HEALTHINFO 2017

The Second International Conference on Informatics and Assistive Technologies for Health-Care, Medical Support and Wellbeing

ISBN: 978-1-61208-597-5

October 8 - 12, 2017

Athens, Greece

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HEALTHINFO 2017

Forward

The Second International Conference on Informatics and Assistive Technologies for Health-Care, Medical Support and Wellbeing (HEALTHINFO 2017), held on October 8 - 12, 2017- Athens, Greece, tackles with particular aspects belonging to health informatics systems, health information, health informatics data, health informatics technologies, clinical practice and training, and wellbeing informatics in terms of existing and needed solutions.

The progress in society and technology regarding the application of systems approaches information and data processing principles, modeling and information technology, computation and communications solutions led to a substantial improvement of problems in assistive healthcare, public health, and the everyday wellbeing. While achievements are tangible, open issues related to global acceptance, costs models, personalized services, record privacy, and real-time medical actions for citizens' wellbeing are still under scrutiny.

We take here the opportunity to warmly thank all the members of the HEALTHINFO 2017 technical program committee as well as the numerous reviewers. The creation of such a broad and high quality conference program would not have been possible without their involvement. We also kindly thank all the authors that dedicated much of their time and efforts to contribute to the HEALTHINFO 2017. We truly believe that thanks to all these efforts, the final conference program consists of top quality contributions.

This event could also not have been a reality without the support of many individuals, organizations and sponsors. We also gratefully thank the members of the HEALTHINFO 2017 organizing committee for their help in handling the logistics and for their work that is making this professional meeting a success.

We hope the HEALTHINFO 2017 was a successful international forum for the exchange of ideas and results between academia and industry and to promote further progress in health informatics research. We also hope Athens provided a pleasant environment during the conference and everyone saved some time for exploring this beautiful historic city.

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Utilizing Smartwatches for Supporting the Wellbeing of Elderly People

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***Abstract* — We present a new approach for securing the wellbeing of elderly people via a smartwatch based personal health assistant. On the smartwatch, an app featuring an artificial neuronal network (ANN) analyzes the activity patterns of the smartwatch wearer. The ANN recognizes health relevant events and activities of daily living (EDLs, ADL). Especially activities associated with body care tasks are considered. From the sequence and timing of recognized EDLs, ADLs, an individual wellbeing function will be continuously calculated, summarizing the specific personal health state. If the wellbeing function value falls below a defined threshold, external alerts will be issued by the smartwatch. Such alerting will be done automatically, if the smartwatch wearer is not able to respond. It can be done autonomously via the integrated cellular radio module of the smartwatch. The system architecture of the app, the data acquisition process, the selection and design of suitable data models and the advantages of ANNs versus other recognition engines are discussed.**

Keywords — smartwatches; automatic recognition of activities, events of daily living (ADLs, EDLs); artificial neuronal networks (ANN); universal recognition model; wellbeing function.

I. INTRODUCTION

A self-determined and safe living of elderly people in their familiar home, as long as possible, is a desirable objective for many of us. Ambient intelligent assistance technologies safeguard such a life by regularly monitoring the wellbeing and potential health hazards. Programmable smartwatches are one of the most promising devices for such health assistance technologies, because i) they carry many of the necessary sensors for monitoring wellbeing and health parameters on board, ii) do not require expensive demolition / construction work at home and iii) can be used at home as well as outdoors. Moreover, they are available at reasonable costs. In our work, we focus on mainstream smartwatches with an integrated mobile cellular radio (like the Samsung Gear™ 3G, LG Urbane LTE™ 2 or Sport™, Huawei Watch 2™). These smartwatches allow to establish a speech connection autonomously to clarify the situation on the spot in case of a concluded emergency [1]. Moreover, relevant data (e.g., current geographic position of the smartwatch wearer, the heart rate) can be transferred directly and without the (necessary) additional utilization of a smartphone (as it is the case for the Apple Watch 2™).

Current smartwatches directly can only measure the performed steps of the smartwatch wearer and/or the heart rate, pulse. All other aspects of the wellbeing and potential health hazards for the smartwatch wearer must be concluded form condensed sensor data and suitable comparisons with data acquired, learned from the past. A common approach is to recognize - using the smartwatch sensors - those *activities of daily living* (ADLs) which are present in a healthy life of everyone and structure the days and nights. The conclusions about the wellbeing will then be based on the *presence, duration* and *intervals* between those recognized activities of daily living. Direct health hazards – like tumbles/falls, heart palpitations – need to be considered and recognized by the smartwatch sensors (as events of daily living, EDLs).

After a short description of relevant previous work in Section II we present our system architecture in Section III. This section also addresses the selection of a suitable set of EDLs, ADLs for the purposes of our app. The research questions around EDL, ADL recognition are described in Section IV. For answering the research question regarding the aptitude of a *universal recognition model,* our experiment is described in closer detail in Section V. Results of the experiment are presented in Section VI. This section also widens up the discussion on critical issues of present smartwatch technology and the inherent difficulties of recognizing (the EDL) *»tumbling«*.

II. PREVIOUS WORK

ADLs [2] have been a central issue in organizing professional nursing practice and for determining the independency status of elderly people, introduced by Sidney Katz more than 60 years ago. Automatic EDL, ADL recognition in smart homes has been a focal research point for supporting the elderly [3].

Suryadevara and Mukhopadhyvay [4] have proposed a wellbeing function w based on the components *absence* and *excess duration of ADLs*. Their approach stems on a rich instrumentation of the household by a net of wireless sensors. The wellbeing function w maps the recognized ADLs and their characteristics into $[0,1] \subset \Re$. For ideal wellbeing, the function value of w is 1; if the function value falls below a defined threshold (e.g., 0.5), a health alert is issued. In [5], we have extended the w definition for accounting a third independent wellbeing component *agility*, which measures the typically step distribution walked over the course of the day by the smartwatch wearer. The nominal values for a typical interval between the ADLs, the typical execution time of a specific ADL and the typical step sum achieved by a specific hour of the day all are individual

 ISBN: 978-1-61208-597-5

values and specific for a certain day of the week. These nominal values have to be acquired by an initial training phase of the system with at least a one-week duration and will be further adapted by time series analysis [4] [5], taking into account also seasonal factors.

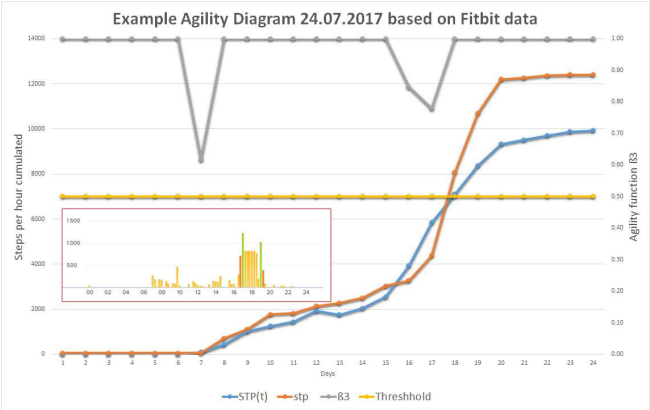

Figure 1: Typical agility for a 24-hour period.

When no recognized ADL in the household is taking place, $ß_1$, the wellbeing sub-function for *inactivity* measurement, is applied based on the definition in [4] as $ß_1(t, T) = e^{-t/2*T}$, where t is the current (time) duration of inactivity since completion of the last recognized ADL, and T is the specific average inactivity between ADLs learned from the past for the current day of the week. On the opposite, as long as a recognized ADL is ongoing, $ß_2$, the wellbeing sub-function for the measurement of *excess duration* of this specific ADLs will be applied, which has been defined in [4] to $ß_2(TN, ta) = e^{(TN - ta) / TN}$, for ta > TN; 1, otherwise where ta is the actual duration of the (ongoing) ADL and TN is the specific maximum duration of the corresponding recognized ADL in a normal situation learned from the past for the current day of the week. The agility subfunction $ß_3$ measuring the movement profile of a person at current time t is defined in [5] to

$$ß_3(t, stp, STP) = \begin{cases} e^{\frac{(stp(t)-STP(t))}{STP(t)}}, for\ stp(t)<STP(t) \wedge \quad \neg E_1 \\ 1, for\ stp(t) \geq STP(t) \wedge \neg E_1 \\ 0, if\ E_1 = tumble \end{cases}$$

where stp(t) is the sum of steps performed during the current day until actual time t, F(t) is the cumulative distribution function of steps over the day, SN is the specific total number of steps learned from the past for the current day of the week and with STP(t) = SN*F(t) estimated from the nominal step sum for the current day at time t. $ß_3$ will be calculated all over the day, Figure 1 shows a typical distribution of daily steps for a 24-hour period based on an $\alpha = 0.1$ (giving heavy weights for historical values). Left scale denotes the accumulated steps (orange: actual steps of the day, blue: the estimated accumulated steps for the period, grey: the agility value $ß_3$ and yellow: the threshold for $ß_3$). The small subfigure inside denotes the step distribution on a 15 minutes basis. As can been seen the agility value is far above the threshold indicating that no agility problems are present. One exception is the period around 6pm. The decline can be explained by a later get up in the morning.

The wellbeing function w: SensoricEvents -> [0,1], [0,1] $\subset \Re$, will be formally defined as:

$$w = \min \{ß_1, ß_2, ß_3\}$$

This means that whenever the *inactivity* (missing any recognized ADL) or the *excess duration* of an ongoing activity category or the lacking *agility* gets critical and the w value falls below 0.5, a *health hazard alert* will be issued.

Lacking *agility,* which we added to the Suryadevara and Mukhopadhyvay wellbeing definition [4], is often overlooked in daily nursing activities. It is one of the symptoms of dementia, a typical indication of pain and not unusual consequence of age related complaints for elderly people [6]. In our context, we focus on the subset of basic ADLs, which

- can be recognized by the usual integrated smartwatch sensors (*3D accelerometers, and gyros, magnetometer, barometer, heart rate monitor / pulsometer, GPS for the smartwatch class chosen)* and communication technologies *(Bluetooth, Wi-Fi, 3G/4G cellular)*
- will be typically carried out each single day and by everyone, independent from culture and/or sex, ideally independent from a dominant hand (on the wrist of which the smartwatch has to be worn),
- will be carried out multiple times within a day and thus allow for a preferably equidistant partitioning and structuring of the day / night.

With respect to their eminent negative health consequence for the targeted user group, additionally the EDL »*tumbling*« needs to be considered. One third of all elderly persons of age of 65 or more tumble at least one time per year [23].

III. System Design Considerations

A. System Structure

The implemented system, smartwatch app, utilizes the Samsung Gear™ S smartwatch device for providing assistance in the four dimensions: I) *communication* (manually and automatically established speech connections to family members on duty or a home emergency call center), II) *orientation*, III) *localization* and IV) *health hazard detection.* The implemented scope of personal health assistance is described in [1] [5] in closer details, Figure 2 shows some screenshots. Figure 3 depicts a block diagram of the smartwatch personal health assistance app with its layered architecture: layer 0: smartwatch HW with sensors, I/O; layer 1: smartwatch OS; layer 2: motion analysis via ANN and location analysis via GPS monitoring – geofencing; layer 3: simultaneous health hazard recognition handling via a multitude of simultaneously running finite state machines; layer 4: health hazard presentation and dialogue control vis a blackboard based scheduler more architectural details can be found in [7] [8].

 ISBN: 978-1-61208-597-5

The application architecture is based on a hierarchical structure. On the lower layer the EDL, ADL recognition via a ANN takes place (see section III). The recognized EDLs, ADLs will evoke actions in a structured description of the *health hazard handling* process executed on the upper layer. Health hazard handling is described in a declarative way via UML (finite) state machines. This declarative description is well suited for maintaining and updating the volatile, best practice *health hazard handling* knowledge [7]. The suitability and advantages of utilizing UML for modelling caregiving and medical processes is pointed out in [9].

Figure 2: Smartwatch Samsung Gear™ S

Example: In Figure 2, which shows the app displaying *communication* and *orientation* information (left), internal pre-alert (middle), indication of an external alert with data transmission and automatic speech connection (right), the health hazard handler »monitoring drinking« consists of two states. Upon (re)entering the initial state »normal health«, the timer *thirst-timer* is reset. Thus, the state machine stays in this specific state, as long as the ADL *»liquid ingestion«* occurs in sufficient frequency.

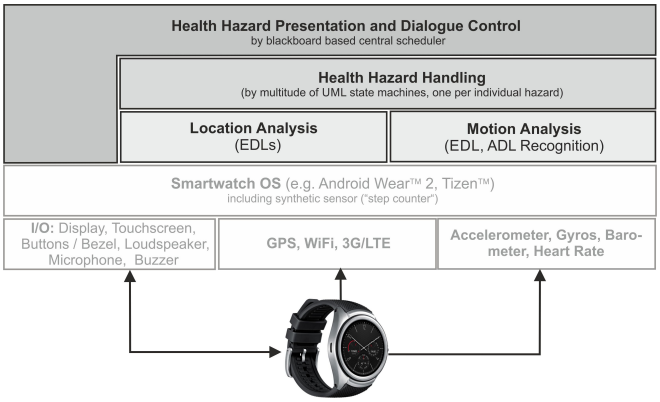

Figure 3: Block diagram of the smartwatch app

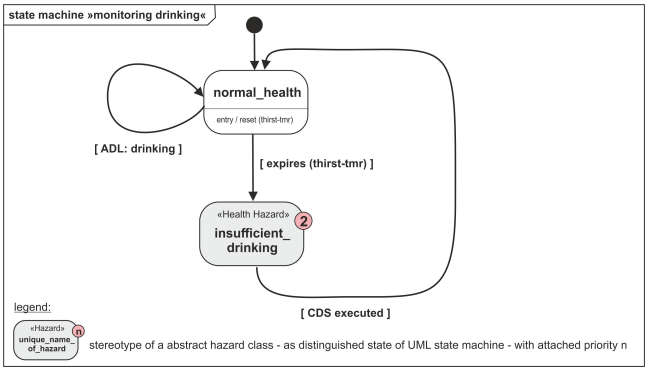

Figure 4: Simple state machine for concluding about the health hazard resulting from insufficient liquid ingestion

In Figure 4, if the *thirst-timer* expires because the time period since last recognized drinking ADL is exceeded, the state machine transfers to the new state »insufficient drinking«. This new state is of special type *critical dialogue section* and will be posted on a central blackboard (see below). Such a posting indicates an execution request with attached priority "2" for the associated internal dialogue activity flow for this state. The intended dialogue sequence with the smartwatch wearer is described in a corresponding UML activity diagram modelling the principal schema of the dialogue. This schema systematically covers all necessary dialogue steps for: a) *informing* the smartwatch wearer about the specific situation ("pre-alert"), b) *requesting a decision* from the smartwatch wearer, c) *responding* with the dialogue in case of an affirmative or rejecting user reaction, as well as a non-reaction of the user. In addition, the potential data transmission of relevant health data, which takes place in the background of the dialogue, will be covered by the schema as well as the follow-up clarification call ("external alert"). See [8] for the details of the model based dialogue management.

Isolated health hazards are typically modelled and described by a separate handler, in order to alleviate an independent representation and maintenance of the incorporated pragmatic handling knowledge. This is the case for the »monitoring drinking« state machine. But, more frequent in practice are joint hazard handlers for contextually combined *security and/or health hazards*. A state machine for jointly handling all hazards associated with the ADL *»absence from home«* is depicted in Figure 5 which handles security and health hazards resulting from an absence from home, including the health hazards for a runaway situation and an excessive absence from home. In a single state machine, only one of these hazards can be present at a time.

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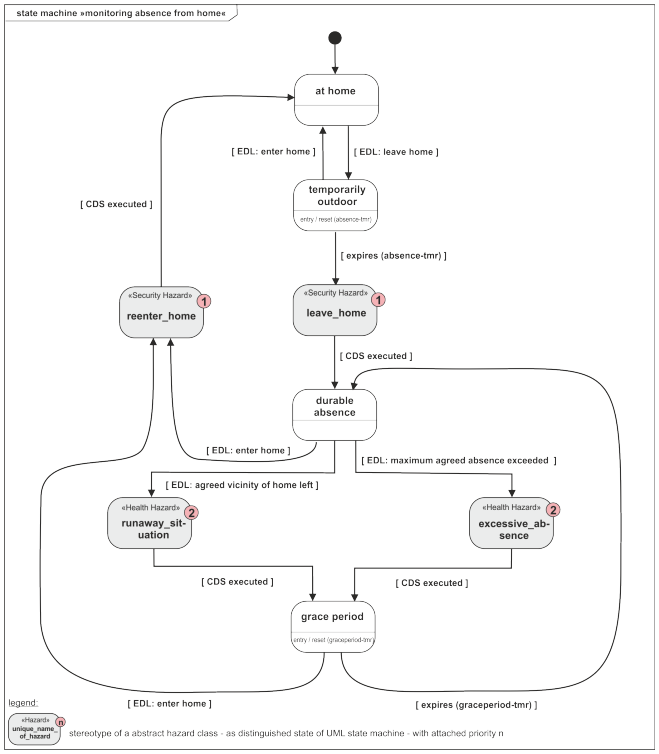

Figure 5: Complex state machine

The implemented app gains its complexity by the fact that a multitude of potential hazards have to be monitored by the smartwatch app simultaneously. This is done by executing the set of finite state machines describing all hazard handling *simultaneously*. Hazards from *insufficient drinking, absence from home, tumbles, ...* may occur all at the same time. Thus, the situation may arise that more than one finite state machine or health hazard handler wants to communicate to the smartwatch wearer at the same time. This situation will be dealt with a priority – or exactly: severity – based health hazard communication management. The I/O devices of the smartwatch (touchscreen, bezel, mic, buzzer / loudspeaker) may be attached to at most one health hazard handler at time and for a short time interval. In order to realize this, we have introduced the concept of a *critical dialogue section* [8]. As soon as the smartwatch I/O resources have been granted to a selected health hazard handler, the handler will use them *exclusively* until termination of the execution of the corresponding critical dialogue section. The selection of the suitable health hazard handler for executing a dialogue sequence with the smartwatch wearer is supported via a central blackboard, on which all current communication requests are posted by the different handlers. From all current requests on the blackboard, a central scheduler selects the most appropriate health hazard handler for execution based on the medical or situational severity of the posted request and all other present requests on the blackboard (see [7] [8] for details of the scheduling algorithm).

B. Determining a Suitable Set of ADLs

A tradeoff has to be made between the plenitude of ADLs, which shall be recognized, and the reliability of the recognition results. The more ADLs the system knows and is looking for, the more fine-grained the course of the day can be partitioned into different ADLs and periods of time in between. The shorter these periods of time are, until the next ADL will typically occur, the earlier a deviant behavior influencing wellbeing and / or indicating potential health hazards can be detected. But, the more ADLs need to be discriminated by the recognition engine, the less reliable the recognition result will typically be.

Based on the aforementioned criteria, we have decided to recognize the following seven ADLs:

1. Nightly sleep
2. (midday) nap, rest
3. absence form home (for social activities/visits, strolling, shopping, etc.)
4. liquid ingestion, drinking (see [10] [11] [12] for details)
5. hand washing / drying (typically carried out after toilet activity, before eating)
6. teeth brushing
7. shaving
8. combing

ADL no. 1 »*nightly sleep*« *can* only be observed indirectly, in that the smartwatch is typically not worn during this period due to nightly battery recharging and usual sleeping habits. But, placing down the smartwatch when retiring to bed at night and reattaching the watch in the morning after rising can be reliably detected via movement analysis and the heart rate sensor, pulsometer.

Assuming that the smartwatch will be worn all over the day, ADL no. 2 »(*midday) nap, rest*« can be directly observed and easily detected by the smartwatch app via its characteristic non-movement pattern. Also, ADL no. 3 »*absence from home*« can be directly followed by the smartwatch app via loss of the known home Wi-Fi signal and GPS. (GPS will be further used for tracking and geofencing outdoor activities (see Figure 6 and [1] [5] for details). The process of recognizing the ADL from the delimiting EDLs »leave home« and »*enter home*« is described in the state machine of Figure 4.

For the recognition of ADLs no. 4 to 8, these ADLs can only be discriminated from each other by their characteristic movement pattern. This holds also for the recognition of tumbles. Based on literature research we have decided to do this recognition process via data mining and artificial neuronal networks (ANNs). Input layer of the feed forward ANN are the (condensed) specific signals from the smartwatch sensors. The ANN has one hidden layer and each ADL no. 4 to 8 will be represented by a specific output neuron, with the EDLs »*tumbling*«, »*heart palpitations*« as additional 6^{th} and 7^{th} output neuron of the ANN and a 8^{th} output neuron for any other unclassified activity. ANNs have been chosen with respect to their favorable recognition quality and renunciation

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of additional runtime packages in comparison to logistic regression and other tested methods (see [11] for details). Another strength of ANN is their suitability for incremental training with the *backward propagation* algorithm (see [13], especially chapter 5.2).

ANN have successfully been used for detecting tumbles with quite a high precision, [16] reports an accuracy of 91%. [17] gives an overview about various sensor based implementations, most of them with an accuracy rate about 90% using various data mining techniques like multilayer perceptrons, support vector machines or naïve Bayes approaches. A good discussion about the challenges of tumble detection is given in [18], focusing not only a wearable system but also on camera bases approaches. It is important to note at least in Europe any detection techniques based on video is not accepted because of privacy concerns. Thus, only foot mat related sensor technologies which require expensive hardware investments remain as an option or any kind of wearable sensor. Lisowska et al. [19] show that Convolutional Neuronal Network (CNN) perform best for supervised learning techniques, while overall the differences to other approaches like SVM are not very high. Our work differs from those as we aim for detecting several different ADLs in one model, and not just the binary decision between tumble and not not-tumble. Weiss et al. [20] compare smartwatch based ADL detection with smartphone based detection showing that smartwatches can detect a wider variety of ADLs. Smartwatches gain their strength in tumble detection in that they are reliable worn at the wrist and will be on duty during the whole course of a day. In contrast, smartphones are typically put aside from time to time, especially during accident susceptible activities like showering.

C. Handedness and Relevance of ADLs.

ADL no. 4 »*drinking« and* no. 6 »*teeth brushing«* will be typically carried out only with the dominant hand. It turned out for the test persons that it is not a problem to wear their smartwatches on the wrist of their dominant hand (see Section IV). This is alleviated by the fact that smartwatches can rotate their display so that sideward control elements always remain at the familiar location pointing towards the hand of the wearer. *ADL* no. 4 »*drinking«* has been selected with respect to the dangerous effects of dehydration for elderly people caused by the decreasing natural thirst sensation at higher age [5].

ADL no. 5 »*hand washing / drying«* and the EDL *»tumbling«* are typically independent from the arm or wrist, on which the smartwatch will be worn. The ADL has been primarily included for technical reasons because they are typically executed several times a day and provide a good partitioning of the day into shorter time spans between those ADLs.

The importance of ADLs no. 5 »*hand washing / drying«* and 6 »*teeth brushing«* is not only given by the fact, that they have a characteristic movement pattern, which makes it suited for automatic activity recognition, but also for their social relevance. Regular teeth brushing and hand washing are significant symptom for a well-managed life. Stopping these activities typically indicate a loss of self-esteem / self-control and might be symptoms of progressing mental disorientation or dementia [14].

IV. Research Questions

A central question is whether a universal, person independent model of the ADL / EDL recognition process is sufficient or if an individually trained model will be necessary, at least for personal activities like *teeth brushing*. The additional effort for processing and building an individual model will be counter-balanced by the prospect to utilize this individual model for an authentication of the smartwatch wearer.

From this central question, several follow-up research questions have been derived:

1. Which is the best prediction model? Candidates are neuronal networks, regression models or decision trees [15].
2. Is one universal neuronal network model sufficient to recognize the relevant ADLs/EDLs based on a target recognition rate of at least 90%?
3. Are there differences in the acquired sensor data between the various smartwatch types (operating systems like Android Wear or Tizen)?
4. Are there differences based on the ADLs with regard to universal / individual model, thus while one ADL just requires a universal model, another ADL requires individual training?
5. How many training data have to be collected per person?
6. How many different persons are required to create a stable model?

In the analysis of this paper, we concentrate on research question 2 and neuronal network models. Research question 1 has been tested in [21], results show that neuronal networks perform at least as good as logistic regression, while decision trees perform much worse. To answer questions 3 to 6 the number of data currently available are not sufficient for a definite answer. First results show that at least 20 – 30 activity instances have to be collected per person for stable trainings models with a high recall and precision. Question 6 is partially answered by the results for hypothesis 2.

V. Experiment

An experiment was run over a period of one and a half year between spring 2015 and year's end 2016. The experiment included multiple test cycles of 2 to 3 weeks with different test objectives (especially ADLs to be recognized) and different sets of test persons of various ages. Between the test cycles, the smartwatch application software has been continuously improved by the authors based on prior test results. Test persons were of age between 25 and 63, predominantly males. One test group are students of one the authors, the other group are friends and family members of both authors. All test persons have been informed in advance about the capabilities of the smartwatches, especially the application software installed and the purpose of the specific tests. After being informed about the intended test objectives, the test persons agreed to the intended utilization of their collected anonymized data for research purposes. From their

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personal background, all test persons were fluent in utilizing digital devices in their daily life. In this paper, we present the results of the experiment in the area of personal health and body care, one of the most promising application area learned from our tests.

1) In a *first step,* we developed a sensor data gathering app where we collected about 2375 different activity instances starting from the above-mentioned core ADLs and EDLs like drinking, brushing, tumbling, combing, shaving, washing, etc. The data were collected using several different smartwatches running Android Wear (Sony Smartwatch 3, Samsung Gear Live) and Tizen (Samsung Gear S). For this analysis, we only used the data from the Gear S (overall 1394 activities). The Gear S based collection tool is depicted in Figure 6 and the distribution of the collected ADLs is shown in Tables I and Table II. For this analysis, ADLs, which did not fit into the category analyzed (like tumbling, walking etc.), were mapped into Other ADLs. Users are denoted by U_i, $1 \leq i \leq 5$. The user selects the ADL (Figure 5), enters a user name, pushes Collect (1) and from (2) he can start the data collection process. (3) shows a pre-countdown start, informing the user that the data collection will start in 1 second. (4) indicates that data collection has started and will last for 10 seconds. (5) indicates data collection will be finished in two seconds. (6) informs the user that now a second data collection will start. This step (6) depends on the type of activity recorded. In case of a short activity like tumbling or drinking just one ten second interval is recorded at once, in case of tooth brushing as an example of a longer activity up to five ten second interval are recorded at once.

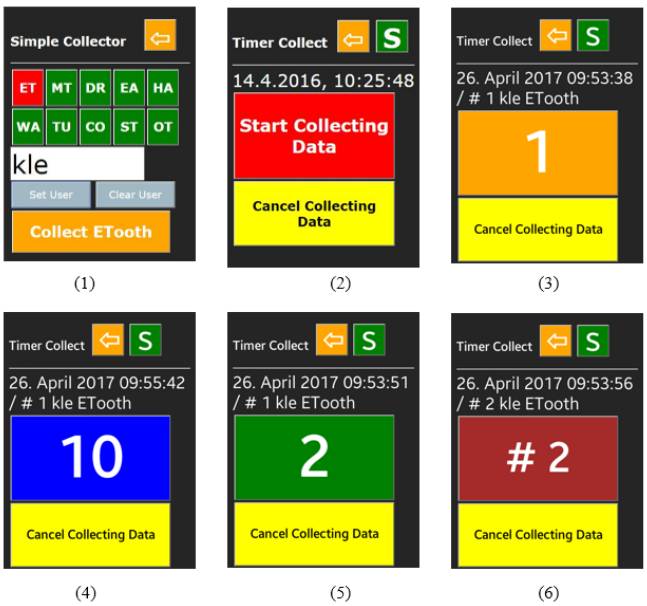

Figure 6: Samsung Gear S GUI for collecting ADLs

TABLE I: DISTRIBUTION OF FREQUENCIES OF THE COLLECTED 1394 ADLS (WITH SAMSUNG GEAR S SMARTWATCH) USED FOR THE TRAINING OF THE NEURONAL NETWORK MODEL.

ACT	U1	U2	U3	U4	U5	Sum
Other	0	0	634	78	18	**730**
Comb	0	0	39	0	0	**39**
Shave	0	0	126	0	0	**126**
Tooth	59	40	261	0	100	**460**
Wash	**0**	**0**	**15**	**0**	**24**	**39**
Sum	**59**	**40**	**1082**	**78**	**142**	**1394**

TABLE II: DISTRIBUTION OF FREQUENCIES OF THE COLLECTED 66 TEST ADLS USED FOR THE TESTING THE NEURONAL NETWORK MODEL. TEST DATA WERE GENERATED BY USER U3.

ACT TEST U3	Other	Comb	Shave	Tooth	Wash
Distribution	6	33	11	10	6

The next steps are based on a standard CRISP (Cross Industry Standard Process for Data Mining) process [22].

2) In the *second step,* the gathered sensor data are normalized:

   a) All sensor data are standardized and interpolated into a fixed time interval (20 milliseconds). This was achieved by applying some filters, e.g., a high/low pass filter.

   b) A core set of statistical attributes (39 attributes like means, standard deviations, minimum, maximum, inter quartiles…) are computed for each ADL. Dependent variable is ADL type (Activity), independent variables are the 39 statistical attributes.

   c) For each ADL (experiment) a data record is written into a new csv summary file together with the information which type of ADL is performed and the user name. This resulted in several ADL summary files depending on the hypothesis.

3) In a *third step,* the data were checked for missing values (e.g., sometimes the smartwatch did not collect gyrometer or magnetometer data for whatever reason). Those cases were ignored from the analysis.

4) In a *fourth step,* we applied several data mining techniques using R and Rapid Miner (Figure 7): multinomial logistic regression, clustering, decision trees and for the results presented in this paper neuronal networks using the normalized sensor data. For the data mining process, we grouped the ADLs in two categories: a) drinking, teeth brushing, and tumbling and b) all other activities recorded like walking, running, washing, sitting etc. into a common ADL category called other.

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TABLE III: TRAINED GENERAL MODEL: RECALL AND PRECISION

ACTIVITY TRAIN	true Other	true Comb	true Shave	true Tooth	true Wash	class precision
pred. Other	**718**	0	0	6	0	99,17%
pred. Comb	1	**39**	0	0	0	97,50%
pred. Shave	2	0	**123**	4	0	95,35%
pred. Tooth	9	0	3	**450**	0	97,40%
pred. Wash	0	0	0	0	**39**	100,00%
class recall	98,36%	100,00%	97,62%	97,83%	100,00%	**1394**

TABLE IV: TEST DATA: RECALL AND PRECISION

ACTIVITY TEST U3	true Other	true Comb	true Shave	true Tooth	true Wash	class precision
pred. Other	**6**	1	0	0	0	85,71%
pred. Comb	0	**28**	0	0	1	96,55%
pred. Shave	0	0	**10**	0	0	100,00%
pred. Tooth	0	3	1	**10**	0	71,43%
pred. Wash	0	1	0	0	**5**	83,33%
class recall	100,00%	84,85%	90,91%	100,00%	83,33%	**66**

VI. RESULTS UND DISCUSSION

Our above hypothesis 2 stated that one universal model is sufficient to recognize the relevant ADLs/EDLs based on a target recognition rate of at least 90%. Considering the limited number of test persons and the specific test environment different from a real field test, our results seem to affirm this hypothesis 2.

The results of training the neuronal networks model are shown in Table III. Neuronal networks performed best compared to other data mining methods applied which is in line with the results in [10] [21]. It shows that all relevant recognition rates are above 90%. Table IV shows the results when this general model is applied to data the system has not seen before. The data were generated by user U3. User U3 was part of the training set. Combing and washing are not recognized perfectly, anyway the distinction between "hygienic ADLs" and other ADLs is nearly perfect. As one can conclude from the results, the recognition gets much better if a test person is part of the training set, which per se is not astonishing. For real world application, this could induce that before using the smartwatch as an ADL recognizing device users should be encouraged to train typical activities and use an improved neuronal network model.

A. ADL Recognition and Smartwatch System Support

Continuous monitoring of EDL, ADL recognition in the smartwatch app requires an ongoing execution and adaption of the ANN, as soon as there will be new sensor signals. This requires a reliable background operation of the smartwatch app, even when the user is not looking at the smartwatch screen and the display therefore will be shut off. Unfortunately, and for energy saving purposes, smartwatch OSs tend to hibernate the app execution in situations, were the display is shut off. Smartwatch OS like Tizen™ or Android Wear 2.0™ are featuring such (background) service operations in their most advanced versions. Reliable background operations are mandatory and of crucial importance for a wide acceptance and trust in assistance apps for the elderly.

B. EDL »Tumbling«

This EDL entails a lot of difficulties. First of all, the detection of the EDL requires a barometric sensor in the smartwatch. This sensor typically is only present in "high-end" smartwatches. Second, the training of the EDL is inherently *dangerous* for the test persons with respect to potential injuries. Trained stuntmen or young people would be no alternative because their tumbling behavior will deviate too much from tumbles of elderly people. For the same reasons, crash dummies from the automotive field also would be no alternative, in that they would remain passive and would not show the characteristic last fraction of a second active (panic) reaction against the ongoing tumble, which is typical for humans. Therefore, we used "young elderly" of about sixty years of age for our tumble tests. But, it is still an open issue whether our trained tumbles – as planned, conscious event – really are representative for the majority of everyday accidents, sudden tumbles in the household. Unfortunately, practically no video sequences are available for such real tumbles as objective illustrative evidence.

VII. CONCLUSION AND FUTURE WORK

EDL, ADL recognition based on an ANN works on today commercial smartwatches and delivers the necessary input for calculating the wellbeing of the smartwatch wearer. Continuous reliable detection of the EDL *»tumbling«, the ADLs* described requires durable background operations of the smartwatches, which only now will be supported by the most advanced smartwatch operating systems (OSs).

Universal models collected from different smartwatches, OSs and test persons are sufficient for achieving the targeted minimal 90% precision and recall rate for EDL, ADL detection. Best rates could be achieved by an individual model trained for a specific smartwatch. Such an individual model could be used even for user identification (e.g., in the scope of a benefit plan for good teeth brushing practice). But, the sensitivity of the individual model will require a substantial retraining even in cases of a smartwatch model change or even a major OS update.

A future application of the ANN based motion analysis will be dedicated to the combined analysis of the motion patterns, heart rate and blood glucose data from continuous glucose monitoring (CGM) systems. This will allow to conclude whether a change of glucose measurement data can be explained by the agility patterns of the smartwatch wearer. CGM systems like DEXCOM G5™ and Abbott's FreeStyle Libre™ already are or will be capable to deliver these data via Bluetooth or NFC to smartwatches. The unobtrusive presence of those data on the wrist will support better self-management of the widespread diabetes mellitus type 2.

 ISBN: 978-1-61208-597-5

REFERENCES

[1] R. Lutze and K. Waldhör, "Smartwatches as Next Generation Home Emergency Call Systems, *8th German AAL Conference* 2015, 29.-30.4.2015, Frankfurt/Germany, Paper A1, VDE Press *(in German)*.

[2] S. Katz, Assessing Self-maintenance: Activities of Daily Living, Mobility, and Instrumental Activities of Daily Living, Journal of the American Geriatrics Society, vol. 31 (1983), no. 12, pp. 721-727

[3] V. G. Sanchez, C. F. Pfeiffer, and N.O. Skeie, A Review of Smart House Analysis Methods for Assisting Older People Living Alone, Journal of Senor and Actuator Networks (JSAN), 2017, 6 11, pp 1-38, MDPI

[4] N. K. Suryadevara and S. C. Mukhopadhyvay, "Determining Wellness through an Ambient Assisted Living Environment", *IEEE Intelligent Systems,* Vol. 29(2014), No3, pp.30-37.

[5] R. Lutze and K. Waldhör, "Integration of Stationary and Wearable Support Services for an Actively Assisted Liiving of Elderly People: Capabilities, Achievements, Limitations, Prospects – A Case Study", in: R. Wichert, E. Mand (eds) "Ambient Assisted Living", Springer Int. Publishing 2017, pp. 3-26.

[6] B. Plooij, E. JA Scherder, and L. HP Eggermont, "Physical inactivity in aging and dementia: a review of its relationship to pain", JCN Journal of Clinical Nursing, Vol. 21, Issue 21-22, November 2012, J. Wiley Online, pp. 3002–3008.

[7] R. Lutze and K. Waldhör, "A Smartwatch Software Architecture for Health Hazard Handling for Elderly People*", 3rd IEEE International Conference on HealthCare Informatics (ICHI),* 21.-23.10.2015, Dallas, USA, pp. 356-361.

[8] R. Lutze and K. Waldhör, "Model Based Diaglogue Control for Smartwatches", 17th HCI International Conference, 9.-14.7.2017, Vancouver, BC, Canada, in: K. Masaaki (ed.) "Human–Computer Interaction Contexts", Lectures Notes in Computer Science (LNCS), Vol. 10272, Springer Int. Publishing 2017, pp. 225-239.

[9] S. Ferrante, S. Bonacina, G. Pozzi, F. Pinciroli, and S. Marceglia, "A Design Methodology for Medical Processes", Applied Clinical Informatics, vol 7, no. 1, p.191–210, Schattauer Publishing, 2016.

[10] R. Lutze, R. Baldauf, and K. Waldhör*,* "Dehydration Prevention and Effective Support for the Elderly by the Use of Smartwatches"*, 17th IEEE International Conference on E-Health Networking, Application & Services (HealthCom),* 14.-17.10.2015, Boston, USA, pp. 404-409.

[11] K. Waldhör and R. Baldauf, "Recognizing Drinking ADLs in Real Time using Smartwatches and Data Mining", *Rapid Miner Wisdom / Europe Conference,* Ljubljana, Slovenia, 2015.

[12] R. Baldauf, "Mobile sensorbasierte Erkennung von Trinkbewegungen", Thesis, FOM, Nürnberg, 2015 (in German).

[13] C. M. Bishop, "Pattern Recognition and Machine Learning", Springer Science+Business Media, 2nd ed., 2006.

[14] "Dental care and oral health". Report of the British Alzheimer's Society, 2015.

[15] D. T. Larose and C. D. Larose, "Data mining and predictive analytics" Hoboken, New Jersey: John Wiley & Sons, 2015.

[16] H. Kerdegari, K. Samsudin, A. Rahman Ramli, and S. Mokaram, "Development of wearable human fall detection system using multilayer perceptron neural network", *International Journal of Computational Intelligence Systems*, vol. 6, no. 1, pp. 127–136, 2013.

[17] T. Prajapati, N. Bhatt, and D. Mistry, "A Survey Paper on Wearable Sensors based Fall Detection," *IJCA*, vol. 115, no. 13, pp. 15–18, 2015.

[18] R. Igual, C. Medrano, and I. Plaza, "Challenges, issues and trends in fall detection systems," *BioMed Eng OnLine*, vol. 12, no. 1, p. 66, 2013.

[19] A. Lisowska, G. Wheeler, V. C. Inza, and I. Poole, "An Evaluation of Supervised, Novelty-Based and Hybrid Approaches to Fall Detection Using Silmee Accelerometer Data", 2015 *IEEE Int. Conf. on Computer Vision (ICCV), Workshops, pp.10-16, Chile.*

[20] G. M. Weiss, J. Timko, C. Gallagher, K. Yoneda, and A. Schreiber, "Smartwatch-based Activity Recognition: A Machine Learning Approach", *IEEE-EMBS International Conference on Biomedical and Health Informatics (BHI) 2016,* 24.-27.2.2016, p. 426-429, Las Vegas, USA.

[21] K. Waldhör and R. Lutze, "Smartwatch Based Tumble Recognition – A Data Mining Model Comparison Study", *18th IEEE Int. Conference on E-Health, Networking, Application & Services (HealthCom*), 14.-16.9.2016, Munich, Germany.

[22] D. S. Putler and R. E. Krider, "Customer and Business Analytics: Applied Data Mining for Business Decision Making Using R", CRC Press, Taylor & Francis Group, 2012.

[23] S. Yoshida ,"A Global Report on Falls Prevention Epidemiology of Falls", WHO, Geneva, 2007

 ISBN: 978-1-61208-597-5

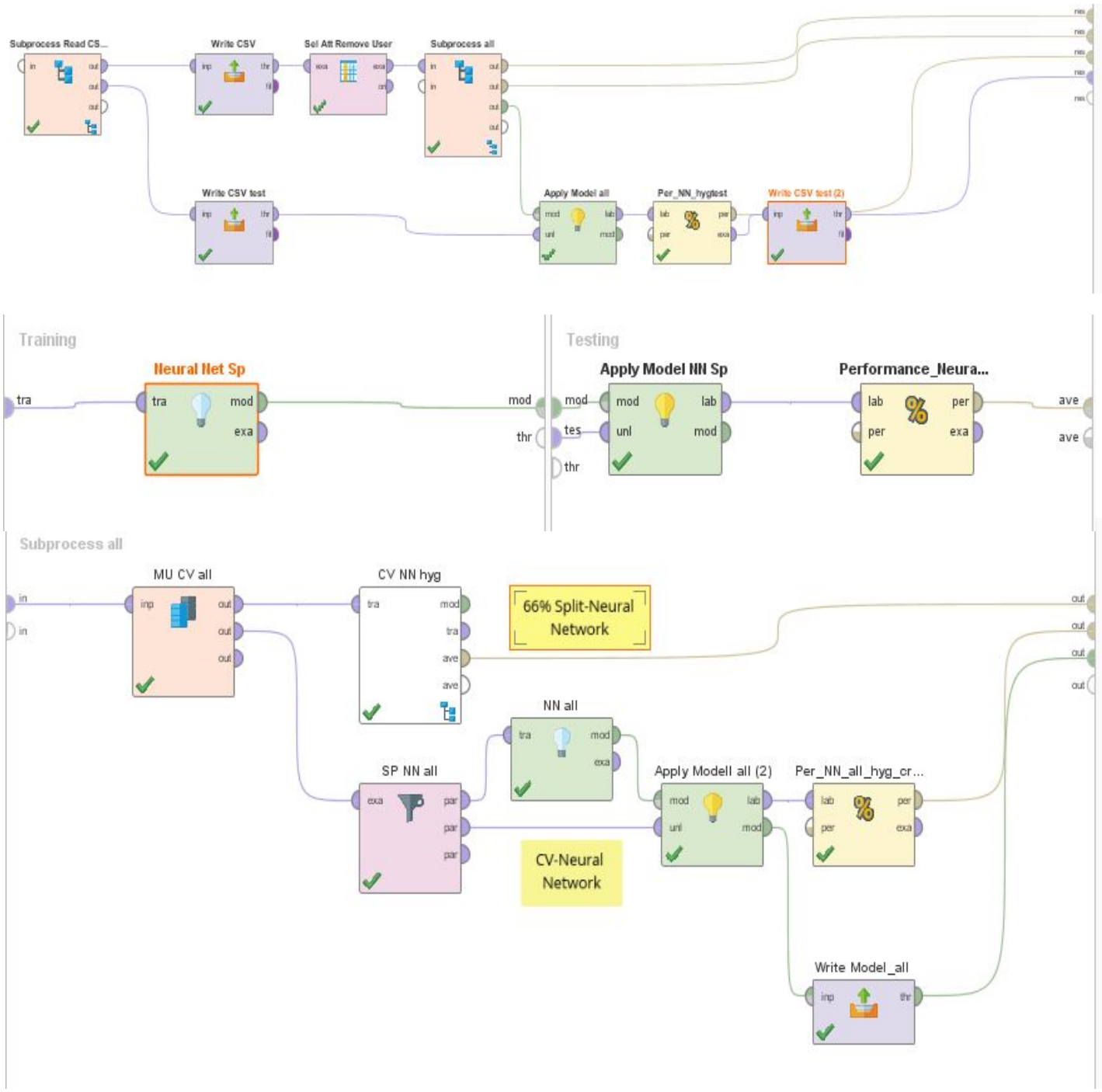

Figure 7: The Rapid Miner models used for training and testing

 ISBN: 978-1-61208-597-5

Serious Games for Rehabilitation: Requirements for a Collaborative Environment

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Abstract - **Healthcare is continually being improved, especially regarding the use of the current technologies. In the field of rehabilitation, the use of serious games and related technologies may help to develop new rehabilitation procedures. An example is a collaborative environment, in the broad sense of the word, a place where people from all areas can exchange information about the area under study. So, these possibilities create endless opportunities of use in those games and attract attention from other areas of knowledge. This contribution presents research on environments applied to the rehabilitation, focusing on the elderly. It provides an overview of the use of technological environments by health professionals who perform functions related to the rehabilitation process. For this, a questionnaire and a set of interviews with health professionals of the rehabilitation area were carried out, in order to understand the needs. The study intends to be a support for the future work in this area. The aim of this work is to study and provide a patient-adaptive collaborative environment with recourse to serious games in order to facilitate rehabilitation.**

Keywords - Serious games; rehabilitation; multidisciplinary approach; support technology; collaborative platform.

I. INTRODUCTION

The proximity of the technologies with rehabilitation has been accentuated in recent times as a result of technological developments, which led to the evolution of a traditional approach based almost exclusively on a connection between therapist and patient for systems that resort to technologies that take on a supporting role to therapy. The assistive technologies, according to several studies, enable user to have a better quality of life as well as assist in various tasks. In the construction of assistive technologies in the rehabilitation process, it is not only necessary to know the physical principles that govern their designs, but also to adhere to some key principles that govern the applications of technologies for people with disabilities. To be successful, the needs, preferences, abilities, limitations, and even environment of the individual seeking the assistive technology must be carefully considered. There are at least some considerations that exist in the field of assistive technology. Although assistive devices can make accomplishing tasks easier, technology alone cannot mitigate all the difficulties that accompany a disability. Assistive technologies are sometimes complicated and expensive. Sometimes low technology devices are the most appropriate and even preferred for their simplicity, ease of use, maintenance, and low cost [1].

As with other technologies, there has been an increased interest in serious games for elderly people over the last few years. This can be largely attributed to the worldwide increase in aging population. According to [2][3], the proportion of the world's population aged 60 years or over is growing.

This paper focuses on serious games in the rehabilitation area, with emphasis on the study of requirements for an interactive collaborative environment for rehabilitation activities.

Rehabilitation, defined as "a set of measures that assist individuals, who experience or are likely to experience disability, to achieve and maintain optimum functioning in interaction with their environments", is instrumental in enabling people with limitations in functioning to remain in or return to their home or community, live independently, and participate in education, the labour market and civic life.

Rehabilitation measures are aimed at achieving the following broad outcomes: prevention of the loss of functions, slowing the rate of loss of functions, improvement or restoration of functions, compensation for lost functions and maintenance of current functions [4]. In that sense and after the study of several data, such as concepts and numbers associated with the rehabilitation process, an opinion survey was conducted, with the collaboration of rehabilitation centers, as well as health professionals related to this area. To this end, a questionnaire was distributed and interviews were conducted with health professionals with links to the rehabilitation process.

The rest of the paper is structured as follows. Section 2 presents an introduction to serious games in the rehabilitation process including terminology and concepts. Section 3 introduces the motivation of collaborative environment. Section 4 presents suggestions and opinions on the requirements of a collaborative environment, focused in particular on the elderly, through the collection of data from a questionnaire and interviews with health professionals. Finally, in Section 5, conclusions are drawn and referred future work.

 ISBN: 978-1-61208-597-5

II. SERIOUS GAMES IN THE REHABILITATION PROCESS

There are several definitions for serious games, but all have in common the fact that such games have an explicit educational purpose as their priority, rather than serving just for fun and entertainment [5]. However, this does not mean that such games are not or cannot be a form of entertainment [6]. Serious games can be used in various fields such as education, medicine, in the business environment and by the military community. It should be noted that one cannot apply any given game for rehabilitation purposes. As noted in [7], there are games, generally called "common games", that could be interesting for patients, but they present small therapeutic potential because they generally require rapid responses from the users or complex movements that the patient cannot perform at that moment, thus making their use impracticable. It is therefore necessary to adapt the game to the limitations of the patient [8]. In [9], it is expressed the need to customize the experience of the treatment and to make the game highly adaptable, either by means of algorithms that will adapt the game during the session or by the use of predetermined settings defined by the health professional before the session. Although it requires more development time, the real-time adaptive approach with algorithms can provide better results in motivating the patient, for it would be easier to identify his difficulties and modify the game to make it easier to play before it can cause frustration; in the same way, the algorithm could gradually increase the difficulty, for instance, when the game is too easy for the patient, so that he feels challenged and does not get tired of the activity [10].

The rehabilitation provided along a continuum of care ranging from hospital care to rehabilitation in the community [11] can improve health outcomes, reduce costs by shortening hospital stays [12], reduce disability, and improve quality of life [13]. Educating people with disabilities is essential for developing knowledge and skills for self-help, care, management, and decision-making. People with disabilities and their families experience better health and functioning when they are partners in the rehabilitation [4].

By using serious games therapy, it is possible to provide real-time visual feedback, besides offering a challenge to the patient and strategies that can increase his motivation by giving meaning to the movements being performed [14].

Depending on the necessary equipment, these games can be used by the patient even in the comfort of his own home. But, in order to avoid a complete lack of monitoring by a health professional, serious games can register the patient's performance and/or his movements, making the data available for further medical follow-up [10]. There are several serious games projects, some of them with quite impressive results in the recovery of functionality, while others have not yet had enough time to yield conclusive results, but have managed to please the patients [15]. Besides their entertainment value, serious games can have beneficial therapeutic effects for elderly people that improve their health and well-being.

As with other technologies, there has been an increased interest in serious games for elderly people over the last few years. This can be largely attributed to the worldwide increase in aging population. According to [16], the proportion of the world's population aged 60 years or over reached 12% in 2013 and this proportion is growing. As a result, we will have more elderly people needing healthcare and support services than ever before [3].

III. COLLABORATIVE ENVIRONMENT

With the development of information and communication technologies, new forms of training and knowledge transfer have emerged and are spreading. Knowledge is accessible anywhere, anytime. To access knowledge does not require being locked in a specific location at a specific time with a specific trainer [17].

The idea of computer supported collaborative learning has been investigated for the last few years. Since a few years, game-based approaches like video games for learning (Serious Games) offer new fields of application [18].

Collaborative environment is often defined by describing it as a construction of shared knowledge through activities with others, where the participants, patients, health professionals or others, are committed to or engaged in shared goals and problem solving. Thus, members of the group are not only engaged in individual activities but also in group interactions such knowledge sharing [19]. This environment offers the opportunity to create a highly social learning environment, characterized by participation and interactivity between elements, for example for both patients and health professionals.

In a collaborative learning environment, knowledge is shared or transmitted among users as they work towards common rehabilitation goals, for example, a shared understanding of the subject at hand or a solution to a problem. These environments offer an opportunity to build social networks linking different stakeholders. This may allow health professionals to use a serious gaming approach to combine the advantages of gaming-based learning with collaborative environments to support the rehabilitation process. However, there are many design challenges that must be addressed in the development of collaborative environments for rehabilitation.

The combination of serious games based learning concepts with collaborative learning may enable new methods. The design of such games, however, is challenging. The gameplay has to fulfill requirements of traditional games (fun, narration, immersion, graphics, sound) and serious games design (seamless inclusion of content, adaptation & personalization). Furthermore, requirements of collaborative environment have to be considered, like communication and a proper group setup [20].

The concept of collaborative learning is being used in various training scenarios today, ranging from mere group works over concepts like mutual teaching to collaborative working on complex projects. Whereas soft skills like the ability to work in teams and to communicate with group members are vital, they can be trained specifically by using collaborative learning principles. So, it seems promising to combine the concept of Serious Games with the concept of collaborative learning. Games, inherently offer many of the

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features which are necessary for collaborative learning to be successful, like common goals, or the necessity to communicate with fellow users [21].

IV. REQUIREMENTS AN COLLABORATIVE ENVIRONMENT

Making therapy sessions more fun is one of the factors that can contribute to patient compliance and improved rehabilitation outcomes. In this sense, a pleasant and focused environment in the area of therapy and the intended audience can complement the dynamics of the sessions.

Patients are not passive receptacles but are active in their process of rehabilitation as they participate in discussions, search for information and exchange opinions. In the same sense, health professionals seek information and exchange opinions with their peers in the area of therapy techniques. Knowledge is co-created and shared among peers. A collaborative environment should be a place where health professionals can participate in interactive rehabilitation sessions with patients in different therapies, as well as with other health professionals from different areas where it is possible to share knowledge about topics of interest, so that they can be help in community and contribute to an evolution of the process of rehabilitation.

After the study of several data, such as concepts and numbers associated with the rehabilitation process, a survey was conducted, with the collaboration of rehabilitation institutions and other professionals in this area of health, in Portugal, through a questionnaire distributed to people performing functions related to the rehabilitation process.

We conducted a questionnaire centered on health professionals with a total of 35 participants of ages between 22 and 46 years of both genders. At the same time, a series of meetings were held with health professionals in a total of 9 interviews. In this case, it is important to point out the importance of these direct contacts and through electronic mail that allow a greater knowledge of the existing reality and in this way a relevant contribution to the creation of the environments.

The purpose of the questionnaire is to characterize the type of needs currently in existence, to analyze opinions that health professionals, family members, patients and other elements related to this area. Through the study it is possible to check opinions and suggestions on existing applications and possible developments. The responses were translated into categories constructed based on the results obtained.

The questions presented were related to the use of Multidisciplinary Collaborative Platforms for rehabilitation purposes. For each of the affirmations, the agreement was asked to evaluate the agreement from 1 to 5, where 1 corresponds to "Strongly Disagree" and 5 to "Strongly Agree". If it was not known what to answer in any statement could indicate "I do not know". If the question does not apply you have been asked to check "Not applicable".

In general, the known platforms present a pleasant and attractive environment for the elderly, with 57.9% with positive levels (3, 4 or 5), emphasizing the 11.8% of higher agreement (levels 4 and 5).

They present good readability, clarity and consistency in an appropriate way to an elderly person, the opinion is shared by 42.1% of the respondents. This shows that there are still needs in presenting these types of environments and platforms for these resources.

Regarding the navigability of the technological tools used, only 42.1% of the professionals interviewed affirm that they are intuitive, simple and efficient. Asked about this fact they suggested as possible improvements resources for environmental control, such as letter increase, color, sound volume, messages with vocabulary, simple and easy, to be understood, possibility to configure the desired level of difficulty, since some tools used are of general use and not specific for rehabilitation.

In the opinion of these professionals, if the platforms used or known can arouse the attention of the elderly and maintain motivation throughout the use of the same, only 36.9% agree, indicating that it is a very specific public and which requires differentiated attention and care.

Only 26.3% of the participants in this questionnaire agree that the known environments are designed specifically for the elderly. However, 57.9% agree that platforms used or known contribute to the process of rehabilitation of the elderly.

In this study, it was also possible to understand that in the opinion of health professionals interviewed, older people have little formal training on how to successfully interact or work with others and that the social milieu of online activities is quite different from in-person interactions, thus requiring new skills and behaviors.

Table 1 displays the levels of agreement to the affirmations in the questionnaire described in this section.

TABLE I. LEVELS OF AGREEMENT TO THE AFFIRMATIONS

Questions **In general, the known platforms present:**	**1 / 2**	**3/ 4 / 5**	**Not know / Not applicable**
A pleasant and attractive environment for the elderly	10,5%	57,9%	31,6%
Present good readability, clarity and consistency	26,3%	42.1%	31,6%
They have intuitive, simple and efficient navigation	26,3%	42.1%	31,6%
They promote the attention and motivation of the elderly throughout their use	26,2%	36,9%	36,9%
Intended for the elderly	36,9%	26,3%	36,8%
They contribute to the process of rehabilitation of the elderly	10,5%	57,9%	31.6%

In addition to the questionnaire, we asked the participants to give feedback in form of critics or suggestions for improvement. The most frequently mentioned were:

- Exchange of opinions among specialists on the most appropriate forms and methods for the treatment of different pathologies (12 / 35)

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- Improvement of character control (10 / 35)
- Allow to adjust everything, for example, letter size, letter color, background color, visual contrast (10 / 35)
- Detailed information about each icon (9 / 35)
- Visual information complemented with auditory information (9 /35)
- Specificities for the study population with games of their interest and difficulty regulation (8 / 35)

New challenges for tools developed for this purpose, such as memory games, physical exercises for patients to do at home or in another place in a family environment, games that stimulate the sensitive and motor part of the patients, the latter ones that deserved more attention and comments.

While collaborative environments and their resources offer much promise for improving therapies outcomes, it is necessary to understand and explore the perceptions of these technologies from the viewpoint of health professionals working in rehabilitation. Numerous factors may influence a professional's decision to adopt this type of intervention in therapeutic practice. An analysis of serious games in rehabilitation revealed a possible of barriers to adoption, including concerns about how to design effective, efficient and easy-to-learn systems, challenges with platform compatibility, immature engineering processes, ethical challenges, limited awareness and unrealistic expectations by therapists, and perceptions this use eliminates the need for therapists [22][23]. These concerns were also mentioned throughout the interviews for this study.

Table 2 displays the concerns and favorable elements mentioned throughout the interviews.

At the end of the interviews and in order to explore the therapists' perceptions, the author presents his ideas about potential technological tools in order to address their needs.

TABLE II. CONCERNS AND FAVORABLE ELEMENTS

Barriers	Facilitators
Increased complexity	Motivation
Older people have little formal training of online activities	Different and customizable interactive sessions
Platform compatibility	New skills and behaviors
Perceptions this use eliminates the need for therapists.	Exchange of opinions among specialists

To date, some research has examined these professionals' views and acceptance of available or rehabilitation-specific gaming technology as interventions [24][25]. Because heath professionals are instrumental in mediating patients' use of technology for rehabilitation, it is pertinent to understand their perceptions. If their views are not understood or incorporated in the development of these technology-based interventions, use may be limited [22]. Thus, one of the purposes of this study were to health professionals perceptions of how use gaming technology in rehabilitation and to identify barriers to the use of these technologies in rehabilitation.

According to Tatla et al. [22], therapists are the key stakeholders who determine the appropriateness of interventions, designing and implementing rehabilitation programs by combining their clinical reasoning with the needs and preferences of their clients. Through this process, they tailor interventions to meet the unique needs of each patient, modify the challenge and difficulty as the client's abilities change, and respond flexibly to the patient's learning and performance needs [26]. These studies indicate the complexities of implementing new technologies in therapy. Despite reporting several challenges with serious games adoption, health professionals interviewed and questioned were open to helping shape the development of serious games and collaborative environments for rehabilitation. Moreover, as an advantage of these tools, they refer to the possibility of increasing adherence to exercise programs against traditional therapy programming.

There is preliminary evidence to suggest positive effects of using a gaming environment compared to conventional therapy [27][28][29]. Several studies have explored the application of technology to promote rehabilitation outcomes [30][31][32].

The collaborative environment should function in such a way that a participant who uses it is aware of the presence of other participants. This puts special emphasis on how participants can contact each other through the use of the system, and how they can keep track of each other's activities and comments and work.

Rehabilitative therapy is usually very expensive and confined to specialized rehabilitation centers or hospitals, leading to slower recovery times for corresponding patients. Therefore, there is a high demand for the development of technology-based personalized solutions to guide and encourage patients towards performing online rehabilitation program that can help them live independently at home [33].

At the end of the interviews, a suggestion of a structure design for a collaborative platform of serious games applied to rehabilitation was presented for discussion, having as a concern its use in elderly people. This environment would be composed of several modules in order to provide a useful tool for its purpose. The "configuration module" of personal needs, such as color and size, was referred by some therapists as interesting and a possible starting point for customizing and motivating patients to their use.

The "presentation module" contains global functions such as the personal area and areas of intervention. The "communication module" contains proximity tools such as email, forum and other relevant elements. It's a module made up of usage data. The "intervention area module" can be customized according to the needs of the patient and type of rehabilitation, cognitive or physical, with connection to the resources module that has adaptive tools such as serious games and exercises. The latter have aroused a greater interest in therapists because, in their opinion, they are possible complementary tools to the conventional treatment.

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Table 3 displays a simple view to the suggestion of structure design for a collaborative platform of serious games applied to rehabilitation.

TABLE III. SUGGESTION OF STRUCTURE DESIGN COLLABORATIVE (SIMPLE VIEW)

Module	Topics
Configuration	Personal Needs • Color • Size
Presentation	Global Functions • Personal Area • Areas of Intervention
Communication	Proximity Tools • Email • Forum • Others
Data	Data Base
Intervention	Cognitive Rehabilitation • Memory Physical Rehabilitation • Mobility
Resources	Adaptive Tools • Serious Games • Exercises

V. CONCLUSIONS AND FUTURE WORK

Today's society is turning into a digital society, with the growing influence of the technology in our daily lives. It is present in so many places, sometimes without people realizing it, that being already frequent is considered natural. This society increasingly directs its attention to new technologies, fostering their development and reaching a closer approximation of knowledge, making it increasingly accessible to all.

With this study we conducted an opinion survey through questionnaires and interviews with health professionals in this area, in order to verify opinions and suggestions about existing applications and possible developments. The research topic arises from the concern to understand and adapt the use of technologies for rehabilitation. There are some concerns that a collaborative environment must have to support the most relevant and attractive aspects of the elderly public.

Future work aims to relate the rehabilitation process of the patient to the existing technological means and to investigate how that relationship can contribute to a more effective solution in the rehabilitation process, since there are a number of concerns, especially related to the patient's motivation, as well as enabling better communication throughout the process between health professionals and patients.

Contributions that are using the new technologies, with emphasis on collaborative environments and serious games, aim to create added value and better understand the evolution of the process. Keeping healthy is another interest. We felt that offering technologies which would motivate exercising would be a big asset to the users of this group.

The study and design of technologies continue to increasingly provide more specific tools. As a result, we are developing a prototype of a collaborative environment, using serious games that meet the needs, especially concerning the elderly, such as allowing patients to carry out the rehabilitation process in more familiar environments under the supervision of health professionals, but without the need to commute regularly to rehabilitation centers. The study of the prototype also aims to offer new contributions, such as multiple resources in adaptive environments, improve communication between patient and therapist, as well as being a facilitator of rehabilitation with evolution data and different exercises. Several studies have demonstrated that by offering virtual rehabilitation exercises as games, greater efficiency is obtained in the rehabilitation process, and the patients are motivated to perform the rehabilitation exercises and their adherence to the treatment is also greater.

REFERENCES

[1] S. Andrew, “Introduction to biomedical engineering: chapter 5 - rehabilitation engineering and assistive technology”, 2nd ed., Elsevier, USA, 2011.

[2] United Nations, Department of Economic and Social Affairs, Population Division. World Population Ageing 2013. ST/ESA/SER.A/348, 2013.

[3] H. Nguyena, et al., “Impact of Serious Games on Health and Well-being of Elderly: A Systematic Review”, Proceedings of the 50th Hawaii International Conference on System Sciences, pp. 3695-3704, Waikoloa, Hawaii, 2017.

[4] World Health Organization, “Concept paper: WHO guidelines on health-related rehabilitation (rehabilitation guidelines)”, Switzerland, 2014.

[5] M. Minhua, A. Oikonomou and J. C. Lakhmi, “Serious games and entertainment applications”, Springer London, 2011.

[6] D. R. Michael and S. Chen, Serious games: games that educate train and inform, Thomson Course Technology, 2006.

[7] E. Flores, et al., “Improving patient motivation in game development for motor deficit rehabilitation”, ACE’08 Proceedings of the 2008 International Conference on Advances, pp. 381-384, Japan, 2008.

[8] N. Hocine, A. Gouaich, I. Loreto and L. Abrouk, “Techniques of adaptation in games playful and serious”, Revue d’Intelligence Artificielle, vol. 25 (2), pp. 253-280, France, 2011.

[9] N. Hocine and A. Gouaich, “Therapeutic games difficulty adaptation: an approach based on player’s ability and motivation”, 16th International Conference on Computer Games, pp. 257-261 Louisville, 2011.

 ISBN: 978-1-61208-597-5

[10] A. Gouaich, N. Hocine, L. V. Dokkum and D. Mottet, "Digital-pheromone based difficulty adaptation in post-stroke therapeutic games", Proceedings of the 2nd ACM SIGHIT International Health Informatics Symposium, pp. 5-12, Miami, 2012.

[11] G. Stucki, J.D. Reinhardt and G. Grimby, "Organizing human functioning and rehabilitation research into distinct scientific fields, part II: conceptual descriptions and domains for research", Journal of Rehabilitative Medicine, vol. 39 (4), pp. 299-307, European Board of Physical and Rehabilitation Medicine, 2007.

[12] A. Rauch, A. Cieza and G. Stucki, "How to apply the international classification of functioning disability and health (ICF) for rehabilitation management in clinical practice", European Journal of Physical Rehabilitation Medicine, vol. 44 (3), pp. 329-342, 2008.

[13] E. J. Davies, "Exercise based rehabilitation for heart failure", Cochrane Database of Systematic Reviews, 2010.

[14] J. Burke, M. Mcneill, et al., "Optimising engagement for stroke rehabilitation using serious games", The Visual Computer, England, 2009.

[15] C. Moritz, et al., "Neurogame therapy: neurogame therapy for improvement of movement coordination after brain injury - developing a wireless biosignal game therapy system", 2011 IEEE Global Humanitarian Technology Conference, pp. 72-77 Seattle, 2011.

[16] U. N. (United Nations), Department of Economic and Social Affairs, Population Division (2013). World Population Ageing 2013.

[17] S. Cooper and M. Sahami, "Reflections on Stanford's MOOCs", Communications of the ACM, vol. 56 (2), pp. 28-30, 2013.

[18] V. Wendel, M. Gutjahr, S. Gobel and R. Steinmetz, "Designing Collaborative Multiplayer Serious Games", Education and Information Technologies, vol. 18, Issue 2, pp. 287-308, Springer, June 2013.

[19] K. Oksanen, "Serious Game Design: Supporting Collaborative Learning and Investigating Learners' Experiences", Finnish Institute for Educational Research, University of Jyväskylä, Finland, 2017.

[20] C. Reuter, V. Wendel, S. Göbel and R. Steinmetz, "Multiplayer Adventures for Collaborative Learning With Serious Games", Patrick Felicia: 6th European Conference on Games Based Learning, pp. 416-423, Academic Conferences Limited, October 2012.

[21] V. Wendel et al., "Designing a Collaborative Serious Game for Team Building Using Minecraft", Proceedings of the 7th European Conference on Games-Based Learning, vol. 2, pp.569-578, October 2013.

[22] S. K. Tatla, et al., "Therapists' Perceptions of Social Media and Video Game Technologies in Upper Limb Rehabilitation", JMIR Serious Games, vol.3, Issue 1:e2, 2015.

[23] A. Rizzo and G. J. Kim, "A SWOT Analysis of the Field of Virtual Reality Rehabilitation and Therapy", Presence: Teleoperators and Virtual Environments, vol. 14, Issue 2, pp. 119-146, April 2005.

[24] S. M. N. Glegg, et al., "Factors influencing therapists' adoption of virtual reality for brain injury rehabilitation", Cyberpsychol Behav Soc Netw, vol. 16, Issue 5, pp. 385-401, May 2013.

[25] B. A. Walker, "Understanding the acceptance and use of virtual gaming as an intervention strategy with older adults in occupational therapy", Dissertations & Theses – Gradworks, Indiana University, 2012.

[26] D. E. Levac and J. Galvin, "When is virtual reality "therapy"?", Arch Phys Med Rehabil, vol. 94 (4), pp.795-798, April 2013.

[27] G. Saposnik and M. Levin, "Virtual reality in stroke rehabilitation: a meta-analysis and implications for clinicians", Outcome Research Canada (SORCan) Working Group, Stroke, vol. 42 (5), pp. 1380-1386, May 2011.

[28] K. Laver, et al., "Use of an interactive video gaming program compared with conventional physiotherapy for hospitalised older adults: a feasibility trial", Journal Disability and Rehabilitation, vol. 34 (21), pp. 1802-1808, March 2012.

[29] J. A. Gil-Gómez, R. Lloréns, M. Alcañiz and C. Colomer, "Effectiveness of a Wii balance board-based system (eBaViR) for balance rehabilitation: a pilot randomized clinical trial in patients with acquired brain injury", Journal of NeuroEngineering and Rehabilitation, vol. 8 (30), May 2011.

[30] K. E. Laver, S. George, S. Thomas, J. E. Deutsch and M. Crotty, "Virtual reality for stroke rehabilitation, Cochrane Database Syst Rev, February 2015.

[31] K. Lohse, N. Shirzad, A. Verster, N. Hodges and H. F. M. Van der Loos, "Video games and rehabilitation: using design principles to enhance engagement in physical therapy", J Neurol Phys Ther, vol. 37 (4), pp. 166-175, December 2013.

[32] J. H. Crosbie, et al., "Virtual reality in the rehabilitation of the arm after hemiplegic stroke: a randomized controlled pilot study", Clinical Rehabilitation, vol. 26 (9), pp. 798-806, September 2012.

[33] I. Afyouni, et al., "A therapy-driven gamification framework for hand rehabilitation", User Model User-Adap Inter, vol. 27 pp.215-265, 2017.

[34] J. E. Brindley, C. Walti and L. M. Blaschke, "Creating Effective Collaborative Learning Groups in an Online Environment", The International Review of Research in Open and Distributed Larning, vol. 10 (3), 2009.

[35] M. J. Johnson, R. C. V. Loureiro and W. S. Harwin, "Collaborative tele-rehabilitation and robot-mediated therapy for stroke rehabilitation at home or clinic"Intel Serv Robotics, vol.1 pp.109-121, 2008.

[36] H. Barbosa, H. Leal; A. C. Vieira and E. Carrapatoso, "Games and Exercises Applied to Rehabilitation Adaptable Environments for Mobility of Elderly People and/or People With Low Mobility", International Journal of Scientific and Engineering Research, vol.7 (10) pp.1172-1175, 2016.

[37] H. Barbosa, A. C. Vieira and E. Carrapatoso, " Exercises and Serious Games Applied to the Rehabilitation for Older Adults", Proceedings of the Portuguese Association for Information Systems Conference, pp. 354-361, Guimarães, 2017.

 ISBN: 978-1-61208-597-5

CIPROS – An Instrument for Evidence-based Evaluation of EDC Systems and the DBFORM Example

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***Abstract*—The success of medical research projects depends on efficient and powerful information systems. To assess the needed range of functionalities of such systems, we developed the evidence-based Checklist with Items for Patient Registry sOftware Systems (CIPROS), consisting of 72 items, organized within 12 aspects/topics. In this paper, we demonstrate how CIPROS can be used to assess the functionality of an information system. To this end, we evaluated an in-house Electronic Data Capture (EDC) system DataBase FORM generator (DBFORM). The assessment is helpful for project managers and medical scientists to select EDC systems for their own projects. The assessment may also help system developers to assess their systems and inspire them to develop new features. It may also be an efficient tool to evaluate research proposals with respect to the suitability of the selected software.**

Keywords-Information Systems; Software; Checklist; Evaluation.

I. INTRODUCTION

Efficient information systems are essential to successfully perform medical research projects such as clinical trials and medical registries. Various commercial and open-source Electronic Data Capture (EDC) systems support biomedical researchers handle complex data collections. Academic institutions often develop systems in-house in order to accommodate changing requirements. But provide existing information systems sufficient functionalities which are needed in innovative research projects?

An instrument to assess the range of functionalities of register systems is the Checklist with Items for Patient Registry sOftware Systems (CIPROS), consisting of 72 items, organized within twelve aspects/topics [1]. The CIPROS checklist was developed to evaluate existing information systems. While the evaluation has to be done in cooperation with the system specialists the result indicates to the medical scientist how appropriate the system may be for a planned project. A special elaboration paper in which each item is explained and enhanced with examples is prepared which can help to perform the systems assessment [2].

In contrast to common generic Software Requirements Specification (SRS) templates [3]-[5] or standards [6] available for developing software systems for all fields and considering the different steps which must be done in software engineering, CIPROS is a comprehensive assessment tool specifically designed for the evaluation of patient registry software systems and the specification of requirements for patient registry software systems. The evaluation can be done in a few hours or less.

Since requirements engineering is also essential in the medical domain [7], it is of interest, that the evaluation is done by applying a domain specific requirements engineering process.

The purpose of this paper is to demonstrate the use of the CIPROS checklist in assessing a registry system and how the assessment can be used to plan downstream developments of a system. We apply it to assess our in-house EDC system DataBase FORM generator (DBFORM), which has been used to implement medical research projects in recent years.

In Section 2, RELATED WORKS, the in-house developed EDC system DBFORM is presented and some projects in which DBFORM has been used are introduced. In Section III, METHODS, we first introduce the evidence-based CIPROS checklist and then the way the evaluation of the EDC system DBFORM with the CIPROS checklist was done is described. Section IV, RESULTS AND DISCUSSION, first presents the results of this evaluation. Then results are discussed, as well as the implementation of special items in special projects. Section V, CONCLUSION AND FUTURE WORK, gives a conclusion of this work and an outlook to the next planned steps.

II. RELATED WORKS

In this section we first introduce the in house developed electronic Case Report Form (eCRF) system DBFORM. Then we describe some projects in which the DBFORM system is used to complement the IT infrastructure of the projects.

A. The EDC System DBFORM

The system was first described in 2002 [8] and its functionality has been extended and adapted during the

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following years to the specific requirements of several research projects. In brief, the core system provides a generic implementation of EDC functionality for a variety of data types, including unstructured text, numeric data, coded data, and other more structured types. Major components of DBFORM are a generic configurable web forms generator (dbform.cgi) and a form compiler (ddict.pl) that derives the appropriate configuration data from a tabulated data dictionary. The form generator runs on a platform providing a webserver and DataBase Management System (DBMS) environment. Specifically, Linux, Apache [9], and PostgreSQL [10] are used, but other environments are possible. The major implementation programming language is Perl [11]. A schematic overview of the DBFORM system and how it is used in a project is shown in Fig. 1.

The basic DBFORM project environment consists of development systems and a live (or production) system with nearly the same structure. Each type of system can accommodate multiple DBFORM instances for separate EDC projects. The development systems should be connected to a Common Software Repository (CVS). The deployment process is automated. The system developer develops the core system functionalities, while the project developer develops the project-specific functionalities and communicates with the users.

One of DBFORM's key features is its extensibility via a number of interfaces. In several instances data dictionary entries can call on other resources to perform additional processing, for example as SQL or JavaScript phrases, or via a shell-like environment providing access to any other programming language. While DBFORM computes its own form layout for convenience, overrides can be taken from custom HTML/JavaScript templates. These tools allow adaption to project-specific requirements, albeit at different levels of expertise. The basic project development requires managing the data dictionary according to the specifications in the DBFORM documentation. The following paragraphs describe several instances of this adaptability.

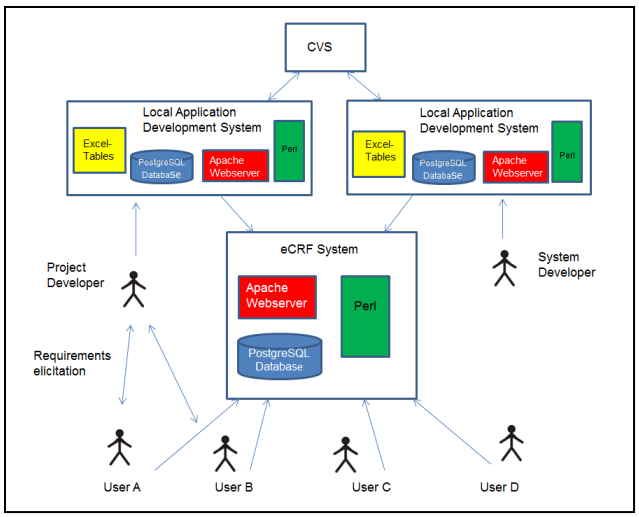

Figure 1.A schematic overview of DBFORM used in a data capture project.

B. *The EUTOS Population-based registry*

The EUropean Treatment and Outcome Study (EUTOS) Population-based registry collected baseline, treatment, and outcome data from patients with Chronic Myeloid Leukemia (CML) across Europe [12][13].

Part of the requirements called for a differentiated access authorization scheme for clinical centers in various countries. Role-based authorization is included in DBFORM's core functionality and can be configured in the data dictionary. Furthermore, we complemented DBFORM with an extension to manage offline-generated queries to support this project. The queries were imported into the system ready to be processed online. Implementation made use of the "report"-programming interface, originally intended for reports, but suitable for any additional arbitrary functionality.

The extension of DBFORM with the query module is shown in Fig. 2.

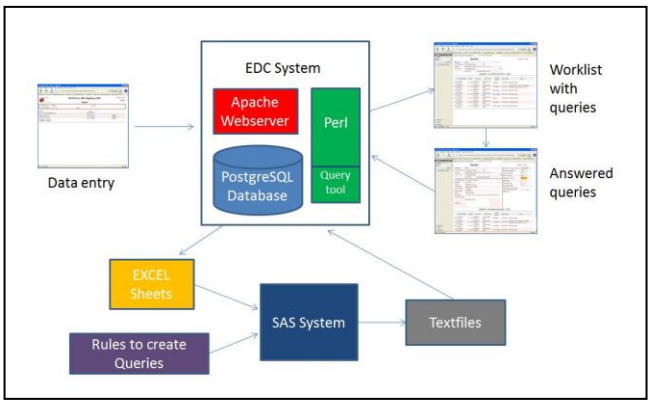

Figure 2.Extension of DBFORM with an automatic Query module.

Initially, the captured data is extracted from the database and verified offline using a SAS software system according specific rules. The query information is stored in a simple tabular format in text files. These are uploaded into the query tool of the EDC patient registry software system. Each query consists of a unique number, a query text with a question about the variable, and the corresponding unit. It is also possible to add new queries during the project. A worklist of queries can be executed by the study groups. The correct replies will be adopted automatically in the database and the query will be removed from the worklist. The described online query module is an efficient tool to communicate a large number of queries at low cost.

Fig. 3 shows a Query screenshot. The wrong value is highlighted. When the Query is answered the correct value will be inserted automatically in the database.

C. *The BreathEase study*

The BreathEase study was designed to evaluate palliative care in support of patients with respiratory distress. Participating patients were visited and interviewed by a study nurse in their homes using a variety of questionnaires. The responses were documented in an offline instance of DBFORM, residing on a notebook computer as a mobile system. In this case, the challenge consisted of providing a

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means to update the mobile "slave" systems and stationary "master" system with the study nurse's assignment details and questionnaire responses.

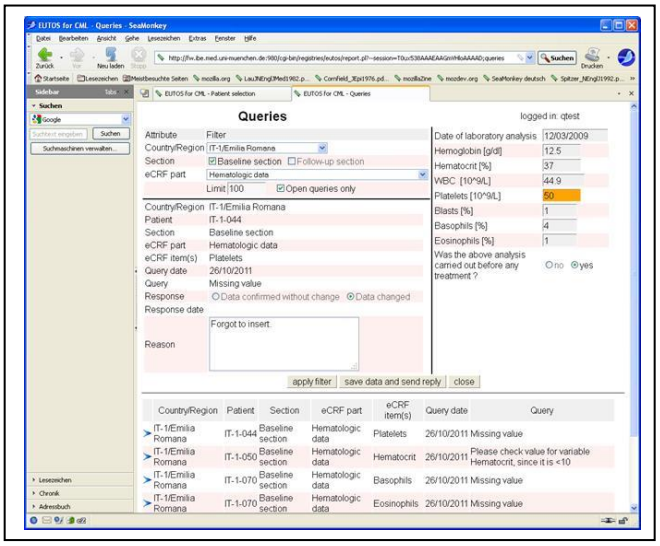

Figure 3.A selected Query with answer and reason.

The BreathEase implementation was based on a generic synchronization module that can be configured by a special part of the data dictionary.

The additional functionality is found in the web application's patient selection or “home” menu as shown in Fig. 4.

Most clinical research projects can be documented with this repertoire of automatically generated layouts: lists, plain forms, and overview forms. In addition, more specific combinations and options are available.

Fig. 5 shows an example of an ordinary questionnaire or Case Report Form (CRF), documenting the patients Integrated Palliative Outcome Scale (IPOS).

D. *The HTCR project*

Two instances and two major extensions were necessary to fill the requirements of the bio-banking project HTCR [14]. The first is related to identifying and characterizing biomaterial samples, i.e., including it in the data model as a separate entity.

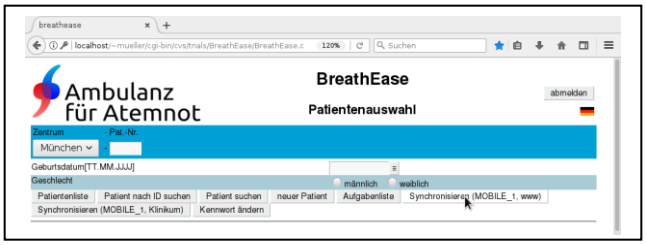

Figure 4.This is the user's root menu where all tasks begin. The mouse pointer marks the button triggering the synchronization process.

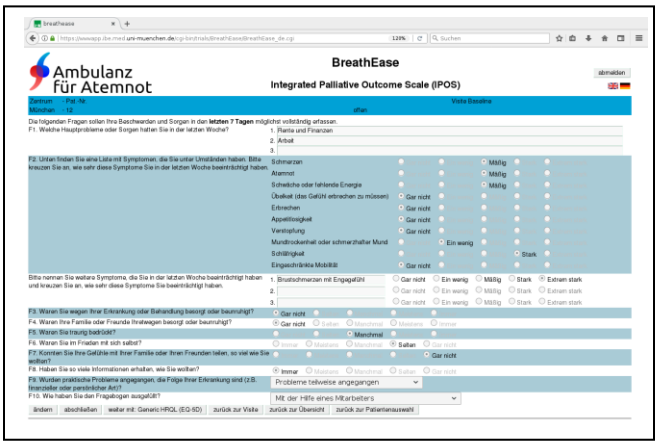

Figure 5.A questionnaire that is part of the “Baseline” documentation.

The second enhancement is related to data protection requirements, and consists of separating identification data and medical data into two separate databases. These are linked using a common arbitrary key and an encrypted version as a logical link between corresponding records. This link can only be accessed by authorized users of both datasets, thus providing additional privacy protection. Again, logical links were implemented as an extension subject to configuration in the respective data dictionaries.

E. *The PASTURE project*

The PASTURE project [15] investigated the conditions for allergy development during childhood in four different countries and required three different languages (Finnish, French and German), as well as English as the common language. While translated forms are part of the DBFORM core functionality, site-specific questionnaire dependencies and fixups at the template level were needed to correctly implement some of the country-specific variants (e.g., slightly different questions asked, different units of measure, etc.) of the questionnaires used.

F. *The RESIST study*

The RESIST study is a translational research project using xenograft mouse models to find an individualized therapy for secondary resistance for colorectal carcinoma patients. The RESIST study consists of two parts. The first part is a registry for an avatar model. Patients are registered and have to agree to give a tumor tissue sample to be used in the avatar model. The second part is the clinical study. Special challenges in this project are the combination of the two studies with clinical and biomedical data, the collaboration of different user-groups, and a sophisticated data protection model. We extended DBFORM to provide various pseudonyms.

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III. METHODS

In this section we first introduce the evidence-based CIPROS checklist. Then we describe how the CIPROS checklist is used to evaluate the DBFORM system.

A. The evidence-based CIPROS checklist

CIPROS is an evidence-based checklist, to assess patient registry software systems [1]. It consists of 72 items, organized within twelve aspects/topics. The CIPROS checklist was developed after an initial Systematic Literature Review (SLR) in PubMed. The papers were analyzed using Qualitative Content Analysis (QCA) methods published for social research [16] and adapted to the field of patient registry software systems. In an iterative process the items were assorted in the CIPROS checklist.

In this paper we describe the use of CIPROS to evaluate the in house developed EDC system DBFORM.

B. Evaluation of the EDC system DBFORM with CIPROS

The evaluation was performed by two raters (DL and TM). First, each rater evaluated DBFORM with the CIPROS items independently. Each item of the CIPROS checklist was considered and whether or not the item was implemented in DBFORM or not. The evaluation showed that a simple yes/no answer is not for all items possible. Some items are implemented fully in DBFORM and some are not. Some items are implemented for individual projects, while a few items are only partly implemented. Other items can be configured for special projects, if necessary. Both raters discussed their results and reached an agreement in the answers for all items. For some items it was easy to find an answer, while other items needed to be discussed to find an appropriate answer. In the latter case it was very helpful to refer to the elaboration paper [2] and review the item to clarify the meaning of the item.

In order to avoid misunderstandings, and for unambiguous assignment, we recommend using the full CIPROS checklist [1] in the evaluation where each item is described and not just the Aspect/Topic list, as shown in Table I. If there are still ambiguities in special items, we recommend using the elaboration paper [2], in which each item includes examples from the literature and explanations by the authors, for the evaluation.

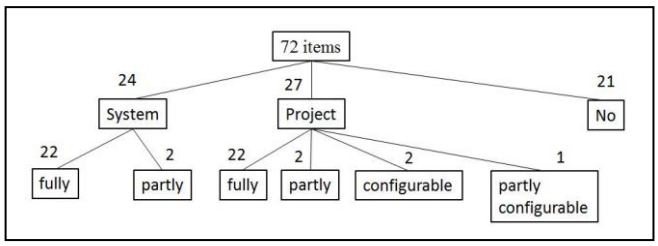

Figure 6.Evaluation result of the EDC system DBFORM with CIPROS.

IV. RESULTS AND DISCUSSION

In this section we first present the cumulative evaluation results and the detailed results for each item. Then we give further insights in the implementation of the items and discuss them.

A. Overall evaluation results

The evaluation of DBFORM shows substantial conformity with CIPROS. Compliance is achieved in 44 out of 72 items: 22 are fully implemented in the system and another 22 are implemented at the project level.

In four items DBFORM agrees partly with CIPROS, two are implemented partly in the system and two are implemented partly in projects. Two items can be configured in projects and one item can be configured partly at project level. Only 21 items of CIPROS are not available in DBFORM. The evaluation result is shown in Fig. 6.

The overall result of the evaluation for each CIPROS item is shown below in Table I. Because of the limited space only the Aspect/Topic and the Item-No., of each item and the corresponding result if it is implemented in DBFORM or not is listed. For a description of each item we refer to the full CIPROS checklist [1].

If the item is fully implemented in the DBFORM system, the answer is “Yes, System” if it is implemented for special projects, the answer is “Yes, Project”, if the item is partly implemented the answer is “Partly System” or “Partly, Project”, respectively. If it is not implemented, the answer is “No”, if the item is configurable for Projects it is stated with “Conf. Project”.

A summary of the items by the possible answers is given in Table II. The first column contains the possible evaluation answers for the items. The second column contains the item numbers and the third column gives the summary number of the items for this answer.

B. Features generally implemented in DBFORM

Here we describe shortly the items which are generally implemented in the system DBFORM.

DBFORM provides a multi-tier system architecture and a framework for the development of new projects. DBFORM also provides a table-based questionnaire builder. The framework supports early field tests. The system provides a web-interface which is compatible with the major web-browsers. In addition E-mail alerts are possible. The system provides a programming interface with third-party access and an Application Programming Interface (API) for inserting and retrieving data. Extensibility is possible. All data types are supported in the system. The system has an interface for a manual data check. Datasets can be downloaded, complete or selected cohorts only. The system has a role-based authorization module and supports encrypted data transfer. All changes are documented in an audit trail. The server is behind a firewall and located in a server room. The costs are controlled, because we have to pay no license costs for the system.

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TABLE I. EVALUATION OF THE EDC SYSTEM DBFORM WITH THE CIPROS ITEMS.

Aspect / Topic	Item-No.	In DBFORM implemented
System Architecture	1.1	Yes, System
Platform independence	1.2	No
Open Source	1.3	Partly, System
Design model	2.1	No
Framework-based design	2.2	Yes, System
Questionnaire builder	2.3	Yes, System (table-based)
Usability testing	2.4	Yes, System
Performance testing	2.5	Partly, Project (estimated)
Web Interface	3.1	Yes, System
Compatibility	3.2	Yes, System
Email-alert	3.3	Yes, System
Messaging interface	3.4	Yes, Project
Online discussion forum	3.5	No
Mobile interface	3.6	Partly, Project (offl. No app)
Patient interface	3.7	No
Third party access	3.8	Yes, System
API for inserting data	3.9	Yes, System
API for retrieving data	3.10	Yes, System
Data update mechanism	3.11	Yes, Project
Interface to HIS / CIS	3.12	No
Integration of biological data	3.13	Yes, Project
Extensibility is possible	3.14	Yes, System
CRFs	4.1	No
Data	4.2	No
Metadata	4.3	No
Vocabularies	4.4	No
XML Schema	4.5	No
Multilingualism	5.1	Yes, Project
Pseudonymous patient identifier	6.1	Yes, Project
CRF is divided in parts	6.2	Yes, Project
Customizable CRF parts	6.3	Yes, Project
Minimal and extended dataset	6.4	Yes, Project
All data types are supported	6.5	Yes, System
Special data types are possible	6.6	Yes, Project
Multiple choice is used	6.7	Yes, Project
No predefined selection	6.8	Yes, Project
Data validation components	6.9	Yes, Project
Data query tool	6.10	Yes, Project
Interface for manual data check	6.11	Yes, System
Manual data queries	6.12	No
Data Query Flags	6.13	No
Plausibility Flags	6.14	No
Insertion of unplanned visits	6.15	Yes, Project
Software ergonomics	6.16	Partly, System
Query builder for researchers	7.1	No
Report generation	7.2	No
Download of datasets	7.3	Yes, System
Graphical Presentation of results	7.4	No
Risk Analysis	7.5	No
Authorized users	8.1	Yes, System
Role-based access	8.2	Yes, System
Encrypted data transfer	8.3	Yes, System
Encrypted data storage	8.4	No
Audit trail	8.5	Yes, System
Master-Slave replication	8.6	Conf.,Project
Backup management	8.7	Yes, System
Firewall	8.8	Yes, System
Server room	8.9	Yes, System
Data Protection concept	9.1	Yes, Project
Double pseudonymization	9.2	Conf., Project
Costs	10.1	Yes, System (no licence costs)
Multi-client capability	10.2	No
Update mechanism	10.3	No
Source documentation in pdf	10.4	No
Compliance with regulations	11.1	Yes, Project
Informed Consent	11.2	Yes, Project
Rights on the data	11.3	Yes, Project
Data protection guidelines All	11.4	Yes, Project
User manuals	12.1	Yes, Project
User training	12.2	Yes, Project
User feedback	12.3	Yes, Project
Online help	12.4	Partly conf., Project

 ISBN: 978-1-61208-597-5

TABLE II. SUMMARY OF THE EVALUATION OF DBFORM WITH CIPROS.

Is the Item implemented in DBFORM?	Item numbers	∑
Yes, System	1.1, 2.2, 2.3, 2.4, 3.1, 3.2, 3.3, 3.8, 3.9, 3.10, 3.14, 6.5, 6.11, 7.3, 8.1, 8.2, 8.3, 8.5, 8.7, 8.8, 8.9, 10.1	**22**
Yes, Project	3.4, 3.11, 3.13, 5.1, 6.1, 6.2, 6.3, 6.4, 6.6, 6.7, 6.8, 6.9, 6.10, 6.15, 9.1, 11.1, 11.2, 11.3, 11.4, 12.1, 12.2, 12.3	**22**
Partly, System	1.3, 6.16	**2**
Partly, Project	2.5, 3.6	**2**
Configurable, Project	8.6, 9.2	**2**
Partly configurable, Project	12.4	**1**
No	1.2, 2.1, 3.5, 3.7, 2.12, 4.1, 4.2, 4.3, 4.4, 4.5, 6.12, 6.13, 6.14, 7.1, 7.2, 7.4, 7.5, 8.4, 10.2, 10.3, 10.4	**21**
		72

C. Features partly fulfilled in DBFORM

Open-source components are used to create DBFORM but it is not yet made open-source, so this item is only partly fulfilled. Software ergonomics, defined in ISO 9241-110 are only partly fulfilled in DBFORM, because they are mostly dependent on the implementation of web-forms for the special project.

D. Features implemented in DBFORM in special Projects

In this sub-section, we describe the items which are implemented in special projects. This generally indicates that while the feature is not strictly part of DBFORM, there is an appropriate configuration or at least a workaround to obtain a satisfactory result.

Many of the Project items are fulfilled in several projects. For example item 6.1, pseudonymous patient identifier, is implemented in several projects, for example in EUTOS and in RESIST. Also item 6.2, CRF is divided in parts, item 6.5, all data types are supported, item 6.7, multiple-choice is used, and item 6.8, no predefined selection, are used in EUTOS and in RESIST. Also the regulatory items 11.1, compliance with regulations, 11.2, informed consent and 11.4, data protection guidelines, are fulfilled in EUTOS and in RESIST.

1) The EUTOS Population-based registry

In the EUTOS population-based registry we implemented an automatic query tool to perform queries as explained in Fig. 2. This enhancement is implemented in the system at the project level. The questions can be answered by the users and the given results were automatically inserted into the database, so Items 3.11 and 6.10 of CIPROS are implemented in EUTOS with this feature. We have also a messaging interface in EUTOS to send messages to the users, this fulfilled item 3.4. Item 6.15, insertion of unplanned visits is also implemented in EUTOS, since it was necessary to collect the results of all performed cytogenetic and molecular samples.

Since EUTOS was a pan-European project with many participants we held a user training session at the study start. We also provided a user manual and collected user feedback. Hence the items 12.1, 12.2 and 12.3 of CIPROS are implemented in EUTOS.

All participating study-groups had the right to access their own data at any time during the project phase from the central database by placing a request via the project manager. With this statement item 11.3 was fulfilled in EUTOS. In the EUTOS population-based registry we had many study-groups and users, we determined the performance of the system before we started, so item 2.5 performance testing was estimated in this project.

2) The BreathEase study

The mobile system used in the BreathEase study to collect the answers from the patients needed to be synchronized with the central database. The synchronization mechanism was implemented as a DBFORM extension subject to configuration in the data dictionary [17]. So with this study item 3.6, mobile interface, from the CIPROS list was partly fulfilled. This means that data can be collected offline and integrated in the central database at a later time, however, there is no special app for mobile phones.

3) The HTCR project

Due to the implementation of an identification module of biomedical data and a special privacy model item 3.13, integration of biological data and item 6.1, pseudonymous patient identifier are fulfilled within this project [18]. Identification data and medical data are stored in two separate databases. Corresponding records are linked using a common arbitrary key and an encrypted version as a logical link, which can only be accessed by authorized users.

4) The PASTURE project

DBFORM supports multilingualism, which means that the complete eCRF can be displayed in different languages. Since this study was performed in Germany, France, and Finland, all items were translated and inserted in different languages in addition to English. The user can select the language in which the eCRF will be displayed. With this feature item 5.1, multilingualism, of CIPROS is fulfilled.

5) The RESIST study

In the RESIST study a sophisticated data protection concept was established, this included double pseudonymization. DBFORM was enhanced to support this data protection concept [19]. A schematic overview how the role-based access and the double-pseudonymization with different identifiers for different users were implemented is shown in Fig. 7. The users in the clinics have access to the medical data with a Patient IDentifier (PID). They retrieve the tumor_no and send it with the tumor to the pathology. The users in the pathology have access to the molecular tumor analysis data with the tumor_no. They are able to retrieve the av_no and send a tumor sample with this av_no to the laboratory with the AVATARMODEL.

 ISBN: 978-1-61208-597-5

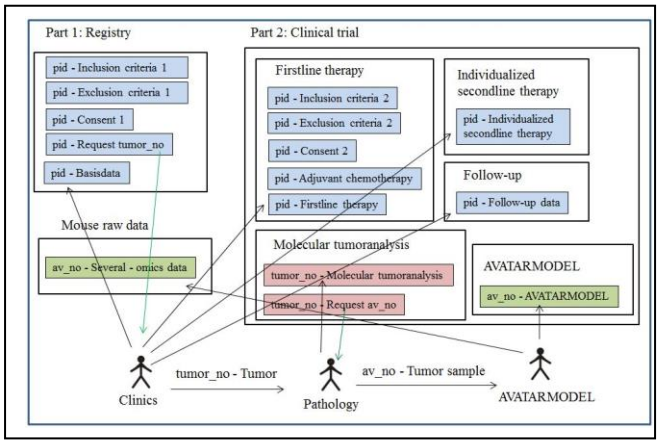

Figure 7.Simplified data model of the RESIST study.

The users in the AVATARMODEL have access to the data in the AVATARMODEL with the av_no. Using this mechanism the data is strictly separated through different identifiers for different users and role-based user access. So in this project, beside other items mentioned before, items 9.1 and 9.2 of CIPROS are fulfilled.

6) Influence of the project features for CIPROS

Since some projects were performed before the CIPROS checklist was developed, the project features also influenced the development of the CIPROS checklist by bringing own experiences into the development of the CIPROS items. For example item 6.10 Data query tool, was implemented in the EUTOS Population-based registry and then introduced in the CIPROS checklist as own experiences.

The mobile interface which was implemented in the BreathEase study is also part of the CIPROS checklist, but this item is not solely based on own experiences, since it was also found by the SLR.

E. Configurable Features

Item 8.6, Master-slave replication is not yet implemented but it is configurable, the same applies to item 9.2, double-pseudonymization. We have no complete online-help implemented, but some features, for example mouse-over-field help can be configured, so we considered item 12.4 online-help as partly configurable.

F. Features not implemented in "DBFORM"

Our system runs on Linux, therefore we decided to reply "no" for item 1.2 platform independence. Since all major components (DBMS, webserver, and the main programming language) are available on multiple platforms, DBFORM should be portable to other environments with reasonable effort, but this has not yet been attempted. The system was not developed following a design model, item 2.1, but we have our own design model for new projects. The idea is shown in Fig. 1, which is an adaption of agile software development. We have no implemented online discussion forum, item 3.5, since we have mainly relied on email correspondence with the users until now. We have no patient interface, item 3.7 implemented, because there has not been any project until now for which it was necessary. We have no interface to Hospital Information Systems / Clinical Information Systems (HIS/CIS), item 3.12. We replied "no" for standardization of CRFs, data, metadata, and vocabularies (items 4.1 – 4.4) because we have no implemented thesaurus. However, we use standardized answers with multiple choice menus. We have no eXtensible Markup Language (XML)-procedure for data exchange (item 4.5.), manual data queries (item 6.12), are not possible also data query flags (item 6.13), and plausibility flags (item 6.14), are not implemented. We have no query builder for researchers (item 7.1), and report generation (item 7.2), graphical presentation of results (item 7.3), and risk analysis (item 7.5), are not possible. Encrypted data storage at the single-item level (item 8.4) is not possible, except for user passwords. Multi-client capability, (item 10.2), is not supported, there is no update mechanism, (item 10.3), and source documentation of CRFs in pdf format (item 10.4) is also not possible.

G. Planned improvements of DBFORM

The evaluation of DBFORM with the CIPROS checklist showed some shortfalls of DBFORM. In the near future we want to implement some of the features proposed in the CIPROS checklist. For example, source documentation in pdfs (item 10.4), was regarded as very helpful and will be implemented soon. Also item 3.7, patient interface, is on the list of features to be implemented. It will most likely rely on the more general tool of form templates. Also the standardization of CRFs, data, metadata and vocabularies is regarded as very important and is considered for implementation. If a project includes monitoring visits in the study centers it is also very helpful to document the results of these visits in the system near the captured data. Therefore the system should provide data query flags (item 6.13).

V. CONCLUSION AND FUTURE WORK

The evaluation detailed above has shown that the CIPROS checklist is a practical solution for the assessment of patient registry software systems. It also showed that a simple yes/no answer is not possible for many of the items. So a more differentiated assessment was applied (implemented at System or Project level, partly implemented, etc.) see Table II. It is also highly recommended to use the full CIPROS checklist [1] for the assessment, and not just the aspect/topic list as shown in Table I of this paper. If the two raters chose different answers when the intention of the item was not clear the elaboration paper [2] helped to clarify the meaning of the items.

The evaluation also showed that it would be very helpful to have a quantification mechanism for the answers to generate a rating scale. So if different patient registry software systems would be compared the users would have an objective instrument to choose the appropriate system for their projects. This rating scale may be developed in the future.

It is also planned to update the CIPROS checklist with a new SLR and with input from other persons, for example

 ISBN: 978-1-61208-597-5

performing a workshop or establishing a focus group to get input.

The evaluation was successful for both, the system DBFORM because it showed the advantages and the deficiencies, and the CIPROS checklist because it showed that there are possibilities for improvements, such as a scale to rate the replies.

This was the first evaluation of an EDC system using the CIPROS checklist.

The presented evaluation of DBFORM with CIPROS can be a template for other researchers to evaluate their systems using the CIPROS checklist. It can also be an inspiration for scientists and system developers to develop new features of their own systems.

REFERENCES

[1] D. Lindoerfer, U. Mansmann, "A comprehensive assessment tool for patient registry software systems: the CIPROS checklist," Methods Inf Med. vol. 54(5), pp. 447-54, 2015, doi: 10.3414/ME14-02-0026.

[2] D. Lindoerfer, U. Mansmann, "Data for the elaboration of the CIPROS checklist with items for a patient registry software system: Examples and explanations," Data in Brief, 2017 Aug 3; 14:494-497. doi: 10.1016/j.dib.2017.07.075. eCollection 2017 Oct.

[3] K. Wiegers, J. Beatty, Software Requirements, Third Edition. Redmont, Washington. Microsoft Press. 2013

[4] AD. McKinnon, "Software requirements specification template," [Online] Available from: http://users.tricity.wsu.edu/~mckinnon/cpts322/cpts322-srs-v1.doc. 2017.08.18

[5] Volere Requirements Specification Template. [Online]. Available from: http://www.volere.co.uk/template.htm. 2017.05.07

[6] IEEE STANDARD. 29148-2011 - Systems and software engineering -- Life cycle processes --Requirements engineering. [Online] Available from: https://standards.ieee.org/findstds/standard/29148-2011.html. 2017.08.18

[7] Kossmann M, The significance of requirements engineering for the medical domain, J Med Eng Technol. 38 (2014), 238-43. doi: 10.3109/03091902.2014.918199.

[8] TH. Müller, K. Adelhard, "A web-based central diagnostic data repository," Stud Health Technol Inform. vol. 90 pp. 246-250, 2002.

[9] Apache HTTP SERVER PROJECT. [Online]. Available from: https://httpd.apache.org/ 2017.08.18

[10] PostgreSQL. [Online] Available from: https://www.postgresql.org/ 2017.08.18

[11] The perl programming language. [Online]. Available from: https://www.perl.org/ 2017.08.18

[12] D. Lindörfer, TH. Müller, „Integration und analyse von patienten mit chronischer myeloischer leukämie (CML) in 25 europäischen ländern mit webbasierter elektronischer datenerfassung," in: P. Schmücker, K-H. Elsässer, S. Hayna, Eds.: Tagungsband der 55. GMDS Jahrestagung 2010, Mannheim, pp. 494-5, 2010.

[13] VS. Hoffmann, et al., "The EUTOS population-based registry: incidence and clinical characteristics of 2904 CML patients in 20 european countries," Leukemia. vol. 29(6) pp. 1336-43, Jun 2015, doi: 10.1038/leu.2015.73.

[14] WE. Thasler, TS. Weiss, K. Schillhorn, PT. Stoll, B. Irrgang, KW. Jauch, „Charitable state-controlled foundation human tissue and cell research: ethic and legal aspects in the supply of surgically removed human tissue for research in the academic and commercial sector in germany," Cell Tissue Bank. vol. 4(1) pp. 49-56 2003.

[15] U. Gehring, et. al., "Endotoxin levels in cow's milk samples from farming and non-farming families - the PASTURE study," Environ Int. vol. 34(8) pp. 1132-6 Nov 2008, doi: 10.1016/j.envint.2008.04.003.

[16] P. Mayring, "Qualitative content analysis. Forum Qualitative Sozialforschung / Forum: Qualitative Social Research," Vol. 1, No. 2, Art. 20, June 2000. ISSN 1438-5627. [Online]. Available from: http://www.qualitative-research.net/index.php/fqs/article/view/1089/2386 2017.08.18

[17] TH. Müller, "Synchronising mobile electronic case report forms with a central database," Stud Health Technol Inform. vol. 228 pp. 307-11, 2016.

[18] TH. Müller, R. Thasler, "Separation of Personal Data in a Biobank Information System," Stud Health Technol Inform. vol. 205, pp. 388-92, 2014.

[19] D. Lindoerfer, U. Mansmann, "IT infrastructure of an oncological trial where xenografts inform individual second line treatment decision," Stud Health Technol Inform. vol. 235 pp. 226-30, 2017.

 ISBN: 978-1-61208-597-5

Graphical Bioinformatics – a Tool for the Characterization of Influenza Viruses

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***Abstract*—One of the *Graphical bioinformatics* methods, called *2D-dynamic representation of DNA sequences*, is presented. A new application of this approach is discussed.**

Keywords–Bioinformatics; Alignment-free methods; Descriptors.

I. INTRODUCTION

Bioinformatics is a young, interdisciplinary area of research. It has been created in 1982 and it was related to projects aiming at creation and studying databases containing information about Deoxyribonucleic acid/Ribonucleic acid (DNA/RNA) and protein sequences. Nowadays, bioinformatical studies are defined as analysis and interpretation of these biological data using theoretical methods taken from mathematical, physical and biological sciences.

Deriving the information from the DNA or protein sequences became a modern tool for solving many problems in biology and in medicine. Bioinformatical studies not only constitute an important supplement of experimental works, but in many cases they can replace experiments. It is particularly important if animals have to be used in the experiments and if the experimental studies are expensive and time consuming. Therefore, developing high quality theoretical methods is of particular importance. Fast development in this area of research has been observed during the last two decades.

In particular, we have implemented nonstandard methods which have not been used in bioinformatics so far: ideas borrowed from the dynamics of the rigid body and from the statistical spectroscopy. We have constructed algorithms which can discover differences in a single base for a pair of DNA sequences. We can tell which base it is and indicate its approximate location in the sequence. Our methods can be applied to DNA sequences of an arbitrary length and the calculations can be performed in a short time.

The aim of our studies is both application of our methods to the studies which are directly related to biology and medicine and a construction of new methods which may be useful for studies, for example, the mutations of viruses or the creation of phylogenetic trees. We are going to predict directions of the mutations of the influenza viruses and the Zika virus by combining physico-chemical calculations with similarity analyses of DNA sequences (due to a large practical significance). Different modes of implementation of our methods and searching for methods useful for the description of the dynamics of the mutation processes is another aim of our studies. Such studies are particularly important in designing new kinds of vaccine.

Moreover, we plan to work on the classification of biological structures by finding new similarity properties, defining new descriptors which in a numerical way characterize these properties and on the construction of new methods of comparison of these structures. It is worth mentioning that finding new classification schemes often led to important developments in the understanding of the research area for which these schemes have been created (standard examples are the periodic table of elements in chemistry, the Herzsprug-Russel diagram in astronomy, the systematics of living organisms in biology).

In Section II we present the *Graphical bioinformatics* method called by us *2D-dynamic representation of DNA sequences.*

II. METHOD AND EXPECTED RESULTS

Methods known in the literature as Graphical Representations of DNA/RNA Sequences [1] combine ideas from different areas of science. They enable both graphical and numerical comparisons of DNA sequences. Contrary to the frequently used methods based on the alignment of the sequences [2], graphical representations allow us to consider each aspect of similarity separately. Another advantage of these methods is that they are not demanding computationally.

In this work, we present a graphical representation method introduced by us and called *2D-dynamic Representations of DNA Sequences* [3]. A specific feature of this approach is a simple adaptation of some ideas of the classical dynamics. Examples of 2D-dynamic graphs representing DNA sequence are shown in Figures 1 and 2. As we can see, the shapes of the graphs corresponding to different DNA sequences are different. The issues related to the choice and to the properties of the numerical characteristics of the graphs (descriptors), are also discussed. We have defined the following descriptors of 2D-dynamic graphs:

- Moments of the mass-density distributions,
- Angles between x axis and principal axis of inertia of the graphs,
- Coordinates of the centers of mass of the graphs,
- Principal moments of inertia of the graphs.

The n-th moment of a discrete distribution ρ_E is defined as

$$M_{E,n} = c_E \sum_i \rho_{E_i} E_i^n,$$

$E = x, y$ and the normalization constant

$$c_E = \left(\sum_i \rho_{E_i} \right)^{-1}.$$

 ISBN: 978-1-61208-597-5

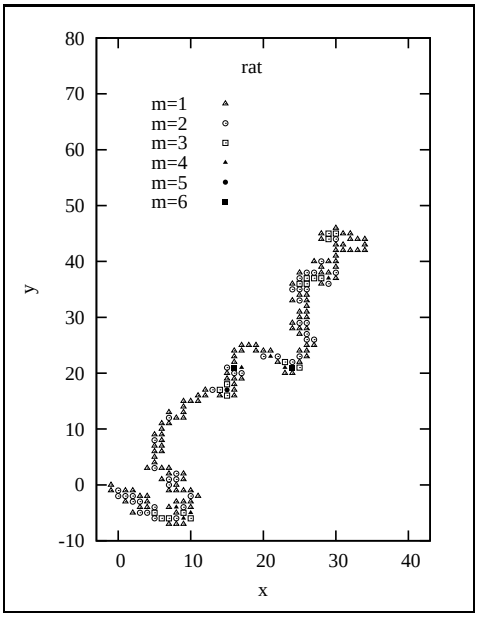

Figure 1. 2D-dynamic graph.

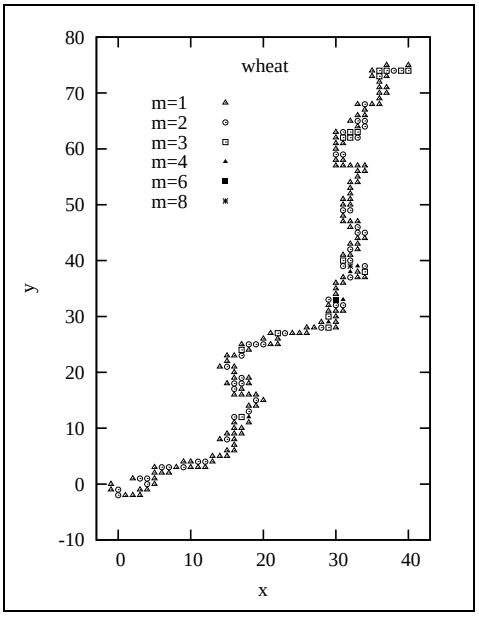

Figure 2. 2D-dynamic graph.

Moments normalized to a mean value equal to zero ($M'_{E,1} = 0$) are

$$M'_{E,n} = c_E \sum_i \rho_{E_i} (E_i - M_{E,1})^n.$$

We also consider moments, for which additionally the variance is equal to 1 ($M''_{E,2} = 1$):

$$M''_{E,n} = c_E \sum_i \rho_{E_i} \left[\frac{(E_i - M_{E,1})}{\sqrt{M_{E,2} - (M_{E,1})^2}} \right]^n.$$

Coordinates (μ_x, μ_y) of the centers of mass of the graphs are

$$\mu_a = \frac{1}{N} \sum_i m_i a_i,$$

where $a = x, y$, and the normalization constant

$$N = \sum_i m_i.$$

x_i, y_i are the coordinates of the point mass with mass m_i of the 2D-dynamic graph.

The moment of inertia tensor is

$$\hat{I} = \begin{pmatrix} I_{xx} & I_{xy} \\ I_{yx} & I_{yy} \end{pmatrix}$$

where the matrix elements are

$$I_{xy} = I_{yx} = -\sum_i^N m_i x'_i y'_i,$$

$$I_{xx} = \sum_i^N m_i (y'_i)^2,$$

$$I_{yy} = \sum_i^N m_i (x'_i)^2.$$

Principal moments of inertia are the eigenvalues of $\hat{I}$: ω_{11}, ω_{22}. We have shown that the coordinates of the center of mass divided by the principal moments of inertia are good descriptors

$$D_k^\gamma = \frac{\mu_\gamma}{\omega_{kk}},$$

where $\gamma = x, y$ and $k = 1, 2$.

Summarizing,

- 2D-dynamic representation of DNA sequences allows for both graphical and numerical analysis of similarity/dissimilarity of DNA sequences.
- The accuracy is high.
- Negative:
  The history of emergence of a graph is lost since the graphs self-overlap. This point is corrected in 3D-dynamic representation of DNA sequences.

We have already applied this method for a characterization of the Zika virus genome [4]. The aim of the future work is an application of this approach to a characterization of influenza viruses. We expect that the nonstandard method can reveal some new features of the considered objects.

REFERENCES

[1] M. Randić, M. Novič, and D. Plavšić, "Milestones in Graphical Bioinformatics", Int.J.Quant.Chem.vol. 113, pp. 2413–2446, 2013.

[2] S. Altschul, W. Gish, W. Miller, E. Myers, and D. Lipman, "Basic Local Alignment Search Tool", J. Mol. Biol. vol. 215, pp. 403–410, 1990.

[3] D. Bielińska-Wąż, T. Clark, P. Wąż, W. Nowak, and A. Nandy, "2D-dynamic representation of DNA sequences", Chem. Phys. Lett. vol. 442, pp. 140–144, 2007.

[4] D. Panas, P. Wąż, D. Bielińska-Wąż, A. Nandy, and S.C Basak, "2D-Dynamic Representation of DNA/RNA Sequences as a Characterization Tool of the Zika Virus Genome", MATCH Commun. Math. Comput. Chem. vol. 77, pp. 321–332, 2017.

 ISBN: 978-1-61208-597-5

New Mathematical Description of the Zika Virus Genome

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***Abstract*—A new method of similarity/dissimilarity analysis of Deoxyribonucleic acid/Ribonucleic acid (DNA/RNA) sequences, is briefly outlined. The sequences are represented as a set of material points in a 3D-space. Such a 3D-dynamic graph is characterized numerically by the values analogous to the ones used in the classical dynamics. Application of such an approach for a characterization of the Zika virus genome is also discussed.**

Keywords–Bioinformatics; Alignment-free methods; Descriptors.

I. INTRODUCTION

A fast development of databases stimulated designing of new mathematical methods aiming at similarity/dissimilarity analysis of biosequences (DNA, RNA, protein). One branch of the methods, *Graphical Representations*, was created already in the eighties [1]. Originally, only a visual inspection on the considered objects was the aim of these studies. The DNA/RNA sequences are long and are composed of four letters. Therefore, in a natural way they can be represented as complicated objects in a 4-dimensional space. Since the human perception is limited, the reduction of the space to a lower dimension became desirable. This resulted in developing many different *Graphical Representation* methods [2][3][4][5][6] (for reviews see [7][8]). Alternatively, one can also characterize the sequences numerically, using so called *descriptors* [9]. Assigning descriptors to the graphs is far from being trivial.

In Section 2 we briefly outline a *Graphical Representation* method introduced by us several years ago and its application to a characterization of the Zika virus genome.

II. METHOD AND EXPECTED RESULTS

Recently, we have introduced a new Graphical Representation method called by us *3D-dynamic Representation of DNA/RNA Sequences* [10][11]. The inspiration for the numerical description of the 3D-dynamic-graphs came from the classical dynamics. We treat the graphs as rigid bodies. As descriptors characterizing the 3D-dynamic graphs we took coordinates of the centers of mass and the moments of inertia of these bodies. Two examples of the 3D-dynamic graphs are shown in Figure 1. The shapes and the locations of the graphs in the 3-dimensional space of different sequences are different. The aim of the new studies is an application of this approach to a new mathematical description of the Zika virus genome. Preliminary results are presented in Figures 2-5. Figure 2 and 3 show 3D-dynamic graphs representing the complete genome sequences of Zika virus. As we can see, the time evolution of the complete genome sequence of Zika virus is well represented graphically.

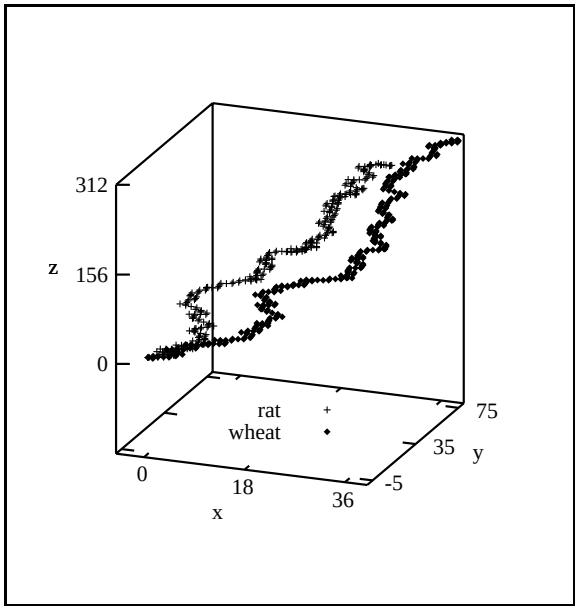

Figure 1. 3D-dynamic graphs.

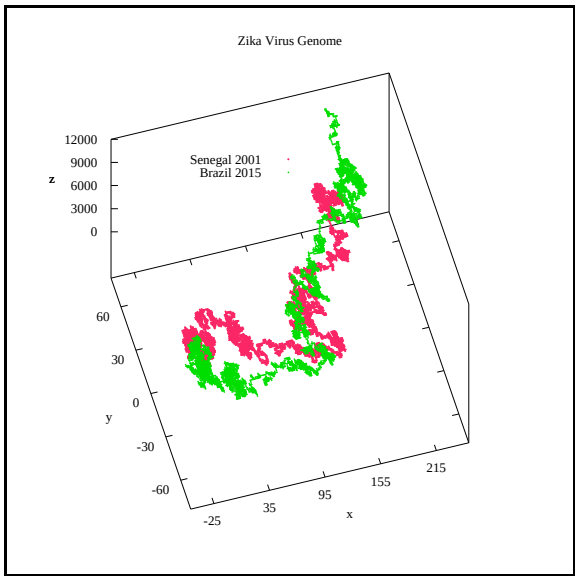

Figure 2. 3D-dynamic graphs representing the genomes of the Zika virus.

 ISBN: 978-1-61208-597-5

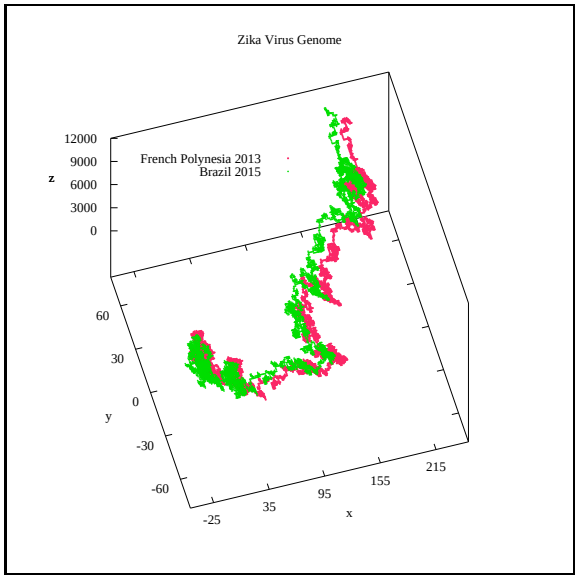

Figure 3. 3D-dynamic graphs representing the genomes of the Zika virus.

A pair of graphs is similar to each other: French Polynesia 2013 and Brazil 2015 (Fig. 2) and different: Senegal 2001 and Brazil 2015 (Fig. 3). This observation is confirmed by the calculations of the descriptors presented in the axes of Figures 4 and 5. μ_x, μ_y, μ_z are the coordinates of the centers of mass of the 3D-dynamic graph, in the $\{X, Y, Z\}$ coordinate system. They are are defined as

$$\mu_x = \frac{\sum_i m_i x_i}{\sum_i m_i}, \quad \mu_y = \frac{\sum_i m_i y_i}{\sum_i m_i}, \quad \mu_z = \frac{\sum_i m_i z_i}{\sum_i m_i}, \quad (1)$$

where x_i, y_i, z_i are the coordinates of the mass m_i. As the descriptors we also select the square roots of the normalized principal moments of inertia:

$$r_1 = \sqrt{\frac{I_1}{N}}, \quad r_2 = \sqrt{\frac{I_2}{N}}, \quad r_3 = \sqrt{\frac{I_3}{N}}, \quad (2)$$

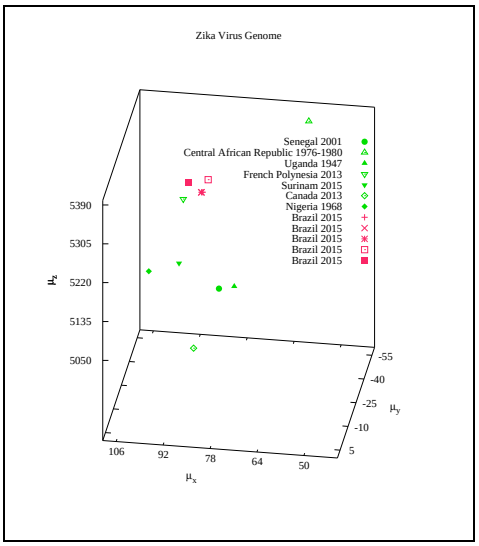

Figure 4. Classification diagram for the genomes of the Zika virus.

where I_1, I_2, I_3 are the principal moments of inertia of the 3D-dynamic graph and N is the length of the sequence.

In the Figures we observe concentrations of points in particular parts of the diagrams. We have already applied the 2D-dynamic representation of DNA/RNA sequences for a characterization of this virus [12]. In the future work, we are going to check if the third dimension supplies any new and relevant information.

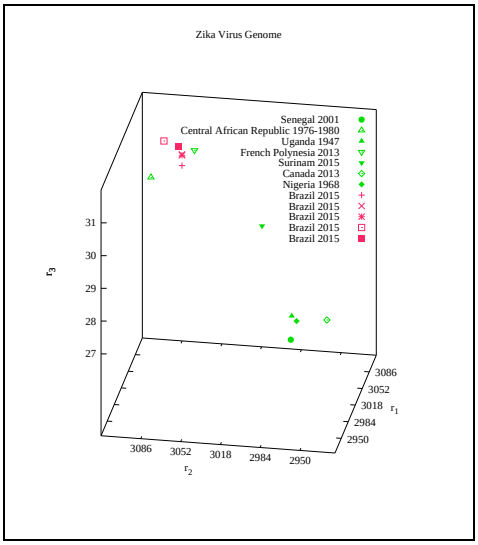

Figure 5. Classification diagram for the genomes of the Zika virus.

REFERENCES

[1] E. Hamori and J. Ruskin, "H Curves, a novel method of representation of nucleotide series especially suited for long DNA sequences", J. Biol. Chem. vol. 258, pp. 1318–1327, 1983.

[2] P. M. Leong and S. Morgenthaler, "Random walk and gap plots of DNA sequences", Comput. Appl. Biosci. vol. 11, pp. 503–507, 1995.

[3] Q. Dai, X. Liu, and T. Wang, "A novel graphical representation of DNA sequences and its application", J. Mol. Graph. Model. vol. 25, pp. 340–344, 2006.

[4] H. González-Díaz et al., "Generalized lattice graphs for 2D-visualization of biological information", J. Theor. Biol. vol. 261, pp. 136–147, 2009.

[5] Z. Zhang, T. Song, X. Zeng, Y. Niu, Y. Jiang, L. Pan, and Y. Ye, "ColorSquare: A colorful square visualization of DNA sequences", MATCH Commun. Math. Comput. Chem. vol. 68, pp. 621–637, 2012.

[6] N. Jafarzadeh and A. Iranmanesh, "C-curve: a novel 3D graphical representation of DNA sequence based on codons", Math Biosci. vol. 241, pp. 217–224, 2013.

[7] D. Bielińska-Wąż, "Graphical and numerical representations of DNA sequences: Statistical aspects of similarity", J. Math. Chem. vol. 49, pp. 2345–2407, 2011.

[8] M. Randić, M. Novič and D. Plavšić, "Milestones in Graphical Bioinformatics", Int. J. Quant. Chem. vol. 113, pp. 2413–2446, 2013.

[9] A. Nandy, M. Harle, and S.C. Basak, "Mathematical descriptors of DNA sequences: development and applications", Arkivoc ix, pp. 211–238, 2006.

[10] P. Wąż and D. Bielińska-Wąż, "3D-dynamic representation of DNA sequences", J. Mol. Model. vol. 20, 2141, 2014.

[11] P. Wąż and D. Bielińska-Wąż, "Non-standard similarity/dissimilarity analysis of DNA sequences", Genomics vol. 104, pp. 464–471, 2014.

[12] D. Panas, P. Wąż, D. Bielińska-Wąż, A. Nandy, and S.C Basak, "2D-Dynamic Representation of DNA/RNA Sequences as a Characterization Tool of the Zika Virus Genome", MATCH Commun. Math. Comput. Chem. vol. 77, pp. 321–332, 2017.

 ISBN: 978-1-61208-597-5

Identifying Influential Factors of Patient Length of Stay in a Surgery Center: a Simulation Modelling Approach

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***Abstract*— Simulation is increasingly being used in the healthcare sector. The dynamic management of resources and patient levels requires a computational and evaluative approach for staff to examine their impacts on the performance of the system. In this paper, a sensitivity analysis via Monte Carlo Simulation is developed to identify influential factors of patient length of stay in a surgery center. The operation of a selected surgery center is re-created by a Discrete-Event Simulation model as a basis for the sensitivity analysis. We compute elasticity measurements for comparing relative influences of identified pertinent on the system output. Results suggest that the patient length of stay is more sensitive to capacity extractions than additions. The capacity of surgery slots is a rewarding option on increased patient level. We suggest healthcare planners are aware of dedicated surgery types and hospital fixtures due to effects on patient length of stay.**

Keywords-discrete-event simulation; monte-carlo simulation; logistics; healthcare

I. INTRODUCTION

Performances of surgery centers are determined by complex interactions of agents such as patients, health care staff and infrastructure. According to the Healthcare Financial Management Association, surgery centers are described as the most resource-intensive as well as profitable hospital departments [1], where measurements to gain new efficiencies and reduce costs are vital. To address hospital logistical problems, recent growing utilization of simulation techniques in the healthcare sector encourages its wider adoption by exploring resource options and system control strategies. The operational environment of surgery centers, configured by parameters of different resources, can be defined by healthcare planners and decision makers. In practice, the logistical issues of surgery centers are examined by means of optimizations [2], event-driven simulations or a hybrid model integrating the above techniques [3]. Optimization models could be suitable for engineering systems of low uncertainties. The health system is however a complex and multi-actor system. Simulation models could help project knowledge for networks of high uncertainties. The impacts of configurations on system outputs of surgery centers, important section of the hospital, could be obtained by calculating average length of stay or surgery throughputs.

Routine surgery center simulation models are primary decision-support systems comparing metrics of scenarios with pre-defined values of parameters. However, it is worthwhile to note that this endeavor has a restricted user's capability to understand how the simulated system changes in the entire feasible area, the impacts of capacity uncertainty and demand profiles. Even though simulation models are used in the healthcare-related topics, previous researches on the performance of surgery centers failed to consider variation of resource parameters via sensitivity analyses. Very few studies extended departmental simulation models to a sensitivity analysis, which could hinder a holistic consideration of potential managerial solutions on logistical issues in surgery center operations.

In order to fill this gap, this work presents a simulation framework combining Discrete-Event Simulation (DES) and Monte Carlo Simulation (MCS) for surgery center operations. It is expected that this method will re-create the flow of patient entities and solve the inconvenient endeavor without the ability to discover the most influential pertinent in a numerical way. This complies the positioning of MCS as the major simulation technique [4], pointed out by Mustafee and Taylor in their work with a retrospect of healthcare simulation. Different staffing configurations and demand scenarios are identified as the influencing factors for patient length of stay, together with governing rules and reference to the infrastructure layout. Elasticity measurements are also computed to uncover if additional resources are rewarding towards patient length of stay under increased demand. The method presented in this paper could be generalized to similar surgery centers that are dedicated to specific surgery types. The main contribution of this work is two-fold: 1) it provides a relatively novel method to explore managerial decisions and deal with resource constraints; 2) it aggregates computational results based on a large amount of simulations into the feasible area of the parameter.

The remainder of this article is arranged as follows: a literature review on MCS and sensitivity analysis in healthcare in general and in surgery-related topics in particular is performed in Section 2. Following this, Section 3 presents its application into a real surgery center of a hospital in Jiangsu, China. A simulated environment is constructed for measuring the impact of the managerial decisions on the performance of the system, which is in the form of patient length of stay in this study. A discussion and

 ISBN: 978-1-61208-597-5

conclusion on recommendations for continued researches is presented at the end of the paper.

II. LITERATURE REVIEW

The construction of MCS models enables visualization and analysis purposes within various sectors, such as transportation, logistics, energy and healthcare. Banomyong and Sopadang provided a conceptual framework for emergency response logistics in which the MCS presented a range of possible results [5]. MCS has also been applied in healthcare economies and societal cost-benefit evaluations. Barton et al. stated that MCS can achieve the same effect of increasing states of systems to overcome homogeneous assumptions in Markov models [6]. Huang et al. framed a MCS model by simultaneous progression of diseases [7].

Besides above achievements, however, very few previous simulation applications were reported to address logistical related issues in surgery center operation. Logistical related issues in hospital departments revolve around scheduling, patient flow management and staffing configurations. A holistic query of all necessary keywords was used to search in title/abstract/keywords in the Web of Science Core Collection database from the year 1996 until present. Following this, collected publications were obtained after eliminating abstracts book reviews and papers without full access. The data collection was further defined by reading through the main texts and led to 14 reviled surgery-related studies performed either through MCS for various purposes or by a sensitivity analysis by deterministic approaches. To authors' knowledge, these papers have not addressed above mentioned logistical related issues. One previous study of surgery quality and patient output suggested that MCS was promising method for analyzing human factors [8]. Luangkesorn and Eren estimated the surgery duration by combining expert inputs and historical data in a Markov Chain Monte Carlo model [9]. Lymperopoulou et al. used MCS for improved treatment planning for the post-operative state [10]. Huberts et al. studied interval control between surgery and postoperative radiotherapy [11]. Computer-aided clinical practice enhanced by MCS or sensitivity analysis is the main focus in Cerveri et al.'s works [12].

In addition, several feasibility studies have compared MCS with other alternatives. Radioactive seed localization (RSL) was found to reduce health care costs for patients and transferred into increased facility margin [13]. Different beta minus detection strategies were compared by Gigliotti et al. with an emphasize on spatial resolution of medical images [14]. Instead of clinical practices, Stone et al. examined the implementation costs of an Enhanced Recovery after Surgery (ERAS) program with inputs of patient length of stay in the hospital and recommended investments into the ERAS to US hospitals [15].

With the exception of Huberts, previous studies did not consider system-wide performance improvement through logistical activities but rather accounted for variations in clinical practices, human factors or individual health models. There were several limitations in simulation models: 1) none of existing simulation models fully investigates the uncertainty of logistical parameters and its effect on the operational level, leading to trade-offs identified based on a limited set of alternatives; 2) the information gained from studies of MCS or sensitivity analysis rarely consider patient length of stay in the center and potential improvements from managerial controls. Hence, the MCS method can complement this and allows for the evaluation of a wider range of design scenarios and strengthen the managerial insights by establishing connection between the health care planning phase and the operational variations. 3) very scarce examples considered staff workflows in researches on surgical center operations.

This paper utilized MCS to perform the sensitivity analysis for decision supports of managerial controls in the surgery center. Based on the positive results by [16] and a process simulation model of the same hospital [17], this study employs the same method, DES, to re-create flows of entities in a selected surgery center with real data of staffing boundaries, surgery types and movement rules for different participants. On top of this DES model, MCS is conducted by assigning a normal distribution to parameter values. A combined simulation modelling and analysis approach provides the following contributions: visualization of entity flows, convenient interventions to parameter settings, and prediction and comparison of outputs in a numerical manner.

III. THE SIMULATION MODEL

The model proposed in this paper is a hybrid-simulation model of DES and MCS, developed to form the operational logistics. The operational logistics is detailed simulated using DES, whereas the MCS explores system outputs in response of parameter variations. AnyLogic, a dynamic simulation tool, is used for various recourse-related choices and the sensitivity analysis. The surgery types, operational logistics and staffing configurations are modelled in reference to the real physical settings of the department. The layout of the surgery center includes location-to-location information of paths, rooms and facilities. Staffing configurations and primary operation types are allowed to have independent options with the current default values.

The simulation model considers arrival schedules and add-ons, thus enabling the mixed nature of different urgencies, which is an important aspect in the real operation of a surgical center. Patients go through the care pathway and coerce resource sizes so that patient might have excessive waiting times for available rooms, physicians, nurses, beds, or a combination of them. Care provision is event-driven and consists of patient-and material-centric logistics. These two aspects are elaborated in the next sections. Such a simulation model allows the visualization of concrete interactions between the supply-side factors, such as appointment, staff decision making and material supplies, with delays and waiting times at a cross-units level. Since the surgery center consumes approximately 40% of hospital expenditure, decisions upon adding more capacity or altering current control policies need to be wise. This question is to be answered by the sensitivity analysis quantifying the effects of existing resources. Based on this simulation model, a sensitivity analysis accompanied by MCS is conducted to

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investigate the relative uncertainty of chosen parameters and their effects on the outcomes. Interventions are suggested for resources of which the parameters present higher degrees of responses.

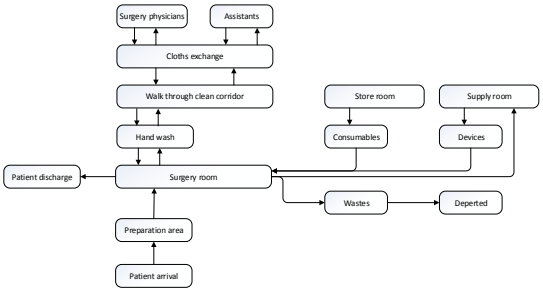
A. Operational Logistics

Located in the middle of the 5th floor, this surgery center receives requests from upstream diagnoses and emergency drop-ins. As a main hospital in the urban area, the surgery center is dedicated to elective patient types. With a capacity of 8 surgery slots, 14 dedicated beds, 8 surgery physicians and 16 nurses, the surgery center completes 10 missions on the daily basis. The high workload of surgery teams is one of the major problems in the Chinese healthcare sector. Although the center predominately serves elective patients, some dedicated beds and a separate preparation room closer to the entrance of the hospital are provided for non-elective requests. As long as the patient is at the front of the queue, he is able to seize required resources upon availability and start his scheduled session. A non-elective patient seizes the first available bed for preparation and is prioritized available for surgery. Since a surgery center both consumes considerable expenditure and generates a major port of revenue for the hospital, principle instructors might think about if there is any untouched potential of the current configuration to increase patient throughput, average length of stay or even reduce workload of health care staff. Since the main objective is to minimize patient length of stay, improved management for reducing work pressure and maximizing throughput are not discussed in this study.

We have combined patient and staff workflows in the conceptual model, as Fig. 1 shows. This conceptual model is established according to the feasibility study report for expanding the hospital complex and an interview of the project development team designing the units. In order to represent them adequately in the simulation model, empirical data of layouts, default staffing configurations, surgery types and agent movement rules are collected. The clinical pathway consists of functional rooms: Elective surgery arrival area (zone 1), non-elective surgery arrival area (zone 2), preparation area (zone 3), nurse stations (zone 4), surgery slots (zone 5), store supply room (zone 6), cleaning corridor (zone 7) and surgeon offices (zone 8).

A simulation model is then constructed to model the patient flow from arrival to discharge. Elective and non-elective patients arrive from upstream units and are sent to different surgery preparation rooms with bed capacities of 4 and 2. In all cases of decided surgeries, each individual is allocated a surgery bed and gets prepared with the help from nurses. After preparation, the patient waits to be transported to the specific surgery slot for his session processed by the surgery team. The surgery types decide surgery time periods and material supplies.

There are two types of logistical activities carried out by the healthcare staff. These include the assignment of human resources and the provision of necessary materials. The healthcare staff has different levels in the organization and is associated with different movement rules in the center. Surgery physicians and assistants sit in offices and nurse stations during idle times. Upon request, they are obliged to go through several intermediate stages, such as exchanging clothes and a walk through the clean corridor, for contamination purposes. Meanwhile, consumables and facilities have to be ordered from the store and supply room. Demand for these materials is generally greater (with 2 units) for long-duration operations (type I and II) and become less (with 1 unit) for light operations (type III and IV). Each request is fulfilled with the stock and then proceeds to the patient. Approximately 2 times per day, the store room is checked for inventory sufficiency.



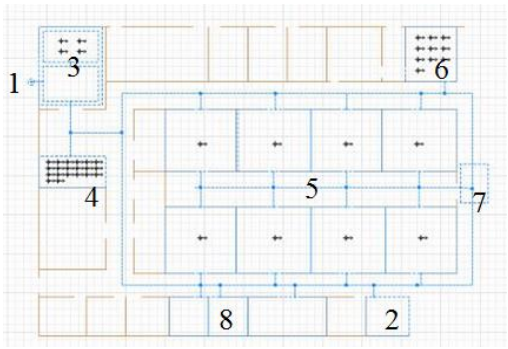


Figure 1. Operational logistics and layout of the surgery center

B. Simulated Entities

Patient demand is represented by an arrival rate and types of surgeries according to historical data, the technical setting and function of this hospital in the regional healthcare network. There are 11 categories of patient entities in the model, one representing patients in need of long-duration surgeries and the other ten require relatively short-duration surgeries, as shown in Table 1. The surgery center predominantly addresses eleven kinds of surgeries varying from 30 minutes to 5 hours, including 4 categories of surgical incision. Each incision is fulfilled with a particular type of surgery slot. The surgery slot of special clean has the least pollution parcels in the air and is able to implement all incision categories, whereas the normal clean and clean can handle only forensic surgery, anorectal surgery and similar cases with relatively lower level of requirements of contaminations. Together these capture a majority of the total surgeries executed in this hospital since its dedication to type I and II. Time periods of surgical durations are modelled using uniform distributions.

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TABLE I. SURGICAL INCISION CATEGORY, SLOT REQUIREMENTS AND AVERAGE DURATIONS.

Incision Category	Type of Surgery Slot	Notes on Suitable Types of Surgeries (Estimated durations in hours)
I	Special clean	Joint replacement (1-2), transplant (2-3), aural surgery(4-5), cardiac surgery (3-5), glaucoma and dacrocystitis (0.6-2) ;
II	Special clean	Pleural surgery (5), orthopedics(0.5-0.6), urethra (15-25), liver pancreas (3-4), bone surgeries (1), forensic surgery (1)
III	Normal or Special clean	Forensic surgery (excluding Surgical Incision Category Ⅰ),gynecology and obstetrics (1-2);
IV	All slots	Anorectal surgery (1), pollution class (1)

The surgery center is controlled by FIFO policy in the simulation study. Routine elective patients are served on the FIFO basis since they are assigned the surgeries according to the admission date. Although both patient- and material-centric logistics are incorporated, we put more details on simulating the patient flows and fewer efforts on the regulation of inventories. The simulation model calculates performance metrics such as the total length of stay, waiting times, resource utilizations and stock levels. When a mission finishes, the staff leave the surgery slot and returns to offices and nursing stations. We also consider the possibility of no-shows. This occurs before the preparation phase with a given probability of 5%. The cancelled agents are immediately removed from the simulation model.

C. *Sensitivity Analysis via MCS*

The purpose of sensitivity analysis is to identify influential factors governing patient length of stay. The length of stay in this study did not include the surgical duration since it is already determined by the surgery type of the patient and cannot be changed. In variations of assumptions and policies, it is important to discover parameters that highly affect the key outputs of the system. Although theoretically the supply is already at optimal value to accommodate forecasted health care demand at the feasible study phase, demand might increase or decrease in the operation phase, leading to potential redesign efforts. The feasibility of additional resources enables decision makers updated of the current state of the system. A comprehensive view of potential constraint factors of the system is therefore needed.

A sensitivity analysis through MCS makes up for the disadvantage of using deterministic sensitivity analysis. In the deterministic way, the replications occur with relative lower numbers and might result in analysis biases if the system is inherently stochastic. During a Monte Carlo simulation, values are sampled randomly from the input probability distributions. Each set of samples is operated within a simulation run, and the resulting outcomes from that sample are recorded with a great amount of replications. In this way, Monte Carlo simulation provides more freedom of configurations and is able to realize factors of greater impacts.

The MCS in this study uses the normal distributions with realistic boundaries to detect response to an uncertainty of parameter value by a number of replications. In the surgery center simulation model, the size of each resource along the care pathway is defined as a parameter, where the value can be potentially varied. This variation is useful to quantify magnitude of responses. To this end, a MCS study examines the performance of different managerial alternations with an experimental design consisting of six one-way estimations. 20 replications starting from idle were conducted for each scenario to simulate a 7-day time span. The total running time for the 200 runs is around 4 minutes on a standard PC.

IV. RESULTS AND DISCUSSIONS

Simulation showed that all the function blocks of the model achieved unhindered entity flows with the default staffing setting and historic admission rate. Fig. 2 illustrates the distribution of average length of stay and relative differences of performance metrics with empirical estimation from the interview. For the waiting time, the time period centralized between 50 to 60 minutes with an average of 53.51 minutes, because the surgery team has not fully prepared yet, (e.g., due to the inability to seize the appropriate surgery slot, surgeon or materials) or because of the inability to start pre-surgery tasks (due to unavailable nurses busy on earlier patients). An interview with the project development team produced estimation of the average length of stay and the utilization of different resource types. Overnights did not occur because patients were transferred to downstream units for postoperative activities. The calculated average waiting time of 50 minutes from the simulation model is in line with practices (55 minutes) in real; the consistency also applies to resource utilizations. Above all, the simulation model is considered to be validated for investigating parameter variations in staffing configurations, surgery types and patient levels.

To the author's knowledge, this simulation model of specific procedures is of high accuracy that uses the already defined staffing settings, such as the details of surgery slots, beds and human resources (i.e., sizing and movement rules), and explicitly incorporated 11 surgery types requiring specific slots and surgical case durations. This is of particular importance in sensitivity analysis since the already defined values can be employed as upper or lower boundaries used to detect outputs.

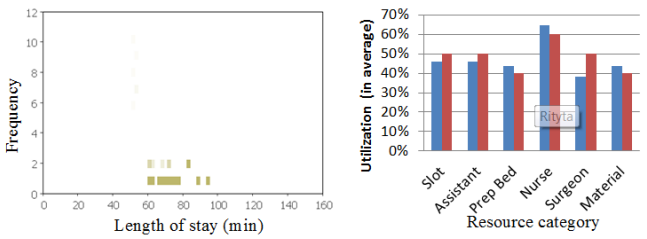

Figure 2. Outputs of simulation: a) scatter diagram of average length of stay; b) resource utilizations per category

Studying the sequential responses of staffing variations can provide more insights on whether the efficiency of the presented patient flow management has potential to be improved, identify by which sources and directions it can be improved and detect lower capacity threshold. To this end, this paper identified parameters related to sizing of beds, nurses, surgery slots and materials by analyzing the average length of stays within each particular feasible interval. We explored potential parameter values by modifying the current setting with resource extractions or additions. The magnitude of extractions and additions are around 4-5 units for all resource types. A uniform distribution was used to assign parameter values the same probability of occurrence.

The simulations demonstrated the benefits and penalties of changeable capacities towards average length of stays. The parameters and corresponding length of stays identified are illustrated in Fig. 3. We implement both increases and decreases on resource sizing, attempting to cover the whole ranges of them. It could be seen that the average length of stay becomes longer with greater deviations as long as the capacities are decreased. Especially for surgery slots and preparation beds, the capacities are not recommended to be lower than 3 and 2 units since the average length of stays will tip up dramatically. The small change implied that the average length of stays is more sensitive to capacity reductions of current levels rather than additions.

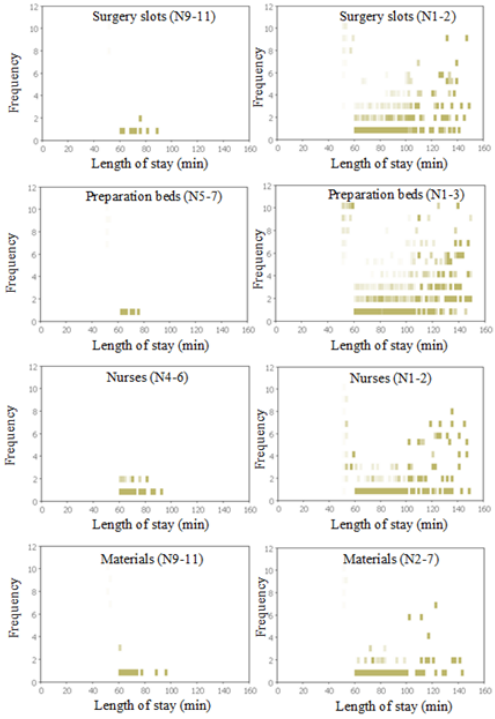

Figure 3. Scatter diagrams of length of stays and frequencies under staffing configurations

While length of stays could be eliminated by a larger-capacity staffing, analyzing focused types of surgeries enable further insights on impacts from demand scenarios. In contrast to previous attempts to implement resource changes, types of surgery also result with variations in average length of stays—as Fig. 4 shows, the noticeable longer length of stays were identified by a 30% demand increase of either of type I. On the other hand, there is a moderate increase from a 30% demand increase of current type III and IV. This means that the stay duration tends to be more acceptable in case of increased type 3 and 4 surgeries. The surgery center or regional health system planners shall be aware of consequences of receiving additional type I and II (special clean) at this hospital.

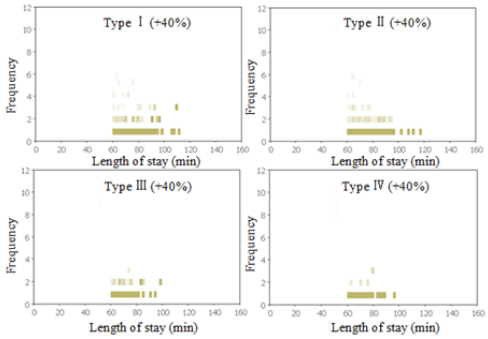

Figure 4. Scatter diagrams of length of stays and frequencies under patient levels

In this study, the sizing of surgery slots and nurses as well as the share of type I cases in the global list are indicated as the most influential factors. Moreover, the corresponding demand profile (+40%) results in surgery slots as the most important source of affecting the patient length of stay with a mean elasticity over 80%. In contrast, nurse sizing is first the most important factor in the baseline scenario but ended in less influential compared to surgery slots. In practice, there is a shortage of nurses to complete pre-surgery tasks under the current demand profile of 75 cases per week. Hence, effects of resources do not necessarily stay the same through all demand profiles as indicated by the proportional output on the total length of stay. Marginal differences presented by such a frontier [Fig. 5] provide valuable information on magnitudes of changes that are not easily captured from the healthcare planners' point of view.

The patient length of stay also depends on configuration of surgery types. This is identified with the current patient level in Fig. 5. As an example, the output is more sensitive to the amount of type I surgery received than type II, although they share surgery slots. However, this influence is smaller from type III and IV. We can conclude that type I affects the waiting time most. The effect of type I is almost 8 times than the one of type IV. The proper combination of surgery types need to consider various factors, amongst others case urgency, resource availability and accountability. In this study, the central point is the impact of category on patient waiting times. It remains as a research question for future studies to identify the exact combination of surgery types

 ISBN: 978-1-61208-597-5

associated with different surgical complexities and case durations when the system performance is to be improved.

The influences of candidate factors with the subject change were investigated by MCS. In line with the expectation, there was a correlation between amid resource levels and the performance of the system. Furthermore, there existed a noticeable difference for the average patient length of stay for increased demands of type I and II. The findings implied that the MCS method was able to alleviate the computational efforts than deterministic technique in sensitivity analysis of parameters under the described values. Given the current form, patients spent less waiting times with increased nurse level than they did with increased surgery slot level. However, it did appear that additional surgery slots were a rewarding option under increased demand scenario.

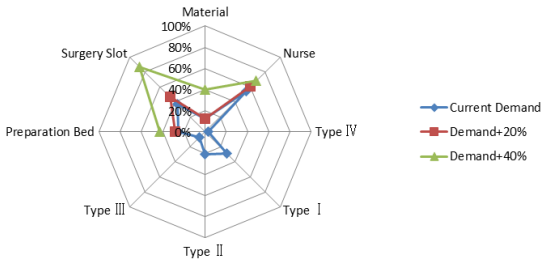

Figure 5. Scatter diagrams of length of stays and frequencies under demand scenarios

V. CONCLUSIONS

In this paper, an event-driven simulation approach for sensitivity analysis was developed to a surgery center of a general hospital. Since implementation of staffing configuration changes and demand management strategies would be difficult in the use case, influential factors on patient length of stay are identified based on sensitivity analysis. This sensitivity analysis is conducted via MCS in which each parameter is assigned the same probability of occurrence. The results of the sensitivity indicate that effects of changing resource capacities might vary in different demand profiles. In addition, the patient length of stay in the surgery center is more vulnerable to capacity reductions rather than additions. The moderate reductions of patient length of stay by increasing capacities of corresponding resources indicate that adding more infrastructures might not be a feasible way of improved system performance.

The following conclusions are subject to the conditions and limitations of this study: 1) the MCS approach is more effective than the deterministic analysis in evaluating the sensitivity of resource- and demand-related parameters; 2) fluctuations with the type III and IV had limited effect on average patient length of stay compared to type I, and; 3) the magnitude of responses by the resource levels subjected to patient levels were not significantly consistent as long as given increased surgery assignments.

The elasticity measures defined in Section 2 are utilized for the purpose of identifying influential factors towards patient length of stays. In particular, three demand profiles are implemented to further recognize important resource candidate for future scenarios. It examines to what extent the patient length of stay respond to influences from different staffing configurations. This sensitivity analysis via a MCS and elasticity measurements enable understanding of the relation between design factors and system outputs and how well the latter can be determined and improved by design efforts especially in the planning phase.

A sensitivity analysis generates clues and references for effectiveness of controllable resources to improve patient length of stay. Follow-up researches shall enable modelling participants as agents, so that both master and decision rules of staffing relocations can be fully deployed to approximate the reality. Besides the lack of agent's interactions, we admit that detailed scheduling has not been integrated into the current table. Apart from regulations, in what way the surgery scheduling is better engineered with above reinforcements is also worthwhile to tackle based on a simulation approach. In one of the studied patient levels, the amount of surgery slots was found to heavily affect the performance. It is therefore recommended that it may be beneficial for stay duration reductions to increase the provision of slots in case that the hospital is assigned more surgery missions. In what way to better design and distribute dedications considering tolerances of local surgery centers in the regional health care network constitutes another interesting research question in the future.

ACKNOWLEDGMENT

The authors would thank participants of project development team of use case for their assistances with data.

REFERENCES

[1] Achieving Operating Room Efficiency through Process Integration: https://www.ncbi.nlm.nih.gov/pubmed/12793445

[2] B. Denton, J. Viapiano, and A. Vogl. "Optimization of Surgery Sequencing and Scheduling Decisions under Uncertainty," Health Care Management Science, vol. 10, Nov. 2006, pp. 13–24, doi: 10.1007/s10729-006-9005-4.

[3] F. Liang, Y. Guo, and R. Fung, "Simulation-Based Optimization for Surgery Scheduling in Operation Theatre Management Using Response Surface Method," Journal of Medical Systems, vol. 39, Sep. 2015, pp. 1-11, doi: 10.1007/s10916-015-0349-5.

[4] N. Mustafee, K. Katsaliaki, and S. Taylor, "Profiling Literature in Healthcare Simulation," Simulation, vol. 86, Feb. 2010, pp. 543–558, doi: 10.1177/0037549709359090.

[5] R. Banomyong and A. Sopadang, "Using Monte Carlo Simulation to Refine Emergency Logistics Response Models: A Case Study," International Journal of Physical Distribution & Logistics Management, vol. 40, Aug. 2010, pp. 709–721, doi: 10.1108/09600031011079346.

[6] P. Barton, S. Bryan, and S. Robinson, "Modelling in the Economic Evaluation of Health Care: Selecting the Appropriate Approach," Journal of Health Services Research & Policy, vol. 9, Apr. 2004, pp. 110–118, doi: 10.1258/135581904322987535.

 ISBN: 978-1-61208-597-5

[7] E. Huang, Q. Zhang, S. Brown, M. Drum, D. Meltzer, and M. Chin, "The Cost-Effectiveness of Improving Diabetes Care in U.S. Federally Qualified Community Health Centers," Health Services Research, vol. 42, May. 2007, pp. 2174–2193, doi: 10.1111/j.1475-6773.2007.00734.x.

[8] S. Schutte, J. Polling, F. Helm, and H. Simonsz, "Human Error in Strabismus Surgery: Quantification with a Sensitivity Analysis," Graefe's Archive for Clinical and Experimental Ophthalmology, vol. 247, Oct. 2008, pp. 399-409, doi: 10.1007/s00417-008-0961-x.

[9] K. Luangkesorn and Z. Eren-Dogu, "Markov Chain Monte Carlo Methods for Estimating Surgery Duration," Journal of Statistical Computation and Simulation, vol. 86, May. 2014, pp. 262–278, doi: 10.1080/00949655.2015.1004065.

[10] G. Lymperopoulou, L. Petrokokkinos, P. Papagiannis, M. Steiner, V. Spevacek, J. Semnicka, P. Dvorak, and I. Seimenis, "Monte Carlo Simulations to Optimize Experimental Dosimetry of Narrow Beams Used in Gamma Knife Radio-Surgery," Nuclear Instruments and Methods in Physics Research Section A: Accelerators, Spectrometers, Detectors and Associated Equipment, vol. 39, Sep. 2007, pp. 548-551, doi: 10.1016/j.nima.2007.05.227.

[11] W. Huberts, C. Jonge, W. Linden, M. Inda, J. Tordoir, F. Vosse, and E. Bosboom, "A Sensitivity Analysis of a Personalized Pulse Wave Propagation Model for Arteriovenous Fistula Surgery. Part A: Identification of Most Influential Model Parameters," Medical Engineering & Physics, vol. 35, Jun. 2013, pp.810–826, doi: 10.1016/j.medengphy.2012.08.012.

[12] P. Cerveri, A. Manzotti, M. Marchente, N. Confalonieri, and G. Baroni, "Mean-Shifted Surface Curvature Algorithm for Automatic Bone Shape Segmentation in Orthopedic Surgery Planning: A Sensitivity Analysis," Computer Aided Surgery, vol. 17, Apr. 2012, pp. 128–141, doi: 10.3109/10929088.2012.670667.

[13] V. Loving, D. Edwards, K. Roche, J. Steele, S. Sapareto, S. Byrum, and D. Schomer, "Monte Carlo Simulation to Analyze the Cost-Benefit of Radioactive Seed Localization Versus Wire Localization for Breast-Conserving Surgery in Fee-for-Service Health Care Systems Compared With Accountable Care Organizations," American Journal of Roentgenology, vol. 202, Jun. 2014, pp. 1383–1388, doi: 10.2214/AJR.13.11368.

[14] C. Gigliotti, L. Altabella, F. Boschi, and A. Spinelli, "Monte Carlo Feasibility Study for Image Guided Surgery: From Direct Beta Minus Detection to Cerenkov Luminescence Imaging," Journal of Instrumentation, vol. 11, Jul. 2016, doi: 10.1088/1748-0221/11/07/P07021.

[15] A. Stone, M. Grant, C. Roda, D. Hobson, T. Pawlik, C. Wu, and E. Wick, "Implementation Costs of an Enhanced Recovery After Surgery Program in the United States: A Financial Model and Sensitivity Analysis Based on Experiences at a Quaternary Academic Medical Center," Journal of the American College of Surgeons, vol. 222, Jan. 2016, pp. 219–225, doi: 10.1016/j.jamcollsurg.2015.11.021.

[16] R. Ferreira, F. Coelli, W. Pereira, and R. Almeida, "Optimizing Patient Flow in a Large Hospital Surgical Centre by Means of Discrete-Event Computer Simulation Models," Journal of Evaluation in Clinical Practice, vol. 14, Nov. 2008, pp. 2127–2130, doi: 10.1111/j.1365-2753.2007.00939.x.

[17] C. Zhang, H. Hanchi, S. Meijer, "Evaluating the Effect of Centralized Administration on Health Care Performances Using Discrete-Event Simulation," Proc. IEEE 17th Portland International Conference on Management of Engineering and Technology, in press.

 ISBN: 978-1-61208-597-5

Towards a Smart Dental Healthcare: An Automated Assessment of Orthodontic Treatment Need

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***Abstract*—With increasing demands for dental healthcare becoming one of the regular life health factors, this work focuses on the automation of diagnostic imaging in the field of orthodontics. The automated diagnostic imaging of oral images can evaluate the severity of malocclusion and jaw abnormality, and it is beneficial for both doctors reducing their workload and patients periodically performing self-assessment without visiting clinics. In this paper, we propose a deep learning-based model that assesses oral images and gives the severity of orthodontic treatment need. Unlike a traditional image classification model, the proposed model successfully deals with the case that one class label (e.g., the severity score) is assigned to a set of images (e.g., oral images of a patient). The experimental results show that the proposed model improves the classification accuracy by 11% (18% in the best) compared to other conventional models.**

Keywords–Orthodontic treatment; Diagnostic imaging; Deep learning.

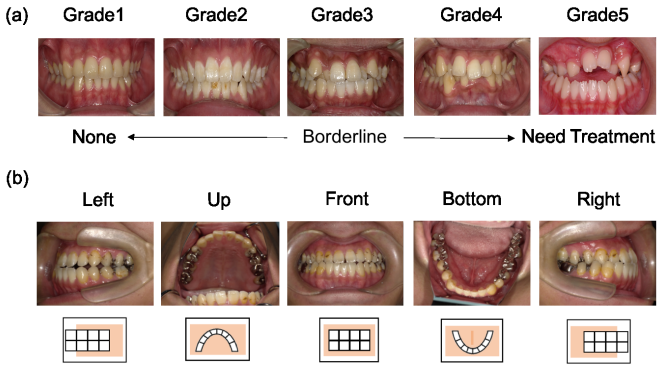

Figure 1. (a) IOTN Grades in 5 scales and the corresponding sample oral images. (b) Oral images taken from five different directions and their illustrations (used in the rest of the paper).

I. INTRODUCTION

The recent breakthrough in image recognition technology using deep convolutional neural network (CNN) model [1][2] brings further improvement in diagnostic imaging that can diagnose the presence of tuberculosis in chest x-ray images [3], detect diabetic retinopathy from retinal photographs [4], as well as locate breast cancer in pathology images [5]. The automated diagnostic imaging is eagerly desired in the field of orthodontics as well, along with the increasing demands for dental healthcare, becoming one of the regular life health factors. For example, it enables individuals to self-check the degree of malocclusion and jaw abnormality from oral and facial images, which are the causes of masticatory dysfunction, apnea syndrome and pyorrhea, etc. Moreover, it leads to providing objective diagnosis that is important for both doctors and patients because the diagnosis directly affects the treatment plan, treatment priority and insurance coverage.

Orthodontists generally use Index of Orthodontic Treatment Needs (IOTN) to determine whether individuals qualify for further orthodontic treatment. IOTN [6] is one of the severity measures for malocclusion and jaw abnormality, which determines whether orthodontic treatment is necessary. Typically, the value ranges between Grade 1 (None) and Grade 5 (Need Treatment) as shown in Figure 1(a). A primary care doctor or general dentist checks the dental healthcare of his/her patient with IOTN, and if the score is high, he/she refers the patient to the other specialist for further treatment. The IOTN assessment is a significant key process to prevent oral diseases from becoming worse. However, to provide the accurate assessment of IOTN requires special training. Many patients tend to miss the appropriate treatment timing due to an incorrect assessment by an inexperienced doctor.

Here, we consider the automation of IOTN assessment, which brings several benefits as follows. Firstly, it helps provide an objective diagnosis that minimizes the diagnosis variation among doctors. The objective diagnosis is quite useful for Informed Consent and training inexperienced doctors. Secondly, the automated diagnostic imaging is highly expected to assist doctors reducing their workload. For example, in Osaka University Dental Hospital, a few doctors take care of over a hundred patients every day. What's more, it benefits people who are able to take their oral photo using smartphone or mobile device, and periodically perform self-assessment at remote without visiting clinics.

To achieve the automation of IOTN assessment, we employ a deep CNN model based on historical records, i.e., oral images of patients, and solve a problem as an image classification. However, there is an issue that we cannot simply apply a conventional CNN to our problem. Unlike typical image classification problems assuming that each image is paired with

 ISBN: 978-1-61208-597-5

one class or label, one class (i.e., a IOTN grade) is paired with a set of images of a patient. As shown in Figure 1(b), each patient is taken his/her oral images from five different directions, and one IOTN grade is given to each patient. There might be a case that a malocclusion at right lower molars is observed in the right image but cannot see in the left and up images, and the alignment of left teeth is clean.

In this paper, we propose a parallel CNN model that independently runs multiple CNNs, each of which deals with images taken from one direction, and then concatenates feature vectors (i.e., outputs of the multiple CNNs) to one vector, namely a patient vector. The patient vector preserves the feature information of all images of a patient. It is input to a multi-layer perceptron (MLP) whose output is one of IOTN grades. We verify that the proposed model achieves 11% (18% in the best case) improvement in its accuracy, compared to a MLP and a CNN model.

The remainder of this paper is organized as follows. Section II introduces some related work in image classification. Section III first reviews a CNN, and explains why the conventional CNN does work well to our problem, followed by the description of the proposed model. Section IV shows the evaluation and discusses some future work.

II. Related Work

A large number of researches has been done already in conventional machine learning. Image classification is typically performed in two steps, a feature extraction and a classification. It relies much more on the extraction of the features of targets in images. Even though many researches have proposed their own features, such as Histograms of Oriented Gradients (HOG), Scale-Invariant Feature Transform (SIFT), Haar-like, etc., a great amount of time and effort has been spent.

Recently, deep learning technique has emerged as a powerful approach to solve many problems in computer vision fields [7][8]. Convolutional neural network (CNN) [1][2], especially, has been successfully applied for image classification, object recognition, segmentation, etc. It lets the model automatically learn the features of targets in images using a large scale of training data.

The deep learning technique brings further improvement in diagnostic imaging as well, which can diagnose the presence of tuberculosis in chest x-ray images [3], detect diabetic retinopathy from retinal photographs [4], as well as locate breast cancer in pathology images [5]. However, a little has been done in the filed of dentofacial orthopedics.

Typically image classification problems assume that each image is labelled with one or more classes. Unlikely, the problem we focus in this paper is that one class label (e.g., a IOTN grade) is assigned to a set of images (e.g., for a patient); thus, a conventional CNN cannot be directly applied. There is a promising technique called boosting [9][10] that creates a strong classifier/predictor by combining multiple weak or less accurate classifiers/predictors trained by sampled data. Inspired by the idea of such aggregation, we consider multiple CNNs, each of which takes care of different subset of images. However, it is difficult to find the way of how we aggregate the results of each CNN. Thus, we try to investigate a concatenated feature (i.e., a representation of a patient), implemented in the proposed model.

III. The Proposed Model

As briefly explained in Introduction, we design a deep learning-based model to classify sets of patients' oral images into the corresponding IOTN grades. This section first reviews a convolutional neural network (CNN); then explains a reason that we cannot simply apply the conventional CNN model to our problem in Section III-B, and then describes the proposed parallel CNN model in Section III-C.

A. Review of CNN

A conventional CNN for image classification consists of multiple, repeating components that are stacked in layers namely convolution, pooling, fully-connected and softmax layers.

Convolution layer is to extract features from the input image. Convolution preserves the spatial relationship between pixels by learning image features using small squares called filters. The convolution operator convolves the input $\mathbf{x} = \{x_{ij}\}$ with a filter $\mathbf{w} = \{w_{pq}\}$. The output for a neuron at (i,j) in the next layer ℓ is computed by

$$\begin{aligned} z_{ij}^{(\ell)} &= f(u_{ij}) \\ &= f(\sum_{p=0}^{M-1}\sum_{q=0}^{M-1} w_{pq} \cdot z_{i+p,j+q}^{(\ell-1)} + b_{ij}) \end{aligned}$$

where M indicates the filter size, b is a bias and $z_{ij}^{(0)} = x_{ij}$. f applies the nonlinearity to the convoluted value, namely an activation function. (Note that the layer index $^{(\ell)}$ of w and b is omitted for simplicity.) When considering the input with K channels and S filters, we need to sum up u_{ij} for all channels using each of S filters by

$$\begin{aligned} z_{ij,s}^{(\ell)} &= f(u_{ij,s}) \\ &= f(\sum_{k=0}^{K-1}\sum_{p=0}^{M-1}\sum_{q=0}^{M-1} w_{pqk,s} \cdot z_{i+p,j+q,k}^{(\ell-1)} + b_{ij,s}). \end{aligned}$$

Pooling layer is normally operated in-between successive convolution layers to reduce the spatial size of the representation and the amount of parameters. The pooling layer operates independently on every depth slice of the input using max or averaging operation. The most common max pooling operation downsamples the input using $H \times H$ filter by

$$u_{ijk} = \max_{(p,q)\in P_{i,j}} z_{pqk}$$

where P_{ij} indicates a set of pixels in any $H \times H$ subregion of input, whose center is (i, j).

Fully-connected layer is a traditional neural network layer where the features of the next layer are a linear combination of the features of the previous layer. The output value is computed by

$$y_k^{(\ell)} = f(\sum_h w_{k,h} \cdot x_h^{(\ell-1)} + b_k)$$

where y_k is the k-th neuron, and $w_{k,h}$ is the weight between x_h and y_k.

 ISBN: 978-1-61208-597-5

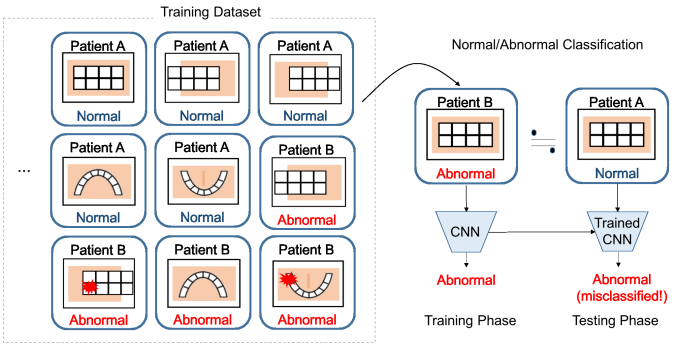

Figure 2. An illustration of misclassification due to the mislabelled training data. The blue rounded box indicates one input sample including a patient image with the corresponding label.

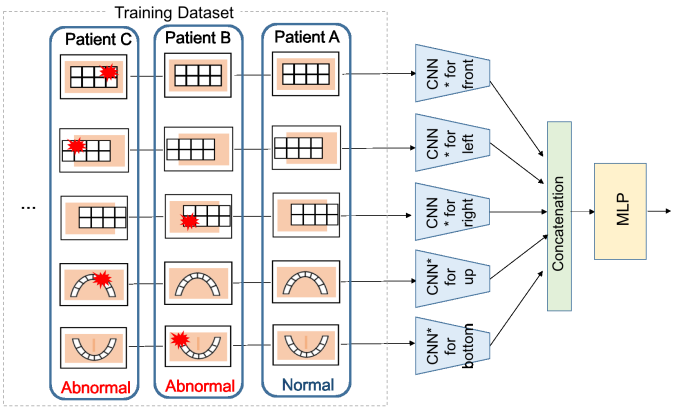

Figure 3. An illustration of the proposed parallel CNN model. The blue rounded box is one input sample including a set of five images of a patient. "CNN*" denotes a CNN without fully-connected and softmax layers

Finally, Softmax layer converts feature vectors into class probabilities. It normalizes the vector of scores by

$$y_k^{(L)} = \text{Prob}(\text{class} = j|\mathbf{x}, \mathbf{w}) = \frac{\exp(y_j^{(L)})}{\sum_{j=1}^{C} \exp(y_j^{(L)})}.$$

Then, the model is trained (i.e., updates their weights) in such a way that the class label with the highest probability becomes a true label. Note that multi-layer perceptron (MLP) usually indicates the neural network consisting of fully-connected layers and a softmax layer.

B. Issues to be considered

As a preliminary evaluation, we investigated the classification accuracy when using a conventional CNN model. We collected 300 patients' images (i.e., 1,500 images in total), and we intentionally assigned each image with one of two labels, *Normal* if IOTN grade is less than or equal to 3 and *Abnormal* if IOTN grade is larger than 3. In the result, we observed 60.4% of binary classification accuracy by 6-fold cross-validation.

The reason of such low accuracy comes from the mislabeling of training data because of the mixed oral images with five different directions. As explained, one IOTN grade is given to a patient based on a set of his/her oral images. There might be a case that a malocclusion at right lower molars is observed in the right images but cannot see in the left and up images. For example, as illustrated in Figure 2, Patient B has a problem in his right lower molars that can be observed in the right and bottom images, but the other front, left and up images are clean even though it was labelled as *Abnormal*. In such case, misclassification occurs when classifying Patient A's *Normal* front image, which is similar to Patient B's front image.

In fact, doctors did not set a label for each image. It is time-consuming work or nearly impossible for doctors to annotate each of all images with correct label.

C. Description of the Proposed Model

In order to solve the issue, we consider a promising technique called boosting [9][10], one of the ensemble learning approaches, which creates a strong classifier/predictor by combining multiple weak or less accurate classifiers/predictors trained by sampled data. We employ the idea of such aggregation. For doing so, we revise the format of training dataset in such that each input sample contains five images (of different directions) of a patient and one corresponding label. Then, we run multiple CNNs, each of which deals with images taken from one direction. However, the results of CNNs are still independent each other, so it is difficult to find the way of how we aggregate the results to improve the accuracy.

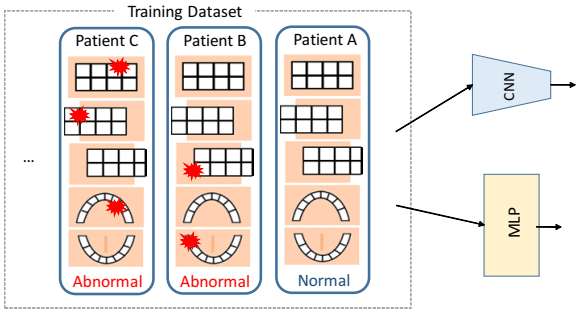

Figure 4. An illustration of alternative training dataset. The blue rounded box indicates one input sample containing one image combining five images at pixel level, and the corresponding label.

Thus, we design a parallel CNN model as illustrated in Figure 3. The proposed model independently runs multiple CNNs and concatenates intermediate feature vectors from the multiple CNNs to one vector preserving all information of different directions. The concatenated vector is named a patient vector, which is the input of a multi-layer perceptron (MLP) whose output is one of class labels after a softmax operation. In this model, CNNs (denoted by "CNN*" in Figure) do not have fully-connected layers and softmax layers (except the last layer of the proposed model).

As an additional investigation, we performed another experiment. In this experiment, we train a MLP or a conventional CNN using the dataset where five images are combined to one image at pixel level as illustrated in Figure 4. However, the accuracy does not improve as expected. We discuss more about it in the next section.

IV. Evaluation

This section shows the experimental results to evaluate the proposed model in terms of the classification accuracy of IOTN assessment, and compares it with a few different models.

 ISBN: 978-1-61208-597-5

TABLE I. THE PROPOSED MODEL STRUCTURE AND PARAMETER VALUES.

Name	Filter size	Stride	Output size	Activation
input	-	-	90 × 120 × 3	-
conv1	3 × 3	1	90 × 120 × 32	ReLU
pool1	2 × 2	2	45 × 60 × 32	-
conv2	3 × 3	1	45 × 60 × 64	ReLU
pool2	2 × 2	2	23 × 30 × 64	-
conv3	3 × 3	1	23 × 30 × 128	ReLU
pool3	2 × 2	2	12 × 15 × 128	-
conv4	3 × 3	1	12 × 15 × 256	ReLU
pool4	2 × 2	2	6 × 8 × 256	-
conv5	3 × 3	1	6 × 8 × 512	ReLU
pool5	2 × 2	2	3 × 4 × 512	-
concat	-	-	3 × 4 × (512 × 5)	-
flat	-	-	1 × 30720	-
fc1	-	-	1 × 4096	ReLU
fc2	-	-	1 × 512	ReLU
fc3	-	-	1 ×# of classes	Softmax

TABLE II. THE CLASSIFICATION ACCURACY OF DIFFERENT MODELS (%).

Model	2-class		5-class		2-class - G3	
	Mean	Best	Mean	Best	Mean	Best
MLP	58.2	59.5	20.9	21.2	-	-
CNN	60.4	61.4	21.3	21.6	-	-
Parallel CNN	71.8	79.0	40.2	45.0	73.1	81.3

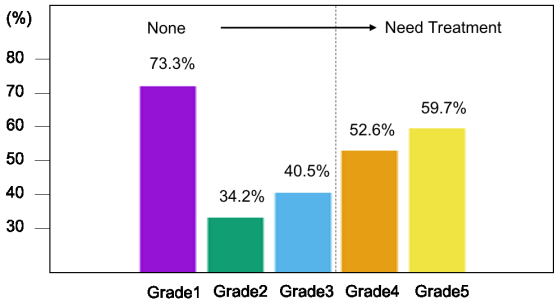

Figure 5. The classification accuracy of 5-class case for IOTN grades.

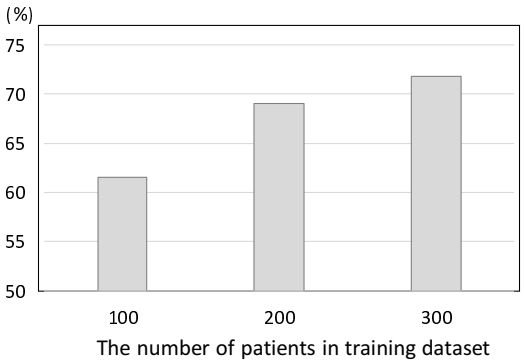

Figure 6. The classification accuracy of the model trained over the different size of training samples.

A. Environment Settings

For this experiment, we use a machine of Windows10 with Intel(R) Xeon(R) CPU E5-1620 v3 @ 3.50GHz and 16GB memory. The proposed model is trained with GeForce GTX TITAN x 12GB. We implement the model using TensorFlow [11].

Department of Orthodontics and Dentofacial Orthopedics in Osaka University Dental Hospital provides a dataset containing the oral images (taken from five directions) of 300 patients for this experiment. Each patient is assessed by one IOTN grade, and there are 60 patients per each grade.

B. Experimental Results

Table I shows a list of model parameters such as the filter size of convolution and pooling layers, and their stride size. The model consists of five pairs of convolution and pooling layers followed by a concatenation layer and three layers of MLP. We use Retified Linear Unit (ReLU) function [12] for an activation function. During a training phase, we set a learning rate to 1e-4, and use Adam [13] for the optimizer. Although there are various choices of hyper-parameters for layers, activation functions, learning rates, and optimizers, we showed the best case among several trial and error. For the accuracy evaluation, we perform 6-fold cross-validation by 90%/10% of training/validation data.

Table II shows the classification accuracy of different models. ”2-class” indicates a binary classification of Normal (Grades 1,2,3) and Abnormal (Grades 4,5). ”5-class” indicates the classification of five IOTN grades. ”2-class-G3” indicates a binary classification of Normal except Grade 3 and Abnormal. The proposed model successfully improves the mean and best of cross-validation accuracy by 11% (18% in the best case) for 2-class (*Normal/Abnormal* classification) case and 19% (24% in the best case) for 5-class (IOTN grade classification) case, compared with the accuracy using a MLP and a conventional CNN (as described in Figure 4).

For 5-class classification, it seems that less than 50% accuracy is a quite low, but there are a few clear reasons as follows. As seen in Figure 5, the accuracy for Grade 2 is a very low compared to the others. Most of Grade 2 samples are classified as Grade 1 because the images of “Perfect” and “Slight” are very similar. In addition, the accuracy for Grades 3 and 4 is also relatively low. Correctly classifying Grades 3 and 4 is really significant to determine whether if a patient needs treatment. However, we observe that most of Grade 3 samples are classified as Grade 4. In practice, doctors also tend to diagnosis a patient of Grade 3 as Grade 4. This difficulty can be seen in the performance improvement when the model is trained on all training samples except Grade 3 samples. In this case, the accuracy improves to 73.1% (81.3% in the best case) as shown in Table II.

Another reason of the low accuracy might be the size of training data. To learn clear features of five grade samples, we need more data with correct label. Figure 6 shows the results when training the parallel CNN model on 100, 200 and 300 patients’ samples. We observe the trend of increasing performance, so we believe that the accuracy will increase as the number of samples increases. We are now collecting more samples for training, and also perform data cleansing to correctly label the samples.

 ISBN: 978-1-61208-597-5

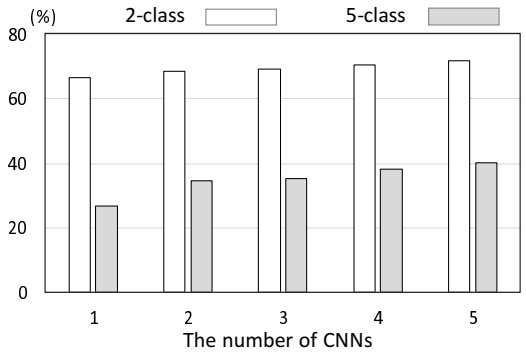

Figure 7. The classification accuracy of the model with the different number of CNNs.

Finally, we evaluate the effectiveness of running multiple CNNs in parallel. For doing it, we train the model on only front images; and then, we perform the experiment on additional set of images such as left images (i.e., front and left images). We repeat the same experiment by adding the other sets of images one by one. The result of accuracy comparison is shown in Figure 7. As the number of CNNs for the different set of images increases, the accuracy also increases.

V. Conclusion

In this paper, we proposed a parallel CNN based image classification model that assesses IOTN grades. Technically, it deals with a training dataset including pairs of a set of images and its corresponding class label. We verify that the proposed model outperforms the other conventional models in terms of classification accuracy.

In future work, we will increase the number of accurate data to retrieve features that clearly separate IOTN Grades 3 and 4 samples. Eventually, we plan to build a dental healthcare application that fully or semi-fully automates the process of IOTN assessment and treatment plan generation using smartphone or mobile devices. The successful remote or automated diagnostic imaging will also be expanded to other fields, such as otolaryngology (ear and nose) and ophthalmology (eye).

Acknowledgment

This work was supported by JSPS KAKENHI Grant Number JP17KT0083, and partly supported by JSPS KAKENHI Grant Number JP16H02802 and JP17K00168. The authors would like to thank Prof. Takashi Yamashiro and Assistant Prof. Kazunori Nozaki, Osaka University Dental Hospital, for setting up environment and medical dataset for the experiments.

References

[1] A. Krizhevsky, I. Sutskever, and G. E. Hinton, "Imagenet classification with deep convolutional neural networks," Advances in Neural Information Processing Systems, vol 1, pp. 1097-1105, 2012.

[2] J. Gu, et al., "Recent advances in convolutional neural networks," arXiv preprint arXiv:1512.07108, Jan. 2017.

[3] P. Lakhani and B. Sundaram, "Deep learning at chest radiography: Automated Classification of Pulmonary Tuberculosis by Using Convolutional Neural Networks," Radiology, vol. 284, no. 2, pp. 574-582 2017.

[4] V. Gulshan, et al., "Development and validation of a deep learning algorithm for detection of diabetic retinopathy in retinal fundus photographs," JAMA, 316(22), pp. 2402-2410, 2016.

[5] A. Janowczyk and A. Madabhushi, "Deep learning for digital pathology image analysis: A comprehensive tutorial with selected use cases," Journal of Pathology Informatics, 7(292), 2016.

[6] Jarvinen S., "Indexes of orthodontic treatment need," the American Journal of Orthodontics and Dentofacial Orthopedics, 120(3), 2001.

[7] Y. Bengio, A. Courville, and P. Vincent, "Representation learning: A review and new perspectives," IEEE Transactions on Pattern Analysis. Mach. Intell., vol. 35, no. 8, pp. 1798-1828, Aug. 2013.

[8] Y. Lecun, Y. Bengio, and G Hinton, "Deep learning," Nature, vol. 521, no. 7553, pp. 436-444, 5 2015.

[9] Y. Freund and R. E. Schapire, "Experiments with a new boosting algorithm," In Proc. of the 13th International Conference on Machine Learning, vol. 96, pp. 148-156, Jul. 1996.

[10] T. Kanamori, K. Hatano, and O. Watanabe, "Boosting - Design method of learning algorithms," , Mori Publishing, Sep. 2006.

[11] TensorFlow, https://www.tensorflow.org, retrieval: Aug. 2017.

[12] X. Glorot, A. Bordes, and Y. Bengio, "Deep sparse rectifier neural networks," Aistats, vol. 15, no. 106, pp. 275, Apr. 2011.

[13] D. Kingma and J. Ba, "Adam: A method for stochastic optimization," arXiv preprint arXiv:1412.6980, Dec. 2014.

 ISBN: 978-1-61208-597-5

Evaluation of the Malfunctions of a Clinical Decision Support System Dependent on Electrocardiograms and Measurement of the QT Interval

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***Abstract*—Malfunction of clinical decision support (CDS) systems could lead to undesirable consequences. We evaluated CDS malfunctions associated to the use of electrocardiograms (ECG) as data source to detect a delta in the corrected QT interval (QTc) ≥ 60 milliseconds (QTc current ECG minus QTc previous ECG). Our preliminary results showed that several common clinical conditions can cause changes in the electrocardiogram and result in errors when calculating the QTc interval and subsequently the delta QT between 2 serial ECGs. These errors cannot be easily identified by the electronic systems and are a source of CDS malfunction.**

Keywords-QT prolongation; electrocardiography; decision support systems; prognosis.

I. INTRODUCTION

Clinical decision support (CDS) systems integrated with the electronic health record (EHR) have the potential to enhance patient safety, improve quality of care, and decrease cost [1]. These systems are excellent tools to screen for rare but potentially life-threatening conditions. However, their accuracy depends on the structured data available in the EHR. If these data have errors, the CDS systems may be unable to provide accurate recommendations, or even worse, could provide false recommendations leading to unintended consequences for patients and clinicians.

Prolongation of the QT interval in the electrocardiogram (ECG) is a rare clinical condition that is an independent risk factor for Torsades de Pointes (TdP), a ventricular arrhythmia that can cause syncope, seizure or sudden cardiac death. QT prolongation can be congenital (long QT syndrome) or secondary to several medications, electrolyte abnormalities, and comorbidities. Because of these risks, international guidelines [2] recommend the use of electronic systems to detect potentially arrhythmogenic QT prolongation in hospitalized patients. QT prolongation is defined as a heart-rate corrected QT (QTc) value > 470 milliseconds (ms) in men and > 480 ms in women. For both genders, a QTc > 500 ms is considered potentially life threatening and is associated with a 2- to 3-fold higher risk for TdP. As the QT interval is relatively stable over the course of one's life, a delta QTc > 60 ms on serial ECGs is a potential warning sign, reflecting new/additional QT stressors might have occurred. Our institution has developed and implemented several CDS interventions to identify high risk patients showing QT prolongation, and provide appropriate management to prevent complications [3]. Herein, we present our preliminary results of the evaluation of the CDS malfunctions associated to the use of ECGs as the data source to detect a delta QTc ⩾ 60 ms.

II. METHODS

We evaluated a CDS system (QT Alert System) integrated with the EHR designed and implemented to improve awareness of a new clinically significant increase of the QTc by ⩾ 60ms in two consecutive ECGs. All ECGs were obtained and initially analyzed using the MUSE Cardiology Information System (GE Healthcare), which provided initial measure of the QT interval and QTc value. All electronically generated reports were evaluated by an ECG technician trained in ECG interpretation and, where needed, corrected. All pediatric and questionable abnormal ECG findings were evaluated subsequently by a pediatric or adult cardiologist. The QT Alert System screened all ECGs transmitted to the EHR to detect a delta QTc ⩾ 60ms by comparing the last two ECGs, and if positive, alerted the ordering provider (outpatient) or the primary hospital service (inpatient) by sending a semi-urgent inbox message. All event data were electronically stored for reporting.

A preliminary review of the ECGs was done using electronic searches to identify events with potential errors in measurement of the QTc focusing on extreme outliers. A sample of 50 alerts (100 ECGs) was reviewed independently by two physicians (TDG and NL), who manually re-calculated the QTc and assessed the ECGs for potential sources of errors that could have led to an erroneous delta QT. The ECG pairs were selected for review when the time between the ECGs was less than 7 days and (1) both QTc > 500 ms or (2) previous QTc < 360 ms and current QTc >500ms. These criteria were chosen because of the extreme QTc changes. The kappa statistic for initial agreement between the two reviewing physicians was 0.432. All differences were resolved by mutual consensus.

III. RESULTS

Overall, we analyzed 6,798 events (inbox messages) in 6,039 unique patients (52.2% male, mean age 60.1 years, SD ± 19.5 years) over a 6-year period. Patients could have more

 ISBN: 978-1-61208-597-5

TABLE I. DISTRIBUTION OF THE EVENTS BASED ON THE QTC VALUE, N (%).

Previous ECG	Current ECG		
	QTc <360	QTc 360-500	QTc >500
QTc <360ms	10 (0.1%)	439 (6.5%)	43 (0.6%)
QTc 360-500ms	None	3132 (46.1%)	3000 (44.1%)
QTc >500ms	None	none	174 (2.6%)

than one event. The messages were sent to 6,434 unique providers. The time interval between consecutive ECGs was highly variable; for 27.35% of alerts, the interval was less than 2 days, 23.4% between 2 to 7 days, 34.25% between 8 to 365 days, and 15.0% between 1 and 5 years. Table I shows the distribution of the events based on the QTc value of the ECGs. A large proportion of events (47.3%) occurred with a current QTc > 500 ms that by itself was a risk factor for complications. A few events (n = 10; 0.1%) occurred with both QTc values below 360 ms (short QTc). Some events (n = 43; 0.6%) showed a very large delta QTc (mean delta QTc = 237 ms; SD = 89 ms).

TABLE II. CAUSES OF ERRORS IN MEASURING THE QTC.

Cause	N	%
Permanent pacemaker	28	26.92
Flat T-waves	20	19.23
Sinus tachycardia	12	11.54
Right bundle branch block	8	7.69
Atrial tachycardia	7	6.73
Supraventricular tachycardia	6	5.77
Cardiac ischemia	5	4.81
Ectopic beats	4	3.85
Acute myocardial infarction	3	2.88
Bradycardia	3	2.88
Temporary pacemaker	3	2.88
Atrial fibrillation	2	1.92
Atrial flutter	2	1.92
Cardiac arrest	1	0.96

Table II shows the result of the manual review by the clinicians. The most common causes of errors were the presence of a pacemaker, flat T-waves, tachyarrhythmia and bundle branch block.

IV. DISCUSSION

Our results suggest that ECG data can be a source of malfunction of CDS systems. In the case of detecting QTc abnormalities, several common clinical conditions (Table II) can change the morphology of the QT wave or the heart rate introducing significant errors when the QTc is measured by an electronic system.

The ECG is the source of high value data related to the cardiac function and can be used to identify patients at risk for complications due to abnormal changes in the QT interval. However, these data are unstable and influenced by several factors that may not be easily recognized by a CDS system. Nevertheless, most of these errors are detected easily by a clinician reviewing the ECG.

To improve the accuracy of CDS systems that use ECG data, it may be necessary to use additional EHR data indicating new changes of the patient's clinical condition. Potential changes include identifying new interventions (i.e., pacemakers), new cardiac events (i.e., ischemia, arrhythmias), or transfer to a different clinical setting (i.e., monitor bed, intensive care unit, operating room). Better standardization of ECG interpretation and reporting [4] is also needed to minimize data errors. These changes could help in the design of more accurate, context sensitive CDS systems able to improve performance while decreasing burden and alert fatigue.

In conclusion, erroneous ECG data can impact significantly the outcome and the clinical recommendations provided by CDS systems. These malfunctions could lead to alert fatigue and mistrust of the recommendations provided by CDS systems.

ACKNOWLEDGMENT

This study was supported partially by a generous gift from the Frederick W. Smith family and the Windland Smith Rice Comprehensive Sudden Cardiac Death Program. Its contents are solely the responsibility of the authors.

REFERENCES

[1] T. J. Bright et al., "Effect of clinical decision-support systems: a systematic review," Ann. Intern. Med., vol. 157, no. 1, pp. 29-43, 2012.

[2] B. J. Drew et al., "Prevention of Torsade de Pointes in hospital settings: a scientific statement from the American Heart Association and the American College of Cardiology Foundation," J. Am. Coll. Cardiol., vol. 55, no. 9, pp. 934-947, 2010.

[3] K. H. Haugaa et al., "Institution-wide QT alert system identifies patients with a high risk of mortality," Mayo Clin. Proc., vol. 88, no. 4, pp. 315-325, 2013.

[4] P. M. Rautaharju et al., "AHA/ACCF/HRS recommendations for the standardization and interpretation of the electrocardiogram: part IV: the ST segment, T and U waves, and the QT interval: a scientific statement from the American Heart Association Electrocardiography and Arrhythmias Committee, Council on Clinical Cardiology; the American College of Cardiology Foundation; and the Heart Rhythm Society: endorsed by the International Society for Computerized Electrocardiology," Circulation, vol. 119, no. 10, pp. e241-245, 2009.

 ISBN: 978-1-61208-597-5

Detecting Agitation Onset in Individuals with Dementia Using Smart Phone Sensors

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***Abstract*—Individuals living with dementia (ILWD) often experience problematic agitated behaviors, this occurs in up to 80% of ILWD. These behaviors lead to stress for caregivers and increased frequency of institutionalization. There are many proven methods to intervene during agitated behavior outburst and the earlier these methods are used the better the results. Technology has been used successfully to monitor many aspects of health monitoring for older adults. Technology is now being investigated to evaluate the effectiveness of predicting the onset of problem behaviors, especially escalating agitation in ILWD. Off the shelf technology, smart watches and android phones, are being tested to measure limb movements, vocalizations, heart rate and location in facility, to evaluate their ability to provide data that is helpful in predicting agitated behaviors about to occur. This project is a collaboration between nursing and computer science in a major university setting. Currently, work has been completed on volunteers acting as patients to evaluate the ability of this technology to measure the desired parameters. Positive results have been obtained; the goal is to trial this technology on ILWD that have documented history of agitation in an assisted living environment.**

Keywords- dementia; behavior problems; wearable technology; bio measures

I. INTRODUCTION

Dementia affects over 5 million in the U.S and the numbers are projected to climb to over 7 million by 2025 [1]. Additionally, it is estimated that over 46 million people worldwide are living with dementia with the fastest growing population of older adults occurring in China, India, South Asia and the Western Pacific [2]. Those with Alzheimer's and other forms of dementia often go through a period of significant behavioral symptoms of dementia (BSD). It is estimated that between 60 and 80% of these individuals will suffer from BSD during the time they are dealing with this disease [3]. BSD's are generally divided into several categories; physical and non-physical agitation or aggression and verbal agitation. Non-physical behaviors include, disrobing, hording, hiding things, and exit seeking behavior. Physically aggressive behaviors include biting, hitting, kicking, pushing, scratching, and unwanted sexual advances. There can also be verbal concerns such as cursing, yelling and repeated calling out attention seeking behavior [4]. These behaviors are very difficult for caregivers to manage and are positively correlated with caregiver distress [5]. They also contribute to increased cost of care for persons with dementia and are a primary reason for institutionalization [6] [7] [8]. Behavioral problems are a safety concern for family members and professional caregivers as well as other older adults living in communal environments.

There are well-validated non-pharmacologic methods to deal with BSD. These methods include redirection, music therapy, one-on-one socialization, art therapy and animal assisted therapy [9]. A pressing issue concerning BSD is the recognition of triggers – those events that can precede an unwanted behavior [10] [11]. In an attempt to identify these antecedents, various technologies have been used to augment or enhance the input from staff in a facility or caregivers at home. These technologies include video monitoring to capture the event and review the events surrounding the behavioral incident [12]. Another technology that is less intrusive to the communal living or home environment involves using actigraphy sensor technology to monitor disruptive behaviors [13] [14]. One group of researchers used this technology by placing a wearable device that measured movement at the wrist, waist and ankle on individuals identified as having dementia and behavioral issues [14]. The wearable technology demonstrated usefulness by measuring the severity of agitation and showing it compared well to a more established observer measures, such as the Cohen-Mansfield Agitation Inventory (CAMI) [14] although accuracy depended on the time of the day measurements were taken.

There is currently very little known about the ability to use technology to *predict* agitation in persons with dementia in real time. Over the years, use of smart devices and wearables has increased dramatically in the field of healthcare. These wearables are used for a variety of applications ranging from safety to monitoring health measures such as sleep quality and quantity [15]. Pansiot et al discussed how ambient and wearable sensors could be used in health monitoring of patients by recognizing the human activity [16]. Sudden agitated behaviors can be harmful to these individuals and the caregivers or others around them, often leading to aggressive behaviors that are more difficult to ameliorate when they occur.

 ISBN: 978-1-61208-597-5

In this paper we discuss the various tools and methods used for data collection followed by a description of the experiment. Finally we discuss the results and state our conclusions for this study.

II. METHODS

Our hypothesis is that we will be able to first detect agitated behavior and second recognize the onset of agitated behavior in dementia patients using regular, off-the-shelf sensors that can be found in smart watches and/or smart phones. We report in this paper on the development of a feasibility study that is planned to ascertain whether or not we can recognize agitated behavior in actors that simulate such behavior using the fusion of three sensors: a tri-axial accelerometer, an optical heart rate monitor, and a microphone.

The preliminary data was obtained from a series of experiments consisting of five volunteers acting in the role of a patient. Each person was instructed to wear an android Moto 360, which sends the accelerometer and the heart rate values to a server. The volunteers were asked to show agitation or aggressive behaviors that includes random arm movements, such as punching in the air for 2 minutes and then they were instructed to be stable (sitting, sleeping, walking, eating) which involves hand movements but not at a pace as before. Each volunteer performed these actions 10 times wearing the wearable on both the right and left hands. There was a time gap between the actions while training to allow us to label the data with the specific activity performed.

Standard machine learning algorithms used for classification cannot be directly used to predict the mood of a person from the raw data obtained from the wearable. As the device's sensor readings contribute to a lot of noise in the data due to its hardware sensitivity, there is a need of filtering to attenuate the spikes in the data. We used 3rd order low-pass Butterworth filter with a cutoff frequency of 25Hz which removed the outliers in the data. We then used a low pass filter to smooth the remaining spikes in the data, experimenting with different threshold values. We set the threshold to 0.3 by comparing filtered data to well-known data.

According to our experiments, any agitated human activity takes 1-2 seconds to get completed, so we divided the entire data into continuous windows of 2 seconds and all the relevant activities were then captured. Each sample has a length of 2 seconds with 50% overlap so that we do not lose the data in between the samples as we are considering real time data.

The architecture shown in Fig. 1 consists of wearable sensors attached to patients where the sensors send a stream of data over a Wi-Fi to a processing module at a backend server. Heart rate is measured through a smart watch which also measures limb movement through its accelerometer.

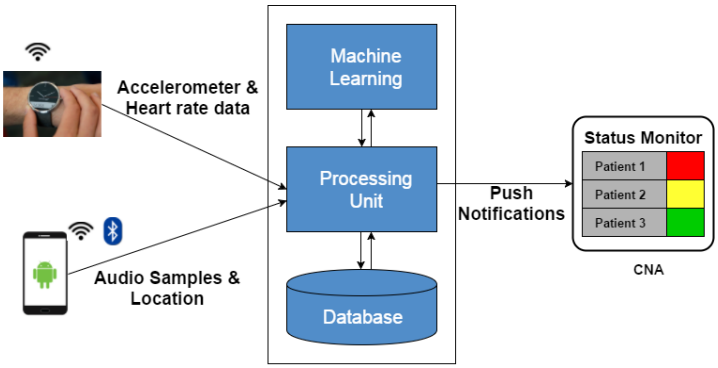

Figure 1. Architecture of the Monitoring System

Audio is sensed by a smart phone and also transmitted to the processing module. Bluetooth beacons are installed in the lab at the University; the smart phone will be able to sense how far it is from what beacon and transmit a stream of location data to the processing unit. The processing unit stores the raw data in a data base for later report analysis and it also produces output data sent to an observer's smart phone. That observer can then display the status of any patient being monitored.

III. EXPERIMENT

The experiment collected data on several measurement parameters. The limb movements of the dominant arm, the emotions and decibel level of the voice, the heart rate and specific location.

A. Limb movement

We attached to an actor a wearable and send the sensor values to the backend server in 5 second intervals. The range of values is [0.0 - 6.0] measured in g. (1g =9.8m/s2); 0 m/s2 is the lowest value recorded when the wearable device is kept on the table without movement; 6.0 m/s2 is the highest value recorded when a normal person wearing device punches into a wall with extreme force. At the server, we pre-process the raw values obtained from the sensor using the box filter and Butterworth filter of 3rd order to remove outliers from the data, after which the values are normalized. We next invoke a machine learning module for further processing. We have used three different models: Support Vector Machine (SVM), Random forests and K Nearest Neighbors (KNN). Among the three algorithms, SVM gave us the results with highest accuracy of 87% and hence we are using this model for all our studies. The features we select include the mean of four seconds of accelerometer values, standard deviation, relative differences between the vectors, angle between them, interquartile values, correlation between values obtained from different axes, so that we can increase the accuracy of prediction.

 ISBN: 978-1-61208-597-5

B. Emotions

Using a smart phone that was located at a fixed position on the actor's waist, we recorded the audio on the phone and send it to a server for analysis. For the analysis of emotion, we used the default natural language processing techniques provided by the Vokaturi software. The training set of the Vokaturi software consist of speech databases like Emo_DB and Savee. The contents of these databases store annotated speech recordings to predict the patient's emotional state. During the training phase, we verified the accuracy of the model by correlating the results with the observations recorded by human observers who are visually observing the patient and making notes on the emotional state of the patient. On the backend, Vokaturi extracts the acoustic features of a user's voice including: pitch, intensity, spectral scope, which is the energy difference between the frequency bands and computes the relative emotion probabilities for fear, anger, sadness, happiness and no emotion. This is computed with a neural network with three levels of linear connections (2 hidden layers). Once the analysis on the audio is done, the raw audio data is deleted to ensure patient privacy. We focused on predicting aggression, and only considered the probabilities of anger and fear. For both of these emotions the software produces values in the range [0 - 1]; ranging from 0 meaning not being angry/fearful at all through 0.2 meaning somewhat angry/fearful, to,…, 1 meaning extremely angry/fearful.

C. Heart rate

We collected heart rate readings of the patients and also pitch of the audio from sensors in the wearable devices. The sensor produces values in the range [40-130] heartbeats per second; 40 hbps corresponds to a very low resting rate of an extremely athletic person; 130 hbps is the maximum heart rate for a 60-year-old person. So far, our experiments have not shown any significant correlation between aggression and changes in heart rate. The same is also true with the pitch of the voice. We are currently sending the data collected from the wearable instantly to the server, analyzing it and storing the data. We have a website to view the current status of each patient and we present the readings from the wearable in the form of graphs.

D. Decibel level

We also have the emotion software produce a loudness measure. The values range in the interval [20 – 80] decibel (dB); 20dB corresponds to whisper or rustling of leaves; 80dB corresponds to the sound the typical garbage disposal makes.

E. Bluetooth

We use Bluetooth beacons to track the patient's location and this information can be provided to the caregiver making it easier to locate the patient exhibiting changes. We plan to place the Rad beacons at pre-determined locations in the facility. We then use the signal from the Bluetooth of the android phone to identify the position of the patient in the facility. We make use of the push notifications to update the caregiver on the patient's location and the status of a patient.

IV. RESULTS

We have obtained useful results from our initial volunteer patient trials. The wearable devices are able to measure changes in movements and voice pitch and then relay this change to a volunteer caregiver. In Fig. 2 we show the output of the system for a patient that has been identified by the system as behaving aggressive. The figure shows a red threshold line that is being crossed by the accelerometer reading. At this time the red line is simply one deviation from the average. In the future we want to use machine learning techniques that will analyze the five measurements streams and produce a classification of agitated or not. We will use various algorithms such as simply summing the values of the streams to more complicated ways of defining agitation such as a weighted sum of the streams. We will use the observations of trained nurses that have categorized patients as being agitated at various points as the gold standard for the machine learning algorithm to decide which the best predictor of agitation is.

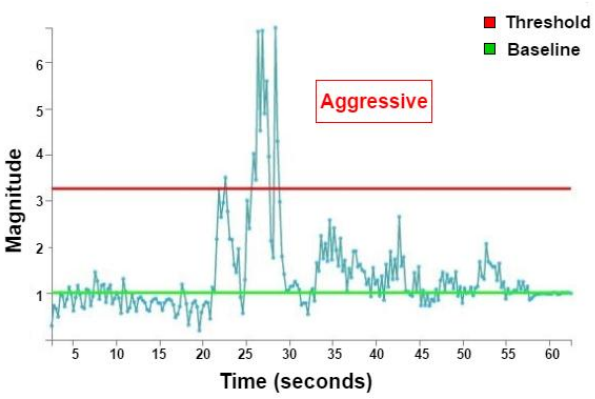

Figure 2. Alert by system

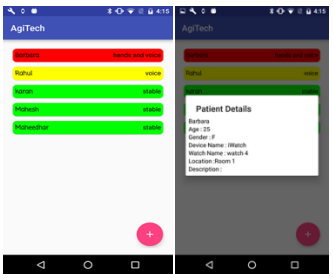

Figure 3. Caregiver monitoring

The details of our volunteer patients' wearable's and their status, whether they are aggressive or stable, are presented in

 ISBN: 978-1-61208-597-5

a mobile application. Fig. 3 displays the list of users wearing the wearable. Each cell in the view represents a user with their name on the left and action by which we are recognizing the user is agitated. The background color of each user cell represents the status of the user where red means the person is agitated, yellow means the person is slightly agitated and green means the person is stable.

V. CONCLUSION

We will perform a study with patients in an assisted living facility specializing in dementia care. This study will evaluate how accurate the various algorithms of our system detect agitation and whether or not we will be able to identify the onset so that caregivers can be alerted and deliver remedial actions. This next phase of our work will involve 6-10 individuals with documented BSD such as, unsafe wandering, resisting care, striking out at staff and other individuals, throwing objects, yelling, screaming or likely a combination of these behaviors. Individual residents displaying these behaviors will be selected and their medical power of attorney will be approached for consent to have their loved one participate. These patients will wear the devices for 4-hour blocks of time over several days, totaling 24 hours of monitoring. Each patient will be followed by a trained person (student nurses) that will record any behavior as identified on the CAMI scale. We have already developed a convenient interface that will automate the recording and send the data to the database on the backend server. The major emphasis of this next study will be to ensure that the data streams from the sensors on the patients agree with observations the trained persons have recorded. The IRB of a major research university has approved this research plan.

Once this next phase is complete and all of our data is evaluated, if the systems provides helpful for these individuals with dementia and their caregivers, we plan to perform a larger study. The larger study would involve individuals in various settings, those living in other institutions as well as at home. This system could also be considered for other populations that also have potential adverse behavior issues such as those with traumatic brain injury (TBI) or special needs children for example. Finding methods to intervene earlier when behavior problems occur can reduce caregiver stress, overall cost of care and likely reduce the amount of medications provided to individuals with BSD. The emotions experienced by people with BSD are real, and developing tools to predict outbursts will improve their overall wellbeing as well.

REFERENCES

[1] Alzheimer's Association. 2016 Alzheimer's disease facts and figures. Retrieved from: http://www.alz.org/alzheimers_disease_stages_of_alzheimers.asp, 2016.

[2] Alzheimer's Disease International. Dementia Statistics. Retrieved from: https://www.alz.co.uk/research/statistics, 2017.

[3] D. L. Woods, M. Yefimova, and M. L. Brecht,"A method for measuring person-centered interventions: detecting and characterizing complex behavioral symptoms of persons with dementia," Clinical Gerontologist, 37(2), pp. 139-150, 2014.

[4] J. Cohen-Mansfield, "Agitated behavior in persons with dementia: the relationship between type of behavior, its frequency, and its disruptiveness," Journal of psychiatric research, 43(1), 64-69.

[5] L. L. Tan, H. B. Wong, and H. Allen, "The impact of neuropsychiatric symptoms of dementia on distress in family and professional caregivers in Singapore," International Psychogeriatrics 17(2), pp. 253–263, 2005.

[6] H. Brodaty, M. H. Connors, J. Xu, M. Woodward, and D. Ames, "Predictors of institutionalization in dementia: a three year longitudinal study," Journal of Alzheimer's Disease, 40(1), pp. 221-226, 2014.

[7] M. E. de Vugt, F. Stevens, P. Aalten, R. Lousberg, N. Jaspers, and F. R. Verhey, "A prospective study of the effects of behavioral symptoms on the institutionalization of patients with dementia," International Psychogeriatrics, 17(04), pp. 577-589, 2005.

[8] D. L. Murman, Q. Chen, M. C. Powell, S. B. Kuo, C. J. Bradley, and C. C. Colenda, "The incremental direct costs associated with behavioral symptoms in AD," Neurology, 59(11), pp. 1721-1729, 2002.

[9] J. Cohen-Mansfield, K. Thein, M. S. Marx, M. Dakheel-Ali, and L. Freedman, "Efficacy of nonpharmacologic interventions for agitation in advanced dementia: a randomized, placebo-controlled trial," The Journal of clinical psychiatry, 73(9), pp. 1255-1261, 2012.

[10] K. Pillemer, E. K. Chen, K. S. Van Haitsma, J. Teresi, M. Ramirez, S. Silver, G. Sukha, and M. S. Lachs, "Resident-to-resident aggression in nursing homes: results from a qualitative event reconstruction study," The Gerontologist, 52(1), pp. 24-33, 2013.

[11] N. Ferrah, B. J Murphy, J. E. Ibrahim, L. C. Bugeja, M. Winbolt, D. LoGiudice, L. Flicker, and D. L. Ranson, "Resident-to-resident physical aggression leading to injury in nursing homes: a systematic review," Age and ageing, 44(3), pp. 356-364, 2015.

[12] K. Williams, A. Arthur, M. Niedens, L. Moushey, and L. Hutfles, "In-Home Monitoring Support for Dementia Caregivers A Feasibility Study," Clinical nursing research, 22(2), pp. 139-150, 2013.

[13] M. Yefimova, and D. L. Woods, "Using Sensor Technology to Monitor Disruptive Behavior of Persons With Dementia," In AAAI Fall Symposium: Artificial Intelligence for Gerontechnology. October, 2012.

[14] A. Bankole, M. Anderson, T. Smith-Jackson, A. Knight, K. Oh, J. Brantley, A. Barth, and J. Lach, "Validation of noninvasive body sensor network technology in the detection of agitation in dementia," American journal of Alzheimer's disease and other dementias, 27(5), pp. 346-354, 2012.

[15] C. N. Fowler, K. Kott, M. N. Wicks, and C. Rutledge, "Self-Efficacy and Sleep Among Caregivers of Older Adults With Dementia: Effect of an Interprofessional Virtual Healthcare Neighborhood," Journal of Gerontological Nursing, 42(11), pp, 39-47, 2016.

[16] J. Pansiot, D. Stoyanov, D. McIlwraith, B. P. Lo and G. Z. Yang, "Ambient and Wearable Sensor Fusion for Activity Recognition in Healthcare Monitoring Systems," In: Leonhardt S., Falck T., Mähönen P. (eds) 4th International Workshop on Wearable and Implantable Body Sensor Networks (BSN 2007). IFMBE Proceedings, vol 13. Springer, Berlin, Heidelberg,2007.

 ISBN: 978-1-61208-597-5

Analysis of Medical Records Management in Brazilian Basic Healthcare Units: A Qualitative Approach

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***Abstract*—Researchers around the world have searched for ways to control access of Electronic Medical Records (EMR) in the healthcare environment, from primary to tertiary sectors. Each country, state and city has particular means of controlling that access. However, there are places where there is no digital control, and this is the reality of several Brazilian regions. The objectives of this work were to understand how Basic Healthcare Units (BHU) control access to patients' medical records, to verify the existence of both paper and electronic medical records, and to compare the situation in BHUs with the current legislation. A qualitative research was conducted through semi-structured interviews with 29 employees from BHUs in five regions of the city of Londrina - Paraná (Brazil). Afterwards, the content analysis proposed by Bardin was carried out. The results show that the healthcare environments studied in this research lack computerization and electronic control of patients' medical records and they still use paper medical records. This research makes it possible to compare the reality practiced in the BHU with the current legislation. The paper seeks an understanding of the requirements of the healthcare servers to support future research into the implementation of computational models in electronic records and access control effectively applicable in the healthcare context. The findings of this qualitative research provide deeper knowledge of the reality of healthcare environments, the employees' behavior, patients behavior and the interaction between these elements and the medical records.**

Keywords–Electronic Medical Record; Qualitative Research; Basic Healthcare Units; Cloud Computing.

I. INTRODUCTION

A medical record can be defined as the patient's or client's organized and concise documentation, containing a record of medical care provided, as well as all information, examinations, procedures and any pertinent documents. The medical record belongs to the patient, the records are under the care and responsibility of the doctors and health institutions. Therefore, it is an extremely relevant document mainly for the healthcare system (containing an easy-to-handle chronological evolutionary data, that allows a global view of the patient's clinical status, permitting communication among the different healthcare professionals), education (being used to discuss cases among teachers and students); scientific research (the information contained in the medical record can serve as secondary data for research), quality control (enabling the management of medical and hospital activities), and for the control of the costs that are dependent on the accuracy and details of the information contained in the medical records.

The management of medical records has become easier in the last decades through computational advances that allow previously-known technologies to be improved and used in different ways in computational environments. The advances in technology and its increasing presence in the patient care process, such as Electronic Health Record (EHR), Electronic Medical Record (EMR) and Picture Archiving and Communication System (PACS), have increased the demand for the collaborative sharing of patient clinical data among healthcare professionals. However, the degree of technological development of Brazilian health services is highly heterogeneous and, in this context, the medical record is usually one of the last to be computerized. This is mostly due to economic and cultural problems related to the resistance to informatics by the possible users, difficulties or lack of access to software, and even presumed legal and/or ethical impediments.

Research on healthcare information systems in the cloud has been intensified because of the need for technologies that may be considered both attributes and characteristics of the environmental context. Nonetheless, in general, studies in this area are based barely on the information contained in the current legislation and does not encompass observation reports of the real healthcare environment. This makes it difficult to understand the actual needs of the users so that the implemented solutions can be applied in an efficient way.

Based on the above, the objective of this study was to understand how the BHU controls access to patients' medical records, to verify the occurrence of the use of paper and digital medical records, and to compare the reality with the current legislation.

This paper is structured divided into six Sections. In Section 1, the challenges of the healthcare environment regarding medical records are presented. In Section 2, related studies are presented. In Section 3, the concept of the patient's electronic medical record is presented. Section 4 describes the methods used in this qualitative research. In Section 5, the results obtained through the qualitative research are presented, and finally, in Section 6, the work is concluded.

II. RELATED WORK

The main objective of the research projects using qualitative research around the world is to understand the reality from the point of view of the individuals involved in that environment or situation.

The qualitative research with semi-structured interview presented in this study identified, through the workers of the basic healthcare units, the most important characteristics that should exist in the control of access in a web system containing

 ISBN: 978-1-61208-597-5

the electronic medical records. The related works described in this section are related to this work because they present qualitative research methodologies that aim to know the reality of the healthcare environments and the patients.

Miller [1] used the methodology of qualitative research through the semi-structured interview and sought to evaluate the acceptance of the use of health websites or portals containing the electronic medical records. The results of these studies showed concerns about the consequences of improper access such as alteration of medical records by unauthorized persons and exclusion of treatments and medications prescribed by physicians.

The results of Miller's research can also be noticed in this current study. The research demonstrated that the medical records are exposed in inappropriate places where authorized and non-authorized people constantly pass through to handle the medical records. This concern about improper access was also evidenced through the responses of some interviewees indicating that many medical records are lost partially or totally.

Web information system for access to electronic medical records has been developed around the world. In his work, Shimada [2] does a qualitative research with transversal analysis to identify the patient's adoption of the web platform containing the electronic medical record.

The results of the study revealed that patients with life-threatening condition and those in need of intensive treatment are likely to adhere to the use of eletronic medical records on the web. On the other hand, patients who are not critically ill or patients who are only in a regular clinical follow-up are less likely to use a web system containing their electronic medical records.

These results were not evidenced in this study since the electronic records in the observed BHU are not implemented and patients do not have easy access to them. Patients need to undergo bureaucratic authorization requests to access the document, even if the current legislation ensures them the right to obtain it.

Lester [3] conducted a literature review with the analysis of 34 papers on the benefit of personal health records or electronic medical records. The results identified concerns related to patients' understanding of the medical records, legal liability, response time of access providers, and the need for the US health system to ensure the protection of information, its usefulness and ease of access.

The results evidenced in this review corroborate with those found in this study, since the same indications cited above were listed as concerns of the health servers about the handling of the paper medical record and indicated as possible benefits of the medical records computerization.

III. Electronic Medical Record (EMR)

The EMR was developed by physicians and nurses to systematically as a way of remembering the clinical facts and events of each patient.

The EMR represents the best means of communication between the healthcare team members responsible for the patient assistance. The EMR subsidises the continuity and the verification of the evolutionary state of the patient's health condition and in a more comprehensive perspective can also be used to assess procedures and their results.

Over the evolution of the EMR, in 1997, the Institute of Medicine defined it as [4]:

> *An electronic record residing in a system specifically designed to support users by providing access to a complete set of accurate data, alerts, decision support systems and other features such as links from displayed information to pertinent literature.*

As Patrício [4] states, efforts began in the 1990s in isolated centres in Brazil for the development of electronic medical records. Due to the need of standardization of the medical record, the Ministry of Health proposed in 2002 the minimum information about the patient that should be included in the EMR and the entities that should supervise its filling.

According to article 5 of the Brazilian Federal Constitution [5], all Brazilians are ensured of the inviolability of the right to the security of their information. The CFM (CFM, Portuguese for "Federal Council of Medicine"), through the CFM Resolution No. 1.331 / 89, Ordinances No. 1.638 / 2002 and No. 1.639 / 2002, informs how the temporality, custody and handling of the medical records have to be processed, as well as how the computerized systems have to be used. These resolutions and ordinances ensure: authenticity, integrity, confidentiality, privacy and document storage.

Following the advance of the EMR, the Federal Council of Medicine created the CFM Resolution No. 1.821 / 2007, which approved the technical standards for documents digitization and the use of computerized systems for the storage and handling of patient records, authorizing the elimination of the paper records.

After the resolution, all healthcare professionals can check clinical information from patients, regardless the professional's location. Technology provides integration and cost savings. However, the authentication and authorization process has become a major challenge in these domains.

IV. Methods

In this study, a qualitative study was conducted with a semi-structured interview at BHUs in Londrina - Paraná (Brazil). The information collected from the interviews can be extrapolated to the other Brazilian locations, as Brazil does not have any national unified system that meets the demands and characteristics required for a computer access control system, and also because there is no sharing of information between BHU and Hospitals in Brazil. In order to carry out this study, an authorization from the Municipal Health Department was obtained and approved by the Ethics Committee of the Evangelical Beneficent Association of Londrina - AEBEL - (CAAE 51829215.5.0000.5696); This study is also in accordance with the Resolution No. 466/12 of the National Health Council [6].

For data collection, a semi-structured interview schedule was elaborated and submitted to content analysis by experienced judges in the area, who analyzed the content of the questions and whether they were adequate and coherent to what was proposed. Then, three preliminary interviews were carried out to calibrate the researcher and verify the application of the questionnaires for the purpose of possible readjustment. There was no need to readjust the interview schedule questions

 ISBN: 978-1-61208-597-5

and these preliminary interviews were discarded from the final results.

The final script contained 17 questions, five of them related to the characterization of the participants (age, occupation, function in the BHU, time working in that function, length of higher education course) and the others were related to the medical record use (use of paper and electronic medical records, purpose of medical records, frequency of use, required information and registration, initial process of medical records, difficulties in handling and interpretation of the recorded information, transfer of medical records to other healthcare units and homes, professionals who access these medical records, document archiving and collection).

Next, one BHU from each region of the city - North, South, East, West and Centre was drawn. For each selected BHU, the respective coordinator was contacted in order to explain the purpose of the research and to schedule interviews with the professionals.

The interviews were conducted with healthcare professionals and administrative technicians who agreed to voluntarily attend in this study and signed the free and clarified consent form.

The number of interviewed individuals depended on the saturation of the interview. Individuals from different areas that access the medical records in different ways were interviewed until the answers began to repeat themselves, which occurred after three to four interviews in each BHU, having been safely extended to 5 to 6 interviews in each of them, with a 15 minutes average duration each, totalling 29 interviews.

Subsequently, the process of literal transcription of the recordings of each interview began. After the transcriptions, a content analysis was performed as proposed by Bardin [7]. The author describes the content analysis as "set of techniques of communications analysis that uses systematic and objective procedures to describe the content of messages, indicators (quantitative or not) that allow the inference of knowledge regarding the conditions of production/receipt (inferred variables) of these messages".

After the literal transcription, the following categories were established: 1) Medical records information, 2) Advantages using of handwritten medical records, 3) Disadvantages of handwritten records, 4) Sharing and transfer of medical records, 5) Use of the medical records in home care, 6) Release of medical records to the patient, 7) Collection of medical records.

The observation was also made aiming a real participation of the researcher in the researched community and through the senses as seeing, hearing and examining facts or phenomena to obtain certain aspects of reality. The observation technique has the objective of observing the subjects' environment and describing it from the researcher's perspective. In this work, the unstructured observation was chosen for data collection. The analysis included aspects as coverage area, address changes, systems, paper medical records, eventual medical records, patient care, medical records room, lost medical records, medical records exposure and exposure of BHU servers.

V. RESULTS

The qualitative research presents a methodological rigor that must be followed for its application. Among these rigors are the semi-structured interview and the observation process that is done by the researcher in the study environment of the research.

The standard statistic for this type of research is the descriptive one. 29 subjects aged 20 to 58 years were interviewed, the average age being about 38 years. The occupation of the interviewees were: interns - 1 (3.44%), administrative technician - 2 (6.89%), oral health technician - 1 (3.44%), nursing auxiliary - 14 (48.27%), physician - 1 (3.44%), community agent - 4 (13.79%), nurse - 5 (17.24%) and physiotherapist - 1 (3.44%). Working time in basic health units varied between 1 month and 30 years, the average time spent working in a BHU was 8 years. The working time in the specific BHU varying between 1 month and 27 years, the average time spent working at that specific BHU was 5 years.

The employees in administrative positions, administrative technician and accountant, had restricted access to the medical records - they accessed only the patient's registration data, the other positions had full access to the medical records. All employees use the medical records daily and for every single patient. In this Section, the results found in the semi-structured interview and on the observation are described.

A. *Semi-structured interview*

The categories resulting from the process of analysing interviewees' responses are described below. The quotations displayed in quotation marks represent the words of the interviewees, respecting the way of speaking of each one.

1 - Medical records information: In this category, the interviewees' statements about the notes contained in the medical record and the difficulty with the lack of annotations pertinent to the patient's medical history are described: "All the patient's medical history is in the medical records, right? (...) Ideally, each care or service should be reported. This does not always happen. There are things that are abbreviated, others are just not written (...)" (interviewee 4).

By these reports, it was possible to notice that many important information to the medical record registration are omitted. As a consequence, it puts the next heath care at risk. It also can affect the search of the previous patient history if this one presents a future disease, as well as hamper the diagnosis of possible drug interactions that may interfere with the patient's health. Furthermore, vaccines reapplications can occur if there is a missing registration of vaccinations or if a new request has been made because no previous requests are found.

These reports indicate not only that the patient health is at risks but also the misuse of public money, since due to a lack of information the patient may unnecessarily go through the same vaccines or health unnecessary examinations [4].

2 - Advantages of using handwritten medical records: In this category, the interviewees highlight the difficulties dealing with poor and outdated electronic equipment and also indicate that the fact that handwritten pleases some people [4]: "If the medical record was electronic, under the conditions we have today, it would be a bit complicated because there is no enough computers, the system is very slow"(interviewee 5).

Regarding this topic, some individuals reported the precariousness of the computer equipment, the difficulty in handling

the technology and the software, plus the shortage of equipment that suit their needs. In general, there are little equipment available and the ones available, according to the interviewees, are in a state of dereliction and outdated and the people who are supposed to use the system do not receive adequate training for the use of the equipment and software.

3 - Disadvantages of handwritten records: There are more reports in this session and they generally talk about the spelling unintelligibility, the loss of documents, difficult handling the records and the storage insufficiency [4]. "But sometimes we are looking for the result of an exam to know if the physician has already seen it and the difficulty is huge. The difficulty in searching, reading, interpreting." (interviewee 1). "The patients do not know what medication they are taking, so they come to the BHU to collect the medication, you take a look at the previous prescription and sometimes it is unreadable or there are some not listed medications" (interviewee 3), "A major problem is the individual's handwriting" (interviewee 29), "(...) besides the loss of document there are a lot of new sheets so we kind of just clip them together(...)" (interviewee 1).

In this category, many different points are cited as disadvantages. The main concern among the interviews was the fact that the colleagues' spelling was sometimes unintelligible. One of the interviewees reported, after the recorder was disconnected, that in some cases when it is not possible to understand the handwriting, the nurses search on "Google" possible names of medicines used for that problem indicated by the doctor. This practice results in a big risk to the health of the patients who go through the proposed treatment without knowing what is being given to them, trusting the service and believing that the treatment is being given by competent professionals.

Another issue mentioned is the difficulty in handling the medical record due to the large number of pages attached to it, this situation facilitates the loss of information and also the detachment of parts of the medical record. Moreover, the collection, more detailed in category 7, was indicated as a disadvantage due to the difficulty in finding the medical record and when not found it is necessary to open a new medical record titled as "eventual". The same patient may have several "eventual" folders. The original medical record and the eventual folders in some cases are attached to the same medical record when it is found but in other cases this records are not found.

4 - Sharing and transfer of medical records: In this topic the interviewees report how information sharing occurs between BHU and hospitals. "But here in Brazil it does not exist. There is a different medical record to each place the patient is assisted" (interviewee 19); "The city hall is not paired with the hospitals of the region. We do not have access to their medical records." (interviewee 20).

The interviewed individuals report that there is no sharing of information between BHUs or hospitals. An individual can present a proof of address and register in several regions of the city and in several hospitals using the same SUS (SUS - Portuguese for "Brazil's Unified Health System") identification card and have a distinct medical record in each different health environment. Likewise, even without a proof of address, this individual, if necessary, may attend several BHUs who will register their visit in an "eventual" folder and their complete medical record would be in their original BHU.

In this aspect of the problem, it is important to point out that the lack of adequate sharing between the BHU and hospitals leads to a poor service provided, it offers risk to the patients in a state of fragility. As an example, if a victim of an accident arrives at a hospital incapable to report its previous history, this person may suffer complications due to the lack of important information provided for the maintenance of its life. This may also facilitate fraud and inappropriate use of the health system [8].

5 - Use of the medical records in home care: This topic describes the management of medical records in external use situations. "We write observations down. There is an annotation notebook. When we come back to the BHU we transfer the information to the medical records." (interviewee 18), "We separate the medical record and carry it with us, particularly during medical visits. In nursing and community agents visits, they do not carry the records along" (interviewee 28).

In this category, two different situations are observed: professionals who remove the medical records from the BHU, leading to the risk of loss of the document, and those who just write down the information when they return to the BHU, may losing some relevant information.

6 - Release of medical records to the patient: This item reports the procedure for the removal of the medical record by the individual or family member. "The patient goes to the administration department to fill out a form requesting the medical record. This request goes to the "Vila da Saúde" (freely translated as "Health Village"), they run an evaluation process and after the "Vila da Saúde" sends to the patient a copy of its medical record" (interviewee 5), "The family does not have access to medical records" (interviewee 6), "We only provide a copy of it if there is a judicial request" (interviewee 9).

7 - Collection of medical records: Respondents reported the use of a catalog system that can be confusing and bring the system into disrepute. "When (...) the person ID, (...) is, for example, 1505 (...) we know it ends in 5. So, we look for the lowest number of 4 and find the records. (...) Sometimes you do not find it though. (...) There are those records placed in the visiting folder, because they are hospitalized (those lying on a bed), and there are the pregnant women who have separated records" (interviewee 24).

When the patients first look for the health service, they are registered in an internet system called e-SUS using their personal data and address. The system generates a unique ID number. From this ID a page header is generated and then printed, giving rise to the medical record.

The medical record is stored from its final number, 0 to 9, which represents the quadrants of the physical shelves of the storage room of each BHU. Within each quadrant the medical records are organized manually from the lowest number to the highest, which may vary from unit to thousand, for example: at the end 5 there are the medical records with IDs 5, 15, 105, 1005, 10.015 and so on.

This arrangement can be even more complicated in the separation of pregnant woman or a diabetic and hypertensive person. For instance, a patient who is hypertensive and diabetic

 ISBN: 978-1-61208-597-5

would be registered in which part of the storage, among diabetics or among hypertensive? This type of classification can hamper the management and searching of the medical records.

B. Observation

In the course of the observation it was found that:

1 - Coverage area. Each BHU provides assistance to a specific area defined by the Unified Health System. This coverage area corresponds to the boundaries of the neighbourhoods surrounding the BHU. All patients residing within this defined area can be assisted and monitored through their medical records kept at their specific BHU.

2 - Systems. The metropolitan region of Londrina possess in digital format only the basic register of the citizens of the region in the e-SUS web software (integrated with SUS) and Saúde Web (software integrated to e-SUS and focused on vaccines and some exams in the health area).

This register is restricted to the identification number - ID, name, date of birth, gender, National ID, marital status, city of birth, telephone number, home address, zip code, other contact numbers, name of the person responsible for supervision and safety (if applicable), occupation, place of work and vaccine registration.

3 - Paper medical records. When the patient is assisted in the UBS for the first time, its personal information available in the e-SUS system is confirmed with the patient or responsible person, from that moment a proof of address is requested to the patient to verify if it lives in the area of coverage of that specific UBS.

After this verification, the technician informs that within 24 hours he/she will personally go to the patient's residence to confirm the address. Next, a form with the basic patient data is printed and placed in a new envelop, this envelop will have the patient's ID manually written on the front of it. From that moment on, every time this patient comes to the BHU, a single sheet with the annotations of the appointment is inserted in this envelope. These sheets have no header, they are white A4 papers with lines. It is worth mentioning that the patient's data are only on the first sheet, the one which starts the medical record. The medical record, then, is formed by this initial sheet with the basic data and the other single sheets with the appointments' information.

4 - Eventual medical record. In some situations the BHU receives patients who do not reside in its area of coverage. As BHUs are not allowed to deny assistance, a temporary medical record is made. This type of document is called an eventual medical record. The eventual medical record is a register with the basic personal data of the patient and will also contain the information about the service performed at BHU.

They are kept in the BHU. This record is transferred to another BHU (the BHU in the patient's area) only when requested. It has been found that this medical record is most often forgotten by patients and is not transferred.

5 - Home address change. When a family or patient changes its home address beyond the BHU coverage area (moves to another location), the patient must notify the other BHU (the one that provides healthcare at their new address) to request the transfer of their medical records. In this case, these medical records are stored in specific boxes in the BHU that provided this service. If there is no request for transfer this file by the corresponding BHU of the patient's region, this health history will be lost.

6 - Services. It has been verified that during the operating hours of the BHUs the medical records are exclusively managed on paper. Each BHU receives an average of 400 to 1000 patients per day, depending on the period of health surveillance or the absence of epidemics.

In order to provide care for each patient, the BHU applies the following procedure: first, the technician consults the patient's ID in the web system and confirms the personal data. Secondly, the server asks the patient to wait in the waiting room while the technician goes to the room of the medical records to retrieve the file with the respective ID and after finding the medical records they proceed with the service.

Searching for the medical record can be quick if the last person who handled it saved the file in the correct location. If the patient resides outside the coverage area of this specific BHU, he/she will be advised to go to another BHU, but if it is an emergency the patient will be assisted in this BHU.

7 - Medical records room. The average size of the medical records room in the BHU is approximately 15m2. There are vertical and horizontal wood shelves forming fixed squares on the wall. These squares are called "quadrants" by BHU officials. The quadrants are sorted from digit 0 (zero) to 9 (nine), they are called "finals". These final numbers represent the last ID number of each patient and they are used to organize and store the medical records, for example: if the patient has an ID 5, ID 1205, ID 1000005 or ID 15, it will be stored in the quadrant of number 5. Inside each quadrant, the medical records are ordered from the lowest number to the highest.

In most BHUs, the medical records of those who are hospitalized (those lying on a bed) are placed in plastic or cardboard boxes separated by numerical order and not by final number. In some BHU, patients with diabetes and high blood pressure are also separated into boxes and are not in the quadrants.

In the course of the everyday healthcare, the already used medical records are placed in a box and at the end of the day they are stored in their respective quadrants or specific boxes.

As verified each BHU has approximately 25,000 possible patients in its coverage area, which generates an average of 10,000 to 20,000 medical records per BHU. Each medical record has an average of 20 sheets. However, some medical records have up to 200 sheets. As a result, the employees reported that this type of organization is sometimes inefficient and many medical records are lost or damaged in this process.

8 - Loss of medical records. When the administrative technician does not keep the medical record at the correct place (quadrant or specific box) after a service or at the end of the day, a serious problem is caused.

The probability of this medical record disappears is very high. In cases of loss of medical records, the technician normally takes an average of 15 minutes looking for it before give up trying to find it. In these cases, a new medical record is made with the patient's cadastral data.

Afterwards, during the service the technician seeks to retrieve the most recent history of the previous visits, such

 ISBN: 978-1-61208-597-5

as: medical prescriptions, health problems and treatments. As verified, the loss of medical records is constant, including those older than 5 or 10 years.

9 - Exposure of medical records. There is a constant patient flow during BHU's opening hours, especially in poor neighbourhoods and epidemics periods.

What has been noticed during the BHU's operation time is the onerous and frequent search of medical records, besides its exposure due to poor structural and organizational conditions of the BHU.

In some BHUs it was observed that the medical records already used were kept in desks, with no organization, in the hall where patients transit before and after the appointments or they were all placed in boxes by the hall and then stored at the end of the day, after the working hours.

As stated previously, the medical records have a header with identification only on the first page and the rest of it is made by just white sheets with lines that do not identify the patient, which facilitates the loss of part of the medical record or the entire record itself. In other BHUs, there was a technician allocated to work all day storing medical records, it corresponds to at least one less employee treating the patients.

10 - Exposure to health risks for employees and patients. The fact that medical records are on paper puts the health of BHU workers at risk. As a consequence of the constant patient flow and the costly search/loss of medical records, the health carers cannot invest much time in reading the patient's history. Likewise, there is no place in the medical record highlighting the information with the highest level of relevance.

The servers commonly retrieve only the latest information about the patient, from the latest sheet. This fact exposes them to situations of risk. As reported in an interview, the nursing technician Maria (fictitious name) was told by a nurse friend that the patient she dealt with was diagnosed with HIV infection only after she gave the patient an antibiotic injection. This situation occurred because Maria did not look all over the patient's medical record, she looked over the last sheets only.

VI. Conclusion

This article presented a qualitative research carried out in the context of the Brazilian Basic Healthcare Units, aiming to understand the reality of the manipulation processes of patients' medical information by health professionals.

This research rigorously followed all the necessary procedures to apply the qualitative research to fulfil the objectives of this work.

This study made it possible to experience the real environment of BHUs health and as the control of access to the patient's medical records happens, verifying that the medical records are exclusively in paper. On the other hand, the identification of the patient and some records of exams and vaccines are recorded in Electronic format, but employees do not always include these data in the system.

The research shows how the patient data is managed, who can access/change them, how they are used and for what purpose. The interviewees' reports revealed situations that reflect problems in the area of systems integration, access control, privacy and information storage.

It was observed that the absence of a computerized health system integrated between the BHUs and hospitals impairs the patient care, increasing the waiting time for service, causes the patient to need to report his previous history in each appointment at different BHUs (and their verification tests can be accessed), generating a greater demand for time to each service, unnecessary spending of public money for having to redo exams that have already been carried out, which leads to delays in general care, increasing queues and frustration with the health system.

The BHU routine demonstrates the fragility of safety in accessing the patient's medical records. Due to the physical conditions of the BHU there are no appropriate places for the medical records. They are placed in makeshift halls, inappropriate shelves, counters and in many improper places in the BHU. There is a regulation that determines which people can write down in the medical record and/or read its information. However, there is no way to prevent undue access.

This research will serve as a subsidy for the elaboration of computational models of electronic medical records and of access control to the information that are close to users' needs, promoting greater consideration of the confrontation of the reality found in the environment against the current legislation in the country, as well as other countries that use electronic medical records in their clinical-hospital practice.

References

[1] D. P. Miller Jr, C. Latulipe, K. A. Melius, S. A. Quandt, and T. A. Arcury, "Primary care providers'views of patient portals: Interview study of perceived benefits and consequences," Journal of Medical Internet Research, vol. 18, no. 1, 01 2016, p. e8. [Online]. Available: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4733220/

[2] S. L. Shimada, Brandt, and et al., "Personal health record reach in the veterans health administration: A cross-sectional analysis," Journal of Medical Internet Research, vol. 16, no. 12, 2014-09, p. e272. [Online]. Available: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4275468/

[3] M. Lester, S. Boateng, J. Studeny, and A. Coustasse, "Personal health records: Beneficial or burdensome for patients and healthcare providers?" Perspectives in Health Information Management, vol. 13, no. Spring, Spring 2016, p. 1h. [Online]. Available: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4832132/

[4] C. M. Patricio, M. M. Maia, J. L. Machiavell, and M. d. A. Navaes, "O prontuário eletrônico do paciente no sistema de saúde brasileiro: uma realidade para os médicos," Scientia Medica, vol. 21, no. 3, 2011, pp. 121–131.

[5] Brasil, "Constituição da república federativa do brasil de 1988," 1988, acessado: 2017-09. [Online]. Available: http://www.planalto.gov.br/ccivil_03/Constituicao/Constituicao.htm

[6] N. d. S. d. B. Conselho, "Resolução n. 466, de 12 de dezembro de 2012," 2012, acessado: 2017-09. [Online]. Available: http://www.conselho.saude.gov.br/web_comissoes/conep/index.html

[7] L. Bardin, Analyse de contenu (L'), 2nd ed. Presses Universitaires France, 2007.

[8] R. Zhang and L. Liu, "Security models and requirements for healthcare application clouds," in Proceedings of the 2010 IEEE 3rd International Conference on Cloud Computing, ser. CLOUD '10. Washington, DC, USA: IEEE Computer Society, 2010, pp. 268–275. [Online]. Available: http://dx.doi.org/10.1109/CLOUD.2010.62

 ISBN: 978-1-61208-597-5