A PERSONAL HEALTH RECORD FOR EVERY MOTHER BABY DYAD - A GROWTH ORIENTED PHR (GO-PHR) : AN IMPLEMENTATION AND FEASIBILITY STUDY

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SYNOPSIS

This is a implementation and feasibility study on the deployment of a Personal Health Record (PHR) in Sri Lanka. In this study we will focus on a selected deployment strategy which in our opinion is one of the most practical way of doing it. All persons start life at a postnatal ward and all persons have a mother at least on discharge. So what other best place we have to start something which is going to be much value right throughout one’s life. We planned this as an incentive for the participation of another already ongoing project called MOM-R project. The project will evaluate the use of s personal health record given to both the mother and the child in the first year of deployment.

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WHAT IS A PERSONAL HEALTH RECORD

Personal health record is also called a personally controlled health record (PCHR), or a personal electronic health record (PEHR), among others. This is a record of health owned and maintained by an individual—the emphasis here is on the ownership and maintenance which is important. Strictly speaking, PHRs do not include records owned or maintained by physicians and hospitals — those are called electronic medical records (EMRs) or electronic health records (EHRs) (Eren and Webster 2015). American Health Information Management Association (AHIMA 2005) defined the PHR as an electronic, lifelong resource of health information needed by individuals to make health decisions. Individuals own and manage the information in the PHR, which comes from healthcare providers and the individual. The PHR is maintained in a secure and private environment, with the individual determining rights of access. The PHR does not replace the legal record of any provider (American Health Information Management Association AHIMA 2005). One of the simplest of definitions is that PHR is a set of records that the patient controls (Al-Ubaydli 2011). Some authors define PHRs are addenda for EMRs/HER because in the history of PHR development it was initially considered helpful to share data collected by the physicians with the patients (Tang et al. 2006, Spil and Klein 2015). However as technology matured and advanced PHR concept was widened and came to be defined as a representation of the health information, wellness, and development of a person (ISP 2016-04013).

Personal Health Records are defined by many authorities in many ways. While there is some overlap of the concepts there are unique characteristics too in many of these definitions. Taken together for our purposes the unique features of PHR can be listed as follows :

1. It is electronic - paper based

2. The records belong to the patient - access control is purely a patient wish and consent

3. Record is controlled by the patient - data entry, editing, updating, content, deletion all by the patient

4. It is lifelong - not limited to a consultation or an illness episode, from birth to death

5. PHR content is predicated on what is necessary for the patient's self care

6. It may include information from Electronic Medical Record of physicians or hospitals

7. May record not only illness data but also wellness data, check up data,

8. Common data elements are health history, treatments, general information about the patient and diagnostics

9. Common data types were mostly text and numeric

10. Most PHR data are populated through the EMR/EHR

Common data elements in descending order of frequency are : health history, laboratory tests results, treatments, general information, diagnosis, prevention data, educational resources, scheduling, patient provider communication, health care admin data, visits, daily living patterns, patient environment, outcomes. The 4 most frequently occurring data elements were typically added from patients' EMR. The most common data type were text and numeric while images, videos, voice and GIS data were seen occasionally (Bouayad et al. 2017).

As mentioned earlier the design consideration of the study PHR was guided by many socio-cultural and local HIT environment of the country which will be discussed in detail in the Method section

HOW DOES THE PHR BENEFITS THE PATIENTS

Following is a list of PHR benefits (Ammenwerth et al. 2012, Archer et al. 2011, Delbanco et al. 2012, Tenforde et al. 2011, California Healthcare Foundation, 2010, Baan et al. 2018, Engelfriet et al. 2018, Poos et al. 2018, Huber et al. 2011, WHO 2002) :

1. Opportunity for self-management support

2. Provision of empowerment

3. Opportunity for engagement

4. Enhanced communication between patient and physicians

5. Data sharing between the patient and physician

6. Improve the CD management

7. Improve the monitoring of CD

8. Improve the monitoring of drug compliance

9. Improve the drug compliance

10. Caregiver coordination enhanced, effected and ensured

11. Future proof - as the prevalence of CD rises in the community and as the healthcare delivery is transformed from time limited acute care to more to unlimited continuous care the need of PHR will certainly be morei12. Missing dimensions of illness which are essential for better outcomes in healthcare delivery are possible only with PHR - PROMS, PREMS, Caregiver views and opinions,

13. The evidence suggests that provider-to-provider telemedicine may improve health worker performance, reduce the time for clients to receive appropriate care or follow-up, and decrease length of stay among individuals visiting the emergency department (WHO 2019). The PHR as envisaged in this study is in fact a channel of information which enhances and augments the clinical expertise of both providers

14. PHR mostly contain prospective data while EMR contain mostly retrospective data

15. Possibility of widespread use of Computerized Decision Support Systems (CDSS) by the patients and deployment by system developers

HOW DOES THE PHR BENEFITS THE PHYSICIANS :

1. Helps better documentation - see above medication reconciliation, shared decision making

2. Increase the quality of consultation - with more data better medical decision making

3. Saving on valuable consultation times - 30% of doctors' time is spent on documentation. If even a few minutes can be saved. This will help them to focus more on healing aspects of the medical encounter

4. Patient’s engagement and empowerment is enhanced if the PHR data are also considered by the physicians during the medical encounter

5. Medical reconciliation is made easier by the drug charts of the PHR

6. Possibility of extracting prospective data for clinical practice and research through the PHR

These potential benefits are to be realized only by wider deployment of PHR as planned and implemented in this study. Successful PHR implementation represents a social change and operational project catalyzed by a technical solution. The key to clinician acceptance is making their work easier. However, organizations will likely not achieve the value they want from PHRs unless they target specific populations and monitor their uptake (Wells et al. 2015). Therefore a list of important considerations made at the design stage of the current project were :

1. Collect as much relevant information from patient as possible so that information can be shared with the patient's clinician

2. Help the clinicians in the following areas :

a. Medication reconciliation

b. Increasing medication compliance

c. Increasing the non-drug compliance

d. Support mental health assessments as much as possible to ease the burden of patient's physician

3. Focus on persons who will benefit most from the PHR :

a. CD patients

b. High risk persons who are not yet having any disease

c. Pregnant mothers, newborns, elderly, who need much nutritional and behavioral support for a healthy life as well as the fact of unparalleled frequency of regular contact with the healthcare industry

4. Documentation of everything from recruitment, refusals, registration into systems, usage of the systems, feedback/patient reported outcomes and patient reported experiences and outcome analyses.

CHARACTERISTICS WHICH ARE CONDUCIVE FOR EMR IMPLEMENTATION IN PERINATAL PERIOD

Whatever the reason may be, pregnancy can and should be viewed as a window of opportunity offering a glimpse of forthcoming adverse maternal health conditions. This may allow for heightened awareness, a priori prediction, early detection, and most importantly, an opportunity to implement appropriate preventive interventions (FIGO 2019). The target audience of the FIGO postpregnancy initiative is Healthcare provider (which included all those qualified to care for pregnant women, in particular those responsible for prenatal and postnatal follow-up (general practitioners/family physicians, midwives, community health workers, nurses, obstetricians, maternal–fetal medicine specialists, internists, pediatricians, nutritionists, pharmacists, etc.). According to the guidelines performance of the recommended action could also be used as a quality criterion or performance indicator, unless the patient refuses.

1. Most of the pregnancies in Sri Lanka do take place in hospitals (Family Health Bureau Annual Report 2019). For instance pregnant women attending antenatal care more than 4 visits are 99.3%, average number of Antenatal clinic visits per mother is 13.5, average number of antenatal home visits per mother by a public health midwife (PHM) is 4.0, 91.9% of pregnant women visited at least once by PHM at home, 84.5% of mothers receive at least 1 postpartum visit during 1st 10 days postpartum, the average number of postpartum visits by a PHM during 1st 10 days is 1.8, 88% of pregnancies have a documented outcome for pregnancy, 99.9% of all pregnancies are delivered at hospitals, 66.6% mothers had a postpartum visit within 1 - 5 days, postpartum mothers receiving at least 1 visit by PHM during 1st 10 days out of estimated births are 85.9% and postpartum visits by PHM around 42 days (out of estimated births) covers 73.5% of mothers.

2. Over and above the institutional delivery status the high contact rate of the mothers and babies as shown in the above statistics are also very helpful in implementing a PHR in the pregnant mothers and the babies

3. As almost all the babies are born in hospital and if all the babies are started on a PHR right at birth the implementation of PHR in Sri Lanka may be successful in terms of coverage at least

4. Entire spectrum of functionality of a PHR can be tested on pregnant mothers - frequent visits, chronic disease management, referral, care coordination, primary care and continuity care IT requirements.

5. If every baby is started on a PHR and PHR data are collect as when the data entry requirements arise PHR really will give more valid data than when data is collected for a disease while in the hospital as an adult.

6. Implementation fidelity which is an essential pre-requisite for successful implementation can easily be measured in perinatal period very easily.

7. Exposure and participant responsiveness which are significant determinants of PHR implementation success are comparatively high in perinatal patient population (Sieverink et al. 2019) -

8. One of the key components of PHR implementation success is training - training may easily be carried out due to the very high contact rates and times with the healthcare workers.

9. Sri Lankan primary health care workers closely match the concepts of WHO lay health workers and community health workers. Health workers, particularly lay health workers in low- and middle-income settings, also perceive digital health technologies as allowing them to better coordinate the delivery of care through connecting them to other people and sectors in the health system and to clients and communities (WHO 2019). Therefore use of these categories of healthcare workers may help us to implement the PHR successfully in the selected population.

10. An important consideration in implementation of PHR and other Health Information Technology (HIT) solutions is the prevention of digital divide or at least not making the resource mal-distribution worse. It is anticipated that language and socio-cultural barriers may to a good extent be cleared by using the services of lay health workers and community health workers as defined by the WHO. For instance the language barrier as a reason for disconnection (not using ICT services programmed in English) from our services may be relieved by these healthcare workers with their modest English knowledge with the experience of working in healthcare environments where the common spoken language is English.

11. Digital approaches, most notably telemedicine between different types of health workers, have emerged as a potential way to overcome the barriers of long distances to qualified health workers and shortages in their numbers. Provider-to-provider telemedicine, as with client-to-provider telemedicine (WHO 2019), facilitates the provision of health services at a distance and is primarily used to link less skilled health workers with more specialist ones. In this context the primary care delivery workforce of Sri Lanka is the best bridge between the clinical expertise and the rural and the remote patient.

12. In the field of provider to provider telemedicine the PHR can act as a channel of clinical information as a properly maintained PHR will have a dynamically collected and loaded information on the patient. For all the consultations a patient plans to carry out wherever the patient is PHR may provide a functionality to share the most current clinical information for the attending physician of patient's choice.

OBJECTIVES

General Objectives

To evaluate an Personal Health Record (PHR) software program which is called Growth Oriented Personal Health Record (GO-PHR) written specifically for the Sri Lankans.

Specific Objectives

1) To assess the feasibility of using GO-PHR given to the mother baby dyad

2) To assess the implementation fidelity of a PHR in the first year of deployment

**Methodology**

**Study Setting**

The study setting is the De Soysa Hospital for Women of Colombo which is the professorial unit for the Faculty of Medicine Department of Gynaecology and Obstetrics of the University of Colombo. This is a tertiary care referral center. In short we plan to implement a personal health record called GO-PHR or Growth Oriented PHR given as a reward for the participation of the MOM-R project which is currently ongoing after the ethical approval. The document stewardship is retained by the principal investigator. A steering committee comprising head of the department and other lecturers of unit and 1 representative from the administrative department of the Institute.

**Study Design**

An implementation and feasibility study (See the GO\_PHR\_Appendix.doc for details)

**Participants**

Consecutive, unduplicated, unselected ward admissions and discharges from the post-natal ward of the said unit.

 **Study Flow**

All the mothers of the postnatal ward will be approached by the research assistants of the unit. The GO-PHR is offered as a reward for participation in the MOM-R project which had been given the ethical approval by the Ethical Review Committee of the University of Colombo and is currently ongoing in the same ward. If the mother accepts the reward the consent is taken separately for the GO-PHR project for both the mother and the baby after explaining the nature of the project to the mother (GO\_PHR\_infoSheet\_consent\_TL.doc)

Entire study flow is executed under the supervision of the principal investigator and project coordinator Dr Ananda Perera (See office Secretariat in GO\_PHR\_Appendix.doc)

**Study Instruments**

The GO-PHR comprises 12 pages as follows :

Home Page

Initial Health Questionnaire Page

Quarterly Data Collection Page

Annual Data Collection Page

Service Data Quality Page

Laboratory Reports Data Collection Page

Diagnostic Data Collection Page

Medication Data Collection Page

Follow up data Collection Page

Symptom Data Entry Page

Illness Data Entry Page

Search Data Page

Each page represents one page in the smartphone display. Except the Home page all the pages have a common structure which is the password field, notes and the questionnaire or the data collection form and a save data button. When the questionnaire button is clicked a data collection form is shown to the patient for data entry. All the 12 questionnaires are shown in the GO\_PHR\_Questionnaires .doc in sequence. The Screenshots of the above pages are shown in the Figures GO\_PHR\_SS-1.png - GO\_PHR\_SS-12.png.

**Data Collection**

The data collection is done by several ways – self-data entry, research assistants, assisted data entry with the help of members of the Independent Medical Practitioners’ Association. The study flow chart and the data collection procedures are shown in the Figure – 2 (GO\_PHR\_Project\_flow)

In summary the following steps are taken in sequence :

1. Information Sheet is read by the patient and Consent is given

2. Initial Health Questionnaire is filled by research assistants

4. Patient is given access to suite of software programs for self management of wellness and illness - https://247econsult.net/dhc/digiHealth.html (but guided help is available online from the research assistants, office secretariat and trained telenurses and interviewers)

5. At the end of 1 year : Patient reported outcome and experiences measured - e\_PROMS\_PREMS\_trilingual.xls

A special feature of this study is the unique process of data collection. We designed and developed a method of data collection which is scalable to national level based on the existing Information and Communication Technology.

At the design stage of the project we gave much thought to the data collection procedures in view of the following statistics. Computer literacy (able to use a computer alone) rate for Sri Lanka total population is 32.0% and computer literacy rate of employed Sri Lankans is 64.5%. Digital literacy (able to use a computer laptop, tablet, smartphone alone) rate for Sri Lanka total population is 49.5% and the computer ownership for Sri Lanka 22.2%. Health literacy rates among school teachers in Sri Lanka 32.4% Denuwara and Gunawardane 2017). As our peoples' computer and digital literacy rates are much higher than the health literacy rate we expect some relief from the data entry burden. But again the IMPA has a large pool of volunteer physicians from all over the country who will support the patients in filling up the forms through technology. However we also encourage the users self data entry, assisted data entry (help is available anytime for any user through the IMPA, volunteer research assistants), proxy data entry (patients can nominate a caregiver - we expect the employed persons in the household will fit into this role, even research assistants’ help is also available). This multimodal data entry will help us to resolve many problems of data entry like language barriers, sociocultural barriers.

Also consider the following. There were 10.10 million internet users in Sri Lanka in January 2020 with an internet penetration of 47% reported for Sri Lanka. Social media users were 6.4 million in January 2020 and the social media penetration of the island being 30%. The number of mobile connections reported for Sri Lanka January 2020 was 31.8 million connections with 149% of total population having the connectivity (Dataportal 2020).

We decided in favor of automated data collection using ChatBot technology (See under Technology). Our assumption was low health literacy with higher computer and digital literacy favors an approach of multimodal data entry sessions as planned and explained above rather than a traditional physician based or trained research assistant based face to face interviews.

The GO\_PHR\_Questionnaires.doc shows all the questionnaires of the study.

Following Principles of Data Collection were formulated first and the design and development

of the PHR were strictly done in alignment with these principles :

1. Interrupted data entry - Data collection and entry were never meant to be a one time exercise.

2. Data entry as and when required - Data collection sometimes require this usage pattern - for instance

when lab report data entry with the availability of the results, consultation data entry after a consultation etc.

3. Convenience of the data entry officer - each duration of data entry is kept to be as short a time duration as possible - few minutes mostly. This was a major design consideration for the development of the PHR

4. Convenience of the patient - each duration of data entry is kept to be as short a time duration as possible - few minutes mostly - so that the patient is not put into inconvenience

5. Data entry duration for a given task is kept to a minimum - mostly several minutes

6. Data entry mode by CLICKS and click count is kept to a minimum. Actionable clicks at most a few but data selection is comprehensive

7. Data collection is done based on the dynamics of the historical data changes - for instance some questionnaires are completed once in 4 months (clinical data), some only annually (family history), some only once for the entire duration of the project Patient Reported Outcome Measures and Patient Reported Experience Measures (PROMs and PREMs questionnaires)

**Technology**

See the Appendix for details (See PHR\_Appendix.doc)

**Sampling and Sample size calculations**

Sample size calculation for binary variables was done using the following formula :

n = N\*X / (X + N – 1), where X = Zα/22 ­\*p\*(1-p) / MOE2, and Zα/2 is the critical value of the Normal distribution at α/2 (e.g. for a confidence level of 95%, α is 0.05 and the critical value is 1.96), MOE is the margin of error, p is the sample proportion, and N is the population size [url - statistics.co.uk]. For a margin of error 5%, CI of 95%, for approximate population size of 7000 and an approximate proportion of 40% minimal sample size required is 351. Adding a 20% drop out rate that sample size will be 425.

Sample size for quantitative variables was not calculated due to unavailability of the required standard deviation (SD) values.

Sample size for nominal or ordinal variables were calculated as n = (Z 1-alpha/2)^2\*(p)(q) / d^2 where n is the desired sample size, Z1−α/2 = Critical value and a standard value for the corresponding level of confidence. (At 95% CI or 5% level of significance (type-I error) it is 1.96 and at 99% CI it is 2.58). P is the expected prevalence or based on previous research, q is 1-p, d is the margin of error or precision, Z1-α/2 equals 1.96, P equals 40% or 0.4, q equals 1−0.4 or 0.6 and d equals 5%. Therefore minimal sample size is 368.79 and adding 37 (10% drop out rate) it becomes 406 [Sharma et al. 2020].

Dependent variables

Outcome measures : feasibility and implementation statistics

Independent variables

demographic data, contact data, laboratory data, diagnostic data, followup data, chronic disease management data, personal risk profiler data

(All the questionnaires are shown in the PHR\_Questionnaires.doc)

**Statistics - Calculation of the Fidelity and Feasibility Metrics**

Implementation metrics include :

Adherence

Exposure

Quality of delivery

Participant responsiveness

Program differentiation

Feasibility metrics include :

Limited Efficacy testing

Data Quality Dimensions of the PHR

Adherence to an intervention - degree to which the intervention is delivered as designed or written

Total number of persons and patients approached = x (Count taken from the project secretariat)

Number of unique persons or patients entered into the PHR = y (Counted from the database)

Adherence = y / x (point estimate of 95% CI)

Exposure or dose - amount of intervention received by the participants OR the frequency and duration of the intervention designers of the intervention wanted and achieved

Number of hours/minutes the program is to be used in the daily schedule = x ( 2 hrs or 120 minutes)

Number of hours/minutes the program was actually used in the daily schedule = y (Counted from the database logs)

Exposure = y / x (point estimate with 95% CI)

Quality of delivery - manner in which the research assistants, volunteer or staff member delivers the intervention (see the office secretariat)

number of unique patients or persons registered in the database = x (counts taken from PHR database)

number of patients or persons with complete set of demographic information / x (point estimate with 95% CI)

mean number of automation based on PHR data

Automation based on PHR data include :

Sharing of data done by the chronic disease patients (this is done with the help of the research assistants during the study period)

number of patients or persons with any automation carried out = y

proportion of patients with automation done = y / x (point estimate with 95% CI)

Participant responsiveness - degree of engagement of the participants of the program

This will be calculated as follows.

Each person or patient in the database will be checked for the use of services made available for them free of charge.

Following services are available for all the registrants as incentives : data sharing with the personal physicians, risk factor analysis, diet prescription generation, checkup prescription generation, vaccine prescription generation, exercise prescription generation,

Number of services used per patient or person is counted.

Mean number of services will be reported with the other descriptive statistics

program differentiation - component analysis and usage patterns (See under data collection for details of PHR components)

Enlist all the components of the program = x

Enlist the essential components of the program = y

Mean number of essential components used in the study

Mean number of all components used in the study

Requests for new functionality - Total recorded number during the study period

Limited Efficacy testing

number of persons registered in the database = x

number of persons with essential component filled / x (point estimate with 95% CI)

mean number of essential components filled

number of patients with any automation carried out = y

proportion of patients with automation done = y / x (point estimate with 95% CI)

Essential items – Following data fields in the PHR system were categorized as essential -

Name, Age, Sex, NIC, phone number, Initial Health Questionnaire, allergy history, disposition.

The rest of the data fields were considered non-essential.

Mean number of essential items / Sample size

Mean number of essential items / Sample Size

Non Essential items - Rest of the data fields / Sample Size

Mean number of non-essential items / Sample Size

Mean number of non-essential items / Sample Size

All the above data are taken from the database and calculated.

Data Quality Dimensions of the PHR :

Concordance will be measured by the agreement between the admission symptoms, investigations and management.

Each patient will be measured along the scale of 0 (No agreement) -100 (Perfect).

Mean concordance level for the sample will be reported

Completeness of the data entry will be measured by the number of entries where all the essential items are collected.

Each patient will be checked for the number of essential items marked.

Mean Completeness score will then be calculated with the other descriptive statistics

Currency of the data will be measured by the placement of the historic data and the current data at the respective places.

Current and ongoing symptoms in the symptom inventory and the illness data panels

Past medical, surgical and developmental history in the annual data collection pages

Current medical, surgical data in the laboratory reports, quarterly and service quality data collection forms

Each patient will be checked for the data collection in the above areas to assess the accuracy

Each patient with data entry errors will be counted and reported as a proportion of all the patients in the database.

**ETHICAL CONSIDERATIONS**

Ethical compliance for this project was ensured by taking into detailed consideration of the documents and guidelines in these references [ Tan 2005, MOH 2021, HIPAA Rules 1996]. The definitions of privacy, confidentiality and security and personal health information (PHI) mentioned in these documents were followed almost verbatim. Privacy will be honored and confidentiality will be maintained by authentication and authorization processes on accessing the systems and more importantly granting the proportionate rights based on the user roles of the systems. Security is maintained in strict adherence to the guidelines drafted by the MOH health information unit and other good practices collected from the peer reviewed literature on the subject. There is a policy document in place for public reference in the help files of the systems which detail all the policies of the technology partners. This gives the details of security, privacy and confidentiality as relevant for the Medica systems. Then our next ethical consideration was to follow the national guidelines on the PHI. For this we studied the Information Security Guideline for Healthcare Institutions published as a draft by the MOH [MOH 2021] and applied those best practices in our design and development of the Medica systems. Third we developed a checklist of best practices extracted from peer reviewed journal and authoritative guidelines on the subject as published in the reference [Huckvale et al. 2019]. The score card for this is shown below :

1. MOBIOS documents required for the good practices of the security, privacy and confidentiality issues

2. Health Institutions Security Assessment – Scorecard. Quarterly returns before the end of the 1st week of every quarter

3. Checklist of good security, privacy and confidentiality practices from the reference [16]

Privacy Criteria - check this list with the partner of the MOBIOS company Ltd.

Apps with a privacy policy - MOBIOS privacy policy, MOBIOS DOCUMENTS

Primary uses of collected data - clinical, administrative, contacting users, providing and improving services

Secondary uses of collected data - selling data, sharing data for purposes such as subpoena or conducting investigations, repackaging data

Sending data to online services - app developer database or cloud

Sending data to a third party - NO

Sending data for analytics or research - NO

Sending data to advertisers or marketers - NO

Sending data while loading content - YES for searching

Asserting non-identifiable data collection only - NO

Technical and procedural security arrangements - YES anonymization, Secure Sockets Layer, secure servers, limited access, backups

How long data will be retained - 6 years because of HIPAA compliance and may change depending on the national digital guidelines standards in future

Inherent risks or limitations of security using public internet - INDSUTRY STANDARDS, MOBIOS DOCUMENTS

How cookies will be used - NOT USED

Procedures for opting out of online data sharing - YES

Consequences of not providing or sharing data - NONE

Procedures for subject access requests - YES. Writtent requests by the patient or the system registered person

Procedures for editing data held by developers or third parties - YES, Audit trails of the database access, time, place, person, content

Procedures for deleting data held by developers or third parties - YES, Data owner. Medica 1 by the physician, Medica 2 by the physician, Medica 3 by the patient

Complaints procedures - YES, In writing

Special procedures for vulnerable or at-risk users and/or children - YES

Identity of data controller or responsible legal entity - YES

Legal jurisdiction governing policy - SRI LANKA

Legal jurisdictions governing data processing - SRI LANKA

Date of policy - MOBIOS DOCUMENTS

Date of next review - MOBIOS DOCUMENTS

Procedures for changing the terms of the policy - MOBIOS DOCUMENTS

Procedures after takeover or dissolution of legally responsible body - MOBIOS DOCUMENTS of Non disclosure agreement, memorandum of understanding

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The principal investigator for the project is Dr Gamini Navaratna, supported by trained house staff. This is a self funded project undertaken by him and there are no collaborative partnership with anybody in terms of scientific nor financial. The beneficiaries of the project and the benefits are :

a. Dental Institute - enhance the quality of the services and particularly the documentation of all relevant medical records clinical data

b. Clinical staff - better decision making, enhance the quality of the services provided and the possibility of taking remedial actions based on clinical audits

c. Patients - Possibility of receiving higher quality of primary health care services and also the evidence based primary health care. Patients will also be benefited by the availability of universal health coverage (UHC) (WHO 2017) as defined by WHO. WHO is of the opinion that UHC achievement requires a e-Health strategy as laid down in this project – an offprint from the WHO document (WHO 2017) on e-Health is as followed : “It has become increasingly clear that UHC cannot be achieved without the support of eHealth. The impetus for the global surveys on eHealth came from the increasing use of information and communication technologies (ICTs) in support of health services in both developed and developing countries since the early 2000s. This was acknowledged by the World Health Assembly in resolution WHA58.28 (2005): “eHealth is the cost-effective and secure use of ICT in support of health and health-related fields, including health-care services, health surveillance, health literature, and health education, knowledge and research.”

d. Patients – the availability of all the components of the UHC – namely preventive, promotive, palliative, curative, rehabilitative health care services with equity, quality and affordability – through a holistic ICT strategy of a documentation continuum is a pre-requisite of equity, quality and affordability. Preventive and promotive aspects are based on the follow up and detailed risk factor assessments of the patients during the hospital stay. These are fully automated and the functionality is assured although not available at the first year.

Once the data collection is over we plan to publish the data in peer reviewed national and international dental and medical journals. We also plan to discuss the possibility of adopting the current system with other clinical departments in the dental institute and university dental faculties.

**Main Ethical Issues Discussion**

Identification of potential risks/benefits.

Invasive procedures – none.

Risk to participants – privacy, confidentiality and security issues.

Harm avoidance strategy -

* User sign in.
* User authentication.
* Conduct of the research under competent leadership
* Conduct of the research with local champions

2 levels of security

 Entry into the Medica System are based on authentication and access credentials

* Database level of security
* Use of industry standard security features to maintain the server side activities

Research benefits to participants/community

* Increased health care quality.
* Avoiding obligation of participation - Patients are allowed to join, rejoin, withdraw from the study at anytime.
* Patient's usual care is continued irrespective of study participation.
* Standard therapies are not interfered with.
* Wellness advice given free of charge

Ethical Principles and the Use of Electronic Health Records

Maintenance of highest ethical standards in EMR implementations is technically a very demanding activity. On the other hand ethical breaches are not purely a matter of machines. In fact a nearly perfect security can be compromised by a single human with devious mind and motive. Further security issues need to be evaluated in the context of interoperability, exchange of patient data, scalability, and extensiveness of the implementation. For the current implementation of the EMR as planned for the current project, following steps have been adopted to maintain the highest possible ethical standards (17-20).

1) Patient consent mandatory for data mining.

2) Patient consent mandatory for data exchange between physicians.

3) Ethical dilemmas finally resolved by concurrence with the patient.

4) Maintenance of patient's privacy at any cost.

5) Steps taken to ensure patient's privacy are:

a) Encryption of identification data of the patient

b) De-identification of data – Clinical notes are decoupled from identification data. Report generation programmatically matches the clinical data with identification data.

c) Physician user authentication is unifactor authentication and based on login into the system with usernames and password.

d) Registration of physician users.

e) Data exchange and data sharing disabled.

f) Prevention of hacking, cracking at the server level as web site functionality

g) Use of SSL (secure socket layer) for data transmission.

h) Database queries are minimized and confined to the servers, limited to the principal investigator at this stage of the project.

i) Database queries are encapsulated as independent objects and saved in the database itself and any other pattern of query is disabled currently

j) Denying public access to the EMR except to the physician users registered with the principal investigator

6) Patient privacy will further be enhanced by allowing the patient of right:

a) To see or get a copy of the medical record.

b) To request to have any mistakes corrected.

c) To get a notice about how your health information is used and shared.

d) To say how and where you want to be contacted by your health care provider.

e) To file a complaint if you think any of these rights have been violated.

7) Principal investigator will be given an update weekly of the system access and activity for him to verify the actions in the systems

8) Principal investigator will constantly remind the physician users and the data entry officers (DEOs) about the importance of not sharing and not divulging the username and password given to them to access the EMR and the rest of the Computerized Decision Support Systems (CDSS). This is because medical identity theft, financial identity theft and snooping do not require high tech hacking if the username and password is shared.

9) In case of breach of security following actions will be taken:

a) Immediate notice of the patient.

b) Immediate disclosure of the possible repercussion of the breach.

c) Support all actions taken that places the patient's interests above all others.

d) Take the entire system offline

e) Identify the system breach and rectify the problem

f) Any data retrieval requirements for daily patient management will have to be made in writing by the user physicians and they would be honored promptly and responded

f) Do the vulnerability test and if it is negative system would be commissioned again.

g) An audit of the breach would be done to make necessary recommendations and also to prevent further data breach in future

10) Data integrity - almost all the data entries are date and time stamped, this ensures that updating, deleting and editing are audited.

11) Data availability is ensured by using industry standard servers from reputable companies which had served well in the past in the server transactions with the said companies. .

12) Collection of mobile phone number: This adds a yet another layer of security for the patient data by allowing the authentication of the users and passwords by connecting them with the patients’ phone number.

**Data disposition**

At the end of the study the patient data will be handed over to the principal investigator in whatever the format he requires and the data from the servers will be flushed.

**Budget-**

Self funded

REFERENCES

AHIMA 2005. AHIMA e-HIM Personal Health Record Work Group. "Defining the Personal Health Record." Journal of AHIMA 76, no.6 (June 2005): 24-25.

Al-Ubaydli M. Personal Health Records: A Guide for Clinicians, 1st edition. © 2011 Blackwell Publishing Ltd. ISBN: 978-1-444-33252-0. Pa xx.

Ammenwerth E, Schnell-Inderst P, Hoerbst A. The impact of electronic patient portals on patient care: a systematic review of controlled trials. J Med Internet Res 2012;14:e162. [PMC free article] [PubMed] [Google Scholar]

Archer N, Fevrier-Thomas U, Lokker C, et al. Personal health records: a scoping review. J Am Med Inform Assoc 2011;18:515–22. [PMC free article] [PubMed] [Google Scholar]

Baan CA, Poos MJJC. Diabetes mellitus - Cijfers en Context - Huidige Situatie. Available from: https://www.volksgezondheidenzorg.info/onderwerp/diabetes-mellitus/cijfers-context/huidige-situatie. Accessed 1 July 2018.

Bouayad L, Ialynytchev A, Padmanabhan B. Patient Health Record Systems Scope and Fucntionalities : Literature Review and Future Directions. Med Internet Res 2017;19(11):e388. doi: 10.2196/jmir.8073.

Bowen DJ, Kreuter M, Spring B, Cofta-Woerpel L, Linnan L, Weiner D, Bakken S, Kaplan CP, Squiers L, Fabrizio C, Fernandez M, How We Design Feasibility Studies. Am J Prev Med. 2009 May ; **36**(5): 452–457. doi:10.1016/j.amepre.2009.02.002.

Consumers and Health Information technology: A national survey. California Healthcare Foundation, 2010. http://www.chcf.org/publications/2010/04/consumers-and-health-information-technology-a-national-survey (Accessed Nov 2012).

Delbanco T, Walker J, Bell SK, et al. Inviting patients to read their Doctors’ notes: a Quasi-experimental Study and a look ahead. Ann Intern Med 2012;157:461–70. [PMC free article] [PubMed] [Google Scholar]

Engelfriet PM, Poos MJJC, Rutten FH. Hartfalen - Cijfers en Context - Huidige Situatie. Available from: https://www.volksgezondheidenzorg.info/onderwerp/hartfalen/cijfers-context/huidige-situatie. Accessed 1 July 2018.

Eren H and Webster JG Pa 300. Telehealth and Mobile Health Edited by Eren H and Webster JG. The E-Medicine, E-Health, M-Health, Telemedicine and Telehealth Handbook. Volume 2. CRC Press Taylor and Francis Group. Pa 300.

Family Health Bureau Annual Report 2019. Family Health Bureau Ministry of Health Sri Lanka. Annual Report 2019. May 2021, Volume XXIX, ISSN 2345-9484

FIGO 2019. https://obgyn.onlinelibrary.wiley.com/doi/full/10.1002/ijgo.12926 Accessed 6:24 AM 12/14/2021

Huber M, Knottnerus JA, Green L, Horst H, Jadad AR, Kromhout D, et al. How should we define health? BMJ. 2011;343:d4163.

ISO [2016-04-13]. Health informatics — Personal health records — Definition, scope and context.Switzerland: ISO; 2012. https://www.iso.org/obp/ui/#iso:std:iso:tr:14292:ed-1:v1:en webcite.

Poos MJJC, Nielen M. COPD - Cijfers en Context - Huidige Situatie. Available from: https://www.volksgezondheidenzorg.info/onderwerp/copd/cijfers-context/huidige-situatie. Accessed 1 July 2018.

Sieverink, F., Kelders, S., Braakman-Jansen, A. et al. Evaluating the implementation of a personal health record for chronic primary and secondary care: a mixed methods approach. BMC Med Inform Decis Mak 19, 241 (2019). https://doi.org/10.1186/s12911-019-0969-7

Spil T, Klein R. The personal health future. Health Policy Technol. 2015 Jun;4(2):131–136.doi: 10.1016/j.hlpt.2015.02.004.

Tang PC, Ash JS, Bates DW, Overhage JM, Sands DZ. Personal health records: definitions, benefits,and strategies for overcoming barriers to adoption. J Am Med Inform Assoc. 2006;13(2):121–6.doi: 10.1197/jamia.M2025. http://jamia.oxfordjournals.org/cgi/pmidlookup?view=long&pmid=16357345.

Tenforde M, Jain A, Hickner J. The value of personal health records for chronic disease management:

what do we know? Fam Med 2011;43:351–4. [PubMed] [Google Scholar]

Wells S, Rozenblum R, Park A, Dunn M, Bates DW. Organizational strategies for promoting patient and provider uptake of personal health records. J Am Med Inform Assoc. 2015;22(1):213-222. doi:10.1136/amiajnl-2014-003055

World Health Organization. Innovative care for chronic conditions: building blocks for actions: global report. 2002.

WHO guideline: recommendations on digital interventions for health system strengthening. Geneva: World Health Organization; 2019. Licence: CC BY-NC-SA 3.0 IGO.