Introducing the Adherence Strategy Engineering Framework (ASEF)

Support for Developing Technology-based Self-care Solutions

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Summary

Background: Patients performing self-care in the unsupervised setting do not always adhere to the instructions they were initially provided with. As a consequence, a patient’s ability to successfully comply with the treatment plan cannot be verified by the treating healthcare professional, possibly resulting in reduced data quality and suboptimal treatment.

Objectives: The aim of this paper is to introduce the Adherence Strategy Engineering Framework (ASEF) as a method for developing novel technology-based adherence strategies to assess and improve patient adherence levels in the unsupervised setting.

Methods: Key concepts related to self-care and adherence were defined, discussed, and implemented as part of the ASEF framework.

ASEF was applied to seven self-care case studies, and the perceived usefulness and feasibility of ASEF was evaluated in a questionnaire study by the case study participants. Finally, we reviewed the individual case studies usage of ASEF.

Results: A range of central self-care concepts were defined and the ASEF methodological framework was introduced. ASEF was successfully used in seven case studies with a total of 25 participants. Of these, 16 provided answers in the questionnaire study reporting ASEF as useful and feasible. Case study reviews illustrated the potential of using context-aware technologies to support self-care in the unsupervised setting as well as ASEF’s ability to support this.

Conclusion: Challenges associated with moving healthcare to the unsupervised setting can be overcome by applying novel context-aware technology using the ASEF method. This could lead to better treatment outcomes and reduce healthcare expenditures.

1. Introduction

Several studies have investigated the potential of moving patient care out of the hospitals and clinics and into the home setting [1–5]. The resulting increase in patient autonomy and self-care present several challenges with regard to ensuring a high quality of treatment [6–8].

In the clinical setting, a nurse or doctor is trained to measure a patient’s blood pressure (BP) in the correct manner. A nurse will provide the prescribed dosage of medicine at the prescribed time. A physio-

therapist will observe the required exercises and report on patient progress. When a patient is sent home, however, it is left to the patient to follow instructions and comply with the prescribed treatment plan and procedures. Thus, with patients in the unsupervised setting, either at home or while self-measuring at the clinic, the healthcare personnel no longer have the ability to verify that the measurement is performed in a reliable and valid manner, following the instructions, or even performed on the right person [8].

Several studies report that patients performing self-care, including self-measurements [8–12], self-medication [13, 14], and self-rehabilitation [15, 16] do not necessarily follow the instructions they were initially given at interviews or training sessions [8–18]. As a consequence, a patient’s ability to successfully comply with the necessary treatment plan cannot be verified by the healthcare professional, and the quality of the data cannot be determined. Manual intervention by healthcare professionals is expensive and may potentially be experienced as an invasion of privacy. We argue that there is a need to better quantify and assess the quality of healthcare data obtained in the unsupervised setting using alternative means such as technology-based aids.

The aim of this paper is to introduce the Adherence Strategy Engineering Framework (ASEF) for developing novel technology-based adherence strategies to assess and improve patient adherence in the unsupervised setting. This could lead to higher data quality of healthcare measurements.
2. Methods

Challenges to patient adherence during self-care in the unsupervised setting were initially identified from the literature. Following this, in order to establish a common terminology in the self-care domain, we identified and defined several key concepts related to self-care, adherence, and reliability in the unsupervised setting. These concepts were then implemented as part of the ASEF framework, and a practical guide to ASEF usage was introduced for researchers and developers of adherence-related projects.

We evaluated ASEF by asking 23 students and their two research supervisors from the Department of Engineering, Aarhus University to apply the framework as part of seven self-care research projects during a one year period. The 25 participants were invited to use ASEF in their projects, and provide feedback on ASEF's perceived usefulness and feasibility in a questionnaire study.

Also, using open-ended interviews we reviewed the seven projects usage of ASEF during the analysis, design, and evaluation phases in order to understand how ASEF was being used during the process, both on a conceptual, methodological, and practical level.

The seven projects included case studies on 1) measuring movement and noise levels during home blood pressure self-measurement, 2) detecting correct leg position during blood pressure self-measurement, 3) detecting patient talking during ambulatory blood pressure measurements, 4) supporting medication and measurement adherence for diabetic nephropathy patients, 5) supporting measurement and rehabilitation adherence of chronic obstructive pulmonary disease (COPD) patients, 6) medication adherence for anticoagulation self-treatment patients, and 7) adherence during weight monitoring of heart and kidney disease patients.

3. Key Concepts

3.1 Self-care

Self-Care is defined by the US National Library of Health as the “Performance of activities or tasks traditionally performed by professional health care providers. The concept includes care of oneself or one’s family and friends [19].

Self-care has been used to describe patients performing self-measurements, self-medication, and self-rehabilitation [20–22].

3.2 Reliable Measurements

Merriam-Webster’s Medical Dictionary gives the following definition of reliable: “giving the same result on successive trials” [23]. For instance, a reliable BP measurement device should persistently measure the same BP readings under the same circumstances in order to be considered reliable. However, the measurement itself is not only dependent on the biomedical device used but also on the patient’s ability to handle the device properly and adhering to the guidelines.

Improving user-level reliability is important to consider when designing self-care systems as the sensor device and platform may be working in a reliable manner, but if the patient is not following the guidelines, the resulting data could be severely biased as a consequence [17].

3.3 Adherence

A patient’s ability to follow prescribed guidelines and treatment plans is covered by the clinical concept of “adherence”. The level of adherence relates to the degree to which a patient correctly follows given clinical advice. Adherence is thus tightly coupled to user-level reliability and reliable measurements.

Adherence is defined as “the process in which a person follows rules, guidelines, or standards, especially as a patient follows a prescription and recommendations for a regimen of care” [24] or as “the extent to which the patient continues the agreed-upon mode of treatment under limited supervision when faced with conflicting demands, as distinguished from compliance or maintenance” [25]. A range of alternative definitions of adherence exists from various sources varying in definition specificity and wording [24–27].

3.4 Adherence Strategies, Measures, and Interventions

Interventions, measures, and means to increase adherence fall under the category of disease management relying on the focused application of resources in order to improve care and outcomes [28, 29]. However, no coherent conceptual definition is available that clearly specifies and delimits the meaning of these concepts over time and space.

We define an adherence strategy as the means, measures, and interventions used to facilitate patient adherence during a healthcare process as part of the overall disease management. A healthcare process could include a series of individual actions for example taking medication, performing rehabilitation training, and measuring healthcare data. In the home setting, adherence strategies have traditionally been based on manual or low-technology based measures such as patient training, paper instruction leaflets, etc. However, more advanced adherence strategies exist such as persuasive technologies, automatic reminder systems, and artificial intelligence systems [2, 30].

To a large extent, current adherence strategies, e.g. in the home BP monitoring domain, rely on patient training and on the ability to follow the paper instructions handed out in the clinic or at the pharmacy. In fact, patient education through patient-nurse training sessions, mailings, and phone calls is the most widely used adherence strategy [26, 31]. Such strategies incorporate various providers of the education including physicians, pharmacists, nurses, and trained educators [26].

4. The ASEF Framework

Designing adherence strategies requires knowledge of the various factors influencing patient adherence. To define these, we take inspiration from the PACT framework [32], which addresses the challenges of designing interactive systems that are situated in specialized settings. The main elements of PACT are People, Activities, Context, and Technology which are all necessary elements to understand and address when
designing interactive systems. We adopt the concepts of Stakeholders (People), Technology, and Context which is further divided into Domain and Context as two separate elements. We differentiate between these two concepts in order to distinguish between the overall background-context of the disease and the disease management as the Domain and the context in which each measurement or other intervention occurs as the Context.

The ASEF framework is divided into the main elements of Adherence, Stakeholders, Domain, Context, and Technology which all have significant challenges that need to be addressed when designing new adherence strategies both separately as well as in a mutual interaction perspective. The adherence element ties the other four elements together as the unifying concept (Figure 1). It is within the boundaries of these five elements that we introduce and define the various concepts of the framework and tie them all together as part of the ASEF framework. Each element can also be considered a design perspective that can be useful during the analysis and design phases.

Several key concepts are important to define in order to appreciate the main elements of the ASEF framework. We will introduce these concepts within the scope of the main five elements of the ASEF framework starting with Domain in the following sections.

4.1 Domain

Domain represents all facts about the disease under investigation, the healthcare process, and specific state-of-the-art interventions including devices and methods used. For instance, in order to investigate patients suffering from hypertension and their ability to reliably self-monitor at home, we need to understand the disease under consideration. This includes the background of the disease, the interventions used, when, how, and under which conditions the patient is expected to self-measure, and when and how data is reported to the healthcare professionals. We will also denote this as the disease domain and the disease management domain. Disease management represents the entire workflow associated with the patient’s disease.

Understanding the domain and being able to transform this into a functional domain model that can be used to design technological support systems require insight into the clinical medical domain, the technical domain, and the domain of the patient and his preferences including the home of the patient and the conditions under which the interventions occur. We will also denote this as the context-of-use and the clinical context.

4.2 Stakeholders

When investigating novel adherence strategies it is important to identify all stakeholders in the process and assess their individual roles and the healthcare processes they are involved in.

The main stakeholders in a healthcare process will most often include patients and their treating healthcare professionals. Other stakeholders include relatives, friends, neighbors, and even visitors in the use-setting. Stakeholders could also be medical researchers who are interested in obtaining high quality data.

4.3 Context

Context is defined as “the circumstances in which an event occurs; a setting” [25]. This includes location (home, clinic, work), environmental factors (temperature, noise, light), and patient-related factors (rested, stressed, excited, exercising, working, talking, watching television etc.). All actions occur in a context including healthcare processes.

The context in which a healthcare-intervention is expected to occur is important for the choice of adherence strategy and the type of technology used. In the clinical setting for instance, patients are guided or supervised by healthcare-professionals in order to ensure the correct process is being followed, thus ensuring the quality of the resulting data. In the home setting or at an outpatient-clinic with a high level of patient-autonomy, the healthcare-professional no longer supervises the process and cannot guarantee a successful outcome of the process with regard to contextual factors that might affect measurements, or the patient’s ability to take medication or perform rehabilitation exercises. Simply guiding the patients through paper, audio, or video guides may not be enough depending on the domain and the stakeholders involved. The context can be a distraction to the patient or even affect the measurement directly as is the case with BP readings. Watching television affects your BP levels, but it might also make you forget taking your medication or cause transfer-bias when reporting measurements to paper [8].
We propose defining the potential bias that context dependent factors can introduce into the healthcare-process as contextual-bias. In the clinical setting, contextual-bias could include the patient having rushed to the doctor resulting in a faulty BP reading due to the physical strain and its effect on the heart rate. Also, the psychological stress induced in some patients when attending the clinic could also raise the BP levels significantly above the patient's real BP. This is known as the white coat effect [33, 34]. White coat effect is also an example of contextual-bias as it only occurs in a specific context, namely the clinic.

In the home setting, a range of contextual factors can have an impact on the intended healthcare-process. These could include distractions by activities-of-daily-living, television, radio, phone-calls, physical strenuous activities, children, friends, and spouses. Such sources of contextual-bias must be analyzed with regard to consequences on the measurement itself. If the bias can have a significant impact on the process, it should be addressed and handled accordingly. A high level of contextual-bias may require more advanced adherence strategies to overcome the challenges, and the tagging of healthcare data with the level of contextual-bias during the process may also be deemed necessary by the involved stakeholders in order to ensure reliable and high quality data for decision support.

4.4 Adherence

Adherence is a central ASEF concept and the most important design perspective to consider when developing adherence strategies for supporting self-care solutions. We differentiate between several conceptual sub-topics of adherence that are useful for creating a common ASEF terminology, as well as for operationalizing ASEF.

4.5 Adherence Level

We define the adherence level to be a measure of the extent to which a patient adheres to the prescribed treatment plan. Adherence levels can be specified as a multi-vector value, a graded value, or a more basic value. In many cases, it might not be feasible to quantify the exact level of adherence but simply state whether the guidelines were followed or not. This is determined by cost-benefit induced constraints such as price of sensors and device capabilities vs. value of the increased knowledge. For instance, within one domain, it may be beneficial for the healthcare professional to see whether medication was taken on a daily basis as a percentage of adherence levels. In other cases, the ability to take medication or measurements within a two-hour timespan may be important or it could be valuable to know how many minutes a patient had rested before measuring BP.

We do not necessarily need to know all details of the patient behavior during a healthcare process. However, if we are to detect discrepancies to the recommended behavior, we need tools to sense, register, and report this for later use. We can never model and describe all details of a healthcare process but must rely on a more coarse-grained model of reality. Such a model should be able to hold sufficient knowledge of the problem under consideration or at least provide a model based on what we are able to feasibly detect.

4.6 Adherence Model

The adherence model (AM) is used to model and describe the healthcare process that patients need to follow in order to adhere to the associated guidelines. It reduces the healthcare process into a series of elements that are measurable, quantifiable, and feasible to transform into a data-model. For instance, an adherence strategy designed to support coronary heart disease patients who need to take an aspirin every morning could operate within an AM describing successful adherence as one where medication is taken within 7–10 a.m. Failure to take the medication within this timespan may be modeled as a partial failure while failure to take the medication before 12 a.m. could be modeled as a full failure depending on the importance of the timing of the medication in this disease domain. As discussed earlier, the AM may also require a longitudinal element providing information on the patient’s persistence to treatment over time.

4.7 Full vs. Reduced Adherence Model

The full adherence model (FAM) seeks to model all relevant elements of the healthcare intervention in question. The FAM can be considered a full or ideal reference model for achieving optimal reliability and validity of data in the unsupervised setting provided that all relevant information can be extracted from the healthcare process. However, a FAM is not likely to be implemented in real life as the amount of sensors and data required could potentially be very large and costly.

Instead, the reduced adherence model (RAM) is used to denote what can be observed in a meaningful way with the technologies currently available. For instance, when using a paper-based leaflet-instruction adherence strategy, it is only possible to verify a fraction of the FAM, e.g. that the patient has accepted to initiate the treatment plan, but not whether the patient has adhered to all guidelines. The true adherence levels cannot be determined with such choice of technology. Domain stakeholders must decide on the level of fidelity needed to ensure reliable data in a given healthcare process.

With a state-of-the-art home BP device for example, it can be registered that the patient has measured his BP at a given time and date. However, it cannot be verified whether the patient has rested sufficiently or followed the other recommendations specified by the expert organizations within this domain [35, 36]. A BP device that can store the readings electronically can be used with a RAM that takes this into account while another device that cannot store the data must rely on the patient not to introduce transfer-bias while transferring the data to paper [8]. Thus, it is the technology used that limits the RAM.

4.8 Technology

Traditional technology such as paper-based instruction-leaflets is cheap to manufacture, does not run out of power, is easy to store, and easy to use. However, paper guides do not ensure that users actually read them or follow the instructions while
performing the measurements. They are purely passive adherence aids.

Technology-support can be viewed as a spectrum ranging from traditional low-cost technologies to intelligent platforms and environments. Traditional technologies include paper and phone-call follow-ups, which can be used and understood by all stakeholders involved but do not offer much verification support. Advanced tele-monitoring gateways, such as the Intel Health Guide PSH6000 (IHG) [37] and the Tunstall mymedic TeleHealth Monitor (TTM) [38], features automatic store-and-forward of data, partial verification support, automated reminders, and communication capabilities. These systems have been investigated in several research projects [3, 7, 30].

At the far end of the spectrum, we find intelligent environments such as context-aware furniture and smart homes that sense and record all activities-of-daily-living and provide easy access to data, both in real time and as retrospective data [39].

Traditional technologies are cheap and easy to use while more advanced technologies incur a considerable cost-increase and contain several points-of-failure. When designing new adherence strategies, it is important to consider which end of the technology spectrum to target. Hospitals, out-patient clinics, and nursing homes may be suitable for deploying advanced solutions requiring major infrastructure support. However, for solutions targeting a general practitioner and patients living in traditional housing types, it might not be feasible to use smart home technology. Technology-levels should be determined by the stakeholders, the context-of-use, clinical context, and disease-domain under consideration.

Rather than just passively instructing the user through paper, audio, and video guides, it could be useful to consider more intelligent and adaptive technology-support in the healthcare devices and gateways deployed in the home setting. Context-aware technologies [30, 40, 41] such as movement and noise sensors could be useful for better detecting the relevant user context during the measurement process. These data could be registered with the measurements being sampled for later re-view by relevant stakeholders. We define this concept as contextual-tagging of healthcare data.

Contextual-tagging of healthcare data includes traditionally used contextual-properties such as time and date, but also user-identification (the patient currently using the device), geospatial position (where was the measurement taken), environment-factors (noise-level, temperature, humidity), and use-context (wake-up time, time rested before taking the measurement, movement-level, stance, posture, food intake, toilet visit).

4.9 Adherence Verifiers

We introduce the concept of adherence verifiers as entities that can sense the actions of patients and verify them against a RAM. A verifier would typically be a sensor, such as a sound-level sensor, that can register whether the patient is in quiet surroundings. Another type of sensor could be attached to a medication-container registering when the patient takes the medication [42].

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.

4.10 Adherence Aids

We define adherence aids as tools and technologies that will help the patient to better adhere to a prescribed treatment plan by providing passive or active guidance.

Passive adherence aids can be paper-instructions, labels, or video guides while active adherence aids could present context-relevant feedback to the patient. An adherence aid may use the same sensors as an adherence verifier uses for the verification of data in order to better guide the patient through the healthcare process. For example, the previously mentioned adherence verifier component for registering whether the patient is in quiet surroundings could also be used to guide the user to remain silent during the measurement process by providing a feedback mechanism.

Active adherence aids are more useful when the patient is cognitively weak, the healthcare process is complicated and error-prone, or training resources are limited. Active adherence aids can be further divided into cognitive aids, persuasive aids, and self-reporting aids. Cognitive aids assist users by warning of non-adherent behavior, e.g. the user moving excessively during a measurement, or reminding the user if medication was not taken within an hour. Persuasive aids help motivate the user through incentives that might motivate for higher compliance and prolonged persistence, e.g. through competitions, games, or other incentives known from the field of persuasive technologies [30]. Self-reporting aids support the patient to report any relevant events that could have an impact on the healthcare intervention it is part of. This could include the patient reporting having had a stressful morning, having not rested sufficiently, or having smoked a cigarette prior to the measurement. Self-reporting aids have the potential to empower the patients to provide more accurate data, including on non-adherent behavior that is not feasible to model with cognitive aids.

Active adherence aids could be considered the “gold standard”, as compared with adherence verifiers, with regard to increasing patient autonomy and empowerment. However, they are also potentially more complex and expensive to develop, requiring the inclusion of relevant user interface technology in the adherence strategy implementation. Also, adherence aids may themselves cause bias to the measurements if they are not carefully designed and evaluated before being applied in the clinic.

5. Using ASEF

For applying ASEF in practice we recommend the following guide to be used by researchers and system developers working with self-care solutions. We suggest a main flow through three phases; analysis, design, and evaluation, divided into 10 steps. Each step features relevant guidelines that can be adapted to the individual project.
5.1 Analysis Phase

For the analysis phase, we suggest the following steps:

1) Investigate the problem domain under consideration, the disease and its consequences, state-of-the-art healthcare interventions in current use including existing healthcare processes, adherence strategies, and technologies

2) Identify the different stakeholders and their roles in the healthcare process and how they view and engage in the healthcare process.

3) Identify guidelines and recommendations used by healthcare professionals as part of the currently used state-of-the-art healthcare process.

4) Identify possible sources of bias that are currently not quantifiable by state-of-the-art strategies and technologies. Analyze potential adherence strategies in cooperation with the stakeholders, and formulate a FAM.

5) Select relevant sensor technology to detect and quantify adherence levels and design an adherence strategy with a RAM utilizing relevant adherence verifiers and aids.

6) Select a relevant reporting format to present adherence levels to patients, healthcare professionals, and other stakeholders.

7) Develop evaluation prototypes for investigating the suggested adherence strategy.

5.2 Design Phase

For the design phase, we suggest the following steps:

5) Select relevant sensor technology to detect and quantify adherence levels and design an adherence strategy with a RAM utilizing relevant adherence verifiers and aids.

6) Select a relevant reporting format to present adherence levels to patients, healthcare professionals, and other stakeholders.

7) Develop evaluation prototypes for investigating the suggested adherence strategy.

5.3 Evaluation Phase

For the evaluation phase, we suggest the following steps:

8) Qualitatively evaluate the suggested adherence strategy through evaluation prototypes in the laboratory.

9) Qualitatively evaluate the suggested adherence strategy through evaluation prototypes in situ.

10) Consider clinical evaluation in cooperation with clinical community if feasible, or refine the adherence strategy and RAM in a new iteration.

The phases, steps, and guidelines should not be considered a rigid waterfall sequence, but rather a practical toolkit and a set of guidelines for organizing work. The three phases may be repeated in an iterative process e.g. as part of a participatory design process [43].

6. Detailed Case Study on ASEF Usage

We have evaluated the feasibility of the ASEF framework in seven pervasive healthcare projects. We will present the findings from these in section 7. Here we present ASEF applied to a project on home blood pressure self-measurement (HBPSM) as a detailed example of ASEF usage.

HBPSM is used to diagnose patients suspected of hypertension as well as for long-term monitoring of a number of chronic patient groups including diabetics, pregnant women with complications, and kidney disease patients [5, 17, 18].

Following the recommended ASEF methodology, the project takes its outset in the analysis phase step 1: investigating the problem domain under consideration, including background on hypertension as a disease and its consequences. In order to clarify these aspects, a range of field studies were undertaken at hospitals, general practitioners’ clinics, and in the patients’ home. Literature and product search revealed a range of state-of-the-art healthcare interventions in current use including automatic home blood pressure devices and 24-hour ambulatory devices which are used more rarely in the clinics but more often in the specialized hospital departments. The healthcare process was mapped out, and adherence strategies identified as being dependent on initial healthcare professional training and paper guides.

In step 2 of the analysis phase, the different stakeholders and their roles in the healthcare process were identified and described. This included the healthcare professionals (a physician or a nurse) and the patient interacting only during the initial training session, followed by a three day measurement period, data being collected on a preformatted paper sheet which also acted as a passive adherence aid with written instructions.

In step 3, the guidelines and recommendations used by healthcare professionals were identified. From the literature, it was established that HBPSM is considered a valid method for determining the blood pressure of the identified patient groups provided that the best-practice recommendations for obtaining the measurements are followed [5, 17, 18]. These recommendations are defined by a range of national and international clinical associations of clinical experts [35, 36]. The recommendations consist of several elements including that the patient should have rested for five minutes before measurement, be seated correctly during measurement, reside in a quiet environment, and not talk or move during measurement.

Following analysis step 4, the project identified possible sources of bias that are currently not quantifiable by state-of-the-art processes and technologies employed at the clinics today including reporting bias (errors while transferring data) and contextual bias which means that neither of the contextual factors could be verified. This implies that it is not possible to detect whether a user is rested sufficiently before the measurement or whether the user is talking during measurement with currently available medical devices. Such sources of bias could affect the measured blood pressure to an extent of causing misdiagnosis possibly resulting in under or over medication of the patient [44]. Following this, the project modeled the healthcare process into a FAM as a detailed description of the HBPSM healthcare process consisting of the three stages: the training phase, the three days of self-measurement phase, and the follow-up consultation phase, the latter included any follow-up self-measurement repetitions after 3, 6, or 12 months. Also, the FAM contained detailed descriptions of all sources of bias that may affect the measurement process, including those who can be meaningfully addressed using technology and those who are not feasible to
counter with present day context-aware technology. Several relevant adherence level markers were identified, including time-to-rest, noise level, back-supported during measurement, which were used to map out a full adherence model for the treatment plan of hypertensive patients. Also, as part of the analysis, several candidates for adherence strategies were identified that might be used for better describing and possibly improving patient adherence in the healthcare process under analysis. This included adherence verifiers for each of the guidelines, as well as adherence aids for providing context-aware instructions to the user. However, the FAM in itself does not identify any specific technical solution to counter the identified sources of bias, which is the role of the RAM. The FAM is merely a textual description of the entire process and the possible solutions.

In the design phase, step 5, the project modeled selected elements from the healthcare process into a RAM and formulated a specific adherence strategy. The RAM addressed those potential sources of bias such as unverifiable context and reporting bias from the FAM that appeared feasible to address using state-of-the-art technology. Specifically it was suggested to use a sensing chair for detecting whether the user is sufficiently rested and correctly seated before and during measurements. Both of which can bias a measurement critically if not adhered to. This implied implementing two adherence verifiers as sketched out in the FAM. Using this, a RAM was modeled that would be able to verify the current adherence strategy using the two adherence verifiers and whether the user had been properly rested prior to measurement, and correctly seated during HBPSM.

In step 6, a relevant reporting format to indicate the adherence level of the verifier was discussed with a focus group consisting of a general practitioner, three hypertensive patients, an industrial designer, and three engineers. Displaying the blood pressure readings with a simple red, yellow, green indicator appeared to be a feasible and usable solution for both practitioners and patients [45]. The levels of non-adherent behavior (red), and adherent behavior (green) was defined, and yellow was used for borderline measurements. It was discussed whether these levels should be configurable by the treating healthcare professionals. To exemplify, the American Heart Association guidelines calls for two minutes interval between BP measurements. However, at one visited hospital department where they utilize patients self-monitoring in the clinic, they rely on 15 seconds intervals only, in order to speed up the self-measurement process during “patient rush hours”.

In step 7, The RAM was turned into an XML based decision tree model defining the rules for adherence vs. non-adherence. A research prototype was implemented to use the XML based RAM to evaluate the data provided programmatically by the context sensors in the sensing chair. After a measurement is received from the wireless BP device, the context data from the adherence verifiers is evaluated by the research prototype application against the rules specified in the XML based RAM, which then provides an indication of whether the user has adhered to the RAM or not. It is important to note, that ASEF does not require the RAM to be formulated in a formal language such as XML. It could alternatively be implemented as an algorithm in the application’s source code.

As part of the evaluation phase, steps 8 and 9, an evaluation prototype was developed featuring a standard home blood pressure device used in the clinic with wireless capabilities combined with a sensor chair used as an adherence verifier and for establishing baseline data. Data was collected on a test computer and stored at a dedicated web server with a database for later review. Here, all of the patients’ blood pressure readings were presented along with the adherence level indicating whether the user had been sufficiently rested before measurement or not. Red indicated an insufficient rest-period, yellow a suboptimal rest-period, and green indicated full adherence. The prototype was evaluated in the laboratory setting in step 10 indicating 89% reliability in detecting user behavior [46]. In situ testing with actual hypertensive patients, step 11, was carried out with four test subjects in their home setting. Following this, a large scale clinical trial was undertaken at the department of Renal Medicine at Aarhus University Hospital, in their patient blood pressure self-measurement room. More than 642 individual blood pressure measurements were successfully captured on patients over a 35-day period, including the relevant context data as specified in the case study RAM. As an important point, we note that clinical evaluation should not be undertaken before the qualitative evaluation trials of steps 10 and 11 have proven successful. This is due to the large administrative tasks and certification costs related with preparing a product for clinical evaluation due to national and international regulation within the field of medical devices and systems.

The case study demonstrates that the framework is able to address relevant aspects of adherence strategy engineering. Being able to successfully capture contextual healthcare data and determine patient adherence levels as defined by the RAM indicate that the system could be used to investigate and evaluate various adherence strategies.

7. Results

We evaluated the usefulness and feasibility of the ASEF framework in seven projects with a focus on developing novel adherence strategies.

Seventeen out of 25 project participants responded to our evaluation questionnaire. Findings indicated that all project participants considered ASEF useful and feasible for supporting the development process of their respective case studies (100%). Also, most respondents considered ASEF concepts helpful in order to better understand the healthcare project’s domain (94%). ASEF was used primarily in the analysis (94%) and design phases (82%), and less in the evaluation phase (35%).

By reviewing the outcome and intermediaries of the individual projects, in the shape of interviews, draft papers, as well as proof-of-concept prototypes, we found that all projects successfully managed to identify sources of contextual bias in their respective disease domains that had not previously been reported in the literature.
Also, all projects managed to design relevant reduced adherence models, and built functional adherence verifier or aid prototypes using relevant sensor technology for evaluation purposes.

We also found that the ASEF terminology was being used progressively throughout analysis, design, and evaluation, and also in conjunction with other methods, including field studies, qualitative interviews, usability evaluations (think aloud, heuristic evaluation), pilot testing, and more. ASEF was primarily followed on an ad-hoc basis, rather than purely sequentially.

Case study participants did not initially fully grasp the differences between full and reduced adherence model, just as the differentiation between an adherence aid and verifier was not always clear to all participants until being specifically corrected by the supervisors.

Also, it was not possible to find clearly stated medical guidelines and recommendations on unsupervised self-care in all investigated disease domains, while others found conflicting sources.

### 7.1 Specific Findings from the Case Studies

Case study 1 investigated the challenges related to the adherence of patients performing blood pressure self-measurement in the home setting. Using ASEF they undertook field studies at a general practitioner and at the home of hypertensive patients. They subsequently identified the recommendations made by the American Heart Association (AHA) for performing valid blood pressure self-measurements. Two recommendations were investigated which requires the patient to be rested for five minutes, prior to measurement, as well as not to talk before and during measurements. Failure to adhere to these recommendations causes significant bias to a measurement. Following ASEF guidelines, they created a reduced adherence model and two adherence verifiers. One using two movement sensors for detecting patient movement levels, and one for detecting talking and noise during measurement using a noise-level sensor. The resulting research prototype was able to detect user behavior, and is able to provide meta-data on the adherence level of the patient along with the blood pressure measurement data obtained. The research prototype was subsequently expanded to also include a visual, active, and context-aware adherence aid to guide the patient to keep still and quiet during measurements using an Android tablet computer along with a wireless context-aware sensor platform. This solution was evaluated in the homes of four diabetic senior citizens for a period of six days each. Results indicate that it is feasible to measure specific elements of non-adherent behavior precisely and that adherence aids could provide improved adherence. However, a larger patient study is needed in order to specify the exact resulting increase in patient adherence.

Case study 2 investigated the challenges of detecting correct leg position during blood pressure self-measurement of pregnant women, using ASEF. Field studies were undertaken at an obstetrics department, with women self-measuring in the clinic. The set of recommendations discussed in case study 1 additionally include that the patient must be seated with legs not crossed during measurement. A reduced adherence model was created to model this recommendation, and an adherence verifier was constructed in the shape of a sensor seat that is able to detect the user's leg position. Thus, the resulting blood pressure measurement data are enriched with meta-data containing the adherence level of the patient's ability to be seated correctly with his or her legs not crossed. The solution was tested with 22 test subjects, and could accurately detect any non-adherence of the test subjects.

Also, the research prototype was later improved with a visual, active, and context-aware adherence aid guiding the user using a tablet Windows computer, to sit correctly with legs not crossed. The prototype was tested at the Obstetric department, Aarhus University Hospital, with 41 patients during a six-week period. Here, the pregnant diabetics once a week self-measure in the waiting room before attending the consultation. Results indicated close to 100% non-adherence during patient self-measurement. However, a larger patient study relying on a more specialized active cognitive adherence aid is needed in order to determine the potential of the sensor seat as an intervention aid.

Case study 3 investigated the potential of creating an adherence verifier for detecting non-adherent patient behavior during 24-hour ambulatory blood pressure measurements. Field studies were undertaken at two general practitioner's clinics and at two hospital departments. During ambulatory blood pressure measurements it is important that the patient does not talk during measurements as recommended by national and international best practice guidelines. A research prototype was created that can detect talk using an artificial neural network classification algorithm based on an Android platform. Used in conjunction with an ambulatory blood pressure device it can present the physician with the patient's ability to remain silent during the blood pressure measurements occurring with a 15-minute interval. The research prototype was evaluated with 20 test subjects and provided 99.3% precision on determining adherence. An adherence aid was not deemed necessary for this domain, as physicians are primarily interested in obtaining evidence for non-adherent behavior.

Case study 4 investigated the combined medication and measurement adherence for diabetic nephropathy patients. With this chronic group it is important to monitor the blood pressure levels prior to taking the morning medication in order not to provide an artificial low reading. In this study, a reduced adherence model and an active, context-aware adherence verifier was constructed for detecting when the patient would leave bed, take his morning medication, and perform the morning blood pressure measurement. By using sensor fusion, the research prototype was able to detect and report untimely blood pressure measurements as modeled by the reduced adherence model. Furthermore, an adherence aid was constructed that would remind the patient not to take medication before measuring the blood pressure.

Case study 5 investigated supporting measurement and rehabilitation adherence of chronic obstructive pulmonary disease (COPD) patients. Using ASEF, a range of important guidelines on the valid use of saturation sensors was identified from lit-
erature. These guidelines were turned into a reduced adherence model. Following this, an adherence verifier was created that would secure the correct use of a saturation sensor device, while also providing an adherence aid instructing the patients through rehabilitation exercises. The verifier and aid was qualitative evaluated with four senior test users. The constructed adherence verifier appears feasible for identifying non-adherent behavior in the domain. However, a larger user study is needed to determine the effect of the constructed adherence aid prototype.

Case study 6 investigated the challenges of medication adherence for anticoagulation self-treatment patients. Following ASEF, a guideline of the importance of always taking medication at the same time of day was identified from the literature. A field study was undertaken at a hospital department and at the home of a patient discussing both relevant adherence verifiers and aids. The resulting research prototype contains a reduced adherence model as well as both an adherence verifier and aid, and is able to detect when medication is removed from the medication container, and communicate with a context-aware reminder system. Furthermore, using a bed sensor, the device is able to detect whether the patient has left his bed or not, and will only remind the patient after leaving bed. If the patient does not react on the local alert, an SMS text message is sent to the patient’s mobile phone.

Finally, in case study 7 patient adherence during weight monitoring of heart and kidney disease patients was investigated. Following ASEF, it was identified from the literature that frequent weight monitoring of heart and kidney disease patients is necessary in order to detect the onset of organ failure, manifesting itself in a sudden weight gain due to fluid build-up in the body, also known as Edemas. In order to increase the reliability of the daily weight measurements, it is important to know whether the measurement is performed before or after a toilet visit, and with or with-out clothes. Also, a challenge with automatic weight scales is the validation of the identity of the user in a possible multi-user setup. An adherence verifier solution was implemented for automatically identifying patients based on biometric features and measuring and registering their weight automatically while performing their toilet routine, ensuring that the measurements were performed after toilet visits at all times as required by the recommendations. Two adherence verifiers were constructed. One for automatically identifying the user, and one for verifying whether a measurement was performed before or after a toilet visit. Field studies were undertaken at a care facility and at a hospital department. A follow-up research prototype was tested with 10 patients at a care facility (nursing home).

8. Discussion

With ASEF we have proposed a terminology and methodology for designing self-care solutions using adherence strategies, aids, and verifiers. However, the framework also provides a common way of describing and discussing the various aspects of adherence when introducing technology into the existing disease management domain processes used in the clinic today, including existing biomedical technologies and systems. It allows system developers and medical researchers to communicate and exchange ideas and may provide inspiration for better technological solutions. Such lingua franca is important for an emerging field such as the pervasive healthcare community which is lacking suitable methods and design tools for moving the field forward [30].

ASEF usage was evaluated as part of seven individual case studies on self-care technology-support, with a total of 25 participants, primarily engineering students recruited externally. While findings indicated that ASEF was indeed useful and feasible, this kind of evaluation also poses a number of validity issues. The participants were biased by the authority and power relationship between themselves and the project supervisors, and the participants may have been more motivated to use ASEF as a consequence. Even though the questionnaire was kept anonymous, participants may have felt obliged to provide overly positive feedback. Also, the participants had access to help directly from the framework inventors, which may have led to easier comprehension of ASEF concepts and methods than would be the case for external research groups. Thus, future evaluations will take place in a less biased context in order to draw more reliable conclusions about ASEF. Several relevant projects are already planned with the participation of external research groups, including medical clinical research groups.

Also, three of the seven case studies focused on designing, implementing, and evaluating adherence verifiers only. While four of the case studies also developed adherence aids, this limits the scope of our investigation of adherence aids as a design tool.

As adherence aids could be considered “the gold standard” for improving patient empowerment and self-care ability, it could be argued that adherence aids should be prioritized in adherence strategy engineering projects. However, adherence aids have proven to be more complex to design and implement, and are much more invasive in the healthcare process, as well as more challenging in a scientific setup. In fact, adherence aids could be the cause of unacceptable bias during healthcare measurements, and potentially lead to adverse effects. Therefore, we reiterate the importance of investigating the domain and context-of-use very thoroughly before introducing new adherence strategies, and that researchers consider starting clinical evaluation using adherence verifiers only, in order to learn more on in situ patient context and behavior before moving on to more advanced adherence strategies.

The use of self-reporting adherence aids has not been addressed in any of the seven case studies investigated in this study. Self-reporting aids may have its relevance in areas where it is not feasible to create an automated and accurate context model based on context-aware sensor input only. Designing hybrid reduced adherence models should be investigated in more detail, including the reliability of self-reported data, which have previously proven to be low. However, this might change when following a hybrid adherence strategy.

While other and more general frameworks and design methodologies, e.g. the PACT framework [32], the Unified Soft-
9. Conclusion

We have discussed several challenges associated with moving healthcare to the unsupervised setting. These challenges include how to verify patient adherence levels and the resulting data quality when the patient is left to self-measure at home or at the outpatient clinic, or perform other unsupervised self-care tasks. We have also argued that these challenges may be overcome by applying context-aware technology for creating adherence verifiers and adherence aids as part of creating novel adherence strategies for better supporting such autonomous patient self-care as well as being a tool for improving the quality of data for clinical diagnostic purposes, possibly leading to reduced healthcare costs.

We have presented the ASEF framework as a means of aggregating a range of facets and concepts identified as being relevant when dealing with adherence strategies, and we have provided a suggestion for a terminology and methodology for analyzing, designing, and evaluating such adherence strategy projects.

The ASEF framework has been successfully used in seven case studies, and was evaluated as being useful and feasible for this purpose.

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