Desarrollo de Plataforma para la Gestión de Expediente Clínico Electrónico e Imágenes Médicas como complemento de Colposcopio para Clínicas de Primer Nivel

Development of Platform for the Management of Electronic Clinical Record and Medical Images as a Colposcope Complement for First Level Clinics

Plataforma de Desenvolvimento para o gerenciamento de registro eletrônico Saúde e Medical Imaging Clínicas complemento colposcópio para Primeiro Nível

Juan Manuel Peña Aguilar
Grupo Gestión Inteligente S de RL, México
juan_manuelp@hotmail.com

José Gerardo Zertuche Zuani
Grupo Gestión Inteligente S de RL, México
josezertuche@hotmail.com

Ezequiel Ríos Hernández
Universidad Autónoma de Querétaro, México
ezequielrh@hotmail.com

Denisse Perla Ramirez Diaz
Grupo Gestión Inteligente S. de R.L., México
denis_ramdi@yahoo.com.mx

Resumen

El presente artículo expone el desarrollo de un conjunto de sistemas que complementan el colposcopio de luz actínica, ya que permiten la captura y manipulación de imágenes médicas que posteriormente se anexan al expediente clínico electrónico incorporado en el primer sistema, una plataforma web, que cumple con las normas mexicanas de registro electrónico y expedientes clínicos para la salud.

El segundo sistema es una aplicación de escritorio que permite la manipulación de las imágenes para una mejor visualización con herramientas como anotaciones, lupa, así como la visualización de múltiples imágenes.

Este tipo de sistemas promueve el intercambio de información en salud al gestionar la información proporcionada por el paciente y llevar su registro, facilitando el seguimiento y la atención en clínicas de primer nivel, complementado con un sistema para el almacenamiento y distribución de imágenes médicas.

Palabras clave: gestión de expediente clínico electrónico, PACS, colposcopio de luz actínica.

Abstract

This article presents the development of a set of systems that complement the Actinic light colposcope, since they allow the capture and manipulation of medical images which then attach to the electronic clinical record incorporated in the first system, a web platform that meets the Mexican standards of electronic registration and clinical health records.

The second system is a desktop application that allows manipulation of the images for better viewing with tools such as annotations, magnifying glass, as well as the display of multiple images.

This type of system promotes the exchange of information on health to manage the information provided by the patient and keep his/her record, facilitating the monitoring and care in clinics of first level, complemented by a system for the storage and distribution of medical images.

Key words: management of electronic clinical records, Picture Archiving and Communication System, PACS, Actinic light colposcope.

Resumo

Este trabalho apresenta o desenvolvimento de um conjunto de sistemas que complementam a luz actínica colposcópio, permitindo a captura e manipulação de imagens médicas que são então anexado ao construído no primeiro sistema de prontuário eletrônico, uma plataforma web que atenda padrões mexicanos de registro eletrônico e registros médicos para a saúde.

O segundo sistema é uma aplicação desktop que permite a manipulação de imagens por melhores ferramentas de visualização, tais como anotações, Magnifier e exibição de múltiplas imagens.

Tais sistemas promove a troca de informações de saúde para gerenciar as informações fornecidas pelo paciente e levar o seu registo, facilitando o monitoramento e atendimento em clínicas de primeiro nível, complementado por um sistema de armazenamento e distribuição de imagens médicas.

Palavras-chave: gestão de prontuário eletrônico, PACS, colposcópio luz actínica.

Introduction

Nowadays, one of the tasks of greater impact on companies is the search for competitive advantage, that is achieved mainly bringing to market innovative products and services, new or optimized, or existing manufacturing processes have been improved, thus making them more profitable. One of the main features of technological innovation is the combination of various technologies, knowledge, disciplines and business sectors.

Currently the health sector in the first level of care with obsolete medical devices where it is possible to make incremental innovations, in other words, combine various technologies, enhance its performance and allow this type of technology to be used at those levels of care that do not have the means or resources to do so, thus modernizing existing devices and reducing costs that would mean for the sector health make new devices currently offered by the market.

The software developed is intended to be a mixed software tool, that is to say, based on Web (electronic clinical record) and desktop (system of storage and manipulation of medical images), and comply with Mexican health standards for the management of patients as well as your clinical history, clinics, appointments, handling, etc. Also transfering files from medical devices is required, especially since the colposcopy of Actinic light developed by the GGI team, and perform different operations with images such as annotations and measurements using the automated medical format Digital Imaging and communication in Medicine (DICOM), in order to facilitate the processing, transmission and modification of the information for the doctor, and make timely diagnoses to patients and make them accessible to the first level of health care. Systems of storage and distribution of images, also known as Picture archiving and communication system (PAC), are also a form of low-cost with greater social impact applications (Aguilar, 2013), and enable the organization and easier distribution of medical images even for remote diagnostics (Palma, 2010). This system was developed in a triple helix scheme supported by educational institutions of the entity, that allow to maximize the results obtained in the bindings of the companies with the environment (Peña, 2014).

Methods and materiaals

    A) Analysis of components

The main objective of this analysis is research and delimitation of the different components to be used as a complement to the Actinic light colposcope. In the forthcoming paragraphs, colposcopy is defined and then the software elements that have been developed.

Colposcopy is the procedure used in gynecology to examine the epithelium of the lower female genital tract by applying a set of knowledge to evaluate its diseases. The instrument used is called a colposcope, which is similar to a stereoscopic microscope, that is, an optical system that modulates the photon energy by which it increases the size of the image.

The Actinic Light Colposcope serves specifically to diagnose the lesions caused by Human Papilloma Virus, the etiological agent of most Neoplasias and Cervical Cancer, the leading cause of cancer death in women in the third to Seventh decade of life, as well as the second

most frequent malignant neoplasm in the world, with incidence in the industrialized countries of 10/100 000 inhabitants, and in the developing countries of 40/100 000 inhabitants. In Mexico, in women older than 25 years, cervical cancer is 50/100 000 inhabitants and 16 000 new cases are detected each year according to the statistics of the Ministry of Health. Every 2 hours a Mexican woman dies from cervical cancer. HPV is the most important risk factor for Cervical Intraepithelial Neoplasia (NIC) (Sánchez, 2013).

The Actinic Light Colposcope will adapt to a high definition camera that has the ability to expose the image on a screen or projector in real time, thus allowing easier manipulation of the device. Also the camera will be conditioned to, through a button, capture snapshots that will be saved with the standard of Digital Images and Communications in Medicine (DICOM), recognized worldwide for the handling, visualization, storage, printing and transmission of medical images, in A USB memory to be delivered to doctors or stored in the Clinical Information Management system for later visualization and manipulation, so that it is possible to perform diagnoses and clinical history effectively.

Intelligent Hospital Information Manager and PACS

1. Clinical Information Manager is based on a HIS (Hospital Information System) and is the tool that includes the management of the patient's clinical record, about the unique set of information and personal data of a patient , Which can be composed of written, graphic, imaging, electronic, magnetic, electromagnetic, optical, magneto-optical and other technology documents, through which different interventions of the Health personnel, as well as describing the patient's health status (NOM-004-SSA3-2012, 2012).
2. PACS: The Picture Archiving and Communication System (PACS) is a network of display stations along with image storage and acquisition systems. PACS systems are responsible for the acquisition, storage, display and transmission of medical images. Its main objective is to allow the operation of an image service without the need to archive them in paper or film documents (González, 2014).

Today, the need to use information and communication technologies (ICT) for the use of technology management on a daily basis, is leading to the use of information systems such as PACS to access and use existing information. In this way the user can access data and analyze them, it is a computer solution that allows the indexing, extraction and export of DICOM images and metadata (Santos, 2015).

A) Analysis of Mexican health standards

Once the needs and general characteristics are evaluated, it starts with the revision of laws and regulations that were showing the necessary requirements for the development of the software.

The documents analyzed were:

1. Laws

- General law of health

2. Standards

- Official Mexican Standard NOM-014-SSA2-1994. For the prevention, treatment and control of cervical cancer and breast cancer in primary care.
- Official Mexican Standard NOM-004-SSA3-2012. Medical records.
- Official Mexican Standard PROY-NOM-007-SSA2-2010. For the care of women during pregnancy, childbirth and the puerperium, and the newborn.
- Official Mexican Standard NOM-016-SSA3-2012. That establishes the minimum characteristics of infrastructure and equipment of hospitals and specialized health care practices.
- Official Mexican Standard NOM-005-SSA3-2010. Establishing minimum infrastructure requirements and facilities equipment for outpatient medical care.
- Official Mexican Standard NOM-039-SSA2-2002. For the prevention and control of sexually transmitted infections.

In the development of the software, the legal requirements that the system for the management of patients, clinics, appointments, manipulation, transfer, annotation of images in the process of interpretation and application of legal rules were mapped. Thus it was

possible to determine the obligatory fields that must have the information of each patient, which were the base tool for the assembly of each of the windows and accesses that the user of the software has in storing the patient's medical history.

From the analysis of the Mexican health norms we can emphasize as a main purpose to establish with precision the scientific, ethical, technological and administrative criteria in the integration, use, management, archiving, conservation, ownership, ownership and confidentiality of the clinical file.

The above described was embodied in the functional specification for the development of the system.

B) **Specifications**

At this stage the specifications were delimited in terms of content of the system to be developed based on all standards and guidelines:

In summary, Figure 1 shows the overall content of the clinical information management system.
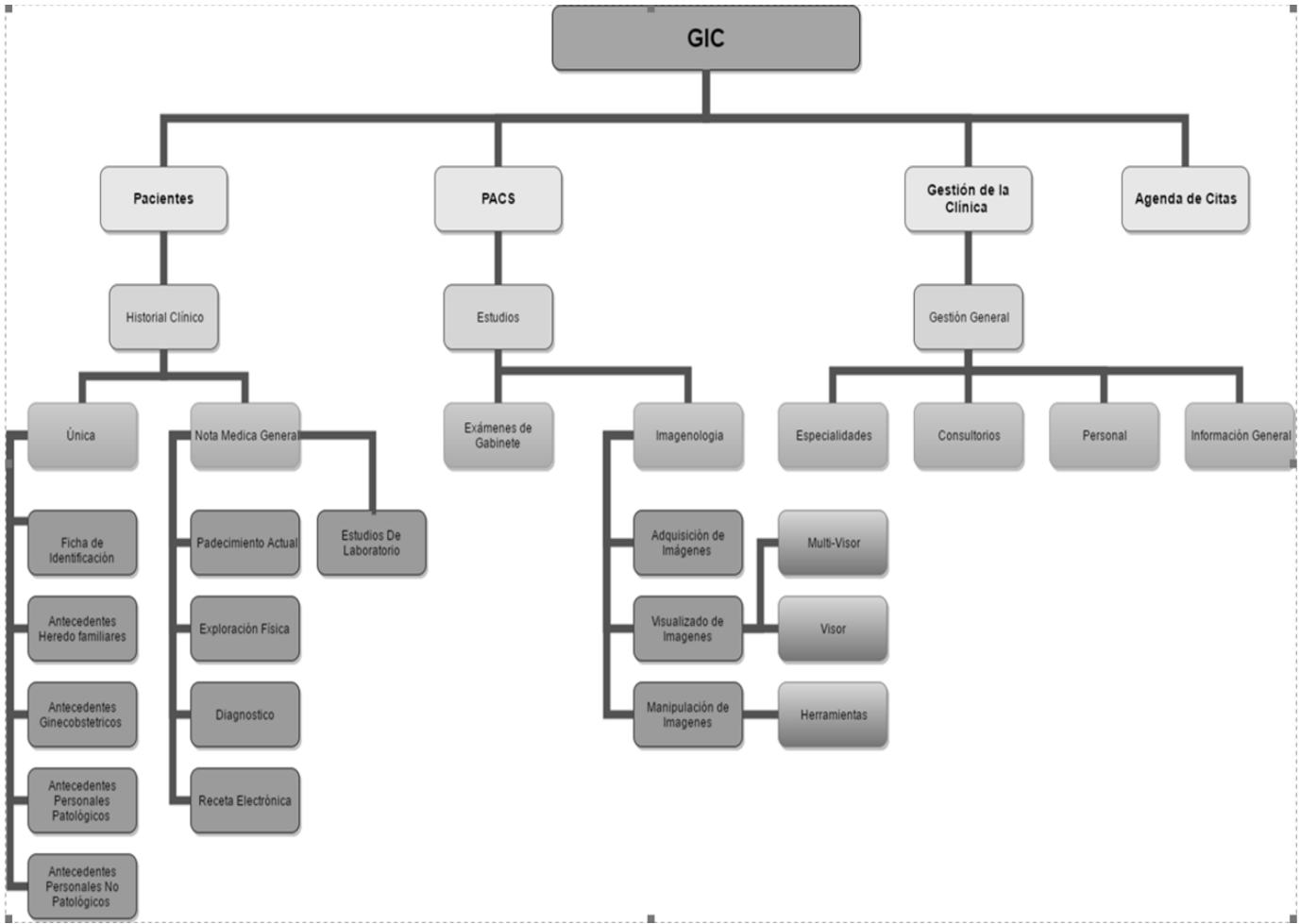
Figure 1. Conceptual map of the GIC system

Patient Module

This module includes all the information of the patients' clinical history, according to the requirements established in Mexican Mexican health laws and regulations. As a result, we find in the patients module:

- **Identification Card:** allows to store the necessary data of a patient such as: full name of the patient, age, sex, information of his address and contact information.

- **Hereditary Family History:** allows to enter the description provided by the patient of hereditary family history.

- **Personal Background:** the patient's pathological and non-pathological personal history is stored.

- **Gynecological-Obstetric history:** it allows to enter information of menarche, menopause, the characteristics of the menstruation, if previous pregnancies have been taken, if the patient uses contraceptive methods, dates of the last cervical smear, date of last mammography and also allows to enter a Brief description of gynecological diseases or conditions.

- **Medical Studies:** allows to order the taking of a new examination, to register the type of examination and to enter some special observation, to attach an accomplished study, to publish the observations of a study or to eliminate it from the clinical file.

- **New Visit:** every time the patient has a new visit to the doctor can enter the information of the type of the consultation for which the patient comes, enter a description of the patient's current condition, the patient's progress notes; Vital signs (temperature, heart rate, respiratory rate, blood pressure, height and weight).

- In the new visit, the doctor performs a physical examination where he has special fields to enter the observations resulting from this exploration; These are recorded in specific fields for: external habitus, head, neck, thorax, abdomen, genitals, extremities, skin.

- The questioning that the doctor makes to the patient during the medical consultation may be of a different type. For this purpose, specific screens are designed according to the type of information to be entered. There are interrogations of type:

- **Cardiovascular:** allows to enter the description of: chest pain, edemas, dyspnea, nocturnal paraxistic dyspnea, orthopnea, palpitations, syncope, presyncope.

- **Respiratory:** allows to enter the description of: cough, chest pain, dyspnea, hemoptysis, epithexis, cyanosis "hands, feet or around the lips".

- **Gastrointestinal:** allows to enter the description of: anorexia, hyporexia, hyperorexia, polydipsia, nausea, vomiting, dyspepsia, dysphagia, odynophagia, rectorragia, melenas, abdominalgia, pyrosis, hematemesis, acolia, meteorism, tenesmus.

- **Genitourinary:** allows entering the description of: dysuria, pollakiuria, incontinence, polyuria, oliguria, anuria, nocturia, hematuria, tenesmus, alterations of urine color.

- **Gynecologic:** allows to enter the description of: pain, menstrual disorders, hypermenorrhea, hypomenorrhea, amenorrhea, metrorrhagia, leucorrhoea, dysmenorrhea, dyspareunia, impotence, libido (increase or decrease).

- **Hemic and Lymphatic:** allows to enter the description of: pallor, hemorrhages, lymphadenopathy, glossitis, purpura, hematoma.

- **Endocrine:** allows to enter the description of: asthenia, polyuria, polydipsia, polyphagia, obesity, thinness, goiter, exophthalmos, alterations of height, hirsutism.

- **Nervous:** allows to enter the description of: headache, vomiting, epilepsy, convulsions, transient deficit, confusion, obnubilation, sleep-wakefulness, sensitivity alterations, motor alterations, alterations of the senses (taste, smell, hearing, sight and touch).

- **Skeletal Muscle:** allows to enter the description of: myalgias, arthralgias, joint rigidities, inflammations.

- **Skin:** enter the description of: rashes, pruritus, hair loss, hypertrichosis, excessive sweating, change of nails.

Module of interaction with studies

Loading of studies. The study load will allow the user to observe previously saved files and studies, and create new studies. When creating a study the colposcopy reading interface is opened, the information collected is immediately saved on the server and linked to the studies and patient record.

If the user comes to occupy previously stored files, there is the screen of search of studies where you have access to all studies done with the system.

Once the study screen is accessed, the visualization tool is used; Is the accessory in charge of reading the files stored inside the server.

PACS module

The PACS module consists of a section of studies, which represent the examinations that a patient has performed. These studies contain different Series of Medical Images in DICOM format, which are obtained through the camera of the cospolcope, and through an interface sent to the server and from there administered by the Clinical Information Manager.

The DICOM medical imager has the following functions:

- The magnifying glass allows zooming in and out of specific points of the image, in order to observe them in detail.
- The zoom is in charge of expanding the image to the desired size.
- The rules are used as a method of measurement and location of some point to highlight the image.

- With the notes tool you can add different figures and notes in relation to the corresponding study.
- Contrast allows you to change the type of brightness at will, thereby highlighting the less illuminated areas of the image and giving an idea of the depth of the dark areas.
- Image filters

Module of Management of the Clinic

The Clinic Management module includes all the Administrative information of the First Level Clinic, according to the requirements established in Mexican Mexican health laws and regulations. As a result we find in the module:

- Specialties
- Consulting
- Personal
- General information

Within the functional specification the different scenarios expressed in use cases have been defined. Here are some examples:

C) **Design of Graphical Interfaces**

At this stage a document was developed in which the user interface components, which integrate each of the screens that are included as part of the System to be developed with the purpose of serving as a guide for the development of the system, are described graphically.
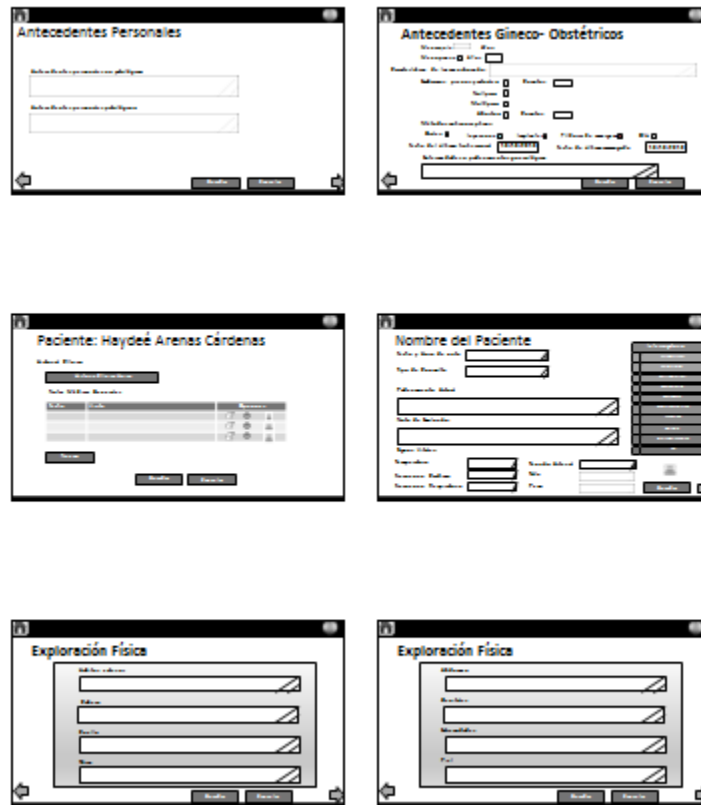
Figura 2. Ejemplo de Pantallas del Gestor de Información Clínico

D) Software Development:

In the development of the web-based Clinical Information Manager software, .NET technology was used with the C # programming language coded in Object Oriented programming. In addition, the MVC 4.0 and ASP model was used. The Framework used is .NET FrameWork 4.5 . The coding is done following programming standards clearly defined by the development team and in English language. For access to the database from code a data access layer was generated, which is composed of a main abstract class that contains the properties required for every table, and whose basic functions are to use generic objects that serve to perform Inheritance and generate the different models that make up the system and its basic functions in a very simple way to implant

Team Foundation Services (TFS) is used for source code support and development activity management. Team Foundation Service is a Microsoft service that provides the necessary tool for application lifecycle management.

Results

As results show some of the main screens of the software, it is important to mention that for reasons of intellectual property these screens are for explanatory purposes and are not the final version of the design.

Figure 3 shows the login screen. In this screen the user and the password must be entered; If these data are correct the screen will automatically take the user to the patient screen, in which according to the user entered and the permissions of the patient will be available.

Figure 3. Clinical Manager Login

The general patient list can be seen in Figure 4. In this screen you can search for patients, add patients, remove patients, or edit any existing patient.

In the case of adding a new patient the function will create a new record of each patient and fill a format that includes all the fields established in NOM 004.

Figure 4. Patient List

Figure 5. Identification file

Conclusions

In conclusion, the technological development proposed here is compatible with official Mexican standards in terms of electronic clinical records and is easily scalable to the standards of Latin American countries, where the regulations are similar, in addition to its ease of use and low cost Of implementation. The application complements well with the

desktop station, which allows easy storage and manipulation of medical images of the studio and then be incorporated into medical devices.

Bibliography

Aguilar, J. M. P., Pérez, L. R. V., Álvarez, A. L., Palma, A. P., Quevedo, J. C., Becerril, A. J. J., y Rojano, G. R. (2013). Creación de un laboratorio-observatorio-consultorio vinculando universidad, empresa y gobierno para generar aplicaciones innovadoras con impacto social en el campo de la medicina. Caso de éxito PACS-WEB. Biblioteca Digital de la Asociación Latino-Iberoamericana de Gestión Tecnológica, 1(1).

Association, N. E. (2007). Digital Imaging and Communications in Medicine (DICOM) Part 1: Introduction and Overview. Virginia, USA.

Azpiroz Leehan J., M. M. (1998). Instalación y Operación de Sistemas PACS (almacenamiento y comunicación de imágenes): Características fundamentales. Revista Mexicana de Ingeniería Biomédica, 19 (3), 21-30.

Carlos Ruiz, A. T. (diciembre de 2007). Aproximación a la Representación en XML de objetos DICOM para fotografía médica digital. Revista EIA, 147-163.

Dahilys González López, L. M. (2014). Implementación de estándares DICOM SR y HL7 CDA para la creación y edición de informes de estudios imagenológicos. Revista Cubana de Informática Médica, 6 (1), 71-86.

DRAE (2014). Diccionario de la Real Academia de la Lengua Española. Consultado en: [http://dle.rae.es/].

Milton Santos, L. B. (2015). DICOM metadata Access, Consolidation and Usage in Radiology Department Performance Analysis. A non-proprietary approach. Procedia Computer Science, 64, 651-658.

Palma, A. P., Aguilar, J. M. P., Perez, L. R. V., Alvarez, A. L., Munoz, J. F. R., Omana, O. A. N., & Ruz, M. T. (2010, August). Web based picture archiving and communication system for medical images. In Distributed Computing and Applications to Business Engineering and Science (DCABES), 2010 Ninth International Symposium on (pp. 141-144). IEEE.

Peña Aguilar, J. M. (2014). Creación de un laboratorio autosustentable de Gestión Tecnológica e Innovación en la FCA de la UAQ (Doctoral dissertation).

Salud, S. d. (2006). Manual operativo para el llenado de formatos del expediente clínico para unidades médicas de segundo nivel de atención. México: Gobierno del Estado de México.

Salud, S. d. (2012). Norma de Salud Mexicana: NOM-004-SSA3-2012, Del expediente clínico, México.

Sánchez Joel Gerardo Díaz, Z. J. (2013). México.

SSA (s.f.). NOM-024-SSA3 Registros clínicos interoperabilidad, México.

SSA (1993). Norma Oficial Mexicana NOM-007-SSA2-1993, Atención de la mujer durante el embarazo, parto y puerperio y del recién nacido. Criterios y procedimientos para la prestación del servicio, México.

SSA (2002). NORMA Oficial Mexicana NOM-039-SSA2-2002, Para la prevención y control de las infecciones de transmisión sexual, México.