UNIVERSIDADE DE BRASÍLIA

FACULDADE DE TECNOLOGIA
DEPARTAMENTO DE ENGENHARIA
ELÉTRICA

UMA PROPOSTA DE UM PADRÃO PARA SOFTWARE ORTODONTICOS

ANTONIO FERDINANDO MAGNI

ORIENTADOR: PROF. RAFAEL TIMÓTEO DE SOUSA JUNIOR

DISSERTAÇÃO DE MESTRADO EM ENGENHARIA ELÉTRICA

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DISSERTAÇÃO DE MESTRADO SUBMETIDA AO DEPARTAMENTO DE ENGENHARIA ELÉTRICA DA FACULDADE DE TECNOLOGIA DA UNIVERSIDADE DE BRASÍLIA, COMO PARTE DOS REQUISITOS NECESSÁRIOS PARA A OBTENÇÃO DO GRAU DE MESTRE.

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RESUMO

UMA PROPOSTA DE UM PADRÃO PARA SOFTWARE ORTODONTICOS

Autor: Antonio Ferdinando Magni

Orientador: Prof. Rafael Timóteo de Sousa Junior

Programa de Pós-graduação em Engenharia Elétrica

Brasília, mês de agosto (2006)

Resumo do meu trabalho.

ABSTRACT

PROPOSAL FOR THE FIRST ORTHODONTIC ELECTRONIC PATIENT RECORD STANDARD

Author: Antonio Ferdinando Magni

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Programa de Pós-graduação em Engenharia Elétrica

Brasília, month of August (2006)

Abstract of my work.

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LIST OF ABBREVIATIONS

ADA	American Dental Association
ASC	American Standards Committee
ASTM	American Society for Testing and Materials
CD-ROM	Compact Disc Read Only Memory
CMET	HL7: Common Message Element Type
DIM	HL7: Same as D-MIM, probably an older acronym
DIMSE-C/N	DICOM Message Service Element Composite/Normalized
D-MIM	Domain Message Information Model
DSTU	HL7:
HDF	HL7 Development Framework
HIPAA	Health Insurance Portability and Accountability Act
HL7	Health Level Seven
HMD	HL7: Hierarchical Message Descriptions: A common description of the exact fields of a message and their grouping, sequence, optionality, and cardinality
IE	DICOM: Information Entity
IEEE	Institute of Electrical and Electronics Engineers
IOD	DICOM: Information Object Definition: An abstraction of a real information entity (e.g., CT Image, Structured Report, etc.) which is actd upon by one or more DICOM commands.
ITS	Implementation Technology Specifications: Separate syntax specifications, describing the algorithms used to encode and transmit the messages in an XML based character stream syntax
DICOM	Digital Imaging and COmunications in Medicine
MIME	Multipurpose Internet Mail Extensions
NEMA	National Electrical Manufacturers Association
PACS	Picture Archiving and Communication System
R-MIM	HL7: Refined Message Information Model
SCDI	Standards Committee for Dental Informatics
SOP Class	DICOM: Service-Object Pair Class: A formal description of an IOD which includes a description of its purpose and teh attributes it possesses. It does not include values for these attributes.
SOP Instance	DICOM: Service-Object Pair Instance: A representation of an occurance of a real-worl entity, which includes values for the attributes of the SOP Class wo which the entity belongs.

1 INTRODUCTION

Over the past decades, personal computers have found their way in almost every field of medicine(Szolovits, 1982, Embi, 2001, Mixdorf and Goldsworthy, 1996). The advantages of using a computer in an orthodontic practice have been evident for many applications(Phillis, 2003, Ricketts, 1969, Bearn and Lowe, 2001, Halazonetis, 1997, Williams and Thurow, 1973), such as digitizing x-rays, automatically drawing tracings and collecting measurements, modelling patient growth(BeGole, 1980, Sloan, 1980), storing patients pictures, placing brackets automatically, and many more. The rapid development and spread of computer hardware has enabled the performance of increasingly complex operations, forcing software vendors to quickly meet the demands of the public. At the beginning it was believed that one company could provide a solution to meet all orthodontic requirements. Software engineers were planning their software to be independent, and the relationship with other software vendors tended to be very competitive[1]. After some years, with various high quality software products sharing the market, the need to interchange electronic data gained importance.

At the time of writing, the interchange of orthodontic electronic data among different programs is very difficult. This difficulty can be broken down in two problems:

1. There is no easy, straightforward way for an orthodontist to share selected electronic patients records (EPRs) with an other orthodontist;
2. There is no mainstream way for two or more orthodontic programs to access the same pool of EPRs.

The first problem can be exemplified through the following scenario. Carl is a recently-graduated orthodontist. Unsure of the treatment of choice of one particular patient, he opts to recur to the help of a more experienced colleague, Magda, to clear his highly specific clinical doubt. Magda enjoys assisting Carl with his difficult cases, and asks Carl to send the patient record over, to take a look at it. Albeit the patient's electronic record in Carl's patient managing program already includes impressions, x-rays, tracings and notes, it is not the same patient management program that Magda utilizes. After various failed attempts, Carl is unable to send his information over to her in a compatible format. He thus resorts to printing out the printable material, and sends it over to her. However, Magda would like to analyze the impressions too, which even when printed, are not easily analyzed. Although they are already digitized in the computer, her software does not allow her to view them, and

[1]This statement has been induced by observing features of commercial orthodontic software.

must pay Carl a personal visit to solve this problem. Carl and Magda work in the same city, and are somehow able to work around their problem of software incompatibility. But what would happen if they lived in different cities or even different countries?

The next scenario will help us explain the second problem. Recently graduated, Carl wants to build his new practice. Among other choices, he must decide which software program to purchase, and is able to find a great patient management software that attends his needs.

After purchasing and using the program for some time, however, he discovers that its cephalometric analysis part is weak, and that he could increase patient care by using the same cephalometric analysis program Magda uses in her practice. Once purchased, he realizes that the two software programs he now owns do not communicate with each other! If, for example, one patient record claims the patient's date of birth to be May 13, 1993 and another one erroneously to be May 13, 1983, Dr. Carl will have to modify (add or remove) the patient record twice, once for each system. Should he forget, he may end up with inconsistent patient records, which makes a big difference from an orthodontic perspective. Suppose Dr. Carl decides to add a new image management program, or maybe a CBCT scanner to his institution... will he have to modify three, four or five EPR databases for each change?

Assuming computer programs are to improve patient care by making processes more efficient, the above mentioned situations are unacceptable. These issues need to be addressed immediately. The use of already developed clinical standards has been limited to observation and prototyping by vendors and experimentation in academia, mainly because the use of proprietary design maintains the vendors' competitive position in the market place. A standard only gains commercial value once it has been widely implemented. This explains why vendors are reluctant to implement a new informatics standard. Currently there is increasing interest in theses standards owing to current US federal government initiatives in health information interoperability, following a trend already present in other regions like Europe (where there is heavy government involvement in health care programs). Now is the right time to illustrate one practical way to solve the above mentioned issues.

Instead of starting the development of the Orthodontic Electronic Patient Record (Ortho-EPR) standard from scratch, the answer lies in a standard composed of two already existing and well established informatics standards: Health Level Seven (HL7(The Health Level Seven, 2006), see Sec. 3.2) for non-imaging data and of DICOM(National Electrical Manufacturers Associations, 2004) (see Sec. 3.4) for imaging data (refer to Figure Figure 3.20). The integration of the two will be coordinated and published by the American Dental Association (ADA) Standards Committee for Dental Informatics (SCDI) in order to ensure its functionality in an orthodontic context. From a technological point of view, the standard

would define the processes and interactions involved during everyday clinical and financial orthodontic practice: in short, a computer standard for software vendors and programmers. Among its tasks, the standard will document all the fields necessary to fully represent the orthodontic patient records as well as their transferability, and be recognized by a large community of orthodontic specialists. In addition, it will include an implementation manual for software vendors to demonstrate its intended operation. Once completed and implemented, the standard will allow seamless and efficient patient information exchange and synchronization.

1.1 OBJECTIVES

The objective of this work is to lay the foundations for the creation of the orth-EPR standard. This is accomplished in two parts: first we present a full plan for the development of the standared; then we introduce a first full proposal for a cephalometric standard in DICOM.

The orthodontic domain is too large to embrace in toto within a masters thesis. For this reason, the intention is *not* to present a *complete* solution to the problems described in the previous section. The scope is limited to the modus operandi of how the problem can be solved. In addition, the orthodontic domain is narrowed down to a specific, yet very important element of the orthodontic record[2], and present a messaging standard for it. Finally, we prove its functionality through a simple JAVA implementation.

1.2 STRUCTURE

This document is broken down into six main parts: this here is the introduction, which contains the background of today's situation, our objectives and the structure of the document.

The second part deals with with orthodontics. Since the topic of the work is very related to the orthodontic field, it is important for the read to know at least the basic elements that make up an orthodontic patient record.

The fulcrum of the work is contained in the third part: this is were we talk about how the problems presented in the introduction can be solved with the help of standards. We then present a standard for digital cephalograms using the DICOM standard.

[2]That is cephalograms, x-rays of the skull taken in such a way that they can be used to produce accurate measurments. These measurements are the starting point for the planning of the orthodontic cure, hence a crucial element for orthodontists.

In the fourth part, we present a JAVA implementation of the standard developed in the previous part.

Finally the conclusion, where we summurize the entire work, and discuss possible future work.

2 ORTHODONTICS AND ITS DIAGNOSTIC DATA

This chapter provides the reader with the necessary orthodontic background to be able to understand the ideas and discussions presented in chapters 3 and 4: a brief orthodontic history, its definition, the information elements it deals with and today's unfulfilled requirements.

2.1 ORTHODONTICS

Orthodontics, as a specialty, dates back to the turn of the 20th century. The year 1900 is arbitrarily selected as a date for the beginning of this oldest specialty of dentistry, because it was in that year that the first Orthodontic school was founded (Angle School of Orthodontia, in St. Louis, IL).

The name of the specialty, "orthodontics", comes from two Greek words: "orthos", meaning right or correct, and "dons", meaning tooth (Fisher, 1957, p.1). In 1907 Angle (Angle, 1907) stated that the objective of the science of orthodontics is "the correction of the malocclusions of the teeth". In 1911 Noyes (Noyes, 1911) defined orthodontics as "the study of the relation of the teeth to the development of the face, and the correction of arrested and perverted development". In 1922 a more precise definition was proposed by the British Society of Orthodontists: "Orthodontics includes the study of growth and development of the jaws and face particularly, and the body generally, as influencing the position of the teeth; the study of action and reaction of internal and external influences on the development, and the prevention and correction of arrested and perverted development". (White et al., 1954)

Orthodontics differs from general dentistry in that it doesn't deal with tooth health, the treatment of cavities and other oral diseases. Although both fields' area is the oral cavity, their objectives are very different. The orthodontist doesn't cure, but repositions and remodels: this entails the biomechanics of tooth movement, bone resorption and apposition, growth and development. He looks and measures hands and wrists, oriented frontal and lateral head X-rays, facial photographs and cephalometry[3], all components that general dentists don't usually work with. This explains the demand for an orthodontic specific electronic data standard.

Orthodontic diagnostic data can roughly be divided in imaging and non-imaging data. The non-imaging data of the patient record includes demographics, case history and orthodontic clinical visit data. The imaging data of the patient record includes: frontal, lateral and

[3] Angels and distances which define the geometry of the skull.

panoramic radiographs (from regular x-ray machines), cephalometric analysis tracings, tomographs (from cone beam computed tomography scanners), plaster study casts and soft tissue photographs. These are individually described in the following sections.

2.2 NON-IMAGE DATA

The use of definitive diagnostic criteria such as cephalograms, dental radiographs, panoramic films or cone beam CT scans, has not made examination of the patient himself any less important. The data collected during these examinations is stored in text form, and referred to as “non-image data".

Non-image patient data can be roughly divided in three parts: patient demographics, case history and clinical examination. It is important to remember that each individual orthodontist makes use of a fairly customized method of collecting and organizing non-image patient data. Most times forms and records are created to meet each specialists specific preferences. Some specialist emphasize the importance of some kind of information which others might consider irrelevant. The forms and records presented in this section have been designed by Prof. Franco Magni, who has successfully used them for over 40 years.

Demographics

Patient demographics includes all general information such as name, patient ID, gender, race, telephone numbers, other family or friends contacts, physical address, referring phisician, scheduling preference, patient and parent collaboration and special care are items that can be categorized as demographics.

Case History

The case history is usually made up of medical, dental and orthodontic history. Medical history includes information related to allergies, psychological and central nervous system problems, drug usage, or any other medical related information. Dental history is more specific to the oral health and deals with data like tooth agenesis, extractions, treatments. Orthodontic history instead, is more focused on previous orthodontic treatments, habits, skeletal deformities and any other orthodontic specific information. Malocclusions as well as other dental

Prof. Franco Magni e Dott.ssa Cinzia Magni
Studio di Ortognatodonzia e delle disfunzioni Cranio- Mandibolo-Cervicali

QUESTIONARIO DI PRIMA VISITA

La visita clinica potrà rivelare la necessità di specifici esami diagnostici. Il personale di segreteria è a disposizione per fornire tutte le informazioni necessarie per l'esecuzione dei suddetti esami che potrebbero richiedere anche un successivo appuntamento. Si prega di scrivere con chiarezza, sbarrando le caselle corrispondenti.

Cognome …… Nome …… Tel: ……. Cell:……

Abitante a:…… CAP: …… Via: ……N°……

Nato il: …… a: …… Età: ……Occupazione: ……

CODICE FISCALE: | | | | | | | | | | | | | | | | |

1) DI QUALE DISTURBO DELLA MASTICAZIONE OD ANOMALIA DENTARIA O DEL VISO PENSA DI ESSERE AFFETTO?

……

……

2) Chi si è accorto per primo dei disturbi del paziente? Lui stesso ☐; madre ☐; padre ☐; altro familiare ☐; dentista ☐; pediatra ☐; medico curante ☐; medico scolastico ☐; altri ☐;

3) Chi vi ha consigliato questo studio specialistico Ortognatodontico e per la Terapia delle Disfunzioni Stomatognatico- Cranio- Mandibolari? Dentista ☐; pediatra ☐; medico curante ☐;
medico scolastico ☐; altro specialista medico ☐; parente o conoscente ☐.

Indicarne il nome: …… Telef.: ……

4) PER I MINORI. Durante la giornata, a causa della occupazione dei genitori, si viene affidati da altri?
mai ☐; saltuariamente ☐; per lunghi periodi ☐.

A chi si viene affidati? ……

5) Sono già stati portati apparecchi per la correzione masticatoria? Sì ☐; No ☐;
Se sì di quale tipo? fissi ☐; rimovibili ☐; misti ☐;

Per quanto tempo?……

6) Il paziente è disposto a portare apparecchiature in bocca? Sì ☐; No ☐; indifferente ☐.
Per quale motivo il paziente non è disposto a portare apparecchiature in bocca:

……

7) Il paziente è spesso raffreddato? Sì ☐; No ☐; soffre di rinite da fieno? Sì ☐; No ☐;
soffre di asma? Sì ☐; No ☐; è allergico? Sì ☐; No ☐;

Di quali sostanze è allergico? ……

1

Figure 2.1: Questionnaire used to collect case history data. Page 1/2 (Courtesy of Prof. Franco Magni).

8) Gli sono state tolte le tonsille? Sì ; No ; Se sì a che età?.....
sono state tolte le adenoidi? Sì ; No ; Se sì a che età?.....

9) Il paziente dorme con le labbra socchiuse od addirittura a bocca aperta? Sì ; No ;
Il paziente quando dorme russa? Sì ; No ;

10) È sotto qualsiasi terapia ormonale o comunque medicinale? Sì ; No ;

Se sì quale? ……..

11) Quante volte al giorno si spazzola i denti e le gengive con cura? una ; due ; tre ; + di tre .
Usa anche il filo interdentale? Ogni giorno ; talora ; mai ;

12) Quando si lava i denti le gengive sanguinano (anche un poco)? sempre ; talora ; mai .

13) Ha già sofferto di mal di denti? Sì ; No . Se sì, quante volte: ……..

14) Mastica gomme, caramelle o dolciumi lontano dai pasti ? Tutti i giorni ; talora ; mai .

15) Ha l'abitudine di succhiarsi un dito, le labbra od altro? Sì ; No ;

Se sì, che cosa: ……

16) Indicare nome, telefono ed indirizzo del proprio dentista di fiducia:

Cognome……..……....Nome…….…….. Tel: ……..……

Via: ……..…..Città…….…… CAP: ……..……

17) Indicare nomi e indirizzi dei medici che vi hanno curato durante gli ultimi 2 anni:

A) Cognome…….……....Nome…….…….. Tel: ……..……

Via: …….. Città……..…… CAP: ……

Specialità: ……

B) Cognome…….... Nome……..…….. Tel: ……

Via: …….. Città……..…… CAP: ……..…

Specialità: ……

18) Il paziente, da quale organizzazione assicurativa sanitaria è assistito?

……..……..

19) Eventuali altre informazioni che si ritiene utile aggiungere:

……..……..……

……..……..……

……..……..……

……..……..……

2

Figure 2.2: Questionnaire used to collect case history data. Page 2/2 (Courtesy of Prof. Franco Magni).

abnormalities present in other family members are considered to be relevant information as well because of the significant role of heredity (Graber, 1972, p.399).

This part of the patient record can mostly be compiled by the patient itself through a questionnaire during the patients first visit. Such a questionnaire is included in Figure 2.1 on page 7 and Figure 2.2 on the previous page.

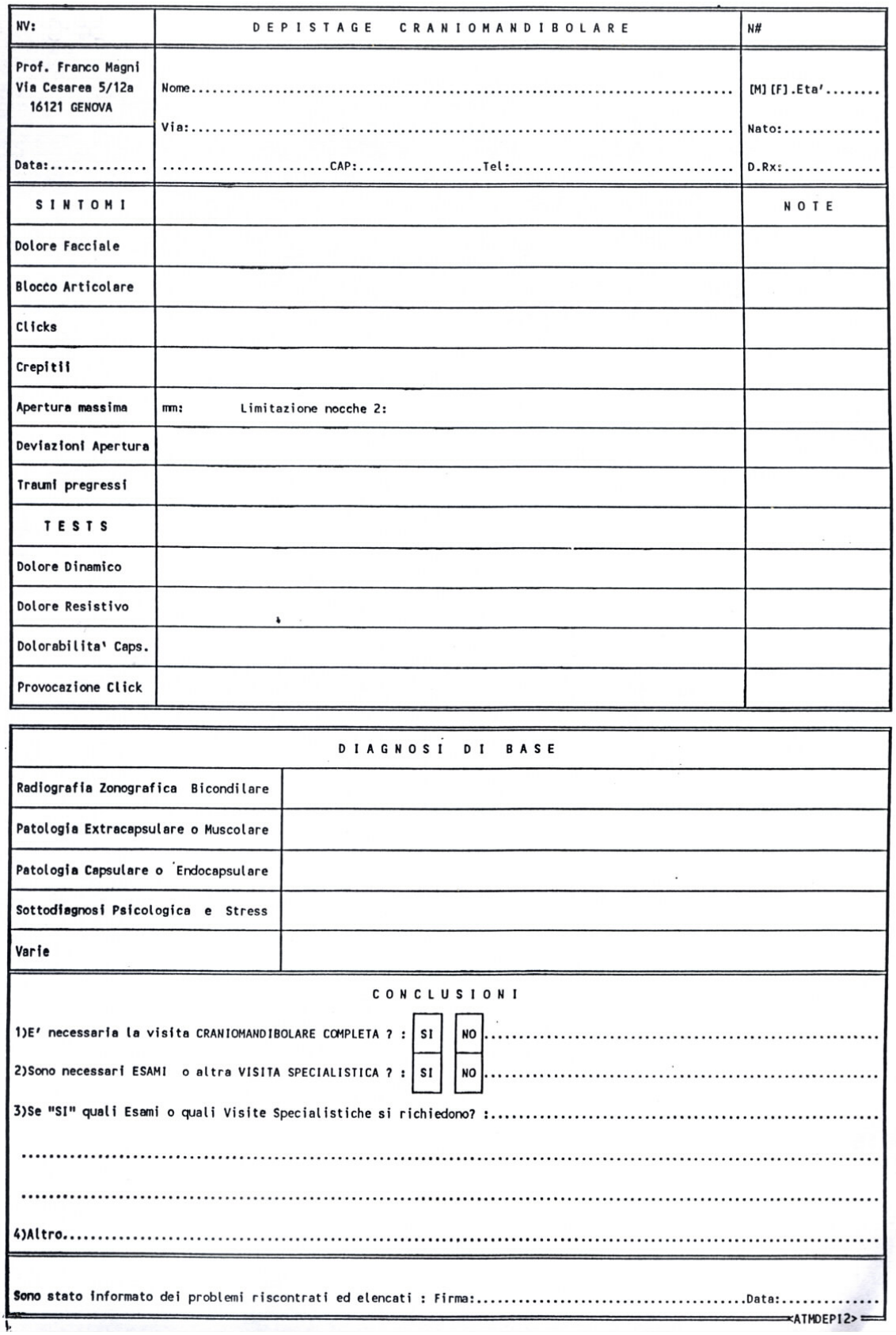
Clinical Visit Data

During the clinical examination the dentist will collect most of the information making use of a mouth mirror, a tongue blade, articulating paper, a Boley gauge and a pair of dividers. This data is more orthodontic specific and is collected in a patients first visit form, as the one in Figure 2.4 on page 11 and eventually also Figure 2.3 on the next page. This information is then digested and stored in a more compact form in the clinical patient record which is used at every visit (see Figure 2.5 on page 12).

These forms contain data such as temporomandibular joint (TMJ) related information, clinical tracking, maximum jaw opening, opening and closing clicks and noises, TMJ pains, asymmetrical movements and limitations, facial type, profile analysis, lip posture, relative symmetry of facial structure, size/shape of nose, muscle activity, classification of malocclusion, examination of teeth, identity of teeth present, tooth to bone ratio, oral hygiene, color/texture of gengivae, labial frenum, tongue shape/size vestibular mucosa appraisal, postural resting position, path of closure from resting position to occlusion, prematurities, point of initial contact, displacement or tooth guidance, range of mandibular motion, clicking, excessive mobility of individual teeth when palpitated by finger tips, skeletal, dental, soft tissues, occlusal function, asymmetry of mandibular lateral movements, breathing habits, cooperation attitudes and capabilities to the orthodontic treatment, growth and development stage, etc.

It is believed that patient posture can influence the outcome of some orthodontic cases (Mew, 2004, Soytarhan and Aras, 1990). Therefore some orthodontists are starting to make use of postural analysis data as well. This is done measuring scoliosis and foot pressure distribution over time. The obtained graphs can then be stored in an analyzed form within the patient record.

In addition, plaster cast analysis data would also fall into this category. This includes all information that can be obtained from measuring and observing a study cast, such as: classification of malocclusion, over-jet, overbite, upper to lower arch midline, palatal contour,



NV:	D E P I S T A G E C R A N I O M A N D I B O L A R E	N#
Prof. Franco Magni Via Cesarea 5/12a 16121 GENOVA	Nome.....	[M] [F].Eta'.....
	Via:.....	Nato:.....
Data:.....	.....CAP:.....Tel:.....	D.Rx:.....
S I N T O M I		N O T E
Dolore Facciale		
Blocco Articolare		
Clicks		
Crepitii		
Apertura massima	mm: Limitazione nocche 2:	
Deviazioni Apertura		
Traumi pregressi		
T E S T S		
Dolore Dinamico		
Dolore Resistivo		
Dolorabilita' Caps.		
Provocazione Click		

D I A G N O S I D I B A S E	
Radiografia Zonografica Bicondilare	
Patologia Extracapsulare o Muscolare	
Patologia Capsulare o Endocapsulare	
Sottodiagnosi Psicologica e Stress	
Varie	

C O N C L U S I O N I

1)E' necessaria la visita CRANIOMANDIBOLARE COMPLETA ? : SI NO .....

2)Sono necessari ESAMI o altra VISITA SPECIALISTICA ? : SI NO .....

3)Se "SI" quali Esami o quali Visite Specialistiche si richiedono? :.....

.....

.....

4)Altro.....

Sono stato informato dei problemi riscontrati ed elencati : Firma:.....Data:.....

<ATMDEPI2>

Figure 2.3: Form used to collect data relevant to TMJ clinical tracking visit data. (Courtesy of Prof. Franco Magni).

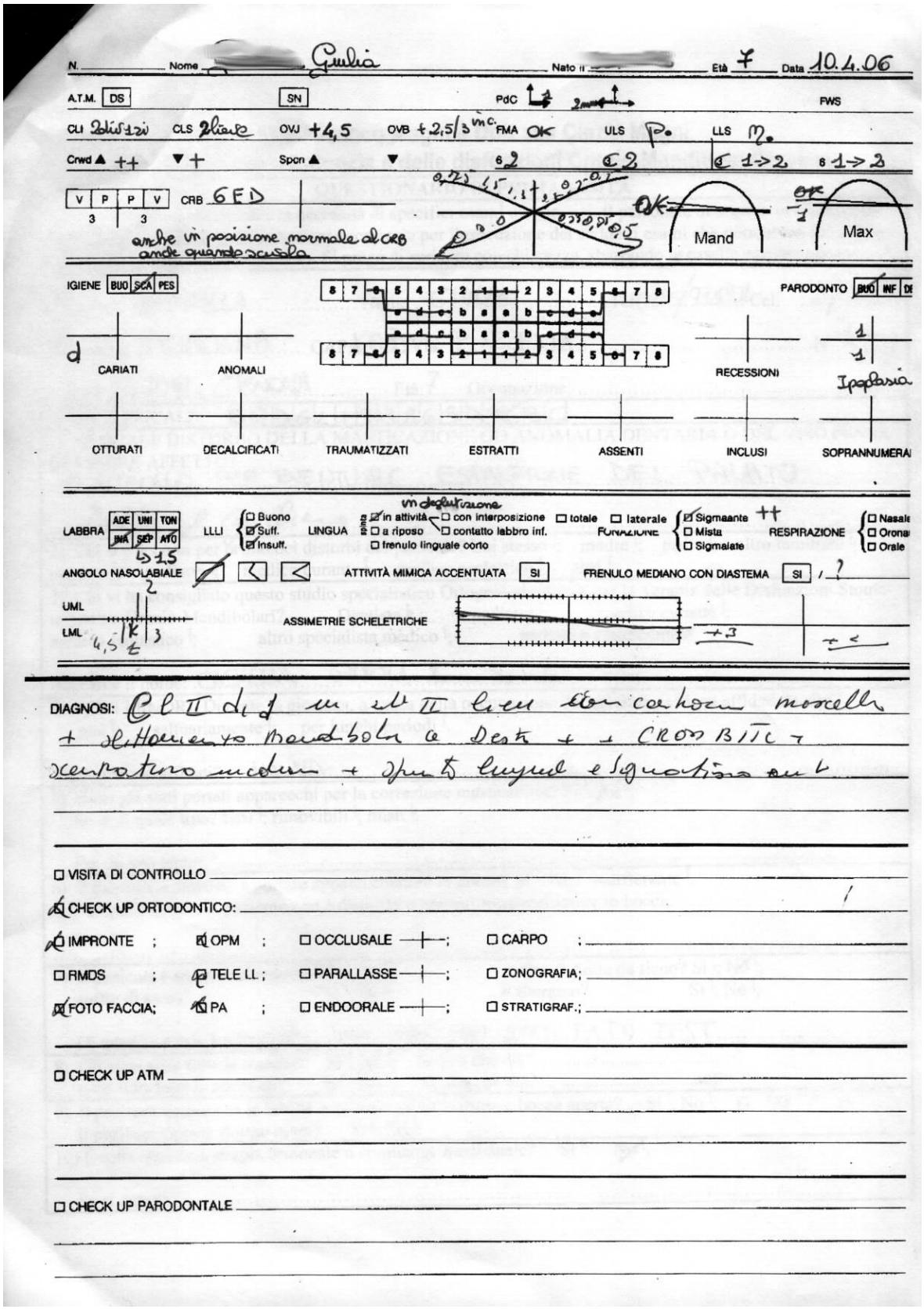


Figure 2.4: Form used to store data collected during patients first visit. (Courtesy of Prof. Franco Magni).

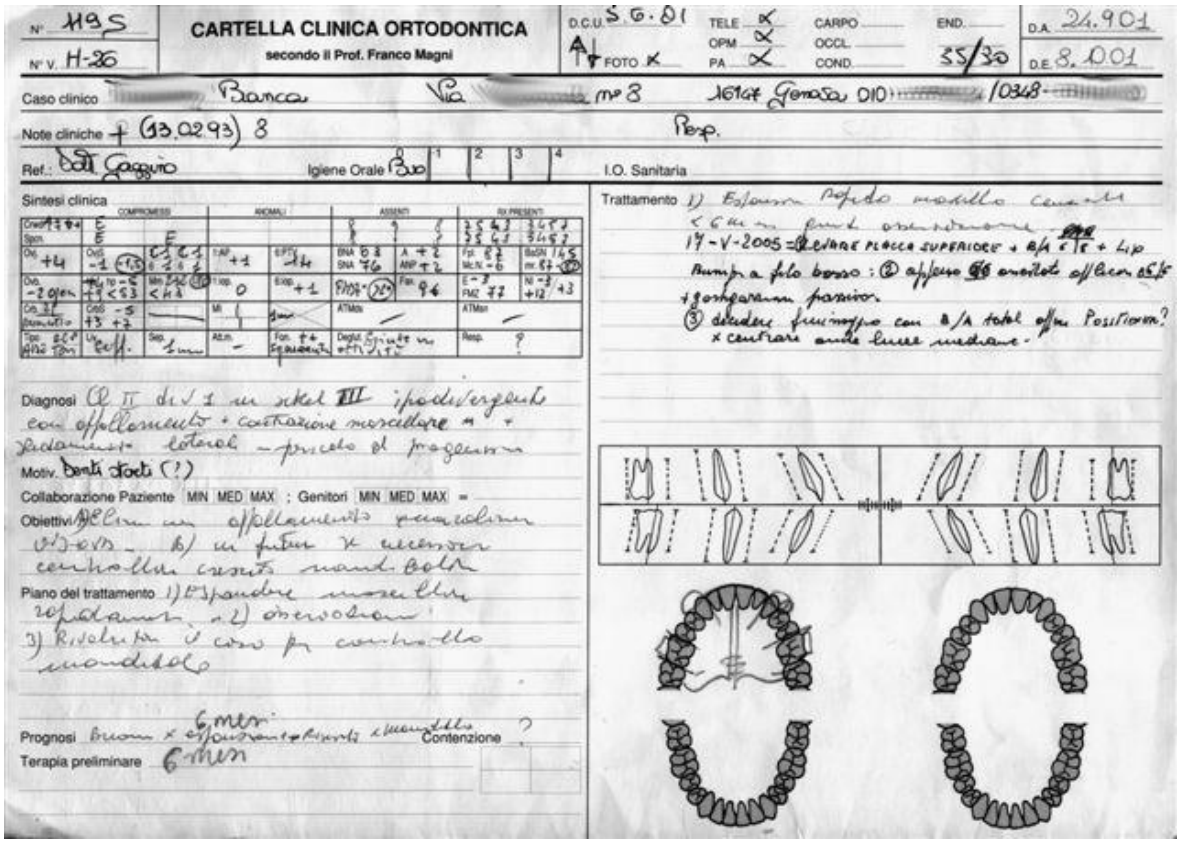


Figure 2.5: Clinical patient record compiled from first visit information. (Courtesy of Prof. Franco Magni).

teeth clinically present, tooth measurements, arch form and symmetry, incisor midline to jaw midline, vertical/horizontal tooth malpositions, abnormal tooth morphology, arch length determination, axial inclination of teeth, facets of wear and muscle attachments.

2.3 IMAGE DATA

2.3.1 Intra-oral and Panoramic Radiographs

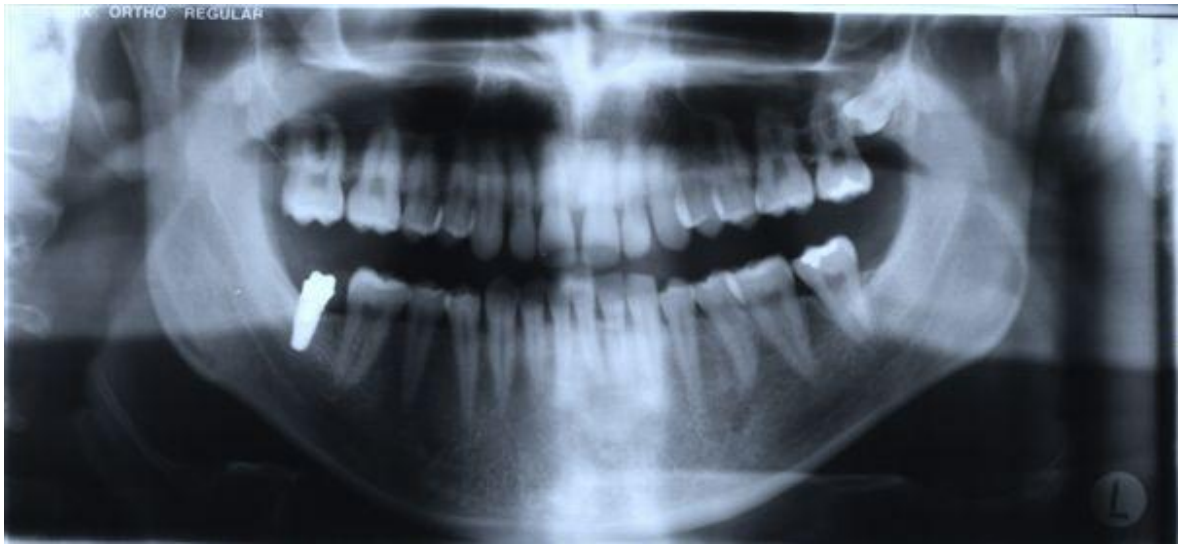


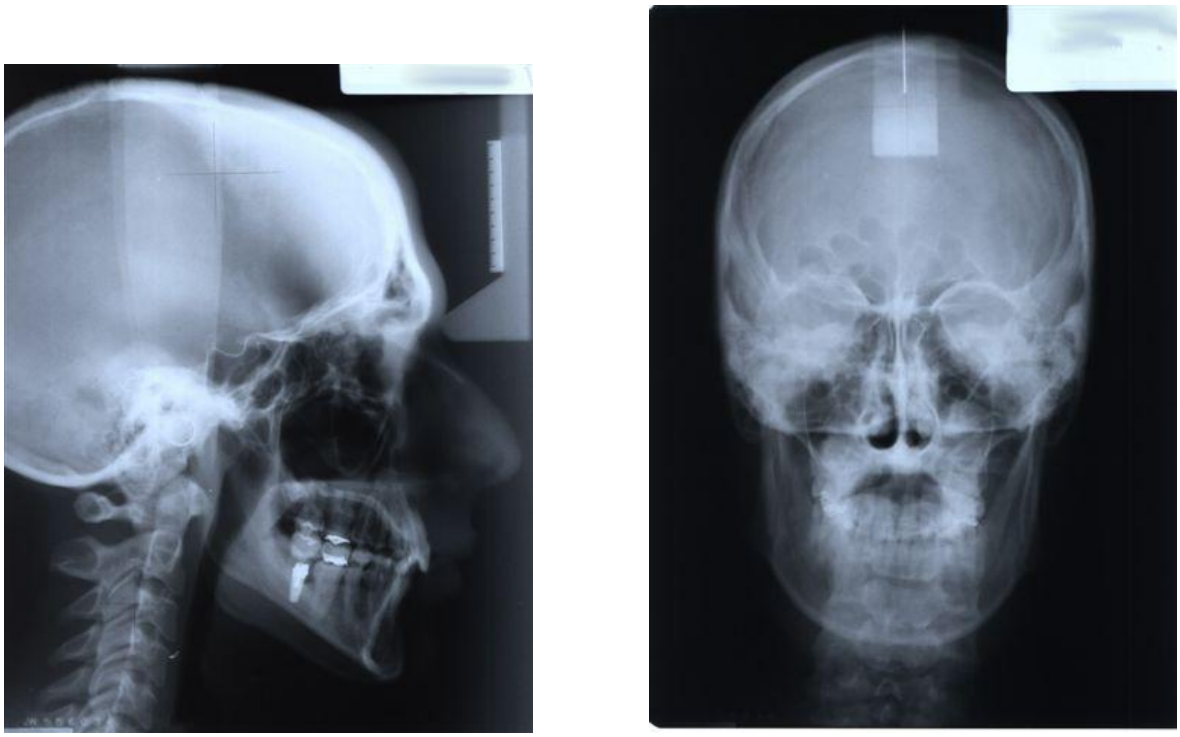
Figure 2.6: A panoramic radiograph. (Courtesy of Prof. Franco Magni.)

As with an iceberg, hidden factors may be of greater importance than those which are readily apparent. An astute orthodontist with sensitive fingers and a sharp eye may palpate canine bulges or note other suspicious bulges in the palate. Indeed he might see a number of things clinically, but he must turn turn to the intra-oral radiograph or panoramic radiograph for confirmatory evidence of his clinical observations. Frequently the information obtained from the radiographic examination may not have been suspected clinically. But dental radiographs by themselves, like study casts alone, are incomplete. Information should be gathered from a number of sources, and should be corroborated or correlated by more than one diagnostic criterion, if possible.

Special consideration must be given to panoramic radiography (Figure 2.6). By virtue of its ability to take a single picture of the entire stomatognathic system (teeth, jaws, temporomandibular joints, sinuses, etc.) important information may be obtained routinely with a fraction of the radiation needed for a full mouth intra-oral examination and without even placing the film in the mouth. The entire picture taking procedure takes less than 90 seconds,

and developing is limited to one film (Graber, 1965, 1967, Hauck, 1970). The panoramic view assists in the synthesis of the diagnostic and therapeutic phases of patient management.

2.3.2 Cephalograms



(a) Lateral (b) Posteroanterior

Figure 2.7: Cephalograms. (Courtesy of Prof. Franco Magni.)

Ever since 1791, anthropologists have been interested in the ethnographic determination of facial form and pattern. Anthropometrics, or "the measurement of man", found the human head a fertile source of information because of the relatively little change in the bony parts as a result of death. By studying different ethnic groups, different age groups, male and female, and by measuring the size of the various parts and recording variations in position and shape of cranial and facial structures, it became possible to devise certain broad standards that were descriptive of the human head. As a specialized part of anthropometrics, study of the head became known as *craniometrics* or *cephalometrics*. Certain landmarks and measure points were developed to assist the anthropologist in interpreting craniofacial relations. Much of what we know today about facial types and growth and developmental changes was first described in anthropological literature (Hellman, 1932).

A cephalogram (Figure 2.7), also referred to as oriented craniofacial x-ray, is an oriented ra-

diograph of the head and face used to make reliable measurements of the subject's anatomy. This is possible by projecting x-rays at fixed and well known angles and distances with respect to the subject. The first paper on radiographic cephalograms was published in 1922 (Pacini, 1922), but cephalograms and cephalostats gained popularity with Broadbent (Broadbent, 1931) and with Hofrath (Hofrath, 1931), both publishing similar techniques in the USA and in Germany respectively.

Even as the conventional intra-oral radiographic examination and panoramic views augment the clinical examination, verifying the clinical impression and providing new information, so also does the oriented craniofacial x-ray picture add to the image of the teeth, jaws and cranium.

Cephalograms are the most inexpensive (financially and in terms of radiation dosage) way to extract three-dimensional measurable data from a subject's skull. This explains their wide popularity in orthodontics. 3D information can be extracted by combining the lateral with the posteranterior cephalogram: with the two projections, a careful and trained eye is able to reconstruct a certain level of depth.

Cephalograms and cephalometry have many applications, including the following:

Study of craniofacial growths Because of the method's reliability, subjects may be examined repeatedly, permitting comparisons of the cephalograms. Serial cephalometric growth studies of both humans and animals have been a a major factor in broadening the knowledge of craniofacial growth. This is very valuable in orthodontics, as it allows for a more accurate treatment planning therefore improving patient treatment.

Planning of orthodontic treatment Although cephalometric studies revealed that a normal occlusal relationship could be obtained in a variety of forms, clinicians soon began to realize that some positions of teeth were more stable than others after treatment and that orthodontic treatment goals could be quantified by means of cephalometric geometry. Thus, cephalometric analyses evolved, permitting the orthodontists to plan, prior to treatment, the desired position for each tooth within a given patient's skeleton.

Evaluation of treated cases Cephalometric analysis of treated cases has revealed much concerning the nature of orthodontic relapse and the stability of treated malocclusions.

Cephalometers

A cephalomter is the equipment needed to produce cephalograms. It consists of a cephalostat, an x-ray source and a cassette holder all at a fixed known distance from each other[4]. The cephalostat is a device used to position the head in a desired orientation. Cephalometers allow the patient to be placed facing the cassette holder for posteroanterior (PA) cephalograms or perpendicular to the x-ray beam for lateral cephalograms[5]. The position of the patient's head is very important because it is necessary to produce reliable measurements. If, for example, in a PA cephalogram, the patient tilts his/her head[6] too much, the resulting cephalogram will be either elongated or shortened. Measurements taken from this distorted cephalogram will not match those of its matching lateral cephalogram and will therefore be useless. This explains the importance of the cephalostat.

Nonetheless, some distortion is unavoidable and arises from a different source: the point-like nature of the x-ray source prevents its beams from leaving the tube parallel to each other. Consequently, the image produced by projecting the shadow of such radial beams on a film will be magnified. This kind of distortion can be minimized by placing the x-ray source further away from the subject: the greater the distance between subject and x-ray source, the more parallel the rays, and the smaller the distortion. This is a similar effect of when a lamp is placed very close to a subject, and its shadow is observed: the further the lamp, the more the shadow will be a faithful projection of the subject.

It then becomes a question of finding a good equilibrium between distortion and space. Research (Broadbent, 1931) has shown 152.4cm (or 5ft) (between the x-ray source and the subject) to be the minimum distance necessary to produce a radiograph with acceptable distortion.

Magnification

When working with x-rays, one has to accept the fact that magnification and distortion cannot be fully avoided. Differently from visible light, x-rays interact only weakly with matter and are not affected by electric or magnetic fields. It has therefore been a challenge to produce

[4]Usually 152.4cm (60in) between x-ray source to mid-sagittal plane, and 18cm (7.09in) between mid-sagittal plane and film.

[5]An exception for the Broadbent-Bolton cephalometer which utilizes two x-ray sources and two film holders so that the subject need not be moved between the lateral and PA exposures. In this case the cephalostat is fixed in one position.

[6]The cephalostat secures the head by the ear, hence avoiding lateral head movements, but the rotation about the transmeatal axis (axis that passes through both ears) is still possible.

optics that produce sufficiently large deflections. It is not practical to build and make use of x-ray optics, which explains why they are not used in x-ray devices like cephalometers to correct for distortion and to avoid magnification.

Cephalometric magnification also depends on the distance between the subject and the film: the further away the film from the subject, the greater the magnification. In order to be able to relate the distances on the cephalogram with those on the subject, the magnification factor is a necessary piece of information. Hence, the distance of the film from the subject and from the x-ray source must be known. Conventionally, the distance between the source and the subject is never changed. So the magnification solely depends on the location of the film cassette.

In order to obtain an image with the highest quality, the film cassette has to be placed as close as possible to the subject. This, though, requires the technician to record the distance between the film cassette and the mid-sagittal plane of the subject for each patient. In addition, the orthodontist has to perform different conversions for each patient each time he/she needs measurements from the cephalogram. This explains why some prefer maintaining the distance between the patient and the film always fixed (e.g. 6in to give a magnification of 10%, when the tube is placed at the standard distance of 60in from the subject). This produces slightly less contrasted images[7], but greatly simplifies the conversion between cephalogram and subject distances.

SB Corner Fiducials

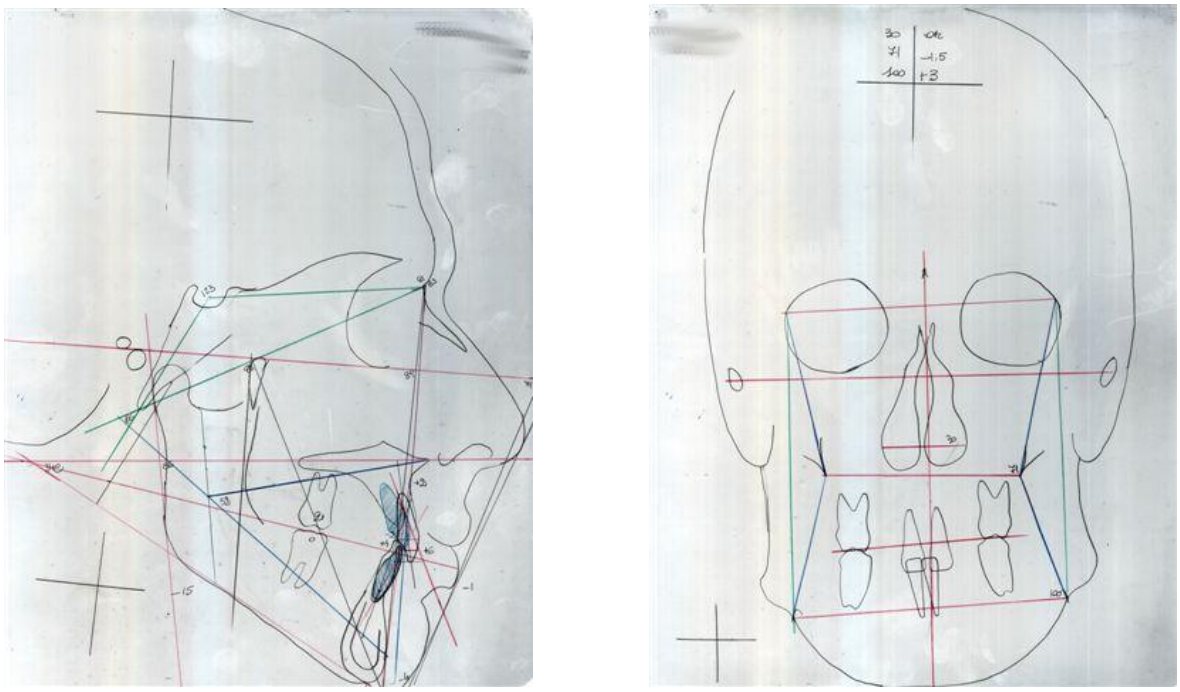
SB Corner Fiducials are used to guarantee consistency between the analog x-ray and its scanned digitized version. They consist of four pinholes punched with a template on the film at known distances. Once the film is digitized, these pinholes are located on the computer and compared to the distances of the holes on the template. The digital cephalogram is then only considered accurate if the distances between the digital fiducials match the distances of the fiducials on the template.

The name SB comes from Sheldon Baumrind, who first published the use of these fiducials in (Baumrind and Miller, 1980). Initially they were used to superimpose replicate "tracings" of the same sets of landmarks, however the fact that different users employ different scan resolutions when scanning older analog images, coupled with the ease with which the aspect ratios of images can be altered, appears to have made the use of the SB fiducials in the digital

[7]The further away the film from the x-ray source, the dimmer the image.

application even more important than before.

2.3.3 Tracings (Cephalometric Analysis)



(a) Lateral (b) Posteroanterior

Figure 2.8: A tracing of anatomical contours and cephalometric planes. These are obtained by placing a trans-lucid sheet over the lateral cephalogram, and identifying anatomical landmarks on it. (Courtesy of Prof. Franco Magni.)

A number of so called "analyses" have been developed by orthodontists to assist in evaluating the original malocclusion and in projecting what the measurements should be at the end of orthodontic treatment. These analysis are usually confined to the lateral cephalogram with the teeth in occlusion.

Analysis are performed by identifying landmarks on the radiograph, and connecting them to form lines and planes. Distances between points, and angles between lines and planes are compared to standards. Traditionally, these drawings are performed on trans-lucid overlays, which contain anatomical contours as well as the traced lines and identified landmarks (see Figure 2.8).

There are three basic components of a representative cephalometric analysis: skeletal, profile and denture, each of which with a different purpose. The intention of this document is not to detail cephalometric analysis but rather to expose the reader of its vast domain.

2.3.4 Tomography (CBCT)

Cone Beam Compute Tomography (CBCT) is a new imaging technology that is substituting other forms of x-ray patient imaging in the orthodontic field. It consists of a special CT scanner which is capable of scanning the same area as a regular CT scanner with one tenth of radiation dosage. This is possible because it only rotates around the subject once, making use of a cone shaped x-ray beam (instead of a much finer, more collimated beam), and a much wider detector.

The process can be better understood by imagining the CBCT scanner as a rotating cephalometer: by taking cephalograms at various angles, the computer has enough information to be able to (a) reconstruct a full volume of the imaged subject and (b) correct for the distortion introduced by the cone-shaped beam. The radiation dosage therefore lies between a CT scanner (most dosage) and a pair of lateral and posteroanterior cephalograms (least dosage).

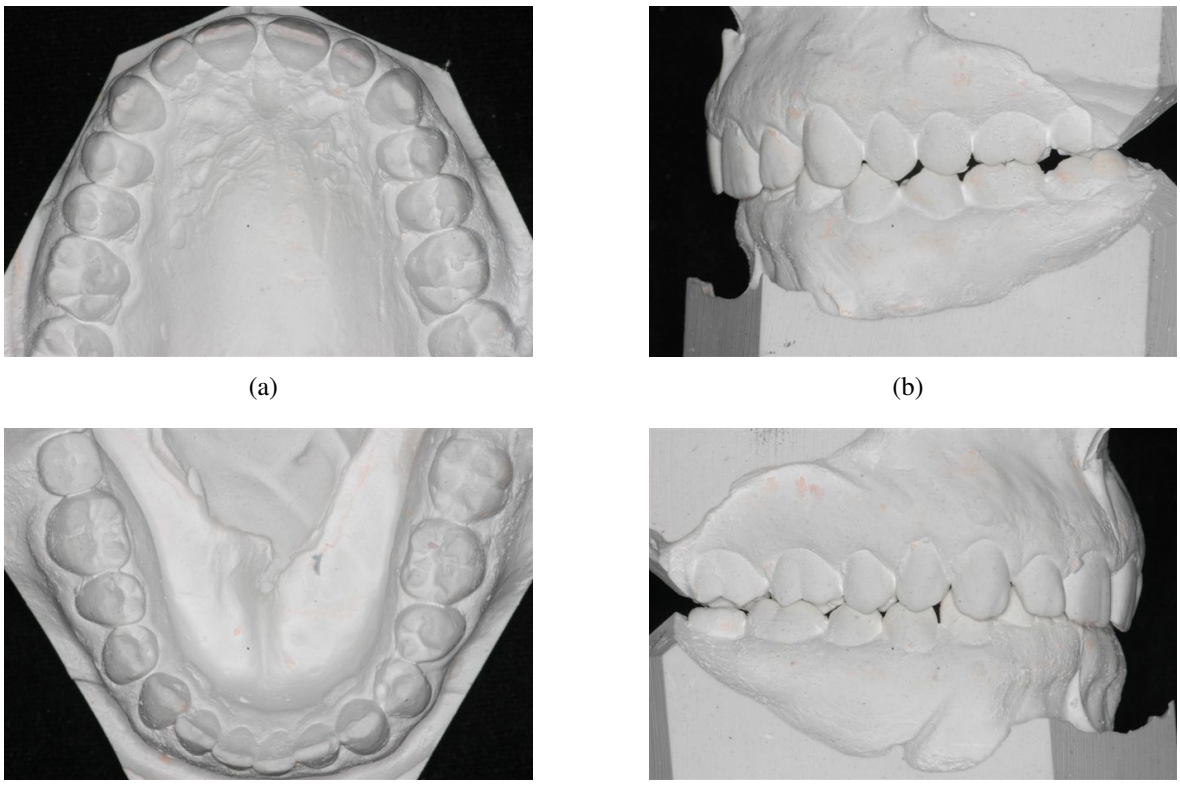
Although the resolution of the images produced by CBCT scanner will never be able to compare with that obtained from a regular CT scanner, it seems to be high enough for accurate orthodontic measurements.

2.3.5 Plaster Study Casts

Plaster casts provide a reasonable facsimile of the occlusion of the patient (Figure 2.9 on the following page). Despite a comprehensive clinical examination, it is still better to have a set of plaster casts to correlate additional information from intra-oral and cephalometric radiographs. Study casts taken at a particular time in the development of the child provide a permanent record of the time-linked situation. In addition, study casts are also needed for the production of orthodontic appliances.

2.3.6 Photographs

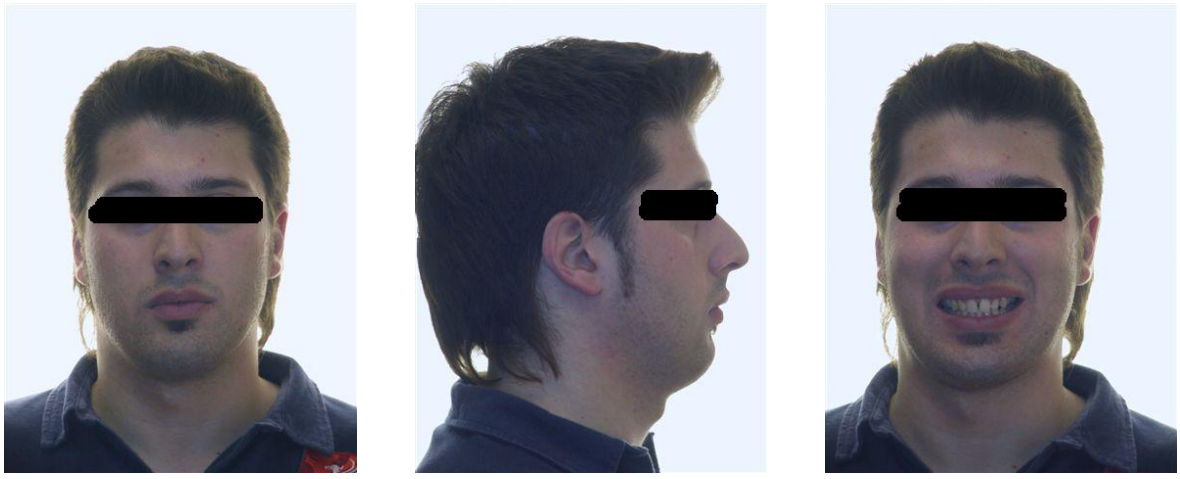
Even as plaster casts serve as a record of the teeth and investing tissues at a specific time, so does the photograph. The photograph assumes even greater importance when the dentists does not have equipment permitting him/her to take cephalometric head-plates (Graber, 1972, p.428). Facial harmony and balance are considered important therapeutic objectives by the orthodontist. A permanent record of the original profile and full face appearance (making use of extra-oral photography, Figure 2.10 on the next page) as compared with sim-



(a) (b)

(c) (d)

Figure 2.9: A symmetrically smoothly finished study cast. (Courtesy of Prof. Franco Magni.)



(a) Frontal at rest (b) Lateral at rest (c) Frontal smiling

Figure 2.10: Extra-oral photographs. (Courtesy of Prof. Franco Magni)

(a) Superior arch (b) Left side

(c) Inferior arch (d) Right side

Figure 2.11: Intra-oral photographs. (Courtesy of Prof. Franco Magni.)

ilar post-treatment records is a graphic example for both patient and parent of what can be accomplished by orthodontics. The same holds true for intra-oral photographs (Figure 2.11) which also constitute a non-invasive record of treatment progress.

2.4 THE NECESSITIES OF TODAY'S ORTHODONTIST

A discussion of the requirements that orthodontists have developed over the past 10-15 years is discussed in this section.

During the development of the digital era, it frequently was the case for technology to be ahead of the user. Much of such development was caused by industry basing its designs on what technology could offer rather than on what the consumer would use. This caused the production of devices with for example, 30 features, when the user really would only make use of maybe 5 or 10. The result was a system very difficult to use, very complex and not so reliable. Experience teaches to pay more attention to the consumer's demands.

For this reason, it is important that this project focuses on the orthodontist's demands, which can be summarized in four main requirements. The orthodontist needs:

1. A way to easily exchange patient data between colleagues;
2. A way to easily port patient data from one system to another;
3. A way to share patient data between different software systems within the same practice, thus eliminating the need of having to maintain different sets of the same patient data;
4. A way to secure patient data, s.t. patient's rights will not be violated (i.e. implement Health Insurance Portability and Accountability Act (HIPAA) regulations);

Exchanging data between colleagues is necessary to be able to cope with situations as described in the introduction: clinical communcation between orthodontists (as holds true for any other medical specialization) means better patient care. Today this is not possible, as different software products do not have a fully developed "export/import" option.

When changing system or software vendor, the orthodontist believes he/she should be able to move all of his/her clinical data from the old software to the new software, without extra expense, major time investment, or any kind of hindrance. This has become a mojor concern ever since the development of various different orthodontic software products.

This same development has caused yet another need: to be able to use different systems at the same location at the same time. It is often the case, in fact, that different orthodontic software products co-exist in the same practice (for different applications). Hence, software products not only need to be able to export or import a whole set of patient data, but they also need to be able to deal with a centralized patient data base. This would allow various applications to keep their clinical data efficiently synchronized.

With the recent government intervention on patient privacy, orthodontists are also concerned about their patient's confidentiality. They believe that computers should be able to automatically deal with all necessary tasks required to ensure full HIPAA (or other equivalent non-US regulations) compliance.

Basically, orthodontists need common definitions, structures, formats and encodings of data relevant to the orthodontic treatment of patients, in a language- and platform-neutral and extensible fashion. There is also a demand for application-level protocols for the secure and reliable data exchange between applications and sites, with the goal of facilitating sharing and collaboration between patients, doctors, other therapy and service providers, etc (Align Technology Inc. et al, 2004). Many software products have been developed for various

orthodontic related tasks, ranging from clinical to administrative use. Yet none of them conform to a well accepted international standard. In fact, current digital dental standards do not adequately cover all the requirements of the orthodontic domain. Orthodontics has information elements related both to treatment[8] and imaging that do not exist in the dental domain. A new standard that covers the structure formats and relationships of these additional elements is needed (Harrell et al., 2005), as it would be the most complete solution for the four main requirements described above.

The following chapter focuses on informatics standards and their development first in general, then specifically for three well established medical informatics standards.

[8]Diagnosis, treatment planning, outcomes analysis, appliances, root anatomy.

3 STANDARD ASSESSMENT

This chapter is divided in three parts: the first section, 3.1, deals with the process involved in developing and releasing an informatics standard. Sections 3.2 to 3.7 contain a revision of three analyzed standards and their respective standards developing organization. Finally, section 3.8.1 is used to present the reader with the authors proposed solution to the problem.

The next chapter, Chapter 4, focuses on one particular detail of the solution presented in section 3.8.1. It was decided to limit the scope of this work because the implementation of the full solution is too large a project for a Master's Thesis.

3.1 WRITING AN INFORMATICS STANDARD

Creating an informatics standard involves various steps: forming a community, defining the domain, research, defining the technology, building the standard, ballotting/releasing and finally implementing and testing. Special attention must be given to defining the domain and defining the technology, as they are the two steps which will have the greatest amount of influence on the outcome of the standard.

While true that the information contained in this section is applicable to any informatics standard, these general concepts have been blended with the current status of the Ortho-EPR development. Most work is currently being done by members of the ADA SCDI described in detail in 3.6 on page 62. This explains why the reader will find various references to this association.

Forming a community

The process of developing a standard starts by forming a community of interested parties which eventually develops into a formal body. In order to achieve this, on May 2004 a new working group within the American Dental Association (ADA) Standards Committee for Dental Informatics (SCDI) was formed by Philippe deSmedt (Align Technology) and Steve Bartingale (3M). Called *WG11.6 Integration of Orthodontic Standards*, this working group as of today counts with the membership of 3M, University of Northern Carolina, University of Illinois at Chicago (Illinois, USA), University of the Pacific (San Francisco, CA, USA), University of Missouri Kansas City (USA), Case Western Reserve University, University

of Pittsburgh (PA, USA), Loma Linda University (Los Angeles, CA, USA), Universidade de Brasília, Kodak, Dolphin Imaging, Ortho Computer Systems, Inc., Orametrix and Drake Visual LLC.

The process of community-forming has successfully created a formal group (ADA WG 11.6) of interested parties from academic, commercial (industry) and clinical fields.

Defining the domain

Domain is the specific sphere of activity and working elements of a given project. The domain is defined through a combination of diagrams[9] and written text to represent each individual real-world scenario that need to be represented by the standard.

This is one of the most important steps during the development of an informatics standard, as it creates the skeleton of the standard itself. The future of the standard is set during this process: if one defines the domain to be too broad, the standard development process could become unnecessarily complicated. On the other hand if the domain is defined to be too narrow, down the road it might happen that some necessary data is not accounted for, requiring a major restructuring of the standard.

Once the domain has been clearly defined through diagrams and text, data types and attributes can be defined for each scenario. These can later be translated into a specific standard language (like HL7 (see section 3.2) or DICOM (see section 3.4)).

It has been decided for the domain of the standard to include all orthodontic data currently used in digital format. This encompasses the entire orthodontic domain, which can be grossly divided in imaging data (photos of patients, x-rays, CBCT scans, . . .) and non-imaging data (patient demographics, clinical information, financial information, . . .) (see 2 on page 5). A more refined definition is currently taking place within ADA SCDI working group 11.6 (see section 3.6), and will produce a collection of use cases with associated required data types and attributes.

[9]For these diagrams, the use of UML use-case diagrams is suggested. Nonetheless, any kind of modelling diagrams that helps convey the point can be used. For example, Specification 1000 (see section 3.6.2) employs the U. S. Federal Information Processing Standard (FIPS) modeling methodologies IDEF0 and IDEF-1X.

Research

This step involves researching existing standards and their respective developing organizations with the intent to decide whether to adhere to an existing standard/organization (and if so, which one) or whether to start a new standard/organization. The infrastructure of an existing organization can greatly simplify the development process of the Ortho-EPR. For this reason, preference is given to the adhesion to existing standards.

A preliminary evaluation of existing imaging, medical, dental, orthodontic, other data and data exchange standards[10] has already taken place. Its results can be found in sections 3.2 to 3.7. The author evaluated the organizations, their internal processes and implementations as well as the structure of their standards to find a match for this project. A more in depth analysis will take place in the form of a gap analysis, once the domain has been defined (as specified above).

The research process will see the collection of various proposals from the group members of ADA SCDI WG 11.6. Proposals should contain a brief summary of the suggested standard, how it would benefit the development of the project as well as the details of the relationship between the working group and the mentioned organizations.

Define the technology

Based on the documents delivered in the previous phase, there will be a meeting for the group to decide which proposal(s) to advance. Upon reaching a consensus on which path to take, the group will deliver a document specifying which standard organizations to adhere to and the details of the relationship between this group and the external organizations. The document will include how to divide the group into subgroups to work towards the delivery of the final product.

A standard can only be considered succesful if it is implemented by many vendors. Therefore, during this stage one must keep into consideration not only the technical and practical details of each standard/organization, but to also their implementability. In fact, which technology to use will greatly affect the divulgation and the implementation of the standard itself. Adhering and extending a standard that is widely accepted and implemented amongst hospitals and clinics will probably have greater chances of success than writing one from scratch,

[10] Such as DICOM WG 22 (Dentistry) and American Dental Association WG 12.1 (DICOM) for imaging data, HL7 for patient data, IGES (or perhaps STL or VRML) for geometry, CDISC and ADA(/ANSI) SCDI dental informatics standards, among others.

or extending one that has never been implemented, even if this decision implies a greater amount of development time.

The above mentioned considerations make this a crucial step of the standard development which, just like defining the domain, has a great impact on the future of the standard itself.

Build the standard

In this phase each subgroup will work individually according to the plan established in the previous phase. At the end of this task, the individual work will be harmonized in order to put together the Ortho-EPR standard.

This phase will deliver a first draft of the Ortho-EPR standard.

Ballot and Release

The first draft of the standard delivered in the previous phase needs to be balloted, such that every steakholder may have a chance to review it. This process will cause revisions and re-balloting, eventually delivering a first implementable release of the standard.

Implementation and Testing

The first release of the standard must get implemented and tested before it can be considered complete. Subgroups formed primarily by vendors and software developers should take over this task to produce software that can handle orthodontic information stored or transmitted in the newly developed format. Should this stage highlight errors, a new cycle of revision, balloting, release, implementation and testing will take place. Hence, it is foreseeable that once this stage has been reached, the group will find itself cycling between balloting, releasing, implementing and testing until a satisfactory version of the product is delivered.

The following sections contain a summary of the research on HL7, DICOM and ADA/ANSI Specification 1000 standards and could be considered a deliverable of the research phase described in the research section described above. These three standards and their respective

organizations have been chosen based on the fact that they are the most prominent, better defined and developed medical informatics standards available to the public. However, each standard evaluation contains a section which compares these to existing similar standards. Here the reader can find a more specific information on other standards.

These documents were analyzed keeping in mind how they could be used in an orthodontic context.

3.2 HEALTH LEVEL SEVEN (HL7)

This section aims to introduce HL7 and to expose the process of its refinement. The refined HL7 would allow the transfer of orthodontic electronic data using an already existing and well established standard. Binary data such as images are not part of HL7, which requires the cooperation with another standard: HL7 suggests the integration with DICOM to represent imaging data.

This section is organized in the following way: context of the standard, introduction to HL7 and its core elements, summary of what is needed to refine the standard and a list of items that need to be taken care of while writing the digital orthodontic standard in HL7. The intention is to provide the reader with a summary of what HL7 is and how it could be applied to orthodontic data.

3.2.1 The Organization

HL7 is the acronym for both an organization and the standard that the organization supports and maintains. This and the next section contain an introduction to HL7 as an organization and a standard respectively.

Founded in 1987, Health Level Seven is an American National Standards Institute (ANSI)-Accredited Standards Developing Organization (SDO) which focuses on the electronic interchange of clinical, financial and administrative information among independent healthcare-oriented computer systems. HL7 is a not-for-profit volunteer organization whose members are providers, vendors, consultants, government groups and others who have an interest in the development of healthcare standards. According to HL7(The Health Level Seven, 2005b, p. 2), 90% of healthcare system vendors are members, comprising over 2,200 health industry members. HL7 was designated by the ANSI as an ANSI-accredited SDO and since then has

published and received ANSI approval for various medical standards. HL7 collaborates with 14 other standard committees and has affiliates in 27 different countries.

The organization is well structured and subdivided in 26 Technical Committees (TC) and 18 Special Interest Groups (SIG). TCs focus on the creation, maintenance and extension of the HL7 Protocol Specifications, each of which specializing on a different subject matter. SIGs are concerned with projects that aid the application and implementation of the standard itself. The Java SIG, for example, is concerned with developing a Java Application Programming Interface (API) to the HL7 information model.

The goal of HL7 is to specify a standard way for programs of different vendors to be able to communicate by easily exchanging patient data. It focuses on the communication level, defining how to build a well formed message that can be read by HL7 complaint systems. It does not cover the format in which data should be stored. The documentation is very specific and makes frequent use of pseudo-code, flow charts and UML diagrams (for example to aid the reader in understanding how to compose a well formed HL7 message).

Currently, the members of HL7 are working on version 3 of their standard. They claim it to be substantially more advanced and more complete than their previous version 2. The latest ANSI approved version, however, is still 2.5.

3.2.2 The Standard

As a standard, HL7 is an application protocol for electronic data exchange in healthcare environments. The number seven refers to the highest level of the International Organization for Standardization (ISO) communications model for Open Systems Interconnection (OSI) - the application level. The application level addresses definition of the data to be exchanged, the timing of the interchange, and the communication of certain errors to the application. The seventh level supports such functions as security checks, participant identification, availability checks, exchange mechanism negotiations and, most importantly, data exchange structuring.

The HL7 developed documentation to structure medical information in a universal and coherent fashion. The different object classifications and subdivisions are mainly oriented towards textual information. That is, HL7 did not deem necessary to define how to encode or store binary data (i.e. digital images, movies, audio files, 3-dimensional volumes, ...). Many different encoding formats for such data have already been developed, making it unnecessary for HL7 to define a new one. Instead, HL7 created a well organized structure for all medical

knowledge, including a placeholder for binary data. Thus, if it were necessary to send a patients X-ray over the network using HL7 messaging, it would first be necessary to choose which format to save and send our X-ray in (hopefully picking one that is readable at the receiver's end!). Next the X-ray would be wrapped by a newly created HL7 message. At this point the X-ray could be transferred between HL7 compliant systems.

Although HL7's latest approved ANSI standard is version 2.5, over the past 14 years HL7 has been working on version 3, which is still in a ballot state.

Version 2.x (v2)

ANSI has approved the first version of HL7, v2.1 back in 1991: currently version 2.5 is the latest ANSI approved[11] version. It specifies a set of rules on how to organize medical data so that it can be sent and received across networks and removable devices efficiently and reliably. This is all taken care of at the application level only, as basic network operation, such as error control, character conversion and message length are assumed to already be taken care.

Data is transferred using atomic units called *messages*. Within each message, data *fields* are grouped in *segments*. Each field is nothing but a string of characters with attributes[12] associated with it.

Version 2.x is a simple static documentation of messages and their fields. It does not define interactions between processes and actors. In addition is not encoded using XML. It uses a system called *vertical bars*[13] instead. However, HL7 has released a document on how to encode HL7 messaging version 2.x using XML(The Health Level Seven, 2003b).

Although widely[14] used and still an international standard, Version 2.x is being phased out. HL7 thought it was necessary to make major improvements that would require a complete reorganization of the methodology used to develop the specification. The following quote of the introduction to the manual(The Health Level Seven, 2006) helps better understand why the organization began a new, completely revised edition of their standard:

[11] Approved on June 23, 2003.

[12] These are position, max length, data type, optionality, repetition, table, ID number and name.

[13] Vertical bars (a.k.a. "pipe" character) are used to separate the fields in the messages. Hence the name.

[14] According to HL7 board members, 90% of hospitals in the USA make use of some kind of implementation of v2.x

> The HL7 v2.x development process is entirely ad-hoc. There is no explicit methodology. Members receive no formal guidance in constructing messages. Trigger events and data fields are described solely in natural language. The structural relationships among data fields are not clear. Segments are reused in many messages and message definitions are reused for many trigger events. In order to accommodate this extensive reuse, most data fields are optional. Chapters are inconsistent in their use of trigger events versus status codes. There is no specification as to when a specific kind of healthcare information system should be expected to honor a trigger event or accept a message.
>
> With v2.x, a Technical Committee creates messages by editing word processing documents directly. The meta-data is not available in a structured form until the staff and volunteers tediously extract it from the word processing documents after publication.
>
> In summary, there is substantial need to improve this old process in order to handle the breadth and complexity of the challenges HL7 faces today. Our industry will benefit because this new process results in a more rigorous specification.

In addition, Version 2.x does not take care of security and patience confidentiality(The Health Level Seven, 2003a, p. 1-13) and is silent on messages to support the integration of a patients health record across multiple delivery entities of a healthcare delivery system. This would also include messages to insure central control and integrity of information that was "merged" between multiple delivery entities. (The Health Level Seven, 2003a, p. 1-15)

Despite the above mentioned drawbacks, development of v2.x still continues. HL7 is working on 2.6 and some Special Interests Groups of HL7 are talking about 2.7. This is because it has been widely implemented and it works. The transition to HL7 v3 would be very costly, and to the front-end user, it would not show any apparent change.

Version 3 (v3)

In 1992 HL7 made a fundamental shift in the methodology used to develop its standard specifications. The new methodology, referred to as HL7 Version 3.0 or just v3, is a model-driven methodology based upon modern object-oriented software and domain modelling practices. The v3 project represents a new approach to clinical information exchange. It is built from the ground up around a single object model, the Reference Information Model (RIM) and a rigorous UML based methodology that ties model to messages and finally to the message's

expression in XML syntax.

The v3 specification is built around subject domains, for each of which it provides storyboards descriptions, trigger events, interaction designs, domain object models (derived from the RIM), hierarchical message descriptors (HMDs) and prose description of each element. Implementation of these domains further depends upon a non-normative v3 Guide and normative specifications for data types, the XML Implementable Technical Specifications (ITS) (or message wire format), message control wrappers and transport protocol. HL7 v3 is the most definitive HL7 standard thus far, incorporating more trigger events and message formats than any previous version.

HL7's primary goal for v3 is to offer a standard that is definite and testable, and to provide certification of vendor's and implementer's conformance. Thus the development principles behind v3 lead to a more robust, fully specified standard.

Effectively, the main difference between v2.x and v3 is that v3 specifies actors and processes and the relationship between them along with how to send and encode messages. v2.x only deals the messages themselves.

As of the time of this writing[15], v3 is still in a ballot state, although it has just released its first revision (the documentation was shipped out to members in November 2005).

Further discussion and analysis will be limited to v3 only. In our opinion the orthodontic community would not benefit from using v2.x.

3.2.3 Building blocks of v3

In order to make any of use of the standard, it is essential to first understand its basics. v3 is not a simple read: its concepts are abstract and complex. In this section the reader is presented with the elements of v3 necessary to understand the refinement process described in Section 3.2.4. This is not a comprehensive description of HL7 v3.

HL7 messaging components can be of two types: static and dynamic. Dynamic components describe interactions between systems (Storyboards (Sec 3.2.3), application roles (Sec 3.2.3), trigger events (Sec 3.2.3) and interactions), while static components describe the static content of the messages (D-MIM (Sec 3.2.3), R-MIM (Sec 3.2.3), HMD (Sec 3.2.3) and MT

[15] December 2005.

(Sec 3.2.3)).

Static components: RIM

At the heart of v3 there is an *Information Model Component* such called *Reference Information Model* (RIM). The RIM serves as a common source of information for the entire specification. It provides an explicit representation of the semantic and lexical connections that exist between the information carried in the fields of HL7 messages. The RIM is used to express the information content for the collective work of the HL7 Working Group. It is the information model that encompasses the HL7 domain of interest as a whole(The Health Level Seven, 2006, Sec. 2.2.2). In other words the RIM provides a means of specifying the information content of messages through a common information model that clarifies the definitions and ensures that they are used consistently across all v3 messages defined by all Technical Committees.

The HL7 RIM is a critical component of the v3 development process. It is the root of all information models and structures developed as part of the v3 development process. It is the heart of the HL7 v3 standard.

The RIM is documented using pure UML diagrams. The RIM is built in an object-oriented fashion, making use of *classes*[16], *generalizations*[17], *associations*[18], *data types*[19] and *attributes*. Class attributes are the core components of the information model. They are the source for all the information content of HL7. The RIM contains six core classes (Act (Actions), Entity (People, Places and Things), Role, Act_Relationship (connects Acts), Participation (connects Roles to Acts), Role_Link (connects Roles)) from which all other classes derive.

The majority of attributes are descriptive in nature. All of these elements are controlled by *constraints*[20] and *vocabulary*[21].

Furthermore, the documentation contains a whole section that defines the implementation

[16] A *class* is an abstraction of things or concepts that are subject of interest in a given application domain. Classes are the people, places, roles, things, and events about which information is kept. Classes have a name, description, and sets of attributes. Instances of classes are called *objects*.

[17] A generalization relationship is a connection between classes (as opposed to objects).

[18] An association defines a relationship between objects.

[19] Data types are the basic building block of attributes. They define the structural format of the data carried in the attribute and influence the set of allowable values an attribute may assume.

[20] Constraints narrow the set of possible values that an attribute can take on.

[21] A vocabulary domain specifies all valid values in an instance of a field or attribute.

technology, called ITS or *Implementation Technology Specification.* This part defines how to represent RIM objects for transmission over some kind of media (email, CD, removable disks, ...). This is the most low-level definition of the standard as it descends into ISO levels 6 and 5. HL7 has adopted XML for its initially balloted ITS, and has selected the XML schema recommendation as the best method within the XML family of standards.

Static components: D-MIM

Like the other models included in the v3 documents, the Domain Message Information Model (D-MIM) is a diagram that shows the relationships between the classes. Differently from the RIM, though, the D-MIM (as well as the R-MIM) make use of a modified UML. The D-MIM is a subset of the RIM (see Section 3.2.3) that includes a fully expanded set of classes (always clones of RIM classes), attributes and relationships that are used to create messages for any particular domain. For example, the set of classes that are used by the Medical Records/Structured Documents domain is quite different from that used by the Patient Administration domain. The D-MIMs for these two domains, then, will be quite different, although both will be derived from the RIM.

The D-MIM provides a solution to the information requirements of a particular problem domain. The mapping of the requirement's domain information model to the RIM is used to identify which RIM classes need to be included in the D-MIM. In some cases it may be necessary to include multiple clones of the same RIM class. Each clone is given a unique name that is reflective of its business use.

Static components: HMD

In simplest terms, an HMD (hierchical message descriptor) is a tabular representation of the sequence of elements (i.e., classes, attributes and associations) that define the message without reference to the implementation technology. The HMD defines a single base message structure - the "common" message type. This base message structure is never sent and thus has no corresponding trigger event. It is the template from which the other specific and corresponding message types are drawn. The HMD and its contained message types may be represented as a spreadsheet.

Static components: R-MIM

Refined Message Information Models (R-MIMs) are used to express the information content for one or more HMDs that originate from the root class identified by the Entry Point in the R-MIM. Each R-MIM is a subset of the D-MIM and contains only those classes, attributes and associations required to compose the set of messages derived from the HMDs that originate from the R-MIM root class. Classes, attributes and associations that are not required for those HMDs are eliminated and the generalization hierarchies are also collapsed.

Static components: MT

A message type (MT) represents a unique set of constraints applied against the common message.

Dynamic components: Storyboards

While reading through the HL7 specifications and other resources, one can find various ways of defining storyboards, each of them pointing to the same or similar definition. Since the term "storyboard" is not common within standard development, we thought the reader could benefit from the following collection of some defintions:

- A Storyboard details a temporally sequenced series of actions/interactions involving one to many participating entities (e.g. human and/or system), and may, over its course, provide specific value to one or more of the involved entities.
- A Storyboard is a plain language description of a series of steps involving some exchange of information between different participants to achieve the objectives of a healthcare business process. The list of steps can be in generalized, abstract terms, or in the form of a real-world example.
- The Storyboard answers the question "for what purpose is this information being shared?"
- Storyboards are a means of providing context to the definitions of trigger events(Section 3.2.3).
- The process of storyboarding lays the foundation for describing HL7 messages and their content.

- A storyboard narrative is a description of a real-life event that provides the necessary context for the development of a specific interaction described in the storyboard.
- A storyboard consists of a short description of its purpose and an interaction diagram that shows the progression of interactions between the application roles (see Section 3.2.3).
- Storyboards are informative as opposed to normative: they exist to clarify other normative sections of the standard.

The storyboard concept is borrowed from the movie and animation industry, and is useful to the development of HL7 messages for the same reasons proven in that industry:

- A storyboard depicts a story using a series of "snapshots" or events in chronological sequence;
- Each snapshot represents a recognizable, meaningful moment in the sequence of events that the reader must know about to understand the overall sequence and result;
- Each snapshot illustrates the key participants in the storyboard and their interaction with other players;
- The whole series of snapshots provides a coherent description of a complete process or activity.

Storyboards are like description of UML use case diagr

Dynamic components: Application Roles

Application roles represent a set of communication responsibilities that might be implemented by an application. Thus they describe system components or sub-components that send and/or receive interactions. Practically, an application role represents a computer or a program that plays a role within the scenario of sending/receiving HL7 messages.

Dynamic components: Trigger Events

A trigger event is an explicit set of conditions that initiate the transfer of information between system components (application roles). It is a real-world event such as the placing of a

laboratory order or drug order. In the v3 standard, trigger events are one of interaction[22], state-transition[23] or user-request trigger[24]. Most trigger events are State-Transition based and will be encountered when reading the dynamic message information model (D-MIM) defined to support a particular message interaction.

Dynamic components: Interactions

Interactions are used to explicitly define interactions between application roles. It is a unique, one-way transfer of information.

A single Interaction explicitly answers the questions: 1. Which type of system component sends a particular type of message; 2. To what type of receiving system component the message type is sent; 3. How a system knows when to send a particular type of message; 4. What the particular message type is;

Interactions are typically represented using interactions diagrams (Fig. Figure 3.16) and used within storyboards.

3.2.4 Refining HL7

In this section we discuss the steps involved in adding new domains to the HL7 specifications.

Currently, HL7 does not provide a dental or orthodontic domain. Therefore, if we would like to implement the orthodontic electronic data standard using HL7 we must learn how to refine and expand the current HL7 specifications.

The HL7 Development Framework(HDF)(The Health Level Seven, 2005a) is a document which details the processes of the HL7 development methodology. The full process of creating an HL7 specification is divided in seven steps(The Health Level Seven, 2005a):

1. Project Initiation

[22]Trigger events can be based on another interaction. For example, the response to a query (which is an interaction) is an Interaction Based trigger event.

[23]Trigger events resulting from a state transition as depicted in the State Transition Model for a particular message interaction. The trigger for canceling a document, for example, may be considered a State Transition Based trigger event

[24]Trigger events may be based on a user request. For example, the trigger event that prompts a system to send all accumulated data to a tracking system every 12 hours is considered User Based.

2. Requirements Documentation
3. Specification Modelling
4. Specification Documentation
5. Specification Approval
6. Specification Publication
7. Implementation Profiling

The following subsections were copied as is from the HDF. The HDF contains individual chapter for each of the seven steps listed above. Please refer to the HDF(The Health Level Seven, 2005a) for further details, examples, tools and templates.

Project Initiation

During project initiation the project is defined, a project plan is produced, and project approval is obtained. The primary deliverable produced during project initiation is the project charter. The objectives of the project charter are to: (a) Define project scope, objectives, and intended deliverables; (b) Identify project stakeholders, participants, and required resources; (c) Document project assumptions, constraints, and risk; (d) Prepare preliminary project plan and document inter-project dependencies; (e) Obtain project approval and launch the project.

Requirements Documentation

During requirements documentation the problem domain is defined, a model of the domain is produced, and the problem domain model is harmonized with HL7 reference models. The primary deliverable produced during requirements documentation is the requirements specification. The sequence of steps to create the requirements specification are: (a) Document Business Process: Dynamic Behavior and Static Structure; (b) Capture Process Flow: UML Activity Diagram; (c) Capture Structure: Domain Analysis Model and Glossary; (d) Capture Business Rules: Relationships, Triggers, and Constraints; (e) Harmonize the Domain Analysis Model with HL7 Reference Models.

Specification Modeling

During specification modeling reference models are constrained through a process of iterative refinement driven by requirements specifications and following specification design rules, conventions, and guidelines. The primary deliverable produced during specification modeling is a set of specification design models (D-MIMs). The steps are: (1) Build models of static information views; (b) Construct models of behavioral views; (c) Define reusable model components; (d) Construct models of collaboration and interaction; (e) Harmonize models with HL7 Reference Models.

Specification Documentation

During specification documentation the specification design models are packaged into logical units, supplemented with explanatory text, and prepared for approval. The primary deliverable produced during specification documentation is a proposed specification. The steps to produce specification documentation are: (a) Organize design model elements into logical packages; (b) Compose explanatory text, examples, and design rationale; (c) Update design models and requirement specifications; (d) Assemble a proposed specification package; (e) Submit specification for approval.

Specification Approval

During specification approval the proposed specification is subjected to a series of approval steps. The specific approval steps vary by kind of specification, level of approval, and realm of interest. The primary deliverable produced during specification approval is an approved specification. The approval steps are: (a) Obtain TSC and Board approval to ballot specification; (b) Form a ballot pool and conduct specification ballot; (c) Assess negative ballots and affirmative comments; (d) Modify specification in response to ballot comments; (e) Resolve negative ballot responses and if necessary re-ballot.

Specification Publication

During specification publication the approved specification is prepared for prepared for publication and distribution. The primary deliverable produced during specification publication

is a published specification. The steps to publication are: (a) Obtain TSC and Board approval to publish specification; (b) Prepare specification for publication; (c) Submit publication to standards authorities (ANSI/ISO); (d) Render the specification in various forms of publication media; (e) Post and distribute approved specifications.

Implementation Profiling

During specification profiling, models are further refined and specifications further constrained. This refinement and constraining follows the same set of design rules, conventions, and guidelines used in the development of the specification for use in a particular environment by a defined community of users. The primary deliverable produced during specification profiling is a set of specification profiles and conformance statements. The steps to produce these profiles and conformance statements include: (a) Identify community of uses for published specification; (b) Further refine and constrain specification design models; (c) Document exceptions, extensions, and annotations to specifications; (d) Prepare and publish specification profile; (e) Prepare and publish conformance statements.

3.2.5 Comparing HL7 to other standards

This is a difficult task, as there are no standards as complete as HL7 to compare to. The only standard with similar goals is MEDIX, but recent work is not available on the Internet (the most recent documentation is dated 1997). MEDIX stands for Medical Data Interchange and was being developed by IEEE. HL7 was closely collaborating with MEDIX in order to provide compatibility between the two.

While numerous standards for materials, equipment and techniques have been developed in the dental and orthodontic field, very few actually specify electronic data. Most work in this field has been done by the ADA. On the other hand, various electronic medical data standards have been developed over the past few decades: The American Standards Committee (ASC), American Society for Testing and Materials (ASTM) and Institute of Electrical and Electronic Engineers (IEEE) all have produced complete and usable standards. None of them, though offer an integrated solution: for example, the ASC X12 is a standard for business documents only, while the ASTM standards defines limited domains, such as electronic health records, authentication of health care information, universal healthcare identifier properties, users authentication amongst others.

HL7 took some of these standards, worked together with their committees and formed a new, integral standard that offered a complete solution for the medical environment. Now in its third major version, it offers the most elaborate and modern standard currently available for the medical field.

3.3 HL7 AND ORTHODONTIC DATA

This section is devoted to the evaluation of refining HL7 with respect to orthodontic electronic data.

After analysing HL7, we realized that it provides a stable framework to aid the development of an orthodontics electronic health record standard. But what would it mean, specifically, to implement our standard using HL7? How much work would ADA SCDI WG 11.6 need to accomplish?

3.3.1 Implementing the standard in HL7

This section contains a summary of the process of refining HL7 for orthodontics. It is intended to give the reader an idea of what it would be like to follow this path. Please refer to the HL7 Development Framework (The Health Level Seven, 2005a) for more details on the process.

HL7 defines the exchange of messages between applications. Using HL7 to define an orthodontic data standard would mean looking at orthodontic data from a communication perspective. As an example HL7 looks at a patients first visit as information that needs to move from one system (application role) to another. The patient data would be exported and imported from and to applications within messages.

The Modelling and Methodology technical committee at HL7 has developed a manual(The Health Level Seven, 2005a) which details the processes of the HL7 development methodology. In general, refinement of HL7 starts from the creation of storyboards. Orthodontic experts should write a set of storyboards, one for each exchange of clinical and financial information. These can then be used to create an orthodontic D-MIM and R-MIMs. From R-MIMs HMDs and message types can be created.

According to the HDF, the full process of creating an HL7 specification is divided in seven

steps (see Section 3.2.4). All seven steps require, within the working group, the presence of orthodontics domain experts, HL7 facilitators and memberships, and an HL7 expert.

In the next sections we review the seven steps listed in Section 3.2.4 applying them to the particular task of developing an orthodontic electronic standard.

Project Initiation

This entails getting a consensus from the working group to go ahead and use HL7 for orthodontics. A project charter has already been produced by the ADA SCDI WG11.6 ex co-chair Philip DeSmedt at Align Technology and should be available off of the ADA SCDI web site. It needs to be adapted and focused towards creating a new HL7 domain, according to HL7 regulations.

Requirements Documentation

These are the steps involved in delivering a **requirements specification**.

Storyboards

The first step in the requirements gathering process is to develop a description of the orthodontic electronic data exchange problem. This is done using Storyboards (see Section 3.2.3).

Documentation of the orthodontic electronic data processes involves unambiguously describing both the structure and the behavior/function of the entities involved in the processes. This documentation should be created making use of the knowledge of orthodontic professionals and the project charter, and should be captured in a Storyboard.

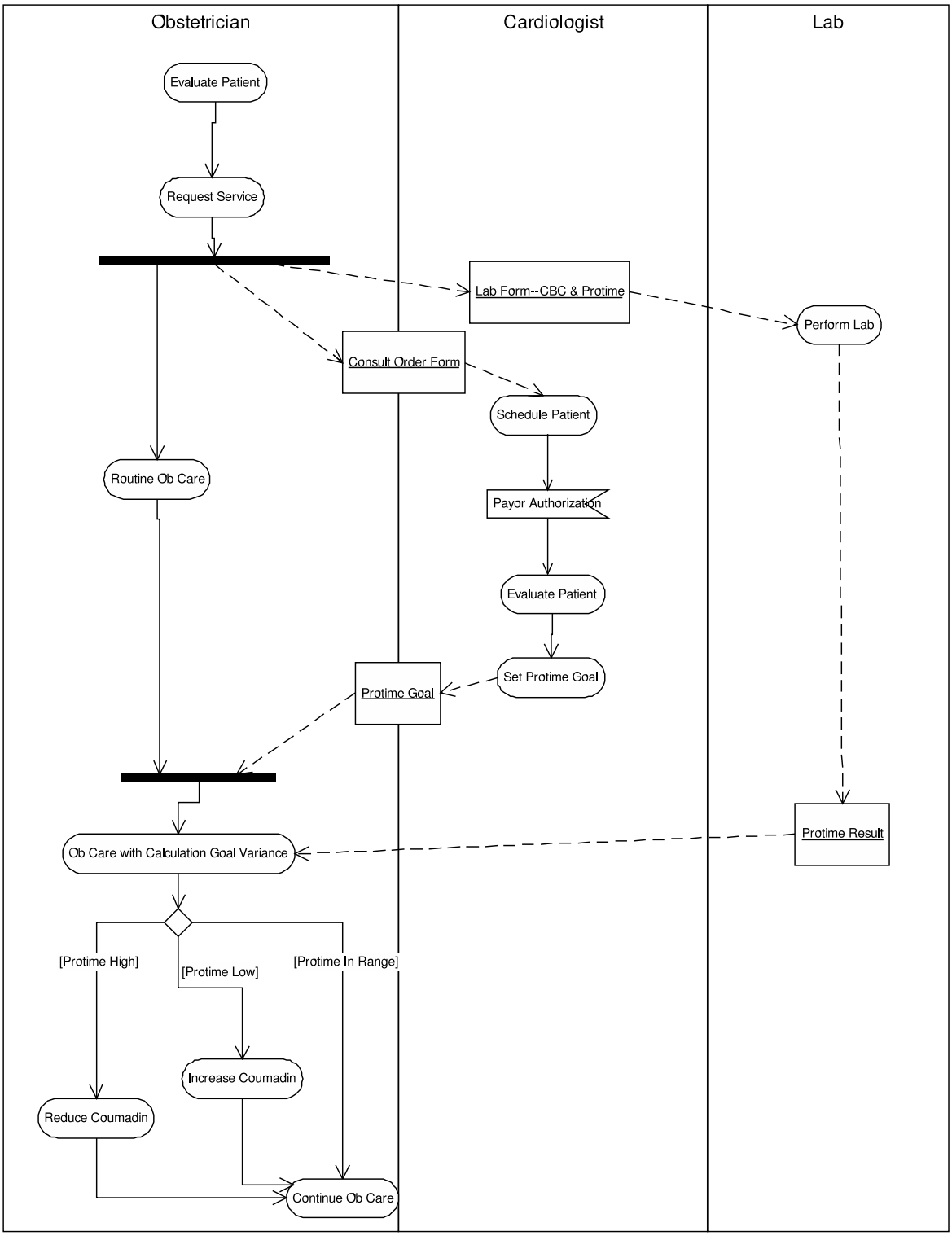


Figure 3.12: An Activity Diagram identifies a sequence of steps and the information that is transferred from one participating role to another. Sometimes called a "Swim-lane Diagram", the pictures represent the flow of control among the steps and help identify what information is required to be transmitted to achieve the objectives of the Storyboard. Of particular interest, is the data information exchange focus of HL7, are the Activity Diagram semantics that depict the passing of objects (e.g., data, information, messages, documents) between swim-lanes.

Activity Diagram

Currently[25] ADA SCDI working group 11.6 is partially working on this by defining an information model framework of the orthodontic data domain. This work, though, would need to be steered toward the creation of Storyboards. With storyboards, it will be possible to expand them into activity diagrams[26] (see Figure Figure 3.12).

Domain Analysis Model and Glossary

It will then be necessary to develop a Domain Analysis Model using a UML Class Diagram. The class diagram simply needs to identify the domain concepts-of-interest and their static inter-relationships using UML's tools[27]. It does not need to be fully implemented (i.e. ready to be translated into code), with all methods and attributes (see Figure Figure 3.13).

The glossary is needed to clarify the terms used by orthodontic professionals to identify the processes themselves. A draft of orthodontic data types could be a useful resource for this task and can be found in (Align Technology Inc. et al, 2004). The glossary should ultimately be in the form of a two-column table: Term vs. Definition.

Relationships, Triggers and Constraints

With the activity diagram, domain analysis model and domain glossary it will be possible to carefully describe the structure of the data/information to be exchanged. This is then added to the activity diagram using the object/instance iconography[28].

[25] As of October 5th, 2005.

[26] Activity Diagram is defined in version 1.4 of the UML - "An Activity (Graph) Diagram is a variation of a state machine in which the states represent the performance of actions or sub-activities, and the transitions are triggered by the completion of the actions or sub-activities. It (therefore) represents the state machine of a procedure (or process) itself. The purpose of this diagram is to focus on the flows driven by internal processing (within a system or subsystem)."

[27] Associations, association names and multiplicities.

[28] The object/instance iconography is an object-oriented programming terminology where an object is an abstract thing (for example "pine tree") and an instance is one specific object (for example "The specific pine tree located at the corner of 12th St and Houston in Cleveland, OH").

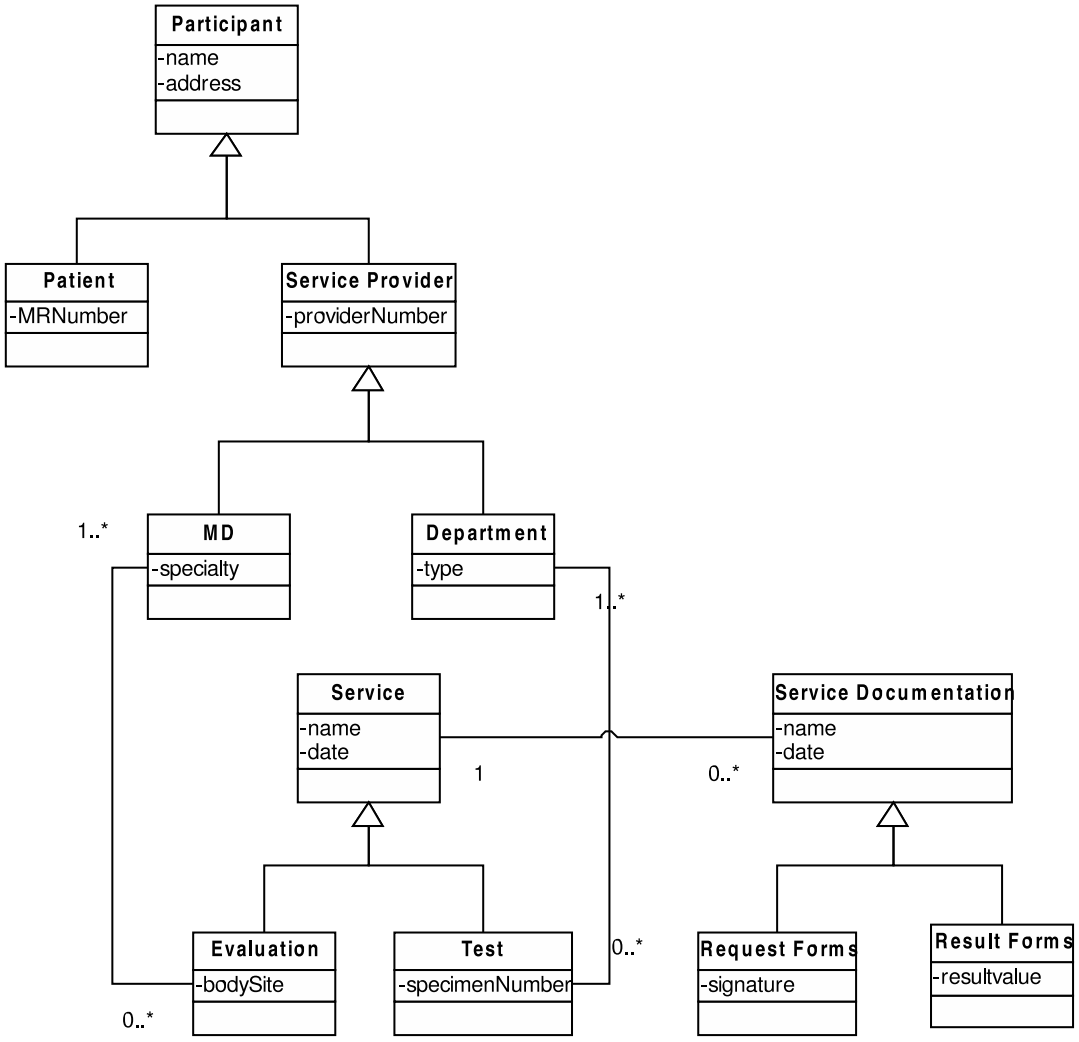


Figure 3.13: The Domain Analysis Model describes the key information needed to be shared to achieve the objectives of the Storyboard.

Harmonization

Finally it will be required to harmonize the artifacts developed in the preceding steps with the existing HL7 reference models. To do so, any inconsistencies, redundancies and omissions must be aligned.

Specification Modelling

For the specification modelling, the deliverable is a specification design model, i.e. a set of D-MIMs (refer to Section 3.2.3). This is another five step process, similar to the one needed to deliver a requirements specification. At this stage it is necessary to be more detailed, in order to be able to produce an HL7 compliant specification model. This entails looking for an already existing D-MIM in the HL7 standard that somewhat meets the requirements specifications. If one already exists, it should be modified by adjusting the class clone names, attributes and relationships. Otherwise a new one should be created by cloning already existing classes from the RIM.

In order to do so, it will be necessary to:

- iteratively refine the activity diagrams from the requirements specifications using UML Sequence, Collaboration and State Transition Diagrams;
- construct collaboration diagrams from the system responsibilities for sending and receiving information(see Fig. Figure 3.14);
- construct a sequence diagram to show the set of interactions between the application roles in the sequence required to meet the objectives of the Storyboard (see Fig. Figure 3.16);
- translate the glossary into a Vocabulary Specification Schematic.

Finally, it will be necessary to harmonize the design models with HL7 reference models. It is advisable to make extensive use of the suggested tools listed in the HDF(The Health Level Seven, 2005a) for this process.

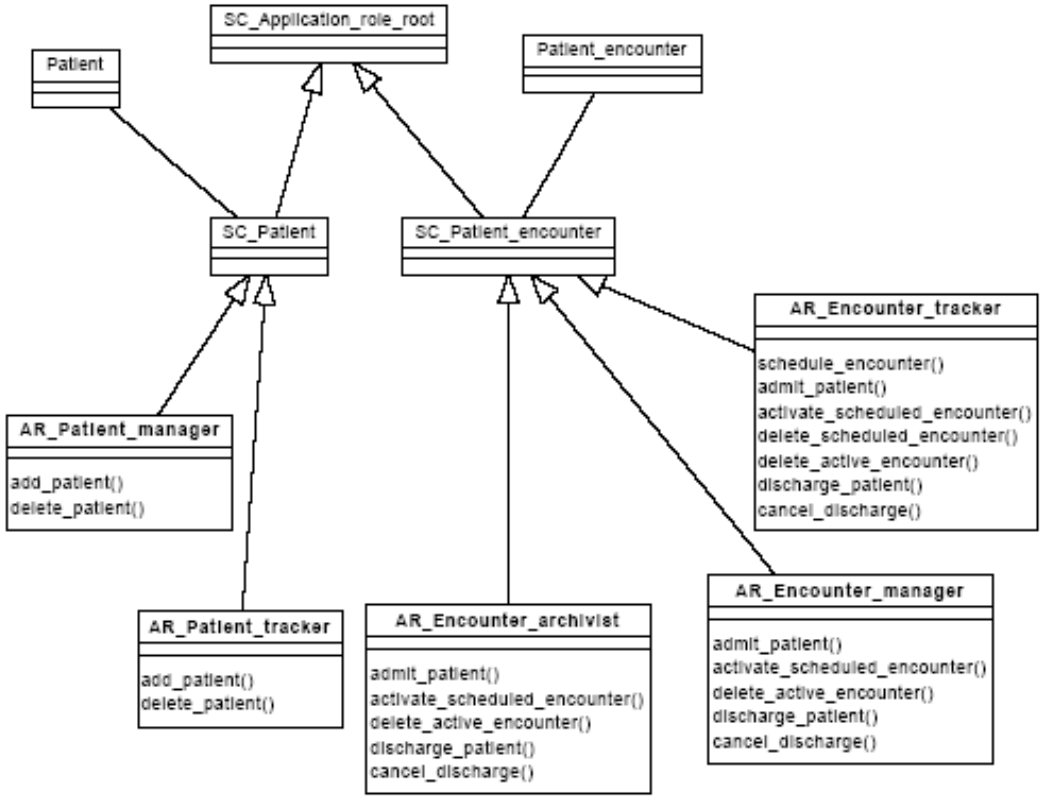


Figure 3.14: An example of a UML Collaboration Diagram.

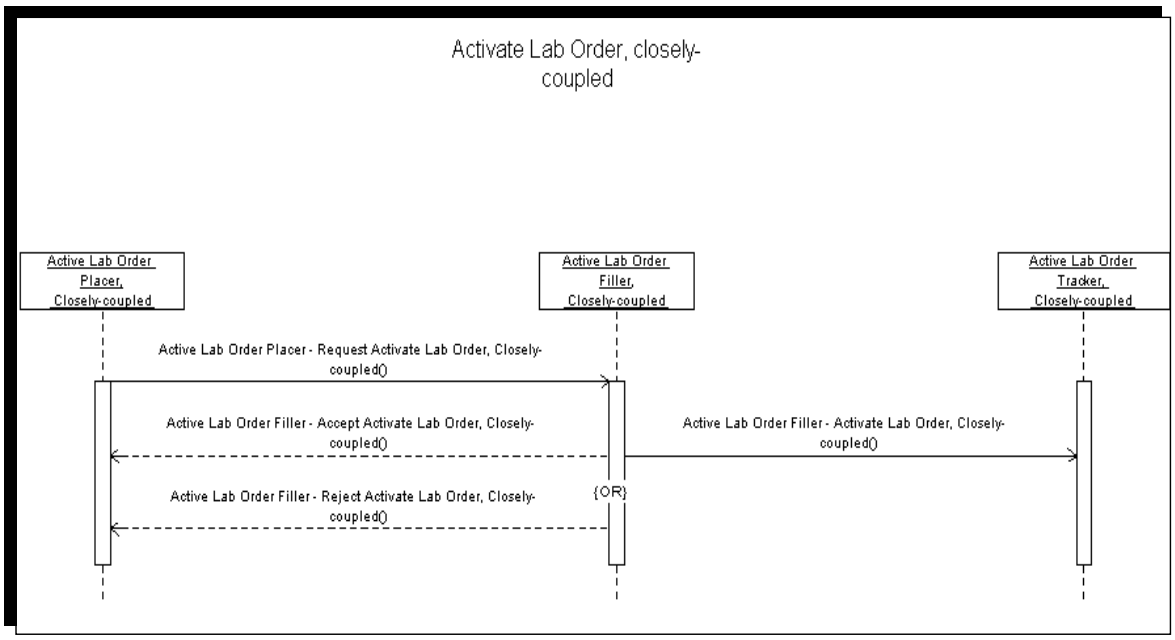


Figure 3.15: The UML Sequence Diagram details an interaction, i.e. specific trigger event, sending application role, receiving application role, receiver responsibility and optionally the interactions the receiving application must initiate.

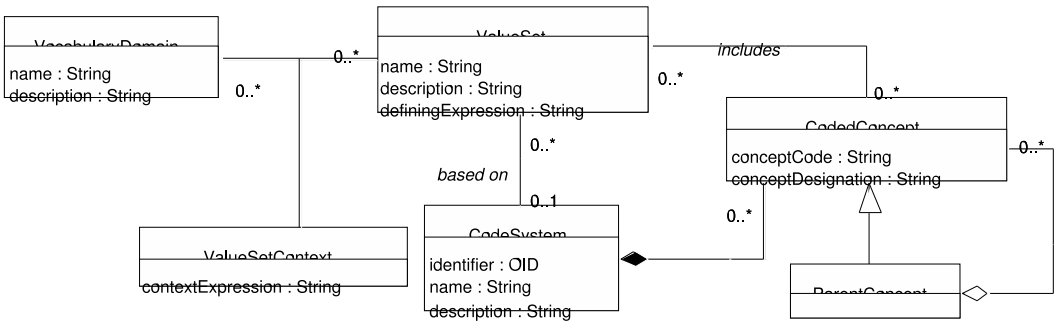


Figure 3.16: An example of a Vocabulary Specification Schematic.

Specification Documentation

For the specification documentation, the primary deliverable is a proposed specification. This step focuses on documenting what has been designed so far. This includes:

- Using correct naming according to artifact naming convention defined in the HL7 v3;
- Writing explanatory text, design rationale and examples for each design artifact;
- Making sure there aren't any inconsistencies in the design models (Section 3.3.1) and requirements specification (Section 3.3.1) ;
- Create and test links to all referenced files;
- Zip and submit the package for approval;

Specification Approval

During specification approval, the proposed specification is subjected to a series of approval steps, which may vary by kind of specification, level of approval, and realm of interest. The general steps include obtaining approval to ballot specification from technical committee and board, conducting a ballot, assessing ballots, modifying specifications and resolving negative ballots by eventually re-balloting.

The primary deliverable is an approved specification.

Specification Publication

Finally the specification is ready for publication. This last step produces as a primary deliverable a published orthodontics HL7 specification. This entails obtaining approval to publish from board and technical subcommittee, preparing and submitting publication to standard authorities (ANSI/ISO), post and distribute the specification in various forms of publication media.

Implementation Profiling

Once the specification is finished, it is ready to be implemented and/or further refined. This step involves performing tasks to directly aid the implementation of the specification by further constraining it for a variety of purposes, depending on the user. For example the orthodontic specification could be further constrained to conform with local medical laws, or local practice procedures. In addition, this step produces conformance statements used by system sponsors such as vendors to communicate to a user how their products meet HL7 specifications.

It is also possible to define sub-domains through constraints. This means that the orthodontic HL7 specifications could refine an already existing sub-domain, instead of the RIM directly.

Implementation profiling must also undergo HL7 approval.

3.3.2 Images and other binary data

Images are one of the most used elements of an orthodontic electronic health record. Although HL7 only specifies how to send/receive *textual* data, it does leave space for any kind of binary data. Implementers can therefore choose, through MIME[29] types, how to encode their data with flexibility. HL7 suggests the use of DICOM, in which case the patient's image would be stored in the patient record in DICOM format using the Encapsulate Data (ED) data type(The Health Level Seven, 2006, in Foundation, Data Types, Sec. 2.4). The HL7 organization has a special interest group (SIG) that specifically focuses on this issue. The Imaging Integration SIG works closely with DICOM (their members are also members of DICOM Working Group 20: *Integration of Imaging and Information Systems*): their scope

[29] A set of rules that defines how to send binary data (audio, images, movies,...) through email. This same set of rules can be used for any kind of information transmission, not just email.

is

> "To develop DICOM and HL7 standards for image-related information for areas where the consistent use of HL7 and DICOM is of prime concern, and for the coordination and mutual education and understanding between the HL7 and DICOM organizations and their technical committees/working groups."

Hence to implement images it is necessary to first define the orthodontic images domain (in storyboards, D-MIMs and R-MIMs), then define how to encode the image data (in the case of DICOM, the DICOM standard would need to be revised to be able to accommodate for orthodontic data.) and eventually pick the HL7 message that best represents the use case and define how to store orthodontic images as an ED data type. This would entail using an image format that is capable of optimally storing orthodontic images. Choosing HL7 as the basis for the Orthodontic Standard would therefore not alleviate the task of defining the image encoding.

3.3.3 Discussion

HL7 is a well developed, widely used medical specification framework that focuses on medical data transmission over electronic medium. It already includes a wide variety of medical domains, and is working towards including more. Although it is not sufficient to define the entire orthodontic domain, it allows for the integration of any number of other standards, so to accommodate for the needs of even the most complex domains.

After evaluating HL7, we summarized pros and cons into the following lists.

Pros

1. HL7, being a communications standard, provides a way to easily exchange patient data between colleagues, provided the colleagues make use of HL7 certified software systems;
2. HL7 provides a way to easily port patient data from one system to another, provided both systems implement HL7;
3. HL7 provides a way to share patient data between different software systems within the same practice, provided the different softwares implement HL7;

4. HL7 v3 provides specifications for conformance testing.
5. HL7 provides a distribution schema to popularize their specifications.
6. HL7 is a well established and spread out standard (v3 already implemented, even if still in ballot state!).
7. HL7 is complete, as it already specifies most medical processes (patient records, medical documents, financial and insurance documents...).
8. HL7 provides detailed documentation for extending, refining or adding domains to the standard.
9. HL7 is fully compatible with DICOM.
10. HL7 has a large community of developers and users.
11. HL7 has an active community, with responsive mailing lists.
12. HL7 is the only accredited standard to provide all these features.

Cons

HL7 does not specify a way to secure patient data This task is left for the software vendors to implement, but does not constitute a major problem: each message needs only to be wrapped in an encrypted transaction such as the HIPAA 275 transaction.

HL7 does not specify a way to encode images It only specifies how to send them. Non-textual data must be stored in an external format (e.g.. DICOM) before being encapsulated into HL7 messages. On the other hand, being fully compatible with any kind of image encoding scheme, it provides an extra level of flexibility. From the ADA SCDI WG 11.6 standpoint, this means research and refining yet another standard.

HL7 is very complex in nature Mastering HL7 requires a good knowledge of UML, object-oriented concepts and modelling tools. All the different diagrams, definitions, classes, models and domains can cause the HL7 learning curve to be steep. Nonetheless, once mastered, its strict and organized nature makes it straightforward to manage and modify.

As mentioned above, images are beyond HL7's scope. They could be stored in their raw form within HL7 messages using the Encapsulated Data (ED) fields. Nonetheless, this would require defining a whole new set of image related attributes withing HL7 messages. We therefore suggest making use of a separate imaging standard. DICOM is a good candidate as its compatibility with HL7 is constantly being monitored by HL7 SIG *Imaging Integration* and DICOM WG 20 *Integration of Imaging and Information Systems.* Images could then be used in conjunction with HL7 messages to form the complete orthodontic domain.

3.3.4 HL7 Summary

According to our evaluation, HL7 is an adequate framework for defining the specifications for orthodontic electronic data. We advise making direct use of HL7 by refining it to accommodate for the orthodontic necessities. Nonetheless, if the ADA SCDI working group 11.6 considers this not an ideal approach, the HL7 documentation remains a rich and useful resource for the development of our standard.

3.4 DICOM

The Digital Imaging and Communication in Medicine (DICOM) specification is the only internationally recognized standard for the communication of images and related information in the health domain. DICOM's domain doesn't overlap with HL7's or Specification 1000's in that it focuses on images .

DICOM is being extensively used in many countries and medical environments and is undergoing considerable development to include images from new devices and medical fields. Extensions to the DICOM standard now encompass all aspects of digital and digitized dental radiographs.

To the best of the author's knowledge, up to this day no attention has been given directly to the orthodontic domain within DICOM.

The University of Brasília (Brasília, DF, Brazil), in collaboration with Case Western Reserve University (Cleveland, OH, USA) is currently developing a proposal for a DICOM standard for cephalograms (see Chapter 4). Cephalograms must meet some minimum requirements

of resolution and information (such as magnitude and calibration landmarks) in order for them to be useful for research and clinical applications. These minimum requirements will be embedded in the DICOM standard and will be based on the findings of Hans (Hans et al., 2003). The proposal will be submitted to DICOM for approval.

3.4.1 The organization

DICOM is a standards organization administered by the NEMA Diagnostic Imaging and Therapy Systems Division[30]. Working groups of the DICOM Committee perform the majority of work on the extension of and corrections to the Standard. Working groups are formed by the DICOM Committee to work on a particular classification of tasks. Once formed, working groups petition the DICOM Committee to approve work items for which the working group will execute the plan delineated in the work item. Once the output of a work item (generally a supplement or correction proposal) has been completed, it is submitted to Base Standards Working Group (WG-06), for their review. Supplements to the standard then go through a public comment period, after which the DICOM Committee authorizes the supplement for letter ballot by DICOM members. Letter ballots require approval by two-thirds of those voting affirmative or negative and return of more than one-half of the ballots sent to members in good standing relative to letter ballots. Since the working groups perform the majority of work on the extension of and corrections to the Standard, the current status and future directions of the DICOM standard are best represented by review of each working group (National Electrical Manufacturers Associations, 2005).

3.4.2 The standard

DICOM originated in 1983 when the American College of Radiology (ACR) and the National Electrical Manufacturers Association (NEMA) identified the need for interoperability among imaging equipment from various vendors. This led to the adoption of the ACR-NEMA Standard version 1 in 1985 and subsequently version 2 in 1988. In 1992, DICOM version 3 was adopted, which for the first time embraced networking (Diehl, 2003). This version embodies a number of major enhancements to previous versions of the ACR-NEMA Standard:

Networking It is applicable to a networked environment. The ACR-NEMA Standard was

[30]The complete bylaws of the DICOM Standards Committee are available on the NEMA web site at `www.nema.org`.

applicable in a point-to-point environment only; for operation in a networked environment a Network Interface Unit (NIU) was required. DICOM supports operation in a networked environment using the industry standard networking protocol TCP/IP.

Off-line media It is applicable to an off-line media environment. The ACR-NEMA Standard did not specify a file format or choice of physical media or logical filesystem. DICOM supports operation in an off- line media environment using industry standard media such as CD-R and MOD and logical filesystems such as ISO 9660 and PC File System (FAT16).

New Commands It specifies how devices claiming conformance to the Standard react to commands and data being exchanged. The ACR-NEMA Standard was confined to the transfer of data, but DICOM specifies, through the concept of Service Classes, the semantics of commands and associated data.

Conformance It specifies levels of conformance. The ACR-NEMA Standard specified a minimum level of conformance. DICOM explicitly describes how an implementor must structure a Conformance Statement to select specific options.

Multi-part Document It is structured as a multi-part document. This facilitates evolution of the Standard in a rapidly evolving environment by simplifying the addition of new features. ISO directives which define how to structure multi-part documents have been followed in the construction of the DICOM Standard.

New Objects It introduces explicit *Information Objects* not only for images and graphics but also for waveforms, reports, printing, etc.

Improved Identification It specifies an established technique for uniquely identifying any *Information Object*. This facilitates unambiguous definitions of relationships between *Information Objects* as they are acted upon across the network.

The DICOM Standard facilitates interoperability of devices claiming conformance. In particular, it addresses the semantics of Commands and associated data. For devices to interact, there must be standards on how devices are expected to react to commands and associated data, not just the information which is to be moved between devices. DICOM also addresses the semantics of file services, file formats and information directories necessary for off-line communication. In addition, the standard is explicit in defining the conformance requirements of its implementations. In particular, a conformance statement must specify enough information to determine the functions for which interoperability can be expected with another device claiming conformance. Another goal of DICOM is to facilitate operation in a networked environment as well as to make use of existing international standards wherever applicable, and to conform to established documentation guidelines for international

standards. Finally, it is structured to accommodate the introduction of new services, thus facilitating support for future medical imaging applications.

Even though the DICOM standard has the potential to facilitate implementations of PACS solutions, use of the standard alone does not guarantee that all the goals of a PACS will be met. This standard facilitates interoperability of systems claiming conformance in a multi-vendor environment, but does not, by itself, guarantee interoperability. It has been developed with an emphasis on diagnostic medical imaging as practiced in radiology, cardiology and related disciplines; however, it is also applicable to a wide range of image and non-image related information exchanged in clinical and other medical environments (National Electrical Manufacturers Associations, 2004, PS 3.1).

3.4.3 Building blocks of DICOM

The general communication model of the standard, which spans both network (on- line) and media storage interchange (off-line) communication, is presented in Figure 3.17 on the next page. Applications may relay on either one of the the *Upper Layer* service (which provides independence from specific physical networking communication support and protocols such as TCP/IP) or the *Basic DICOM File* service (which provides access to storage media independently from specific media storage formats and file structures).

The DICOM standard is composed of Service Class Specifications, Service-Object Pair Classed, Service Groups, Image Object Definitions, DICOM Message Service Elements and/or Media Storage Services and Attributes. The relationship between these elements can be found in the representation of DICOM's major structure of Figure 3.18 on page 57. In the subsections to follow, the reader can find a description of these major DICOM building blocks.

Image Object Definitions (IOD)

An Information Object Definition (IOD) is an object-oriented abstract data model used to specify information about real-world objects. An IOD provides communicating Application Entities (AE) with a common view of the information to be exchanged.

An IOD does not represent a specific instance of a real-world object, but rather a class of real-world objects which share the same properties. An IOD used to generally represent a single

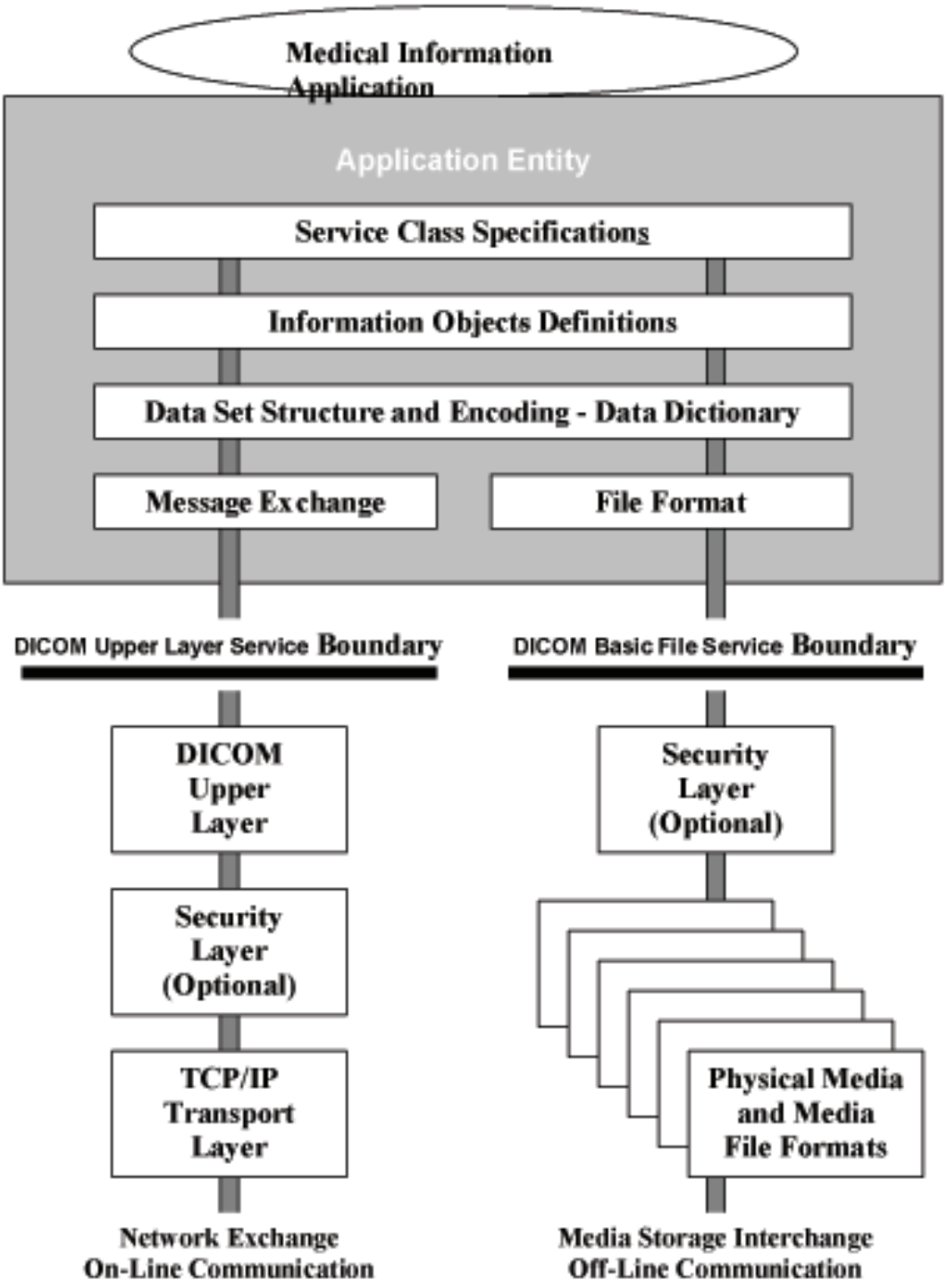


Figure 3.17: DICOM general communication model.

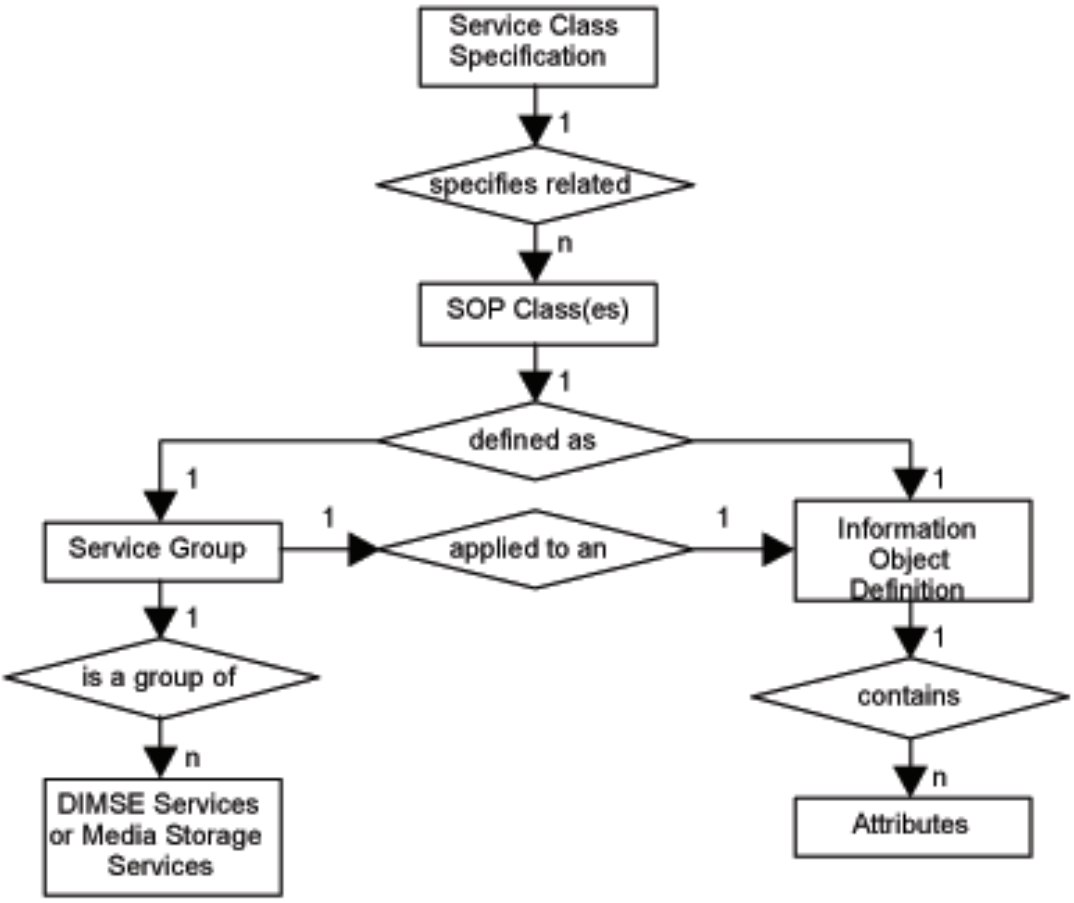


Figure 3.18: DICOM Major Structure.

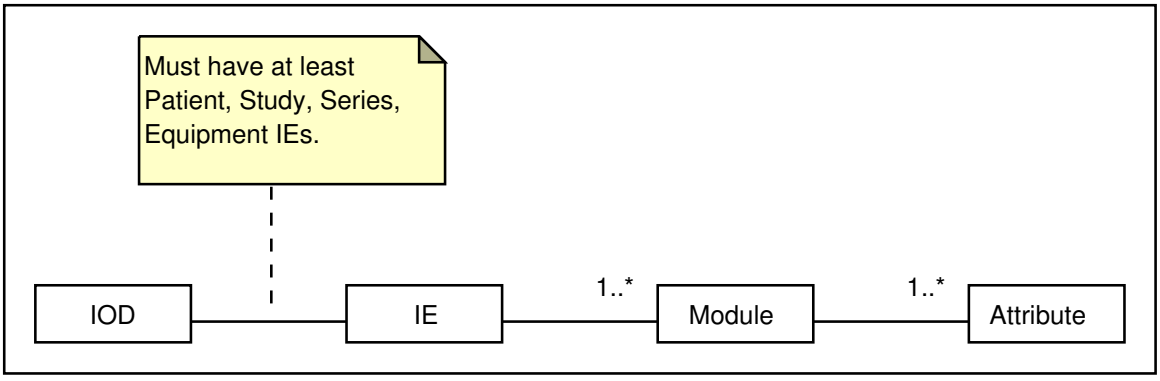


Figure 3.19: DICOM Information Object Definition (IOD) Structure. Information Entity is abbreviated IE.

class of Real-World Objects is called a Normalized Information Object. An IOD which includes information about related Real-World Objects is called a Composite Information Object (National Electrical Manufacturers Associations, 2006, PS 3.3 - Page 49).

An IOD is the highest level of object in the DICOM model. Looking at Figure 3.19 on the previous page, one can see that IODs are composed of Information Entities (IE), which contain modules, which contain attributes. Each IOD must define at least the Patient, Study, Series and Equipment information entities.

Modules and Macros

Modules are a set of attributes within an information entity (IE) or normalized IOD which are logically related to each other. They define a way of grouping attributes into topics. They are referenced by information entities in the IOD tables.

Service Class Specification

The official definition of a Service Class, as defined in (National Electrical Manufacturers Associations, 2006, PS 3.1, p.8), is:

> "A structured description of a service which is supported by cooperating DICOM Applications using specific DICOM Commands acting on a specific class of Information Object."

Service classes represent one of the new (since version 3) features described in section 3.4.2 on page 53: they provide the vocabulary needed for different AEs to exchange IODs between each other. This is an essential feature, as it standardizes communication between medical imaging devices. DICOM specifies various Service Classes, such as the Verification Service Class (National Electrical Manufacturers Associations, 2006, PS 3.4, Annex A), used to verify communication between two AE or the Storage Service Class (National Electrical Manufacturers Associations, 2006, PS 3.4, Annex B), used to send IODs (i.e. images, waveforms, reports...) between AEs.

Service-Object Pair (SOP) Classes

Service-Object Pair (SOP) Class is defined by the union of an IOD and a DIMSE Service Group. The SOP Class definition contains the rules and semantics which may restrict the use of the services in the DIMSE Service Group or the Attributes of the IOD.

SOP classes are specified along with Service Class Specifications in Part 4 of the DICOM documentation. There can be more than one SOP class for each Service Class Specification. For example, the Verification Service Class specifies only one SOP class (called *Verification SOP Class* with UID "1.2.840.10008.1.1"), which consists of the C-ECHO DIMSE-C service (National Electrical Manufacturers Associations, 2006, PS 3.7, p. 31) (a service used to verify end-to-end communication, similar to the *ping* Internet Control Message Protocol (ICMP) service). On the other hand, the Storage Service Class specifies various SOP classes: these are the standard SOP classes, for each defined image type, or any storable IOD. The SOP classes table for the storage service class occupies almost three pages (see (National Electrical Manufacturers Associations, 2006, PS 3.4, p. 22)).

The selection of SOP Classes is used by Application Entities to establish an agreed set of capabilities to support their interaction. The SOP Class, as defined in the DICOM Information Model, is equivalent in ISO/OSI terminology to the Managed Object Class. Readers familiar with object oriented terminology will recognize the SOP Class operations (and notifications) as comprising the methods of an object class.

Service Group

A service group is nothing more than a grouping of DIMSE operations and/or notifications which are applicable to an IOD.

DICOM Message Service Element (DIMSE)

The DIMSE defines an application service element (both the service and protocol) used by peer DICOM Application Entities (AE) for the purpose of exchanging medical images and related information. The DIMSE provides its services by relying on the DIMSE protocol. The DIMSE protocol defines the encoding rules necessary to construct messages, and is therefore limited to network communications (i.e. it is not used for interchanging data over storage media).

Attributes

A property of an Information Object. An attribute has a name and a value which are independent of any encoding scheme.

The attributes of an IOD describe the properties of a real-world object. Related attributes are grouped into modules which represents a higher level of semantics documented in the module specifications (found in (National Electrical Manufacturers Associations, 2006, PS 3.3)). Attributes are encoded as *data elements* using the rules, the *Value Representation* and the *Value Multiplicity* concepts specified in (National Electrical Manufacturers Associations, 2006, PS 3.5). For specific data elements, the *Value Representation* and *Value Multiplicity* of data elements are specified in the data dictionary in (National Electrical Manufacturers Associations, 2006, PS 3.6).

3.4.4 Refining DICOM

Refining and/or adding parts to the DICOM standard is not as specifically defined as it is within HL7. There is a process one must follow in order to get passed the balloting stage. It is necessary to build a proposal document and present it to the appropriate working group at one of DICOM's workig group meetings. The proposal must contain a detailed explanation of the use case scenarios that the current DICOM standard is not able to represent

3.4.5 Comparing DICOM to other standards

It is not possible to compare DICOM with other standards, as there are no other competitors. Most medical devices either make use of DICOM, or of their proprietary format, which is not of public domain, and does not allow interoperability.

However, throughout the development of DICOM, much attention was devoted to establishing working relationships with other related standard initiatives throughout the world. The initial version of the standard leveraged prior work by ASTM. The Internet protocol TCP/IP was adopted in 1993. In the nineties, solid cooperation with CEN, the European Committee for Standardization, resulted in a number of jointly developed supplements. CEN has created and approved a normative reference to the DICOM standard in EN 12052, an official European Norm. In parallel, the convergence of a Japanese interchange media format (IS&C) with DICOM required much joint work where JIRA, the Japan Industries Association of

Radiological Systems, played a major role. In the USA, DICOM participated in the early coordination efforts for healthcare standards with the ANSI-HISBB from which DICOM adopted a harmonized patient name structure, and started progressively to define links with HL7. This cooperation has now entered in a very active phase with the creation, in 1999, of a joint DICOM-HL7 working group. DICOM established a Type A liaison with the ISO Technical Committee 215 at its creation in 1999. ISO TC 215 has decided not to create an imaging working group, but to rely on DICOM for bio-medical imaging standards. It is foreseen that ISO will create and approve a standard that will reference the DICOM standard, as CEN has done. In 2003, the DICOM Standards Committee became a member of the E-health Standardization Coordination Group, a group endorsed by the ITU with the objective to promote a stronger coordination amongst the key players in the e- Health Standardization area.(National Electrical Manufacturers Associations, 2005)

3.5 DICOM AND ORTHODONTIC DATA

Because of DICOM's nature the orthodontic data that can be represented in DICOM format is limited to medical images. Orthodontists make use of visible light images (photographs of soft tissue and intra-oral photographs), x-ray images (cephalograms, panoramics and cone-beam CT volumes) and overlays (cephalogram tracings). Most of this data can be fully represented with the current version of DICOM. However, cephalograms, cone-beam CT volumes and possibly also tracings, need some special attention.

Since cephalograms are considered to be amongst the most important pieces of information to constitute the orthodntic patient record, an entire chapter of this thesis is dedicated to representing cephalograms in DICOM. See chapter 4 on page 77.

Cone-beam CT volumes are receiving special attention within DICOM working group 22 (Dentistry), 02 (Projection Radiography and Angiography) and 15 (Mammography and CAD) in that these groups are collaborating to develop a DX multi-frame supplement. This supplement will allow 3D scans to be stored as 3D volumes, using voxels, rather than as a collection of 2D slices. This will simplify the processing on the client's/viewer's side, because no reconstruction will be necessary: the scanner will collect 3D data, and store it directly into a volume, skipping the unnecessary step of computing slices. The task of computing slices from the volume is much lighter and can be done only when necessary.

Visible light images, such as intra-oral and soft-tissue photographs, can be represented using the existing VL (Visible Light) Photographic IOD (National Electrical Manufacturers Associations, 2004, PS3.3-A.32.4). The exisiting defined modules suffice for the correct

representation of orthodontic photographs.

3.6 ADA SCDI

The American Dental Association (ADA), the world's biggest and most influential dental association, founded standards developing organizations accredited by the American National Standards Institute (ANSI). The ADA is the sponsor and secretariat of the standards program for all areas of dentistry, including all types of dental materials and products (ADA Standards Committee on Dental Products, SCDP) and Dental Informatics (ADA Standards Committee on Dental Informatics, SCDI). The ADA standards committees comprise a balance of interests between dentists, government, academia and industry and develop standards according to rigorous protocols that ensure consensus among all interested parties (Harrell et al., 2005).

3.6.1 The organization: ADA SCDI

ADA SCDI is currently launching a project to extend Specification 1000 (and its other dental informatics standards) to cover the requirements of the orthodontic domain. Although much of the existing dental informatics standard is applicable to orthodontics, many elements specific to orthodontic treatment (diagnosis, treatment planning, treatment monitoring over time, outcomes analysis, appliances, root anatomy, etc.) and imaging (face, teeth, model scans and other geometric (3D) data, X-rays, photographs, cephalometric data, Cone- Beam CT, & yet-to-be developed technologies, etc.) may not currently be included. The objective of the new initiative is to extend and/or modify the existing electronic health record architecture to include the structure, format and relationships of these additional information elements. This should also include the protocols for exchanging these elements among stakeholders.

The ADA endorses the use of DICOM as the standard means for exchange of all digital dental images. However, the DICOM standard extends well beyond the needs of dentistry, making it therefore necessary to select the relevant parts with applicability to dentistry (American Dental Association, 2004). The ADA SCDI (Standards Development for Dental Informatics) has formed a working group called *Application of the DICOM Standard to Dentistry* (also known as WG 12.1), whose members are part of an equivalent working group within the DICOM Standards Committee. This tight collaboration ensures that DICOM developments satisfy requirements of dental professionals by delivering documents such as Technical Report No. 1023: *Implementation Requirements for DICOM in Dentistry* (American Dental Association, 2004).

3.6.2 The standard: Specification 1000

Specification 1000 refers to ANSI/ADA Specification No. 1000 *Standard Clinical Data Architecture for the Structure and Content of an Electronic Health Record*, the only American national standard that defines the fundamental data structures used to build EPRs. Specification 1000 defines the data structure of a generic health record. This means it defines rules about how to program a database so it can be used as a virtual health record file cabinet. This differs greatly from HL7 and DICOM which primarily specify how programs should send information related to healthcare between different computer systems. When implemented, Specification 1000 would ensure that two programs could directly access the same health record data pool at the same time. It does not, however, define how to exchange the data across different medias or networks.

The only ADA SCDI standard that deals with informatics, Specification 1000 was the first standard to have been derived from a ballotted clinical process model. This means modelling out all clinical processes, requiring all members to officially agree on the model and only then defining the informatics standard from the model. The clinical process model becomes therefore a normative part of the standard documentation. Specification 1000 comes with an implementation manual (Diehl, 2003) but, to the best of the author's knowledge, Specification 1000 has been limited to observation and prototyping by vendors, and experimentation in academia. In addition, it does not contain any dental-specific definitions. More information on the history of Specification 1000 can be found in Appendix A.

3.6.3 Comparing ADA SCDI to other standards

The ADA SCDI is unique in what it produces: no other organizations are developing dental informatics standards to the extent of the ADA SCDI. Researching dental informatics standards leads either to ADA SCDI, or to ANSI, whose work origins from the ADA itself, since the ADA is an ANSI accredited standards developing organization.

On the other hand, various dental standards have been developed for dental materials (Viohl, 1981), dental care (Boston Public Health Commission, 1998), dental education, dental services (Commonwealth Bureau of Dental Standards, Australia) and many more. Informatics though, being a relatively new application within the dental field (most of its use has developed over the past 10-15 years), has not received too much attention from the standards developing committees.

3.7 ADA SCDI AND ORTHODONTIC DATA

Until recently, the ADA SCDI had done none or little work for the orthdontic field. In 2004, Align Technology, Inc in conjunction with 3M Unitek, OraMetrix and PracticeWorks formed a community of inteterested parties and started a new working group within committee 11-*Electronic Dental Records* called 11.6-*Integration of Orthodontic Standards*. Ever since then the working group has been actively working on the project, mostly struggling with the hurdles which characterize the beginning of a new era. The first deliverables are scheduled for the second half of 2006. The author has been working with WG11.6 since 2004, and became a member in 2005.

3.8 THE PROPOSAL

The previous sections give an introduction first on the general, then on the more specific processes involved in the development of an informatics standard. This section presents the author's solution to the problems described in the introduction.

Most of the times, a problem has more than one solution. It is therefore important to consider as many solutions as possible in order to follow through with the most reasonable one. Here the reader will find a list of solutions which were considered to solve the problems described in Section 1 as well as the reasoning used to discard or accept each one of them.

Solution 1: Purchase the orthodontic software companies, and implement a way to interoperate between each other.

Solution 2: Develop a central datacenter free of charge, that can be used to perform translations between one format and another. Agreements between this central service and individual software vendors could then be established that would ensure the correct communcation between the software products and the central datacenter.

Solution 3: Develop small applications that run on the computer where the database of one software is located. These applications could have plugins that know how to read and write to the databases of all major software vendors. This way, if clinic A wants to send information to clinic B, all that needs to be done is install the client on both clinics. These clients would know how to communicate with each other, hence allowing the transfer of information between one software and another.

Solution 4: Develop an open source free orthodontic product that is way more advanced/efficient

than anything available on the market today. Every orthodontic clinic will be so enthusiastic by the functionality of this product that they will want to stop using what they are using and move to this new product. Once everybody will have a copy of this new miracle product, interoperability will not be an issue, because everybody will be making use of the same software.

Solution 5: Start a campain/movement that would force something to happen. This could be either at a political level (where local authorities could pass laws requiring software vendors to produce interoperable software products) or at a commercial level (where users would boycott non-interoperable software vendors).

Solution 6: Start a project to document exactly how to transfer information from one system to another with current commercially available software. With detailed instructions on exactly what to do to at least be able to somehow get to transfer some patient information from one system to another, the end-user will (1) spend less time in trying out different possibilities, (2) know which software to purchase to get maximum ease of interoperability, (3) learn more about their orthodontic software.

Solution 7: Start by developing a standard for the orthodontic electronic data, then implement it (either by writing an open source software, or with Solution 3 or 2 described above, or maybe through a software vendor) to prove its functionality.

The first solution would definitely solve the problem, but the drawbacks are the initial as well as the maintenance cost of the project. In addition many countries would not accept the monopoly caused by the agglomeration of the many software companies. Besides, this solution, although a very plausible one, is megalomaniacal in nature and, honestly, quite absurd.

Solutions 2 and 3 solve the problem in a more elegant way. For the development of the applications though, it would still be necessary to decide how to translate all existing orthodontic data into a higher level container. This could be more efficiently solved once a standard has been developed (see Solution 7).

In this respect, solution 4 is similar: if the intention is to develop the ultimate orthodontic software, it is necessary to start with a careful planning of orthodontic data through the development of a standard, in order to guarantee the success of the software. So one would necessarily need to start from Solution 7. Another drawback of this solution, is that it is quite pretentious to believe that one can develop and maintain a software that is close to perfect for all orthodontic applications amd practices. As described in chapter 2, orthodontic computer

usage spans a large set of applications, which are fairly different from each other. This makes solution 4 practically impossible.

Solution 5, although having good intentions, does not guarantee the success of the project. Although it has been proven that by insisting, success is bound to happen, the success of this solution might require so much time, that it would lose its importance.

Solution 6 presents the reader with yet a different approach to the problem: Instead of trying to change commercially available software, why not simply accept the fact that interoperability is poor, and try to educate the users how to get the most out of it. This project could be proposed to orthodontic foundations for funding, such as the AAOF (American Association of Orthodontics Foundation), and would probably receive interest and support. Nonetheless, similarly to Solution 5, it does not promise an improvement in orthodontic electronic data interoperability with time: the solution promised is temporary and not complete.

Solution 7 lays the foundation for further development and opens the doors for a wide array of applications. Once a standard is developed, the development of more stable and efficient software solutions to directly address more specific issues is rendered possible. On the other hand, this solution does not *directly* address the original problem: a standard for orthodontic electronic patient records does not per-se make existing orthodontic applications interoperable. Once the standard has been completed, it will need to be implemented by software vendors and/or non profit software developers.

3.8.1 The Orthodontic Electronic Patient Record Standard

Considering the above analysis, it has been decided to follow Solution 7: developing a standard for the Ortho-EPR making use of already existing, well established standard organizations. In this section an efficient way of harmoniously integrating three standards into one higher level standard for the orthodontic electronic patient record is proposed.

Earlier in this chapter, three medical informatics standards have been presented to the reader: HL7, DICOM and Specification 1000. Are these standards good candidates for the development of the Ortho-EPR standard? The following sections contain individual analyses of each standard and a description of how they can be useful for this project.

3.8.2 HL7

Making use of HL7 to develop the Ortho-EPR standard would yield a series of advantages. First of all, the HL7 community is very large and includes international members, which would confer the opportunity to obtain quality feedback to deliver an improved product. Secondly, HL7 makes use of modern technologies: mixing the clinical approach (starting from Storyboards) with object-oriented modelling, promises better planning and a more flexible end-product. Furthermore, HL7's widespread use among hospitals could facilitate the product's appeal to software companies, an issue of notable weight considering that a widespread implementation is equivalent to a successful standard, hence better integration between orthodontics and existing clinics and hospitals. On the other hand, HL7 does not provide any specifications for images. It does however integrate well with DICOM.

Although no official dental technical committee exists in the USA, the Canadian Dental Association and HL7-Canada already have completed some work with dental insurance claims and have shown interest in joining efforts with the ADA to form an HL7-USA dental technical committee.

3.8.3 DICOM

DICOM is a very well developed standard for medical images. It offers specifications for medical images of almost all specializations. Not too many changes and additions will need to be made to permit full orthodontic support.

Like HL7, DICOM has a large community of implementors and developers. It also already has a formed working group for the dental community, which collaborates closely with the ADA SCDI. In addition, the integration of DICOM with HL7 is guaranteed through a joint working group.

In summary, DICOM is a very good candidate for the image domain of the Ortho-EPR. It is reccomended to make use of as much of the DICOM framework as possible.

3.8.4 ADA SCDI and Specification 1000

Being the biggest, most influential dental association in the world and having a well developed standards committee, the ADA can provide a solid infrastructure to house the devel-

opment of the Ortho-EPR standard. The SCDI comprises members from different areas, which can contribute their knowledge and resources for the project: while orthodontists provide the more technical necessities and contribute their specialized knowledge, industry and government representatives can supply resources for meetings, implementations and testing. In addition, the committee is specialized in developing and distributing standards and is an ANSI-accredited institution.

Although Specification 1000 is very general in nature, and does not defien anything for the dental domain, it is the first and only informatics standard to be developed from a balloted and well defined clinical model. It is recommended to take this as an example and to develop the Ortho-EPR standard in a similar fashion.

3.8.5 Integrating HL7, DICOM and ADA SCDI

Refining HL7 by adding an orthodontic domain alone cannot solve the problem of defining a standard for digital orthodontic data: orthodontic data include images, which HL7 does not know how to handle. Nonetheless, HL7 integrates very well with DICOM. In order to benefit from HL7, it would therefore be necessary to also refine the DICOM imaging standard to be able to accommodate orthodontic images. Refinement of these two standards alone also is not sufficient for the Ortho-EPR: the integration of the two standards should be coordinated by the ADA SCDI. Its responsibility should be to define the orthodontic domain and to provide the community with documentation that specifies a standard way of implementing the two lower level standards.

The concepts in this and the next chapter have not yet been presented to the mentioned organizations (ADA, HL7 and DICOM): they should not be held responsible for any of the concepts in these chapters. Even though it is very likely that at least some parts of this proposal will be implemented, ADA, HL7 and DICOM have not yet agreed to complete or to execute the below mentioned ideas, neither as a whole, nor as a part.

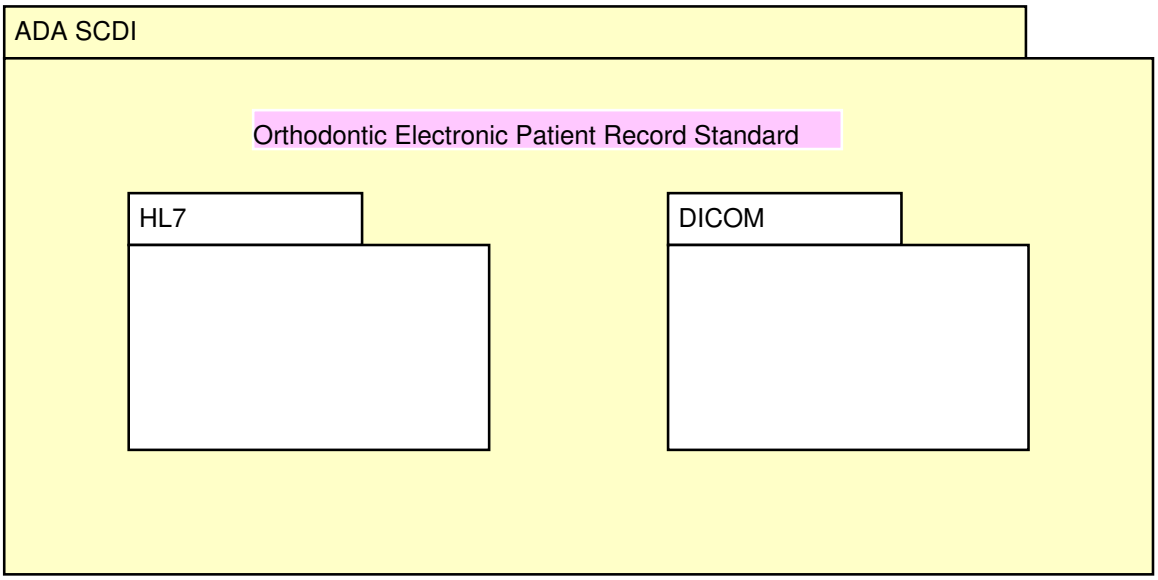


Figure 3.20: Basic structure of the organizations for the development of the orthodontic electronic patient record (ortho-EPR) standard. The ADA is the supervising organization, making sure that the standard fulfills the needs of the orthodontic community. DICOM and HL7 are used to represent imaging and non-imaging data respectively in order to ensure the maximum amount of data interoperability with existing systems.

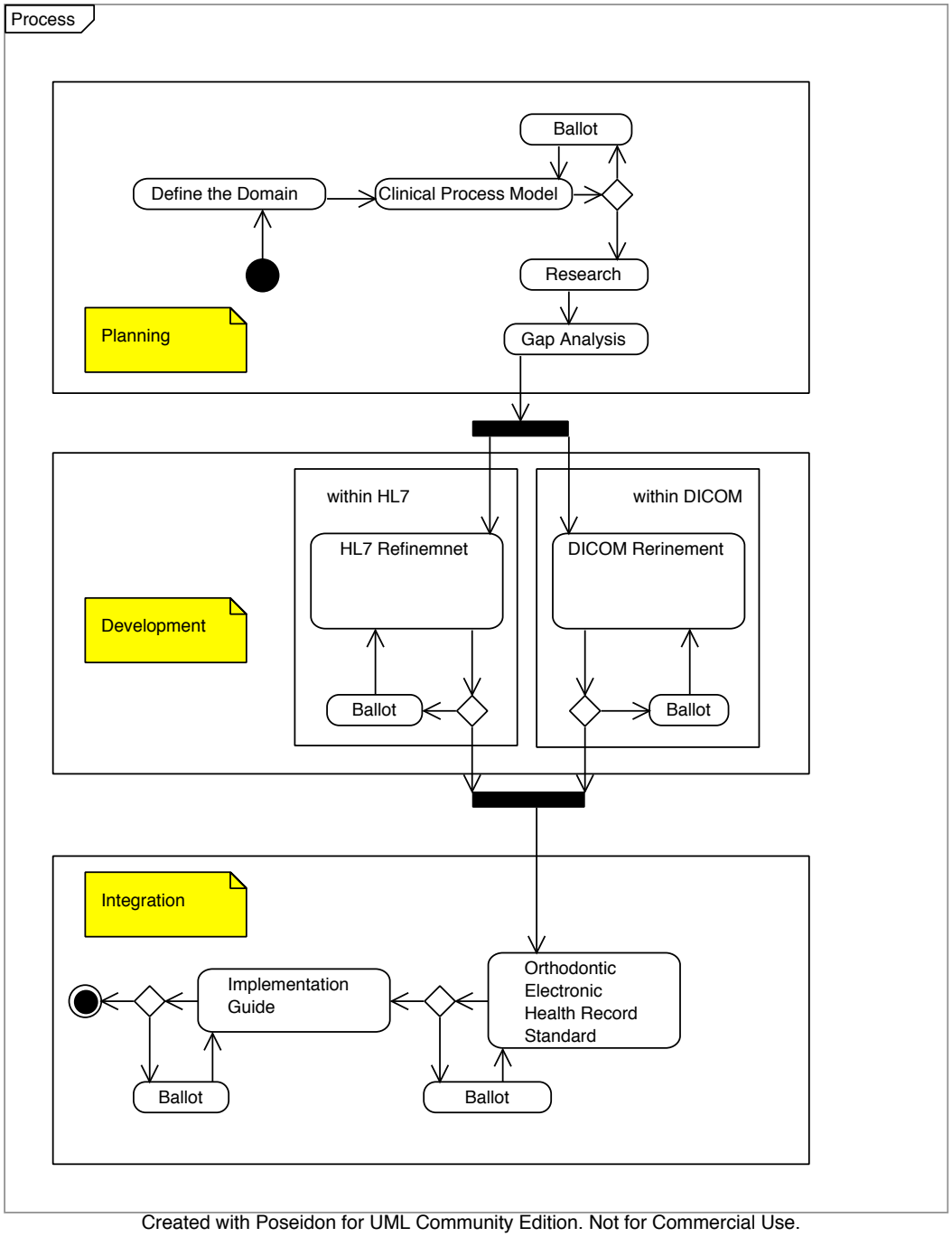


Figure 3.21: Activity diagram of the proposed process for the development of the orthodontic electronic patient record standard. The DICOM and HL7 refinement processes are done by subgroups of our working group (ADA SCDI WG 11.6) within the respective organizations.

From the outcome of the above mentioned analysis the structure represented in Figure 3.20 on the preceding page is proposed for the Ortho-EPR standard: an ADA/ANSI standard that is composed by the integration of HL7 with DICOM. Using this approach, it can be

made sure that the data will be most compatible with existing systems[31], while at the same time delivering a complete orthodontist-approved Ortho-EPR standard. The ADA SCDI would provide the official standard and standard implementation documentation (similar to Specification 1000 and its accompanying Technical Report 1027). This process is better understood through the activity diagram of Figure 3.21 on the previous page, where it is divided in three main phases: planning, developing and integration.

Planning

In the planning stage it is necessary to develop a model of the clinical processes. It will begin from use cases (HL7-like storyboards), which will then mature into a balloted and diagrammed clinical model. Once the clinical model is complete, a set of attributes for each use case will be created. These attributes will allow the production of a gap analysis between these attributes, and those already present in current standards. This will lay the grounds for the next two stages.

This phase is currently taking place at the ADA SCDI working group 11.6, more precisely from the members representing Loma Linda University, University of Chicago and Universidade de Brasília. The first two members are field specialists, and will therefore deliver the more orthodontic specific documentation, i.e. the description, making use of text and diagrams, of each orthodontic scenario that needs to be represented electronically. The author of this thesis will then intervene and aid the production of classes and attributes needed to represent the use cases. With this information, a gap analysis based on the research of available standards will be produced.

The planning phase concludes with the definition of the technology to be used (see section 3.1). Based on the current research performed by the author, the suggested technology to be used is HL7 for textual data, DICOM for orthodontic images, and ADA SCDI to combine the two in an organic, and ADA approved way.

Developing

Once it has been officially agreed upon to make use of the above mentioned technology, the gap analysis will be presented to HL7 and DICOM experts respectively. These will suggest the most efficient method to include the missing attributes and classes in their respective

[31] Most medical systems understand HL7, DICOM or both.

standards in order for the resulting refinements to be fully HL7 and/or DICOM compliant. Most likely, this process will entail the formation of a dental/orthodontic technical committee within HL7 and the inclusion of interested parties in the appropriate DICOM working group (DICOM WG 22/ADA SCDI WG 12.1).

In order for this process to take place, the orthodontic electronic patient record developers (i.e. the ADA SCDI WG11.6) will be divided in imaging and non-imaging groups, based on interests. Each group will be the official DICOM and HL7 representative responsible for communications between the working group and these standard organizations.

This stage will deliver the inclusion of missing elements in the ballots for the future HL7 and DICOM releases.

Integration

Once the two standards are ready, the ADA/SCDI will publish a higher level standard to instruct the implementors on the joint use of HL7 and DICOM in an ADA/ANSI approved way. This document is to be balloted and released, and will act as the official standard reference. In addition, another sub-group of the working group will develop a less technical companion to guide the reader through the process of implementing and using the standard.

Integration will necessarily also have to produce a compliance document. Since both HL7 and DICOM have well defined compliance regulations, the need will arise for another sub-group to form, this time responsible for the creation of conformance regulations.

3.8.6 Sub-Groups

As the development evolves and grows larger, it will be necessary to divide responsibilities into more specific sub-groups. Each sub-group should consist of at least one member and should develop expertise in its assigned subject. The subdivision should follow, but not limit itself to the following description.

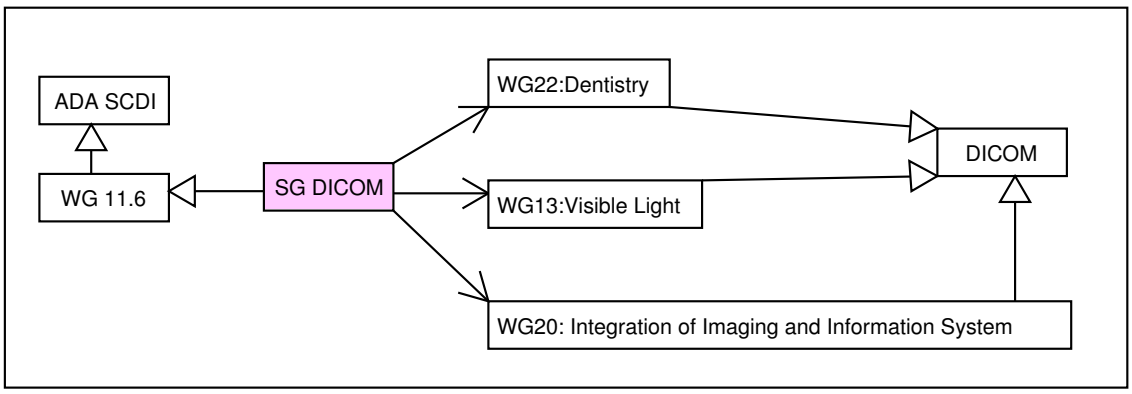


Figure 3.22: Interactions between DICOM subgroup and other working groups.

DICOM

Members of this subgroups shall be responsible for developing contacts and expertise within the DICOM standard and its developing organization. This subgroup will be responsible for a more accurate research of the DICOM standard for the development of the gap analysis to be delivered in the planning phase. In the development phase, the subgroup will be responsible for the process of the including the necessary fields and attributes. During the integration phase it will be necessary for the subgroup to research the DICOM side of conformance, documentation and testing.

The relationship between the DICOM subgroup and other working groups can be found in Figure Figure 3.22. The subgroup will interact directly with the DICOM *Dentistry*, *Visible Light* and *Integration of Imaging and Information Systems* working groups.

HL7

Members of this subgroups will have similar responsibilities as those of the DICOM subgroup, except they will be held responsible for the HL7 aspect of the standard, rather than the DICOM one. Refer to the DICOM subgroup definition for more details.

The relationship between the HL7 subgroup and other working groups can be found in Figure Figure 3.23. The subgroup will interact directly with the HL7 *Medical Records Information Management* and *Vocabulary* Technical Committees as well as *Imaging Integration* and *Conformance* Special Interest Group.

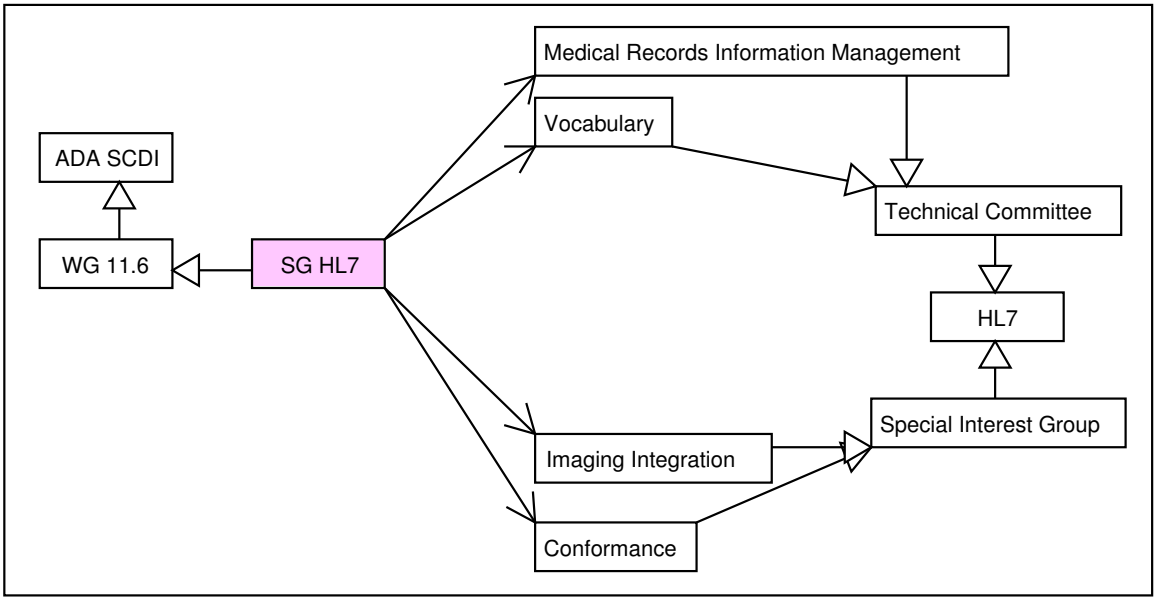


Figure 3.23: Interactions between HL7 subgroup and other working groups.

Documentation

The documentation subgroup will be responsible for collecting appropriate information from the DICOM and HL7 subgroups and organizing it into a well structured implementation manual. This subgroup will only become active during the Integration phase.

As can be seen from Fig. Figure 3.24, the Documentation subgroup will be interacting with the *Education* and the *Vocabulary* Technical Committees of HL7, and with DICOM. Since DICOM does not have a specific working group related to standard documentation, the group will establish contacts with individuals of various working groups that master this subject.

Conformance

Standard compliance is a complicated issue, which is usually discussed in detail in each standard documentation. This subgroup will be held responsible for developing compliance statements that do not conflict or interfere with existing HL7, DICOM or ADA compliance statements.

The relationship between the Conformance subgroup and other working groups can be found in Figure Figure 3.25. The subgroup will interact directly with the HL7 *Conformance* Special Interest Group. Since DICOM does not have a specific working group related to conformance development, the group will establish contacts with individuals of various working

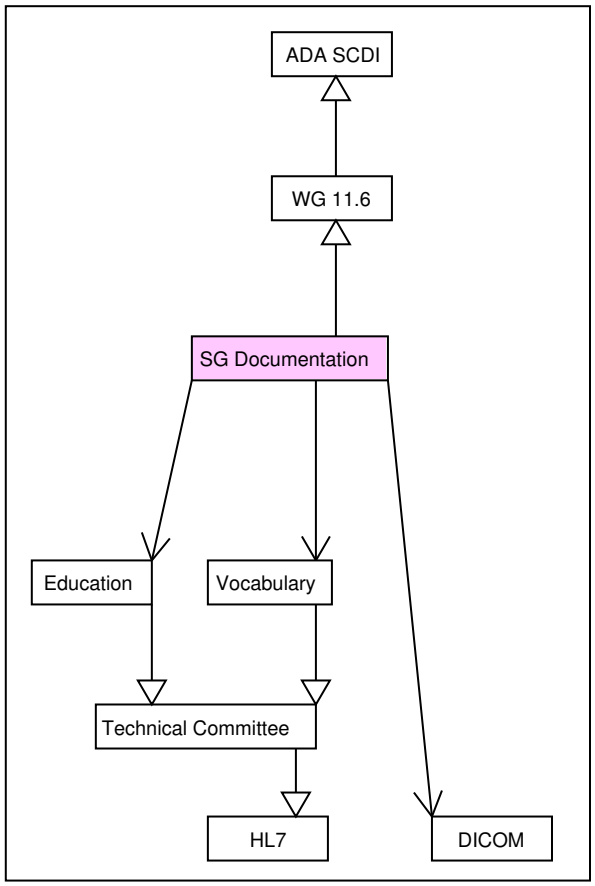


Figure 3.24: Interactions between Documentation subgroup and other working groups.

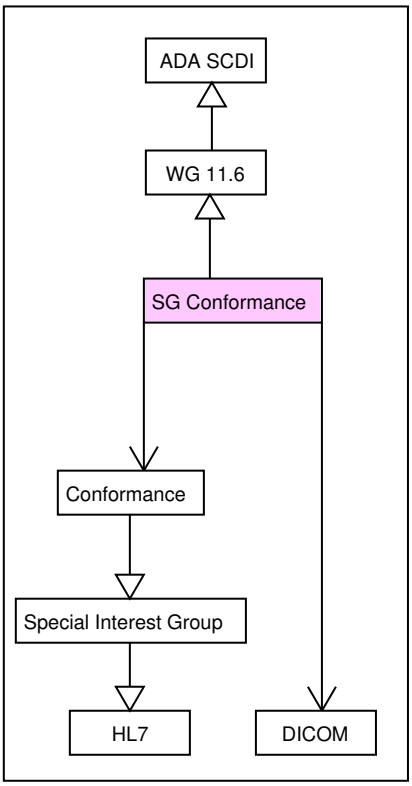


Figure 3.25: Interactions between conformance subgroup and other working groups.

groups that master this subject.

Summary

The proposed solution for the development of the Ortho-EPR standard delivers a complete, functional and easy way to implement the standard. The close collaboration with HL7 and DICOM ensures the highest level of compatibility with already existing health care systems in most medical fields.

Nonetheless, the entire developing cycle requires some time, 3 years for a first, fully official release to be approved. Most of this time would be spent in creating a new technical committee within HL7 and in the balloting cycles of HL7 and DICOM. Nonetheless usable test releases will be available for early implementation, which will accelerate the urgent and necessary implementation of the standard.

In the next section a digital standard for cephalograms is proposed. This constitutes a fundamental element of the orthodontic electronic patient record standard.

4 A STANDARD FOR DIGITAL CEPHALOGRAMS

It was only in 1991, during the annual meeting of the American Association of Orthodontics (AAO), that the belief of the new information age reaching into the orthodontic world was accepted. Unfortunately, the introduction of computer technology into the orthodontic office occurred before the analytic requirements of a computerized orthodontic record keeping system could be determined. To continue to communicate effectively in the information age, a standard way of storing and retrieving computerized orthodontic records needs to be established.

Currently, the profession is being challenged to provide more information on the efficacy of various treatment methods. In addition, valuable cephalogram film series belonging to studies performed during the first half of the 20th century, are now starting to decay. Various growth studies have been done in the past century, where patients where voluntarily x-rayed periodically (sometimes even with implanted artificial landmarks) in order to research cranial growth and development. Today, such studies would be impossible to perform, which makes the preservation of these films a high priority project for many institutions. These challenges has increased the need for a standardized cephalogram database of treated and untreated orthodontic cases. The personal computer may provide a solution to this problem because it is easy to make and access copies of computerized information and because digital copies don't suffer from deterioration. However, for the copies to be useful, they must be compatible among various computers and computer software programs.

To date, no standards have been proposed or adopted by the orthodontic profession for storage and exchange of computerized patient information. During a 1991 meeting of Orthodontic Educators, three issues were identified that need to be addressed before standards can be established:

1. Lexicon issues: what terms will be used to describe orthodontic conditions.
2. Resolution issues: what is the resolution (spatial and grey-scale) necessary for orthodontists to use digital representations of x-ray and models instead of the originals.
3. Registration issues: how should digitized records be registered and scaled.

Two years after the 1991 educators meeting, Hans organized a workshop sponsored by the American Association of Orthodontics Foundation (AAOF) which was held at the Bolton-Brush Growth Study Center (Case Western Reserve University, Cleveland, OH, USA) in

March 1993. It was entitled *Standards for Digital Storage, Retrieval and Analysis of Orthodontic Records* (American Association of Orthodontics Foundation, 1993) and was the first attempt to discuss the technical details of creating a standard for digital orthodontic data. The workshop only focused on digital x-rays and delivered a rather broad set of minimum requirements necessary for digital cephalograms to be of orthodontic use. After the workshop, interest in the project faded. It was only ten years later that Hans et al. proved the conclusions held at the workshop to be true (Hans et al., 2003).

The intention of this document is to apply the image resolution issues presented in (Hans et al., 2003) and the registration issues discussed in (American Association of Orthodontics Foundation, 1993) into a DICOM extension for cephalograms. Lexicon issues are not addressed, as they are believed not to be necessary for the storage and retrieval of digital cephalograms.

4.1 REQUIREMENTS FOR DIGITAL CEPHALOGRAMS

The need for the development of a standard for digital cephalograms has existed for about 15 years. Over all these years, the details of the requirements for digital cephalograms have been drafted, yet have never been applied. In this section we summarize the necessary attributes needed to fully represent digital cephalograms.

The following is a description of the attributes which should accompany all cephalogram:

Patient Demographics

The cephalogram is part of the patient record, and should therefore contain information for its proper identification. Such information should be patient name, ID, gender, date of birth, date/time when exposure was taken.

Magnification

Magnification is an essential element that allows the correct interpretation of the distances within a cephalogram. Magnification can be stored in various forms: distance between mid-sagittal plane and film associated with the distance between source and film; ratio between these two distances; ratio between 1 mm on cephalogram and 1 mm on the subject, as for

example, the scale of a map; percentage; inclusion of a 10 cm x-ray visible scale in each and every exposure... Of all the above, percentage is the preferred unit for magnification, because it represents the desired information. The distances of the film from the subject and from the x-ray source, or the 10 cm scale on the image are only needed to compute the magnification factor. All that is needed is a quick and easy way to translate between the two coordinate systems (real world to cephalogram). The percentage allows this conversion easily with the following equation:

$$d\left(1+\frac{p}{100}\right)=d' \tag{1}$$

where d is a distance on the subject (a real world distance), d' the distance as measured on the cephalogram and p magnification of the cephalogram in percentage.

Orientation

The orientation of the head with respect to the x-ray beam must be known in order to be able to accurately relate the x-ray distances with the subjects measurements. Normally this is done with the cephalostat by keeping the subject in a locked position, and by orienting the central x-ray beam exactly through the transmeatal axis. The cephalostat, which secures the subject by the ears, only allows movement about the transmeatal axis. In lateral cephalograms, this kind of rotation is of little importance, since it can be easily corrected by physically rotating the x-ray film after it has been developed (no distortion inserted). Yet for PA (posteroanterior) cephalograms such rotation causes a distorted projection of the skull. This prevents a correlation between cephalogram and patient measurements, because the angle of rotation is unknown.

For this reason it has been decided to define, within the PA cephalogram, the angle about the transmeatal axis with respect to the Frankfort plane[32] as a mandatory field. This has two advantages: (1) The distances on the cephalogram can be accurately related to measurements on the subject and (2) the technician is forced to pay particular attention to the orientation of the head.

Assuming the distortion caused by the point-like x-ray source to be negligible, distortion in the PA caused by rotation about the transmeatal axis can be corrected with the following

[32]The Frankfort plane is defined by the left orbitale (the lowest point on the lower edge of the orbit) and the right and left tragions (upper edge of the tragus). This plane is usually held horizontal, i.e. parallel to the ground.

relation:

$$d' = \frac{d''}{\cos \alpha} \tag{2}$$

where d'' is an anatomical measurement performed on the cephalogram, α the angle of rotation with respect to the Frankfort plane and d' what the anatomical measurement would be, were there no rotation (no transmeatal distortion). Eq. 2 can complement Eq. 1 by forming the following more complete magnification correction relation:

$$d = \frac{d''}{\cos \alpha \left(1 + \frac{p}{100}\right)} \tag{3}$$

Eq. 3 can substitute Eq. 1 in any situations: the cosine term disappears when the angle is zero degrees, reducing to Eq. 1.

SB Corner Fiducials

SB Fiducials are to be used for digitized analog cephalograms: they guarantee that the digitalization process has not added any distortion, and provide an additional way to compute the scale of the digital image (hence the size of each pixel). Refer to 2.3.2 on page 17 for more detailed description.

There are four pinholes punched at the corners of the cephalogram with a template. The distance between these points is known and should remain constant after digitization. This can be accomplished by either storing each fiducial as a point (in x,y coordinates) or by storing the distances of the fiducials from each other. The latter method provides two advantages: (1) there are only 6 numbers to store, instead of 8 (each point has 2 values: x and y) and (2) there is no need to account for possible coordinate shifts introduced by the scanning or the pinhole-punching process. We therefore decided that SB Fiducials will be stored with the cephalogram making use of six fields representing the six distances of the points with each other. Only if all six distances are known, can the relation between all points be guaranteed.

A cephalogram must contain all six distances if it is digitized from film. In the case when a cephalogram originates directly from a digital x-ray sensor, making use of SB corner fiducials is still suggested: It has been proven that some digital cephalometers can produce distorted images. By placing four SB fiducials at known distances close to the patient inside the field of view of the cephalometer, this distortion can be easily detected.

Resolution

The main purpose of cephalograms is to measure angles and distances between anatomical landmarks. It is therefore essential to be able to accurately identify anatomical landmarks. Based on a research held at Case Western Reserve University (Hans et al., 2003), the minimum resolution needed for a cephalogram to be useful for orthodontic treatment or research is of 4096 shades of grey and 1536x1024 pixels on an 8”x12" film, which translates into a resolution of 128dpi x 12 bits of greys. This means that a pixel cannot be bigger than 1/128th of an inch, or 0.19mm.

The standard should therefore require the pixel size to be smaller than 0.19mm both horizontally and vertically and have a depth of 12 bits.

Implementation manual

Another essential element is the implementation manual, which details how to apply the standard to a real world application such as a cephalometric analysis program or a cephalogram database. The manual should be written by the ADA SCDI (as described in 3.8 on page 64) for any software developer interested in the standard as a companion to the already existing DICOM documentation.

4.2 DICOM FOR DIGITAL CEPHALOGRAMS

DICOM (Digital Imaging and Communications in Medicine) is a well established standard maintained by the National Electric Manufacturing Association (NEMA). It defines how to store and transfer images related to the medical field. Currently, most medical equipment which deal with images, can interpret the DICOM format[33]. DICOM was chosen as the framework to implement the standard because of its popularity and its advanced stage of development. In fact, the widespread use of DICOM in the medical field will greatly facilitate the integration of the cephalometric images with existing software. Integration and implementation are a keystones of standards development, since a well developed standard that remains unimplemented (as is the case for many other existing medical informatics standards) is of little use.

In part 3 of the DICOM documentation, a Digital X-Ray (DX) Image Information Object

[33]Refer to section 3.4 on page 52 for more information on DICOM.

Definition (IOD) is defined (Appendix A.26). This is the most appropriate IOD to use to represent digital cephalograms. Its attributes and modules

Magnification

DICOM accounts for two ways to store the geometric magnification along with the x-ray image. The first method stores the ratio between the source to patient and the patient to film distances; the second stores the distance between two pixel centers in the real world.

Using SID/SOD

Radiographic magnification can be encoded within a DICOM DX IOD making use of the *DX Positioning Module* (National Electrical Manufacturers Associations, 2006, PS 3.3 - Page 631). The module contains three useful attributes: *Estimated Radiographic Magnification Factor* (0018,1114) which is defined to be the "Ratio of Source Image Receptor Distance (SID) over Source Object Distance (SOD)."; *Distance Source to Patient* (0018,1111) and *Distance Source to Detector* (0018,1110). By making use of either the first, or a combination of the last two attributes, magnification information can be accurately preserved along with the image.

In most cases, the SOD and SID distances are kept constant for all cephalograms. Utilizing these attributes is therefore relatively practical and suggested.

Using pixel spacing

Alternatively, radiographic magnification can be encoded within a DICOM DX IOD making use of the *DX Detector Module:* the module contains the *Basic Pixel Spacing Calibration Macro* where the *Pixel Spacing* (0028,0030) attribute can be used to store what one pixel to the left and/or one pixel down corresponds to on the patient. From the DICOM documentation (National Electrical Manufacturers Associations, 2006, PS 3.3 - Page 80), the official definition is:

> "The Pixel Spacing (0028,0030) attribute specifies the physical distance in the patient between the center of each pixel."

The macro even allows for specifying how the calibration was performed, if through the use of fiducials, or if it was just known. This can be specified through the optional attribute *Pixel Spacing Calibration Type* (0028,0402):

> "The type of correction for the effect of geometric magnification or calibration against an object of known size, if any. Enumerated Values:
>
> GEOMETRY: the Pixel Spacing (0028,0030) values account for assumed or known geometric magnification effects and correspond to some unspecified depth within in the patient; the Pixel Spacing (0028,0030) values may thus be used for measurements of objects located close to the central ray and at the same depth.
>
> FIDUCIAL: the Pixel Spacing (0028,0030) values have been calibrated by the operator or image processing software by measurement of an object (fiducial) that is visible in the pixel data and is of known size and is located close to the central ray; the Pixel Spacing (0028,0030) values may thus be used for measurements of objects located close to the central ray and located at the same depth within the patient as the fiducial." (National Electrical Manufacturers Associations, 2006, PS 3.3 - Page 81)

Similarly, the attribute *Object Pixel Spacing in Center of Beam* (0018,9404) could be used: it defines the pixel spacing at the center of the beam.

Although this method would also solve the problem of knowing what the distance of the digital image corresponds to in real life, it is less practical, because it needs to be calculated from the resolution, the *Imager Pixel Spacing* (0018,1164) and the actual SID/SOD ratio.

Orientation

As described above, it is important to be able to store, along with the cephalogram, which side the beam hit the patient first at exposure time. Also, the angles at which the patient is oriented with respect to the detector and beam are important to be able to accurately calculate distortion. DICOM provides a way to store this information in the DX Positioning Module defined in (National Electrical Manufacturers Associations, 2006, PS 3.3, C.8.11.5). *View Code Sequence* (0054,0220) allows for storing which kind of cephalogram it is (postero-anterior, antero-posterior, right-lateral,...). This field already defines which side the beam hits the patient first. For example postero-anterior specifies the beam direction: from posterior to anterior. In addition, this field also allows oblique sequences (see Table E.5 on page 116). However, this attribute does not allow storing specific non-standard angles.

Such angles can easily be stored using *Positioner Primary Angle* (0018,1510) and *Positioner Secondary Angle* (0018,1511) attributes. The *Positioner Primary Angle* definition is like longitude (in the equatorial plan). This is the angle that defines whether the accompanying image is a lateral or PA cephalogram. The *Positioner Secondary Angle* definition is like latitude (in the sagittal plane). This is the angle that defines the rotation about the transmeatal axis. For example, a patient facing the x-ray source for an antero-posterior image would be encoded with Primary Angle 0 degrees and Secondary Angle 0 degrees, whereas a patient oriented for a lateral Cephalogram, with the beam coming from the right side of the face, with Primary Angle -90 and Secondary Angle 0.

A note on *Positioner Secondary Angle*

In DICOM, the secondary Angle is defined as follows:

> "The Secondary Axis is in the Patient Plane and is perpendicular to the Primary Axis at the isocenter. The Positioner Secondary Angle is defined in the Sagittal Plane at the isocenter with zero degrees in the direction perpendicular to the patient's chest. +90 degrees corresponds to the cranial direction. The Secondary Positioner Angle range is -90 to + 90 degrees."(National Electrical Manufacturers Associations, 2006, PS 3.3, p. 439)

While mainly sufficient, for cephalograms, this needs to be adjusted slightly. The cephalostat only allows for rotation about the transmeatal axis. Hence, the axis of rotation can only be the axis that passes through the ears (transmeatal). Therefore the angle of 0, instead of being defined as perpendicular to the chest (which is not a region of interest for cephalograms), it shall be defined as zero degrees in the direction parallel to the Frankfort plane: 180 degrees if the patient has its back towards the x-ray source and 0 degrees when the patient is facing it. Positive angles indicate a rotation such that the patient is looking downward, negative angles indicate a rotation such that the patient is looking upward (see Table E.5 on page 116).

For standard cephalograms, the *Positioner Secondary Angle* should conventionally always be 0 degrees. Nonetheless, there could be some applications when it may be convenient to image the patient at different angles. As long as these angles are recorded, the images can be considered useful cephalograms. However, for the cephalostat positioner type, it is not reasonable to have a secondary angle greater than 80 degrees or smaller than -80 degrees: 90 degrees would mean that the whole body is being imaged from head to feet, which would provide an image that could not be considered a cephalogram any longer; a 180 degrees angle

signifies that the patient is being imaged upside down (head down, feet up), which creates an unlikely scenario.

SB Corner Fiducials

DICOM provides for a way to store spatial fiducials in an IOD called *Spatial Fiducials*. This IOD is primarily intended to be used to correctly reference and overlap two separate images. Although it is not possible to store the distance between each fiducial, the IOD has attributes for the coordinates of each SB corner fiducial. With a little math, it is possible to convert from distances to coordinates, and vice versa. Refer to Appendix D on page 104 for a more detailed mathematical explanation.

When the fiducials are placed in the imaging field, they are held at fixed known distances with a frame or a template. These distances can be stored in a *Graphic Data* (0070,0022) attribute, which is part of the *Spatial Fiducials* module, in coordinate form. This attribute is capable of storing the coordinates of fiducials. The first fiducial can start at the origin (0,0) and the others relative to that one. Once the relationship between fiducials are correctly stored in DICOM format, they must be related to the specific scanned image. This can be accomplished in two ways: (a) by storing it along with each and every image or (b) by storing it in a separate dummy patient study and series.

Storing the fiducial relationships along with the image is possible making use of the coordinate system and pixel size of the image. The implementing system would then be responsible for knowing that the fiducial pixel coordinates are not absolute to the referenced image (i.e. the first pixel is not at coordinate (0,0) of the actual image), but they should be considered as relative.

In the second approach, the fiducials can be associated to a dummy patient image of known pixel size. The distances between each fiducial can easily be computed making use of the pixel location of each fiducial in conjunction with the pixel size of the dummy image. Any scans that were performed with this set of fiducials can then be associated to this DICOM representation of the fiducials making use of the *Referenced Image Sequence* (0008,1140) attribute.

The second approach has the advantage of not having to repeat information throughout a large set of images. In addition, various fiducial sets can easily be organized and stored for future use. On the other hand, this method could be more prone to errors during the transportation of images. When an image is copied to a different system, one must pay

attention that the receiving system has the fiducial set already. This consideration should be carefully evaluated and discussed with the members of the DICOM community.

4.3 GAP ANALYSIS

This section highlights the gap between what is required for cephalograms. It serves as background for the formulation of the standard presented in the next section.

As presented in the previous section, DICOM has all the tools necessary to be able to correctly encode cephalograms. Nonetheless, its documents do not directly specify cephalograms (neither as normative, nor as informative), hence some minor refinements need to be made. Most of these refinements could be part of a separate implementation manual, as described in Section 4.1 on page 81. Ideally they could be included within DICOM itself. The following is a list that contains items that need to be addressed:

1. DICOM does not specify minimum requirements for resolution. The specific resolution requirements for cephalograms need to be specified.
2. The DICOM normative documentation considers some fields as *Optional Data Elements*, while, for cephalograms, they should be mandatory. (eg. *Positioner Primary and Secondary Angles* (0018,1111) and (0018,1110), *Estimated Radiographic Magnification Factor* (0018,1508)).
3. DICOM does not specify a way for verifying the accuracy of the digitalization process (discussed in SB Corner Fiducials on page 80).

4.4 A STANDARD FOR STORAGE AND TRANSFER OF DIGITAL CEPHALOGRAMS

This section contains the standard for storage and transfer of digital cephalograms. It explains the details of DICOM technicalities. This information was extracted and interpreted from the DICOM manuals (National Electrical Manufacturers Associations, 2006), and it was used to produce the implementation `dcm4ceph` described in Section 4.6 on page 88.

4.5 Introduction

Digital cephalograms are more than just plain medical radiographs of the skull. They are used to make exact measurements for craniofacial growth studies, as well as for the planning of orthodontic cases. For these applications, it is important that cephalograms be stored in a format that can hold information necessary to guarantee their accuracy. This document specifies how to use DICOM to store such information along with the cephalograms themselves.

This section contains a general overview of the standard. The specifics can be found in two further documents: DX Image IOD Modules (see E on page 107) and Spatial Fiducials Modules (see F on page 119). The first document analyzes each module table of the DX Image IOD and comments the attributes that need special attention. The second document has a similar function but for the Spatial Fiducials IOD Modules.

4.5.1 Standard Overview

The basic elements that comprise a digital cephalograms are medical demographic information (patient name, sex, age, ID, health care institution, physician,...), image information (pixel size, color depth, resolution, ...), radiographic information (detector size, distance between patient source and detector, radiographic magnification, direction of beam, ...) and spatial verification information (information needed to guarantee that the digitalization process did not produce any error). DX Image IOD modules ((National Electrical Manufacturers Associations, 2006, PS 3.3, A.26)) are capable of dealing with almost all information required: medical demographics, image and radiographic. Yet spatial verification requires making use of the Spatial Fiducials IOD modules, which allows storing corner fiducials in coordinate form to verify the validity of the digitization process.

Each cephalogram image should be stored with a resolution of 128dpi or higher and 4096 or more grayscale values.

In the case when lateral and postero-anterior cephalograms are taken at the same time for the same purpose, they should be included within the same DICOM Series making use of *Image Type* (0008,0008) from the *X-Ray Image Module* (C.8.7.1). “BIPLANE A" should be specified for the PA cephalogram, while "BIPLANE B” for the lateral cephalogram. The images must reference each other from within the *Referenced Image Sequence* (0008,1140) of the same module, making correct usage of *Image SOP Instance Reference Macro* (National Electrical Manufacturers Associations, 2006, Table 10-3) as defined by DICOM. This,

though, goes against DICOM specification, as the *X-Ray Image Module* is not part of the DX Image IOD.

4.5.2 SB Corner Fiducials

SB Corner Fiducials are four or more markers located within the imaging area and digitized along with the subject. They are used to verify that the digitization process did not introduce any distortion. Their exact absolute position on the image is unknown, but the distances between each and every point is well known. It is the responsibility of the implementing software to verify that the known fixed distances correspond to the fiducial appearance on the scanned image.

Usually, SB Corner Fiducials are placed in the imaging field making use of templates. The information on the set or template of SB Corner Fiducials should be stored making use of the *Spatial Fiducials* IOD (National Electrical Manufacturers Associations, 2006, PS 3.3, A.40). The implementation details can be found in the tables of Appendix F on page 119.

Each image that makes use of a specific fiducial set, should reference the set making use of the *Referenced Instance Sequence* (0008,114A) within the General Image Module. The SOP Class UID should therefore be set to "1.2.840.10008.5.1.4.1.1.66.2". As no ideal code for this purpose was found, the most appropriate that should be used is the DCM version 01 112171 "Fiducial mark" code.

4.6 dcm4ceph: AN IMPLEMENTATION IN JAVA

This section presents the development and use of a software that implements the standard proposed in section 4.4 on page 86.

In order to test the functionality of the standard proposed in Appendix 4.4 on page 86, it was decided to write a program named `dcm4ceph` that takes a cephalogram image along with its vital information, and packs it nicely into an archive which is readable by any DICOM compatible software. `dcm4ceph` is a set of libraries and utilities to simplify the creation of DICOM cephalogram files. The name stands for "DICOM for Cephalograms" and was chosen to resemble `dcm4che`, a software package it depends on.

Cephalograms need to be stored along with information which cannot be easily saved into a

simple image file (JPEG, tiff...) (see Section 4.1). DICOM is a medical imaging standard which specifies how to store such information. However, the research involved in discovering its details is quite time consuming for the novice DICOM user. `dcm4ceph` allows users to easily encapsulate all cephalogram related information into one single DICOM object, without the need of any prior DICOM knowledge.

`dcm4ceph` is not a full featured DICOM server or client. It does not strive to compete on the market with other medical imaging products or picture archiving (PAC) servers. Its intention is to provide the community with a practical example on how to store cephalograms in a DICOM compatible (and in the future also ADA approved) fashion.

The program was based on the cephalogram sets of the Bolton Brush Growth Study collection, in Cleveland, OH. Each cephalogram set contains a lateral and a poster-anterior cephalogram, both marked with a set of four SB Corner Fiducials. The cephalograms come with information such as gender, patient ID and distances from patient to detector (to calculate radiographic magnification) burned on them.

The inputs of `dcm4ceph` consist of (1) one or two cephalogram files in JPEG format, (2) the cephalogram clinical information in a JAVA .properties text file (one for each JPEG file), and (3) the SB Fiducial Set information also in a JAVA .properties text file. Its output is a DICOM object properly organized and tagged according to the standard proposed in Section **??** on page ??.

In order to facilitate its divulgation and encourage its use a web site for the project was set up. It contains a brief description of the project, its license agreement, history and technology, the API docs as well as a source and a binary package which the visitor can download free of charge. The site is hosted on `http://dcm4ceph.antoniomagni.org`, courtesy of `brillig.org`.

4.6.1 Technology

This section discusses the technology used to develop the software (i.e. programming environment, tools, applications, libraries...).

The intention of the author was to create a software library that would encourage the divulgation of the cephalogram standard discussed above. It was therefore important for the software to be readily available to anyone and for anyone to be able to freely use it. These goals have been accomplished by writing an open source software (under the Lesser GNU

Public License (LGPL)) in JAVA, and by providing information on the project through a publicly accessible web site.

Since dcm4ceph is a library with accompanying utilities, it was decided to make use of the Lesser GNU Public Licence (LGPL). Using the ordinary GPL for a software makes it available only for free programs. The Lesser GPL permits use of the software in proprietary programs as well. This is a very encouraging feature for commercial software implementors. The LGPL was chosen as it is believed that it will help its divulgation.

The language chosen to develop the software was JAVA (TM). Using JAVA means that the software can run on most operating systems (SunOS, Windows, Linux, Mac OS X, ...) without the need of rewriting or recompiling the code. This makes the software extremely portable, therefore helping its divulgation. When developing a software, it is always best to make us of already existing libraries and modules. This greatly improves stability and decreases development time. JAVA's object oriented architecture encourages such attitude by simplifying the integration of different software projects.

For this reason, it was decided to make use of the dcm4che package (http://dcm4che.sourceforge.net). dcm4che is an open source project that provides a JAVA framework to easily access and use DICOM objects. It provides various modules with classes that implement DICOM's networking and media storage features. It also provides a set of command line tools that allow DICOM file manipulation. dcm4che is hosted at sourceforge.net.

dcm4che uses The Apache Maven Project to perform basic project management functionality (keep track of dependencies, build packages,...). Maven is a software project management and comprehension tool. Based on the concept of a project object model (POM), Maven can manage a project's build, reporting and documentation from a central piece of information. In addition, Maven can co-exist with other project builders such as ant or make. Because of Maven's ease of use and portability (Maven is also JAVA based) and its almost unlimited modular capabilities, it was decided to base dcm4ceph on Maven as well. Maven is hosted on http://maven.apache.org.

Software development was done on the Eclipse platform. Eclipse is an open source community whose projects are focused on providing an extensible development platform and application frameworks for building software. Eclipse is also JAVA based, open source and free of charge. There is a Maven plugin for Eclipse, which simplifies its use for this project. Eclipse was chosen because it is the most complete and up to date open source software development platform available. Eclipse is hosted at http://www.eclipse.org.

Backup and software versions are kept track by using Concurrent Versions System (CVS). CVS is a version control system, an important component of Source Configuration Management (SCM). Using it, one can record the history of sources files, and documents.

4.6.2 Modules

The code of `dcm4ceph` was organized in modules to facilitate its maintenance and future expansion. Currently, only three modules are present: `dcm4ceph-core`, `dcm4ceph-tool-ceph2dicomdir`, `dcm4ceph-dist` and `dcm4ceph-site`.

The core module contains classes that lay the foundation for the other modules. This includes objects such as the Cephalogram class (a class to represent a digital cephalogram) and the SBFiducialSet class (a class to represent a set of 4 SB Corner Fiducials).

The tool-ceph2dicomdir module is part of the tool module, which contains front-ends to the packages within the core module. ceph2dicomdir is a tool which delivers a dicomdir directory structure with a cephalogram set and its relative SB Fiducials based on the Bolton Brush Growth Study collection.

The site module contains the code needed to generate the html files for the web site `http://dcm4ceph.antoniomagni.org`. Maven takes care of generating the html files and deploys them automatically onto the web server.

The dist module is used to produce the distribution packages in .zip, .tar.gz, and .bz2 formats. It contains all necessary instructions for Maven to fetch all scripts and .jar files and pack them nicely into a single, distributable archive file.

4.6.3 Usage

In order to convert a digital cephalogram to DICOM format, it is necessary to make use of the `ceph2dicomdir` utility. Inside the distribution package the `bin/` folder contains the shell scripts necessary to execute included `ceph2dicomdir` utility: `ceph2dcm`, to convert to simple .dcm DICOM files and `ceph2dicomdir` to generate a full DICOMDIR directory structure with dicomdir file.

In order to generate a full dicomdir structure execute the script, enter the `bin/` folder and

execute

```
ceph2dicomdir <ceph-image1.jpg> [ceph-image2.jpg] \
<fiducial-set.properties>
```

The command takes two or three arguments. If three arguments are specified, the first two are the filenames of the cephalogram images (in two views, for example a lateral and a postero-anterior view), while the third argument specifies the location of the fiducial set file. If the second filename is omitted, the second argument is considered as the fiducial set file.

The meta information for the cephalogram image files has to be stored in a JAVA properties file and have the `.jpg` extension replaced with `.properties`. A sample properties file can be found in the `etc/` folder of the binary distribution package.

The ceph2dcm file works in a similar fashion, but takes only one argument:

```
ceph2dcm <file1>
```

file1 can be either a fiducial set properties file, or a cephalogram JPEG file, in which case the accompanying properties file must be present and in the same directory as the image file. This command will produce a .dcm file with the appropriate attributes set to either represent an image or a fiducial set.

4.6.4 Development

This section discusses the tasks that were accomplished during the development of the software.

`dcm4ceph` relies on `dcm4che`, which has recently been rewritten to version 2. The contribution of the author to `dcm4che` was in the dcm4che-core and dcm4che-iod modules, validity verification and documentation.

The classes necessary to represent a DX Image IOD and a Spatial Fiducials IOD, along with all of its modules, where missing in the iod package, and therefore needed to be written. dcm4che comes with a specific way to verify the validity of DICOM attributes. Nonetheless,

because of its young age, verification is mostly un-implemented. Besides, the creation of new JAVA IOD representation required the refinement of the verification process.

All code written by the author was properly documented using the *javadoc* conventions. In addition, the author documented some of the existing code as well, which he found to be mostly not documented. During the development of `dcm4ceph`, one of the contributors of `dcm4che` started a documentation project to set up an official and better documented web site. This effort aims to finally provide proper documentation for `dcm4che`.

5 CONCLUSIONS

This work addresses the incompatibilities between orthodontic electronic patient records by proposing a global plan and by presenting a solution for one part of the orthodontic patient record. In addition, it provides a small implementation to prove the validity of the proposed solution.

Solving incompatibilities between orthodontic electronic health records is a large scale project which involves defining, distribuiting and encouraging the implementation of a telecommunications standard. It has been shown that this process can be broken down into the following steps: begin by gathering stakeholders into one working group; define the scenarios of the orthodontic domain (through case diagrams), in order to develop a gap analysis between the orthodontic domain and existing standards; use the gap analysis to complete existing standards with the functionality needed to contain orthodontic data; develop high-level technical reports to document the implementation process; distribute and test the newly formed standard. Such standard developing procedure is best taken care of by official standards developing committees such as the ADA SCDI.

Since the orthodontic electronic patient record is composed of both imaging and non-imaging data, the integration of DICOM for images and HL7 for the more general, text-oriented information was proposed. These were selected because of their popularity: both HL7 and DICOM are the most advanced and well developed implemented informatics medical standards available. The ADA, being the biggest and most influencial dental association world-wide, should be held responsible for the design and higher level specification of the orthodontic electronic patient record standard. It should coordinate the optimization of HL7 and DICOM for representing orthodontic specific data, and the harmonization of the two. The document details a proposal of the ADA SCDI leading the development of such standard making use of HL7 and DICOM for textual and imaging data respectively.

ADA, HL7 and DICOM were selected based on their popularity, support and implementation: each of them represents the best publicly available medical informatics standard for their respective fields. Therefore, making use of such standards, and their respective supporting organizations, would guarantee most success with respect to the implementation of the proposed standard.

Many steps necessary in the evolution of these standard organizations involve ballotting, which requires approval from most members. This is a time consuming process that forced the authors of this work to focus on one specific part of the orthodontic patient record:

cephalograms. Cephalograms are x-rays of the skull taken in such a way as to allow accurate measurments to be takens from them. These form a fundamental element for the planning of an orthodontic treatment. The existance of a standard for digital cephalograms not only provides a starting point for the development of the orthodontic electronic patient record standard, but it also can be used for the preservation of old and very valuable cephalogram film studies (currently an ongoing effort).

In addition a program was developed that implements the rules set by the standard. It was written in a platform independent language (JAVA) and under a free, open source license agreement (LGPL). The program accepts the following inputs: one or two cephalogram images (JPEG), a configuration file for each image (which contains clinical and techinical information that cannot be stored in JPEG format) and a configuration file for the SB Corner Fiducials. It converts each object in DICOM format, and generates a DICOMDIR file (DICOM index file) to accompany the file set. The images were opened and tested with OsiriX, an open source DICOM viewer.

This thesis constitutes the first mile stone towards the development of an orthodontic electronic patient record. Much work is currently being accomplished by the ADA SCDI (which the author is a member of), and entails the process already discussed in Chapter 3.8.

Future work should be directed towards making the cephalogram DICOM standard proposal become part of the next official DICOM release. At the same time, the gap analysis between what the orthodontists need to store their data in digital form, and what DICOM and HL7 can offer today, should be completed and used to produce further DICOM and HL7 proposals in such a way that these also can become integral part of future releases. Finally, the work should be geared towards releasing higher-level implementation and usage documentation by the ADA SCDI.

This work was presented for the first time in poster-form at the American Association of Orthodontics annual meeting (Magni et al., 2005), and was subsequently accepted for publication in the American Journal of Orthodontics and Dentofacial Orthopedics (Magni et al., In Press).

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APPENDIX

A History of Specification 1000

The following paragraphs are taken from an email by Mark Diehl, one of the principal contributors to Specification 1000.

> "The Specification 1000 grew out of a 1994-1996 work effort at the ADA. The scope of the work effort sponsored by the ADA originally was limited to the computer-based oral health record, what we called the COHR at the time. This COHR data model was successfully tested in 1995 in a dental implantology database. However, as we dove into the analysis we found a much broader scope was required - we first modeled the dental care delivery process and found that dentistry shares much with other health professions and must interact with these external processes. This led to the 1996 House of Delegates resolution concerning access to health information across professional and other traditional boundaries - this is the heart of the electronic health record interoperability issues that have arisen in the US these past several years.
>
> With testing showing the data model works, and the acceptance in public review, follow-on standards work expanded and enhanced the data model from the 1996 document into the Specification 1000 from 1997-99. The subject areas were selected to coincide with the major processes, and the logical data names were made more generic to be more broadly applicable in healthcare. We also proposed XML tags, anticipating this need in service-oriented architectures.
>
> As far as using these standards ... this issue is tightly intertwined with the nature of standards in the US. Of the approximately two dozen 'real' electronic health records standards, none have actually been accepted by industry. EHR vendors recognize that in the US, use of these standards is voluntary - one of the principles of our 'voluntary consensus standards' approach. This approach is quite different than found in other nations or regions like Europe, where there is heavy government involvement. Up to this point there has been no market incentive to widely adopt such standards. Our health information system vendors find that continued use of proprietary designs maintains their competitive position in the marketplace - a position they feel would be compromised loss of intellectual property and the proprietary nature of their designs. They also realize that redesign to be consistent with these standards would involve considerable expense, so they are waiting to introduce standards when these fit in their normal product life cycle. Also, when vendors do use such standards, they are reluctant to announce it owing to possible loss of competitive advantage.
>
> Another reason vendors have been slow to employ the Spec 1000 is that it is

patient centric instead of procedure, cost, or event centric, and it addresses the healthcare outcome rather than cost of care or other process parameters. This is unique in the various healthcare models worldwide and our healthcare system is evolving this way and a rare case of the standard being ready in advance of market trend. With no market incentive for these standards, use of the Specification 1000 has been limited to observation and prototyping by vendors, and experimentation in academia. Currently we see increasing interest in these standards owing to current US federal government initiatives in health information interoperability, but the results that these initiatives will have is far from certain.

Currently, there are a number of derivative works on this specification. A Specification 1039, Conceptual Clinical Data Model, revises the 1996 concept model. This is the basis for the version 2 revision of the Specification 1000. The process model has been enhanced (for example, by adding a public health component) by ASTM - this document goes into balloting later this spring. ASTM also is producing a number of implementation standards derived from the Specification 1000. ASTM E2436, for example, presents standard relational database constructs for human characteristics.

There is also a growing interest in cross-mapping the Specification 1000 with other compatible standards.

Dr. Mark Diehl"

B Example of an HL7 storyboard

The following is the Storyboard for an HL7 original document notification.

> "A pathology resident performs a gross dissection examination of the tissue submitted from a surgical procedure to remove the gall bladder of a 37 year old female patient. The pathologist assigns a surgical case number to the study and dictates his observations into a central dictation system. This narrative is exposed to a transcriptionist who keys the text into a transcription manager application. This application generates a message from the Transcription Manager (RCMR_AR000001) to a specialized case of a document manager application called a surgical pathology system (RCMR_AR000002)."(The Health Level Seven, 2006)

C Figures

D Distance to coordinate conversion

The Spatial Fiducials IOD is only capable of storing coordinates, while the SB Corner Fiducial set is stored as a set of distances. It is therefore necessary to perform a basic conversion between distanaces and coordinates.

Consider the setup of Figure D.26 on page 106: four fiducials and six distances. Points $A1$ and $A2$ are set initially to be:

$$\begin{aligned} A_{1x} &= 0 \\ A_{1y} &= 0 \end{aligned}$$

and we arbitrarily choose the x-axis to be superimposed on d_1 such that

$$\begin{aligned} A_{2x} &= d_1 \\ A_{2y} &= 0 \end{aligned}$$

Then A_{3x}can be found making use of d_1,$d_2$and d_3:

$$A_{3x} = \frac{d_1^2 + d_2^2 - {d_3}^2}{2d_1}$$

and by using the pythagorean theorem we can find $A3_y$:

$$A_{3y} = \sqrt{d_2^2 - A_{3x}^2}$$

In a very similar fashion, A_4can be found making use of d_1,$d_4$and d_5:

$$A_{4x} = \pm \frac{d_1^2 + d_4^2 - d_5^2}{2d_1}$$

$$A_{4y} = \pm \sqrt{d_4^2 - A_{4x}^2}$$

It is now necessary to make use of d_6 to find the signs of A_4.

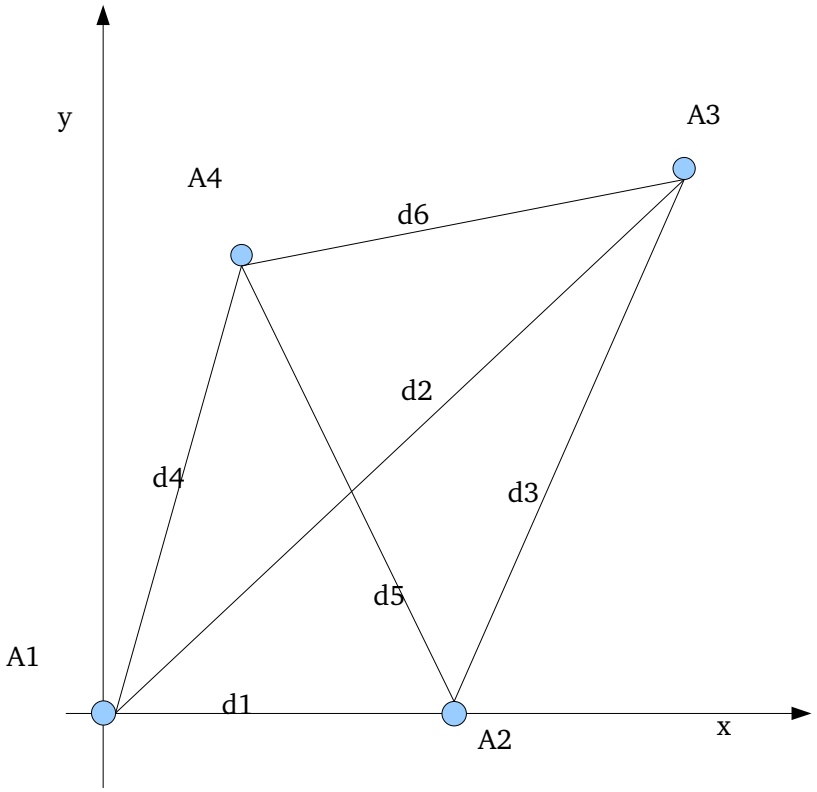

Figure D.26: Fiducials and their distances

E DX Image IOD Modules

The following tables are the Module tables from the DX IOD which need special attention for cephalograms. This section does not contain the full DICOM documentation, nor does it report DICOM tables. Although similar, the tables in this Section do not contain the DICOM Attribute Description and do not directly refer to Macro Tables. We therefore reccomend the reader to refer to the DICOM documentaion Part 3 Annex A and C, which contain the complete version of these tables.

E.1 Patient Module (C.7.1.1)

No modifications necessary. Refer to DICOM documentation.

E.2 Specimen Identification Module (C.7.1.2)

No modifications necessary. Refer to DICOM documentation.

E.3 Clinical Trial Subject Module (C.7.1.3)

No modifications necessary. Refer to DICOM documentation.

E.4 General StudyModule (C.7.2.1)

No modifications necessary. Refer to DICOM documentation.

E.5 Patient StudyModule (C.7.2.2)

No modifications necessary. Refer to DICOM documentation.

E.6 Clinical Trial Study Module (C.7.3.2)

No modifications necessary. Refer to DICOM documentation.

E.7 General Series Module (C.7.3.1)

No modifications necessary. Refer to DICOM documentation.

E.8 Clinical Trial Series Module (C.7.3.2)

No modifications necessary. Refer to DICOM documentation.

E.9 DX Series Module (C.8.11.1)

Attribute Name	Tag	Type	Notes
Modality	(0008,0060)	1	**Must be DX.**
Refernced Performed Procedure Step Sequence	(0008,1111)	1C	Same.
>Refernced SOP Class UID	(0008,1150)	1C	Same.
>Referenced SOP Instance UID	(0008,1155)	1C	Same.
Presentation Intent Type	(0008,0068)	1	**Must be "FOR PROCESSING".**

E.9.1 Presentation Intent Type

This can be either “FOR PRESENTATION” or "FOR PROCESSING”. For presentation is used when the image is not suitable for clinical use anymore (resolution too low, colors modified, or some other processing occured). For the purpose of a cephalogram standard, in order for the cephalogram can be considered valid for clinical use, all requirements must be met, and therefore, this attribute must be set to "FOR PROCESSING". For non clinical use,

the cephalogram standard is not required.

E.10 Frame of Reference Module (C.7.4.1)

No modifications necessary. Refer to DICOM documentation.

E.11 General Equipment Module (C.7.5.1)

No modifications necessary. Refer to DICOM documentation.

E.12 General Image Module (C.7.6.1)

Attribute Name	Tag	Type	Notes
Instance Number	(0020,0013)	2	Same.
Patient Orientation	(0020,0020)	2C	Same.
Content Date	(0008,0023)	2C	Same.
Content Time	(0008,0033)	2C	Same.
Image Type	(0008,0008)	3	Same.
Acquisition Number	(0020,0012)	3	Same.
Acquisition Date	(0008,0022)	3	Same.
Acquisition Time	(0008,0032)	3	Same.
Acquisition DateTime	(0008,002A)	3	Same.
Referenced Image Sequence	(0008,1140)	3	
>Referenced SOP Class UID	(0008,1150)	1	
>Referenced SOP Instance UID	(0008,1155)	1	
>Referenced Frame Number	(0008,1160)	3	
>Purpose of Reference Code Sequence	(0040,A170)	3	
Derivation Description	(0008,2111)	3	Same. See E.12.1 on page 111.

Attribute Name	Tag	Type	Notes
Derivation Code Sequence	(0008,9215)	3	Same. See E.12.1 on the next page.
Source Image Sequence	(0008,2112)	3	
>Referenced SOP Class UID	(0008,1150)	1	
>Referenced SOP Instance UID	(0008,1155)	1	
>Referenced Frame Number	(0008,1160)	3	
>Purpose of Reference Code Sequence	(0040,A170)	3	Not used, since image is not derived.
Referenced Waveform Sequence	(0008,113A)	3	Not used.
>Purpose of Reference Code Sequence	(0040,A170)	3	Not used.
Images in Acquisition	(0020,1002)	3	
Image Comments	(0020,4000)	3	
Quality Control Image	(0028,3000)	3	Normally “NO”, “YES" if phantom scan or other test type image.
Burned in Annotations	(0028,0301)	3	Indicates whether or not image contains sufficient burned in annotation to identify the patient and date the images was acquired. YES/NO.
Lossy Image Compression	(0028,2110)	3	Same.
Lossy Image Compression Ratio	(0028,2112)	3	Same.
Lossy Image Compression Method	(0028,2114)	3	Same.
Icon Image Sequence	(0088,0200)	3	Same.
Presentation LUT Shape	(2050,0020)	3	Same.
Irradiation Event UID	(0008,3010)	3	Same.

E.12.1 Derivation Description

Cephalograms are not derived images. Derived images are images that have been processed in a way that the information contained within the image has changed. Even in the case when a film cephalogram is scanned into digital format, this is not considered derived.

E.13 Image Pixel Module (C.7.6.3)

Attribute Name	Tag	Type	Notes
Samples per Pixel	(0028,0002)	1	**Set to "1" for grayscale.**
Photometric Interpretation	(0028,0004)	1	**Defines the minimum sample value to be white or black. Must be either "MONOCRHOME1" or "MONOCRHOME2".**
Rows	(0028,0010)	1	**Must be greater than or equal to 1536.**
Columns	(0028,0011)	1	**Must be greater than or equal to 1024.**
Bits Allocated	(0028,0100)	1	**Must be 16.**
Bits Stored	(0028,0101)	1	**Must be 12.**
High Bit	(0028,0102)	1	
Pixel Representation	(0028,0103)	1	
Pixel Data	(7FE0,0010)	1	Data Stream comprising the image.
Planar Configuration	(0028,0006)	1C	**N/A. Must be omitted.**
Pixel Aspect Ratio	(0028,0034)	1C	**N/A. Must be omitted.**
Smallest Image Pixel Value	(0028,0106)	3	**Not necessary, can be found from image data.**
Largest Image Pixel Value	(0028,0107)	3	**Not necessary, can be found from image data.**
RGB Palette Color Lookup Table Descriptor	(0028,1101), (0028,1102), (0028,1103)	1C	**N/A. Must be omitted.**
RGB Palette Color Lookup Table Data	(0028,1201), (0028,1202), (0028,1203),	1C	**N/A. Must be omitted.**

E.14 Contrast/Bolus (C.7.6.4)

E.15 Display Shutter Module (C.7.6.11)

E.16 Device Module (C.7.6.12)

E.17 Intervention Module (C.7.6.13)

E.18 DX Anatomy Imaged Module (C.8.11.2)

E.19 DX Image Module (C.8.11.3)

E.20 DX Detector Module (C.8.11.4)

Important attributes here are: FOV shape/dimensions/offset/rotation/flip, Imager Pixel Spacing (required)

E.21 X-Ray Collimator Module (C.8.7.3)

E.22 DX Positioning Module (C.8.11.5)

C.8.11.5.1.2 Patient Orientation Code Sequence: don't understand. Need to clarify. Also View Code Sequence (same place). Could this be used to define the patient orientation with respect to the x-ray beam?

Attribute Name	Tag	Type	Notes
Projection Epnymous Name Code Sequence	(0018,5104)	3	Same.
Patient Position	(0018,5100)	3	Not used (only prone, decubitus and supine options, which are useless)

Attribute Name	Tag	Type	Notes
View Position	(0018,5101)	3	Radiographic view of the image relative to the imaging subject's orientation.
View Code Sequence	(0054,0220)	**1C**	Sequence that describes the projection of the anatomic regions of interest.
>View Modifier Code Sequence	(0051,0222)	3	**N/A. Must be omitted.**
Patient Orientation Code Sequence	(0054,0410)	3	**Either omitted or set Code Sequence to SNM3 F-10440 ERECT.**
>Patient Orientation Modifier Code Sequence	(0054,0412)	3	**Either omitted or set Code Sequence to SNM3 F-10320 STANDING.**
Patient Gantry Relationship Code	(0054,0414)	3	**N/A. Must be omitted.**
Distance Source to Patient	(0018,1111)	**1C**	**Distance in mm from source to center of patient, as measured along the central ray of the X-Ray beam. Required if Estimated Radiographic Magnification Factor (0018,1114) is not present.**

Attribute Name	Tag	Type	Notes
Distance Source to Detector	(0018,1110)	**1C**	**Distance in mm from source to detector center as measured along the central ray of the X-Ray beam. Required if Estimated Radiographic Magnification Factor (0018,1114) is not present.**
Estimated Radiographic Magnification Factor	(0018,1114)	**1C**	**Ratio of Distance Source to Detector over Distance Source to Patient. Required if either Distance Source to Detector (0018,1110) or Distance Source to Patient (0018,1111) is missing.**
Positioner Type	(0018,1508)	**1**	**Must be CEPHALOGRAM**
Positioner Primary Angle	(0018,1510)	**1**	**Position of the X-Ray beam about the patient. See E.22.2 on page 117**
Positioner Secondary Angle	(0018,1511)	**1**	**Position of the X-Ray beam about the patient. See E.22.2 on page 117**
Detector Primary Angle	(0018,1530)	3	Same.
Detector Secondary Angle	(0018,1531)	3	Same.
Column Angulation	(0018,1450)	3	**N/A. Must be omitted.**
Table Type	(0018,113A)	3	**Must be FIXED or omitted.**
Table Angle	(0018,1138)	3	**N/A. Must be omitted.**

Table E.5: Standard cephalogram Primary and Secondary Angle values.

SNM3 code	Prim. Angle	Sec. Angle	Comments
R-10206	0	0	antero-posterior
R-10214	+/-180	0	postero-anterior
R-10232	-90	0	right lateral
R-10236	+90	0	left lateral

Attribute Name	Tag	Type	Notes
Body Part Thickness	(0018,11A0)	3	**N/A. Must be omitted.**
Compression Force	(0018,11A2)	3	**N/A. Must be omitted.**

E.22.1 View Code Sequence

View Code Sequence (0054,0220) describes the projection of the anatomic region or orientation. It includes a Code Sequence Macro, in which one of the following shall be specified.

```
SNM3 R-10206 antero-posterior
SNM3 R-10208 antero-posterior oblique
SNM3 R-10210 right posterior oblique
SNM3 R-10212 left posterior oblique
SNM3 R-10214 postero-anterior
SNM3 R-10216 postero-anterior oblique
SNM3 R-10218 right anterior oblique
SNM3 R-10220 left anterior oblique
SNM3 R-10232 right lateral
SNM3 R-10234 right oblique
SNM3 R-10236 left lateral
SNM3 R-10238 left oblique
```

These values should be conistent with Positioner Primary Angle (0018,1510) and Positioner Secondary Angle (0018,1511) especially when they are not one of the four described in Table E.5.

E.22.2 Positioner Angles

Positioner Primary and Secondary Angle, (0018,1510) and (0018,1511), are used to describe the patient orientation. Since the patient orientation defines the projection, these values are very important for the correct determination of the distances on the x-ray image.

Most cephalograms are performed at fixed and standardized positions, such as the ones described in Table E.5 on the previous page. However, the standard leaves room for oblique cephalograms as well, as long as their angle of obliqueness is known. With such angle it is in fact possible to compute the distortion introduced by the rotation.

The cephalostat only allows for rotation about the transmeatal axis. Hence, the axis of rotation can only be the axis that passes through the ears (transmeatal). Therefore it shall be defined as zero degrees the direction parallel to the Frankfort plane: 180 degrees if the patient has its back towards the x-ray source and 0 degress when the patient is facing the x-ray beam. Positive angles indicate a rotation such that the patient is looking downward, negative angles indicate a rotation such that the patient is looking upward.

E.23 X-Ray Tomo Acquisition Module (C.8.7.7)

E.24 X-Ray Acquisition Dose Module (C.8.7.8)

E.25 X-Ray Generation Module (C.8.7.9)

E.26 X-Ray Filtration Module (C.8.7.10)

E.27 X-Ray Grid Module (C.8.7.11)

E.28 Overlay Plane Module (C.9.2)

E.29 VOI LUT Module (C.11.2)

E.30 Image Histogram Module (C.11.5)

E.31 Acquisition Context Module (C.7.6.14)

I still don't understand this module. I should probably leave it untouched.

E.32 SOP Common Module (C.12.1)

Attribute Name	Tag	Type	Notes
SOP Class UID	(0008,0016)	1	**Must be "1.2.840.10008.5.1.4.1.1.1.1.1", which stands for Digital X-Ray Storage - For Processing.**
SOP Instance UID	(0008,0018)	1	Same.

Attribute Name	Tag	Type	Notes

F Spatial Fiducials Modules

F.1 Patient Module (C.7.1.1)

No modifications necessary. Refer to DICOM documentation.

F.2 Specimen Identification Module (C.7.1.2)

No modifications necessary. Refer to DICOM documentation.

F.3 Clinical Trial Subject Module (C.7.1.3)

No modifications necessary. Refer to DICOM documentation.

F.4 General StudyModule (C.7.2.1)

No modifications necessary. Refer to DICOM documentation.

F.5 Patient StudyModule (C.7.2.2)

No modifications necessary. Refer to DICOM documentation.

F.6 Clinical Trial Study Module (C.7.3.2)

No modifications necessary. Refer to DICOM documentation.

F.7 General Series Module (C.7.3.1)

No modifications necessary. Refer to DICOM documentation.

F.8 Clinical Trial Series Module (C.7.3.2)

No modifications necessary. Refer to DICOM documentation.

F.9 Spatial Fiducials Series Module (C.21.1)

No modifications necessary. Refer to DICOM documentation.

Note, however, that this is a mandatory module, and has only one *Modality* (0008,0060) Attribute, which must be, according to DICOM, set to “FID”.

F.10 General Equipment Modules (C.7.5.1)

No modifications necessary. Refer to DICOM documentation.

F.11 Spatial Fiducials Module (C.21.2)

Attribute Name	Tag	Type	Notes
Content Date	(0008,0023)	1	Same.
Content Time	(0008,0033)	1	Same.
Instance Number	(0020,0013)	1	Same.
Content Label	(0070,0080)	1	Same.
Content Description	(0070,0081)	2	Same.
Content Creator's Name	(0070,0084)	2	Same.
Fiducial Set Sequence	(0070,031C)	1	Same. (VR: SQ)
>Frame of Reference UID	(0020,0052)	**1**	**UID of dummy image used as our physical space.**
>Referenced Image Sequence	(0008,1140)	1C	Same.
>Fiducial Sequence	(0070,031E)	1	Same.
>>Fiducial Identifier	(0070,0310)	1	Same.
>>Fiducial Identifier Code Sequence	(0070,0311)	1C	Same.
>>Fiducial UID	(0070,031A)	3	Same.
>>Fiducial Description	(0070,030F)	3	Same.
>>Shape Type	(0070,0306)	1	A CS that must be "POINT", for typical SB Corner Fiducials, but can be anything. Refer to DICOM.
>>Number of Contour Points	(3006,0046)	1C	Shouldn't be necessary, if Shape Type (0070,0306) is POINT.
>>Contour Data	(3006,0050)	3	Shouldn't be necessary, if Shape Type (0070,0306) is POINT.
>>Contour Uncertainty Radius	(0070,0312)	3	Shouldn't be necessary, if Shape Type (0070,0306) is POINT.
>>Graphic Coordinates Data Sequence	(0070,0318)	1C	

Attribute Name	Tag	Type	Notes
>>>Graphic Data	(0070,0022)	1	Coordinates of fiducial point. Should be stored as X,Y in a concatenation of two 32-bit floating point singles, as specified by IEEE 754:1985.
>>>Referenced Image Sequence	(0008,1140)	1	The image this fiducial set refers to.

F.11.1 Contour Data

The Contour Data (3006,0050) is used to specify the shape of the fiducials, if they are not a single point. The standard even offers a way to store the Uncertainty Radius (0070,0312) if necessary.

In the case of SB Corner Fiducials punched on films before scanning, this feature should not be necessary, as the fiducials are point like and should appear only as a few pixels on the image itself.

F.12 Common Instance Reference Module (C.12.2)

F.13 SOP Common Module (C.12.1)

No modifications necessary. Refer to DICOM documentation.