cohort. Also, it could be relevant to add one or more adherence aids that could guide the user through the measurement process. The effect of introducing such adherence aids should be investigated as a randomized study with three patient groups: one with the BP device used in current practice, one group using a pure adherence verifier solution, and one group using an adherence aid solution for guidance during the measurement process. Also, it might be feasible to use patients as their own controls by first letting them self-measure only using an adherence verifier for validation and then self-measure guided by an adherence aid in order to investigate whether the aid would contribute to a higher quality of measurements.

Furthermore, we find it relevant to investigate additional BPSM recommendations and patient adherence to these, including the feasibility of detecting adherence to arm supported, back supported, and correct cuff size. Also, other contextual factors are known to influence the BP including ambient temperature and noise levels as well as patient activities such as having recently smoked or eaten prior to the measurement [1–3]. These factors are likewise relevant to investigate. While some of these parameters might be easy to measure using state-of-the-art sensor technologies, e.g. ambient temperature and noise, others might require the user to self-report.

Finally, it would be relevant to investigate the potential for basing ValidAid on existing infrastructures capable of classifying activities-of-daily-living [62, 63] based on data collected from embedded smart home sensors, e.g. in a care facility such as a nursing home. If it is possible to infer when the patient is getting out of bed in the morning and to which extent the patient has moved around in the house prior to a measurement, e.g. by using standard movement sensors, it may be possible to provide a much more detailed measure of the relevant context parameters including rest time.

7. Conclusion

In accordance with previous work in the area, we found clear indications that current methods and technologies for BPSM utilized in the waiting room for the pregnant diabetics are facing several challenges regarding the validity of unsupervised BP measurements. Existing BP devices and telemonitoring systems are not capable of addressing these challenges adequately. Instead, we should rely on creating a new class of context-aware clinical support systems which are able to identify non-adherent behavior and alert the staff or guide the patients to be more compliant to the recommendations through the use of targeted adherence engineering following the ASEF framework.

We validated a new method for ensuring reliable BPSM in the clinical setting by observing 41 pregnant diabetic patients using the ValidAid system and comparing manual observations with ValidAid’s classification results. The study focused on measuring context parameters of three selected recommendations that had previously proven feasible to measure in the laboratory using ValidAid. The ValidAid system was able to accurately register and model these three selected recommendations in the clinical setting of the obstetrics department.

The challenges identified in the waiting room may arguably also be found in other unsupervised environments such as patients self-measuring in the home setting. The ValidAid system should be applicable to other self-measurement environments including the home setting and other outpatient clinics, care facilities, and hospital departments as it is based on telemedicine technology and thus well-suited for remote monitoring and diagnosis. Also, ValidAid could be used with other patient groups using the BPSM method such as renal disease, primary hypertension, and chronic obstructive pulmonary disease patients. Thus, we suggest investigating the feasibility of using ValidAid in other settings and patients groups as well.

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