Designing Guideline-based Workflow-integrated Electronic Health Records

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Submitted for the Degree of Doctor of Philosophy in Information Technology (Research)

June 2005

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To my parents, & Cindy and Coko

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ADL	Archetype Definition Language
AM	Archetype Model
API	Application Programming Interface
CCMS	Clinical Context Management Specification
CDM	Chronic Disease Management
CEN	European Committee for Standardization
C*f*MS	Careflow Management System
CiG	Computer-interpretable Guideline
CDA	Clinical Document Architecture
CMET	Common Message Element Type
CHR	Consolidated Health Record
CORBA	Common Request Broker Architecture
CPR	Computer-based Patient Record
DOM	Document Object Model
D-MIM	Domain Message Information Model
DSS	Decision Support System
DVA	Department of Veterans Affairs
EBM	Evidence-based Medicine
EHR	Electronic Health Record
EHRA	Electronic Health Record Architecture
EPR	Electronic Patient Record
ESD	Early Supported Discharge
GAD	Guideline Adapter Document
GAP	Guideline Adapter Processor
GEHR	Good Electronic Health Record
GLIF	Guideline Interchange Format
GP	General Practitioner
GRI	Guideline Reference Identifier

GRP	Graphical Reference Point
GUI	Graphical User Interface
HIN	Health Information Network
HIS	Health Information System
HMD	Hierarchical Message Descriptor
HL7	Health Level Seven
HTML	HyperText Markup Language
ICEHR	Integrated Care Electronic Health Record
IOM	Institute of Medicine
IRM	Instruction Reference Model
JaWE	Java Workflow Editor
KB	Knowledge Base
NHS	(British) National Health Services
NLM	National Library of Medicine
ODSI	Open Directory Services Interface
OT	Occupational Therapist
PRODIGY	Prescribing RatiOnally with Decision-support In General-practice studY
RCT	Randomised Controlled Trial
RDNS	Royal District Nursing Service
RIM	Reference Information Model
RM	Reference Model
RMI	Remote Method Invocation
R-MIM	Refined Message Information Model
RPC	Remote Procedure Call
SAGE	Shareable Active Guideline Environment
SAX	Simple Application Programming Interface for XML
SEHR	Shared Electronic Health Record
SHINE	Stanford Health Information Network for Education
SSL	Secure Socket Layer (protocol)
UI	User Interface
UML	Unified Modelling Language
URI	Uniform Resource Identifier

W*f*MC	Workflow Management Coalition
WfMS	Workflow Management System
WHO	World Health Organisation
XOR	Exclusive OR
XML	eXtensible Markup Language
XPDL	XML Process Definition Language
XSLT	eXtensible Stylesheet Language Transformation

ABSTRACT

Keywords: electronic health record, workflow, decision support, computer-interpretable guidelines, chronic disease management.

The recent trend in health care has been on the development and implementation of clinical guidelines to support and comply with evidence-based care. Evidence-based care is established with a view to improve the overall quality of care for patients, reduce costs, and address medico-legal issues. One of the main questions addressed by this thesis is how to support guideline-based care. It is recognised that this is better achieved by taking into consideration the provider workflow. However, workflow support remains a challenging (and hence rarely seen) accomplishment in practice, particularly in the context of chronic disease management (CDM).

Our view is that guidelines can be knowledge-engineered into four main artefacts: electronic health record (EHR) content, computer-interpretable guideline (CiG), workflow and hypermedia. The next question is then how to coordinate and make use of these artefacts in a health information system (HIS). We leverage the EHR since we view this as the core component to any HIS.

We use the *open*EHR architecture, which allows extension of a core Reference Model via Archetypes, to refine the detailed information recording options for specific points in the healthcare process, to represent decision support information needs, and to represent the *composite instruction* that is the workflow itself. We present an Instruction Reference Model from which composite instructions can be defined and is an extension to the current *open*EHR's Instruction model (revision 4.3). We define constructs for the rationale of the decisions made to be recorded explicitly within the record – including the specific guideline step, didacticism, and links to relevant EHR data items that were used to arrive at a decision.

We develop a prototype system that makes use of two key components: the Breeze workflow architecture, and our implementation of the EHR Persistence Layer – both of which interact in the initiation and execution of instructions. We illustrate our approach on two distinct but common CDM scenarios: Early Supported Discharge and associated Post-stroke Rehabilitation, which is process-oriented and less clinical in nature; and Hypertension in Diabetes which is of a highly clinical nature, and decision-based.

We found that there is a real distinction between the roles that guideline-based recommendations provided by CiGs, workflow and EHR play in supporting and managing patient care: (1) CiGs model decision-making steps and recommended actions; (2) workflows model the work to be done for that recommended action, by whom, when and how, and help ensure that it gets done; (3) archetypes help ensure that the appropriate information is collected within the EHR for the workflow. Moreover, the extent to which each of these components can be used in supporting CDM, particularly CiGs and workflow, is dependent on the clinical context in which it is applied.

Our research has implications on various stakeholders. The extended EHR architecture allows the application designer to choose a usable balance of compliance encouragement and human judgment. The ability to track healthcare process steps within the EHR content is also of medico-legal significance. It is envisioned that extensible EHR recording allows the EHR to serve as the basis for care coordination, and potentially improve communication amongst providers and even improve patient health outcomes. Our open framework can be used to further explore the problem of effective support for CDM (such as presentation of hypermedia), and can inform a range of standards bodies (such as HL7), researchers (such as clinical guideline representation and workflow) and vendors about specific requirements for integrating EHR, workflow and guideline-based decision support.

STATEMENT OF ORIGINAL AUTHORSHIP

I declare that this thesis does not incorporate without acknowledgement any material previously submitted for a degree or diploma in any University; and that to the best of my knowledge it does not contain any materials previously published or written by another person except where due reference is made in the text.

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SISTINE ANN BARRETTO

June 2005

ACKNOWLEDGEMENTS

I would like to thank my principal supervisor A/Prof. Jim Warren for his professionalism, tremendous support, expertise, guidance, encouragement and invaluable advice. Thanks also to my assistant supervisor Prof. Markus Stumptner for sharing his expertise, and to Prof. Michael Schrefl for his assistance on business process modelling and specialisation early in my candidature.

Dr. Sam Heard for his *open*EHR and clinical expertise, and Thomas Beale also for his *open*EHR and technical expertise. Dr. Andrew Goodchild for collaborating with me on the development of the Instruction Reference Model (IRM), providing valuable feedback on my prototype, and advice on my research. Dr. Linda Bird for her assistance. Dr. Hoylen Sue for reviewing chapter 5, and providing useful advice and feedback on my prototype. Zar Zar Tun, Andrea Broglia and Russell Shackel for permitting me to use their Titanium prototypes and assisting me with them when needed. Michael Lawley for his patience and assistance with the use and extension of the Breeze workflow architecture. Heath Frankel for his HL7 v3 USAM expertise.

Dr. Jan Stanek for sharing his clinical expertise and helping me grasp the hypertension management case study. My fellow PhD candidates, Dr. Chunlan Ma also for her clinical expertise as well as her advice, support and friendship; and Eric Browne for his useful feedback on the IRM, workflow discussions, and assistance with the use of Breeze.

Participants in focus groups conducted early in my candidature: Karen Grimmer, Julie Falco (for her insight into the Early Supported Discharge case study and the role of an ESD coordinator), Tal Ellis (for his insight into the role of RDNS), Hugh Stewart (for his insight into the role of Occupational Therapist), Dr. Gary Misan (for giving me a General Practitioner's perspective), and Jean-Pierre Calabretto (for sharing his Pharmacist view of the world). Jacqui Bourke for also providing insight into the role of the Occupational Therapist and providing me a sample home assessment

form. Stephen Nield whose Honours thesis assisted me with understanding the ESD case study early on in my research.

The School of Computer & Information Science (Intelligent Systems Group), University of South Australia, and the Australian Postgraduate Research Award for financially supporting my research. Thank you to the helpful staff in the School of CIS in particular for providing me with needed resources, good working environment, and giving me the opportunity to teach every so often.

A special thank you to my tennis/badminton buddies – Lai Si Wu, Manus Kwan and Bill Daniels for keeping me fit during my candidature and for their friendship.

Last but not least, my parents Norma and Franklin Barretto, family and friends for their love, patience and ongoing support throughout my life.

Sistine Ann Barretto
June 2005

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INTRODUCTION

Our world is in transition. Societies all over the world are becoming more urbanized. Populations are ageing. Physical activity levels are declining as people adapt to more sedentary lifestyles. We see a major shift away from traditional diets, and the increased consumption of energy-dense diets with high levels of fats and sugars, as well as salt. The consumption of fruit and vegetables is also going down. All these factors, as well as tobacco use have dramatically changed the global profile of disease. Noncommunicable conditions now account for approximately 60 per cent of the 56.5 million global deaths annually. [1]

With the rising incidence of chronic illness, developed nations with their aging populations now face the management and prevention of non-communicable and especially chronic diseases such as diabetes, stroke, cardiovascular disease, and cancer as their major health issue. Increasing incidences of smoking, hypertension, high cholesterol and obesity for instance, have accounted for more than 50% of deaths and disability from cardiovascular disease and stroke worldwide [2]. In 1999, stroke caused 5.5 million deaths globally, making stroke the second leading cause of death, whilst recent estimates in diabetes, envisage that the number of diabetes sufferers will more than double, from 140 million to 300 million in the next 25 years if current trends continue [3]. A prediction in the prevalence of cancer sees a further increase by 50% to 15 million new incidences in the year 2020 [4]. A significant proportion of these incidences are expected in developing countries where resources for prevention and management of such diseases are least affordable.

Poor quality of care and escalating health care costs

To address this global health crisis, a key element of health strategies must be to increase the effectiveness of Chronic Disease Management (CDM) activities, includeing chronic disease prevention, where possible. A key aim for effective CDM is to look for opportunities in which a reduction in hospital admissions and earlier discharge from the hospital can be made – thereby, improving the quality of life for the chronically ill, their carers and families, and preventing a crisis-reaction approach and urgent hospital admissions/re-admissions. This in turn, also results in a reduction in overall costs, time and effort in the management of patients with chronic diseases.

Another key aim for CDM is reduction of errors. The rate of errors in health care has been recorded by the Agency for Health Care Policy and Research (now known as the Agency for Healthcare Research and Quality [5]) as being significantly higher than in other industries. In the United States alone, preventable medical errors resulted in an estimate of 98,000 deaths annually [6] – thus, making it the eighth leading cause of death in the U.S. Furthermore, annual costs in the U.S. due to such errors have escalated $17 to $29 billion [6]. In general, these mistakes are a result of flaws (including under-treatment, excessive treatment, and deviations in practice from evidence-based medicine) in the health care system in lieu of incompetence or neglect on the

individual's part. A significant proportion of these errors stem from adverse drug events that are preventable, which has resulted in an estimated annual cost of $136 billion in the U.S. [7].

Improved compliance to clinical practice guidelines and better communications constitute promising avenues to more effective CDM. Results from a recent U.K. trial of a decision-support system (PRODIGY Phase Two) estimated that if all General Practitioners (GPs; i.e., "family physicians") prescribed the same way as the guideline-compliant GPs on three 'tracer conditions', the savings would be approximately £14 million per quarter [8]. Moreover, there is insufficient connectivity (including responsibilities and communication processes) within and between services provided in the primary and community health and acute care sectors [9]. It is therefore, not surprising that the services for the chronically ill are poorly coordinated, disjointed, and frequently duplicated.

Communication and coordination issues

One of the key flaws in current health care systems that contribute to the high morbidity and mortality rates, and escalated health care costs, is the lack of sufficient communication and coordination of services. It has been said that quality of care not only depends on care providers' skills, but also on the levels of collaboration inside the organisation [10]. Mechanisms for effective flow of information amongst patients, their multiple providers and community health services that are vital in resolving the current problems with inter-provider and patient-provider communication is currently lacking.

Care management, advocated for many years as a way of ensuring appropriate and coordinated care, emphasises the involvement of patients and carers in care planning. Evidence suggests that such involvement is unusual. A study in the UK [11] was conducted to discover how services were understood and experienced by those using them. It was found that the majority of service users were left dissatisfied and unclear about how their needs had been assessed and how services had been arranged. They were also disappointed by lack of information available and lack of regular contact with their care providers. Some were dissatisfied to the point that they were com-

pelled to become proactive in order to ensure that the care provided was adequate. Further adding to this problem was the lack of follow-up, as well as patients/care givers having to re-iterate information, and vagueness as to where responsibilities lay and whom they should contact when problems arose as a result of changes of personnel. Ideally, there needs to be explicit encouragement, and services need to encourage people to seek support at an early stage rather than risk a crisis which could lead to the need for more intensive intervention. In other words, prevention must be emphasised rather than a crisis-reaction approach. Finally, most were not aware of their care being reviewed. However, services were given accordingly which suggests that health service providers were in fact, reviewing care needs, informally but invisibly. This lack of explicitness resulted in patients feeling unsupported in spite of this. Those who sought to organise and coordinate their own care found that timely provision of adequate information was of critical importance, but this was in fact greatly lacking. This poor communication also has patient safety implications: gaps in care and conflicting treatments. Two particular types of information that was most sought were information about available services and resources, and information about particular health conditions. Another aspect that was found important, but also lacking was an on-going relationship with a care worker, which enabled them to discuss their health and health care and to access advice or help when needed. Such support plays a significant role in enabling patient participation.

Health professional communication demonstrates many flaws. In general, these include: unnecessary duplications of information or tasks being performed; delays between communication; lack of essential information being communicated; information inconsistencies (such as in patient advice); and the lack of support for wider distribution of potentially beneficial information to other healthcare providers and organisations [12-14]. Such flaws result in unnecessary time, effort and costs being expended in the healthcare process. It has also been pointed out in that a lack in cross-institutional records and communication systems results in leaving it up to the patient to have to convey the treatment plan of one healthcare provider to another [15]. As with face-to-face communication, there are also problems that arise from written communication that pose a serious threat to effective cooperation. Such communication problems include misunderstanding between healthcare providers due to use of different terminologies, and misinterpretation [16]. Among the less obvious

problems are: questioning whether statements made are really true; whether the speaker/writer's intentions can be trusted; or who is the target for a request - these often result in delays in performing tasks, or tasks in a care process not being performed [16].

For effective care of the patient there must be effective communication between the providers themselves to coordinate the activities involved in the care of the patient. There must be support for distributed activities such as scheduling, referrals and reporting, and to support joint decision-making within the multidisciplinary team when necessary. The main obstacles in this important objective include the differences in geographical locations of the providers, and the differences in the roles in which they play. There must be support for asynchronous communication across remote sites, and there must be common ground that the providers understand each other. Relevant information provided to the clinician at the point of patient treatment can alleviate the paper and telephone intensive processes that are currently typical in multiple health-plan environments.

Promoting support for chronic disease management

The nature of chronic disease care processes especially, make it challenging to devise Healthcare Information Systems (HISs) that can sustain the continuity and coordination of evidence-based practice for chronic disease as they unfold over a long time-scale, often occur in the presence of co-morbidity, and require care and services from multiple healthcare providers, sites and institutions. With respect to health policy for CDM, the Australian Commonwealth (federal) Government has taken a significant step through its Enhanced Primary care (EPC) framework, which introduces a variety of new reimbursement items for health care providers through the Medical Benefits Schedule (MBS). In particular, healthcare providers can be reimbursed through the MBS for care planning and discharge planning activities [17]. As an administrative system, the EPC MBS items allow GPs and others to make claims *if* they perform the right set of activities at the right time *and* properly document those activities. This has given rise to localised guidebooks that are an interesting blend of evidence-based medicine and administrative how-to manual (e.g., [18]).

It is generally accepted that, when properly contextualised and deployed, clinical practice guidelines systematically developed from the best available evidence can lead to improved outcomes across a wide spectrum of healthcare activities [19]. Moreover, there is a widely held optimism (at least in the medical informatics community) that the use of clinical decision support systems – i.e., systems that provide patient-specific advice – can facilitate the practice of evidence-based medicine and thereby substantially improve health care quality [20]. The empirical record shows that many clinical decision support systems do appear to be effective [21], however, the record of successes in CDM is patchy. In fact, a recent evaluation of primary care decision support for asthma and angina in the UK found the system to have no influence on healthcare process or outcomes [22] [1]. There is still much to be learned about successful development and deployment of information technology to improve CDM outcomes. Thus, with the rising prevalence of chronic illness, there is a growing pressure to develop systems that engender evidence-based care. In addition, the potential for workflow support to coordinate services and improve communication in the context of CDM is intuitively appealing, but is still a challenging (and hence, rarely seen) accomplishment in practice.

1.1. Objective of the Thesis

This thesis aims to address the problem of building ideal systems that provide support for guideline compliance and process enactment in the context of chronic disease management. In particular, it aims to define the practical boundary of applicability of workflow approaches versus decision support system approaches in supporting guideline-based care. An approach is examined that features a close relationship of the Electronic Health Record (EHR) content to other components of a Health Information System (HIS): guidelines, decision support and workflow. We examine and build on current work from three relatively distinct research areas: clinical guideline representation, decision support systems and workflow technology, with particular emphasis on identifying the relationship between them, and demonstrate an

[1] Letters to the editor subsequent to this article indicate some ambiguity on the issue of whether this was in fact the PRODIGY system for which no significant benefit was reported; to which the answer would appear to be that an early variant of PRODIGY was employed for the evaluation. Nonetheless, this is the best comprehensive evaluation of a primary care DSS for CDM available.

approach to integrating the aforementioned components to assist service coordination, communication, and promote evidence-based medicine.

1.2. Motivation for System Integration

In order to address the aforementioned chronic disease management issues, the 'holy grail' for HISs is increasingly geared towards the integration of patient-specific information and decision knowledge into clinical processes [22]. Despite (or possibly due to) numerous "standards" in health information technology [23], [24], there are relatively few examples of integrated inter-site HISs [25]. Information is available and there exists networking to provide a means to exchange and share the information, however, HISs must also offer ways for relevant and much needed information to go through the appropriate communication channels at the point of care. Thus, effective communication, let alone, improved health outcomes, does not rely solely on having a network – the technology must be useable and effective in the real world setting, as well as addressing significant opportunities for process improvement, in particular, effective and efficient communication.

Although the potential for workflow support to coordinate services and improve communication in Chronic Disease Management (CDM) has been recognised, there has been little accomplishment in this area, due first and foremost to the fact that it has been proven as a challenging thing to achieve in practice. Recent trials in the UK using the PRODIGY decision support system have shown this [22][2], and have brought about the need to resolve issues such as the need for patient-specificity of guideline recommendations, and support for the recommendations' timely positioning within the provider's workflow.

The Role of Guideline-based Decision Support

According to the National Electronic Decision Support Taskforce [26]:

[2] Letters to the editor subsequent to this article indicate some ambiguity on the issue of whether this was in fact the PRODIGY system for which no significant benefit was reported; to which the answer would appear to be that an early variant of PRODIGY was employed for the evaluation. Nonetheless, this is the best comprehensive evaluation of a primary care DSS for CDM available.

> *Electronic decision support systems have three main components: knowledge, rules, and software. Knowledge stored electronically includes published clinical practice guidelines, commercial databases, and custom-designed knowledge bases based on expert opinion. Knowledge is translated into active rules used within the electronic decision support system. The software applies the knowledge, rules, and local patient and clinical data, and presents the electronic decision support functionality on the clinician desktop.*

Guideline-based decision support systems are traditionally used within clinical applications such as prescribing and dispensing medications, for example, to perform drug-drug interaction checking. In order to provide patient-specific recommendations, patient data is often obtained by prompting clinicians to enter the relevant data into the system at the point of care. However, there is an increasing recognition and hence, development of these systems to be integrated with the patient's EHR to provide this information – particularly to query about the patient's medical history and other related information that remain significant over time (such as current medications, active problems and diagnoses). At the same time, it is viewed that EHRs will belong in a *shared* central repository from which all clinical information systems such as decision support systems can access patient information both locally and internationally. This ensures that such systems only need to have a single and central point of access to all of the data. Furthermore, a single, shared EHR better ensures the quality and completeness of patient data, which allows clinicians to reason and make better decisions in conjunction with the use of decision support systems.

In general, guideline-modelling research (the foundation from which decision support systems are built) focuses specifically on modelling the *clinical decision making processes* of (typically, a single) provider (such as a General Practitioner). Many of the electronic decision support systems implementations based on the guideline representations are alert-and-reminder systems where integrating into the workflow comes down to the timing, modality, and format of *notification* (Krall, 2002 cited in [27]). However, for successful implementation of chronic disease guidelines and integration of workflow within the primary care setting (as well as community-based setting), the user interface design and decision-support services that a system provides are necessary points for consideration (Shiffman, 1994 cited in [27]). We argue that it

is important to differentiate between the process of arriving at clinical decisions, and the process of carrying out the actions that were decided upon. The latter point is particularly important in CDM where healthcare services are very often delivered and coordinated within a multidisciplinary team (i.e. multiple provider roles) – with each team member sharing the common goal of delivering evidence-based or guideline-based care. However, guideling-based care has to be performed according to some larger business process model that incorporates resource management, institutional policies and procedures, etc, which is what *workflow* modelling entails.

The Role of Workflow

According to the Workflow Management Coalition (WfMC), a workflow is:

> *"The automation of a business process, in whole or part, during which documents, information or tasks are passed from one participant to another for action, according to a set of procedural rules".*

Workflow modelling researchers look specifically at business processes and, increasingly, at how to incorporate flexibility in those models to account for the changes that occur in work practices. Again, this area is not tied to any specific business domain such as healthcare (in fact, there is little that has been done in this area).

Traditional applications of workflow include manufacturing, insurance claims, document management, travel and order processing. While the potential for workflow technology to coordinate services and improve communication within healthcare processes is recognised as intuitively appealing, the implementation of which is highly challenging, and it is rarely accomplished in practice.

Besides the present research, there are a few groups aiming to support workflow in healthcare. Among these few are Pavia University (Italy) in particular, and increasingly other guideline modelling researchers and the UK-based PRO*forma* [28]. The Pavia work (see below) is virtually unique in taking a direct workflow approach to guideline modelling. The PRO*forma* approach is founded on Process Description Language [29], which is grounded in a logical model of decision-making and plan enactment. While this may model the flow of decision making, it does not model the

larger levels of inter-task coordination characteristic of 'workflow' as intended in this thesis (see Chapter 2 for extended definition of *workflow* and related terms). Nonetheless, under OpenClinical (see http://www.openclinical.org/about.html), the scope of Pro*forma*-integrated guideline modelling methods and technologies is expanding into true workflow management systems (WfMSs).

Our view is that the workflow models used by WfMSs can *further augment* guideline representations. This can assist the coordination between providers and across consultations or 'sessions' for instance, by incorporating into the model *explicit* notions about workflow activities being enacted by *multi-provider roles*, automated invocation of decisions support tools or applications, scheduling and prioritisation. We believe that such workflow models in conjunction with their use in WfMSs provides added value and a more practicable solution to guideline-based decision support for CDM in particular at the point of care since the "workflow" in this context is typically broader and covers multiple provider roles and inter-organisational care processes.

Panzarasa et al. from the Pavia Medical Informatics Laboratory report the successful representation of evidence-based post-stroke rehabilitation guidelines as a workflow model from which a 'careflow' management system is implemented using Oracle Workflow tools [30]. This system illustrates that, at least in some cases; a very significant aspect of the knowledge from an evidence-based guideline for CDM can be expressed through the design of a patient-centred workflow. However, this workflow is not fully integrated with the EHR, which makes it difficult to build clinical information systems that provide *patient-specific* decision-support seamlessly within the provider's workflow, or to provide support for what data needs to be captured at a given point in time.

The Role of the Electronic Health Record (EHR)

The EHR realm is specific to the domain of healthcare, and EHR instances are each on its own a representation of a patient/case. EHR standards aim to develop standards that enable all the data related to the health of a patient to be modelled and implemented within an IT system that manages it. Furthermore, because uncertainty and incompleteness are inherent in the health domain, these standards aim to find the

balance between being specific enough to their domain, as well as being generic and flexible enough to account for future knowledge. While EHR research is much about data, and management of data, it is also increasingly, about the *sharing* of the data.

HL7 (Health Level Seven) is an international body that has predominantly supported this latter facet via messaging. In particular, it has a USAM (Unified Service Action Model) that specifies relationships between clinical 'acts' and things/entities. However, this information lies within a messaging framework, and must have support for capturing the context and state of the progression of care, and relevant messages in a persistent manner.

Leveraging the EHR for Integration with Decision Support and Workflow

Traditional paper-based health records only stored information regarding the patient's condition, and medical care of the patient – the "workflow" was left up to the humans to make sure activities were performed accordingly, and moreover, to ensure the timely flow of information between participants in the workflow (e.g. the requirement of signatures on documents for authorisation is required before orders could take place, etc). Its use was fairly limited, and relatively passive in nature, however, with the emergence and rapid developments in information technology – the necessity of EHRs and its potential to be shared across domains and international boundaries are increasing. Our view is that it should at least provide mechanisms for other potential electronic system components and applications to use it, and do so as easily and as practicably as possible. Moreover, we view the EHR to be a central component of any HIS, and the increasing need for its use and the way it can be used undeniably places greater responsibilities on the EHR and its architectural design.

A good case can be made for the use of EHRs in chronic disease management. A case study that looked into the effect of using electronic data exchange in a diabetes coordinated care environment found that communication between health care providers increased, they had better access to data, and there was a small improvement in patient's health over a short period of time [31]. The question remains, is it possible to reap further benefits in CDM via the use of guidelines? PRODIGY Phase Two results estimate that if all General Practitioners (GPs; i.e., "family physicians")

prescribed the same way as PRODIGY-compliant GPs on three 'tracer conditions', the savings would be approximately £14 per quarter [8]. Experience in PRODIGY Phase Two, however, indicates challenges for achieving effective decision support for CDM [8, 32]. These challenges include the need to provide guidance using information across successive consultations; provision of structured guidance within a minimal user interaction; and providing guidance-positioning information [32]. The Phase Three architecture aims to address these problems – a key feature being clinical *scenarios* (patient states) with sets of available actions associated with each scenario. Actions taken indicate scenario transitions for following consultations. Despite the innovations, however, recent evaluation using the scenario-based decision support in general practice shows no effect on management of chronic conditions [22], most likely due to the significant barriers to its usability [33].

Work in one of the Australian Commonwealth's Health*Connect* projects [34] have had related experience. It was observed that, in concert with domain experts, one can design an 'event summary' data collection form that describes all information that is potentially needed for a given event (e.g., GP contact with a diabetes patient). However, clinicians find these unwieldy because the form documents a maximal data set, too much to record in a given consultation, and it is unclear when to record which information.

It must be recognised that from the perspective to where the EHR fits in a clinical information system (and incidentally, it is the core component of it (without the patient, there is no need for a health record, let alone a whole system)), there is the need to support for other components within that system: guideline-based decision support and workflow. More specifically, how the output of decision support and workflow-support applications gets maintained *persistently* within a repository such as the EHR for future use and for accountability has not been explicitly explored in detail. The notion of information persistence is of particular importance for chronic disease management where information about the care of the patient remain significant over a long period of time, requiring the coordination of services from multiple healthcare disciplines, which are often geographically dispersed.

In general, while we acknowledge the validity of each research perspective (i.e., guideline-based decision support, workflow, and EHR), we also acknowledge the need for an integrated approach if future clinical information systems are to meet the requirements of chronic disease management. Our approach presented in this thesis explores specifically how the EHR can be leveraged to integrate with workflow and decision support applications in consideration of the current work undertaken by researchers in the field. In particular, we make use of workflow standards such as the WfMC's XML Process Definition Language (XPDL); we align our model with WfMC's workflow reference model, and the various workflow patterns identified by workflow researchers. We also extend the EHR to have explicit constructs for recording guideline-based recommendations produced by decision support systems that make use of computer-interpretable guidelines. While the latter maintains the history of decision-making for future reference, it also enables decision support systems to directly and efficiently access or query the patient's EHR about previous guideline steps taken and reason about the next valid step(s) that can be taken. The aforementioned problem of maximal data sets is addressed by introducing more specific linkage of the associated guidelines to the EHR content items. In this way, information is considered a priority for a given encounter can be clearly identified in the point-of-care application.

1.3. Research Proposal

We take the position that guidelines can be knowledge-engineered into four main artefacts:

(1) EHR content,
(2) Computer-interpretable Guideline (CiGs),
(3) Workflow and
(4) Hypermedia.

To coordinate and make use of these artefacts in a clinical system, we propose to leverage the electronic health record since we view this as the core component to any HIS. We extend the record to support the recording requirements of other components in an HIS such as workflow and decision support, and therefore to assist in the coordination, communication between patients and health care providers, and the care

of patients. We use the *open*EHR architecture to form the basis of our approach. The *open*EHR framework uses two models:

(1) *Reference model* that is a representation of the generic datatypes and data structures; and

(2) *Archetype model* that defines the types of constraints that can be placed on those generic datatypes and data structures.

Instances of archetypes are then specified to define domain-specific concepts. The *open*EHR framework consists of basic archetype model constructs that directly correlate to guideline attributes that assist us in our approach with the requirement of further extensions to the model. Such constructs include: observation, evaluation and instruction record entry types. We find that guidelines can inform the EHR content – such that:

(1) *Observations* correlate with guideline input parameters (as they specify what to record and when);

(2) *Evaluations* correlate with the guideline algorithm (as the specify likely diagnoses, goals and targets); and

(3) *Instructions* correlate with guideline output parameters (as they specify the recommendations, treatments, and patient recalls/reassessments or follow-up visits and so forth).

To coordinate decision support and the EHR, the EHR should have the capacity to record exactly how decision support was used to arrive at a given evaluation or instruction. We define constructs for the rationale of the decisions made to be recorded explicitly within the record. This includes the specific guideline step, justification statement, and links to relevant EHR data items that were used to arrive at that decision (e.g., blood pressure value). The rationale is either pre-populated with justified recommendations provided by an electronic decision support system based on a computer-interpretable guideline, or alternatively populated manually by the clinician whose decisions may deviate from those of the guideline. Thus, at any point in time, the rationale for a decision can be ascertained explicitly from the EHR, making it easier to reconstruct a series of related decisions that were made about the patient at various consultations with the provider. The tracking of guideline compliance is also of medico-legal significance, and where deviations from guideline occur, new evid-

ence could *potentially* be discovered that could assist with further clinical guideline developments.

To coordinate workflow and the EHR, the EHR should have the capacity to record exactly how the steps or activities within a workflow were performed, when, how, by whom, and why. Furthermore, the specific information that results from performing each activity should be recorded in a timely fashion, and part of being able to facilitate this is to provide information that pertains to both past/historical activities that were undertaken, as well as information about the future activities that are required to be and/or are able to be undertaken. We present our Instruction Reference Model (IRM), which is an extension of *open*EHR's Instruction into *composite* Instruction entries, and sub-class it into instruction *definition* and instruction *execution* entries, where –

- Instruction Definition entries answers questions about:
  - What to do;
  - What to record; and
  - Who will do it; and
- Instruction Execution entries describe the progression of the workflow as it is being executed according to its corresponding Instruction Definition, and therefore answers questions about:
  - What was done;
  - What was recorded (which may be further Observation, Evaluation and/or Instruction entries);
  - Who did it;
  - What else to do (i.e. the future allowable and/or required activities);
  - Who will do them; and
  - What else to record.

The coordination and linkage of the EHR with workflow using our composite Instructions allow a close and structured correspondence between the workflow and the EHR. Moreover, the EHR Instruction Definition and Instruction Execution entries can be synchronised with a WfMS, which can provide automated assistance at various points in the workflow, and other potential tools such as scheduling and invocation of applications (e.g. decision support applications).

1.4. Research Aims

The general aims of this research include:

- Defining requirements of EHR, guideline, and workflow integration (including defining key roles they each play, where they function independently of each other, and where they interact to form a seamless, integrated clinical information system).
- Building a system prototype that integrates EHR, WfMS and Decision Support to demonstrate the potential interaction of the guideline-engineered artefacts.
- Extending the openEHR instruction model to define workflow and data to collect during specific activities, and allow execution and synchronisation with a WfMS.
- Identifying the advantages of our approach, and where shortcomings are identified, a discussion of why and possible future work to be addressed.

1.5. Research Method

In order to achieve our research aims, we follow the research method, which involves the following specific steps –

(1) Engineering guidelines into the following artefact set: EHR content, CiG, workflow, and hypermedia.

(2) Using and extending the *open*EHR framework: A particular focus of our research is on exploring the potential of the *open*EHR architecture, which allows extension of a core Reference Model via Archetypes, to –
   - Refine the detailed information recording options for specific points in the healthcare process,
   - Represent decision support information needs,
   - Represent the chain of instructions that is the workflow itself.

(3) Illustrating our approach using a prototype system with a focus on two distinct but common chronic disease management scenarios: Early Supported Discharge and associated Post-stroke Rehabilitation which is process-oriented and less clinical in nature; and hypertension in diabetes which is of a highly clinical nature, and decision-based. This involves going through a guideline engineering process consisting of the following phases:

- Analysis phase: taking a source clinical guideline document and abstracting from it the required set of actors/roles, the interaction between them, actions to be performed, decision points, and the data or information flows – all of which assist in the development of scenarios, task detail tables, and a guideline ontology.
- Conceptual design: producing process model diagrams based on the analysis of the guideline document; formalising the diagrams into UML activity diagrams; and the creation of mock-up user interface screens to simulate possible interactions with the system and to further refine the requirements of the system.
- Design phase: producing workflow schemas for actions recommended in the guideline (based on the process models developed in the conceptual design phase); creating the Guideline Adapter Document (GAD) schema (based on the guideline ontology); and the user interface screens to be used in the prototype.
- Implementation phase: producing instruction definition archetypes from the workflow schemas as well as other EHR archetypes needed for data collection as a result of performing the tasks in the workflow; and the computer-interpretable guideline instance itself (which is an instance of the GAD, and is therefore validated against the GAD schema).

The goals of executing these steps are to illustrate how the guideline document should be conceptually sliced to produce the required set of artefacts; and demonstrate our approach using a proof-of-concept prototype of the coordination of workflow, decision-support and the EHR using two distinct case studies.

1.6. Organisation of the Thesis

The thesis is organised as follows:

- Chapter 2 defines the key concepts used in this research, and discusses existing models and technologies in the literature.
- Chapter 3 describes our approach of guideline engineering, the relationship between the EHR, guideline and workflow, our Instruction Reference Model

(IRM), our method of applying it in a context, and introduces the two case studies chosen for our approach to be applied in.

- Chapter 4 describes our architecture that integrates the EHR, decision support, and workflow. It also describes the specific technologies used in our implementation – in particular, how we used and extended (where required) specific open source tools to build the system, including the Java Workflow Editor (JaWE), and Breeze workflow tools: a workflow monitor (Brzmon), the workflow engine itself (Breezed), and workflow instance invocator (Breeze).
- Chapter 5 and 6 describes the application of our approach using our architecture in the context of the two case studies in Early Supported Discharge for Post-stroke Rehabilitation, and managing Hypertension in Diabetes Mellitus in Adults respectively.
- Chapter 7 concludes the thesis and discusses the implications of our research, and areas of future research.

2

BACKGROUND

2.1. Introduction

For all languages, successful communication only occurs when the language, and in particular, the *terminology* is used and understood in a common context. The terms *evidence-based medicine*, *guideline*, *protocol*, *care plan*, *pathway*, and *workflow* are referred to in a myriad of sources. However, these terms are often defined and used loosely, ambiguously, or even interchangeably depending on individual and organisational preferences. Section 2.2 reviews the definitions of these terms found in the literature, and defines the terms in the context of the clinical domain. Where there are similarities between the terms, it identifies where there are differences or variations (some lying within their properties whilst others may lie in the purposes of their use) and consequently draws a line of distinction between them and establishes a

more concrete set of *definitions* along with their *properties* and the *objectives/purposes* of their use in table format. Each of these tables is a result of our own synthesis informed by the relevant literature reviewed. Section 2.2 also defines the other key terms in this thesis, namely, *workflow management system, electronic health record (EHR), and EHR architecture*.

Section 2.3 reviews the models and technologies that have been developed in the field of facilitating in some way, evidence-based medicine, guideline, protocol, care plan, pathway, and workflow. These models and technologies include health information networks, messaging, electronic health records, computer-interpretable guidelines, decision support, and various workflow approaches and workflow research.

2.2. Key Terms Defined

2.2.1. Evidence-based Medicine

Evidence-based medicine (EBM) is defined by [35] as:

> *"Evidence based medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. This practice means integrating individual clinical experience with the best available external clinical evidence from systematic research".*

A more detailed and precise definition is provided in [36], which we will use as the preferred definition of EBM:

> *"The process of systematically finding, appraising, and using contemporaneous research findings as the basis for clinical decisions. Evidence-based medicine asks questions, finds and appraises the relevant data, and harnesses that information for everyday clinical practice. Evidence-based medicine follows four steps: formulate a clear clinical question from a patient's problem; search the literature for relevant clinical articles; evaluate (critically appraise) the evidence for its validity and usefulness; implement useful findings in clinical practice."*

There are efforts to improve the organisation and dissemination of evidence. In this thesis, when we refer to 'evidence', or to something (such as a guideline or practice) being 'evidence-based', we are referring to the relationship with EBM. Notably, the Cochrane Collaboration [37] collects, prepares, maintains and disseminates up-to-date systematic reviews of evidence on a quarterly basis, and relies upon the voluntary efforts of health care providers, consumers, and scientists from around the globe. The National Library of Medicine also provides a resource for patients, carers and the general public for up-to-date information specifically about clinical research studies [38], as well as the Health Services/Technology Assessment Text (HSTAT), which allows freely allows access to various documents on health information and guideline-based decision making [39] to various groups such as health care providers, health service researchers, policy makers, and consumers..

EBM is geared towards the practice of medicine that is founded upon well-established findings of randomised controlled trials in an effort to help providers in making *well-informed* decisions about what practices have proven to be effective and efficient in the process of care. In general, clinical decision making based on EBM is founded upon the underlying principles that [40]:

- Clinical experience is important but observations must be recorded systematically and without bias;
- Regular reference must be made to original literature; and
- The results of studies must be critically examined using rules of evidence.

These principles should be applied above and beyond [40]:

- Observational data used to build knowledge about a patient's progress and prognosis;
- New treatments and diagnoses evaluated using traditional medical education and common sense;
- Answering problems by asking colleagues and local experts; and
- Reading textbooks (which can often be out of date by the time they are published) or searching through massive amounts of information in journals.

Limitations and barriers

Clinicians find it difficult to keep up-to-date as new evidence is discovered as these get reported within journals due to lack of available time for reading. According to Davidoff et al. (1995) (cited in [35]), for general medicine, one would require enough time to examine 19 articles per day, 365 days per year, which is no where near in comparison to the actual available time – e.g. well under an hour a week by British medical consultants, even on self reports according to Sackett (cited in [35]).

Despite the support and promotion of EBM, there are still those that remain sceptical. Notably, a recent journal article [41] paints a rather humorous and cynical view about individuals who insist that all interventions need to be validated by a randomised controlled trial (RCT). The article discusses their argument by studying the effectiveness of parachutes to reduce the risk of injury after gravitational challenge, in which its effectiveness has not been proved by RCTs, but solely on the basis of observational data, understanding and knowledge of the domain (in this case, the natural history of free fall), as well as basic common sense and good judgement. Nonetheless, as is with all clinical interventions (similarly to the parachute case) there are also associated iatrogenic complications or unfavourable responses to the clinical interventions/treatments that are induced by the therapeutic efforts themselves (Lasczkowski et al. 2002 cited in [41]). Thus, there is also the need to perform a risk and benefit analysis for undertaking such interventions. Another scepticism brought about in [41] is with regards to the reliability of results from RCTs. If such trials for instance, are to be sponsored by industries then these industries will more likely be biased towards their product for the sake of commercialism – arguing that parachute industries have profited billions without having their product undergo a RCT. They also argue that, if all clinical decision-making was dependent on the use of EBM, there is the question of how to ethically recruit the numerous subjects to be involved in these trials.

In essence, [41] makes some strong points, if from a perspective ostensibly in opposition to EBM advocates. Its basic standpoint is that EBM can *inform*, but can never replace, individual clinical expertise and common sense based on risk and benefit analysis, and it is this expertise that decides whether the external evidence

applies to the individual patient at all. However, the article can be perceived as perhaps a little unjust in the use of the parachute scenario. Some would argue for instance that EBM does not necessarily imply the specific method used, and hence, does not limit itself to the use of a RCT to acquire the evidence. Moreover, it is important to recognise that the clinical question to be answered poses much greater uncertainty about its outcome (as compared to the effectiveness of parachutes reducing risk of injury/death on free-fall).

The application of EBM to individual patients itself, and how it should be integrated into a clinical decision, currently is a non-trivial problem that is faced by stakeholders. Various reasons for the variance in practice are documented in [42] – particularly, why some clinicians choose to even use treatments that simply do not work. Because clinical intervention entails human activity not just science, there are rituals, customs, personal preferences, and expectations of clinicians, patients and society in general that play an influential role in the decision making process. Thus, patients for instance, largely expect or assume clinicians to always have a solution to a presenting problem, which can often lead clinicians to be inclined to have to do something about it, irrespective of, the treatment's actual effect.

2.2.2. Key Terms from Evidence-based Medicine

Evidence-based care is established with a view to improve the overall quality of care for patients, reduce costs, and address medico-legal issues. EBM is the foundation from which *clinical guidelines*, *protocols* and *pathways* (defined hereafter) are developed.

Guideline

There is a proliferation of definitions for the term *guidelines* depending on organisational and individual preferences. *Practice guidelines* can sometimes serve as an umbrella label for practice standards, protocols, parameters, algorithms, and various other types of statements about appropriate clinical care; at other times, sharp distinctions are drawn. A guideline is defined as "an indication or outline of policy or conduct" [43]. In the clinical field, physicians strive to improve the quality of healthcare through better awareness of proper patient management techniques whilst

also trying to reduce costs. Such techniques usually exist in the development of guidelines. These guidelines are often referred to as *clinical procedures* or *protocols* that describe recommended or evidence-based set of steps in treating a patient with a particular disease. There is abundant literature that refers to guidelines with a variety of nuances. In the generic sense, a guideline is defined in [44] as a:

> *"Set of statements, directions, or principles presenting current or future rules or policy. Guidelines may be developed by government agencies at any level, institutions, organizations such as professional societies or governing boards, or by the convening of expert panels. The text may be cursive or in outline form, but it is generally a comprehensive guide to problems and approaches in any discipline or activity. This concept relates to the general conduct and administration of health care activities rather than to specific decisions for a particular clinical condition. For that aspect, practice guideline is available".*

Referring to guidelines in a clinical sense, [45] describe a clinical *practice* guideline as a "predefined policy that allows a health care organisation to manage patients with a certain presenting condition in a standardized manner". A more detailed definition is given from [44]:

> *"A set of directions or principles to assist the health care practitioner with patient care decisions about appropriate diagnostic, therapeutic, or other clinical procedures for specific clinical circumstances. Practice guidelines may be developed by government agencies at any level, institutions, organizations such as professional societies or governing boards, or by the convening of expert panels. They can provide a foundation for assessing and evaluating the quality and effectiveness of health care in terms of measuring improved health, reduction of variation in services or procedures performed, and reduction of variation in outcomes of health care delivered".*

A definition from [46] states that guidelines are:

> *"Often used synonymously with the term protocol, the term emphasises that the role of the patient management instructions is to offer guidance*

> *rather than dictate a specific course of action. When used outside the clinical trial setting in routine care, most protocols or guidelines are intended to be advisory, and rely on the clinician to use their judgement when the instructions to do not seem appropriate for a specific patient."*

An increasingly accepted definition for clinical guidelines given by Field and Lohr [47] is:

> *"Systematically developed descriptive tools or standardized specifications for care to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances".*

Many researchers in the field of computerised guideline representation and implementation have adopted Field and Lohr's definition. Clinical guidelines (which are generally either text-based narratives or clinical algorithms with appended annotations [48] are typically developed through a formal process and are based on authoritative sources, including clinical literature and expert consensus with the goal that they should have general application. Guidelines make explicit recommendations, with a definite intent to influence what clinicians do. The intention of compliance to these guidelines is to reduce unacceptable or undesirable variations in practice and provide a focus for discussion among health professionals and patients. They enable a multidisciplinary team to arrive at an agreement about treatment and devise a quality framework, against which practice can be measured [49].

Guidelines should provide extensive, critical, and well-balanced information on benefits and limitations of the various diagnostic and therapeutic interventions so that the physician may exert the most careful judgement in individual cases (World Health Organisation [WHO] hypertension guideline cited in [50]). Generally, however, the greater the strength of evidence that is incorporated into the guidelines, the better their quality [51] and hence their acceptance for use in the clinical setting. Whilst there are many sources that often refer to guidelines as "protocols", [52] advise against this and emphasise the distinction between nationally and locally developed clinical guidelines. The status of guidelines as guidance, rather than instructions or commands (i.e.

protocols (see following section for definition)), is reinforced. They are seen as *aids* to, rather than substitutes for, clinical judgment. As stated in [53], guidelines –

> *"Suggest a set of typical pathways for a class of management tasks, explicitly allowing for modification of the standard recommendation in cases which present atypical factors not addressed in the guideline".*

In addition, it also states that they are designed for use within a –

> *"complex, open-ended healthcare process where many guidelines concern themselves with care planning and management over time, not (just) the single big decisions".*

Furthermore, according to the NHS Executive (cited in [50]), clinical guidelines cannot be used to mandate, authorise, or outlaw treatment options. Under the United Kingdom common law for example, minimum acceptable standards of clinical care are obtained from responsible customary practice, rather than from guidelines. Their justification is that guidelines *presuppose* an average patient rather than the individual patient whom a physician is endeavouring to treat, and that knowledge and analysis that go into development of guidelines stem from the minds of guideline developers (who are distant from the consultation) rather than from the mental processes of the clinicians themselves [50].

In the realm of computerised guideline representation, guidelines share the following key constituents [54]:

- *Decision*: a selection from a set of alternatives based on some guideline criteria.
- *Action*: clinical task/intervention to be done or recommended.
- *State*:
- *Patient state*: description of the patient's status based on the actions performed and decisions made within the context of a guideline.
- *Execution/system state*: description of a guideline implementation system based on the stages of process with regard to the decisions and actions defined in a guideline.

There is of course, a close relationship between patient and execution states. Most of the guideline representations consider only one of these, but due to their similarity,

their guideline models are still relatively expressive. However, as patient state can be affected outside the control of a guideline application, there may be a deviation between patient and execution states. Moreover, there is no real decidability (i.e. determining the exact circumstances under which an action is recommended) when executing clinical guidelines. That is, whilst conventional guidelines rely on deterministic, all-or-none reasoning, clinical practice often requires reasoning with incomplete and imprecise information – hence the need for physician expertise and experience for interpretation of clinical guidelines [55].

Examples of guidelines include the Joint National Committee Report on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure [56], and Hypertension Algorithm for Diabetes Mellitus in Adults [57].

From a review of some of the literature that define clinical guidelines, we derive the following definition, along with a set of properties a guideline has, and purposes of its use:

Guideline definition
Incorporating the most suitable definition from [44], a guideline is a set of *evidence-based* recommendations developed by governmental bodies and medical experts to *assist* rather than instruct the health care practitioner with patient care decisions about appropriate diagnostic, therapeutic, or other clinical procedures for specific diseases or clinical circumstances.
Guideline properties
❖ Goal-oriented ❖ Disease-specific rather than patient-specific ❖ Developed based on varying levels of research or evidence that range from expert opinion through to randomised control trials ❖ Generally has a long life-span/cycle ❖ Generally a narrative description of the care of a patient – often specific to one problem or disease. ❖ Specifies how to apply clinical knowledge in the care of patients for a specific problem and the possible consequences of those clinical decisions.

- Present a number of possible ways in which the guideline goal(s) may be achieved depending on patient circumstance.
- It is a *generalised* documentation of how specific ailments in patients should be diagnosed, treated, prevented, or rehabilitated based on evidence-based medicine.
- May also specify the handling of *known* clinical exceptions, as well as possibly how to terminate 'gracefully' from the guideline.
- Physicians are able to deviate from steps recommended in the guideline for unusual or atypical circumstances that are not covered by the guideline (see Figure 2.1).
- Unlike protocols, guidelines are subject to individual interpretation and thereby require use by experts who have broad knowledge or background and experience of the domain at hand.
- Due to the uncertainties inherent in the medical domain, guidelines are generally open-ended, as they usually do not cover every possible decision criterion in the problem space.
- In general, guidelines constitute the following main elements:
    - Criteria for guideline use or patient eligibility criteria
    - Guideline author and date of release
    - Goal/intention(s) of guideline
    - Medical background
    - Patient state
    - Sub goals
    - Condition(s)/sub-criteria for guideline step to be taken
    - Decision steps
    - Actions (e.g. prescribe medication, refer to specialist)
    - Evidence (reference to evidence-based medicine)
    - Justification or reason for action or decision
    - May be graphically represented (e.g. flow chart) and/or narrative.

Guideline objectives

- Promote/encourage the practice of evidence-based medicine as to reduce adverse clinical practice variations and consequently minimising adverse patient health outcomes.

- Provide decision *support* for clinicians (i.e. assist them in reaching conclusions with more certainty), thus improving the overall quality of care.

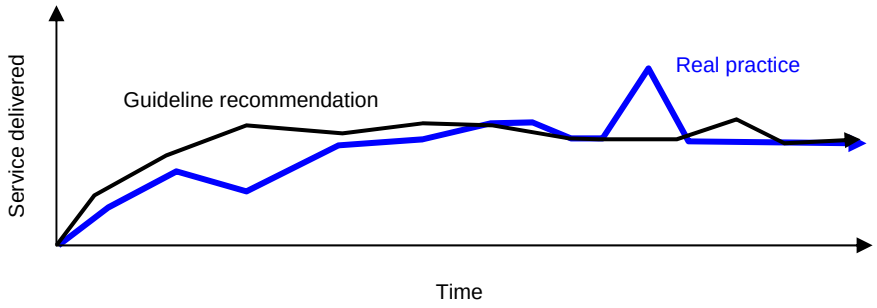


Figure 2.1. Guideline recommendations versus real practice decision-making.

Protocol

As defined by [43], a protocol is:

> *3 a: a code prescribing strict adherence to correct etiquette and precedence (as in diplomatic exchange and in the military services) b: a set of conventions governing the treatment and especially the formatting of data in an electronic communications system. 4: a detailed plan of a scientific or medical experiment, treatment, or procedure.*

As discussed in the previous section, a number of sources use the terms "protocol" and "guideline" interchangeably. There are also several that make no distinction between "clinical pathways" and "protocols".

In the clinical context, *protocols* may take the form of algorithms, which set out, in sequential form, particular treatment choices for particular circumstances [58]. Similarly, van Bemmel and Musen [45] define a protocol as a standard algorithm (which is a "*set of unambiguously defined rules describing how to obtain the solution to a problem*") that defines one precise manner in which certain classes of patients should be evaluated or treated.

One paper that does make a distinction between protocols and guidelines is [59]. They define the difference between guidelines and protocols as lying in the fact that guidelines –

> *"Free the individual from the burden of having to estimate and weigh the pros and cons of each decision. In so doing they bring order and discipline to their decisions but allow interpretation for differing clinical situations. Whereas protocols force a discipline that has to be followed."*

In addition, they state that protocols are rules and suggest that they are –

> *"Mainly suitable as instruments to control actions once those decisions are made. This distinction between decisions and actions is perhaps arbitrary but it does highlight the differences between the indications for the potential of guidelines and protocols".*

Joughin (1997) (cited in [49]) also share the same perspective in that protocols are:

> *"Rigid statements allowing little or no flexibility or variation. A protocol sets out a precise sequence of activities to be adhered to in the management of a specific clinical condition. There is a logical sequence and precision of listed activities".*

Similarly, [46] gives the following definition:

> *"Typically a protocol describes all the steps in the management of a clinical condition, and may cover the steps taken to both secure a diagnosis, or treat the illness. When used as part of a formal scientifically conducted clinical trial, a protocol is a strict set of instructions that must be adhered to for the patient to remain within the trial. Typically a clinical protocol will be based on the latest evidence found in the literature, and often be the product of consensus discussions amongst a panel of experts, who pool their collective skills to resolve any ambiguities found in the literature."*

Due to the nature of protocols (specifically the short duration of their execution), they are typically used, for example, in emergency procedures and in paramedics. Specific examples of protocols include the ABCs of CPR: Airway, Breathing and Circulation [60], [61]; and pre-operative/surgical care protocols.

Incorporating the most appropriate definition from Joughin (1997) (cited in [49] and [46]), we derive the following definition of a protocol, and establish the typical properties of a protocol and purposes of its use from the aforementioned examples and definitions:

Protocol definition
A locally standardised algorithm, often based on evidence, that defines one precise manner in which certain classes of patients *must* be evaluated or treated. Protocols are rigid in that they present concise steps that must be followed in a clear sequence and allows for little to no deviation. They are most useful in cases when there is little to no time to make decisions and little to no data available to base decisions on as they are utilised under specific assumptions and such criteria (usually made explicitly within the protocol) must be met before its execution. Moreover, protocol development is subject to organisational policies and therefore any deviation from the protocol steps are subject to litigation.
Protocol properties
❖ Clinical (evidence-based) and institutional ❖ Must be followed with little to no variation or deviation from the specified protocol steps ❖ Process-oriented rather than patient-specific ❖ Has a short life cycle (short-lived process) ❖ A set of explicit, well-established and concise steps to be taken for assessing and treating a patient. ❖ Includes explicit and concise criteria for executing the steps. ❖ Does not require interpretation or deep clinical knowledge and expertise – only need to know if criteria are met for executing the protocol and the protocol steps. ❖ Describes a clinical procedure in terms of:

- What has to be done
- When it has to be done
- Criteria/condition(s) for the step to be executed
- How it has to be done
- By whom it must be done

Protocol objectives

- Promoting the level of quality and efficiency through consistent and predictable application of care for all patients.
- To carry out the care of a specific patient whilst meeting organisational/institutional needs, preferences and policies.

Care plan

From Merriam-Webster's Collegiate Dictionary [43], a plan is:

> *2 a: a method for achieving an end b: an often customary method of doing something: PROCEDURE c: a detailed formulation of a program of action d: GOAL, AIM. 3: an orderly arrangement of parts of an overall design or objective. 4: a detailed program (as for payment or the provision of some service).*

Care plan definition

A high level description of the overall plan of actions for the care of a patient (usually for an extended period of time – weeks, months or years), accompanied by the goals or intentions of carrying out those actions. It is constructed from the basis of one or more guidelines that the patient should follow into one whole description along with an intended time frame or timeline that the goals are to be met, and when actions have to be done. In essence, the care plan specifies *what* is to be done for achieving specific *goals*, and *when* they have to be done. A care plan does not include the notion of resource allocation or management or *how* items will be done in the care plan. Care plans are typically devised between the primary care provider and the patient, and often within a multidisciplinary team for chronically ill patients or particularly

patients that suffer from co-morbidity.
Care plan properties
❖ Patient-specific ❖ Goal-oriented ❖ Long life cycle/span ❖ Timeline of activities for the patient's care (similar to a check list) ❖ Results/outcomes are non-deterministic/undecidable ❖ Constructed based on one or more guidelines ❖ Usually involves a multidisciplinary team to execute the patient's care plan – this is implicit in the care plan (i.e. there is no role/organisation that is explicitly allocated to be responsible). ❖ Focus is on *what* and *when* care plan activities are to be done. ❖ Has the following basic elements: o Goals/intention(s) o Time/period that goal is to be met o Activities may be recurrent or once off, or duration may vary. o Current progress/status of patient with respect to the care plan.
Care plan objectives
❖ Establish a set of goals for achieving the desired patient health outcome. ❖ Formulate a plan of activities/actions based on the medical assessment of the patient in order to meet the goals.

Pathway

The term *pathway* has been likened to a treatment plan of care, clinical protocol, and even a "protocol workflow" [62] against which progress is measured. There is some degree of overlapping between these terms as will be discussed. A pathway is simply a sequence of steps to be taken to achieve a particular goal. The National Pathways Association (1998) (cited in [49]) give the following definition:

> *"Care pathways determine locally agreed, multidisciplinary practice, based on guidelines and evidence where available, for a specific patient/client group. Care pathways form all or part of the clinical*

record, document the care given and help to evaluate outcomes for continuous quality monitoring".

An *integrated* care pathway is a multidisciplinary plan of care identifying daily treatments to produce the best outcomes. The following detailed definition for an integrated care pathway is given in [63]:

"A multidisciplinary outline of anticipated care, placed in an appropriate timeframe, to help a patient with a specific condition or set of symptoms move progressively through a clinical experience to positive outcomes. Variations from the pathway may occur as clinical freedom is exercised to meet the needs of the individual patient".

Other common equivalent terms used for integrated care pathways include "coordinated care pathways", "care maps", "anticipated recovery pathways" [64], or "clinical paths". A pathway is essentially a treatment regime agreed upon by consensus (or group of providers), that includes all the elements of care, regardless of the effect on patient outcomes, and gives a broader look at care which may include miscellaneous tasks such as tests and x-rays that do not affect patient recovery.

The Australian Department of Health and Ageing Online Health Glossary; and Pearson and Bradley (1994) (cited in [65]) both concur that a pathway is a documented plan of the optimal sequencing and timing of agreed interventions by doctors, nurses and other staff for a particular diagnosis or procedure, designed to improve the use of resources, maximise the quality of care and minimise delays. All key patient care activities (e.g. documentation of problems, expected outcomes/goals, and clinical interventions/orders) in a pathway are specifically intended to achieve expected outcomes within designated time frames. Some hospitals provide clinical pathway documents to patients, setting out the treatment during the patient's stay and enabling the patient to understand the complex net of public hospital care (an example is shown in [63]). Pathways provide a structured way to identify care activities and caregiver workflow needed to care for a patient with a particular condition or disease. Paths through a clinical pathway can be adjusted for the particular needs of an individual patient. Moreover, clinical pathways for separate diseases can be combined into one clinical pathway. A definition of the term is given in [66] with

emphasis on service and resource management (similar to "workflows" (to be discussed after this section)):

> *"Treatment plan devised by a team that organises and documents the process of care, and checks progress so that patients, carers, and managers can see what has been done and what needs to be done to achieve stated outcomes. The ability to tailor the ICP to local resources and expertise also confers flexibility whilst the audit facility allows clinicians and managers to test outcomes and plan services".*

> *"Pathways are most commonly used in nursing, and describe not just the steps to be taken in managing a patient, but the expected course of the patient's management. A pathway would, for example, describe the whole length of stay for a patient in hospital in terms of expected clinical findings at each stage in the management, and what actions need to be taken at every stage" [46].*

Integrated care pathways also allow support for variance tracking (like guidelines, they too are not incontrovertible) [66]. There are many reasons for variance from the expected pathway and recording of such variance and reasons for their occurrence can be analysed to uncover potential improvements in the pathway and also contribute to audit trails.

Recalling the guideline definition given in [53] that suggests that a guideline is a "set of pathways", we can further conclude that a pathway is one particular path, route or sequence of steps taken within a guideline. Similarly, it can be said that an individual patient that follows a guideline has its own "pathway" or is executing its own guideline instance or case. At a higher level than a guideline, a pathway can be likened to a care plan. However, most of the definitions for pathway emphasise the interaction of a multidisciplinary team and management of resources for the care of a patient, which implies similar meaning to workflow. However, pathway definitions do not imply the notion of any automation of processes whereas workflows do. Therefore, a pathway can be viewed as either a guideline execution path or case at the lower level, or an individual patient's care plan at a higher level, but with a major underlying difference of emphasis being placed on efficient resource and time management, and auditing. Pathways are perceived at a much higher level than

protocols. Pathways are re-evaluated and revised specifically to meet efficiency and cost-saving goals as needed, whereas protocols tend to be based on a well-established set of procedures that remain more or less fixed and may or may not necessarily be based on resource and efficiency goals of the institution.

Examples of pathway implementations include pre-admission and post-discharge for patients receiving inpatient care, and referral pathway for diabetic foot care. Currently, integrated care pathways are principally hospital-based, however trends show increasingly that they will continue to be developed and implemented in the primary care and community settings [64].

Pathway definition
A multidisciplinary, specific to an institution, and process-oriented set of procedures and outcome targets for managing the overall care of a specific type of patient. They are developed with the intention of reducing costs or increasing efficiency, monitoring resource usage, as well as enabling medical audits to occur and enhance communication between providers and patients, whilst also striving to meet desired health outcomes. They may be specific to one specialty or to a multidisciplinary team. Pathways typically indicate *what* is to be done, *when* they have to be done, by *whom*, *where* it was done, *how much* it cost to get done, and *why* it was done.
Pathway properties
❖ Clinical and institutional ❖ More process-oriented than patient-specific (i.e. specific to an *individual* patient rather than a type/group of patients) ❖ Based on one or more guidelines ❖ Includes one or more protocols ❖ Specifies a process in terms of: o What has to be done (usually known as activities or tasks) o When it has to be done o Who it has to be done by (in terms of roles and organisations) o How it has to be done (e.g. ordering, patient screening, referrals) o Where it has to be done (e.g. pathology centre) o How much it cost to get it done.

○ Resources used to get it done (drugs, equipment, etc). ○ Why it was done (includes justification for any changes to pathway were made).
Pathway objectives
❖ Reduce clinical practice variations by ensuring that providers conform to the agreed interventions of care by making those interventions explicit. ❖ Support for complex, multidisciplinary decision-making. ❖ Support for auditing with use of documents that record the actual interventions performed, when they were performed, and what resources were used. ❖ Support for variations in clinical practice and documenting justification of those variations. ❖ Reduce costs and increase efficiency in the patient care process. ❖ Maximise the quality of care and minimise delays.

2.2.3. Workflow

As defined by the WfMC, workflow is –

> *"The automation of a business process, in whole or part, during which documents, information or tasks are passed from one participant to another for action, according to a set of procedural rules".*

The main purpose of workflows is to provide the correct, relevant and right amount of information and appropriate resources to the right person at the right place and at the right time, coupled with the appropriate procedures of how to use it. A *workflow* comprises cases, resources, and triggers that relate to a particular process whereas a *workflow definition* consists of the definition of a process, a summary of the resources required, and the classification of those resources into classes [67].

A *clinical* workflow includes embedding activities within the process of patient care that enhance care without directly affecting decision-making [48]. In a clinical setting, care plan activities of a patient (especially the chronically ill or those who suffer from co-morbidities and therefore required to undergo multiple therapies) are

often carried out by a multidisciplinary team. The workflow for the care of a diabetic patient for example, may involve the coordination of the GP, dietician, podiatrist and the specialist nurse. Completion of tasks between them can usually span days, weeks or months. The coordination of these tasks and providers forms a workflow. A workflow is described as a "*network of actions by professionals or providers, linked in time*" [68]. Typically these processes are managed or controlled by clerks, referral forms that are passed between providers, and the patient him/herself. Workflows provide the knowledge or the model of care for the patient that specify what has to be done, when they should occur, how they should be done and by whom. Analogous to a database management system, a *workflow management system* provides the driving force (i.e. execution and control) behind these workflows.

Similarly it can be said that care plans, pathways and protocols can all provide the model of care or workflow of the patient given their definitions. However, workflows differ in that they also specify the following additional functionalities [69]:

- Authorisation
- Authentication
- Scheduling
- Monitoring
- Event processing
- Queues
- Prioritisation
- Escalation
- Load balancing
- Task termination, and
- Auditing

Furthermore, the property of *state* differs in workflows. Whilst guideline state refers to the guideline *execution* state, and like care plans, guidelines also carry the *patient* state attribute, which is specific to the *medical* condition of the patient, workflow state refers to the workflow *execution* state. That is, the workflow state pertains to the state of the process that is being executed (for example, "patient_referred_to_dietician", "patient_foot_assessment_scheduled", "patient_GP_consultation_cancelled"). Another major underlying difference between states pertaining to processes (workflow) and states pertaining to patient's medical condition (i.e. the patient state) is that workflow

states are non-deterministic. They are dependent on the outcomes of events and activities, whereas patient states are dependent on the patient's medical condition and are very often not decidable [69]. To illustrate, a patient drug prescription will result in the patient receiving and taking the drug prescribed, however, the patient state "to_lower_blood_pressure" may not necessarily result in the state "blood_pressure-_lowered" due to the unpredictable nature of the medical domain.

Workflow activities/tasks, in the clinical context, may result in updates to the patient's EHR to be made, as well as updates made to the workflow state data or the workflow items list (which specifies the what tasks have been done and what tasks have to be done next). In addition, documents such as referrals will be delivered to appropriate role(s)/person(s)/organisation(s) according to the workflow specification, and activities may also result in notifications or reminders to be sent about manual tasks that have to be done, or automating a task(s). In essence, organisational characteristics such as structures, commitments, roles, policies and preferences are highly ingrained within a workflow.

Much research is yet to be conducted in applying workflow to the health care domain, however, a few such examples include the Patient Workflow Management System [10] that assist in the management of acute myeloid leukaemia in children based on guidelines; a rule-based system that supports long-term therapy in the domain of distributed cancer therapy called HematoWork [70]; an Internet-based workflow automated system for hospital care planning, called OzCare that interfaces with Arden Syntax Medical Logic Module (MLM) server [71]; and a conceptual illustration of how workflow activities can be posted as events in a patient EHR for analysis and access by actors in the multidisciplinary care process, as well as the individualisation of these workflows according to individual patient and provider needs [72].

Clinical workflow definition
Deriving from the most appropriate definition given by the WfMC, we define a clinical workflow as the automation of a clinical process, in whole or part, during which documents, information or tasks are passed from one healthcare provider to another for action, according to a set of procedural rules.

Workflow properties

- Institutional
- Process-oriented not patient or clinically-oriented
- Domain-independent (i.e. is independent of clinical knowledge)
- May be intra- or inter-organisational, or multidisciplinary
- Deterministic/decidable
- Whilst a guideline presents a set of options or decisions in caring for a patient and the consequences or those decisions, the workflow defines the *resource implications* of the decisions made.
- Specifies a process in terms of:
    - What has to be done (usually known as "activities" or "tasks")
    - When it has to be done
    - Who it has to be done by (in terms of roles and organisations). They are commonly referred to as "actors" or "roles" in workflow.
    - How it has to be done (generally speaking: manually or automated; or specifically may come in various forms such as document passing/creation/modification, reminders, alerts, scheduling, notifications, running of programs, ordering).
- Usually consist of the basic workflow elements: states (this refers to the system/workflow state rather than the patient state) for example: pending, executing/active, aborted, suspended, cancelled, scheduled, re-scheduled), activities/tasks and transitions, conditions/criteria for the transition or activity/task to occur, and the workflow state data (parameters used within the workflow being executed such as the patient's identification).

Workflow objectives

- Enable automation of tasks in a business process, thereby improving efficiency by eliminating many unnecessary steps.
- Support for inter-organisational, multidisciplinary communication and coordination.
- Improve management and control of processes by standardising working methods and providing audit trails.

2.2.4. Relationship Between the Concepts

Toward this end, we reviewed, from a collection of sources, the definitions of the terms: *guideline*, *protocol*, *care plan*, *pathway* and *workflow*, and established a more concrete set of definitions in the context of the clinical setting. Guidelines, protocols, care plans and pathways in particular were found to overlap to some degree, although key differences and variations were also uncovered. Table 2.1 shows a summary comparison of the concepts or terms, whilst Figure 2.2 illustrates the overall relationship between the concepts and where some overlapping occurs.

Table 2.1. Comparison of concepts.

	Clinical	Institutional	Longevity	Patient-specific	Goal-oriented	Subject to interpretation
Workflow	No	Yes	Variable	No	No	No
Pathway	Yes	Yes	Variable	No	No	No
Care plan	Yes	No	Mainly long term	Yes	Yes	No
Guideline	Yes	No	Variable	No	Yes	Yes
Protocol	Yes	Yes	Short term	No	No	No

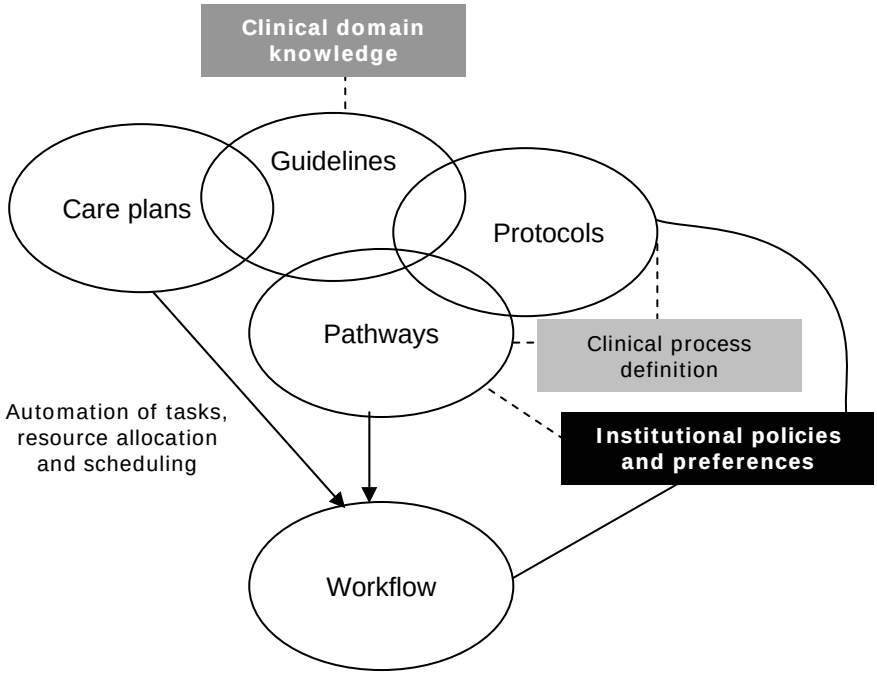


Figure 2.2. Relationship between the concepts.

In summary, we conclude the following:

- Care plans are usually devised according to one or more guidelines.
- Protocols are also usually devised according to one or more guidelines and customised to meet institutional policies and preferences.
- Pathways are also based on one or more guidelines and may also require one or more protocols to be executed within the specified pathway.
- A clinical workflow can be established based on the care plan (what clinical activities have to be done along with its goals/intentions), and the pathway (which specifies which organisations/roles the activities are allocated to, as well as when, why and how they have to be done).

2.2.5. Electronic Health Record (EHR)

> *"An electronic longitudinal collection of personal health information, usually based on the individual, entered or accepted by health care providers, which can be distributed over a number of sites or aggregated at a particular source. The information is organized primarily to support continuing, efficient and quality health care. The record is under the control of the consumer and is stored and transmitted securely." [73]*

> *"The Electronic Health Record (EHR) is a secure, real-time, point-of-care, patient centric information resource for clinicians. The EHR aids clinicians' decision-making by providing access to patient health record information where and when they need it and by incorporating evidence-based decision support. The EHR automates and streamlines the clinician's workflow, closing loops in communication and response that result in delays or gaps in care. The EHR also supports the collection of data for uses other than direct clinical care, such as billing, quality management, outcomes reporting, resource planning, and public health disease surveillance and reporting." [74]*

"The health record of an individual that is accessible online from many separate, interoperable automated systems within an electronic network" [75].

> "*The* electronic health record *is used to describe* the concept of a longitudinal record of patient's health and healthcare -- from cradle to grave . . . *In theory the EHR is therefore a combination of the bulk of*

> *the primary care EHR for a patient together with linking information from other record systems for that patient." [76] (cited in [75])*

There are also various synonyms used, such as *patient record*, *electronic patient record (EPR)*, and *computer-based patient record (CPR).* Some sources state differences between the terms. For instance, the British National Health Services (NHS) (cited in [75]) distinguish the terms *electronic patient record (EPR)* and an *electronic health record*, where the EPR is used to describe:

> *"The record of the* periodic care provided mainly by one institution. *Typically, this will relate to the healthcare provided to a patient by an acute hospital. EHRs may also be held by other healthcare providers…"*

That is, the EPR pertains information about the *individual healthcare occurrence* rather than the occurrences that a person experiences throughout their lifetime.

*open*EHR [77] defines two types of data that constitute the EHR, that is, those that pertain to a clinical event, known as *event (EHR) transactions* (e.g. clinician encounter notes, drug prescription, surgical procedure), and those that have long-term significance, called *persistent (EHR) transactions* (e.g. prescribing history, problem list, family history, care plan) (see Chapter 3 of this thesis for more detail).

From the Institute of Medicine (IOM), United States (cited in [75]), specifically in its 1997 publication, *Computer-Based Patient Records*, offers a series of definitions to represent various views of patient data (cited in [75]):

> *"A* patient record *is the repository of information about a single patient.*
>
> *A* computer-based patient record (CPR) *is an electronic patient record that resides in a system specifically designed to support users by providing accessibility to complete and accurate data, alerts, reminders, clinical decision support systems, links to medical knowledge and other aids."*

United States Department of Veterans Affairs (DVA) (cited in [75]) defines a *computer-based patient record* as:

> *"An electronic record stored in the Decentralized Hospital Computer Program...or any other automated system using an electronic storage system (e.g. optical disk that provides easy retrievability of complete, accurate and timely medical information)."*

EHR Objective

> *"The primary purpose of the EHR is to provide a documented record of care to be used as a means of communication among healthcare agents contributing to the consumer's care. This information can also be interpreted by automated decision support systems, which may provide alerts and advice to healthcare agents." [78]*

> *"The primary purpose of the EHR is to provide a documented record of care that supports present and future care by the same or other clinicians. This documentation provides a means of communication among clinicians contributing to the patient's care. The primary beneficiaries are the patient and the clinician(s). Any other purpose for which the health record is used may be considered secondary, as are any other beneficiaries. Much of the content of EHRs is currently defined by secondary users, as the information collected for primary purposes was insufficient for purposes such as billing, policy and planning, statistical analysis, accreditation, etc." [79]*

EHR Properties

The types of information that can be accrued in an EHR according to (Rector, 1992 (cited in [78]) include:

- *Retrospective information*: historical view of health status and interventions (e.g. test results, family history, prescribing history, physician encounter notes)
- *Concurrent information*: a current view of health status and active interventions (e.g. current medications, active problems, allergies and adverse reactions, lifestyle)
- *Prospective information*: a future view of a patient's care (e.g. care plans, goals and targets).

More specifically, the EHR has the following properties as identified in [77]:

- *Durability*: each unit of information committed to the EHR remains persistent.
- *Atomicity*: each unit of information committed and accessed has a minimal unit of integrity and security.
- *Consistency*: the EHR remains in a consistent state with each committal of information.
- *Isolation*: no conflict occurs when simultaneous users commit information.
- *Indelibility*: committal to the EHR is indelible for medico-legal and process improvement purposes (e.g. to support access to previous states of the EHR for later investigations).
- *Modification*: users are able to modify the contents of the EHR (e.g. correct errors, and update concurrent information such as current medications); and
- *Traceability*: the EHR carries with it a sufficient audit trail during committal for the purposes of clinical and legal tracking.

Types of EHRs

Institute of Medicine (IOM), United States (cited in [75]) defines the following types of EHRs:

Primary Patient Record

> *"Is used by health professionals while providing patient care services"*.

Secondary Patient Record (CHR)

> "*Is derived from the primary record and* contains selected data elements *to aid non-clinical users...in supporting, evaluating or advancing patient care."*

Consolidated Health Record (CHR)

United States Department of Veterans Affairs (DVA) (cited in [75]):

> *"The scope of the DVA medical record expands the traditional concept of a patient record by using a CHR. The VA CHR reflects the skills used by the professional and administrative specialists throughout the patient's period of health care. It may be maintained as a paper record or a computer-based patient record. The CHR can be called the medical record, the patient record, the health record and the computer-based patient record. The CHR usually contains two divisions, which are:*
> Medical Record: *An official record documenting the diagnosis, treatment or care of a patient.*
> Administrative Record: *An official record pertaining to the administrative aspects of the care of a patient."*

Shared EHR (SEHR)

The EHR can also be viewed in terms of a *shared EHR* (i.e. shared between multiple healthcare organisations) and a *local EHR* [78], where the former is used as a secondary source of information thereby improving communication between a group of disparate clinics, and the latter is used as a primary source of information within a local clinic and typically belong to a single provider clinic. In [79], a shareable EHR is defined as "an EHR with a commonly agreed logical information model", and that the sharing of EHR information can take place at three different levels:

(1) Between different clinical disciplines or other users, all of whom may be using the same application, requiring different or ad hoc organisation of EHRs,
(2) Between different applications at a single EHR node – i.e. at a particular location where the EHR is stored and maintained, and
(3) Across different EHR nodes – i.e. across different EHR locations and/or different EHR systems.

The shareable EHR used for levels 1 and 2 will contain mainly detailed information required for patient care within a single site and it will be managed on a local EHR system.

Integrated Care EHR (ICEHR)

> *"A repository of information regarding the health of a subject of care in computer processable form, stored and transmitted securely, and accessible by multiple authorised users. It has a commonly agreed logical information model which is independent of EHR systems. Its primary purpose is the support of continuing, efficient and quality integrated health care and it contains information which is retrospective, concurrent and prospective." [79]*

An ICEHR supports level 3 EHR sharing as it supports the integrated care of patients across and between health enterprises.

Virtual EHR

An EHR (more specifically, an ICEHR) that is constructed dynamically and in real-time "through a process of federation of two or more EHR nodes" [79]. The virtual EHR is essentially a logical view from the extraction of EHR data across multiple EHR sources, which are largely consisting of legacy systems.

Summary

In summary, the EHR is an electronic longitudinal record that documents the condition/state(s) and care (past, present and future) of the patient in order to support his/her present and future care by all providers in the patient's care team. The EHR must assist decision support and safety initiatives; meet medico-legal requirements; support many clinical information systems, and be able to be transmitted/shared safely and securely.

2.2.6. EHR Architecture (EHRA)

In order to define what an EHR Architecture (EHRA) is, let us firstly consider the *architecture*. It is defined in [80] as:

> *"The structure of a system's components and connectors, their interrelationships, and the principles and guidelines governing their design and evolution over time."*

Similarly, Zachman, 1996 (cited in [79]) establishes it as the:

> *"Set of design artefacts or descriptive representations that are relevant for describing an object such that it can be produced to requirements (quality) as well as maintained over the period of its useful life (change)".*

From this, we review a couple of key sources that define specifically, the term "EHR architecture". In [81], the term is simply defined as "the generic structural components from which all EHRs are built, defined in terms of an information model". Whilst, the EU-CEN, 1997 (cited in [79]) gives a more comprehensive definition of EHRA, which is:

> *"A model of the generic features necessary in any electronic healthcare record in order that the record may be communicable, complete, a useful and effective ethico-legal record of care, and may retain integrity across systems, countries, and time. The Architecture does not prescribe or dictate what anyone stores in their healthcare records. Nor does it prescribe or dictate how any electronic healthcare record system is implemented. ... [It] places no restrictions on the types of data, which can appear in the record, including those, which have no counterpart in paper records. ... Details like "field sizes", coming from the world of physical databases, are not relevant to the electronic healthcare record Architecture."*

In this thesis, we will use the more recent and more widely accepted definition of EHR architecture from (CEN, 1999), which defines it as:

> *"Set of principles governing the logical structure and behaviour of healthcare record systems to enable communication of the whole or part of healthcare record" (CEN, 1999).*

In essence, the EHR architecture must support the use, sharing, and exchange of EHRs across different health domains, sectors, different countries, and different models of healthcare delivery.

2.2.7. Clinical Decision Support

Clinical decision support

Clinical decision support is founded upon artificial intelligence. Clancey & Shortcliffe (1984) cited in [46] define artificial intelligence in medicine as:

> *'Primarily concerned with the construction of AI programs that perform diagnosis and make therapy recommendations. Unlike medical applications based on other programming methods, such as purely statistical and probabilistic methods, medical AI programs are based on symbolic models of disease entities and their relationship to patient factors and clinical manifestations.'*

Early on much of artificial intelligence in the clinical context was applied in diagnostic systems, but have since moved to other areas such as provision of alerts and reminders, medical prescribing, acute care systems, laboratory systems, educational systems, quality assurance and administration, and medical imaging [46].

> *The capability of a data system to provide key data to physicians and other clinicians in response to "flags" or triggers which are functions of embedded, provider-created rules. A system that would alert case managers that a client's eligibility for a certain service is about to be exhausted would be one example of this type of capacity. It is also a key functional requirement to support clinical or critical pathways [82].*

> *Clinical Decision Support Systems are "active knowledge systems which use two or more items of patient data to generate case-specific advice"(Wyatt & Spiegelhalter, 1991 cited in [83])*

> *Clinical DSSs are typically designed to integrate a medical knowledge base, patient data and an inference engine to generate case specific advice. [83]*

There are various definitions of what constitutes an electronic decision support system. The National Electronic Decision Support Taskforce has adopted the following definition:

Access to knowledge stored electronically to aid patients, carers, and service providers in making decisions on health care. The Taskforce definition is restricted to clinical decision support systems, principally used by health care providers. The Taskforce acknowledges that it is important for consumers to also have access to high quality information that is evidence-based in electronic decision support systems developed for consumers.

Electronic decision support systems have three main components: knowledge, rules, and software. Knowledge stored electronically includes published clinical practice guidelines, commercial databases, and custom-designed knowledge bases based on expert opinion. Knowledge is translated into active rules used within the electronic decision support system. The software applies the knowledge, rules, and local patient and clinical data, and presents the electronic decision support functionality on the clinician desktop.

Electronic decision support systems vary in complexity. The more complex systems match characteristics of individual patients with a computerised knowledge base and generate patient-specific and situation-specific recommendations. The systems are usually embedded in other computer applications, such as those used for prescribing and dispensing medicines, electronic health records, and other information systems used in health settings. Ideally, the patient information used in the systems would come from existing electronic sources, such as electronic health records. [26]

Perceived benefits of clinical decision support include: improved patient safety, quality of care, and efficiency in health care delivery [46].

Clinical Decision Support definition
Active clinical systems which uses knowledge rules represented by computer-interpretable guidelines, and patient data to generate case-specific advice about the *clinical* care of the individual at a particular point in time.
Clinical Decision Support properties
❖ Clinical decision support systems typically give advice in the form of alerts and reminders. ❖ Typically make use of an underlying knowledge base that is a repository of

computer-interpretable clinical guidelines.

- Suggests *what* should be done given the patient's clinical condition (i.e. *why*), but does not often suggest about *how* it should be done, or *by whom*.

Distinguishing between Clinical Decision Support System and WfMS

In this thesis, when we refer to 'decision support', we are referring to guideline-based *clinical* decision support or a clinical decision support whose logic or reasoning defined by a computer-interpretable guideline. We also make the distinction that the decision support system (DSS) is a separate application that could be invoked by the WfMS. That is, it is invoked by a running instance of an activity within a workflow instance. As will be shown in Chapter 6, the DSS executes the computer-interpretable guideline (CiG) to provide appropriate recommendations. Thus, overall, we view that the engineering of the guideline document itself results in the development of workflows from the recommended actions, and CiGs, which are executed by a DSS; and that their interaction can potentially be coordinated with the assistance of a WfMS.

2.3. Models and Technologies

2.3.1. Health Information Networks, HL7 Messaging and EHRs

Use of the Internet by consumers seeking healthcare information has been an area of much interest and concern, both with respect to the issues surrounding quality of the Internet-based information [84-86], as well as equity of access [87, 88]. Particular areas of opportunity for patients coping with chronic illness have been identified for some time [89], especially for children [90]. The problems and opportunities have been taken seriously enough by the Australian federal government to prompt its collection of comprehensive quality assessed health information links for its citizens under Health*Insite* [91]. While a comprehensive review of the information seeking behaviour of isolated consumers is outside the scope of this chapter, what is more relevant is the potential for Internet-based services to allow consumers to take on a more active role in their healthcare [88] – i.e., to serve as "co-producers of quality" in health [92].

A particular opportunity in consumer-empowered chronic disease management arises when the Internet is used to create a "sharing" of the EHR between the patient and his/her healthcare providers, with all parties having a browser-based view of the EHR [93]. Such a shared record can serve as a form of home telecare, in that the patient can provide monitoring information to the GP including self-assessments and physiological measurements, potentially extending to automated measurements (such as an electrocardiogram) and even alarms (e.g., detection of falls by an accelerometer on a worn ambulatory device) [94]. Similar technology can implement a Hospital in the Home Information System (HHIS) to provide a virtual extension of a hospital's information systems to ease the paperwork burden associated with home-based assessments of ambulatory patients undergoing care in their own homes (e.g., as part of post-acute recovery) [95]. Web-based forms allow direct input to a hospital-based database management system from the patient's home over the Internet.

Intranet-based Web technology provided a powerful solution for integration of institutional legacy information systems within a hospital environment [96], thus allowing health data to be shared locally. In this fashion, as long as each legacy information system can achieve a bridge to the Internet, a browser-based 'workstation' environment can be devised for integrated access to the originally diverse systems. Moving beyond the boundaries of the hospital, rapid growth in computer networks and its potential for coordinating geographically dispersed healthcare providers has resulted in numerous efforts to establish Health Information Networks (HINs) for less expensive and improved quality of care [97]. Moreover, there has been a popular proposal for the use of *smart cards* [98] to either store patient information records, or alternatively (with the emergence of the Internet) for use as a key to encrypted Internet access of patient information [99]. Many developed countries are considering or have already in their midst a national HIN based on an access card (e.g., France [100]).

Demands to keep up-to-date with the ever-changing medical knowledge have seen physician portals being integrated with various medical knowledge bases, medical vocabularies, and drug databases. SHINE [101] (Stanford Health Information Network for Education) is an example of a HIN that supports the online education of physicians with the aim of improved decision-making. There have also been HINs

developed for child immunisation [102] – serving as a central repository for all children's immunisation records that can only be accessed by authorised users. Its aim is to provide healthcare professionals access to information about immunisation for patient care and provide mechanisms for tracking, recall and reporting. This provides a single access point for providers even if the patient decides to change healthcare providers/institutions.

In Australia, a proposal for a national health information network was made (Health*Connect*) [73] in the year 2000 with the aim of allowing personal health information to be collected, safely stored and securely transmitted (manifested as 'event summaries' that are nationally agreed upon) with the patient / health consumer's consent at the point of care. Potential users of the system include consumers, providers and health care administrators, researchers and planners. Other types of transactions supported include: online booking and reminder systems (e.g., consultations and hospital admissions, decision-support systems); provider access to medical knowledge bases and clinical guidelines; provider education and training; telehealth services; secure inter-provider communications; and consumer access to their own health record.

A prevalent concern with the growing demands for Internet / Intranet-based HINs is the issue of security, in particular, maintaining confidentiality of EHRs. The World Wide Web client-server interactions are inherently stateless (i.e., there is no notion of a continuous session between the client and server) - presenting challenges in executing the traditional process of identifying, authenticating and authorising only once during user access, and monitoring user's interactions with the system. One example [103] presents a solution through the use of encryption (via the standard Secure Socket Layer (SSL) protocol), identification, authentication and authorisation (via an initial log on process requiring a unique user identification and password), and monitoring of all patient data accesses. It also prompts users accessing the system externally to the site for a second password obtained at random from a SecurID (manufactured by RSA Security) card that generates a changing code. To prevent subsequent illegal logons using the same identification in the case that a SecurID was not required, each form is given a unique identifier that is verified with the Web server's registry once submitted, and is then deleted permanently. The server also

keeps track of the unique URL that comprises of the user ID, patient record ID, and session ID, that is invalidated once the user logs out of the system, attempts to establish another session, or when the session has "timed-out" (i.e., remained idle for a given period). In general, a set of key requirements for maintaining confidentiality of EHRs is addressed in [104], and includes explicit patient consent, or a doctrine of implied consent for patient deemed incompetent to communicate consent for releasing their record over the Internet; confirmation of emergency need for record access; and the patient's right to review record of release. Transfer of records over the Internet is particularly useful for emergency departments where immediate access to the patient's record can be the difference between the life and death of the patient such that the lack of information may cause delays, misdiagnoses, and improper treatment. Moreover, such errors and adverse events add to healthcare costs.

Standards play a critical role in the design of health information networks. If information is to be shared between providers, organisations and clinical information systems, there need to be standards in place that enable interoperability both at the knowledge and at the system level. That is, two aspects of interoperability need to be achieved: (1) *semantic* interoperability – which enables information shared between systems to be understood at the level of formally defined domain concepts [79]; and (2) *functional* interoperability – which is the ability for information systems to reliably exchange information without error [79]. In short, standards are required in order for information to be safely and securely exchanged such that the meaning and context of the information are not lost. Standards are also essential for software developers to be able to implement systems in a consistent manner, and maintain them accordingly as changes occur over time. For instance, if software developers are given *standard* representations of information, there is no ambiguity about how these might be implemented. Moreover, standards can reduce costs in software development and information interchange (e.g. purchased software built upon standards is likely to be able to communicate without major software changes). Some examples that aim to contribute towards standardisation are discussed below.

CORBAmed [105] is geared towards standardised interfacing of healthcare systems, and is driven by the HealthCare Domain Task Force of the Object Management Group [106] – the developer of the Common Request Broker Architecture (CORBA – an

enterprise-scalable infrastructure for distributed systems). CORBAmed's approach is based on an object-oriented clinical information model, and views a set of healthcare services as "business objects" where hosts are able to specify and control the allowable services on the data that clients may use. Currently, CORBAmed is working toward interoperability with HL7.

HL7 Messaging

Health Level Seven (HL7) emerged in 1987 to develop standards for the electronic interchange of clinical, financial and administrative information among independent HISs, clinical documents and decisions support [107]. The version 2.x HL7 messaging standards are currently being used worldwide, including several European countries, New Zealand, Australia and Japan. The majority of its application has been in the interchange of information between HISs within the same hospital, as well as between hospitals and external laboratories. Having been approved and adopted as a national standard in the United States since 1996, it is used by the majority of large hospitals in the U.S.

HL7 version 2.x

HL7 uses a core Reference Information Model (RIM) to model healthcare information via six classes:

- Act (actions to be executed),
- Participation (provides the context of an act such as the performer of the act, and where it was done, etc), Entity (the objects involved in healthcare),
- Role (played by an entity when participating in an act),
- ActRelationship (relationship between acts), and
- RoleLink (relationship between roles).

HL7 version 2.x, has provided two protocol standards, namely, the Clinical Context Management Specification (CCM version 1.0) that allows seamless integration of disparate clinical applications to end-users, and the HL7 Arden Syntax for Medical Logic Systems (version 2.0). HL7 v2.x has resulted in reduced efforts and time involved in interfacing systems, particularly in its application in hospitals for the exchange of laboratory/pathology requests and results.

The ability to share EHRs is particularly complex, especially since there is a great diversity of individual hospital organisations, and complexity in clinical workflows that vary according to the mix of specialities and the variety of individual preferences of the different users. Thus, with these challenges, there is an increasing need for the development of standards in conjunction with an EHR standard that provide a common framework for building systems that can communicate with each other (e.g. messaging, security, terminology, identification). In addition, the complexity and dynamic nature of the health domain requires that flexibility and extensibility be supported in the development of standards. Two main EHR standards are currently being developed, namely CEN 13606 and the HL7 v3 EHR Messaging models. To continue from HL7 v2, the following sections will first elaborate on HL7 *v3*, which is the standard messaging model that now aims to support persistence/storage of messages within EHR documents.

HL7 version 3

Originally offering a traditional message-based functionality, HL7 has since 1997, evolved to its current version 3.0. HL7 messages are derived via restriction process beginning with the RIM (see Figure 2.3). The restriction process generally involves placing constraints on the vocabulary, cardinality and relationships. Concepts from the RIM are instantiated, cloned and constrained into Domain Message Information Models (D-MIMs). Cloning involves copying core classes from the RIM to represent each concept in a domain such as a 'patient', and a 'clinician'. The D-MIM represents the refined subset consisting of the set of cloned classes, attributes and relationships used to create messages for a particular domain (e.g. patient administration). D-MIMs are then refined further to produce Refined Message Information Models (R-MIMs). R-MIMs defines the information content for sets of messages. Further refinement on R-MIMs produces the Common Message Element Types (CMETs), which are reusable components for defining common concepts in a domain, and are included as "common messages" that specify the least strict constraints in the final derived model, known as Hierarchical Message Descriptors (HMDs). HMDs specify the order and constraints of particular set of attributes and relationships derived from the relevant RIM classes with each unique pattern of attributes and

relationships made explicit as 'cloned' classes. Each CMET can specify different patterns of constraints for the same set of attributes above and beyond the mandatory set of constraints that of the common message for the HMD, thereby allowing a single HMD to meet the requirements of a number of related interactions within a given scenario or 'storyboard' developed to reflect the business model in a domain.

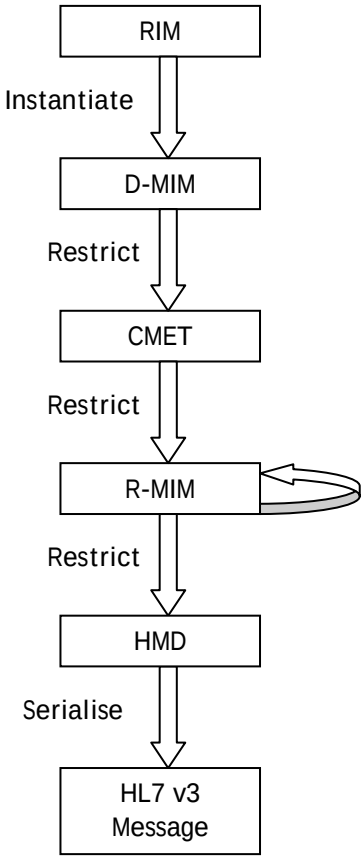


Figure 2.3. HL7 v3 Methodology.

The HL7 version 3.0 messages are then generated and encoded in XML (eXtensible Markup Language) to describe the syntax of the healthcare information, and define it with information tags. The use of XML, which is a growing standard for structuring the content of documents, will provide greater possibilities in the exchange of health-care information, and provide better interfacing between healthcare systems.

Included in the HL7 v3 is the Clinical Document Architecture (CDA) that provides a framework for the exchange of clinical documents (e.g., discharge summaries and

progress notes), and enables clinical information to 'persist' outside of the messaging context. The CDA specification consists of a *Header* and a *Body*. The Header describes information about who wrote the document, who it is intended for and the type of document. The Body contains the content of the document (e.g. text, codes and/or multimedia), which may be structured under headings or sections. The CDA has been developed in three levels. Level 1 has a structured header and structured body of message with limited coding capacity for content. Levels 2 and 3 enforce more structure to allow representation of the information context or constraints and coded data, and as such require a standard EHR reference model to be used, and the use of archetypes and templates (see Section 3.2 for discussion) to define health concepts – e.g. blood pressure, height, body mass index.

EHRs

CEN

CEN is the European Committee for Standardization [108]. This standards body has published two generations of EHR standard – in 1995 and 1999. The 1995 EHR architecture standard is known as ENV 12265, and is the basis from which the basic principles of the EHR architecture should be built upon. In 1999, a four-part standard was developed for EHR communication known as the ENV 13606, which consisted of:

- *Part 1* describes the Extended Architecture of the ENV 12265 standard, which included components for describing the structures and semantics in EHRs conforming to a range of requirements to allow the content of the EHR to be constructed, used, exchanged and maintained.
- *Part 2* is the Domain Term list, which defines a set of terminological measures to support various degrees of interoperability of the EHRs created on different systems or by different teams on the same system.
- *Part 3* is the Distribution Rules that specifies the data object set representing the rules for defining access privileges to part or whole EHRs, and the means by which security policies and attributes can be defined and implemented.
- *Part 4* defines a set of messages that enable the communication of EHRs (in part or whole) in response to request messages or need to update a mirror repository of a patient's EHR.

Note that the 1999 CEN ENV 13606 standard is currently being replaced by EN 13606 to be published in 2006 as a five-part standard. The CEN Reference Model described below is based on this forthcoming standard.

CEN Reference Model

The CEN Reference Model (shown in Figure 2.4) is based on the following core components:

- *EHR Extract*: The piece or set of information communicated from an EHR. That is, an EHR extract is serialised from an EHR, sent, received, and de-serialised upon request. This is intended to represent part or all of an EHR communicated from an EHR system.
- *Folder*: Provides a navigational hierarchical structure for compositions. A folder may contain other folders and references to compositions. Multiple folders may refer to a composition. Folders themselves do not contain data values, but pointers to data values within compositions, and thus folders are optional; are concerned only with the way data is organised, and do not affect the semantics of the data. Folders for instance, may be created for organising information belonging to a care team, by organisation, or specialty (e.g. Pathology).
- *Composition*: Represents the smallest unit of data committed to the EHR. It also carries with it the audit information that identifies the user, location and committal timestamp. For instance, a composition may be the unit of information that corresponds to a clinical session such as a provider encounter, which also contains information about the particular context of that session (e.g. session start and end time, healthcare setting (such as General Practice), actual location).
- *Section*: Another component used for organising EHR data – in particular, the entries that reside in compositions. It enables 'headings' to be defined (for instance, as would appear on a document or form) that divide the information into logical groups. Sections are optional, and may contain further Sections and Entries and/or reference Entries that are in other parts of the EHR.
- *Entry*: Contains the actual EHR data. An entry is representative of a 'clinical statement', such as an observation (e.g. weight, height, blood pressure

measurement), care plan, a diagnosis (i.e. clinical evaluation) or a specification for an action to be performed (e.g. medication order). It also contains information about the context in which the data was used such as temporal context and provider details. Multiple entries may be contained within a single composition.

- *Cluster*: A component used to group elements and other clusters into a hierarchical structure that represents the 'value' of an entry, such that entries may be grouped within a composition. Thus, a single observation for instance, might be defined into multiple parts that are logically structured using tables, lists, or time series. That is, clusters are representations of compound data. E.g. a physical examination may be structured into a list containing entries including the patient's weight, pulse rate, and blood pressure.
- *Elements*: Components that contain the actual data values themselves. It represents a node within a cluster.
- *Data Values*: value of the EHR data item that may be of the type text, coded text, quantity, interval, date/time, etc.

The latest version of the CEN 13606 Reference Model is currently under review, and is primarily harmonised with the *open*EHR Reference Model (see Chapter 3). The intention is to be able to develop archetypes (see *open*EHR discussion below) based on the CEN 13606 reference model.

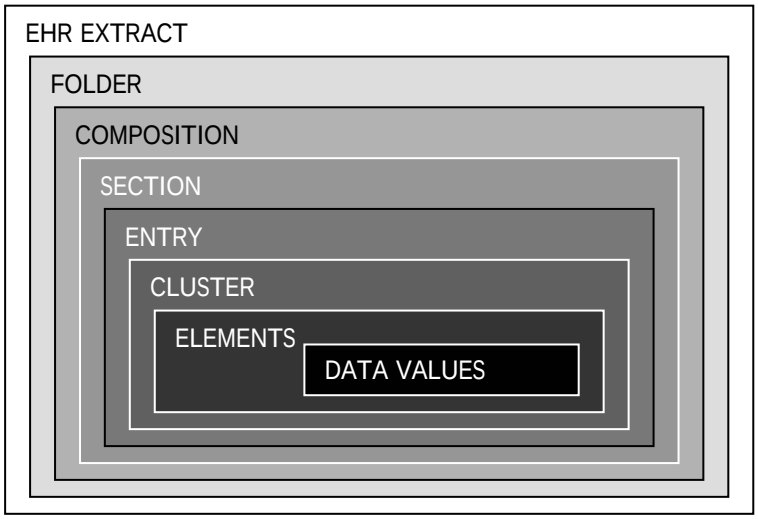


Figure 2.4. CEN 13606-1 model.

open*EHR*

*open*EHR has evolved from the Australian Good Electronic Health Record (GEHR) [109], which itself evolved from the European Union Third Framework Project [110]. *open*EHR is established under the *open*EHR Foundation, which is a non-profit organisation that actively contributes to the EHR community through the development of open-source specifications and software. Although this foundation is not an official standards body, it has made a significant impact on health informatics research and EHR standards development – i.e. the HL7 v3 EHR messaging standard and CEN 13606.

*open*EHR provides a method of implementing the clinical content of records through a two-level model framework: (1) a **Reference Model** (that represents generic data structures), and (2) **Archetype Model** (which is a constraint model on the generic data structures). Figure 2.5 shows the *open*EHR two-tier model that result in a knowledge-driven EHR system. The separation between the models reduces complexity in building and maintaining information systems over time.

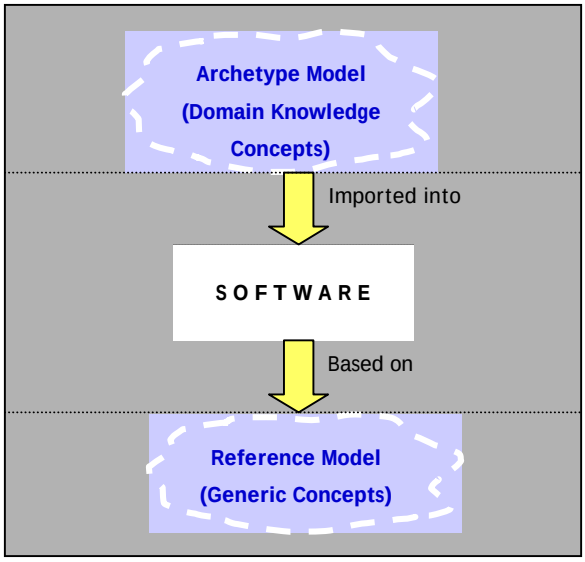


Figure 2.5. Knowledge-driven EHR System resulting from an *open*EHR Approach.

*open*EHR uses *archetypes*, formal structured constraint definitions of clinical concepts (expressed using constraints on instances of an underlying reference model),

which define the particular configuration or desired composition of instances of those concepts. For example, an entry archetype may be for the concept "blood pressure", and constrains the particular arrangement of instances underneath that entry object as having two content item children for the systolic and diastolic values, and further constrains the valid range of their values and unit type. Such archetypes then serve as building blocks for producing instances of EHRs (see Figure 2.6). These archetypes can be used to allow for guideline-specific and case-specific information to be recorded in a general and extensible EHR framework. The *open*EHR Reference Model and archetypes are described in more detail in Section 3.2.

Figure 2.7 illustrates where the *open*EHR models and their instances fit during the lifecycle of an information system. The models are built into the system, and the archetypes, which are authored by domain experts during design-time, are imported, and the system's EHR instances generated during run-time are validated against these archetypes.

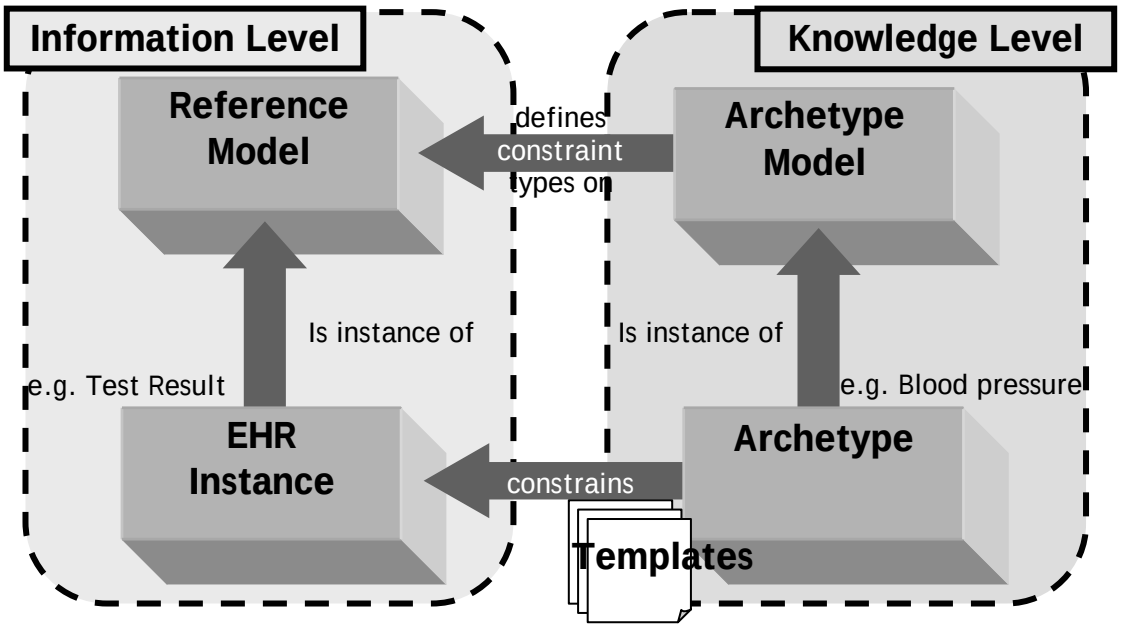


Figure 2.6. Relationship Between Models and Instances in *open*EHR Architecture.

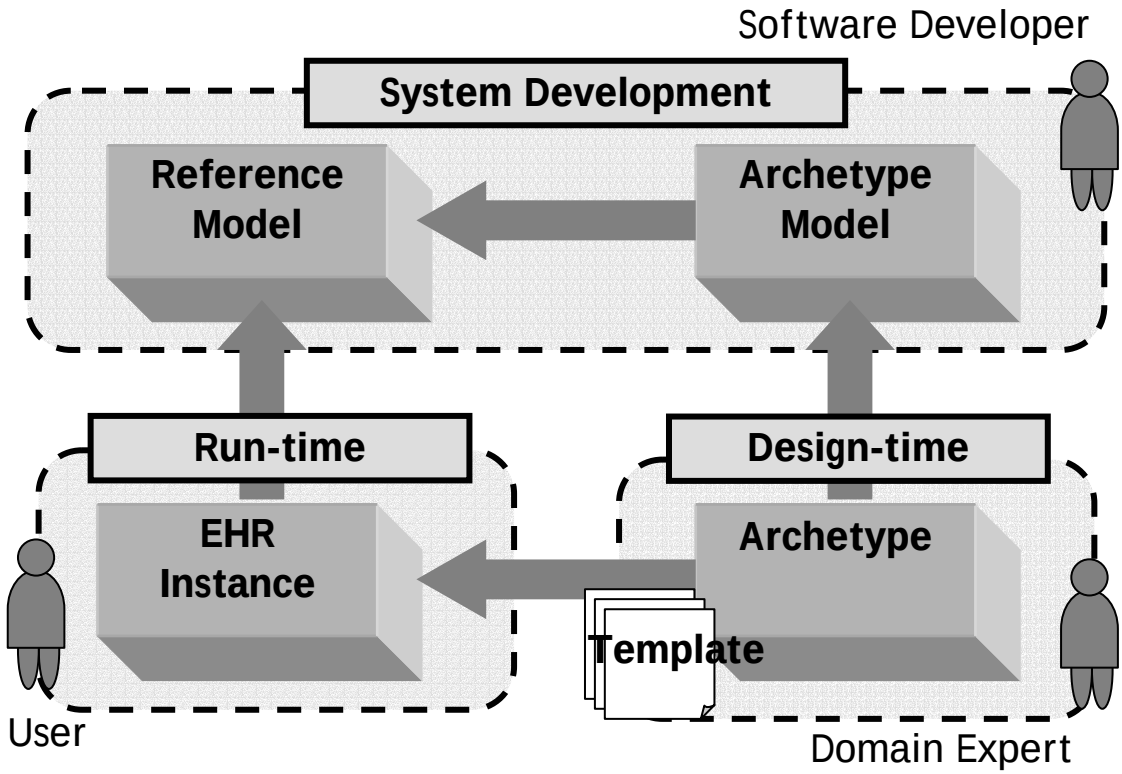


Figure 2.7. Development, Design, and Execution of an *open*EHR System.

As mentioned, there are two main EHR standards are currently being developed, namely CEN 13606 and the HL7 v3 EHR Messaging models. The *open*EHR framework is chosen in this thesis for key reasons including:

- the provision of a more complete set of EHR specifications (e.g. versioning, auditing, datatypes, data structures, validation rules, linkages between data items) compared for instance, to CEN 13606, which only models EHR Extracts;
- the clear separation of concrete/fixed EHR concepts that can be directly embedded into software systems, and the clinical knowledge/domain-specific concepts that overall, enable EHR systems to:
  - have semantic and functional interoperability;
  - be 'future-proof' or allow EHR systems to evolve over time despite changes in clinical knowledge;
- explicit and a more controlled approach to modelling domains compared to the HL7 approach, where the underlying RIM attempts to model all the classes or clinical concepts within the health domain in terms of 'Act' and

'Act_Relationships'. The HL7 approach therefore, requires its RIM to be quite stable in order for it to be used. Moreover, the classes require 'mood' codes to further qualify them – allowing for more extensible messages to be defined in different contexts. However, as the number of mood codes increase, so does the complexity in terms of comprehending the model and knowing all of the mood codes, and how they might be best used for a specific purpose. This is in contrast to *open*EHR, which aims to be much more disciplined in its modelling by having a relatively minimal set of EHR constructs (e.g., observation, evaluation, instruction), and using the relevant EHR classes for their intended purpose via archetyping (i.e. to define the clinical concepts).

- archetyping offers an EHR architecture that can be extended and can improve manageability of clinical knowledge such that they can be versioned, reused and specialised to suit more specific requirements.

2.3.2. CiGs and Clinical Decision Support

Unlike other fields, there are many unresolved and unforeseeable problems that lie within medicine. Medical domain knowledge does not cover all aspects with full certainty. Despite the uncertainties and incompleteness in the knowledge, physicians strive to improve the quality of healthcare through better awareness of proper disease management techniques whilst also trying to reduce costs. Such techniques usually exist in clinical guidelines and protocols. Compliance to evidenced-based guidelines has been shown to improve quality of care [111], [112]. Currently, most of these guidelines reside in paper-based format, and in many cases, physicians have little time to spare in referring to such information at the point of patient care. GP consultations, for example, last only a few minutes. In addition to finding the most relevant guidelines, physicians must also be able to interpret and customise these (general) guidelines in order to apply the actual treatment plan that is specific to a patient. Ideally, there should be a reduction in physician cognitive burden and workload while trying to meet guideline objectives [113]. This increases physician compliance to evidence-based guidelines. Moreover, the medical knowledge base changes constantly. New guidelines are added or modified as new evidence is found.

In an effort to improve the quality of care as well as reducing the costs of such a goal, much research has gone into transforming paper-based clinical guidelines and protocols into computable or machine-readable formats. This presents a number of advantages over paper-based guidelines. Firstly, these formats allow readily accessible reference to the guidelines at the point of care. Secondly, they also allow the guidelines to be analysed for their use and their effectiveness (for quality assurance). Substantial work has been done on one of the key aspects of implementing computer-based clinical guidelines – its representation. Table 2.2 gives a brief description of some of the guideline representation models, but some of the more recent projects in this area will be discussed in detail later.

Table 2.2. Examples of clinical guideline representations and their key characteristics.

Arden Syntax
❖ Encodes medical knowledge in knowledge base form as Medical Logic Modules (MLMs). ❖ Uses a hybrid between an "if-then" production rule and a procedural formalism.
EON
❖ Uses a simple object-oriented language, temporal query and abstraction language, and first-order predicate logic. ❖ Supports the reusability of medical domain knowledge, temporal queries and abstractions.
PROforma
❖ Represents pros and cons of competing recommendations in a guideline so as to enable reasoning from such guidelines. ❖ Graphical and tasked-based. ❖ Uses classes of tasks: action, enquiry, decision, and plan.
GLIF
❖ Emphasis is on enabling sharing of guidelines among institutions and across computer applications, including their associated documentation. ❖ Specifies an object-oriented model for representation and syntax for guideline transport.

❖ A GLIF encoded guideline is essentially a flowchart of a temporally ordered sequence of steps. ❖ Different types of steps in the flowchart show clinical actions (recommendations) or decisions.
Asbru
❖ Time- and intention-oriented. ❖ Enables the intentions and goals of a guideline to be inherently defined in the guideline.
PRODIGY
❖ Based on the EON model. ❖ Supports guideline modelling a series of decisions that a GP may have to make in different patient encounters. ❖ Represented as network of patient scenarios (which describes the patient's condition and current treatment), management decisions and action steps. ❖ Scenarios are associated with: a consultation template that describes the best-practice workup for a patient in that scenario, and a choice between alternative courses of action. Outcomes of those actions are then used as the scenarios for following consultations.
GUIDE
❖ Based on Petri-Net representation. ❖ Uses a component-based and hierarchical architecture that integrates workflow management system and a virtual medical record.
SAGE
❖ A Shareable Active Guideline Environment (SAGE). ❖ The model consists of recommendation sets that has either *Activity Graphs*, which are guideline directed processes, or *Decision Maps*, which represent recommendations that involve decisions at a specific time.

Almost all of the above guideline models share the same key primitives for representation presented in [54] – i.e., decision, action, and state. Furthermore, the guideline primitives must be arranged into a structure in order to be used. Most of the models' structures are defined as temporal constraints (that specify temporal ordering) on primitives and nesting of guidelines (that enable complex guidelines to be decomp-

osed into multiple levels of sub-guidelines). Typical temporal constraints include recurrence/iteration, suspension and abortion, and concurrence/parallelism. However, in general, current guideline models vary depending on the type of processes they try to express. A typology of four modelling formalisms used by guideline models is identified in [114]:

- Flowcharts for algorithmic problem-solving processes;
- Disease-state maps to relate decisions made during the course of patient care;
- Sequencing of activities in care plans that aim to meet goals; and
- Workflows to model care processes in an organisation.

Flowcharts generally assume a clinical algorithm that is a step-by-step procedure for solving a problem that contains conditional logic (i.e., the procedure is expressed as a set of clinical states, binary decisions that may be expressed as 'yes/no' questions, and a set of actions). Such representations are usually most suitable for paper-based guidelines, and the rigid sequencing of "*if-then*" statements imposes strict ordering. Moreover, the decision model is limited to a definite "yes/no" choice set. PRODIGY3 is an example that uses disease-state mapping as it uses the concept *scenario* to represent the patient/disease state and/or treatment settings (for example, "Hypertension treated with combinational therapy"). Asbru is an example of a plan-based representation, as it explicitly models the process and outcome intentions and goals of a guideline (or a *skeletal plan*, which may in turn, be recursively refined into sub-plans). Furthermore, it is based on guideline *objectives* (i.e., targets, pre/post-condition satisfaction) as opposed to decision-making, or patient-states/scenarios). The guideline-based *patient/careflow system (CfMS)* [115] illustrates a workflow-based representation of guidelines. Its underlying model is called GUIDE, which uses the Petri Net formalism to support modelling of complex concurrent processes and integrate clinical tasks specified in guidelines with organisational models to manage patient care workflow. There are also hybrid approaches that use a combination of the four process types. These include GLIF3, EON, and PRO*forma* (the applications of which are discussed later in this section). In particular, GLIF3 and EON use the scenario and decision model of PRODIGY3, with the addition of *branch* (for parallel/unordered actions and decisions) and *synchronisation step* constructs (for modelling control flow of multiple sequencing of actions that converge). EON associates goals with guidelines and sub-guidelines to drive the decision-making process.

PRO*forma* explicitly models decision-making and task scheduling that informs the diagramming conventions used by a guideline modeller. Its decision model uses a "*for/against"* argumentation structure, and its standard tasks include decisions, actions, enquiries (data requests), and plans (recursive decomposition of tasks, where like Asbru, each task can have a goal, precondition and a post-condition).

Research has investigated ways to take advantage of computable guidelines by integrating them with EHRs, and therefore, providing decision-support systems (DSS) for physicians whereby reminders and recommendations about the care plan of an individual patient are automatically generated in a timely manner. Unlike expert systems that previously gained much attention for application in medical diagnoses, DSSs allow for physician-system interaction, thereby providing greater flexibility and receives greater acceptance due to the fact that it does not attempt to replace the physician. In addition, because DSSs aims to support the physician in finding a solution to a problem by merely *suggesting*, its use is not restricted to problems that can easily be solved. Any errors, complexities and so forth can be left to the physician to deal with. In other words, the physician always has the final say and control, and can therefore be allowed to override any suggestions made by the computer, and thus rely on his/her own judgment and expertise [32]. The following describes some recent applications of a few of the aforementioned computer-based clinical guidelines in DSSs.

Application of EON

The EON model uses an ontology approach to mapping patient data encoded in guidelines to an external EHR. It also makes use of Protégé 2000 as its application-authoring environment. Protégé is an integrated knowledge base editing environment for creating customised knowledge-based tools [116], for example, to support the development of models and clinical knowledge applications. Applications of the EON model include the T-HELPER system for the management of HIV patients [117]. The model has also been used to build the ATHENA decision support system for the management of hypertension [118]. ATHENA aims at controlling the blood pressure of patients and is used to construct suitable drug therapies. With support from DARPA (Defence Advanced Research Projects Agency: the main research and

development centre of the Department of Defence), the project team is currently looking at how EON might be used to aid protocol-based care at the National Naval Medical Center, Breast Care Center in Maryland, U.S., and other military healthcare institutions.

Application of PRODIGY (Prescribing RatiOnally with Decision-support In General-practice studY) Model

PRODIGY is a project developed in the United Kingdom that builds on the EON model [83]. It also uses Protégé as an authoring tool. Applications of PRODIGY include DSSs for GPs to manage patients with asthma and hypertension. The model itself represents a set of choices for the physician and patient scenarios that drive decision-making and is used to synchronise the management of a patient with guideline recommendations. The diagnosis is made up of possible patient scenarios, and each scenario choice has a list of possible actions depending on EHR findings [119]. Actions include on-line explanations, printed drug-prescriptions, and printed patient information leaflets. The PRODIGY guideline representation provides a strategic view in which a map of whole area of disease management is covered by a guideline. Ideally, the patient should fit somewhere in the map moving only if disease management changes. PRODIGY determines likely scenario that patient is currently in based on previous activities; alternatively, it looks at a scenario's precondition for it to be true [119]. It then chooses depending on EHR and consultation template, else manually (criteria as Boolean expressions). Accepting a recommendation usually results in printing a drug prescription and changes made to the EHR, and change of state of the patient in the guideline for use in the next consultation. Support and manual choice for GPs allows the system to cope with insufficient information well and hence, performs better the more information is given. Execution engines were also built to verify the computability of the model. Unlike EON, PRODIGY focuses more on allowing for GP interactions with the system, thereby enabling system suggestions to be overridden at any point in time. Thus, it does not rely solely on the EHR data.

PRODIGY3 is currently in use in two U.K. primary care vendor systems, and over 150 guidelines are currently specified in this format [83].

Application of PROforma

PRO*forma* is applied in DSS [28] in which guidelines, care pathways, and other knowledge-based services (such as clinical decision-making, planning and scheduling) are delivered to the point of care via the Internet. The clinical user is guided along the "pathways" of a guideline relevant for a specific patient. Data is entered as requested to enable a patient profile to be built up, decisions to be made and courses of action to be proposed. Guidelines can be run through the Internet using a PRO*forma* enactment engine that runs the web-based applications and Java-based communications technology called Solo. This project is currently in its preliminary stages – undergoing a number of evaluation projects. Among them involves integration with an ORACLE EHR system to manage guideline compliance as part of a leukaemia trial.

Application of GLIF (GuideLine Interchange Format)

A proposed architecture for flexible guideline execution engine for use in clinical DSSs is presented in [120], which executes guidelines represented in an extended version of GLIF. Extensions to GLIF included:

- Cardinality and temporal and logical constraints on data values to be specified in the patient data model and guideline references to meta-data in external sources (such as data dictionaries).
- An object-oriented model for actions in recommendations to support different types (specialisation of classes) of actions (e.g. prescription, notification, or referral) in the action model.
- Syntax for logical constraints: Logical constraints in GLIF are used to specify decision logic in conditional steps, eligibility criteria for the guideline, and constraints on values of patient data. A modified Arden Syntax logic grammar was adopted to specify the logic.
- Attributes were added for version control and for unique identification (with facilities for assigning guidelines to categories to aid retrieval and management of guidelines).

XML was used for GLIF instead of the original Object Data Interchange Format due to its growing popularity and potential for increased sharability. The architecture can

be used for referral management, medical education and conducting clinical trials. It is also used for developing an educational application aimed at testing knowledge of guideline recommendations. The workflow engine traverses the guideline by evaluating logic conditions specified in the guideline against patient data values. Evaluation results are used to generate patient-specific recommendations from the guideline. At the time of its research publication [120], enhancements to the architecture were being made to provide improved facilities for mapping from patient data items to EHRs. The architecture for the engine was implemented in a prototype system, and it is being used in two pilot clinical applications in the domains of neurology and dermatology.

Application of SAGE

SAGE is a standards-based Shareable Active Guideline Environment. Prototypes of SAGE have been developed in the contexts of immunisation and diabetes management. Other guidelines to be encoded also include community-acquired pneumonia, and hip replacement. However, it has yet to be deployed and to undergo actual clinical trials depending on funding availability [83].

Application of GUIDE

According to [83], two large scale systems have been built based on the GUIDE model. One of which has been used and evaluated in four hospitals in the context of the management of stroke patients. The other was built in the context of managing patients with heart failure, and is currently being evaluated by General Practitioners. Prototyped applications have been built for the management of breast cancer in a hospital care setting, as well as health care pathways to support the same disease within the home.

Limitations and current challenges

A number of limitations arise from the aforementioned clinical guideline representations. These include the following:

1. Interaction with clinical databases is required in order to provide alerts and reminders. Due to lack of standardisation, database schema, clinical voc-

abulary and data access methods vary widely, which is a hindrance to clinical knowledge sharing.

2. There is lack of support for actually incorporating these clinical guidelines into the clinical workflow that spans across multiple organisations rather than limitting their application to a particular physician's desktop, or for a single institution.
3. Currently, the guidelines are set out as reasonably fixed. In order for guidelines to be applicable to the care of chronically ill patients (such as diabetics) who very often suffer from additional illnesses, guidelines need to be flexible in order for them to be patient-specific. This involves finding a way to be able to combine various clinical guidelines and tailoring them for the long-term.
4. Although the development of CiGs is currently not routine in clinical practice, the desire to have guideline-based electronic decision support could *potentially* see the need to adopt a common standard for automated guideline representation. Authoring tools that can encode a set of medically sound, well-validated guidelines to link them seamlessly to the EHR [121] might also be desirable in order to facilitate their use within routine clinical workflow.

It has been pointed out in [122] and [19] that, for proper and effective implementation of decision support, it is vital to provide *patient-specific* recommendations at the point of care, and in accordance with the physician's workflow.

2.3.3. Workflow Approaches

The main purpose of workflows is to provide the correct, relevant and right amount of information to the right person at the right place and at the right time, coupled with the appropriate resources and procedures of how to use it [123]. Hence, unlike traditional systems where functions are more or less built on top of databases, workflow systems provide knowledge about *what* needs to be done, *when* it has to be done, *who* needs to do the work, *why* it needs to be done, and *how* it needs to be done. It has been defined in [124] that coordination (i.e. using the combination of the concepts of communication and collaboration, and adding control or synchronisation) is the main domain of WfMS.

Levels of 'Workflow'

In general, there are different levels of workflow representations:

1. *Workflow*: typically, workflows are executed and handled on a case-by-case basis – e.g., for a particular patient. In this situation, the WfMS assists in the management of the creation and execution of the workflow instances for a particular case or workflow definition.
2. *Intra-organisational* workflow: management of workflows within individual organisations [125] (e.g., multiple cases (patients) within an organisation).
3. *Inter-organisational* workflow: management of workflows crossing organisational boundaries (e.g., multiple cases (patients) between multiple organisations [125].

Support tools for intra- and inter-organisational workflows may be requesting for work items to be done by somebody, and responding to that work item request ('accept', 'decline', 'forward'); scheduling; and prioritisation. Thus, organisational workflows can be viewed as workflows requiring additional WfMS operations, perhaps for 'batch' processing (e.g. the WfMS may handle wheelchair orders for all patients that have made requests for a wheelchair, which may involve prioritising each request depending on resource availability and the level of urgency the patient requires the wheelchair).

Dealing with Exceptions

Currently, information systems are relatively inflexible, because the flows of data and control are implemented in the program logic [126]. The real world environment is dynamic and is constantly changing, thus information systems must be able to dynamically adapt to suit the real world. However, there is little support for these changes (e.g., allowing one to modify a process model), especially once the process has begun execution [127], [128], [129].

Exceptions, which are deviations from an ideal collaborative work process in the workflow, arise very often in reality and are caused by errors, failures, resource or requirements changes [130]. Other causes or sources of exceptions include: inconsistent data; divergence of tasks from the underlying workflow model; unexpected contingencies; un-modelled or unanticipated changes in the environment; as well as

efforts to evolve, expand and optimise the workflow process (that must be accommodated by the workflow system) [127]. Systems are currently ill suited to dealing with exceptions [130]. Traditional approaches have used inflexible control policies that make reactive control and graceful exception handling difficult, if not impossible, tasks [127]. Modelling of exceptions requires a high effort and becomes very complex [126]. The obvious answer to how they are currently handled (detected, diagnosed and resolved), has been to include predefined conditional branches to deal with anticipated exceptions, but these procedures are often done within (rather than separately) from "main-line" processing, which makes it difficult to define, understand and modify [130] the workflow processes. Such branches complicate the process models and hence, obscure the "preferred" process [129]. Furthermore, it is difficult to anticipate all possible exceptions [129]. Current workflow technologies also provide no support for uncovering what kinds of exceptions can occur in a give process model, and how they can be resolved. Process designers are then forced to rely on their own, probably incomplete, experience and intuitions about possible exceptions and how they can be managed [130]. Moreover, if exceptions are not detected promptly and handled effectively, they can result in severe impacts on the effectiveness (cost and schedule performance) of collaborative work [129]. Even such systems that do support exception modelling and dynamic workflow model modification do not help determine the best response to a given exception (this requires effort from humans instead), which can include changing the current process instance or making lasting changes to the process model template followed by future instances [129]. However, it is important to be aware of the patient safety risks involved in dynamic modifications to workflows. There must be full consideration of the consequences on other workflow steps when these modifications are made.

Ad hoc Workflows

At least three factors were identified in [131] that limit the flexibility of organisations: handling uncertainty and incomplete information; resolving conflicts between individuals and units; and incorporating organisational learning. Challenges that remain include WfMS, whether production or ad hoc, remain stand-alone and isolated; users do not and often cannot take control over a process; and what we learn from a process is seldom used to create a new process. An approach presented in

[124] integrates ad hoc WfMS with traditional WfMS that handle predefined workflows, and proposes a more participative workflow design and execution. The need for WfMSs to support transformation of ad-hoc (additional, partially planned and short-lived) workflows into predefined, structured workflows (or templates) is discussed in [124]. This is required in situations where such ad-hoc workflows are used more than once and eventually become part of the structured workflow of the organisation. This transformation should occur dynamically, whilst the workflow is executing, and with only minor modifications necessary. Current WfMSs also lack the support for allowing the implicit knowledge that end-users (actors within organisations) have about the workflow to become explicitly incorporated into the structured workflow. This deficiency in providing end-user control and participation needs to be addressed in order to increase efficiency and have greater acceptance of the implemented workflows within an organisation [124]. Still, one of the great challenges however, with achieving this, is in the design of an intuitive user interface that enables the non-technical end-users to design and execute these ad hoc workflows [124].

Dynamic and Adaptive Workflows

A WfMS is typically composed of two main components: workflow model, which is the workflow specification module, and workflow engine, which executes or drives the workflow model. The workflow model must be sophisticated enough to capture the important aspects of the organisational environment and simple enough to be dynamically changed when necessary [123]. Organisational processes are often not static and evolve over time. This has lead to increasing attention for adaptive workflows, especially from a modelling perspective. To adapt to its environment, a workflow should be flexible such that necessary modification to its workflow models and instances are allowed [132]. The aim of adaptive workflow systems is to adapt effectively to deviations from the "ideal" process during execution.

Further to this is the growing belief that the specification and execution modules need to be tightly interconnected. For example, to allow the workflow model of a procedure to be edited and therefore, dynamically and safely change how the steps of the procedure are being executed [123]. Dynamic workflows are defined in [123] as

workflows that allow changes to be made “on the fly” in the midst of continuous execution of the changing procedures. WfMS currently provide little support for dynamic and adaptive processes, which is essential for systems to fit into the real world situation of dynamic, uncertain and error-prone environments [129]. An example of this concept was implemented in a WfMS, known as ADEPT (Application Development Based on Encapsulated Pre-modelled Process Templates). ADEPT is based on block-structured process description languages with added control structures and facilities for pre-modelling envisaged exceptions, modelling complex organisational structures, as well as temporal aspects [14]. It has been developed using Java to create a platform-independent WfMS whose clients can be run as Java applets in web browsers. This approach however has brought about several challenges that involve security issues, persistent storage of distributed workflow data, and error handling such as communication failures.

A number of approaches were proposed in [127] for building dynamic adaptive workflow systems:

- Contingency management and hand-off: involves providing mechanisms for handling and recovering from both expected and unexpected divergence from the intended process.
- Partial execution: provides support for the dynamic creation and execution of processes and parts of processes “on the fly”.
- Dynamic behaviours: for both the execution model and behaviour of workflow objects to have flexibility in modifying workflow paths, and behaviours during execution.
- Reflexivity: for allowing a workflow to examine, analyse, produce, and change its own process and data during workflow execution.
- Evolution and optimisation: via tracking, measurement and reuse of process parts to improve the workflow adaptability to new applications and uses in the long term.

These approaches were applied in a workflow support system called Endeavors [127].

Dynamic change issues include correctness and consistency of dynamic procedural change in WfMSs. As described in [133], supporting dynamic changes to organisational procedures can cause “dynamic bugs”. For example, changing steps in a

process that were originally done in sequence so that some of the steps could be done in parallel may result in the mistiming of information being received at various states in the process. It is hard to predict all possible dynamic bugs, especially in realistically large workflows due to high complexity. A modelling language for the unambiguous specification of procedural change, called ML-DEWS is presented in [133]. ML-DEWS makes use of timed Petri-net extension and formal verification to ensure correctness of dynamic change and to propose error-free change structures. Here, change is viewed as a process itself, and since changes frequently dictate other accompanying changes, it is often necessary to perform a set of changes as one unit that contains some partial ordering of activities. However, the chosen approach of formal verification makes it unable to be used by end-users (non-technical users) [133].

Efforts towards supporting modelling of adaptive workflows are still limited with respect to the changing situations and uncertainties. These need to be complemented with execution support or run-time solutions identified in [132], such as dynamic scheduling, dynamic resources binding, runtime workflow specification, infrastructure reconfiguration which are the essential techniques used in dynamic workflows.

Inheritance of Workflows

Inheritance of workflows uses concepts from computer science and from coordination theory about managing dependencies [134]. Literature in this area generally use a petri-net-based approach as this technique proves to be more powerful than state charts due to their ability to handle concurrency or processes that run in parallel [135]. Most process mapping techniques analyse processes using only one primary dimension: breaking a process into its different *parts*. Representation in [134] adds a second dimension: differentiating a process into its different *types* (see Figure 2.8 below).

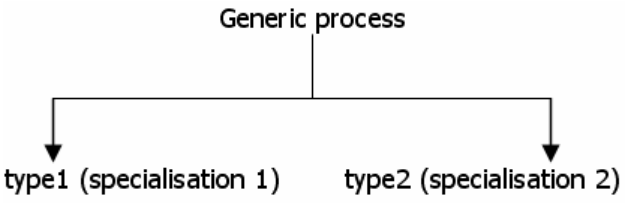


Figure 2.8. Process type hierarchy.

The concept of *object life cycles* has been proposed in [135],[136], where variants of workflows (defined as objects) are generated from inheritance of data and behaviour from other object types. An object life cycle refers to a Petri-net specifying the dynamics or behaviour of an object class [136]. Object-oriented methodology provides knowledge of the relationships between object types and how they relate to each other via inheritance, thus, it enables us to establish relationships between workflows, making the concept intuitively applicable [136]. For instance, if a newly defined process replaces an existing one, those existing cases can be handled the original way by referring to its super-class object. This is achieved through consistent specialisation of object life cycles [135], [136]. Both work present similar methods of consistency checking – *extension* and *refinement* of object life cycles.

In general, there is not much literature found on this concept. Although literature on the concept of object life cycle inheritance and specialisation discusses its applicability to workflow modelling, much of it so far has been illustrated in the context of relatively simple problems, such as hotel reservations. Nonetheless, the technique shows great potential for solving large, complex workflow problems such as in healthcare. This area is still yet to be explored in greater detail.

Workflow Modelling Languages

There are several workflow modelling languages that are currently in use, albeit none of which have been selected as *the* standard language. Among these are Petri-nets, YAWL, BMPL and XPDL, which are discussed below.

Petri-net-based Workflows

Petri-nets have long been used and over time they have been extended with colour, time and hierarchy to increase its expressiveness and utility (see Jensen, 1990, 1997 & Marsan et al. 1995 cited in [137] respectively). Petri-nets basically carry 'tokens' as data, which are coloured. Petri-net-based workflows are also primarily 'state-based' such that decision points within a workflow are driven by states rather than activities and events. That is, the transition from one state to another may involve certain tasks to be done. For instance, for a given workflow for auctions, there may be a set of

states including ‘proposed’, ‘accepted’ and ‘rejected’. At any point, certain parties to the offer may have actions they are allowed to do, but that they have choices. Thus, if the offer is in the "proposed" state, then the seller may optionally cause it to enter the "accepted" or "rejected" states, and either of those choices may require action from the seller, the buyer, or other parties [138]. Thus, Petri-net transitions, traditionally occur instantaneously on receipt of a token(s) at particular ‘place(s)’ within the petri-net-based workflow. However, the semantics of Petri-nets has since been extended in order for activities to take time to complete (e.g. object life cycle representations using object/behavior diagrams [135]).

van der Aalst [137] points out that Petri-nets are powerfully expressive for representing workflow patterns [139] in comparison to other existing workflow languages. However, Petri-nets pose limitations when modelling control flow, particularly with respect to: (1) patterns involving multiple instances; (2) advanced synchronisation patterns; and (3) cancellation patterns – e.g. cancellation of whole cases (workflow instances) or parts of workflow instances [137].

YAWL (Yet Another Workflow Language)

YAWL aims to overcome the three aforementioned control flow problems when using the Petri-net approach. Each of the problems are addressed (retrospectively) via: (1) an explicit OR-join task; (2) multiple instances of a task (atomic or composite); and (3) a ‘remove tokens’ task for cancelling a part/region of a workflow instance [137]. YAWL also provides explicit support for all the workflow patterns identified in [139]. Furthermore, it offers formal semantics and graphical representations for many of its concepts, making it potentially useful as an intermediate language when translating between different workflow languages [137]. However, it has only been recently that implentation efforts have been put towards a first-cut prototype supporting YAWL [140], [137]. Efforts need to be directed at testing YAWL and its implementation against complex application scenarios and how it might be used as an interchange format in future [137].

BPML (Business Process Modeling Language)

BPML is an XML-based Business Process Modeling Language developed by the Business Process Management Initiative (BPMI) [141]. BPML provides an abstract model and grammar for representing generic processes, making it usable for not only enterprise business processes, but also for defining complex Web services and multi-party collaborations [142]. BPML supports transaction and exception management. BPMI is currently developing a specification for the Business Process Query Language (BPQL) to enable business analysts to query the state and control process instance executions.

XPDL (XML Process Definition Language)

XPDL is the language proposed by the WfMC to interchange process definitions between different workflow products (i.e. it aims to be 'tool-independent') [143]. XPDL defines a common interchange format that can be used the basis for a process definition interface, which can support the transfer of process definitions between WfMS products and modelling tools. This thesis has chosen XPDL as the interchange format between the workflow specification generated by our chosen workflow architecture (DSTC's Breeze) and our Instruction model (see section 3.4 for a detailed discussion).

Despite the efforts of the WfMC, there is still a great diversity of languages and concepts based on different paradigms that existing WfMSs use [137]. Most of the products available use a proprietory language rather than tool-independent language. Some WfMSs are Petri-net based, but typically add both product-specific extensions and restrictions (van der Aalst, 1998; van der Aalst & van Hee, 2002; Ellis & Nutt, 1993 cited in [137]). All these variations are attributed to the different ways in which business processes can be described, and the lack of consensus of what constitutes a workflow specification [137]. Part of deciding which to use as a standard is to determine the advantages and disadvantages of each of these workflow models and languages as a starting point. A critique of some of the existing workflow languages with respect to their capabilities has been made by van der Aalst [137, 144].

Workflow in Healthcare

As mentioned, traditional workflow technologies have achieved relative success in the workplace when dealing with relatively simple problems that are of limited scope and scale [127]. Thus, the realisation of *process-oriented* clinical information systems is a great challenge – if not even the "killer application" for this type of technology. It combines all the problems and challenges usually only found in different application areas. Once the technology has been made powerful enough to adequately support this domain, it will be able to support a broad spectrum of different application areas, and as such, clinical applications can serve as an ideal test bed for process-oriented information systems [14]. Clinical information system architectures need to consider the requirements of flexibility, scalability, manual and partly automated tasks, and integration of legacy systems [126].

According to [126], managing clinical workflows requires:

- Frequent changes with many exceptions and time dependencies (e.g. Emergency interventions without scheduling);
- Control at run-time;
- High correctness and reliability; and
- Connection of workflows made possible.

Further, workflows must consider organisational characteristics like structures, roles, policies and preferences. HISs often do not relate to organisational issues unlike business applications where concept of workflow management has become crucial [145]. Need arises for more process-oriented HISs, where information sharing and collaborative decision-making within healthcare process in a care plan are actively and directly supported [14].

Until now, WfMS in hospitals are used only in single cases for well-defined workflows such that the management of large sets of complex workflows across enterprises cannot be handled by a single WfMS [126]. In addition to this problem, most existing commercial WfMSs currently cannot address the need to acquire data or access functions resident on existing systems, nor can they ensure correction and compensation for aborted workflow transactions across systems (Buffone 1996) cited in [126].

Maintenance is a major issue since process-oriented systems must be adjusted to accurately model the inevitable and often frequent changes in healthcare processes. Such changes – many of which are unforeseen, result from variations in the course of a disease, or a pre-planned treatment process to suit individual as well as current standards [14]. Therefore, ad hoc deviations from planned processes are often required – incorporating flexibility as the key to effective automated support [146]- [147]. Current systems are based on relatively restrictive process models allowing little or no variation in possible sequences in a process [14], [146].

An example relevant to CDM is the HEMATOWORK WfMS [70], which is a rule-based system that supports long-term therapy in the domain of distributed cancer therapy. The treatment is mainly based on standardised treatment plans. However, as patients react differently to long-term treatment, a significant number of treatments have to be adjusted partially and in such a way that it is specific to the patient.

The successful representation of evidence-based post-stroke rehabilitation guidelines is reported in [30, 148] as a workflow model from which a 'careflow' management system is implemented using Oracle Workflow tools. This system illustrates that at least in some cases; a very significant aspect of the knowledge from an evidence-based guideline for CDM can be expressed through the design of a *patient-centred* (i.e. case-based) workflow, which is termed as a 'careflow'.

The MCPOP (Modelling the Clinical Processes of Prescribing) project was recently started due to the variations in the ePrescribing decision support prompts and advices generated by widely used prescribing systems in Australia [149]. The project aims to promote safety and quality in prescribing in the domain of asthma management. MCPOP uses a systematic approach that captures the logic and clinical workflow and associates it with available patient data sourced from the EHR, as well as external health services such as the Australian Medicines Handbook and Therapeutic Guidelines Limited [149]. Clinical workflows are developed and refined via a method of developing a series of vignettes, which are used to discuss with clinicians or experts in the field about how they might make decisions related to prescribing given a vignette, and determine the factors that influence their decisions. The project now

aims to implement the same methodology in other domains such as cardiovascular disease and diabetes, and to expand the use of workflow across systems and jurisdictions (e.g. hospital and community healthcare settings) [149].

From a commercial perspective, there has been an increase in the number of products being made available that try to support workflow solutions within the healthcare domain. Examples of such WfMSs include RIS (Radiology Information System) and PACS (Picture Archiving Communications System), which both support the distribution of clinical imaging [150]; and similarly, Cerner Dynamic Healthcare Technologies Inc [34] provides diagnostic workflow applications for pathology, laboratory and radiology services. However, until standardisation of workflow models and WfMSs occur and are adopted by these vendors, the lack of interoperability between systems remains an issue.

2.4. Summary

This thesis addresses how health information system's (HIS) can support guideline-based care. It is recognised that this is better achieved by taking into consideration the provider 'workflow' or the business process. The application of workflow technology, in particular, to support healthcare delivery is a challenging (and hence rarely seen) accomplishment in practice, particularly in the context of CDM. Furthermore, these guidelines must be individualised to a specific patient (see Figure 2.9).

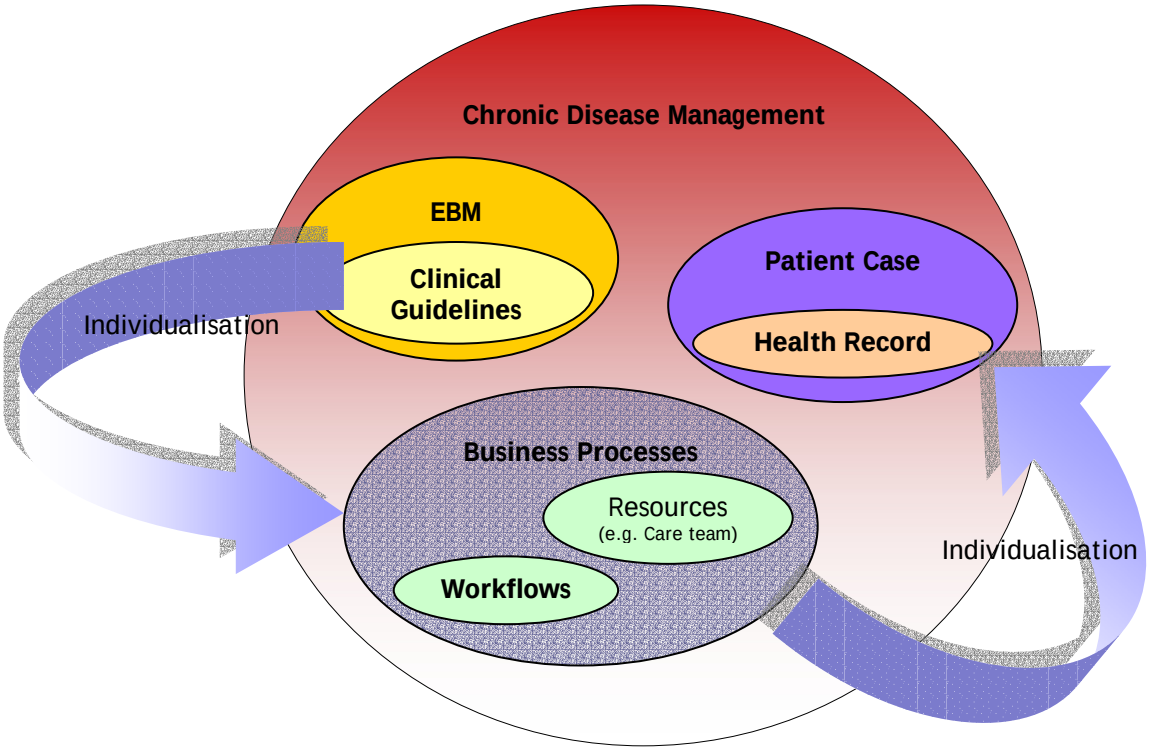


Figure 2.9. Evidence-based Medicine in the context of CDM.

3

APPROACH

3.1. Engineering of Guidelines

Current guideline models vary depending on the type of processes they try to express. A typology of four modelling formalisms used by guideline models is identified in [114]:

- Flowcharts for algorithmic problem-solving processes;
- Disease-state maps to relate decisions made during the course of patient care;
- Sequencing of activities in care plans that aim to meet goals; and
- Workflows to model care processes in an organisation.

We take the position that; in general, engineering of a given guideline for use in clinical information systems with electronic decision support produces a number of artefacts (Figure 3.1). That is, guidelines allow us to specify what needs to be recorded (EHR content), when to record, and how to evaluate/make decisions (comp-

uter interpretable clinical guidelines, CiGs), and what needs to be done (workflow schemas that may include a combination of clinician and system dependent actions). Also, we can produce a human-readable electronic version of the guideline as hypermedia. Thus, while [114] proposes that a workflow is in itself a form of guideline representation, we make the distinction that a CiG (in the narrow sense compared to the four classes of CiG representation suggested by [114]) can reside within a workflow expression of the larger-scale workflow. Thus, an activity within a workflow, for instance, might invoke a decision support application that executes a CiG. For example, the activity of ordering a medication might refer to a CiG to recommend the specifics of the drug to use (name, dose, quantity, duration, frequency, strength, etc). Conversely, a CiG may recommend that a particular action be undertaken (e.g., to refer the patient to a specialist), and hence may refer to a workflow that defines the activities to be undertaken to carry out that action (e.g., in the case of the referral to the specialist, its workflow might involve activities for requesting for an appointment, scheduling it, and organising a follow-up visit after the specialist visit). We assert that maintaining a clear relationship among these artefacts during the design of the system is key to successful computerised support in evidence-based CDM.

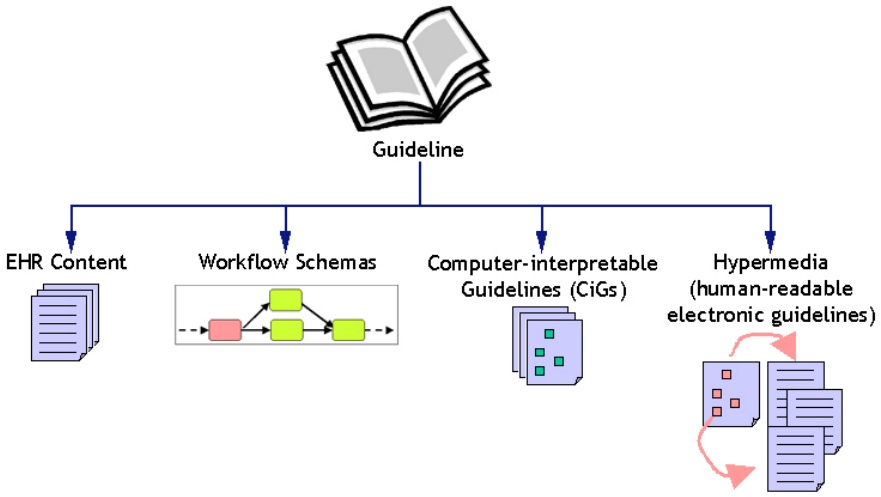


Figure 3.1. Guideline Engineering Artefacts.

3.2. EHR Architecture

We use the *open*EHR architecture as the basis for our EHR approach. As mentioned in Chapter 2, *open*EHR is based on a two-level modelling framework – the *reference* model and the *archetype* model.

3.2.1. *open*EHR Reference Model[3]

EHR Reference Model

The *open*EHR EHR Reference Model has a number of generic concepts it represents with regards to the EHR (see Figure 3.2), namely, folders, transactions, organisers, and entries.

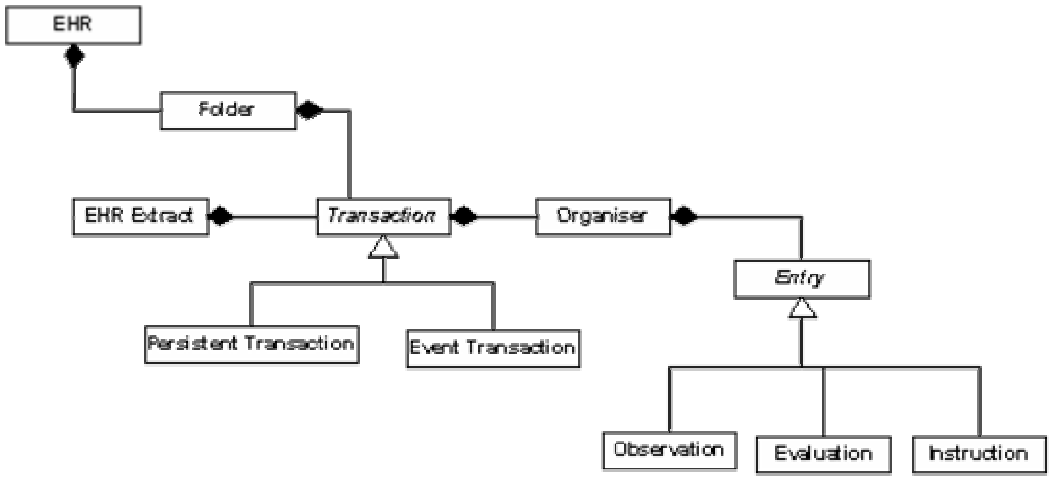


Figure 3.2. *open*EHR EHR Reference Model.

Transaction

A transaction is a unit of information corresponding to the interaction of a healthcare agent with the EHR [77]. In general, EHR transactions have the following properties:

[3] Section 3.2.1 makes heavy use of [77] T. Beale, S. Heard, D. Kalra, and D. Lloyd 2003, *openEHR EHR Reference Model (rev. 4.3)*, updated 18 Mar 2003, viewed 21 Oct 2004, <http://titanium.dstc.edu.au/openehr/requirements-design.shtml>.

durability, atomicity, consistency, isolation, indelibility, modification and traceability. *open*EHR views transactions in terms of data relating to clinical events, and data that can be categorised into sets of relatively long-term significant data. Thus, transactions are either *persistent* transactions or *event* transactions. Persistent transactions are those that contain data that remain pertinent over a relatively long period of time. Such transactions include family history, medication list, problem list, and allergies. Conversely, event transactions contain data collected at a particular instant in time; for example, GP encounter, biochemistry test, medication prescription, and hospital discharge transactions.

Folder

An individual's EHR can consist of any number of *folders* that organise a set of related transactions as they accumulate over time. Folders refer to transactions by reference; thus, more than one folder may refer to the same transaction. Common folders may be created for collating event, persistent, and demographic-related transactions. The main purpose of folders is to provide a method for logically navigating the content of the EHR.

Organiser

The *open*EHR *organisers* provide headings to sections within the transaction content, and also provide references for navigating through an EHR. A commonly used organiser is the 'Problem-SOAP' note headings. Organisers are archetyped as a tree structure such that it has a root organiser, and one or more sub-organisers. Any number of organiser archetypes can be used and combined to form a larger structure.

Entry

The *open*EHR reference model defines the content of all information that occurs in the "clinical statement" context as *entry* instances, sub-typed into three classes: *observation*, *evaluation* and *instruction.* Observations are clinical statements due to observation of a phenomenon and may be measurable or subjective statements (e.g., BP, HbA1c and BMI). Evaluations are clinical statements created as a result of interpretation or analysis of observations (e.g., hypotheses, diagnoses, goals and targets); and instructions are statements of actions to be carried out (e.g., medication order, recall and referral).

Data Structures

*open*EHR has a class of logical data structures including *trees*, *lists*, *tables*, *single data structures*, as well as having an explicit structure for capturing *historical* data. The *data items* within the structures are represented as *compounds* or *elements*, where an element contains a single *data value* and a compound allows data items to be grouped, which may consist of further compounds and/or elements (see Figure 3.3).

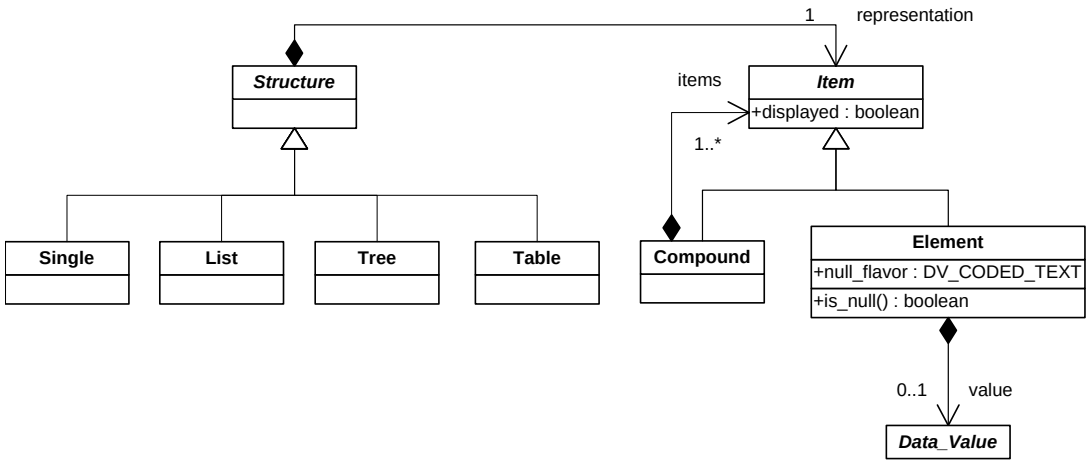


Figure 3.3. *open*EHR Data Structures.

Examples of single data structures include the patient's weight and height (see Figure 3.4).

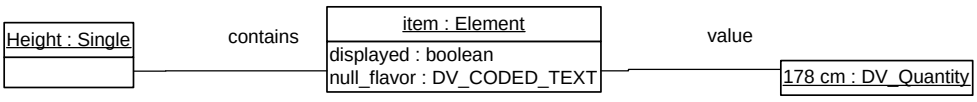


Figure 3.4. Single Data Structure for a Height measurement.

Lists have a structure such that each item has a value and can be referred to by a name and a positional index in the list. Figure 3.5 below shows the list structure for blood pressure, which consists of two list items/elements – the systolic and diastolic blood pressure values.

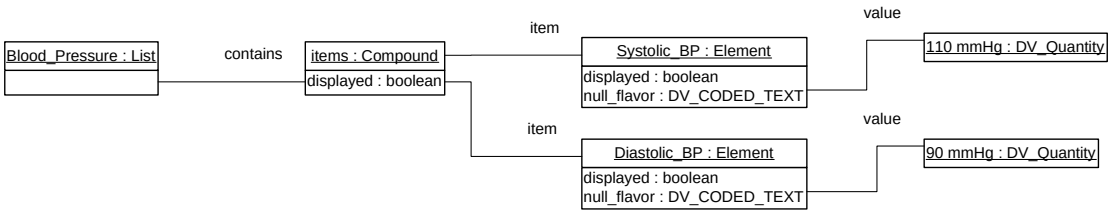


Figure 3.5. Blood Pressure List Structure.

Examples of tree data structures include biochemistry results and microbiology results. Tables have a structure in which columns are named and ordered, and each column represents data of the same type. Some columns may be assigned as 'key' columns, containing key data for each row as in relational tables. Thus, each row can be named – e.g. a row might represent a blood antigen. Examples of table data structures include blood pressure and blood tests.

open*EHR Data Types*

There are a number of data types used in the *open*EHR EHR reference model. These have been derived from the harmonisation of other data types used in GEHR, Synapses and SynEx, CEN 13606, and specifically the HL7 v3 RIM. The Data Types specification is the lowest level technical specification within *open*EHR. The package structure of the *open*EHR data types is illustrated in Figure 3.6 below.

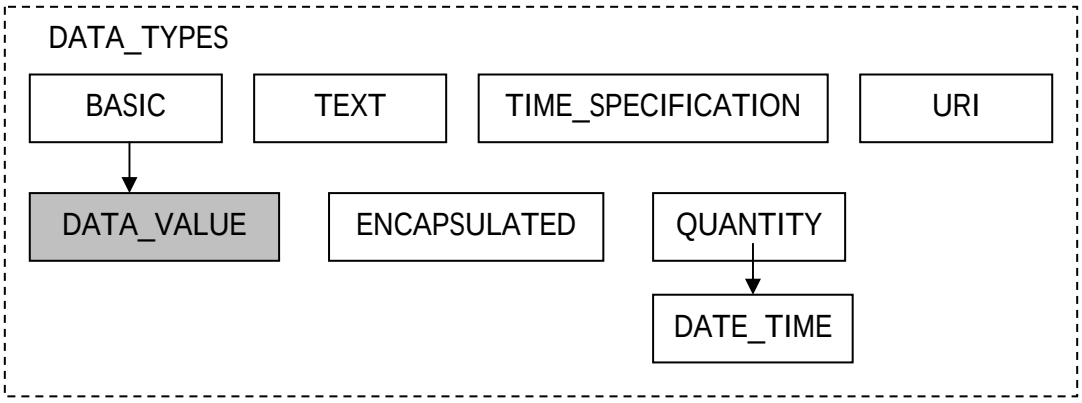


Figure 3.6. *open*EHR Data Types.

The *open*EHR data types are described as follows:

- BASIC: Represents the set of 'basic' types such as INTEGER, and BOOLEAN.
- The data types specified have the prefix "DV_" as they inherit from the DATA_VALUE class, which serves as the common parent of all data value types in *open*EHR.
- DV_URI: allows data values that are references to objects on the World Wide Web to be created. This type is simply a string as in all URIs (Universal Resource Identifier).
- DV_EHR_URI: a specialisation of DV_URI that allows any element in an *open*EHR EHR to be identified in the same way as other objects on the web. The URI has the scheme name "EHR", which makes instances of that type to be globally unique within the scope of the EHR. This data type is used to express all runtime paths in the EHR and used for example in queries to specific elements or data items in the EHR. The DV_EHR_URI is constructed according to the navigational structure of the *open*EHR record, i.e. "ehr_id-/transaction_id/organiser_id/entry_id" (see "*open*EHR Paths" in section 3.2.2).
- DV_TEXT: represents all classes of textual values in the EHR such as plain text, coded terms, and narrative text.
- DV_QUANTITY: represents various clinical quantities which may be dimensioned (e.g. a person's height, weight or blood pressure); dimensionless (e.g. "number of hospital admissions = 5"); quantity ratios; ranges; ordinal values; dates; times and durations.
- TIME_SPECIFICATION: represents a special class that is commonly used in specifying times in healthcare. Typically these include periodic time references (either with respect to the calendar (e.g. "every month"), or a particular real-world 'event' (e.g., "every meal")).
- ENCAPSULATED: represents classes of data whose definition exists outside of the EHR model (e.g., multimedia and parsable data).

3.2.2. Archetypes

As mentioned in Chapter 2, *open*EHR uses *archetypes*, formal structured constraint definitions of clinical concepts (expressed using constraints on instances of an underlying reference model). These archetypes can be used to allow for guideline-specific and case-specific information to be recorded in a general and extensible EHR framework.

Archetypes may be defined in varying degrees of granularity. For example, an archetype may define a collection of concepts that when aggregated, form fixed attributes of a higher-level concept, and in which its constituent concepts are meaningless if they are recorded on their own. A blood pressure measurement for instance, usually consists of a systolic and diastolic blood pressure, the position of the patient during measurement, patient's cuff size, etc as its constituent parts. A generic concept may consist of a collection of values that form a subset of a larger known set such as a diagnosis; where its value is usually accompanied by other attributes such as the date of onset, the stage of the disease, etc. A collection of these higher-level concepts that are typically measured together and hence may also be considered as concepts themselves such as vital signs, which consists of a number of observations about the patient's blood pressure, temperature, blood sugar levels, heart rate and so forth.

Archetype Specialisation

Archetypes can be made more specific for local use via archetype specialisation. Unlike in HL7 version 3, where specialisation occurs by restriction, *open*EHR archetype specialisation conforms to the object-oriented paradigm, where the data instantiated from the specialised archetype is also guaranteed to conform to its parent archetype. Therefore, the specialised archetype will contain all the relevant parts from its parent archetype, and include additions or modifications for specialised use. This approach makes archetypes usable in a standalone fashion. For example, 'Problem' may be specialised to 'Diagnosis', then into 'Diabetes Diagnosis'; where:

- 'Problem' may consists of – text/term, clinical description, date of onset, date of resolution and number of occurrences;

- Diagnosis is a specialised archetype of Problem by further constraining it to contain a term (not text), grading, diagnostic criteria and stage; and
- Diabetes diagnosis is a local specialisation that may be constrained to a term (not text) and a diagnostic criteria constrained to: fasting > 6.1; GTT 2hr > 11.1, and Random > 11.1.

The identifier of the specialised archetype is usually equal to its parent's archetype identifier, with a 'dot' notation to delimit a further name to refer to the specialised archetype. In the case of our example, the identifiers would be as in Figure 3.7:

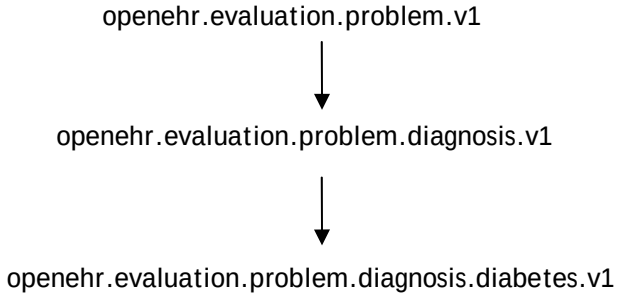


Figure 3.7. Identifiers for Specialised Archetypes of the "Problem" concept.

Templates

Whilst archetypes place constraints on the reference model to define domain-specific concepts, *open*EHR templates describe the higher-level constraints on the actual data that can be collected by specifying the set of archetypes that can be used, and other local system-specific constraints such as how the archetypes are organised to form an EHR document (in particular, how they are grouped into sections within a document – i.e. what set of organisational and primary archetypes to use), the ordering, cardinality, obligation (i.e. specifying data items as mandatory or optional), and the data item constraints such as default values. For example, a laboratory report may contain the results of the tests, the evaluation or interpretation of the results, and any recommendations.

Template specifications, in general, do not affect the semantics of the various individual concepts that are being collected, but rather, to allow the relevant concepts

to be recorded in a manner that is suitable for the *context* it is being used. For example, a blood pressure for a midwife antenatal clinic would, by default, be measured in a sitting position, which differs in the context of a cardiology clinic.

open*EHR Paths*

Any node or leaf item in the EHR can be referred to via a path mechanism similar to a URL (Uniform Resource Locator). The path can be generated by the concatenation of the values of the attributes 'name' and 'meaning' of each element from a particular point to the specific node that is being referred. These attributes are inherited from the LOCATABLE class by most classes in the *open*EHR model. The 'name' value is chosen at runtime by the software application that creates the EHR data that is either obtained from the user, or via an algorithm. The path that uses the 'name' values are called runtime paths, are always unique in data, and therefore, are used to locate data items or parts of the EHR. The 'meaning' value is predefined by the archetypes that were used to instantiate and validate the EHR data against. The path that uses the 'meaning' values are called archetype paths, which are unique within archetypes, but may not be unique in EHR data, thus, archetype paths are used to match subcompositions to their generating archetype structures, to identify matching sub-compositions during archetype querying, or to assist Graphical User Interface (GUI) display. The values for name and meaning may or may not be the same. For instance, the "problem/SOAP" note organiser may have the name "hypertension" at the problem level, but the meaning derived from its archetype may be "problem".

Other open*EHR Components*

There are also other components in the reference model. These include:

- EHR Extract model, which represents an extract or some part of, or in some cases, all of some version (usually the latest) of an EHR. EHR extracts are used as the primary mechanism for the transmission of selected parts of EHRs between multiple EHR systems [2]. HL7 messages for instance, may be transmitted from non-EHR systems and are converted to EHR extracts [2]. This model is equivalent in scope to CEN 13606 standard;
- Demographics model for capturing aggregated EHR data for secondary purposes;

- Common model, which describes archetyping features for the openEHR models, external identifiers (proxy objects), details about participation and attestation for each concept, and change control (including version control); and
- Support concepts for the openEHR reference models. For example, referencing of external informational entities.

Summary

We have introduced *open*EHR's reference model – specifically with respect to the EHR, data structures, and data types as these provide the basic building blocks of workflow-integrated EHR presented in this thesis. The reference model is constrained by an archetype model to represent specific information recording requirements. Archetypes are specified using a formal language such as the Archetype Definition Language (ADL), which is still under development, or using an XML schema (as is used in this thesis carrying on from the GEHR and *open*EHR–based EHR system implementation by DSTC).

Constraining relevant reference model classes produces definitions of clinical domain concepts, which result in a number of specifications being authored by domain experts: primary archetypes (the set of core domain concepts at the most granular level of the EHR content, that is, *open*EHR entries), organisational archetypes (the set of concepts that organise the content or *open*EHR entries, called organiser archetypes), and templates that specify the actual EHR document or form for recording and use in a specific healthcare setting (expressed in terms of both primary and organiser archetypes) [151].

The main intention of archetypes is to represent concepts that are useable across the healthcare domain; to represent them in a standardised format that maintains their semantics such that they can be shared between information systems; and to provide interoperability, extensibility and flexibility in EHR systems via archetype specialisation, re-use of archetypes, and use within template specifications. Figure 3.8 below illustrates the overall relationship between the *open*EHR artefacts.

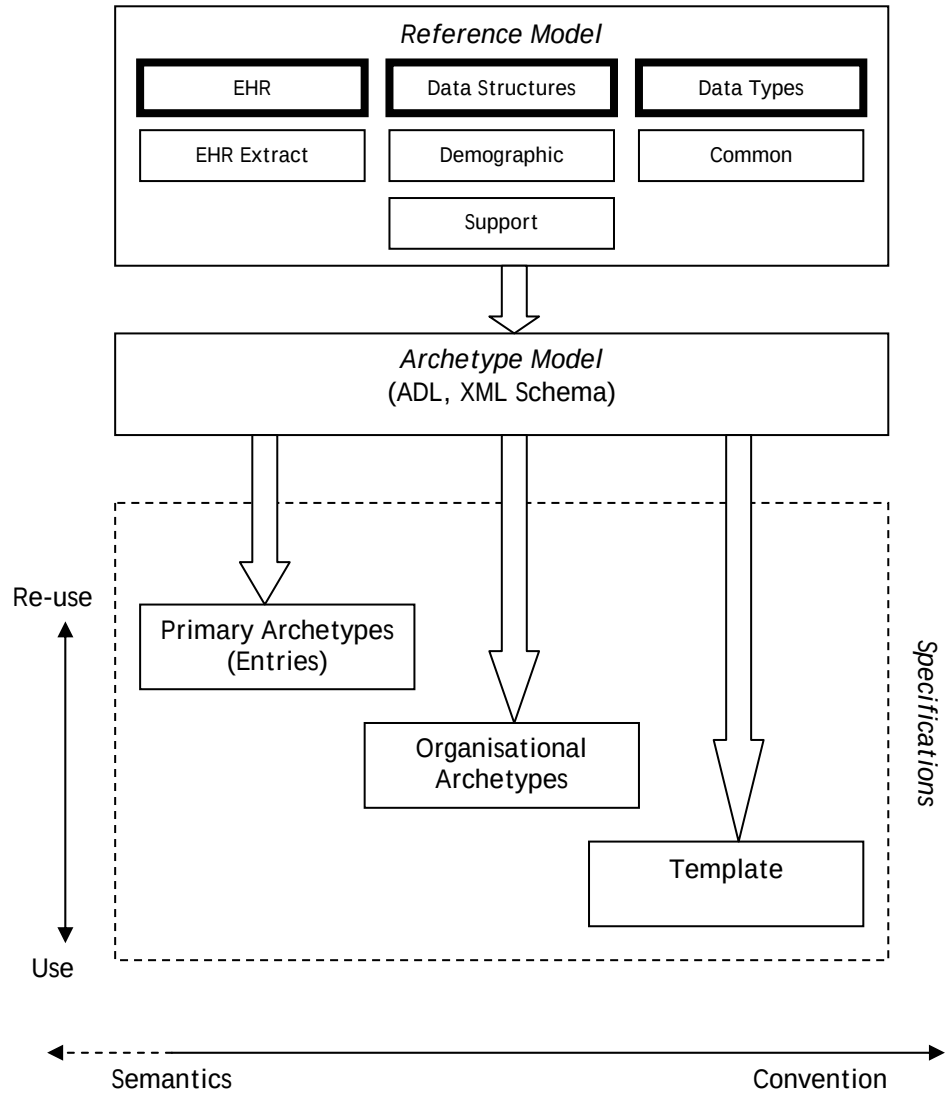


Figure 3.8. Relationship between *open*EHR artefacts (adapted from [151]).

3.3. Relationship between the EHR, CiGs and Workflow

The *open*EHR entries have a direct relationship to components of CiGs as shown in Figure 3.9 – guideline computational requirements can inform the content of the EHR. While the guideline informs facets of the EHR, existence of these components in the EHR can allow the point-of-care application to better promote the guideline with workflow and decision support.

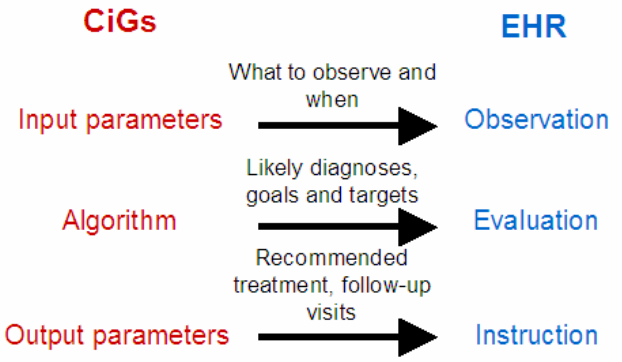


Figure 3.9. Relationship of the CiG to EHR content.

3.3.1. EHR Support for CiGs

In our approach, we are not aiming to model guidelines as such in the EHR, but rather to have support for recording what needs to be captured. Therefore, we see that CiGs play a distinct role, such that they model decision-making steps and recommended actions to take for the care of the patient, and are generally problem-based and developed as a result of evidence based best practice. In particular, they specify the decision-support rules and criteria under which actions and recommendations are to be considered. Thus, CiGs reside within knowledge bases, and are generally executed by a decision support system or application that generates the recommendations usually in the form of alerts and reminders.

Rationale Construct for Entries

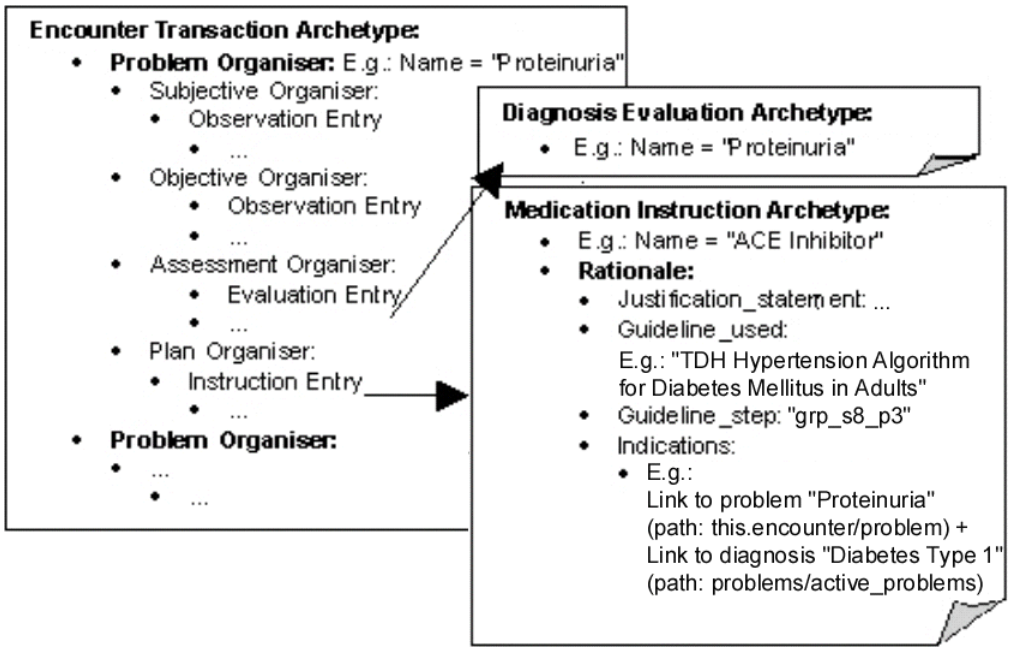
The promise of electronic decision support to promote evidence based practice remains elusive in the context of chronic disease management. We examine the problem of achieving a close relationship of EHR content to other components of a clinical information system (guidelines, decision support and workflow), particularly linking the decisions made by healthcare providers back to the guidelines. Using *open*EHR's archetypes, we refine the detailed information recording options for specific classes of encounter. We can use *open*EHR to track the relationship of a series of clinical encounters to a guideline. Specifically, we can further specialise the encounter transaction archetype with specific *rationale* links into guideline decision rule representation.

The rationale construct allows the clinician and/or the electronic DSS to record justification for decision points made during the patient's care. The rationale construct includes:

- An optional free-text justification statement from the clinician;
- Identifier for the guideline used and its version number;
- The precise step in the guideline that was taken; and
- A set of indications for the decision (observations and/or evaluations).

Values for any of these items can be a link item provided by the *open*EHR framework. For instance, indications for prescribing an ACE inhibitor may be diabetes and hypertension, which can be identified by a navigational path, as defined by the *open*EHR reference model. Figure 3.10 shows an example of a rationale for an instruction within a GP encounter or contact note, where the instruction is to prescribe an ACE inhibitor due to the presence of proteinuria and diabetes type 1.

Figure 3.10. Example of Rationale for an Instruction within an Encounter.



In general, the rationale construct can reside within either type of entry:

- Observations – to explicitly record and link back to the specific step(s) in the CiG that requested certain input parameters such as blood pressure values, BMI (Body Mass Index) values, etc; or
- Evaluations – to explicitly record and link back to the specific step(s) in the CiG that were used to arrive at the decision(s); or
- Instructions – to explicitly record and link back to the specific step(s) in the CiG that indicated the output parameter generated by the decision support application (recommendations, etc).

The attribute *indications* within rationales may contain links that navigate back to specific entry or entries recorded in the EHR that help justify the decision chosen, or where these do not exist in the EHR, it may simply be natural-language text entry, which the provider records.

3.3.2. EHR Support for Workflow

'Workflow' has often been modelled in terms of a single clinician's decision-making process with the 'action' being, for instance, medication treatment. Furthermore, the action or instruction in this sense is often left rather declarative rather than procedural, as there is no description and detail of the steps required to perform the action. An example of an instruction within a GP encounter or contact note is shown in Figure 3.10 where the instruction is to prescribe an ACE inhibitor to the patient. As mentioned in Chapter 1, we argue that it is important to differentiate between the process of arriving at clinical decisions, and the process of carrying out the actions that were decided upon. We view the following to be key requirements to support these two aspects in healthcare: (1) explicit recording of rationale (*how* the decision [e.g. evaluation and instruction] was arrived at), and (2) describing *how* to carry out the actions. In this thesis, we view the latter to be the actual workflow.

The timely flow of information (i.e. actual *documents*) in workflows between participants and/or organisations is also critical, which goes above and beyond that of data pertaining to decision variables required for executing the workflow itself. For instance, it is often a requirement that clinical observations will need to be recorded at a granular level at specific points in the workflow (e.g. recording of blood pressure

during an encounter), which is data that may not necessarily be used as part of a decision-point evaluation that decides the control flow in a process either at that instant, or in future decision-points. At a higher level of granularity, the control flow within workflows is very often dictated by the recording of documents (rather than data items within documents). For instance, the action to order a wheelchair for a patient cannot be performed without receiving the provider's documentation of assessment and recommendation. Moreover, it is often useful to have the ability to explicitly link between the information (whole or part of documents) recorded as a result of actions having taken place.

In this thesis, we identify the need to be able to explicitly specify what to record at specific points in the workflow; specify who should record or enact the activities; and therefore, be able to have explicit constructs in the EHR that retains detailed information about the actual steps that were taken. We present our Instruction Reference Model (see section 3.4.2) to support these facets of workflow in particular, and demonstrate its use via a case study (see Chapter 5).

3.3.3. Summary

The intention is that a CiG can complement the workflow aspects of the EHR. Workflow models the work to be carried out, by whom, when and how. In conjunction with a WfMS, workflows ensure that the work to be done gets done, which varies across institutions. *open*EHR archetypes can help ensure that the appropriate information is collected within the EHR for the workflow. For instance, a guideline recommended action might be to enrol the patient in a "post-stroke rehabilitation program", and the workflow for this action is then specified (describing all the activities involved in the program). The information that is collected as part of this workflow is then constrained by archetype definitions. Figure 3.11 below depicts the overall relationships between CiGs, EHR and workflow. In this thesis, we present an approach by which workflow, EHR and decision support can interact practicably.

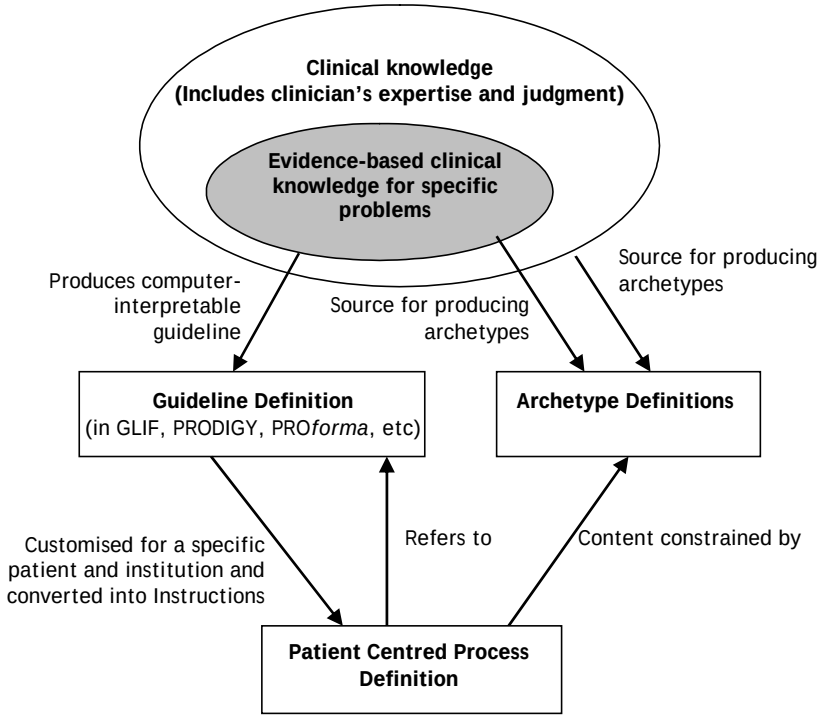


Figure 3.11. Relationship Between Guidelines, Archetypes and Instructions.

3.4. Modelling Instruction

Semantics of Instruction

The ability to model instructions requires an understanding of the types of semantics that can be placed on the concept of instructions themselves, and moreover, to make a distinction between these types of 'concepts' that are being modelled, and define the specific scope in which they are to be used in the context of healthcare delivery. There are two semantics of 'action' identified by [77]: *system-executed* actions (such as notifications generated by an EHR system, and reminders and alerts generated by a clinical decision support application), and *real-world actions* which are performed by humans (e.g., patient self-administering a drug; or a nurse administering the drug to the patient). We recall that *open*EHR instructions are defined as statements describing actions to be enacted, and more specifically –

> *"Are detailed enough to be enactable without further details. E.g. while an evaluation may mention that 'oral cortico-steroids are indicated at a peak flow of 401/m', an instruction is required to detail which actual drug, route, dose, frequency, and so on. Instruction may also describe non-clinical intentions such as consent." [77].*

Furthermore, the executor of the instruction is either explicitly stated or can be implied easily. Beale [77] also makes the distinction between (care) plans, which are statements of intent rather than readily processable actions.

Instructions result from evaluations, or clinical decisions being made. This is also true in the field of clinical guideline representation, where *decisions* and *actions* appear as distinct guideline modelling primitives that have a direct relationship [152]. In this thesis, the relationship between the decision-making steps and corresponding instructions are explicitly recorded in the EHR as described in section 3.3.1 (and demonstrated in a case study in Chapter 6).

openEHR Action Specification

The current *open*EHR instruction entry reference model in [77] supports recording of relatively 'simple' instructions, e.g., "take this medication 3 times per day for the next month" – it has the notion of "do this action". More specifically, the model presents and makes use of an *open*EHR Action Specification (i.e. revision 4.3) for instructions, which is intended to add the notion of *Action* to consider the idea of *Acts* and *Participations* as in HL7. The intention of that model is to record the acts that have taken place as a kind of observation entry (i.e. observation of acts having taken place), and to have Action_Specification that specifies the Acts that will happen in the future. The action specification includes:

- *Profile*: configuration data mappings from archetyped model of action, and includes the (decision) variables, e.g. minimum PAP smear age, and PAP recall period; event criteria; list of notifications; and EHR queries required for any system processing, e.g. query about the current age of the patient.
- *Action*: description of the action to be performed, e.g. recall action.
- *Data*: the *execution data* as a result of actions having taken place, e.g. suspend count, and 'last notified' date.

- *State*: current state of the action according to a state machine description.
- *Guideline Identifier*: Identifier of the guideline that initiated this action (if applicable).

The profile and (execution) data are only required for action specifications that require system processing to occur such as system notifications. For medication instructions that do not require system processing (such that they are left up to the patient to administer as prescribed) – they will only specify the action and the state of the execution of the action. Instructions in the current *open*EHR reference model are joined using *open*EHR's LINK object, which has the concept meaning of "next action". Figure 3.12 below shows an example of a plan for a chained medication order that links a 'first course' medication order instruction to the 'second course' medication order instruction. Note, this example does not detail the profile or execution data (save for the instruction status) since there is no system processing required.

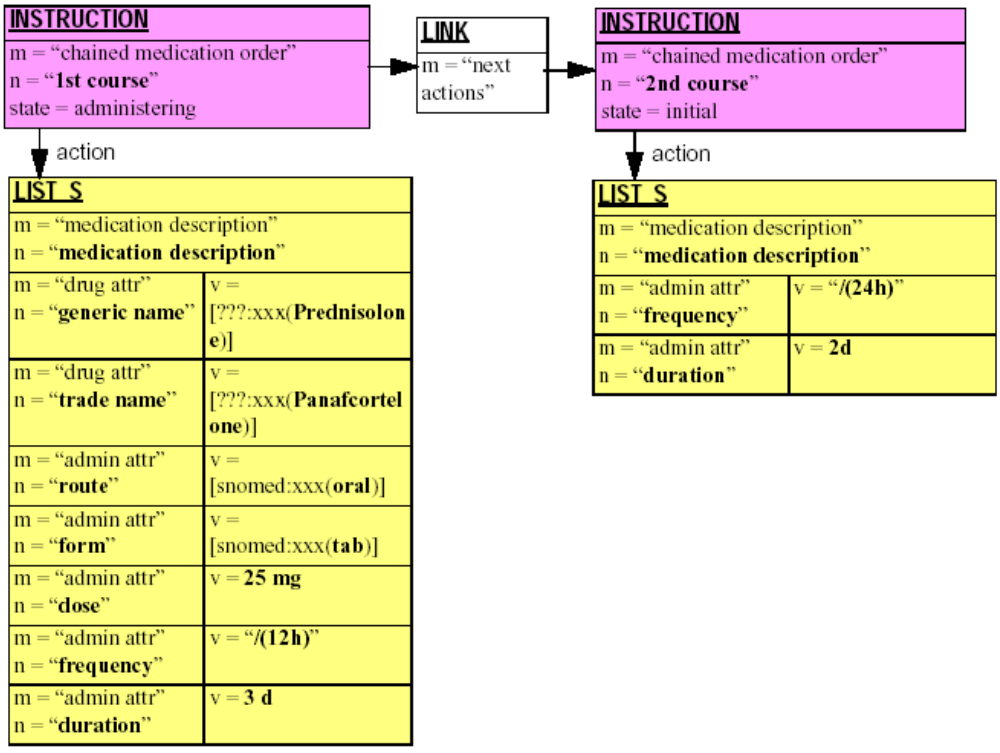


Figure 3.12. Plan for a Chained Medication Order (Figure 23 of [77])[4].

[4] "m" attribute represents the meaning of the node; and "n" attribute represents the "name" of the node.

3.4.1. Modelling Workflows via Composite Instructions

Design Rationale

There is no concrete model in *open*EHR that can specify business models in terms of *workflow*. Action specifications do not allow complex linkage of actions to support more complex types of instructions that model workflow. There is no explicit mechanism to specify pre- and post-conditions that have to be satisfied for each instruction as well as other temporal constraints. More specifically with respect to modelling business processes in healthcare, it does not take into account conditional branching and parallel execution of activities that workflows support. This thesis has therefore aligned *open*EHR instructions with workflow models to have explicit constructs for various types of branching and temporal sequencing of activities in a workflow; allowing a close and structured correspondence between the workflow and the EHR; and the EHR system to be seamlessly integrated with a WfMS.

Our view is that relatively simple instructions such as administering medication can be modelled and hence, recorded as a declarative or passive instruction, and those more complex instructions that represent workflows are modelled in terms of *composite* instructions. We have therefore, extended the *open*EHR instruction reference model (IRM) to support workflow. Our design is based on the idea that the EHR itself contains more "clinically" oriented workflows (such as care plans, chained medication orders, pap smear recalls, etc), which may in turn may need to be coordinated with other workflows around the organisation, such as administration related activities (e.g. ordering of new pharmaceutical stock, scheduling appointments, movement of patients between wards/beds, etc). There following are three different levels which in workflow is considered in our design: generalised process definition, patient-centred process definition and process instance.

Generalised Process Definitions

The WfMC defines a *process definition* as:

> "*The representation of a business process in a form which supports automated manipulation, such as modelling, or enactment by a work-*

> *flow management system. The process definition consists of a network of activities and their relationships, criteria to indicate the start and termination of the process, and information about the individual activities, such as participants, associated IT applications and data, etc." [153]*

In our design, the generalised process definition is a generic template for a whole class of process definitions (e.g. a chained medication order, diabetes care plan, PAP smear recall, etc). These generalised process definitions are described as an instruction definition archetype in *open*EHR and stem directly from clinical guidelines.

Patient Centred Process Definitions

This is a tailored process definition for a specific patient. Often it will be based on a generalised process definition, which has had specific activities and/or work items added to it. Within the *open*EHR model, we will capture this as an "Instruction Definition" entry, which is stored in a specific patient's EHR. The content instruction definition is constrained by the archetype for a "chained medication" instruction definition. For example, an "instruction definition" may use the "chained medication order" instruction definition archetype to state that a patient "John Smith" must take aspirin twice a day for 2 weeks and then aspirin once a day for one month.

Process Instance

As defined by the WfMC, a process instance is "the representation of a single enactment of a process", and is "created, managed and (eventually) terminated by a workflow management system, in accordance with the process definition" [153]. In the healthcare context, this may be a procedure or surgery that is currently being performed for a specific case or individual patient. Furthermore, it uses its own process instance data, and which is usually capable of independent control and audit as it progresses towards completion or termination. Specifically, in the IRM context, this is the current state and recorded history of the execution for a patient centred process definition, and where the process instance data is essentially, the patient's EHR. Within the *open*EHR model this is captured as an "Instruction execution" entry within a specific patient's EHR. The contents of the instruction execution refer to its

associated instruction definition and have a trace of the execution of the workflow. For example, the patient "John Smith" has an instruction execution, which states that the definition is as defined above, and currently he has taken two aspirins a day for two weeks, but has not yet started his next course of medication.

The Role of Persistent and Event Transactions in Executing Instructions

In this model persistent transactions are used to remember state information, whereas event transactions contain new data, which is used to drive the creation and update of persistent transactions. In particular, persistent transactions are used to contain "Instruction Executions". Whereas an event transaction is used to carry "Instruction Definitions" and other content which may drive the update of instruction executions. Thus, using the scope of event and persistent transactions, it allows us to differentiate between past, current and future work and recording to be done, for whom, by whom, and when. Persistent transactions record past and current state of the care process. One can record that an instruction needs to be done within an event transaction by referring to an instruction definition archetype instance (workflow schema) – effectively instantiating an instruction execution instance (workflow instance), which is recorded within a persistent transaction, and readily executable by a WfMS. Figure 3.13 shows the sub-classing and scope of composite instructions, and the various questions that are addressed by the subclasses.

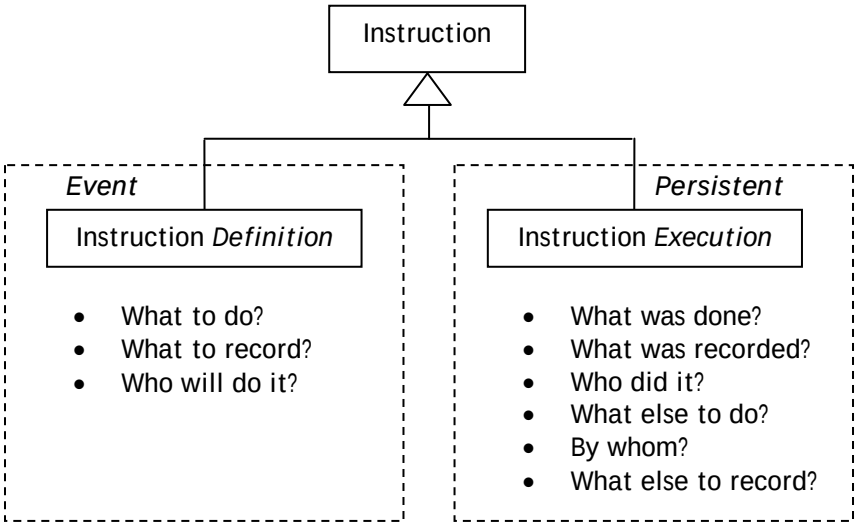


Figure 3.13. Sub-classing and Scope of Composite Instructions.

The key advantages of the use of our composite instruction include:

- Provision of richer context information that aids in the recording of the care process of the patient (having medico-legal significance);
- To assist service coordination within the patient's care team and so if executed according to a workflow/instruction definition, and in conjunction with a WfMS can help ensure that what needs to be recorded is actually recorded by that care provider when needed.

Data Collection

While the current *open*EHR instruction specifies a future action to be performed (which most likely results in recording of other data) – there is no explicit way to specify what recording is required for that action, nor an explicit way for the resulting data recorded to be linked back to the instruction that initiated it. Although there are ways to specify EHR links within entries in *open*EHR (as we have done with the rationale construct), this is left up to the archetype author to explicitly specify this. This method is still kind of 'arbitrary' because the actual recording of links should be done by the EHR system itself (e.g., when updating medication persistent transaction when new prescription event transaction get recorded), the DSS or the WfMS. As such, we have included an explicit class of activity that involves data collection within our IRM in order to support EHR recording requirements at various stages of the workflow. Data is recorded as a result of an instruction activity being executed – the rationale for that data then includes a link to the data collection activity within the instruction execution entry that initiated it. However, while we can use instruction definitions to say what to record, and provide a link (back to that definition that specified what data to collect) in the rationale construct for an entry that was made as a result of an instruction activity being performed, we still need to know exactly where to look for that EHR data in the first place. Where it was initiated is recorded, but where to look for it? The definition only specifies the set of archetype ids/templates needed for data recording, but does not specify a reference to the actual resulting EHR instance. The execution entry allows for this. Thus, it enables the relevant instruction-related data to be grouped and reside in a particular place for a particular care process and activity. The execution entry allows a direct and efficient way to retrieve the source data. Furthermore, while persistent transactions allow for similar da-

ta items to be grouped accordingly (e.g., medications list, problem list, family history, etc), so too do our composite instructions (i.e., care processes).

3.4.2. Instruction Reference Model (IRM)

In general, instructions may contain one or more activities, which are either atomic or composite (i.e. containing two ore more activities). Activities are linked via connectors. These connectors represent the valid types of ordering and execution of activities within an instruction, namely, sequence, split, conditional_loop, and-_join, and choice_joins. The pre- and post-conditions for executing activities (i.e. the conditions pertaining to the workflow or instruction execution state rather than the patient state) are implied by the type of connector. For example, for the sequence connector, an activity will only ever be able to be started, if its preceding activity has completed.

Instruction Definition Entries

The instruction definition entry (Figure 3.14) plays the role of a process definition, and has the following attributes, which at minimum, are used to capture notes that the provider may have about the instruction: data, protocol and rationale. The instruction definition entry may only be included in an event transaction, and is referred to by a single instruction execution entry within a persistent transaction. It also identifies the guideline to be followed (if required). Thus, the instruction definition entry is used to indicate that some “activity” needs to be undertaken.

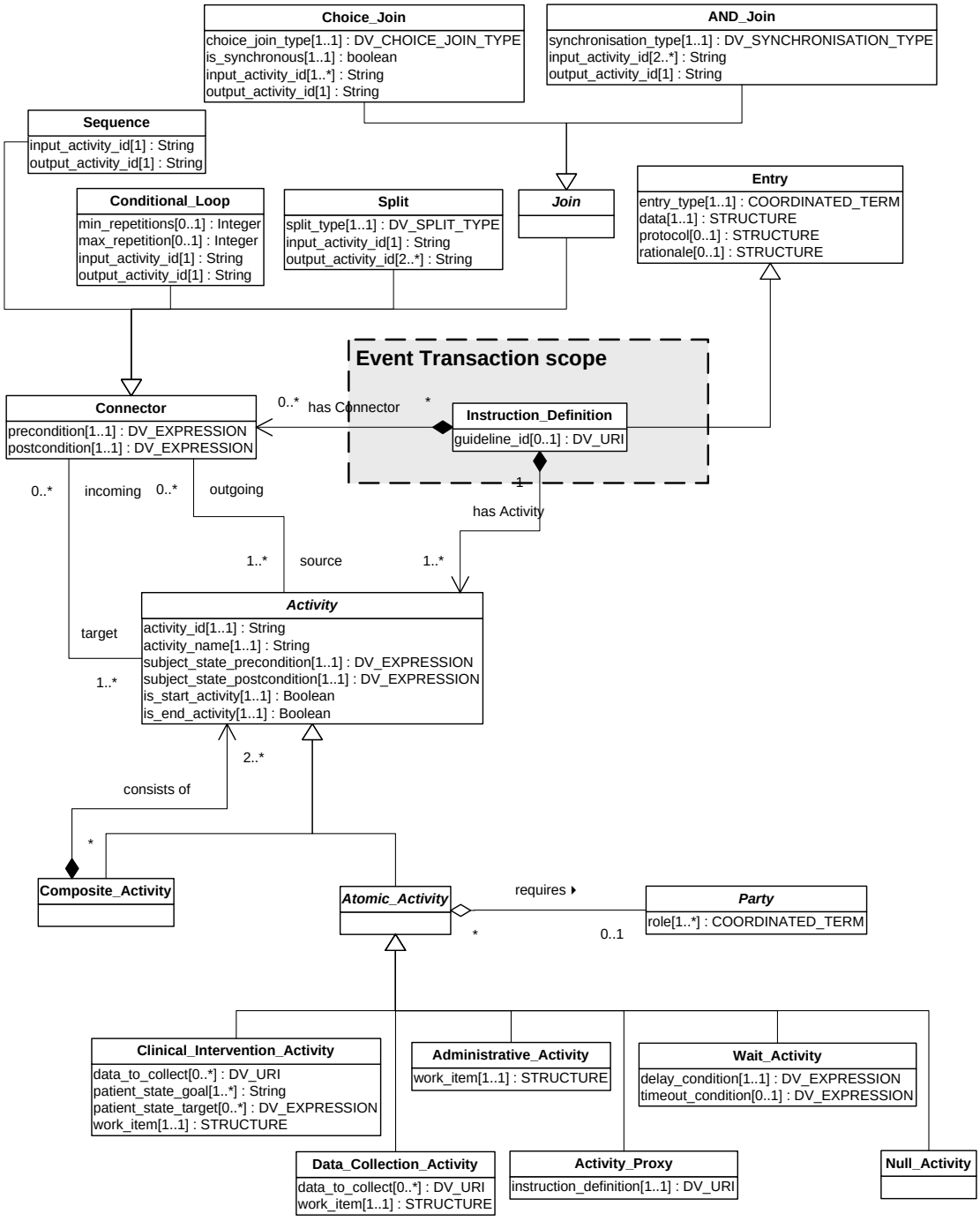


Figure 3.14. Reference Model for Instruction Definition.

An activity may be structured (i.e. contains composite activities) and some activities (proxy activities) may refer to other instructions (e.g. when a guideline relies on another guideline), or they may be atomic. The IRM has several classes of atomic activities including:

- Clinical_Intervention_Activity: a clinical act or fact of interfering with the intention to modify (i.e. to change somewhat the form or qualities of) the patient's health [44]. E.g. "administer anti-hypertensive drug". The activity allows one to state the goal or desired patient health outcome of undertaking the intervention, as well as being able to define a specific patient variable target such as a blood pressure target of 130/80 mmHg;
- Data_Collection_Activity: the activity of collecting observations only rather than an act intended to influence the patient state. However, all clinical interventions generally result in data collection, although not necessarily observations. For instance, assessments will result in the collection of evaluation entries, and care plans, which result in instructions being recorded.
- Administrative_Activity: Non-clinical/health-related type of activity that may be performed manually (human task), or allocated to some administrative application. E.g. system notifications and reminders. Data collected as a result of administrative tasks undertaken are not considered to be stored in the EHR itself; therefore, there is no data_to_collect attribute. Other application(s) or system(s) (such as a clerk's desktop) may store this information instead.
- Activity_Proxy: an activity that refers to another instruction definition generally used when referring to another clinical guideline; and
- Wait_Activity: an explicit activity to delay before the next activity takes place. This is generally used for specifying relatively long waiting periods, such as recalls for immunisation.
- Null_Activity: an activity that is used for representing complex routing or conrol flow that cannot be defined efficiently using conventional process definition notation (see Instruction Connectors explained later in this section). The Null_Activity has no associated work, resource or application definition. This activity is equivalent to the WfMC's Dummy Activity, and also referred to in other workflow literature as a Route Activity.

A work item as defined by the WfMC is "the representation of the work to be processed (by a workflow participant) in the context of an activity within a process inst-

ance" [153]. Usually, an activity may require one or more work items, which together constitute the task to be undertaken by the user or the performer of the activity. Thus, the work item of activities describes the work to be done once an *atomic activity instance* has been assigned to a *party* or role.

An important aspect considered in the model is the ability to explicitly specify the "data_to_collect" for clinical interventions and data collection activities. This may include data for accountability purposes, negative findings and excluded or rejected management options. The "data_to_collect" attribute value may specify the archetype ID from which the required EHR form needs to be instantiated from and made available for data entry when that activity is eligible to be undertaken (e.g. an assessment form for an OT home assessment activity), and only completes when that record has committed.

The subject state pre and post conditions on activities are used for capturing conditions related to the subjects state (e.g. age > 25 and smoker), rather than connector conditions, which relate more to execution state (e.g. executing, complete). Pre- and post-conditions for execution (not subject conditions) were removed as they are implied by the type of connector that is used.

The following describe the subset of the *open*EHR data types that are used by the IRM:

- COORDINATED_TERM: A fully coordinated (i.e. all "coordination" has been performed) term from a terminology service (as distinct from a particular terminology). This data type is part of a DV_CODED_TEXT.
- DV_EXPRESSION: This is simply an expression consisting of operators (Boolean, relational, arithmetic, set operators and functional operators) and operands (EHR data items such as weight, blood pressure; variables obtained from external sources such as from a user or machine (e.g. pulse, temperature); environmental variables such as time, room temperature; and constants of appropriate types.
- DV_CHOICE_JOIN_TYPE: An enumerated type that has the following set of valid values: "XOR_join", and "OR_join".

- DV_SYNCHRONISATION_TYPE: Enumerated type that may have the following values: “synchronous”, “partly_synchronous”, and “asynchronous”.
- DV_SPLIT_TYPE: Enumerated type that has the following possible values: “AND_split”, “XOR_split”, and “OR_split”.
- DV_STATE: Data type that represents state values according to some defined state machine such as a variable representing the states of an instruction or care process.
- DV_EXECUTION_STATE: A specialised DV_STATE data type pertaining to the state of a system’s execution. It is an enumerated data type that has the following valid data values: “Initial state”, “Final state”, “Ineligible”, “Eligible”, “Executing”, “Completed”, “Aborted”, and “Suspended” (see section on “State Machine Model for Instruction”).
- DV_EXECUTION_STATE_CHANGE: An enumerated type of the value set: “Initialise”, “Enable”, “Disable”, “Start”, “Complete”, “Abort”, “Suspend”, “Resume”, “Re-enable”, and “Destroy”. This data type specifies the set of possible state changes that drive the execution state, and thus has a direct relationship to DV_EXECUTION_STATE.

Instruction Execution Entries

Instruction execution entries (Figure 3.15) are created within persistent transactions as a result of an event transaction being loaded which contains instruction definition entries. The instruction execution entry may only reside in the EHR as (or as part of an existing) persistent transaction, and is referred to by a single instruction definition entry within an event transaction that initiated it. The instruction execution entry plays the role of a *process instance*, and maintains similar attributes to its instruction definition counterpart except that most of these will contain actual values as a result of executing the instruction. In particular:

- Instruction execution entries record the state of each activity as an activity instance identified in the instruction definition. An activity instance may be atomic, composite or a proxy that refers to other instruction executions (if they have in fact been initiated and are currently executing), otherwise they may refer to other instruction definitions (which are yet to be executed at some point in the future).

- The work list manager queries the atomic instruction activity instances to find work currently assigned to a user.

In our implementation, the subject_state_pre- and post- conditions are specified in a compressed version of GELLO, which is an object-oriented expression language that is built upon the previous work on the GLIF guideline representation that led to the development of the expression language called GEL. The original intent of GEL was to reconcile the differences between the Arden Syntax data model and that of the HL7 RIM v3 making it directly compatible with the HL7 RIM. Furthermore, it supports basic types as well as complex data structures, and allows methods to be associated with classes in addition to attributes [154]. A locally coded term set is also used as part of the expressions within our subject_state_pre- and post-conditions, for allowing the use of locally defined code that covers those terms not likely to have a UMLS. More complex GELLO data query and expressions (especially, complex composite ones) may be allocated to a decision support application for evaluation of CiG decision criteria. However, for our prototype, in particular in its application to our case study in Chapter 5, it can be decomposed into relatively simple Boolean expressions (that may be determined from the data values attainable from the EHR, or alternatively queried from the provider at the point of care. In our prototype demonstration, these relatively simple expressions are evaluated via the WfMS.

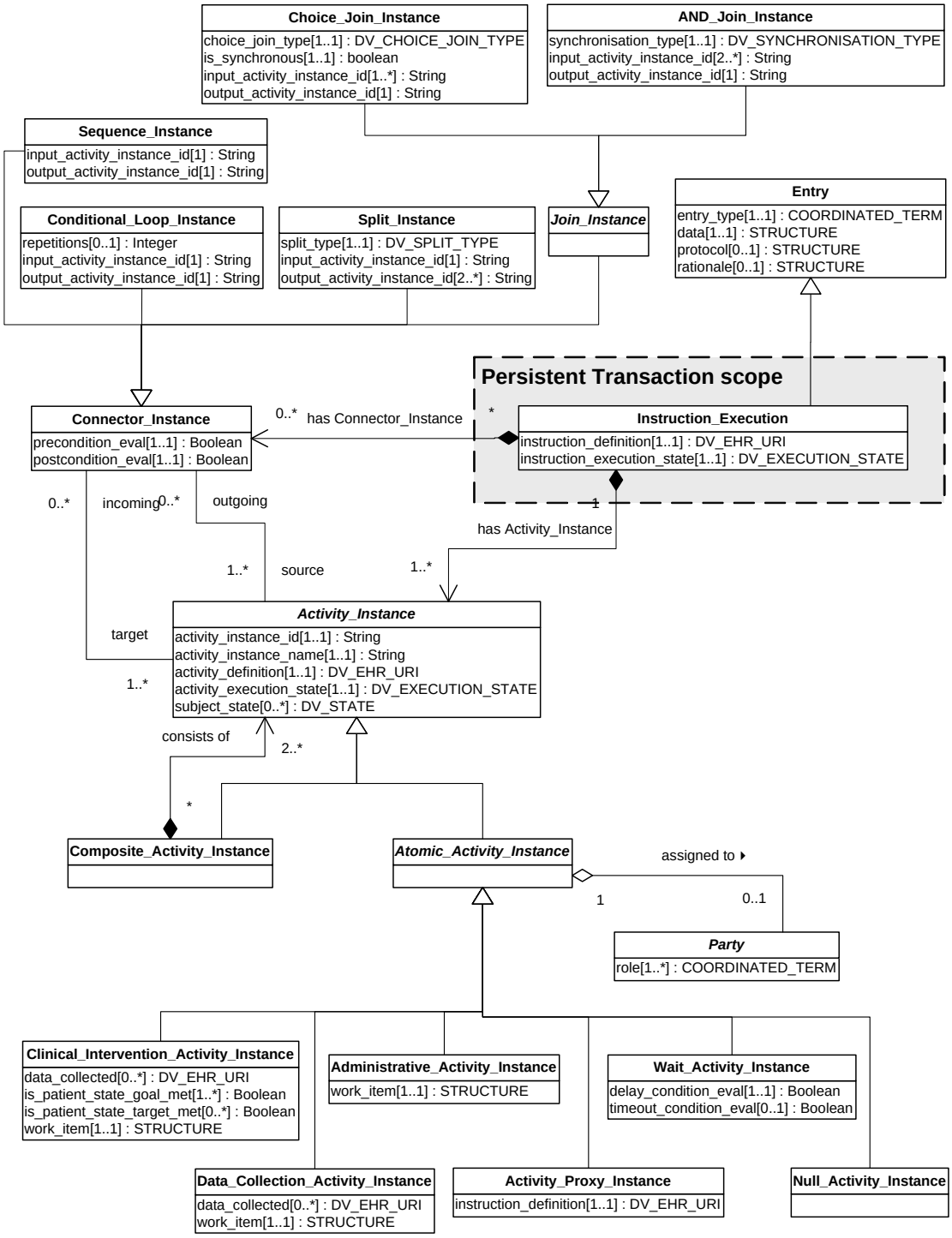


Figure 3.15. Reference Model for Instruction Execution.

Standards Alignment with the WfMC's Workflow Specification

Our IRM specification introduced in this thesis (see Figure 3.14 and Figure 3.15 in particular) *extends* the current *open*EHR instruction reference model presented in [77], and is designed to align with the WfMC's workflow specification [155]. The WfMC's reference model was chosen because it is widely implemented by a number of commercial workflow system vendors. Table 3.1 below shows the alignment of concepts within our IRM to the concepts within the WfMC's standard workflow model.

Table 3.1. Alignment of our IRM to the WfMC's workflow model.

WfMC Concept and Definition	**IRM *Equivalent***
Process Definition: Definition of a business process, which consists of one or more activities (Synonyms: Workflow schema, workflow definition)	A patient centred definition is captured as an **Instruction definition** in the EHR reference model. A generic process definition is captured as an **Instruction definition** in the archetype model of the EHR.
Process Instance: An enacted process definition, consisting of one or more activity instances (Synonyms: Workflow instance)	**Instruction execution**
Activity: Definition of a piece of work that forms one logical step within a process definition. (Synonyms: Task)	**Activity**
Activity Instance: (Synonyms: Task instance)	**Activity Instance**
Sub process: (Synonyms: subflow, sub workflow)	**Activity Proxy**
Activity Block: (Synonyms: activity set)	**Composite Activity**

Transition: A point during the execution of a process instance where one activity completes and the thread of control passes to another.	**Connector**
	Connector Instance
Event: An occurrence of a particular condition (which may be internal or external to the workflow management system), which causes the workflow management software to take one or more actions.	Handled as part of the "EHR work list manager"
Activity Instance: An enacted activity, which is part of a process instance. An activity instance usually results in the creation of one or more work items.	**Activity Instance**
Work Item: A representation of the work to be performed within an activity instance. A work item is to be performed by a specific workflow participant	**Atomic Activity.work_item**
Workflow participant: A participant in a workflow.	Atomic Activity Instance *assigned to* **Party**
Work list: List of work items allocated to a workflow participant	Extracted by work list manager (see Chapter 4)

Instruction Connectors

There are a number of workflow patterns identified by workflow researchers, and in particular, those identified in [139]. This section will discuss how some of the more commonly used workflow patterns are supported, and the extent to which our IRM's Instruction Connectors can capture them.

Note that a few of the workflow patterns identified in [139] are not currently explicitly representable in the WfMC's XML Process Definition Language (XPDL), namely the Multi-Merge, the Discriminator, and the N-out-of-M-join patterns. The

level of support for the workflow patterns provided by XPDL is detailed in [144]. This mapping from XPDL to Instruction is particularly important as will be seen in Chapter 4 as we transform from XPDL to Instruction models. Where there is no direct and explicit support of a workflow pattern, an alternative or workaround solution is presented. It is also important to note that the less commonly used patterns are not directly supported by most WfMSs. These include: Synchronising Merge, Mult-Merge, Discriminator, and N-out-of-M-join. The Arbitrary Cycle pattern is also one that is not directly implementable in all WfMS.

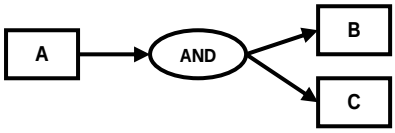
Instruction Reference Model Workflow Pattern Equivalence

Sequence

The enabling of one activity after the completion of another activity in the same process.

IRM Connector Equivalent: Sequence connector.

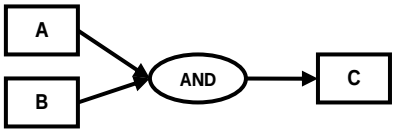
Parallel Split



A point in the process where a single thread of control splits into multiple threads of control and can be executed in parallel (at the same time or in any order).

IRM Connector Equivalent: Split connector with attribute split_type = AND_split.

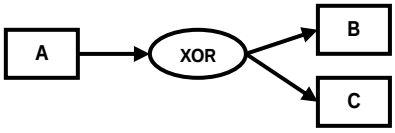
Synchronisation



A point in the process where multiple parallel branches merge into a single thread of control.

IRM Connector Equivalent: AND_Join connector with attribute synchronisation_type = synchronous.

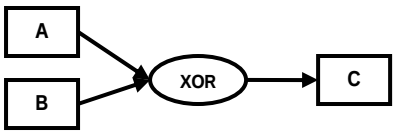
Exclusive Choice



A point in the process where based on decision data, only one of several branches is chosen.

IRM Connector Equivalent: Split connector with attribute split_type = XOR_split.

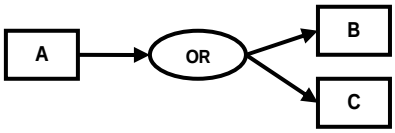
Simple Merge



A point in the process where two or more alternative branches meet without synchronisation.

IRM Connector Equivalent: AND_Join connector with attribute synchronisation_type = asynchronous.

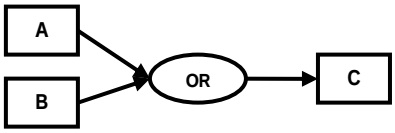
Multi-Choice



A point in the process where based on decision data, one or more branches are chosen and executed in parallel.

IRM Connector Equivalent: Split connector with attribute split_type = OR_split.

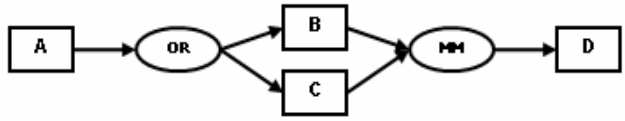
Synchronising Merge



A point in the process where multiple executing threads merge into a single thread of control. Not all branches may be executed.

IRM Connector Equivalent: Choice_Join connector with attribute choice_join_type = OR_join, and is_synchronous = true.

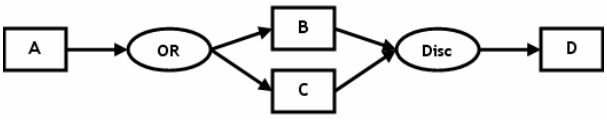
Multi-Merge



A point in the process where one or more threads reconverge without synchronisation. That is, if more than one branch is executed then they are executed in parallel, but are then reconverged asynchronously such that activity "D" is started for every incoming branch.

IRM Connector Equivalent: Split connector with attribute split_type = OR_split, and Choice_Join connector with attribute choice_join_type = OR_join, and is_synchronous = false.

Discriminator



A point in the process where the process waits for one out of one or more threads to complete before starting the subsequent activity. It then waits for all remaining threads to complete and 'ignores' them. Once all incoming branches have been triggered, it resets itself so that it can be triggered again.

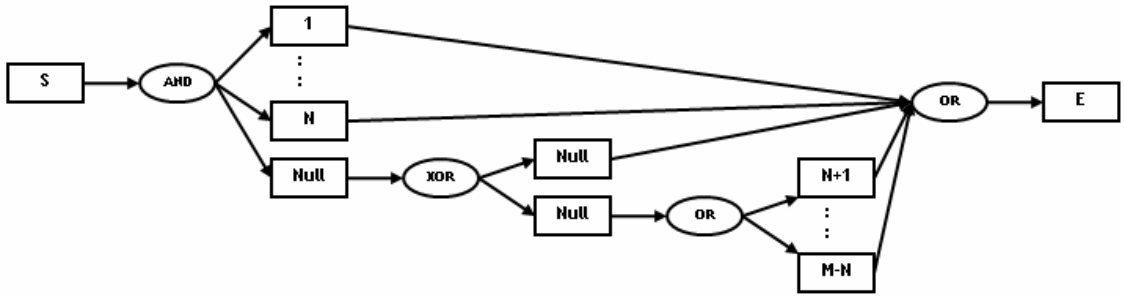
E.g. a clerk might send requests to multiple orthodontic organisations on behalf of a patient to be booked for a surgical appointment. The clerk waits until she has received a response from each of the organisations she sent a request to. The organisation that responds with the earliest available time is chosen and the other responses are ignored. The clerk then schedules the patient for an appointment at the chosen time.

IRM Connector Equivalent: Split connector with attribute split_type = OR_split, and Choice_Join connector with attribute choice_join_type = XOR_join, and is_synchronous = true.

Setting synchronisation to true ensures that the subsequent activity can be started when it receives an incoming branch that was triggered, but does is not considered 'complete' until all branches that were triggered have completed. Only when that subsequent activity is complete, it can be enabled again (e.g. if it has a loop).

Setting synchronisation to false will allow the subsequent activity to start as soon as one of the incoming branches completes, and completes and allows it to be enabled again without waiting for the other triggered branches to complete.

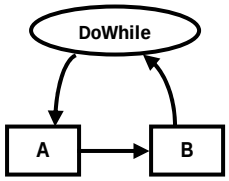
N-out-of-M-join



A point in the process where "M" parallel threads converge into one, but the subsequent activity can only be enabled when "N" threads have completed. Similar to the discriminator, completion of any remaining thread is ignored.

IRM Connector Equivalent: Split connector with attribute split_type = AND_split that splits an activity into "N" number of activities, and a Null_Activity. The Null_Activity is followed by a split connector of split_type = XOR_split that splits into two activities of type Null_Activity. One Null_Activity is for simply choosing not to do any of the "M-N" activities. The other splits using the OR_split into the set of "M-N" number of activities. All of these threads are then converged using the OR_Join that has the attribute is_synchronous = true.

Arbitrary Cycles



A point in the process where based on decision data, one or more activities can be executed repeatedly until it no longer satisfies the loop condition.

IRM Connector Equivalent:

Conditional_Loop connector with optional attributes: min_repetition, max_repetition set to the desired values; otherwise, the pre-condition (attribute inherited from Connector class) sets the condition for executing the looping branch. When this pre-condition is no longer satisfied, the flow of control exits the loop.

Instruction Definition Examples

Figure 3.16, 3.17 and 3.18 show examples of relatively basic instructions to illustrate the use of our different types of IRM connectors using Unified Modelling Language (UML) Object Diagrams. Object diagrams illustrate instances of classes captured at a particular point in time. The diagrams consist of Objects and Associations. The notation for associations between activities and connectors in particular, conform to the notation used for associations between *activity nodes* and *activity edges* in Figure 177 (p. 269) of [156] such that an activity may have an associated 'incoming' and/or 'outgoing' connector(s), and a connector may have one or more associated pairs of 'target' and 'source' activity/activities.

Example of a "Sequence" connector

A good example of an Instruction that has sequential activities is a chained medication order. A chained medication order is a medication order in which a drug consists of segments (essentially, a separate drug order) that have administration details such as route, form, frequency and dose changed [77]. This is typical in hospitals for instance, where a drug may first be administered intravenously, followed by the same drug being administered in the form of a tablet [77]. The first example (Figure 3.16) illustrates the use of the sequence connector for a chained medication order instruction in which the number of aspirins and the frequency of intake in particular, are reduced between the first and second medication orders.

Example of a "Conditional loop" connector

Recalls are typically communication actions (e.g. system notifications) or appointments that need to occur at a particular point in time. They are usually generated by care plans – common to chronic disease management including podiatry visits for diabetes patients, or public health procedures such as vaccination programs and Pap smear checkups [77].

Figure 3.17 illustrates the use of a conditional loop connector within a Pap smear recall. The relatively simple instruction shown includes a data collection activity of collecting Pap smear observation every 3-4 years. Although the instruction may be modified to include an administrative activity in which system automatically sends a notification to the provider and patient reminding them of the appointment.

Example using "Exclusive OR" connector

The third example (Figure 3.18) illustrates the use of the exclusive OR connector in the context of the inpatient medication order, which is a more complex instruction than the chained medication order. In this case, the medication order may be cancelled/aborted, or administration of the drug may commence. Once the drug is being administered, the drug may continue to be administered over a period of time (via a conditional loop connector), or its dosage may be altered, or ceased. Note that other aspects of the drug may be altered also such as the form, frequency, etc. Thus, the

‘Alter Dose’ activity within the instruction may be modified to a more generic ‘Alter Drug Attribute’ or something similar to support the types of alterations to the drug.

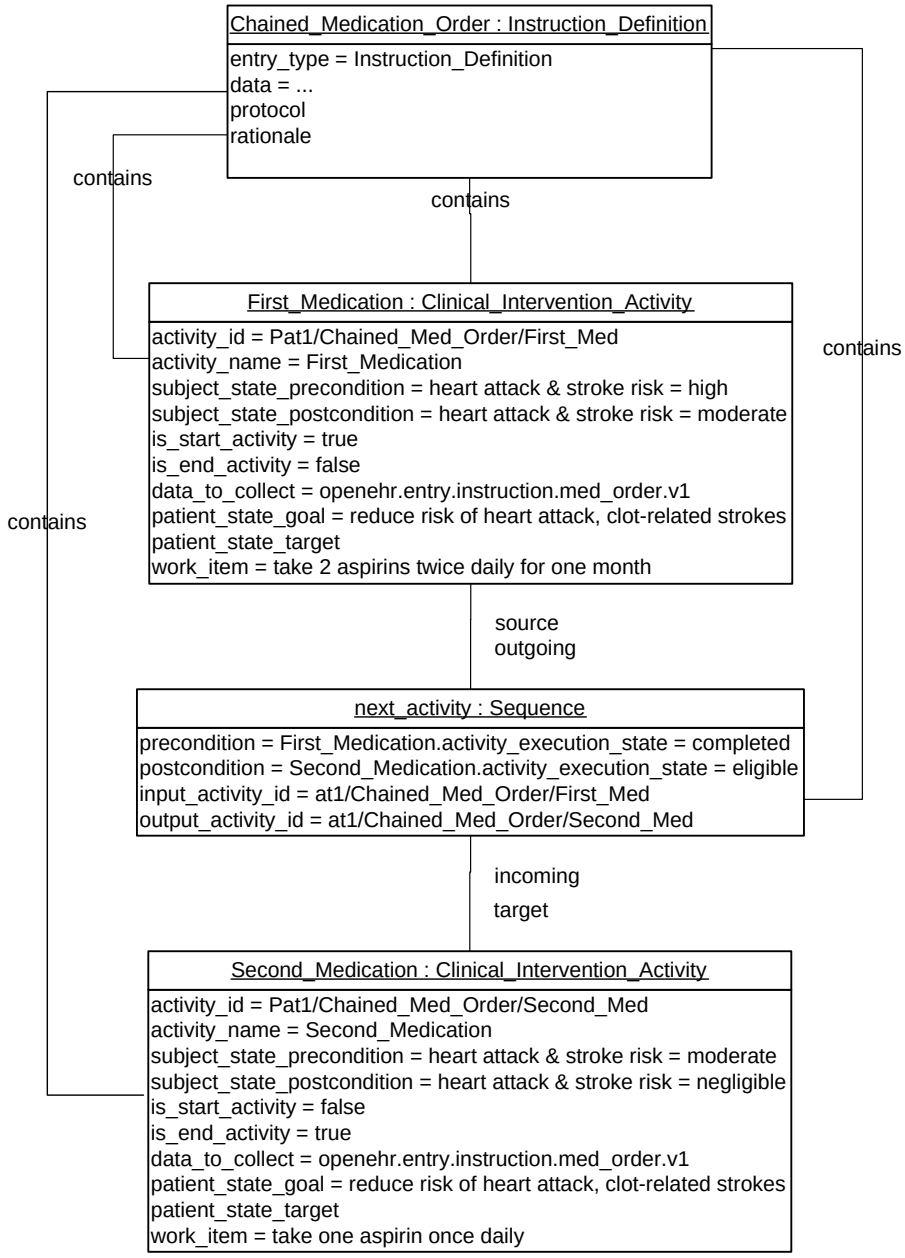


Figure 3.16. A chained medication order in an instruction definition.

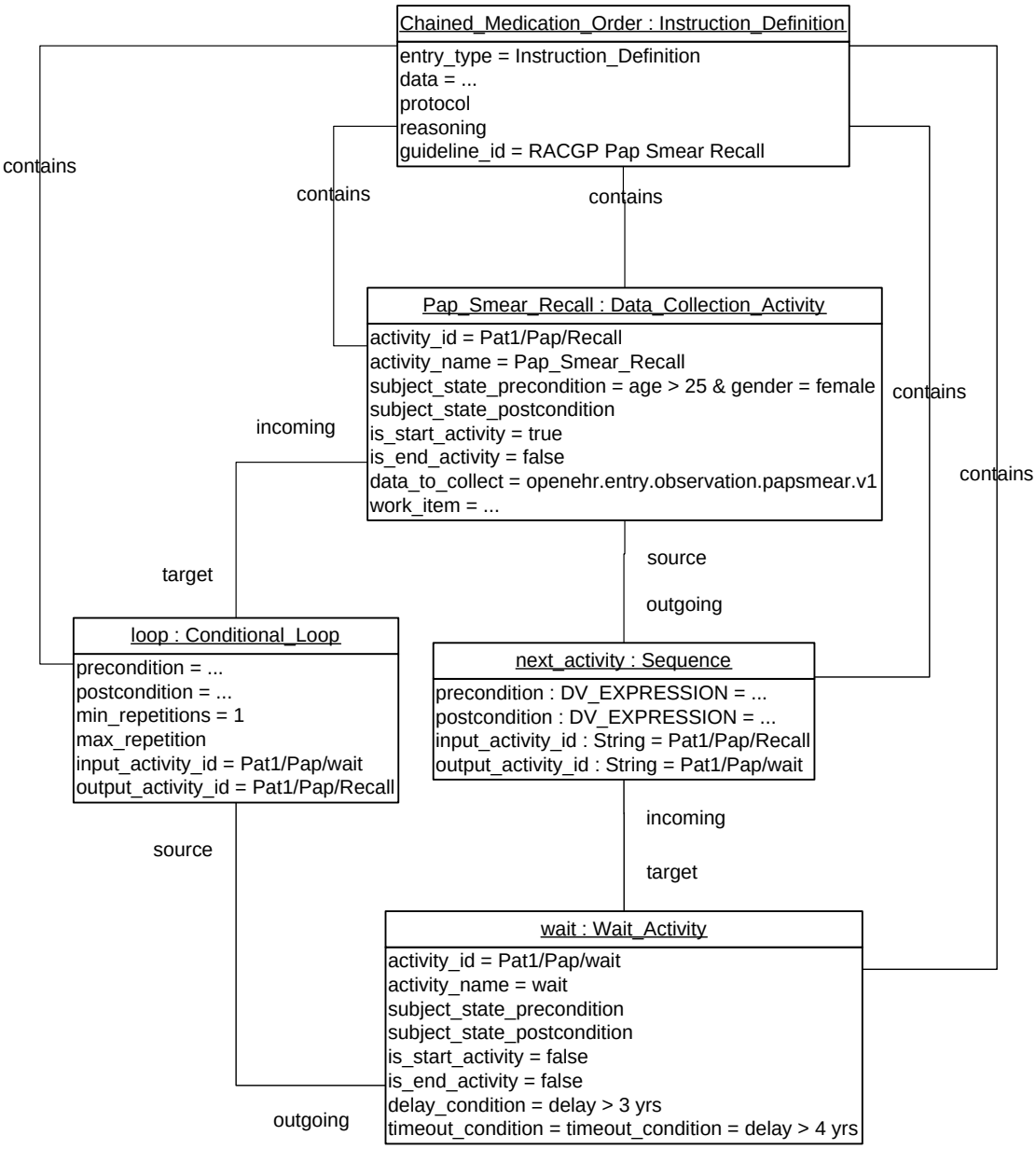


Figure 3.17. PAP smear recall in an instruction definition.

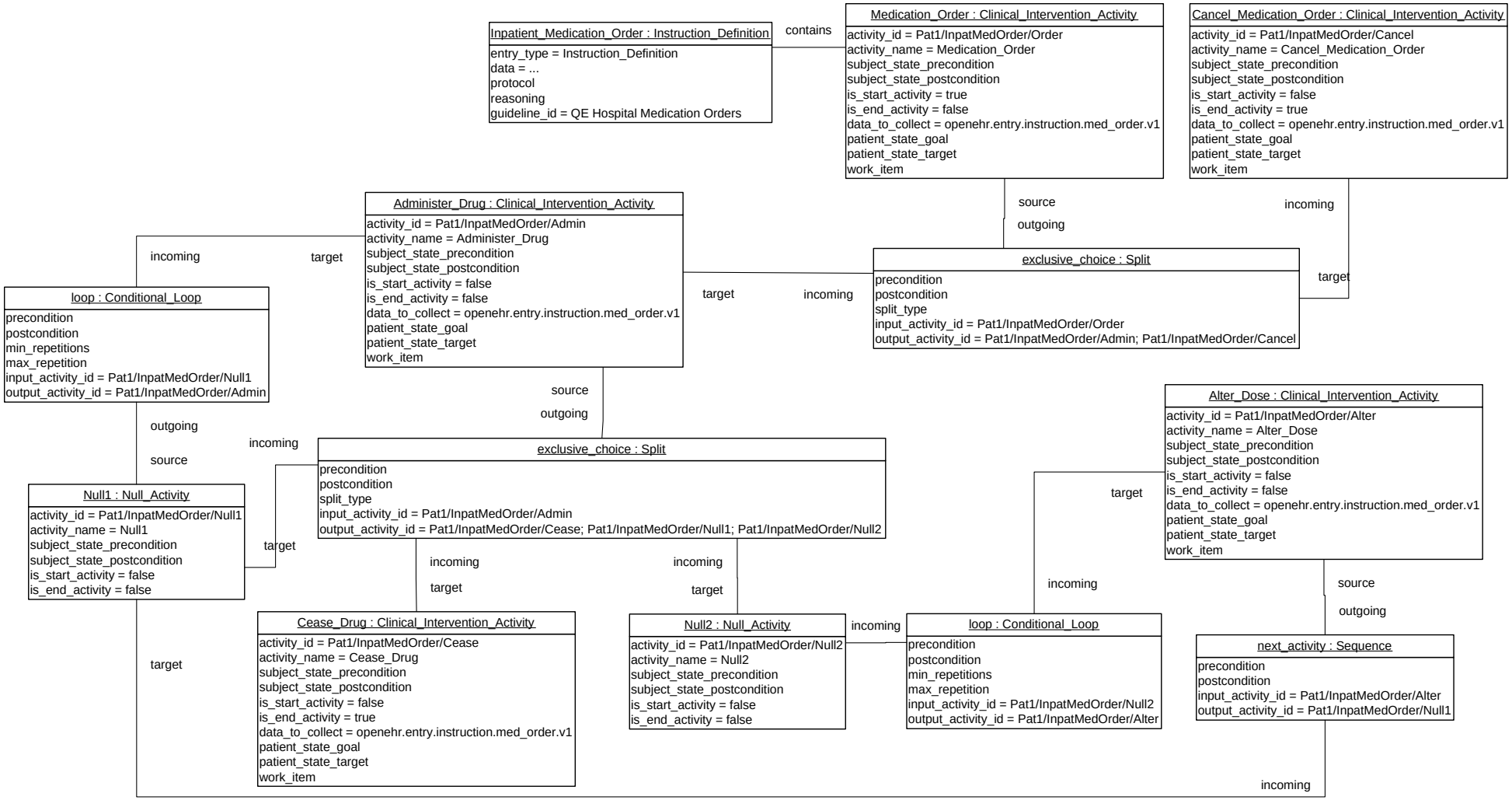


Figure 3.18. Inpatient medication order instruction definition.[5]

[5] The association labelled “contains” between the Instruction_Definition object and each of its connector and activity objects have not all been drawn for the purposes of readability.

State Machine Model for Instruction Execution

Instructions specify the actions that are intended to occur in the real world, and typically they include conditions for starting, delaying, repeating, stopping or canceling – all of which are influenced by real world events. For example, the instruction to begin administering a particular pain reliever to a patient might be due to migraine headaches, but the administration of that drug might be ceased due to adverse drug events. In general, instructions and activities within instructions progress through meaningful states of execution as a result of the occurrence of events. Figure 3.19 shows the state machine model for instruction execution entries.

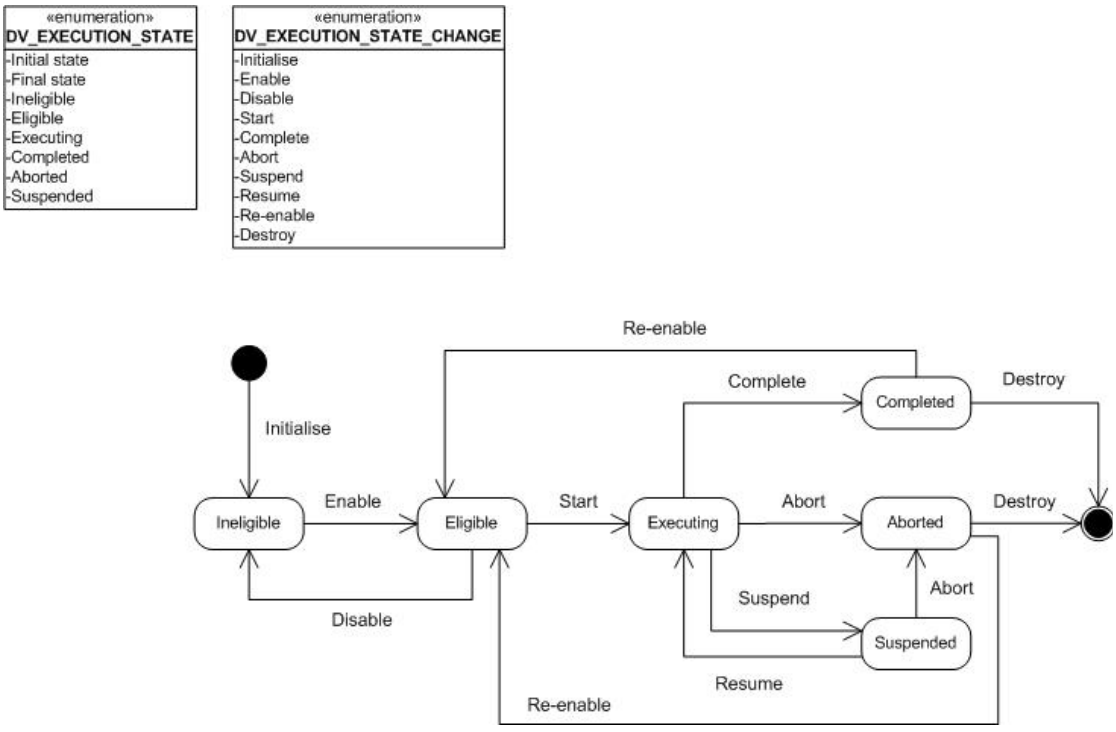


Figure 3.19. State Machine Model for Instruction Execution.

- *Ineligible*: service object is disabled and cannot be started.
- *Eligible*: service object is in preparation awaiting or enabled to be started or executed.
- *Executing*: service object is running.

- *Completed*: service object execution is completed.
- *Suspended*: execution of a service object is temporarily suspended.
- *Aborted*: executing service object is terminated due to an exception.

It is worth noting that the state machine model may be too granular to be executed by the system itself for some instances of instruction, especially those that are largely executed in the real world. For instance, not all states may necessarily be set – e.g., the administration of a medication may go from 'enabled' to 'completed' without having been set to 'executing' beforehand, because execution entailed the patient administering the drug in the real world. Thus, the progression of states in such circumstances will largely depend on the incoming events, and how much the provider interacts with the system. There is also the healthcare provider prerogative to ignore the preconditions of the Instruction Definition and go ahead and execute an activity if he/she deems it in the patient's interest, even if the state is 'ineligible'. In this sense, the 'ineligible' state represents the semantics of the model, but not necessarily of the real world.

3.5. Guideline Engineering Process

Chapters 5 and 6 provide case studies that demonstrate our approach to engineering the guideline document into a set of EHR, CiG, and workflow artefacts, and illustrate the coordination of these artefacts within an integrated system. By undertaking the guideline engineering process described herein, we are able to take a source guideline document and develop the required set of artefacts (i.e. specifications).

3.5.1. Analysis

The process shown in Figure 3.20 begins by an analysis of a source clinical guideline document and abstracting from it the required set of actors/roles, the interaction between them, actions to be performed, decision points, and the data or information flows – all of which assist in the development of scenarios.

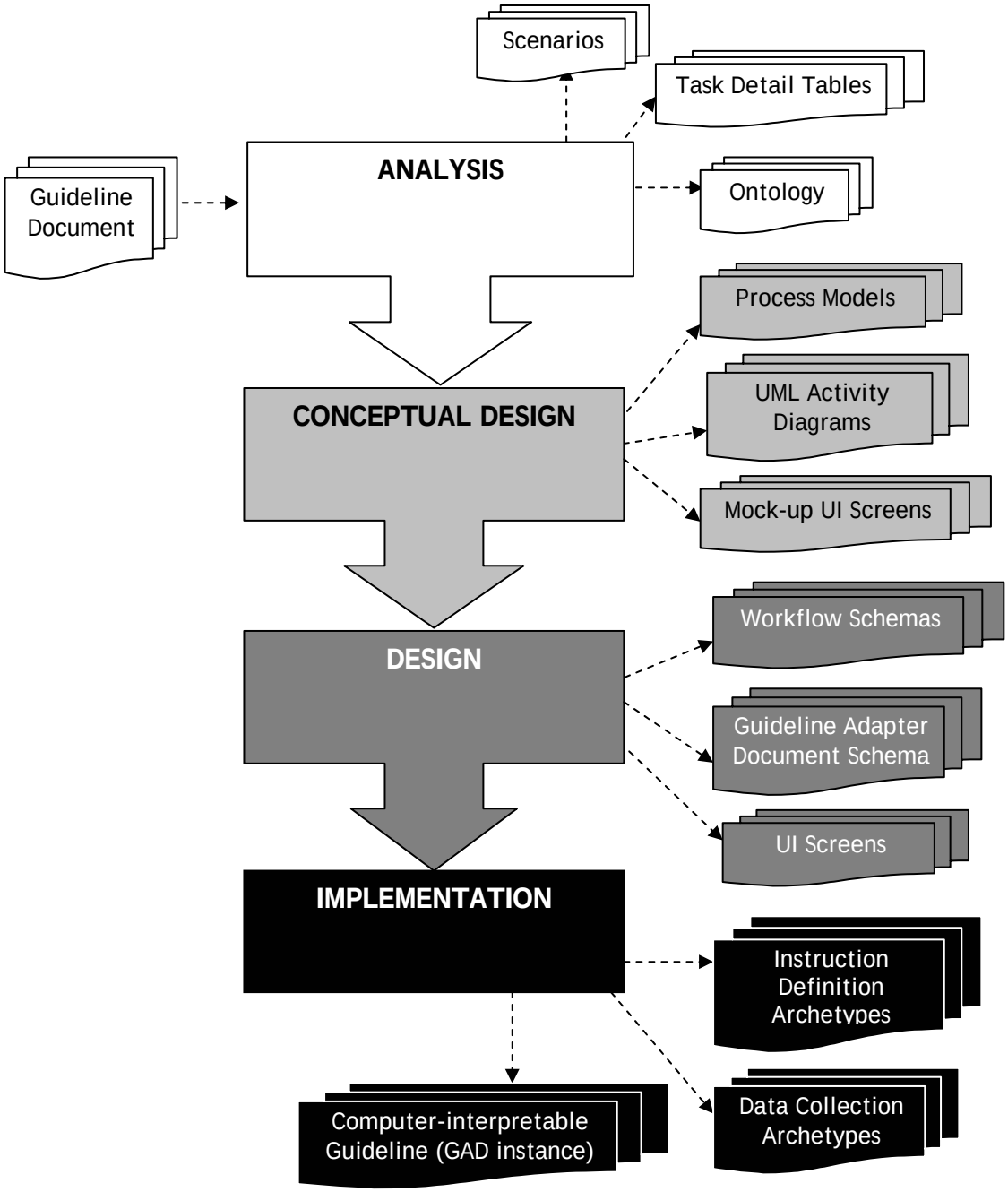


Figure 3.20. Guideline Engineering Process and Associated Key Deliverables.

Scenario Development

A *scenario* is described as "a sequence of events especially when imagined; *especially*: an account or synopsis of a possible course of action or events" [43]. Scenarios provide a description of interactions between identifiable entities, "actors", or participants (that may be either human or system), as well as the documentation of

the temporal sequencing of a set of actions. A single scenario is usually developed to achieve one or more goals by one or more participants. The term "scenario" is also synonymous, or at least has *some* similarities with a number of other terms such as "case", "case study", "user study", "storyboard", and "use case". The latter (in UML) however, usually implies a more structured and abstract description of a "scenario" in that its temporal sequencing is defined in terms of pre- and post-conditions, and that it describes the interaction between two participants (i.e., human-to-system interaction, or system-to-system interaction) to achieve a single use or goal. Thus, a scenario itself can be decomposed into a set of use cases. In other words, scenarios are 'walkthroughs' of the use case using real world data, and are essentially purposeful in validating the use cases through real world applications. Furthermore, scenarios are usually directly comprehensible by stakeholders. "Storyboard" is a term used in HL7 in preference to "use case" [157], and is equivalent to the meaning of "scenarios" to be developed in this section. In general, each scenario should document the:

- Business process, goal(s), or application(s) that drive the scenario;
- Business and technology environment;
- Set of people and system components (i.e., "actors") who perform the scenario;
- Desired outcome of proper performance of the scenario;
- Business process as a temporal sequence of activities to enact;
- Mapping of actor(s) to activity/ies;
- Mapping of environment to activity/ies; and
- Data/information flow throughout the scenario between actors.

Scenarios are usually documented in a natural language or narrative format, or graphical models (such as UML Activity Diagrams [see section 3.5.2] for capturing the dynamic nature of scenarios) supplemented with a narrative (e.g., some modified, less-structured version of a UML Use Case Specification to suit *scenarios* rather than "use cases").

From the narrative formatted scenarios, the actors and the specific roles they play are identified, and a task detail table is created for each actor/role. The task detail table describe each of the steps or tasks to be undertaken by an actor/role in the scenario. The tasks are also numbered to indicate the ordering of the steps and to also serve as

task identifiers for later reference within the software development process. Furthermore, each table also describe the input data requirements for each task. The tables are used to demonstrate how our proof-of-concept prototype works to support an actor in each task within a given scenario, and the task identifiers are used as a reference when describing in detail the types of system interactions that occur for the relevant task.

Guideline Ontology

One of the most commonly used and detailed definitions of the term *ontology* in the realm of artificial intelligence (AI) and knowledge representation is given in [158]:

> *"Ontology is an explicit specification of a conceptualization. The term is borrowed from philosophy, where an Ontology is a systematic account of Existence. For AI systems, what "exists" is that which can be represented. When the knowledge of a domain is represented in a declarative formalism, the set of objects that can be represented is called the universe of discourse. This set of objects, and the describable relationship among them, are reflected in the representational vocabulary with which a knowledge-base program represents knowledge. Thus, in the context of AI, we can describe the ontology of a program by defining a set of representational terms. In such an ontology, definitions associate the names of entities in the universe of discourse (e.g. classes, relations, functions, or other objects) with human-readable text describing what the names mean, and formal axioms that constrains the interpretation and well-formed use of these terms. Formally, an ontology is the statement of a logical theory".*

The use of ontologies have become increasingly important as they serve as the critical semantic foundation for many technologies such as software agents, e-commerce and knowledge management [159].

Simple ontologies are used for a number of reasons [159]:

- Controlled vocabulary
- Site organisation and navigation support
- 'Umbrella' structures from which to extend content
- Browsing support

- Search support
- Sense disambiguation support

Whilst structured ontologies provide the following uses [159]:

- Consistency checking
- Completion
- Interoperability support
- Support validation and verification testing
- Encode entire test suites
- Configuration support
- Support structured, comparative, and customised search
- Exploit generalisation/specialisation information.

Since the use of declarative knowledge representations in AI such as semantic networks and frames, there have been a number of developments for specifying ontologies, including the World Wide Web Consortium (W3C)'s Semantic Web initiative [160] that developed the DARPA Agent Markup Language and Ontology Inference Layer (DAML+OIL) [161], its predecessor the Resource Description Framework (RDF) (which is based on URI and XML technologies) [162]; and Web Ontology Language (OWL) [163].

For our case study presented in Chapter 6, we develop an ontology based on the Texas hypertension management for diabetes guideline [57] (see also Appendix G) as part of our analysis of the domain or case study in question, and conceptual design of a system that integrates guideline-based decision support, workflow and EHR. We use the term 'ontology' and represent it in the simplest form by abstracting the *concepts* and *relationships* between the concepts in the universe of discourse hypertension management for diabetes, and representing them in diagrammatical and hierarchical format for human readability. Furthermore, this simple ontology allows us to extend it with further concepts and relationships required for specifying the archetypes and templates for data collection.

3.5.2. Conceptual Design

After developing scenarios, further abstraction is made during the conceptual design phase to produce process models, which may be represented as data flow diagrams. Mock-up user-interface screens are also developed to simulate the interactions between the providers and the clinical information system and to further refine requirements from the system. UML activity diagrams are also produced to illustrate the system component interactions when DSS and/or WfMS are used.

3.5.3. Design

In the design phase, UML sequence diagrams are produced to formalise the interactions in these guideline usage and workflow scenarios. We also produce any workflow schemas required from actions recommended in the guideline. The workflow schemas provide the formal specifications of the process models developed during conceptual design, and ideally should be in a machine processable format such as XPDL (which is the WfMC's XML Process Definition Language – format chosen in this thesis).

We develop a computer-interpretable specification of the guideline based on the ontology created in the analysis phase. The chosen specification format in this thesis is XML Schema. (Note that there would be considerable merit in modelling with Protégé [116] and exporting from this tool to OWL. The example presented herein is only suggestive of the general process). Our specification is referred to as the Guideline Adapter Document (GAD) Schema. The schema is used to create valid instances of CiGs.

The last step in the design phase is to create the finalised version of the mock-up user interface screens that were developed in the conceptual design phase. This step usually requires several iterations to achieve the desired user interface and may undergo actual usability testing.

3.5.4. Implementation

Implementation is the final phase in which we produce the corresponding instruction definition archetypes from the workflow schemas, as well as other EHR archetypes needed for data collection as a result of performing the tasks in the workflow. The data collection archetypes include the GP contact/encounter transaction, SOAP note organiser, blood pressure observation entry, hospital assessment transaction, etc.

From the perspective of using the DSS, a computer-interpretable guideline is required to provide the logic/reasoning, recommendations, and other details such as hyper-media information of the clinical guideline being considered. The CiG instances or GAD instances are created and validated against the GAD XML schema.

3.6. Application to Two Case Studies

We chose to demonstrate our approach using a proof-of-concept prototype (the components of which are described in detail in Chapter 4) of the coordination of workflow, decision-support and the EHR using two distinct case studies: (1) early supported discharge for post-stroke rehabilitation, and (2) hypertension management in diabetes mellitus in adults.

3.6.1. Early Supported Discharge for Post-stroke Rehabilitation

There are particular opportunities for coordinating and supporting the flow of information as a patient is being prepared for discharge from hospital, at which time it is vital to correctly identify and service the needs related to sustaining the patient in the community. Thus, we illustrate our proposed EHR architecture and workflow interaction in the context of an ESD based on a hospital in suburban South Australia, and [164]. ESD requires coordination of the hospital discharge planner, occupational therapists (OTs), domiciliary care nurses (through the Royal District Nursing Service (RDNS)), general practitioners (GPs), long-term domiciliary care organisation, and various local government services. Such discharge processes require intensive hands-on approach and comprehensive knowledge of how to access services available in the community, allowing about 100 cases per year to be managed through a two-week

post-hospital-discharge period. A clinical information system that supported the coordination would allow significant expansion of the program. This case study allows us to investigate and explore a scenario that has emphasis on a relatively non-clinical, multi-provider system with the key characteristics including:

- Focuses on community-based care;
- Multi-site;
- Multi-disciplinary;
- Has a two-week time-frame;
- Driven by one care coordinator;
- Service-oriented

A service-oriented scenario requires much knowledge about the available services to coordinate the care of the patient and achieve patient goals. The service availability is generally driven by the demand and supply of available resources such as finance, and often these needs will have to be prioritised based on the level of urgency. Furthermore, the decision of what services are required are most often already decided during the review of the patient and rarely is there then a requirement for the needs to change during the ESD time-frame.

With these characteristics, we take the position that the scenario will provide us with an interesting and a relatively re-current situation in CDM (such that a given chronically ill patient can often have frequent hospital admissions) that requires much emphasis on the workflow process, which the system will have to support. In particular, the case study would allow us to explore the problem of providing support at a much higher level than traditional decision-support systems would provide.

3.6.2. Hypertension in Diabetes Mellitus in Adults

In contrast to problems such as post-stroke rehabilitation where workflow support features highly in the coordination of care among service providers, management of hypertension in diabetes presents more opportunities for clinical decision support and guidance with only some aspect of workflow support required. The case study has key characteristics including:

- Heavily driven by clinical decision making rather than workflow of services;

- Longer-term/life-time process;
- Care managed by the GP;
- Some workflow involved (recalls, referrals).

The purpose of choosing this case study is to investigate the implementation requirements of systems that have emphasis on highly clinical guideline and EHR interactions, and single-provider systems. In particular, we investigate a guideline-compliant scenario.

While traditional decision support systems provide alerts about guideline recommendations, the linkage to the EHR is largely left unknown or implicit. At the most, any linkage occurs one way – i.e. queries to EHR data items required for evaluating conditions and criteria for guideline recommendations. The recording of EHR data as a result of the decision being made, or the decision to comply with the recommendation is largely implicit or does not happen at all.

In this case study, we examine the problem of achieving a close relationship of EHR content to other components of a clinical information system (guidelines, decision support and workflow), particularly linking the decisions made by providers back to the guidelines. This case study shows the contribution guideline content can have on problem-specific EHR structure and demonstrates the potential for a constructive interaction of electronic decision support and the EHR.

The guideline document we have chosen to base our case study on is the [57], mainly due to its brevity and conciseness compared for example to other guideline documents in the same problem domain such as [56].

4

ARCHITECTURE

4.1. Introduction

We develop a prototype system that integrates the EHR, decision support system and a workflow management system to allow the coordination of the guideline artefacts introduced in Chapter 3. In this chapter, we describe our system architecture as shown in Figure 4.1. It makes use of two key components: the Breeze workflow architecture, and our implementation of the EHR Persistence Layer – both of which interact in the initiation and execution of instructions. Other components include the decision support system, which is based on a guideline ontology that provides the guideline recommendations from which we populate the rationale within EHR entries,

and the archetype repository that stores the standard EHR archetype instances (i.e. clinical concepts) and instruction definition archetype instances. Since the underlying models among the Breeze workflow architecture, WfMC's XPDL, and our instruction differ, some transformations are required. This chapter will describe our mappings between the models and the required transformation processes. Moreover, this chapter explains the specific extensions/modifications made to the Breeze workflow architecture for integration and implementation requirements of our approach, as well as how each of these system architecture components interact as instructions are invoked and executed.

For the purposes of demonstrating the main features our proof-of-concept prototype using the two case studies (described in the following chapters), some of the components that were not considered essential in our demonstration were not implemented. These components include the *open*EHR kernel, archetype server, and the component for presenting the hypermedia.

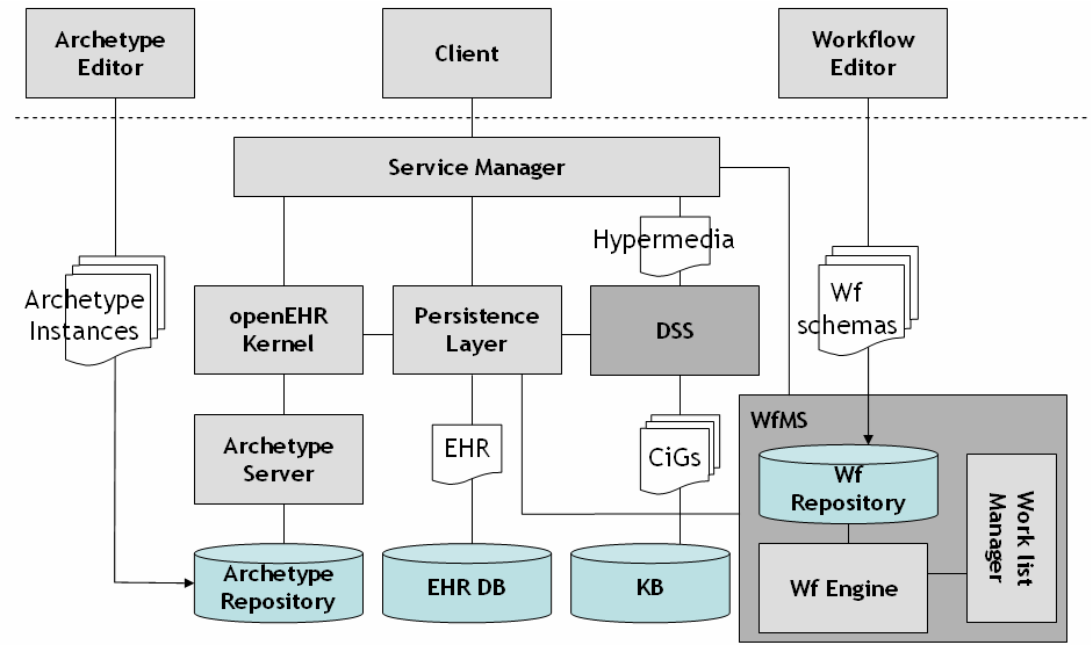


Figure 4.1. Workflow-integrated EHR System Architecture[6].

[6] Note this a 'general' architecture diagram and does not show the technology used in our prototype implementation. The specific technologies used to implement the architecture are detailed and shown in figures appearing in later sections of this chapter.

4.2. EHR System

EHR Persistence Layer

The EHR Persistent Layer records incoming event transactions to the EHR database, and updates any affected persistent transaction(s). In the event of an incoming event transaction that contains instruction definition(s), the persistence layer creates the instruction execution entry/ies (appends it to the persistent transaction), assigns identifiers to it and its activity instances, and initialises the activity statuses. It also updates the instruction execution activity statuses that may have changed as a result of required event transaction(s) being posted, and/or user interaction with the worklist, and/or updates made by the application (handler framework). Moreover, it invokes the workflow engine to instantiate and executes the workflow for that instruction.

Archetype Editor

The archetype editor is a GUI-based tool used by domain experts for authoring archetype instances. An open source archetype editor has recently been made available by the *open*EHR foundation. This editor is based on the ADL that is currently being developed. As mentioned, ADL did not exist at the time we started implementing, thus, we used whatever open source XML editors (Cooktop [165] and XMLSpy [166]) were available.

Archetype Repository

The archetype repository simply stores instances of archetypes (i.e. a knowledge base). In our prototype, we simply used a file directory for storing the XML files of archetype instances.

open*EHR Kernel* [7]

The purpose of the *open*EHR Kernel is to validate EHR instances against their corresponding archetype instances.

[7] Not implemented in the prototype.

Archetype Server [8]

The archetype server handles multiple requests from the *open*EHR Kernel for archetype instances required for EHR instance validation, retrieves the queried archetypes from the knowledge base (KB) and returns them.

4.3. Workflow Management System

The workflow management system (WfMS) performs the following key functionalities:

- Ensure that the work required is done.
- Ensure that what needs to be recorded is recorded.
- Coordinate tasks between participants
- Invoke tools/applications needed to support an activity
- Allocate resources
- Scheduling, escalation, load balancing, notifications, etc.

4.3.1. Integrated Workflow Engine and Tools

We used the Breeze workflow engine and appropriate tools used for integration with our EHR provided by [167] (currently available for free for non-commercial and academic use), which includes:

- Workflow engine,
- Graphical workflow monitor that enables viewing of the workflow instance as it executes,
- Workflow client for invoking the instantiation of a workflow instance,
- Application handler framework for building domain-specific applications (as well as providing some basic and generic tasks via scripting), and
- Database for storing workflow schemas.

The overall workflow architecture is shown in Figure 4.2 below (where components belonging specifically to the Breeze workflow architecture are shaded), and the description of its components is described thereafter.

[8] Not implemented in the prototype.

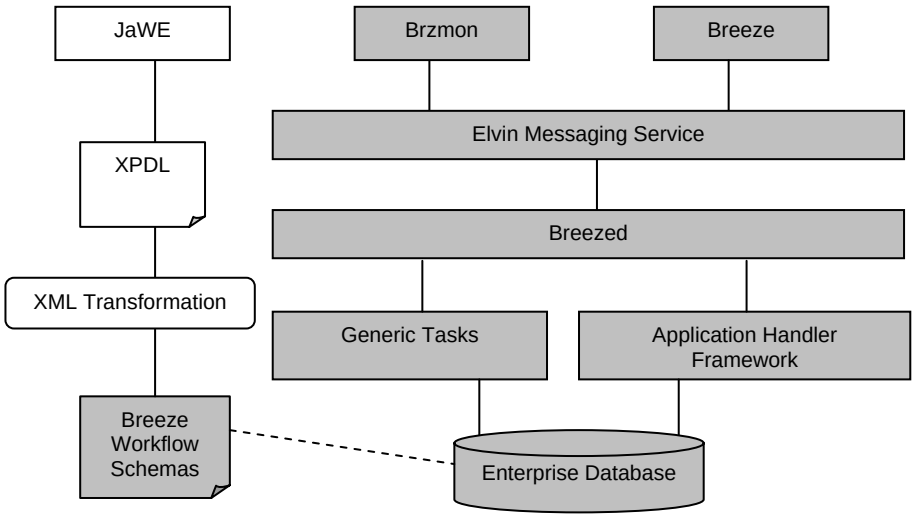


Figure 4.2. Basic Workflow Architecture.

Breeze [168] is a prototype of a multi-platform, lightweight, component-based workflow architecture for non-commercial and academic use. Its main features include:

- Input and Output Data Parameter Mapping
- Exception handling via use exception 'ports' (which are entry and exit points of an activity in which input and output transitions are placed to link activities together) in activities for connecting to an activity that handles the exception should the transition take place. Figure 4.3 shows a transition from Task.1 to Task.2 (via the green output port of Task.1 to the green input port of Task.2) when normal workflow execution occurs, and another transition from Task.1 to the Exception_Handler_Task when an exception occurs (via the red output port of Task.1 to the green input port of the Exception_Handler-_Task).
- Synchronous nested workflows
- AND-join, OR-join (sync/barrier), AND-split
- Boolean expression language for conditions
- Scripting language for simple tasks
- Message based

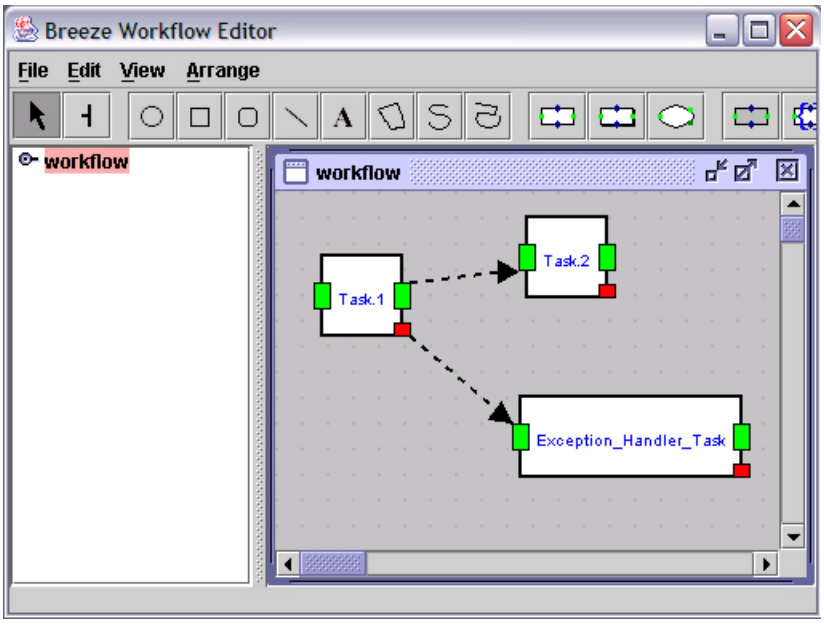


Figure 4.3. Example Workflow Definition in Bred using the Exception Port.

Breeze Workflow Engine

Breezed is a message-driven workflow engine. Incoming request messages for the execution of existing workflow definitions are received by the workflow engine, and carries out the requests by sending messages that consists of a request and any necessary data to the relevant services at the appropriate times. These requests may, in turn, be re-directed back to the workflow engine - allowing for nested workflows to be executed, as well direct or indirect recursive instantiation of workflows. Moreover, the messaging mechanism allows Breeze to support a potential need for storage of messages for the purposes of historical analysis and even prediction of future trends. The Breeze engine is dynamic such that a workflow activity can specify the instantiation of a template or invocation of a schema that may not yet exist or be defined but which will be created and/or instantiated at some point during the execution of the workflow.

There are several implementation methods that can be used by the current prototype including the "peer architecture", which suits point-to-point event channel middle-

ware, and the publish-subscribe notification middleware, which allows subscribers to register their interest in an event, or pattern or events, and are asynchronously notified of events generated by publishers. The publish-subscribe notification is therefore, suitable to scalable and loosely coupled systems [169]. The current implementation (latest version is 1.1) provides an extensible API through Java RMI (Remote Method Invocation).

Elvin Messaging Service

The Elvin Messaging Service [170] is a content-addressable, publish-subscribe notification system. An asynchronous RPC (Remote Procedure Call) mechanism was layered on Elvin to provide a communication layer between the workflow engine and external applications. Later, an alternative transport layer was implemented using Java RMI. The same asynchronous RPC interface is provided for external applications and the use of this alternative transport is completely transparent.

*JaWE (*Ja*va* W*orkflow* E*ditor)*

The Breeze workflow architecture also includes the graphical workflow editor, Bred, which is used to define Breeze workflows, and allows them to be saved in XML format. These XML workflows can then be exported into the enterprise database (workflow repository) to be accessed by Breeze to load a workflow from its schema and subsequently be executed by Breezed. However, this tool was not used to create and define our workflow schemas due to the limitations of the Breeze workflow reference model (see section 4.3.2) to be able to express, define and align with our Instruction Reference Model. In particular, the Breeze workflow reference model is much simpler and does not directly conform to the WfMC's standard workflow reference model, which our IRM does.

Bred includes other limitations such as lack of support for additional properties to be defined for an activity such as the role or participant it is allocated to, and other domain-specific properties. Also, the current prototype implementation of Bred does not allow removal or deletions of items (such as activities and transitions) from the workflow model or schema, which is a major required functionality of a workflow

editor. If a removal of an item were required, the user would need to create a completely new workflow definition from the start instead of simply being able to modify the existing model.

Due to these limitations of Bred, we used another workflow editor, called Enhydra JaWE [171] (source graphical *Ja*va *W*orkflow *E*ditor) version 1.3, which is also an open-source tool available from the ObjectWeb (Open Source Middleware) Consortium. The editor produces workflows specified in WfMC's XPDL [143] version 1.0, and due to its status as a widely known and emerging workflow standard used by a number of vendors, we have chosen to use this.

The main features of the JaWE tool are:

- Graphical representation of the process definition (see Figure 4.4),
- Export of process definitions to XPDL,
- Import of any valid XPDL and its graphical representation,
- Text view to display the XPDL tree, and its human-readable/friendly text format. It allows workflow modellers to quickly move through the XPDL, and edit its elements by using right-click, and
- XPDL document validation against the XPDL Schema, activity connection validation, graph conformance validation and logic validation. An example report produced after validation is shown in Figure 4.5.

The XPDL output of JaWE is then parsed using Java DOM (Document Object Model) XML parser API and transformed into Breeze workflow definitions to be able to be made executable by the Breeze workflow engine. The mapping between XPDL and the Breeze model is discussed in section 4.3.3.

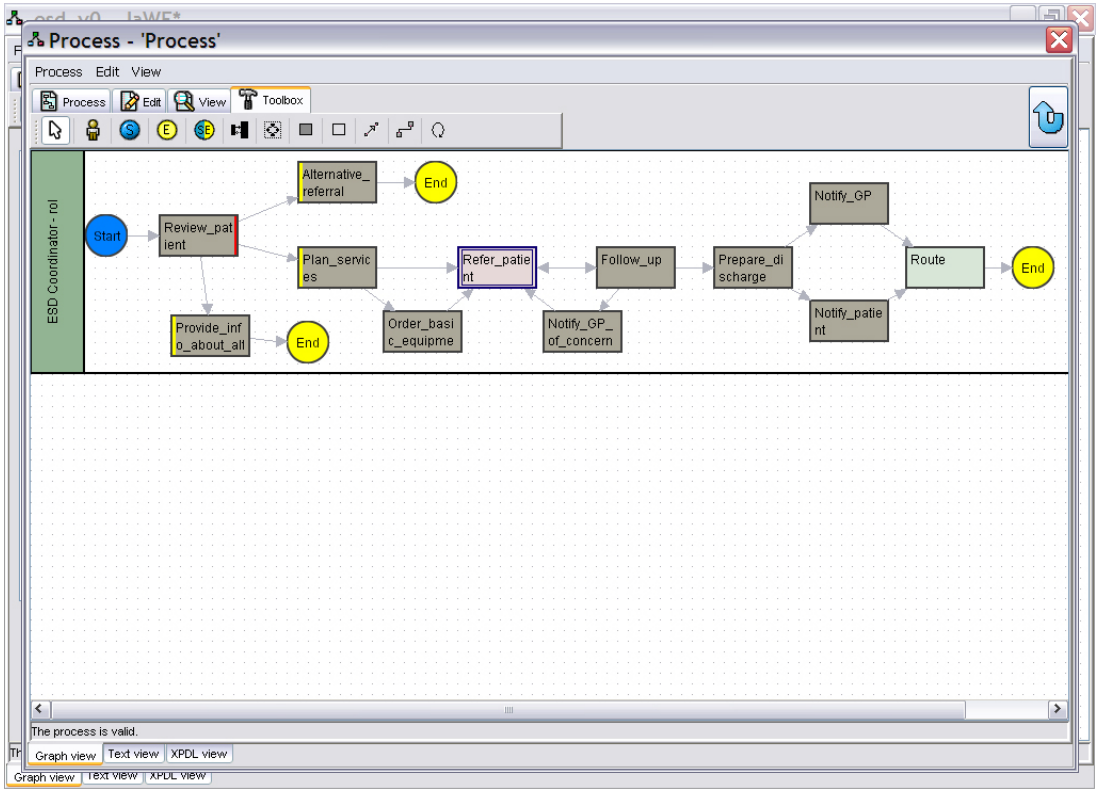


Figure 4.4. JaWE Graph View.

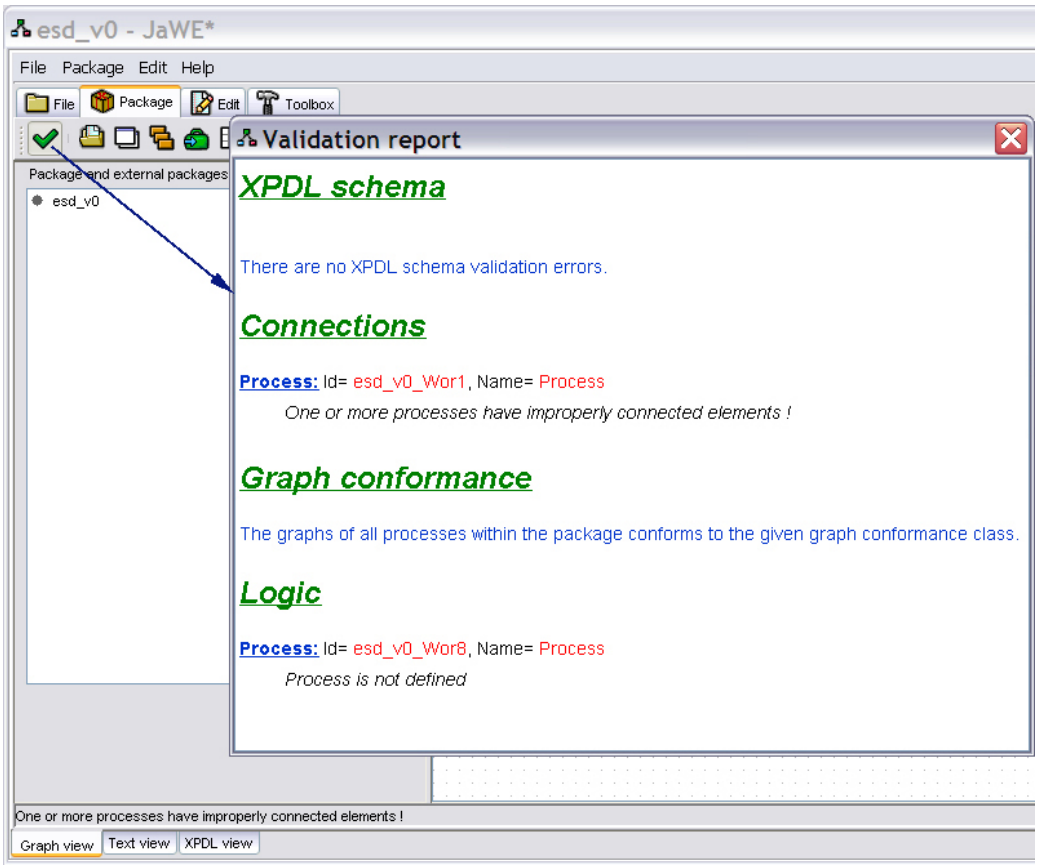


Figure 4.5. XPDL Document Validation.

Graphical Breeze Workflow Monitor

The Java-based graphical user interface workflow monitor, Brzmon, is used to monitor the execution of Breeze workflow instances. Brzmon functions by 'eaves-dropping' on the messages passed between Breezed, and the application handlers.

Breeze Workflow Repository

Breeze uses a simple relational database using MySQL (see http://www.mysql.org) for storage of workflow schemas. It can make use of, but does not require an explicit enterprise model.

Breeze Application Handler Framework

The Breeze application handler framework allows two main types of applications to be implemented and subsequently invocated by tasks as they are executed. They are:

- Generic Tasks: The engine implements a Java-like scripting language for tasks that do not require external services. This is extremely useful for simple data manipulation operations.
- Domain-specific Tasks: Using a supplied class library for Java or Python, applications are easily 'wrappered' to provide any data they may need.

4.3.2. The Breeze Workflow Model

The underlying Breeze workflow model is based on workflows consisting of task nodes and edges that connect a *source* task to its *destination* task. A task node is an atomic activity, and a sub-task node is an activity that refers to another workflow definition, and is equivalent to a sub-workflow. Each task node is defined by a name; join type (AND, OR) (discussed further in the section "Breeze Workflow Patterns" in this chapter), input and output data parameters, and an *interface*, which refers to an external application method that does the 'work' to be performed. Other types of task nodes include the conditional task (that defines a Boolean expression, evaluates it, and triggers the transition via the true edge or false edge depending on the result); a null task (which is equivalent to the Instruction Null Activity, or a routing activity);

and a script task (which executes a light-weight Java script, called BeanShell that is passed in as a string input parameter). Table 4.1 below shows the direct equivalence between our Instruction Model and the Breeze Model where applicable.

Table 4.1. Instruction Model and Breeze Model Equivalence.

Instruction Activity	Breeze Task Type
Composite_Activity	-
Activity_Proxy	Sub-workflow
Null_Activity	NULL Task
Activity with condition attributes	Conditional Task
-	Script Task
-	Application Task

Table 4.2 shows how we equate the Instruction state model to the Breeze state model. Despite the primitive set of states that the Breeze model provides, we are still able to use it to drive the updates of the Instruction statuses based on our equivalence table as its workflow instance is run by the engine. The Breeze engine in general will mark an activity 'running' as soon as it has created an instance of that activity (i.e., when it has received an event that states that the previous activity/ies have completed successfully, or that a new workflow has been instantiated). For Instructions, we consider an activity to be executing only if the relevant application has started (such as data collection), but not yet completed; or when a user has indicated manually that it has been started but not yet complete.

Table 4.2. Instruction and Breeze Workflow Status Equivalence.

Instruction Activity statuses	Breeze Workflow statuses
Ineligible	Null
Eligible, Executing	Running
Completed	Succeeded
Aborted	Aborted
-	Failed, Timeout

4.3.3. Transformation Processes

There are two main transformation processes required to produce instruction definition archetypes, and the Breeze workflow schemas from the XPDL as shown in Figure 4.6. The full XPDL definitions for the ESD workflows (for the chapter 5 case study) are provided in Appendix A.

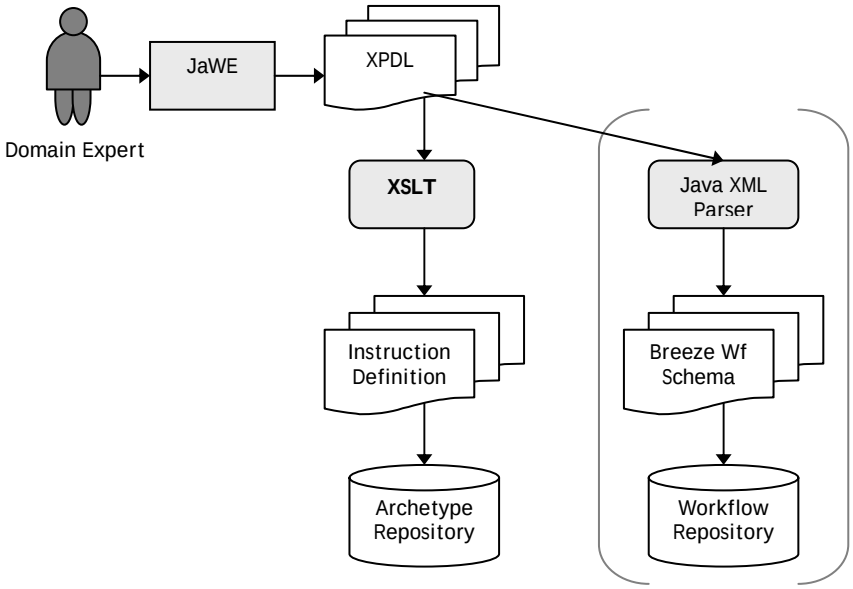


Figure 4.6. Workflow-to-Instruction Transformations.

The ESD instruction definition produced from the XPDL is shown in Appendix A. The Instruction XML is also validated against the XML Schema[9] presented in Appendix B. The additional transformation to produce Breeze workflows (a fragment of which is shown in Appendix C) is necessary due to the current lack of workflow engines available for XPDL[10]. Due to the limitations with XSLT in particular, the lack of programmatic variables and ability to perform iterations makes maintenance of the XSLT script very cumbersome, the XPDL was parsed using the Java DOM parser API to produce the Breeze workflow. However, as more workflow engines support XPDL (or a single workflow language that is adopted as a standard) then this extra

[9] The full Instruction XML Schema is in the Appendices.
[10] Shark is one XPDL workflow engine, but is only operable through its GUI interface and thus currently is not usable for our purposes.

transformation will not be necessary. The XPDL to Breeze transformation produces a separate Breeze schema (XML) file per workflow, and per sub-workflow definition.

Mapping XPDL joins to Breeze joins

There are a number of workflow patterns as identified and reviewed in chapter 3 of this thesis. Similarly to the comparison among the typical workflow patterns, XPDL and Instruction Connector model presented in that chapter, this section will discuss how a few of the more commonly used workflow patterns are supported, and the extent to which the Breeze workflow model can capture them as we transform from XPDL to Breeze workflow model. Where there is no direct and explicit support for a workflow pattern, an alternative or workaround solution is presented.

Breeze Workflow Patterns

Breeze does not explicitly have constructs for split constructs, but supports AND and OR joins, and AND splits. We will illustrate the use of these two types of joins by showing the execution of a workflow with tasks A, B, C, and D. A task that has completed is indicated in black; tasks that can be started are indicated in white; and tasks that cannot be started are indicated in shaded boxes. In the case of OR joins, as shown in Figure 4.7 below, task D can be started if at least one of task B or C has completed.

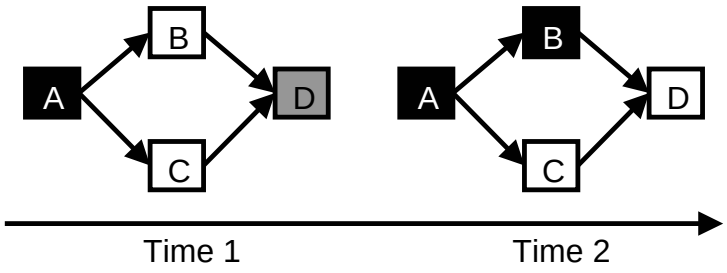


Figure 4.7. Breeze Execution of OR Join.

In the case of AND joins, as shown in Figure 4.8, task D can only be started if both tasks B and C have completed.

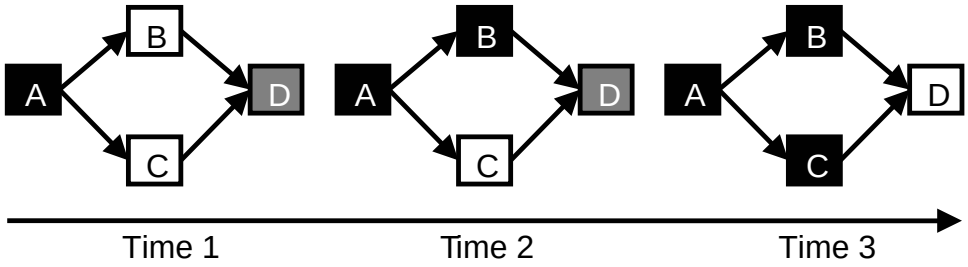


Figure 4.8. Breeze Execution of AND Join.

Breeze currently has no support for representing mutually exclusive choice, i.e., XOR split or join. However, it does have a condition node that can model this sort of workflow pattern, although a condition needs to be specified as shown in Figure 4.9 that either evaluates to true or false. The transition taken when the condition evaluates to true is denoted with a white output port, and the transition taken when the condition evaluates to false is denoted with a shaded output port.

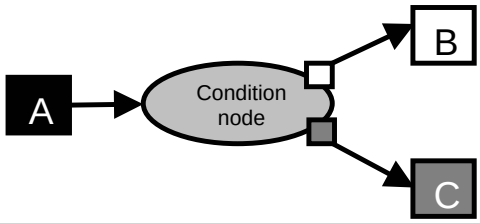


Figure 4.9. Breeze Execution of XOR via a Condition Node.

For a given point in a workflow that has a number of mutually exclusive activities greater than two, it is required in Breeze to use its Null Task. This task type is equivalent to the WfMC's definition and purpose of a Dummy Activity, which is an activity used for representing more complex routing or process control conditions in workflows, and has no inherent processing related to the business process. That is, it has no associated work, resource or application allocated to it. This type of activity is supported in the IRM by an activity called Null Activity. Therefore, for a mutually exclusive choice of three, we replace one of the two activities with a Null Task, and add another condition node that provides two possible leaf nodes; and this process is

repeated every time the number of activities increases by one. Figure 4.10 shows the constructs that have to be used (indicated within the dashed box) to replace one of the activities.

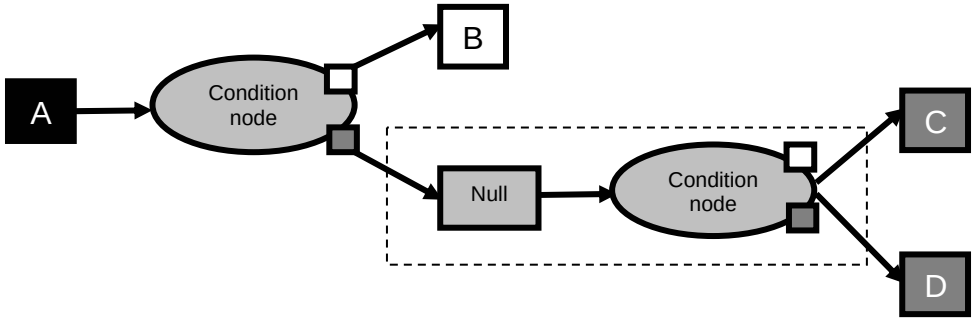


Figure 4.10. Breeze Null Task for Complex Routing.

Defining Activity Attributes, Breeze I/O Parameters and Mapping

Breeze uses a dictionary data structure consisting of a set of key-value pairs for input and output data parameters to tasks. However, these key-value pairs are currently limited to string and numeric data types. Each of these parameters must map between source and destination tasks via the edges in order to be considered complete or valid as part of a workflow definition. To illustrate more clearly, we open a workflow defined in Breeze using Bred to take a look at its properties shown in Figure 4.11 below. The dialog in the left of the figure shows the input and output data defined for the task from the Review_patient, which may also be assigned default values, while the right dialog shows the mapping of the data from the source task node, Review_patient to the destination task, the XOR condition task node.

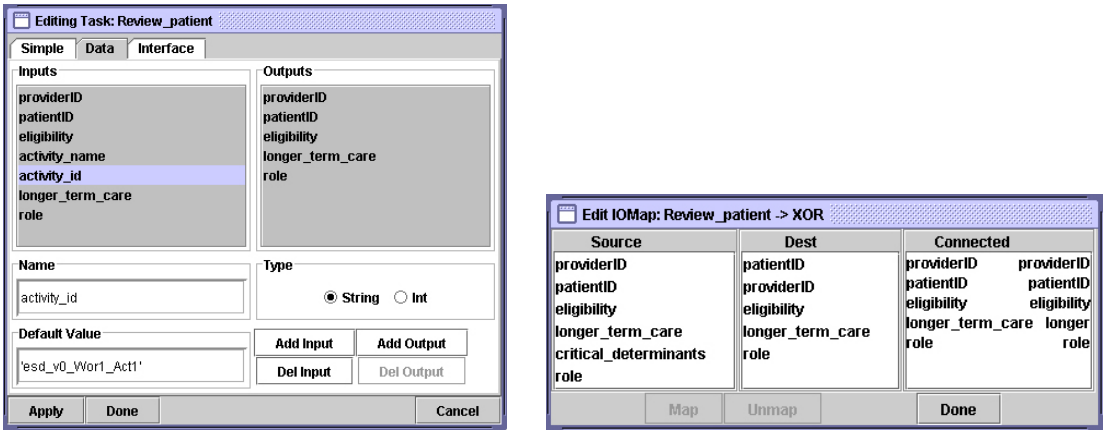


Figure 4.11. Breeze I/O Parameters and Mapping.

Unlike JaWE, and most other workflow tools, Breeze does not allow workflow modellers to define additional properties about or specific to an activity – i.e., beyond that of its name, pre-condition type when it has two or more input activities, the workflow parameters, and the interface to applications or procedures. For example, it does not allow for an activity to be allocated to a participant or role – an essential property of any activity – and moreover, it does not allow modellers to define domain-specific activity properties. To work around some of these deficiencies, we had to define additional activity properties as input and output data parameters, and their values as "default values".

Specifying and Assigning Domain-specific Applications to Activities in Breeze

Application Handler Framework

Breeze provides a Java-based framework for implementing Application Handlers (also known as 'wrappers') for domain-specific tasks. A wrapper has a name and a set of methods that can be referred to and invoked by the workflow engine. All of these methods use the dictionary input and output parameters.

A wrapper can be implemented in two ways: *synchronous* and *asynchronous*. Synchronous wrapping simply involves taking dictionary input parameter(s) to the wrapper method, executing the method, and returning a dictionary of results.

Asynchronous wrapping also takes as input a dictionary, but with another input parameter, token, which is an opaque Object used to transmit results back to the Application Handler Framework. Conversely, methods implemented in this way do not return a dictionary of results as it is expected that the processing may be executed in another thread and may take time to complete. Thus, the Application Handler Framework invokes the method, but does not consider it complete until an abstract server method has been explicitly called with the token provided to either complete with succession, complete with failure, abort, or marked as timed out using the methods: returnSucceeded, returnFailed, returnAborted, or returnTimeout respectively.

4.3.4. Further Extensions to Breeze Workflow Architecture

A few essential WfMS components that did not come with Breeze are the Worklist, Worklist Manager, and the Worklist User Interface. We had to implement these components (shaded areas in Figure 4.12) ourselves and integrate it as per our EHR Instruction-based system architecture introduced in chapter 3 of this thesis. A particular critical deficiency in Breeze is the lack of workflow persistence, where knowledge about the running workflow instances is persistently stored in a database, maintained, and 'recovered' from their last running state in the event of failure or suspension of one or more workflow engines. Recalling from chapter 3, the worklist is defined by the WfMC as –

> *"A list of work items associated with a given workflow participant (or in some cases with a group of workflow participants who may share a common worklist). The worklist forms part of the interface between a workflow engine and the worklist handler".*

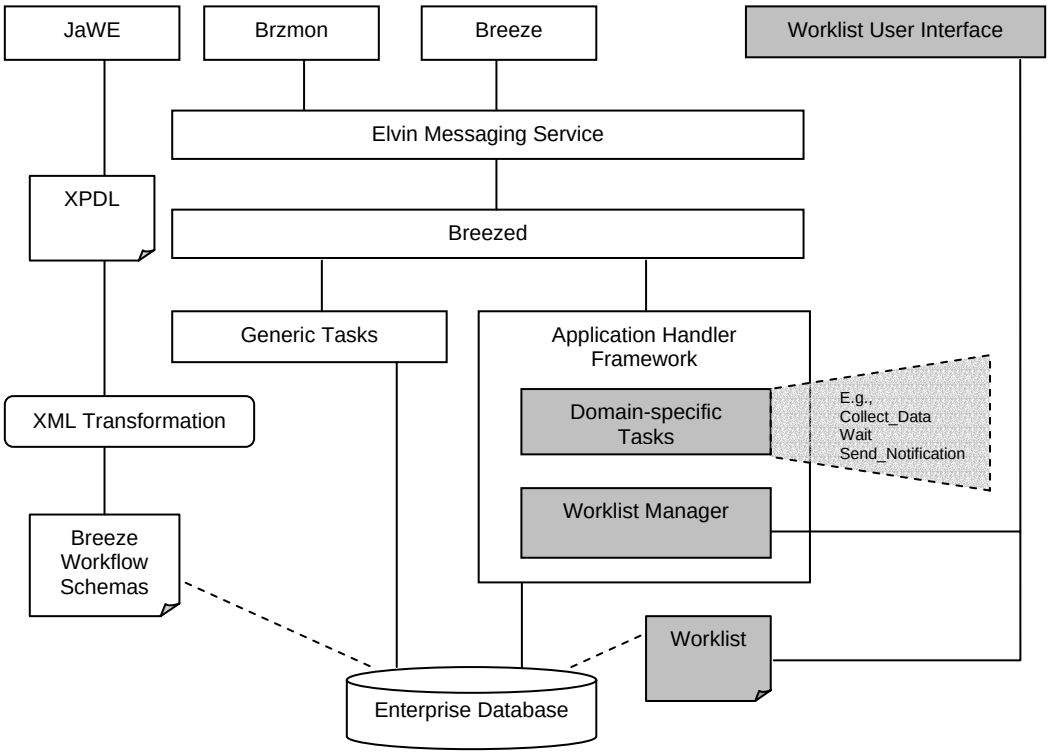


Figure 4.12. Further Extensions to the Workflow Architecture.

The worklist is often synonymous with terms such as “work queue”, “in-tray”, or a “to-do list”. Typically, workitems on the worklist are created as the workflow engine instantiates activities, and therefore worklists show a history of the tasks undertaken as well as tasks currently executing. In this respect, the worklist offers persistence regarding the history and current state of the workflow instance, but requires the workflow engine to be responsible for any workflow instance recovery from failure or suspension, and to continue the execution of that instance from its last running state. However, for the purposes of sufficiently demonstrating the use of our Instruction within a workflow-integrated EHR system in the context of both case studies, the latter WfMS mechanism is deemed out of scope. We implemented the worklist simply as a relational table as part of the enterprise database, the definition of which is shown in Table 4.3.

Table 4.3. The Worklist Relational Table Definition.

Field	Type	Null	Key	Default	Extra
workitemID	int(32)		PRI	NULL	auto_increment
actInstanceId	varchar(200)	YES		NULL	
actInstanceName	varchar(200)	YES		NULL	
ODSIKey	text				
workitem	text				
taskname	varchar(32)	YES		NULL	
status	varchar(16)	YES		NULL	
dataToCollect	varchar(255)	YES		NULL	
role	varchar(32)	YES		NULL	
providerID	varchar(32)	YES		NULL	
patientID	varchar(16)	YES		NULL	
scheduledDate	datetime	YES		NULL	
startDate	datetime	YES		NULL	
endDate	datetime	YES		NULL	
guideline	varchar(100)	YES			

The Worklist is initially generated from the Instruction Execution Entry with additional key attributes provided and therefore, required by the Breeze workflow engine in order to execute it, in particular, the –

- ODSIKey: an opaque string (whose field is the 'ODSI.Instance') that is used as a 'key' for the RPC-mechanism layered on the messaging infrastructure used by Breeze. It is passed back as a part of the result dictionary when invoking one of the abstract server methods in the asynchronous mode in order to communicate back to the Breeze workflow engine changes in the workitem state;
- workitem: unique identifier of the workitem derived from the workflow schema and activity ID, in combination with an arbitrary integer that is incremented per instantiation (e.g., "esd:112.esd.Task.1:201"); and
- taskname: the name of the Application Handler and method for the workitem (which may simply serve as additional information to the participants, particularly if the workitem is to be carried out by a system application rather than a human participant). E.g., "AppHandlerClass collect_data".

The values of these attributes are generated as Breeze instantiates an activity at a particular point in time, only when it can be executed, so a workitem cannot be generated ahead of time. Thus, the ability to generate a worklist from the Instruction Execution Entry has its advantage in that *all* the workitems are created, as part of the worklist once the Instruction is 'eligible' to be started. This is because the Persistence Layer pre-initialises the statuses of each of the Instruction activities and are used for worklist generation. The worklist then gets stored in the Enterprise Database. The availability of future workitems to participants gives the opportunity for workitems to be scheduled, or requested to be assigned to a particular resource (human or non-human) ahead of time. Moreover, it allows them to foresee any potential conflicts that might occur in the workflow such as misallocating or over-loading resources, and thus be better informed to make decisions about resource allocation, scheduling of future activities, load balancing and prioritisation.

Worklist Manager

The Worklist Manager is the component that manages the interaction between the participants, or group of participants, and is maintained by the workflow engine. Worklist Manager is synonymous with such terms as a "task manager" and "worklist handler". It serves as the interface between the participants and the WfMS by passing the workitems to participants, as well as sending notifications regarding completion or workitem states between them as the workflow instance progresses. There are two main methods by which to implement a worklist manager on top of the current Breeze implementation:

1. Workitems show up as a single task in a workflow. This task blocks until completion.
2. Two tasks in a workflow – one to schedule the workitem, and the other to block and wait for completion.

In our prototype implementation, we applied the first method, but in both methods, the value of the ODSI.Instance field in the Elvin notification of the blocking request is required. This value must be stored in the database, and when the worklist is up-dated to mark the workitem as complete, this value is used to construct the response notification with. Note that the contents of the Breeze notifications can be seen using the Elvin command line tools, in particular using the command –

```
> ec -e elvin://my.elvind.hostname.com 'require(ODSI.Instance)'
```

The Worklist User Interface is the actual representation or display of the worklist to the user (see section 4.5.1 for more details). It is the interface through which users can perform functions such as selecting workitems to perform, allocating or reallocating them to participants, and marking them as 'complete' or 'cancelled' or 'suspended'. We implemented the worklist user interface using HTML tables (to be discussed in detail further in this chapter in the section "Worklist Views").

Exporting Breeze Workflow Definitions to the Enterprise Database

Once the Breeze workflow definitions are produced from the XPDL definition through transformation, they are exported and stored into the enterprise database in XML format for access by the Breeze workflow engine, Breezed, and the workflow launcher, Breeze. The exporting can be done easily via the workflow editor, Bred.

4.4. Decision Support System

In general, we take the approach of using the decision support system to pre-populate the appropriate sections of the EHR form with the recommendations at the point of care when requested by the clinician. We view that this approach in *conjunction* with the *timely* display of alerts and reminders for information considered more critical, offers a more practicable, less invasive approach and reduce the potential for distraction from the task at hand that would otherwise occur when recommendations always appear *only* in the form of alerts and reminders. Users often prefer to turn off such alerts and reminders after a period as many of these alerts and reminders can either be deemed not so important or critical, or are already known in advance. Further to this problem is that they can either be difficult to switch off, or in the worse case scenario, are unable to be switched off.

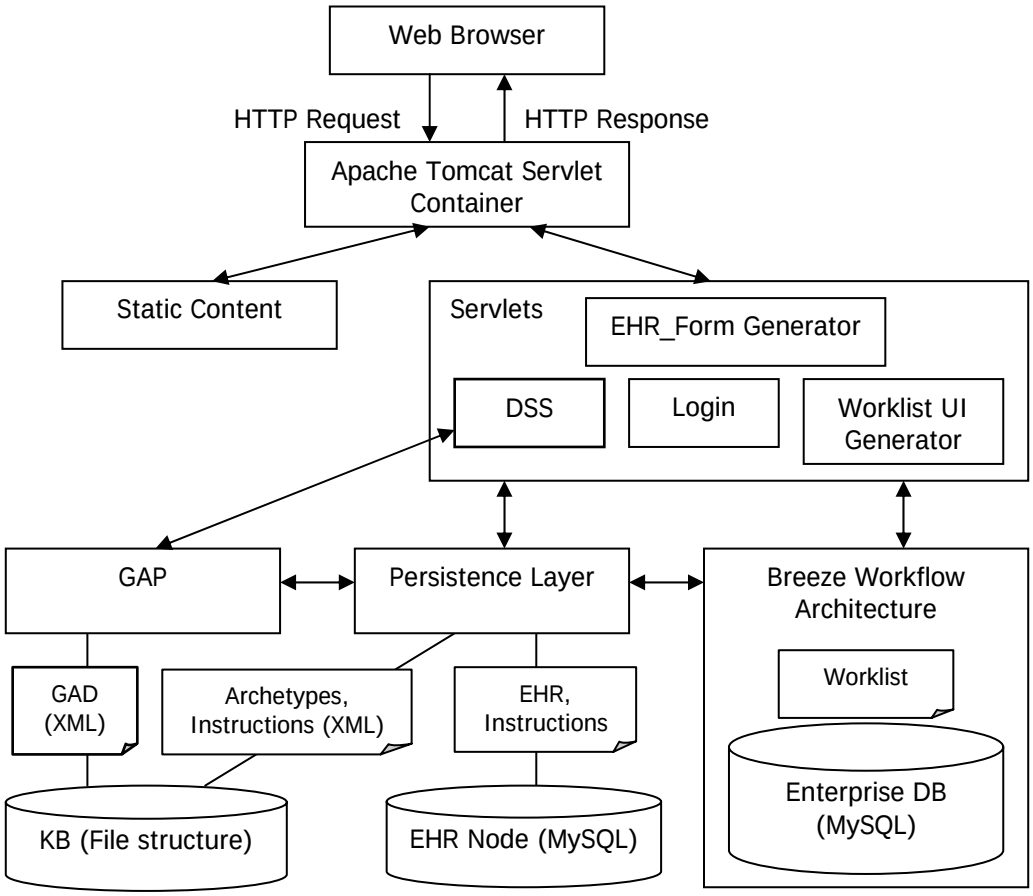


Figure 4.13. Prototype Implementation using Web-based Client and Java Servlet Technology.

The decision support system that we have prototyped uses an engine we call the Guideline Adapter Processor (GAP) that is implemented in Java. Figure 4.13 illustrates the use of a browser-based client and Java Servlet technology in our prototype implementation of a workflow-integrated EHR system with decision support. The GAP takes the requested CiG (from a KB), which we call the Guideline Adapter Document (GAD). The GAD is an XML file instantiated according to an XML Schema (see Appendix D) that was constructed based on the guideline ontology we have developed (see section 6.2.2). The GAP parses it (using the Java DOM API), to get the relevant guideline recommendations, rationales, corresponding archetype identifiers necessary for data collection, and potentially other items required for use in the hypermedia component (i.e., the guideline graphic reference points [GRIs]). The GAD essentially serves as the guideline ontology with relevant interfacing information to the EHR artefact or data model, DSS (also known as a CiG engine), and the

guideline hypermedia artefact (which to our knowledge is not currently addressed in the realm of guideline representation). The option to use an existing guideline representation model such as GLIF, and extending it to support hypermedia content was considered, but the decision to develop our own type of CiG is mainly due to the lack of CiG engines available for various guideline representations such as GLIF, and Arden Syntax (the latter of which has a proprietary engine). It is envisioned that a health information system that integrated a general guideline-based DSS would be made more feasible as CiGs mature and become standardised. However, this will be difficult until there is the ability to interface to *standardised* EHR data models and terminologies. Moreover, there should be potential to provide direct support for hypermedia presentation and content, and to develop and make available CiG engines for guideline execution.

Unlike other guideline representations such as GLIF and Arden Syntax, the GAD is relatively static (as ontologies are) or declarative, with only limited embedding of (implicit) guideline rules defined within simple expressions. For example, a concept 'target' has a variable name 'blood pressure', and its 'expression' attribute value of '<= 130/90', and implicit rules gained from concept relationships (e.g. the recommendation for 'ACE Inhibitor' as a drug should only occur if the following indications exist: 'Type 2 Diabetes', or 'Type 1 Diabetes with Microalbuminuria/Proteinuria'). In our approach, it is a purpose-built Java program that interprets the CiG and executes the guideline *algorithm* and explicit high-level rules.

DSS Interaction with the EHR

A patient may be at a particular step within the guideline, or in the initial step (if the guideline has not been executed for this patient before). The DSS decides which next step(s) that can be taken based on some criteria that have to be satisfied, queries the EHR for the relevant values (else prompts the user to enter data), makes an evaluation, and returns the recommendation(s) at that point in time with links to appropriate EHR data items, and hypermedia content that were used to arrive at the decision (see sequence diagram Figure 4.14).

Since the data in the EHR conforms to the constraints defined in the corresponding archetypes, they also conform to the path structure of the archetypes, as well as any terminological constraints [77]. Therefore, the archetypes that were used to create the data at run-time are recorded into the data as archetype identifiers, as well as the archetype node "meanings" as the basis for paths [77]. The "meaning" is an attribute inherited from the openEHR LOCATABLE class. This class is inherited by every structural element in the EHR model and ensures that each of these elements have both a runtime *name*, and a *meaning*. The name and meaning may be the same or different (e.g. the "problem/SOAP" organiser at the problem level might be "diabetes", but its meaning will be "problem" according to the archetype that defined it) [172]. Since we have chosen to use XML to implement archetypes, and the CiG, we also give mappings of the archetype identifiers to their corresponding XPaths[11] (XML Path Language) [173] within a particular EHR transaction. For example, for a given blood pressure archetype ID and the specific transaction that it resides in (e.g. GP contact), we have a mapping to its XPath in its EHR instance (which is produced as an XML instance). Items that correspond to data collection within the GAD are also mapped to the relevant archetype identifiers via their code terms – where a code term is composed of a code ID and the code source (provided by a terminology server).

If any instruction definition entries are made (such as recalls and referrals), then the EHR persistence layer will instantiate an instruction execution entry (added to the patient's EHR persistent 'care plan' transaction), and invoke the WfMS to execute its workflow (as shown in the lower portion of the sequence diagram in Figure 4.14).

At any point in time, the clinician may choose to accept, reject, or modify the guideline recommendation, and/or rationale for the chosen action. Free-text entry is provided for the clinician to enter the justification for deviation to the guideline recommendation, and option to select 'other' and enter the action to be recorded (e.g. alternate drug name to prescribe). Either option provides a way for the decision taken to be explicitly recorded in the EHR, and therefore, be retrieved at any point in time – providing contextualised information for subsequent decision making by the clinician,

[11] Xpath (see http://www.w3.org/TR/xpath) is a language for addressing parts of a XML document, designed for use by both XSLT and XPointer.

and potentially be used for medico-legal purposes, as well as secondary uses, quality review, etc.

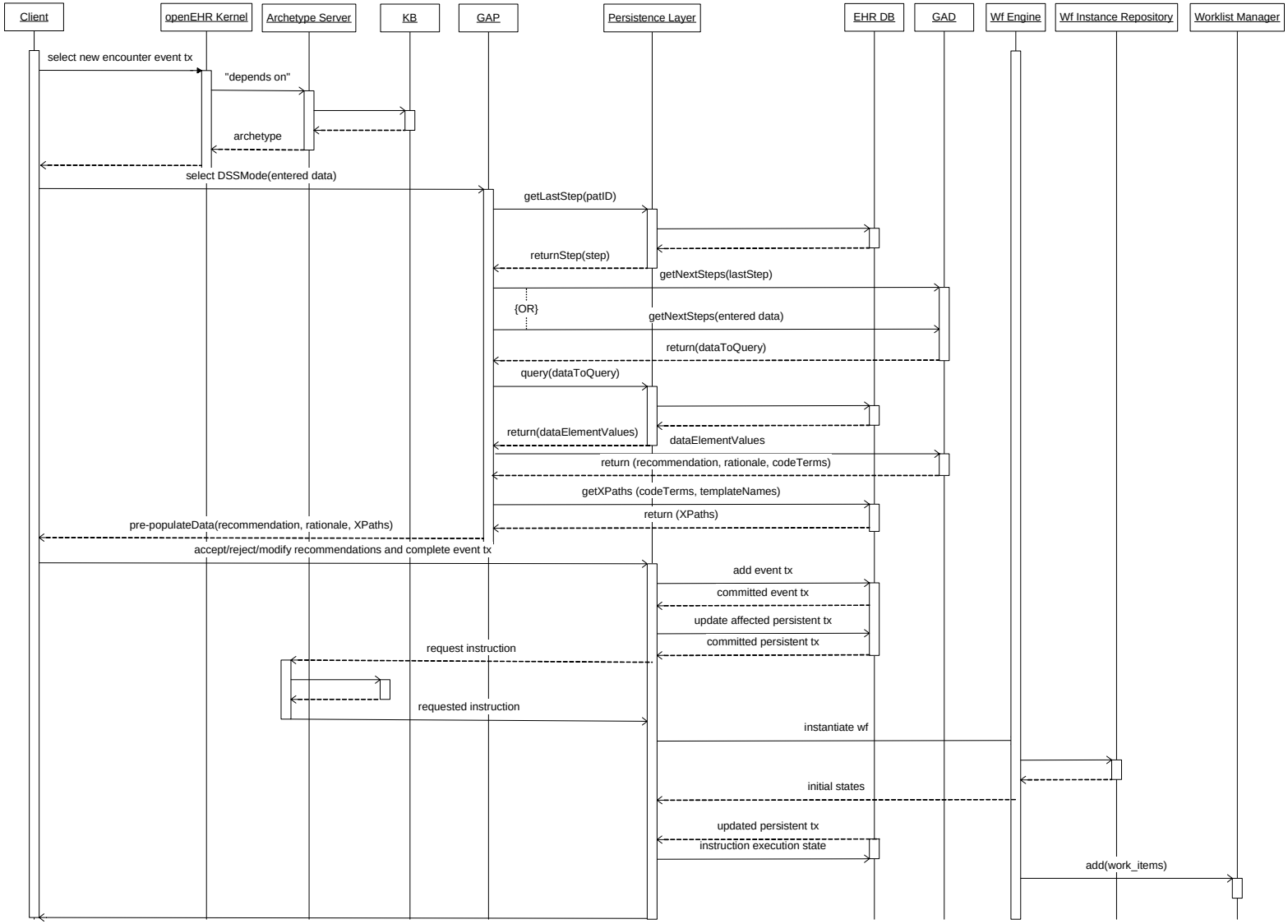


Figure 4.14. Sequence Diagram Showing Interaction with DSS[12].

[12] The *open*EHR kernel validates the EHR data based on their archetypes, and is currently not implemented in this prototype. We assume that the data recorded is valid at this point.

4.5. Client and User Interface Design

In our prototype, we have directly modified and built upon an existing set of mock-up HTML forms for use within a GP encounter to include the recording options specific for a guideline (as will be discussed in detail in this section and in Chapter 6 in particular). Ideally, however, the EHR user interface would be generated according to a template specification in a fully implemented system.

We make use of and further extend the web-based mock-up user interface developed by the Titanium Project [174] in DSTC for our prototype implementation. The user interface prototype (Figure 4.15 below shows the overview web page of the consumer details) is primarily developed for a shared EHR system for the Brisbane Southside Health*Connect* trial focused on diabetes management. Their prototype has undergone a series of usability tests performed by different providers such as doctors, podiatrists, dieticians, nurses, etc. during its iterative development; the details of these tests and results are discussed in [175]. The prototype from which we are working is the one developed in phase 3. The extension added for this thesis is the worklist user interface, a number of other HTML forms required for the data collection activities, a login facility to allow access according to role, and modifications to their GP Contact Forms to support decision support recording needs.

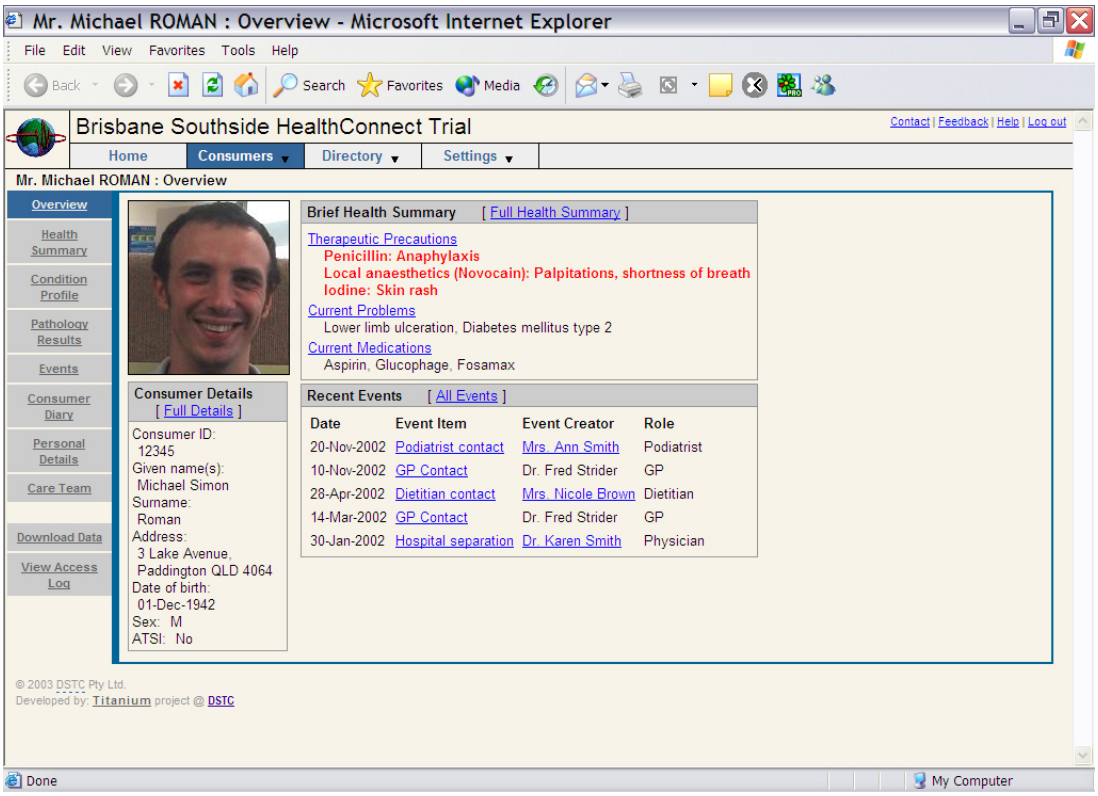


Figure 4.15. Mock-up User Interface Showing Consumer File Overview [175].

4.5.1. Worklist User Interface Design

In general, the worklist user interface provides a user interface for providers to:

- Select eligible workitem(s) to start or complete;
- Click on any required form(s) required to be filled-in per activity. This should also include potential for forms of currently ineligible activities to be filled-in in advance. In this sense, we do *not* (1) try to avoid control flow being violated (because our model is not a perfect representation of the universe), at least in terms of the form being filled out; and (2) we do not try (for this research thesis) to simulate the future of the patient, instead, we simply follow what the user(s) say is 'complete'. Thus, the hyperlinks on the form names are available to be clicked at any point in time to either fill-in a form, or to view a form that has already been filled-out.
- Schedule and/or allocate activities to a provider of a specified role;

- Like scheduling, requests are typically the responsibility of the WfMS to support, and are therefore outside of the workflow definition scope. The worklist user interface should provide ways to:
    - Request for activities to be done by another provider. The advantage of being able to view all activities ahead of time (workflow management systems typically only generate worklists of workitems that have been done (i.e., capturing past tasks), and current workitems, as workitems are only created as activities are instantiated), therefore, there is no need for tasks to be eligible to request and/or schedule them;
    - Accept or reject incoming requests for tasks to be done;
- Filled-in forms specified in the instructions result in event transactions being recorded into the EHR, and subsequently updates affected persistent transactions (e.g., problem list, medication list, etc) and updates to the corresponding instruction execution entry/ies); and
- Instruction execution entries store information such as the activities to be performed or was performed, the current statuses of the activities, links to the filled-in forms, and specifies the forms required for future tasks.

Worklist Views

We implemented a few different variations of the worklist user interface during the development of our prototype. Default worklist view when the provider logs in is all the workitems specific to that provider's *role* and patient that has been done, currently doing, and the workitems that have to be done in future. The workitems are grouped according to their instruction definition or guideline.

Other worklist views:

(1) All the workitems specific to that provider and patient that has been done and the workitems those have to be done in future. The workitems are grouped according to their instruction definition or guideline.

(2) All the provider workitems that have yet to be done – i.e., the provider's 'to-do' list, grouped according to instruction or guideline.

(3) All workitems for the patient grouped by instruction or guideline – this includes all workitems that are assigned to other roles and/or providers, and in

order of when they were or have to be done. That is, all past, present, and future workitems for a patient.

(4) All current and future workitems for the patient grouped by instruction or guideline, to be performed by all roles/providers, in order of when the have to be done.

For worklist view options 2 and 3, the logged-in provider's workitems are highlighted in light green on the left-most side of each workitem.

Further worklist view customisation:

Instruction/guideline worklist can be sorted in ascending or descending order by any of the following attributes – i.e., by clicking on the column heading of:

- Scheduled date (if any);
- Status;
- Start date;
- End date;
- Role (alphabetical order); or
- Allocated to (alphabetical order of provider's surname).

A further attribute (not implemented) may be added on the worklist indicating 'priority' or urgency, to support sorting on that attribute.

Worklist Presentation of Sub-Workflows

Sub-workflows are used for the following situations:

- To simplify the workflow;
- Synchronous or asynchronous execution of a set of concurrent/parallel activities; and
- Re-use of existing workflow definitions.
- During the design of the worklist user interface, there was a specific issue that arose with the display of sub-workflows. Initially, an attempt was made to display the worklist in a hierarchical fashion – allowing nesting of sub-worklists to occur where sub-workflows appeared. Figure 4.16 shows our initial design for this. However, this proved cumbersome given that our implementation used HTML tabling, and probably impossible in situations of deep nesting within workflows. The other option considered was to display the sub-workflow details in a new window, but this has the potential problem of the

difficulty in managing multiple browser windows at the same time. After brief consultation with the Titanium Project team, a decision reached that it would be sufficient for the worklist to be displayed as one, single-hierarchical list (as shown in Figure 4.17).

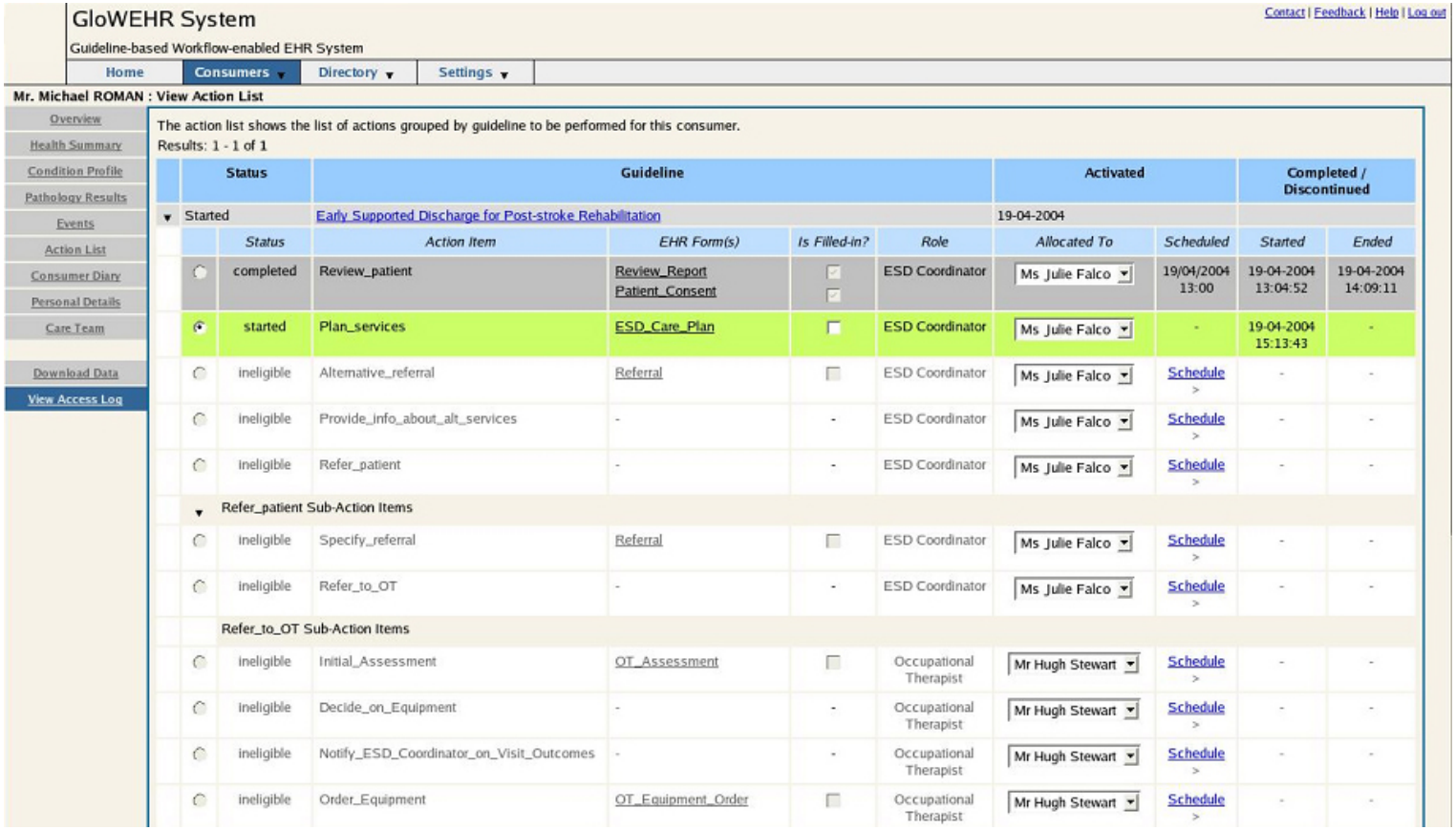


Figure 4.16. Worklist UI with Nested Worklists of Sub-workflows.

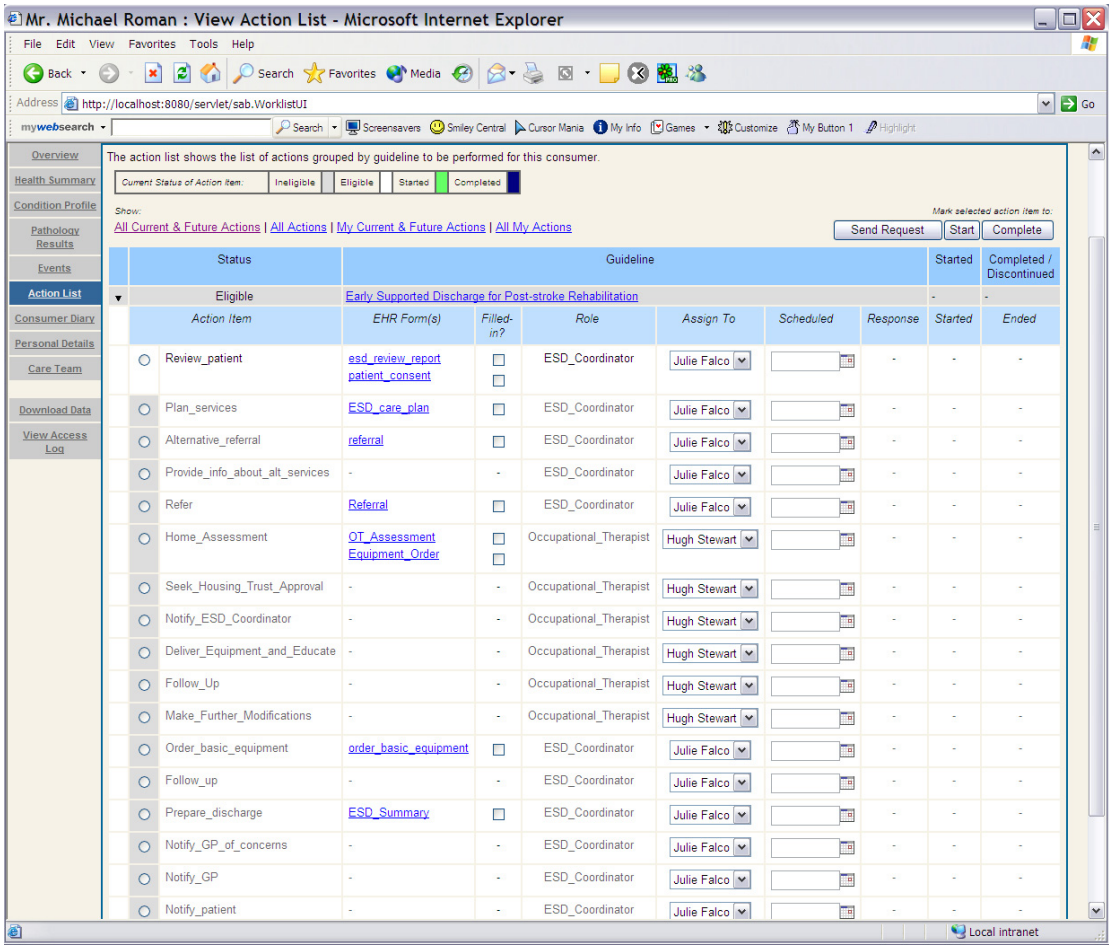


Figure 4.17. Non-hierarchical Worklist UI.

Worklists for multiple guidelines:

This type of view is relevant to provider roles that undertake activities for an individual patient from two or more guidelines. This would typically be the patient's General Practitioner. For example, the snapshot below in Figure 4.18 shows the GP's display of multiple worklists from multiple guidelines (namely, influenza vaccination, and hypertension management in diabetes) for a patient. The worklist view options in this case would include:

- Worklist grouped by guideline; or
- All workitems from all the guidelines as one worklist (but with the originating guideline as a column/attribute) in order of any of the following attributes:
  - Scheduled date;
  - Status;

- Start date; and/or
- End date.

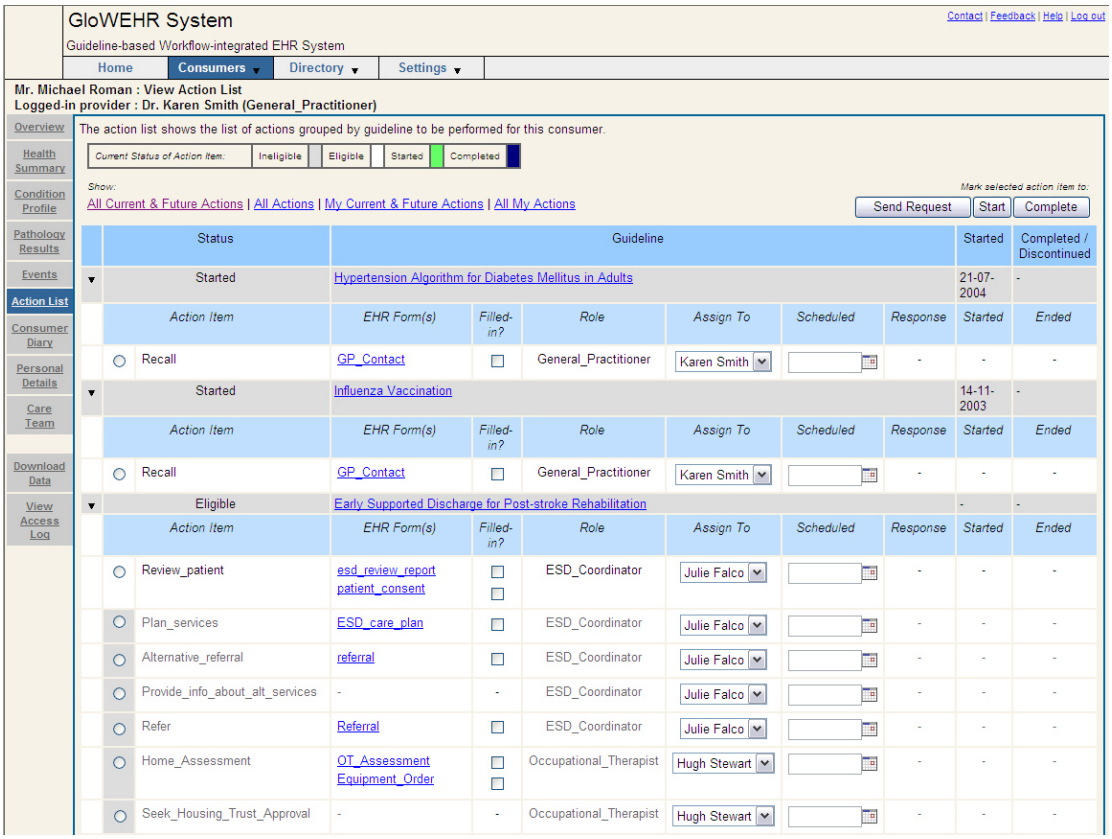


Figure 4.18. Display Showing Multiple Worklists from Different Guidelines.

Referral versus request:

A referral is essentially equivalent to a request (for a transfer of care of an individual patient). However, in our context, referral is a more 'formal' type of request in that a form has to be filled-in, and recorded as an EHR event transaction, whereas a request is not recorded in the EHR – instead, it is a communication mechanism in the form of messages that is external to the EHR system – a functionality of the WfMS (involving handing off tasks to other participants), and does not alter the workflow definition itself (in terms of what data to collect during that activity, etc). A further slight distinction worth noting is that typically –

- Where the provider(s) is known in advance, then it is a request. The provider has a set of people/organisations that he/she can refer to (on behalf of the patient); or the request is for another provider (most likely within the same

organisation) of the same role – i.e., the worklist is shared amongst a group of people (with the same role).

- Where the provider is *not* known in advance, then it is a referral. E.g., it is quite a common occurrence that the provider gives the referral letter to the patient who is then responsible for forwarding it to his/her preferred specialist. However, in this situation, the outcome of a referral is often left unknown, as there is no direct, explicit or automated mechanism to provide feedback from that request once it is handed to a potentially unknown provider/organisation.

We therefore conclude from our aforementioned observations and distinct analysis of referrals and requests that in general, it is necessary to be able to provide mechanisms for both in order to support intra- and inter-organisational communications, in terms of handing off activities from one party to another. The basic service request/response model is shown in Figure 4.19.

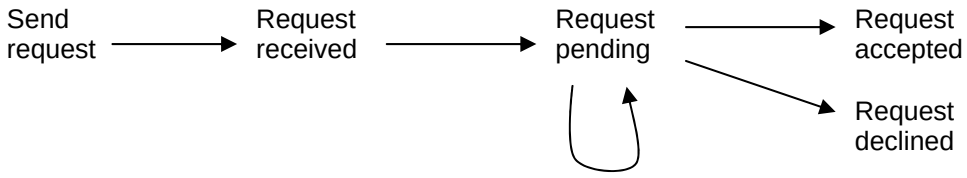


Figure 4.19. Basic Service Request/Response Model

Revised Worklist User Interface

Figure 4.20 shows a revision of the worklist user interface. To reduce user interface 'clutter' on the screen and to account for lower resolution screens, we perceive that detailed information about an action item can be made viewable within a pop-up window[13] if users choose to click on the relevant hyper-linked action item name. In particular, the 'Role' column has been removed, as it is the same for all action items presented in the default worklist view – i.e. 'All My Actions'. Other information pertaining to the action item may also include a description of the action item, and any associated request/response information (such as who requested it and to whom).

[13] This functionality was not implemented in the prototype.

Furthermore, users should also be able to access the less commonly used functions such as re-doing an existing EHR form, and to abort/cancel the action-item from the same action item details window.

The colour coding for the action item statuses was also revised using more intuitive colours. The checkboxes within the 'Filled-in?' column have been removed, and only appear as non-editable 'ticks' as EHR forms get filled-in. Selecting an item from the pull-down list within the 'Assign To' column opens a pop-up window to fill-in a request for the action item to be assigned to someone else. The response of the respondent is shown in the 'Response' column, and may be either 'Pending', 'Accepted', or 'Declined'.

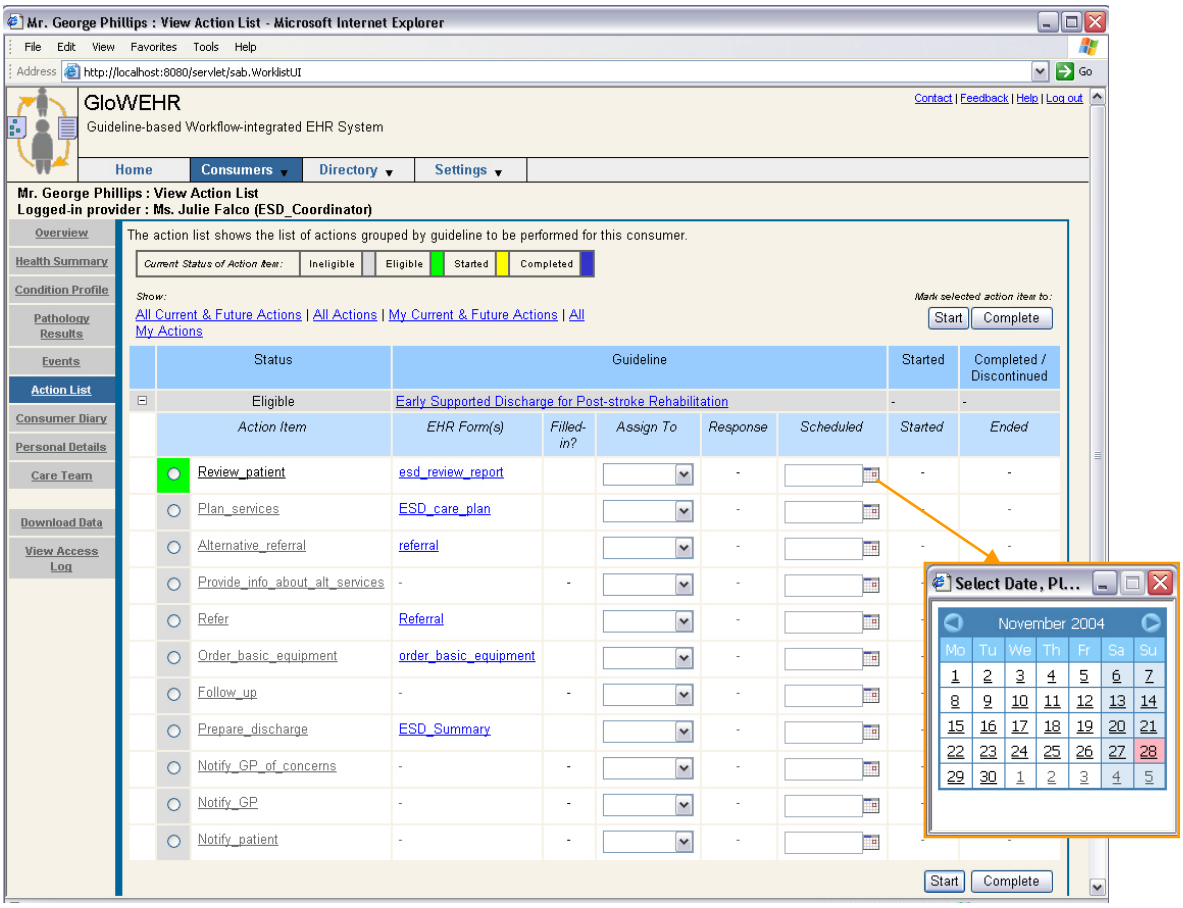


Figure 4.20. Revised Worklist UI.

4.5.2. DSS User Interface Design

We use the ‘GP Contact’ form is used when the patient makes a visit to a general practitioner (i.e. provider encounter is made). Again, this is using the same web-based mock-up user interface developed by DSTC’s Titanium Project [174] and extend it to support decision support recording needs. The existing form uses a ‘tab’ layout. A slight modification was made to the original ‘Objective’ section such that the default sub-forms that would be made visible included those observation entries specific to the guideline (i.e. an EHR template that uses a specialised set of archetypes). Figure 4.21 for example, shows the ‘Objective’ section with the blood pressure and urinalysis pre-selected as the set of required data collection items when using the hypertension management in diabetes guideline.

Selecting any of those options initiates a ‘drop-down’ sub-form, which is implemented in JavaScript. Any of the sub-forms can be made visible and invisible by ‘ticking’ the appropriate checkbox. This ability to ‘hide’ items for instance is useful for reducing information overload and user interface ‘clutter’ that is often a problem faced given the limited screen resolution.

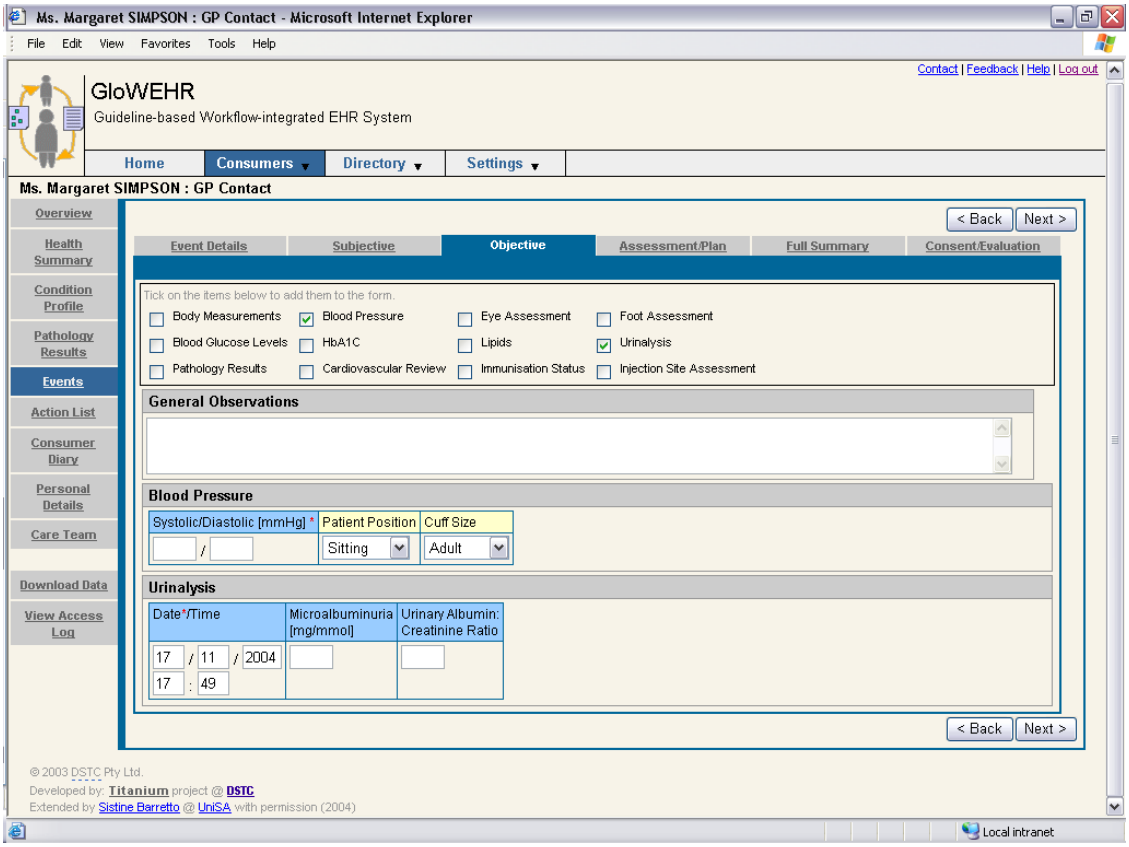


Figure 4.21. Guideline-specific GP Contact Form Showing 'Objective' Section.

The other optional items such as body measurements, blood glucose levels and eye assessment that are not specified by the guideline are still able to be recorded, but are not marked as default items for recording. This ensures that the GP is not ever restricted as to what can be recorded within a given GP contact.

The original 'Assessment/Plan' section includes the basic sub-forms for recording the 'Assessment Notes' and 'Plan Notes', as well as sub-forms for recording the following optional items:

- Problems;
- New Immunisations
- Prescriptions
- Follow-up Appointments
- Medications Stopped
- Referrals, and
- Procedures.

The ‘Assessment/Plan’ section within a GP Contact form (shown in Figure 4.22) was extended to provide additional recording components for the rationale, and other assessment and plan sub-forms required based on our EHR template for hypertension management in diabetes.

DSS Invocation

The provider can choose to use the DSS and which specific guideline to use (Figure 4.22). The guideline document can be viewed when clicking the ‘View Guideline >’ button. If DSS mode is chosen, and the ‘Get Recommendations’ button is clicked (see Figure 4.22), the form is pre-populated with the recommendations at that point of care for the patient.

Figure 4.23 shows an example of a recommendation given by the DSS. In this case, the recommended drug is ACE Inhibitor, and therefore appears as the ‘default’ selected drug on the list, with the related rationale for the drug below. Details of the rationale can be hidden (or ‘minimised’) by the clinician by clicking on the ‘-‘ symbol that appears to the left of the ‘Rationale’ label. From here, the clinician may choose to accept, reject (i.e. completely deviate from the guideline), or edit (i.e. editing parts of the recommendation without completely deviating from the guideline) the guideline recommendation. ‘Editing’ the guideline recommendation in this particular case for example, may involve changing the drug to ‘ARB’ (since the guideline recommends either a choice of ‘ACE Inhibitor’ or ‘ARB’ at this particular point in time), and/or adding another indication on the ‘indications’ list, and/or adding to the justification statement. Selecting an entirely different drug from the list would imply the clinician’s rejection of the guideline recommendation.

The clinician can also request to view the hypermedia by clicking on the ‘Hypermedia >’ button, which shows the guideline document with statements of the rationale, and related didactics (or explanations) for the particular guideline step taken highlighted, and contextualised with the patient’s actual EHR data values (appearing as ‘sticky notes’ next to the relevant guideline document statement)[14] that were used to arrive at

[14] The hypermedia component was deemed out of scope for this thesis, and was therefore not implemented. However, a discussion (in section 6.7 and 7.3.2) is made with relation to this future work with a proposed mock-up of how it might appear to the clinician.

that decision point. The clinician can also select an indication from the 'Indications' list and click on 'View Detail >' to view the EHR transaction that recorded the indication (e.g. selecting to view the details of the 'Diabetes' indication will query the EHR for the patient's 'Problem' list from his/her persistent transactions where the 'Diabetes' problem was first recorded, and display it to the clinician).

Problem entries in this contact note transaction are collated by the DSS as well as queried from a separate "Current Problems" transaction (a persistent transaction recording all the patient's diagnoses) to determine indications for a particular drug. (Other relevant transactions such as "allergies/drug intolerances" may also be queried).

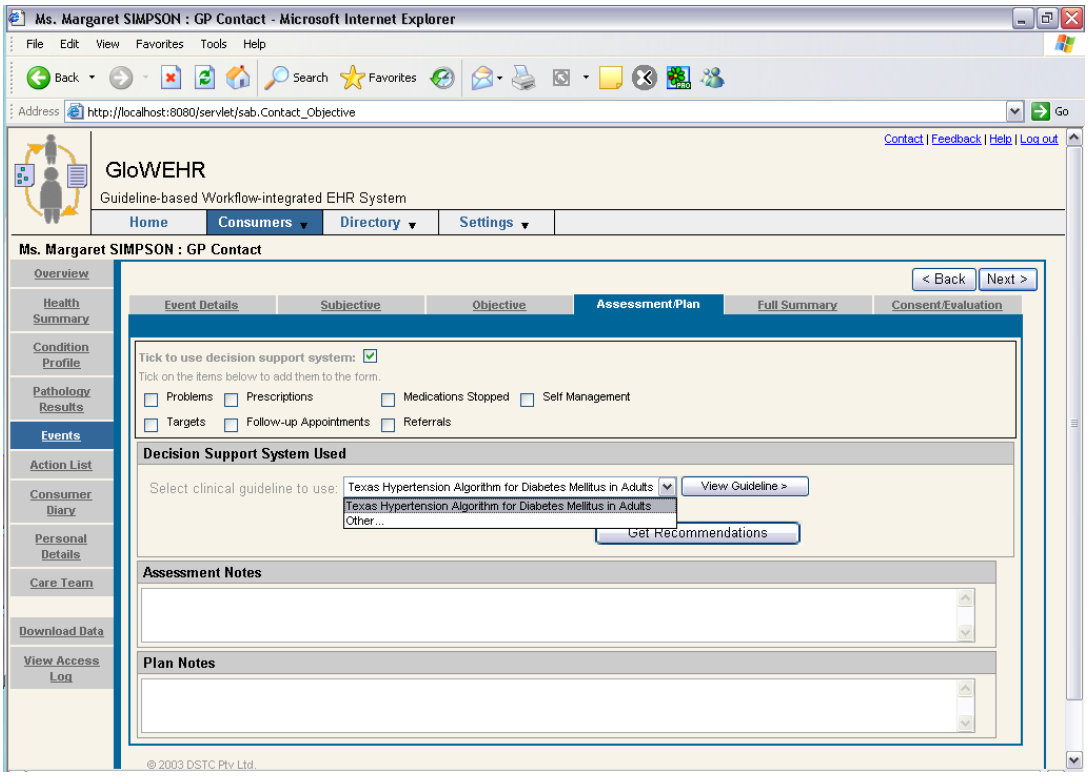


Figure 4.22. GP Contact User Interface.

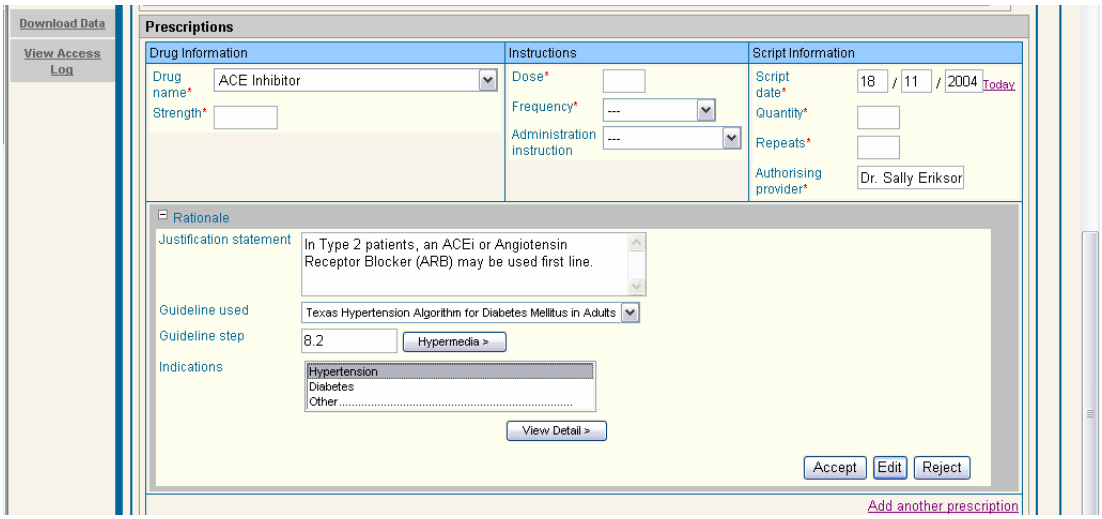


Figure 4.23. Portion of the Form Showing the Drug Recommendation Pre-populated by the DSS.

4.6. Achieving Workflow with Instruction

Based on our workflow-integrated EHR system architecture presented in chapter 3, and the Breeze workflow system architecture, the execution of EHR Instructions can achieved by the system as described in the UML sequence diagrams illustrated in Figure 4.24, and Figure 4.25. Note that the messages between the relevant system components[15] are quite high level, but do indicate the main events that occur, and the main data that is passed. The diagrams show respectively, the sequence of system interactions required for the instantiation or invocation of an Instruction Execution, and the data collection, and updating of the Instruction Execution as the workflow instance progresses.

[15] The *open*EHR kernel validates the EHR data based on their archetypes, and is currently not implemented in this prototype. We assume that the data recorded is valid at this point.

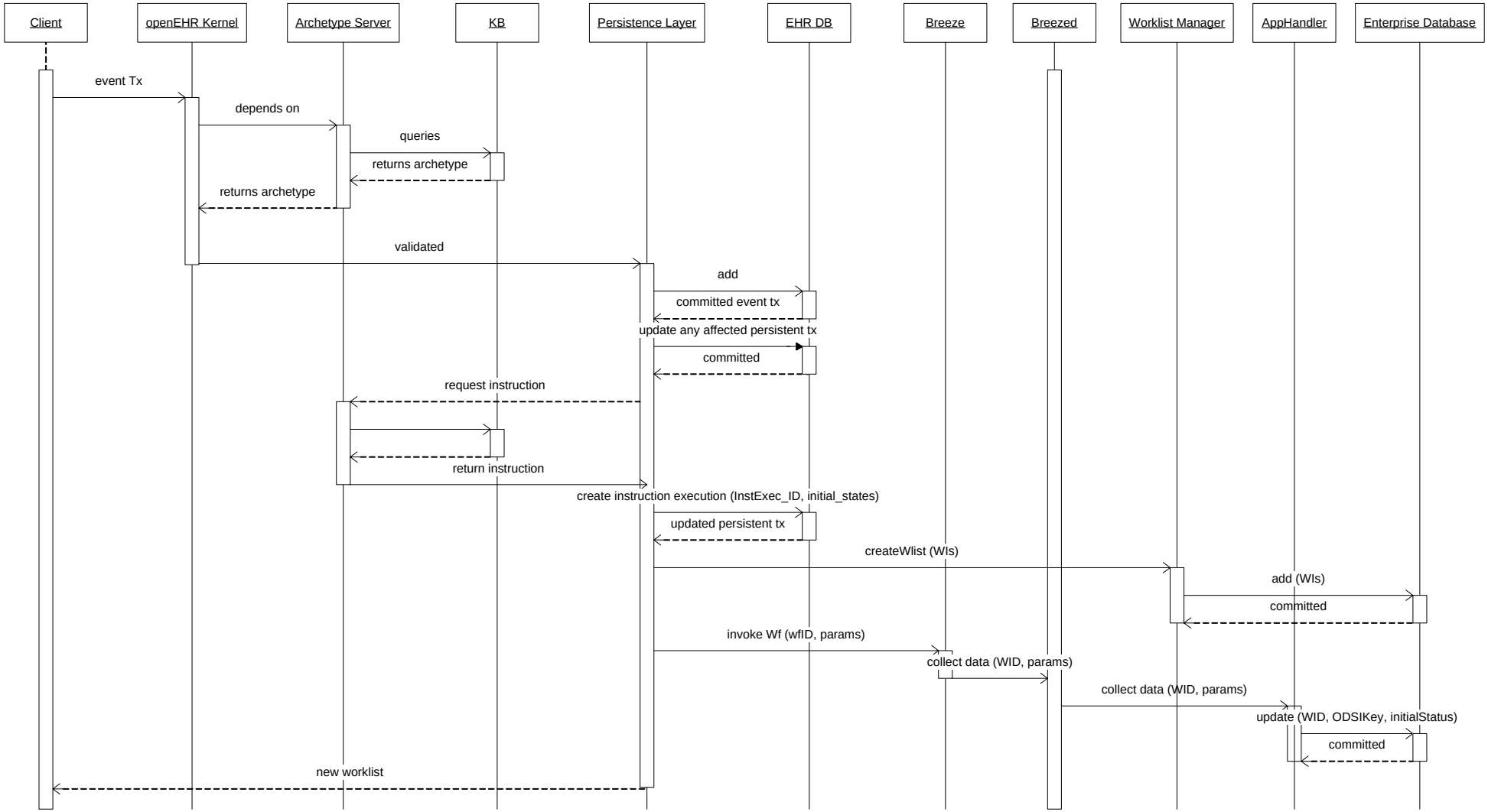


Figure 4.24. Sequence Diagram for Instantiating an Instruction Execution Entry.

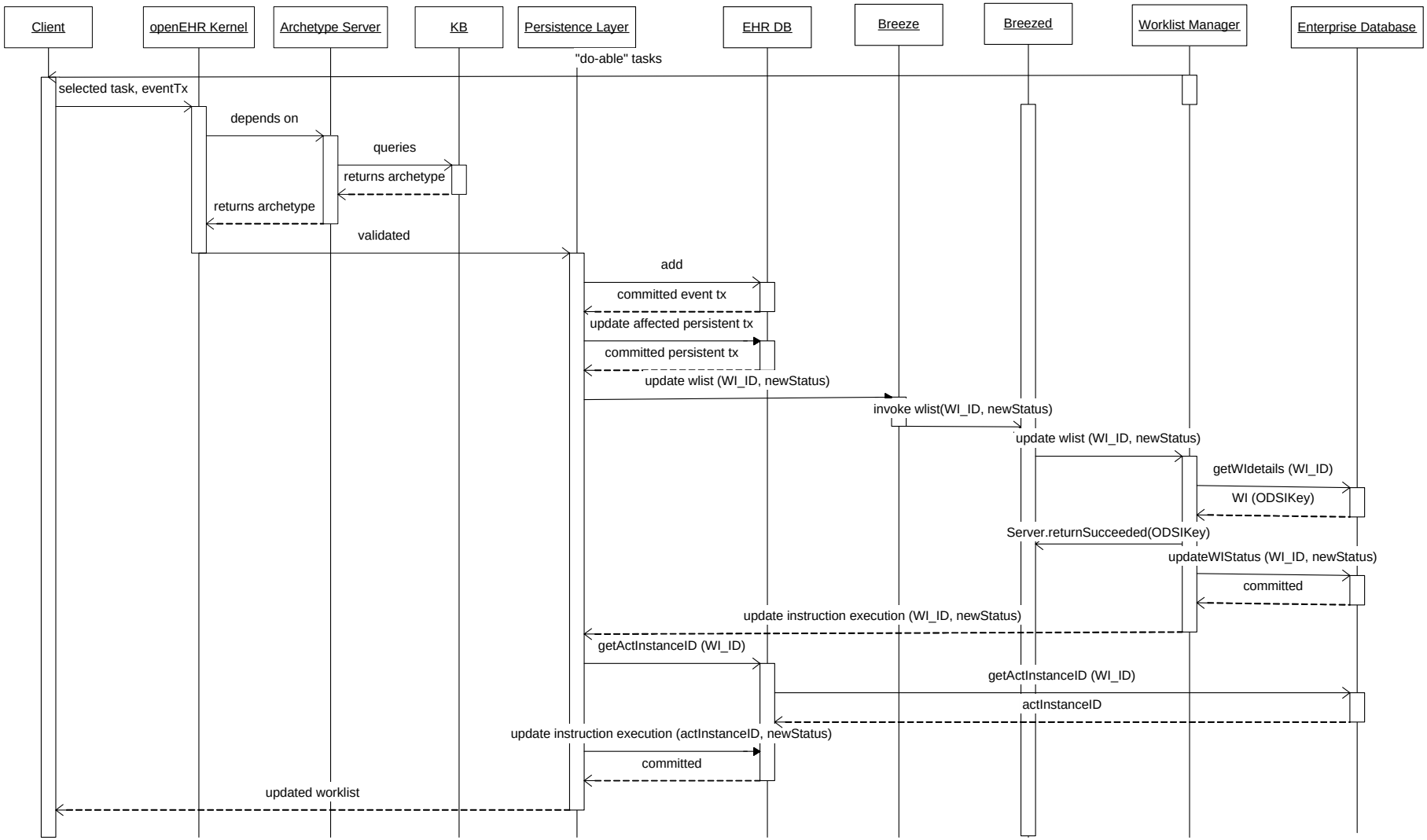


Figure 4.25. Sequence Diagram for Data Collection and Instruction Execution Entry Update.

5

CASE STUDY: EARLY SUPPORTED DISCHARGE FOR POST-STROKE REHABILITATION

5.1. Case Overview

Stroke is the sudden death of a portion of the brain cells due to lack of oxygen, and occurs when blood flow to the brain is cut off due to a blockage or rupture of an artery to the brain. Stroke is the third on the list of the most common causes of death (after coronary artery disease and cancer) and one of the most frequent causes of severe adult disability. The recovery from neurological impairment as a result of stroke amongst survivors varies from weeks to months in terms of survivors regaining their full

independence. The three main settings of the rehabilitation process usually occur in the order of the hospital acute care unit, stroke unit, and the community - keeping in mind that this process is a continuum that begins soon after the occurrence of stroke and ends only when rehabilitation is no longer producing any further positive effect.

Stroke unit care usually involves an early assessment of patient needs when he/she is discharged from hospital, hence, the discharge planning that partakes both the patient and his/her care team. The Scottish Intercollegiate Guidelines Network's (SIGN's) post-stroke rehabilitation, prevention and management of complications and discharge planning guideline [164] indicate that an early supported discharge (ESD) program can reduce the length of hospital admission in the selected stroke patients. Such a program is provided by a well resourced, multi-disciplinary team who assessed patients during hospital admission, organised their discharge, and provided post-stroke rehabilitation after their discharge from hospital. This approach can significantly reduce costs over a normal hospital stay, and increase the availability of hospital beds. Moreover, this transfer of care back to the community also appears to give at least the same level of good outcome as a patient would in hospital.

An Example ESD Scenario

After one month of formal post-stroke rehabilitation within the Lyell McEwin Hospital, Mr. George Phillips has shown substantial improvements. In particular, he is able to eat a normal diet, and can now walk safely with another person's assistance. Ms. Julie Falco, the ESD Coordinator from the hospital, sees Mr. George Phillips after his attending hospital ward nurse has advised of his readiness to be discharged. During this review with Ms. Falco, it is noted that Mr. Phillips will require assistance with personal activities of day-to-day living. He seems able to comprehend most simple instructions, and can utter short sentences. In addition, he will need a medication supply of aspirin, anti-hypertensive drugs, and a lipid-reducing drug. His wife participates in the review, and because she no longer works, she can greatly assist in his care, and is very keen for him to be sent home as soon as possible. Ms. Falco organises for an Occupational Therapist (OT) to do a home assessment for Mr. Phillips.

He is referred to the OT, Mr. Hugh Stewart who visits his home, and during which, Mr. Stewart takes notes regarding Mr. Phillips's lifestyle and daily living activities, his mobility, and the effects that it may have on those activities. While Mr. Phillips has the assistance of his wife, she does suffer from arthritis, which will limit some of the assistance that her husband will need. In particular, Mr. Phillips will need to have handrails installed in his bathroom for safety and support. Mr. Stewart notifies Ms. Falco informally via a phone call of the outcome, and sends an order of the required equipment for the handrails to his equipment company, along with the request for it to be delivered and installed with the required specifications. Mr. Stewart then writes up the home assessment report and sends it to Ms. Falco.

After Mr. Stewart has been notified that the handrails have been installed, he makes a follow-up visit, and finds that everything is in order, and that Mr. Phillips is educated on proper use of the handrails to ensure his safety. Mr. Phillips raised no further issues, but assured that he would contact Mr. Stewart of any in future.

5.2. Analysis of the ESD Scenario

This section describes the scenario developed for the ESD case study based on the analysis of the ESD scenario derived from the Lyell McEwin Hospital and its associated guideline to illustrate our approach of guideline-based workflow-enabled EHRs via our instructions.

5.2.1. System Data Flows

ESD Coordinator's Data Flow

We derive a set of data flows that describe the set of documents (i.e., data to be recorded) required in specific points in the business process of the ESD program. The ESD data flow is as shown in Figure 5.1.

(1) Through a hospital assessment, the nurse in a hospital ward identifies a patient as a potential ESD patient thus, the patient is 'flagged' for ESD. Successful discharge is dependent on accurately assessing the patient's domestic situat-

ion, and establishing the networks to meet critical needs such as day-to-day self-care, domestic assistance, and home modifications

(2) The ESD coordinator reviews the patient and the patient's details and ESD coordinator's report are placed in a file. At this point, the patient may:

   a. Reject the ESD option – usually, because they feel they are well enough to cope by themselves, or the ESD coordinator may not allow the patient to be admitted into ESD if the patient has a drug problem, a history of violence or alcohol abuse. In such cases, information about alternative services will be sent to the patient. A final state can then be reached in the ESD data flow where in most cases, the patient will be sent home.
   b. Alternatively, the patient may be deemed unlikely to achieve independence within the short intervention timescale of ESD, and hence may be referred to a long-term (domiciliary) care organisation or perhaps to a nursing home.
   c. Otherwise, the patient will then be enlisted into the ESD with the patient's consent.

(3) Once the patient is accepted into ESD, a plan of services and schedule is made for the patient that includes referrals to other healthcare professionals, namely, the OT (Occupational Therapist), RDNS (Royal District Nursing Service), Physiotherapist, Speech Therapist, and/or the Social Worker. The ESD coordinator also determines, based on the review, whether or not the patient requires any basic equipment (such as a shower chair, non-slip mat, or bath rails) for his/her home so that the equipment can be set up when the patient arrives home from hospital.

(4) The final state of the patient in this ESD data flow is the patient being discharged from ESD at the end of its two-week duration.

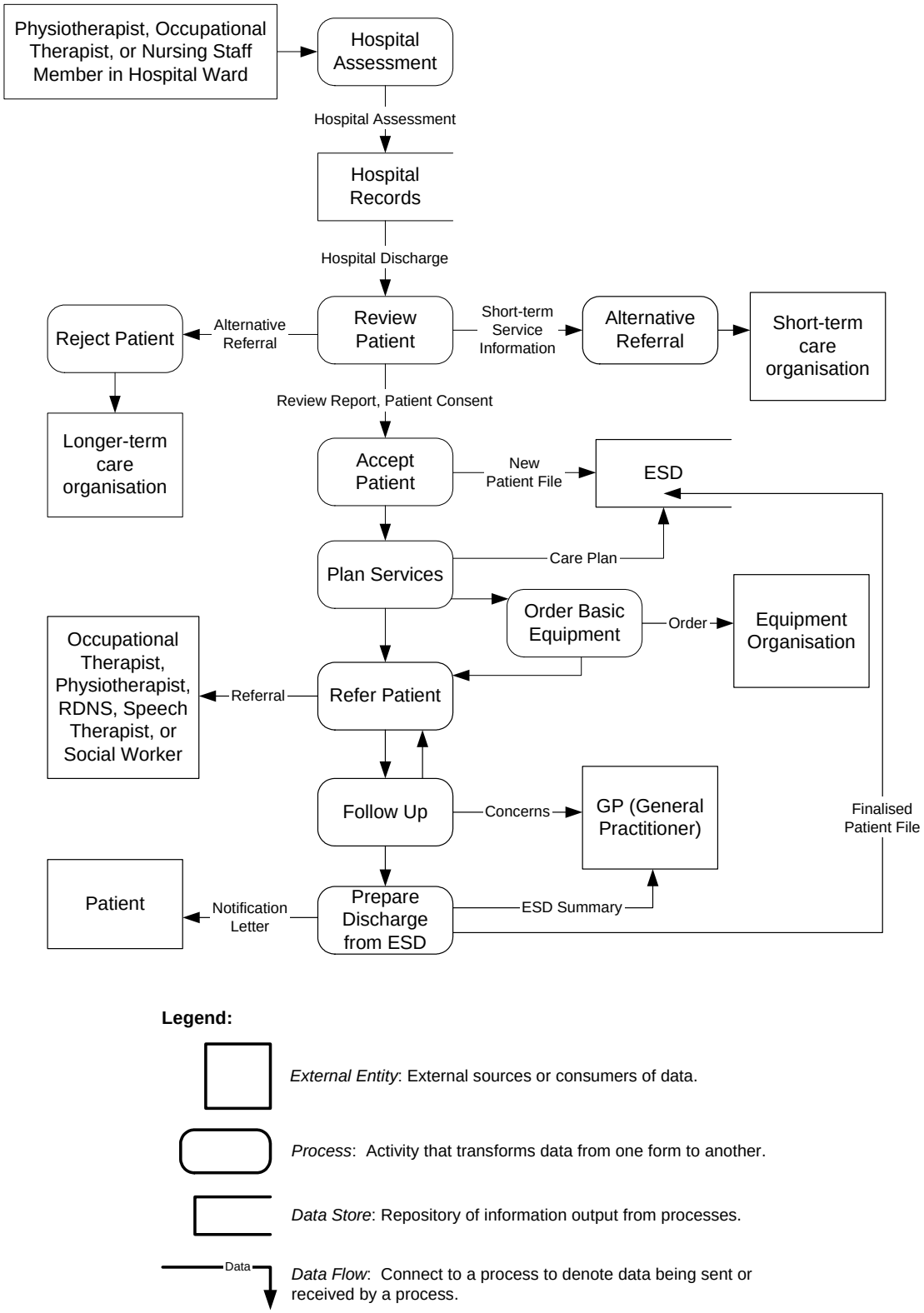


Figure 5.1. ESD Data Flow Diagram.

Occupational Therapist's Data Flow

The role of the Occupational Therapist (OT) is to treat individuals with impairments, restricted levels of activity, and limited ability to participate due to injury or illness, in order to attain the highest level of independence possible for the individual to perform their day-to-day living. Part of the OT's tasks include identifying the activities that are undertaken by the individual's daily living, assessing the individual's skills of carrying out those activities (from social activities to self-care (e.g. showering, cooking, cleaning, shopping)), assessing the individual's physical environment (home, workplace), and providing a number of interventions such as patient education, advise and provide any appropriate equipment to assist the patient's tasks (e.g., wheelchair, shower mat, shower chair, fitted bathroom rails, etc), and liase with support groups, etc.

Figure 2 illustrates the data flow for the OT. The OT makes a visit to the patient's house and makes an assessment. The OT then identifies any need for equipment for the patient, and also notifies the ESD Coordinator to inform him/her of the outcomes of the visit (this is usually on the day of the visit). The OT then either organises for the equipment to be sent to the patient's home; or alternatively, the OT may deliver the equipment him/herself and educates the patient on proper equipment use (for patient safety) in their home. For the installation of semi-permanent to permanent fixtures in the patient's home, the OT is required to write a letter to the housing trust requesting approval for any changes to the house. The OT does a follow up on the equipment and the patient, and may make any further required modifications to the equipment, which may need re-ordering of items. Finally, the OT writes a written report on the home visit, and forwards a copy of it to the ESD Coordinator (generally the day after the visit).

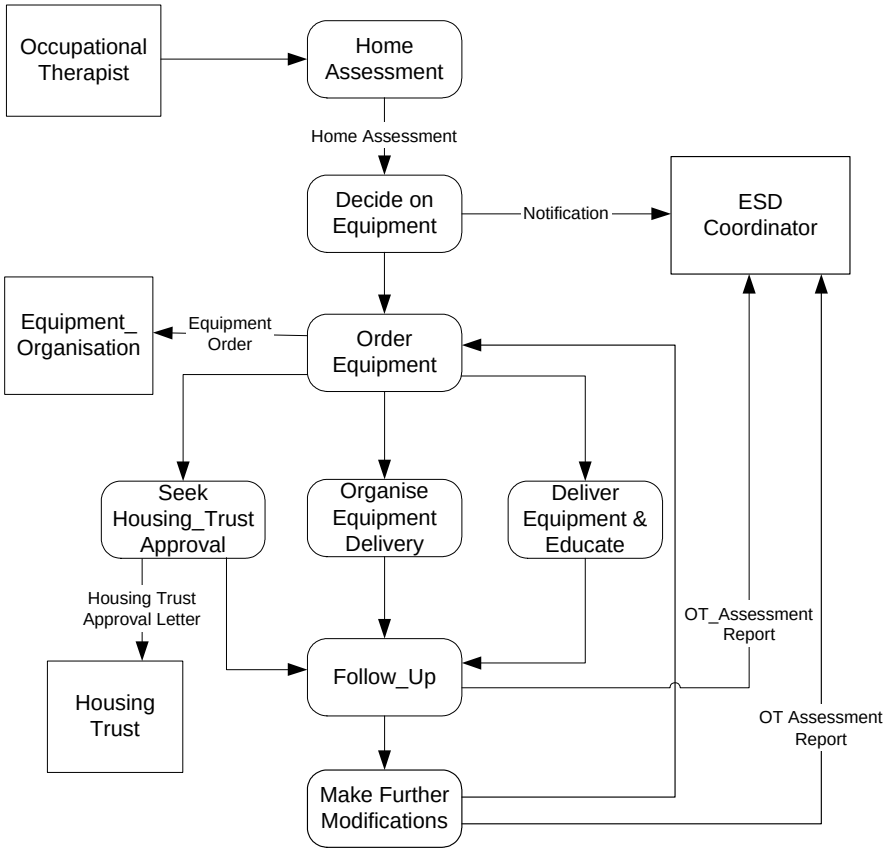


Figure 5.2. Occupational Therapist's Data Flow Diagram.

5.2.2. Task Detail Tables

Table 5.1. Stakeholders in the Scenario.

Actor	Role
Mr. George Phillips	Stroke patient
Ms. Karen Smith	Hospital Ward Nurse
Ms. Julie Falco	ESD coordinator
Mr. Hugh Stewart	Occupational Therapist

Table 5.2. Task Detail Table for the Hospital Ward Nurse.

Task #	Task	Input Requirements
1.0	Hospital Assessment	Hospital Separation

Table 5.3. Task Detail Table for the ESD Coordinator.

Task #	Task	Input Requirements
2.0	Review patient	Review report
2.1	Plan services	Care plan
2.2	Refer patient	Referral
2.3	Follow up	
2.4	Prepare discharge from ESD	Notification letter ESD summary Finalise care plan
2.5	Notify GP	
2.6	Notify patient	

Table 5.4. Task Detail Table for the OT.

Task #	Task	Input Requirements
3.0	Home assessment	Home assessment
3.1	Order equipment	Equipment order
3.2	Deliver equipment and educate	
3.3	Follow up	OT assessment report

5.2.3. Specific Interactions

From the data flows, we illustrate the specific interactions required in enacting the scenario via an activity diagram. The activity diagram is partitioned into a number of 'swim lanes' that indicate who/what is performing the activity. These actors align with those identified in section 4.2.2. The diagram in Figure 5.3 is somewhat simplified in that the activities for the other providers (RDNS, physiotherapist, speech therapist, and social worker) have been omitted since they are out of scope for the specific scenario we are investigating. The swim lanes (actors), and specific sequence of activities (or 'running workflow instance' or 'case') that are the focus of the walk-through later in this chapter are indicated in the shaded areas (again, based on the task detail tables presented in the previous section).

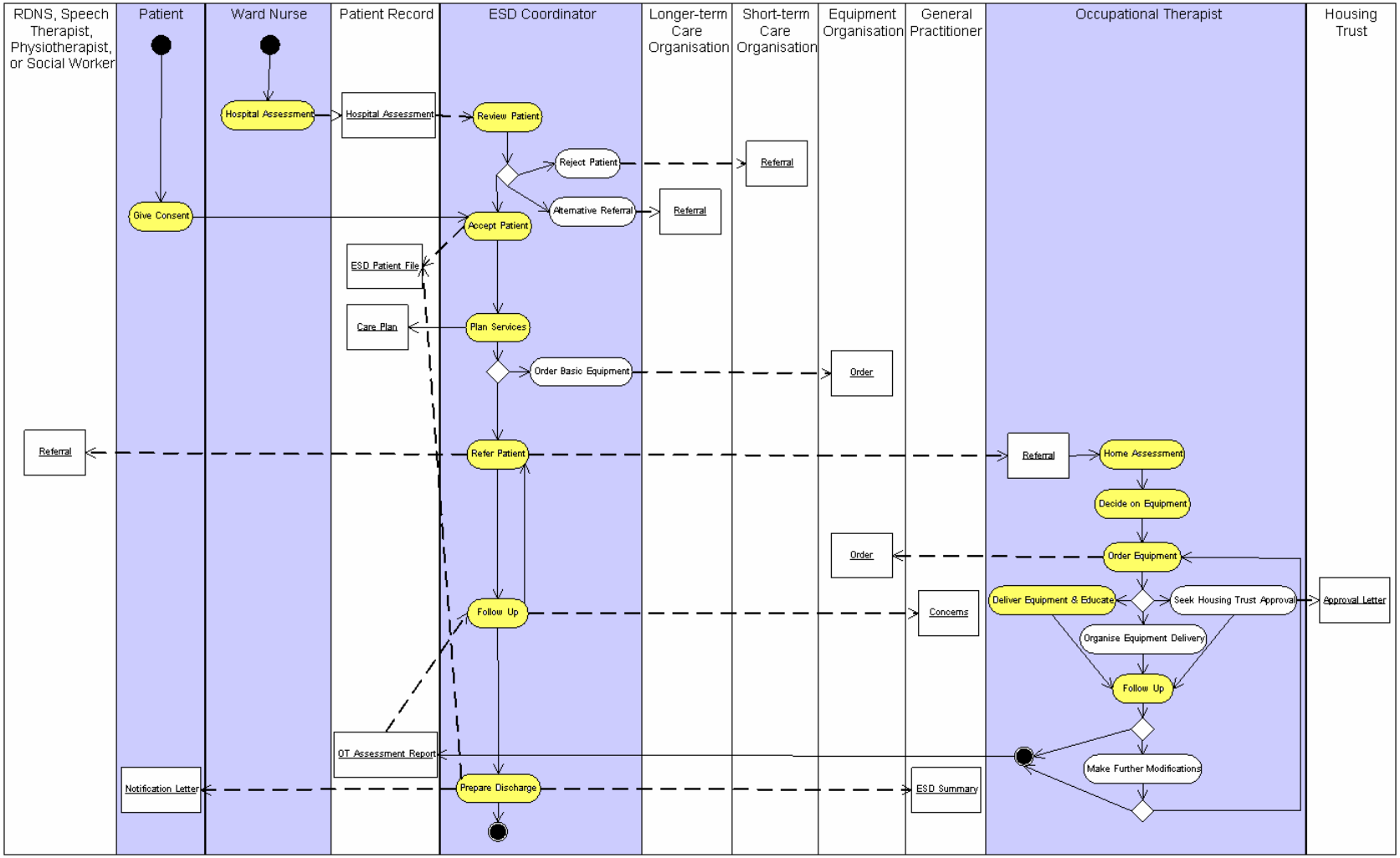


Figure 5.3. Activity Diagram for the ESD Case Study.

5.3. Case Workflow

From identifying and defining the data flow and the specific interactions (via activity diagramming) required from the guideline/business process above (i.e., conceptual design), we define the *workflow* model for the case. This design process involves further abstracting the conceptual design to more concrete terms:

- Defining the workflow activities
  - This may involve adding, removing and/or modifying activities identified from the conceptual design.
    - Adding activities for complex routing of activities; system/-automated activities.
    - Removing activities that are not needed in terms of system interaction in order to simplify the workflow.
- Assigning activities to participants
  - A participant may be a role, human, resource, resource set, organisational unit, or a system/external application; and where they are abstract entities until run-time when they are replaced by the actual performers – i.e., a real person, or a program/computer procedure.
  - This should correlate with the participants identified in the conceptual design, but may involve adding new participants that are system-based, and/or replacing existing activities whose participants are currently human with system-based roles.
- Specifying the temporal sequencing and branching of activities
  - This step involves specifying the required temporal sequencing and types of branching that occur between activities in the workflow; as well as
  - Specifying pre- and post-conditions for enacting activities.
- Defining the workflow data/parameters
  - Data that is used to make decisions (i.e., evaluating conditions) or refer to data outside of the workflow that is passed between activities and sub-workflows (i.e., parameters).
  - What are the data that are commonly required by all activities in a workflow (i.e., for all its instances)?

- The workflow data may be parameters required by workflow tools/applications for processing, and may be returned by those applications back into the workflow.

- Defining new activity attributes
  - Workflow models are not domain-specific and therefore require additional activity attributes to make them more usable and relevant to a domain. Such attributes will come from attributes from the instruction activity reference model in this case.
- Specify additional workflow and activity properties such as:
  - Priority: the level of importance or urgency of performing a workflow or activity;
  - Validity: the dates that the workflow process definition remains valid;
  - Duration: expected duration time of performing the activity;
  - Working/effort time: the amount of time the participant of the activity will need to undertake the activity;
  - Scheduling: specifying the dates and/or times that an activity is scheduled to start.
- Specifying and assigning workflow applications to workflow activities
  - This involves specifying the applications or tools required and invoked by the workflow, and where
  - An application is a computer-executed tool used to perform a set of activities.

This section will discuss how we defined the workflow schemas from the data flows and interactions acquired earlier.

5.3.1. Defining the Workflow Activities

The following figures show the workflow graphs produced using JaWE. The ESD coordinator's workflow shown in Figure 5.4 shows a few activities that have been added, namely the start and end nodes, and a routing activity.

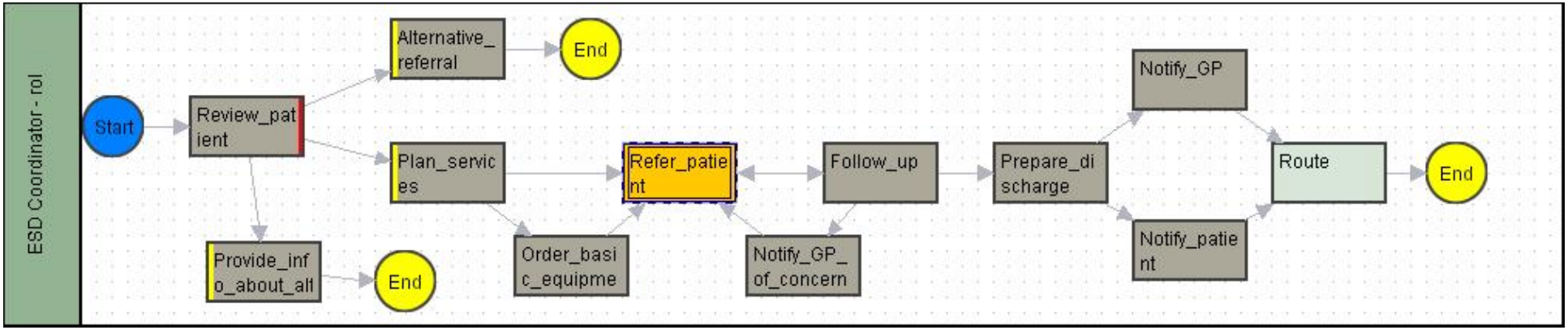


Figure 5.4. ESD Coordinator's Workflow.

Start and End Nodes

The Start and End nodes are added for explicit indication of where the workflow execution starts, and where the execution can terminate (this may be one or more terminal points in the workflow).

Route Activity

In general, the Route activity is a 'dummy' activity that has no participant, or application, and does not have any effect on the workflow in terms of data, but enables complex routing structures to be represented. Routing activities are usually used in situations where certain combinations of transitions cannot be expressed within a single transition from the output activity or a single incoming transition to an activity. For example: an XOR and AND split combination on output transitions from an activity; XOR and AND join conditions on input transitions to an activity; and transitions requiring conditional AND joins of a subset of threads, with continuation of individual threads. In Figure 5.4, the Route activity is added to merge/synchronise more than one incoming transitions as the End node can accept only one input transition at a time.

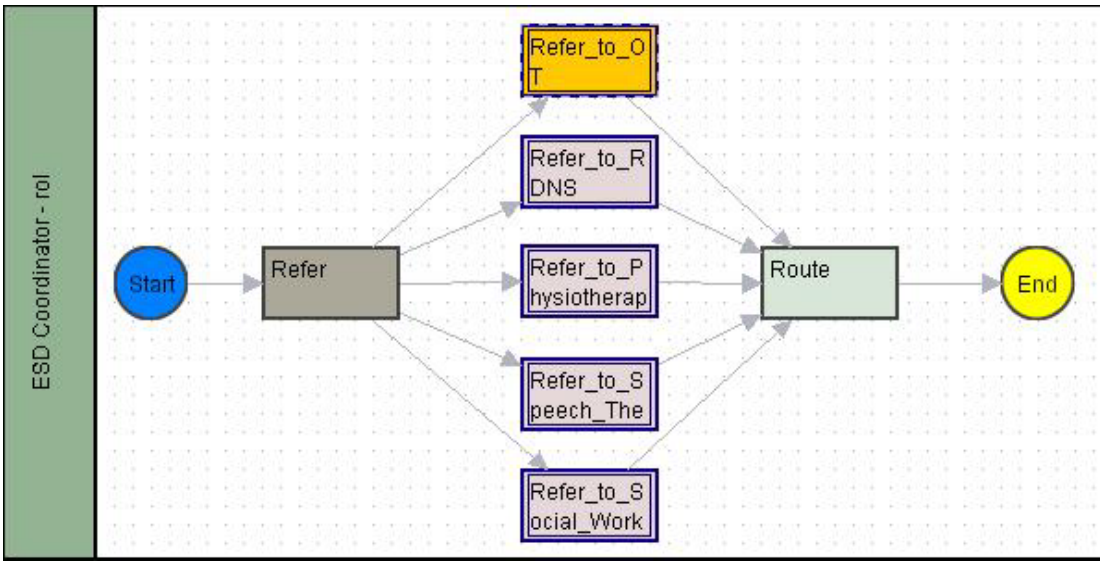


Figure 5.5. Refer_patient Sub-workflow.

Workflow Granularity

A number of decisions had to be made regarding the granularity of the case workflow representations. There are two general ways in which the level of workflow granularity could be dictated by:

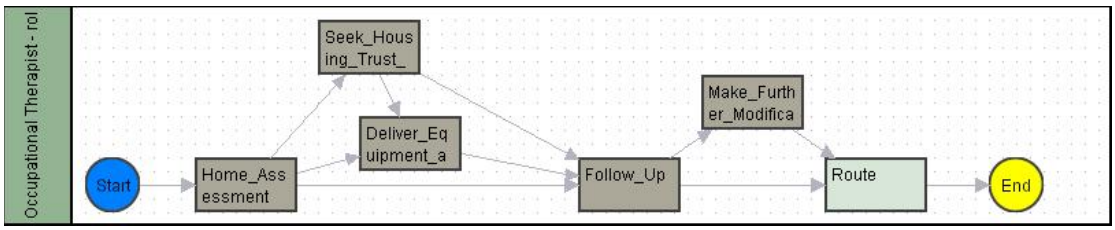
(1) System interaction: Activities are defined according to system-based (automated) tasks (handing off an activity to be executed by an application); user tasks are defined according to usage of the system (worklist) – e.g., entering data. The latter implies user tasks not necessarily being strongly aligned with the actual work undertaken in the real world. That is, two or more distinct 'bits' of work might be required to be undertaken in order to complete an activity, and the result of that task might be the collection of data. Thus, all tasks would require some form of system interaction.

(2) Need for a general 'to do' list: Tasks are defined whether or not they require system interaction. The key advantage of this is that users have the full list of tasks and 'bits' of tasks available to them. The 'bits' of (manual) tasks – may not be known or have direct relevance to the system, but may nonetheless serve as passive or implicit forms of reminders to the user. These can be 'ticked' off the list as they are done. These tasks may be represented as 'sub-items' under a particular task. This approach would be better suited to users who generally have access to the system a lot of the time to keep track of workitems; or require an almost 'wizard-like' system that guides them step-by-step in the workflow. The latter is particularly useful in the context of training participants who have little knowledge of the business process.

The first method was adopted in our illustration due to its practicality in that the participants within the scenario already have underlying knowledge and expertise in the work they do, and moreover, their activities are very often performed out in the field and are therefore, less likely to have direct and ongoing access to systems. In the ESD coordinator's scenario, the OT activity of Home_assessment in Figure 5.6 could be further broken down into a few steps: Initial_assessment, Order_-equipment – each of which requiring data collection. However, in reality, these steps would be performed in one OT appointment or session, thus they were combined to one. There is also the potential for having the notification to the ESD Coordinator of

the outcome of the OT's visit to be an activity on its own, such that the system can automatically send this notification (via a procedure call), as soon as the home assessment is made. However, in this case, we assume that the notification is done via a phone call during the Home_assessment activity as it is currently done in the Lyell McEwin scenario. The Follow_Up activity is really a generic type of activity, which might involve any or a number of these aspects: following up on the housing trust approval letter; checking if the patient has received the equipment that was ordered; checking if the patient has any further issues with the equipment on its use, as well as other issues. If modifications need to be made with the equipment, then this activity must be done following, and includes ordering of any modifications/parts needed. Thus, in general, the granularity of the workflow definition needs to be matched according to its purpose and utility. Multifaceted tasks to be performed by a single person/role in one session as a fixed routine will rarely need to be decomposed.

Figure 5.6. Occupational Therapist's Workflow.



5.3.2. Defining and Assigning Activities to Participants

In JaWE, we can define a set of participants at a package-level, which allows these participants to be used within any of the processes defined within that package; otherwise, they can be defined to be used only within the scope of a single process. Figure 5.7 shows the JaWE dialogs for defining a new participant at the package-level by a unique identifier (usually automatically generated by the editor itself using a combination of the workflow package name, version, workflow identifier, and a unique participant identifier), participant name, and participant type (resource set, role, human, resource, organisational unit, or system). Listing 5.1 shows the resulting XPDL fragment declaring the participants of all processes in the workflow package.

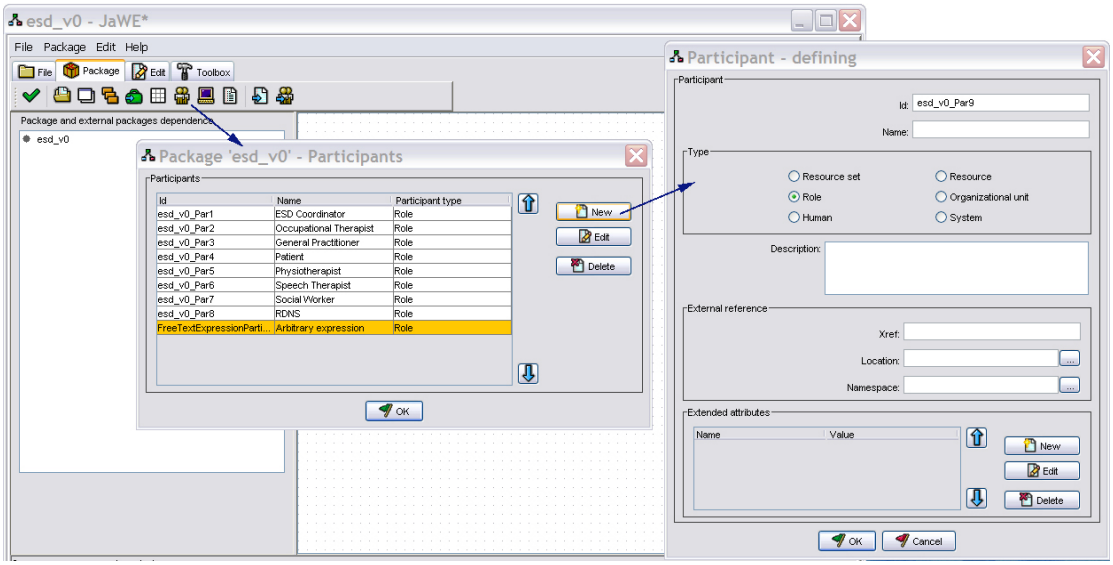


Figure 5.7. JaWE Dialogs for Defining Workflow Participants.

Listing 5.1. Participant Declaration in XPDL.

```
<Participants>
    <Participant Id="esd_v0_Par1" Name="ESD Coordinator">
        <ParticipantType Type="ROLE"/>
    </Participant>
    <Participant Id="esd_v0_Par2" Name="Occupational Therapist">
        <ParticipantType Type="ROLE"/>
    </Participant>
    <Participant Id="esd_v0_Par3" Name="General Practitioner">
        <ParticipantType Type="ROLE"/>
    </Participant>
    <Participant Id="esd_v0_Par4" Name="Patient">
        <ParticipantType Type="ROLE"/>
    </Participant>
    <Participant Id="esd_v0_Par5" Name="Physiotherapist">
        <ParticipantType Type="ROLE"/>
    </Participant>
    <Participant Id="esd_v0_Par6" Name="Speech Therapist">
        <ParticipantType Type="ROLE"/>
    </Participant>
    <Participant Id="esd_v0_Par7" Name="Social Worker">
        <ParticipantType Type="ROLE"/>
    </Participant>
    <Participant Id="esd_v0_Par8" Name="RDNS">
        <ParticipantType Type="ROLE"/>
    </Participant>
</Participants>
```

After defining the workflow package participants, we can then begin to define the workflow process for the participant. Figure 5.8 below shows how we do this via the JaWE dialogs. By selecting an existing participant from those defined in the package (in this case, the ESD Coordinator role), a process 'workspace' is added within the process dialog box where we can then add activities that are to be performed by that participant. In XPDL, the participant for an activity is defined within the `<performer>` tags as shown in Listing 5.2.

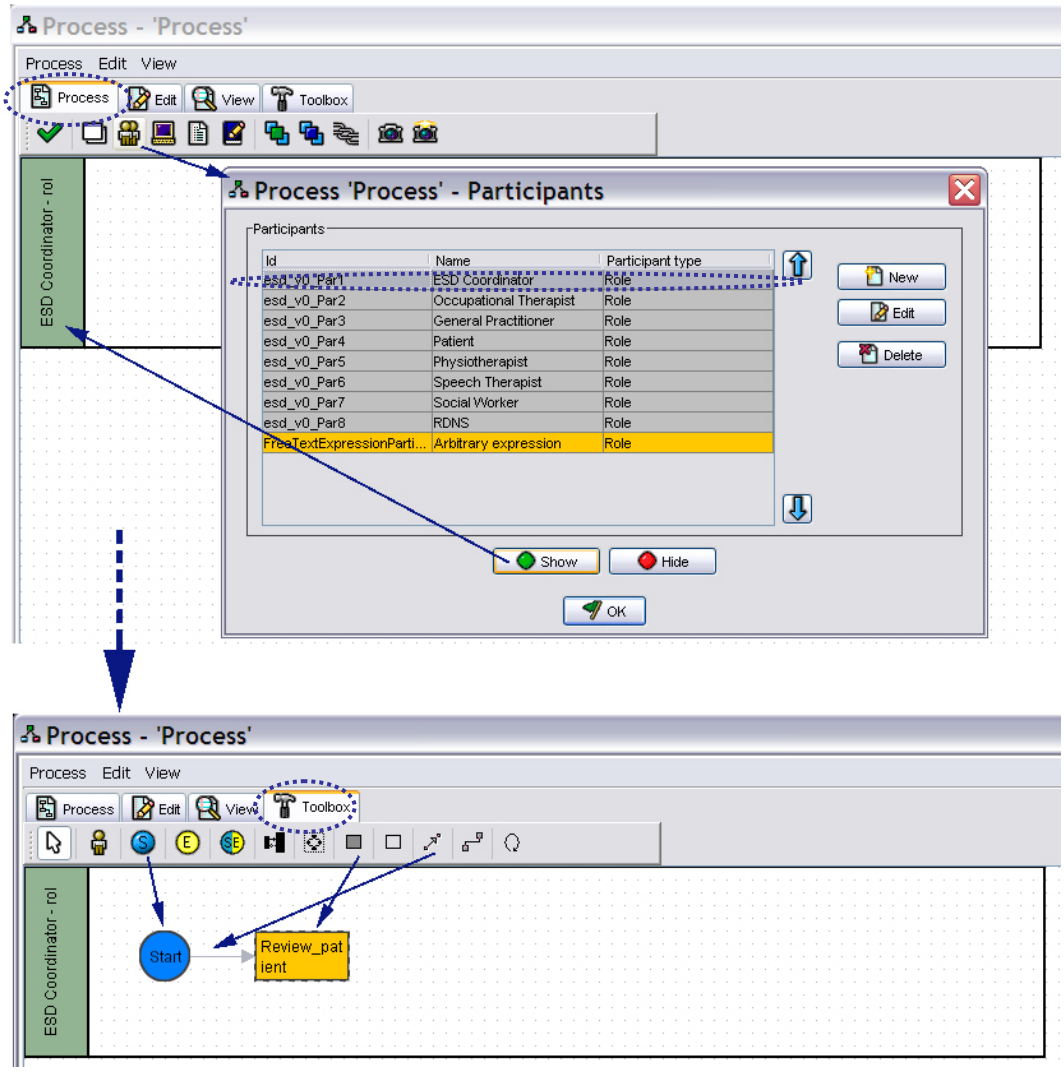


Figure 5.8. Assigning Activities to Participants in JaWE.

Listing 5.2. Fragment XPDL for Defining the Participant of Review_patient **Activity.**

```
<Activities>
     <Activity Id="esd_v0_Wor1_Act1" Name="Review_patient">
         <Implementation>
             <Tool Id="esd_v0_App1" Type="PROCEDURE">
                 <ActualParameters>
                     <ActualParameter>data_to_collect</ActualParameter>
                 </ActualParameters>
             </Tool>
         </Implementation>
         <Performer>esd_v0_Par1</Performer>
         …
         <TransitionRestrictions>
         …
         </TransitionRestrictions>
         <ExtendedAttributes>
          …
         </ExtendedAttributes>
     </Activity>
     …
 </Activities>
```

There may be situations where more than one role can be assigned to an activity, set of activities, or workflow (i.e., 'group of roles'). For example, in the OT's workflow, there is an activity to seek housing trust approval, which may also be performed by the ESD Coordinator due to it being a longer-term activity in terms of its duration for approval/resolution. JaWE currently does not allow for workflows or activities to be specified without the assignment of a participant, nor does it allow for multiple participants to be assigned. Due to this limitation, the task to seek housing trust approval was therefore, assigned to the OT as a compromise, because it is an activity that arises from or dependent on the activities of the OT. However, it should be a requirement that JaWE be extended if it is to be really usable in this way.

5.3.3. Defining New Activity Attributes

In general, workflow tools should allow a set of generic attributes to be used, which are considered common for all workflow instances, thus allowing it to potentially be used in all types of domains. However, such tools should also allow workflow implementers to define their own attributes that are specific to the context in which they

will be using it. The latter is one of the important functionalities that JaWE supports. Additional attributes that are specific to instructions were defined in XPDL as *extended attributes*. Extended attributes allow application/domain-specific activity attributes to be defined. An example of a fragment of the XPDL for the ESD activity Review_patient is given in Listing 5.3 with extended attributes defined from lines 27-41.

Listing 5.3. Domain-specific Activity Attributes Defined as External Attributes in XPDL.

```
<Activity Id="esd_v0_Wor1_Act1" Name="Review_patient">
   <Implementation>
   <Tool Id="esd_v0_App1" Type="PROCEDURE">
      <ActualParameters>
         <ActualParameter>data_to_collect</ActualParameter>
      </ActualParameters>
   </Tool>
   </Implementation>
   <Performer>esd_v0_Par1</Performer>
   <StartMode>
      <Manual />
   </StartMode>
   <FinishMode>
      <Manual />
   </FinishMode>
   <TransitionRestrictions>
      <TransitionRestriction>
         <Split Type="XOR">
            <TransitionRefs>
               <TransitionRef Id="esd_v0_Wor1_Tra4" />
               <TransitionRef Id="esd_v0_Wor1_Tra3" />
               <TransitionRef Id="esd_v0_Wor1_Tra2" />
            </TransitionRefs>
         </Split>
      </TransitionRestriction>
   </TransitionRestrictions>
   <ExtendedAttributes>
      <ExtendedAttribute Name="ParticipantID" Value="esd_v0_Par1" />
      <ExtendedAttribute Name="XOffset" Value="120" />
      <ExtendedAttribute Name="YOffset" Value="60" />
      <ExtendedAttribute Name="activity_type"
Value="Clinical_Intervention_Activity"/>
      <ExtendedAttribute Name="subject_state_precondition" />
      <ExtendedAttribute Name="subject_state_postcondition" />
      <ExtendedAttribute Name="is_start_activity" Value="true" />
      <ExtendedAttribute Name="is_end_activity" Value="false" />
      <ExtendedAttribute Name="is_mandatory" />
      <ExtendedAttribute Name="work_item" Value="ascertain patient needs" />
      <ExtendedAttribute Name="data_to_collect" Value="openehr.transaction-
event.review_report.v1" />
      <ExtendedAttribute Name="patient_state_goal" />
      <ExtendedAttribute Name="patient_state_target" />
   </ExtendedAttributes>
</Activity>
```

5.3.4. Specifying the Temporal Sequencing and Branching of Activities

JaWE supports the following types of transitions between activities:

- Sequence: has one input and one output activity (i.e., one transition between two activities).
- Types of branching:
  - AND Join: has more than one input activity and one output activity;
  - AND Split: has one input activity and more than one output activity;
  - XOR Join: has more than one input activity – only one of which can be executed; and one output activity (line 79 of Listing 5.4 shows how this is defined in XPDL);
  - XOR Split: has more than one output activity – only one of which can be executed; and one input activity (see lines 6 and 29 of Listing 5.4 for examples).

Additional extended attributes were defined to align with the instruction reference model to aid and/or support more complex types of control flow between activities (lines 19-21 in Listing 5.4 shows how these can be defined in XPDL):

- is_start_activity: denotes that this activity is the first activity in the workflow to execute.
- is_end_activity: denotes that this activity is the last activity in the workflow to execute.
- is_mandatory: to denote whether or not an activity within a set of inclusive activities is mandatory or optional.

Pre- and post-conditions are expressed as relatively simple Boolean type condition expressions based on workflow data/parameters. These conditions are equivalent to subject_state_precondition and subject_state_postcondition attributes, and are defined as extended attributes in activities. In JaWE, the pre-conditions for an activity to take place is defined by the join type – i.e., AND or XOR join, while the post-condition for successfully undertaking an activity can be defined by defining the set of 'target' activities – i.e., its direct output activities followed by the condition expression for each of those activities to take place (see Figure 5.9).

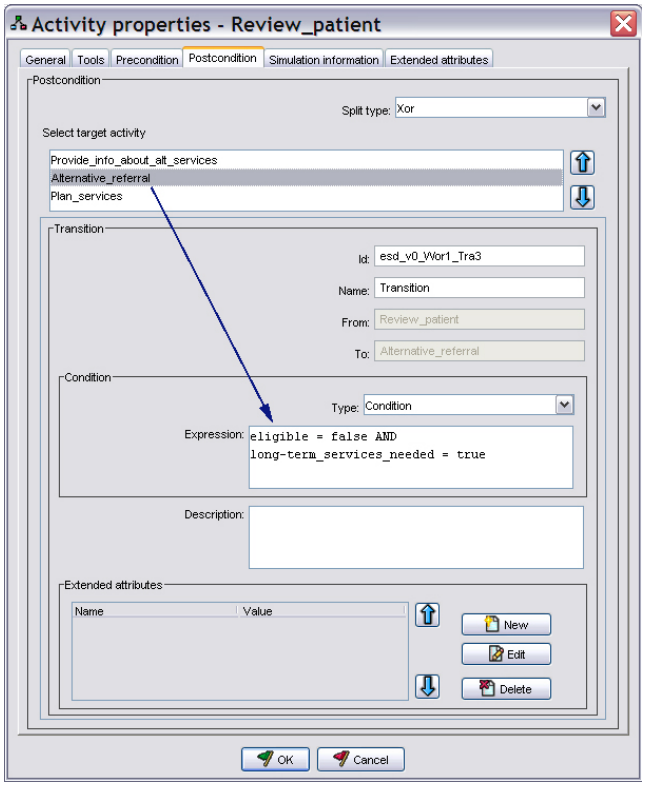


Figure 5.9. Post-condition Properties for Review_patient **Activity.**

Examples of the resulting XPDL definitions of these conditions can be seen in lines 95, 101 and 107 of Listing 5.4. However, for the purposes of direct alignment of the workflow definition and our instruction definition, and ease of transforming the XPDL to instruction definition and other workflow modelling specifications, we take advantage of JaWE's extended attributes and define these same condition expressions within the subject_state_precondition (e.g., lines 40, 50 and 63 of Listing 5.4) and subject_state_postcondition attributes as well.

In JaWE, sub-workflow execution can be defined as synchronous or asynchronous, but synchronisation cannot be directly defined for (atomic) activities that merge a set of activities altogether (AND join), or inclusively (OR join[16]) as it can using our instruction reference model. Instead, this can be done in JaWE by defining it as part of another extended attribute. Line 72 of Listing 5.4 below shows how to define a synchronous sub-workflow in XPDL. When merging activities, the default would be set as synchronous, however, there may well be cases when future activities can be

[16] JaWE does not support OR joins.

started without having to wait for all of the previous activities to complete, but should all complete by the time the workflow instance completes. This is especially useful in the likelihood these activities will take a long time to complete.

Listing 5.4. XPDL Fragment Showing Key Control Flow Properties.

```
<Activities>
    <Activity Id="esd_v0_Wor1_Act1" Name="Review_patient">
    …
        <TransitionRestrictions>
            <TransitionRestriction>
                <Split Type="XOR">
                    <TransitionRefs>
                        <TransitionRef Id="esd_v0_Wor1_Tra4"/>
                            <TransitionRef Id="esd_v0_Wor1_Tra3"/>
                            <TransitionRef Id="esd_v0_Wor1_Tra2"/>
                        </TransitionRefs>
                </Split>
            </TransitionRestriction>
        </TransitionRestrictions>
        <ExtendedAttributes>
            …
            <ExtendedAttribute Name="subject_state_precondition"/>
            <ExtendedAttribute Name="subject_state_postcondition"/>
            <ExtendedAttribute Name="is_start_activity" Value="true"/>
            <ExtendedAttribute Name="is_end_activity" Value="false"/>
            <ExtendedAttribute Name="is_mandatory"/>
            …
        </ExtendedAttributes>
    </Activity>
    <Activity Id="esd_v0_Wor1_Act2" Name="Plan_services">
        …
        <TransitionRestrictions>
            <TransitionRestriction>
                <Split Type="XOR">
                    <TransitionRefs>
                        <TransitionRef Id="esd_v0_Wor1_Tra6"/>
                        <TransitionRef Id="esd_v0_Wor1_Tra5"/>
                    </TransitionRefs>
                </Split>
            </TransitionRestriction>
        </TransitionRestrictions>
        <ExtendedAttributes>
            …
            <ExtendedAttribute Name="is_mandatory"/>
            <ExtendedAttribute Name="subject_state_precondition"
Value="eligible = true"/>
            <ExtendedAttribute Name="subject_state_postcondition"/>
            <ExtendedAttribute Name="is_start_activity"
Value="false"/>
            <ExtendedAttribute Name="is_end_activity" Value="false"/>
            …
        </ExtendedAttributes>
    </Activity>
    <Activity Id="esd_v0_Wor1_Act3" Name="Alternative_referral">
        …
        <ExtendedAttributes>
            <ExtendedAttribute Name="subject_state_precondition"
Value="eligible = false AND long-term_services_needed = true"/>
            <ExtendedAttribute Name="subject_state_postcondition"/>
            <ExtendedAttribute Name="is_start_activity"
Value="false"/>
            <ExtendedAttribute Name="is_end_activity" Value="true"/>
            <ExtendedAttribute Name="is_mandatory"/>
            …
        </ExtendedAttributes>
    </Activity>
```

```
    <Activity Id="esd_v0_Wor1_Act6" Name="Provide_info_about_alt_services">
        …
        <ExtendedAttributes>
            …
            <ExtendedAttribute Name="is_mandatory"/>

            <ExtendedAttribute Name="subject_state_precondition" Value="eligible = false"/>
            <ExtendedAttribute Name="subject_state_postcondition"/>
            <ExtendedAttribute Name="is_start_activity" Value="false"/>
            <ExtendedAttribute Name="is_end_activity" Value="true"/>
            …
        </ExtendedAttributes>
    </Activity>
    <Activity Id="esd_v0_Wor1_Act9" Name="Refer_patient">
        <Implementation>
            <SubFlow Execution="SYNCHR" Id="esd_v0_Wor2">
                <ActualParameters>
                    <ActualParameter>data_to_collect</ActualParameter>
              </ActualParameters>
            </SubFlow>
        </Implementation>
        <TransitionRestrictions>
            <TransitionRestriction>
                <Join Type="XOR"/>
            </TransitionRestriction>
        </TransitionRestrictions>
        <ExtendedAttributes>
            …
            <ExtendedAttribute Name="activity_type" Value="Composite_Activity"/>
            <ExtendedAttribute Name="is_mandatory"/>
            <ExtendedAttribute Name="subject_state_precondition"/>
            <ExtendedAttribute Name="subject_state_postcondition"/>
            <ExtendedAttribute Name="is_start_activity" Value="false"/>
            <ExtendedAttribute Name="is_end_activity" Value="false"/>
        </ExtendedAttributes>
    </Activity>
</Activities>
<Transitions>
    <Transition From="esd_v0_Wor1_Act1" Id="esd_v0_Wor1_Tra2" Name="Transition" To="esd_v0_Wor1_Act2">
        <Condition Type="CONDITION">eligible = true</Condition>
        <ExtendedAttributes>
            <ExtendedAttribute Name="RoutingType" Value="NOROUTING"/>
        </ExtendedAttributes>
    </Transition>
  <Transition From="esd_v0_Wor1_Act1" Id="esd_v0_Wor1_Tra3" Name="Transition" To="esd_v0_Wor1_Act3">
      <Condition Type="CONDITION">eligible = false AND long-term_services_needed = true</Condition>
      <ExtendedAttributes>
          <ExtendedAttribute Name="RoutingType" Value="NOROUTING"/>
      </ExtendedAttributes>
  </Transition>
  <Transition From="esd_v0_Wor1_Act1" Id="esd_v0_Wor1_Tra4" Name="Transition" To="esd_v0_Wor1_Act6">
      <Condition Type="CONDITION">eligible = false</Condition>
      <ExtendedAttributes>
          <ExtendedAttribute Name="RoutingType" Value="NOROUTING"/>
      </ExtendedAttributes>
  </Transition>
   …
</Transitions>
```

5.3.5. Defining the Workflow Data/Parameters

Parameters that are interchanged with the application via the invocation interface are called formal parameters – i.e., data that is passed during invocation and return of control (e.g. of an invoked application). The Data Field represents the variables of a workflow schema, and are usually used to maintain decision data – i.e., used in conditions. Listing 5.5 below shows the XPDL fragment for defining workflow parameters.

Listing 5.5. XPDL for Defining Workflow Parameters.

```
            <FormalParameters>
                <FormalParameter Id="data_to_collect" Mode="IN">
                    <DataType>
                        <BasicType Type="STRING"/>
                    </DataType>
                </FormalParameter>
            </FormalParameters>
            <DataFields>
                <DataField Id="data_to_collect" IsArray="FALSE"
Name="data_to_collect">
                    <DataType>
                        <BasicType Type="STRING"/>
                    </DataType>
                </DataField>
            </DataFields>
```

5.3.6. Specifying and Assigning Workflow Applications to Workflow Activities

Listing 5.6 shows the XPDL fragment for declaring the applications namely, collect_data, send_notification, and wait required by a workflow for all its instances. Activities that have applications assigned to them should have a resulting XPDL that contains Tool activities with AUTOMATIC Start and Finish modes. Listing 5.7 shows the fragment XPDL for assigning software tools (that may be of type application or procedure) per activity.

Listing 5.6. XPDL for Specifying Workflow Applications.

```
<Applications>
    <Application Id="esd_v0_App1" Name="collect_data">
        <FormalParameters>
            <FormalParameter Id="data_to_collect" Mode="IN">
                <DataType>
                    <BasicType Type="STRING"/>
                </DataType>
                <Description>archetype ID of data to collect</Description>
            </FormalParameter>
        </FormalParameters>
    </Application>
    <Application Id="esd_v0_App2" Name="send_notification"/>
    <Application Id="esd_v0_App3" Name="wait"/>
</Applications>
```

Listing 5.7. XPDL Fragment for Assigning Applications per Activity.

```
<Implementation>
    <Tool Id="esd_v0_App1" Type="APPLICATION">
        <ActualParameters>
            <ActualParameter>data_to_collect</ActualParameter>
        </ActualParameters>
    </Tool>
</Implementation>
```

5.4. Data Collection

Although all activities result in some data being recorded into the EHR, such as updating the activity status, there are specific types of activities that enable one to explicitly specify the required set of data to be collected. These activities are Data_Collection_Activity and Clinical_Intervention_Activity. As mentioned, data collection is defined in terms of archetype identifiers or template identifiers. The data collected in this particular case study are specific types of event transactions, and thus refer to event transaction type archetypes, which result in the generation of new forms consisting of a number of data items to be filled in. There may be other cases in which the data collection is of smaller granularity. That is, cases where a single "event" (hence, one event transaction) might span over a longer duration, and/or require more than one participant to complete the recording of the full event

transaction, such that a certain set of the data items or sections within the event transaction can only be filled in by a certain participant. For instance, the (non drug) medication order form during a patient's hospital stay can be filled-out by different providers (e.g., nursing staff and practitioners). Another instance may be laboratory tests, where the laboratory technician/observer who actually collected the data may populate the observational data within a laboratory test, and then have the authorised provider to record the actual assessment and recommendations based on the observations. Such situations will require the specification of a lower-level data collection specification – i.e., the data collection is specified to the *organisational* archetype level (i.e., sections within the document), or even to the *entry* archetype level (i.e., data items within a document section).

The general syntax of the archetype/template identifier is in accordance with the *open*EHR approach, which is similar to a file directory path structure, i.e.,

"[EHR architecture].transaction-[transaction type].[transaction name].[archetype version]"

where –

- Transaction type may be an *event* or *persistent*;
- Transaction name comes from the transaction meaning attribute (which is the attribute used for archetype paths, as opposed to the name attribute of the archetype, which is used during paths at run-time); and
- Archetype version is the version number of the authored archetype definition.

One event transaction archetype is used for the required data collection in undertaking the Review_patient activity, i.e., for the Review Report forms. Listing 5.8 shows a fragment of the XPDL that specifies the data collection as an external attribute.

Listing 5.8. Example Data Collection in XPDL.

```
<Activity Id="esd_v0_Wor1_Act1" Name="Review_patient">
      ...
   <ExtendedAttributes>
      ...
      <ExtendedAttribute Name="data_to_collect" Value="openehr.transaction-
event.review_report.v1" />
   </ExtendedAttributes>
</Activity>
```

There may also be cases where an archetype can constrain the set of instructions that can be used. For example, a referral archetype can constrain the referral_to attribute value to only a specific set of organisations/provider roles. In the ESD case, the referral archetype may only allow referral_to values to "OT_Instruction", "RDNS_Instruction", "Social_Worker_Instruction", "Physiotherapist_Instruction", and "Speech_Therapist_Instruction". We will see this approach to be common in the Hypertension in Diabetes case study (see chapter 5). Consequently, this type of constraint currently cannot be supported by XML itself (for example, there are no XML data types that allow for this), nor has the *open*EHR standard group explored it in this context or level of detail – instead it would be specified within templates. We denote the set of allowable values like this via a special notation to support it, where the allowable values are delimited by a "|".

Specialisation of Data to Collect

An example case for specialisation of data collection is for the referral activity in our scenario. Specialised archetypes and template can be used to restrict the set of valid provider roles or organisations that the patient can be referred to based on the instruction definition. In particular, the activity Refer's data collection is specified to use a specialised referral template with restrictions on the set of provider roles whom the referral is for – i.e., OT, RDNS, physiotherapist, speech therapist, or social worker.

5.5. Implementation

This section will illustrate the step-by-step process of implementing our approach based on the ESD scenario described in section 5.1. The intention of the implementation walkthrough is to demonstrate how our approach works for users within a scenario, and the system interactions that occur as the scenario unfolds. More specifically, it will show:

- the instruction definition entry archetype;
- the archetypes for the various EHR data collection and html forms;
- how the users interact with the system at run-time via the worklist and recording of data via web-based forms;
- the resulting graphical view of the workflow as the instruction execution entry progresses;
- the specific artifacts (in full or fragments of) produced as a result of the interaction such as:
    - the instruction definition entry instance that results from the recording of an event transaction;
    - the instruction execution entry and the statuses of the activities within the instruction as the scenario unfolds;
    - the worklist; and
    - EHR data collection instances as they are recorded per activity enactment.

Breeze Workflow Schemas

Figure 5.10 shows the graph of the Breeze workflow schema for the ESD workflow (using the workflow editor, Bred). In particular, it illustrates the use of the Null Task and condition nodes for complex routing. Figure 5.11 and Figure 5.12 respectively show the Breeze workflow schemas for the 'Refer' sub-workflow, and the OT workflow. Note that the first line of the label for each node in the graph indicates the name of the task or condition node, and the second line (for task nodes only) indicates the application handler name, and the method invoked for that activity. For tasks that are sub-workflow tasks (see Figure 5.11), the second line in the label indicates the name of the sub-workflow to be invoked (in this case, they are equivalent).

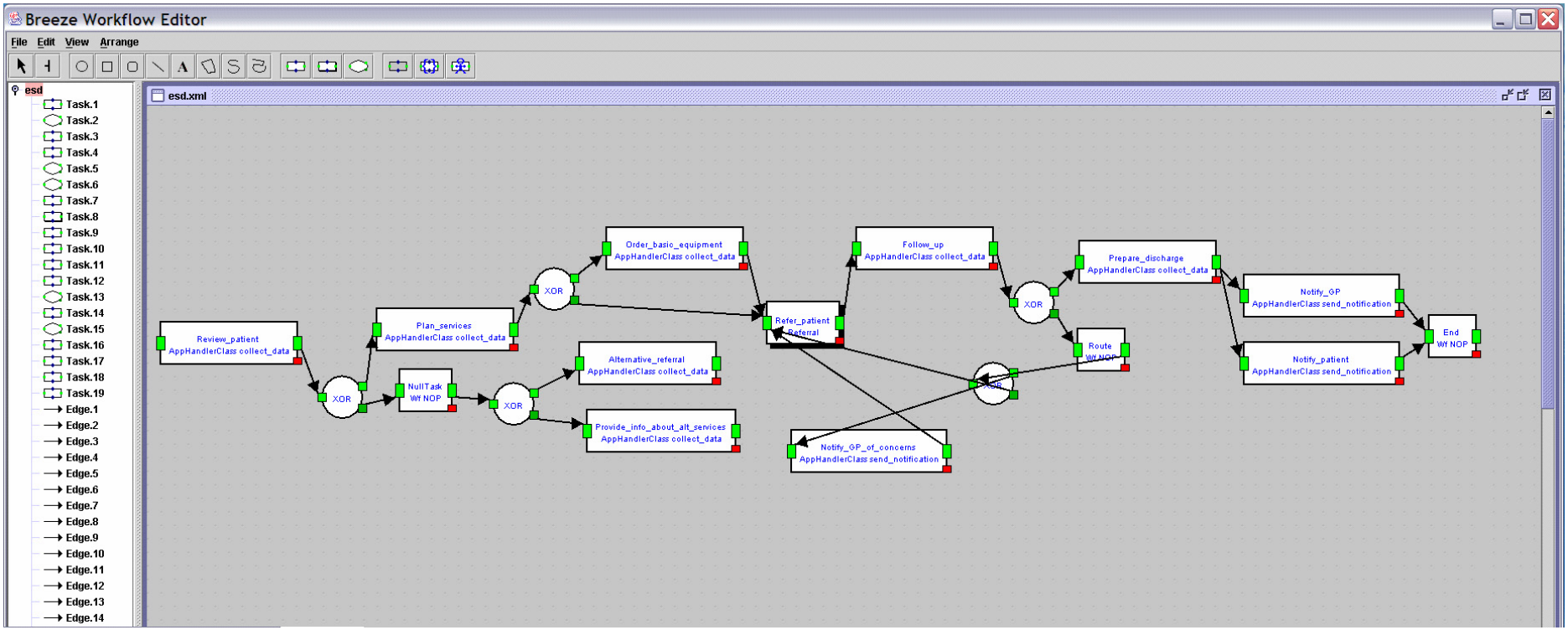


Figure 5.10. Breeze Workflow Schema for ESD With Null Tasks & Condition Nodes.

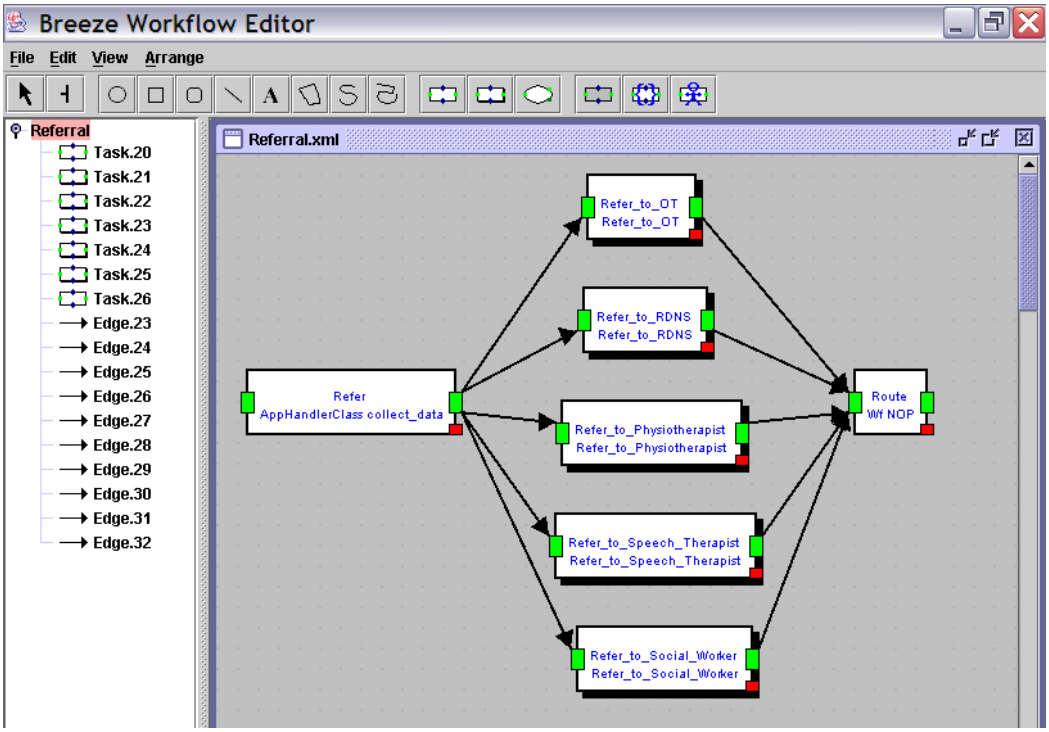


Figure 5.11. Breeze Workflow Schema for Refer**.**

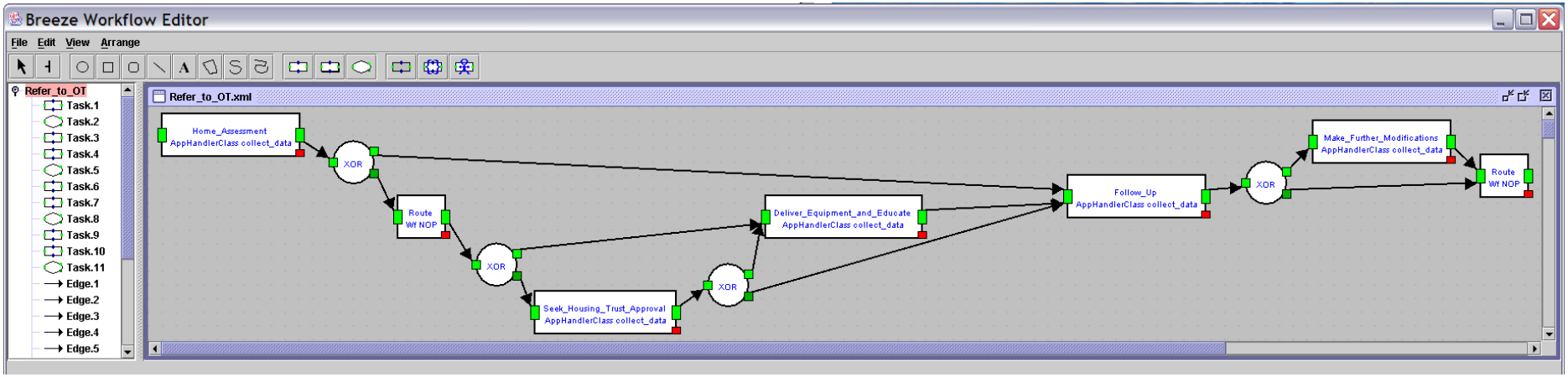


Figure 5.12. Breeze Workflow Schema for the OT.

5.5.1. Walkthrough

Task 1.0: Hospital Assessment

Assuming successful login to the system, Ms. Karen Smith, a nursing staff member in Mr. George Phillips's hospital ward finalises the hospital separation, and 'flags' him as a potential ESD patient (Figure 5.13).

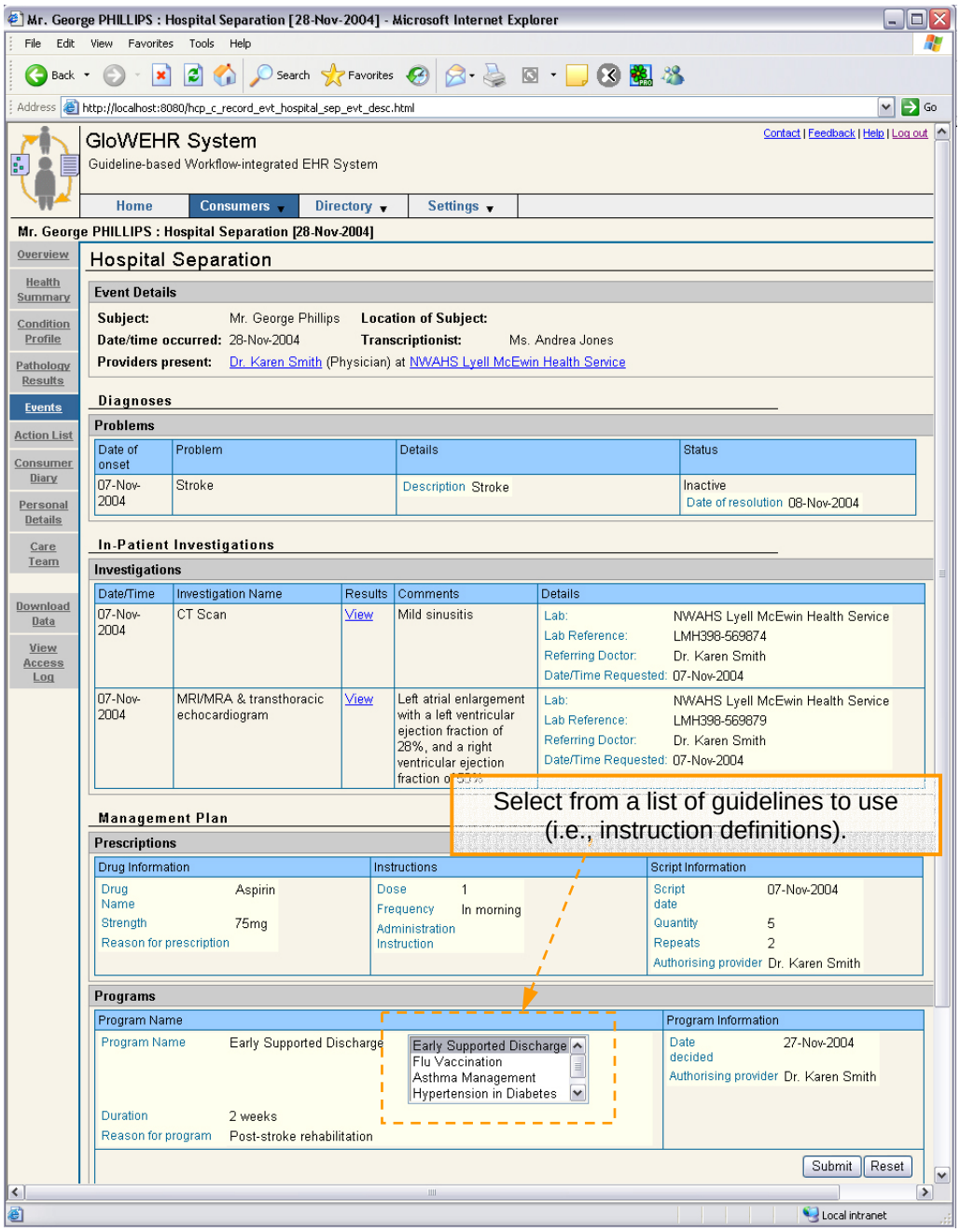


Figure 5.13. Selecting an Instruction Definition from a Hospital Separation Form.

The hospital separation event transaction is recorded into the EHR by the persistence layer along with the ESD instruction definition entry instance (see Appendix E). An ESD instruction execution entry in the Mr. Phillips's current care plan persistent transaction is created as a result of detecting the ESD instruction definition entry within the hospital separation event transaction with all activity identifiers set, and their statuses initialised to ineligible (see Appendix F).

The persistence layer then generates a worklist from the instruction execution entry in the enterprise database, and invokes Breeze to launch an instance of the ESD workflow with the required input parameters of the patient and provider identifiers (‘pat1’ and ‘falco’ respectively), and the provider’s role (ESD Coordinator). Breezed creates an instance of the first activity “Review patient” and is therefore in its “running” state (as illustrated in the Brzmon display in Figure 5.14 below), and subsequently updating the status of that activity in the instruction execution entry to “eligible” within the persistent transaction as shown in Listing 5.9.

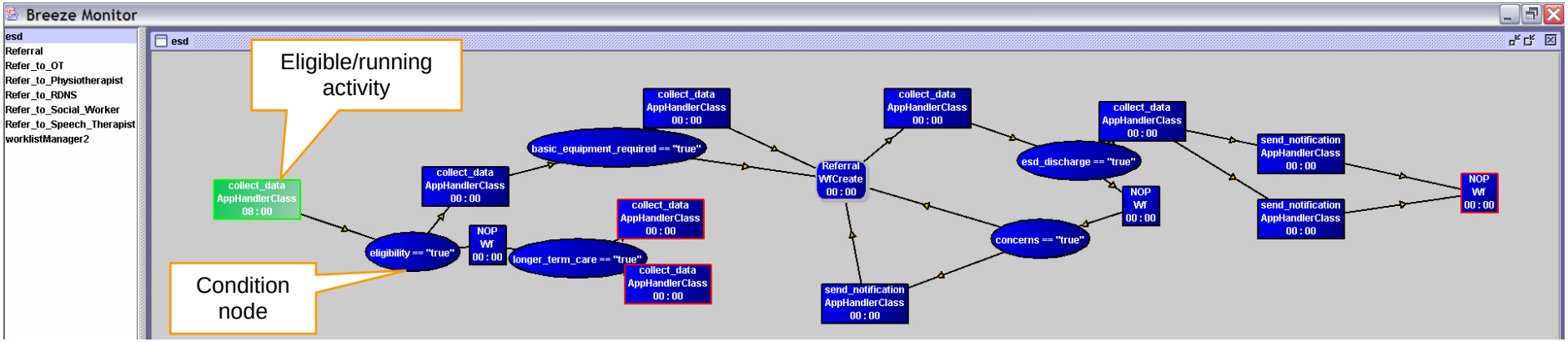


Figure 5.14. Brzmon Output at Task 1.0.

Listing 5.9. Fragment of ESD Instruction Execution Entry with Review_patient **Activity Status Updated.**

```
<Clinical_Intervention_Activity>
    <activity_instance_id>
        pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1/esd_v0_Wor1_Act1(falco@05August 2004)
    </activity_instance_id>
    <activity_instance_name>
        Review_patient
    </activity_instance_name>
    <activity_definition>
        openehr.instruction_definition.esd.v1/esd_v0_Wor1_Act1
    </activity_definition>
   <activity_execution_state>
        eligible
    </activity_execution_state>
   <subject_state/>
   <data_collected>
        openehr.transaction-event.esd_review_report.v1;
       openehr.transaction-event.patient_consent.v1
    </data_collected>
   <patient_state_goal/>
    <patient_state_target/>
   <work_item>
        ascertain patient needs
    </work_item>
   <role>
        ESD_Coordinator
    </role>
</Clinical_Intervention_Activity>
```

Task 2.0: Review Patient

Ms. Falco successfully logs in as the ESD coordinator (Figure 5.15) and views her incoming health services request (Figure 5.16). From here, she accepts the ESD request for Mr. Phillips, and views her newly made worklist for Mr. Phillips (Figure 5.17).

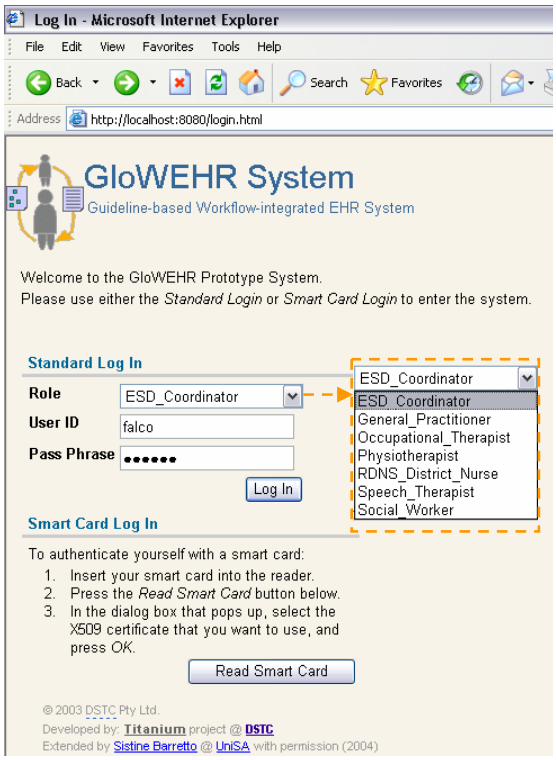


Figure 5.15. Login Screen.

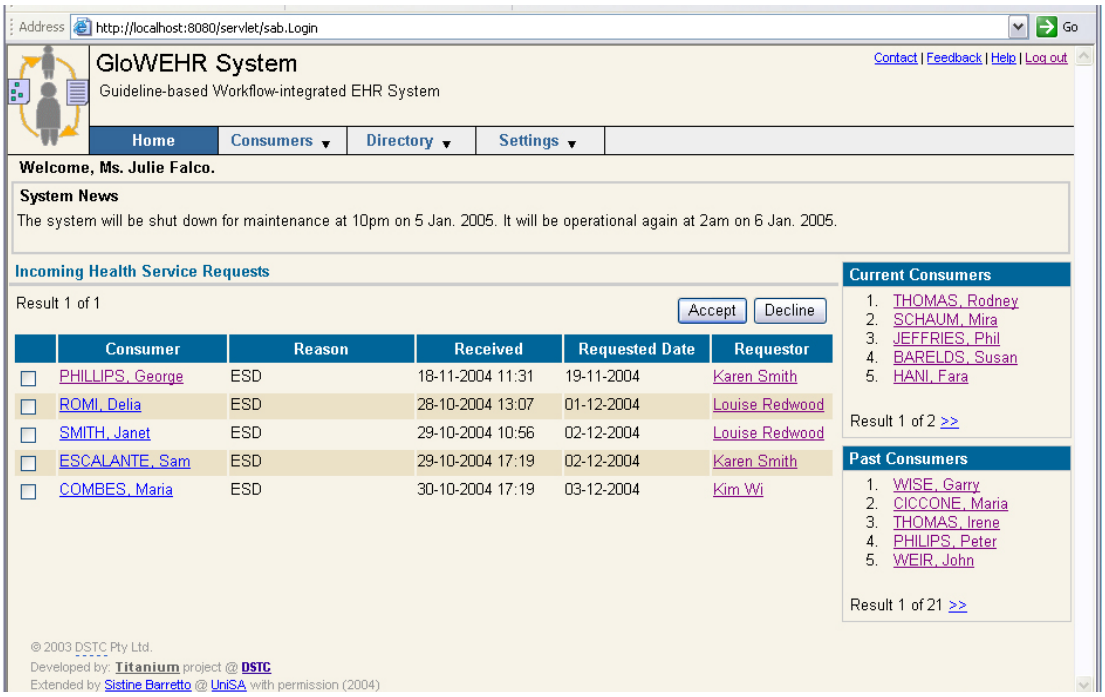


Figure 5.16. ESD Coordinator's Homepage.

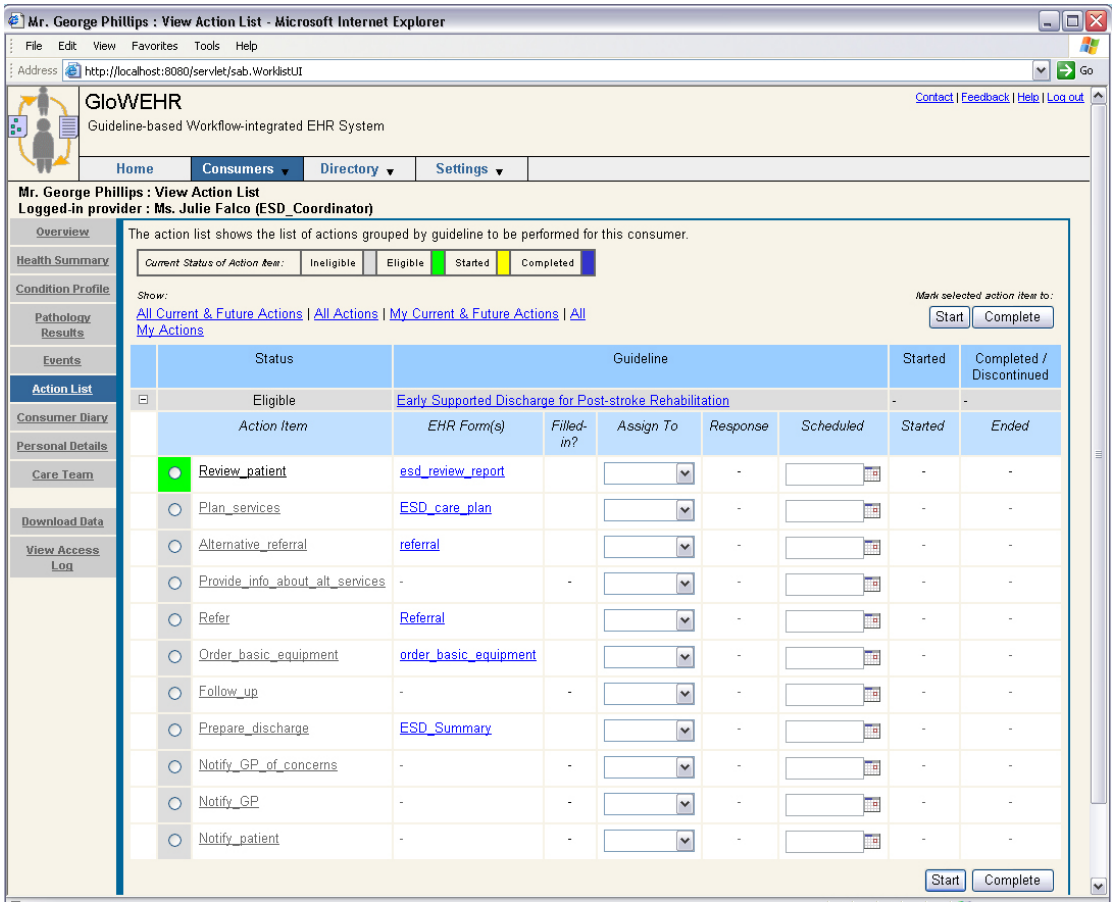


Figure 5.17. ESD Coordinator's Initialised Worklist.

Ms. Falco starts the Review_patient workitem, and selects the esd_review_report form to be filled in (Figure 5.18). Once it is recorded into the EHR, Ms. Falco marks the activity as completed (Figure 5.19).

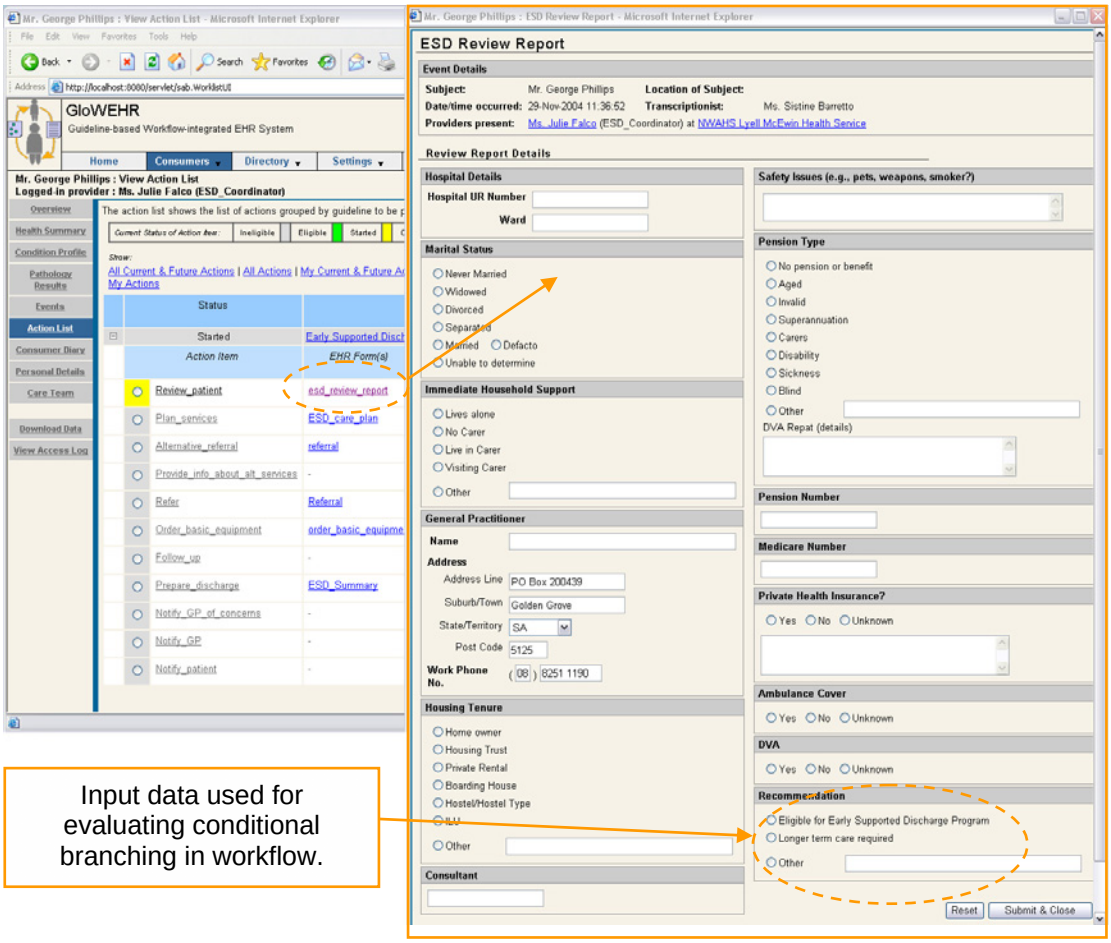


Figure 5.18. ESD Review Report

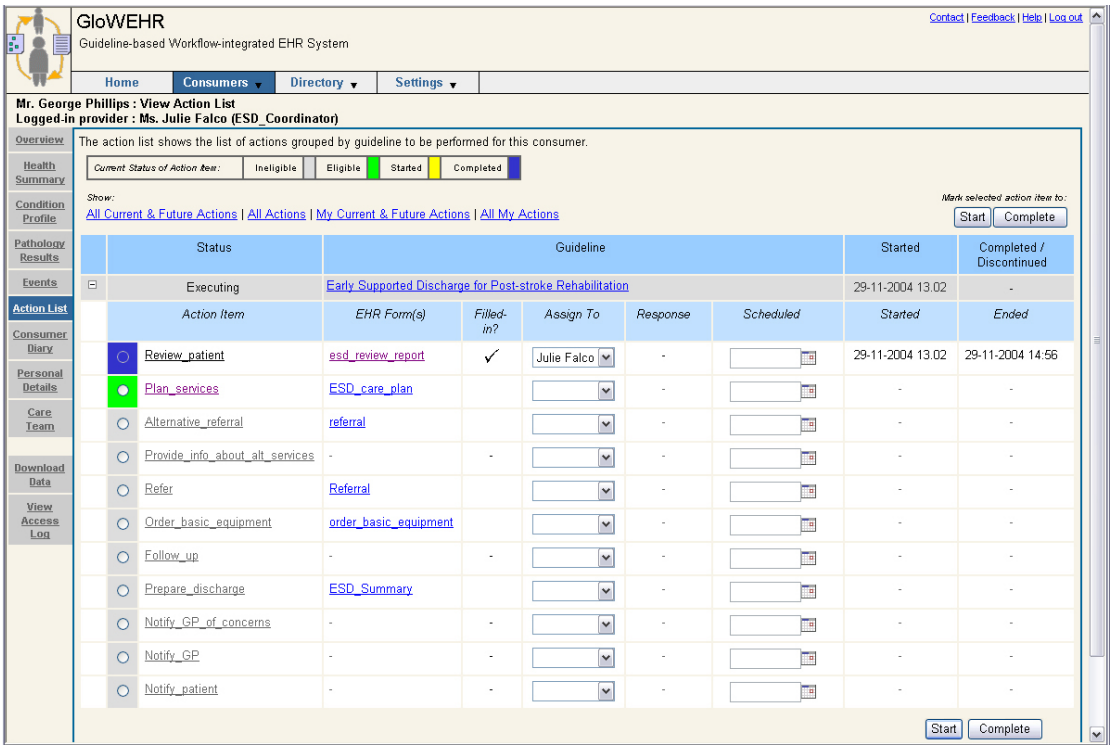


Figure 5.19. Updated ESD Coordinator Worklist.

This results in the activity status to progress to the 'executing' state, and its data collection item, esd_review_report to be updated from its archetype instruction definition identifier to its actual EHR identifier (Listing 5.10). The Plan_services activity is immediately set to 'eligible' on completion of the first workitem (Listing 5.11). Figure 5.20 shows the updated Brzmon display as a result of undertaking this step. It shows Breeze running an instance of the Plan_services activity after receiving a message from the Worklist Manager that the Review_patient was marked as complete.

Listing 5.10. Fragment of ESD Instruction Execution Entry with Review_patient **Activity Status Updated.**

```
<Clinical_Intervention_Activity>
    <activity_instance_id>
        pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1/esd_v0_Wor1_Act1(falco@05August 2004)
    </activity_instance_id>
    <activity_instance_name>
        Review_patient
    </activity_instance_name>
    <activity_definition>
        openehr.instruction_definition.esd.v1/esd_v0_Wor1_Act1
    </activity_definition>
   <activity_execution_state>
        executing
    </activity_execution_state>
   <subject_state/>
   <data_collected>
        pat1@ehr.unisa.edu.au/ESD_Review_Report(falco@20040805082811);
        openehr.transaction-event.patient_consent.v1
    </data_collected>
   <patient_state_goal/>
    <patient_state_target/>
   <work_item>
        ascertain patient needs
    </work_item>
   <role>
        ESD_Coordinator
    </role>
</Clinical_Intervention_Activity>
<Clinical_Intervention_Activity>
    <activity_instance_id>
        pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1/esd_v0_Wor1_Act2(falco@05August 2004)
    </activity_instance_id>
   <activity_instance_name>
        Plan_services
    </activity_instance_name>
    <activity_definition>
        openehr.instruction_definition.esd.v1/esd_v0_Wor1_Act2
    </activity_definition>
   <activity_execution_state>
        ineligible
    </activity_execution_state>
   <subject_state/>
   <data_collected>
        openehr.transaction-event.ESD_care_plan.v1
    </data_collected>
   <patient_state_goal>
        patient self-management in the home
    </patient_state_goal>
    <patient_state_target/>
    <work_item>
        planservices
    </work_item>
   <role>
        ESD_Coordinator
    </role>
</Clinical_Intervention_Activity>
```

Listing 5.11. Fragment of ESD Instruction Execution Entry with Review_patient **and** Plan_services **Activity Statuses Updated.**

```
<Clinical_Intervention_Activity>
    <activity_instance_id>
        pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1/esd_v0_Wor1_Act1(falco@05August 2004)
    </activity_instance_id>
    <activity_instance_name>
        Review_patient
    </activity_instance_name>
    <activity_definition>
        openehr.instruction_definition.esd.v1/esd_v0_Wor1_Act1
    </activity_definition>
   <activity_execution_state>
        completed
    </activity_execution_state>
   <subject_state/>
   <data_collected>
        pat1@ehr.unisa.edu.au/ESD_Review_Report(falco@20040805082811);
        pat1@ehr.unisa.edu.au/Patient_Consent(falco@20040805094042);
    </data_collected>
   <patient_state_goal/>
    <patient_state_target/>
   <work_item>
        ascertain patient needs
    </work_item>
   <role>
        ESD_Coordinator
    </role>
</Clinical_Intervention_Activity>
<Clinical_Intervention_Activity>
    <activity_instance_id>
        pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1/esd_v0_Wor1_Act2(falco@05August 2004)
    </activity_instance_id>
   <activity_instance_name>
        Plan_services
    </activity_instance_name>
    <activity_definition>
        openehr.instruction_definition.esd.v1/esd_v0_Wor1_Act2
    </activity_definition>
   <activity_execution_state>
        eligible
    </activity_execution_state>
   <subject_state/>
   <data_collected>
        openehr.transaction-event.ESD_care_plan.v1
    </data_collected>
   <patient_state_goal>
        patient self-management in the home
    </patient_state_goal>
    <patient_state_target/>
    <work_item>
        planservices
    </work_item>
   <role>
        ESD_Coordinator
    </role>
</Clinical_Intervention_Activity>
```

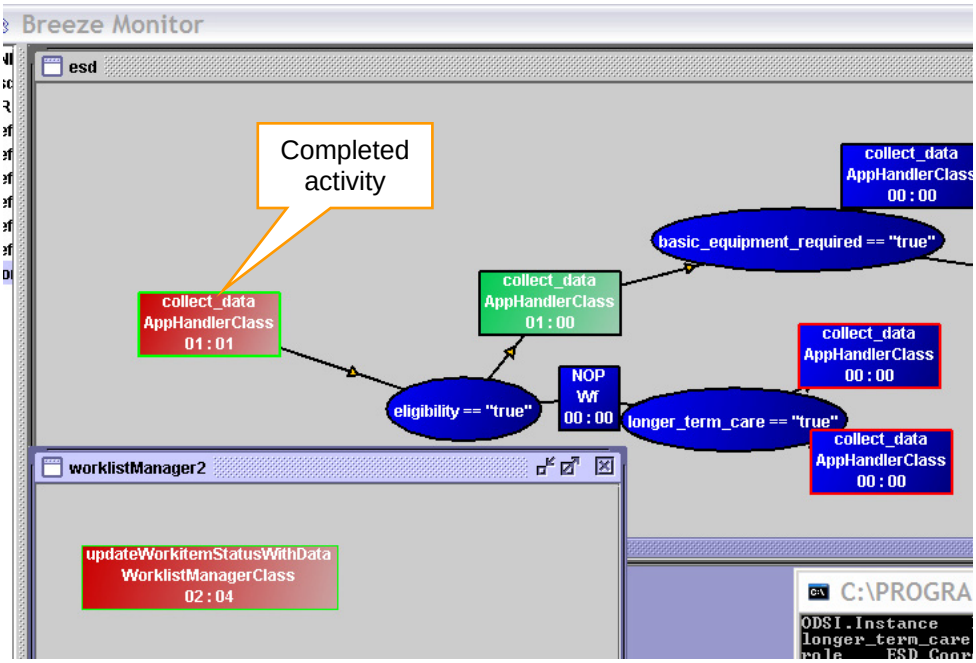


Figure 5.20. Updated Brzmon Display.

Task 2.1: Plan Services

After reviewing the services available, Ms. Falco logs back into the system and begins the next activity of planning Mr. Phillips's services. A care plan form is recorded into the EHR, and the activity is marked completed. From here the system components interact in a similar fashion as in the previous task – constantly updating the worklist and instruction execution entry accordingly.

Task 2.2: Refer Patient

Ms. Falco then organises for Mr. Phillips to be referred to Mr. Hugh Stewart to assess his home with a requested appointment date and time. She selects the 'Assign To' pull-down menu for that workitem, and presses the 'Send Request' button to send the request, and awaits his response.

Task 3.0: Home Assessment

Mr. Hugh Stewart logs into the system, views his incoming health service requests, and accepts the oldest pending request, which is the request for Mr. Phillips (Figure 5.21). Mr. Phillips's name and link to his EHR then appears under his 'Current

Consumers' box. He clicks on the link to view his new worklist for Mr. Phillips (Figure 5.22).

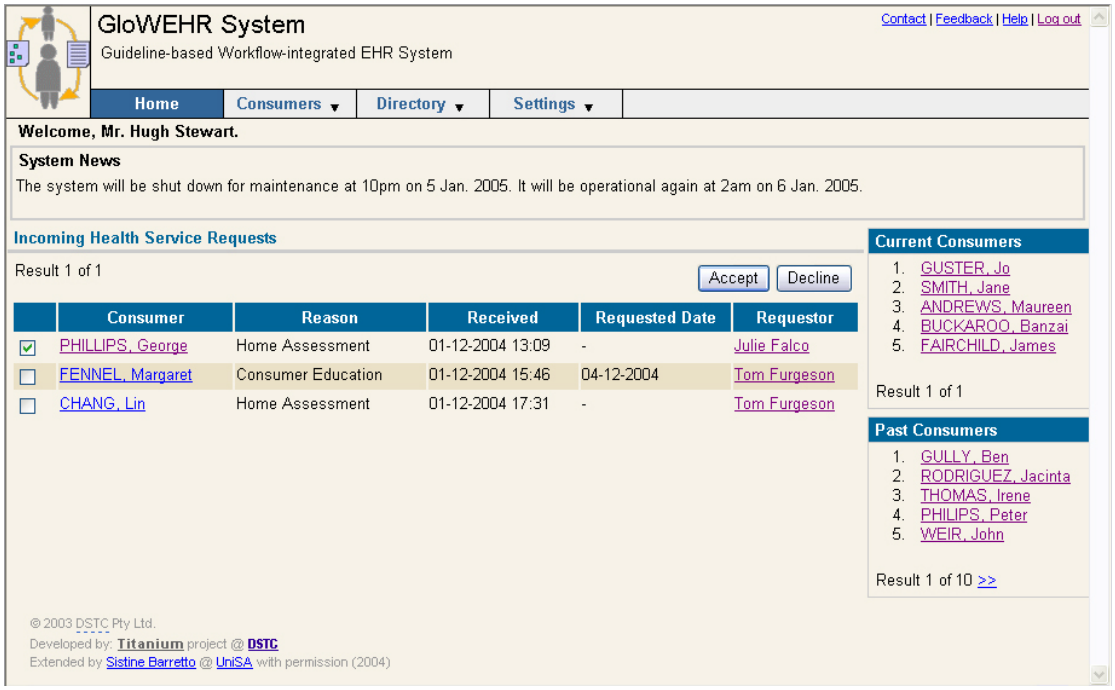


Figure 5.21. OT's Home Page.

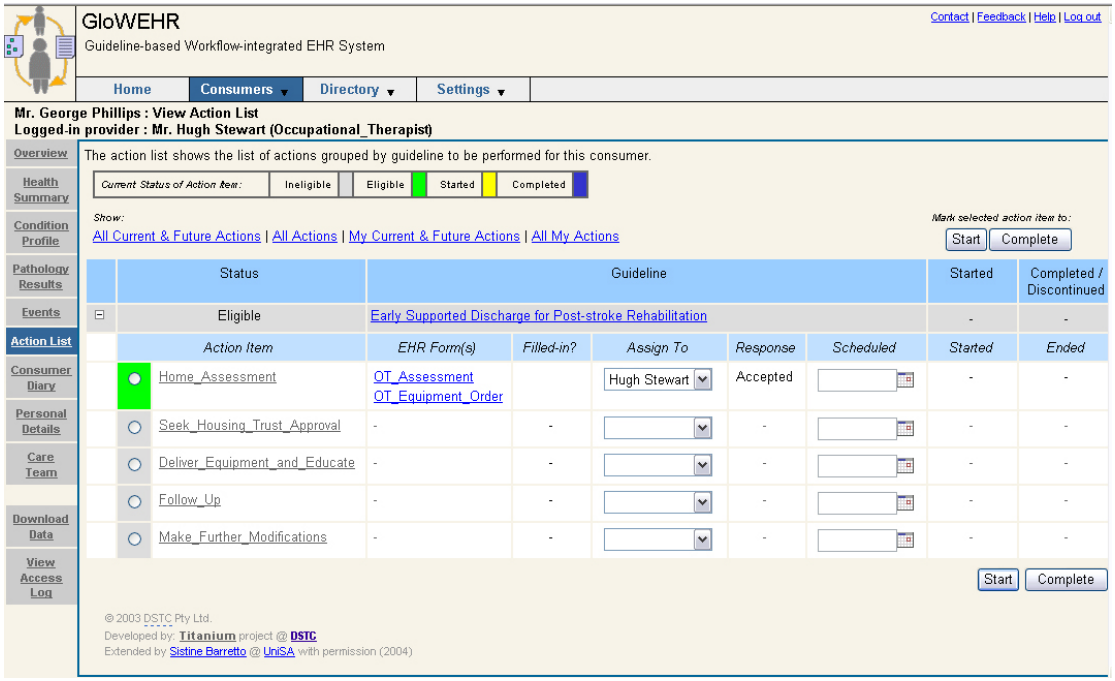


Figure 5.22. The OT's Initialised Worklist for Mr. Phillips.

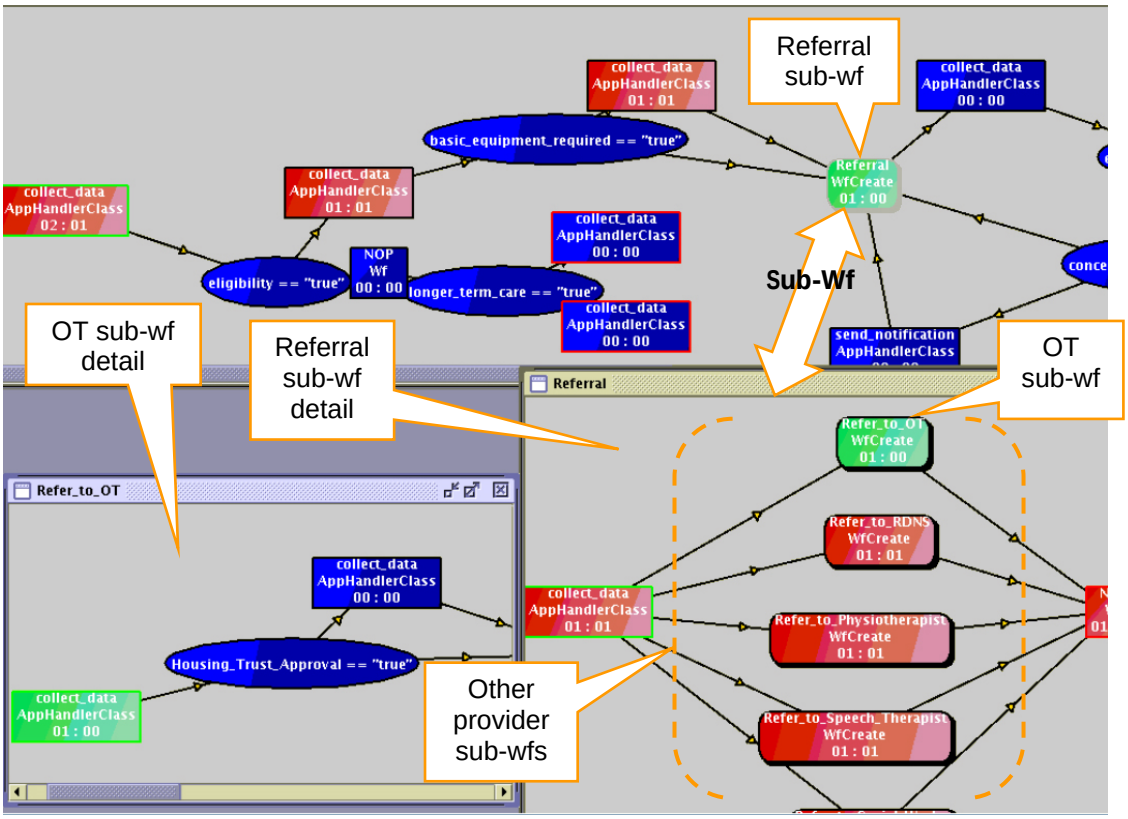


Figure 5.23. Brzmon Output For OT, and Referral Sub-Workflows.

As can be seen from Figure 5.23, the Referral sub-workflow is invoked and executed. This sub-workflow also consists of a number of further sub-workflows including the Refer_to_OT sub-workflow, which is currently at the first activity Home_Assessment as a result of being at Task 3.0. At this point, the activity is blocking and waiting for a request to be received from the Worklist Manager to be as 'completed' before proceeding to the next set of activities. [Note that the other sub-workflows (that are out of scope in this scenario) are assumed to be marked as 'completed'].

The walkthrough of the tasks from Task 3.0 when the data of the home assessment form has been collected continues in a similar fashion as described in previous steps until all of the workitems for the OT has been done. At which point, the next workitem in the ESD coordinator's worklist – i.e., Task 2.3 (Follow_up activity) becomes 'eligible' to be undertaken. The ESD coordinator's workflow then proceeds to perform Tasks 2.4, 2.5 and 2.6 – collecting the required data, updating the instruction

execution entry, until all of the workitems are completed, and the workflow instance is subsequently successfully completed by the workflow engine.

5.6. Discussion

Scalability and Performance Issues

Additional Worklist Functionalities

In our prototype implementation, the worklist is generated from its Instruction Definition, and it is therefore currently constrained to that definition. We take the position that the design of the worklist should provide as much flexibility as possible in order to be of practical use to providers. We view that the following additional worklist functionalities (for future work) may increase the potential for the use of guideline-based workflow-integrated EHR systems in various healthcare settings:

- Need ability to shut workflow, and start another workflow;
- Ability to remove irrelevant tasks or add;
- Specify an action as '*not* to be done' or 'skipped' and the reason;
- More complex state machine – e.g. an additional state for an action item that has been 'abandoned' because it was deemed irrelevant to the patient at a particular point in time, or refused, for instance, by the patient;
- Ability to customise the worklist (i.e. saving and reusing workflow templates);
- Ability to 'cancel' a worklist (i.e. workflow or instruction) altogether;
- Ability to 'cancel' (or perhaps consider 'completed') a whole workflow;
- Ad hoc addition of tasks to the workflow (and how could we fit in their pre-conditions). Currently, in our implementation, at least, the XSLT transformation cycle from the XPDL using the JaWE tool to Instruction Definition can be done relatively quickly to add an activity to "personalise" a workflow to a particular healthcare setting or site that required some additional kind of activity (e.g. specialised assessment).

The aforementioned functionalities may require the potential for the WfMS automated assistance to be abandoned/disabled at any point in the care process, should for instance, the need for the worklist to be substantially modified arose. Otherwise, the development and availability for more advanced WfMS may be needed to deal with

such complex situations as workflow instance modification at run-time, and migration of workflow instances to newly modified workflow schemas (i.e. latest version of the Instruction Definition archetype).

Whose role is empowered to perform relatively significant customisations to worklists will need to be considered. Thus, there will need to be a further functionality of being able to set permissions for potentially various levels of administrative rights on worklists, and instruction definitions. Permissions might also be used to protect certain workflow steps from dynamic modification or customisation if this might have patient safety implications.

Expressiveness of Constraint Language and Workflow Definition Language

XML in itself poses limitations on its ability to express the types of constraints that are required in information modelling – as an example, the data types within XML are relatively primitive compared to those defined in the openEHR reference model. It is envisioned that the Archetype Definition Language will provide a much more expressive language, and further development of the language and tools that support it (particularly with respect to developing Instruction Definition archetypes) would be required.

There are also some limitations with the modelling capabilities of XPDL as discussed in detail in [144]. In particular, not all types of control flow defined in [144] can be modelled explicitly, and there are also a few that cannot be modelled at all in XPDL.

Standardisation of Models and Languages

A standard workflow model and language will need to be further developed, implemented and tested in different and more complex domains such as the case study presented herein. In addition, such standards need to be adopted by vendors and furthermore, to interpret and implement them in a consistent manner. van der Aalst in [139] for instance, discusses some of the different interpretations and therefore, implementations of some of the workflow patterns by different WfMSs. Conflicts would inevitably arise as a result of this variance, and would potentially make

integration and interoperability between multiple, different WfMSs difficult if not impossible to achieve.

Although transformations from one standard format into another are likely to be required (especially in the health domain where linkage to legacy systems is common), and XML transformations (for instance) can make the transition relatively easily, however, unless there is a common understanding of the differing formats and how they are to be translated from source to target formats (without losing structure or meaning), then interoperability is then diminished.

All the above aspects are essential for consideration in the implementation of large-scale EHR systems – and increasingly so as the need for shareable EHRs and coordinated care becomes also increasingly desirable especially in the context of chronic disease management.

Processing of EHR Instances

XML parsing can be performance intensive. A single patient's EHR event transaction for instance can be several hundreds of lines in length. Other alternatives will need to be considered and tested for giving better system performance, otherwise XML support tools will need to be further developed and improved. This becomes particularly important within a real large-scale EHR system where large amounts of data will be managed, often concurrently and increasingly between geographically distant and often disparate systems.

Better WfMSs and Tools

As mentioned in this chapter, Breeze has a number of limitations which notably includes the lack of a worklist manager and interface; lack of persistence about workflow instances and the lack of the ability to restart or resume these instances in their original states should use of the WfMS be suspended (or when workflow engine failures occur). The Breeze workflow model is also quite simplistic and does not provide direct support for some of the workflow patterns. Alignment to the WfMC's workflow specification would be required, as well as the support for various workflow

and activity properties or attributes such as role assignment. It also requires support for more complex data types (other than a Dictionary) to be used for workflow parameters.

Workflow as a Separate Service

In our research, we have considered whether or not the workflow should be kept as a separate EHR service. There are benefits in keeping the workflow as a separate service as it is easier to manage the engineering from a system's architecture perspective – in particular, not all EHR installations will necessarily have workflow. In terms of running systems, however, it will require the WfMS (as another process or service layer) communicating to the EHR. In this sense, the EHR can still maintain persistence regarding all patient workflow states, but the WfMS needs to maintain workflow models and other non-patient-patient specific information. From the standards developer perspective, it also makes it difficult for standardisation and specification given that much research and experience is still required about workflow. Therefore, one could argue that for at least separate EHR and workflow specifications and models for now.

A difficulty with most distributed applications is their tendency to have too many 'chatty services'. These services are systems that are not well encapsulated and are often overly dependent on other services. Clinical workflow for instance is often driven by the arrival of new event transactions to the EHR, and therefore, it requires the ability to query clinical content as well as record back state information to the EHR. The latter aspect has been demonstrated in the use of our approach (in particular, our Instruction Definition and Instruction Execution Entry models), which apart from our research has not yet been clearly explored in the literature, but has particular importance for example, from a medico-legal perspective. We concluded that the clinical workflow system should reside within the EHR, but possibly separate it from the rest of the EHR by creating a new 'clinical workflow service' package that extends the basic EHR functionality.

Modelling Referrals

In the ESD case study, it is possible to have an explicit workflow modelled for its referral process given that there is that two-week time frame, a coordinator and a multidisciplinary team (what services to provide next can be dependent on the outcome of previous services). However, in other, more typical cases such as a visit to a dentist resulting in the patient being referred to an orthodontist for the wisdom teeth to be removed. This situation does not usually require the patient to go back to the dentist as in most cases; there is no need to (i.e. wisdom teeth removal was successful, and patient does not want to visit the dentist again). The question then arises of whether the dentist ever need know the *outcome* of the orthodontist visit.

There are a number of ways of modelling the workflow. One option is that the referral may be a request for transfer of care to the oral surgeon where the state machine can go to completion without the patient having to come back to the dentist; the alternative is that the patient has to contact the dentist to say it all went well, or else the dentist has to log into a shared EHR system to find out the status. Neither of these will usually ever happen - no one has the time or need. Thus, if there is any formal model of this workflow then it needs to allow completion without return to the referring clinician. However, not all workflows need formal models – only the ones where there is any advantage in automated processing, but what is still relatively important in the case of the orthodontist referral are the following EHR data collection and updates to occur:

- The referral is recorded into the shared EHR
- The post-operative report is recorded into the EHR
- Someone removes the "impacted wisdom teeth" from the problem list, if it was there.

We therefore, perceive that to help ensure that the above occurs, a WfMS would play a supportive role for example, by providing reminders and alerts that the key EHR transactions need to have been received, and that once received, the appropriate updates are made to affected persistent transactions in the EHR given explicit (albeit relatively simple) workflow model of a referral.

5.7. Conclusion

In this particular chapter, we focused on two artifacts produced in the Early Supported Discharge case study associated with Post-stroke Rehabilitation: (1) the EHR content (what to record and when to record it); (2) the specification of what needs to be done (workflow schemas/definitions that may include a combination of clinician and system dependent actions).

Panzarasa et al. report the successful representation of evidence-based post-stroke rehabilitation guidelines as a workflow model from which a 'careflow' management system is implemented using Oracle Workflow tools [30]. This system illustrates that at least in some cases, a very significant aspect of the knowledge from an evidence-based guideline for CDM can be expressed through the design of a *patient-centred* workflow. However, this workflow remains disconnected from the EHR, which effectively makes it difficult to build integrated clinical information systems that provide *patient-specific* decision-support seamlessly with the provider's workflow, and providing support for what needs to be captured at a given point in time. Revisiting the definitions (given by the *WfMC*) presented in chapter 2 of this thesis: a workflow is:

> *"the automation of a business process, in whole or part, during which documents, information or tasks are passed from one participant to another for action, according to a set of procedural rules"*, and the

Workflow Management System (WfMS) is defined as:

> *"a system that defines, creates and manages the execution of workflows through the use of software, running on one or more workflow engines, which is able to interpret the process definition, interact with workflow participants and, where required, invoke the use of IT tools and applications"*.

Thus, workflows, in general are executed and handled on a case-by-case – e.g., for a particular patient as we have illustrated in our scenario. The WfMS assists in the

management of the creation and execution of the workflow instances for a particular case or workflow definition. However, there is the further notion of workflows that may be *inter-organisational* workflows, with which a WfMS can play a major role in their coordination and timely execution using additional workflow management tools (not explored in the scenario presented in this chapter) such as load balancing, authorisation, authentication, event processing, queues, prioritization, escalation, task termination, inter-organisational resource allocation, and auditing. Investigation and exploration into such level of management can greatly increase the efficiency and quality of healthcare delivery in a multi-site, multidisciplinary setting, and when dealing with multiple cases at the same time. A WfMS for instance, would be of immense benefit in assisting in the management of large numbers of patients within a hospital, and in the timely allocation of staffing resources required for a particular time, and also to be able to foresee and resolve any potential conflicts that may occur in the execution of workflows in organization(s). In such situations, staff resources are very often 'misallocated' – or staff are allocated duties that are not their main responsibilities due to lack of resource and workflow management support. A WfMS in this instance would therefore help resolve some of these issues that are currently occurring in healthcare.

Based on our analysis herein, and other work in a closely related domain [30], we believe that workflow models with closely aligned EHR design provide a good representation of key guideline elements for evidence-based post-stroke rehabilitation and early supported discharge. Through extension of the *open*EHR instruction archetype constructs, we uncover a feasible approach to incorporating the workflow (including representation of the associated assessment activities) with the EHR, which allows these elements to interact in a clinical information system. The linkage of workflow knowledge with the EHR enables a system to be aware of *what* needs to be recorded, by and for *whom*, and *when*. In addition, the availability of a WfMS, can make use of the 'workflow-able' EHR to provide knowledge about *how* the workflow should be executed, and the resource allocation – i.e., *who* should carry out the activities, and when (e.g., automated scheduling). As such, the system can run on the EHR itself, or in conjunction with a WfMS (as we have demonstrated in this chapter) – in either case, a workflow-integrated EHR allows for a more active system than in

current traditional EHR systems. Such an approach could contribute to a substantial improvement in the management of chronic disease.

While the workflow helps to ensure that the work is done, archetypes help ensure that the required data set is recorded at specific points in the workflow. Close EHR and workflow linkage allows information pertaining to the actual care process of the patient to be recorded and no just limiting it to the recording of the patient's state/health condition – thus, having medico-legal significance. The systems interacting in support of the clinical care process need to facilitate the documentation made by providers to demonstrate their competence. Some data that do not contribute directly to care provision might, therefore, be collected and committed to an EHR for accountability purposes. This is particularly relevant to negative findings, excluded or rejected management options. It also applies to shared care communications: mandates to refer or appoint a new professional for instance, and feedback to confirm to the referring provider that referred care requests have been accepted, acted upon, and so on. This issue is a growing concern as care is increasingly fragmented across multi-disciplinary care teams, and begs the question of who is responsible for the overall coordination of care and ensuring that each actor does participate in a timely fashion. In this particular case study, for instance, the ESD coordinator would most likely be held responsible for the overall progression of the early supported discharge process for the patient.

It has been pointed out in [19, 122] that, for proper and effective implementation of decision support, it is vital to provide *patient-specific* recommendations at the point of care, and in accordance with the physician's workflow. Hence, there needs to be substantial integration of the patient's EHR with CiGs (as will be investigated and discussed in the following chapter in the case study of the management of Hypertension in Diabetes).

Our view is that a similar approach must be followed when integrating the EHR with clinical workflows. Much research has been put towards designing workflow systems that provide flexibility and elegant exception handling – e.g., [176], [177], [178] – application to a complex and ever-changing domain such as health care calls for sufficient support of relatively unstructured workflows. Since the EHR is a central

component in many clinical information systems, our approach provides an EHR framework that allows for extensible EHR recording that is also directly *integrated* with workflow-support and decision-support. Thus, where workflow is too rigid for a particular domain, the proposed EHR framework alone is still able to provide the information regarding what was done, and when, who it was done by, and what should be recorded next (via archetype definitions at the knowledge level). This approach is also open for use in decision support systems where tracking of decisions made is key to patient management, and suggestions of what should be recorded next effectively implies what the guideline-based recommendations are at that point in time.

In this chapter, we developed a functional demonstration prototype of post-stroke rehabilitation implemented based on the evolving *open*EHR model and a prototype implementation architecture from the Titanium group of DSTC [174]. Through the detailed prototyping effort, we were able to refine models such as *open*EHR – the *open*EHR representations of instructions have been influenced by the case study presented herein.

6

CASE STUDY: HYPERTENSION MANAGEMENT FOR DIABETES MELLITUS

6.1. Case Overview

Diabetes is the world's fastest growing chronic disease, and is the sixth leading cause of death in Australia [179]. Diabetes is a metabolic disorder in which the body is unable to produce insulin (a hormone necessary for glucose to be absorbed into the cells and be converted to energy) or use it properly, and is thus characterised by high blood glucose levels [179]. There are two main types of diabetes:

(1) Type 1, which is insulin dependent (i.e. the individual has absolute insulin deficiency) and occurs when the pancreas gland no longer produces the required insulin. This type of diabetes is often developed during childhood.

(2) Type 2 (or diabetes mellitus), which is non-insulin dependent (i.e. the individual has insulin resistance) and occurs when the pancreas is not producing enough insulin and the insulin is not working effectively. This type of diabetes is most often influenced by lifestyle factors, developed due to risk factors such as obesity, and typically occurs during adulthood. It is also the most common form of diabetes.

Diabetes requires ongoing medical care and education. Appropriate self-management and compliance play a critical role in managing the disease. Treatment usually consists of lifestyle modification (e.g. smoking cessation, healthy diet, and regular exercise), and/or insulin injections [179]. The ultimate goal of diabetes management is to reduce/prevent the numerous possible complications that can occur with the disease such as retinopathy (eye complications), nephropathy (renal complications), neuropathy (complications with toes, feet, legs, hands and arms), and cardiovascular disease [180]. It is therefore essential that three main individual factors be closely monitored and maintained throughout the lifetime of the individual: blood glucose levels, cholesterol levels, and blood pressure [180]. As a result, diabetes sufferers usually have a multidisciplinary care team consisting of the dietician, GP, podiatrist, physiotherapist, endocrinologist, etc.

In this case study, we focus on the management of hypertension in adults with diabetes mellitus. In particular, we use the Texas hypertension algorithm for diabetes mellitus [57] (see also Appendix G). Although it may slightly vary between guide-lines, hypertension occurs when the blood pressure is greater than 130/80 mmHg (according to [57]). Hypertension is an extremely common co-morbidity in diabetes, and should therefore be carefully managed on an ongoing basis to prevent the occurrence of the aforementioned complications. Hypertension management alone usually entails non-pharmacological therapy (such as diet and exercise) and/or pharmacological therapy, and therefore, the care coordination usually lies (at least) between the patient and the GP (who monitors, assesses, advises the patient and prescribes the necessary drugs), or the patient, GP and a specialist under more extreme circumstances.

The promise of electronic decision support to promote evidence based practice remains elusive in the context of chronic disease management such as hypertension

management in diabetes. In this chapter, we examine the problem of achieving a close relationship of EHR content to other components of a clinical information system (guidelines, decision support and workflow), particularly linking the decisions made by providers back to the guideline. We use the *open*EHR architecture, which, is described in Chapter 3, allows extension of a core Reference Model via Archetypes to refine the detailed information recording options for specific classes of encounter. We illustrate the use of *open*EHR for tracking the relationship of a series of clinical encounters to a guideline via a case study of guideline-compliant treatment of hypertension in diabetes. This case study shows the contribution guideline content can have on problem specific EHR structure and demonstrates the potential for a constructive interaction of electronic decision support and the EHR.

An Example of a Hypertension Management for Diabetes Mellitus Scenario

We illustrate our method using a case study of guideline-compliant treatment of hypertension in diabetes with reference to the guideline algorithm from the Texas Diabetes Council (Texas Department of Health) [57] (see also Appendix G).

Patient Demographic, History and Current Situation

Age: 57

Gender: Female

Problem History: myocardial infarction 13 months ago.

Active Problem: diabetes Type 2

- Duration: diagnosed 2 years ago
- Therapy: diabetic diet
- HbA1c (%): 10
- BP (mmHg): 140/110 (hypertension)
- BMI (kg/m^2): 30 (obese)

Lifestyle:

- Ceased smoking 5 months ago and still uses nicotine patches to aid smoking cessation.
- Alcohol intake: reduced from approximately 3 times a week to once a week 9 months ago.
- Nutrition: diabetic diet since diagnosed with Diabetes Type 2.
- Employment: retired from secondary school teaching.

- Sport/leisure activities: plays golf once a week; walks for 20 minutes to purchase the newspaper every day since diagnosis.

Social circumstances:

- Socio-economic status: retired
- Home circumstances: lives with husband of 30 years.

Encounter 1: ACE Inhibitor therapy and counseling on diet and exercise.

Margaret has been experiencing consistent heart palpitations and is even more concerned as she has already suffered a myocardial infarction 13 months ago. For the first encounter, Margaret's blood pressure is measured at 140/110. Her urine sample was also taken for protein levels and is found to be 1.65g/24 hours (which is above normal). Thus, the physician is presented with two problems: proteinuria and hypertension, and therefore prescribes ACE Inhibitor to the patient as a primary recommendation according to the guideline to lower the blood pressure to less than or equal to 125/75 mmHg (rather than 130/80 mmHg due to high urine protein level). The patient is also encouraged to self-monitor her blood pressure and is educated by the GP about proper blood pressure readings and technique. Continuance of proper diet (i.e. low sodium diet of less than 2.4 g/day) to increase exercise, and to limit the alcohol intake to 1 oz (29.57 mL) is also advised. The GP then advises Margaret to return for therapy reassessment in 4-8 weeks time.

Encounter 2: Drug substitution due to poor tolerance to ACE Inhibitor therapy.

After 4 weeks of taking her medication as prescribed, her blood pressure is measured at 130/85 mmHg, and her protein level to be 1.40 g/24 hours (which is still above the desired target). In addition, Margaret has also been experiencing a mild, dry cough. The patient is reassessed and although marginal improvement in hypertension and proteinuria level was found, the symptom of coughing suggests Margaret's intolerance to the ACE inhibitor. Therefore, verapamil has been recommended by the guideline for substitution due to its renal protective effects.

Encounter 3: Add Beta Blocker.

For the third encounter, the blood pressure target is still not reached. Complying with the guideline's recommendation, Beta Blocker has been chosen as an additional agent due to the patient's history of a myocardial infarction (MI).

Encounter 4: Refer to specialist.

Margaret has been taking her drugs as prescribed. Symptoms of the mild, dry cough have disappeared. Her blood pressure is now measured at 130/80, and her protein level at 1.22 g/24 hours (still above normal and blood pressure target). Although there is improved control of (diastolic) blood pressure and protein level, the blood pressure and protein level targets are still not reached despite 3 months of combined non-drug and drug therapy. The GP refers Margaret to an endocrinologist; and advises her to schedule for a follow-up appointment after consultation with the specialist.

6.2. Analysis of Hypertension in Diabetes Scenario

6.2.1. Task Detail Tables

Table 6.1. Stakeholders in the Scenario.

Actor	Role
Ms. Margaret Simpson	Patient
Dr. John Mondoe	Endocrinologist
Dr. Sally Erikson	General Practitioner

Table 6.2. Task Detail Table for the General Practitioner.

Task #	Task	Input Requirements (from user)
1.0	ACE inhibitor therapy and counselling on diet and exercise	Encounter note with symptoms/complaints, blood pressure, urinalysis observations[17].
1.1	Drug substitution due to poor tolerance to ACE inhibitor therapy	As above.
1.2	Add beta blocker	As above.
1.3	Refer to specialist	As above.

6.2.2. Ontology

In this case study, we develop an ontology based on the Texas hypertension management for diabetes guideline [57] (see also Appendix G) as part of our analysis of the domain or case study in question, and conceptual design of a system that integrates guideline-based decision support, workflow and EHR. We use the term 'ontology' and represent it in the simplest form by abstracting the *concepts* (Figure 6.1, Figure 6.2) and *relationships* (Figure 6.3) between the concepts in the universe of discourse hypertension management for diabetes, and representing them in diagrammatical and hierarchical format for human readability. Furthermore, this simple ontology allows us to extend it with further concepts and relationships required for specifying the archetypes and templates for data collection. Figure 6.1 for example, shows the hierarchy of sub-concepts within the concept "drugs" taken from the guideline. These were then extended to include the set of generic brand name drugs taken from the Australian Pharmaceutical Benefits Scheme (PBS) [181] for each drug type, which would ultimately be used for specifying further constraints to allow it to be used locally within an Australian GP healthcare setting. These constraints would be used at the EHR template level, where the set of allowable generic drugs that can be entered are constrained to those specified in the ontology. Figure 6.4 extends the concept relationships for 'indications for drugs' shown in Figure 6.3 to the concept-to-guideline-point relationships, which constrains the rationale – in particular, the indications for a drug, and the related justification text entry (shown in shaded boxes).

[17] Any previous guideline step taken by the patient is queried by the DSS from the EHR.

Concepts

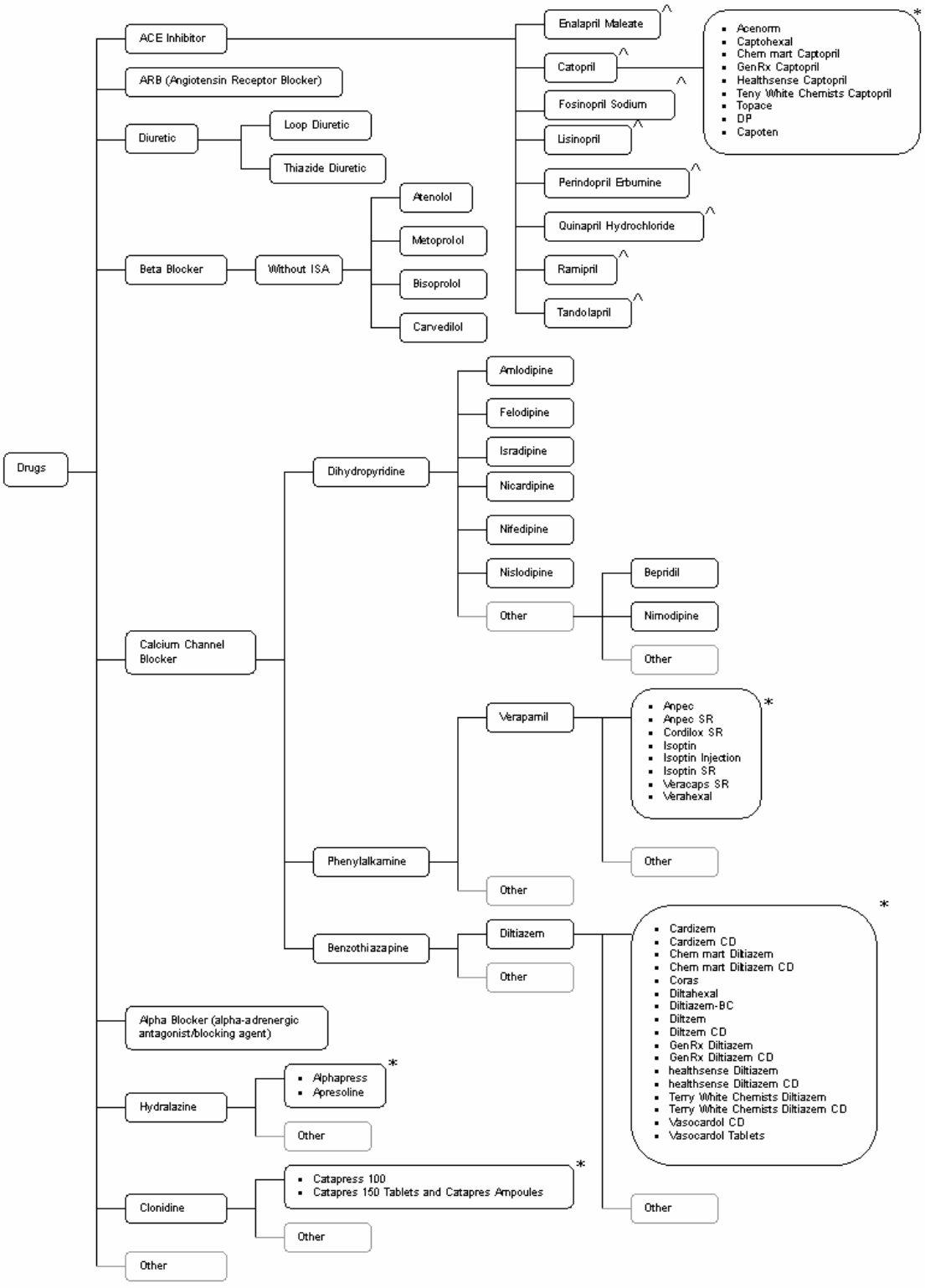


Figure 6.1. Hierarchical concepts for the concept 'Drugs' [181].* ^

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* The *brand* names are taken from the Australian Pharmaceutical Benefits Schedule [176].

^ These *generic* names are taken from the Australian Pharmaceutical Benefits Schedule [176].

Note: Not all brand names and generic names have been included for all the drugs in the ontology – only those that are used in our case study demonstration.

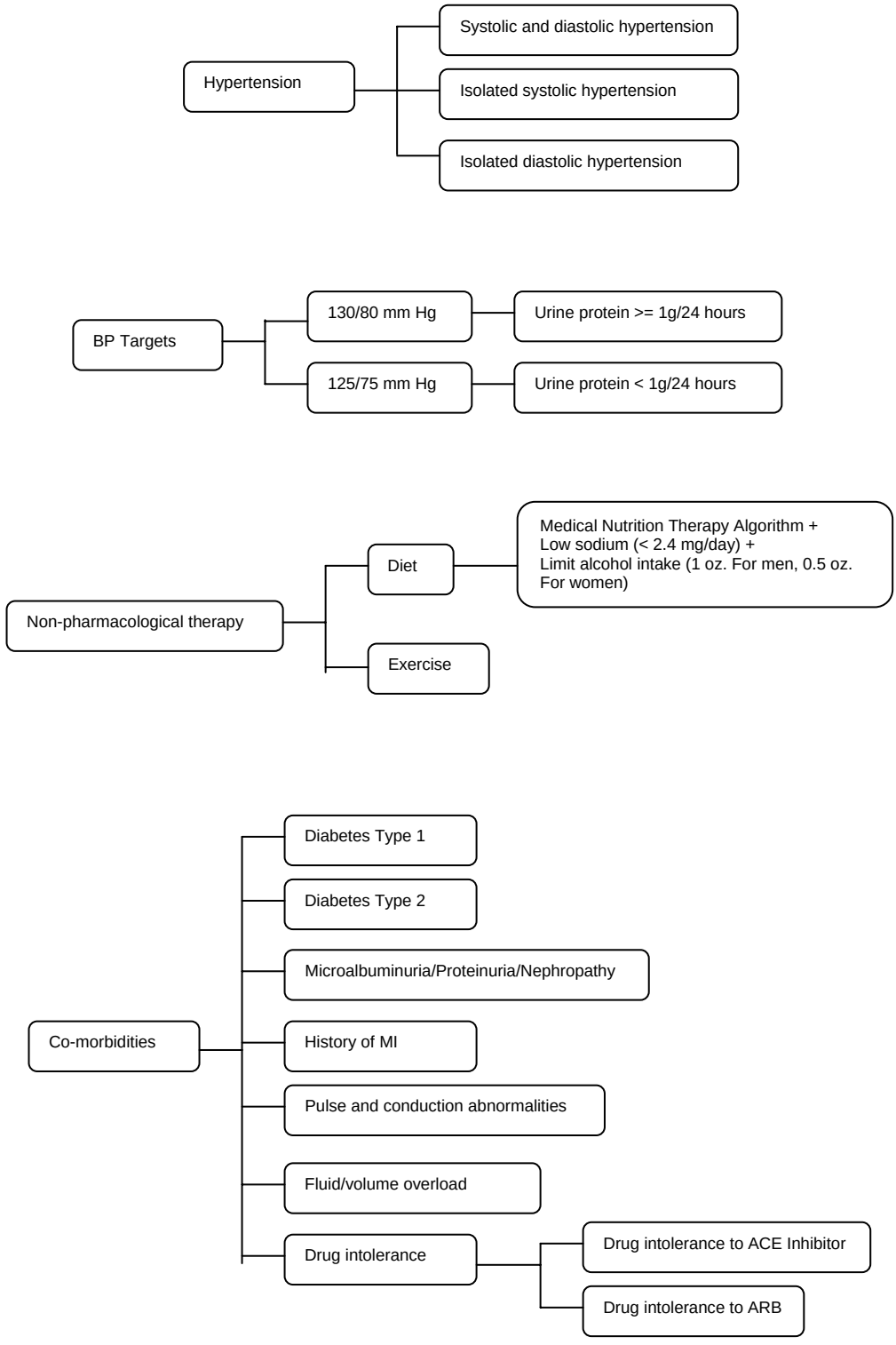

Figure 6.2. Hierarchical concepts for the concepts "Hypertension", "BP Targets", "Non-pharmacological therapy" & "Co-morbidities".

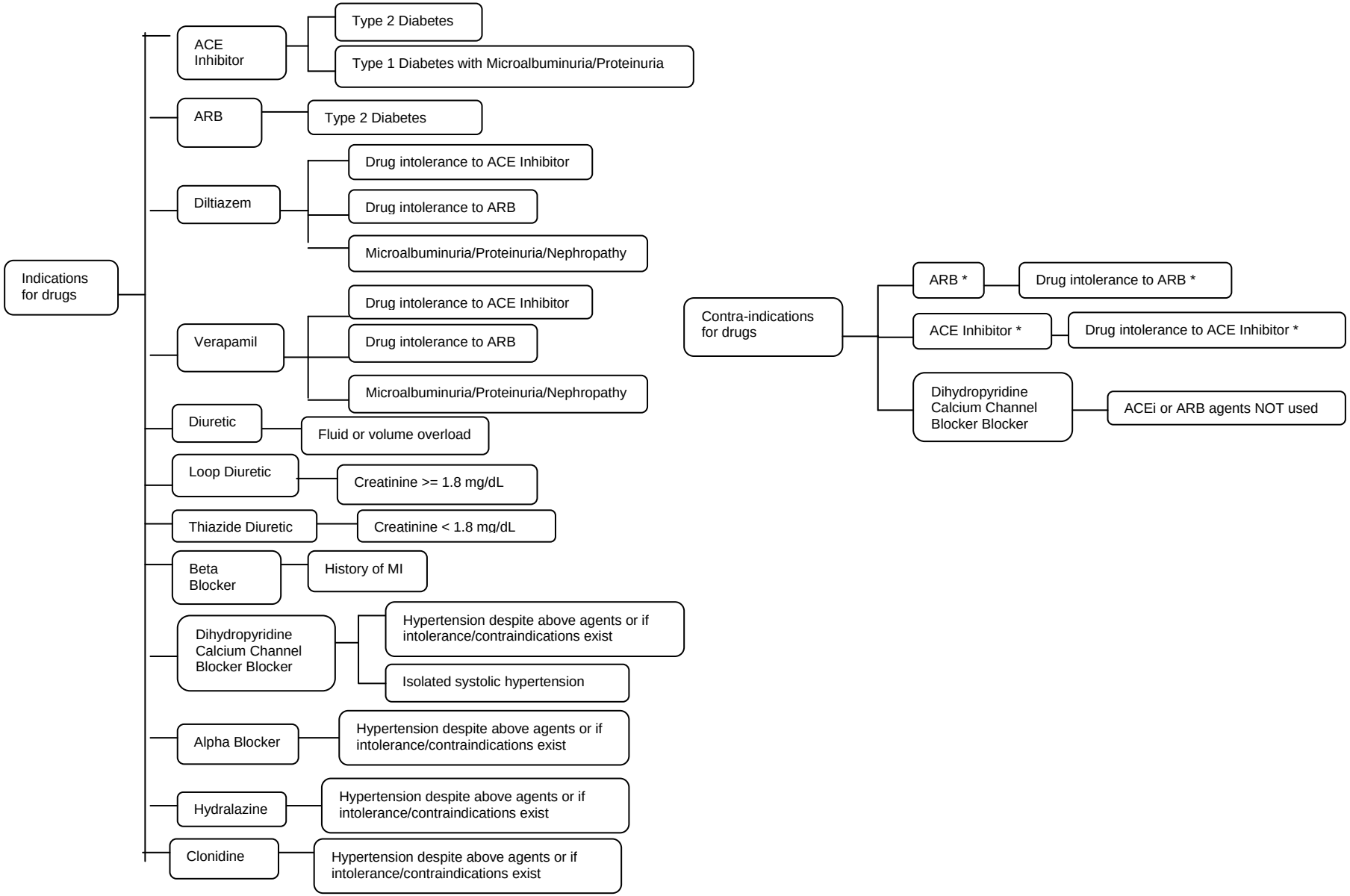

Figure 6.3. Concept Relationships *

* According to the guideline 'intolerance contrainidications' may exist in any of the agents prescribed from guideline steps 1 to 6.

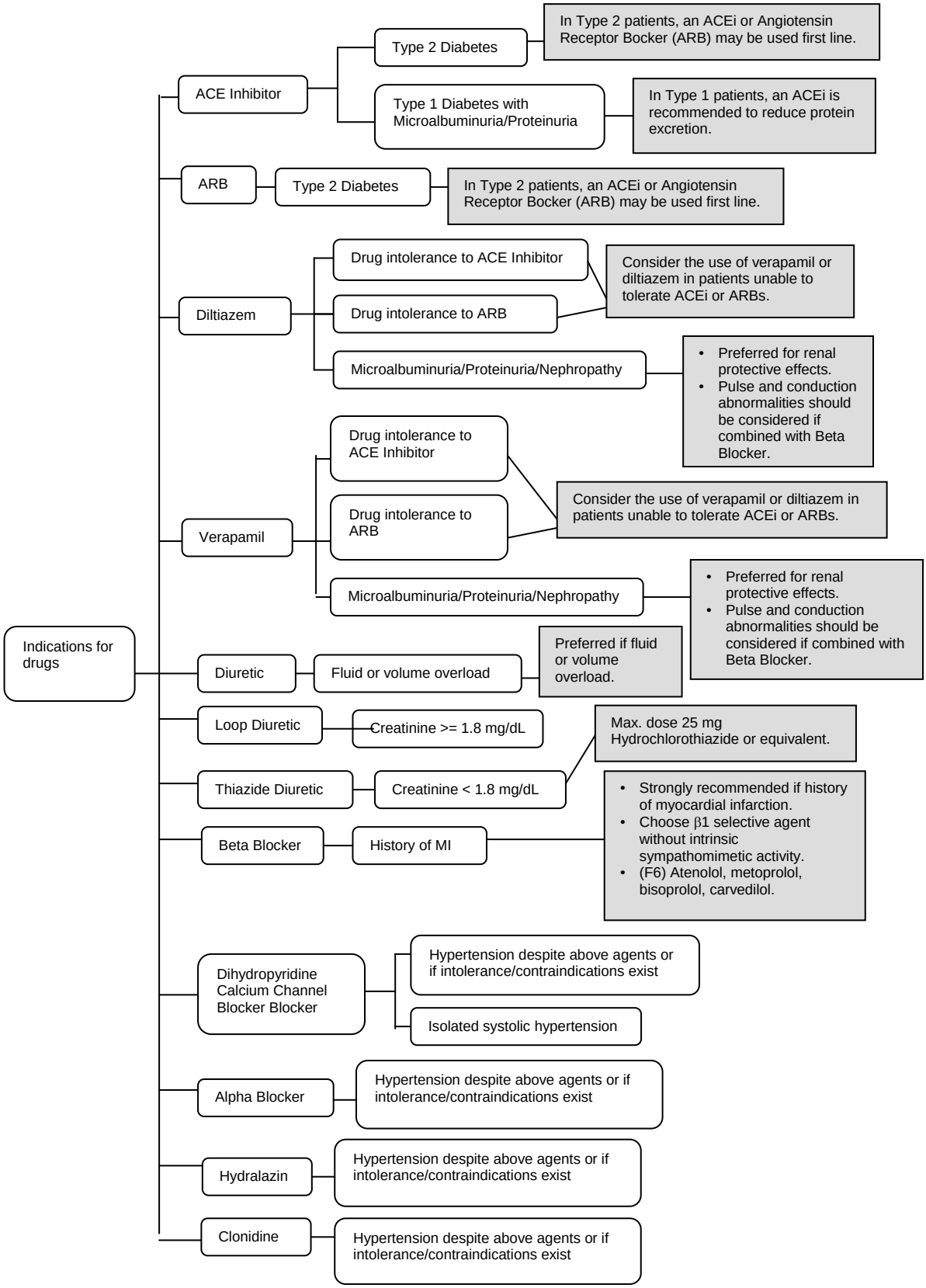

Figure 6.4. Concept to Guideline-point Relationships (Constrains the Rationale).

6.3. Hypertension with Diabetes CiG

Based on the ontology we developed from our analysis of the guideline for hypertension management in diabetes mellitus in adults, we constructed a guideline adapter file that represents the underlying structure of the ontology from which knowledge about a specific guideline document (such as the hypertension management in diabetes guideline) can be encoded into.

The tree structure of the ontology (shown in Figure 6.5) basically consists of a descriptor, which allows information about the guideline document to be encoded into metadata elements such as its: Unique Reference Identifier (URI) that uniquely identifies the guideline, the fileSource (full directory path or URL to the actual guideline document), which may also have a graphicSource (full directory or URL to the guideline document as a graphic file used for presentation as hypermedia), title, description, version, the author (i.e. the individual person(s) who wrote the guideline), institution that the author(s) belongs to (which consequently may also be the institution that the guideline is to be used for such as a local hospital), use (criteria for proper of the guideline), and possibly a description of potential misuse of the guideline (e.g. this guideline cannot be applied if some other co-morbidity exists in the patient that cannot be managed independently; as a more specialised guideline may be used to efficiently and safely manage both problems/diseases).

The ontological structure for concepts and concept relationships are illustrated in Figure 6.6 and Figure 6.7 respectively with most of the concepts having links to their terminological code ID and code source.

The guideline hypermedia (Figure 6.7) can also be encoded XML-based ontology in terms of its guideline reference identifier (GRI) value that uniquely identifies a specific ‘step’ in the guideline; its graphic reference point, which are the coordinates in the graphic source this step points to (e.g. to enable appropriate guideline ‘animation’ to occur on presentation of the current state of the patient in the guideline and decisions that were taken); the URL to the guideline source; and the associated didactics (or explanation) for the guideline step (in this case, we found that the footnotes in the guideline served primarily as didactics associated with specific steps

in the guideline). We consider a 'step' in the guideline to be a *statement or set of statements*, which may describe a specific *condition or rule* (which may also be composite or made up of a number of rules) to be followed that assist in the decision making; or an *action* that needs to be undertaken. All these steps are generally considered to be *decision points* either with regards to the patient's condition (e.g. blood pressure >= 130/80 mmHg), or a recommended action in the guideline (e.g. ACE Inhibitor therapy). In the guideline we have chosen, the guideline steps are relatively clear in that it is presented in a graphical flow chart. Thus, the numbering of the steps is made according to the boxes or nodes in the flow chart – beginning from 1 (the start node of the flow chart) through to 7 (the last flow chart node), and step 8, which refers to the table in the guideline. The individual statements within those steps are then given level two numbering (e.g., 1.1, 1.2, …n) in order in which the steps occur in the guideline.

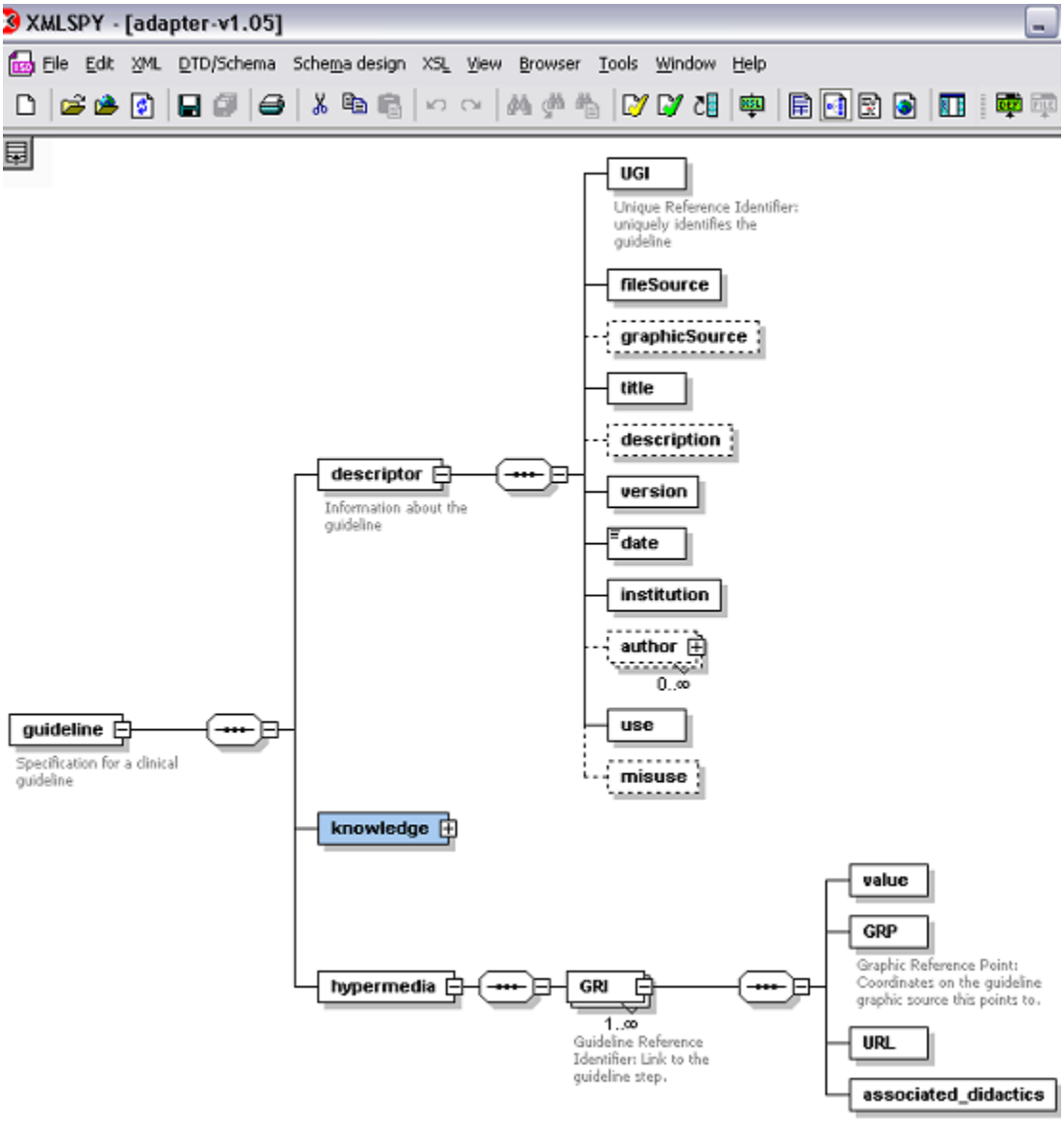

Figure 6.5. XML schema of the guideline adapter document (viewed as a tree).[18]

[18] Generated using XMLSPY version 5 (rel. 4) Enterprise Edition XML editor [160] (similarly for Figure 6.6 and Figure 6.7).

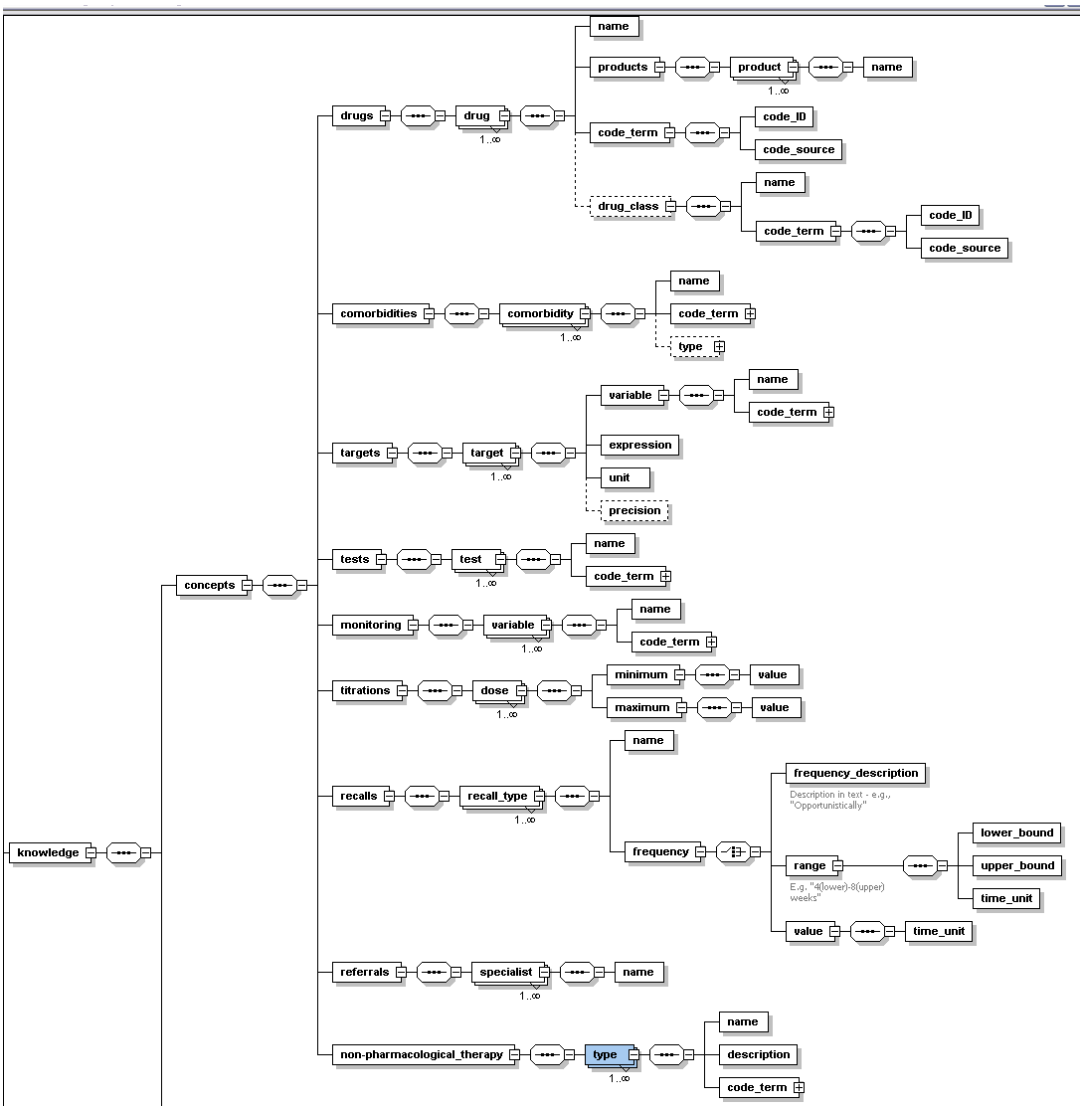

Figure 6.6. Portion of XML schema for concepts in the ontology.

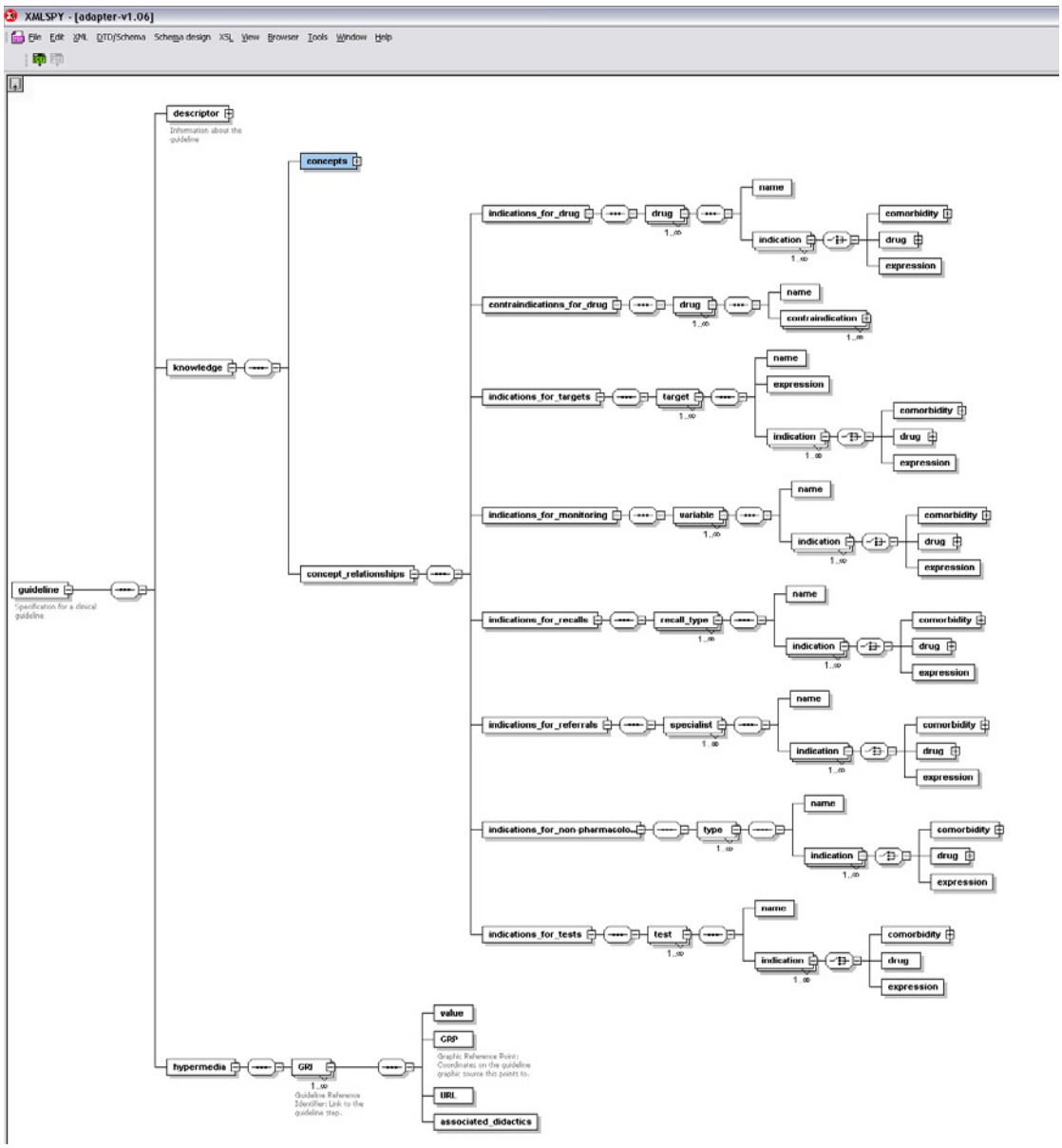

Figure 6.7. Portion of XML schema for concept relationships and hypermedia information in the ontology.

6.4. Case Workflow

The basic 'workflow' of the guideline is as illustrated in Figure 6.8. Note that the blood pressure (BP) target may change depending on other patient variables such as having a high level of urine protein. "Adjust Therapy" may specify an inclusive choice of activities such as non-pharmacological therapy, changing or adding new agent, adjusting the dosage, and / or referring the patient to a specialist.

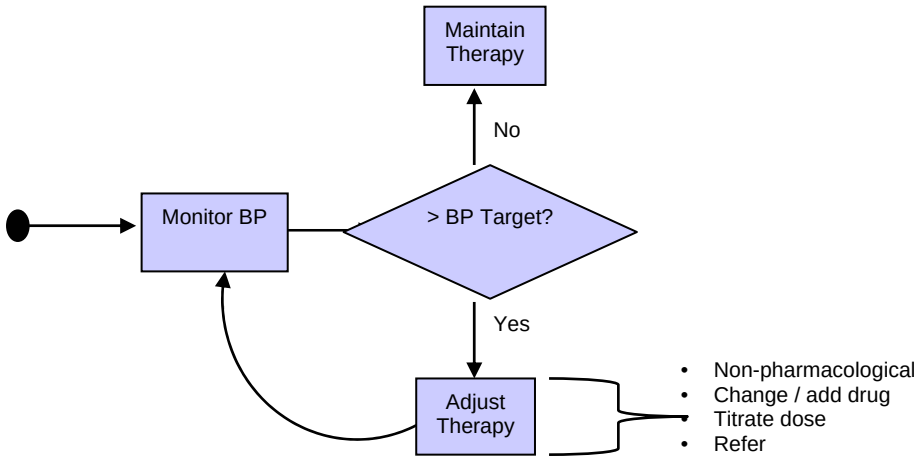

Figure 6.8. Hypertension Management in Diabetes Workflow.

It may seem natural to implement the workflow of Figure 6.8 directly, but we have opted against this. Since the activities of monitor the blood pressure, maintain therapy, and adjusting the therapy all occur within a single encounter or session, these do not require the assistance of a WfMS. Instead, we view the actual workflow to be at a much higher level. The workflows that result from the guideline would therefore include referral (Figure 6.9) and recall for assessment/monitoring (Figure 6.10). Both workflows can be implemented with the assistance of a WfMS – allowing automated scheduling and booking of the patient to be made.

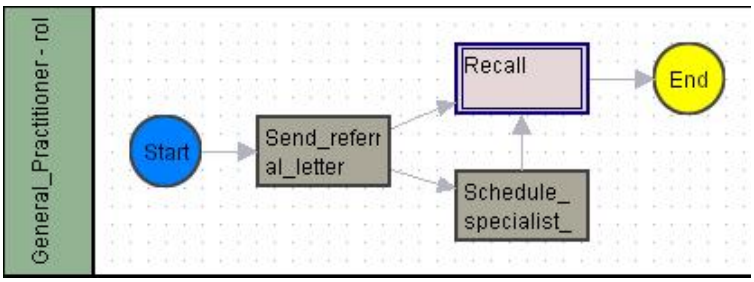

Figure 6.9. Referral Workflow Schema. [19]

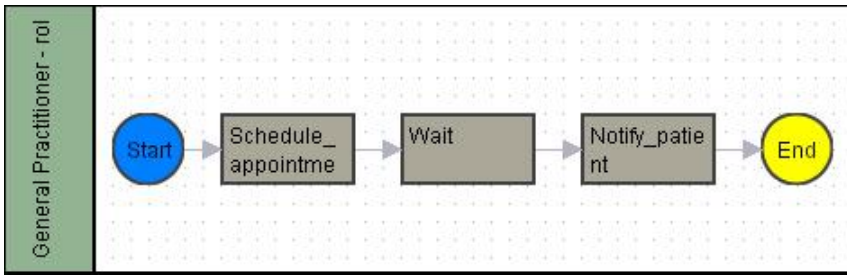

Figure 6.10. Recall Sub Workflow Schema.[19]

6.5. Data Collection and Decision Support

6.5.1. Data linkage to Decision Support

Values for any of these items can be a link item provided by the *open*EHR framework. For instance, indications for prescribing an ACE inhibitor may be diabetes and hypertension, which can be identified by a navigational path, as defined by the *open*EHR reference model [77].

We use our prototype to demonstrate the interrelation of guideline-specialised EHR content and other guideline artefacts. Information about the guideline as well as the collated indications is automatically populated by the DSS whenever the clinician chooses to comply with its recommendations (with provision for explanation of variation from the guideline where some aspect of the guideline intention is preserved). Furthermore, such information is used to link back to the online guideline document and enable clinicians to view the hypermedia guideline document with the specific decision point highlighted. The prototype system architecture is shown in Figure 4.1.

[19] Workflow diagram generated by JaWE v1.3 [165].

With respect to the medication and target archetypes, we have included a construct for recording "rationale". This is often a requirement for explaining the change of medication for instance. Whilst an archetype definition can be made for recording the rationale, and allow it to be specialised – e.g. for change of medication – we view this information to be used to describe the reason for any type of information. For example, why an observation was taken (for observation entries), why the blood pressure target was lowered (evaluation entries), or why a referral to a specialist was made (instruction entries). Moreover, the rationale contains attributes that provide a direct link to any guideline document or DSS used. We have chosen to use 'rationale' as an optional attribute within either type of *open*EHR entry.

The attribute 'indications' within the rationale simply collates a list of relevant links to EHR data items that provide indications to arrive at a particular decision. These EHR data items would come from either or a combination of problems (e.g. diabetes), observations (e.g. blood pressure) and assessments or evaluations (e.g. poorly tolerated beta-blocker).

Should the clinician decide to use the guideline recommendation, the particular guideline used and the specific step within the guideline are also recorded within the rationale. Moreover, one might choose a different format to the one used in our prototype for identifying a particular guideline and step.

6.5.2. Archetypes for Data Collection

We developed a set of archetypes to be used specifically for encounters associated with the management of hypertension in diabetes patients. The hierarchy of archetypes within the specialised Problem-SOAP note is shown in Figure 6.11. The archetype is structured such that for each encounter a Problem-SOAP note formatted event transaction will be made. For example, under the "Objective" heading, the blood pressure and urine protein levels (which indicates any kidney problems the patient may have which then affects the type of medication prescribed, as well as any goals and targets) need to be recorded (and possibly others, such as creatinine levels).

Some issues arose with regards to dealing with multiple problems within a single encounter. As an example, for "Assessments" there is the question of whether or not we combine all problems into one statement/element value (as 'severe hypertension *and* proteinuria', or to record them as separate entities.

In some way it may be more beneficial and sensible to combine the problems together if they are related or have some dependencies between them. Proteinuria for instance, is an indicator of kidney problems, which often develops as a result of a diabetes problem. This then affects the decision as to which medication is prescribed as one type that is beneficial to the treatment of one problem may have adverse effects on other problems the patient has. It is relatively 'obvious' to the expert that the drug choice and lower blood pressure target are the result of the combination of the problems as linked to the specific target and treatment. The proteinuria might become a problem that is an indication for the ACE inhibitor (blood pressure treatment) and the target blood pressure might be much lower – with a description of the reason.

From a system's perspective, it makes sense for the two problems to be recorded separately as they are in fact, two different, albeit, related assessments. The relationship between the two can be inferred by the knowledge and expertise of the clinician, as well as be referred to separately or together as required by a DSS. Thus, this is the structure we have chosen to use in our approach. Listing 6.1 shows an example of how a Problem-SOAP note may look like in the EHR when recording the problems as separate entries.

Listing 6.1. Example Problem-SOAP Note Structure.

(Problem =) "Proteinuria"
S: (Archetype = Symptoms) No haematuria
O: (Archetype = Biochemistry result) Test = Urinary protein, Value = 1.5 g/24hr
A: (Archetype = Assessment/Conclusion) Microalbuminuria; warranting commencement of an Ace Inhibitor
P: (archetype = Medication order) Medication name = Ramipril
Indications: diabetes, hypertension, proteinuria

(Problem =) "Hypertension"
S:
O: (Archetype = Blood pressure) 140/80 mmHg
A: (archetype = Assessment/Conclusion) hypertension is not adequately controlled in view of proteinuria.
P: (Archetype = Target) BP\Systolic < 125 mmHg BP\Diastolic < 75 mmHg

The way we record a problem in the event transaction might be different than how it is done in a health 'summary' of the patient's current problems/diagnoses, which would be a persistent transaction that gets updated as relevant event transactions get recorded. Thus, the SOAP organisers can be under a problem heading "Diabetes" SOAP. Then the assessment may just say 'proteinuria'. This is likely to be added to the 'summary' as a complication of diabetes – that is, as separate problem with a link from the complication attribute of diabetes and hypertension (as shown in Listing 6.2). The terminology may allow a code phrase that is suitable to be used.

Listing 6.2. Example 'Health Summary' Structure.

(Persistent Transaction=) "Health Summary (Current Problems List)"

(Problem =) "Diabetes" <link from "Diagnosis" event transaction that recorded "Diabetes">

(Problem =) "Hypertension" <links from SOAP Note that recorded "Hypertension" as a problem as well as from the "Assessment/Conclusion" heading that it is recorded under>

(Problem =) "Proteinuria" <links from the SOAP Note that recorded "Proteinuria" under the "Assessment/Conclusion" heading>

Based on the ontology derived from the Texas hypertension in diabetes guideline, the specific archetypes required within a problem-SOAP note event transaction would include:

- Recommended therapy (prescription transaction)
- Self-monitoring of blood pressure
- Lab test for microalbuminuria
- Notification for reassessment (two possible types):
  - Opportunistic (whenever the patient next comes in not necessarily just for BP check-up; this is often what is more convenient in practice)
  - Guideline recommendation (i.e., 4-8 weeks)
- Care plan index problem of hypertension.

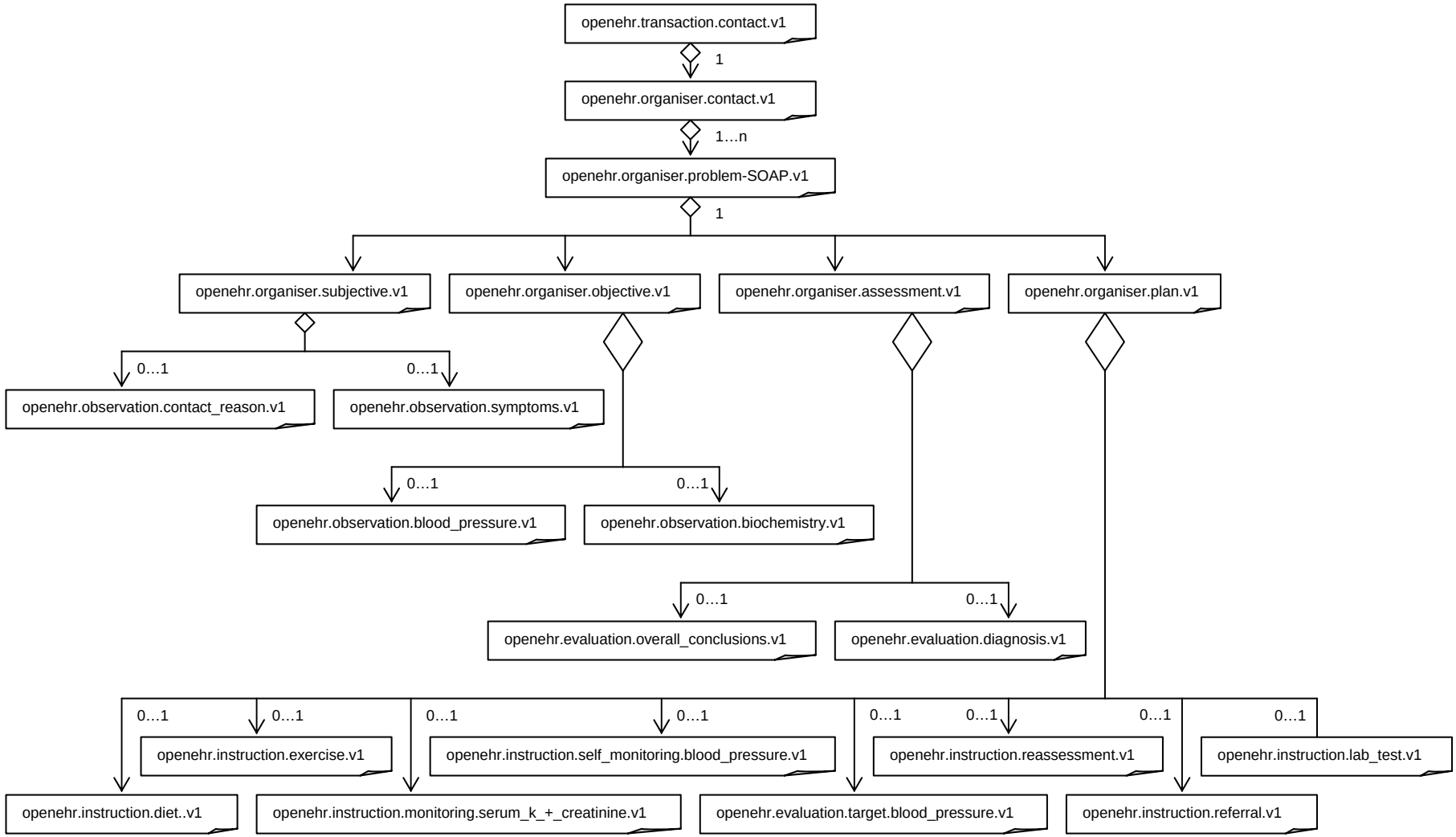

Figure 6.11. Hierarchical structure of archetypes for encounters relating to Hypertension in Diabetes.

6.6. Implementation

We illustrate the interaction required between the EHR and electronic decision support, and provide segments of the EHR transactions produced during four patient-provider encounters described in sections 6.1 and 6.2.1. In particular, we track the relationship of these encounters to the guideline. As mentioned, EHR transactions are encoded in XML, but for the sake of readability, we illustrate them in abbreviated textual format and show only specific fragments (rather than the complete transaction). We designate a transaction relating to an encounter as a 'GP contact' note, and demonstrate a step-by-step walkthrough of the user's interaction with the user interface, and the resulting data recorded in the EHR.

Creating a new GP Contact

Similarly in our ESD case study implementation, the user logs into the system, but as the role of the 'General_Practitioner' (Figure 6.12).

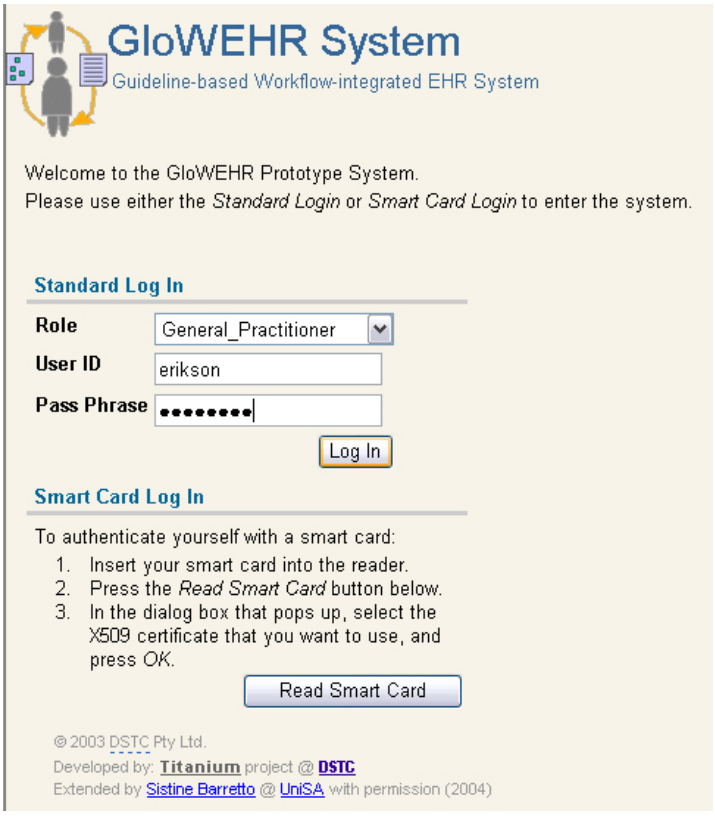

Figure 6.12. GP login screen.

On successful login, the GP users are presented with a 'main' web page as shown in Figure 6.13 from which they are able to view any 'system news' or alerts and reminders, and search for a 'consumer's'[20] EHR to view either by name and date of birth, ID, or using the advanced search functionality (Figure 6.13). Alternatively, the GP may select from a list of 'Recently Viewed Consumers' that the system generates by getting the last five patients whose EHRs were last accessed by the GP. In this case, the GP, Dr. Sally Erikson is consulting with the Mrs. Margaret Simpson, and therefore, selects her from the list of 'Recently Viewed Consumers' to view her EHR.

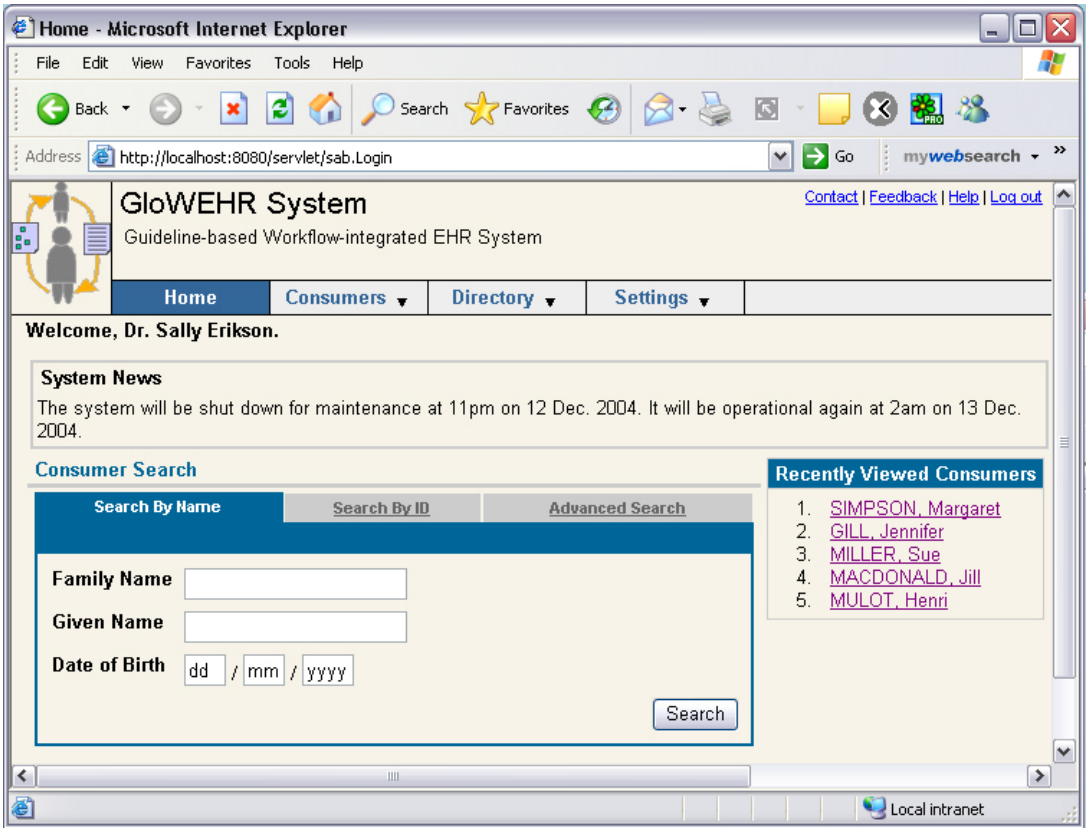

Figure 6.13. 'Search for patient' screen.

Similarly to the ESD case study, Figure 6.14 shows the overview information about Mrs. Simpson, in particular – 'diabetes mellitus type 2' is listed in her 'current problems' list.

[20] From here onwards in this implementation walkthrough, we refer to the 'consumer' as the 'patient'.

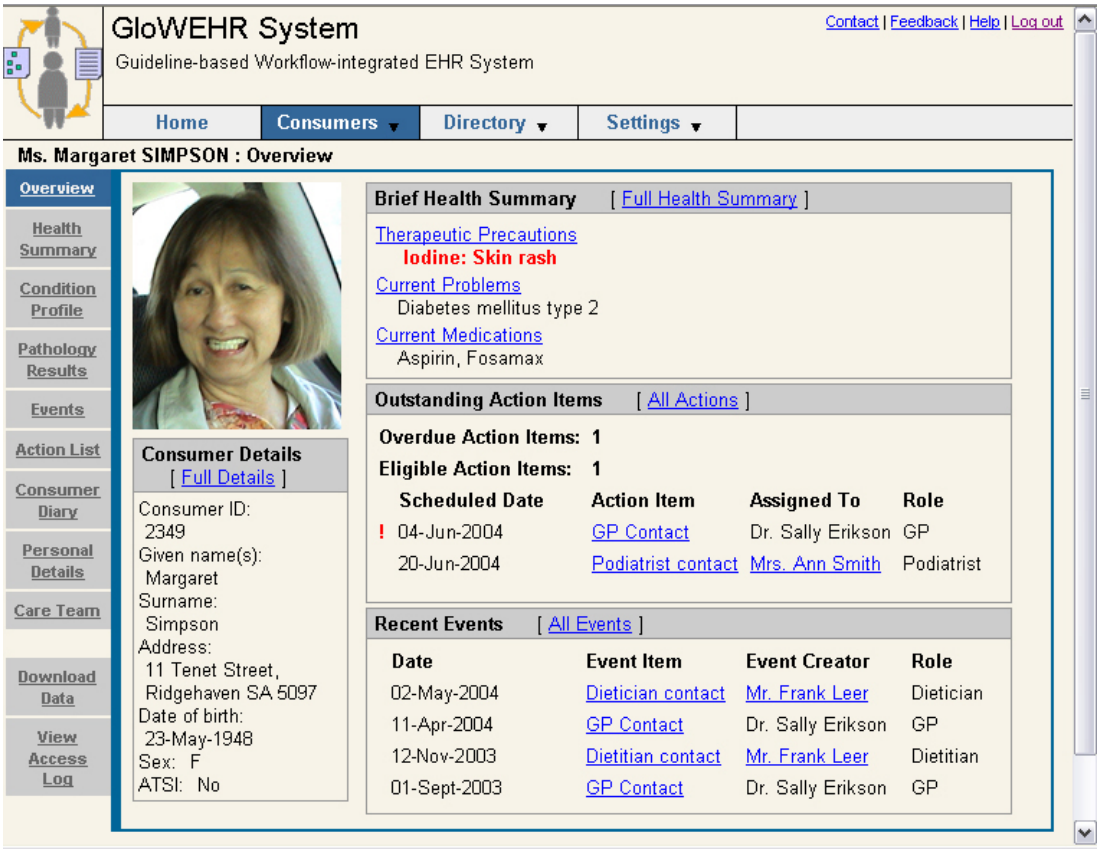

Figure 6.14. Patient overview screen. [21]

To create a new encounter note for Mrs. Simpson, Dr. Erikson clicks on the 'Add Event' button in the sub-menu from the 'Events' side menu button as shown in Figure 6.15, which opens a list of available event transactions that can be created including the encounter note. The GP should now be presented with an GP Contact form in 'tab' layout, which initially opens up with the first tab form to enter in the 'Event Details' (i.e. subject, location, date/time of consultation and provider details), followed by the 'Subjective' tabbed form shown in Figure 6.16, where Mrs. Simpson's complaint of heart palpitations is recorded.

[21] The patient identification details (including photograph) have been altered to protect confidentiality.

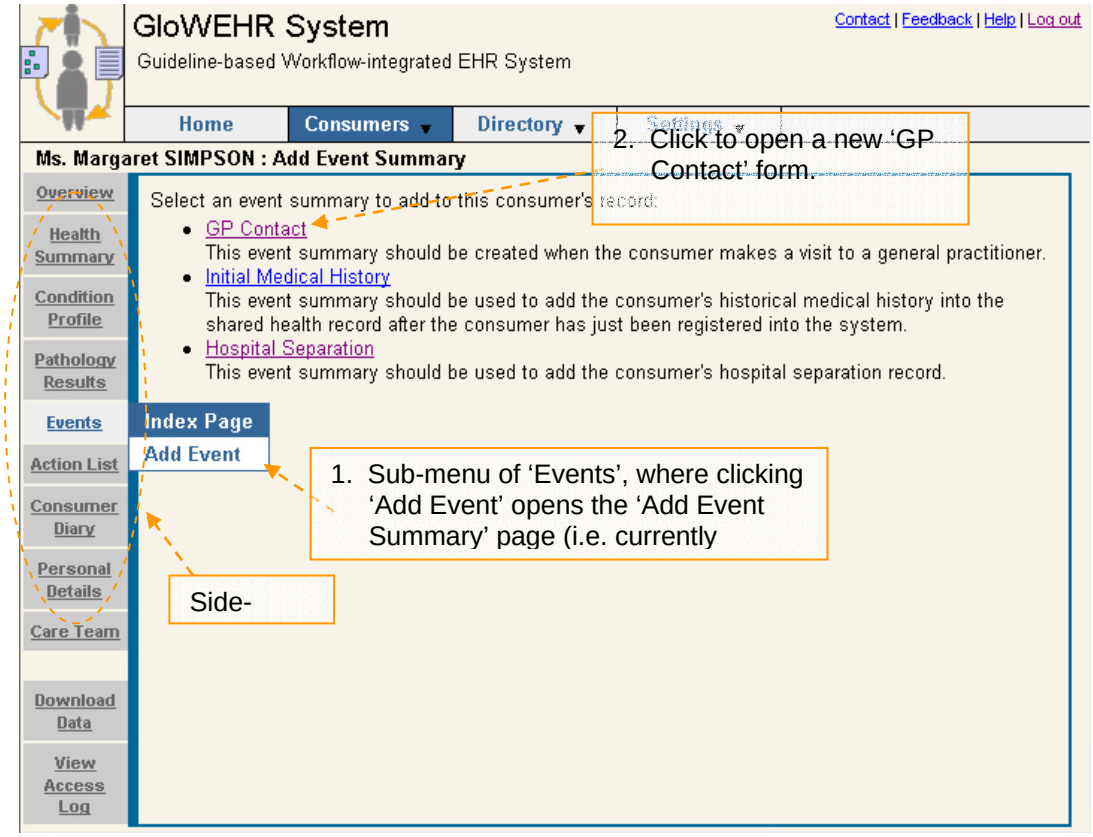

Figure 6.15. Add Event screen.[22]

[22] In the user interface, an 'event summary' refers to an 'event transaction'. The term 'event summary' originates from [26], and was kept as it is a more user-friendly term compared to the more technically-oriented use of the term 'transaction'.

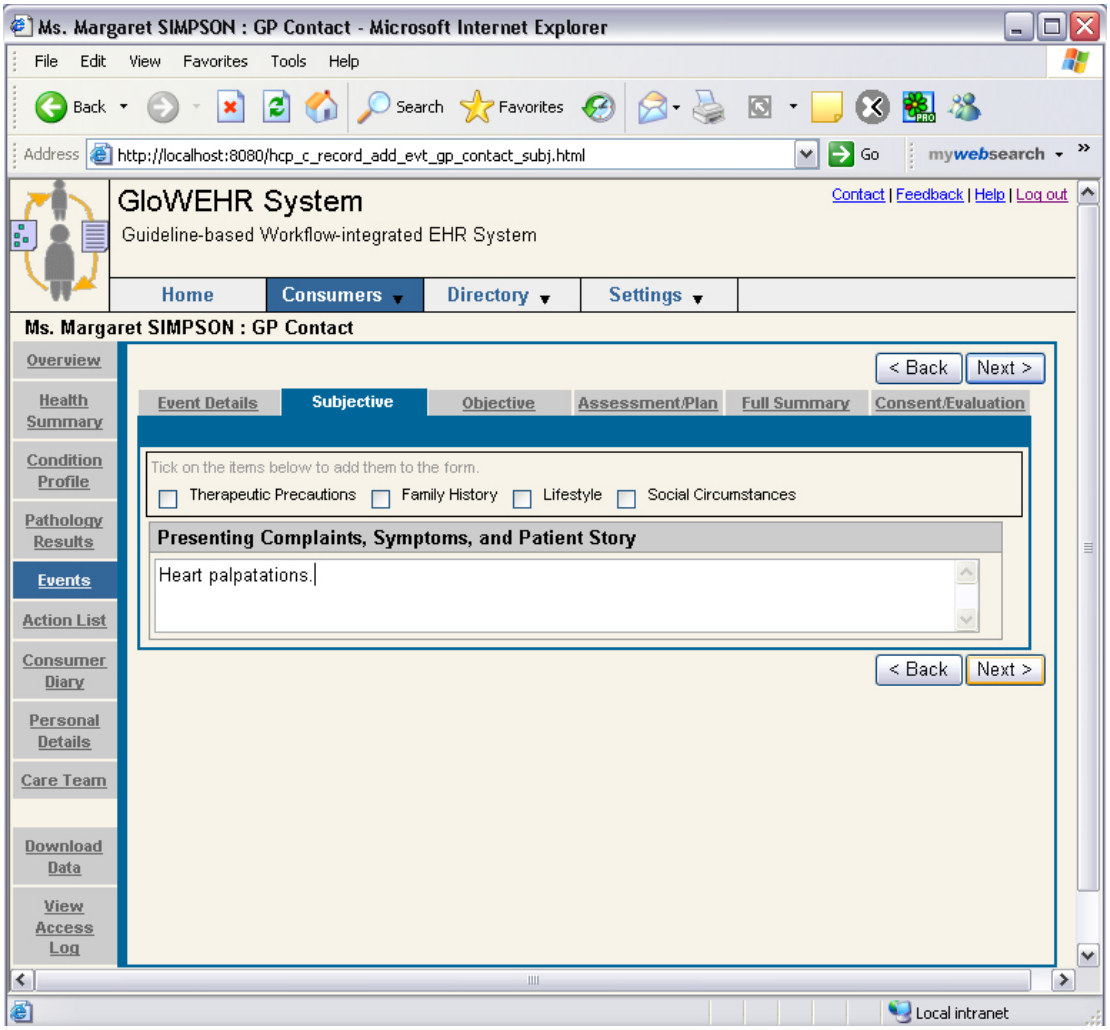

Figure 6.16. 'Subjective' EHR sub-form.

Task 1.0: ACE inhibitor therapy and counselling on diet and exercise

After recording observations for the blood pressure and proteinuria within the 'objective' section (Figure 6.17), the clinician opens the tab form for entering the 'assessment/plan' (Figure 6.18).

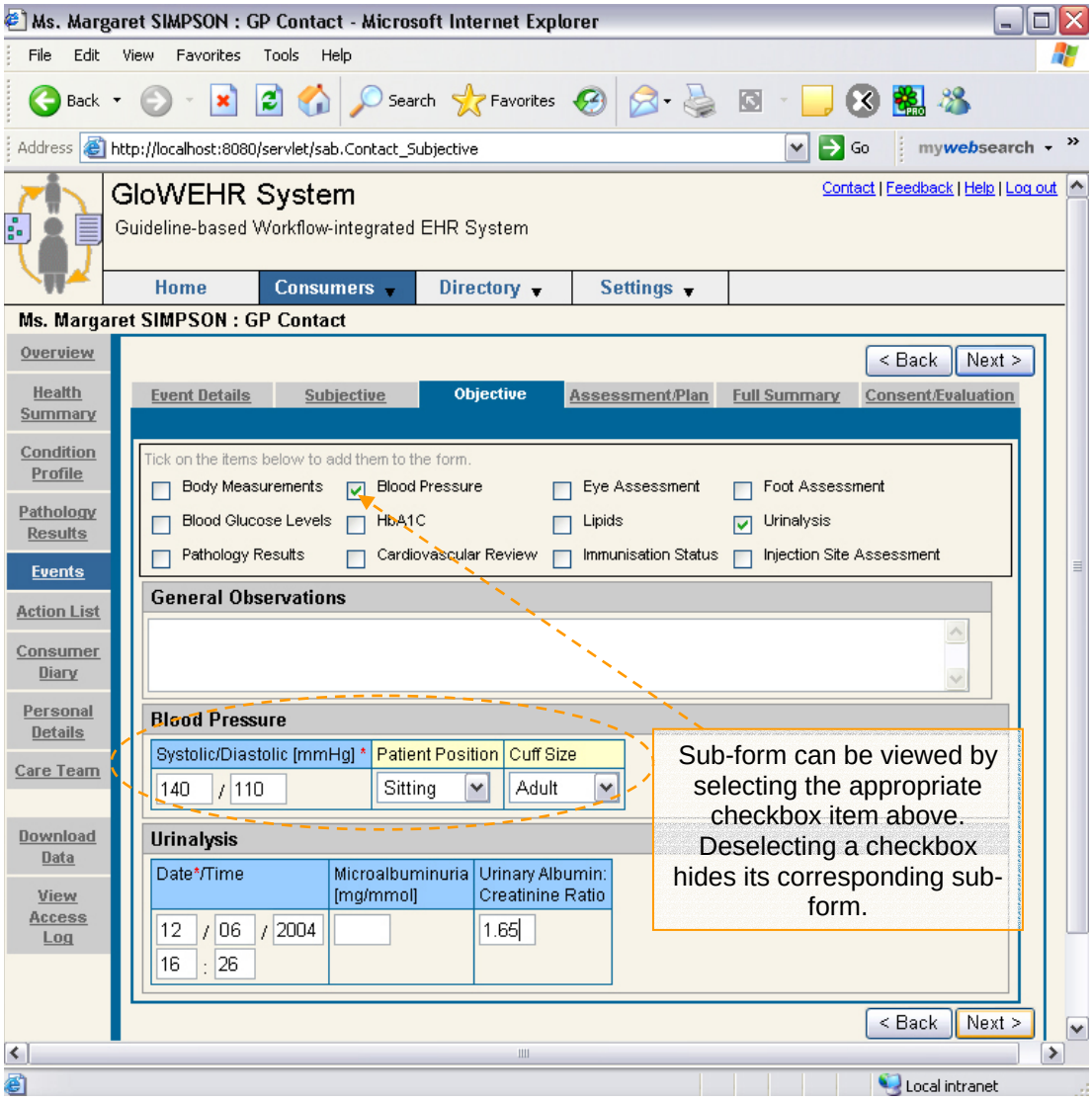

Figure 6.17. 'Objective' EHR sub-form.

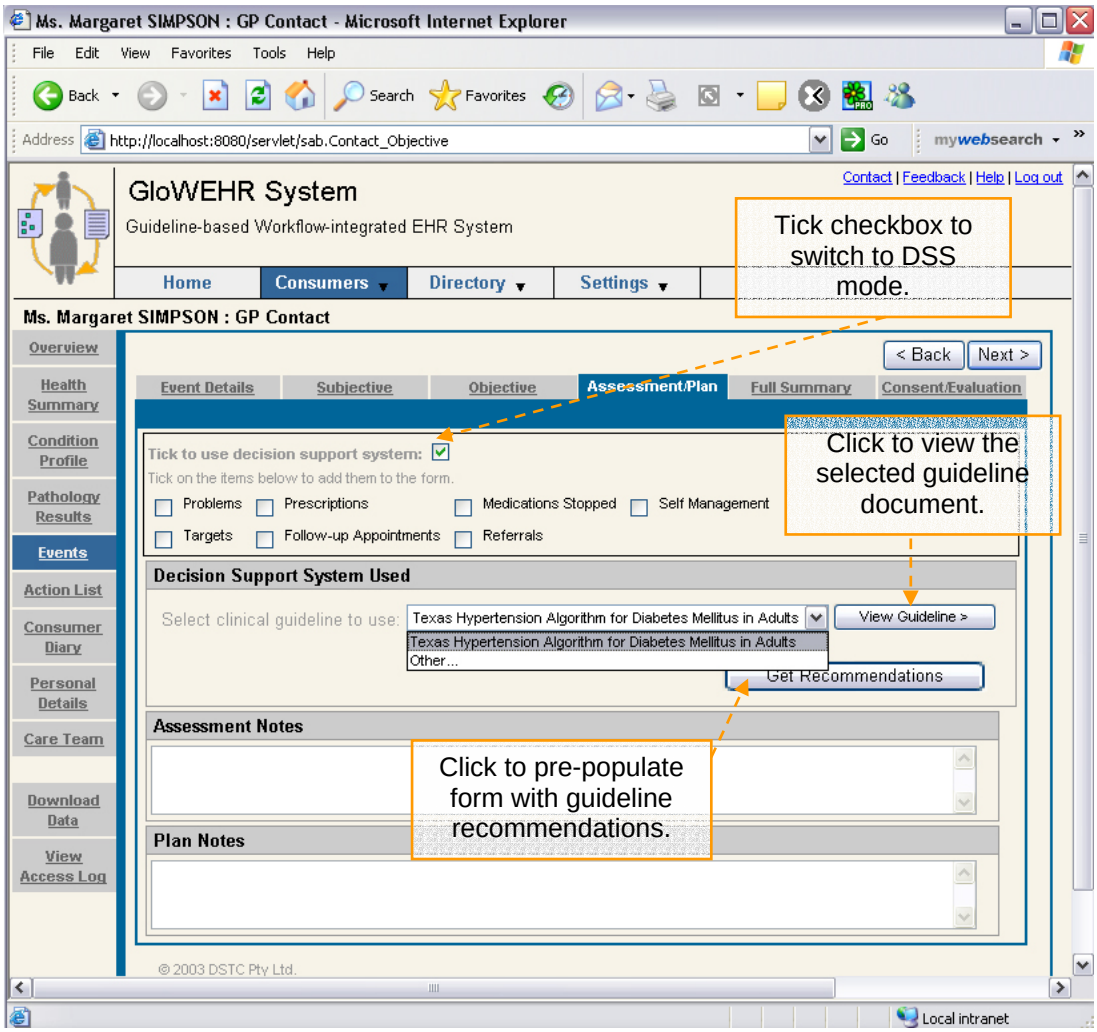

Figure 6.18. 'Assessment/Plan' EHR sub-form.

The clinician selects the option for using the DSS and the guideline to use. The DSS searches for the last guideline step that the patient was in from the EHR by searching through all of the encounter notes that use the appropriate guideline-specific archetype identifier, and getting the guideline step recorded from the latest encounter note. At this particular point in the patient's care, no previous guideline step was found, and the DSS therefore assumes that the patient will be in the initial state of the guideline.

The pull-down menu for Problem contains a problem list that is constrained to the set of co-morbidities in the guideline, which are provided by the DSS (Figure 6.19). The list also includes an item for selecting "other" problems that are not given by the guideline, which then gives a blank text field for entering the actual problem using

Javascript. The problems that have been identified based on clinical observations and judgment (i.e. diagnoses) are then stored as evaluation entries within the EHR. The clinician selects proteinuria and hypertension as the two problems identified in this encounter (Figure 6.19). The DSS then populates the relevant 'assessment/plan' fields with initial recommendations from the guideline based on the parameters recorded by the clinician.

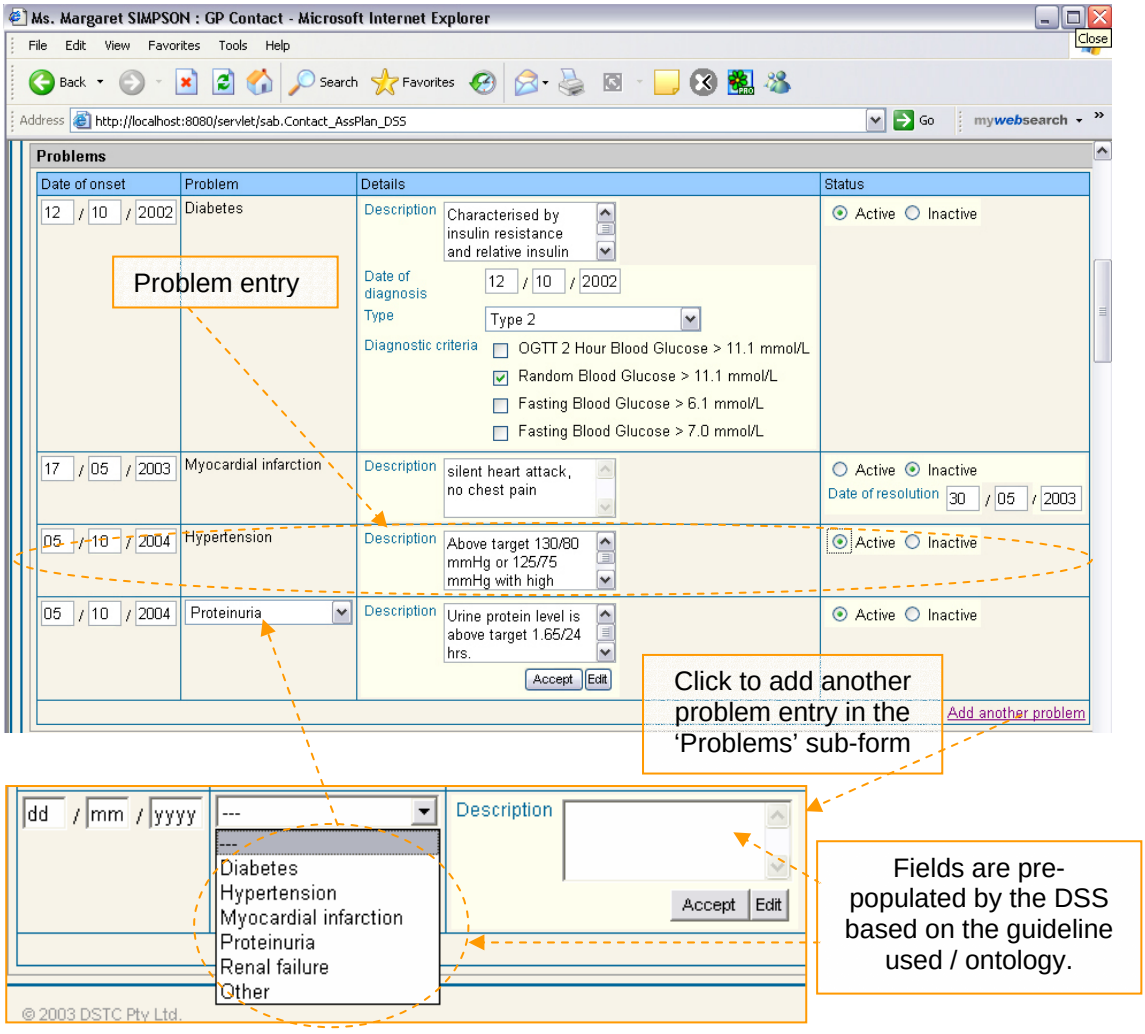

Figure 6.19. Hypertension and proteinuria added to Problems List in the Assessment/Plan section.

The patient is also encouraged to self-monitor her blood pressure and is educated by the GP about proper blood pressure readings and technique. Continuance of proper diet (i.e. low sodium diet of less than 2.4 g/day) to increase exercise, and to limit the alcohol intake to 1 oz (29.57 mL) is also advised (Figure 6.20).

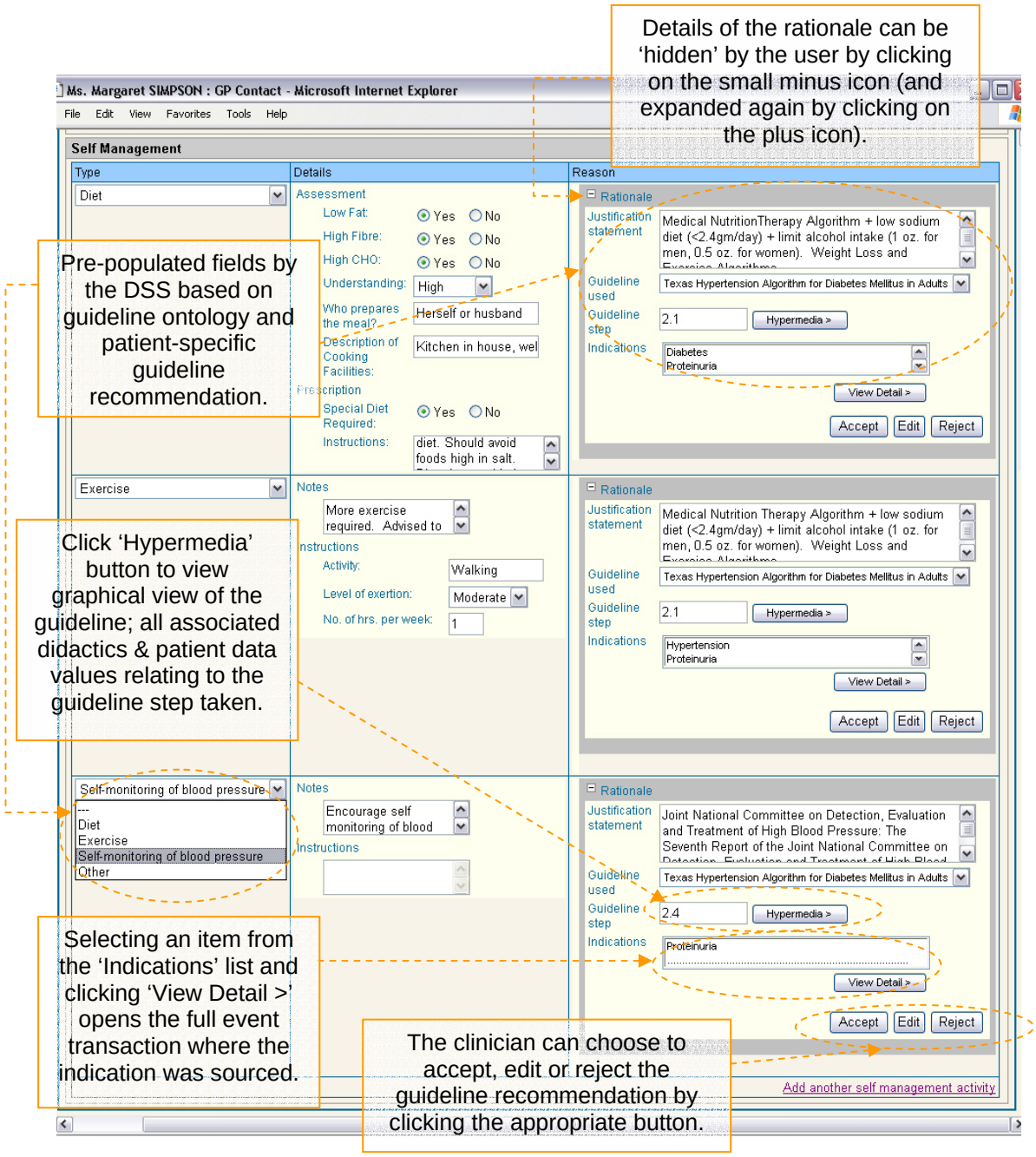

Figure 6.20. Guideline-recommended Self-Management activities (non-pharmacological therapy and monitoring) at the first encounter.

Figure 6.21 shows the pre-population of the targets as recommended by the DSS according to the guideline with details of the decision rationale. The DSS pre-populates the target values for the urine protein level to less than 1 g/24 hrs, and the blood pressure to less than or equal to 125/75 mmHg (rather than 130/80 mmHg due to high urine protein level) (see Figure 6.21).

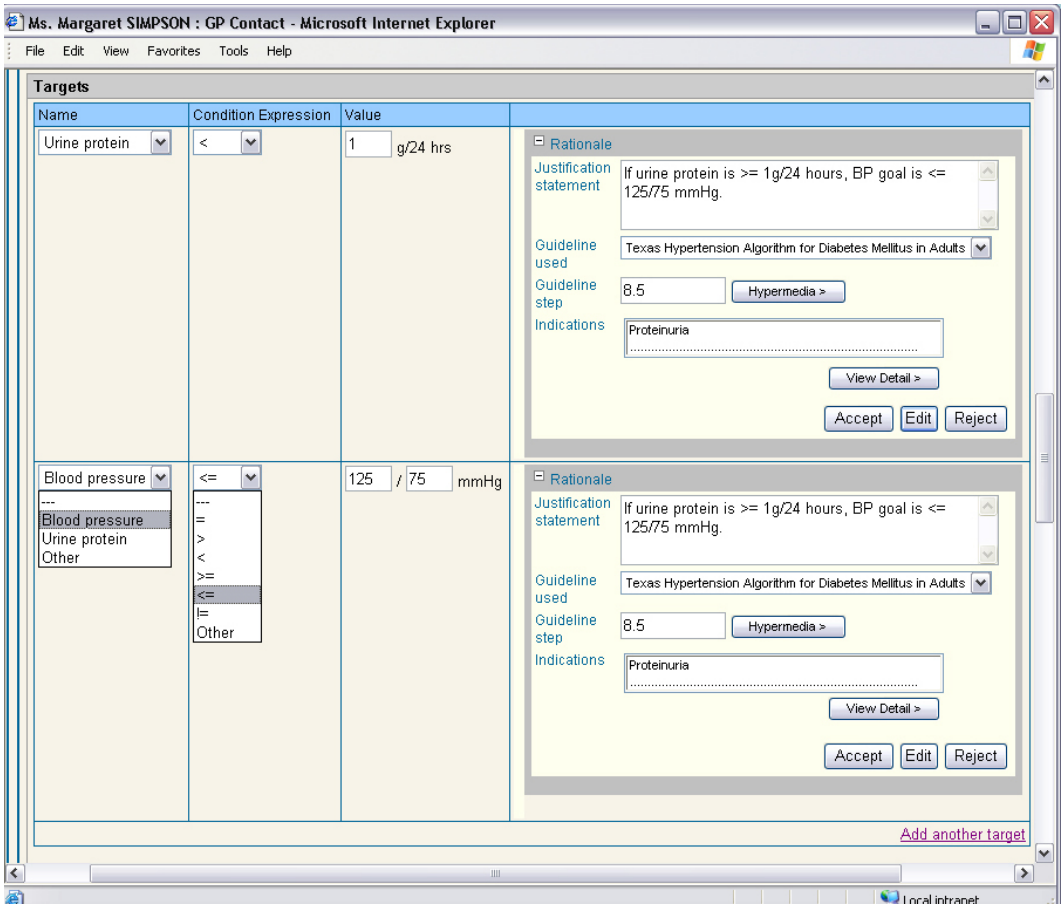

Figure 6.21. Guideline-recommended Targets at the first encounter.

ACE inhibitor is the drug class prescribed to the patient as a primary recommendation according to the guideline to lower the blood pressure to less than or equal to 125/75 mmHg. Figure 6.22 shows the 'Prescription' form within 'Assessment/Plan' with pre-populated guideline-recommended values from the DSS.

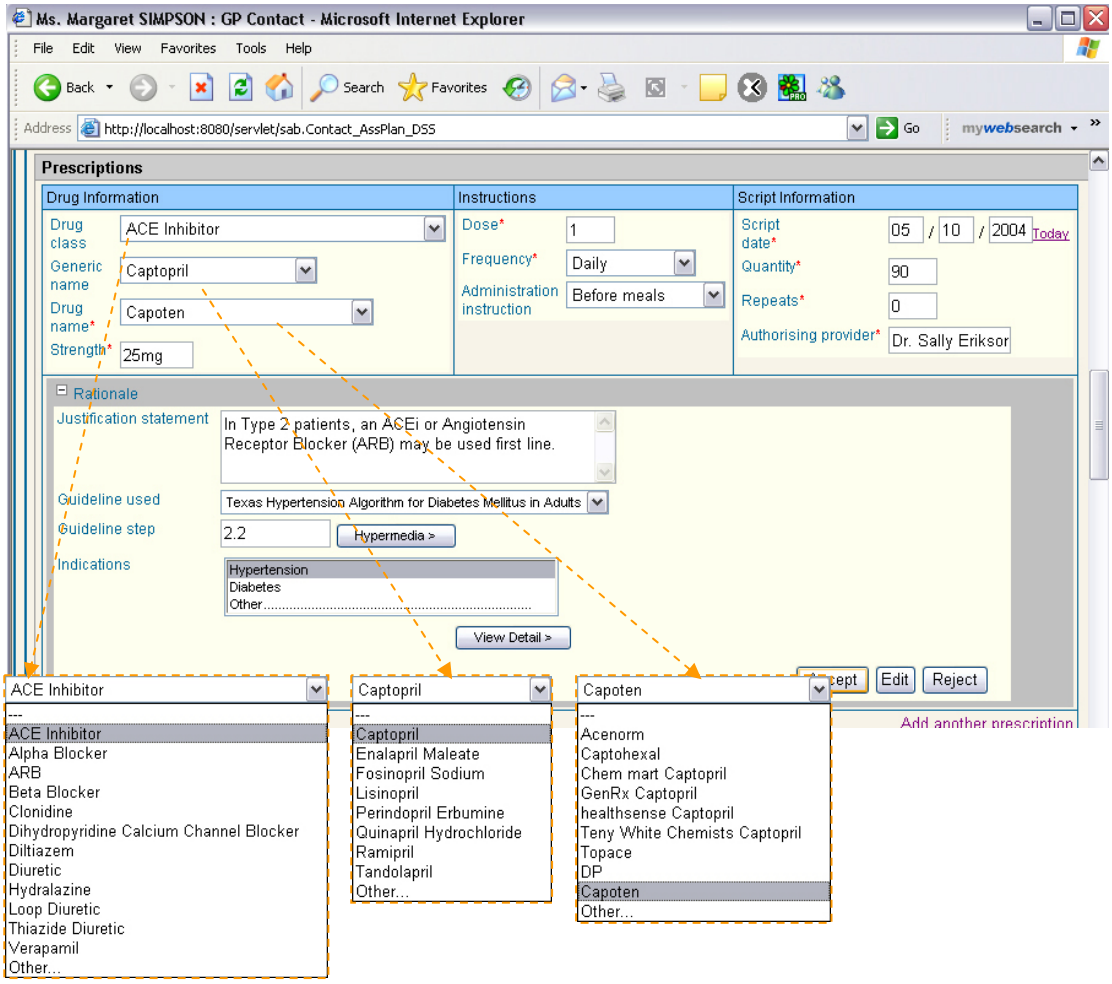

Figure 6.22. Guideline-recommended drug to prescribe at first encounter

Note that the fields marked with an asterisk are mandatory fields that must be filled-in. Clinicians usually prescribe using a drug name or brand/product. One of the most commonly used GP software in Australia known as Medical Director for instance, prescribes using a drug name only. Recalling from our guideline ontology, we extended the drug classes and generic names that the guideline specifies (for sharability purposes across jurisdictions and 'future-proofing' systems from changes that occur with drug names associated with generic and/or drug class names over time) to include the set of valid drug names taken from the Australian PBS [181]. This then allows the GP to select the preferred drug name from a list, which is constrained by the guideline-recommended drug class, and/or generic name. In addition, the GP is able to select 'Other' from the list of drug names and enter an item that is outside of Australian PBS. Alternatively, the GP may decide to deviate from the guideline, and

select ‘Other’ from the list of drug class and/or generic names to enter an item outside the guideline-recommended set. The GP may also choose not to specify the drug class and/or generic name, and leave them blank (i.e. selecting ‘---‘ from the list).

The alternative approach may be taken such that the drug names are provided by a separate knowledge base/server, or prescribing software. However, there must be a mechanism available to enable the EHR, DSS and medication knowledge-base/prescribing software to interact practicably, and according to the GP’s usual interaction with the EHR system.

Finally, at then end of the encounter, the GP advises Margaret to return for therapy reassessment in 4-8 weeks time (Figure 6.23). This results in an instruction definition entry for ‘Recall’ being recorded in the GP Contact event transaction, and a corresponding instruction execution entry is instantiated by the Persistence Layer for execution by the WfMS. The instruction definition entry for recall as an XML instance is listed in Listing 6.3.

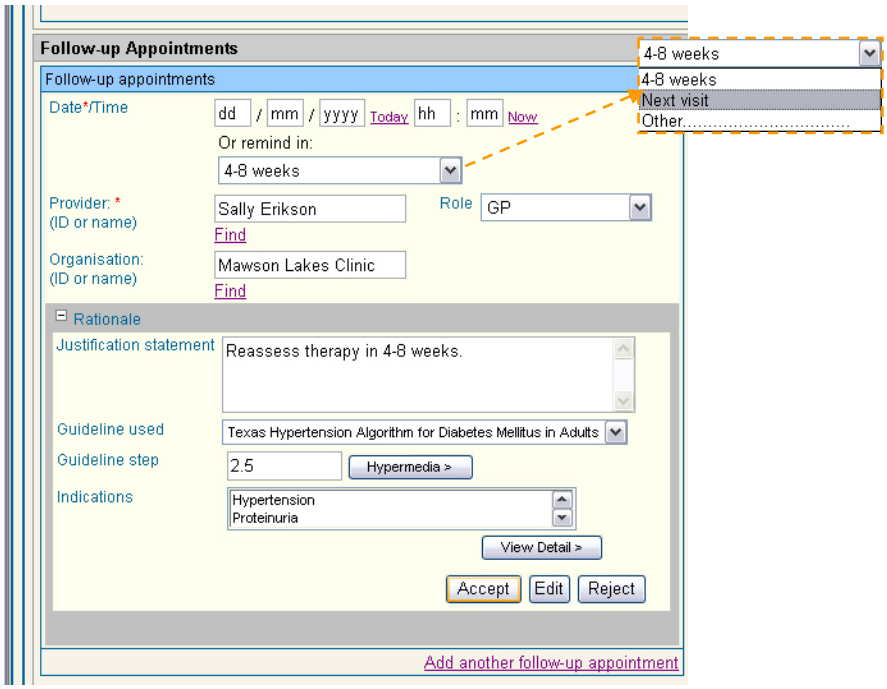

Figure 6.23. DSS pre-population of RECALL recommendation and rationale.

Listing 6.3. Instruction definition entry for Recall.

```
<Entry xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xpdl:"http://www.wfmc.org/2002/XPDL1.0">
  <entry_type>Instruction_Definition</entry_type>
  <data>
      <list>
          <Items>
              <name>Recall</name>
              <date>19/07/2004</date>
              <time>16:00</time>
              <provider_name>Sally Erikson</provider_name>
              <role>General Practitioner</role>
              <organisation>Mawson Lakes Clinic</organisation>
          </items>
      </list>
  </data>
  <protocol />
  <rationale>
      <name>
          <value>Justification statement</value>
      </name>
      <value>Reassess therapy in 4-8 weeks.</value>
      <guideline>
          <name>
              <value>Guideline used</value>
          </name>
          <value>Texas Department of Health: Hypertension Algorithm for Diabetes
Mellitus in Adults</value>
          <guideline_step>
              <value>2.5</value>
          </guideline_step>
      </guideline>
      <indications>
          <indication>
              <name>
                  <value>Hypertension</value>
              </name>
              <link>
                  <meaning>indication link</meaning>
                  <target>pat2349::"contact note:Dr Sally Erikson@mawson-
lakes.clinic.au05/10/2004T11:35:24' / "Problem List" / "Hypertension" | "Assessment" |
"Problem"</target>
              </link>
          </indication>
          <indication>
              <name>
                  <value>Proteinuria</value>
              </name>
              <link>
                  <meaning>indication link</meaning>
                  <target>pat2349::"contact note:Dr Sally Erikson@mawson-
lakes.clinic.au05/10/2004T11:35:24' / "Problem List" / "Proteinuria" | "Assessment" |
"Problem"</target>
              </link>
          </indication>
      </indications>
  </rationale>
  <instruction_definition_id>openehr.instruction_definition.recall.v1</instruction_definition
_id>
  <guideline_id>Hypertension Algorithm for Diabetes Mellitus in Adults</guideline_id>
  <Connectors>
      <Sequence>
          <precondition />
          <postcondition />
          <input_activity_id>recall_v0_Wor1_Act1</input_activity_id>
          <output_activity_id>recall_v0_Wor1_Act2</output_activity_id>
      </Sequence>
      <Sequence>
```

```
            <precondition />
            <postcondition />
            <input_activity_id>recall_v0_Wor1_Act2</input_activity_id>
            <output_activity_id>recall_v0_Wor1_Act3</output_activity_id>
        </Sequence>
    </Connectors>
    <Activities>
        <Administrative_Activity>
            <activity_name>Schedule_appointment</activity_name>
            <activity_id>recall_v0_Wor1_Act1</activity_id>
            <role>General_Practitioner</role>
            <subject_state_precondition />
            <subject_state_postcondition />
            <is_start_activity>true</is_start_activity>
            <is_end_activity>false</is_end_activity>
            <work_item>Schedule appointment for reassessment of patient.</work_item>
        </Administrative_Activity>
        <Wait_Activity>
            <activity_name>Wait</activity_name>
            <activity_id>recall_v0_Wor1_Act2</activity_id>
            <role>General_Practitioner</role>
            <subject_state_precondition />
            <subject_state_postcondition />
            <is_start_activity>false</is_start_activity>
            <is_end_activity>false</is_end_activity>
            <delay_condition>ScheduledDateTime != Now()</delay_condition>
            <timeout_condition />
        </Wait_Activity>
        <Administrative_Activity>
            <activity_name>Notify_patient</activity_name>
            <activity_id>recall_v0_Wor1_Act3</activity_id>
            <role>General_Practitioner</role>
            <subject_state_precondition />
            <subject_state_postcondition />
            <is_start_activity>false</is_start_activity>
            <is_end_activity>true</is_end_activity>
            <work_item>Notify patient about reassessment of therapy.</work_item>
        </Administrative_Activity>
    </Activities>
</Entry>
```

Summary of encounter 1 decisions and resulting EHR transaction

For the first encounter, the physician is presented with two problems: proteinuria and hypertension. Problem entries in this contact note transaction are collated by the DSS as well as queried from a separate “Current Problems” transaction (a persistent transaction recording all the patient’s diagnoses) to determine indications for a particular drug. (Other relevant transactions such as “adverse reactions and allergies” may also be queried). An ACE inhibitor is recommended due to presence of proteinuria, hypertension and diabetes type 1 – these are recorded as link items within the “Indications List” as part of the rationale for the medication order instruction. The name of the guideline used and the precise step from which it came are also recorded. A similar process applies for recording the rationale for targets. Moreover, the second SOAP note’s plan refers to the first SOAP note since the ACE inhibitor is used to address

both the proteinuria and hypertension problems. We implement this reference by providing a link item (Figure 6.24).

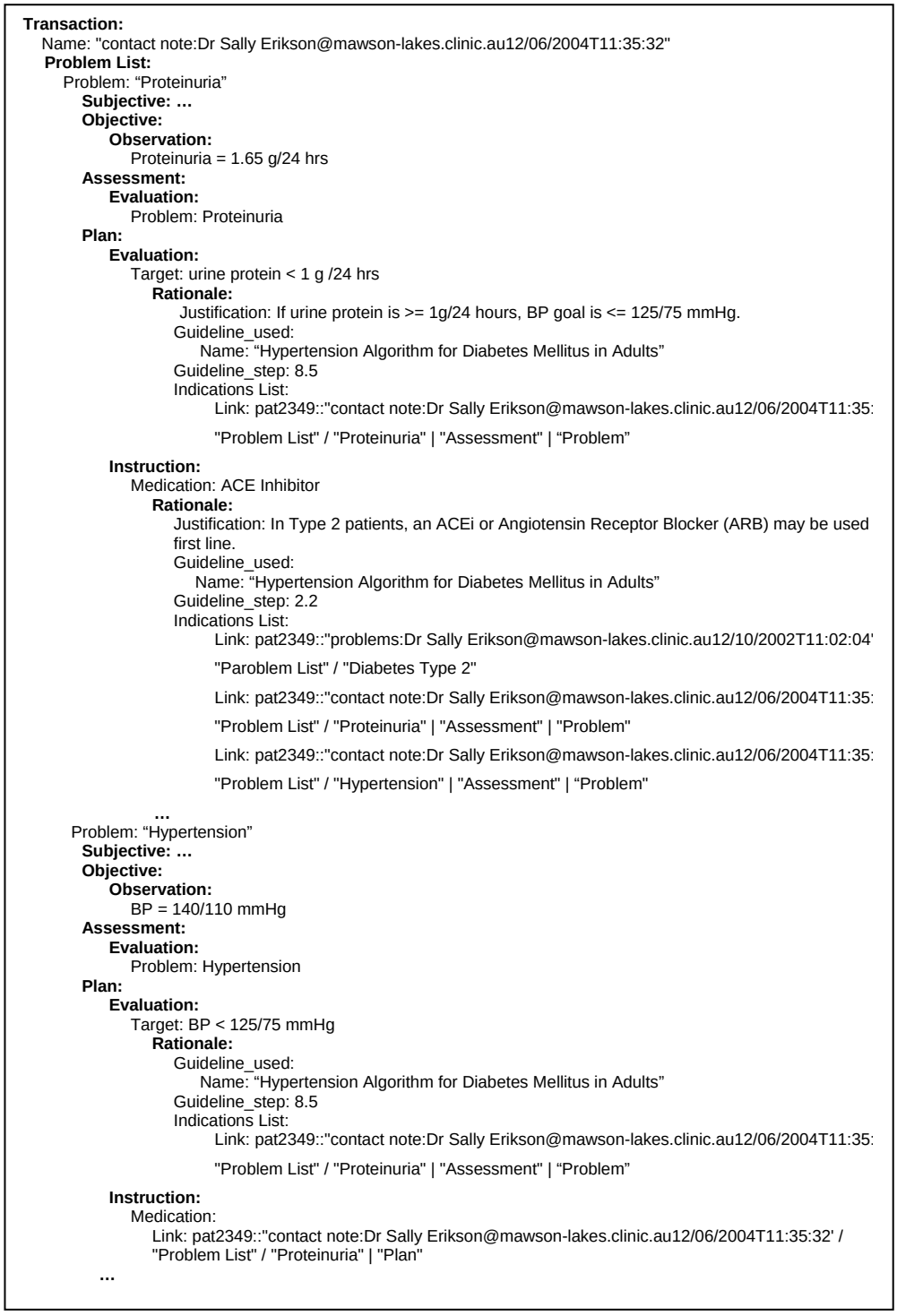

Figure 6.24. EHR transaction for Encounter 1.

Task 1.1: Drug substitution due to poor tolerance to ACE inhibitor therapy

After four weeks, the patient is reassessed and found to have poor tolerance of the ACE inhibitor. After creating a new GP contact note, the clinician enters the patient's intolerance to the ACE inhibitor therapy as a new 'adverse reaction' entry under the list of 'Therapeutic Precautions' in the 'Subjective' EHR sub-form – including the drug or substance name, the type of reaction (i.e. 'mild, dry cough'), and any other comments about the adverse reaction (Figure 6.25).

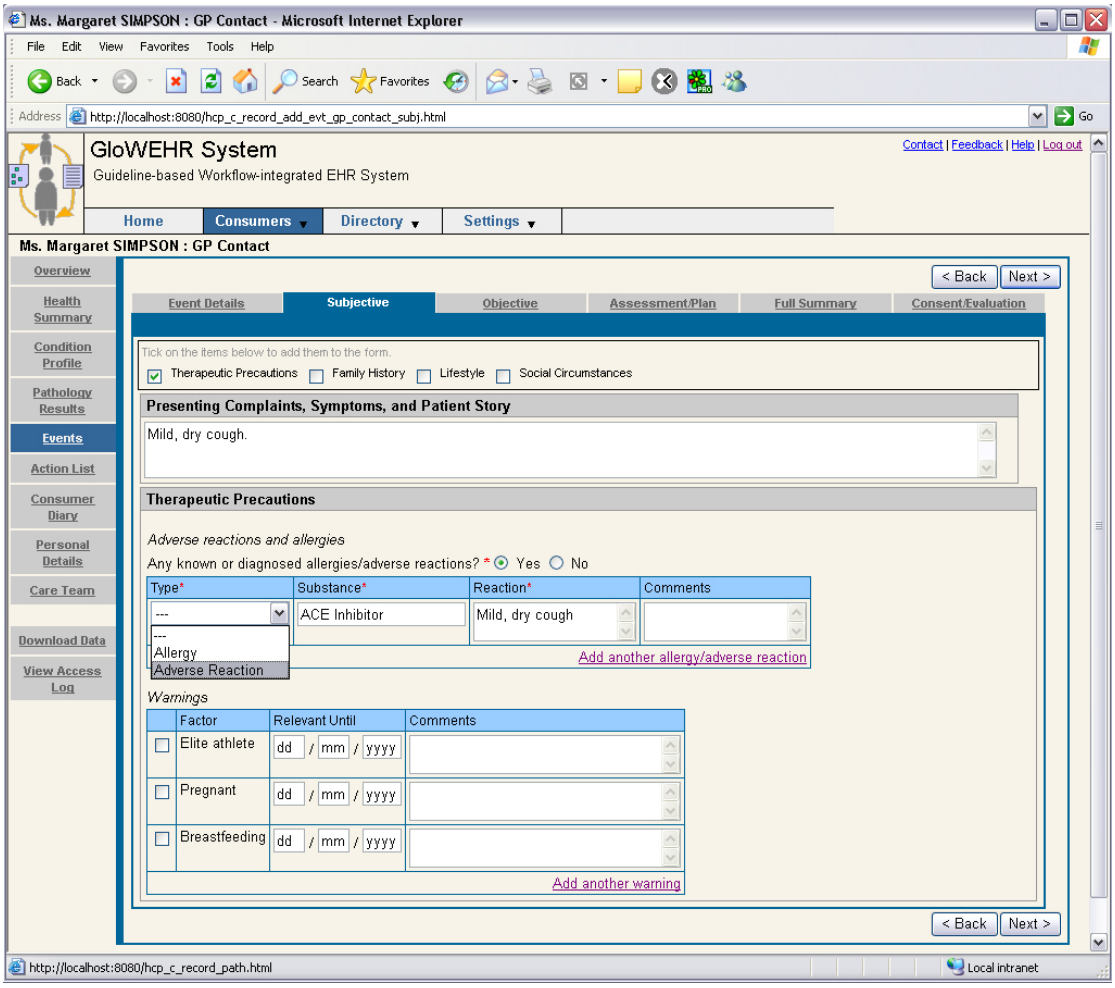

Figure 6.25. New drug adverse reaction added.

Existence of this entry in the EHR allows the DSS to search and query for all (most recent) EHR data as covered by the Problem-SOAP note archetype specialised for the guideline (blood pressure targets, drugs prescribed, blood pressure and urine protein

level observations, etc), as well as any other types of entries that can serve as indicators for the guideline recommendations (e.g. current and past problems/diagnoses, adverse reactions/allergies, current medications), and make recommendations based on the data, and furthermore, to prompt for required data where they do not exist, or are no longer considered the most recent.

Again, hypertension and proteinuria level are measured and recorded in the 'Objective' EHR sub-form (as in the first encounter), and are found to be only marginal improvements to reaching the guideline-recommended targets. Dr. Erikson again chooses to use the DSS mode, which returns the first recommendation of drug substitution. The normal practice for drug substitution entails simply *ceasing* the drug to be substituted, and then *prescribing* the new drug that substitutes the previous drug. Therefore, the poorly tolerated ACE inhibitor drug 'Capoten' is added to the list of 'Medications Stopped' shown in Figure 6.26, whilst verapamil has been recommended by the guideline as a substitute to the ACE inhibitor (and similarly if ARB was used and had adverse reactions to the patient), and also due to its renal protective effects (Figure 6.27). The indications for this drug include the fact that the patient has intolerance to the ACE inhibitor, hypertension and proteinuria.

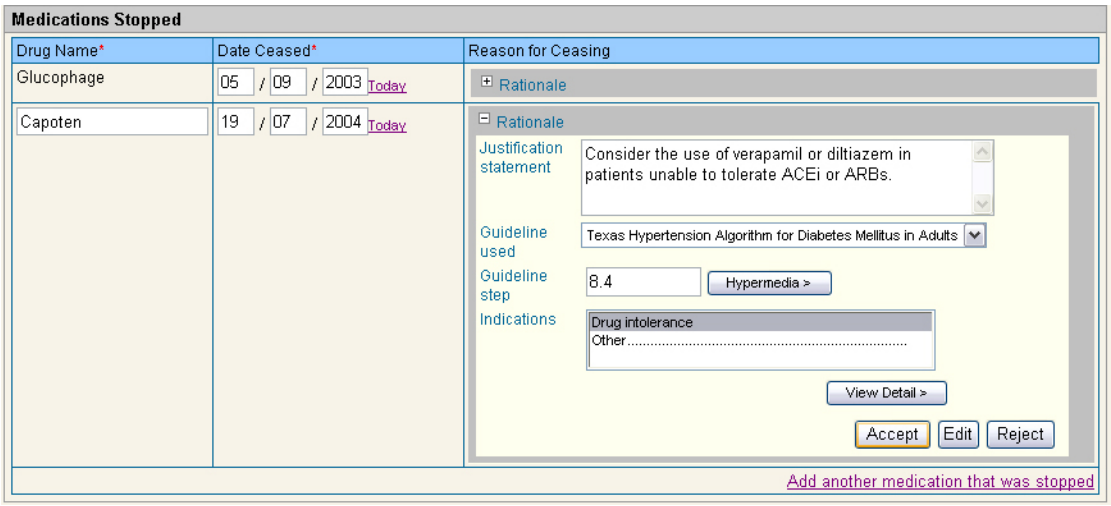

Figure 6.26. Adding an entry to list of stopped (ceased) medications.

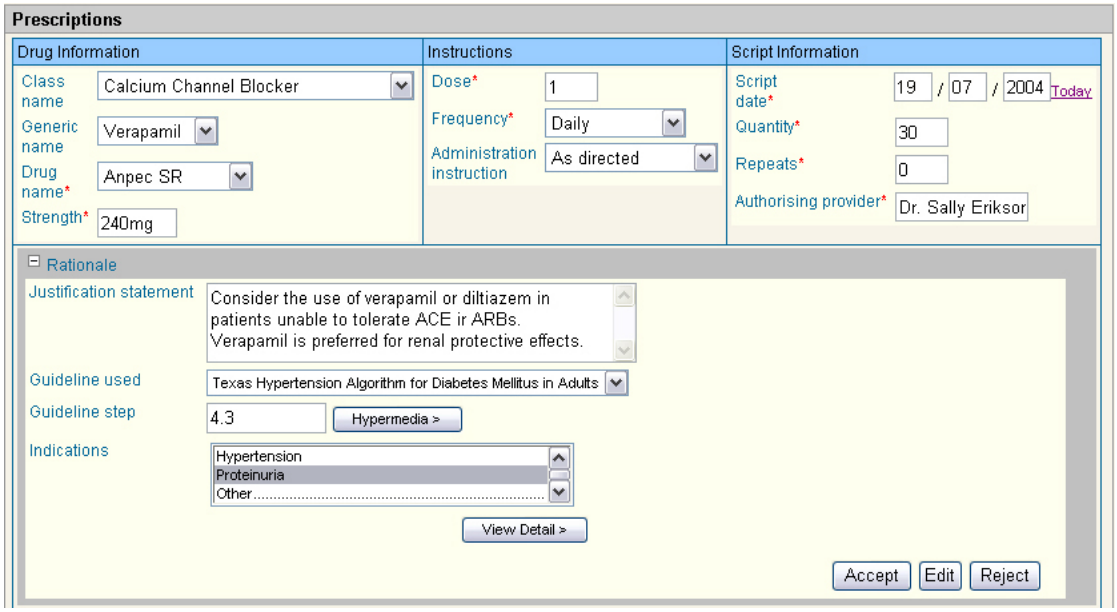

Figure 6.27. New guideline-recommended drug substitute.

Once again note that should the GP decide to edit or reject the guideline recommendation, the fields are reset to blank, and they can choose to enter manually their own recommendation by selecting 'other' from the relevant pull-down menus; and furthermore, to enter their own rationale for that decision – i.e. entering free-text explanation in the 'Justification statement' field; leaving the 'Guideline used' and 'Guideline step' fields blank; and manually adding the set of indications for their decision. The latter can be done by selecting 'Other' from the 'Indications' list, which then pops up a separate window (Figure 6.28) showing the set of 'Health Summaries' (i.e. data extracted from event transactions and sorted/filtered into the relevant persistent transactions such as 'current medications' and 'prescribing history') that contain the patients EHR data items that may serve as indications for a particular GP recommendation. These then get recorded as URLs or links in the 'Indications' EHR entry to the relevant event transactions that recorded the EHR data item.

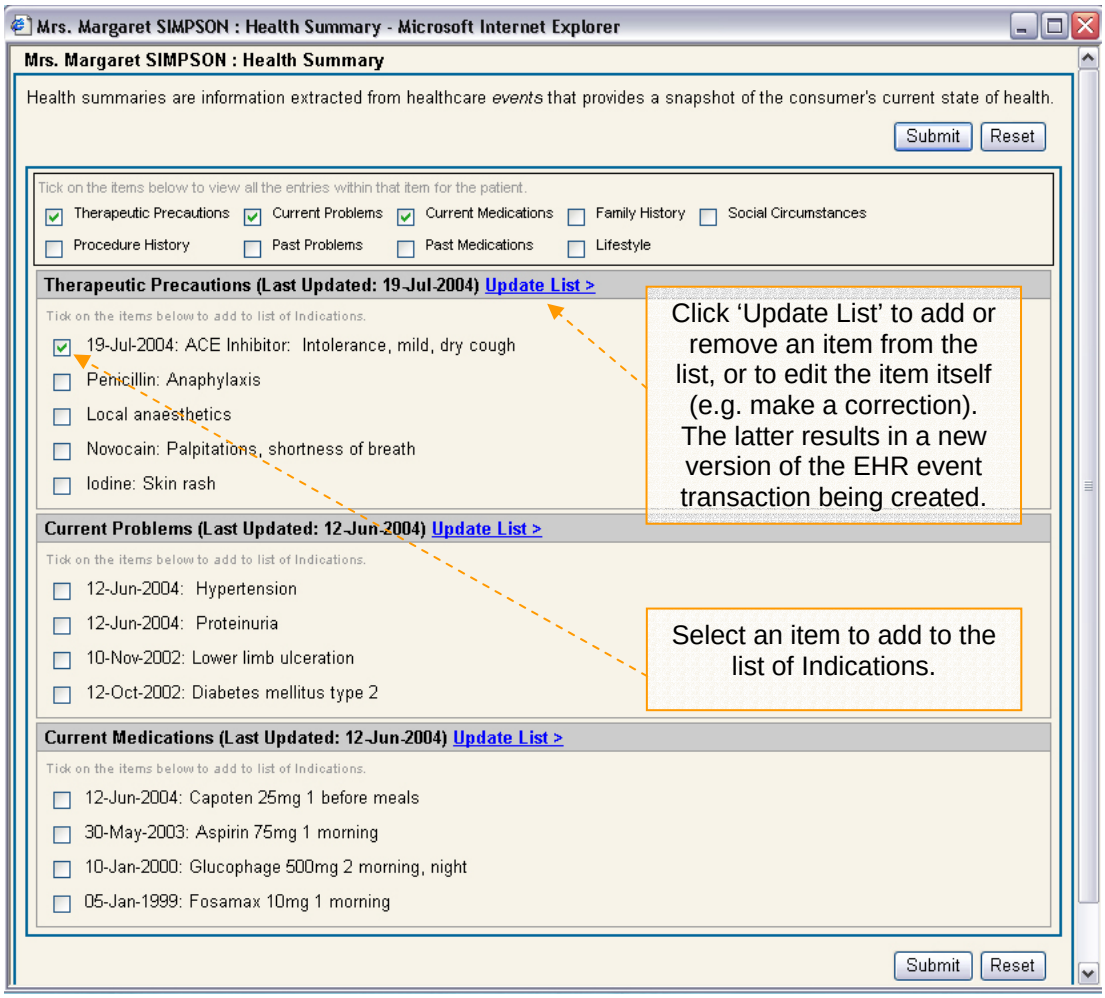

Figure 6.28. Form for manually selecting EHR data items for Indications.

The other guideline recommendations such as continued monitoring of blood pressure, the targets, diet and exercise, and schedule for reassessment of therapy/recall are done (as in the first encounter). The resulting extract of the GP contact EHR transaction from this second encounter is as shown in Figure 6.29 (note in particular, the recording of the references to the step and links to relevant indications).

Transaction:
Name: "contact note:Dr Sally Erikson@mawson-lakes.clinic.au19/07/2004T16:09:47"
Problem List:
Problem: “Drug intolerance”
Subjective:
Observation:
Symptom = Mild, dry cough.
Observation:
Adverse reaction = Drug intolerance to ACE inhibitor.
Objective: …
Assessment: …
Plan:
Instruction:
Medication: Verapamil
Rationale:
Justification:
Consider the use of verapamil or diltiazem in patients unable to tolerate ACEi or ARBs. Verapamil is preferred for renal protective effects.
Guideline_used:
Name: “Hypertension Algorithm for Diabetes Mellitus in Adults”
Guideline_step:
4.3
Indications List:
Link: pat2349::"contact note: Dr Sally Erikson@mawson-lakes.clinic.au19/07/2004T16:09:47' / "Problem List" / "Drug intolerance" | "Subjective" | "Observation" | “Adverse reaction”
Link: pat2349::"contact note: Dr Sally Erikson@mawson-lakes.clinic.au19/07/2004T16:09:47' / "Problem List" / "Proteinuria" | "Assessment" | Problem: “Proteinuria”
…
Urine protein level = 1.40 g/24 hrs
Assessment:
Evaluation:
Problem: Proteinuria
Plan:
Instruction:
Medication:
Link: pat2349::"contact note: Dr Sally Erikson@mawson-lakes.clinic.au19/07/2004T16:09:47' / "Problem List" / "Drug intolerance" | "Plan" | “Medication”
Problem: “Hypertension”
…
BP = 130/85 mmHg
Assessment:
Evaluation:
Problem: Hypertension
Plan:
Evaluation:
Target: BP < 125/75 mm Hg
Rationale:
Guideline_used:
Name: “Hypertension Algorithm for Diabetes Mellitus in Adults”
Guideline_step:
8.5
Indications List:
Link: pat2349::"contact note: Dr Sally Erikson@mawson-lakes.clinic.au19/07/2004T16:09:47' / "Problem List" / "Proteinuria" | "Assessment" | " Diagnosis "
Link: pat1324195::"contact note: Dr Sally Erikson@mawson-lakes.clinic.au19/07/2004T16:09:47' / "Problem List" / "Hypertension" | "Assessment" | " Diagnosis "
Instruction:
Medication:
Link: pat2349::"contact note: Dr Sally Erikson@mawson-lakes.clinic.au19/07/2004T16:09:47' / "Problem List" / "Drug intolerance" | "Plan"

Figure 6.29. EHR transaction for Encounter 2.

Task 1.2: Add beta blocker

For the third encounter, the blood pressure target is still not reached. Complying with the guideline's recommendation, Beta Blocker has been chosen as an additional agent due to the patient's history of a myocardial infarction (MI). Similar interaction with the user interface occurs as in previous encounters. Figure 6.30 shows the recording of the precise decision step that was taken and indications as the rationale.

Transaction:
Name: "contact note:Dr Sally Erikson@mawson-lakes.clinic.au01/09/2004T13:05:24"
Problem List:
Problem: "Proteinuria"
Subjective:
Objective:
Observation:
Urine protein level = 1.35 g/24 hrs
Assessment:
Evaluation:
Problem: Proteinuria
Plan:
Instruction:
Medication: Beta Blocker
Rationale:
Justification: Beta blocker is preferred for history of MI.
Guideline_used:
Name: "Hypertension Algorithm for Diabetes Mellitus in Adults"
Guideline_step: 4.1
Indications List:
Link: pat2349::"problems:Dr Sally Erikson@mawson-lakes.clinic.au17/05/2003T07:55:24' / "Problem List" / "Myocardial Infarction"
Link: pat2349::"contact note:Dr Jim Warren@mawson-lakes.clinic.au01/09/2004T13:05:04' / "Problem List" / "Proteinuria" | "Assessment" | "Problem"
Problem: "Hypertension"
…
BP = 130/90 mm Hg
Assessment:
Evaluation:
Problem: Hypertension
Plan:
Evaluation:
Target: BP < 125/75 mm Hg
Rationale:
Guideline_used:
Name: "Hypertension Algorithm for Diabetes Mellitus in Adults"
Guideline_step: 8.5
Indications List:
Link: pat2349::"contact note:Dr Sally Erikson@mawson-lakes.clinic.au01/09/2004T13:05:24' / "Problem List" / "Proteinuria" | "Assessment" | " Problem"
Link: pat2349::"contact note:Dr Sally Erikson@mawson-lakes.clinic.au01/09/2004T09:05:24' / "Problem List" / "Hypertension" | "Assessment" | "Problem"
Instruction:
Medication:
Link: pat2349::"contact note:Dr Sally Erikson@mawson-lakes.clinic.au01/09/2004T09:05:24'/ "Problem List" / "Proteinuria" | "Plan"

Figure 6.30. EHR transaction for Encounter 3.

Task 1.3: Refer to specialist

By the fourth encounter with the GP, Margaret's self administration of the combined verapamil and beta blocker therapy has brought her blood pressure down to 130/80, and her protein level at 1.22 g/24 hours (still above normal and blood pressure target). Although there is improved control of (diastolic) blood pressure and protein level, the blood pressure and protein level targets are still not reached despite 3 months of combined non-drug and drug therapy. The GP refers Margaret to an endocrinologist (Figure 6.31); and advises her to schedule for a follow-up appointment after consultation with the specialist. The resulting fragment of the EHR instance looks similar to Figure 6.32.

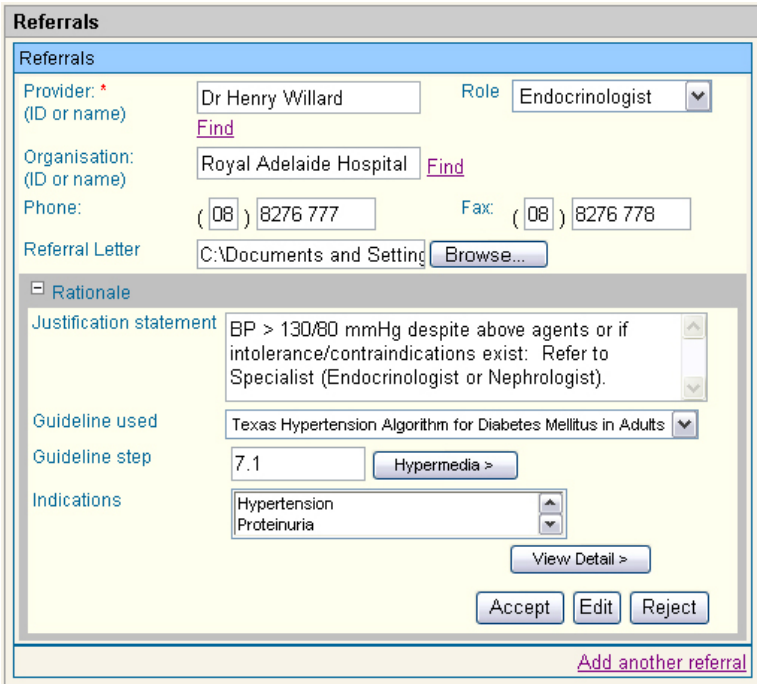

Figure 6.31. Referral to specialist and guideline-based rationale.

Transaction:
Name: "contact note:Dr Sally Erikson@mawson-lakes.clinic.au05/10/2004T10:05:01"
Problem List:
Problem: “Proteinuria”
Subjective:
Objective:
Observation:
Proteinuria = 1.22 g/24 hrs
Assessment:
Evaluation:
Problem: Proteinuria
Plan:
Instruction Definition Entry:
Referral
Rationale:
Justification: BP > 130/80 mmHg despite above agents or if intolerance/contraindications exist: Refer to Specialist (Endocrinologist or Nephrologist).
Guideline_used:
Name: “Hypertension Algorithm for Diabetes Mellitus in Adults”
Guideline_step: 7.1
Indications List:
Link: pat2349::"problems:Dr Sally Erikson@mawson-lakes.clinic.au05/10/2003T10:05:01” / "Problem List" / "Hypertension" | “Assessment” | “Problem”
Link: pat2349::"contact note:Dr Jim Warren@mawson-lakes.clinic.au05/10/2004T10:05:01” / "Problem List" / "Proteinuria" | "Assessment" | "Problem"
Problem: “Hypertension”
…
BP = 130/80 mm Hg
Assessment:
Evaluation:
Problem: Hypertension
Plan:
Evaluation:
Target: BP < 125/75 mm Hg
Rationale:
Guideline_used:
Name: “Hypertension Algorithm for Diabetes Mellitus in Adults”
Guideline_step: 8.5
Indications List:
Link: pat2349::"contact note:Dr Sally Erikson@mawson-lakes.clinic.au05/10/2004T10:05:01” / "Problem List" / "Proteinuria" | "Assessment" | " Problem"
Link: pat2349::"contact note:Dr Sally Erikson@mawson-lakes.clinic.au05/10/2004T10:05:01” / "Problem List" / "Hypertension" | "Assessment" | "Problem"
Instruction:
Medication:
Link: pat2349::"contact note:Dr Sally Erikson@mawson-lakes.clinic.au05/10/2004T10:05:01” / "Problem List" / "Proteinuria" | "Plan"

Figure 6.32. EHR instance for Encounter 4.

6.7. Discussion

Option for deviation from the guideline

We allow free-text for the provider to state the reason for an action taken that does not comply with the guideline's recommendation, and this information can be easily found in the EHR (via the rationale construct). Our view is that recording of deviation and rationale for the deviation from the guideline would be of great interest to the GP. This assists in monitoring the actual care practice and the level of compliance to the guideline that can potentially provide feedback to guideline developers. Such feedback could include issues about the quality of care delivery, variance in practice, and even any new or varied types of actions that could potentially provide 'new evidence' and could be used to build knowledge.

In future, there may be the potential for the reason for provider's guideline deviation to be selected from a term list/terminology (e.g. as presented within a pull-down menu), and hence allow *standard* terms to be inputted into the EHR. This would improve interoperability between systems, and improve the ability for systems such as DSS to make efficient queries and reason intelligently with the data. Moreover, the ability to select from a pull-down menu, a list of valid terms/values, greatly reduces the number of errors (e.g. typing/spelling mistakes) in the data, that would otherwise result from the provider manually typing it in.

Specialisation of archetypes according to the guideline

The question of whether or not specific archetypes should map to scenarios or steps in the guideline arose during implementation. It was decided to use a single archetype that is able to model the entire guideline. We see two factors that influence the decision to use a single archetype versus using several for a guideline: (1) the type of information to be recorded and for what purpose (e.g., the 'contact' or 'encounter' archetype required for a specialist such as an endocrinologist would be a much more specialised archetype than a GP's. Furthermore, the specific decisions and actions of the endocrinologist are beyond the scope of the guideline); and (2) the guideline

complexity (e.g. a guideline with greater than 7 predicates involved may require several archetypes). Overall however, we conclude that archetypes do not seem to get very complicated for guidelines such as the Texas hypertension management in diabetes as compared with modelling healthcare processes that span several types of healthcare providers (e.g., our investigation in the Early Supported Discharge case study).

System Interaction

The system will need to ensure it supports the various types of interactions seamlessly and also produce the most accurate recommendation (or rationale – which ever comes first). Moreover, the system will be required to pick out and compile the antecedents of the decision made (i.e. backward chaining) if a step has been decided on initially, as well as being able to pre-populate the decision with its rationale when no decision has been made first hand (i.e. forward chaining).

If the system is responsible for deciding what archetypes to use to record EHR data then this should be left to the knowledge level (i.e., decision support or guideline) to dictate dynamic/run-time archetype specialisation. That is, to have the DSS inform during run-time of which parts of the archetype are optional, and which are mandatory to the specific scenario that the patient is currently in. However, it should also allow the clinician to override the system by manually selecting which archetypes to use (e.g. via selection from a combo box or pull-down list, or check boxes).

Interactive DSS

High level of interaction required versus low-level interaction: in our prototype, the level of interaction required is relatively low, with the option to view the hypermedia only on request by the clinician. There are a number of advantages in our approach such that:

- Information overload is avoided. The clinician, being the 'real' expert is assumed to only consider the recommendations at the point of care rather than the details such as the didactics and explanation from the guideline. In addition, there is often little time within a given consultation period to navigate and/or read through all of that information. As an alternative option

to a full hypermedia web page that the clinician can view and navigate through, the didactics and explanations could also be viewable when the clinician needs to by clicking on a '?' button for 'query for explanation'. Such information could be presented as simple 'pop-up' boxes (or using 'sticky post-it note' metaphor) near the relevant guideline-based rationale entry that is implemented in JavaScript or dynamic HTML for example. A mock-up of the hypermedia user interface is shown in Figure 6.33, which allows conversations to be embedded in the hypermedia document 'about the work at the point of work' and assists in the capturing and communication of the decisions made at a particular point in time. The importance of this requirement is discussed in [182].

- User interface 'clutter' is avoided. There is the problem of how to present a lot of information on a single screen and to ensure that the most important items are presented as the most visible items. Furthermore, in the case of web pages, there is the need for all information to be loaded without delay.

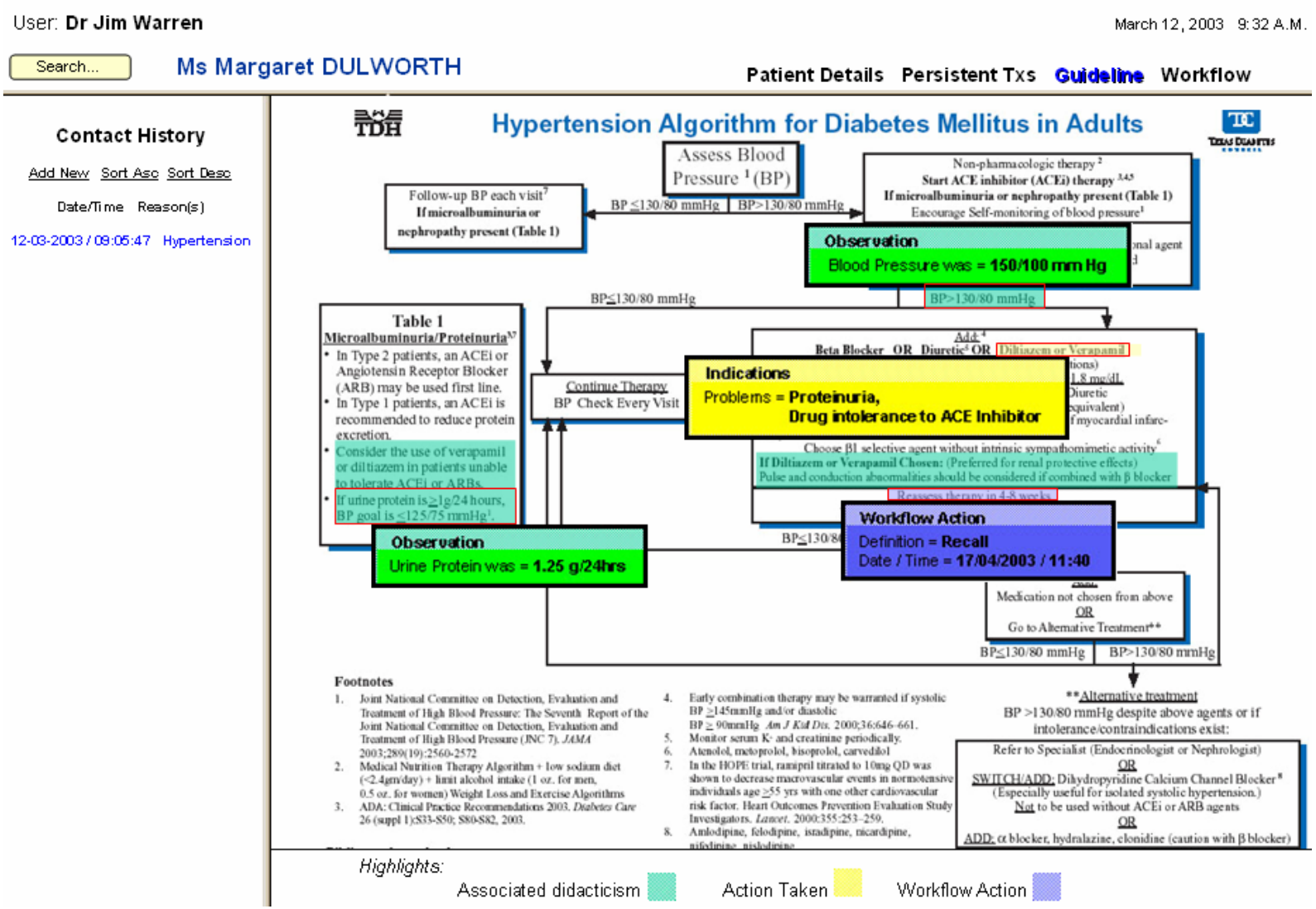

Figure 6.33. Mock-up design of the hypermedia interface.[23]

[23] See Appendix D or [57] for the guideline document.

Persistence of patient and guideline execution state

One of the key advantages of the approach presented in this chapter is that information pertaining to the patient's condition/health status as well as the patient's current state in the executing guideline persists within the EHR. Furthermore, the full context and rationale behind the guideline execution state as it progresses is captured in an explicit location within the EHR with the use of archetypes. Notably, persistence of such information and the capacity for integration of clinical information system and guideline-based decision support was one important aspect that the DSS used in a similar primary care chronic disease management context [22] for instance, lacked – such that if the guideline was exited, it was only possible to return to it at the beginning of the pathway. In short, persistence of patient and guideline execution states is important to support transparency, accountability, distributed access and interoperability.

Limitations of the chosen guideline

There are a few limitations of the way the guideline is modelled. The guideline has no notion of what to do in terms of the varied extent by which a target is missed or degree of response of the patient to the therapy – choice is only binary (either above 130/80 or not). E.g., what if the patient's blood pressure is only marginally above 130/80? Also, the importance of the rules in the guideline with respect to each other is not clearly defined. The rules within footnotes, for instance, suggest that they may possibly be less important than those specified in the flow diagram itself. Only the domain expert would be able to interpret the guideline more clearly. Hence, there remains a need for clinical judgement in adhering to guidelines, or not.

The role of terminology

In a real-world and a much larger scale implementation, each problem item ideally, could have a code from a standard terminology set such as the International Statistical Classification of Diseases and Related Health Problems (tenth revision) – also known as ICD-10 [183] developed by the World Health Organization (WHO). In this sense, the EHR system and DSS are able to interpret the semantics of the data in the same

way using standardised terminologies and information models, and thereby increasing the sharability of information across various clinical information systems.

6.8. Conclusion

The natural-language artefact of a guideline document can be engineered into a number of on-line and computational artefacts. In the operation of a chronic disease management system, the artefacts sourced from a common guideline must coordinate – notably, as a guideline is followed across a series of consultations, the EHR content should provide clear documentation of the decisions taken (drugs prescribed, targets set, and return visits scheduled). The relationship of those decisions to precise steps in the guideline must be readily reconstructable. Toward this end we have discussed the coordination and linking of the EHR structure with the computer interpreted clinical guideline (decision support rules) with a demonstration in the context of management of hypertension in diabetes mellitus.

While we make no claim of overcoming the usability problems reported in [33], application of the openEHR architecture as we have outlined provides an open framework for a range of researchers and vendors to explore further the problem of effective support for chronic disease management. The architecture supports integration of EHR content, workflow models, computable guidelines and guideline hypermedia, while allowing the application designer to choose a usable balance of compliance encouragement and human judgement.

7

CONCLUSIONS

7.1. Summary of Findings

The increasing prevalence of chronic disease has become a major health issue. In particular, there are issues regarding the poor quality of care, escalating healthcare costs, as well as communication and coordination issues – consequently, having a spiralling effect on the problems associated with chronic disease management. It has been recognised that there is potential for workflow support to coordinate services and improve communication in Chronic Disease Management (CDM). Since chronic disease care processes unfold over a long time-scale, often occur in the presence of co-morbidity, and span multiple healthcare providers, sites and organisations, it makes

it difficult to devise HISs that can sustain the continuity and coordination of evidence-based practice for chronic disease.

Our view (presented in this thesis) is that there is the need for a Health Information System (HIS) that can support Electronic Health Record (EHR), guideline-based decision support and workflow. Each of these three components should be designed in direct correspondence to evidence-based clinical practice guidelines and must operate in integration with other components. In this thesis, we investigated how the output of decision support and workflow-support applications can be maintained *persistently* within an EHR for future use. We explored how the EHR can be leveraged to integrate with workflow and decision support applications in consideration of the current work undertaken by researchers in the field. In particular, we made use of workflow standards such as the WfMC's XML Process Definition Language (XPDL); we aligned our model with WfMC's workflow reference model, and the various workflow patterns identified by workflow researchers. We also extended the EHR to have explicit constructs for recording guideline-based recommendations produced by our guideline-based Decision Support System (DSS) prototype that made use of an ontologically based computer-interpretable guideline implemented in XML. While the latter maintained the history of decision-making for future reference, it also enabled our DSS to directly and efficiently access or query the patient's EHR about previous guideline steps taken and reason about the next valid step(s) that can be taken. The aforementioned problem of maximal data sets was addressed by introducing more specific linkage of the associated guidelines to the EHR content items. In this way, information considered a priority for a given encounter could be clearly identified in the point-of-care application.

More broadly, in this thesis, we have introduced an approach to developing systems that assists in achieving care that conforms to guidelines. We have shown how we can produce four main artefacts from a guideline document with attention to the needs of CDM:

(1) EHR content,
(2) Computer-interpretable Guideline (CiGs),
(3) Workflow and
(4) Hypermedia.

We have illustrated in the context of the case studies how the EHR, workflow and the CiG components can be coordinated. Through extension of the *open*EHR framework with our Instruction Reference Model (IRM), we have shown how we can leverage the EHR to assist in the coordination of the artefacts. We have found that there is a real distinction between the roles that guideline-based recommendations provided by CiGs, workflow and EHR play in supporting and managing patient care:

(1) CiGs model decision-making steps and recommended actions;

(2) Workflows model the work to be done for that recommended action, by whom, when and how, and help ensure that it gets done;

(3) Archetypes help ensure that the appropriate information is collected within the EHR for the workflow. Moreover, the extent to which each of these components can be used in supporting CDM, particularly CiGs and workflow, is dependent on the clinical context in which it is applied.

We have shown that a guideline can complement the workflow aspects of the EHR, and see the distinction as follows:

- *Guidelines* are generally problem-based; model decision-making steps and recommended actions for patient care; and are developed based on evidence-based practice;
- *Workflows* model the work to be done, by whom, when and how. They help ensure that the work gets done. Workflows vary across institutions; and
- *Archetypes* help ensure that the appropriate information is collected within the EHR for the workflow.
- Defining requirements of EHR, guideline, and workflow integration (including defining key roles they each play, where they function independently of each other, and where they interact to form a seamless, integrated clinical information system).
- Proposing and demonstrating an approach to the construction/building of an integrated system, identifying its advantages and shortcomings, with a discussion of why and possible future work to be addressed.

7.1.2. Features of the Approach

The key features of our approach to the integration of workflow, EHR and decision support presented in this thesis include:

- To coordinate workflow and the EHR, we extended the EHR to have the capacity to record exactly how the steps or activities within a workflow were performed, when, how, by whom, and why. Furthermore, the specific information that resulted from performing each activity could be recorded in a timely fashion, and part of being able to facilitate this is to provide information that pertains to both past/historical activities that were undertaken, as well as information about the future activities that are required to be and/or are able to be undertaken. More specifically, we presented an extension of *open*EHR instruction model to define workflow and data to collect during specific activities. In our model, the Instruction entries are not merely a data type or construct that specify valid recording requirements, but can also serve to allow the EHR to contain explicit knowledge about the process of care, and record the statuses of the care process as it progresses. This transcends the traditional passive capabilities of an EHR, such that it can be synchronised with a WfMS.
- To coordinate decision support and the EHR, we extended the EHR to have the capacity to record exactly how decision support was used to arrive at a given evaluation or instruction. We defined constructs for the rationale of the decisions made to be recorded explicitly within the record. This included the specific guideline step, justification statement, and links to relevant EHR data items that were used to arrive at that decision (e.g., blood pressure value). The rationale is either pre-populated with justified recommendations provided by an electronic decision support system based on a computer-interpretable guideline, or alternatively populated manually by the clinician whose decisions may deviate from those of the guideline. Thus, at any point in time, the rationale for a decision could be ascertained explicitly from the EHR, making it easier to reconstruct a series of related decisions that were made about the patient at various consultations with the provider. The tracking of guideline compliance is also of medico-legal significance (e.g. accountability for negative findings and excluded or rejected management options), and where

deviations from guideline occur, new evidence could *potentially* be discovered that could assist with further clinical guideline developments.

- Explicit recording of successive decisions with rationale from CiG-usage into the EHR. While this maintains the history of decision-making for future reference, it also enables DSSs to directly and efficiently access or query the patient's EHR about previous guideline steps taken and reason about the next valid step(s) that can be taken.
- Data template and instruction instance generation from guidelines in conjunction with a guideline adapter file at design time.
- Complete history of the care process for patient is captured within the EHR. Whole workflow activities, flow and their statuses are viewable at any point in time when instantiated. This allows participants to foresee what will happen or intended to happen in the process and better estimate the timing and resources required to enact the process ahead of time. Workflow instances traditionally do not instantiate all activities initially – only the start node. Instruction definition archetype instances are re-usable.

7.1.3. Technical Contributions

This thesis has resulted in a number of technical contributions as a result of implementing our guideline engineering framework, and approach for building an integrated EHR system. These include the following key items being developed and built:

- A prototype system that makes use of two key components: the Breeze workflow architecture, and our implementation of the EHR Persistence Layer – both of which interacted in the initiation, execution and synchronisation of instructions to the workflow. We also illustrated our approach on two distinct but common CDM scenarios: Early Supported Discharge and associated Post-stroke Rehabilitation and Hypertension in Diabetes.
- Mappings between XPDL and Instruction Connector types to support various workflow patterns.
- XPDL-based workflow schema to instruction archetype instance transformation based on the mappings.

- Extensions to the Breeze Workflow Architecture: A few essential WfMS components were built to support the invocation of applications to perform activities, as well as, in particular, support for user interaction with the worklist – i.e., the Worklist itself, the Worklist Manager, the Worklist User Interface, and required AppHandler methods (e.g. for data collection).
- Instruction Model as XML Schema.
- Instruction Definition archetypes required for the two case studies – namely, the Early Supported Discharge, referral and recall instruction definitions.
- Development of the Rationale archetype.
- Development of the Guideline Adapter Document, Guideline Adapter Processor and Decision Support System.
- Development of EHR templates and various archetypes such as the GP encounter event transaction.
- EHR System Interface, which included extensions to existing EHR forms developed by Titanium, as well as a number of new EHR forms.
- Identified the advantages and shortcomings of the different models used, as well as the technological tools used such as JaWE and Breeze, and where appropriate, discussed ways of overcoming the limitations.

7.1.4. The Role of Workflow and Decision Support

While an approach heavily based on a patient-centered workflow model appears very appropriate for the post-stroke situation (and, in fact, we selected the early supported discharge for post-stroke rehabilitation case study because of its goodness of fit), we are equally confident that workflow should *not* play a dominant role in the representation of guideline evidence in many other CDM contexts. If one looks at a guideline for treatment of hypertension in diabetes (see case study discussed in chapter 6) – the Texas Department of Health Hypertension Algorithm for Diabetes Mellitus in Adults is a nicely presented example [57] – it is suggestive of a type of 'workflow' in which care progresses from non-pharmacological approaches, to drug mono-therapy, then combination therapy, and (if blood pressure is still not controlled) to specialist referral. It is precisely this sort of 'disease-state' flow model that has been employed in the guidance for GPs in the UK's large-scale PRODIGY phase III project. However, as discussed in chapter 3 of this thesis, it is in fact a PRODIGY-

based system that has recently been evaluated as ineffective [57]. A detailed qualitative analysis of user perceptions of this system revealed a wealth of problems; notably among these was difficulty in 'navigation' of the guideline and considerable perception by the GPs that the advice given was not worth the effort [33]. Looking back at the Texas Department of Health guideline [57], it is perhaps not surprising – in light of the eight explicit footnotes, sidebar table of supplementary considerations and many additional subtleties that are implied in word choices such as "preferred" versus "strongly recommended" options – that much of the important advice of the guideline is not explicit in the 'workflow' of the algorithm or associated data collection (hence EHR) requirements.

In this thesis (see Chapter 6), we built a guideline-based workflow-integrated EHR system, which pre-populated the relevant fields in the EHR form with values (or presented a set of valid values for the clinician to choose from) recommended by the guideline when the clinician chose to use the DSS. It also allowed for the clinician to reject any of the recommendations, or make any modifications or adjustments to them. We also presented our approach of having explicit constructs within the EHR for recording the *rationale* for clinical decision making either based on the guideline-based recommendations, or based solely on the clinician's expertise and judgment (and therefore, entered manually by the clinician). We allowed for the rationale to be made visible/invisible at the discretion of the clinician, with the option to view the guideline hypermedia content for detailed information (including links to specific patient data items used for reasoning) about the decisions made with respect to the guideline algorithm. We view our approach to be less invasive and less distracting to the clinician compared with DSSs that are based solely on an alert and reminder approach. Pre-filled forms also save time and increase the likelihood of user acceptance of CiGs. Moreover, the direct linkage with the EHR ensures that the entire context is captured persistently (including the explicit recording of the steps in the guideline that were taken with each successive consultations). This can increase the quality in the data being used by DSSs, and allows clinicians to make better clinical decisions during subsequent consultations.

With respect to workflow, we view this aspect to be *complementary* to decision support systems. Our view is that workflow models can further augment the more granular level of modelling that is inherent in clinical guideline representations with

additional information required to support business process modelling. More simply, it provides detailed information about the process of carrying out the actions (in particular, *when*, *how* and *by whom*), whilst guideline models describe the process of clinical decision-making (i.e. how to arrive at decisions and why). However, application to a complex and ever-changing domain such as healthcare calls for sufficient support of relatively unstructured workflows. Panzarasa et al. [30] give considerable attention to the handling of exception in their careflow modelling approach – any successful workflow system in health must address this well – however, at some point the density and nature of exceptions renders the approach inappropriate. As pointed out in [33], for hypertension management, the exceptions will include the fact that the patient will very often receive treatment (and notably begin treatment) outside the scope of the system's record; this challenge is much less present in the Early Supported Discharge case study, where the patient is apt to at least begin the care protocol in a relatively controlled environment.

Our modelling choice in this thesis is not to model 'everything', particularly since not all possible exceptions can ever be known in advance. In our example of the hypertension management in diabetes, for instance, we largely avoid workflow exceptions in the hypertension management in diabetes case study, by making the workflow more abstract. As such, our approach leaves more to the narrowly contextualised DSS, which is in contrast to PRODIGY 'state maps', for example. Providers however, can still explicitly document DSS rule exceptions in the EHR. Overall, we view the chosen level of modelling to demonstrate the two case studies, to be an improvement over current systems.

Since the EHR is a central component in many CISs, we provided an EHR framework that allows for extensible EHR recording that is also directly *integrated* with workflow-support and decision-support. Thus, where workflow (and therefore, use of a WfMS for workflow automation in particular) is too rigid for a particular domain, our EHR framework alone is still able to provide the information regarding *what* was done, and *when*, *who* it was done by, and *what should be recorded* next via archetype Instruction definitions at the knowledge level. This approach is also open for use in DSSs where tracking of decisions made is key to patient management, and suggestions of what should be recorded next effectively implies what the guideline-based recommendations are at that point in time.

7.2. Research Implications

7.2.1. Implications on End-users

Our research has implications on various stakeholders. The extended EHR architecture allows the application designer to choose a usable balance of compliance encouragement and human judgment. The ability to track healthcare process steps within the EHR content is also of medico-legal significance. It is envisioned that extensible EHR recording allows the EHR to serve as the basis for care coordination, and potentially improve communication amongst providers and even improve patient health outcomes.

Providers

- Ensures that the required work is done in a timely manner, and that the required (minimum) data set is recorded at a particular point in time in the healthcare process, thereby avoiding a number of issues that affect the efficient delivery of care processes such as:
  - Missing data;
  - Duplicated data recording;
  - Delayed (untimely) recording of data; and
  - Misallocation of resources.
- Extensible EHR recording allows the EHR content to serve as the basis for coordinating the care of the patient especially amongst a number of different providers.

Patient/Consumer Perspective

Improved quality and receipt of care and consequently increased likelihood of improved health and well-being.

Legal Perspective

One of the principles of designing electronic health records is the support for capturing the different contexts defined in [184] – i.e., (1) the *information generating* context where real-world clinical actions such as making a diagnosis, and performing

physical examinations result in individual information items being recorded; (2) the context of the *clinical session* in which the individual information items were recorded such as a GP visit, or hospital admission; and (3) the *EHR system interaction* context or system access such as querying, or recording information. The context is captured by recording aspects about who/what/when/where and why questions, and that this information is permanently recorded and preserved as part of the EHR, and can be acquired in future internally or externally for auditing and medico-legal purposes (e.g. documenting information pertaining to accountability, negative findings and excluded or rejected management options).

Our approach enables tracking of healthcare process steps and guideline compliance that can be ascertained from the EHR content, thereby having medico-legal significance. As the number of information items in the EHR grow over time, whose sources often come from multiple providers, and potentially numerous disparate systems, it can become increasingly difficult to manage, let alone, decipher what the relationships between the information items are. As an example, our Instruction Execution entry allows explicit linkage to event transactions that get recorded as a result of activities relating to a guideline or workflow being performed. This 'grouping' of EHR event transactions gives an overall context to the history the patient's care and allow users for instance, to ascertain the purpose for which the *collection* of EHR data items / transactions were collected, and in addition be able to have direct links to each of the items.

Guideline Developers

An important facet of using guideline-based decision support is developing quality assessments to measure concordance of provider actions and patient outcomes with respect to the guideline [185]. The ability to track guideline compliance from the EHR potentially allows guideline developers to compare and infer about actual patient outcomes given the provider's compliance to the guideline. Furthermore, new evidence or clinical knowledge may be discovered where deviations from the guideline are found because they are recorded explicitly within the record. The explicit recording of clinician's justifications of such deviations can also be used to build the clinical knowledge. Such information assist in the development, main-

tenance and further improvement of clinical guidelines as clinical evidence changes over time.

7.2.2. Implications on Workflow, EHR and CiG Research

Our open framework can be used to further explore the problem of effective support for CDM (such as presentation of hypermedia), and can inform a range of standards bodies (such as HL7), researchers (such as clinical guideline representation and workflow) and vendors about specific requirements for integrating EHR, workflow and guideline-based decision support. Our approach provides a way to build systems that:

- are interoperable via the *open*EHR framework
- allow reusability via archetypes
- allow specialisations of specifications via archetypes
- allow more 'seamless' integration with other clinical information system components (guidelines and workflow) via use of standards such as WPDL and *open*EHR.
- use of existing and emerging international standards means that systems being built will more likely to be accepted by vendors on a local and global scale.
- *open*EHR framework allows a knowledge-driven system to be built thereby increasing system maintainability as domain knowledge changes.

In general, we believe this research will provide valuable design guidance to health system developers (e.g., Health*Connect*) whether or not they choose to work in the *open*EHR framework.

EHR and Messaging Standards

Relationship to the HL7 Version 3 Unified Service Action Model

Core to the HL7v3 model, is the Unified Service Action Model (USAM), which specifies the relationship between clinically relevant activities (acts) and things (entities). In HL7, all clinical concepts are considered an "Act", and their "Act" and "Act_Relationship" constructs can be viewed essentially in terms of nodes and arcs. Acts within v3 are qualified by a "mood" code, which specifies additional semantics

about the act – i.e. a code that specifies the particular kind of Act that the Act-instance represents within its class.

Act Moods

There are a wide number of act mood codes, however, the moods that are of direct relevance to the EHR include the Act Mood "intent", and "predicate" moods. The "intent" mood indicates an intention of plan to perform a service. A number of ActMood classes derive from the ActMoodIntent class:

- Appointment: A planned Act for a specific time and place.
- Appointment Request: A request for the booking of an appointment.
- Promise: An intent to perform a service that has the strength of a commitment, i.e., other parties may rely on the originator of such promise that said originator will see to it that the promised act will be fulfilled. A promise can be either solicited or unsolicited.
- Proposal: A non-mandated intent to perform an act. Used to record intents that are explicitly not Orders. Professional responsibility for the 'proposal' may or may not be present.
- Request: A request or order for a service is an 'intent' directed from a placer (request author) to a fulfiller (service performer).
- Event: A service that actually happens may be an ongoing service or a documentation of a past service.

Furthermore, each Act with a particular mood also has a corresponding ActStatus, which is an attribute of Act. Thus, an Act in the 'event' mood may either be in the 'new', 'active', 'aborted', 'suspended', 'completed', 'held' or 'cancelled' state. As such, our *open*EHR Instruction and Instruction Activity execution state model is similar to the HL7 Act state model.

Given the above information, we view the Instruction to be representative of a HL7 Clinical Statement consisting of Acts that have the ActMood "Intent", where a clinical statement is an expression of a discrete set of clinical/clinically related information that is recorded due to its relevance to the patient[24]. The Instruction Execution Entry however, would be a clinical statement that may consist of Acts in

[24] The clinical statement can be viewed as a 'choice box', and is a generalised HL7 abstract pattern used in multiple HL7 domain message information models (D-MIMs).

the “Event” mood – i.e. at least have one activity that has been started; whereas the Instruction Definition Entry would only be a clinical statement consisting only of Acts that are not in the “Event” mood.

The predicate moods define criterion under which acts can occur. Predicate moods relate to activity pre- and post-conditions and connector types (see Table 7.1).

Table 7.1. IRM equivalence to the HL7 Predicate Moods.

Act completion track “predicate” mood	*IRM Equivalent*
Event criterion: An assessment of a situation with the possible definite outcomes true or false. It is called an "event-criterion" because it is tested against act events that actually occurred (e.g., observation results). Event criterion are used to set reference ranges and patient goals.	Reference range data is handled as a separate part of the *open*EHR data type model. Patient goals can be set as subject state pre- and post- conditions on activities.
Option: An option is an alternative set of property-value bindings. Options specify alternative sets of values, typically used in definitions or orders to describe alternatives. An option can only be used as a group, that is, all assigned values must be used together	Options between activities are specified for example, using the “exclusive-or” and “inclusive-or” connector types.

ActRelationships

Attributes of the Service class describes who, whom, where, with what, how and when the action is done. The questions ‘who’, ‘whom’, ‘with what’, and ‘where’ can be ascertained by Act Participations that associates an Act and a Role with an Entity playing that Role, and where the kind of involvement in the Act is specified by the Participation.typeCode.

The questions of ‘how’ and ‘when’ are determined by the descriptive attributes. The question of *why* a Service was or is to be performed may also be ascertained by the ActRelationships that link Acts – more specifically, using the three types of

"collecting relationships" represented by ActRelationship instances: whole/part (e.g., lab or test batteries); rule-based (e.g., care plans, protocols); and cognitive actions (e.g., judgement, renaming, replacement, subsumption, supported by/reason for). HL7 also states, that each Act can be further decomposed into plan-components. Furthermore, that for representing sequential plans for example; the Act has a sequenceNumber attribute that specifies the ordering sequence of those Acts. The clinical reasoning can be captured for example, by an instance of ActRelationship Reason (e.g. "supported by"), which could be used to form a link from an instance of an observation Act representing a specific lab test (e.g. sedimentation rate = 48 to an instance of an observation Act representing a particular diagnosis (e.g. DX = Systemic Lupus Erythematosus).

The HL7 model is such that "every intent should be at some point be brought to closure by a corresponding action event, and that action event should be linked to the intent" [186]. The ability to be able to link to the actual object(s) that were used to evaluate the event criterion may be done via a clinical statement. The object(s) exist and they are uniquely identifiable by their object identifiers, however, ideally, there should be a way for them to be linked explicitly if decisions about the services that were performed are to be easily reconstructable at the point of care to assist communication and understanding about what has happened before and why in order to make subsequent well-informed decisions. In our approach, this is done by having an explicit EHR construct for recording or linking the set of Indications (that may be other observation, evaluation or instruction EHR entries) that were used to lead towards a particular decision point or Service or Act. In the HL7v3, an additional Act.Reason code may be required that indicates that reason for the Act is provided by a decision support system, or an external computer-interpretable guideline, and may either provide a way to store the actual justification statement, or have a link or reference which points to the guideline statement.

HL7 also has a number of ActRelationship sub-classes such as:

- ActRelationshipSplit, which may have the code "exclusive try once"; "exclusive wait" (i.e. a branch may be entered later when the condition turns true); "inclusive try once"; or "inclusive wait" (i.e. one or more branches may be entered later when their conditions evaluate to true); and

- ActRelationshipJoin, which has code types that specify concurrency and synchronisation of Acts, etc.

Related HL7 Work

Work on the HL7v3 Care Provision Domain [187] relates closely to the idea of clinical workflow in the *open*EHR model. The Care Provision Domain can be used to represent information pertaining to all types of care provision activities such as the ongoing care of patients, transfer of care, and related 'episodes of care' that are managed between providers in a patient's care team (e.g. hospital discharge to community-based care). The particular moods relevant to the Care provision Domain are "request", "promise" (which is equivalent to a 'yes'/'no' response to the "request"[25]), and the "event" mood, which results from the 'promise' being fulfilled.

The Care Provision Domain uses a sub-type of Act known as the WorkingList, which is a dynamic list consisting of individual Act instances that reflect the needs of a Participant (e.g. individual worker, care team, or an organisation) to view groups of Acts for clinical or administrative reasons. These grouped Acts are related to the WorkingList via an ActRelationship of type 'COMP' (component). Thus, a single WorkingList may be composed of Acts relating to multiple patients that are managed by the same Participant. Examples of WorkingLists include care plans, medication lists, problem lists, goal lists, allergy lists, and to-do lists.

As acts within the bodies of HL7v3 messages are exchanged between systems, there are likely to be corresponding updates to the process instances in the EHR. The HL7v3 WorkingList could potentially be recorded as an Instruction Execution entry that gets updated as a result of changes in the Act moods.

Implications on HL7 v3 USAM

The numerous HL7 mood codes allow for more extensible messages to be defined in different contexts, however, as the number of mood codes increase, so does the complexity in terms of comprehending the model and knowing all of the mood codes,

[25] This does not include scheduling an appointment, which is a separate message that can be sent at the same time as the promise or 'response' to the request.

and how they might be best used for a specific purpose. This is in contrast to *open*EHR, which aims to be much more disciplined in its modelling by having a relatively minimal set of constructs (e.g., observation, evaluation, instruction), and using the relevant classes for their intended purpose via archetyping.

It may be possible to map *open*EHR Entry types to HL7 Acts with Mood codes, however, due to the comprehensiveness of the HL7 RIM, this mapping would not be one-to-one. Moreover, the *open*EHR observation and evaluation entries within HL7 would be considered both as observation acts. Mapping between the two information models is widely viewed as an important area for future work for harmonisation of the efforts of the various EHR and Messaging standards bodies.

Whilst the HL7 v3 USAM also discusses timed and conditioned care plans to provide a concise way of representing care plans, scheduling, protocol, guidelines and workflow processes, it must still enable support for other models or standards to be used. E.g. other CiG representations that are likely to be used and/or preferred to be used. There must be a way for such systems that implement these other models to be able to integrated with HL7 v3-based messages and other HL7 standards such as the emerging CDA (Clinical Document Architecture) for specification of persistent documents (e.g. whether it be querying, linking, or producing messages or a HL7 v3 Service object as a result of GLIF-based DSS being used, for example; or maintaining the guideline recommendation as part of the rationale for a Service object to be performed). If one were to use the HL7-adopted guideline representation Arden Syntax, then its expression would be defined within the "Derivation Expression" attribute of an Act, and this expression would be used to create the recommendation. However, the potential to use an external guideline representation and the rationale/justification produced from it is not yet known. It may be possible to reference an external guideline format/standard, or an actual guideline *document* via the HL7 RIM's Document class from which the CDA is derived, but this is yet to be explored in detail.

The HL7 v3 USAM could also be further informed by Workflow research to be able to support the more complex types of workflow patterns that can occur in terms of modelling business processes. In this case, additional mood codes may be needed to

support these workflow patterns as opposed to potentially 'overloading' the condition expressions in order to support them (see section 3.4.2. for discussion on workflow patterns and Instruction connector equivalence). Another question of interest is how these might map to the WfMC's workflow specification, and therefore, potentially be able to be integrated with or used by existing WfMSs (i.e. how it might allow system/semantic inter-operability, which is key to systems integration).

Further exploration with regards to HL7 standards and integration with DSS and WfMSs for instance, and the contributions that each of these areas of research give will need to be made. In particular, it may become increasingly difficult to model many if not all of these aspects completely based on the HL7 RIM, USAM, and the complexity of the HL7 models in themselves require much understanding – for instance, all of the numerous HL7 codes. We therefore suspect that the right balance has to be made between being able to model as many things as possible (i.e. making the model as generic as possible) without losing the ability to model things as *well* as possible (i.e. making the model usable in a specific context or domain whether it be workflows, guidelines or clinical data).

Other requirements

To increase the potential and scalability of integrated systems that support guideline-based care and workflow, standardisation of information models and various types of specifications will need to occur and furthermore, be *interpreted consistently* in order to achieve consistent implementations of those specifications across systems. It can often be a problem that a model or specification is understood differently by implementers and therefore, result in them being implemented differently – making interoperability difficult if not impossible to achieve between systems, because the actual semantics is not maintained.

Terminology and terminology servers will also need to be standardised and incorporated into such systems in order to further achieve semantic interoperability, and to support a more seamless integration between EHR systems, DSSs and WfMSs. Some major issues of concern with regards to terminologies have been identified by TermINFO [188]. A major problem identified with some terminologies is the

inclusion of coordinated terms. One compound code is given that could otherwise be represented in several Elements. Pre-coordinated terms can result in a combinatorial explosion making the management of terminologies difficult if not impossible. Pre-coordination of terms can potentially be a problem for systems such as electronic decision support to be able to perform queries on terminology servers efficiently. Mapping of terms is also complicated, especially when there are multiple terminologies that can be used – hence, the need to select only one as a standard. The alternative option to post-coordinate terms as required by providers/users at run-time can also pose a problem such that it can be left uncontrolled. Non-sensical terms for instance can potentially be added thereby reducing the overall quality and usability of terminologies.

There are terminologies that do not provide explicit definitions or descriptions of each term. Instead, the description is implicitly attainable based on its hierarchical path or classification it belongs. Again, this is further complicated when a term can potentially exist in multiple classes (also known as 'poly-hierarchical' terminology). For example, the term 'severity', may have two hierarchical paths within a terminology – under the term 'burn' and under the term 'adverse reaction' – resulting in two different meanings of the same term 'severity'.

It is important to realise that terminologies by themselves cannot be used. They require higher level domain-specific concept specifications such as archetypes to be used for clinical information exchange that are based on some concrete clinical information model such as that of the *open*EHR, CEN 13606 or HL7v3 RIM. In this way, terminologies provide the 'vocabulary' and the information model provide the 'grammar' for describing structured, meaningful concepts that can be *reused* for different contexts. For instance, the term 'blood pressure' has a structure containing diastolic and systolic data elements, etc, specified using an archetype and that single concept can be reused in a number of different contexts such as 'blood pressure at a point in time', 'blood pressure average over a period of time', and 'target blood pressure'. Conversely, archetypes require terminology to obtain terms for:

(1) the name of the concept being described by the archetype;
(2) identifying parts of the archetype – i.e., the 'labels' for data elements and compound data elements (otherwise known as 'clusters'); and

(3) the allowable set of term(s) that can be used for constraining the data element values (e.g. the 'blood pressure patient position' data element may only have the following terms 'lying', 'sitting', 'standing' as its allowable set of values).

7.3. Future work

7.3.1. Investigation of Further Case Studies and Usability Testing

The applicability and limitations of our approach on a much wider scale can only be determined through investigation of further, more complex case studies. A particularly complex aspect of chronic disease management is the management of multiple problems/diseases for a single patient. There needs to be a further mechanism for an integrated clinical information system to be able to handle multiple guidelines being used concurrently. There may be situations where guideline recommendations are duplicated. For example, the recommendation to cease smoking may be given by both a hypertension management guideline, and the asthma management guideline. There may be cases where guideline recommendations conflict with other guidelines being used, or cases where a guideline recommendation may need to be adjusted with respect to recommendations provided by another guideline in order to be more contextualised and be more specific to the patient. In addition, the recommendations from multiple guidelines may need to be prioritised in terms of their criticality to the patient's health outcome, and/or depending on the available resources. At a lower level of abstraction, each guideline is typically documented such that it may contain many different recommendations based upon different levels of evidence (e.g. a recommendation based on the results of at least one high quality randomised controlled trial with very low risk of bias would be based upon level 1++ evidence, and would therefore be classified as a 'Grade A' recommendation). Thus, the prioritisation of recommendations also has to take into account the level of supporting evidence for each recommendation.

The decision support system will need to be able to handle the types of complexities mentioned above, and be able to reason intelligently with multiple guidelines. At the very least, the DSS should be able to detect and present duplicate recommendations and any potential conflicting recommendations that occur, and prompt the clinician to

make the appropriate adjustments and make the final decision. However, decision support systems for CDM will need mechanisms for explicitly recording the reasoning, any adjustments made, the *set* of multiple guidelines used (as opposed to what we have investigated in our research, which is based only on using a single guideline), and their supporting evidence, into the EHR. Thus, for the example recommendation to cease smoking, the system will need to record that it was sourced from both the hypertension and asthma management guidelines being for a particular patient suffering from these two chronic illnesses.

Guideline complexity may also be characterised by the number of predicates it uses, which may impact on system design and implementation. Where guidelines have a complexity of >7 predicates for instance, there may be a need to investigate the potential for dynamic/run-time specialisation of archetypes, and EHR template modification based on the current state of the patient within the guideline(s) and the provider's decisions. This dynamic archetype specialisation and EHR template modification is particularly useful in cases where the total set of archetypes (i.e. the maximum data set) cannot be determined in advance (particularly due to uncertainty about the patient's health and health outcomes, which may require further guidelines to be used), and therefore, cannot be predefined. This approach may also prove to be more practical in the long term as evidence changes or new knowledge is discovered over time. Implementing the dynamic approach essentially means that the information recording options are *actively* being 'demoted' and 'promoted' as required by the DSS at *run-time* depending on guideline recommendations at the point of care, without losing the ability for the provider to choose to override the recommendations at any point in time.

While we have examined highly realistic scenarios for use in our EHR, DSS and WfMS integrated prototype system presented in this thesis – with advice received from DSTC on some design issues; more formal usability testing with providers would be the next step for further development and improvement on the practicability of our approach. Ideally, in the longer-term there should be the potential to be able to formally assess its overall effect on the larger problem with which provides the motivation for our research – i.e. inter-provider communication; service coordination;

decision support; and more importantly, patient health outcomes – such as through a clinical trial.

7.3.2. Implementation of Hypermedia Artefact

Determining the method and extent of supporting interactive DSS via hypermedia artefact – such as the mock-up display of the hypermedia interface we developed earlier in our research (shown in Figure 6.33) – is a non-trivial exercise. For instance, a compromise must be made regarding the amount of information that can be displayed at a time due to technological limitations with screen resolutions, and screen readability. In addition, the user interface must be as intuitive and simple as possible to enable providers to perform their tasks efficiently. The system should also deliver the right information at the right time to suit the provider's workflow. This is critical for instance, in General Practice where consulations on average last five to ten minutes per patient.

Research and development into the implementation of the guideline hypermedia artefact will assist in improving the usability of clinical decision support systems in terms of providing a tool with which providers can effectively visualise, track, understand, and potentially communicate amongst each other the decisions made in the care process of a specific patient. As an example mentioned earlier in the thesis, the recent evaluation using the scenario-based decision support in general practice showed no effect on management of chronic conditions [22], most likely due to the significant barriers to its usability [33]. Our view is that improved usability inevitably results in greater *user acceptance* and therefore, greater use of such systems. Increase use of these systems better allow researchers to make proper evaluations about the overall effect (e.g. chronic disease management and health outcomes) of using decision support systems in the field.

7.3.3. Advanced Workflow and Workflow Flexibility

Whilst our worklist user interface prototype works relatively well when the actual execution of activities occurs according to the Instruction Definition or with the workflow engine's automated updating of activity statuses, various exceptions will

need to be supported to enable the system to be fully accepted and be of practical use in a healthcare setting. For example, the facilities to cancel workflow instances, or change the workflow at run-time. These may be made more feasible as workflow management systems further develop and are able to handle such exceptions gracefully, and similarly with the EHR Persistence Layer. Further investigation will need to be made when the user decides to deviate from performing the activities within the Instruction Definition at run-time. In particular, whether or not the Instruction Execution should be subsequently 'abandoned', and allow the user to define a completely new Instruction Definition. There should also be support for users to create an Instruction Definition by modifying an existing one. The approach of modifying and specialising the archetypes dynamically at run-time (i.e. using specific archetypes only as required) may be needed, which may be sufficient in terms of allowing the user to choose which EHR event transaction types to collect for a data collection activity.

Integration with a more advanced WfMS (as opposed to the relatively basic workflow tools of the Breeze architecture) that supports features such as prioritisation, order handling, load-balancing and other functionalities relating to making complex decisions about optimal management of multiple workflow instances would allow the potential for support of larger-scale systems such as between hospitals to be explored.

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A

APPENDIX

Early Supported Discharge Workflow Schema in XPDL

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<?xml version="1.0" encoding="UTF-8"?>
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```

```
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event.order_basic_equipment.v1"/>
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patient."/>
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event.ESD_Summary.v1"/>
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concerns."/>
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Value="esd_v0_Wor2_Par1;esd_v0_Wor2_Act12;540;130;NOROUTING"/>
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event.OT_Assessment.v1; openehr.transaction-event.OT_Equipment_Order.v1"/>
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on equipment use."/>
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To="esd_v0_Wor3_Act15">
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Value="esd_v0_Wor11_Par1;esd_v0_Wor10_Act1;290;60;NOROUTING"/>
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        <ExtendedAttribute Name="Version" Value="1.2"/>
    </ExtendedAttributes>
</Package>
```

B

APPENDIX

Instruction Reference Model XML Schema

```
<?xml version="1.0" encoding="UTF-8" standalone="yes"?>
<!-- edited with XMLSPY v5 rel. 4 U (http://www.xmlspy.com) by cissab@reason.levels.unisa.edu.au (none) -->
<xs:schema targetNamespace="http://www.openehr.org/2002" xmlns="http://www.openehr.org/2002"
xmlns:xs="http://www.w3.org/2001/XMLSchema" xmlns:html="http://www.w3.org/1999/xhtml"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" elementFormDefault="qualified" xml:lang="EN">
    <xs:include schemaLocation="E:\CURRENT FILES-Z-r\briefcase\openehr\4_openEHR\xsd\openEHR-rm-transaction.xsd"/>
    <xs:include schemaLocation="E:\CURRENT FILES-Z-r\briefcase\openehr\4_openEHR\xsd\openEHR-rm-support.xsd"/>
    <!-- ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ -->
    <!-- CLASS:  Entry -->
    <!-- ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ -->
    <xs:element name="Entry" type="Entry" abstract="true"/>
    <xs:complexType name="Entry">
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            <xs:element name="data" type="STRUCTURE"/>
            <xs:element name="protocol" type="STRUCTURE" minOccurs="0"/>
            <xs:element name="reasoning" type="STRUCTURE" minOccurs="0"/>
        </xs:all>
    </xs:complexType>
    <!-- ==================================================================================================== -->
    <!-- -->
    <!-- D E F I N I T I O N -->
    <!-- -->
    <!-- ==================================================================================================== -->
```

```
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<!-- ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ -->
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                <xs:element name="activity" minOccurs="0">
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                            <xs:element ref="Atomic_Activity"/>
                            <xs:element ref="Composite_Activity"/>
                            <xs:element ref="Clinical_Intervention_Activity"/>
                            <xs:element ref="Data_Collection_Activity"/>
                            <xs:element ref="Administrative_Activity"/>
                            <xs:element ref="Activity_Proxy"/>
                            <xs:element ref="Null_Activity"/>
                            <xs:element ref="Wait_Activity"/>
                            <xs:element ref="Connector"/>
                        </xs:choice>
                    </xs:complexType>
                </xs:element>
            </xs:all>
        </xs:extension>
    </xs:complexContent>
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<!-- ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ -->
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        <xs:element name="subject_state_precondition" type="DV_EXPRESSION"/>
        <xs:element name="subject_state_postcondition" type="DV_EXPRESSION"/>
        <xs:element name="start_activity" type="BOOLEAN"/>
        <xs:element name="end_activity" type="BOOLEAN"/>
    </xs:sequence>
</xs:complexType>
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```

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                            <xs:element ref="Administrative_Activity"/>
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                            <xs:element ref="Data_Collection_Activity"/>
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                            <xs:element ref="Data_Collection_Activity"/>
                            <xs:element ref="Administrative_Activity"/>
                            <xs:element ref="Activity_Proxy"/>
                            <xs:element ref="Null_Activity"/>
                            <xs:element ref="Wait_Activity"/>
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                            <xs:element ref="Wait_Activity"/>
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<!-- ============================================================================================================ -->
<!-- -->
<!-- E X E C U T I O N -->
<!-- -->
<!-- ============================================================================================================ -->
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                            <xs:element ref="Administrative_Activity_Instance"/>
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maxOccurs="unbounded"/>
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            <xs:extension base="Atomic_Activity_Instance">
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                                <xs:element ref="Data_Collection_Activity_Instance"/>
                                <xs:element ref="Administrative_Activity_Instance"/>
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                            <xs:element ref="Administrative_Activity_Instance"/>
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                            <xs:element ref="Administrative_Activity_Instance"/>
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                            <xs:element ref="Composite_Activity_Instance"/>
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                            <xs:element ref="Data_Collection_Activity_Instance"/>
                            <xs:element ref="Administrative_Activity_Instance"/>
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                            <xs:element ref="Data_Collection_Activity_Instance"/>
                            <xs:element ref="Administrative_Activity_Instance"/>
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<!-- ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ -->
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            <xs:sequence>
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                <xs:element name="input_activity_Instance" minOccurs="2" maxOccurs="unbounded">
                    <xs:complexType>
                        <xs:choice>
                            <xs:element ref="Activity_Instance"/>
                            <xs:element ref="Atomic_Activity_Instance"/>
                            <xs:element ref="Composite_Activity_Instance"/>
                            <xs:element ref="Clinical_Intervention_Activity_Instance"/>
```

```
                            <xs:element ref="Data_Collection_Activity_Instance"/>
                            <xs:element ref="Administrative_Activity_Instance"/>
                            <xs:element ref="Activity_Instance_Proxy"/>
                            <xs:element ref="Null_Activity_Instance"/>
                            <xs:element ref="Wait_Activity_Instance"/>
                        </xs:choice>
                    </xs:complexType>
                </xs:element>
                <xs:element name="output_activity_Instance">
                    <xs:complexType>
                        <xs:choice>
                            <xs:element ref="Activity_Instance"/>
                            <xs:element ref="Atomic_Activity_Instance"/>
                            <xs:element ref="Composite_Activity_Instance"/>
                            <xs:element ref="Clinical_Intervention_Activity_Instance"/>
                            <xs:element ref="Data_Collection_Activity_Instance"/>
                            <xs:element ref="Administrative_Activity_Instance"/>
                            <xs:element ref="Activity_Instance_Proxy"/>
                            <xs:element ref="Null_Activity_Instance"/>
                            <xs:element ref="Wait_Activity_Instance"/>
                        </xs:choice>
                    </xs:complexType>
                </xs:element>
            </xs:sequence>
        </xs:extension>
    </xs:complexContent>
</xs:complexType>
<!-- ========================================================================================================== -->
<!-- -->
<!-- D A T A   T Y P E S -->
<!-- -->
<!-- ========================================================================================================== -->
<!-- ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ -->
<!-- DATA_TYPE:  DV_EXECUTION_STATE -->
<!-- ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ -->
<xs:element name="DV_EXECUTION_STATE" type="DV_EXECUTION_STATE"/>
<xs:complexType name="DV_EXECUTION_STATE">
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        <xs:element name="value" type="DV_STATE"/>
    </xs:all>
</xs:complexType>
<!-- ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ -->
<!-- DATA_TYPE:  DV_EXPRESSION -->
<!-- ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ -->
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    <xs:all>
        <xs:element name="value" type="DATA_VALUE"/>
    </xs:all>
</xs:complexType>
<!-- ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ -->
<!-- ENUMERATION:  DV_SPLIT_TYPE -->
<!-- ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ -->
<xs:element name="DV_SPLIT_TYPE" type="DV_SPLIT_TYPE"/>
<xs:simpleType name="DV_SPLIT_TYPE">
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        <xs:enumeration value="AND_split"/>
        <xs:enumeration value="XOR_split"/>
        <xs:enumeration value="OR_split"/>
    </xs:restriction>
</xs:simpleType>
<!-- ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ -->
<!-- ENUMERATION:  DV_CHOICE_JOIN_TYPE -->
<!-- ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ -->
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    <xs:restriction base="xs:string">
        <xs:enumeration value="XOR_split"/>
        <xs:enumeration value="OR_split"/>
    </xs:restriction>
</xs:simpleType>
<!-- ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ -->
<!-- ENUMERATION:  DV_SYNCHRONISATION_TYPE -->
<!-- ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ -->
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<xs:simpleType name="DV_SYNCHRONISATION_TYPE">
    <xs:restriction base="xs:string">
        <xs:enumeration value="synchronous"/>
        <xs:enumeration value="partly_synchronous"/>
        <xs:enumeration value="partly_synchronous"/>
        <xs:enumeration value="asynchronous"/>
    </xs:restriction>
</xs:simpleType>
</xs:schema>
```

C

APPENDIX

ESD Breeze Workflow Definition in XML

```
<?xml version='1.0'?>
<!DOCTYPE workflow SYSTEM "dstc/editor/Breeze-
20001121.dtd"
[
]>
<workflow class='dstc.editor.WorkflowModel'
    id='esd'
>
    <!-- Parameters -->
    <!-- Nodes -->
    <task class='dstc.editor.TaskNode'
          id='Task.1'
          name='Review_patient'
    >
      <interface>AppHandlerClass
collect_data</interface>
      <join>AND</join>
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      >
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      >
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      >
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      >
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      >
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  >
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  >
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  >
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  >
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  >
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<condtask class='dstc.editor.CondTaskNode'
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     name='XOR'
     condition='eligibility == "true"'
>
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  >
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  >
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  >
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  >
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  >
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     name='Plan_services'
>
  <interface>AppHandlerClass
collect_data</interface>
  <join>AND</join>
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  >
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  >
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  >
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  >
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  >
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      >
      </parameter>
    </task>
    <task class='dstc.editor.plugins.NullTask'
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          name='Route'
    >
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      <join>AND</join>
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      >
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      >
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    <condtask class='dstc.editor.CondTaskNode'
          id='Task.5'
          name='XOR'
          condition='basic_equipment_required ==
"true"'
    >
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      >
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      >
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      >
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      >
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      >
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      >
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    <condtask class='dstc.editor.CondTaskNode'
          id='Task.6'
          name='XOR'
          condition='longer_term_care == "true"'
    >
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      >
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      >
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      >
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      >
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      >
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            name='role'
            type='string'
            defaultVal="'ESD_Coordinator'"

      >
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    </condtask>
    <task class='dstc.editor.TaskNode'
          id='Task.7'
          name='Order_basic_equipment'
    >
      <interface>AppHandlerClass
collect_data</interface>
      <join>AND</join>
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            type='string'
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      >
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```

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  >
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  >
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        type='string'
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  >
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  >
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        type='string'
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  >
  </parameter>
</task>
<subtask class='dstc.editor.SubTaskNode'
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>
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  >
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  >
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  >
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  >
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  >
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  >
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  >
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  >
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  >
  </parameter>
</subtask>
<task class='dstc.editor.TaskNode'
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     name='Alternative_referral'
>
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collect_data</interface>
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  >
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  >
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  >
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  >
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  >
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```
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      <interface>AppHandlerClass
collect_data</interface>
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      >
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    <task class='dstc.editor.TaskNode'
         id='Task.11'
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```

```
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  >
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  >
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  >
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      name='XOR'
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  >
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  >
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        condition='concerns == "true"'
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        >
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            name='Prepare_discharge'
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        <interface>AppHandlerClass
collect_data</interface>
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            name='Notify_GP'
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```
            defaultVal="'ESD_Coordinator'"

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send_notification</interface>
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          name='Route'
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          </map>
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          >
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              dst='role'
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          </map>
    </edge>
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          id='Edge.2'
          src='Task.2'
          dst='Task.3'
          srcKind='then'
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              dst='providerID'
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          </map>
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          >
          </map>
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          </map>
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          src='Task.2'
          dst='Task.4'
          srcKind='else'
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              dst='providerID'
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          </map>
          <map class='dstc.editor.Map'
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        </map>
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        src='Task.3'
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        srcKind=''
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      dst='Task.16'
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      dst='Task.17'
      srcKind=''
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          dst='Task.19'
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          id='Edge.22'
          src='Task.18'
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          srcKind=''
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        width='172'
        height='50'
  >
  </figtask>
  <figtask class='dstc.editor.FigCondTaskNode'
        id='Fig1'
        owner='Task.2'
        x='202'
        y='320'
        width='58'
        height='50'
  >
  </figtask>
  <figtask class='dstc.editor.FigTaskNode'
        id='Fig2'
        owner='Task.3'
        x='267'
        y='240'
        width='172'
        height='50'
  >
  </figtask>
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D

APPENDIX

Guideline Adapter Document (GAD) XML Schema

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                                                        <xs:element name="drug">
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                                                                        <xs:annotation>

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```

```
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```
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                                                        <xs:element name="drug">
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                                                        <xs:element name="drug">
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```

```
                                                    </xs:complexType>
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                            </xs:complexType>
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maxOccurs="unbounded">
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                                                        <xs:choice>
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                                                            <xs:element name="expression"/>
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                                    <xs:element name="GRP">
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guideline graphic source this points to.</xs:documentation>
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                                    <xs:element name="associated_didactics"/>
                                </xs:sequence>
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</xs:schema>
```

E

APPENDIX

ESD Instruction Definition Entry Instance[26]

```
<Entry xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns:xpdl="http://www.wfmc.org/2002/XPDL1.0">
   <entry_type>Instruction_Definition</entry_type>
   <data />
   <protocol />
   <reasoning />
   <instruction_definition_id>openehr.instruction_definition.esd.v1</instruction_definition_id>
   <guideline_id />
   <Connectors>
<!-- Connectors for process id: esd_v0_Wor1 -->
      <Split>
         <precondition />
         <postcondition />
         <split_type>XOR_split</split_type>
         <input_activity_id>esd_v0_Wor1_Act1</input_activity_id>
         <output_activity_id>esd_v0_Wor1_Act6</output_activity_id>
         <output_activity_id>esd_v0_Wor1_Act3</output_activity_id>
         <output_activity_id>esd_v0_Wor1_Act2</output_activity_id>
```

[26] Note, fragments of this listing have been removed and are denoted by "…" – where repeated information may occur (e.g., connector information).

```
      </Split>
      <Split>
         <precondition />
         <postcondition />
         <split_type>AND_split</split_type>
         <input_activity_id>esd_v0_Wor1_Act2</input_activity_id>
         <output_activity_id>esd_v0_Wor1_Act10</output_activity_id>
         <output_activity_id>esd_v0_Wor1_Act9</output_activity_id>
      </Split>
      <Sequence>
         <precondition />
         <postcondition />
         <input_activity_id>esd_v0_Wor1_Act9</input_activity_id>
         <output_activity_id>esd_v0_Wor1_Act11</output_activity_id>
      </Sequence>
      <Sequence>
         <precondition />
         <postcondition />
         <input_activity_id>esd_v0_Wor1_Act10</input_activity_id>
         <output_activity_id>esd_v0_Wor1_Act9</output_activity_id>
      </Sequence>
      <Split>
         <precondition />
         <postcondition />
         <split_type>XOR_split</split_type>
         <input_activity_id>esd_v0_Wor1_Act11</input_activity_id>
         <output_activity_id>esd_v0_Wor1_Act14</output_activity_id>
         <output_activity_id>esd_v0_Wor1_Act12</output_activity_id>
      </Split>
      <Split>
         <precondition />
         <postcondition />
         <split_type>AND_split</split_type>
         <input_activity_id>esd_v0_Wor1_Act12</input_activity_id>
         <output_activity_id>esd_v0_Wor1_Act20</output_activity_id>
         <output_activity_id>esd_v0_Wor1_Act19</output_activity_id>
      </Split>
      <Split>
         <precondition />
         <postcondition />
         <split_type>OR_split</split_type>
         <input_activity_id>esd_v0_Wor1_Act14</input_activity_id>
         <output_activity_id>esd_v0_Wor1_Act15</output_activity_id>
         <output_activity_id>esd_v0_Wor1_Act9</output_activity_id>
      </Split>
      <Sequence>
         <precondition />
         <postcondition />
         <input_activity_id>esd_v0_Wor1_Act15</input_activity_id>
         <output_activity_id>esd_v0_Wor1_Act9</output_activity_id>
      </Sequence>
      <Sequence>
         <precondition />
         <postcondition />
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         <output_activity_id>esd_v0_Wor1_Act21</output_activity_id>
      </Sequence>
      <Sequence>
         <precondition />
         <postcondition />
         <input_activity_id>esd_v0_Wor1_Act20</input_activity_id>
         <output_activity_id>esd_v0_Wor1_Act21</output_activity_id>
      </Sequence>
   </Connectors>
<!-- Activities for process id: esd_v0_Wor1 -->
   <Activities>
      <Clinical_Intervention_Activity>
         <role>ESD_Coordinator</role>
         <activity_id>esd_v0_Wor1_Act1</activity_id>
```

```
         <activity_name>Review_patient</activity_name>
         <subject_state_precondition />
         <subject_state_postcondition />
         <is_start_activity>true</is_start_activity>
         <is_end_activity>false</is_end_activity>
         <is_mandatory />
         <work_item>ascertain patient needs</work_item>
         <data_to_collect>openehr.transaction-event.esd_review_report.v1; openehr.transaction-
event.patient_consent.v1</data_to_collect>
         <patient_state_goal />
         <patient_state_target />
      </Clinical_Intervention_Activity>
      <Clinical_Intervention_Activity>
         <role>ESD_Coordinator</role>
         <activity_name>Plan_services</activity_name>
         <activity_id>esd_v0_Wor1_Act2</activity_id>
         <subject_state_precondition>eligible=true</subject_state_precondition>
         <subject_state_postcondition />
         <is_start_activity>false</is_start_activity>
         <is_end_activity>false</is_end_activity>
         <is_mandatory />
         <work_item>plan services</work_item>
         <data_to_collect>openehr.transaction-event.ESD_care_plan.v1</data_to_collect>
         <patient_state_goal>patient self-management in the home</patient_state_goal>
         <patient_state_target />
      </Clinical_Intervention_Activity>
      <Clinical_Intervention_Activity>
         <role>ESD_Coordinator</role>
         <activity_name>Alternative_referral</activity_name>
         <activity_id>esd_v0_Wor1_Act3</activity_id>
         <subject_state_precondition>eligible = false AND long-term_services_needed =
true</subject_state_precondition>
         <subject_state_postcondition />
         <is_start_activity>false</is_start_activity>
         <is_end_activity>true</is_end_activity>
         <is_mandatory />
         <work_item>refer to longer-term care services</work_item>
         <data_to_collect>openehr.transaction-event.referral.v1</data_to_collect>
         <patient_state_goal>longer-term management</patient_state_goal>
         <patient_state_target />
      </Clinical_Intervention_Activity>
      <Clinical_Intervention_Activity>
         <role>ESD_Coordinator</role>
         <activity_name>Provide_info_about_alt_services</activity_name>
         <activity_id>esd_v0_Wor1_Act6</activity_id>
         <subject_state_precondition>eligible=false</subject_state_precondition>
         <subject_state_postcondition />
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         <is_end_activity>true</is_end_activity>
         <is_mandatory />
         <work_item>provide patient with information about alternative services.</work_item>
         <data_to_collect />
         <patient_state_goal>
         </patient_state_goal>
         <patient_state_target />
      </Clinical_Intervention_Activity>
      <Composite_Activity>
         <activity_name>Refer_patient</activity_name>
         <activity_id>esd_v0_Wor1_Act9</activity_id>
         <subject_state_precondition />
         <subject_state_postcondition />
         <is_start_activity>false</is_start_activity>
         <is_end_activity>false</is_end_activity>
         <is_mandatory>
         </is_mandatory>
         <Connectors>
            …
         </Connectors>
<!-- sub activities -->
```

```
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               <role>ESD_Coordinator</role>
               <activity_name>Refer</activity_name>
               <activity_id>esd_v0_wor2_Act16</activity_id>
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               <subject_state_postcondition />
               <is_start_activity>true</is_start_activity>
               <is_end_activity>false</is_end_activity>
               <is_mandatory />
               <work_item>make a referral.</work_item>
               <data_to_collect>openehr.transaction-event.Referral.v1</data_to_collect>
               <patient_state_goal>
               </patient_state_goal>
               <patient_state_target />
            </Clinical_Intervention_Activity>
            <Composite_Activity>
               <activity_name>Refer_to_OT</activity_name>
               <activity_id>esd_v0_Wor2_Act6</activity_id>
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               <subject_state_postcondition />
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               <is_mandatory>
               </is_mandatory>
<!-- sub connectors -->
               <Connectors>
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               </Connectors>
<!-- sub activities -->
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                  <Clinical_Intervention_Activity>
                     <role>Occupational_Therapist</role>
                     <activity_name>Home_Assessment</activity_name>
                     <activity_id>esd_v0_wor3_Act1</activity_id>
                     <subject_state_precondition />
                     <subject_state_postcondition />
                     <is_start_activity>true</is_start_activity>
                     <is_end_activity>false</is_end_activity>
                     <is_mandatory>
                     </is_mandatory>
                     <work_item>perform home assessment of patient.</work_item>
                     <data_to_collect>openehr.transaction-event.OT_Assessment.v1; openehr.transaction-
event.Equipment_Order.v1</data_to_collect>
                     <patient_state_goal />
                     <patient_state_target />
                  </Clinical_Intervention_Activity>
                  <Administrative_Activity>
                     <role>Occupational_Therapist</role>
                     <activity_name>Seek_Housing_Trust_Approval</activity_name>
                     <activity_id>esd_v0_wor3_Act6</activity_id>
                     <subject_state_precondition />
                     <subject_state_postcondition />
                     <is_start_activity>false</is_start_activity>
                     <is_end_activity>false</is_end_activity>
                     <is_mandatory>
                     </is_mandatory>
                     <work_item>send request of request for approval.</work_item>
                  </Administrative_Activity>
                  <Clinical_Intervention_Activity>
                     <role>Occupational_Therapist</role>
                     <activity_name>Deliver_Equipment_and_Educate</activity_name>
                     <activity_id>esd_v0_wor3_Act8</activity_id>
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                     <subject_state_postcondition />
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                     <is_mandatory>
                     </is_mandatory>
```

```
                  <work_item>deliver equipment to patient and educate patient on equipment use.</work_item>
                  <data_to_collect>
                  </data_to_collect>
                  <patient_state_goal />
                  <patient_state_target />
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               <Clinical_Intervention_Activity>
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                  <is_end_activity>false</is_end_activity>
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                  <patient_state_target />
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                  <is_end_activity>false</is_end_activity>
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                  </is_mandatory>
                  <work_item>make any further modifications on equipment.</work_item>
                  <data_to_collect>
                  </data_to_collect>
                  <patient_state_goal />
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            </is_mandatory>
<!-- sub connectors -->
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            </Connectors>
<!-- sub activities -->
            <Activities>
             …
            </Activities>
         </Composite_Activity>
         <Composite_Activity>
            <activity_name>Refer_to_Physiotherapist</activity_name>
            <activity_id>esd_v0_Wor2_Act13</activity_id>
```

```
                <subject_state_precondition />
                <subject_state_postcondition />
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                <is_end_activity>false</is_end_activity>
                <is_mandatory>
                </is_mandatory>
<!-- sub connectors -->
                <Connectors>
                 …
                </Connectors>
<!-- sub activities -->
                <Activities>
                 …
                </Activities>
             </Composite_Activity>
             <Composite_Activity>
                <activity_name>Refer_to_Speech_Therapist</activity_name>
                <activity_id>esd_v0_Wor2_Act14</activity_id>
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                <subject_state_postcondition />
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                <is_end_activity>false</is_end_activity>
                <is_mandatory>
                </is_mandatory>
                <Connectors>
                 …
                </Connectors>
<!-- sub activities -->
                <Activities>
                 …
                </Activities>
             </Composite_Activity>
             <Composite_Activity>
                <activity_name>Refer_to_Social_Worker</activity_name>
                <activity_id>esd_v0_Wor2_Act15</activity_id>
                <subject_state_precondition />
                <subject_state_postcondition />
                <is_start_activity>false</is_start_activity>
                <is_end_activity>false</is_end_activity>
                <is_mandatory>
                </is_mandatory>
                <Connectors>
                 …
                </Connectors>
<!-- sub activities -->
                <Activities>
                 …
                </Activities>
             </Composite_Activity>
             <Null_Activity>
                <activity_name>Route</activity_name>
                <activity_id>esd_v0_wor2_Act12</activity_id>
                <subject_state_precondition />
                <subject_state_postcondition />
                <is_start_activity>false</is_start_activity>
                <is_end_activity>true</is_end_activity>
             </Null_Activity>
          </Activities>
       </Composite_Activity>
       <Clinical_Intervention_Activity>
          <role>ESD_Coordinator</role>
          <activity_name>Order_basic_equipment</activity_name>
          <activity_id>esd_v0_wor1_Act10</activity_id>
          <subject_state_precondition />
          <subject_state_postcondition />
          <is_start_activity>false</is_start_activity>
          <is_end_activity>false</is_end_activity>
          <is_mandatory>
          </is_mandatory>
```

```
   <work_item>order and deliver basic equipment for patient.</work_item>
   <data_to_collect>openehr.transaction-event.order_basic_equipment.v1</data_to_collect>
   <patient_state_goal>assist patient in the home via basic equipment installment.</patient_state_goal>
   <patient_state_target />
</Clinical_Intervention_Activity>
<Clinical_Intervention_Activity>
   <role>ESD_Coordinator</role>
   <activity_name>Follow_up</activity_name>
   <activity_id>esd_v0_wor1_Act11</activity_id>
   <subject_state_precondition />
   <subject_state_postcondition />
   <is_start_activity>false</is_start_activity>
   <is_end_activity>false</is_end_activity>
   <is_mandatory>
   </is_mandatory>
   <work_item>follow up on patient.</work_item>
   <data_to_collect>
   </data_to_collect>
   <patient_state_goal>
   </patient_state_goal>
   <patient_state_target />
</Clinical_Intervention_Activity>
<Data_Collection_Activity>
   <role>ESD_Coordinator</role>
   <activity_name>Prepare_discharge</activity_name>
   <activity_id>esd_v0_wor1_Act12</activity_id>
   <subject_state_precondition />
   <subject_state_postcondition />
   <is_start_activity>false</is_start_activity>
   <is_end_activity>false</is_end_activity>
   <is_mandatory>
   </is_mandatory>
   <work_item>prepare ESD discharge.</work_item>
   <data_to_collect>openehr.transaction-event.ESD_Summary.v1</data_to_collect>
</Data_Collection_Activity>
<Null_Activity>
   <activity_name>Route</activity_name>
   <activity_id>esd_v0_wor1_Act14</activity_id>
   <subject_state_precondition />
   <subject_state_postcondition />
   <is_start_activity>false</is_start_activity>
   <is_end_activity>false</is_end_activity>
</Null_Activity>
<Administrative_Activity>
   <role>ESD_Coordinator</role>
   <activity_name>Notify_GP_of_concerns</activity_name>
   <activity_id>esd_v0_wor1_Act15</activity_id>
   <subject_state_precondition />
   <subject_state_postcondition />
   <is_start_activity>false</is_start_activity>
   <is_end_activity>false</is_end_activity>
   <is_mandatory>false</is_mandatory>
   <work_item>send notification to GP about patient concerns.</work_item>
</Administrative_Activity>
<Administrative_Activity>
   <role>ESD_Coordinator</role>
   <activity_name>Notify_GP</activity_name>
   <activity_id>esd_v0_wor1_Act19</activity_id>
   <subject_state_precondition />
   <subject_state_postcondition />
   <is_start_activity>false</is_start_activity>
   <is_end_activity>false</is_end_activity>
   <is_mandatory>
   </is_mandatory>
   <work_item>notify the GP.</work_item>
</Administrative_Activity>
<Administrative_Activity>
   <role>ESD_Coordinator</role>
   <activity_name>Notify_patient</activity_name>
```

```
         <activity_id>esd_v0_wor1_Act20</activity_id>
         <subject_state_precondition />
         <subject_state_postcondition />
         <is_start_activity>false</is_start_activity>
         <is_end_activity>false</is_end_activity>
         <is_mandatory>
         </is_mandatory>
         <work_item>notify patient.</work_item>
      </Administrative_Activity>
      <Null_Activity>
         <activity_name>End</activity_name>
         <activity_id>esd_v0_wor1_Act21</activity_id>
         <subject_state_precondition />
         <subject_state_postcondition />
         <is_start_activity>false</is_start_activity>
         <is_end_activity>true</is_end_activity>
         <is_mandatory>
         </is_mandatory>
      </Null_Activity>
   </Activities>
</Entry>
```

F

APPENDIX

ESD Instruction Execution Entry within a Persistent Transaction[27].

```
<transactions>
   <versioned_transaction>
      <version_audit>
         <node>EHR@UniSA.edu.au</node>
         <committer>
<!-- provider ID -->
         </committer>
         <time_committed>28-07-2004 09:14</time_committed>
         <change_type>
<!-- e.g., initial creation, update, correction -->
         </change_type>
         <version_id>v1.0</version_id>
         <parent_version_id></parent_version_id>
      </version_audit>
      <transaction>
         <name>Post-Stroke Rehabilitation Plan</name>
         <meaning>Post-Stroke_Rehabilitation_plan</meaning>
```

[27] Note, fragments of this listing have been removed and are denoted by "…" – where repeated information may occur (e.g., connector information).

```
         <content>
            <items>
               <item>
<!-- ORGANISER -->
                  <organiser>
                     <name>Problem_Plan_Headings</name>
                     <meaning>Problem_Plan_Headings</meaning>
                     <content>
                        <items>
                           <item>
<!-- PROBLEM heading organiser -->
                              <organiser>
                                 <name>Problem</name>
                                 <meaning>problem</meaning>
                                 <content>
                                    <items>
                                       <item>
<!-- ENTRY -->
                                          <entry>
<!-- OBSERVATION -->
                                             <name>Stroke</name>
                                             <meaning>diagnosis</meaning>
                                             <entry_type>observation</entry_type>
<!-- some other attributes here that we dont really need for the prototype -->
                                          </entry>
                                       </item>
                                    </items>
                                 </content>
                              </organiser>
                           </item>
                           <item>
<!-- PLAN heading organiser -->
                              <organiser>
                                 <name>Plan</name>
                                 <meaning>plan</meaning>
                                 <content>
                                    <items>
                                       <item>
<!-- INSTRUCTION EXECUTION ENTRY -->
                                          <?xml version="1.0" encoding="UTF-8"?>
                                          <Entry xmlns:xpdl="http://www.wfmc.org/2002/XPDL1.0"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
                                             <entry_type>Instruction_Execution</entry_type>
                                             <data />
                                             <protocol />
                                             <reasoning />
                                             <instruction_execution_state>eligible</instruction_execution_state>
<instruction_definition>/openehr.instruction_definition.esd.v1</instruction_definition>
<instruction_execution_id>pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1(falco@28 July
2004)</instruction_execution_id>
                                             <Connector_Instances>
                                                …
                                             </Connector_Instances>
                                             <Activity_Instances>
                                                <Clinical_Intervention_Activity>
<activity_instance_id>pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1/esd_v0_Wor1_Act1(falco@28 July
2004)</activity_instance_id>
                                                   <activity_instance_name>Review_patient</activity_instance_name>
<activity_definition>openehr.instruction_definition.esd.v1/esd_v0_Wor1_Act1</activity_definition>
                                                   <activity_execution_state>eligible</activity_execution_state>
                                                   <subject_state />
                                                   <data_collected>openehr.transaction-event.esd_review_report.v1;
openehr.transaction-event.patient_consent.v1</data_collected>
                                                   <patient_state_goal />
                                                   <patient_state_target />
                                                   <work_item>ascertain patient needs</work_item>
                                                   <role>ESD_Coordinator</role>
                                                </Clinical_Intervention_Activity>
```

```
                                        <Clinical_Intervention_Activity>
<activity_instance_id>pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1/esd_v0_Wor1_Act2(falco@28    July
2004)</activity_instance_id>
                                            <activity_instance_name>Plan_services</activity_instance_name>
<activity_definition>openehr.instruction_definition.esd.v1/esd_v0_Wor1_Act2</activity_definition>
                                            <activity_execution_state>ineligible</activity_execution_state>
                                            <subject_state />
                                            <data_collected>openehr.transaction-
event.ESD_care_plan.v1</data_collected>
                                            <patient_state_goal>patient     self-management     in     the
home</patient_state_goal>
                                            <patient_state_target />
                                            <work_item>plan services</work_item>
                                            <role>ESD_Coordinator</role>
                                        </Clinical_Intervention_Activity>
                                        <Clinical_Intervention_Activity>
<activity_instance_id>pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1/esd_v0_Wor1_Act3(falco@28    July
2004)</activity_instance_id>
<activity_instance_name>Alternative_referral</activity_instance_name>
<activity_definition>openehr.instruction_definition.esd.v1/esd_v0_Wor1_Act3</activity_definition>
                                            <activity_execution_state>ineligible</activity_execution_state>
                                            <subject_state />
                                            <data_collected>openehr.transaction-
event.referral.v1</data_collected>
                                            <patient_state_goal>longer-term management</patient_state_goal>
                                            <patient_state_target />
                                            <work_item>refer to longer-term care services</work_item>
                                            <role>ESD_Coordinator</role>
                                        </Clinical_Intervention_Activity>
                                        <Clinical_Intervention_Activity>
<activity_instance_id>pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1/esd_v0_Wor1_Act6(falco@28    July
2004)</activity_instance_id>
<activity_instance_name>Provide_info_about_alt_services</activity_instance_name>
<activity_definition>openehr.instruction_definition.esd.v1/esd_v0_Wor1_Act6</activity_definition>
                                            <activity_execution_state>ineligible</activity_execution_state>
                                            <subject_state />
                                            <data_collected />
                                            <patient_state_goal />
                                            <patient_state_target />
                                            <work_item>provide  patient  with  information  about  alternative
services.</work_item>
                                            <role>ESD_Coordinator</role>
                                        </Clinical_Intervention_Activity>
                                        <Composite_Activity>
<activity_instance_id>pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1/esd_v0_Wor1_Act9(falco@28    July
2004)</activity_instance_id>
                                            <activity_instance_name>Refer_patient</activity_instance_name>
<activity_definition>openehr.instruction_definition.esd.v1/esd_v0_Wor1_Act9</activity_definition>
                                            <activity_execution_state>ineligible</activity_execution_state>
                                            <subject_state />
                                            <Connector_Instances />
                                            <Activity_Instances>
                                               <Clinical_Intervention_Activity>
<activity_instance_id>pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1/esd_v0_wor2_Act16(falco@28   July
2004)</activity_instance_id>
                                                   <activity_instance_name>Refer</activity_instance_name>
<activity_definition>openehr.instruction_definition.esd.v1/esd_v0_wor2_Act16</activity_definition>
<activity_execution_state>ineligible</activity_execution_state>
                                                   <subject_state />
                                                   <data_collected>openehr.transaction-
event.Referral.v1</data_collected>
                                                   <patient_state_goal />
                                                   <patient_state_target />
                                                   <work_item>make a referral.</work_item>
                                                   <role>ESD_Coordinator</role>
                                               </Clinical_Intervention_Activity>
                                               <Composite_Activity>
<activity_instance_id>pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1/esd_v0_Wor2_Act6(falco@28    July
2004)</activity_instance_id>
```

```
<activity_instance_name>Refer_to_OT</activity_instance_name>
<activity_definition>openehr.instruction_definition.esd.v1/esd_v0_Wor2_Act6</activity_definition>
<activity_execution_state>ineligible</activity_execution_state>
                                                    <subject_state />
                                                    <Connector_Instances />
                                                    <Activity_Instances>
                                                       <Clinical_Intervention_Activity>
<activity_instance_id>pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1/esd_v0_wor3_Act1(falco@28    July
2004)</activity_instance_id>
<activity_instance_name>Home_Assessment</activity_instance_name>
<activity_definition>openehr.instruction_definition.esd.v1/esd_v0_wor3_Act1</activity_definition>
<activity_execution_state>ineligible</activity_execution_state>
                                                          <subject_state />
                                                          <data_collected>openehr.transaction-
event.OT_Assessment.v1; openehr.transaction-event.Equipment_Order.v1</data_collected>
                                                          <patient_state_goal />
                                                          <patient_state_target />
                                                          <work_item>perform      home      assessment      of
patient.</work_item>
                                                          <role>Occupational_Therapist</role>
                                                       </Clinical_Intervention_Activity>
                                                       <Administrative_Activity>
<activity_instance_id>pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1/esd_v0_wor3_Act6(falco@28    July
2004)</activity_instance_id>
<activity_instance_name>Seek_Housing_Trust_Approval</activity_instance_name>
<activity_definition>openehr.instruction_definition.esd.v1/esd_v0_wor3_Act6</activity_definition>
<activity_execution_state>ineligible</activity_execution_state>
                                                          <subject_state />
                                                          <work_item>send    request    of    request    for
approval.</work_item>
                                                          <role>Occupational_Therapist</role>
                                                       </Administrative_Activity>
                                                       <Clinical_Intervention_Activity>
<activity_instance_id>pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1/esd_v0_wor3_Act8(falco@28    July
2004)</activity_instance_id>
<activity_instance_name>Deliver_Equipment_and_Educate</activity_instance_name>
<activity_definition>openehr.instruction_definition.esd.v1/esd_v0_wor3_Act8</activity_definition>
<activity_execution_state>ineligible</activity_execution_state>
                                                          <subject_state />
                                                          <data_collected />
                                                          <patient_state_goal />
                                                          <patient_state_target />
                                                          <work_item>deliver equipment to patient and educate
patient on equipment use.</work_item>
                                                          <role>Occupational_Therapist</role>
                                                       </Clinical_Intervention_Activity>
                                                       <Clinical_Intervention_Activity>
<activity_instance_id>pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1/esd_v0_wor3_Act10(falco@28   July
2004)</activity_instance_id>
<activity_instance_name>Follow_Up</activity_instance_name>
<activity_definition>openehr.instruction_definition.esd.v1/esd_v0_wor3_Act10</activity_definition>
<activity_execution_state>ineligible</activity_execution_state>
                                                          <subject_state />
                                                          <data_collected />
                                                          <patient_state_goal />
                                                          <patient_state_target />
                                                          <work_item>follow up on patient.</work_item>
                                                          <role>Occupational_Therapist</role>
                                                       </Clinical_Intervention_Activity>
                                                       <Clinical_Intervention_Activity>
<activity_instance_id>pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1/esd_v0_wor3_Act11(falco@28   July
2004)</activity_instance_id>
<activity_instance_name>Make_Further_Modifications</activity_instance_name>
<activity_definition>openehr.instruction_definition.esd.v1/esd_v0_wor3_Act11</activity_definition>
<activity_execution_state>ineligible</activity_execution_state>
                                                          <subject_state />
                                                          <data_collected />
                                                          <patient_state_goal />
                                                          <patient_state_target />
```

<work_item>make any further modifications on equipment.</work_item>
<role>Occupational_Therapist</role>
</Clinical_Intervention_Activity>
<Null_Activity>
<activity_instance_id>pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1/esd_v0_wor3_Act15(falco@28 July 2004)</activity_instance_id>
<activity_instance_name>Route</activity_instance_name>
<activity_definition>openehr.instruction_definition.esd.v1/esd_v0_wor3_Act15</activity_definition>
<activity_execution_state>ineligible</activity_execution_state>
<subject_state />
</Null_Activity>
</Activity_Instances>
</Composite_Activity>
<Composite_Activity>
<activity_instance_id>pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1/esd_v0_Wor2_Act7(falco@28 July 2004)</activity_instance_id>
<activity_instance_name>Refer_to_RDNS</activity_instance_name>
<activity_definition>openehr.instruction_definition.esd.v1/esd_v0_Wor2_Act7</activity_definition>
<activity_execution_state>ineligible</activity_execution_state>
<subject_state />
<Connector_Instances />
<Activity_Instances />
</Composite_Activity>
<Composite_Activity>
<activity_instance_id>pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1/esd_v0_Wor2_Act13(falco@28 July 2004)</activity_instance_id>
<activity_instance_name>Refer_to_Physiotherapist</activity_instance_name>
<activity_definition>openehr.instruction_definition.esd.v1/esd_v0_Wor2_Act13</activity_definition>
<activity_execution_state>ineligible</activity_execution_state>
<subject_state />
<Connector_Instances />
<Activity_Instances />
</Composite_Activity>
<Composite_Activity>
<activity_instance_id>pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1/esd_v0_Wor2_Act14(falco@28 July 2004)</activity_instance_id>
<activity_instance_name>Refer_to_Speech_Therapist</activity_instance_name>
<activity_definition>openehr.instruction_definition.esd.v1/esd_v0_Wor2_Act14</activity_definition>
<activity_execution_state>ineligible</activity_execution_state>
<subject_state />
<Connector_Instances />
<Activity_Instances />
</Composite_Activity>
<Composite_Activity>
<activity_instance_id>pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1/esd_v0_Wor2_Act15(falco@28 July 2004)</activity_instance_id>
<activity_instance_name>Refer_to_Social_Worker</activity_instance_name>
<activity_definition>openehr.instruction_definition.esd.v1/esd_v0_Wor2_Act15</activity_definition>
<activity_execution_state>ineligible</activity_execution_state>
<subject_state />
<Connector_Instances />
<Activity_Instances />
</Composite_Activity>
<Null_Activity>
<activity_instance_id>pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1/esd_v0_wor2_Act12(falco@28 July 2004)</activity_instance_id>
<activity_instance_name>Route</activity_instance_name>
<activity_definition>openehr.instruction_definition.esd.v1/esd_v0_wor2_Act12</activity_definition>
<activity_execution_state>ineligible</activity_execution_state>
<subject_state />
</Null_Activity>
</Activity_Instances>
</Composite_Activity>
<Clinical_Intervention_Activity>
<activity_instance_id>pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1/esd_v0_wor1_Act10(falco@28 July 2004)</activity_instance_id>
<activity_instance_name>Order_basic_equipment</activity_instance_name>
<activity_definition>openehr.instruction_definition.esd.v1/esd_v0_wor1_Act10</activity_definition>

<activity_execution_state>ineligible</activity_execution_state>
<subject_state />
<data_collected>openehr.transaction-event.order_basic_equipment.v1</data_collected>
<patient_state_goal>assist patient in the home via basic equipment installment.</patient_state_goal>
<patient_state_target />
<work_item>order and deliver basic equipment for patient.</work_item>
<role>ESD_Coordinator</role>
</Clinical_Intervention_Activity>

<Clinical_Intervention_Activity>
<activity_instance_id>pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1/esd_v0_wor1_Act11(falco@28 July 2004)</activity_instance_id>
<activity_instance_name>Follow_up</activity_instance_name>
<activity_definition>openehr.instruction_definition.esd.v1/esd_v0_wor1_Act11</activity_definition>
<activity_execution_state>ineligible</activity_execution_state>
<subject_state />
<data_collected />
<patient_state_goal />
<patient_state_target />
<work_item>follow up on patient.</work_item>
<role>ESD_Coordinator</role>
</Clinical_Intervention_Activity>
<Data_Collection_Activity>
<activity_instance_id>pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1/esd_v0_wor1_Act12(falco@28 July 2004)</activity_instance_id>
<activity_instance_name>Prepare_discharge</activity_instance_name>
<activity_definition>openehr.instruction_definition.esd.v1/esd_v0_wor1_Act12</activity_definition>
<activity_execution_state>ineligible</activity_execution_state>
<subject_state />
<data_collected>openehr.transaction-event.ESD_Summary.v1</data_collected>
<work_item>prepare ESD discharge.</work_item>
<role>ESD_Coordinator</role>
</Data_Collection_Activity>
<Null_Activity>
<activity_instance_id>pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1/esd_v0_wor1_Act14(falco@28 July 2004)</activity_instance_id>
<activity_instance_name>Route</activity_instance_name>
<activity_definition>openehr.instruction_definition.esd.v1/esd_v0_wor1_Act14</activity_definition>
<activity_execution_state>ineligible</activity_execution_state>
<subject_state />
</Null_Activity>
<Administrative_Activity>
<activity_instance_id>pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1/esd_v0_wor1_Act15(falco@28 July 2004)</activity_instance_id>
<activity_instance_name>Notify_GP_of_concerns</activity_instance_name>
<activity_definition>openehr.instruction_definition.esd.v1/esd_v0_wor1_Act15</activity_definition>
<activity_execution_state>ineligible</activity_execution_state>
<subject_state />
<work_item>send notification to GP about patient concerns.</work_item>
<role>ESD_Coordinator</role>
</Administrative_Activity>
<Administrative_Activity>
<activity_instance_id>pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1/esd_v0_wor1_Act19(falco@28 July 2004)</activity_instance_id>
<activity_instance_name>Notify_GP</activity_instance_name>
<activity_definition>openehr.instruction_definition.esd.v1/esd_v0_wor1_Act19</activity_definition>
<activity_execution_state>ineligible</activity_execution_state>
<subject_state />
<work_item>notify the GP.</work_item>
<role>ESD_Coordinator</role>
</Administrative_Activity>
<Administrative_Activity>
<activity_instance_id>pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1/esd_v0_wor1_Act20(falco@28 July 2004)</activity_instance_id>

```
                                                <activity_instance_name>Notify_patient</activity_instance_name>
<activity_definition>openehr.instruction_definition.esd.v1/esd_v0_wor1_Act20</activity_definition>
                                                <activity_execution_state>ineligible</activity_execution_state>
                                                <subject_state />
                                                <work_item>notify patient.</work_item>
                                                <role>ESD_Coordinator</role>
                                             </Administrative_Activity>
                                             <Null_Activity>
<activity_instance_id>pat1@ehr.unisa.edu.au/openehr.instruction_definition.esd.v1/esd_v0_wor1_Act21(falco@28    July
2004)</activity_instance_id>
                                                <activity_instance_name>End</activity_instance_name>
<activity_definition>openehr.instruction_definition.esd.v1/esd_v0_wor1_Act21</activity_definition>
                                                <activity_execution_state>ineligible</activity_execution_state>
                                                <subject_state />
                                             </Null_Activity>
                                          </Activity_Instances>
                                       </Entry>
                                    </item>
                                 </items>
                              </content>
                           </organiser>
                        </item>
                     </items>
                  </content>
               </organiser>
<!-- append any additional problem/plans here for Post-Stroke Rehabilitation -->
               </item>
            </items>
         </content>
         <context>
            <health_care_facility>EHR@UniSA</health_care_facility>
            <time>
<!-- start and end times of the clinical session -->
28-07-2004 09:14; 28-07-2004 10:02
            </time>
            <participations>
<!-- parties involved in the clinical session. e.g., GP, and the patient. -->
               <participation>
<!-- patient ID -->
pat1
               </participation>
               <participation>
<!-- provider ID -->
smith
               </participation>
            </participations>
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   </versioned_transaction>
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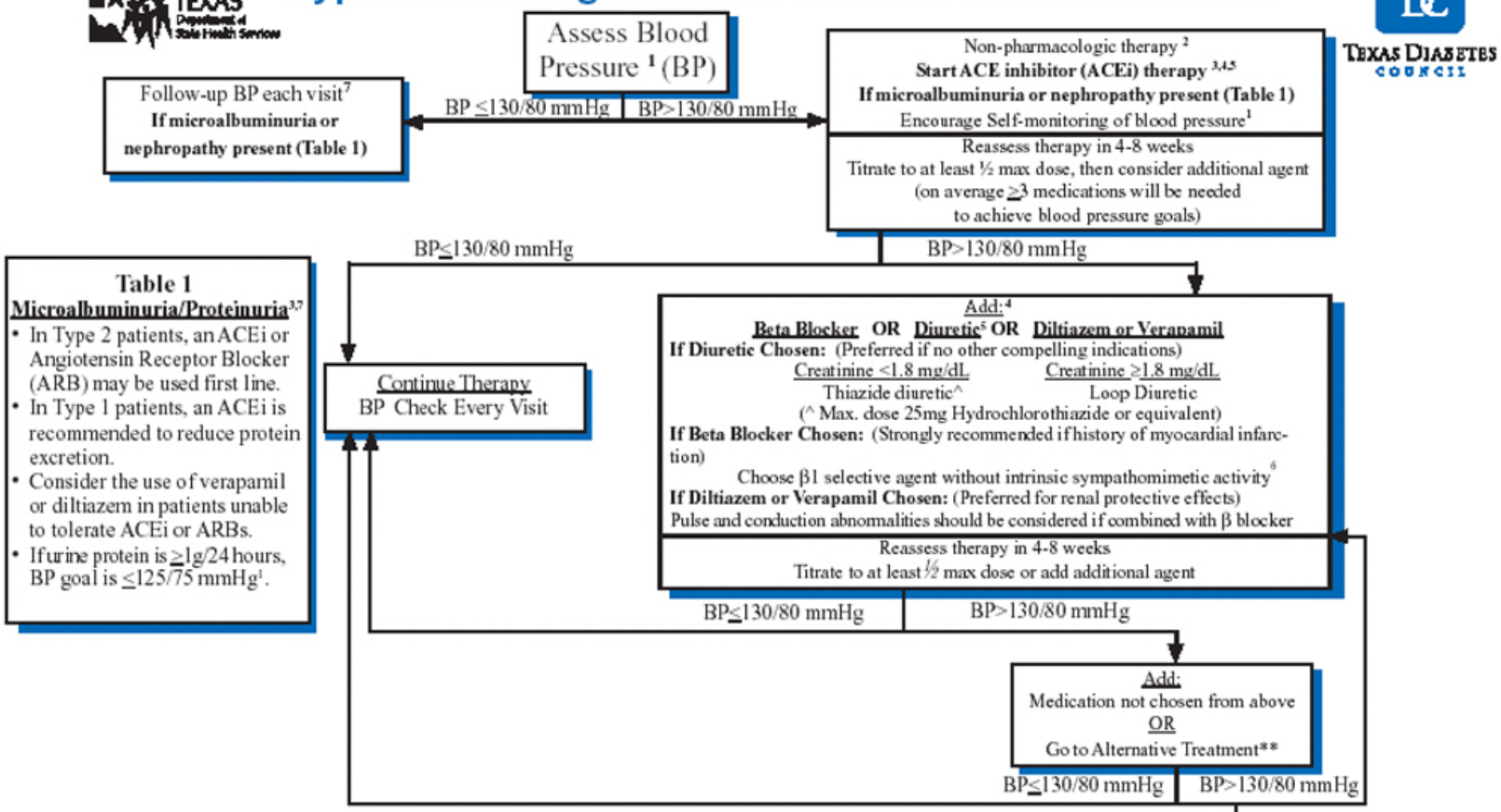
Publication # 45-11267

TEXAS Department of State Health Services

Hypertension Algorithm for Diabetes Mellitus in Adults

Revised 01-22-04

TEXAS DIABETES COUNCIL



Footnotes

1. Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure: The Seventh Report of the Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure (JNC 7). *JAMA* 2003;289(19):2560-2572
2. Medical Nutrition Therapy Algorithm + low sodium diet (<2.4gm/day) + limit alcohol intake (1 oz. for men, 0.5 oz. for women) Weight Loss and Exercise Algorithms
3. ADA: Clinical Practice Recommendations 2004. *Diabetes Care* 27 (suppl 1):S15-S35; S65-S68, 2004.
4. Early combination therapy may be warranted if systolic BP ≥145mmHg and/or diastolic BP ≥ 90mmHg *Am J Kid Dis.* 2000;36:646–661.
5. Monitor serum K+ and creatinine periodically.
6. Atenolol, metoprolol, bisoprolol, carvedilol
7. In the HOPE trial, ramipril titrated to 10mg QD was shown to decrease macrovascular events in normotensive individuals age ≥55 yrs with one other cardiovascular risk factor. Heart Outcomes Prevention Evaluation Study Investigators. *Lancet.* 2000:355:253–259.
8. Amlodipine, felodipine, isradipine, nicardipine, nifedipine, nislodipine

Bibliography on back

****Alternative treatment**

BP >130/80 mmHg despite above agents or if intolerance/contraindications exist:

Refer to Specialist (Endocrinologist or Nephrologist)
OR
SWITCH/ADD: Dihydropyridine Calcium Channel Blocker[8]
(Especially useful for isolated systolic hypertension.)
Not to be used without ACEi or ARB agents
OR
ADD: α blocker, hydralazine, clonidine (caution with β blocker)

See web site (http://www.tdh.state.tx.us/diabetes/healthcare/standards.htm) **for latest version.**

APPENDIX G