Development and Evaluation of a Web-based Electronic Medical Record System Without Borders

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Abstract

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Despite implementation of electronic medical record (EMR) systems in the United States and other countries, EMRs often lack global access, standardization, an efficient interface, and effective knowledge-based tools at the point of care. Consequently, the information needs of patients, practitioners, administrators, researchers, and policymakers often go unmet, leaving providers especially dissatisfied. To address this multifaceted problem, a novel EMR design referred to as "Electronic Medical Records Without Borders" (EMR WB) was created to ensure that the most vital pieces of patient clinical records are available to make health care decisions. A web-based, standardized, family medicine, clinical history model was developed and evaluated as an EMR clinical core that integrates state-of-the-art terminology, peer-reviewed, evidence-based protocols with real-time access to diagnostic decision support systems and the biomedical literature, using a unified, navigable, intuitive computer interface. This project aimed to facilitate structured clinical documentation, usability, global access, and decision-making processes to better address not only local, clinical, and psychosocial primary care problems in targeted underserved communities in the state of Guanajuato, Mexico, but also to mitigate transnational migration health issues based on information exchange among primary care settings. A survey of post-exposure EMR WB use indicated a measurable, positive effect was made on provider satisfaction compared with a previously used, paper-based record system. Data were analyzed using descriptive statistics.

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DEDICATION

As I learned throughout this journey, it takes quite a bit of isolation and solitude to undertake a project of this scope including research, implementation, evaluation, and of course, writing. My wife Merrie was exceptionally patient and supportive during this whole process. I am so grateful to her, as well as the committee and faculty members who all helped to make this exciting and meaningful endeavor a reality.

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Chapter I: Introduction

The patient record is the principal repository for information concerning a patient's health care [1,9,10,12]. It affects virtually everyone associated with providing, receiving, or managing health care services. Despite the many technological advances in health care over the past few decades, the typical patient record of today is remarkably similar to the patient record of 60 years ago [9,57]. This failure of patient records to evolve is now creating additional stress within the already burdened US health care system and in other countries as the information needs of patients, practitioners, administrators, researchers, and policymakers often go unmet.

Transferring accurate data from the clinical encounter into the medical record, making health care decisions, and sharing and retrieving patient information is a difficult undertaking, but all are instrumental to the effective practice of medicine and biomedical research. Without accurate data, patients cannot be properly diagnosed and treated, and without structured data, computer tools such as diagnostic decision support systems cannot parse that data and assist health care providers. Research in translational medicine also depends on the ability to document patient medical records so they can be related to the vast genome data [18,41]. Current electronic medical records (EMRs) have been unable to provide evidence that clinical documentation and practice is more efficient than in the past [1,3,4,65]. In addition, many studies indicate low levels of satisfaction with overall EMR use and deficiencies in the record-keeping process as currently practiced by health care providers, which leads to medical records that often fail to include and share critical information [6,9,17,57].

1.1. Statement of Problem

The literature indicates that the present EMR structure fails to help providers effectively document, store, share, and access clinical findings; achieve independent thinking and integration of knowledge; or improve clinical care workflows and decision-making [1,2,3,4,13,57]. Also, mixed results from the implementation of EMRs in specialized settings suggest that their use has had a limited effect on quality improvement in US hospital care [3]. Despite the expense, time, and broad implementation of EMRs, there is little hard evidence of benefits in the form of provider satisfaction, patient outcomes, or standardized terminology [4,9]. The importance of the system proposed here, Electronic Medical Records Without Borders (EMR WB), is centered on the premise that current EMRs lack open global access [1,4,11], standardization [5,10,45], efficient interface [4,10,13], effective knowledge-based tools at the point of care [21-27,36], and a clear definition [5,10,19,45]. Consequently, the information needs of patients, practitioners, administrators, researchers, and policymakers often go unmet. These critical barriers have a negative impact on provider and patient satisfaction, quality of life, health outcomes, clinical care workflows, and health care costs [4,5,7,8,17,57,64].

1.1.1. Historical context

To best understand the nature of current EMRs, it is important to review their foundation and evolution. Many current EMRs still follow the traditional organization and characteristics of the original paper-based system and have simply automated that system. Narrative documentation, for example, is far more prevalent than standardized structured text [65].

The beginnings of medical record-keeping

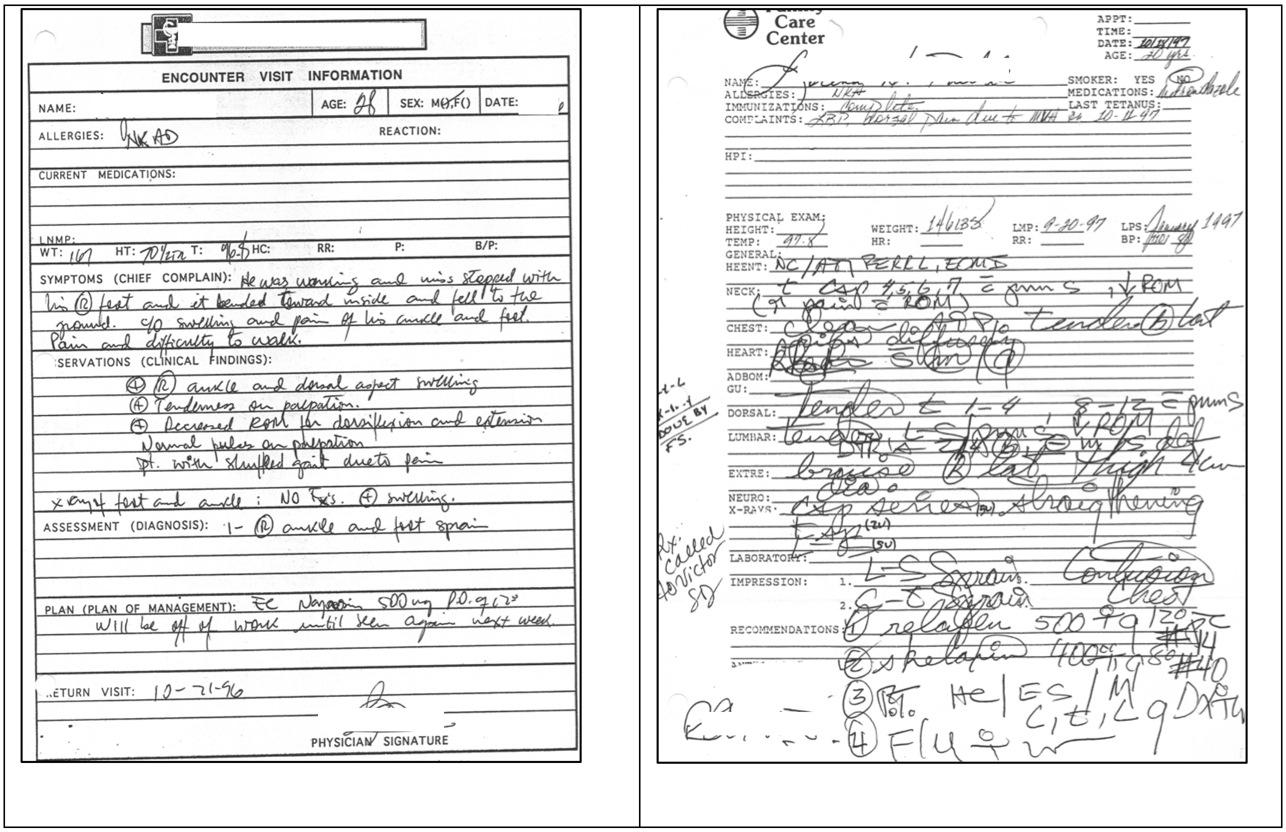
While the central idea of this project is to bring patient records out of the ink-and-paper era and into the state-of-the-art computer age, the paper-based record is not all negative. The notion that an EMR is inherently better than a paper one is weak [19]. The content in the record clearly has a large impact on a record's effectiveness, independent of the medium of delivery. The most vital aspect of the medical record is well-defined and structured documentation [45,65]. Knowing this, an efficient design has to take into consideration the well-known, mature, structured, and clinically-oriented paper-based system that has been supporting the health care system for centuries. Nearly 2,500 years ago, Hippocrates called for the careful recording and sharing of evidence about patients and their illnesses. He developed the first known medical record in the fifth century BC[1] with two goals: to 1) accurately reflect the course of disease and 2) indicate the probable cause of disease. While this charge sits at the foundation of modern medicine, large amounts of valuable health care data still go unrecorded. These goals are still appropriate, but electronic health record (EHR) systems can also provide additional functionality, such as standardized structured documentation [65], interactive alerts, interactive flow sheets, and computerized physician order entry (CPOE)[2] systems [1,19]. Information systems capturing increasing amounts of health care data have ignited interest in the exciting possibilities ahead for leveraging large quantities of patient and hospital data to increase the quality of care while reducing costs.

1 J.H. van Bemmel and M.A. Musen, ed., Handbook of Medical Informatics, Springer, The Netherlands, 1997, p. 99.
2 CPOE or medical order entry systems are computer-assisted information networks that enable providers to initiate medical procedures, prescribe medications, etc. These systems support medical decision-making and error reduction during patient care. NLM-MeSH Year introduced: 2006.

Although the physical nature of the paper record has remained relatively the same, the formal structure of the information contained within the record has undergone considerable change in the last 60 years [2,19,51]. The first step to creating effective EMRs should consider simply digitizing a well-structured paper medical record. After this has been proven successful, the next area of focus should be ways to facilitate providers sharing insights into the complexities of modern medicine to support specific clinical decisions. It is also important to be aware that EMRs and paper-based records are different artifacts that support different cognitive processes, and therefore do not have the same usability problems [19,51,52].

To fully appreciation these differences, it is necessary to have a clear notion of the physical aspects of the paper record. Paper is portable and access is direct, self-contained, and practical (no power supply, network, information technology [IT] support systems, or internet access required) [19]. It is a highly familiar method of recording information (no special training needed as compared with a computer system). Another advantage of paper is how little structuring it demands because it is unconstrained in both form and content in a relatively informal medium (e.g., a long detailed history with marginal annotations, physical exam with drawing of the affected area, lab results using special characters, and handwriting diagrams), and it can be classified as a general-purpose tool for capturing data (see Figure 1) [5,14,19].

Despite its benefits, a paper record can only be used for one task at a time, has access constraints (e.g., lab and X-ray results or clinical notes might be in a different office), consumes space, can be physically cumbersome, is susceptible to damage and degradation over time, and is dependent on production practices that are not ecologically sound (e.g., deforestation and water pollution). Also, because its creation and modification can be very personal, it may be difficult to understand for those other than the writer (see Figure 1). In addition, the lack of any formal structure to guide record creation increases the possibility for errors, misunderstandings, and omissions of relevance [5,16,51].


ENCOUNTER VISIT INFORMATION

NAME: AGE: 28 SEX: M(✓) F() DATE:

ALLERGIES: NKAD REACTION:

CURRENT MEDICATIONS:

LNMP:
WT: 167 HT: 70 T: 96.8 HC: RR: P: B/P:

SYMPTOMS (CHIEF COMPLAIN): He was working and miss stepped with his (R) foot and it bended toward inside and fell to the ground. c/o swelling and pain of his ankle and feet. Pain and difficulty to walk.

SERVATIONS (CLINICAL FINDINGS):
(+) (R) ankle and dorsal aspect swelling
(+) Tenderness on palpation.
(+) Decreased ROM for dorsiflexion and extension
Normal pulses on palpation
Pt. with shuffled gait due to pain

x-ray of foot and ankle: NO Fx's. (+) swelling.

ASSESSMENT (DIAGNOSIS): 1- (R) ankle and foot sprain

PLAN (PLAN OF MANAGEMENT): EC Naprosyn 500 mg P.O. q 12°
Will be off of work until seen again next week.

RETURN VISIT: 10-21-96

PHYSICIAN SIGNATURE

Care Center

APPT:
TIME:
DATE: 10/18/97
AGE: 30 yrs

NAME:
SMOKER: YES NO
ALLERGIES: NKA
MEDICATIONS:
IMMUNIZATIONS: Complete
LAST TETANUS:
COMPLAINTS: LBP, dorsal pain due to MVA on 10-11-97

HPI:

PHYSICAL EXAM:
HEIGHT:
WEIGHT: 146 LBS
LMP: 9-20-97
LPS: January 1997
TEMP: 97.8
HR:
RR:
BP:
GENERAL:
HEENT: NC/AT, PERRL, EOMI
NECK:
CHEST:
HEART:
ADBOM:
GU:
DORSAL: tender 1-4, 8-12 c̄ pms
LUMBAR:
EXTRE: bruise (R) lat thigh
NEURO:
X-RAYS:
LABORATORY:
IMPRESSION: 1. L-S Sprain 2. C-T Sprain 3. Contusion Chest
RECOMMENDATIONS: (1) relafen 500 q 12° #14
(2) skelaxin 400 q 8° #40
(3)
(4)

Rx: called to Victor SD

Figure 1: **Two anonymous examples of handwritten medical record documentation**.

EMRs as the next step

The most important motivations for creating EMRs are the drawbacks of paper-based records outlined above. In simple terms, the current EMR is the computer replacement for the paper medical record system. It provides a mechanism for capturing information during the clinical encounter, stores it in a secure and organized fashion, and permits use of that information only by those with a clinical need [19]. The EMR has a number of powerful attributes that make it ideal for data capture and storage, including the enormous quantity of data that is possible to store in a small space (e.g., cloud computing), and the ease of creating copies, backups, and secure data sharing. Also, it facilitates more structured data, portability, access, availability, interoperability, and structured care around automated protocol-guided care (e.g., e-prescribing, alerts, reminders, task-specific views of data, and clinical audit and outcomes assessment) [17].

The current EMR allows an institution to replace its paper charts with electronic charts. This offers the potential for improving productivity and efficiency. Some EMR systems provide reminders and alerts, CPOE [14], and links to data for improved health care, but the impacts on health indicators are mixed or not well understood. Most EMR systems in place are evolving concepts that tend to respond to the dynamic nature of the health care environment and take advantage of technological advances and the recent financial motivation for their implementation and meaningful use [10,14,15].

Current EMR system limitations

As W.E. Hammond pointed out in 2009 [9], "For much of the world, truly productive and functional EMRs remain an elusive goal of the future." Ellwood added that since 1988, "the intricate machinery of our health care system can no longer grasp the threads of experience… Too often, payers, physicians, and health care executives do not share common insights into the life of the patient… The health care system has become an organism guided by misguided choices; it is unstable, confused, and desperately in need of a central nervous system that can help it cope with the complexities of modern medicine" [2].

Hammond [9] also noted that "After a history of almost 60 years, the development of the use of computers in health care—Healthcare Information Technology (HIT)—is still lacking in delivering its perceived potential. The reasons are many: 1) the lack of definition and clarity of what is important and required in health care; 2) the lack of consistency in the practice of medicine; 3) the variety in evidence in an evidenced-based-medicine delivery model; 4) the lack of a business model that proves a return on investment for HIT; 5) lack of standards to support interoperability across various sites, domains, and models for health care; and 6) the lack of an infrastructure enabling the necessary connectivity to support the bringing together of data about a single patient." His overall assessment is that "For the most part, today's EMR is not even a good representation of the paper record, which is still unorganized and contains unstructured content."

According to Kush et al. [18], "We can travel almost anywhere in the world and find a machine that will dispense local currency, taking the money from our home account with the use of a bank card. Yet, when we go from a primary care physician to a specialist in our hometown, we must begin at square one, providing the new doctor's office with all our demographic and medical information, often by completing paper forms." Also, they pointed out "if we were traveling abroad and needed access to our health information, we would face formidable difficulties." Financial institutions in particular have for years developed and used standards for electronic exchange, but not the health care industry [1,18].

Finally, low usability, concerns about privacy, and inability to use secondary information for research represent additional major current limitations to EMR functionality and adoption across institutions not only in the United States, but globally [55,57].

The ideal EMR system

Based on Mandl and Kohane's 2012 [64] assessment of what is still needed to update the management of health care, the ideal EMR system would affordably provide efficient means of communication among providers and with their patients, secure private storage of health care data in the cloud, standardized documentation tools, integrated workflow of multi-disciplinary users, clinical decision support, and interoperability.

Some medical institutions in the United States are approaching this ideal by adapting emerging technologies to their health care systems. Harvard Medical School-affiliated Beth Israel Deaconess Medical Center (BIDMC) in Boston was selected as the most innovative US user of business technology in 2012 by *InformationWeek* magazine as part of their 24th annual ranking based on BIDMC's IT department creating "Clinical Query," a search engine tied to a database of patient records, along with a Web-based, cloud-hosted EMR system that runs on tablets, called Online Medical Record, which allows both physicians and patients access to medical information.[3]

[3] Beth Israel Deaconess Medical Center Embraces Analytics BIDMC, the No. 1 company in the InformationWeek 500 2012. http://www.informationweek.com/global-cio/interviews/beth-israel-deaconess-medical-center-emb/240006766

1.2. Proposed Solution

This dissertation describes the approach to how the most critical problems with conventional EMR systems were resolved with the design, implementation, and evaluation of a new EMR system (see Table 1). The proposed changes are aimed at contributing to the EMR of the future, which would first positively impact provider satisfaction. The ultimate goal is higher quality of life as a result of improved health outcomes.

Table 1: Aspects of currently available web-based EMRs compared to EMR WB.

	Themes	OpenEMR, OpenMSR	Practice Fusion	Epic, Epocrates	EMR WB
1	**Access**. Openly accessible on a web-based system from any platform.	Limited	Yes	Limited	Yes
2	**Standardization**. Consistently includes patient histories as part of a standardized clinical family medicine core EMR.	No	No	No	Yes
3	**Interface**. Compiles and condenses an all-inclusive intuitive EMR interface into one navigation system.	No	No	No	Yes
4	**Decision Support**. Uses knowledge-based point-of-care systems to support health care decision-making processes.	Limited	Limited	Limited	Limited
5	**Structure**. Design based on a thorough definition centered around patient histories.	No	No	No	Yes
6	**Communication Range**. Available in more than one language (i.e., English and Spanish)*	No	No	No	Yes*
7	**Multidisciplinary.** Medicine, psychology, nutrition, nursing, and social work.	No	No	No	Yes
	Web pages	http://www.oemr.org, and http://openmrs.org/	http://www.practicefusion.com	http://www.epic.com/, and http://www.epocrates.com/	http://www.emrwithoutborders.com

*EMR WB is a fully bilingual system, and the structure and terminology is available in English and Spanish. The user can indicate the language of preference when logging in. The system does not automatically translate from one language to another.

EMR WB builds the technical capability to 1) make EMRs accessible on a web-based system from any platform; 2) consistently include patient histories as part of standardized clinical core EMR; 3) compile and condense an all-inclusive intuitive EMR interface onto one navigation system; and 4) provide effective knowledge-based tools at the point of care to support health care decision-making processes. These features will provide access to scientific knowledge and build specific needed infrastructure to better address not only local, clinical, and psychosocial primary care problems in targeted underserved communities around the globe, but transnational migration health issues based on data transfer of clinical information in primary care settings, in particular free clinics serving patients traveling between Mexico and the United States.

By making EMRs accessible on a web-based system from any platform—PC, Mac, tablet, or smartphone, each with their corresponding operating systems—there will be a substantial simplification and expansion of the ways in which health care providers access and input clinical information. They will switch from local, restricted onsite use of paper-based medical records or EMRs to a system that takes advantage of cloud computing. This change will allow them to input, retrieve, store, share, and access patient medical records anywhere (rural or urban settings) when needed [1,9]. Also, they will be able to remotely access and use knowledge-based tools at the point of care to support clinical decision-making. With this new service, the patient, as the owner of their personal medical record and its access code, can travel almost anywhere in the world and find a provider that can access their EMR, thereby avoiding the need to reenter demographic and medical information onto paper forms. This represents a potentially significant savings in time and frustration, and improvement in health care quality for patients who seek medical attention while traveling or living abroad [18].

The application of this project clearly challenges the current EMR paradigm by shifting away from the fragmented, difficult-to-use EMR system that has been unable to provide evidence that clinical practice is more efficient than in the past [1,3,4,5]. This novel proposed design counteracts the predominant health care system paradigm that prioritizes the quantity of care rather than the quality of it. EMR WB represents the cost-saving health care innovation that drug companies and private insurers have failed to provide [1,4,27].

EMR WB is patient-centered rather than system-centered, based on the premise that a standardized, easy-to-use, well-defined, and accessible EMR that integrates best evidence, provider clinical expertise, and patient choice will improve health care. It is a network of tools that recognizes the primary information in the EMR—clinical documentation—is the keystone on which the health care decision-making process is based. Provider interaction with such an integrated system is expected to be a satisfying experience. A system that is centered on efficiency and quality of information will be one way to reduce health care costs, as the evidence points out [8,17,27,30,65]. In addition, this model could be generalized as a valid frame of reference for other similar populations (primary care centers aimed at providing services in limited resource settings).

1.2.1. EMR WB project background

The research, development, implementation, and evaluation of EMR WB required international, multidisciplinary collaboration. This approach was based on an established need to share clinical information in a global context, starting with specific populations on both sides of the US and Mexican borders as part of a pilot project in a well-structured primary care setting in the city of Leon, Mexico. A series of progressive steps was carried out that involved the identification of specific problems with sharing information using current EMR systems.

International collaborative research

In December 2009, the University of Guanajuato School of Medicine Department of International Affairs in Mexico, the University of Pittsburgh Center for Global Health,[4] and the University of Pittsburgh-affiliated community clinics in the metropolitan area (i.e., Squirrel Hill Health[5]) approached me to participate in a three-day collaborative international research conference titled "Workshop of Transnational Migration and Global Health: The Case of Guanajuato and Pittsburgh, 2010." The rationale for this meeting was to discuss and analyze the quality of health care for migrant workers traveling between Pittsburgh, Pennsylvania, and the urban community of León, as well as rural communities in the state of Guanajuato (Ocampo and Los Lorenzos), Mexico.

The basis of this request to participate in the April 2010 global health workshop was a series of successfully implemented collaborative research and exchange programs between the UW School of Medicine and University of Guanajuato medical students and faculty over five years. When the idea to develop a project that would address the issues raised at the workshop was proposed to José Luis Lucio-Martínez, PhD, President of the University of Guanajuato Campus León, and Ana María Chávez-Hernández, PhD, Director of the

[4] University of Pittsburgh Center for Global Health: http://www.globalhealth.pitt.edu/education/International-scholars.php
[5] Squirrel Hill Health Center: http://www.squirrelhillhealthcenter.org/

University of Guanajuato Center for Health Services (CUSS), both officially gave their support to the plan in July 2010 with regard to collaboration, funding, and advising.

My participation was centered on researching the following question: What would be the best approach to sharing clinical information across borders (i.e., between Leon, Mexico, and Pennsylvania, Pittsburgh)? Initially, the plan was to include the University of Pittsburgh-affiliated community clinics and several free clinics in the state of Guanajuato, Mexico. The identified need for sharing clinical information on an international scale was born, primarily based on the documented occurrence of patients moving one or several times a year between these communities, and using the local health clinic services. Health care providers were isolated in terms of patient data sharing, and dependent upon what patients could provide during office visits to the clinics. Vital information was lost, such as the description, severity, evolution, and prognosis for specific conditions; medication types, doses, and regimens; responses to treatments; and the type of and results for laboratory and image studies performed—essentially entire health records. The preliminary conclusions were that rural and urban public clinics in the state of Guanajuato, Mexico, lack a modern, standardized EMR system, open global access, efficient interface, and knowledge-based point-of-care systems to efficiently collect, store, share, manage, and access patient files. As a result, the vital information needs of patients, practitioners, administrators, researchers, and policymakers were often unmet, and negative financial and health outcomes were escalating. The same problem has to be addressed at the University of Pittsburgh-affiliated clinics, and they have to be prepared to access the EMR WB to mitigate transnational migration health issues based on information exchange between the CUSS and corresponding primary care settings in Pittsburgh. It is expected that University of Pittsburgh-affiliated primary care clinics would implement the EMR WB project after the completion of the pilot project at the CUSS, in particular the Squirrel Hill Health Center.[6]

Based on these findings, combined with the knowledge that interlinked communities across borders is a common situation all over the United States and Mexico as well as in other countries, the creation of a research project originally titled "A Web-based EMR Regional Primary Care Network System for Urban and Rural Public Clinics in the State of Guanajuato, Mexico: A Pilot Project" was proposed. This international, multidisciplinary, multinstitutional collaborative research effort involved Ana María Chávez-Hernández, José Luis Lucio-Martínez, and Brigitte Lamy, PhD, Professor of Sociology at the University of Guanajuato Campus León, as the key network collaborators in Mexico. Other collaborators included 1) Robert Dickow, PhD, Associate Professor, University of Idaho; 2) Kathleen Musante DeWalt, PhD, Director of the University of Pittsburgh Center for Latin American Studies and Professor of Anthropology and Public Health; 3) Joanne L. Russell, MPPM, RN, CCRC, Director of the University of Pittsburgh Center for Global Health and Assistant Professor of Global Health; 4) Kenneth S. Thompson MD, Medical Director of the Center for Mental Health Services at the US Department of Health and Human Services; 5) Sergio Aguilar-Gaxiola, MD, PhD, Director of the Center for Reducing Health Disparities at the University of California-Davis and Professor of Internal Medicine; 6) Edward P. Hoffer, MD, Associate Clinical Professor of Medicine at Harvard Medical School and researcher at the Massachusetts General Hospital Laboratory of Computer Sciences; 7) Andrea Fox, MD, MHP, Associate Professor of Family Medicine at the University of Pittsburgh School of

[6] Squirrel Hill Health Center: http://www.squirrelhillhealthcenter.org/

Medicine and Medical Director, Internist, and Geriatrician at Squirrel Hill Health in Pittsburgh; and 8) Alfonso Barquera, local Latino leader and active member of the Hispanic Outreach Project of the Community Social Justice Project in Pittsburgh. The roles of the collaborators were diverse, from direct clinical care of migrant patients on both sides of the border, to research in fields such as migrant health, anthropology, sociopsychological factors of migration, economics, and global biomedical informatics.

The EMR theoretical model that was developed incorporated a comprehensive concept of multidisciplinary standardized family medicine clinical history that integrates state-of-the-art terminology (controlled vocabularies, syntaxes, ontologies, and semantics) and evidence-based (EB)[7] clinical protocols and guidelines into an ethnically-oriented and culturally-sensitive English-Spanish language EMR system. The goal was to better address not only the current local and public health problems, but also transnational migration health problems based on the need for data transfer of clinical information to improve provider satisfaction and health outcomes in the targeted populations. Although EMRs were being used in many areas of medicine and research indicated they had potential to improve patient quality of life and health outcomes, their implementation, standardization, and use in Latino populations was limited, particularly in underserved rural and migrant sectors.

Due to the international nature of this research and the need to implement a pilot project, two international summer independent research programs were applied for through UW International Programs and Exchanges (IPE) in 2010 and 2011. Both were accepted and

[7] Evidence-based: Characterized by "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients and populations integrating individual clinical expertise and patients' choice/preference." (Sackett DL. BMJ. 1996 Jan 13;312(7023):71-2)[28]

credit was granted to travel, begin a feasibility study, and implement a research pilot project at the University of Guanajuato.

During visits to Mexico, EMR WB was developed with the intent to provide a user-friendly and efficient computerized system for recording patient medical histories in a global context. This is a multidisciplinary, standardized, state-of-the-art EMR using cloud computing to enable accessibility anywhere from any platform (PCs, Macs, tablets, and smart phones with their respective operating systems). Using this model, a pilot project was implemented at the University of Guanajuato Center for Health Services (CUSS), in the City of Leon, state of Guanajuato, Mexico. Beginning in the summer of 2010, this pilot project was led in collaboration with the University of Washington Department of Biomedical Informatics and Medical Education (UW BIME) under the supervision of Fredric M. Wolf, PhD, and the University of Guanajuato.

During the summer of 2010, onsite work on project feasibility was begun by setting up a focus group with CUSS end users (health care providers). The results showed that potential issues with EMR WB acceptability would need to be addressed because CUSS providers were used to a paper-based system for creating and maintaining health records. The new system was therefore adapted to their clinical environment using existing information technology architecture within the University of Guanajuato: in particular, the same hardware, internet access, and local technical support from their Information Technology Department. Modifications that made the system unique to the CUSS included computerization of the clinical data gathering and access to it in their own clinical context. To achieve these basic features, the services of several companies that could potentially program the EMR and provide cloud services were evaluated. Based on these preparations, research questions were constructed and project feasibility was corroborated with the providers and university administrators.

After completing this preliminary work, the interface design was begun, which included standardization of clinical histories (for the domains of medicine, psychology, nursing, nutrition, and social work) using shared terminologies with controlled vocabulary (terms), ontologies (relations), semantics (meaning), and syntaxes (structure). EB and peer-reviewed clinical protocols and knowledge-based diagnostic decision support tools at the point of care were also included. Next, a contract was set up with the most promising US company (Arvixe Web Hosting) for the cloud services. Implementation and beta testing began on May 25, 2011. Robert Dickow, PhD, Associate Professor at the University of Idaho, with more than 30 years of truly exceptional multi-language programming experience, executed and programmed EMR WB in its totality.

The next step of the project was conducted during a trip to León in summer 2011 when the implementation and onsite use of the EMR WB system at the CUSS was evaluated. During this second international summer independent research program, use of the actual working system by the CUSS health care providers in their own settings was witnessed, and discussions were held with them on several occasions to discuss their experiences. This included a series of talks about the standardized EMR pilot software used, demonstrations of how EMRs can facilitate the clinical workflow, and feedback on encountered limitations. Several very productive weekly working meetings were also conducted with Dr. José Lucio Martínez and Dr. Ana María Chávez-Hernández about the project progress and adoption specifics. The beta testing approached its final phase in December of 2011 based on exhaustive feedback obtained from the CUSS health care providers.

Although the feedback from the EMR WB use evaluation at the CUSS was generally positive, some onsite technical aspects and logistics were reconfigured as part of a risk management approach and follow-up study. These included looking into the internet access to ensure that even with some variants in speed, the overall functionality was not compromised. Fields of free text were added or expanded (in particular with nutrition and nursing) with free text, made available across all modules, and deleted if users reported them as duplicates when describing "bugs" in the presentation and structure of the record from different domains (mainly psychology and social work).

Related EMR WB projects and recognition include the following:

- A paper based on an observational study in León, Mexico, in collaboration with Dr. Ana María Chávez-Hernández, which will be submitted for publication to *JAMIA* as "Perception of implementation and use of a standardized family medicine web-based system among providers in urban clinics in the state of Guanajuato, Mexico."
- A story of my experience in Mexico implementing EMR WB published by the UW School of Public Health at http://sph.washington.edu/news/fellows.asp.
- Several talks, poster presentations, and seminars regarding the project, the field of biomedical informatics, and EMRs as a whole, in different settings at the University of Guanajuato (in July 2010, May 2011, August 2011, and January and February 2012).

- An abstract and poster at the Symposium of the Program for Education and Research in Latin America (PERLA) by the UW Department of Global Health in April 2011.

- A keynote speech at the XXVI National Congress in Medical Research in Monterrey, Mexico, September 2011 (http://www.congresobiomedico.org.mx/).

- A poster at the UW Department of Global Health Open House in January 2012.

- The 2011-2012 Thomas Francis, Jr. Global Health Fellowship award from the UW Department of Global Health.

- A focus session presentation to represent the University of Washington at the 2012 National Library of Medicine (NLM) Informatics Training Conference.

This collaborative, multinstitutional research experience has been instrumental in the overall research, development, implementation, and evaluation of EMR WB, aimed at supporting the clinical services provided by the University of Guanajuato to those who need it most: underserved and migrant populations. This research was intended to address one of the most significant problems in migrant health by offering health care providers in the United States and Mexico the ability to access and transfer data to patients' medical records across international borders. EMR WB collaborative partners believe that the system has the potential to be successfully applied anywhere in the world.

The CUSS in the context of Mexican health care

As with most other middle-income countries, Mexico does not provide universal access to health care for its population. About half of Mexico's population does not have health insurance under the current system, as reported by the international Organization for Economic Co-operation and Development (OECD).[8]

Health care in Mexico is provided via public institutions, private entities, and private physicians. Health care delivered through private health care organizations and physicians operates entirely on the free market system, so it is only available to those who can afford it. Public health care delivery, on the other hand, is provided via an elaborate system put in place by the Mexican federal government. The CUSS is part of the public sector and supported through the state government as part of the public university system.

Mexico has a fractionalized health insurance system with a variety of public programs, but coverage is restricted based on employment status and if the person works for the government or in the private sector. There is also a private insurance market, mostly used by wealthy residents. A social security-administered system (IMSS) covers those who are employed unless they have private employer-sponsored insurance, while the "Seguro Popular" program, created in 2003, was set up to help cover the uninsured population. Poor families can participate in Seguro Popular for free. People who do not participate in the insurance program can still access services through the Ministry of Health free clinics (which includes the CUSS), though sometimes with difficulty because these clinics are limited across Mexico. An additional hurdle is that the different public systems and private

[8] OECD Reviews of Health Systems – Mexico. OECD Publishing, 07 Jul 2005. 158 pages. Language: EnglishISBN: 9264008934

insurers all use different medical facilities and providers, each with a wide range in service quality at all levels such as primary, secondary, and tertiary care, as reported by OECD**.**

The social security-based insurance in Mexico provides broad coverage for medical services, including primary, acute, ambulatory, and hospital care, as well as medications. Seguro Popular provides access to an established set of essential medical services and the needed drugs for those conditions, as well as 17 high-cost interventions such as breast cancer treatment. These services are provided through government facilities, usually run by the state.

Out-of-pocket payments by patients represent over half of the financing for the Mexican health care system, according to the World Health Organization (WHO).[9] Government expenditures account for 44 percent of health spending. The public entities, including the Mexican Institute for Social Security and the Institute of Social Security for Government Employees, are financed through general taxes. Payments are determined by salary level. The Seguro Popular program is funded through taxes, contributions from state and federal government, and payments by families as a percentage of income. Participants in Seguro Popular pay nothing at the time of service.

EMR WB in the CUSS workflow

EMR WB was implemented at the CUSS, a multidisciplinary primary care clinic for underserved and migrant populations in the city of Leon, state of Guanajuato, Mexico. The CUSS is a research and training outpatient clinic on the University of Guanajuato Campus Leon that employs a total of 50 health care providers in 24 offices distributed across the

[9] WHO-Mexico: http://www.who.int/countries/mex/en/

different services offered: medicine, psychology, nursing, nutrition, and social work. As a teaching facility, students perform their clinical rotations under close supervision of the providers in their corresponding disciplines.

The CUSS can be defined as a multidisciplinary primary health care institution which provides integrated and accessible health care services by providers who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community.[10] In this context, the workflow of the CUSS is based on a pattern of recurring procedures that include notifications, decisions, and actions to influence quality of life and local public health outcomes.[11]

The front office. When a patient enters the CUSS, they must go directly to the front desk and ask for a consultation in one of the five areas of services provided, according to their own identified needs. The front desk receptionist provides information and instructs the patient regarding the options. At this time, the receptionist inputs patient demographic information into the identifying data—ID (patient name, age, gender, marital status, etc.) and motive for consultation—MC (or reason for the visit). The front desk either creates (in the case of a new patient) a new chart within the EMR WB system using the initial data input, or opens the patient's existing chart within the EMR WB system using the patient's full name and unique identifying number, and corroborates that the patient matches the data.

[10] Primary Health Care. Care which provides integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community. (JAMA 1995;273(3):192) ; MeSH-Year introduced: 1974(1972)

[11] workflow is defined as the description of pattern of recurrent functions or procedures frequently found in organizational processes, such as notification, decision, and action [NLM/MeSH, Year introduced: 2010].

The back office. After the patient has been registered, the nurse takes the patient to the exam or consultation room, sits the patient (on the examination table in the case of medicine, nutrition, or nursing), opens the patient's chart within the EMR WB system, verifies the MC with the patient, and corroborates, adds, or inputs their professional opinion about the MC. At this point, the nurse also checks the file for refills, screenings, or preventive services that might be needed and then flags the chart so the primary health care provider can specify those services during the visit. Then the nurse takes vital signs as appropriate for the consultation in the fields of medicine, nutrition, or nursing (blood pressure—B/P, pulse/heart rate—HR, respiratory rate—RR, body temperature—T, height—HT, weight—WT, and head circumference—HC in children, etc.). Next, the nurse asks the patient to change into a gown if needed, and informs him/her that the physician or nutritionist will enter the room shortly, or the patient continues with the nurse if it is a nurse consultation or health education session. In the case of psychology and social work, the vital signs and physical preparation of the patient are omitted. During this process, the computer screen (mainly desktops) is not in sight of other personnel to safeguard privacy, but the patient is able to see what the clinician sees. Next the provider enters the room, interacts with the patient, and opens the EMR WB system where the ID and MC appear on the front page. If the patient is new, the provider begins the interview to gather the history of present illness—HPI, past medical history—PMH, family history—FH, social history—SH, review of systems—ROS, and health maintenance—HM, as appropriate. The final steps are performing the physical exam (this part is skipped by psychologists and social workers); ordering any needed laboratory or diagnostic image studies; and providing plans for treatment (e.g., prescription for medications or physical therapy, referral to another provider). The provider also has the option to add clinical or follow-up notes to the patient's EMR WB.

The idea behind using EMR WB in the clinical encounter at the CUSS is that the health care providers are able to interview patients while simultaneously inputting the clinical data into the medical record; the file remains open and accessible for consultation and additional input throughout the physical exam, diagnosis, prognosis, treatment, and plans. When the patient returns to the front desk, the receptionist or nurse uses EMR WB to verify/provide some piece(s) of information such as follow-up visits, referrals, or payment arrangements (usually a suggested fee if the patient has the financial means), and the file is then saved and closed.

In the CUSS context, the EMR WB design is centered on a one-page, simplified data entry interface. This format allows providers to see the whole EMR and navigate among the different fields without losing sense of where they are in the chart. Based on the preliminary observational study, providers want and need an easier way to enter patient data while they are interacting with the patient without negatively affecting the patient-provider relationship. EMR WB addresses this issue by providing an interface that is easy to use and navigate, does not interfere with patient interaction during the clinical encounter, and facilitates all the steps of the clinical workflow as defined by the clinicians.

1.3. Research Statements

1.3.1. Thesis statement

Currently, EMRs often lack global access, standardization, an efficient interface, and effective knowledge-based point-of-care tools. Consequently, the information needs of patients, practitioners, administrators, researchers, and policymakers often go unmet, leaving providers especially dissatisfied.

1.3.2. Research questions

Aim 1. Will development of a standardized, web-based family medicine EMR WB system that is accessible from any platform, functions with an intuitive interface, and provides decision support tools for the University of Guanajuato Center for Health Services (CUSS) be achievable?

Aim 2. Will use of the EMR WB system have a positive effect on provider satisfaction compared with a paper-based system?

1.3.3. Objectives

1. Develop a standardized, web-based family medicine EMR WB system that is accessible from any platform, functions with an intuitive interface, and provides decision support tools for the CUSS.
2. Evaluate CUSS provider satisfaction with EMR WB compared to the paper-based system as measured by a quantitative post-implementation follow-up survey.

1.4. Significance

EMR WB is unique for its global yet particularized approach. It was designed to be highly functional in a diverse, global context by providing a familiar structure (clinical core), which was standardized to better address the needs of patient documentation for both unstructured and structured input [65]. Because EMR WB was implemented in free clinics, where services are government-funded and provided for either low or no cost, the coding intended for billing and other administrative avenues does not apply. The structure of EMR WB shifts the priority from administration to the patient, thereby supporting health care decision-making processes.

In addition, EMR WB provides support for a thorough blend of multidisciplinary primary care aimed to work globally. Primary care, in this context, means the integration of medicine, psychology, nursing, nutrition, and social work by sharing longitudinal collections of patient data across these different fields. This approach is ideal for the primary care environment in underserved global settings, as it covers the majority of the population's health needs in a seamless environment.

EMR WB, as a web-based system, is accessible from any platform for its input and output, so providers in limited resource settings will be able to use it with practically any device they have on hand. With the e-Mobile technology (mobile phones) currently used for specific tasks (e.g., infectious diseases, public health data gathering) in many resource-limited settings across the world, EMR WB can provide comprehensive access to an EMR with multidisciplinary primary health care data gathering and sharing capabilities, which is not currently available [9,10,41].

EMR WB is available in both English and Spanish, allowing the provider to use the language of choice. This capability was incorporated for several reasons: 1) Mexico is the primary place for the pilot implementation, where Spanish is the native language; and 2) Spanish is the second most common natively-spoken language in the United States and the world (500 million speakers) after Mandarin Chinese.[12] The Spanish-language EMR WB system will not be a translation, but an integration of linguistics with ethnically-oriented and culturally-sensitive components that have been incorporated in the clinical core to facilitate the input of information.

1.5. Research Goals

The purpose of this project was to create and evaluate a novel multidisciplinary (medicine, psychology, nursing, nutrition, and social work) primary care EMR system that includes global access, standardization, and knowledge-based tools at the point of care, all with an efficient interface. This project aims to facilitate structured clinical documentation, interoperability, global access, and decision-making processes to better address not only local, clinical, and psychosocial problems encountered by patients at the CUSS, but also to prepare CUSS to support transnational migration health issues based on information exchange among primary care settings in the future.

1.5.1. <u>Aim 1</u>. Develop a family medicine web-based EMR WB system that is standardized, accessible from any platform, functions with an intuitive interface, and provides decision support tools. An EMR design aimed at working with underserved

[12] Spanish language, facts: http://en.wikipedia.org/wiki/Spanish_language

populations in a global context will be created that integrates four essential strategies: 1) make EMRs accessible on a web-based system from any platform; 2) consistently include patient histories as part of a standardized clinical core EMR; 3) compile and condense an all-inclusive intuitive EMR interface onto one navigation system; and 4) create access to effective knowledge-based tools to be used at the point of care to support health care decision-making processes. The EMR WB design will be based on both a standardized family medicine clinical history and the terminology outlined by the NLM for medical subject headings (MeSH) to index biomedical articles.

Aim 1.1. Access: Make EMRs openly accessible on a web-based system from any platform. A tool will be created that provides a response to the needs for information exchange and interoperability across institutions, platforms,[13] and borders within the medical care system. This solution is integrated into an efficient web-based system using cloud computing. In this setting, the provider will be able to access the EMR through any platform, anywhere, anytime. Patients will be empowered by guaranteed ownership of their medical record via its access code, allowing them to choose any provider anywhere for informed individualized care. This EMR code will allow the provider to have full privileges to access, retrieve, and add information to the clinical file. The patient, as the owner of the medical record, will be able to access their file and input information regarding demographics, family history, personal medical history (e.g., allergies), current prescription medication, and/or over-the-counter supplements.

[13] Computer platform: The basic technology of a computer system's hardware and software that defines how a computer is operated and determines what kinds of software can be used. Source: http://www.webopedia.com/search/platform. For the purpose of this project, the different platforms that will be considered are PC, Mac, tablets, and smartphones, with their corresponding operating systems.

Aim 1.2. Standardization: Consistently record patient histories as the EMR clinical core using standardized terminology. The use of family medicine clinical history, treated here as the clinical core of the EMR, will be standardized by integrating state-of-the-art terminology (controlled vocabulary, ontologies, semantics, and syntaxes) with EB [28] and peer-reviewed clinical protocols. This model will be used to ensure patient histories are consistently recorded as the EMR clinical core with structured and unstructured clinical documentation. Additionally, another four primary care[14] domains—psychology, nursing, nutrition, and social work—will be included using the same principles of standardization in each respective domain. These domains fulfill the multidisciplinary needs of patients at the primary care level. Standardization of the EMR in this project has three specific objectives: to improve 1) the accuracy of primary unstructured and structured clinical documentation, 2) interoperability, and 3) information exchange within the EMR WB system.

Aim 1.3. Interface: Compile and condense an all-inclusive, intuitive, and efficient EMR interface into one navigation system. An intuitive EMR interface will be created that allows providers to see the whole EMR and its different domains in two top menu bars while navigating among the different fields and applications without losing sense of where they are (i.e., all fields and applications are within the reach of one or two clicks). The patient data entry portion will be intuitive, structured by providing standardized clinical histories for each of the four primary

[14] Primary health care: Integrated, accessible medical services by clinicians who are accountable for addressing a majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community. (JAMA 1995;273(3):192) NLM—Year introduced: 1974(1972)

care domains identified in Aim 1.2. Rate-limiting data entry applications will be created for each different field of the clinical history (e.g., history of present illness—HPI or review of systems—ROS) so that providers can indicate positive and negative findings and use either structured data or free text. The interface will allow users to easily and accurately retrieve, seek, gather, encode, transform, organize, and manipulate pertinent information to accomplish desired tasks.

Aim 1.4. Decision support: Integrate infobuttons as knowledge-based point-of-care tools. A decision support application system will be included that relies on "infobuttons" [21-27,36][15] for access and use of web-based point-of-care systems. An infobutton interface will be set up to have direct access to knowledge-based point-of-care systems in real time. The provider will be able to use the infobutton functions to generate and send queries to electronic health information resources using data manually extracted from the EMR. The infobutton will be displayed to the right of the top menu bar in the EMR interface. When clicked, the infobutton will formulate a menu with three options: 1) DXplain, 2) EB Medicine Calculators, and 3) Knowledge Translation Tools.

1.5.2. Aim 2. Evaluate the family medicine web-based EMR WB system to determine if it has a positive effect on provider satisfaction compared with a paper-based medical record system. An evaluation of EMR WB will be conducted via both qualitative (pre-implementation exploratory focus group) and quantitative (post-implementation survey) analyses centered on provider perceptions of its use compared to other EMR systems and

15 Infobuttons: Decision support tools that offer links to information resources based on the context of the interaction between a clinician and an electronic EMR system. [J Biomed Inform. 2008 Aug;41(4):655-66. Epub 2007 Dec 8]

paper-based records. The focus group will be used as an exploratory pre-implementation tool to gain knowledge of how providers perceive EMRs in general. This information will be used to 1) create a schema of coding data to identify specific needs (needs analysis); 2) establish the feasibility of the project (support and willingness to use the system); 3) obtain input for the EMR WB design; and 4) create the post-implementation questionnaire survey design.

The post-implementation survey will be focused on provider opinion of EMR WB use. A tailored survey will be created to evaluate end user satisfaction based on the themes and codes obtained from the focus group. The Questionnaire for User Interaction Satisfaction [35,38,39] (QUIS)[16] and IBM Computer Usability Satisfaction Questionnaires[17] will be used as frames of reference for its design. The survey will be given to CUSS health care providers, who will be asked to make a decision on their level of agreement with statements assessing their satisfaction with EMR WB use compared to paper-based records. A 7-point Likert scale will be used to measure the data obtained.

1.6. Establishing Feasibility

A focus group was performed in August 2010 aimed at better understanding the potential end user (health care provider) of the proposed EMR. The participants indicated a willingness to participate in the pilot project because of its inherent potential to improve their current work using a paper-based system, and hence their overall satisfaction with

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[16] QUIS Main page: http://lap.umd.edu/quis/
[17] IBM Computer Usability Satisfaction Questionnaires: http://drjim.0catch.com/usabqtr.pdf

patient care. The focus group was conducted to confirm with a high degree of certainty that providers would participate in the project. (See Chapter III: Evaluation, 3.2. Focus Group and Survey.)

In addition, a well-defined professional relationship was established with the top administrator of the University of Guanajuato Campus Leon, Dr. José Luis Lucio-Martínez, who has authority for direct decision-making related to my project implementation and evaluation. An appointment was set up in the summer of 2010, and several follow-up meetings were held during my stay. He enthusiastically welcomed the project, and agreed to its implementation and evaluation. By coincidence, Dr. Lucio-Martínez was in the process of building the CUSS, which allowed me to set up the implementation of EMR WB at the same time that they opened the clinic to the public.

Dr. Lucio-Martínez then introduced me to the clinic's director, Dr. Ana María Chávez-Hernández, who openly welcomed the concept and has ever since been an invaluable collaborator and colleague. A Memorandum of Understanding was established, in addition to the verbal agreement, which allowed management of any potential high-risk aspects of the proposed work such as internet access and local onsite technical support provided by the University of Guanajuato. In addition, coordination for the contracted services that programmed the EMR and cloud computing was provided.

The project, from its early stages in May 2011 when the beta testing was initiated, has gradually advanced towards its full completion, which included 1) Set-up of the EMR home page and commercial service in the cloud to support web-based access, available at www.emrwithoutborders.com; 2) Standardization and programming of the clinical core, including the domains of medicine, psychology, nutrition, nursing, and social work; 3) Establishment of an interface using one navigation system; and 4) Access to knowledge-based decision support tools at the point of care such as an EB medicine calculator, knowledge translation tools, and the decision support system DXplain, all of which are currently available online.

1.7. Resource Sharing Plans

Funding for the development and implementation of EMR WB was provided by the University of Guanajuato Campus León, UW BIME, University of Pittsburgh, UW Office of Financial Aid, NLM, and a Thomas Francis Jr. Global Health Fellowship. The Laboratory of Computer Sciences at Massachusetts General Hospital, Harvard Medical School, offered additional support in the form of free access and use of the diagnostic decision support system DXplain. Access to the knowledge-based tools used in this proposal (EB medicine calculator and knowledge translation tools) are free of charge.

1.8. Summary

Rural and urban public clinics in the state of Guanajuato, Mexico, lack a modern, standardized EMR system with global access, an efficient interface, and knowledge-based point-of-care tools that allow providers to efficiently collect, store, share, manage, and access patient files. As a result, the vital information needs of patients, practitioners, administrators, researchers, and policymakers often go unmet, which leads to negative provider satisfaction and poor quality health care. Also, despite implementation of EMR systems in the United States and other countries, the same limitations and unmet needs exist.

To address this multifaceted problem, a novel EMR design was created as a pilot project to ensure that the most vital pieces of patient EMRs are available to make the best health care decisions for anybody in need. A bilingual web-based EMR family medicine model was developed with an efficient, intuitive interface that integrates state-of-the-art terminology (controlled syntaxes, ontologies, and semantics), EB clinical protocols centered on a patient's clinical history, and knowledge-based point-of-care tools that provide real-time access to a diagnostic decision support system. The newly designed EMR system, EMR WB, was implemented in a public, multidisciplinary family medicine clinic at the University of Guanajuato in an underserved urban community in the city of Leon, Mexico. The CUSS is equipped with computers and/or mobile devices with access to the internet.

The objectives of this independent research project are to 1) Highlight the importance of and need to better understand the logistics of bringing patient records out of the ink-and-paper era and into the state-of-the-art computer age, and 2) Learn about provider satisfaction with EMR WB use in comparison with the paper-based system. During this onsite, hands-on experience, the focus was on answering "why" and "how-to" questions regarding the definition, design, implementation, interoperability, and evaluation of EMR WB.

The focus group was used to establish the feasibility of implementing EMR WB at the CUSS. Evaluation of the system was conducted via the EMR WB Questionnaire for User

Satisfaction (EMR WB QUS) survey focused on provider satisfaction. It was hypothesized that EMR WB use would have an overall positive measurable effect on provider satisfaction.

Chapter II: Methods—Designing the Solution

The possibility that technology can help providers accurately capture unstructured and structured data from the clinical encounter, transfer it into the medical record, and then share and retrieve it offers a solution to the current EMR design that represents a paradigm shift in health care. This change means moving away from the fragmented, difficult-to-use EMR system [1,4] towards well-defined, standardized, easy-to-use processes with decision support and universal access.

The overall strategy used to accomplish the specific aims of the project as described in Section 1.5 was focused on building a system from the beginning, without borrowing codes from open sources or extending existing open EMR systems (e.g., OpenMRS[18] and OpenEMR[19]). This decision was made because the open-source software available carried the same functional limitations in their design that most EMRs have as outlined in this study: 1) Minimal accessibility, 2) Incomplete and inconsistent clinical documentation, 3) Lack of connectivity between medical record categories, and 4) Limited or no decision support tools at the point-of-care. The focus of most original EMR developers and users was to solve specific administrative problems, which included providing service-related functions for admission, discharge, and billing. The central idea of the EMR WB design is a system with a well-structured, standardized foundation that will support taking accurate data from the clinical encounter into the medical record, sharing and retrieving it, and integrating it into the practice of medicine and biomedical research.

[18] OpenMRS offical website: http://openmrs.org/
[19] OpenEMR ofical website: http://www.open-emr.org/

2.1. Access

A tool was created to provide a response to needs for information access, exchange, and interoperability across an unlimited number of institutions, communication platforms, and political borders. This solution was integrated into a web-based system using cloud computing, which refers to subscription-based, fee-for-service utilization of computer hardware and software over the internet [20]. The model is gaining acceptance for business IT applications because it allows capacity and functionality to increase on the fly without major investment in infrastructure, personnel, or licensing fees [5,9]. Large IT investments can be converted to a series of smaller operating expenses. Cloud architectures could potentially be superior to traditional EMR designs in terms of economy, efficiency and utility. Also, the cloud computing model can achieve acceptable privacy and security through cloud providers that specify compliance requirements, performance metrics, and liability sharing [9,20]. In the CUSS setting, providers were able to access EMR WB through any platform (mostly desktop PCs), anywhere, anytime through internet access provided by the University of Guanajuato and local cell phone network using cloud computing.

2.1.1. Strategy

The ability to approach, enter, exit, communicate with, and make use of EMRs across diverse computer and smart phone platforms was created by contracting with commercial services to securely host EMRs "in the cloud," an efficient web-based system. Providers were thus able to access EMRs through any platform anywhere, anytime.

2.1.2. Server hosting

The hosting company maintaining the web server software and computers was selected based on the provision of reliable and low-cost web services 24 hours a day, seven days a week. Arvixe Web Hosting (http://www.arvixe.com) also provides data backup and technical servicing of the software and hardware in a large facility with state-of-the-art equipment and staffing. Arvixe.com is currently considered one of the best hosting services available worldwide and has received numerous web hosting awards (https://www.arvixe.com/awards.php).

2.1.3. Cloud computing

The concept of the "cloud" is an extension of existing computing practices, but places more content and program code in the hands of remote servers rather than the user's local computer [20]. In the case of the EMR WB system, the web server is providing the storage for medical/clinical records and the principal software application (the web application software on the site's server) that manages these records for users.

2.1.4. Administrative management

Access to the application is via the World Wide Web. This makes the application open to patients, providers, and administrators through simple use of web browsers. The user roles are defined as follows: 1) Patient: view clinical records and notes, but may only change certain personal information such as phone numbers and addresses; 2) Administrator (Admin): create and edit patient records, but cannot access deeper levels of system control. Admin cannot edit or create other user roles, for example, nor can they change system configuration settings or delete patient records; 3) SuperAdmin: edit, view, delete patient records, and have similar control over other Patient, Admin, and SuperAdmin user accounts; 4) SuperDooperAdmin: manage problems that may appear in the system to modify, update, and develop the software and/or help other roles recover lost accounts or other information.

The EMR WB site automatically sends different page data according to specific user roles, access devices, and browsers. Testing indicates that most devices such as iPhones and iPads are able to scale the page or arrange it in the display appropriately enough to use. The emulators[20] are more valuable at this point for developing applications that are targeted to run on those particular devices. So far, no device-specific codes have been necessary. At this stage of version 1.5, monitoring indicates that EMR WB is working appropriately. Users have access to the electronic mail addresses of technical support as well as the project supervisor at the EMR WB front page (by clicking "About Us").

2.1.5. Privacy

Security and privacy of the role-based account system relies on the Microsoft (Active Server Pages) ASP.NET membership classes in the Common Language Runtime (CLR)[21] of the .NET system. It uses encrypted cookies and other methods that ensure a malicious user cannot forge or decode information to access someone else's account. Using secure socket layers (SSL) protects user privacy on the internet by encoding the information sent back

[20] In computing, an emulator is hardware or software or both that duplicates (or emulates) the functions of a first computer system (the guest) in a different second computer system (the host) so that the emulated behavior closely resembles the behavior of the real system. This focus on exact reproduction of behavior is in contrast to some other forms of computer simulation in which an abstract model of a system is being simulated (http://en.wikipedia.org/wiki/Emulators).

[21] The CLR is a special runtime environment that provides the underlying infrastructure for Microsoft's .NET framework. This runtime is where the source code of an application is compiled into an intermediate language called CIL, originally known as MSIL (Microsoft Intermediate Language). When the program is run, the CIL code is translated into the native code of the operating system using a just-in-time (JIT) compiler (http://en.wikipedia.org/wiki/Common_Language_Runtime).

and forth from a user's browser [37]. Consequently, EMR WB is fully compliant with the Health Insurance Portability and Accountability Act (HIPAA) and privacy standards recommended by the United States and Mexico [60].

2.1.6. Concurrency

Achieving concurrency of information requires managing information in the data set that may undergo modification from multiple users in different locations. In the case of EMR WB, usage is typically limited to a single health practitioner modifying a record, such as during a consultation or shortly afterward. In the rare instance another user is modifying the same record, the last record entered will overwrite the other user's input. A more complicated scenario is if user 1 uploads a document that was modified by user 2 while user 1 was disconnected from the internet, then user 1's upload could be labeled as a conflicted copy. Further research into concurrency will be needed to address this problem.

Concurrency is a difficult issue in all multi-user environments. Solutions vary, depending on the context and requirements. Database tables can be locked, or a given patient record could be locked for exclusive use by the user who opens the patient record. However, on the web, it is difficult to assess when the "owner" has closed the need for a reservation on the patient record. An open or locked record might exist if a user walks away from a terminal for some reason and forgets to close the patient account. This would prevent another legitimate user from modifying that record.

An “atomic”[22] update for any given page is currently being used to achieve concurrency for EMR WB use. This includes a tracking method that identifies who modified a record most recently, which allows secondary users to communicate about patient records directly with the user who was responsible for recording the information in question. Ways to improve this method are being considered, such as notifying users if a record was updated after they opened it.

2.1.7. Scalability

The EMR pilot project runs on a single server machine. In a production environment with many thousands or millions of records, the system would need to be expanded using server farms. Web requests would be routed to machines with the capacity to accept additional load. The appearance of the system for the public would be that of a single website entity, and the access speed would remain unchanged.

2.1.8. Expandability

In addition to the adaptations mentioned above, other features could be added to expand the practical application of the EMR WB system. For example, the web has the disadvantage that some people may not have consistent access to it. The system may also be subject to failures of various kinds, such as temporary outages due to hardware or software failures, electric storms, etc. One proposed solution is to provide multiple methods to access the database. A stand-alone software application running on a user’s local machine could serve as a proxy for the web application, allowing temporary local storage of patient data. When

[22] Atomicity (database systems): It is an operation during which a processor can simultaneously read a location and write it in the same bus operation. This prevents any other processor or I/O device from writing or reading memory until the operation is complete. Atomic implies indivisibility and irreducibility, so an atomic operation must be performed entirely or not performed at all. Source, Webopedia: http://www.webopedia.com/TERM/A/atomic_operation.html

access to the central database becomes available, the local application could synchronize the records, for example. This application would allow the provider to work offline when internet access is interrupted or otherwise not accessible temporarily, to continue their work uninterrupted when offline, and reconnect automatically when internet access is reestablished. Applications such as these will also be designed for tablet computing platforms or smart phones to allow for data entry in remote or undeveloped locations.

The EMR WB design supports the development of ideas about how practical application of the software can be expanded to be more comprehensive, including meaningful use of certified EMR technology as defined by the US Department of Health and Human Services in the Health Information Technology for Economic and Clinical Health (HITECH) Act. "Meaningful use" of HIT is an umbrella term for rules and regulations that hospitals and physicians must follow to qualify for federal incentives under the American Recovery and Reinvestment Act of 2009 (ARRA). ARRA authorizes the Centers for Medicare and Medicaid Services (CMS) to reimburse eligible professionals and hospitals that meet meaningful use criteria for certified EMR technology. This includes using an EMR for functions that both improve and demonstrate the quality of health care, such as e-prescribing, electronic exchange of health information, and submission of quality measures to CMS.[23] Also, international health care informatics interoperability standards developed by Health Level Seven International (HL7) that are recommended by the America Academy of Family Physicians (AAFP)[24] will be incorporated. Based on these, for example, EMR WB could interface to or incorporate billing and accounting record-keeping systems, appointment

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[23] http://www.gpo.gov/fdsys/pkg/FR-2010-01-13/html/E9-31217.htm

[24] AAFP 2011 HL7 list of EHR functions: http://www.centerforhit.org/online/chit/home/cme-learn/tutorials/ehrcourses/ehr120/basicfunctions/hl7.html

management, scheduling, and other record management as part of the mainstream administrative capabilities of most EMRs in use today.

2.2. Programming Language

The application for EMR WB was written using Microsoft ASP.NET C# programming language for server software. It runs under the Microsoft IIS 7 web server and relies on the .NET platform, version 4.0, at this time. The easiest way to understand what the .NET platform does is to think of it as a standard set of functions that are available for various programming languages to call up when needed. It was intended to be multi-platform, like the Java Virtual Machine, and can therefore allow the same programs to run without change on various operating systems and devices. The .NET now runs on Microsoft Windows and MONO operating environments. The EMR WB application also relies on client-side software, which runs directly in a user's browser software on their local computer. For this, the system uses jQuery javascript and Ajax. The specific programming model used is the Microsoft Web Application model. In this scenario, the executable code resides in a central dynamically-linked library (DLL). The code supports the functionality in the various pages, and is executed on demand when pages are requested from a web server. The programming code is compiled during the software development stage and then stored on the server in the DLL file storage area. In this model, known as a "code-behind" model, the C# programming logic is separated from the page scripts, which are principally responsible for visual presentation of content to the user.

The programming for EMR WB was based on the following process:

(1) Initial Planning. Define the problem and general goals of the project.

(a) Consider the advantages and disadvantages of possible approaches to arrive at a solution. It was at this stage where a web application was chosen over third-party cloud-based and client software application solutions, for example.

(b) Consider the goals for user interaction. At this stage user interactions were considered in terms of certain desirable functional goals. Avoiding problems with existing software due to complex, multi-layered user navigation was an important goal, as was ease of use based on an intuitive interface approach.

(2) Application Design Assessment. What would be the best way to solve the problem?

(a) Consider the platform, programming language, and development tools.

(c) Consider the needs for multi-language functionality.

(d) Consider the data storage requirements and database platform. MySql was chosen due to performance, ease of use, low cost, and availability.

(e) Consider the development time-line. How long would the project take? Set dates for phased testing, deployment, and assessment.

(3) Development. For this a mix of top-down and bottom-up programming strategies were used. The top-down approach involved sketching out a rough framework, including setting up web pages for editing patient records, administrative management, and user account access. This framework was then gradually fleshed out with user interface details and code-

behind logic to support functional behaviors. The bottom-up approach involved doing some detailed functionality at a low level, including developing software object classes for abstraction of database access functions.[25]

The following activities formed the development process, mostly in a cyclical manner (i.e., the debugging process returned me to the programming stage recurrently).

(a) Programming.

(b) Debugging and testing.

(c) Deployment and user testing. This was the beta testing phase in which potential clients used the software, and problems were discovered and fixed.

2.3. Standardization

Standardization is the process of establishing a technical specification that is understood globally.[26] Standardization is a very relevant concern for EMRs because there has been no synchronization of terms, relationships, meaning, construction of sentences, and linguistics, which can compromise the quality of health care [9,50].

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[25] Class (computer programming): In object-oriented programming, a class is a construct that is used to create instances of itself – referred to as class instances, class objects, instance objects or simply objects. A class defines constituent members which enable its instances to have state and behavior. Data field members (member variables or instance variables) enable a class instance to maintain state. Other kinds of members, especially methods, enable the behavior of class instances. Classes define the type of their instances. Source: http://en.wikipedia.org/wiki/Class_(computer_programming)#CITEREFGamma.2C_Helm.2C_Johnson.2C_Vlissides1995

[26] http://en.wikipedia.org/wiki/Standardization

2.3.1. Strategy

The strategy for standardization of EMR WB was based on the premise that the best quality of service is determined by a clear understanding of the patient, an accurate diagnosis, and treatment planned according to the latest EB medical knowledge, experience, and patient choice [27,28]. The framework was based on the belief that the milestone of best quality of service in clinical medicine can be achieved using a standardized clinical history [5,45]. The use of state-of-the-art technology to computerize the clinical history, integrate an easy-to-use interface, and access knowledge facilitated achieving this milestone. As Rector et al. pointed out back in 1991, "structure is essential if the system is to be active in organizing information for the clinician as well as to support valid aggregation of data" [45].

The goal of developing a standardized clinical history model was accomplished by creating an architecture to guide unstructured and structured information pertinent to the process of clinical care. The clinical core is the guidepost that keeps all the different elements of the EMR system moving down the same track. The family medicine clinical history consists of a high-yield condensing of elements from other core clinical and surgical medical specialties; in particular, internal medicine, pediatrics, obstetrics, gynecology, geriatrics, and general surgery. The clinical core was thus structured to incorporate state-of-the-art terminology using 1) controlled vocabulary (terms), 2) ontologies (relationships), 3) semantics (meaning), 4) syntaxes (constructing sentences), and linguistics (technical English and Spanish); then two additional elements were included: 5) EB literature and 6) peer-reviewed clinical protocols.[27] In this context, the master problem list[28] is placed at the

[27] e.g., National Institutes of Health (NIH) Consensus Development Program. NIH State-of-the-Science Conference: Family History and Improving Health (2009, http://consensus.nih.gov/2009/familyhistorystatement.htm)

beginning of the clinical history because it represents patient problems that serve as an index to their record.

2.3.2. Terminology

Rector et al. [50,51] pointed out that clinical terminologies are at the center of efforts to develop and integrate EMR systems. In the standardized EMR context, a terminology is a set of words, expressions, designations, or symbols used in a domain of knowledge that is defined primarily through natural language [46,47]. A terminology describes the concepts within a particular subject and is oriented towards coding and annotating data rather than inference [47]. A terminology generally consists of the technical terms or expressions used in a specific field. The terminology may be organized according to a hierarchy[29] or categories,[30] and terminology developers and curators may use ontology tools and methods for organization and management (see Table 2 and Appendix E). Although terminologies such as the *National Cancer Institute Thesaurus* (NCIt)[31] can be machine-readable and used for inference, the ability to represent and infer knowledge is not as expressive as an ontology. Terminologies are not necessarily intended to be machine-interpretable or executable models for inference. In this context, inference may simply be about properties in a hierarchy of relationships [46,47,48].

[28] The MASTER PROBLEM LIST is an index system of record-keeping in which a list of the patient's problems is made. All of the problems are numbered and the approximate date of onset, date problem recorded, active problems, inactive/resolved problems, and date resolved are documented for each problem placed under the heading.
[29] A hierarchy can be defined as an arrangement of items (objects, names, values, categories, etc.) in which the items are represented as being "above," "below," or "at the same level as" one another. Abstractly, a hierarchy is an ordered set or an acyclic graph. A hierarchy can link entities directly, indirectly, vertically, or horizontally (source: Wikipedia).
[30] A category is a class or division of people or things regarded as having particular shared characteristics (source: Oxford dictionaries).
[31] http://ncit.nci.nih.gov/ncitbrowser/

Table 2: Philosophical approach to standardization. The standardized approach used a multidisciplinary family medicine clinical history as a backbone, called "the clinical core" of the EMR WB system, which integrated state-of-the-art terminology (controlled vocabulary, ontologies, semantics, and syntaxes) with EB and peer-reviewed clinical protocols.
Integration of State-of-the-art Terminology • Controlled vocabulary (terms) • Ontologies (relationships) • Semantics (meaning) • Syntaxes (constructing sentences) • Linguistics (technical English and Spanish) **Clinical History** • EB literature and guidelines • Peer-reviewed clinical formats and protocols

Standard medical terminology common in primary medical domains was used as the vocabulary for accurately describing the clinical core of EMR WB in a systematic, science-based manner. This approach involved reviewing each word and phrase (syntaxes) of the clinical histories and formats described in the literature in a comprehensive and orderly fashion to come up with state-of-the-art clinical content for EMR WB. Häyrinen et al. systematically reviewed the research dealing with EMR content in 2008 due to increased concern about a lack of structure leading to ineffective clinical documentation [5,65]. Hence, one of the most important features of the EMR WB clinical core standardized structure design is its ability to consistently facilitate structured clinical documentation to fill this gap and mainstream limitation.

MeSH[32] were consulted as the primary knowledge source for EMR WB, along with *Unified Medical Language System* (UMLS);[33] *Systematized Nomenclature of Medicine—Clinical Terms* (SNOMED CT: English and Spanish versions);[34] *Generalized Architecture for*

[32] http://www.ncbi.nlm.nih.gov/mesh
[33] http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html
[34] http://www.nlm.nih.gov/research/umls/Snomed/snomed_faq.html#what

Languages, Encyclopedias, and Nomenclatures in Medicine (GALEN);[35] *Logical Observation Identifiers Names and Codes* (LOINC);[36] *National Cancer Institute Thesaurus Terminology* (NCIt);[37] *International Classification for Disease* (ICD)—9 and 10;[38] *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition (DSM-IV);[39] *Medical Dictionary for Regulatory Activities* (MedDRA);[40] and The Clinical Care Classification (CCC) System[41] to check the accuracy of the terminology used to construct the clinical core. In addition, *Medpedia*,[42] *Medicalopedia*,[43] and the *Merck Manual Online Professional Edition*,[44] medical textbooks considered the gold standards in the field of clinical medicine by leading medical schools in the United States and Mexico,[45] were consulted to verify the formal clinical history and physical exam protocols, formats, properties of concepts, and relationships for consistency and accuracy. Such leading textbooks and specialized encyclopedias provided the best approach in the context of this EMR design to 1) identify the specific meaning of terms used based on linguistic semantics to express meaning through natural languages; and 2) use syntax as a means to apply principles and rules for constructing sentences in English and Spanish (see Appendix D-1,2: Standardization Process Sample).

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[35] http://www.opengalen.org/
[36] http://loinc.org/
[37] https://wiki.nci.nih.gov/display/VKC/NCI+Thesaurus+Terminology
[38] http://apps.who.int/classifications/apps/icd/icd10online/
[39] http://www.psychiatry.org/practice/dsm (the fifth edition will be released on May 2013).
[40] MedDRA is a medical terminology used to classify adverse event information associated with the use of biopharmaceuticals and other medical products (e.g., medical devices and vaccines). Coding these data to a standard set of MedDRA terms allows health authorities and the biopharmaceutical industry to more readily exchange and analyze data related to the safe use of medical products. Source: http://www.meddramsso.com/
[41] The Clinical Care Classification (CCC) System is a standardized, coded nursing terminology that identifies the discrete elements of nursing practice. CCC provides a unique framework and coding structure for capturing the essence of patient care in all health care settings. Source: http://www.sabacare.com
[42] The Medpedia Project is a long-term, worldwide project to evolve a new model for sharing and advancing knowledge about health, medicine and the body among medical professionals and the general public. This model is founded on providing a free online technology platform that is collaborative, interdisciplinary and transparent (http://www.medpedia.com/).
[43] Medicalopedia is a medical wiki written collaboratively by healthcare professionals all around the world. It was founded in December 2010 by Burhan Ahmed with the aim of collecting all medical information and making it available at a single portal (http://en.medicalopedia.org).
[44] http://www.merckmanuals.com/professional/index.html
[45] 1) Bates' Guide to Physical Examination and History Taking / Edition 10, December 2008; 2) The Clinical Encounter: A Guide to the Medical Interview and Case Presentation / Edition 2 August 1998, by J. Andrew Billings, John D. Stoeckle; 3) DeGowin's Diagnostic Examination, Ninth Edition / Edition 9, October 2008 by Richard F. LeBlond, Donald D. Brown, Richard L. DeGowin; 4) Physical Examination and Health Assessment / Edition 6 by Carolyn Jarvis; and 5) Introduction to clinical medicine. Janice L. Willms, and Judy Lewis. National Medical Series. January 1991. Lippincott Williams & Wilkins. Paperback , 260pp.

Open-source ontologies, mostly *BioPortal* of the National Center for Biomedical Ontologies supported by the National Institutes of Health (NIH)[46] and *Foundational Model of Anatomy* (FMA),[47] were also consulted because they provide a shared understanding of a domain, in this case the clinical history and anatomy, by defining relationships among clinical terms. The terms denote important concepts (classes of objects) in the domain (e.g., History of Present Illness—HPI; see Appendix E: Example of Standardized HPI Content within the Clinical Core) and the relationships that typically include hierarchies of classes (see Appendix C: The National Center for Biomedical Ontology BioPortal).

Controlled vocabularies were used to build the terminology for EMR WB. First, a draft of the clinical history template was compiled from a variety of protocols in leading US (e.g., UW School of Medicine, and Harvard Medical School), and Mexican (Autonomous University of Nuevo Leon School of Medicine, and the University of Guanajuato School of Medicine) medical schools, and the gold standard textbooks and peer-reviewed literature.[21] After that, the terminology that represents the structure of the clinical history was systematically compared against the controlled vocabulary tools outlined above, creating the state-of-the-art clinical content of the medical record and the other key primary care domains (psychology, nursing, nutrition, and social work) considered in EMR WB.

[46] BioPortal is an open repository of biomedical ontologies that provides access via Web browsers and Web services to ontologies. BioPortal supports ontologies in OBO format, OWL, RDF, Rich Release Format (RRF), Protégé frames, and LexGrid XML. Functionality includes the ability to browse, search and visualize ontologies as well as to comment on, and create mappings for ontologies. http://bioportal.bioontology.org/

[47] The Foundational Model of Anatomy Ontology (FMA) is a reference ontology for the domain of anatomy. http://sig.biostr.washington.edu/projects/fm/AboutFM.html

2.4. Interface

With the recent explosive growth of electronic medical information, the user interface design of EMRs has become a crucial issue. Many interfaces in current EMRs are barriers between users and tasks [4,10]. By re-implementing these interfaces in functionally equivalent but representationally different interfaces, the barriers can be removed or minimized via direct interaction.

For EMR WB, the interface was constructed so that users could easily and accurately retrieve, seek, gather, encode, transform, organize, and manipulate pertinent information to accomplish desired tasks. Two top menu bars are always visible across the screen regardless of where the user is working. The upper bar shows the different domains as buttons (medicine, psychology, nursing, nutrition, and social work).

The user can click once at the desired domain (e.g., medicine), and then the second bar immediately below will open to display a series of buttons that represent the subfields of this specific domain (e.g., Identifying data—ID, Chief Complaint—CC, History of Present Illness—HPI). In addition, the content of the specific chosen subfield is displayed as subheadings across the screen below the bars. Each subheading is executable with one click for input or data gathering. User activities can direct interaction with the task domains rather than generating secondary tasks that demand extra cognitive resources [13]. All the fields are readily accessible without having to move up or down a hierarchy of navigation menu items (see Figure 2).

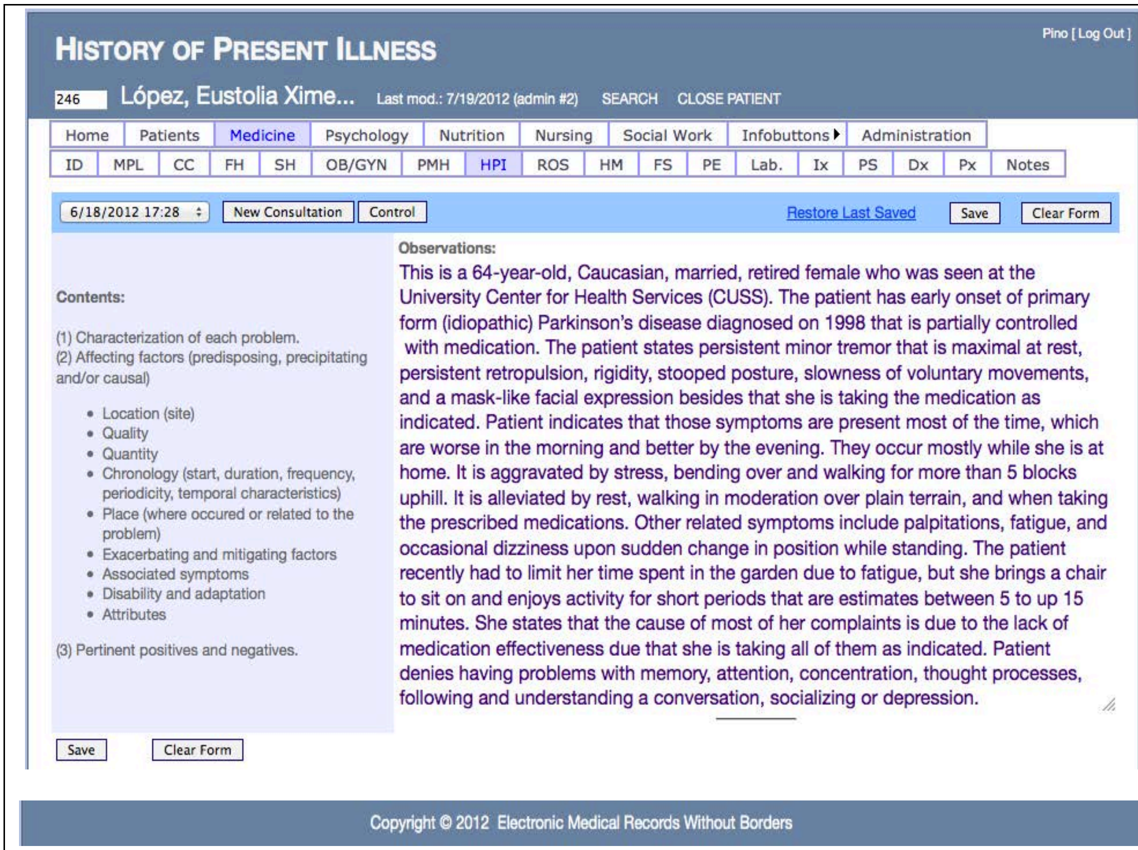

Figure 2: The EMR WB interface.
A screenshot of EMR WB showing two top menu bars that are always visible. The upper bar shows the different domains as buttons (medicine, psychology, nursing, nutrition, and social work). The second bar immediately below opens to display a series of buttons that represent the subfields of each specific domain (medicine e.g., Identifying data—ID, Chief Complaint—CC, History of Present Illness—HPI, etc.).
(Note: this is an anonymous sample for demonstration purposes only).

2.5. Decision Support

Including this function in EMR WB was based on studies that show providers have a high need for information to answer the multitude of questions that arise during clinical care [2,21-27]. These questions often go unanswered due to lack of time or readily available resources. Estimates of information needs are as high as four questions per patient encounter [26]. Failure to answer these questions may result in patient care error and adverse outcomes. Linking to knowledge-based resources at the point of care could be an effective means for addressing these needs and supporting evidence and guideline-based practice.

Infobuttons were considered as a potential solution because they have been used to provide context-sensitive links between clinical information systems (e.g., EMRs) and online knowledge resources [27,49]. "Context" in this sense is what the user is doing at some point in time in the EMR during a clinical encounter. Infobuttons make it easier for providers to access the information they need at the point of care [22].

One study at Partners HealthCare system showed the KnowledgLink medication infobutton to answer 84% of clinicians' questions, thereby altering 15% of patient care decisions [22]. Another study showed that 74% of infobutton users responding to a survey felt the system had a positive impact on their patient care decisions [23]. A recent review of several methods for providing decision support to nurses at the point of care emphasized the need to integrate such contextual information links into clinical workflow in order to effectively support EB nursing practice [24].

Another recent study from Intermountain Healthcare [25] showed a use of infobuttons in the hospital setting steadily increasing over a four-year period. Intermountain Healthcare ("Intermountain") is a not-for-profit integrated delivery system of 21 hospitals; over 70 outpatient clinics, more than 500 physicians, and an insurance plan located in Utah and southeastern Idaho have access to a web-based EMR called HELP2. HELP2 offers access to a wide variety of data and functions, including laboratory results, clinical notes, problem lists, and medication order entry. Infobuttons were first released in HELP2 in September of

2001 in the medication ordering (outpatient), problem list, and laboratory results modules [25].

The EMR WB system uses an infobutton interface for direct access to knowledge-based tools at the point of care in real time. The infobuttons feature three web links that providers need to manually open to input and tie clinical information to health resources such as knowledge-based clinical decision support tools. In contrast, automated systems such as infobutton managers are capable of matching what the user is doing (i.e., "context") to appropriate information resources [21-23]. During the pilot project, EMR WB did not use information managers because a manual infobutton system provided practical, accessible, and useful decision support.

The three tools added to EMR WB for decision support are:

1. **DXplain**: This is a diagnostic decision support system tool that analyzes a patient's historical data, physical findings, laboratory tests, and x-rays, and then generates a ranked list of diseases that can explain these findings. DXplain is a web-based system accessed in real time through the Laboratory of Computer Science at Massachusetts General Hospital, Harvard Medical School[48] (http://dxplain.org/dxp/dxp.pl). DXplain requires that the provider open the site and enter their password in order to access and use the site.

[48] 1) Barnett GO, Famiglietti KT, Kim RJ, Hoffer EP, Feldman MJ. DXplain on the Internet. Proc AMIA Symp. 1998:607-11; 2) Bond WF, Schwartz LM, Weaver KR, Levick D, Giuliano M, Graber ML. Differential Diagnosis Generators: an Evaluation of Currently Available Computer Programs. J Gen Intern Med. 2011 Jul 26; and Katie Hafner. For Second Opinion, Consult a Computer? Software Programs Help Doctors Diagnose, but Can't Replace Them. The New York Times. December 3, 2012. http://www.nytimes.com/2012/12/04/health/quest-to-eliminate-diagnostic-lapses.html?src=me&ref=general&_r=0

2. **EB Medicine Calculator**: This device helps providers make proper diagnoses, devise the best testing plan, choose the best treatment and methods of disease prevention, and develop guidelines for patients (http://ktclearinghouse.ca/cebm/practise/ca/calculators/statscalc).

3. **Knowledge Translation Tools**: These are EB, dynamic, and interactive literature access tools by which relevant information is made available to support health care decision-making processes. They provide two different sets of tools for querying primary studies that represent first-generation and second-generation knowledge (http://ktclearinghouse.ca/tools/practicing).

Version 1.5 of the EMR WB system doesn't include or interface with medication catalogs (e.g., Epocrates), but instead provides free text to input treatments because free text is a familiar and easy-to-use environment in a global context and the systems currently available are costly, time-consuming, unreliable overall, and not offered in both English and Spanish [36]. In addition, because the point-of-care system concept is commonly defined in the literature as the use of diagnostic and laboratory testing provided to patients at their bedside (MeSH),[49] it is important to clarify that the knowledge-based tools used by EMR WB to support the decision-making process are aimed at the point of care as distinct from a patient's bedside.

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[49] MeSH. Point-of-Care Systems. Laboratory and other services provided to patients at the bedside. These include diagnostic and laboratory testing using automated information entry. Year introduced: 1996

2.6. EMR WB Definition

One of the most relevant barriers that impede the development of EMRs is the lack of a clear definition [5,9,60]. This is why design of EMR WB was delayed until a thorough definition could be constructed. Although work on a common definition of a computerized medical records system [3], also referred to in the literature as EMRs, CPRs (computerized patient records), or EHRs [10,60], is under way by various groups, a universal understanding of the concepts embodied in an EMR does not exist. Without a clear understanding, users have a difficult time selecting systems that will meet their needs and vendors have difficulty supplying such systems.

EMRs have been defined as "electronically stored information about an individual's lifetime health status and health care;" a "software that allows you to create, store, edit, and retrieve patient charts on a computer;" and "any information related to the past, present, or future physical/mental health, or condition of an individual which resides in electronic system(s) used to capture, transmit, receive, store, retrieve, link, and manipulate multimedia data for the primary purpose of providing health care and health-related services"[60].

Beyond the definitions mentioned above, however, few details have been worked out and agreed upon. For example, there is no common data model for an EMR, no common set of data elements, no common vocabulary, and no common set of scenarios that are supported. These requirements are fundamental if researchers and developers are to create a patient-centered EMR that links care across different sites, specialties, and circumstances [5,10]. Even the terms "meaningful use" and "certified" in the HITECH Act are not yet clearly defined, and they are neither user-friendly nor designed to meet the ambitious goal of improving quality and efficiency in the health care system as outlined by David Blumenthal, the former national coordinator of HITECH [17]. For the purpose of this project, the EMR WB has been defined as the standardized, multidisciplinary, family medicine clinical history as the EMR clinical core that provides the frame to input structured and unstructured documentation.

Based on the need to have a definition upon which to base the EMR WB design, one of the strategies was to focus on its clinical core. To do this, NLM MeSH was used because it provides a unique and comprehensive systematic historic description of the concept, from its paper-based roots to the latest concept that involves the integration of state-of-the-art technology. According to MeSH, medical records consist of pertinent information concerning a patient's illness or illnesses.[50] Computerized medical record systems are defined as a computer-based arrangement for input, storage, display, retrieval, and printing of information contained in a patient's medical history (year introduced: 1991).[51] EMR is defined as the media that facilitates transportability of pertinent information concerning a patient's illness across varied providers and geographic locations (year introduced: 2011).[52] These definitions describe the natural evolution of the concept from a paper-based version to a computerized format, leading to sharing across platforms and distance. EMR WB is based on the latest definition, and centered on the clinical history that is oriented towards primary health care (see Figure 3).

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50 http://www.ncbi.nlm.nih.gov/mesh/68008499
51 http://www.ncbi.nlm.nih.gov/mesh/68016347
52 http://www.ncbi.nlm.nih.gov/mesh/68057286

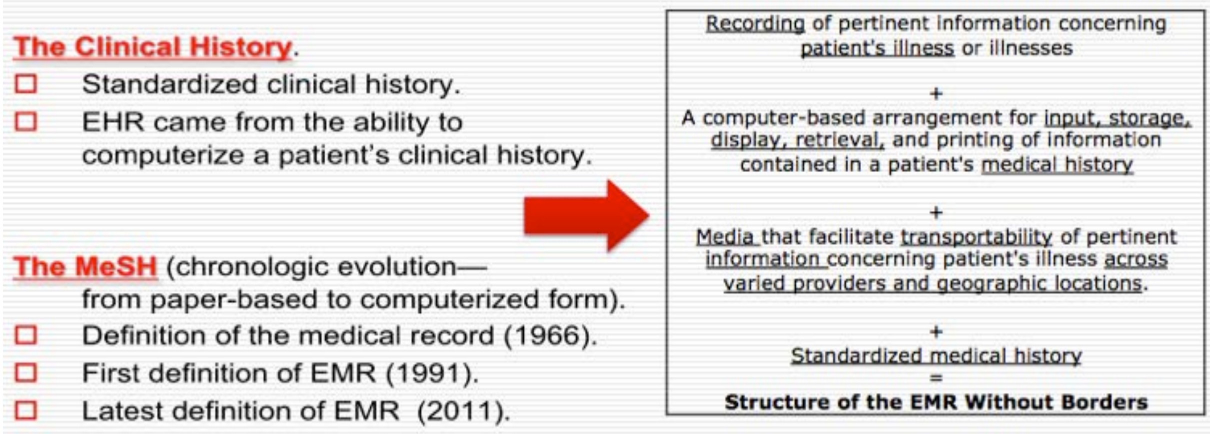

Figure 3: Clinical core-centered EMR definition.
A definition of EMR WB was created to reflect its structure and standardization. A series of steps was followed that integrated the three EMR definitions available in the NLM medical subject headings (MeSH), the original description of a medical record (1966), the first EMR definition (1991), and the latest EMR definition (2011). This information was then combined with a description of the clinical core used as the design foundation for EMR WB.

EMR WB was designed with health information exchange (HIE) in mind in two steps: as a pilot project and as a fully functional EMR. During the pilot project, the HIE had a similar connotation as the meaningful use explained in Section 2.1. At the moment, EMR WB does not rely on Health Level Seven (HL7) standards and hence Clinical Document Architecture (CDA) and Continuity of Care Document (CCD) specifications. For the purposes of this project, the objective of EMR WB was not to be interoperable with other systems, but independently functional. In the future, however, EMR WB will adopt interoperability standards aimed at fulfilling the meaningful use outlined by the US federal government HITECH Act [17].

2.7. Summary

EMR WB was implemented at CUSS, a public, multidisciplinary family medicine clinic at the University of Guanajuato in an underserved, urban community in the city of Leon, Mexico. The central idea was to address the multifaceted problem of the lack of a modern, standardized EMR system with global access, comprehensive interface, and knowledge-based point-of-care tools to efficiently collect, store, share, manage, and access patient files. This system enabled providers from multiple disciplines (medicine, nursing, nutrition, psychology, and social work) at CUSS to create, share, and maintain records of patient care that were standardized (using controlled vocabulary—terms, semantics—meaning, ontologies—relations, syntaxes—construction of sentences, with EB, peer-reviewed clinical protocols), linked to diagnostic decision support (DXplain), and knowledge-based (EB Medicine Calculator and Knowledge Translation Tools) point-of-care systems functionally connected with an all-inclusive, intuitive interface, and accessible anywhere from any platform (PCs, tablets, and mobile phones) using cloud computing. This EMR WB system aimed to better address local, clinical, and psychosocial health challenges, as well as transnational migration health issues based on systematic documentation, interoperability, and transfer of clinical information among primary care providers in targeted, underserved communities.

Chapter III: Evaluation

There is a large gap between the postulated and empirically demonstrated benefits of EMRs [33]. In light of the scarce evidence for improvements in patient health outcomes, provider satisfaction, and cost effectiveness, it is vital that future EMRs are evaluated with both quantitative and qualitative tools [6,32].

EMR WB evaluation aimed to determine the level of satisfaction with use of the system at the CUSS. First, to understand the potential end users of the proposed EMR system, a focus group was held on August 5, 2010, to gather perceptions, interpretations, beliefs, and attitudes towards EMR use. The focus group served as an exploratory tool for creating a schema of coding data that provided the themes used to develop the structure of the questionnaire for user satisfaction, the EMR WB QUS (see Appendix B). Since one of the major aims of this research project is to evaluate provider satisfaction with the implemented EMR system, an evaluation tool that examines end user perceptions was necessary. A survey was formulated into a series of 15 questions aimed at obtaining specific answers related to the perceived satisfaction of the providers with EMR WB compared to the CUSS paper-based medical record system they previously used. Two other sections were added to collect demographic data, amount of use of the system, and suggestions for improvements (a total of five questions). These questions reflected on the definition of “user information satisfaction” outlined by Ives et al. in1983 [12] as “the extent to which users believe the information system available to them meets their information requirements.” A 7-point Likert scale (or summated scale) was used to quantify user satisfaction with features such as access, interface, standardization, knowledge-based tools, and overall design. The scale was from “Much worse” to “Much better,” with -3 as the lowest rating and +3 as the highest rating. The total score (i.e., evaluation) was reported as a sum of the responses.

The timeline criteria for administering the survey was at least three months after the beta testing took place. EMR WB was initially implemented via beta testing in May 2011 at the CUSS, and version 1.5 was implemented at the same facility in January 2012 (the version used to evaluate EMR WB). Providers had the flexibility of answering the online survey over a three-day period. The web-based, one-time, post-implementation evaluation survey took between 20 and 30 minutes to complete.

3.1. Testing EMR WB Versions

Beta testing of the first EMR WB version began at the CUSS on May 25, 2011, and was completed in December 23, 2011. Version 1.5 was implemented in January 06 2012 and evaluated in July 13-16, 2012.

CUSS providers were informed about the introduction and capabilities of the EMR WB system via staff meetings, e-mail, and video conferencing (using Adobe Connect) that included step-by-step scenarios demonstrating how to use the new system. In addition, a web casting video was created for clinicians to observe how EMR WB might work in their own disciplines; this included a demo mode with fictional patients so providers could familiarize themselves with the system to see if it fit their needs. The demo application is currently available on the EMR WB home page at http://www.emrwithoutborders.com.

The vast majority of clinicians at the CUSS used the EMR WB system to support their daily patient care practices for seven months. In response to demand for increased functionality, EMR WB was upgraded to its current version 1.5. The redesign allowed providers to use a system without identifiable "bugs," better response time, more reliable and seamless functionality, and faster and full access to all available medical literature information (infobutton: Knowledge Translation Tools) while they were in clinical encounters with patients by using the EB tools (infobutton: EB Medicine Calculator) and fully incorporated diagnostic decision support system DXplain.

EMR WB is still in operation at the CUSS, where it has proven to be stable and reliable. EMR WB has achieved the goals for Aim 1 as initially outlined:

(1) It is globally accessible on a web-based system from any platform (PCs, Macs, tablets, and mobile phones).

(2) It is standardized across primary care multidisciplinary core domains (medicine, nursing, psychology, nutrition, and social work) and uses shared terminologies, data models, controlled vocabulary, ontologies, semantics, syntaxes, pragmatics, and EB peer-reviewed protocols.

(3) It uses an all-inclusive, intuitive EMR interface into one navigation system.

(4) It uses knowledge-based, point-of-care systems to support health care decisions.

(5) It is completely bilingual in English and Spanish.

(6) It is network-based (web/cloud).

(7) It is intuitive, easy to use and learn, and does not require formal training.

(8) It supports underserved populations in the urban setting of the city of León, Mexico.

3.2. Focus Group and Survey

Evaluations were conducted via both qualitative (pre-implementation exploratory focus group) and quantitative (post-implementation survey) analyses focused on provider perceptions of EMRs in general and EMR WB in particular, respectively.

3.2.1. Focus group

To better understand the potential end users of the proposed EMR system, a focus group was conducted. This qualitative research tool facilitated the collection of perceptions, interpretations, beliefs, and attitudes towards EMR use [34]. As outlined by the literature, an advantage of the focus group methodology is that it reveals the evolution of perceptions in a social context, which tends to be more objective than the isolation of a typical survey or individual interview, hence the results are richer, more complete, and more revealing [59]. However, there are risks involved such as “group think” and consensus-based reasoning.

On August 5, 2010, a group of health care providers was brought together from most of the primary care domains who would be end users of the proposed EMR system. They were asked to provide their opinions of EMRs before EMR WB implementation and beta testing. This same group would also participate in the post-evaluation survey. The focus group was held for one and one-half hours with six providers, approximately 12% (6 out of total of 50) of the existing CUSS providers. The participants were recruited by the CUSS director and myself. The topic was introduced by providing a brief description of the EMR WB project. A discussion guide was used to encourage an open yet focused dialogue. A focus-questioning route (see Appendix A) was used based on the research aims that included opening comments about the topic of EMRs, introductory open-ended questions to engage the participants in the topic, transition questions related to use of EMR WB in their respective clinical settings, key questions regarding the perceived benefits and limitations of its use, and ending questions to summarize the discussions and confirm the main points. At each stage of questioning, sufficient time for all the participants to share their views was allowed. The focus group served as an exploratory tool more than a data-gathering tool, although the results were used to create a schema of coding data for modifications to EMR WB.

All six participant providers were interested in using the emerging EMR technology in their own practices. The overall perception was that EMRs are the computerization of paper records. They perceived this kind of technology to be a useful tool for both them and their patients. They expressed wanting an EMR that is easy to use and read, accessible from different places, supports accuracy of free text and structured documentation, and permits sharing among members of the primary care team. They perceived the input of free text as quite useful based on their paper-based experience with structured clinical forms and guidelines. They commented that a mixture of free text with structured documentation would bring about the needed freedom to create accurate and individualized clinical notes. They also wanted a system that provides continuity of care with systematic follow-ups. In addition, since EMR WB would serve in a teaching environment, they wanted it to facilitate access to supervised work.

There were some overall concerns about privacy and confidentiality, such as how to restrict unauthorized access to information, including the limiting of access to other providers when pertinent (e.g., mental health-sensitive issues, without compromising the safety of others). EMR implementation and use was seen as a challenge, too, because of its demand for new forms of thinking, ethics, and work. A concern of possible intrusion of the computer in the patient-provider relationship during the clinical encounter was also expressed.

Among the perceived benefits, a big savings of materials (paper) and time were emphasized. Although the web-based technology was welcomed, previous negative experience with a local system was used as a frame of reference. Apparently they had been unable to access information from other settings because of dependence on fixed desktops. Limited time spent onsite entering patient data in the clinical encounter was perceived as a helpful feature. Cross sharing of information among other primary care domains (e.g., social work with psychology) was a feature that they wanted to see for comprehensive management of health care information. When asked, "What do you think would be the most important uses of the information?" they expressed interest in clinical decision-making as a primary use, and supporting interventions in the community and research purposes as secondary uses.

The data obtained from the focus group was assessed using content analysis based on coding, categorizing, and counting the types of responses**.** The lists of codes with some representative themes quoted from participants, recommendations for the design of the system, and suggested themes for the post-implementation survey are condensed in Table 3.

Limitations

The sample size was small, but it was representative of the total end user population diversity. The focus group met just once. The other limitation was inherent to the technique itself, namely that providers might not say what they actually do or think because of "group think" (e.g., people expressing an opinion which is in agreement with the rest of the group even if that opinion is at odds with their own personal perceptions, interpretations, or beliefs). This factor was not perceived by the moderator to be present. An additional possible limitation is that respondents were inclined to give the answers they thought their recruiter wanted to hear, which would be consistent with her bias in favor of EMR WB.

3.2.2. Survey

Survey development

Through a series of four well-defined stages, an instrument was developed to evaluate end user satisfaction of EMR WB compared with a paper-based record system, as tested by the health care providers at the CUSS. The central idea behind developing this tool was to create a tailored questionnaire incorporating and optimizing both the accepted literature definition of end user satisfaction as well as the philosophical approach of successfully tested measurement instruments [6]. The instrument was used to determine 1) the onsite professional experiences and approaches associated with using a paper-based system; and 2) the perceptions, interpretations, and beliefs regarding onsite use of the EMR WB system.

Stage I. The Focus Group

As mentioned in Section 3.2.1, the focus group was used as an exploratory tool for creating a schema of coding data for the themes that structured the EMR WB QUS (see Table 3 and Appendix B). The paper-based system previously used by the CUSS health care providers served as a frame of reference for comparison with EMR WB.

Stage II. End-User Satisfaction Definition

The next step to constructing an instrument for measuring satisfaction with EMR WB involved examining "satisfaction" based on how the literature defines it [29].[19] According to Ives et al. (1983) [12], "User information satisfaction is the extent to which users believe the information system available to them meets their information requirements." Synonymous terms are "system acceptance" (Igersheim, 1976) [20], "perceived usefulness" (Larcker and Lessig, 1980) [31], "management information system appreciation" (Swanson, 1974) [42], and "positive feelings about an information system" (Maish, 1979) [43]. Ang and Koh (1997) [44] described user information satisfaction as "a perceptual or subjective measure of system success." This means that the phenomenon will differ in meaning and significance from person to person. In other words, users who are equally satisfied with the same system according to one definition or measure may not be equally satisfied according to another.[53] And, according to Brender et al. [29], "User satisfaction measures the end users' response to the use of the input and output of the EMR and its attributes." The definition provided by Ives et al. [12] outlined

[53] http://en.wikipedia.org/wiki/Computer_user_satisfaction

above was the primary basis for development of the EMR WB satisfaction measurement tool.

Stage III. Frames of Reference: the QUIS and IBM Computer Usability Satisfaction Questionnaires

In addition to the themes and codes obtained from the focus group performed on August 5, 2010 (see Table 3), the *University of Maryland QUIS* Version 7.0 and *IBM Computer Usability Satisfaction Questionnaires* were used as frames of reference to design the user satisfaction questionnaire for EMR WB.

In 1988, researchers from the Human Computer Interaction Laboratory at the University of Maryland developed the QUIS as a standardized general user evaluation instrument for interactive computer systems. The QUIS relies on psychological test construction methods to ensure empirical validity and reliability [39].

The IBM Computer Usability Satisfaction Questionnaires[54] address evaluation at both a global overall system level and a more detailed scenario level. The series of four questionnaires rely on psychometric characteristics (assessment of psychological variables—thoughts, feelings, and behaviors—using mathematical procedures) to measure satisfaction with computer system usability.

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[54] Lewis, J. R. (1995) *IBM Computer Usability Satisfaction Questionnaires: Psychometric Evaluation and Instructions for Use.* International Journal of Human-Computer Interaction, 7:1, 57-78.

Table 3: Focus group. The focus group served as an exploratory tool for creating a schema of coding data for EMR WB design recommendations and the themes to develop the structure of the end-user satisfaction survey.

	Code	Summary of Relevant Themes	Recommendations for EMR Design	Survey Themes
1	**Adoption/ Feasibility**	"I am very interested in using the current technology." "I believe that the EMR will be a useful tool for both providers and patients." "Implementation will be a challenge at the beginning."	EMR WB will be implemented as a pilot project Providers will participate	Acceptability, Achievability
2	**Documentation**	"I believe that the EMR will be a very useful technology to improve documentation in the chart." "I would like to have well defined formats… similar to the ones that I use in my charts (paper based)." "I would like to have the freedom to input both free text and structured information." "Extensive typing not needed during the clinical encounter."	Structure Standardization Documentation guidelines Flexible: use free and structured data	Completeness of documentation
3	**Ease of use**	"I would like to have a system that is easy to use." "I don't want to add more work."	Usable No added work Friendly interface	Easy to use
4	**Access**	"I would like to have an EMR that I can access anywhere." "I welcome the web-based technology."	Open access Web-based Accessible	Ability to access from any location
5	**Privacy**	"I am concerned about overall privacy, confidentiality, and how the system will restrict unauthorized access to information." "Restrict access to sensitive information among providers without compromising safety. "	Privacy Confidentiality Safety	Safeguards, privacy and confidentiality
6	**Communication**	"I would like to share information with the primary care team."	Information exchange / sharing	Ease of communication with other members of the clinical team
7	**Quality improvement**	"It could improve overall patient care." "I am concerned about the possible intrusion of the EMR in the patient-provider relationship." "A system that supports follow-ups."	Improve workflow Continuity of care Not intrusive	Work Flow
8	**Decision support**	"Supports overall care decisions." "I'd like to have access to literature or some guidelines."	Decision support tools	Support care decisions
9	**Research**	"Use data from EMR as a base for interventions in the community." "Research purposes."	Secondary use of data	Facilitate use of data for quality and research purposes

Stage IV: The Evaluation Tool—EMR WB QUS

The last set of components used to create the EMR WB QUS (see Appendix B) were the variables of the study—global access, standardization, interface, knowledge-based access tools, and design—which were cross-referenced with the research questions for consistent correlation with the aims. The CUSS providers were asked to use a 7-point Likert scale to assess agreement with what they thought of EMR WB as compared to the paper-based system on a scale from much worse (-3) to much better (+3) over a series of 15 questions. Dumas (1999) [61] claims, "This is the most commonly used question format for assessing participants' opinions of usability and satisfaction."

In addition to the 15 questions that evaluate user satisfaction with EMR WB (Part 2), another two series of questions (Parts 1 and 3) explored demographic data, system use, and recommendations for improvement. Part 1 considered 1) age, 2) gender, and 3) CUSS professional field (medicine, psychology, nutrition, nursing and social work); while Part 3 asked users to specify 4) how long they had used the EMR WB system and 5) what suggestions they had to improve it. In total, the survey thus consisted of 20 questions (Appendix B). The web-based, one-time, post-implementation user satisfaction survey took approximately 20 minutes to complete, but respondents had the flexibility of answering the questions over a three-day period.

3.3. Subject Population

The population recruited for the EMR WB QUS was defined as the total adult (aged 18 and older) female and male health care providers from all primary care domains (medicine, psychology, nutrition, nursing, and social work) identified from the CUSS that used EMR WB for at least one month or 20 hours (i.e., inclusion criteria). Forty (out of a total of 50, or 80%) self-reported health care providers fulfilled the inclusion criteria, representing the selected subset of EMR WB users surveyed. A total of 36 subjects started the survey, with a total of 33 of the 40 surveyed (82.5%) finishing the survey [62]. The three who did not finish the survey were unable to complete most of the questions, including the demographic information. They did not make any comments; hence the information provided had very limited value in the survey and was not considered. The reasons why they did not finish the survey were not stated.

Inclusion Criteria: CUSS providers (physicians, psychologists, nurses, nutritionists, and social workers, age 18 and older) who used EMR WB for at least one month or 20 hours.
Exclusion Criteria: CUSS providers (physicians, psychologists, nurses, nutritionists, and social workers age, 18 and older) who used EMR WB for less than one month or 20 hours.

Data representing all five primary care domains at the CUSS were taken as of equal importance to match and obtain information from each of the EMR WB corresponding professional domains. Each domain within the overall CUSS population was not sampled independently because there was no control over the respondents to make the subgroup sample sizes proportional to the total population, but responses from all professional domains were obtained.

3.4. Analysis

The specific survey data analysis steps were 1) making sure that the surveys returned were complete and valid (n = 33); 2) checking for response bias; 3) conducting a descriptive analysis; 4) condensing items into scales; and 5) checking for reliability of the scales. Interpretation of data was based on respondent scoring of satisfaction with EMR WB use on a Likert scale. An overall satisfaction score was obtained from Question 15.

Descriptive statistics were used to quantitatively explain the main features of the results. Descriptive statistics are more informative and appropriate than testing a hypothesis in this study, but the results only generalize to other populations similar to the one studied here [62]. Tables 4 and 5 below show the sample size, demographics, and proportion of subjects' satisfaction with EMR WB use compared to the paper-based system.

Table 4 summarizes the demographic characteristics of the sample: gender, age, and profession. Categorization of the 15 survey questions is shown in Table 5. Grouping the raw data from the study population in a contingency table using ranges of values reduced the number of categories to yield interpretable results.

In Table 5, the quantities that summarize the distribution of results (evaluation summary statistics) are expressed as measures of central tendency, representing a "typical value" for a member of a population. The two measures considered are the mean and median, in addition to two measures of dispersion of the distribution, standard deviation (SD), and range. In the statistical approach to the satisfaction questionnaire and analysis, a frequency distribution was used to arrange all of the variables (i.e., responses) measured in the sample (n = 33).

Table 4: Demographic characteristics of study participants (n=33).

1	**Gender**	**n**	**%**
	Male	10	30%
	Female	23	70%
2	**Age**		
	20 – 30	14	42%
	31 – 40	7	21%
	41 – 50	5	15%
	51 – 60	5	15%
	61 +	2	7%
3	**Profession**		
	Physician	6	18%
	Psychologist	14	42%
	Nutritionist	3	9%
	Nurse	6	18%
	Social Worker	4	12%

Total Number of Participants Started Survey: 36. Total Number of Participants Finished Survey: 33 (91.7% completion rate)

The rationale behind managing and operating from frequency-tabulated data is that it is much easier to understand than raw data. Having frequency distribution data allowed the calculation of central tendency via the mean from the survey results, along with measures of variability or statistical dispersion such as the SD and confidence interval (CI) [63].

The mean satisfaction score for each question was reported as a measure of central tendency. While the categories are not necessarily equally spaced, the mean nonetheless conveys information about the positive or negative trend in the responses for each question. Hence, the middle of the scale was coded as 0 so that the range was from -3 to 3. This made it easier to interpret the results (i.e., by looking at whether numbers were positive or negative), and provided the needed symmetry.

Table 5: Evaluation summary for participants (n = 33)

	Responses n (%)									
Questions	Much Worse -3	Worse -2	Somewhat Worse -1	About the Same 0	Somewhat Better +1	Better +2	Much Better +3	n =	$\bar{x}$ (SD)	95% CI
Q1 Helping me complete my tasks	0 (%)	0 (%)	0 (%)	1 (3%)	3 (9%)	8 (25%)	20 (63%)	32	2.5 (0.8)	(2.2, 2.8)
Q2 Facilitating my input of information	0 (%)	0 (%)	1 (3%)	0 (%)	6 (18%)	7 (21%)	19 (58%)	33	2.3 (1.0)	(2.0, 2.6)
Q3 Learning how to use	0 (%)	0 (%)	4 (12%)	4 (12%)	4 (12%)	5 (15%)	16 (48%)	33	1.8 (1.5)	(1.2, 2.3)
Q4 Ease of use	0 (%)	0 (%)	2 (6%)	3 (9%)	1 (3%)	9 (27%)	18 (55%)	33	2.2 (1.2)	(1.7, 2.6)
Q5 Effectively review patient problems	0 (%)	0 (%)	0 (%)	2 (6%)	4 (12%)	5 (15%)	22 (67%)	33	2.4 (0.9)	(2.1, 2.8)
Q6 Safeguarding patient privacy	0 (%)	0 (%)	1 (3%)	2 (6%)	1 (3%)	9 (28%)	19 (59%)	32	2.3 (1.0)	(2.0, 2.7)
Q7 Sharing patient information with my fellow clinical team members	0 (%)	0 (%)	0 (%)	0 (%)	1 (3%)	5 (15%)	27 (82%)	33	2.8 (0.5)	(2.6, 3.0)
Q8 Ease of access to files	0 (%)	0 (%)	0 (%)	2 (6%)	1 (3%)	5 (15%)	25 (76%)	33	2.6 (0.8)	(2.3, 2.9)
Q9 Improving workflow	0 (%)	0 (%)	0 (%)	1 (3%)	5 (15%)	5 (15%)	22 (67%)	33	2.5 (0.9)	(2.2, 2.8)
Q10 Improving the continuity of patient care	0 (%)	0 (%)	0 (%)	1 (3%)	0 (%)	9 (28%)	22 (69%)	32	2.6 (0.6)	(2.4, 2.9)
Q11 Helping make effective evidence-based care decisions	0 (%)	0 (%)	0 (%)	1 (3%)	2 (6%)	9 (28%)	20 (63%)	32	2.5 (0.8)	(2.2, 2.8)
Q12 Facilitating use of information for quality control	0 (%)	0 (%)	0 (%)	2 (7%)	3 (10%)	8 (28%)	16 (55%)	29	2.3 (0.9)	(2.0, 2.7)
Q13 Helping obtain information for research	0 (%)	0 (%)	0 (%)	1 (3%)	1 (3%)	5 (16%)	24 (77%)	31	2.7 (0.7)	(2.4, 2.9)
Q14 Appropriateness for use in my care setting	0 (%)	0 (%)	0 (%)	3 (9%)	5 (15%)	3 (9%)	22 (67%)	33	2.3 (1.0)	(2.0, 2.7)
Q15 Overall satisfaction	0 (%)	0 (%)	1 (3%)	1 (3%)	4 (13%)	4 (13%)	21 (68%)	31	2.4 (1.0)	(2.0, 2.8)

Key: Summary table showing the 15 questions of the EMR WB QUS with the number of responses and percentage of respondents for each response on a 7-point Likert scale, the mean ($\bar{x}$), standard deviation (SD), and confidence interval (CI).
SD = standard deviation, CI = confidence interval.
Coding scale: Much worse (-3), Worse (-2), Somewhat worse (-1), About the same (0), Somewhat better (+1), Better (+2), Much better (+3)

The survey was sent to the total population of the study that fulfilled the inclusion criteria (N = 40), followed by three consecutive electronic mail reminders, to procure as many responders as possible and thus results that would accurately reflect future prospective end users [63]. Once the data were obtained, missing responses were checked, which revealed a total of 36 subjects started the survey and a total of 33 finished the survey (82.5% of the total population); 91.7% of those surveyed were thus included in the study (n = 33).

For the EMR WB QUS survey, CIs were used to determine the reliability of the observed sample mean responses to survey questions compared to the expected results from the population. On the EMR WB QUS survey, Question 15, "Overall Satisfaction," the mean score was 2.4 (95% CI=2.0, 2.8) on a 7-point Likert scale ranging from -3 to +3. A skewed upward distribution was obtained because the majority of health care providers reported a higher level of satisfaction with EMR WB use compared with the paper-based system. Thus, for the majority of respondents, the rating for overall satisfaction with EMR WB was higher than the mean rating.

The information in Table 5 summarizes the total scores given a mean and standard deviation from 1.8 (0.5) to 2.8 (1.5). On average, for most questions, the ratings were "Better" to "Much better," indicating that a large quantity of CUSS health care providers reported favorable levels of satisfaction with EMR WB use compared with the paper-based system.

A "not applicable" option was not included in the survey questionnaire because all questions were pertinent to all providers. This conclusion was based on the research conducted previously to prepare the survey, including the pre-implementation focus group. However, not all participants answered each question. The rationale for including questions such as “Facilitating my use of information for quality control" (Q. 12)[55] and "Helping me obtain information for research" (Q. 13) was based on specific goals related to the local research-oriented setting of the University of Guanajuato where all providers are required to 1) conduct research and 2) provide the university feedback for quality control.

3.4.1. Confidentiality

The design of the one-time, post-implementation evaluation survey ensured the anonymity of the respondents because their identities were not linked to their responses, and the data was not uniquely identifiable. Also, an internet-based SurveyMonkey system was used with the anonymous setting to administer the survey.

Although some of the CUSS health care providers who participated in the survey met me, the CUSS director was in charge of organizing the survey participants onsite, including sending three anonymous email reminders. The online survey was conducted without knowing the identities of the individuals (see Appendix B). The UW Institutional Review Board determined that EMR WB research qualified for exemption status under 45 CFR 46.101 (b) (2) from all 45 CFR requirements (exemption #42999). This is because the EMR WB research posed little to no risk for those human subjects involved, and falls within one or more of six federally-defined categories deemed as “exempt from IRB review.”[56]

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[55] The “Q.” means “Question” of the survey used to evaluate end user satisfaction.
[56] Office for Human Research Protections (OHRP) - Categories of Research: http://www.hhs.gov/ohrp/policy/expedited98.html

3.5. Results

3.5.1. Participants

Part I of the EMR WB QUS is presented in a tabular form as a data set representing the demographic information (Table 4). The first column represents the particular variables of the sample, including age, gender, and all the professional fields considered at the CUSS. Each row corresponds to a given member of the data set in question. It lists values for each of the variables expressed as datum in quantity of occurrences and its corresponding percentages.

Participant characteristics are summarized in Table 4. The mean age of the respondents was 35.5 years (SD 4.5) and ranged from 31 to 40 years old. The distribution of sexes was 10 males (30%) and 23 females (70%). Respondents were frequent users of the previous paper-based system (4–10 hours/week) for at least one year prior to the study. Of the five different professional fields, psychologists represented the majority with 14 (42%), followed by 6 (18%) physicians, 6 (18%) nurses, 3 (9%) nutritionists, and 3 (9%) social workers. On average, participants saw 6.5 patients per week and used EMR WB for at least 20 hours (4–6 hours a week) to assist with clinical encounters with new patients, multiple visits with the same patients, and follow-ups (reported as the most common encounter, especially among psychologists).

Table 4 indicates high proportions of females, younger subjects, and psychologists. There are several possible explanations for these findings. According to current trends in demographics and education in Mexico, women represent more than 50% of those graduating from college, and are especially prevalent in the field of psychology. In terms of age, Mexico has a predominantly young population that impacts the young age overall among professions.[57] Of the total of 50 health care providers at the CUSS, psychologists represent 40% (n=20). Thus, it was expected that a high proportion of participants would be psychologists because they represent the largest proportion of health care providers at CUSS, following by physicians (n=10), nurses (n=9), nutritionists (n=6), and social workers (n=5).

Table 6: User satisfaction question groupings.

Categorization of 15 EMR WB user satisfaction questions into 8 different clusters. The questions (Q) described below are grouped based on the similarity of their mean satisfaction scores, and were organized in hierarchical order from the highest (1) to the lowest (8).

Hierarchy	Questions	$\bar{x}$
1	Q7. Sharing patient information with my fellow clinical team members	2.8
2	Q13. Helping obtain information for research	2.7
3	Q8. Ease of access to files, Q10. Improving the continuity of patient care	2.6
4	Q1. Helping me complete my tasks Q9. Improving workflow Q11. Helping make effective evidence-based care decisions	2.5
5	Q5. Effectively review patient problems Q15. Overall satisfaction	2.4
6	Q2. Facilitating my input of information Q6. Safeguarding patient privacy, Q2 Facilitating my input of information Q12. Facilitating use of information for quality control Q14. Appropriateness for use in my care setting	2.3
7	Q4. Ease of use	2.2
8	Q3. Learning how to use	1.8

57 Source: Index Mundi—Mexico Demographics Profile 2012: http://www.indexmundi.com/mexico/demographics_profile.html.

3.5.2. User satisfaction with EMR WB

The survey results described below are based on the percentage of the survey respondents for each question (Q), along with the average score of the mean and the CI in a hierarchy from the highest (1) to the lowest (8). (See Table 6.)

(1) In the area of "Sharing patient information with my fellow clinical team members" (Q7), 82% of survey respondents indicated that EMR WB was “Much better” than the paper-based system, which had an average score of 2.8 (95% CI: 2.6–3.0). Open-ended comments from participants on the survey included *“EMR WB allows for effective interdisciplinary work, as each health care professional can access the information when needed;” “Yes, because it compiles the information from the health care team in different interventions;”* and *“I have been practicing professionally in several institutions, and this is the first time that I have seen the work for the end user performed in an integral manner, across disciplines, and including the field of social work. I am very pleased to see that the same importance has been incorporated to include all fields (medicine, psychology, nutrition, nursing, and social work). I have carried out several consultations with the same patients many times across different fields in the EMR WB system, and in this same way, other professionals from different fields have also consulted my patients many times.”*

(2) In the area of "Helping obtain information for research" (Q13), 77% of survey respondents indicated that EMR WB was “Much better” than the paper-based system, which had an average score of 2.7 (95% CI: 2.4–2.9). This rating can be correlated to comments such as *“With this kind of platform, we can have quick access to specific data and*

information for research" and *"Yes, because basically we have the recording, evidence, and other fundamental data that are necessary to perform research, epidemiology, and prospective and retrospective studies."* Because the CUSS is a teaching and research facility in a university setting, these reactions seem especially meaningful.

(3) In the areas of a) "Ease of access to files" (Q8), and b) "Improving the continuity of patient care" (Q10), 69–76% of survey respondents indicated that EMR WB was "Much better" than the paper-based system, which had an average score of 2.6 (95% CI: 2.3–2.9).

3a) Related comments for "Ease of access to files" (Q8) were *"Quite convenient accessing files from any place and platform;" "As we commented, knowing the access codes and password;"* and *"When the system has been designed perfectly."* This is consistent with the opinion stated by various clinical system designers over the years that "ease of use" is the single most important determinant of user satisfaction [12,38,58].

3b) Some supporting comments for "Improving the continuity of patient care" (Q10) included *"Only with EMR WB can health care providers document and therefore support the continuity of integral care;" "Yes, because absolutely no intervention is lost;"* and *"If we use the system appropriately, other health care professionals can provide further care."* Since the CUSS provides continual health care beginning with the initial contact following the patient through all phases of multidisciplinary care (medicine, psychology, nutrition, nursing, and social work), the continuity of patient care is one of the elements that providers value the most, as they also outlined during the focus group.

(4) In the areas of a) "Improving workflow" (Q9), b) "Helping me complete my tasks" (Q1), and c) "Helping make effective evidence-based care decisions" (Q11), 63–67% of survey

respondents indicated that EMR WB was “Much better” than the paper-based system, which had an average score of 2.5 (95% CI: 2.2–2.8).

4a) With regard to "Improving workflow" (Q9), some related comments were *“Yes, based on the availability from any space, city, clinic, etc.;” “Yes, as soon as the system becomes ubiquitous with all health care professionals, better access to the internet, and becomes a standard of care;”* and *“Although the first visit could be a time-consuming task inputting all required information, but this also happens with the paper-based system, anyway.”* Such feedback represented a positive response to the design of EMR WB as all-inclusive and multidisciplinary across the most important primary care domains that parallel the same workflow in use at the CUSS.

4b) Some of the favorable comments for “Helping me complete my tasks” (Q1) included *“The EMR WB allows for working easily with the information resources provided in the system, and you’re aware of the work of the other health care providers;” “It's all there with a few clicks, available anytime, anywhere;” “It simplifies the visit, documentation and storage;”* and *“I was dependent upon the training of how to efficiently manage the EMR.”*

4c) Regarding “Helping make effective evidence-based care decisions” (Q11), some supporting comments were *“Yes, because we have access to the evidence when we need it”* and *“Yes, in particular, when we are dealing with uncertainties, we need to be better informed.”*

(5) In the areas of a) "Overall satisfaction" (Q15), and b) "Effectively review patient problems" (Q5) 67–68% of survey respondents indicated that EMR WB was “Much better” than the paper-based system, which had an average score of 2.4 (95% CI: 2.0–2.8).

5a) With regard to "Overall satisfaction" (Q15), it was associated with the following survey comments: *"After working with EMR WB, I realized that this is an excellent tool in order to have a better control of the clinical files, working in a multidisciplinary environment in a timely manner, and facilitating our contact with supervisors;" "EMR WB is an excellent system to provide the users of the system with complete care. I truly congratulate the creators of this project;"* and *"I believe that this is an excellent project. It would contribute to the appropriate management of health information to establish an appropriate control of health care interventions. It would establish a guarantee of overall quality."*

5b) Some related comments for "Effectively review patient problems" (Q5) included *"Definitively, only with EMR WB is it possible to work in an integral and multidisciplinary manner because the information is accessible when it's needed"* and *"Yes, because after we get into the system, we can review all fields."* This reflects the potential benefit that health care providers could receive from using EMR WB to gather data from patients to review problems and support diagnoses and treatment plans.

(6) In the areas of a) "Appropriateness for use in my care setting" (Q14), b) "Safeguarding patient privacy" (Q6), c) "Facilitating my input of information" (Q2), and d) "Facilitating use of information for quality control" (Q12), 55–67% of survey respondents indicated that EMR WB was "Much better" than the paper-based system, which had an average score of 2.3 (95% CI: 2.0–2.7).

6a) With regard to "Appropriateness for use in my care setting" (Q14), they expressed that EMR WB would be appropriate for use in the CUSS due to its primary care multidisciplinary approach that permits sharing among members of the primary care team. Some related comments were *"Yes, because it facilitates the accessibility of the needed health interventions"* and *"Yes, but we all are dependent upon internet connectivity."*

6b) With regard to "Safeguarding patient privacy" (Q6), some related comments included *"This has to be reinforced, in particular with multidisciplinary health care professionals' access"* and *"This is fundamental because everyone in the world can have access to it."*

6c) With regard to "Facilitating my input of information" (Q2), some favorable comments were *"EMR WB offers options to fill out information that facilitates the time and coverage of the documentation"* and *"Yes, it facilitates the input of information because you have clear options at your disposal."* Such responses lend support to success with the design of EMR WB to better address the need for standardized patient documentation using both unstructured and structured input.

6d) With regard to "Facilitating use of information for quality control" (Q12). Some favorable comments were *"Yes, because it's possible to compare with health indicators, standards of care, etc. that could be useful as quality control"* and *"Yes, we can use the data from the system as we have previously envisioned, to perform statistical analysis based on diverse pathologies and treatments."*

(7) In the area of "Ease of Use" (Q4), 55% of survey respondents indicated that EMR WB was "Much better" than the paper-based system, which had an average score of 2.2 (95% CI: 1.7–2.6). This contrasted with the opinion that various clinical system designers have stated over the years that "ease of use" often is the single most important determinant of user satisfaction [12,38,58]. Some related comments were *"Only if I can learn how to access*

it;" "It requires more time to create a new file, as with following up with the patient;" and *"As soon as you get to use it, it's easy to manage."*

(8) In the area of "Learning how to use" (Q3), 48% of survey respondents indicated that EMR WB was "Much better" than the paper-based system, which had an average score of 1.8 (95% CI: 1.2–2.3). This was the eleventh and lowest scored response. Some users commented that *"It takes time to learn how to use the EMR"* and *"To become competent in its management is an achievable but time-consuming task."*

Suggested improvements for EMR WB

Provider feedback to Q20 ("Do you have any comments or suggestions to improve EMR WB?") is summarized here, immediately followed by related verbatim comments:

1. Include a button for additions to patient problems: "*Have a button 'add to problem list' on progress notes to facilitate updating the problem list when a new diagnosis is made*."
2. Expand the variables that are specific to the nursing clinical file: "*In the field of nursing, the variables that are specific to the nursing clinical file need to be expanded. These additions would impact the nursing side of the management of the patient*."
3. Add some guidelines or a tutorial on the home page: "*I consider it important to add some guidelines on the home page to show how to use EMR WB*."
4. Expand to hospital settings: "*I think if physicians could access EMR WB in a private hospital setting it would be a great asset*."
5. Add Spanish-language EB sources of information: "*Have access to sources of information in Spanish because not all of us have mastered English*."

6. Use better hardware: "*I don't have any suggestions for improving EMR WB, but having better hardware would facilitate the speed of inputting information into the system*."

3.6. Discussion

As W.E. Hammond pointed out in 2009 [9], "For much of the world, truly productive and functional EMRs remain an elusive goal of the future." However, opportunities for improvement abound from the availability of HIT funding in the United States, Mexico, and other countries. EMR WB underscored the importance of and need to better understand the logistics of bringing patient records out of the ink-and-paper era and into the state-of-the-art computer age in a global context. This project focused on answering the "why" and "how-to" questions regarding the basic functions needed to ensure user satisfaction with EMRs.

The EMR WB QUS evaluation tool shed light on the system's interface, standardization, access, and offering of knowledge-based tools compared to the paper-based system. The results showed that a majority of respondents found the EMR WB system overall more satisfying than the paper-based system with regard to these aspects by indicating "Much better" on the "Overall satisfaction" question of the survey. The novelty effect was considered as a possible explanation for this finding at the CUSS, where providers may have initially reacted favorably to the institution of new technology rather than to any actual improvement in workflow with EMR WB in comparison with the paper-based system. While it is possible that the higher satisfaction reported with the use of EMR WB via the EMR WB QUS can be attributed to a novelty effect, informal monitoring of user satisfaction after one year indicates the level of interest in EMR WB is still greater than that in the paper-based system. CUSS providers continue to display effort and persistence with the new system, which demonstrates the novelty effect is no longer applicable.

Implementation of EMR WB in the CUSS primary care setting was associated with perceived overall improvements and satisfaction in data sharing across all five primary care domains, as indicated by both the survey responses specifying the highest level of satisfaction reported (Table 5) and associated comments. Respondents believed that EMR WB data sharing allowed them to deliver more effective patient care. These findings were not particularly surprising for two reasons. First, during the focus group CUSS health care providers had expressed great interest in multidisciplinary collaborative work where all different professionals (physicians, psychologists, nutritionists, nurses, and social workers) are able to input and review all available information for the same patient. Second, EMR WB was designed to be all-inclusive and multidisciplinary across the most important primary care domains that parallel the same workflow in use at the CUSS, where the professional health care provider could input and share information as a member of a patient's health team, as was done with the paper-based system.

Perhaps the most revealing findings from the survey were that the second and third highest scored areas (out of 14), "Helping obtain information for research" (Q13), followed by "Ease of access to files" (Q8), contrasted with the score for "Ease of use" (Q4, 13th overall place). Various clinical system designers have stated over the years that "ease of use" is the single most important determinant of user satisfaction [12,38,58]. However, our findings indicated that overall user satisfaction correlated best with the questions that related to the health care providers' ability to use the system to carry out their assigned tasks in terms of access to the clinical information they needed "from any place, any time, and any platform," as one respondent added in the comments at the end of this question.

A possible explanation for the high rating for "Improving the continuity of patient care" (69%, Q10, and 4th overall place) is that health care providers at the CUSS found that the capabilities of the EMR WB system (e.g., electronic data storage, access, sharing information electronically, etc.) offered better support than the paper-based system when following the patient through all phases of health care.

One of the possible explanations for the relatively low rating for "Helping me complete my tasks" (63%, Q1) is that health care providers at the CUSS found the content of EMR WB to be very familiar and therefore similar to the paper-based system previously used. Another related possibility is that the paper-based system was perceived as very efficient at CUSS clinical documentation, and therefore there was no need to replace it. As outlined above in Section 2.2 on standardization, EMR WB was specifically designed to simulate the structure and clinical contents of the CUSS' paper-based system, so these results can be positively interpreted (i.e., correlated with ease of use).

The explanation for the low satisfaction reported for "Facilitating use of information for quality control" (55%, Q12) may be similar to that for "Helping me complete my tasks" (Q1) since CUSS health care providers already had used the paper-based system (for at least one year) for this purpose, as requested by the CUSS. In this context, EMR WB represented an investment of time needed to obtain all the information that users could previously see and corroborate easily on paper for quality control.

In contrast, the overall weak support for decision support tools (61%, Q11) may be due to their newness to the clinical workflow. However, there were enough positive responses to confirm previous reports demonstrating favorable acceptance of decision support tools in global adult primary care and support continued adoption in this environment [9,55, 58].

Computer experience was not evaluated because all providers reported being knowledgeable in basic computer skills, such as the ability to use electronic mail and a word processor, as expressed in the initial focus group. Due to the assumed simplicity of the EMR WB interface, its similarity with the paper-based system, and user familiarity with the clinical contents, no training was considered necessary. However, it seems there is a clear need for training, as only 48% (the lowest rating) of respondents indicated EMR WB was “Much better” than the paper-based system with regard to ”Learning how to use” (Q3). This negative rating might be attributed to the short time period (about two hours) in which health care providers had to become familiarized with the new system. The introduction of EMR WB, with its documentation functions and new interface, brought a radically changed interaction structure and represented a new challenge in terms of learning a different system for regular clinical work. A demo is available upon request, but it requires the user to spend some time becoming familiar with the system, and it does not include step-by-step instructions.

Although specific aspects of system speed were not addressed in the EMR WB QUS, users were asked about this during follow-up onsite visit seven months after EMR WB implementation. None of the CUSS health care providers expressed concerns about speed, and the majority considered the system to be adequately fast to accomplish needed tasks such as information input and retrieval, and to take advantage of decision support tools.

The data indicates that relative to other system features, respondents were the least satisfied with learnability (48%, Q3), and most satisfied with information sharing (82%, Q7). EMR WB facilitation of research (77%, Q13), file access (76%, Q8), and continuity of patient care (69 %, Q10) were also highly rated. Thus, the system may be difficult to learn for some professionals, but once the user is familiar with the system, its biggest payoffs appear to be information sharing, research, ease of access to files, and continuity of care.

3.7. Summary

Apart from the effort to build an all-inclusive interface using one navigation system and the standardization of the clinical core to facilitate the input of structured and unstructured (free text) information, what remains one of the greatest challenges to achieving a highly rated EMR WB user interface is balancing the providers' requirements with an integrated and fully functional system in the global context. In many instances, difficulties in learning how to use the system prevented health care providers from gaining a rapid knowledge of the system capabilities. Too much information and too many functions on a single screen may impede task efficiency rather than improve it. However, less information and fewer functions on a single screen require more screens and thus lead to a more complex user-interaction structure. Fortunately, minor changes in screen design and interaction structure (e.g., making the all-inclusive main menu bars visible all the time) addressed all of these issues and had a positive impact on usability based on direct observation during the onsite visits and comments gathered from the providers. This was achieved with version 1.5, which required an in-depth review focused on interface and documentation structure.

The issues discovered in this project related to the primary care context. Interaction with the system among diverse professions treating the same patient can be linked back to the importance of user-centered system design. For the interaction structure to be effective, the tasks and procedures that users may perform with the EMR WB system need to be organized in a logical and consistent manner [38]. This means that the system functions should specifically correspond with the goals that the health care provider sets for performing tasks, including the order in which the provider wants to attain these goals. Also, the order of information presented should match the order in which a user processes this information, which means clustering related data elements on computer screens across the different primary care domains considered [38, 51].

Technical support is another essential element of successful EMR WB implementation. Follow-up inquiries indicated CUSS users felt they had adequate support from both the University of Guanajuato Information Technology Department, and my team because of the quick response they obtained when faced with onsite technical difficulties such as interrupted internet connections or changes in speed, as well as the rapid and tailored updates to their feedback during the beta testing (i.e., version 1.5). User satisfaction with an EMR system may obviously vary according to the availability and delivery of associated support, especially in global settings where EMR adoption has been less prevalent.

This project demonstrates that despite the associated challenges, we can move from a paper system to an empowering system based on state-of-the-art-technology (e.g., cloud computing and cellular networks now widely available). EMR WB needs to be recognized for its potential to become an intelligent, active partner with the health care provider and patient to enhance health care services globally, without borders [9].

3.8. Limitations of Study

This research has several important limitations. Probably the most significant is that because EMR WB was tested in only one clinic, the CUSS, post-implementation user evaluations reflected the proposed system's functionality and usability in only that environment. A power calculation was not performed with a random sampling of EMR WB users to determine the sample size needed to be able to claim support for generalizability because the study was focused on one setting that represented local, clinical, and psychosocial primary care problems in targeted underserved communities in the state of Guanajuato, Mexico, as well as transnational migration health issues [62]. The main objective of the study was to obtain information about provider satisfaction with the new EMR WB system compared to the old paper-based one by using descriptive statistics rather than hypothesis testing. Therefore, not all conclusions based on how EMR WB worked in the CUSS may be generalized to other countries or institutions. However, presenting information on the study setting may help others apply lessons from the CUSS experience to similar contexts.

A related limitation is the small size of the pre-implementation focus group (6 health care providers), but it is representative of the diverse groups in the total end user population included in the study (i.e., CUSS physicians—1, psychologists—2, nutritionists—1, nurses—1, and social workers—1). Another limitation in this context is that the focus group met just once (for 90 minutes). Other possible limitations are inherent to the technique itself, namely that providers might not have said what they actually think because of "group think" (e.g., people expressing an opinion which is in agreement with the rest of the group even if that opinion is at odds with their own personal perceptions, interpretations, or beliefs) [59]. Similarly, respondents may have been inclined to give the answers they thought their recruiter wanted to hear, which would be consistent with her bias in favor of EMR WB. The moderator did not perceive these factors to be present.

Despite these limitations, this was the first study assessing user satisfaction with an entirely new multidisciplinary, standardized web-based EMR system compared to a paper-based record system in a global primary care setting. At a time when governments, health care organizations, and stakeholders are focused on efficacy, development of a system such as EMR WB that satisfies its users is an important step toward a design supported by solid evidence showing it may actually improve overall provider satisfaction, and eventually patient quality of life as well. Innovations in software technologies, and more particularly the development of cloud and mobile computing, will increasingly encourage the use of EMR research in similar global settings in the future.

3.9. Suggestions for Further Research

Although the study offered important insights about the level of satisfaction with use of EMR WB compared to paper-based records as expressed by health care providers, several related critical questions remain unanswered. One of these is how *patient* satisfaction is affected during clinical encounters with health care providers who use EMR WB. Also, to what extent does use of EMR WB in the same and similar settings impact patients' overall quality of life, specific health indicators, and health outcomes? Fortunately, these unanswered questions have become more focused because of the study. The next suggested step for further research is centered on answering the level of patient satisfaction as it relates to health outcomes and treatment of prevalent chronic conditions such as type 2 diabetes mellitus,[58] hypertension, cardiovascular diseases, and depression as facilitated by EMR WB. These research initiatives should take place in parallel with the software updates and setting expansions in primary care settings not only in Mexico, but the United States and other countries. Additional implementation of EMR WB in multispecialty primary health clinics of varying sizes needs to be done to better understand the functionality that is most associated with high levels of satisfaction with its use.

Several ideas are already being developed to update ongoing future improvements: 1) Meaningful use certification in the United States; 2) Information exchange and interoperability with diverse EMRs; 3) an mHealth-based EMR WB system (mHealth unification initiative); 4) Global expansion (Mesoamerica Health Initiative 2015[59]; United

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[58] Medscape Outpatient EHRs May Improve Diabetes Management (http://www.medscape.com/viewarticle/775233?src=nl_topic). Tenforde M, Nowacki A, Jain A, Hickner J. The association between personal health record use and diabetes quality measures. J Gen Intern Med. 2012 Apr;27(4):420-4.

[59] Belize, El Salvador, Guatemala, Nicaragua, Honduras, Panama, Costa Rica and the Mexican state of Chiapas

States—pilot project in Pittsburgh[60]; Africa—Tanzania; and Europe—the European EMR WB model-pilot project at Heidelberg University, Germany); 5) Personalized medicine integration (e.g., genome infobuttons); 6) Integration of machine translation tools (for English and Spanish); 7) EMR WB new modules (hospital, medical, and surgical subspecialties; public health; and a surveillance-based EMR WB system); 8) EMR WB Lab-on-a-chip (portable medical office lab project); and the EMR WB-based Office of the Future—Integrating Information in the Care System project (e.g., machine learning, knowledge discovery, and data mining).

I look forward to the diffusion and expansion of a ubiquitous, state-of-the-art EMR system to improve global health outcomes in a cost-effective manner.

[60] Squirrel Hill Health Center and the University of Pittsburgh Center for Global Health.

Chapter IV: Ethical Dilemmas

EMRs are increasingly being used in many developing countries, several of which have moved beyond isolated pilot projects to mainstream components of their local (as in the case with EMR WB) and national health strategies. Despite growing enthusiasm for adopting EMRs in middle income and poor countries, almost no attention has been paid to the ethical dilemmas associated with their implementation and use [52]. These ethical issues should be addressed now to avoid problems with maintaining appropriate application of EMRs and their future adoption.

The development and implementation of EMR WB was guided by the HITECH Act, a widely accepted ethical framework currently in use in the United States and Mexico. HITECH has now extended some privacy and security protections as described in the Health Insurance Portability and Accountability Act (HIPAA) to EMR health care provider users.

Despite their promise as a technological innovation capable of reforming health care, many currently unanswered ethical questions threaten the widespread adoption of EMRs. The literature points out that privacy, security, and confidentiality issues appear to be the most common ethical concerns with EMR implementation and adoption [37,52,53]. In addition, there are other concerns that may arise with respect to disclosing clinical information stored electronically [54,56]. One is related to the use of EB tools. By definition, EB implies the use of the best evidence available, the experience of the provider, and patient's preference or choice [28]. The problem arises when the evidence competes with the patient's decision-making process, preference, or best interest, even with good intentions. The lack of provider experience perhaps is a predisposition that has to be considered.

Imposing knowledge-based tools at the point of care over a patient's best interest is a concern that remains to be studied, but because EMR WB uses these tools, it is important to point out the potential ethical issues involved and create the needed awareness. Another concern is related to copying and pasting of clinical notes or information from other patients or other sources that has the potential to add misinformation, create mistakes, and build clinically unrelated files [40,52, 53].[61]

Because the need for access is one of the primary reasons for establishing the proposed EMR system, restriction of access, time of access, place of access, and even provision of access remain sources of ethical concern when dealing with a patient's data across borders. To address these critical areas, the system was designed to be HIPAA compliant, obey the International Organization for Standardization (ISO) confidentiality[62] and privacy rules, and work seamlessly for a patient's best interest. An EMR culture of ethics was created where patients' best interests are the norm, which reflects the overall patient-centered design. Future plans include setting up lines of research to better understand the intricate ethical issues related to the nature of this project and implement better ethical and technological solutions related to overall clinical data management across borders.

[61] Leora Horwitz. Shortcuts in Medical Documentation: Electronic medical records make some things too easy. The New York Times. OP-ED CONTRIBUTOR. November 22, 2012.
[62] ISO definition: Confidentiality is a characteristic that applies to information. To protect and preserve the confidentiality of information means to ensure that it is not made available or disclosed to unauthorized entities. In this context, entities include both individuals and processes. (http://www.praxiom.com/iso-27001-definitions.htm#Confidentiality)

Chapter V: Conclusions

EMR WB attempted to highlight the importance of and need to better understand the logistics of bringing patient records out of the ink-and-paper era and into the state-of-the-art computer age in a global context. This project focused on answering the "why" and "how-to" questions regarding the interface, access, standardization, decision support, definition, and evaluation of the proposed concept. Hence, it was expected that EMR WB would have a measurable, positive effect on provider satisfaction compared with the paper-based system.

The implementation of EMR WB in a primary care setting, the CUSS, was associated with perceived overall improvements in information sharing, research, access to files, continuity of care, workflow, and primary documentation capabilities. Users valued remote access and secure sharing of clinical data across multidisciplinary primary care disciplines in particular. These results confirm previous reports demonstrating favorable acceptance of EMRs in adult primary care, and support continued adoption in this environment [41].

The central idea of this effort was to provide a research-based medical record system with state-of-the-art biomedical informatics applications that would improve provider satisfaction and health care for populations in Mexico with limited resources. This included efficient documentation, the transfer and sharing of technical and clinical information, decision support, technology, and organizational skills.

5.1. Conflicts of interest

One of the priorities for EMR WB is to make it available for free. The intention after completion of the pilot project is to find an institution in the United States and/or abroad to support its updates and expansion (e.g., migration to farm computing when needed) under the same "open source for all" philosophy. No current or potential conflicts of interest have arisen.

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Appendix A

Focus Group Study
Outline of Question Sequence

Opening comments:
Welcome, brief description of the project EMR WB, and statements regarding the purpose of the study, focus group procedures, and ethical issues.

Opening comment:
Please tell us a little bit about yourself.

Introductory question:
The use of EMRs in the clinical setting to collect, store, share, and access patient medical records promises overall vast improvements in health care; many providers are currently using them. In thinking about your daily professional life, what does the use of an EMR mean to you?

Transition questions:
Are EMRs a negative tool in your clinical setting? If so, explain how they are negative.
Are EMRs a positive tool in your clinical setting? If so, explain how they are positive.

Key questions (issues for interactive participation):
How do you define EMRs?
What do you expect from EMRs?
What do you think are the major differences between EMRs and paper-based medical records?
What functions would you like to see?
What do you think are the major, current problems of EMRs?
What fundamental changes can EMRs make in health care practice?
How do you describe the ideal EMR system?
Is an ideal EMR possible?
Among the usability problems with EMRs, which is the most serious one?

Ending questions:
All things considered, what would you say is the major potential benefit of EMR adoption?
Is there anything about the implementation and use of EMRs that I haven't talked about that you would like to raise before I leave?

Appendix B
The Evaluation Tool
EMR WB Questionnaire for User Satisfaction (EMR WB QUS)

SURVEY

PART 1 of 3. Demographic Data.
Please complete:

1) **Age:**	**20 - 30**	**31 - 40**	**41 - 50**	**51 - 60**	**60 +**
	☐	☐	☐	☐	☐
2) **Gender:**	M	F			
	☐	☐			
3) **Field:**	Medicine	Psychology	Nutrition	Nursing	Social Work
	☐	☐	☐	☐	☐

PART 2. User Satisfaction Questionnaire.
For each of the following features, please mark the rating that best describes how you think of Electronic Medical Record Without Borders (EMR WB) in comparison with the paper-based system (PBS).

4) EMR WB in comparison with the PBS:
(Q1) Helping me complete my tasks

Much worse	Worse	Somewhat worse	About the same	Somewhat better	Better	Much better
-3	-2	-1	0	1	2	3
☐	☐	☐	☐	☐	☐	☐

Comments:
____
____

5) EMR WB in comparison with the PBS:
(Q2) Facilitating my input of information

Much worse	Worse	Somewhat worse	About the same	Somewhat better	Better	Much better
☐	☐	☐	☐	☐	☐	☐

Comments:
____
____

6) EMR WB in comparison with the PBS:
(Q3) Learning how to use

Much worse	Worse	Somewhat worse	About the same	Somewhat better	Better	Much better
☐	☐	☐	☐	☐	☐	☐

Comments:

___

___

7) EMR WB in comparison with the PBS:
(Q4) Ease of use

Much worse	Worse	Somewhat worse	About the same	Somewhat better	Better	Much better
☐	☐	☐	☐	☐	☐	☐

Comments:

___

___

8) EMR WB in comparison with the PBS:
(Q5) Effectively review patient problems

Much worse	Worse	Somewhat worse	About the same	Somewhat better	Better	Much better
☐	☐	☐	☐	☐	☐	☐

Comments:

___

___

9) EMR WB in comparison with the PBS:
(Q6) Safeguarding patient privacy

Much worse	Worse	Somewhat worse	About the same	Somewhat better	Better	Much better
☐	☐	☐	☐	☐	☐	☐

Comments:

___

___

10) EMR WB in comparison with the PBS:
(Q7) Sharing patient information with my fellow clinical team members

Much worse	Worse	Somewhat worse	About the same	Somewhat better	Better	Much better
☐	☐	☐	☐	☐	☐	☐

Comments: ____
____

11) EMR WB in comparison with the PBS:
(Q8) Ease of access to files

Much worse	Worse	Somewhat worse	About the same	Somewhat better	Better	Much better
☐	☐	☐	☐	☐	☐	☐

Comments:
____
____

12) EMR WB in comparison with the PBS:
(Q9) Improving workflow[63]

Much worse	Worse	Somewhat worse	About the same	Somewhat better	Better	Much better
☐	☐	☐	☐	☐	☐	☐

Comments:
____
____

13) EMR WB in comparison with the PBS:
(Q10) Improving the continuity of patient care[64]

Much worse	Worse	Somewhat worse	About the same	Somewhat better	Better	Much better
☐	☐	☐	☐	☐	☐	☐

Comments:
____
____

14) EMR WB in comparison with the PBS:

[63] Workflow: Pattern of recurrent functions or procedures frequently found in organizational processes, such as notification, decision, and action (NLM-MeSH—Year introduced: 2010).
[64] Continuity of Patient Care. Health care provided on a continuing basis from the initial contact, following the patient through all phases of medical care. [NLM-MeSH—Year introduced: 1991(1975)]

(Q11) Helping make effective evidence-based care decisions

Much worse	Worse	Somewhat worse	About the same	Somewhat better	Better	Much better
☐	☐	☐	☐	☐	☐	☐

Comments: ____
____

15) EMR WB in comparison with the PBS:
(Q12) Facilitating use of information for quality control

Much worse	Worse	Somewhat worse	About the same	Somewhat better	Better	Much better
☐	☐	☐	☐	☐	☐	☐

Comments:
____
____

16) EMR WB in comparison with the PBS:
(Q13) Helping obtain information for research

Much worse	Worse	Somewhat worse	About the same	Somewhat better	Better	Much better
☐	☐	☐	☐	☐	☐	☐

Comments:
____
____

17) EMR WB in comparison with the PBS:
(Q14) Appropriateness for use in my care setting

Much worse	Worse	Somewhat worse	About the same	Somewhat better	Better	Much better
☐	☐	☐	☐	☐	☐	☐

Comments:
____
____

18) EMR WB in comparison with the PBS:
(Q15) Overall satisfaction

Much worse	Worse	Somewhat worse	About the same	Somewhat better	Better	Much better

☐ ☐ ☐ ☐ ☐ ☐ ☐

Comments:

____

____

PART 3. <u>Use of EMR WB and Recommendations</u>.

19) Approximately how many patient/client visits did you have at the CUSS while using EMR WB?*

1 - 2	**3 - 5**	**6 - 9**	**10 +**
☐	☐	☐	☐

*Please include total encounters—new patients, multiple visits/follow-ups of the same patient.

Comments:

____

____

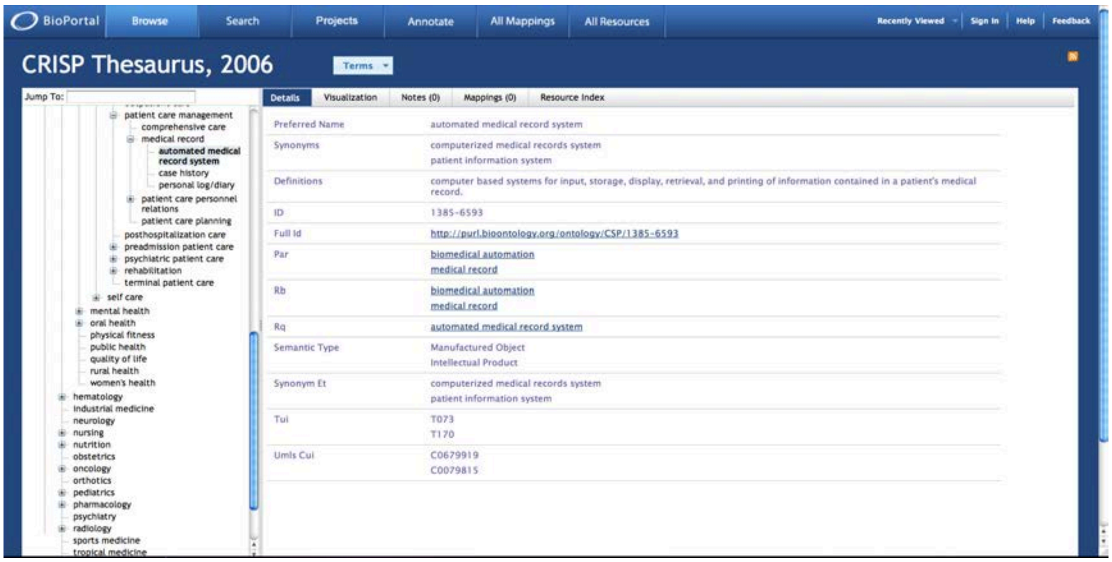
20) Do you have any comments or suggestions to improve EMR WB?

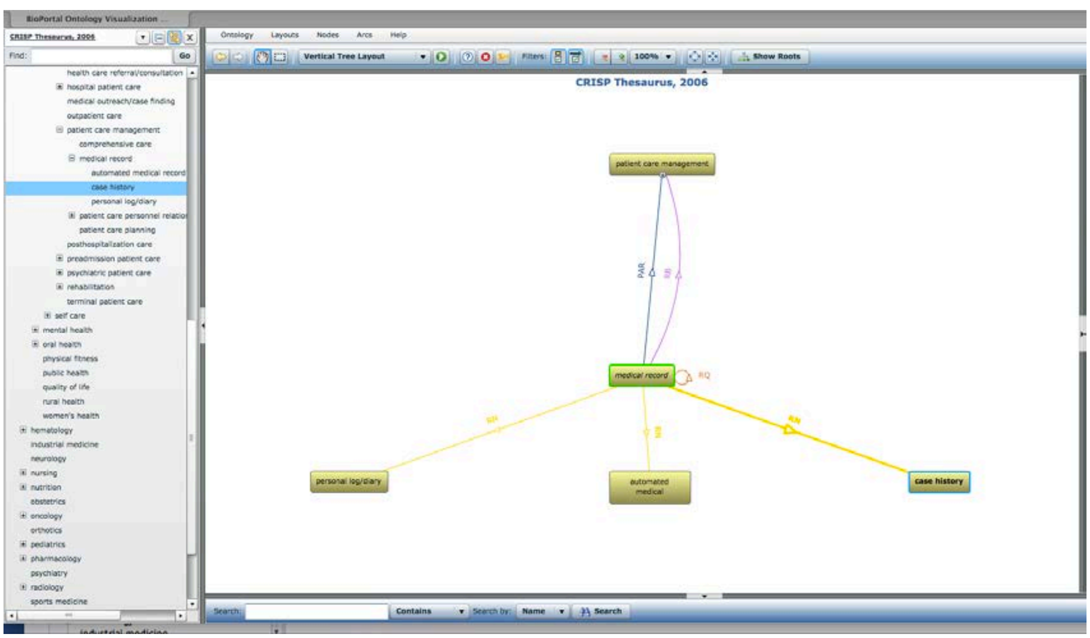
____

____

Appendix C
The National Center for Biomedical Ontology BioPortal

Screen shots of an electronic medical record showing its relationships





Appendix D-1
Standardization Process Sample
History of Present Illness

Here is an example of the standardization process to create the medical history clinical core using one of its components, the History of Present Illness (HPI). It incorporated a comprehensive state-of-the-art terminology consisted in 1) controlled vocabularies (terms), 2) semantics (meaning); 3) ontologies (relations), and 4) syntaxes (sentences). In addition, the backbone of its structure was based on peer-reviewed evidence-based clinical protocols and gold standard clinical guidelines into an English and Spanish language EMR system.

The History of Present Illness—HPI	Principio Evolución y Estado Actual—PEEA
Definition: It is the logical continuation and detailed exploration of the symptoms of the chief complaint (CC), and it represents the central aspect of the history itself.	Definición: Es la continuación lógica y exploración detallada de los síntomas del motivo de consulta (MC), y representa el aspecto central de la historia clínica.
Synonyms: The Present Illness.	Sinónimos: Padecimiento actual.
Rationale: The HPI is essential for providing care that links patients' medical condition with the diagnosis and treatment of their disease.	Lógica: El PEEA es esencial para proveer la atención que une la condición médica del paciente con el diagnóstico y tratamiento de la enfermedad.
The Essentials of the HPI: At the very least, the HPI should briefly describe the symptom modifiers and the pertinent positives and pertinent negatives of each problem.[1] (Useful for the "Bullet" presentations.)	Lo esencial del PEEA: Cuando menos, la HPI debe describir brevemente los factores modificantes de los síntomas, y los pertinentes positivos y negativos de cada problema. (Útil para presentaciones orales breves.)
Contents: 1. Detailed characterization of each problem.	Contenido: 1. Caracterización detallada de cada problema
2. Symptom Modifiers (dimensions to characterize symptoms). Should be applied to each problem: 1) Location; 2) Quality or character; 3) Quantity; 4) Chronology— onset, duration, frequency, periodicity, temporal characteristics; 5) Setting; 6) Aggravating-alleviating factors; 7) Associated symptoms / manifestations; 8) Disability and Adaptation; and 9) Attributions.	2. Modificantes de los síntomas (o dimensiones para caracterizar los síntomas—factores predisponentes, precipitantes y/o causales). Debe aplicar con cada problema: 1) Localización; 2) Cualidad o carácter; 3) Cantidad; 4) Cronología— comienzo, duración, frecuencia, periodicidad, características temporales; 5) Lugar; 6) Factores exacerbantes (agravantes) - atenuantes; 7) Síntomas asociados/ manifestaciones; 8) Incapacidad[2] y Adaptación; y 9) Atribuciones.
3. Pertinent Positives & Pertinent Negatives.	3. Pertinentes positivos y negativos.
Method: Complete use of the HPI contents in a logical & chronological sequence, using the symptoms modifiers, and pertinent positives and negatives for each problem. (Using open-ended and direct questions.)	Método: Manejo completo del contenido del PEEA en una secuencia lógica y cronológica, usando los factores modificantes de los síntomas, y los pertinentes positivos y negativos para cada problema. (Uso de tribuna libre e interrogatorio dirigido.)

[2] Sinónimos: invalidez, discapacidad, minusvalía

Appendix D-2
Standardization Process Sample
Contents of the History of Present Illness

This table below shows the specific meaning of terms used in the contents of HPI based on linguistic semantics to express meaning through natural languages, and the syntax used as a means to apply principles and rules for constructing sentences in English and Spanish. These definitions have been applied to all primary care fields (medicine, psychology, nutrition, nursing and social work).

HPI Contents, Description:	PEEA Contenido, Descripción:
A. Detailed characterization of each problem.	**A. Caracterización detallada de cada problema.**
B. Symptoms Modifiers, Description. (See attached case scenario & descriptions).	**B. Factores Modificantes de los Síntomas, Descripción**. (Ver el escenario clínico adjunto y sus descripciones.)
1. **Location**. Where the symptom is located: • Main site; • Region; and • Radiation.	1. **Localización**. El lugar donde se encuentra (localiza) el síntoma: • Sitio principal; • Región; y • Radiación.
2. **Quality** (Type or Character— the attributes of a symptom). It is a detailed description of what exactly the symptom is. E.g., types of pain—dull, sharp, burning, cramping, tingling, throbbing, etc…	2. **Calidad** (Tipo o carácter—las atribuciones del síntoma). Es una descripción detallada de lo que es el síntoma exactamente. Ejemplo, tipos de dolor—sordo, punzante, quemante, calambres, hormigueo, pulsátil, etc…
3. **Quantity**: is the magnitude or intensity of a symptom. • Severity/amount: e.g. pain scale— "On a scale of 1 to 10, with 10 being the worst, how would you rate your pain?" —; a teaspoon of greenish phlegm; number of loose stools; and/or Degree of functional impairment: e.g., "Unable to walk more than 3 blocks on plain terrain because pain on both legs."	3. **Cantidad**: es la magnitud o intensidad del síntoma. • Severidad/cantidad: Ej., escala del dolor—"En una escala del 1 al 10, el 10 siendo el peor, ¿Cómo clasificaría su dolor?—; una cucharadita de flema verde; numero de evacuaciones diarréicas; y/o Nivel de limitación funcional: ejemplo, "No puede caminar más de 3 cuadras en terreno plana debido a presencia de dolor."
4. **Chronology**. Beginning and course of the problem as follows: [1] • Onset; • Duration; • Frequency (rate of occurrence: how often it presents); and • Course—temporal characteristics: a. Intermittent—on/off: alternately ceasing and beginning again: e.g., *an intermittent pain.* b. Continuous: implies duration or existence without break or interruption; c. Progressive: increasing in intensity and/or frequency d. Periodic: the tendency to recur at regular intervals; e. Steady/fixed: not subject to change or variation; and f. Persistent: continuing to exist despite interference or treatment.	4. **Cronología**. Comienzo y curso del problema: • Comienzo; • Duración; • Frecuencia (periodicidad de ocurrencias: con qué frecuencia se presenta); y • Curso—características temporales: a. Irregular—va y viene/: comienza y de detiene: ejemplo. *Un dolor intermitente.* b. Continuo: implica duración o presencia sin pausa o interrupciones; c. Progresivo: aumentando en intensidad y/o frecuencia; d. Frecuente: la tendencia de persistir en intervalos regulares; e. Constante: No cambia, no varía; y f. Persistente: continuo a pesar de interferencia o tratamiento.
5. **Setting**: it is the context in which the symptom occurs. • Where (place) and under what circumstance it occurs; and	5. **Contexto**: son las circunstancias en las que ocurre el síntoma. • Lugar donde se presenta (¿Dónde se localiza?) y bajo qué circunstancias ocurre; y

[1] Medical Dictionary—Medline Plus, National Library of Medicine by Merriam-Webster, Incorporated 2011.

Appendix E
Example of Standardized HPI Content within the Clinical Core

HISTORY OF PRESENT ILLNESS—HPI:[65] a. **Characterization of each problem** (chronologic order). b. **Symptom modifiers** (or dimensions to characterize symptoms): 1) Location; 2) Quality or character; 3) Quantity (severity or amount); 4) Chronology — onset, duration, frequency, periodicity, temporal characteristics; 5) Setting (under what circumstances it occurs); 6) Aggravating-alleviating factors; 7) Associated symptoms / manifestations; 8) Disability & Adaptation; and 9) Attributions. c. **Pertinent positives & pertinent negatives**.

[65] HPI is the logical continuation and detailed interview prompted by the chief complaint (CC) or presenting symptom, and represents the central aspect of the clinical history itself.

VITA

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