new technology for model-based interface applications; and 3) finally it deals with collecting patients' detailed clinical information. Although the SCUI is still at the prototype stage, it has already provided good insights in the direction of constructing practical and usable medical applications in the coming years.

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5. CONCLUSIONS

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results in a situation where there is a terminology "linkage" between the CoRe model and the SCUI specific model (as shown in Figure 1). For instance, the CoRe model will be able to provide the application with sensible statements of what can be said about dysuria, while the SCUI model will specify that dysuria should be asked for in the "Signs and Symptoms" section of the application.

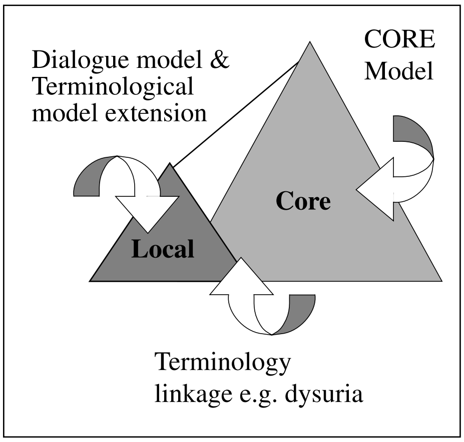

Figure 1: The Conceptual Models

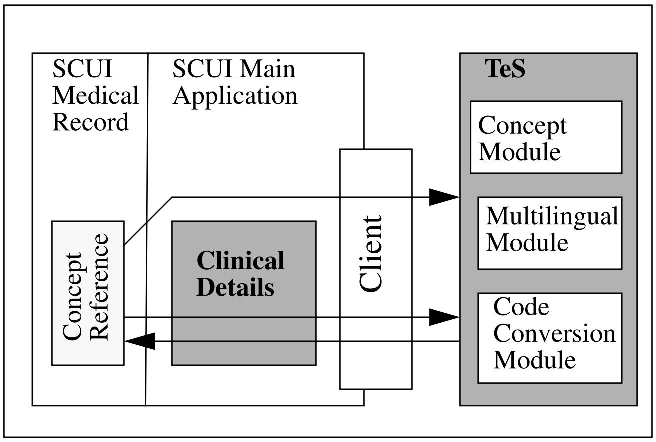

Figure 2 : Connection SCUI / TeS

3.2 TeS SERVICES

The Terminology Server [3], [11] can be viewed as a networked interface to a set of terminological services. The TeS contains different modules, each of which provides a specific set of services to clinical applications, for example the SCUI. The *Concept Module* (CM) [14] provides GRAIL concept services: it allows the navigation and manipulation of expresssions in the CoRe model to answer questions like, for example, "what can be said about dysuria". The *Multilingual Module* (MM) [12] provides naming services: it generates natural language (e.g. English or French) from expressions in the CoRe model. For example, from the expression: "Ulcer which hasLocation Stomach" the generator will produce "stomach ulcer" in English and "ulcère de l'estomac" in French. This module provides the application with a language service, particularly useful when developing a single application to be used in more than one natural language context. The *Code Conversion Module* (CCM) [13] provides coding services: it relates concepts of the CoRe model to codes in existing systems such as ICD-9 or Snomed. For instance, the CCM can answer the request "return the code for the concept: Ulcer which hasLocation Stomach" with ICD-9 531.1.

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A *connection session* between the application and the TeS consists of: connecting to the server, performing a series of requests, and disconnecting from the TeS. By connecting to the server, the application becomes its client (see Figure 2). The TeS which runs as a network server, communicates with the SCUI client using TCP/IP over sockets [14]. The SCUI client is provided with a library which is used to interact with the server. There are three key points when interacting with the TeS which are described below: 1) references to the concepts, 2) specifications for input/output forms, and 3) operations of a TeS request.

Given the compositional nature of the GRAIL formalism, the use of concepts is highly dynamic. Thus, it is not possible to know in advance nor is it desirable to have to enumerate all the possible legal concepts. Furthermore, applications need to be able to store references to concepts with the expectation that they will remain unchanged over time. We need to underline here that it is with the future integration of natural language analysers (e.g [16]) that applications will be able to directly enter the words in order to access the corresponding concepts rather than referring to the concepts they need to use. The TeS provides three ways to refer to concepts: a) global expressions which are valid across all Terminology Servers containing a specific version of the CoRe model. b) Local identifiers which are local to a particular TeS at a particular site. Local identifiers are

2. CLINICAL INFORMATION REQUIREMENTS AND DESIGN

The development of the SCUI is centred around requests made to the microbiology laboratory by the MICU. The initial aim of the SCUI is to improve requests made by the MICU by asking for significant and relevant clinical information about the patients (like state of immunity, state of illness, presence of fever) which would be useful to the laboratory and which is usually missing or incomplete. Morever, the data collected during a microbiological laboratory request is not analysed further, so that the clinical staff can ask for additional information. Thus, the intention is to make that extra information available to the laboratory.

The SCUI is applicable whenever a urinary infection is suspected in the clinical ward. The types of data to be collected while making a request to the laboratory have been grouped into the following sections. It is much more detailed than the information usually presented and is an important aim to make detailed patients' information available to the user where necessary: *1) GENERAL INFORMATION* e.g. the patient's mobility, consciouness, dependency ; *2) URINARY HISTORY* e.g. the patient's past urinary infections as well as any event of lithiasis and nephrectomy*; 3) SIGNS AND SYMPTOMS* e.g. general findings such as fever, chills, and specific findings such as alguria, dysuria, haematuria*; 4) DIAGNOSTIC INFORMATION* e.g. diseases related to urinary infections such as cystitis, pyelonephritis, renal abscess*; 5) PREVIOUS LABORATORY RESULTS* e.g. information about hematology; information about the urine such as the estimation of the red cells, the white cells, the glucose, the pH and the proteins*; 6) SAMPLE COLLECTION* e.g. general information on the sample taken such as the date it was taken, the type of examination, the type of sample, the operator, the place where the sample was taken (the emergency room, the operating room); information on the justification of the exam such as monitoring; information on the type of catheter e.g. transient, indwelling, urethral, on its status e.g. clean or dirty.

The SCUI includes a number of components [8] which are used as follows: At the MICU, the nurse or the physician enters his/her microbiological laboratory request via a user interface component of the SCUI. The SCUI guides the user into adding specific detailed information (via a dialogue component), that is, uses the terminology in the CoRe model which is required in order make a microbiological laboratory request. In other words, the CoRe model contains the medical knowledge needed to collect this detailed patient's data (see section 3.1). The SCUI makes use of the Terminology Server to access the CoRe model. The server provides the application with a set of terminological services such as conceptual and multilingual (see section 3.2 for examples). The SCUI also uses its pragmatic knowledge, that is, dialogue constraints on how to collect the user's answers in an intelligent and intuitive manner. The detailed clinical information collected from the user is then stored into the SCUI database. Once the request has been made, it is available to the microbiology laboratory.

3. THE TERMINOLOGY SERVER

3.1 GRAIL CONCEPTUAL MODELS

Given the clinical requirements described in section 2, the SCUI needs to use a variety of concepts. This means, for example, that the TeS needs to know about urinary devices, signs and symptoms (specific and general) as well as geographical locations (e.g. operating room) and actors (e.g. nurse, doctor). In other words, the TeS is to tell the application what can be sensibly and necessarily said about a concept like dysuria, to support the SCUI interface to help the clinician to enter the information. The GRAIL formalism makes a separation between the definition of a concept and its properties. For example, for the concept dysuria, the TeS will obtain from the CoRe model the definition of dysuria, i.e. pain which occurs during micturition (micturition being itself a complex concept), and properties of dysuria like its causal agent and the types of bacterium that causes it. The collection of clinical information for dysuria by the user is then structured and driven by what comes from the model. Furthermore, the data collection can be made more or less detailed according to what the end-user wants to express about some particular clinical information.

Although it is expected that the CoRe model will be able to support the terminological needs of the application, it is acknowledged that the application has terminology requirements which remain "local" to the application. These local requirements are twofold. First, the terminological extension model i.e. extra detailed concepts specific to the application and which are not found in the Core model. Second, the dialogue model which uses the terminology as a "hook" to add extra information like what concepts are interesting in a particular section of the SCUI application (see for example the model extension for drug interactions in [10]). This

CONSTRUCTING CLINICAL APPLICATIONS: THE GALEN APPROACH

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ABSTRACT

A key problem for developers of clinical applications is to be able to cope with heterogeneous medical language in diverse medical environments, while ensuring that applications are usable in a variety of hospitals and that information can be shared between applications. Existing approaches centre around coding and classification schemes, however they need to be supplemented by a range of sophisticated *terminological services* to enable this problem to be solved. To address this, the GALEN project is developing a software called the *Terminology Server* to provide such a range of terminological services (e.g. conceptual and multilingual services) built upon a re-usable core model of medical terminology. This paper reports on the development of a clinical application called the SCUI (Structured Clinical User Interface) which benefits from these GALEN technologies and thus illustrates an innovative approach towards the construction of future clinical applications. The SCUI is specifically developed and tested in the context of infectious diseases to satisfy the demands made by the medical intensive care unit on the Geneva Hospital's microbiology laboratory.

1. CONTEXT OF THE SCUI DEVELOPMENT

An important challenge faced nowdays by researchers in medical informatics is to develop techniques to represent a common core model of clinical concepts and terminology [1]. This has been stimulated, in part, by the need to have detailed clinical information available in an electronic form via clinical applications. This has resulted in fundamental changes in the requirements for terminologies such as being able to support a large number of complex detailed descriptions or to support multilingual use [2]. The European AIM (Advanced Informatics in Medecine) project GALEN is proposing an alternative approach to medical terminologies in order to meet these requirements. The GALEN project is putting forward the proposition that there is a useful conceptual component of clinical knowledge which can be extracted from other aspects such as terminology and natural language processing, knowledge based systems or user interface design. In particular, GALEN is developing a Terminology Server (TeS) [3] which aims at supporting the development and integration of clinical systems through a range of terminological services. These are built around language-independent, re-usable, shared sets of concepts called the CoRe (Concept Reference) model [1], [4]. The CoRe model is developed and represented using a compositional formalism known as GRAIL (GALEN Representation And Integration Language) [5]. The SCUI (Structured Clinical User Interface) presented in this paper is one of the GALEN applications which is being developed to demonstrate and evaluate these GALEN technologies. It should be stressed that the SCUI is a practical clinical application and is expected to demonstrate key components for future commercial clinical information systems.

The aim of the SCUI [6], [7], [8] is to collect and display clinical information on the domain of infectious diseases, specifically nosocomial urinary infections, in a large hospital like the Geneva University Hospital. The clinical situation of the medical intensive care unit (MICU) ward has been selected for the development of this demonstrator. There is evidence that patients hospitalised in intensive care units run a much higher risk of developing infections diseases than in general wards [9]. The SCUI is expected to be used by clinicians concerned with direct patient care and to structure the clinician's interaction with the system so that detailed and pertinent information is requested and entered. This should improve decision making for individual patients, and enable clinicians to analyse the reasons for investigations and treatment.

new technology for model-based interface applications; and 3) finally it deals with collecting patients' detailed clinical information. Although the SCUI is still at the prototype stage, it has already provided good insights in the direction of constructing practical and usable medical applications in the coming years.

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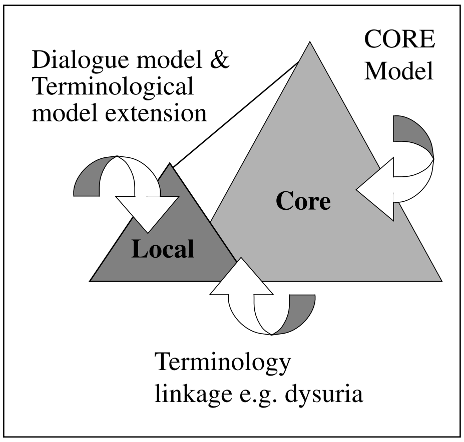

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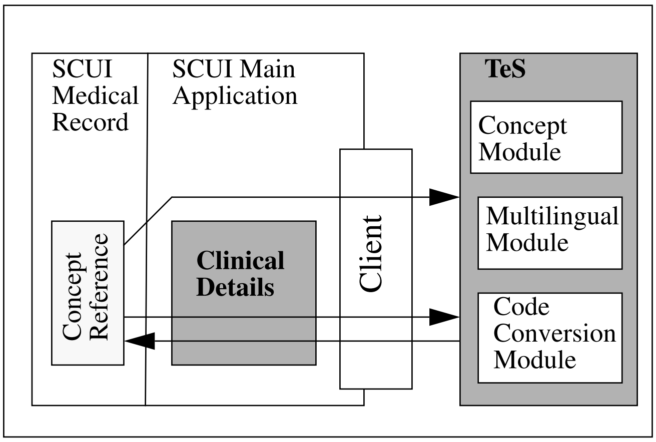

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The development of the SCUI is centred around requests made to the microbiology laboratory by the MICU. The initial aim of the SCUI is to improve requests made by the MICU by asking for significant and relevant clinical information about the patients (like state of immunity, state of illness, presence of fever) which would be useful to the laboratory and which is usually missing or incomplete. Morever, the data collected during a microbiological laboratory request is not analysed further, so that the clinical staff can ask for additional information. Thus, the intention is to make that extra information available to the laboratory.

The SCUI is applicable whenever a urinary infection is suspected in the clinical ward. The types of data to be collected while making a request to the laboratory have been grouped into the following sections. It is much more detailed than the information usually presented and is an important aim to make detailed patients' information available to the user where necessary: *1) GENERAL INFORMATION* e.g. the patient's mobility, consciouness, dependency ; *2) URINARY HISTORY* e.g. the patient's past urinary infections as well as any event of lithiasis and nephrectomy*; 3) SIGNS AND SYMPTOMS* e.g. general findings such as fever, chills, and specific findings such as alguria, dysuria, haematuria*; 4) DIAGNOSTIC INFORMATION* e.g. diseases related to urinary infections such as cystitis, pyelonephritis, renal abscess*; 5) PREVIOUS LABORATORY RESULTS* e.g. information about hematology; information about the urine such as the estimation of the red cells, the white cells, the glucose, the pH and the proteins*; 6) SAMPLE COLLECTION* e.g. general information on the sample taken such as the date it was taken, the type of examination, the type of sample, the operator, the place where the sample was taken (the emergency room, the operating room); information on the justification of the exam such as monitoring; information on the type of catheter e.g. transient, indwelling, urethral, on its status e.g. clean or dirty.

The SCUI includes a number of components [8] which are used as follows: At the MICU, the nurse or the physician enters his/her microbiological laboratory request via a user interface component of the SCUI. The SCUI guides the user into adding specific detailed information (via a dialogue component), that is, uses the terminology in the CoRe model which is required in order make a microbiological laboratory request. In other words, the CoRe model contains the medical knowledge needed to collect this detailed patient's data (see section 3.1). The SCUI makes use of the Terminology Server to access the CoRe model. The server provides the application with a set of terminological services such as conceptual and multilingual (see section 3.2 for examples). The SCUI also uses its pragmatic knowledge, that is, dialogue constraints on how to collect the user's answers in an intelligent and intuitive manner. The detailed clinical information collected from the user is then stored into the SCUI database. Once the request has been made, it is available to the microbiology laboratory.

3. THE TERMINOLOGY SERVER

3.1 GRAIL CONCEPTUAL MODELS

Given the clinical requirements described in section 2, the SCUI needs to use a variety of concepts. This means, for example, that the TeS needs to know about urinary devices, signs and symptoms (specific and general) as well as geographical locations (e.g. operating room) and actors (e.g. nurse, doctor). In other words, the TeS is to tell the application what can be sensibly and necessarily said about a concept like dysuria, to support the SCUI interface to help the clinician to enter the information. The GRAIL formalism makes a separation between the definition of a concept and its properties. For example, for the concept dysuria, the TeS will obtain from the CoRe model the definition of dysuria, i.e. pain which occurs during micturition (micturition being itself a complex concept), and properties of dysuria like its causal agent and the types of bacterium that causes it. The collection of clinical information for dysuria by the user is then structured and driven by what comes from the model. Furthermore, the data collection can be made more or less detailed according to what the end-user wants to express about some particular clinical information.

Although it is expected that the CoRe model will be able to support the terminological needs of the application, it is acknowledged that the application has terminology requirements which remain "local" to the application. These local requirements are twofold. First, the terminological extension model i.e. extra detailed concepts specific to the application and which are not found in the Core model. Second, the dialogue model which uses the terminology as a "hook" to add extra information like what concepts are interesting in a particular section of the SCUI application (see for example the model extension for drug interactions in [10]). This

CONSTRUCTING CLINICAL APPLICATIONS: THE GALEN APPROACH

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ABSTRACT

A key problem for developers of clinical applications is to be able to cope with heterogeneous medical language in diverse medical environments, while ensuring that applications are usable in a variety of hospitals and that information can be shared between applications. Existing approaches centre around coding and classification schemes, however they need to be supplemented by a range of sophisticated *terminological services* to enable this problem to be solved. To address this, the GALEN project is developing a software called the *Terminology Server* to provide such a range of terminological services (e.g. conceptual and multilingual services) built upon a re-usable core model of medical terminology. This paper reports on the development of a clinical application called the SCUI (Structured Clinical User Interface) which benefits from these GALEN technologies and thus illustrates an innovative approach towards the construction of future clinical applications. The SCUI is specifically developed and tested in the context of infectious diseases to satisfy the demands made by the medical intensive care unit on the Geneva Hospital's microbiology laboratory.

1. CONTEXT OF THE SCUI DEVELOPMENT

An important challenge faced nowdays by researchers in medical informatics is to develop techniques to represent a common core model of clinical concepts and terminology [1]. This has been stimulated, in part, by the need to have detailed clinical information available in an electronic form via clinical applications. This has resulted in fundamental changes in the requirements for terminologies such as being able to support a large number of complex detailed descriptions or to support multilingual use [2]. The European AIM (Advanced Informatics in Medecine) project GALEN is proposing an alternative approach to medical terminologies in order to meet these requirements. The GALEN project is putting forward the proposition that there is a useful conceptual component of clinical knowledge which can be extracted from other aspects such as terminology and natural language processing, knowledge based systems or user interface design. In particular, GALEN is developing a Terminology Server (TeS) [3] which aims at supporting the development and integration of clinical systems through a range of terminological services. These are built around language-independent, re-usable, shared sets of concepts called the CoRe (Concept Reference) model [1], [4]. The CoRe model is developed and represented using a compositional formalism known as GRAIL (GALEN Representation And Integration Language) [5]. The SCUI (Structured Clinical User Interface) presented in this paper is one of the GALEN applications which is being developed to demonstrate and evaluate these GALEN technologies. It should be stressed that the SCUI is a practical clinical application and is expected to demonstrate key components for future commercial clinical information systems.

The aim of the SCUI [6], [7], [8] is to collect and display clinical information on the domain of infectious diseases, specifically nosocomial urinary infections, in a large hospital like the Geneva University Hospital. The clinical situation of the medical intensive care unit (MICU) ward has been selected for the development of this demonstrator. There is evidence that patients hospitalised in intensive care units run a much higher risk of developing infections diseases than in general wards [9]. The SCUI is expected to be used by clinicians concerned with direct patient care and to structure the clinician's interaction with the system so that detailed and pertinent information is requested and entered. This should improve decision making for individual patients, and enable clinicians to analyse the reasons for investigations and treatment.

new technology for model-based interface applications; and 3) finally it deals with collecting patients' detailed clinical information. Although the SCUI is still at the prototype stage, it has already provided good insights in the direction of constructing practical and usable medical applications in the coming years.

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useful for communicating with applications using the same TeS. c) Handles which are only valid during a single application's connection session with a particular TeS.

Input/output forms can be references to concept entities using any of those reference forms, linguistic expressions which can be generated from GRAIL expressions, and external codes from coding and classification systems. A TeS request specifies a terminological operation e.g. "specialise relationships" to get the attributes that are used to specialise a given concept, or a miscellaneous operation e.g. "connect" to make a connection to the TeS.

4.2 MODEL-BASED INTERFACE

We have separated the overall task of building the clinical application into two: a) a terminological part that the TeS handles (see section 3) and b) an application part which can be built by the application builders without needing to worry about implementing the terminology. This separation constitutes a new approach in the task of developing clinical applications. In the SCUI, the clinician or the nurse starts the application by giving his/her user name and password. From then on, the clinician interacts with the application using the mouse. An option menu is available to enter a new SCUI request, or to visualise a previous request and possibly to restart a request which was not complete. The user can also access administrative information about the patient such as his/her personal details and his/her SCUI medical record. The SCUI connects to the TeS whenever, depending on the user's action, it needs to access concepts from the CoRe model and in a given language.

There are two important aspects to stress here about the interface. First, the interface construction for each section of the SCUI scenario (see section 2) is not fixed but rather is constructed *dynamically* based upon what comes from the CoRe model via the TeS. This is an advantage of the system over traditional form-based interfaces The application is much more flexible than traditional systems and much better tailored to the particular clinical situation as it has access to a server of terminology rather than to static terminology. This means that if a new concept which is of interest to the SCUI is entered in the CoRe model, it will appear in the corresponding section. Second, when making a request, the clinician clicks on the various concepts and associated attributes which are available to him/her and which are relevant for the given patient. By doing so, the clinician constructs simple or complex concept entities to express and detail the patient's clinical information. For example, he/she can express the fact that an infection has been caused by a bacterium (Infection whichHasCausalAgent Bacterium in GRAIL), and thus builds GRAIL expressions, using any combination of global, local or handle references (see section 4.1).

5. CONCLUSIONS

The development of the SCUI has been carried out through a cycle of "prototyping and testing". The expectations of the first version described in [8] were to explore the modelling process [15] and make use of some of the Terminology Server services such as the Multilingual Module. Following the implementation of a first prototype, a technical estimation in terms of its achievements, limitations and further work was carried out [8]: The work for the first version produced requirements for an "intelligent" dialogue. In addition, it was found that the experimental model was too restricted in its expressiveness and provided a first analysis of the required terminology, whereas the query tool (previously developed at the Geneva University Hospital and which is able to drive interactive medical questionnaires) served as a test bed of the paper-based scenario and its associated constraints. Moreover, the SCUI served as an application test for the multilingual module. Feedback and comments on this first prototype were obtained from doctors in our group and within the GALEN consortium. The current version of the SCUI easily makes a direct and usable connection to the TeS, and uses an elaborated version of the CoRe model [13]. Larger scale user evaluation is expected for the subsequent version of the SCUI in the coming months.

The construction of the SCUI is closely related to a previous experience with the Pen&Pad clinical workstation which is for the use of general practitioners in the consulting room [17]. The Galen project builds upon ideas from the Pen&Pad, and brings more advanced technologies and methodologies. There are key aspects to be kept in mind about the SCUI: 1) the application uses a separate generic server which provides terminological services (e.g. multilingual) and which can be used by other applications simultaneously, this corresponds to a new approach in the development of clinical systems and the sharing of medical knowledge; 2) it exploits

results in a situation where there is a terminology “linkage” between the CoRe model and the SCUI specific model (as shown in Figure 1). For instance, the CoRe model will be able to provide the application with sensible statements of what can be said about dysuria, while the SCUI model will specify that dysuria should be asked for in the “Signs and Symptoms” section of the application.

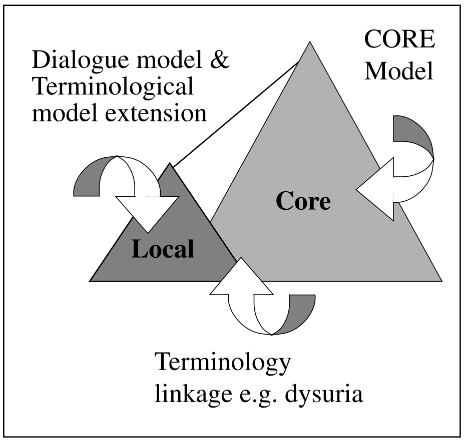

Figure 1: The Conceptual Models

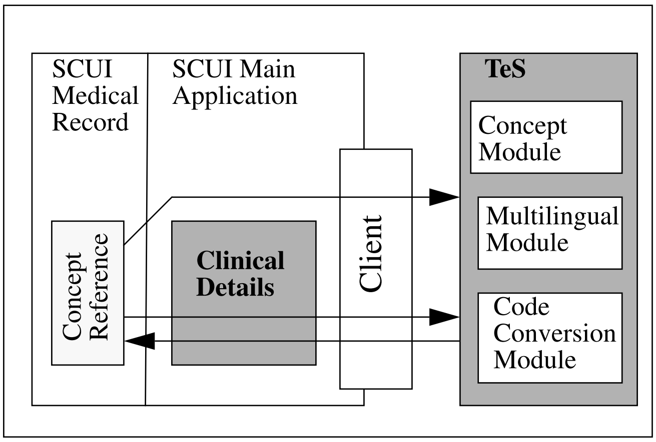

Figure 2 : Connection SCUI / TeS

3.2 TeS SERVICES

The Terminology Server [3], [11] can be viewed as a networked interface to a set of terminological services. The TeS contains different modules, each of which provides a specific set of services to clinical applications, for example the SCUI. The *Concept Module* (CM) [14] provides GRAIL concept services: it allows the navigation and manipulation of expresssions in the CoRe model to answer questions like, for example, “what can be said about dysuria”. The *Multilingual Module* (MM) [12] provides naming services: it generates natural language (e.g. English or French) from expressions in the CoRe model. For example, from the expression: “Ulcer which hasLocation Stomach” the generator will produce “stomach ulcer” in English and “ulcère de l’estomac” in French. This module provides the application with a language service, particularly useful when developing a single application to be used in more than one natural language context. The *Code Conversion Module* (CCM) [13] provides coding services: it relates concepts of the CoRe model to codes in existing systems such as ICD-9 or Snomed. For instance, the CCM can answer the request “return the code for the concept: Ulcer which hasLocation Stomach” with ICD-9 531.1.

4. SCUI / TeS SESSION

4.1 TeS CONNECTION

A *connection session* between the application and the TeS consists of: connecting to the server, performing a series of requests, and disconnecting from the TeS. By connecting to the server, the application becomes its client (see Figure 2). The TeS which runs as a network server, communicates with the SCUI client using TCP/IP over sockets [14]. The SCUI client is provided with a library which is used to interact with the server. There are three key points when interacting with the TeS which are described below: 1) references to the concepts, 2) specifications for input/output forms, and 3) operations of a TeS request.

Given the compositional nature of the GRAIL formalism, the use of concepts is highly dynamic. Thus, it is not possible to know in advance nor is it desirable to have to enumerate all the possible legal concepts. Furthermore, applications need to be able to store references to concepts with the expectation that they will remain unchanged over time. We need to underline here that it is with the future integration of natural language analysers (e.g [16]) that applications will be able to directly enter the words in order to access the corresponding concepts rather than referring to the concepts they need to use. The TeS provides three ways to refer to concepts: a) global expressions which are valid across all Terminology Servers containing a specific version of the CoRe model. b) Local identifiers which are local to a particular TeS at a particular site. Local identifiers are

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