PATIENT EDUCATION BASED ON CLINICAL PRACTICE GUIDELINE RECOMMENDATIONS TO IMPROVE SHARED DECISION MAKING IN HEALTHCARE USING SEMANTIC WEB TECHNOLOGY

by

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Signature of Author

To my parents
Syed Sadiq Hussain and Farhat Hussain

And

My family

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Abstract

Patient education and evidence-based clinical practice are two important issues with respect to improving health outcomes. However, there is a "communication gap" between physicians and patients at the point of care. To improve patient compliance and health outcomes, there is a need to reduce this communication gap, and improve shared decision making between patients and physicians. We propose a patient education framework based on clinical practice guidelines (CPG-PE)—to improve shared decision making in healthcare using Semantic Web technologies. We present a comprehensive knowledge model to represent patient education materials. We demonstrate that computerized CPGs can be used to generate personalized patient education materials from available patient education by incorporating them into our CPG-PE framework. Our CPG-PE framework would serve as a clinical decision support system to the physicians and patients by generating education materials for the patients based on their disease condition(s) and co-morbidities, along with psychosocial and behavioral factors.

List of Abbreviations and Symbols Used

AAT: Alpha -1 Antitrypsin Deficiency

ACOG: American College of Obstetricians and Gynecologists

ALT: Alanine Aminotransferase

aPTT: activated Partial Thromboplastin Time

ARDS: Acute Respiratory Distress Syndrome

ARF: Acute Renal Failure

AST: Aspartate Aminotransferase

BMI: Body Mass Index

CBC: Complete Blood Count

CDSS: Clinical Decision Support System

CEA: Carcinoembryonic Antigen

CHESS: Comprehensive Health Enhancement Support System

COPD: Chronic Obstructive Lung Disease

CPGs: Clinical Practice Guidelines

CPG-PE: Clinical Practice Guideline-Patient Education Framework

Cr: Serum Creatinine

CRC: Colorectal Cancer

CT: Computed Tomography

CVD: Cardiovascular Disease

DCT: Data Capture Template

DKA: Diabetic Ketoacidosis

DVT: Deep Vein Thrombosis

EBM: Evidence Based Medicine

EHR: Electronic Health Record

EPR: Electronic Patient Record

FDG-PET: 2-[18F]-fluoro-2-deoxy-D-glucose positron emission tomography

GEM: Guideline Element Module

GERD: Gastro-esophageal Reflux Disease

Glu: Glucose

HNPCC: Hereditary non-polyposis colorectal cancer

HTN: Hypertension

IBS: Irritable Bowel Syndrome

INR: International Normalize Ratio

IUGR: Intrauterine Growth Restriction

LDH: Lactate Dehydrogenase

LDL: Low Density Lipoproteins

LEAF: Layman Education and Activation Form

LFTs: Liver Function Tests

MI: Myocardial Infarction

MLMs: Medical Logic Modules

MRI: Magnetic Resonance Imaging

MS: Multiple Sclerosis

NICE: National Institute for Health and Clinical Excellence Guidelines

NLG: Natural Language Generating

NSAIDs: Nonsteroidal Anti-inflammatory Drugs

PDF: Portable Document Format

PE: Patient Education

PEMs: Patient Education Materials

PEAS: Patient Education and Activation System

PECS: Patient Education and Counselling System

PEO: Patient Education Ontology

PET: Positron Emission Tomography

PHI: Personalized Healthcare Information

PHIDS: Personalised Healthcare Information Delivery System

PT: Prothrombin Time

PULSE: Personalisation Using Linkages of SCORE and behaviour change readiness to Web-based Education

RA: Rheumatoid Arthritis

SCORE: Systematic COronary Risk Evaluation

SDM: Shared Decision Making

SOGC: Society of Obstetricians and Gynaecologists of Canada

STEMI: ST segment Elevation Myocardial Infarction

TD: Topic-specific Document

TTP: Thrombotic Thrombocytopenic Purpura

US: Ultrasound

VTE: Venous Thromboembolism

WBC: White Blood Cell

XML: Extensible Markup Language

Acknowledgements

As a Medical Doctor, with few years of clinical experience in General Surgery and Urology, along with one academic year of medical school teaching as a full-time lecturer in the Department of Anatomy, I came to Canada to pursue my master in Health Informatics.

When I was working in a tertiary care hospital, I realized the need of health informatics to bridge the knowledge gap in healthcare, which ends up in adverse events and outcomes that are the consequences of preventable errors. It made me to make a temporary transition in my career from Clinical Medicine to Master of Health Informatics, to gain some knowledge about informatics which I could apply in my clinical work in future.

Master of Health Informatics at Dalhousie University was a challenging and different experience due to lack of any background in Information Technology. It would not have been possible to complete this journey without encouragement and moral support of my parents and family, especially constant support of my elder brother, Dr. Syed Sajjad Hussain.

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Chapter 1

1. Introduction

In recent times, along with appropriate clinical practice, patient education has come across as an extremely important issue to improve health outcomes. Along with safe clinical practice based on Evidence Based Medicine (EBM), patient self-education about personal health can create better health outcomes. Physicians and other healthcare professionals usually manage a broad range of issues related to the patient i.e. diagnoses, management, follow-up etc., and if the patient is well-informed and educated about these issues, quality of care is improved [1]. However, patient education does not mean that physician advice is not needed anymore. There is a need for physician advice, patient education, and information interventions to run in parallel. Physician advice acts as a catalyst for change and is supported by a coordinated system of information and educational interventions [2]. Unfortunately there is a "communication gap" between clinicians and patients, which creates patient noncompliance. This noncompliance increases the work load as well as expenditures in healthcare. A number of studies have shown that patient compliance and better health outcomes are strongly correlated to the patients' understanding of their condition, diagnostic procedures, prescribed treatment and surgical or other interventions [3-7]. Better health outcomes require better communication between patients and healthcare professionals, as well as proper knowledge resources that are available and accessible to the patients. Physicians typically do not have large amounts of time to either explain their diagnostic procedures and criteria for differential diagnoses, or discuss their rationale for the prescribed therapy and management plan [6-8]. According to Petrella et al [9], most family physicians do not routinely counsel their patients in clinical practice about risk factors, life style modification, physical activity and exercise. For example, a survey of family physicians in five European countries by Hobbs et al [10] found that 65% of physicians spend 15 minutes or less discussing risk factors and lifestyle modification with patients on risk of coronary heart disease, and 24% spend between only 6 and 10 minutes. Moreover,

physicians and other health professionals have not been using evidence-based medicine and clinical practice guidelines (CPGs) in their routine clinical practices. Therefore, there is a difference between optimal practice and actual care in the health sector. Grol et al [11] reported that at least 30-40% of patients do not receive clinical care according to recent knowledge, such as EBM, and 20% of the care provided is unwarranted or potentially harmful. Some other studies also show that despite many years of efforts to improve the quality of patient care, in terms of disease surveillance and quality of life, many patients receive inappropriate or even detrimental care. For example, American figures point out the *overuse*, *underuse* or *misuse* of care [12, 13]. Patient care in the real clinical settings can be improved by using Evidence-based CPGs in the process of care. However, once the evidence based CPGs are produced, either they are not freely disseminated or fully fitted into the specific clinical settings. Even after dissemination, evidence based guidelines are not used [14], and there are serious deficiencies in the adaptation of CPGs in clinical practice [15]. This is the reason why the proper use of guidelines is a more complex problem than the failure to adapt CPGs for practice [11-13].

Patient compliance and improved health outcomes are strongly related to the patients' understanding of their disease conditions and co-morbidities, and the prescribed treatment and management options [3-7]. To have a better understanding of their conditions and management options, they require appropriate and easily accessible and understandable information regarding all modalities. Studies have suggested that lack of information has been identified as a major and crucial factor among 250 reasons why patients do not take their medicines as prescribed by the physicians [16]. They should know the diagnostic criteria, decision options, and the rationale for the management and therapy in a very simple and layman language. Provision of appropriate and timely available information in a suitable form is therefore crucial [16]. Patient education also depends upon scientific evidence and evidence-based guidelines. Despite the wide availability of a great number of scientific evidence and CPGs in the medical journals and over internet websites, physicians and other health professionals do not often follow evidence-based CPGs in their routine clinical practices, even after widespread dissemination [14, 15]. Also, physicians have identified a number of barriers and

difficulties to implementing guidelines and providing the education and information to the patients which are important for behavioural modification [17].

EBM and use of CPGs are not only important for providing appropriate information to the patient for patient education purposes, but also to improve clinical practice on recent trends and conduct further clinical trials. There were many efforts by physicians, health professionals and other healthcare stakeholders to educate patients about their personal health issues, such as handouts, pamphlets, commercial ads, satellite channels, internet websites and counselling by the physician in his/her office. The major issues regarding these ways of patient education (except counselling by the physicians) is the reliability and authenticity of the source of domain knowledge ─i.e. how much information is appropriate, recent, authentic, and evidence-based. Studies have shown that, there are already over 10 000 health related websites, and more than one third of internet users access the World Wide Web to retrieve health and medical information [18]. Unfortunately, much of this material is inaccurate or misleading to the patients [19, 20]. Moreover, how much of that information is easily available and helpful at the point of care to improve patient compliance and better health outcomes?

1.1. Patient Education Materials (PEMs)

Patient education as defined by Simonds is "the process of changing knowledge, attitudes and skills and influencing behaviour to maintain and improve health" [21]. Patient education refers to a set of educational activities or interventions designed to improve patients' health behaviours and/or health status [22]. Patient Education Materials (PEMs) are the documents intended to help patients to better understand their disease/clinical conditions. PEMs are designed to improve clinical practice that mainly focuses on the patients [23]. The objective of patient education is to encourage patients' active participation in their treatment choices and rehabilitation, which is an integral part of good quality health care [24]. PEMs educate patients about disease conditions, risk factor modification and prevention, treatment choices and self-management. They also provide means of counselling for the patients and improve decision making of the patients. PEMs assist patients in changing behaviour and improving decision-making and coping skills [25]. Patient education does not merely provide information, but it should also improve

the decision making and technical skills of the patients. Studies have shown that, traditionally patient education comprises information and technical skill through which a patient, especially with chronic conditions, must improve their decision making skills and how to cope the problem on a day-by-day basis [26].

1.2. Shared Decision Making (SDM)

Efficient and effective communication provide successful information exchange between the physician and the patient, which is very crucial during the clinical encounter [27]. Shared medical decision making is a process by which patients and physicians or health professionals consider outcome probabilities, patient preferences, and reach a health care decision based on mutual agreement between them [28]. SDM has been called the crux of patient-centered care, and identified as an essential element in the process of change to improve quality and safety in health care, as well as improve health outcomes [29]. The patients and physicians or health professionals interact with each other to exchange information, and combine knowledge and expertise in order to proceed towards a mutually agreed decision, which is best in favor of the patient's health and their wish and desire. This depends on the Patient-Physician relationship. There are various patient-physician relationships or patient education models, such as the libertarian model, the paternalistic model, and the psychodynamic model. These days, healthcare is going from the traditional paternalistic model of medical decision making towards the patient-centered one, i.e. shared decision-making [30].

The psychodynamic model [31] encourages shared decision making between the patients and the physicians to choose the desired and most appropriate diagnostic and therapeutic modalities in the process of care. It describes the educational role of the physicians as well as how physicians feel about patient's concerns and family pressures, and their cultural values and beliefs [31]. This model covers emotional, psychosocial, and all other factors along with the management of the disease condition(s) during the process of care. It aims to facilitate all patient-physician interactions because emotional, psychosocial, and moral issues all are important during a clinical encounter [32]. William Osler said, "*The good physician treats the disease; the great physician treats the patient who has the disease*". It is all about patient satisfaction and compliance, not merely the

treatment of their illnesses. It is the main reason why shared decision making is so crucial in healthcare. The idea is to produce more informed and educated patients, so they can actively participate in the process of care related to their own health condition(s). It will also come in line with their social and cultural beliefs, in order to improve patients' satisfaction, patients' compliance and health outcomes.

1.3. Research Objective

Our Research objective is to develop an ontology based patient education framework (CPG-PE), which delivers the following, based on CPG(s) recommendations upon execution:

1. Delivers patient-specific education based on clinical recommendations provided by CPG(s) related to their disease condition(s) and co-morbidities according to their health profile during the process of care.
2. Addresses and highlights psychosocial aspects of disease condition etiology and their impact on the patient health condition(s) outcomes.
3. Encourages patients' preference and choices among different modalities and options of diagnostics and therapeutics during the course of the management of their disease condition(s).
4. Improves shared decision making between patients and physicians at the point of care.
5. Produces well-informed patients, so they can actively participate in the management of their disease condition(s), and act upon the recommended advises by their physicians i.e. improve patient compliance for better health outcomes.
6. This CPG-PE framework should be comprehensive enough to address and incorporate multiple disease conditions in order to provide patient education related to various disease conditions from different medical disciplines and specialities.

Our aim is to develop a CPG based patient education framework i.e. CPG-PE Framework. Development of a rule-based engine or using decision logic to develop a decision support system is beyond the scope of this research work.

1.4. Research Challenges

During the course of patient care, patients require appropriate, easily accessible and understandable information regarding all modalities to have a better understanding of their conditions and management options. Physicians typically do not have large amounts of time to explain their diagnostic procedures and rationale for the prescribed therapy and management plan [6-8], and physicians and other health professionals have not been using clinical guidelines in their routine clinical practice [11]. There have been various efforts by physicians, health professionals and other healthcare stakeholders to educate patients about their conditions and management options through handouts, pamphlets, commercial ads, satellite channels, internet websites and counselling by the physician in his/her office. However, studies in general practice settings show that the patients had forgotten half of what the doctor had advised to them within a few minutes of leaving the consulting room or doctor's office [16]. It is due to the fact that the information is overwhelming for them or anxiety or fear of a doctor's clinic. Sometimes patients denied that they had been advised by their physicians [16]. In such situations, patients became unaware and uneducated about how to cope with a specific disease condition. Also, due to unavailability and lack of time, handing out lengthy descriptions of different illnesses and possible treatments to the patients may deteriorate the condition [16]. Studies suggest that impersonal, general and decontextualized information has negligible impact on patients and health outcomes as compared to the selective and patient-specific information and educational interventions [33, 34]. On the other hand, a study conducted by Tang and Newcomb [35] suggests that, patients preferred to receive information tailored to their own health condition(s).

To overcome the above mentioned issues, the goal of my research is to propose a Patient Education Framework that, upon execution of CPGs, can deliver patient education messages. Those messages will be highly specific to the individual patient according to their disease condition(s) and associated co-morbidities. Those messages will be coming from PEMs library specific to CPG-based recommendations for that individual patient. Studies have shown that patients do not understand the important clinical documents unless clinical personnel review them with patients to ensure comprehension and answer their questions [8]. For this purpose, patient education

messages about a CPG-based recommendation should be in a very simple language, and should be specific to the given patient condition and behaviour. Aiming towards such a patient education framework, the main research challenges are listed as follows:

1. Identifying domain and operational aspects within existing CPG ontology which have patient education aspects, such as diagnoses, therapeutics, diagnostic investigations, risk factors, prevention, immunization, surgical and medical procedures, prognoses, and follow-up —in order to execute them based on patient conditions. For example, concepts such as Data_Element, Provider, Role etc. does not have any patient education aspect. Therefore, we identified classes, sub-classes and properties within this CPG ontology that have patient education aspects, in order to connect them with the concepts in PEMs.
2. Representing the domain knowledge of PEMs in a computer-interpretable format so it provides patient-specific education messages based on their disease condition(s)/co-morbidities upon execution of CPG(s). Currently, these PEMs are written as PDF documents, so we need to convert them in computer-interpretable/executable format. We need to represent PEMs on ontology, so they can be easily connected to CPG(s).
3. Personalization of relevant educational messages and materials about the CPG-based recommendations, specific to patient conditions, co-morbidities, behavioural attitude, and motivational status towards their health in order to increase patients' awareness, motivation, and willingness to change lifestyle and behaviour, and decision making. It will also improve patient-doctor communication during their clinical encounter as patients will be more educated regarding their conditions, as well as it will improve over all patients' compliance and health outcomes.

1.5. Our Solution Approach

Aiming towards the above mentioned research challenges for patient education, our patient education (PE) approach is based on the psychodynamic model to promote shared decision making during a clinical encounter between physician and patient at the point of care. In this approach, recommendations will be coming from CPG(s) and corresponding

patient education materials that will come from the patient education library using the psychodynamic model. The Psychodynamic Model of Balint [31] promotes more complete and deeper diagnosis, describes the role of the physician as medical professional, and also describes the educational role of the physician. It aims to facilitate all patient-physician interactions because emotional, psychosocial, and moral issues all are important during a clinical encounter [32]. Our main aim is to deliver patient education on each recommendation(s) at different steps at the point of care to promote shared decision making during a clinical encounter. Patients will have information about different modalities and their alternatives for the management of their disease condition(s). It will depend on the patients to choose one based on their own preferences, after discussing it with their physicians. The psychodynamic model gives this flexibility and allows this to occur to promote shared decision making in healthcare settings.

We propose a CPG based Patient Education framework (CPG-PE)—based on the psychodynamic model— to improve shared decision making in healthcare using Semantic Web technologies [36]. In our proposed framework, CPG-PE, we employ Semantic Web technologies by: (i) using a SW-based CPG modelling framework, CPG Ontology [37], to identify domain and operational knowledge within CPGs that require patient education; (ii) Modelling and classifying Patient Education Materials (PEMs) in terms of a Patient Education Ontology; (iii) establishing interoperability between the CPG Ontology and PE Ontology by connecting relevant classes, sub-classes and properties in CPG Ontology with the sub-classes and properties in the PE Ontology. Based on the clinical recommendations provided by CPGs, CPG-PE offers information based on CPGs to patients about their own health conditions in the form of PEMs, and reduces the scarcity of the source of the medical knowledge. It will give patient education messages/ materials in a very simple and layman language which can be easily understood by the patient, as it is usually difficult for the patients to understand medical terminologies. Moreover, the education messages will be highly personalized to the individual patient regarding their specific disease condition(s), which will increase patient interest and improve their motivation towards their own health. It will also improve their decision making ability and willingness to change their lifestyle and behaviour. To be short, it will deliver patient specific education messages related to their

disease condition(s), co-morbidities, behavioural attitude, and motivational status towards their health, which would be evidence-based on one hand while maintaining its simplicity and easy readability on the other hand. The solution approach for building a CPG-PE framework is realized in the following main steps:

i) Identifying domain and operational knowledge within CPGs in the CPG ontology [37] that requires patient education.

ii) Classifying Patient Education Materials (PEMs) in a hierarchy according to the disease conditions and types of patient education.

iii) Modelling the disease condition description, risk factor modification and prevention, self-management, nutritional and dietary advice, diagnostic and therapeutic procedures, pre and post-op care, pain management, drug information and adverse reactions, radiation and chemotherapy, exercise and rehabilitation, decision making and counselling, and follow-up education factors described within a PEM as a Patient Education Ontology (PEO). Currently, these PEMs are available in PDF format, accessible for the patients. These patient education materials are solely written for the patients, in order to guide to manage their own disease condition(s). They are written as a comprehensive document related to different disease conditions.

iv) Reviewing the CPG ontology and identifying relevant classes, sub-classes and properties of CPG Ontology that can be augmented with Patient Education Ontology (PEO).

v) Connecting relevant classes, sub-classes and properties in CPG Ontology by linking with the sub-classes and properties in Patient Education Ontology (PEO) into the final merged ontology, CPG-PE Ontology. The final merged ontology will therefore incorporate patient education materials about the disease condition description, diagnoses, therapeutics, diagnostic investigations, risk factors, prevention, immunization, surgical and medical procedures, prognoses, and follow-up content described within a CPG.

vi) Generating patient education messages and materials, specific to patient's condition, co-morbidities, motivational status, life style and behaviour using

the psychodynamic model in order to promote shared decision making at the point of care.

The intended operation of the framework is that, in CPG-PE Ontology, CPG ontology and PE ontology is connected, so at each and every step in the process of care CPG will give some recommendation(s) through its sub-classes and properties. Alongside those recommendations, PEMs will be generated in parallel related to each recommendation of the CPG, through sub-classes and properties representing PE Ontology. At this point, patients will have an idea about each modality related to the management and treatment of their disease condition(s). Patients will choose one modality based on their cultural and psychosocial background, after discussing the options with their physicians. The psychodynamic model gives this flexibility and encourages SDM between patients and physicians. It also encourages physicians to see the patient as a whole, not merely their illnesses and how the physician feels about the patient's concerns, and social and cultural beliefs.

1.6. Thesis Outline

In Chapter 2, we will review some literature providing i) Background of patient education, patient education or patient-physician relationships models, and importance of shared decision making between the patient and the physician during the process of clinical care, and ii) Related work in the field of computerized patient education. We will discuss both generalized patient education and personalized or individualized patient education systems.

In Chapter 3, we will discuss the research methodology for the development of a CPG-PE framework. We will also re-evaluate the problem statement and research goals and objectives, and we will discuss step by step methodology for the development of CPG-PE framework.

In Chapter 4, we will discuss the ontology engineering methodology for patient education ontology by describing PEM knowledge modeling, development of PE ontology, and merging of CPG and PE ontologies.

In Chapter 5, we will evaluate our CPG-PE framework based on three approaches: 1) *Consistency checking of PEO*: If the ontology model and its instantiation has any

inconsistency; 2) *Extensive case study*: Evaluation of our CPG-PE framework on two comprehensive clinical vignettes; and 3) *Systematic evaluation*: Evaluation of CPG-PE framework by comparison of the framework with other related Patient Education Systems.

In Chapter 6, we will conclude our research work with some working limitations along with future research directions.

Chapter 2

2. Patient Education: Background and Related Work

In this chapter we will discuss: i) Background of patient education and shared decision making, and ii) Related work in the field of computerized patient education.

2.1. Background of Patient Education and Shared Decision Making

We will review some literature providing background history of patient education and factors influencing patient education along with patient education or patient–physician relationship models. We will also discuss about the importance of shared decision making between the patient and the physician during the process of clinical care in terms of achieving better patient compliance and improve health outcomes.

2.1.1. Brief History of Patient Education

The idea of Patient Education as a separate discipline and its foundation in health research have evolved in last few decades. The first scientific journal based on Patient Education and Counselling was founded in 1976, at the First International Conference on Patient Counselling [38]. In the last four decades, patient education has been an important and critical issue in the health sector in improving health outcomes. Patient education and counselling should be a mandatory part of communication between health professionals and patients, so health professionals can educate and counsel their patients through interpersonal communication skills and a variety of other means such as patient education materials including leaflets, pamphlets, and more recently, websites and interactive computer-based patient educational programs [38,39]. Currently, healthcare does not move around the management by the health professionals in primary, secondary or tertiary healthcare, but patients participate in the management and decision making regarding their illnesses. Until the 1960s, the physician was the ultimate authority, responsible for the diagnoses, treatment and management of the patients. Patients were viewed as passive, and were not supposed to participate actively in diagnoses and management, nor did they have any role in decision making regarding their treatment options [38]. The major focus in healthcare was on the management of diseases, and there

was little focus on the cure and prevention of diseases through life style and behavioural modifications. In that worrisome situation, Lalonde (1974) acknowledged for the first time that not only the pathological and biomedical aspects of the disease conditions are important in defining health, but patients could also improve their health through behavioural factors related to their life style modifications [40]. Those life style modifications could include changing to a healthy diet, such as decreasing consumption of bad cholesterol i.e., LDL (Low Density Lipoproteins); increasing physical activity and exercise; and quitting addictions such as smoking and drinking alcohol.

Gradually, more emphasis was made on patient education and self-management by some European countries including the Netherlands in the 1970s [41], and by some patient organizations in the United States [42]. Those patient education initiatives included some patient self-help groups and the self-care managements among feminists such as the Boston Women's Health Book Collective. The organization published "Our Bodies, Our Selves" to educate women, to do their self vaginal examination in 1973 [43]. In the 1980s, patient education had an Information Technology transition. In this period slide presentations and videos were the most famous and frequent modes for patient education programs [38]. In the 1990s, more emphasis was placed on the influence of the factors and people in patient's surroundings including spouses, children, and patients' social networks. The influence of these factors brought the introduction of behaviour change interventions such as Buddy Systems [44, 45]. Furthermore, it was the beginning of the electronic age, and the Internet became a common place for the patients to collect information about the health issues. After the 1990s, patient education bridges to the 21st century in terms of different Interactive Computer-based Patient Education Programs [38].

2.1.2. Factors influencing Patient Education

Patient education has had a transition over time. Technology and biomedical advances, such as DNA-diagnostic and gentechnology, brachy-therapy, radical surgery, precision surgery, MRI, IVF etc., as well as cultural diversity have made a profound impact on patient education and healthcare. As the technology advances, it requires better coordination and communication with the patient up to the optimal level of patients' satisfaction [46, 47]. Aging is also a factor which can influence patient education. Many

elder persons live alone for a longer period of time and are responsible for the management of their daily lives including self-management of chronic conditions [38]. Most chronic diseases such as diabetes, hypertension, cancer, heart diseases and dementia occur more often in the elderly and they are more prevalent to co-morbidities as well in this age group [48-50]. Elderly people like to live as they did in their early life and are very much attracted towards the communication channels, which they used in their early lives, as described by Socialization Theory [51]. So, for elderly people above 65 years of age, the newly developed channels like internet and interactive computer-based patient education programs are less suitable. Besides this, cultural diversity could have a profound impact on patient education, as a lot of people have migrated from different regions to Europe and North America [38]. Sometimes, fear, anxiety or interpretation of pain is strongly related to patients' cultural beliefs. Therefore, for meaningful and effective patient education, health professionals should make sure that these activities are in line with the individual patient and family's cultural values and beliefs [52].

To address these issues, first we would highlight the Patient Education or Patient-Physician Relationship Models "and "Theories of Patient Education".

2.1.3. Patient Education or Patient-Physician Relationship Models

Efficient and effective communication between the physician and the patient is the key factor during the clinical encounter, and provides the basis for successful information exchange between physicians and patients [27]. Patient-Physician relationships, which depend on effective communication between the physician and the patient, are necessary to improve patients' compliance and health outcomes. The Patient-Physician relationship is based on multiple factors, such as interpersonal, intrapersonal, and psychosocial and economic factors and is grounded on trust, some degree of paternalism, family input, and evolving mutual and shared understanding [53]. Different Patient-Physician Relationship models [53] are discussed below:

2.1.3.1. The Libertarian Model

The Libertarian Model believes in patient autonomy and encourages self-sufficiency. It encourages physicians to educate their patients and enable them to actively participate in the process of decision making related to their health condition(s) during clinical

encounters. It can provide too much autonomy to the patients and sometimes results in physicians having to give up their autonomy. In this model, patients have the right and can ask for things to be done according to their wishes, which will not necessarily be the best for them. They have the right to request unnecessary procedures to be done, and it is hard for the physicians to deny their requests.

2.1.3.2. The Paternalistic Model

In this model, physicians act as a parent or teacher to provide some degree of guidance to help patients in decision making at the point of care related to their health condition(s). This model was the rule from the time of Hippocrates and Plato [54], until the rise of the concept of Patient Autonomy in the past four decades. In the process of care, physicians act like a teacher who cannot help but influence the students' view of things and point of view, thus influencing their autonomy. In the Paternalistic Model, the physician would educate the patient or merely inform or tell them and the patient would accept the physician's guidance without any question and concern.

2.1.3.3. Beneficence-in Trust

This model, based on an understanding between the patient and the physician, involves patient autonomy and a level of physician beneficence based on mutual trust [55, 56]. Physicians attempt to get to know the social and cultural beliefs of the patient, and make decisions in parallel to the patient's beliefs. The physician understands the patient's point of view of desired "good", and then the physician would fit these goods to what he or she believes to be the optimal care during the clinical encounter. This process involves patient education as well as some beneficent guidance and supervision by the physician [55, 56], which lead to a compromise acceptable to both the patient and the physician.

2.1.3.4. The Accommodation Model

The Accommodation Model of Seigler [57, 58], involves a dynamic relationship between the patient and the physician, but does not emphasize family and societal input. It considers patient autonomy as well as some degree of physician paternalism. It follows a similar process to the model of Beneficence-in-Trust, includes advocacy for the patients' needs and the duty of both patients and physicians.

2.1.3.5. The psychodynamic Model

The Psychodynamic Model of Balint [31], promotes more complete and deeper diagnosis, describes the role of the physician as medicine, and describes the educational role of the physician. This model was developed in seminars of general practitioners in Britain and dealt mainly with psychosomatic problems. It has application to all patient-physician interactions because emotional, psychosocial, and moral issues all are important during clinical encounters [52]. The psychodynamic model requires a more detailed exploration of underlying fears on the patient's part and how the physician feels about this patient's concerns and family pressures, their cultural values and beliefs.

As we discussed earlier in Chapter 1 (see Section 1.2), the psychodynamic model [31] encourages SDM between the patients and the physicians to choose the desired and most appropriate diagnostic and therapeutic modalities in the process of care. It encourages physicians to see the patient as whole including their disease condition(s) and/ or co-morbidities as well as the emotional, behavioral and psychosocial factors during the course of the management of their disease condition(s) in the process of clinical care. It aims to facilitate all patient-physician interactions because emotional, psychosocial, and moral issues all are important during clinical encounters [32]. The psychodynamic model also facilitates patient preferences and encourages the patient to choose the desired diagnostic and therapeutic regimes based on their own preferences and their cultural, religious and health beliefs. Overall, the psychodynamic model encourages SDM between the patient and the physician in the process of clinical care, and SDM facilitates patient preferences in order to choose the desired diagnostic and therapeutic regimes based on their own preferences in the process of clinical care.

2.1.4. Theory of Psychological Reactance

Before discussing patient education theories, some questions arise in our minds, such as why does the patient still do those things we told her or him not to do? Why do they not just start implementing the recommendations and the care plan? Berhm S. and Berhm J. proposed “The Theory of Psychological Reactance”, which explains why people often do the opposite of what they are asked to do, and why efforts to motivate people are often ineffectual [59, 60]. Each person has their own parameters and beliefs in which they could realistically engage, either at present or in the future. Sometimes, encouraging

a person to do something which he or she may already intend to do may actually result in the individual "digging in" and refusing to comply and obey [61]. This situation leads to patient's lack of adherence and non-compliance. One of the solutions to this issue is patient education, based on the individual patient and the family's cultural values and beliefs, to avoid reactance [52]. For patient education, physicians rely on their domain knowledge and clinical experience as well as their professional status to convince the patient to change. Patient education or health education theories suggest how to bring out these changes and modification to improve patient adherence, compliance and health outcomes. We will discuss these patient education theories in the next section.

2.1.5. Theories of Patient Education

Patient education or health education theories are summaries of formal and non-formal observations in healthcare. They are presented in a systematic and structured way that can help to explain, predict, describe or manage health related behaviors [62]. The clinical encounters or medical visits provide great opportunities for the modification of health beliefs and behaviors. Health education theories provide few explanatory mechanisms for understanding this communication process during this period of modification [63]. We discussed earlier, reactance causes patient's lack of adherence and non-compliance, deteriorating health outcomes. So, health education theories and models suggest more effective methods for accomplishing patient compliance, and other behavior change related to the treatment regimens and improve health outcome [64]. Patient Education theories are broadly classified into six categories [62]:

1. Policy level theories
2. Community-level theories
3. Institutional or Organizational- level theories
4. Interpersonal-level theories
5. Intrapersonal-level theories

The discussion of these theories is beyond the scope of this research thesis.

2.1.6. Shared Decision Making

There are classically three models of decision making i.e. traditional, informed and shared. The traditional model of decision-making is the one where the decision is made by the health professional, and patient accepts their decision. It is based on paternalistic

healthcare model, where the physicians and other health professionals are domain experts and take decisions on behalf of the patient, best in their favor irrespective of their wish and preference. In the informed model, the information exchange is still one-way i.e. from physician to patient, but patients take decisions on their own regarding to their health condition(s). The physician's role in this model is just an information source or just to provide information to the patients regarding their health condition(s). This is described as "*a consumer-oriented model… that emphasizes patient sovereignty and patients' rights to make independent autonomous choices... one where a reasoned choice is made reasonable individual using relevant information about the advantages and disadvantages of all the possible courses of action, in accordance with the individual's beliefs* [65]."

As the healthcare is going from the traditional paternalistic model of medical decision making towards the patient-centered one i.e. shared decision making [30]. The traditional paternalistic model of medical decision-making, in which doctors make decisions on behalf of their patients has been outdated, and healthcare is moving towards patient-centered strategies and the idea of shared decision making [66]. The idea is to produce more informed and educated patients, so they can actively participate in the process of care related to their own health condition(s). The shared decision-making model, in which patients and physicians/health professionals interact with each other for exchanging information, and combining knowledge and expertise in order to proceed towards mutually agreed decision, which is best in favor of the patients as well as according to their wish and preferences. It is described as "*the middle ground between medical paternalism and the other extreme where patients are given the sole responsibility for making decisions* [67]." Shared medical decision making is a process by which patients and physicians/health professionals consider outcome probabilities and patients' preferences, and reach a health care decision based on mutual agreement between them [31]. Patients must understand the rationale behind different treatment modalities and their possible pros and cons. However, to promote shared decision making we should consider patient preference and barriers to shared decision making.

2.1.6.1. Patient preferences

Patient preferences are extremely crucial in achieving shared decision-making in routine clinical practice. Often health-related decisions are very difficult to be made because different patients have different preferences based on their own health beliefs and societal input. There is variation in how patients value different outcomes and states of health, and probability, severity and timing of an adverse outcome. There is evidence, some patients may be willing to opt for any therapeutic or diagnostic modality that will lessen the frequency of their symptoms, regardless of risk, while others may prefer to trade off greater symptom frequency for less procedural risk [68]. Moreover, religious, social and cultural beliefs can have a profound influence on clinical decision making during the process of clinical care. Likewise, the level of patients' involvement and their desire in clinical decision-making can also vary as, "*most patients want to see the road map, including alternative routes, even if they don't want to take over the wheel*" [68]. A number of studies have shown that, clinical decision making and the extent of active participation of patients in decision making depends upon the individual preferences and the level of the clinical decision making as follows:

- In a study of 1012 women with breast cancer, 22 % wanted to select their own treatment modality, 44 % wanted to collaborate with their doctors in the process of decision making (shared decision making), and 34 % wanted to leave this responsibility to their doctors, and their preferences vary with their background and the clinical situation [68].
- A Canadian analysis of three qualitative studies of women's decision-making showed that participants' desire for an active role in the decision-making process, and the decision-making process became more complex and confusing when the information available is unclear, scarcity in evidence, or deeply rooted in personal beliefs and values [69].
- A study regarding preference in decision-making among adult asthma patients in the North West of England, found that most respondents wanted to contribute to or get involved in therapeutic decision-making, but not necessarily want to control it [70].

2.1.6.2. Barriers to shared decision making

As patients' preferences vary, it has a huge impact on the shared decision making in healthcare. There is a substantial discrepancy between the preferences of the patients for the role they wanted to have in clinical decision-making, and what they felt actually takes place during the clinical encounter in the process of care. There are several barriers to shared decision making, both on physicians/health professionals as well as patients' sides. Some of the barriers are [71, 72]: i) doctors may not have the appropriate competences; ii) patients' preferences may differ from those of their doctor or evidence-based guidelines; iii) some doctors may wish to retain the imbalance of power between themselves and their patients; iv) patients may be reluctant to share their preferences v) layman knowledge do not coincide with physicians' medical knowledge, its terminology, and medical vocabulary.

2.1.7. Summary

Based on the overall discussion in this chapter, our patient education approach for CPG-PE framework to promote shared decision making is based on psychodynamic model to deliver personalized patient education materials, in order to produce more informed patients and improve clinical decision making and health outcomes. As we discussed earlier (see Section 2.1.6), the healthcare is going from the traditional paternalistic model of medical decision making towards the patient-centered one i.e. shared decision making [30]. The traditional paternalistic model of medical decision-making, in which doctors make decisions on behalf of their patients has been outdated and healthcare is moving towards patient-centered strategies, and the idea of shared decision making [66]. The psychodynamic model [31] encourages SDM between the patient and the physician in the process of clinical care, and it also facilitates patient preferences in order to choose the desired diagnostic and therapeutic regimes based on their own preferences in the process of clinical care. Due to this reason, we choose this model rather than choosing the paternalistic model, which encourages medical paternalism or the libertarian model, which give patients too much authority and encourages patient autonomy. The idea is to produce more informed and educated patients, so they can actively participate in the process of care related to their own health condition(s).

The psychodynamic model encourages the physician to see the patient as a whole, not merely their illnesses, and how the physician feels about patient's concerns, and their social and cultural beliefs [31]. It covers emotional, psychosocial, and all other factors along with the management of the disease condition(s) during the process of clinical care. Our main aim is to deliver patient education material PEMs at each recommendation of CPG(s), in this way patient will have information regarding different choices and modalities related to the treatment and management of their disease condition(s). It will depend on the patients to choose one based on their own cultural and psychosocial background, after discussing it with their physicians. Here we need that kind of patient education model, which encourages patients' autonomy and preference, based on their individual preferences as well as social and cultural beliefs, as these factors are extremely important in clinical decision making at the point of care, evident from different studies [68-70]. The psychodynamic model address these issues, as it encourages shared decision making between physicians and patients as well as how physicians feel about patients' preferences, concerns, and their beliefs. We will discuss our CPG-PE framework, based on this patient education approach in chapter 3.

2.2. Related Work

We will discuss some of the related work, which people have done in terms of computerized patient education. For description, we have divided into two categories; generalized patient education, and personalized or individualized patient education.

2.2.1. GEM-based CPG to generate tailored patient education material

Brent Jones et al [17-73] proposed an approach to generate tailored patient education materials by using an evidence-based clinical practice guideline, using Guideline Element Module (GEM). They converted a Canadian guideline for managing dyslipidemia into the XML-based GEM formalism, and then modified it to support the tailoring of patient education material. They developed a rule engine to process the newly converted GEM-based guideline, and create tailored documents based on patient data entered into the rule engine. Their main idea was to convert a paper-based CPG to GEM (the Guideline Elements Model) format, so the GEM-based CPG can be used as the basis for generating

tailored education materials. The patient education material created, are tailored to patients based on their specific profiles driven by CPGs. These profiles are used to direct the selection of education materials specific to the patient. They achieved these tasks by first convert CPG into XML-based GEM formalism, so it can be processed by a decision support system for physicians and second, the selection and presentation of information to yield patient-specific education materials. The purpose of the research was to demonstrate how a CPG converted to a GEM document can be used as the basis for generating tailored patient education materials. For this purpose, they took following steps:

1. Conversion of pdf format guidelines into a computer interpretable version using GEM
2. Defined tailoring variables for the profile
3. Develop a message library
4. Create a formatted document structure
5. Develop education packet selection algorithm
6. Mode of document dissemination or channel
7. Development of the system for implementation

Implementation of the GEM guideline was done by processing it with a Cocoon-based application consists of two main components: i) a GEM Implementation System, and ii) the Document Selection Application. (see Figure 1)

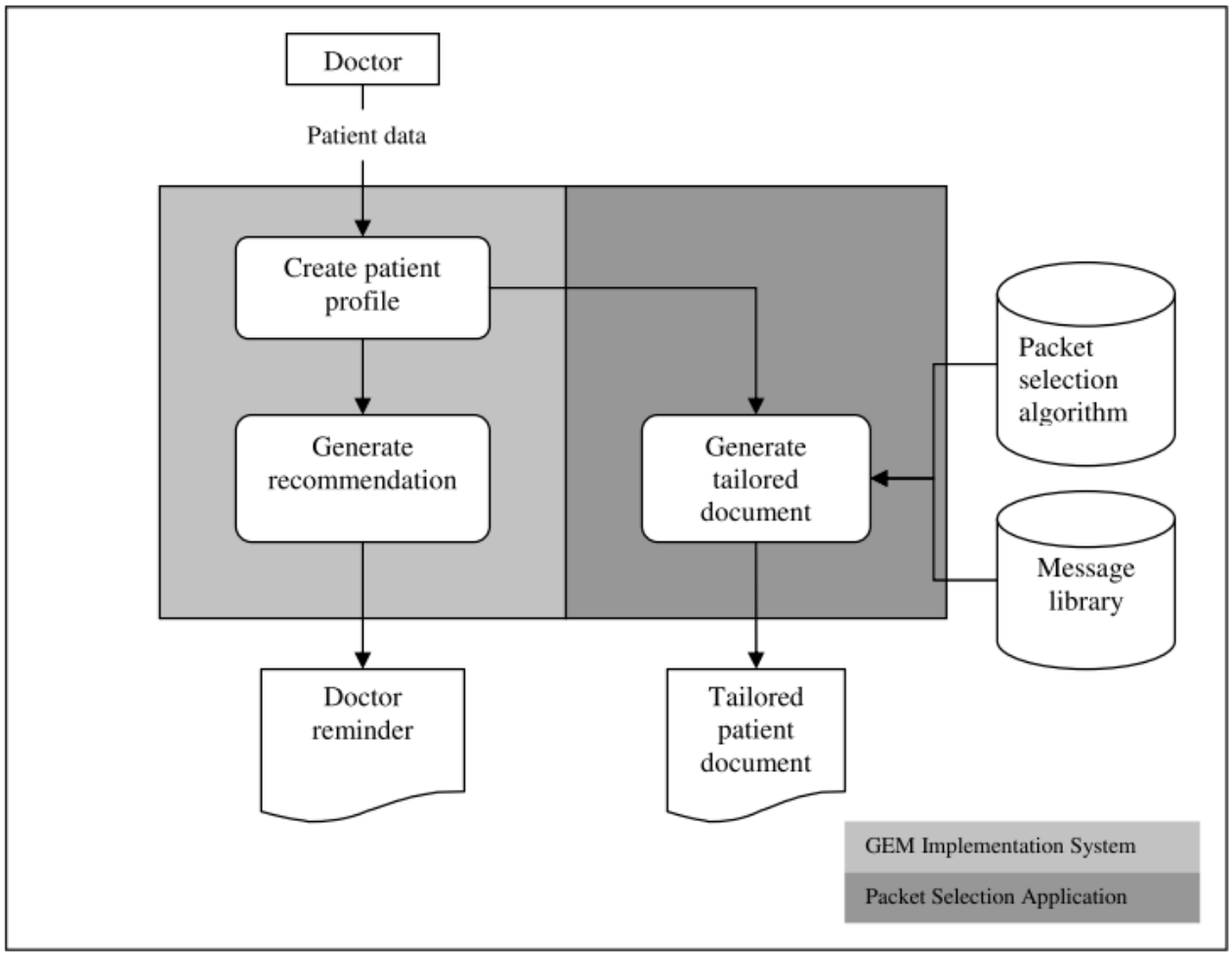

Figure 1: System Design: GEM-based CPG generated tailored patient education materials (taken from [73])

2.2.1.1. GEM implementation system

The purpose of GEM implementation system was to make the guideline case-specific according to individual patient. It was done by allowing clinical data to be entered and showing relevant results. It access and execute through a web browser, and works by dynamically creating input forms for each recommendation in the guideline. It is done by applying an XSLT stylesheet onto the underlying GEM document. This stylesheet, upon entering takes the clinical data and passes it to a rule engine. The rule engine, then processes the data based on this logic (by using logic tags) to determine the appropriate reminder (action statement) to display in the browser for each and every recommendations in the guideline. (see Figure 2)

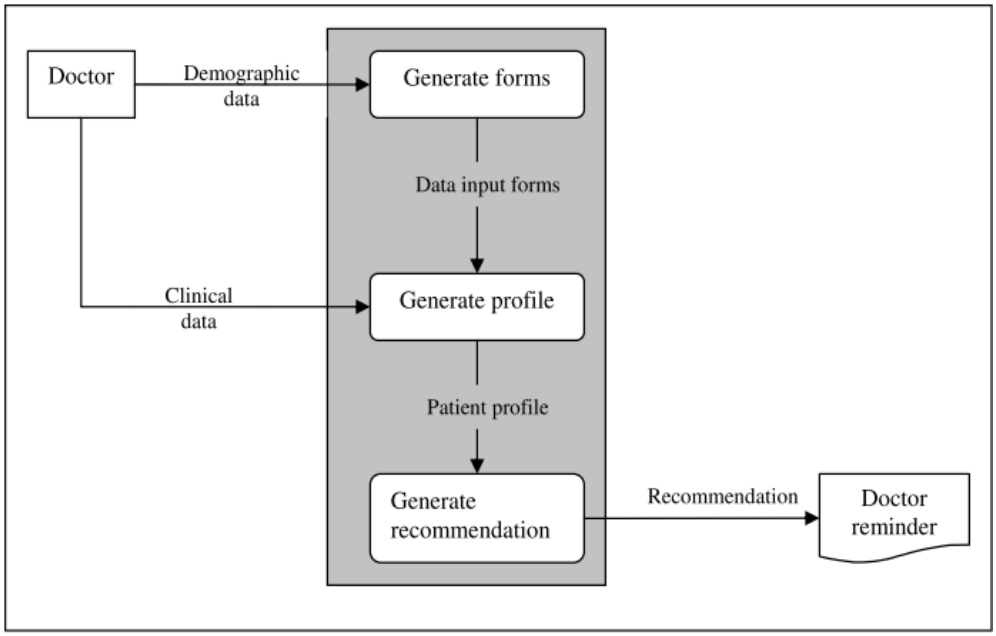

Figure 2: GEM implementation system (Taken from [73])

2.2.1.2. Document selection application

The data collected and generated in the GEM implementation system (i.e. patient's profile) are passed to the document selection application. It is also developed in XML for two reasons: first physicians are likely to able to work on XML rather than JAVA, and second to use the rule engine to process the data and logic. In the document selection application, an XSLT stylesheet takes the data and the logic statements needed to select the documents and passes them to the rules engine. The rule engine uses this to determine the appropriate information packets to assemble from the message library, and the personalized data to insert into those documents. The final result is a complete document tailored to each patient based on his or her own data. (see Figure 3)

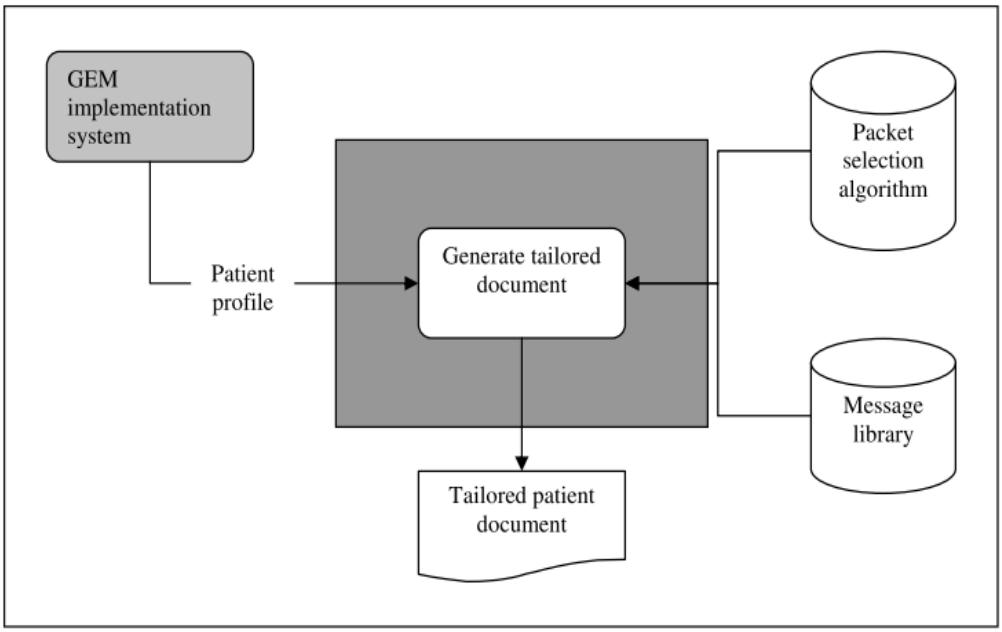

Figure 3: Document selection application (Taken from [73])

2.2.2. Layman Education and Activation Form (LEAF)

The PEAS (Patient Education and Activation System) project [74] aimed to improve medical care by using an artificial intelligence system to educate patients, so that they can actively participate in their health care and play more active role in healthcare decisions. An important component of PEAS is the Layman Education and Activation Form (LEAF) [74, 75]. The LEAF (Layman Education and Activation Form) project consists of a patient history form that explains itself in a dynamic way and addresses patients' questions and concerns in the process of care. LEAF was an intelligent medical history form that provides patients, a relevant set of questions, gives detailed explanations about filling those questions, suggests relevant health topics that the patient might want to pursue, and educates patients on general health issues and conditions. Their main aim and objective was to create more informed, activated and educated patients [75] by taking the kind of data normally input into medical history forms, and using it to help patients by providing the information relevant to their health conditions. The motivation behind the LEAF was to reduce the communication gap between patients and physicians, and to improve doctor-patient communication during the health care process. LEAF aimed to provide a bridge for the communication gap between patients and their doctors [74].

For patients, to get involved in the healthcare process and actively participate in their own health and decision making, they need to have appropriate and relevant information regarding their health condition(s). They should have better understanding about medical terminologies and doctors' vocabulary. LEAF aimed to provide patients, knowledge regarding medical terminologies in a layman language to solve this issue. LEAF tried to make information relevant to patients by using knowledge acquired from the medical forms and gives customized information to the patients without overwhelming the patients [75]. LEAF's main task is to collect medical information about patients from their medical history. To customize health information, it is necessary to have knowledge about patients past medical history, and all previous records related to their health conditions. LEAF undergoes through four main subtasks as follows:

1. To provide patients with instructions on how to fill the form: LEAF can display instructions about the current section of the form being filled by the patient. These instructions are displayed on the patient's request.
2. To acquire knowledge about the patient: LEAF collects information about the patient's medical history through a medical history form.
3. To provide customized medical information to the patient: Patients can obtain customized information about medical terminology and general health matters from LEAF.
4. To suggest relevant topics to the patient: LEAF displays a list of suggested relevant topics to patients on their request.

To accomplish the above four subtasks LEAF used a user model (see Figure 4) - knowledge about the patient that is used to improve the interaction. This user model is very important, because it is used to customize the information displayed, to ask only relevant questions in the medical form, and to suggest relevant topics to the patient.

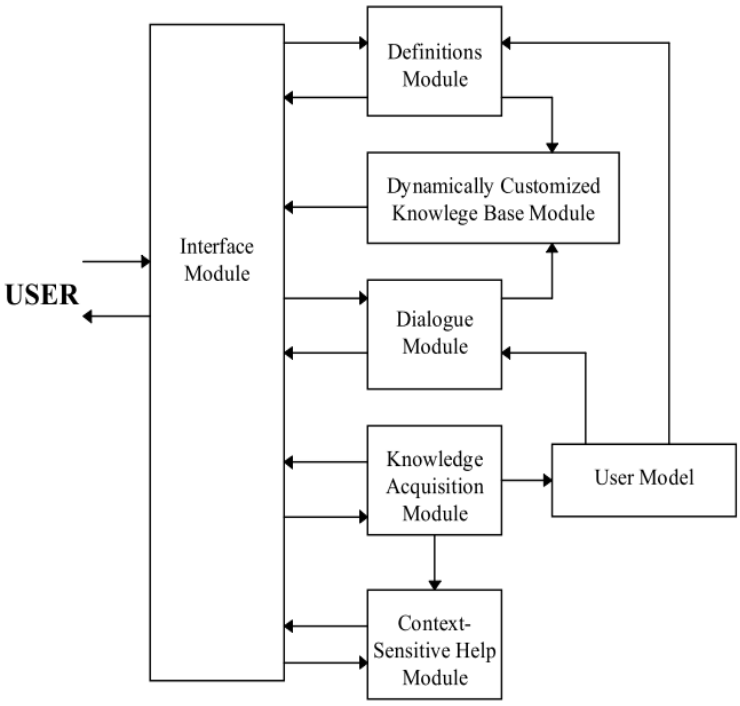

Figure 4: General architecture of the LEAF system (taken from [75]).

The system was written in Java to allow access to it through the World Wide Web (see Figure 5). LEAF accesses only publicly available materials or those that have been hand coded. It let patients fill medical forms online, and initiate questions and concerns about the domain knowledge, medical terminology or vocabulary in the form. The information given to the patients is related with issues of prevention, testing, or treatment. After evaluating the patients' medical history form, LEAF directs the patients to educational material about the disease condition(s) and suggests questions to ask from their doctors. It also provides a question-answering facility which helps to clarify the material offered, and includes a graphical user interface to be used by the patients. Moreover, at the end of a session, patients are presented with a summary of relevant and personalized private information i.e. a list of relevant health topics related to their health condition(s).

Figure 5: LEAF's Interface (taken from [75])

2.2.3. The PULSE Project for Cardiovascular risk management

The PULSE [76, 77] (Personalisation Using Linkages of SCORE and behaviour change readiness to Web-based Education), is a Web-based personalised educational intervention for the management of cardiovascular diseases risk. PULSE is a web-based adaptive hypermedia system, which create and deliver the personalized education material to the patient. The system framework was based on a patient profile created by combining an electronic patient data capture template (DCT), the Systematic Coronary Risk Evaluation (SCORE) algorithm for ten-year risk assessment for fatal cardiovascular disease, and a Stage of behaviour Change readiness model. The system was designed to address both medical and psychosocial aspects of cardiovascular disease risk management. The personalisation decision logic is represented in Medical Logic Modules (MLMs) and implemented in Java. The system design was a Web-based system, so that it can generate and deliver relevant educational materials to the individual patient based on their case-profile.

2.2.3.1. PULSE system design

PULSE system design followed the same framework presented by Jones et al. [17, 73], with an additional component i.e. an evidence-based data capture template. They suggested that, the delivery of personalized information can be accomplished through following steps [76]:

1. A user profile through Patient Data Collection

2. A digital library containing all messages
3. A digital library containing all messages
4. A document template for appropriate allocation and display of messages
5. A medium to deliver the message to the intended user

Patient Data Capture and Profile:

As far as PULSE system design is concerned (see Figure 6), starting point is Physician which enters patient data into the system. There is an electronic patient data capture template (DCT), which inherently comprises a set of evidence-based parameters for patient disease description evaluation and management. Those parameters included the following risk conditions and risk factors: age, gender, personal and family health history related to CVD, smoking status, amount of regular exercise, eating habits, alcohol consumption, weight control values, stress, depression, lipid values, blood pressure (BP) values, glycemic control values, and behaviour change readiness. When clinical experts will make any decision for the patient during care setting, they will enter the patients' data into the system, and it will lead to the generation of the patient-specific case profile. The complete patient profile is designed in a way that it will be mapped with the message library with ease.

Message Library:

The message library contains a collection of educational interventions or materials. It stored educational material from various sources i.e. Canadian sources of clinical and lifestyle modification education and Pro-Change Behavior Systems, Inc. The various sourced materials from message library are broken down into small "snippets of information", <tagged>, and stored in an SQL database. The XML <tag> for each, snippet follows an indexing schematic which provides easy mapping to the patient profile for personalization purposes, to make it specific for the individual patient's condition.

Decision Logic:

Patient-specific profile and a message library containing a collection of education interventions are needed for personalization, which involves the selection of the most relevant set of messages based on the patient's profile. Personalisation is achieved through the processing of a set of symbolic rules based on the decision logic. The decision logic maps the profile elements to the specific messages. Moreover, they developed a rule-based inferencing engine that incorporates the decision logic. Medical knowledge is represented in Medical Logic Modules (MLMs). The entire decision logic set of MLMs is implemented in Java, and represented as a comprehensive decision tree describing each of the risk factors and risk conditions contained in the patient profile. The logic contains "if-then" rules, where the IF part of the rules contains variables for one or more patient profile elements. If the IF part of the rule is satisfied – i.e. the patient's profile matches with the rule constraints, so the THEN part of the rule becomes available for execution. Typically, the THEN part contains a list of messages that are selected as segment of the patient's personalised educational material.

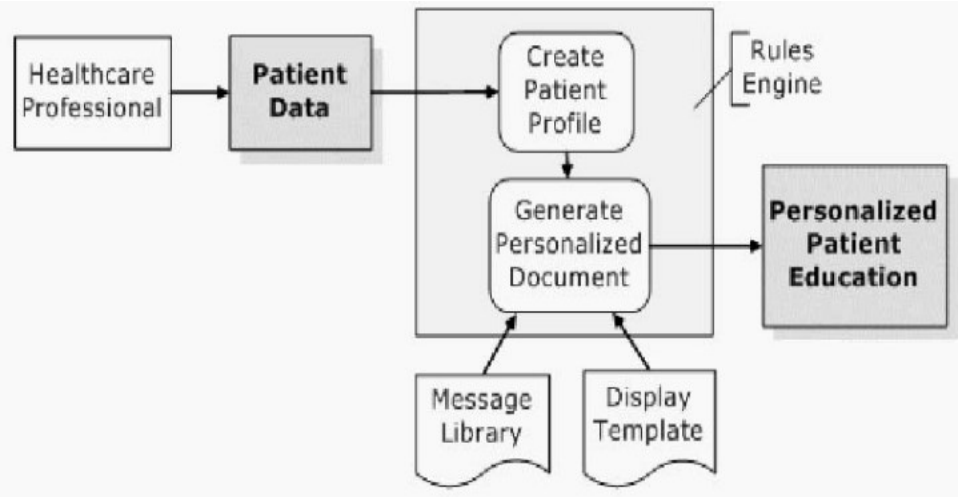

Figure 6: PULSE System Model (taken from [77])

System Implementation and Delivery:

The healthcare practitioner requires a password to log into the system, and enters the data into the DCT in consultation with the patient. The submitted data passes to the rule engine, and the system begins generating the personalised document. The MLM

processes those data on logic statements to determine the patient profile. Once all data is processed, the rule engine uses this information to select appropriate messages specific to case profile of the individual patient. The information is inserted into a display template, and rendered in HTML (Hypertext Markup Language) on the computer screen in a web browser for viewing by the patient and their health professional (see Figure 7). A printable version is available for patients who may not have access to a computer. Patients can access, view and print their educational document at any time by logging onto the website.

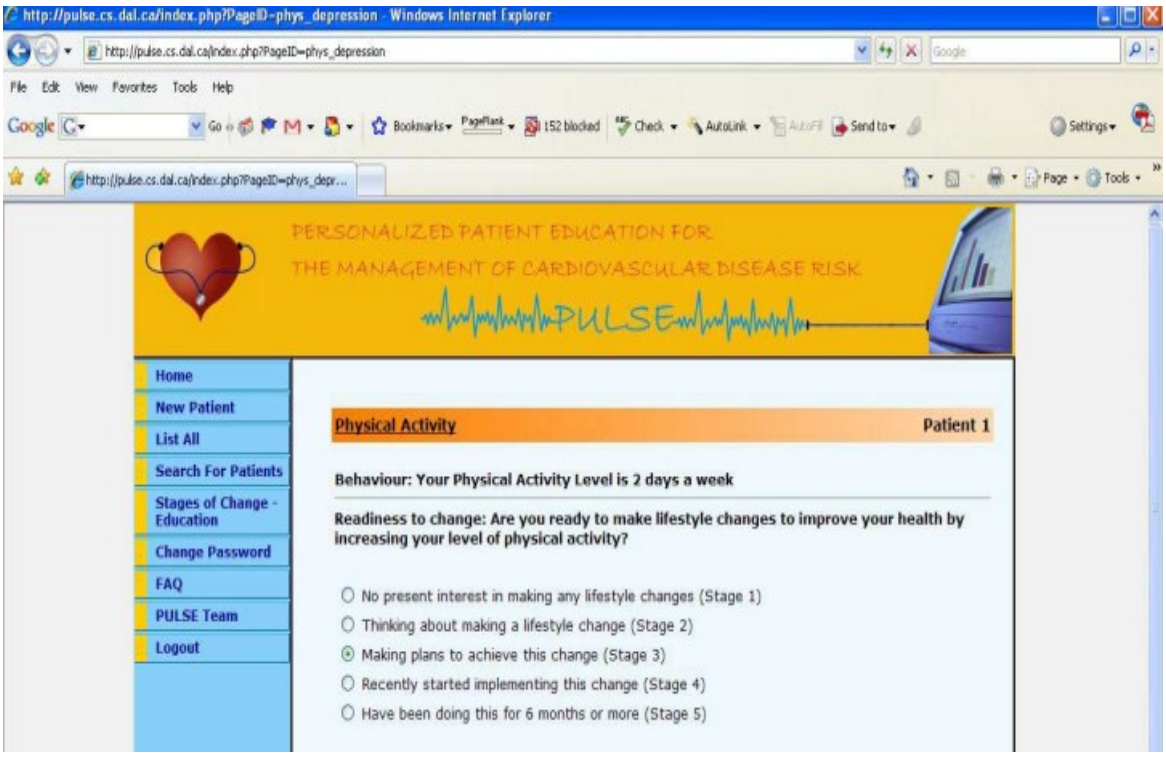

Figure 7: PULSE system prototype (taken from [77])

2.2.4. Migraineur

Migraineur [78] created by Buchanan et al., is an intelligent interactive system for delivering individualized information to the patients. It provides customized information to the patients suffering from chronic or acute migraine headaches. The main objective of this project was to increase the overall effectiveness of physicians' time, and the quality of healthcare, by improving the information exchange between the physicians and the

patients in clinical settings [78]. They initially intended to focus on migraine patients, and provided customized information to patients suffering from migraine headaches. They presented a prototype interactive information system named as Migraineur. It was developed to improve the interaction between the patients and the physicians for effective management of patients' condition.

2.2.4.1. System Overview

The prototype system consists of two major components (see Figure 8): i) an interactive history taking module and ii) an intelligent explanation module. The history taking module is an interactive way of getting information from the patients, in order to save time for the physicians. This module collects information from patients prior to each visit, builds a user model, and summarizes the patient's status and their history of health condition for their physicians. This module consists of about 104 questions, which are asked to the patient during clinical encounter based on their health status.

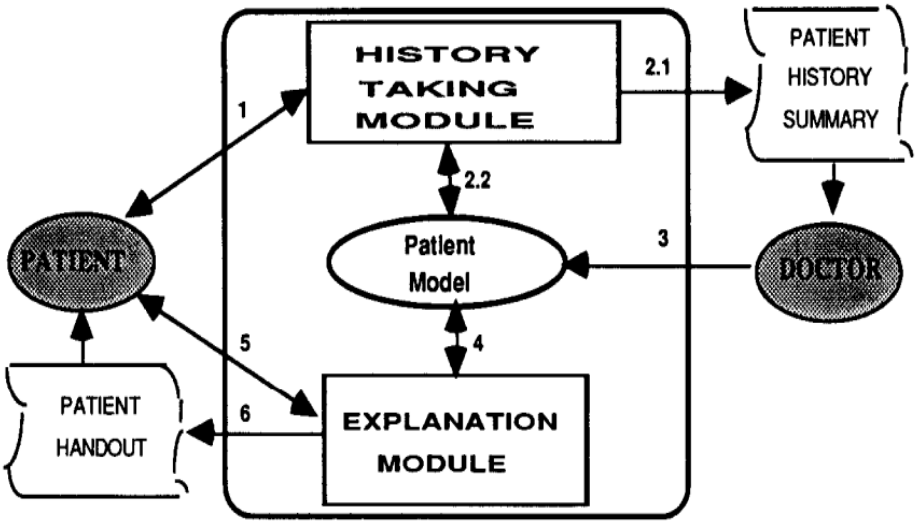

Figure 8: System Architecture of Migraineur (taken from [78])

The intelligent explanation module produces an interactive information sheet, which contains explanations in simple language that are tailored to individual patients, and responds logically to follow-up questions about the topics covered in the information sheet. This information sheet contains generic text that is presented to all the patients, customized text that is presented depending on an analysis of the user model, and text

that when selected will show the patients questions they might ask related to that word in that context. The information presented depends on the discourse history, and it tries to avoid presenting the same text if the same question is selected twice. This information sheet behaves like an HTML document in which information changes dynamically depending on the previously selected links.

The design of the system was adjusted to cover a broader range of questions, and provide explanatory material on the topics that physicians usually do not address. Migraineur is able to provide customized information to patients specific to their health condition, and supplement the explanations given by the physicians and the nurses. It did not attempt to change the behaviour and attitude of health professionals, its main objective was to provide information to the patients in the healthcare process, to improve their interaction with the physicians during healthcare settings.

2.2.5. Health-Doc

HealthDoc [79] offers customized information and health-education materials to patients. The HealthDoc project aimed to develop techniques for producing health information and patient education material highly specific to the disease condition and personal characteristics of the individual patient. The HealthDoc project was inspired by the idea of building a system, which upon execution must be fitted into the following framework:

1. Master documents: Each customized education material on a particular topic is produced from a master document on that topic. The master documents contain all the information including illustrations and annotations.
2. Authoring: Master document should be written by a health professional or a domain expert.
3. Dimensions of customization: HealthDoc education material may be customized with data about the individual patient, and the selection of content and manner of expression of that content may be determined by the patient's health condition and their personal, social and cultural characteristics.
4. HealthDoc in clinical settings: In clinical settings, HealtthDoc would have an access to the electronic/ online medical records of the patients. Whenever a clinician wish to give a patient any education material, he or she will select it from the menu and specify the name of the patient whom it to be given.

5. Multilinguality: HealthDoc would allow the creation and generation of patient education documents in multiple languages.

HealthDoc is executed through Natural Language Generating (NLG) tailoring system. Documents are encoded with standard document description language (XML). Master documents containing personalized health information for various domains and speciality are prepared and marked up with XML tags and attributes. These tagged conditional documents are processed through an XSL transformation that produces a presentation- and print-ready, highly customized document specific to the individual patient health condition using the PHP Hypertext Preprocessor.

2.2.6. CHESS

CHESS (Comprehensive Health Enhancement Support System) [80-82] is a computer-based support system, which provides information and support to people facing different health problems. It consists of an integrated set of services to provide information, referral, skills, training, decision support, and social support to its users [80]. CHESS is designed to reduce barriers to information and support like distance, education, finances, and concern for confidentiality. CHESS was first developed in 1989, and has been tested in several research studies and is now Internet-based. It was developed by a team of scientists specializing in decision and information systems, education, medicine, and communication in the Center for Health Systems Research and Analysis at the University of Wisconsin. CHESS can be access using a personal computer placed at home. People facing life-threatening health conditions and illnesses i.e. breast cancer, HIV infection, heart diseases, Alzheimer's disease, and alcoholism, can read brief answers to hundreds of questions, as well as detailed articles and descriptions of services they may need or interested [83]. Moreover, CHESS decision support tools help patients to monitor their health condition/status and risk behaviors, share in important decisions, and plan how to implement their decisions. The CHESS for different disease conditions have the following components [81, 83]:

2.2.6.1. Information components

1. Question and answers: They are short answers to commonly asked questions about disease condition, treatments, and life with the disease condition. User can

either type a key word they would like to be answered and/or select from the list of questions addressing that key word, or have an overview of all the questions and then select the question they wish to pursue or interested in getting to know about it.

2. Instant Library: includes full-text articles covering a broad range of topics drawn from scientific journals, newsletters, and the popular press. User can review a menu, and select the topics of their interest and related to their disease condition(s).
3. Getting Help/Support: contains descriptions of approximately 300 relevant health services, ways to find a healthcare provider, and how to be an effective consumer of the system and service. Actually it provides a tutorial to the user in very simple English, how to perform all these tasks.

2.2.6.1. Social support components

1. Discussion Groups: They are facilitated online support groups allowing patients and families with similar problems to share information, support each other, and making social network.
2. Personal Stories are real-life accounts of people with similar problems, living and coping with their disease conditions. These stories represent a wide range of experiences and background, as well as diversity in terms of stories from people with different cultures and beliefs.

2.2.6.1. Problem-solving components

1. *Decision Aid*: help patients in decision making, and it uses utility theory to help people to think through difficult decisions and make decision-making easier. It provides access to experts' insights into specific decisions i.e. what kind of surgery is suitable, what kind of chemotherapeutic drug have least adverse effect, and can have better outcome with more efficacy. In this way, patients can get in touch with recent researches regarding their health condition(s) as well. It helps patients to learn about the options, clarify their values and beliefs, the consequences of their actions, and the misconceptions they have. Overall, the

main intention was to provide a structured way to think through a difficult decision.

2. *Action Plan*: help users plan how to successfully implement and sustain decisions. It combines the statistical decision theory, and the change theory to help patients in implementing a decision. This program was designed by the experts in behaviour change, and asks users/patients questions about their plan to implement a decision. It identifies goals and resources, and learns how to overcome obstacles. Overall, it identifies ways in which the patients can strengthen their prospect for successful implementation.
3. *Assessment*: asks questions about a person's life style, assesses the risk, and offers specific advice on how he/she can reduce their risks and prevent it to some certain extent. CHESS also access the severity of the patient condition, and give them relevant content and material specific to the severity of their disease condition(s).
4. *Ask an Expert*: allow patients to write a question and receive confidential responses from experts. Experts can depersonalize the response and place it on Open Expert for other users to see. In this way, it will help to improve research based on new cases in clinical settings during the process of care.

2.2.7. Personalised Healthcare Information Delivery System (PHIDS)

Personalised Healthcare Information Delivery System (PHIDS) [84] intended to enhance technology-enriched solution to web-mediated patient empowerment initiatives through the implementation of an intelligent info-structure that features: 1) dynamic composition of Personalized Healthcare Information (PHI) conformant to an individual's EMR-based health profile (HP); and 2) pro-active Internet-based delivery of PHI. The advantages of these two features are; on one hand, this will ensure that the healthcare content disseminated to an individual is specifically focused on his or her healthcare needs, and on the other hand, the PHI should be periodically pushed to the individual to ensure the timely consumption of the up to date PHI.

2.2.7.1. PHIDS functionality overview

The overall functionality of PHIDS is divided into three main activities:

1. Generation of an Up-to-date Health Profile based on information contained in individual-specific EMR.
2. Composition of a PHI Document by systematically mingling multiple TD (Topic-specific Document) based on the individual's most current HP.
3. Delivery of the PHI Document using both pull (client-mediated) and push (system-mediated) mechanisms.

Health profile generation:

The generation of an up-to-date individual-specific Health Profile demands the collection and subsequent summarization of relevant and the most recent information from the individual's EMR regarding their health condition(s). This up-to-date individual-specific HP will be incorporated for the generation of PHI document.

Composition of the PHI document:

The PHI being composed comprises three main sections: (1) Information about long term-term clinical conditions and the management regimes; (2) Information about the short-term non-acute illness episodes, and the associated therapy, management, and rehabilitation; and (3) General healthcare education for wellness maintenance. The process for PHI composition is as follows (see Figure 9):

1. Based on the individual's HP, a set of TD (contains different medical concept within the HP) are collected from the Healthcare Information Repository. Each TD is represented as an XML document.
2. The collected TD are presented to a Constraint Satisfaction Engine, which employs constraint logic programming techniques to ensure the medical consistency of the multiple, heterogeneous TD when aggregated to yield PHI document.
3. The selected TD is aggregated according to a PHI template, to provide a continuous, structured, and readable PHI document.
4. Finally, the XML-based PHI document is converted to HTML format for internet-based delivery.

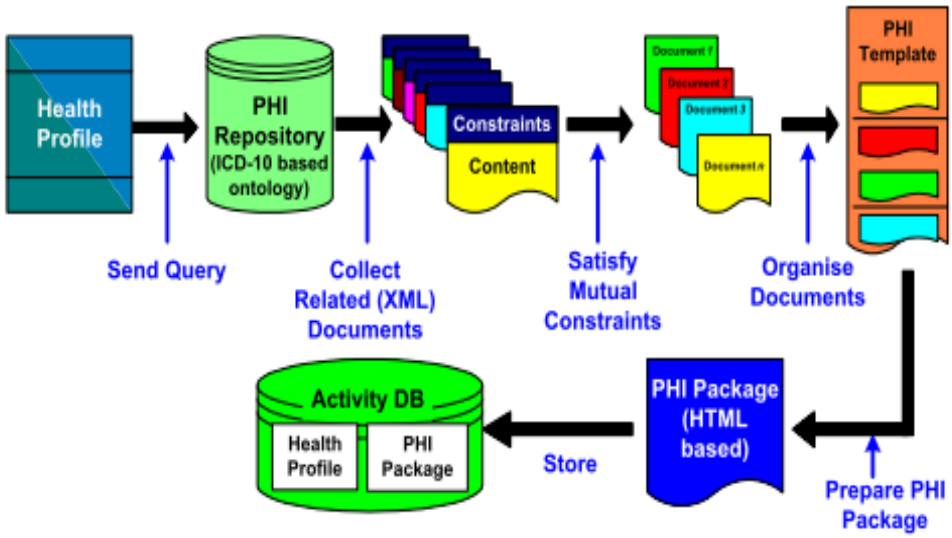

Figure 9: The process flow for PHI composition (taken from [84])

Delivery of the PHI document:

PHIDS incorporates both Push (System-Motivated) and Pull (Client-Motivated) modes for information delivery. Client-Motivated Mode involves the pulling of desired information from a web-site i.e. the user requests for PHI, which is dynamically composed and sent to the user's web browser. On the other hand, System-Motivated Mode is the featured and innovative delivery mode whereby up-to-date PHI is pro-actively and periodically pushed to the users, over the Internet to their email accounts.

2.2.8. Discussion

We discussed some of the related work previously done by other groups in patient education. Some of them had a major intention of patient education, and some focused on the decision making and counselling part as well. We are targeting patient education at each and every step at the point of care in clinical practice. During clinical encounter, at each and every step CPG give some recommendation(s), there will be PEMs related to each recommendation(s) of the CPG in parallel. In this way, when the patients will interact with their physicians during clinical encounters, they will be more informed about the options and modalities for the management and treatment of their disease condition(s). It will improve shared decision making between the physician and the

patient, when they will discuss about those modalities together and comes on one decision after mutual discussion, based on patient's preferences as well as their social and cultural beliefs. This will help to improve the physician-patient relationship, patient compliance, and ultimately it will improve health outcomes.

In Jones et al [17, 73] i.e. GEM-based CPG generated patient education materials, the idea is right; there is a need to create a patient profile which can be the starting point of this process. But, patient profile could be automatically created if we have fully integrated Electronic Health Records (EHR), which can generate patient specific case profile by using the data stored in it regarding patients' past and current medical histories. Electronic Health Record contains patients' health record, such as demographic factors, history of past illnesses, history of surgeries and medications. They are being aggregated into clinical data repositories and warehouses by many healthcare centers [85-87], so those data repository can be used as a starting point to generate patient specific case profile, as it has all the information required to generate patient-specific profile. After generation of patient profile, there are two component of their system i.e. GEM-implementation system and document selection system. In their system, recommendations are only for the physicians as a reminder, they did not use those recommendations to generate tailored patient education materials. They delivered education materials based on patient profile, not on the basis of the recommendations by the physician. It is quite possible, in any patient profile, it is not necessary that all of the information is up-to-date and recent. For an example, a patient profile has a past history of Tuberculosis, which is already eradicated so there is no need to give education about that to the patient. Their tailored education material comes from the patient profile on the decision logic algorithm i.e. packet selection algorithm. So the biggest concern is the authenticity of the delivering material, because they are not coming from physicians recommendation, CPG or care pathways, they are simply coming from the patient profile, which might have already obsoleted information which may be helpful as a past history of the patient, but not necessarily important to deliver educational messages to the patient. In real clinical settings, physicians do back and forth and parallel diagnostic investigations to come to any diagnosis or recommendation. So, the patient education material should be generated based on CPG-based recommendations or physicians'

recommendations rather than being generated on the basis of patient profile. Our work fulfils this problem, as the patient education material would be generated on each and every recommendation step at the point of care i.e. from their first presentation at the doctors' office till the final diagnoses, management, and follow-up of their disease condition(s).

The main objective of LEAF [74, 75] was to create more informed, activated and educated patients, so they should have better understanding about medical terminologies and doctors' vocabulary. It also delivers patient education on their past medical history and patient profile. It asks patients to fill medical forms online, and initiate questions and concerns about the domain knowledge, medical terminology or vocabulary in the form. The information given to patients is related to the issues of prevention, testing, and treatment, but it more or less provide patient information about what should they ask from their doctors. It is a good idea to bring questions for awareness but, not a right choice if the patients will forget to ask about those questions from their physician, as most of the times questions comes in their minds after leaving doctors' offices. It is better to provide information to the patients related to each and every modality in management of their disease condition(s), and explain the rationale behind each and every step taken during the process of clinical care. In our work, we address this issue; CPG(s) recommendation(s) is coming on each and every step and alongside PEMs are also coming to explain the rationale behind each modality of the management and treatment. Those PEMs explain about that specific step, for an example diagnostic step "lumber puncture" (LP). PEM will explain what is LP, what are the indications, outcomes, and complications of the procedure etc.

The PULSE [76, 77] (Personalisation Using Linkages of SCORE and behaviour change readiness to Web-based Education), is a Web-based personalised educational intervention for the management of cardiovascular diseases risk. The system was designed to address both medical and psychosocial aspects of risk management. PULSE system design followed the same framework presented by Jones et al. [17, 73], with an additional component i.e. an evidence-based data capture template. So the biggest concern is simply patient profile is good enough to create tailored or personalized patient education materials or not. It should be created based on CPGs or clinical pathway

recommendations, and education materials must be created on the basis of these recommendations rather being created on the basis of patient profile.

Migraineur [78] is an intelligent interactive system for delivering individualized information to the patients. The main object was to increase the overall effectiveness of physicians' time, and the quality of healthcare, by improving the information exchange between the physicians and the patients through providing customized information to the patients with migraine headaches. The system covers a broader range of questions, and provides explanatory material on the topics that physicians usually do not address. There might be a possibility that, the patient may be required to know the information regarding issues which physicians usually address in the clinical settings. They intended to customize that information to the individual patients related to their health status, but providing only those materials by simply assuming that they might not know about this, and ignoring other aspects and modalities related to management of their disease condition(s) is not a good idea. Knowledge and information should be delivered according to patients' needs and demands not on the basis of the criteria, which topic and issues usually do not addressed by the physicians in their routine clinical practice. Studies have suggested that, most patients want to see the overall picture or road map including all alternatives and possible modalities for the management and treatment of their disease condition(s) [123-125]. So, it is necessary to give information and educational materials to the patients based on their needs and preferences.

The HealthDoc [79] is a fully executed Natural Language Generating (NLG) tailoring system, which provides health information and patient education materials, highly specific to the disease condition and personal characteristics of the individual patient. HealthDoc is a fully executed system and its documents are encoded with standard document description language (XML) and delivers highly customized document specific to the individual patient's health condition using the PHP Hypertext Preprocessor. CHESS [80-82] is a decision support system, which provides information and support to help patients to monitor their health condition/status and risk behaviors, share important decisions, and plan how to implement on their decisions. The main problem with CHESS decision support tools are, it does not provide customized patient education, and sometimes it provides medical literature based on research evidences to the patients

which are mostly overwhelming for the patients with low literacy and least knowledge about medical terminologies and vocabulary.

Personalised Healthcare Information Delivery System (PHIDS) [84] provides the healthcare content to an individual specific to his or her healthcare needs, and also periodically pushed PHI to the individual to ensure the timely consumption of the up-to-date PHI. It drags information and topic-specific documents (TD) from the PHI repository, but the main problem is the recommendations for the patients in the process of care. Patient health information or education material should be generated on the basis of clinical recommendations by the physicians related to either CPGs or care pathways, at each and every step in the process of care or clinical encounter. In this way, patient will have knowledge regarding their own health condition(s), and they can actively participate in the process of clinical care. It will help to improve the physician-patient communication on one hand, and on the other hand, it will improve patient compliance and ultimately better healthcare outcomes.

In this chapter, we have discussed patient education background, shared decision making and related work in the field of computerized patient education. This is a brief summary of the related work by different groups. In the next chapter we will discuss our research methodology for CPG based Patient Education framework (CPG-PE) using Semantic Web technologies.

Chapter: 3

3. Research Methodology: CPG-PE Framework

In this chapter we will discuss the research methodology for the development of a CPG-PE framework, and we will discuss the modeling of PEM and development of PEO/ontology engineering in chapter 4. In this chapter, we will also re-evaluate the problem statement, and research goals and objectives. This CPG-PE framework is intended to provide patient-specific and tailored educational messages to the patients, in order to improve shared decision making between the patients and the physicians at the point and time of care.

3.1. Problem Statement and Research Goals

Patients require easily accessible and understandable information regarding all modalities related to their disease conditions and management options (see Section 1.2). Efficient and effective communication between the physicians and the patients is the key factor during clinical encounters. Therefore, successful information exchange between physicians and patients is important in clinical settings [27]. Patient's satisfaction is related with patient's compliance and efficient communication between physician and patient is an important factor in patient's satisfaction. Research studies have shown that, patient compliance is strongly correlated to the patients' understanding of their condition(s), diagnostic procedures, prescribed treatments and surgical or other interventions [3-7], and also depends on efficient communication between the physicians and the patients. Hence, efficient communication between the physicians and the patients is the key factor in patient's compliance, better health outcomes, and reducing the cost of healthcare. On the other hand, physicians are either too busy to explain their diagnostic procedures and rationale for the prescribed therapy and management plan [6-8] or they may counsel patients in their offices and consulting rooms which is overwhelming for the patients, and they forget almost half of the things which their doctors said to them [16]. Sometimes, physicians do not use evidence based guidelines frequently in clinical practice, which restrict physicians to deliver that education and information to the

patients that are important for the behavioural modification [17]. Patients usually do not know when to do, how to do, and what to do to cope with the disease(s). Sometimes, they get generic information about the disease conditions. Such generic information is not specific for their disease condition or collection of disease conditions. Usually patients have collection of the diseases/multiple diseases or sometimes have some co-morbidity. As a result, generic information provided to the patients does not cover all the co-morbidities and collection of diseases they have during the duration of their illnesses. Usually chronic conditions have multiple co-morbidities, and it requires consultation from different specialties. Therefore, chronic conditions require different types of patient education materials at a glance. Studies have shown that, generic, lengthy and non-relevant information has negligible impact on patients and health outcomes or sometimes even deteriorates the condition(s) [16]. As all information is not knowledge, and sometimes some information could be harmful, and produce anxiety and distress to the patients. Hence, we argue that selective and patient-specific information and educational interventions has better impact on patients and health outcomes as compared to impersonal and generic information.

As we discussed earlier, efficient communication between physicians and patients is the key factor in patient compliance, better health outcomes and indirectly reducing the cost of healthcare [3, 4, 5, 6, 7, 28], but unfortunately there is failure of efficient communication between the doctors and their patients [6-8]. In this scenario, the use of interactive computer based patient education programs can be a choice to consider in order to deliver information to the patients regarding all modalities related to their disease conditions and management options at the point and time of care. We propose a CPG based Patient Education framework (CPG-PE) using Semantic Web technologies. The Semantic Web (SW) is as a logic-based framework for both representing and operationalizing knowledge, where information is given with well-defined semantics that enables a better cooperation between people and computers [36]. As CPGs and PEMs are from different knowledge resources, semantic web offers a logic-oriented framework for both representing and connecting heterogeneous knowledge resources [36].

3.2. Our Patient Education Approach

Our patient education approach for CPG-PE framework to promote shared decision making is based on psychodynamic model (see Section 2.3.5), in order to deliver personalized patient education materials, to produce more informed patients and improve clinical decision making (see Figure 10). In this approach, recommendations will come from CPG(s) and patient education materials corresponding to them will come from patient education library. Our proposed CPG based Patient Education framework (CPG-PE) is based on this patient education approach. This CPG-PE offers information, which is based on evidence-based guidelines, to patients about their own health conditions in the form of PEMs on one hand, and on the other hand reduces the scarcity of the source of the medical knowledge, and also avoids unnecessary information to be given to the patients during the process of clinical care. This CPG-PE framework upon execution, can deliver patient education materials/messages, based on the clinical recommendations provided by CPGs, to the individual patient according to their health profile, and also highlight the psychosocial aspects of the disease condition(s) which have role in the etiology of the diseases as well as their outcomes.

Our main objective is to promote shared decision making between physicians and patients during clinical encounters at the point of care by producing much informed and educated patients. Shared medical decision making is a process by which patients and physicians/health professionals consider different options, their outcome probabilities and patient preferences to reach a mutually agreed healthcare decision during the process of care [28]. They interact with each other for exchanging information, and combining knowledge and expertise in order to proceed towards mutually agreed decision, which is best suitable for the patients and come in line with their preferences as well as their social and cultural beliefs. The psychodynamic model [31] encourages shared decision making between patients and physicians to choose the desired and most appropriate diagnostic and therapeutic modalities in the process of clinical care. This is the reason, we choose this model as the starting point of our research rather than choosing the paternalistic model, which encourages medical paternalism or the libertarian model, which give patients too much authority and encourages patient's autonomy. With the psychodynamic model, we can keep a balance between medical paternalism and patient autonomy to

encourage the shared decision making during clinical encounter at the point of care. The psychodynamic model covers emotional, psychosocial, and all other factors along with the management of the disease condition(s), which have role in the etiology of the diseases as well as their outcomes. We aim to deliver PEMs at each recommendation of CPG(s), in this way patient will have information regarding different choices and modalities related to the treatment and management of their disease condition(s). It will depend on the patients to choose one based on their own preferences, cultural and psychosocial background, after discussing it with their physicians. Our PEMs also have decision making and counseling parts, which will help patient to improve their decision making capabilities or assist them in making the decision in the course of the management of their disease condition(s) during the process of clinical care. It will improve shared decision making between patients and physicians, and help patients to deal with tense situations during the duration of their disease condition(s). The psychodynamic model flexibly allow us to do so, because it covers emotional, psychological, cultural values, family pressure, and personal esteems etc. along with the management of disease condition(s) at the point of care. In patient's health profile, there is demographic data/information i.e. age, gender, address, ethnicity, socio-economic status, religious believes, neighborhood information etc. The psychodynamic model will help us to incorporate these psychosocial and behavioral aspects in the course of the management of patients' disease condition(s) rather than merely treating the disease condition itself, through certain concepts in CPG-PE Ontology, which we will discuss in Chapter 4 i.e. Patient Education Ontology Engineering. We modeled these aspects/ factors in CPG-PE Ontology to represent in our CPG-PE framework to incorporate these aspects in providing personalized PEMs.

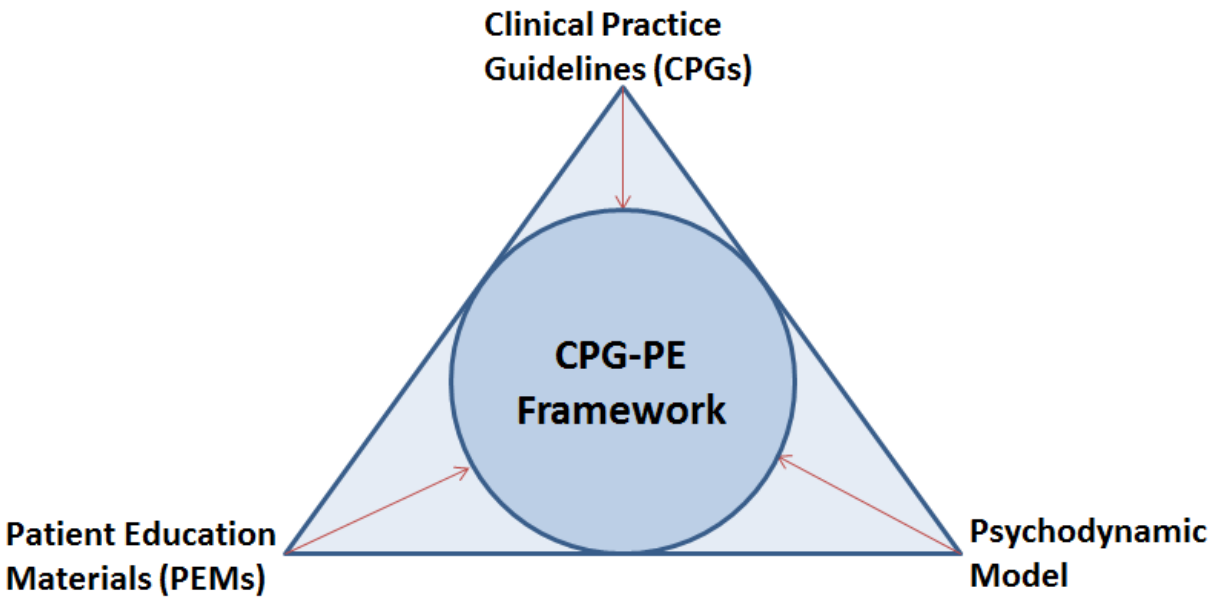

Figure 10: Our Patient Education Approach

3.3. CPG-PE Framework

The CPG-PE framework is designed to generate patient education messages to patients based on the clinical recommendations provided by CPGs. CPG-PE offers evidence-based information to patients about their own health conditions in the form of PEMs. We have taken patient education materials from the PEMs library. PEMs library contains several patient education materials and documents related to various diseases and specialities from different resources i.e. American College of Family Physicians, A.D.A.M., Inc., British Medical Journals (BMJ) patient education leaflets, Ferri's Netter Patient Advisor etc. We modelled those PEMs from PEMs library in our CPG-PE ontology to be used by our CPG-PE framework, to provide specific educational materials about the CPG-based recommendations prescribed to individual patients. This CPG-PE framework is designed to provide patient education messages/materials in a very simple language, by deterring and simplifying complex medical terminologies. This CPG-PE framework aims to generate education messages personalized to the individual patients regarding their specific disease condition(s), co-morbidities, behavioural attitude, and motivational status towards their health. We have modeled these concepts related to disease condition(s) and co-morbidities, as well as psychosocial and behavioral aspects in CPG-PE ontology, which we will discuss in detail in Chapter 4. Using an interaction

between CPGs and PEMs, CPG-PE plays an important role in the shared decision-making, where patients are offered both evidence-based recommendations from CPGs and also recommendation-specific patient educational messages to individual patients according to their disease condition(s) and associated co-morbidities. Upon the generated recommendation options, and their PEMs offered specific to patient disease conditions and behavioural attitudes, both physician and patient can then discuss an optimal CarePlan [88] through a shared decision-making process where (i) a physician, using CPG knowledge, can decide the most beneficial and effective drug/therapy recommendation options for the patient, and (ii) a patient, based on offered PEMs, can educate themselves on the benefits and risk measures of the prescribed recommendations, and decide whether the patient is willing for any of the prescribed recommendations or procedures. Hence, CPG-PE offers an interaction from both parties involved, and facilitates a share decision-making process between them for achieving both optimal and feasible Care Plan for the patients. The system design of the CPG-PE framework is shown in Figure 11.

The CPG-PE framework is realized by proposing an integrated knowledge model, where the knowledge within both CPGs and PEMs can be modelled and integrated. For representing and executing CPGs, the domain and operational aspects of CPGs are already modeled in the CPG Ontology [37]. The Patient Education (PE) Library contains numerous PE documents in a very simple language, in a PDF format. Such PE documents are required to be in a computer-readable format, to represent the domain and operational knowledge within PE documents. The domain and operational aspects of PE documents are modeled in the Patient Education Ontology (PEO). In CPG-PE, we propose the merging of CPG ontology and PE Ontology, in order to augment the patient-specific CPG-based recommendations with patient education materials. Using the integrated CPG-PE ontology, various CPGs along with appropriate PEM can now be represented in the CPG-PE ontology through the corresponding sub-classes and properties of PE ontology in this merged CPG-PE ontology. The CPG(s) recommendations will come from CPG ontology, and the PEMs will generate from their corresponding sub-classes and properties of the PEO in this merged CPG-PE ontology. The CPG-PE framework requires a fully integrated Electronic Patient Record (EPR), which can provide patients'

information such as demographic information (i.e. patients' bio-data, age, gender, occupation, marital status, address, socioeconomic status, educational status, living conditions, housing, religious and other beliefs etc.), which are addressed by psychodynamic model. This information is represented through corresponding classes and sub-classes in our CPG-PE ontology. EPR also contains patients' clinical information i.e. presenting complaint, history of presenting illness, past medical and surgical history, medication and immunization history, diagnostic investigations and interventions, current treatment, management and procedures, outcomes, follow-up and complications. With these patients' information from EPR, patient-specific case profile as well as patients' psychodynamic information can be generated, which contains all the basic information related to their demographic data, and current and past information related to their health conditions. The patient-specific case profile can be used to select CPG or multiple CPGs that addresses the disease condition(s) and/or co-morbidities specific to that individual patient. Unfortunately, CPG do not address those issues which are addressed by the psychodynamic model, so those psychodynamic patients' information will be matched to the classes and properties in our CPG-PE ontology. Based on patient-specific case patient profile and the decision criteria satisfied on the patient profile, CPG-based recommendations and also their related PEMs can be prescribed to the individual patients. Moreover, based on psychodynamic patients' information from the psychodynamic model using CPG-PE ontology, it will offer patients to choice their desired treatment and diagnostic modalities to improve shared decision making between patients and physicians in order to achieve better patient compliance and health outcomes.

Based on the CPG recommendations, CPG-PE is designed to generate personalized Patient Education Materials/messages (PEMs), through the corresponding classes and sub-classes in CPG-PE ontology, which have modeled different aspects of patient education to represent various PEMs related to different diseases from various specialities. We will explain it in detail in Chapter 4, personalization section (Section 4.5). Such PEMs should provide personalized knowledge to the individual patients regarding their specific disease conditions, co-morbidities, psychosocial factors, behavioural attitude, and motivational status towards their health. Moreover, PEMs can

be delivered through an interactive computer web-based program as Patient Education and Counselling System (PECS) or to the mobile devices through text messages or SMS. The key steps in the CPG-PE framework are discussed in the research methodology section below.

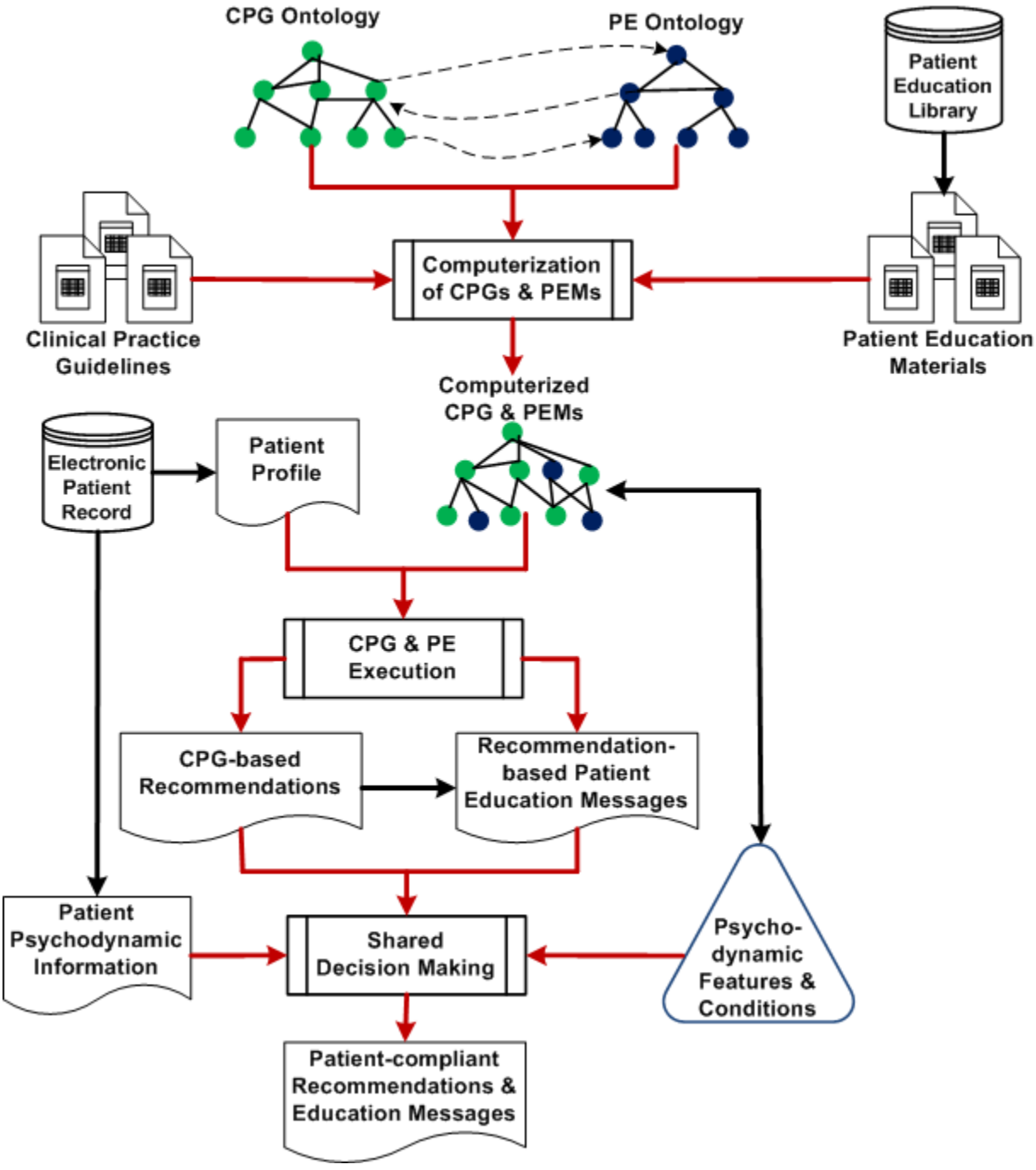

Figure 11: CPG-based Patient Education (CPG-PE) Framework

3.4. Research Methodology

Our solution approach will be realized in the following steps:

Step 1: *Computerization of CPGs:* We need CPGs in computer-interpretable format. In our CPG-PE framework, we have adopted CPG ontology [37] to represent and computerize CPGs.

Step 2: *PEM Knowledge Modeling:* Modelling of the PEMs in the CPG-PE ontology to represent PEMs in our CPG-PE framework.

Step 3: *Development of PE Ontology*: Development of PE Ontology to represent and computerize PEMs.

Step 4: *Merging CPG and PE Ontologies*: Augmentation of PE Ontology with CPG ontology as CPG-PE ontology: We connected relevant classes, sub-classes and properties in CPG Ontology by linking with the sub-classes and properties in Patient Education Ontology (PEO) and the final merged ontology is obtained as CPG-PE Ontology.

Step 5: *Representing PEMs in CPG-PE Ontology*: Encoding specific PEMs related to different disease conditions modalities in the CPG-PE ontology.

Step 6: *Personalization of PEMs*: Delivering patient education materials/ messages, and providing patients information about different modalities and alternative choices related to the management of their disease condition(s). It will promote shared decision making and patients will be more compliant to the physicians' advices/ CPGs recommendations in order to improve their health outcomes.

Step 7: *Evaluation of CPG-PE framework:* We evaluate our CPG-PE frame work, by 1) consistency checking of PEO, 2) an extensive case study, and 3) systematic evaluation. We demonstrate the working of our CPG-PE framework in providing patient educational messages based on CPG(s) recommendations specific to patients' disease condition(s) and co-morbidities at the point of care.

3.4.1 Computerization of CPGs

Studies have shown that, clinical guidelines may improve patient care by providing easily accessible information regarding optimal care in a timely manner, make clinical decisions

more transparent, can increase the efficiency of care and if appropriately used, they also can reduce the overall cost of healthcare, as well as can be used as a reference for professional audit to evaluate the quality of care [32, 89-92]. Due to rapid generation of CPGs, it has become nearly impossible for a clinician to integrate all 1600 of the available CPGs into his/her practice using traditional paper-based systems [93]. This rapid proliferation and turnover of the CPGs across the world, makes the need of computerization of CPGs. Studies, have shown that, the rapid proliferation of clinical practice guidelines (CPGs) has made computerization increasingly useful to clinicians [93]. However, representation of clinical practice guidelines in a computer-interpretable format has been a critical issue for guideline development, dissemination, implementation and evaluation. Computerization requires transformation of the content and operational knowledge within each guideline into a computer-accessible form [93]. As guidelines addresses the problem related to the general population, so it cannot give recommendations for specific patient sometimes. Computerizing guidelines has the potential to develop guideline-based clinical decision support system, which can address these issues by providing recommendations tailored for individual patients at the point of care [37, 73]. In this way we can easily update and disseminate CPGs as well as improve patient compliance and better health outcomes. Studies have shown that, computerization of CPGs has shown improvement in compliance with guideline recommendations and also improves health outcomes [94, 95]. Computerization of guidelines also supports education and new research as well as quality assurance. Studies suggest that, structured, computer-interpretable guidelines cannot merely provide decision support, but also can provide workflow management support, quality assurance, and educational interventions [96, 97]. Computerized CPGs can provide decision support in the form of alerts and reminders to the physicians, and can improve the quality of care, if it is integrated with an Electronic Health Record (EHR) [98, 99].

In order to facilitate CPG-based Clinical Decision Support System (CDSS) [37, 73], creation of computer interpretable formalism and representation of CPGs are necessary [100]. There are number of knowledge modelling methodologies available to convert text-based natural language guidelines into computerized and executable formats. Examples of such methodologies include GEM [101], Asbru [102], EON [103], GLIF

[104], and GUIDE [105], Prodigy [106] and PROforma [107]. Clinical situations also demands merging of multiple CPGs, as mostly patients' conditions require more than one clinical guideline to provide case-specific recommendations.

Nowadays, computerization of CPGs is carried out using Semantic Web (SW) ontologies. Ontology constitutes a formal conceptualization of a particular domain. SW is a logic-based framework for both representing and connecting different sources of knowledge [36]. SW ontologies provide a framework for modelling and representing the underling domain knowledge and operational knowledge within CPGs. In order to represent CPGs in our CPG-PE framework, we used an ontology based knowledge model to represent domain and operational knowledge within CPGs, using the CPG Ontology [37]. The CPG ontology is designed to provide a guideline authoring and execution framework for achieving patient-specific decision support at the point and time of care. We used this CPG ontology as our starting point, as our work required CPG-based patient specific recommendations, on the basis of which we can deliver PEMs using PE ontology.

3.4.1.1. CPG Ontology: Schema Overview

In order to represent the organizational attributes of CPGs, the CPG ontology provides the concept Clinical_Guideline that holds the entry-point of a CPG. This concept includes the following attributes: *approved_by, author, authoring_date, comments, description, desired outcome, encoder, exclusion_criteria, first_step, goals, inclusion_criteria, name, owner, and references.*

To model the sequential nature of CPGs, the CPG ontology defines the concept Guideline_Step to represent clinical steps of a CPG. The sequencing of clinical steps in a CPG is modelled by the property *first_step*—that applies to the Clinical_Guideline concept. In this model, Clinical_Guideline does not directly hold all its steps. Instead, only the first step is specified through the *first_step*, and subsequent or following step(s) are incorporated through the ***next_step*** property (as shown in Figure 12).

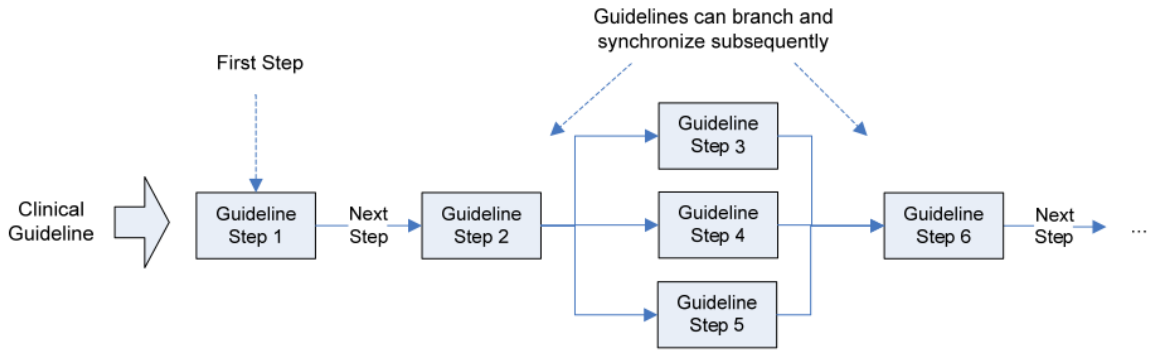

Figure 12: Specifying the sequence of guideline activities through the first step attribute of clinical guideline and next step attribute of each subsequent step. (Taken from [37])

The Guideline_Step concept represents all the clinical steps described within a CPG. The Guideline_Step is further classified into three main types of clinical steps: (i) Action Steps, (ii) Decision Step and (iii) Route Step. These steps are briefly described as follows:

3) Action Steps:

Action steps are modeled through Action_Step that represent clinical activities performed in a guideline-based workflow. Action steps include the following sub-concepts:

i) **Assessment_Step** is defined to model clinical assessments.

ii) **Diagnostic_Step** is defined to model actions that are performed to exclude out the differential diagnoses and make a diagnosis. Diagnostic interventions involve different types of activities including general physical and systemic examination, laboratory investigations, clinical imaging, diagnostic interventions etc.

iii) **Diagnostic_Choice_Step** is defined to model steps that provide different diagnostic options rather than using one particular diagnostic intervention.

iv) **Treatment_Step:** is defined to model the recommended treatment interventions within a CPG. Treatment interventions can range from prescription to radiotherapy and therapeutic procedures (medical or surgical).

v) **Treatment_Choice_Step:** is defined to model steps that provide different treatment options rather than using one particular treatment intervention.

vi) **Visit _Step:** is defined to model situations where the patient is instructed to visit a clinician, referral to another clinicians (for example, a specialist), or a scheduled visit to the same clinician or same healthcare institution.

vii) **Schedule_Step:** is defined to model situations in the health-care process where a clinical activity (i.e. Action_Step) needs to be scheduled to be performed after a period of time.

viii) **Plan_Explication_Step:** is defined to model situations when a clinician defines the next set of care plan steps and notes them in the patient's chart in order to make sure that other clinicians follow the same plan.

ix) **Notification_Step:** is defined to model notifications that are used to communicate with the clinicians and care provider in forms of alerts, reminders, suggestions, or reports.

x) **Admission_Step:** is defined to model situations where a patient's conditions require the healthcare team to admit the patient to hospital or clinic.

xi) **Education_Step:** is defined to model situations where a patient or their next of kin needs to be educated. Education_Step concept includes properties—such as *education_material*, *education_plan*, and *education_receiver*—to refer the patient education material to respective patients.

2) Decision Steps:

The Decision_Step concept represents decisional points in a CPG during care process, where a decision needs to be made to determine the next set of tasks or activities. Decision_Step is further into the following sub-concepts:

i) **Provider_Decision_Step** is used to model decisions that should be made by the clinicians. The *responsible* property specifies the clinician who is responsible for decision making and *decision_support_material* holds evidence-based guidelines or clinical pathways to help them in decision making.

ii) **System_Decision_Step** is used when the decision making logic is clearly specified in the guideline, and the decision is carried out by the computer to expedite the process.

3) Route Steps:

The concept Route_Step specifies the flow of activities in the guideline. Route_Step is further classified into the following sub-concepts:

i) **Branch_Step** models a branching point in the sequence of actions in the guideline, i.e. defines two or more subsequent steps to be executed in parallel.

ii) **Sync_Step** models merge steps that have been previously branched through a Branch_Step.

iii) **Loop_Step** models iterations of one or more guideline steps.

In addition to the above mentioned concepts, the CPG ontology further defines various high-level concepts—such as (i) Intervention, (ii) Medication, (iii) Drug, and (iv) Drug_Order to incorporate therapeutic and diagnosis interventions, medications, drug prescriptions, drug scheduling, drug dosage and their contraindication adverse effects described within a CPG. A fragment of the concept hierarchy and properties described in the CPG ontology is shown in Figure 13.

Figure 13: CPG Ontology: Concept Hierarchy & Properties

3.4.2. PEM Knowledge Modeling

We aim to develop an ontology-based knowledge model to be used by our CPG-PE framework to represent the knowledge within PEMs. We believe that, PEMs have an inherent infrastructure on which all of the PEMs are based on. We analyzed numerous PEMs related to various diseases and specialities from different resources i.e. American College of Family Physicians, A.D.A.M., Inc., British Medical Journals (BMJ) patient education leaflets, Ferri's Netter Patient Advisor etc. in order to identify knowledge elements to model those knowledge structure/ elements in PEMs. We develop an ontology-based knowledge model, Patient Education Ontology (PEO) to represent the knowledge elements within PEMs for our CPG-PE framework. PEO aims to represent all

the knowledge encloses in PEMs and allow following the recommendation steps from the CPGs in order to deliver PEMs upon execution of CPG-PE ontology i.e. whenever CPG(s) will recommend any action step, decision step, intervention step etc. PEMs will be delivered related to that recommendation. However, this PEM knowledge model is not intend to represent all the medical knowledge and terminologies in the complex medical literature, it can only model the knowledge contain in PEMs written to provide education and assistance to the patients regarding their disease condition(s) during the process of care. We will further discuss selection, organization, categorization and modeling of PEMs in detail in Chapter 4.

3.4.3. Development of Patient Education Ontology

Based on knowledge modeling of PEMs, we develop a Patient Education Ontology (PEO) to represent the knowledge elements within PEMs for our CPG-PE framework, in order to represent personalized patient education materials to the patients based on their disease condition(s) and/ or co-morbidities. For developing the PEO, we follow an ontology engineering approach:

- Step # 1: Determine Scope: Define scope of the ontology, i.e. it is intended to represent patient education materials.
- Step # 2: Consider Reuse: We have reused previously made ontology i.e. CPG ontology, to represent clinical practice guidelines and merge PEO with CPG-Ontology as CPG-PE ontology.
- Step # 3: Enumerate Terms: We defined terms based on PE knowledge modeling after analyzing several PEMs related to different disease conditions from various resources.
- Step # 4: Define Classes: We defined classes to represent various concepts within PEMs.
- Step # 5: Define Properties: We defined properties which describe attributes of instances of the class and relationship to the other instances.
- Step # 6: Define Constraints or Anomalies: We identified few constraints in PEO i.e. there are some property constraints; few properties will not cover all the domain concepts in PEO.

- Step # 7: Create Instances: We create instances of the classes and assigned value for the instance frame.

The development of PE ontology/ ontology engineering is described in detail in Chapter 4.

3.4.4. Merging CPG and PE Ontologies (CPG-PE)

In order to achieve an integrated ontology model to incorporate both CPGs and their PEMs, we imported the CPG Ontology and PE Ontology using Protégé. The final merged ontology is named as CPG-PE Ontology. In the CPG-PE Ontology, we identified several concepts, their sub-concepts and properties in the CPG ontology that can have patient education aspect. We augmented the concepts and properties of our PE ontology within those concepts of the CPG ontology that provides patient education aspects, to deliver condition-specific patient education materials based on CPG recommendations to individual patients. We will further discuss the augmentation of the relevant concepts between CPG ontology and PEO in Chapter 4.

3.4.5. Representing PEMs in CPG-PE Ontology

We encode various PEMs related to different disease conditions modalities i.e. their diagnostic options, therapeutic options, complications, risk factor modification, decision making and counselling etc. For this purpose, we analyzed numerous PEMs related to various diseases and speciality from different resources i.e. American College of Family Physicians, A.D.A.M., Inc., British Medical Journals (BMJ) patient education leaflets, Ferri's Netter Patient Advisor etc. in order to identify the knowledge elements within PEMs. We selected PEMs related to several disease conditions and co-morbidities i.e. hypertension, stroke, diabetes, pregnancy, preeclampsia, colon cancer etc. to represent them in our PEO based on the PE knowledge model, which we developed after analyzing several PEMs from different resources. We encoded PEMs for preeclampsia and colorectal cancer from different resources in our PEO. PEMs available in these resources are in PDF format, and they are complex and comprehensive documents for the whole disease condition i.e. causes, risk factor, different diagnostics and therapeutic options etc. Using experiential knowledge of the author and after analyzing knowledge element/ infrastructure of several PEMs, we broken down PEMs based on those knowledge elements. It could be possible some part of PEMs is not necessary or irrelevant for the

patient, so in order to make it personalized to the patient, we broken down into segments based on PE knowledge modeling. In this way, PEMs can be delivered to each recommendation step and only necessary and required information at that point and time will be given to the patients, and it will not overwhelm patients with unnecessary information. We encoded PEMs from several resources and containing PEMs of various natures, complexity and intended purpose for educating patients related to different disease condition(s) modalities during the process of clinical care. For further details see Chapter 4.

3.4.6. Personalization of PEMs

We propose a CPG based Patient Education framework (CPG-PE) using Semantic Web technologies. Upon execution of CPG-PE framework through a computerized decision support system (CDSS), CPG(s) will give recommendations based on patients profile generated through electronic patient record (EPR). Based on the clinical recommendations provided by CPGs, CPG-PE can offer information to patients about their own health conditions in the form of PEMs, which would be evidence-based as the recommendations will come from evidence-based guidelines (see Figure 11). At one point, it will provide patient education and promote shared decision making in clinical settings, on the other hand it will promote the use of evidence-based guideline in routine clinical practice. Personalization will take place at the level of CPG(s) execution, where and when CPG(s) will recommend any action or step in the process of care, the PEMs will be generated through their corresponding sub-classes and properties in the merged CPG-PE ontology. For an example, after the initial work-up, CPG is recommending a diagnostic procedure such as "Colonoscopy" for a patient suspected for Colorectal Cancer. We have modeled this concept "diagnostic procedure" in our CPG-PE ontology to represent PEM related to the diagnostic procedure. Once the CPG will recommend a diagnostic procedure i.e. colonoscopy for this patient, it will generate PEMs related to colonoscopy as ***DiagnosticProcedure*** through CPG-PE ontology in our CPG-PE frame work. We will discuss it detail in Chapter 4 (Section 4.5).

3.4.7. Evaluation of CPG-PE Framework

We evaluated our CPG-PE framework on two comprehensive clinical vignettes, and also compared CPG-PE framework with other related PE systems, as well as consistency checking of PEO. First we checked consistency of our PEO by running Pellet 1.5.2 reasoner on our ontology. Second, we selected two clinical cases: i) *Colorectal Cancer*, and ii) *Preeclampsia*. We first modeled CPG(s) knowledge related to colorectal cancer and preeclampsia in CPG ontology, and then modeled PEMs related to/ or cover these two clinical cases from various PEMs resources, in the CPG-PE ontology. Based on the encoded CPG and PE knowledge in the CPG-PE ontology, we demonstrate the use of our CPG-PE framework in generating personalized PEMs—incorporating both their disease conditions and also their behavioural attitudes. Third, we also provide a systematic evaluation i.e. comparison of CPG-PE framework with other related PE systems and frameworks. PEO consistency checking, an extensive case study, and systematic evaluation will be discussed in Chapter 5.

In Chapter 4, we will discuss PEM knowledge modeling and methodology for Patient Education Ontology (PEO) engineering.

Chapter: 4

4. Patient Education Ontology Engineering

The research methodology for our CPG-PE framework is outlined in 7 key steps: 1) Computerization of CPGs, 2) PEM knowledge modeling, 3) Development of PE ontology, 4) Merging of CPG and PE ontologies, 5) Representing PEMs in CPG-PE ontology, 6) Personalization of PEMs, 7) Evaluation of CPG-PE framework. In this chapter, we will discuss the ontology engineering methodology for the PEO, by describing PEM knowledge modeling, development of PE ontology and merging of CPG and PE ontologies.

4.1. PEM Knowledge Modeling

PEMs have an inherent infrastructure on which all of the PEMs are based on, and we believe that authors of patient education materials and leaflets follow this infrastructure, while developing a new patient education material (see Section 3.4.2). There are two ways to achieve a knowledge model for PEM: i) Comprehensive interviews and surveys with different healthcare professionals and patient education materials developers, and ii) Analyzing a number of patient education materials from various resources as artifacts or samples of the PEM knowledge, and identify their key concepts and knowledge elements to develop a PEM knowledge model accordingly [37]. We aim to identify and explore the inherent infrastructure and model the knowledge elements within PEM, in order to develop an ontology-based knowledge model for PEMs, to be used by our CPG-PE framework to represent the knowledge in the PEMs.

We took the second approach and analyzed numerous PEMs related to various diseases and specialties from different resources i.e. American College of Family Physicians, A.D.A.M., Inc., British Medical Journals (BMJ) patient education leaflets, Ferri's Netter Patient Advisor etc., in order to identify the key concepts and knowledge elements within PEMs to develop an ontology-based knowledge model for PEMs to be used by our CPG-PE framework. We followed the reverse engineering approach to analyzed numerous PEMs related to various specialties, identify their key concepts and

knowledge elements, model those knowledge elements/ structure, and develop a knowledge model for PEMs based on this analysis.

4.1.1. PEM Categorization

We analyzed numerous PEMs from different medical disciplines and specialties related to various diseases from different resources, to explore the inherent pattern or infrastructure of the PEMs. It is our contention that, PEMs should be tailored to the individual patients, specific to their disease conditions and/or co-morbidities, and at the same time, CPG-PE framework should be generic enough to incorporate various disease conditions. For this purpose, we categorize PEMs according to the basis of the following disease specialities: Allergy/ Immunology, Cardiovascular diseases, Critical care, Dermatology, Emergency care, Endocrinology, Gastroenterology/ Hepatology, Genetic diseases, Geriatric Medicine, Haematology, Infectious diseases, Nephrology, Neurology, Neurosurgery, Obstetrics/ Gynaecology, Oncology, Ophthalmology, Orthopedics, Otolaryngology, Pediatrics, Psychiatry, Pulmonary Medicine, Rheumatology, General surgery, Thoracic surgery, Urology, and Vascular surgery.

Unlike CPG categorization [37], in six different aspects: 1) acute care vs. chronic care, 2) primary care vs. secondary care, 3) specialty group, 4) in-patient vs. out-patient management, 5) Adult vs. children, and 6) problem oriented vs. task oriented, we have categorize PEMs only into specialty groups. We believe that, either disease is acute or chronic, treated in in-patient or out-patient, primary care or secondary care, it will belong to any of the above mentioned specialties.

Based on our analysis of numerous PEMs from different resources related to various medical disciplines and specialties encompassing several disease conditions, we identified that most of the PEMs have an inherent pattern or infrastructure, and have certain key concepts and knowledge elements. Those key concepts and knowledge elements are categorized in 14 categories as follows:

1. ***Disease condition description***

These education materials are designed to educate patients about the disease conditions and to provide the medical terminologies in simple language.

2. *Risk factor modification and prevention*

These education materials describe risk factors related to certain disease, e.g. sedentary life style is a risk factor for heart diseases. These materials explain the possible risk factors, how to modify behaviours, and identify preventions of those risk factors, which can make a condition worse or prolong its duration.

3. *Self-management*

These education materials contain information related to homecare for educating patients in managing their illnesses at home, and maintain their health.

4. *Nutrition and dietary advice*

These educational materials contain information related to diet and nutrition. They provide a complete diet plan to the patients related to their disease conditions, to maintain a healthy diet to avoid certain risk factors or to avoid possible harmful effects, which a diet can produce in any specific disease condition(s).

5. *Diagnostic Procedure*

These educational materials provide education about the diagnostic procedures, which they have gone through or will be going through in the process of getting clinical care. They provide explanations about the diagnostic procedure and rational behind it.

6. *Therapeutic procedure*

These educational materials provide patients education about the treatment and therapeutic procedure, which they have gone through or will be going through in the process of getting clinical care. They provide explanations about the therapy and therapeutic procedure and rational behind it.

7. *Pre and Post-Op care*

These educational materials provide education about pre and post-op care. For example, do not eat anything before 12 hours of surgery, and how to take care of your wound after surgery etc.

8. *Pain Management*

These educational materials provide education about how to manage severe pain for example, cancer pain, post-operative pain etc.

9. *Drug information and adverse reaction*

These educational materials provide patients information about the drug, which their doctors have prescribed them. They provide education related to the use of the drug i.e. in

which conditions one can take that drug, and what is the appropriate dose of that drug. Furthermore they also provide information about the indication or contraindication of that drug and their possible adverse effects—such as drug-drug, drug-body and drug-food reactions. Such materials also provide information about other common names of that drug. Overall, these materials provide comprehensive information to the patients, specific to their prescribed medication by their doctors.

10. Radiation and chemotherapy

These educational materials provide patients information about radiation and chemotherapy. These materials explain the procedure to the patients, and possible outcome of radiation and chemotherapy in specific condition.

11. Exercise and Rehabilitation

These educational materials provide education about exercise and rehabilitation. They provide information about the importance of exercise in any specific condition, and also provide information about rehabilitation process in certain conditions for example stroke.

12. Pregnancy

These educational materials provide women, information about pregnancy, especially to nulliparous women who are first-time pregnant. These materials provide information about healthy pregnancy, diet, drug use, baby well-being etc.

13. Decision making and counselling

These educational materials provide counselling to the patients about their disease condition(s) to improve their decision making skills, in order to achieve better patient compliance.

14. Follow-up

These educational materials provide patients education about the follow-up of their condition(s). They describe situations when the patients require a visit to their doctors again, and what are the things need to be done before their follow-up visit. They also describe situations when patients need to consult their doctors immediately.

4.1.2. PEM Selection and Organization

In order to explore the inherent patterns, their key concepts and knowledge elements/ structure within PEMs, we have chosen PEMs from American College of Family Physicians, A.D.A.M., Inc., British Medical Journals (BMJ) patient education leaflets,

Ferri's Netter Patient Advisor etc. Currently, these PEMs are available in PDF format, accessible for the patients. These patient education materials are solely written for the patients, in order to guide them about their own disease condition(s). They are written as a comprehensive document related to different disease conditions and contains the whole information regarding disease condition description, different names of the same condition, causes, risk factors, prevention, sign and symptoms, screening, diagnostic procedure, treatment/therapeutic procedures, information about drugs, chemotherapy and radiation, adverse effects, possible complications, prognosis and follow-up.

Our main objective is to provide patient education messages on each and every recommendation of CPG generated at different steps at the point of care i.e. risk assessment step, diagnostic step, treatment step etc., to improve shared decision making between the patient and the physician during the process of clinical care. As we discussed above, we identified certain key concepts and knowledge elements within PEMs based on our analysis after analyzing several PEMs. We breakdown these comprehensive documents into segments on the basis of 14 categories, which are categorized on the basis of identified key concepts and the knowledge elements within PEMs. We have organized PEMs related to each category accordingly, so we can use them in our CPG-PE frame work in order to deliver patient- specific education materials based on their disease condition(s) and/or co-morbidities and behavioral attitude to improve shared decision making during the process of clinical care.

4.2. Development of PE ontology (Ontology Engineering)

We analyzed a number of PEMs from several specialties related to various diseases from different resources, to explore the inherent pattern or infrastructure of the PEMs. We identified key concepts and knowledge elements within PEMs to develop a knowledge model for PEMs based on our analysis. Based on knowledge modeling of PEMs, we develop an ontology-based knowledge model for PEMs i.e. "Patient Education Ontology" (PEO), to be used by our CPG-PE framework. PEO represents the knowledge elements within PEMs, to deliver personalized patient education materials to the patients based on their disease condition(s)/ co-morbidities.

Protégé tool has two platforms i.e. Frames and OWL [108]. We used protégé OWL to develop our PEO. As our CPG-PE framework is based on the semantic web technology,

so the integration would be much easier if we utilize protégé OWL instead of Frames, this is the reason why we used protégé OWL. We chose protégé editor version 3.4.8 to develop PEO. We adopted the following ontology engineering approach to develop our PEO:

- Step # 1: Determine Scope: Define scope of the ontology, i.e. it is intends to represent patient education materials.
- Step # 2: Consider Reuse: We have reused previously made ontology i.e. CPG ontology [37], to represent clinical practice guidelines and merge PEO with CPG-Ontology as CPG-PE ontology.
- Step # 3: Enumerate Terms: We defined terms for PE knowledge modeling after analyzing several PEMs related to different disease conditions from various resources.
- Step # 4: Define Classes: We defined classes to represent various concepts to model knowledge within PEMs.
- Step # 5: Define Properties: We defined properties which describe attributes of instances of the class and relationship to the other instances.
- Step # 6: Define Constraints or Anomalies: We identified few constraints in PEO i.e. there are some property constraints; few of the properties have constrained domain concepts in PEO.
- Step # 7: Create Instances: We encoded PEMs of various specialties in our PEO by creating instances of the defined classes and then linking them with our defined properties.

4.2.1. Step # 1: Determine Scope

The first step in ontology development is to determine the scope of the ontology. There are certain basic questions we need to answer while determining the scope of the ontology. What is the domain ontology will cover? What is the use of the ontology? What types of question ontology should provide answer. In our case, we intend to develop this ontology (PEO) to represent PEMs in our CPG-PE framework. PEO will be used to provide PEMs specific to patient health profile, disease condition(s), and co-morbidities through CPG-PE framework. PEO is designed to provide patient-specific education based on each recommendation provided by the CPG(s), in CPG-PE framework.

PEO aims to represent all the knowledge encloses in PEMs, and allow execution engine to follow the recommendation steps from the CPGs in order to deliver PEMs upon execution of CPG-PE ontology. During a CPG(s) recommendation at any of the action steps, decision steps, intervention steps etc., PEO is designed to provide patient education specific to that recommendation. However, the PEO is not intend to represent all the medical knowledge and terminologies in the complex medical literature, it can only model the knowledge contained in PEMs, that are written solely intended to provide education and assistance to the patients regarding their disease condition(s) during the process of care. Therefore, this ontology will not be able to provide assistance or answer to those queries which are not recommended by CPG(s), and which is beyond the knowledge contained within patient education materials and documents.

4.2.2. Step # 2: Consider Reuse

We have reused domain ontology for CPG i.e. CPG ontology [37], to represent clinical practice guidelines. In order to achieve an integrated ontology model to incorporate both CPGs and their PEMs, we imported the CPG Ontology and PE Ontology using Protégé. The final merged ontology is named as CPG-PE Ontology. We reviewed the CPG ontology, and identified relevant classes, sub-classes and properties of CPG Ontology that can have patient education aspect. We augmented the concepts and properties of our PE ontology within those concepts of the CPG ontology that have patient education aspects, to provide patient education materials specific to their health profile, disease condition(s) and/ or co-morbidities, based on CPG recommendations during the process of clinical care. See Section 4.3 for further details.

4.2.3. Step # 3: Enumerate Terms

We defined terms based on PE knowledge modeling discussed earlier (see Section 4.1). We analyzed numerous PEMs from different resources related to various medical disciplines and specialties encompassing several disease conditions. We identified certain key concepts and knowledge elements within PEMs. We defined terms for PEO on the basis of those identified key concepts and knowledge elements within PEMs based on our analysis. We made it sure that these terms will be different from those in CPG ontology, if they have the same synonym or intended to represent the same corresponding concept within CPG ontology in our PEO. Hence, we covered all the key concepts and knowledge

elements within PEMs in PEO for our CPG-PE framework, and at the same time made it different to avoid redundancy between the concepts of CPG ontology and PE ontology.

4.2.4. Step # 4: Define Classes

We defined classes after defining the terms based on PE knowledge modeling. We defined classes to represent various concepts within the domain i.e. PEMs. We used the top-down approach while defining the concepts/ classes i.e. we defined the most general concept first, and then specialized them in a hierarchy accordingly. For representing domain concepts in PEMs, we defined 6 general classes: i) **PEMaterial**, ii) **Conditions**, iii) **Factors**, iv) **Considerations**, v) **Obligations** and vi) **Status.**

i) Class **PEMaterials** is further classified into following sub-classes:

1. **Allergy-ImmunologyPEM** is defined to represent PEMs related to Allergy and Immunology such as allergic rhinitis, anaphylaxis, agammaglobulinema, immunodeficiency etc.
2. **CardiovascularDiseasesPEM** is defined to represent PEMs related to Cardiology and Vascular Medicine such as Acute Coronary Syndrome (ACS), Hyperlipidemia, Myocardial Infarction (MI), Deep Vein Thrombosis (DVT) etc.
3. **CriticalCarePEM** is defined to represent PEMs related to Critical Care Medicine such as acute renal failure, angina, aspirin overdose, stroke etc.
4. **DermatologyPEM** is defined to represent PEMs related to Skin Diseases such as pimples, acne rosacea, alopecia, cellulitis etc.
5. **EmergencyCarePEM** is defined to represent PEMs related to Emergency Medical and Surgical Conditions like Alcohol abuse, trauma, drug overdose, acute conditions, etc.
6. **EndocrinologyPEM** is defined to represent PEMs related to Endocrinology and Metabolic Disorders such as Cushing syndrome, Graves disease, Gynecomastia, menstrual disorders, Diabetic Ketoacidosis (DKA) etc.
7. **Gastroenterology-HepatologyPEM** is defined to represent PEMs related to Gastrointestinal and Liver Diseases such as GERD, Heartburn, Gastric ulcers, Hepatitis, Liver Cirrhosis etc.

8. **GeneticDiseasesPEM** is defined to represent PEMs related to Genetics Disorders such as Turner Syndrome, Down Syndrome, Alpha -1 antitrypsin deficiency (AAT), Glucose-6-phosphatase dehydrogenase deficiency etc.
9. **GeriatricMedicinePEM** is defined to represent PEMs related to Geriatric Medicine such as senior abuse, menopause, fall in elderly, dementia etc.
10. **HaematologyPEM** is defined to represent PEMs related to Blood Disorders such as Anemia, Polycythemia, Amyloidosis, beta thalassemia, Malaria infection etc.
11. **InfectiousDiseasesPEM** is defined to represent diseases related to Infectious Diseases such as Pneumonia, Acquired Immunodeficiency Syndrome (AIDs), Chickenpox, Infectious Mononucleosis etc.
12. **NephrologyPEM** is defined to represent PEMs related to medical Renal Disorders such as Nephritis, Nephrotic Syndrome, IgA Nephropathy, Acute Renal Failure (ARF) etc.
13. **NeurologyPEM** is defined to represent PEMs related to Neurologic Disorders such as Alzheimer dementia, Bell Palsy, Multiple Sclerosis (MS), Cerebral Palsy etc.
14. **NeurosurgeryPEM** is defined to represent PEMs related to Neurosurgical Diseases such as Intracranial Haemorrhage, Subdural haematoma, Brain tumors etc.
15. **Obstetrics-GynaecologyPEM** is defined to represent PEMs related to Gynaecological and Obstetric problems, such as women sexual disorders, breast mass, vaginal bleeding, sexually transmitted diseases, pregnancy and its associated complications etc.
16. **OncologyPEM** is defined to represent PEMs related to Cancers and its management such as Colorectal cancer, breast cancer, cervical cancer, prostate cancer, Leukemia etc.
17. **OphthalmologyPEM** is defined to represent PEMs related to Eye Diseases such as Glaucoma, Cataracts, eye infections, vision problems etc.
18. **OrthopedicsPEM** is defined to represent PEMs related to Orthopedic Disorders such as low back pain, arthritis, bone fractures etc.

19. **OtolaryngologyPEM** is defined to represent PEMs related to Ear, Nose and Throat Diseases such as Pharyngitis, sinusitis, Epistaxis, tonsillitis, otitis media etc.
20. **PediatricsPEM** is defined to represent PEMs related to Children and Adolescents such as electrical injuries, mumps, chickenpox, flu etc.
21. **PsychiatryPEM** is defined to represent PEMs related to Psychiatric Disorders such as drug abuse, transsexualism, Schizophrenia, psychosis, eating disorders etc.
22. **PulmonaryMedicinePEM** is defined to represent PEMs related to Respiratory Diseases such as Chronic Obstructive Lung Disease (COPD), Pneumonia, Acute Respiratory Distress Syndrome (ARDS) etc.
23. **RheumatologyPEM** is defined to represent PEMs related to Rheumatic Disorders such as Ankylosing Spondylitis, Rheumatoid Arthritis (RA), Fibromyalgia, etc.
24. **Surgery-GeneralPEM** is defined to represent PEMs related to General Surgical Conditions such as Cholecystitis, appendicitis, lump, carbuncle etc.
25. **ThoracicSurgeryPEM** is defined to represent PEMs related to Thoracic Surgery cases such as Pulmonary Stenosis, Pneumothorax, Aortic Dissection etc.
26. **UrologyPEM** is defined to represent PEMs related to renal surgical disorders such as renal stones, urethral strictures, renal cancers, renal transplantation etc.
27. **VascularSurgeryPEM** is defined to represent PEMs related to vascular surgical cases such as pulmonary embolism, varicose veins, abdominal aortic aneurysm, Venous Thromboembolism (VTE) etc.

ii) Class **Conditions** is further classified into following sub-classes:

1. **Living_Conditions** is defined to represent PEMs in relation to their living conditions i.e. housing, living alone or in a family system, environment, geographic location, availability of healthcare facilities etc.

iii) Class **Factors** is further classified into following sub-classes:

1. **Behavioural_Factors** is defined to represent PEMs in relation to their behavioural factors which come in line of their disease condition management and treatment.

2. **Demotivational_Factors** is defined to represent PEMs in relation to those demotivation factors which come in line of their disease condition management and treatment.

3. **Emotional_Factors** is defined to represent PEMs in relation to those emotional factors which come in line of their disease condition management and treatment.

4. **Motivational_Factors** is defined to represent PEMs in relation to those motivational factors which come in line of their disease condition management and treatment.

iv) Class **Considerations** is further classified into following sub-classes:

1. **Moral_Considerations** is defined to represent PEMs in consideration to their moral values which come in line of their disease condition management and treatment.

v) Class **Obligations** is further classified into following sub-classes:

1. **Cultural_Obligations** is defined to represent PEMs in relation to their cultural obligations which come in line of their disease condition management and treatment.

2. **Religious_Obligations** is defined to represent PEMs in relation to their religious obligations which come in line of their disease condition management and treatment.

vi) Class **Status** is further classified into following sub-classes:

1. **Educational_Status** is defined to represent PEMs in consideration of their educational status in the course of their disease condition management and treatment.

2. **Socio-economic_Status** is defined to represent PEMs in consideration of their socio-economic status in the course of their disease condition management and treatment.

4.2.5. Step # 5: Define Properties

We defined properties or slots, which describe attributes of instances of the class and relationship to the other instances. We defined 2 types of properties: i) Object-type property, and ii) Data-type property. We defined 17 properties i.e. 15 data type properties and 2 object type properties to, link individual from the domain and from the range, and

the relationship between them in our PEO. These properties allow to link domain concepts in CPG ontology to have an integrated ontology model to incorporate both CPGs and their PEMs, as CPG-PE ontology in our CPG-PE framework. These properties are described as follows:

1. ***DiseaseConditionDescription*** (Data-type property): It represents a fragment of a PEM that solely describe the disease and translate the medical terminology in layman language.
2. ***RiskFactorModification-Prevention*** (Data-type property): It represents a fragment of a PEM that describes risk factors related to certain disease, e.g. sedentary life style is a risk factor for heart diseases, and prevention of those risk factors.
3. ***SelfManagement*** (Data-type property): It represents a fragment of a PEM that contains information related to homecare, in order to manage patients' illnesses at home, and maintain their health.
4. ***Nutritional-DietaryAdvice*** (Data-type property): It represents a fragment of a PEM that contains information related to diet and nutrition.
5. ***DiagnosticProcedure*** (Data-type property): It represents a fragment of a PEM that provides patients information about the diagnostic procedure, which they have gone through or will be going through in the process of getting clinical care.
6. ***TherapeuticProcedure*** (Data-type property): It represents a fragment of a PEM that provides patients information about the treatment and therapeutic procedure, which they have gone through or will be going through in the process of getting clinical care.
7. ***Pre-Post-OpCare*** (Data-type property): It represents a fragment of a PEM that provides patients education about pre and post-op care.
8. ***PainManagement*** (Data-type property): It represents a fragment of a PEM that provides patients information about how to manage severe pain for example, cancer pain, post-operative pain etc.
9. ***DrugInformation-AdverseReaction*** (Data-type property): It represents a fragment of a PEM that provides patients information about the drug, which their doctors have prescribed to them.

10. ***Radiation-Chemotherapy*** (Data-type property): It represents a fragment of a PEM that provides patients information about radiation and chemotherapy.
11. ***Exercise-Rehabilitation*** (Data-type property): It represents a fragment of a PEM that provides patients information about exercise and rehabilitation.
12. ***Pregnancy*** (Data-type property): It represents a fragment of a PEM that provides women, information about pregnancy, especially to nulliparous women who are first-time pregnant.
13. ***DecisionMaking-Counselling*** (Data-type property): It represents a fragment of a PEM that provides counselling to the patients, about their disease condition(s) to improve their decision making skills.
14. ***Follow-up*** (Data-type property): It represents a fragment of a PEM that provides patient education about the follow-up of their condition(s).
15. ***SpecificMessage*** (Data-type Property): It represents patient specific messages related to their psychodynamic aspects.
16. ***Applied_Psychosocial_Aspects*** (Object-type property): These educational materials provide patient education based on applied psychosocial aspects. It has sub-properties i) applied_behavioural_factors, ii) applied_motivational_factors, iii) applied_demotivation_ factors, iv) applied_educational_status, v) applied_living_conditions, and vi) applied_socioeconomic_conditions.
17. ***Applied_Religious_Cultural_Aspects*** (Object-type property): These educational materials provide patient education related to applied religious and cultural aspects. It has sub-properties i) applied_cultural_obligations, ii) applied_emotional_factors, iii) applied_moral_considerations, and iv) applied_religious_obligations.

The defined properties and their domain concepts in the PEO are listed in Table 1.

Table 1: PE Ontology: Properties and their Domain Concepts

	Properties	Domain Concepts
1	*DiseaseConditionDescription*	Class: PEMaterial
2	*RiskFactorModification-Prevention*	Class: PEMaterial
3	*SelfManagement*	Sub-classes: OcologyPEM, NephrologyPEM,

		GeriatricMedicinePEM, PulmonaryMedicinePEM, Allergry-ImmunologyPEM, Gastroenterology-HepatologyPEM, EndocrinologyPEM, NeurologyPEM, Obstetrics-GynaecologyPEM, RheumatologyPEM, CardiovascularDiseasesPEM, DermatologyPEM, InfectiousDiseasesPEM and HaematologyPEM
4	*Nutritional-DietaryAdvice*	Class: PEMaterial
5	*DiagnosticProcedure*	Class: PEMaterial
6	*TherapeuticProcedure*	Class: PEMaterial
7	*Pre-Post-OpCare*	Sub-classes: OncologyPEM, OrthopedicsPEM, ThoracicSurgeryPEM, Surgery-GeneralPEM, OtolaryngologyPEM, EmergencyCarePEM, NeurosurgeryPEM, Gastroenterology-HepatologyPEM, OphthalmologyPEM, VascularSurgeryPEM. NeurologyPEM, Obstetrics-GynaecologyPEM, CardiovascularDiseasesPEM, and UrologyPEM
8	*PainManagement*	Sub-classes: CriticalCarePEM, OncologyPEM, OrthopedicsPEM, ThoracicSurgeryPEM, Surgery-GeneralPEM, OtolaryngologyPEM, EmergencyCarePEM, NeurosurgeryPEM, Gastroenterology-HepatologyPEM, OphthalmologyPEM, VascularSurgeryPEM. NeurologyPEM, Obstetrics-GynaecologyPEM, CardiovascularDiseasesPEM, and UrologyPEM
9	*DrugInformation-AdverseReaction*	Class: PEMaterial
10	*Radiation-Chemotherapy*	Sub-class: OncologyPEM
11	*Exercise-Rehabilitation*	Class: PEMaterial
12	*Pregnancy*	Sub-class: Obstetrics-GynaecologyPEM
13	*DecisionMaking-Counselling*	Class: PEMaterial
14	*Follow-up*	Class: PEMaterial
15	*SpecificMessage*	Class: Conditions, Considerations, Factors, Obligations, Status
16	*Applied_Psychosocial_Aspects*	Class: PEMaterial
17	*Applied_Religious_Cultural_Aspects*	Class: PEMaterial

A fragment of the concept hierarchy and their properties defined in the PE Ontology is shown in Figure 14. In Figure 14, the concept Gastroenterology-HepatologyPEM is shown highlighted on the left side of the Figure. The properties associated to Gastroenterology-HepatologyPEM (as shown in right side of the Figure)

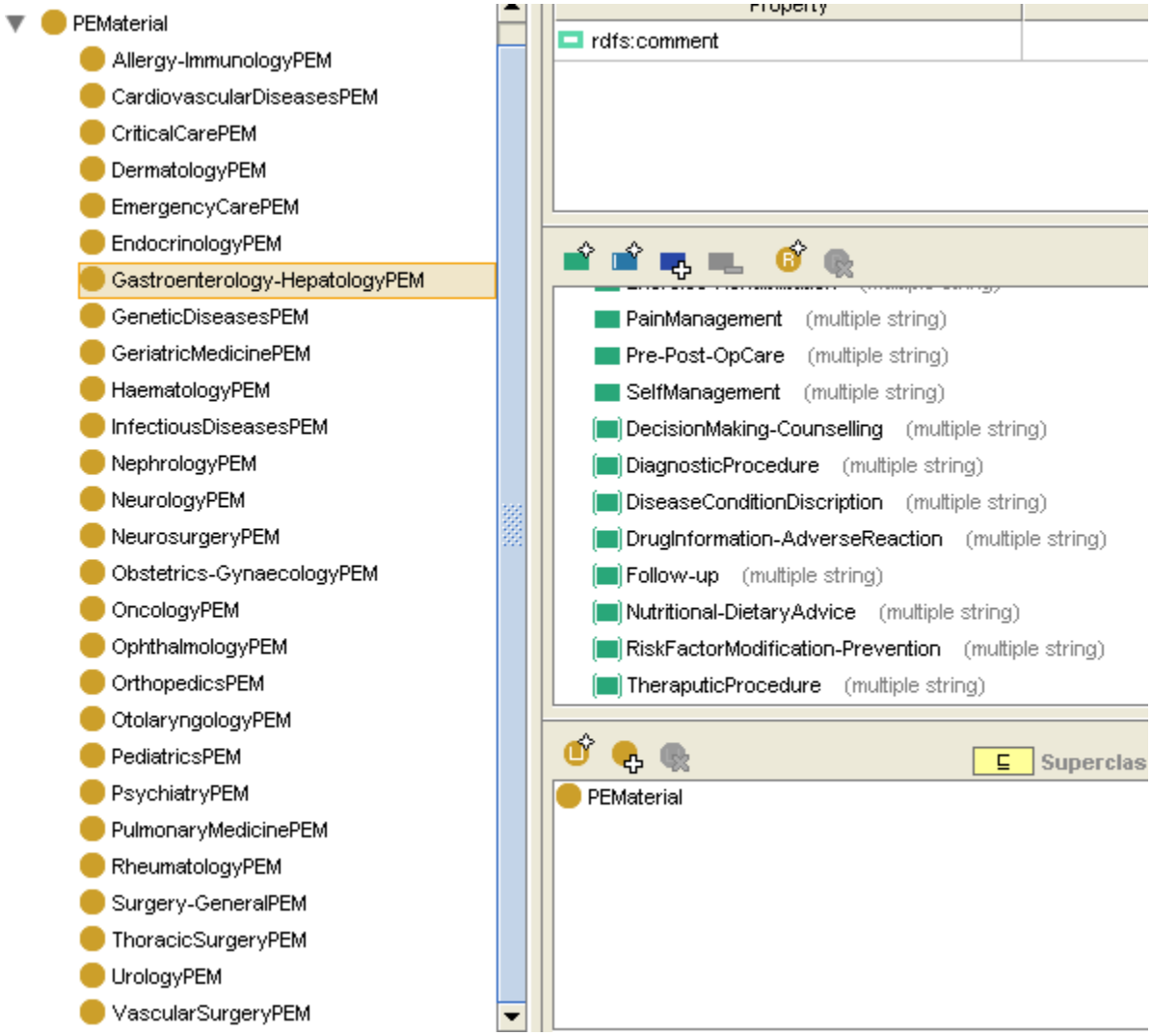

Figure 14: PE Ontology: Concept Hierarchy & Properties

4.2.6. Step # 6: Define Constraints or Anomalies

We defined few constraints in PEO i.e. there are some property constraints (facets). Property constraints (facets) describe or limit the set of possible values for a property or slot. Facets are of cardinality or value type. Slot cardinality represents the number of values for the property or slots for that class i.e. single cardinality or multiple cardinality.

Slot value type represents the type of value for the property or slots for that class i.e. i) string, ii) number, iii) boolean, iv) enumerated type, and v) complex type. We have value type slots or properties in our PEO i.e. string, which can fill in any type of character in it as a set of value. Few properties will not cover all the domain concepts in our PEO, for an example: 1) *Radiation-Chemotherapy*, which describes attributes of instances of the sub-class OncologyPEM, as radiation and chemotherapy is not applicable to all PEMs. It is only applied to diseases in the speciality "Oncology"; 2) *Pregnancy*, which describes attributes of instances of the sub-class Obstetrics-GynaecologyPEM, as it is only applicable to diseases in the speciality Obstetrics and Gynaecology; 3) *Pre-Post-OpCare*, which describes attributes of instances of the sub-classes related to diseases in "Surgical Speciality" i.e. sub-classes: OncologyPEM, OrthopedicsPEM, ThoracicSurgeryPEM, Surgery-GeneralPEM, OtolaryngologyPEM, EmergencyCarePEM, NeurosurgeryPEM, Gastroenterology-HepatologyPEM, OphthalmologyPEM, VascularSurgeryPEM. NeurologyPEM, Obstetrics-GynaecologyPEM, CardiovascularDiseasesPEM, and UrologyPEM.

4.2.7. Step # 7: Create Instances

We create instances of the classes and assigned value for the instance. As we chose, value type slots i.e. string, so it can be filled by any type of characters. First we created instance of the class: PEMaterials, and then we instantiated other classes accordingly to represent each step. We represented various PEMs of different specialties by creating instance of the defined PEO classes, and also linking these instances via defined properties in our PEO. For an example we created instance of pem: Gastroenterology-HepatologyPEM as Gastroenterology-HepatologyPEM_13, and we created instance of pem: Living_Condition as Family_System (see Figure 15)

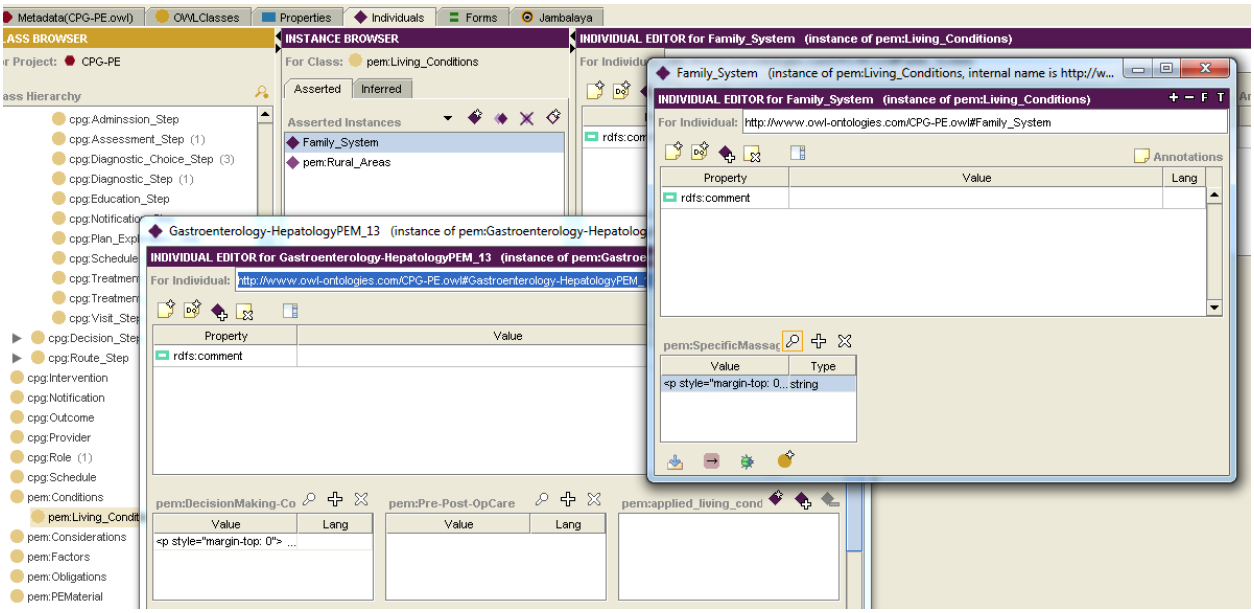

Figure 15: Instances of Patient Education Ontology

4.3. Merging CPG and PE Ontologies (CPG-PE)

We have used CPG ontology [37] in our CPG-PE framework. We imported the CPG ontology and the PE ontology, in order to achieve an integrated ontology model to incorporate both CPGs and their PEMs in our CPG-PE framework. The final merged ontology is named as CPG-PE Ontology. We reviewed the CPG ontology and identified relevant classes, sub-classes and properties of CPG Ontology that can have patient education aspects or in which step there is a need for providing patient education. We augmented the concepts and properties of our PE ontology within those concepts of the CPG ontology that have patient education aspects, to deliver patient education materials based on CPG recommendations to individual patients, specific to their health profile, disease condition(s) and/ or co-morbidities during the process of clinical care. The overview of the identified concepts with in CPG ontology, which can have patient education aspects is shown in Figure 16, and the identified list of CPG concepts that may have correlation with PEMs are shown in Table 2.

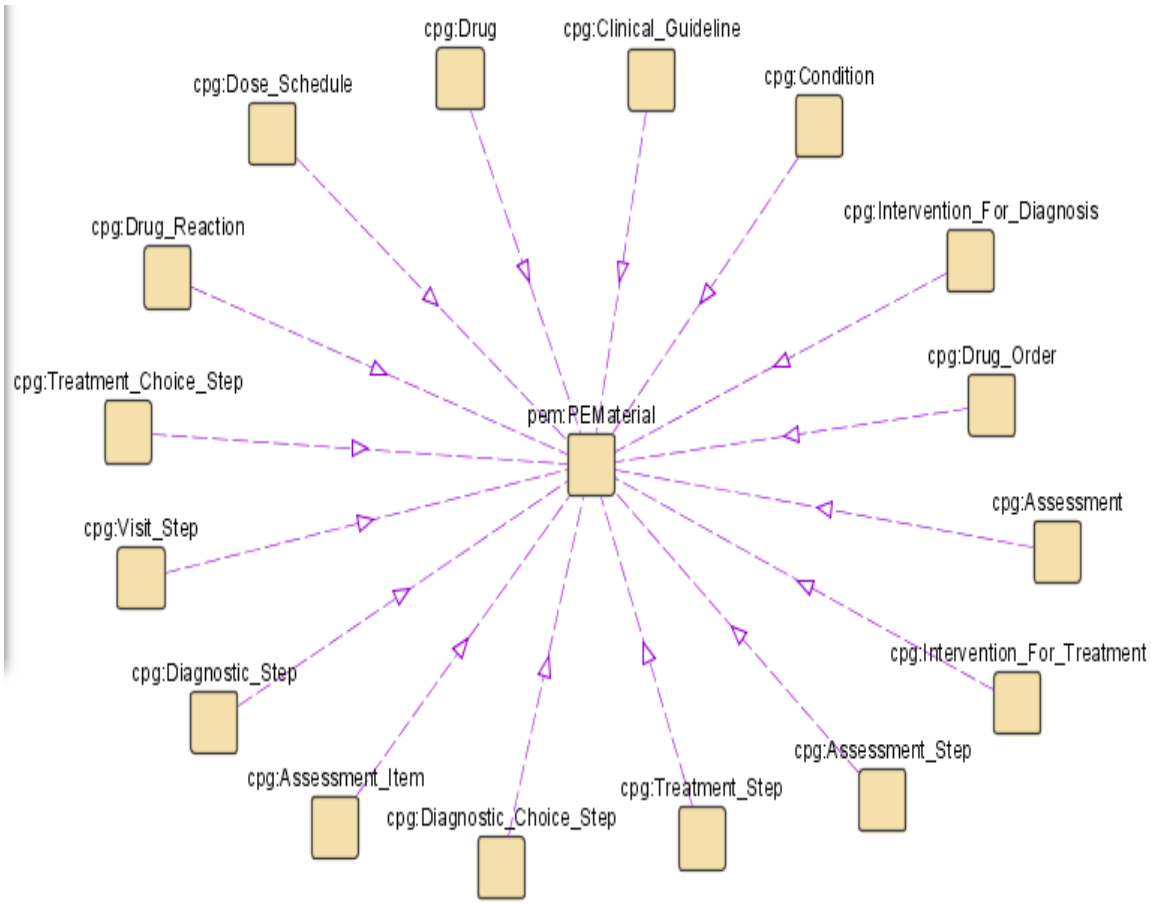

Figure 16: Merging of CPG and PE Ontologies

Table 2: Correspondences between CPG and PE Ontology

CPG Ontology	PE Ontology
Class: Clinical_Guideline	Property: *DiseaseConditionDescription*
Class: Condition	Property: *DiseaseConditionDescription*
Class: Assesment_Step	Property: *DiseaseConditionDescription* Property: *RiskFactorModification-Prevention*
Class: Diagnostic_Step	Property: *DiagnosticProcedure* Property: *DecisionMaking-Counselling*
Class: Diagnostic_Choice_Step	Property: *DiagnosticProcedure* Property: *DecisionMaking-Counselling*
Class: Treatment_Step	Property: *TherapeuticProcedure* Property: *SelfManagement* Property: *DecisionMaking-Counselling* Property: *Pre-Post-OpCare*
Class: Treatment_Choice_Step	Property: *TherapeuticProcedure* Property: *SelfManagement* Property: *DecisionMaking-Counselling* Property: *Pre-Post-OpCare*

Class: Visit _Step	Property: *Follow-up*
Class: Education_Step	PEMaterial
Class: Intervention_For_Diagnosis	Property: *DiagnosticProcedure*
Sub-class: Diagnostic_Imaging	Property: *DiagnosticProcedure*
Sub-class: Group_Of_Diagnostic_Processes	Property: *DiagnosticProcedure* Property: *DecisionMaking-Counselling*
Sub-class: Laboratory_Exam	Property: *DiagnosticProcedure*
Sub-class: Physical_Exam	Property: *DiagnosticProcedure*
Sub-class: Procedure_To_Diagnosis	Property:*DiagnosticProcedure* Property: *DecisionMaking-Counselling*
Class: Intervention_For_Treatment	Property: *TherapeuticProcedure* Property: *DecisionMaking-Counselling*
Sub-class: Prescription	Property: *TherapeuticProcedure* Property: *DecisionMaking-Counselling* Property: *SelfManagement* Property: *DrugInformation-AdverseReaction*
Class: Rx_Medication	Property: *TherapeuticProcedure* Property: *DecisionMaking-Counselling* Property: *SelfManagement* Property: *DrugInformation-AdverseReaction*
Class: Rx_Material_Or_Equipment	Property: *TherapeuticProcedure* Property: *DecisionMaking-Counselling* Property: *SelfManagement* Property: *DrugInformation-AdverseReaction*
Sub-class: Procedure_For_Treatment	Property: *TherapeuticProcedure* Property: *DecisionMaking-Counselling*
Sub-class: Radiotherapy	Property: *TherapeuticProcedure* Property: *DecisionMaking-Counselling* Property: *Radiation-Chemotherapy*
Class: Drug	Property: *DrugInformation-AdverseReaction*
Class: Dose_Schedule	Property: *DrugInformation-AdverseReaction*
Class: Drug_Order	Property: *DrugInformation-AdverseReaction*
Class: Drug_Reaction	Property: *DrugInformation-AdverseReaction*

Based on the above mentioned correspondences (see Table 2), in the CPG-PE Ontology, We augmented the concepts and properties of our PE ontology within those concepts of the CPG ontology that have patient education aspects, by adding the PE

Ontology properties into CPG concepts, to achieve an integrated ontology model to incorporate both CPGs and their PEMs in our CPG-PE framework.. The list of added PE Ontology properties and their corresponding CPG Ontology concepts are shown in Table 3.

Table 3: PE Ontology properties and their augmented concepts in CPG Ontology

	Properties	Domain Concepts
1	*DiseaseConditionDescription*	PEM Class: PEMaterial CPG Class: Clinical_Guideline, Condition, Assesment_Step
2	*RiskFactorModification-Prevention*	PEM Class: PEMaterial CPG Class: Assesment_Step
3	*SelfManagement*	PEM Sub-classes: OcologyPEM, NephrologyPEM, GeriatricMedicinePEM, PulmonaryMedicinePEM, Allergry-ImmunologyPEM, Gastroenterology-HepatologyPEM, EndocrinologyPEM, NeurologyPEM, Obstetrics-GynaecologyPEM, RheumatologyPEM, CardiovascularDiseasesPEM, DermatologyPEM, InfectiousDiseasesPEM and HaematologyPEM CPG Classes: Treatment_Step, Treatment_Choice_Step, CPG Sub-class: Prescription
4	*Nutritional-DietaryAdvice*	PEM Class: PEMaterial
5	*DiagnosticProcedure*	PEM Class: PEMaterial CPG Class: Diagnostic_Step, Diagnostic_Choice_Step, Intervention_For_Diagnosis
6	*TherapeuticProcedure*	PEM Class: PEMaterial CPG Class: Treatment_Step, Treatment_Choice_Step, Intervention_For_Treatment
7	*Pre-Post-OpCare*	PEM Sub-classes: OncologyPEM, OrthopedicsPEM, ThoracicSurgeryPEM, Surgery-GeneralPEM, OtolaryngologyPEM, EmergencyCarePEM, NeurosurgeryPEM, Gastroenterology-HepatologyPEM, OphthalmologyPEM, VascularSurgeryPEM. NeurologyPEM, Obstetrics-GynaecologyPEM, CardiovascularDiseasesPEM, and

		UrologyPEM CPG Class: Treatment_Step, Treatment_Choice_Step
8	*PainManagement*	PEM Sub-classes: CriticalCarePEM, OncologyPEM, OrthopedicsPEM, ThoracicSurgeryPEM, Surgery-GeneralPEM, OtolaryngologyPEM, EmergencyCarePEM, NeurosurgeryPEM, Gastroenterology-HepatologyPEM, OphthalmologyPEM, VascularSurgeryPEM. NeurologyPEM, Obstetrics-GynaecologyPEM, CardiovascularDiseasesPEM, and UrologyPEM
9	*DrugInformation-AdverseReaction*	PEM Class: PEMaterial CPG Class: Drug, Dose_Schedule, Drug_Order, Drug_Reaction CPG Sub-class: Prescription
10	*Radiation-Chemotherapy*	PEM Sub-class: OncologyPEM CPG Sub-class: Radiotherapy
11	*Exercise-Rehabilitation*	PEM Class: PEMaterial
12	*Pregnancy*	PEM Sub-class: Obstetrics-GynaecologyPEM
13	*DecisionMaking-Counselling*	PEM Class: PEMaterial CPG Class: Diagnostic_Step, Diagnostic_Choice_Step, Treatment_Step, Treatment_Choice_Step, Intervention_For_Treatment CPG Sub-Class: Procedure_To_Diagnosis, Group_Of_Diagnostic_Processes, Prescription, Procedure_For_Treatment
14	*Follow-up*	PEM Class: PEMaterial CPG Class: Visit _Step
15	*Applied_Psychosocial_Aspects*	PEM Class: PEMaterial
16	*Applied_Religious_Cultural_Aspects*	PEM Class: PEMaterial
17	*SpecificMessage*	PEM Class: Conditions, Considerations, Factors, Obligations, Status
18	Cpg: *education_material*	CPG Class: Drug, Dose_Schedule, Drug_Order, Drug_Reaction, Clinical_Guideline, Condition, Assesment_Step, Assesment_Item, Assesment, Treatment_Step, Treatment_Choice_Step, Diagnostic_Step, Diagnostic_Choice_Step, Intervention_For_Treatment,

		Intervention_For_Diagnosis, Visit_Step

A fragment of the concept hierarchy and their properties defined in the CPG-PE Ontology is shown in Figure 17. In Figure 17, the CPG Ontology concept *Prescription* is shown highlighted in the left-side of the Figure. Based on the above mentioned correspondences in Table 2, the *Prescription* concept has now more properties after augmentation of PE ontology properties (as shown in right side of the Figure.

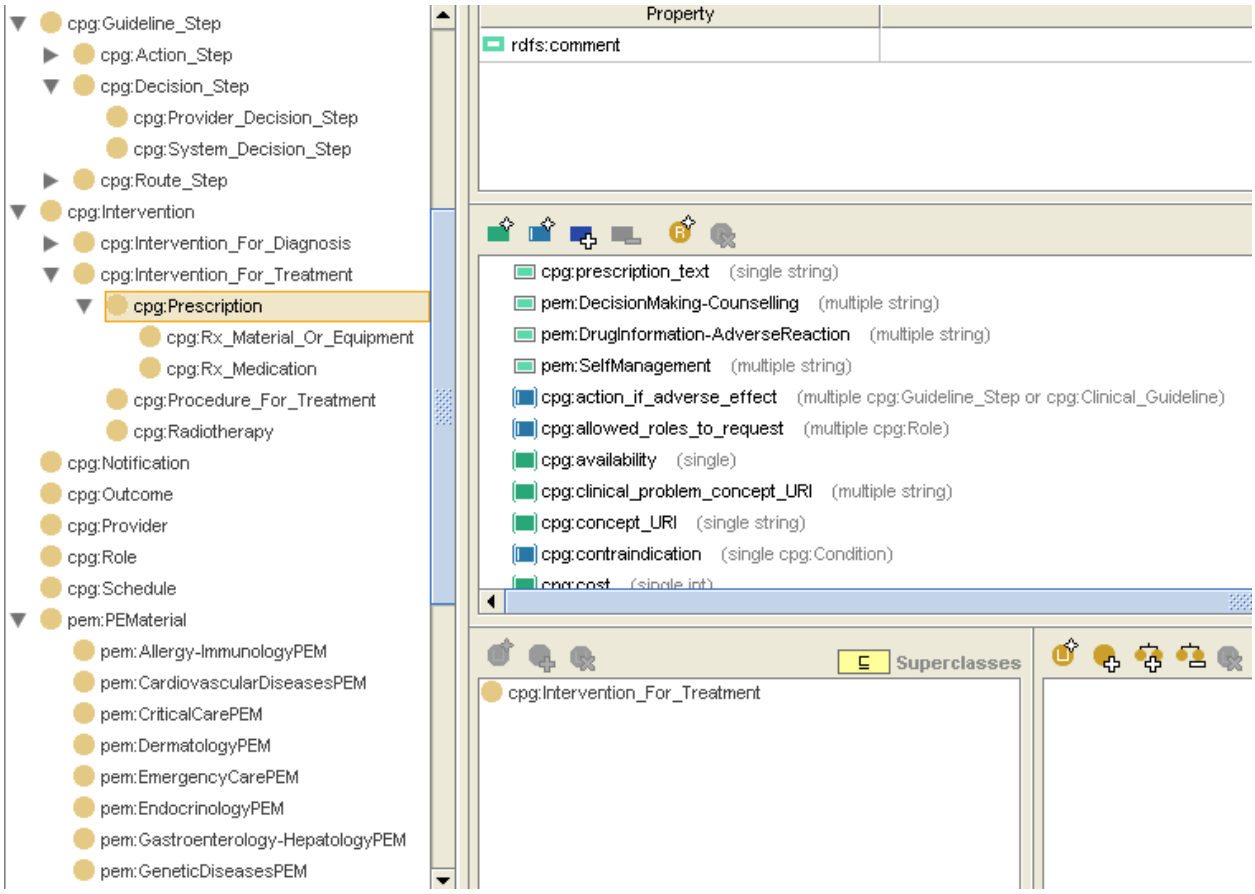

Figure 17: CPG-PE Ontology: Augmenting CPG concepts with PE properties

4.4. Representing PEMs in CPG-PE Ontology

As we discussed earlier in Chapter 3 (Section 3.4.5), we encode various PEMs from different resources related to various medical disciplines and specialties encompassing several disease conditions modalities i.e. their diagnostic options, therapeutic options, complications, risk factor modification, decision making and counselling etc. For this

purpose, we analyzed numerous PEMs from different specialities and medical disciplines related to various disease conditions from different resources i.e. American College of Family Physicians, A.D.A.M., Inc., British Medical Journals (BMJ) patient education leaflets, Ferri's Netter Patient Advisor etc. in order to identify the knowledge elements within PEMs. We selected PEMs related to several disease conditions and co-morbidities i.e. Hypertension, Stroke, Diabetes, Pregnancy, Preeclampsia, Benign Prostatic Hyperplasia (BPH), Prostate Cancer, Renal Failure, Rheumatoid Arthritis, and Colon Cancer etc. to represent them in our PEO based on the PEM knowledge modeling, to be used in our CPG-PE framework.

PEMs available in these resources are in PDF format, and they are complex and comprehensive documents for the whole disease condition i.e. causes, risk factor, different diagnostics and therapeutic options etc. Using tacit and experiential knowledge of the author and after analyzing knowledge element/ infrastructure of several PEMs, we broken down PEMs based on those knowledge elements and key concepts, to be used in our CPG-PE framework. It is possible some part of PEMs is not necessary or irrelevant for any specific patient. Sometimes, there is a need of some other specific information for the patient if he or she has any other associated disease condition(s) and/or co-morbidities, so we need to include that specific information in the PEMs related to associated disease condition(s) and/or co-morbidities which the patient is suffering during the presentation of their present illness. For these reasons, we broken down these complex and comprehensive documents for patient education into segments based on PE knowledge modeling, in order to make them personalized or tailored for any specific patient during the course of the management of their presenting illness, associated disease condition(s), and/ or co-morbidities in the process of clinical care. For an example, Colorectal Cancer, we took PEMs related to colorectal cancer from different resources and modeled them and broken down into segments. It has disease definition, sign and symptoms, risk factors, clinical examination, laboratory tests, diagnostic tests, medications, surgery, radiation and chemotherapy, prognosis and outcomes, complications and follow-up. We have encoded different knowledge elements and key concepts within PEMs as follows:

1. Disease definition, sign and symptoms as "*Disease Condition Description*".
2. Risk factors as "*Risk Factor Modification and Prevention*".
3. Laboratory and diagnostic tests as "*Diagnostic Procedures*".
4. Management and surgery as "*Therapeutic Procedures*",
5. Medication as "*Drug Information and Adverse Reactions*".
6. Medication and management for home care as "*Self-management*".
7. Care after surgery as "*Pre-and Post-Op Care*"
8. Management of pain during the course of the disease as "*Pain Management*".
9. Care for any disability during or after illness as "*Exercise and Rehabilitation*".
10. Consequences of any diagnostic or therapeutic procedure (medical or surgical), and the prognosis, outcomes and complications of any diagnostics and therapeutic modality and the disease condition(s) its self as "*Decision Making and Counseling*".
11. Chemotherapy and radiation therapy as "*Radiation and Chemotherapy*".
12. Nutrition and dietary restrictions during the course of the disease and after the management of the disease as "*Nutrition and Dietary Advice*".
13. Follow-up visit during the course of clinical care as "*Follow-up*".

We have modeled and broken down PEMs for several other diseases as discussed above, from various medical disciplines and specialties in our CPG-PE framework, to deliver patient specific or tailored education materials to patients at each recommendation step by the CPG(s) for the management of their disease condition(s) and/ or co-morbidities during the process of clinical care. In this way only appropriate and required information at that point and time will be given specific to the patient, so they will not be overwhelmed with a lot of unnecessary information provided to them. It will improve shared decision making between the patient and the physician, encourage patients to actively participate in the process of clinical care, increase patient compliance and better health outcomes.

4.5. Personalization of PEMs

We proposed a CPG based Patient Education Framework (CPG-PE), to improve shared decision making between the patient and the physician during clinical care process in healthcare using semantic web technology. As we discussed earlier in Chapter 3 (Section

3.4.6), the personalization will take place while executing CPG-PE framework. Upon execution of CPG-PE framework through a computerized decision support system (CDSS), and if an electronic patient record (EPR) is available; CPG(s) will give recommendations based on patients profile generated through EPR, for the given disease condition(s) and/or co-morbidities. Based on the clinical recommendations provided by CPGs, CPG-PE can offer information to patients about their own health conditions during clinical care process regarding disease condition description, risk factor modification and prevention, diagnostic and therapeutic tests, prognosis, and complications etc. at each recommendation step of CPG(s), in the form of PEMs. Where and when CPG(s) will recommend any action or step in the process of care, the PEMs related to that specific recommended step or action will be generated in merged CPG-PE ontology. These PEMs would be evidence-based as the recommendations will come from evidence-based guidelines (see figure 10). At one point, it will provide patient education and promote shared decision making in clinical settings, on the other hand it will promote the use of evidence-based guideline in routine clinical practice.

As we mentioned earlier that, the CPG-PE framework requires a fully integrated Electronic Patient Record (EPR), which can provide patients' information such as demographic information or those information which are address by the psychodynamic model (i.e. patients' bio-data, age, gender, occupation, marital status, address, socioeconomic status, educational status, living conditions, and other psychosocial factors). EPR also contains patients clinical information i.e. presenting complain, history of presenting complain, past medical and surgical history, medication and immunization history, diagnostic investigations and interventions, and current treatment, management and procedures. After entering patient data both clinical information and psychosocial, behavioral, and motivational attitude information, patient's specific-case profile can be automatically created through an integrated EPR or EHR [17, 37, 73, 76, 77, 84]. A fully integrated Electronic Health Records (EHR), which can generate patient-specific case profile by using the data stored in it regarding patients' past and current medical histories. It contains patients' health record such as demographic factors, history of past illnesses, history of surgeries and medications. They are being aggregated into clinical data repositories and warehouses by many healthcare centers [85-87], so those data repository

can be used as a starting point to generate patient-specific case profile, as it has all the information required to generate patient-specific profile. With these patients' information from EPR, patient-specific case profile can be generated, which contains all the basic information related to their demographic data, and current and past information related to their health conditions.

During Clinical encounter, a patient will come with their presenting complains, and the EPR will generate patient profile based on their disease condition(s) and/ or co-morbidities, behavioral attitude, and psychosocial factors. The patient-specific case profile can be used to select CPG or multiple CPGs, that addresses the disease condition(s) and/or co-morbidities specific to that individual patient through the decision logic, which is beyond the scope of this research as we mentioned earlier. There will be some CPG recommendations in terms of action step, decision step or route step etc. In our CPG-PE ontology, they are connected to 17 properties of the sub-classes and classes. Based on patient-specific case patient profile and the decision criteria satisfied on the patient profile, CPG-based recommendations and also their related PEMs can be prescribed to the patients highly specific to the individual patient according to their disease condition(s) and associated co-morbidities. Moreover, that demographic/psychodynamic information generated by the EPR can be match, using the same patient-specific case profile and the decision criteria satisfied on the patient profile, to our corresponding properties and sub-properties in CPG-PE Ontology i.e. SpecificMessage, Applied_Psychosocial_Aspects (applied_behavioural_factors, applied_motivational_factors, applied_demotivation_factors, applied_educational_status, applied_living_conditions, and applied_socioeconomic_conditions) and Applied_Religious_Cultural_Aspects (applied_cultural_obligations, applied_emotional_factors, applied_moral_considerations, and applied_religious_obligations). This will further personalize educational materials, if any of these psychosocial aspects addressed by the psychodynamic model is applicable to the patient based on the patient-specific case profile and the decision criteria satisfied on the patient profile in the process of clinical care. This will encourage patient's preferences and improve shared decision making between the patient and the physician in the process of clinical care.

For an example CPG is recommending "*colonoscopy*" for a specific patient, based on their case-profile, so the PEM related to the colonoscopy will be generated in parallel to the CPG recommendation as ***DiagnosticProcedure*** in our CPG-PE ontology. On the other side, if the patient is not willing to go for colonoscopy due to some reasons, such as it is invasive or due to some cultural barriers or personal preference, the psychodynamic model will indicate about those barriers using properties Applied_Psychosocial_Aspects and Applied_Religious_Cultural_Aspects to the physician by patient feedback or their wish and preference during the course of management of their disease condition(s) and/ or co-morbidities. They will try to find out another alternative procedure for diagnosis by the CPG recommendations i.e. virtual colonoscopy (CT Colonography), and simultaneous PEM will be generated personalized to that patient, which will come in line of patient's preference. CPGs usually have some alternative options for diagnostic and therapeutic modalities. If there will be no other diagnostic or therapeutic modalities available for any give condition, then patients will be either bound to those diagnostic or therapeutic regimes or they have the right to refuse those diagnostic or therapeutic regimes, which are offered by CPGs or their physicians. Moreover, upon the generated recommendation options and their PEMs offered specific to patient disease conditions and behavioural attitudes, both physician and patients can then discuss an optimal CarePlan [88] through a shared decision-making process where (i) a physician, using CPG knowledge, can decide the most beneficial and effective drug/therapy recommendation options for the patient, and (ii) a patient, based on offered PEMs, can educate themselves on the benefits and risk measures of the prescribed recommendations, and then can decide whether the patient is willing for any of the prescribed recommendations or procedures. Hence, CPG-PE offers an interaction from both parties involved, and facilitates a share decision-making process between them for achieving both optimal and feasible "*Care Plan*" for the patients.

In Chapter 5, we will evaluate our CPG-PE framework based on three approaches: 1) consistency checking of PEO, 2) an extensive case study, and 3) systematic evaluation.

Chapter: 5

5. Evaluation: CPG-PE Framework

Chapter 5 presents the evaluation of our CPG-PE framework. For the evaluation, we have adopted three approaches: 1) *Consistency checking of PEO*: If the ontology model and its instantiation has any inconsistency; 2) *Extensive case study*: Evaluation of our CPG-PE framework on two comprehensive clinical vignettes; and 3) *Systematic evaluation*: Evaluation of CPG-PE framework by comparison of CPG-PE framework with other related Patient Education Systems, discussed in Chapter 2 (see Section 2.2).

5.1. Consistency Checking of PEO

In order to check the consistency of our PE Ontology, we performed two different tasks:

1. Automatic consistency checking
2. Manually verifying results of taxonomy classification and type inferring

We ran Pellet 1.5.2 reasoner on our ontology to perform both of the above mentioned tasks. Consistency checking performed by Pellet checks if the ontology model and its instantiation has any inconsistency. Inconsistencies can be caused by a number of modeling issues. Some possible causes that are more relevant to our case are:

1. Inappropriate instantiation of disjoint classes
2. Inappropriate use of functional, symmetric and inverse functional properties

Our ontology is consistent, and we did not find any inconsistencies on performing consistency checking using Pellet.

Taxonomy classification infers subclass relation between different classes based on the modeled ontology. We performed taxonomy classification on our ontology using Pellet, and the inferred subclass relation only found the transitive closure of the subclass relation and no other inferred cases were found. This result was consistent with our intended model.

Finally we performed type inferring using Pellet. Similar to the above case the only inferred types were the ones where an instance of a subclass was also typed as an instance of the super class. Again this result is consistent with our intended model.

5.2. Clinical Cases (Case Study)

We selected two comprehensive clinical cases i.e.: i) *Colorectal Cancer*, and ii) *Preeclampsia* for the evaluation of our CPG-PE framework. We first modeled CPG(s) knowledge related to colorectal cancer and preeclampsia in CPG ontology, and then modeled PEMs covering these two clinical cases from various PEMs resources, in the CPG-PE ontology. Based on the encoded CPG and PE knowledge in the CPG-PE ontology, we demonstrate the use of our CPG-PE framework in generating personalized PEMs—incorporating both their disease conditions and also their behavioural attitudes, during clinical care process. We used 3 Clinical Practice Guidelines and 55 meta-analysis, clinical trials and systemic reviews to present these two cases to evaluate our CPG-PE framework. The major guidelines we followed are: i) National Institute for Health and Clinical Excellence (NICE) guidelines for evaluation of suspected cancer/ colorectal cancer, ii) Society of Obstetricians and Gynecologists of Canada guidelines for diagnosis, evaluation, and management of the hypertensive disorders of pregnancy, iii) and American College of Obstetricians and Gynecologists (ACOG) guidelines for diagnosis and management of preeclampsia and eclampsia. For evaluation of CPG-PE framework, the clinical cases are as follows:

5.2.1. Vignette 1: Colorectal Cancer

> *A 70-year-old white male presents to his primary care physician with a complaint of rectal bleeding. He describes blood mixed in with the stool, which is associated with a change in his normal bowel habit, such that he is going more frequently than normal. He has also experienced some crampy right-sided abdominal pain and weight loss. He has previously been fit and well and there was no family history of GI disease. Examination of his abdomen and digital rectal examination are normal.*

1. **Highlights:**

Colorectal cancer is the malignant tumors originating in colon and rectum. The majority of colorectal cancers are adenocarcinomas derived from epithelial cells. About 71% of new colorectal cancers arise in the colon and 29% in the rectum. Increasing age is the greatest risk factor for sporadic colorectal adenocarcinoma with 99% of cancers occurring in people aged 40 years or over. Overall, 5-year survival varies according to

different demographic factors and regions across the world. Figure 18 gives a brief summary of the diagnosis, screening and management of CRC as follows:

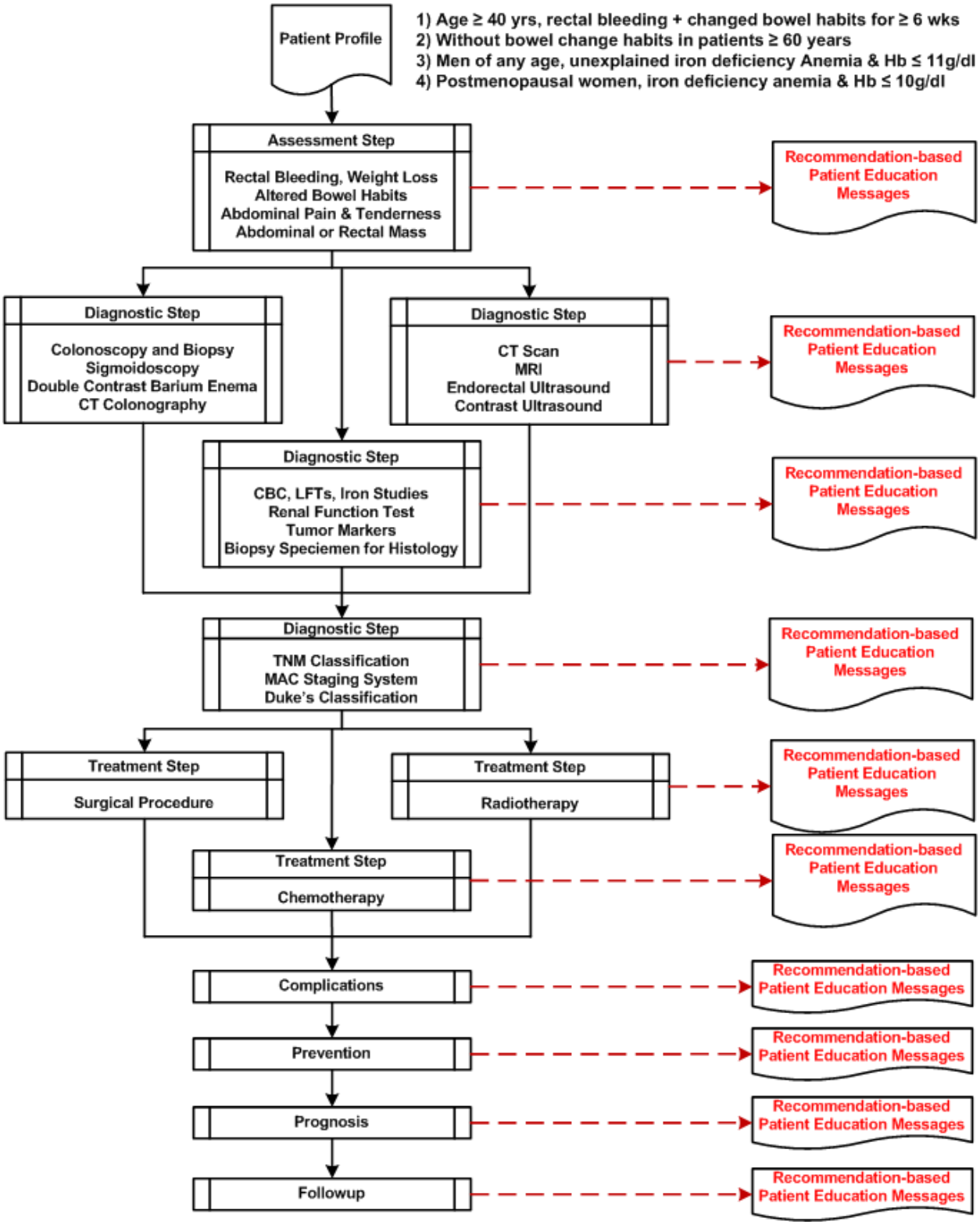

Figure 18: Diagnosis, screening and management of CRC

2. **Presenting Complaints:**

- Bleeding from rectum mixed with stool

- Change bowel habits
- Crampy right-side abdominal pain
- Weight loss
- No family Hx of GI diseases
- Normal abdominal and rectal examinations

3. **History of Presenting Complaints and Examination:**

A 70-year old white male comes with the bleeding from rectum, along with altered bowel habits i.e. on and off constipation and diarrhea with increasing frequency, as he is going more frequently for 2 months. Sometimes, he experienced right-sided abdominal pain which is crampy in nature. Moreover, he also noticed weight loss in previous 2 months. Earlier, he has been previously fit and well, and he has no history of gastrointestinal disease and no related family history as well. As far as his personal habits are concerned, he lives a sedentary life style i.e. physical inactivity and lack of exercise, consumes low fiber and high fat diets as well as consumes red and processed meat. He has a history of smoking 1 pack-year for 35 years, and consumes alcohol, 3-4 drinks per week. His general physical and systemic examinations were normal, with no lymphadenopathy, normal chest, abdominal and rectal examinations. His physician ordered Complete Blood Count (CBC) and Stool test, and significant findings were his hemoglobin was 9.5 g/dl and 4+ occult blood in his stool. His primary care physician had a high suspicion of Colorectal cancer (CRC), based on his history, examination and relevant risk factors (which we discuss later), referred him to the tertiary care hospital for specialist(s) consultation(s).

4. **Differential Diagnoses (DDs):**

- Colorectal Cancer (CRC)
- Other causes of GI bleeding such as:
    - Irritable Bowel Syndrome (IBS)
    - Crohn's disease
    - Ulcerative colitis
    - Hemorrhoids

- Anal fissure
- Diverticular disease

Patient Education:

As we mentioned earlier, our main objective is to provide patient education at each recommendation step, so we will provide PEM when there is any recommendation by CPG(s). In CPG-PE ontology, all these concepts such as presenting complaint, history of presenting complaint and differential diagnoses are encoded in Assessment_1 which has the instance of cpg:Assessment class. They are presented as instance of cpg:Assesment_Items. It gives patient education material about the possible reasons for these signs and symptoms i.e. possible diagnoses, and their associated clinical presentation as pem:DiseaseConditionDiscription, as shown in Figure 20 (see Appendix). Moreover, cpg:Clinical_Guideline encoded the concept Diagnosis_Screening_and_Management of CRC, has patient education in terms of pem:DiseaseConditionDescription as shown in Figure 21 (see Appendix).

5. **Criteria for evaluation of CRC:**

National Institute for Health and Clinical Excellence (NICE) guidelines for evaluation of suspected colorectal cancer [109]:

- in patients ≥ 40 years old, rectal bleeding with change in bowel habits (looser stools and/or increased frequency) for ≥ 6 weeks
- in patients ≥ 60 years old
    - rectal bleeding ≥ 6 weeks without change in bowel habits or anal symptoms
    - change in bowel habits to loose stools and/or more frequent stools for ≥ 6 weeks
- in patients of any age
    - right, lower abdominal mass consistent with large bowel involvement
    - palpable rectal mass (intraluminal, not pelvic)
- in men of any age, unexplained iron deficiency anemia and hemoglobin ≤ 11 g/dl

- in postmenopausal women, unexplained iron deficiency anemia and hemoglobin ≤ 10 g/dl

Patient Education:

In CPG-PE Ontology, criteria for evaluation of CRC is encoded as Condition_1, which is an instance of cpg:Condition, has patient education in terms of pem:DiseaseConditionDescription of CRC, as shown in Figure 22 (see Appendix).

6. **Common clinical presentation for CRC:**

Patients suspected for CRC have the following clinical presentations [110]:

- Rectal bleeding
- Weight loss
- Abdominal pain
- Diarrhea
- Constipation
- Abnormal rectal exam
- Abdominal tenderness
- Hemoglobin < 10 g/dL (100 g/L)
- Positive fecal occult blood
- Blood glucose > 10 mmol/L (180 mg/dL)

7. **Risk Factors:**

Risk factors for CRC are as follows:

- White/Caucasian ethnicity [111]
- Increasing age [112]
- Male sex [112]
- Previous colon polyps or previous colorectal cancer [112]
- History of inflammatory bowel disease (such as Crohn's disease or ulcerative colitis) [113].
- Hereditary syndromes

- 2-3 times risk if relatives with colorectal cancer, based on 27 meta-analyses [114]
- Hereditary non-polyposis colorectal cancer (HNPCC) (Lynch syndrome)
- Familial adenomatous polyposis
- Family history of "cancer family syndrome", heredofamilial breast and colon cancer

- Lifestyle factors
  - Diet (red meat, high-fat, inadequate fibre)
    - High intake of processed meat and red meat associated with increased risk of colorectal cancer [115-117]
    - Higher meat intake and lower fish intake associated with increased risk for colorectal cancer [118]
    - Western dietary pattern associated with increased risk of colon cancer [119]
- Obesity
  - Obesity associated with increased risk of colorectal cancer in men and women [120]
  - Increase BMI associated with increasing risk of colon cancer [121]
  - High energy intake and obesity associated with risk of rectal cancer [122]
- Sedentary lifestyle [123]
- Smoking [124]
- High alcohol consumption [125]
- History of Diabetes Mellitus [126]

8. **Assessment:**

Based on above mentioned evaluation criteria, common clinical presentations and risk factors for CRC, the assessment of patient's condition is as follows:

1. Presence of risk factors—yes. Advance age (70 years old), white male, sedentary life style (i.e. physical inactivity and lack of exercise), life style factors (consumes low fibre and high fat diets as well as consumes red and

processed meat), smoking (1 pack-year for 35 years), and alcohol consumption (3-4 drinks per week).

2. Rectal bleeding—yes. For 2 months.
3. Weight loss—yes. In last 2 months.
4. Abdominal pain—yes. Crampy right-side abdominal pain.
5. Diarrhea—yes. Change in bowel habits and increase frequency for last 2 months.
6. Constipation—yes. Change in bowel habits and increase frequency for last 2 months.
7. abnormal rectal exam—No
8. abdominal tenderness—No
9. Hemoglobin < 10 g/dL (100 g/L)—yes, 9.5 g/dl.
10. Positive fecal occult blood—yes, 4+ occult blood in his stool
11. Blood glucose > 10 mmol/L (180 mg/dL)—No. 9.2 mmol/L.

Patient Education:

Detailed assessment of having risk factors are encoded in Assessment_Step_1 (see Figure 23 and 48 in Appendix), which is an instance of Class cpg:Assessment_Step, has patient education in terms of pem:DiseaseCondition Description, pem:DecisionMaking-Counseling and pem:RiskFactorsModification-Prevention, which gives patient education about CRC, counsel them about the pros and cons of the condition in terms of outcome or prognosis, and risk factors, their modification and prevention (see Figure 24 in Appendix).

9. **Criteria for Diagnosis and Staging:**

Criteria for diagnosis and staging of CRC are as follows [127-131]:

- Initial testing for diagnosis and staging:
  - Colonoscopy (plus barium enema if colonoscopy inadequate)
  - Blood tests
    - Complete blood count (CBC)
    - Liver and renal function tests

- Carcinoembryonic antigen (CEA)
- Imaging to help identify metastatic disease may include:
  - Computed tomography (CT) of chest, abdomen and pelvis
  - Magnetic resonance imaging (MRI) generally used for rectal cancer
  - Chest x-ray
  - Other imaging studies for suspected liver metastases include ultrasound, MRI and positron emission tomography (PET)
- Endorectal (transrectal) ultrasound may be useful for diagnosis and staging of rectal cancer.

- Iron studies (if anemic)
- Other tests which may be useful include:
  - CT colonography may help specify location of tumor
  - Hepatic ultrasound or enhanced MRI may help characterize liver nodules
  - 2-[18F]-fluoro-2-deoxy-D-glucose positron emission tomography (FDG-PET) may be useful for restaging after treatment
- Test colorectal tumors for microsatellite instability (to identify patients for germline MSH1/MLH1 mutation testing) if pathologic features or family history suggests risk for Hereditary Nonpolyposis Colorectal Cancer (HNPCC).

10. **Diagnostic Step:**

(a) ***Diagnostic Procedure:***

- Colonoscopy: Found ulcerating exophytic mucosal lesion that narrow the bowel lumen. Biopsy done and sent the specimen for histological examination.

Complete colonoscopy feasible in most patients and useful to assess for metachronous tumor [127, 128].

- Other options:
  - Sigmoidoscopy
  - Double contrast barium enema
  - CT colonography (virtual colonoscopy).

Patient Education:

In CPG-PE ontology diagnostic procedures such as colonoscopy with biopsy, sigmoidoscopy, double contrast barium enema and CT colonography are encoded as Diagnosis_Procedure which is an instance of class cpg: Diagnostic_Choice_Step. Diagnostic_Choice_Step has an instance of class cpg:Procedure_To_Diagnose and has patient education in terms of pem:DiagnosticProcedure and pem:DecisionMaking-Counseling, which gives patient education about the diagnostic procedure and also provide necessary counseling related to the procedure. We are only showing one diagnostic procedure here i.e. colonoscopy (see Figure 25 in Appendix), likewise CPG-PE ontology has PEMs related to other alternative diagnostic procedures.

(b) ***Diagnostic Laboratory Tests:***

1. CBC : Anemia

Almost 90% of patients with right-sided colorectal cancer are anemic [132].

2. Iron Studies: Iron Deficiency Anemia. Between 6-10% of patients referred for investigation of iron-deficiency anemia are found to have colorectal cancer [133, 134].
3. LFTs: Normal
4. Renal Function Tests: Normal
5. Tumor Marker (serum prolactin): Elevated. Serum Prolactin elevated in 77% patients and 2% controls [135].
6. Tumor Marker (serum CEA): Elevated. Serum CEA level elevated in 60% patients and 2% controls [135]. CEA levels should only be measured after confirmation of the diagnosis, in selected cases.

Patient Education:

In CPG-PE ontology, diagnostic laboratory tests such as CBC, LFTs, tumor markers etc. are encoded as Diagnostic_Lab_Test which is an instance of class cpg:Diagnostic_Step, which has an instance of cpg: Laboratory_Exam. Each individual laboratory test has patient education in term of pem:DiagnosticProcedure to explain about the laboratory test, for example CBC (see Figure 26 in Appendix).

(c) ***Diagnostic Imaging and Radiography:***

1. CT scan of Thorax, Abdomen and pelvis: colonic wall thickening, with no enlarged lymph nodes or metastases seen.

CT scan of chest, abdomen, and pelvis is useful to assess for metastatic disease [127]. All patients with colorectal cancer should have preoperative staging by CT scanning of the thorax, abdomen, and pelvis to determine the local and distal extent of disease and to guide treatment and discuss prognosis.

Other options are:

2. Magnetic resonance imaging (MRI) of abdomen and pelvis (generally used for rectal cancers).
3. Endorectal (transrectal) ultrasound
4. Contrast ultrasound of the abdomen/liver.

Patient Education:

In CPG-PE ontology, diagnostic imaging and radiography such as CT scan, MRI, transrectal ultrasound etc. are encoded as Diagnostic_Imaging_Radiography, which is an instance of class cpg:Diagnostic_choice_Step, which has an instance of cpg: Diagnostic_Imaging. Each individual diagnostic imaging and radiography has patient education in term of pem:DiagnosticProcedure to explain about the diagnostic imaging, for example CT scan (see Figure 27 in Appendix).

11. **Staging:**

i) According to TNM classification [128, 131]: Stage II. Tumor invaded sub-mucosa and into muscularis propria (T2) , No regional lymph nodes involvement (N0), No metastases (M0).

ii) According to Modified Astler-Coller (MAC) staging system (original AC was a modification of Dukes' system): Stage B1

iii) According to Dukes' classification: Stage A

Summary of TNM classification, Modified Astler-Coller (MAC) staging system, and Dukes' classification is shown in the table below:

Table 4: Summary of TNM classification, MAC staging system, and Dukes' classification

Stage Groupings					
Stage	**T**	**N**	**M**	**Dukes**	**MAC**
Stage 0	Tis	N0	M0	-	-
Stage I	T1	N0	M0	A	A
Stage II	T2	N0	M0	A	B1
Stage IIA	T3	N0	M0	B	B2
Stage IIB	T4	N0	M0	B	B3
Stage IIIA	T1-2	N1	M0	C	C1
Stage IIIB	T3-4	N1	M0	C	C1/C2
Stage IIIC	Any T	N2	M0	-	C1/C2/C3
Stage IV	Any T	Any N	M1	-	D

Patient Education:

In CPG-PE ontology, staging criteria for CRC such as TNM classification, MAC staging system, and Dukes' classification are encoded as Diagnostic_for_Staging, which is an instance of class cpg:Diagnostic_choice_Step, which has an instance of cpg: Intervention_For_Diagnosis. For all three classification, there is patient education in term of pem:DiagnosticProcedure and pem:DecisionMaking-Counseling to explain staging criteria for CRC and counsel patient about the treatment options for different stages of CRC (see Figure 28 in Appendix).

12. **Diagnosis:**

Patient is diagnosed as a case of Colorectal cancer, stage II (T2, N0, M0) according to TNM classification, stage B1 according to MAC staging system, and Stage A according to Duke's classification. We will treat patient considering TNM classification, i.e. stage II (T2, N0, M0).

13. **Therapeutic Procedures:**

For stage II (T2, N0, M0) Colorectal cancers, the management option are as follows:

(a) ***Surgical Procedure:***

- Wide surgical resection and anastomosis is standard treatment [128-130].

(b) ***Chemotherapy:***

- Adjuvant chemotherapy is recommended for stage III colon cancer (ESMO Level I, Grade A) and stage II colon cancer with high risk features (ESMO Level II, Grade B) [128-130].
    - Preferred chemotherapy includes oxaliplatin and 5-fluorouracil (5-FU)/leucovorin
        - Oxaliplatin: 85 mg/m2 IV on day 1
        - 5-Fluorouracil: 400 mg/m2 IV bolus, followed by 600 mg/m2 IV continuous infusion for 22 hours on days 1 and 2
        - Leucovorin: 200 mg/m2 IV on days 1 and 2 as a 2-hour infusion before 5-fluorouracil
        - Repeat cycle every 2 weeks for a total of 12 cycles.
    - Alternatives are monotherapy with 5-FU/leucovorin or oral capecitabine
- Intensive follow-up required (ESMO Level I, Grade A) and associated with improved survival after curative surgery for colorectal cancer (level 2 [mid-level] evidence) [128-130].

Alternative option:

- Preoperative Chemo-radiation therapy, plus surgical resection and anastomosis
- Then postoperative chemotherapy.

14. **Complications:**

Complications associated with CRC and its management/procedures are as follows:

1. Bone marrow suppression during chemotherapy: Neutropenia, thrombocytopenia, and anemia may develop with the chemotherapeutic agents.

2. Oxaliplatin-associated liver toxicity: Increase in serum liver enzymes is common during chemotherapy with oxaliplatin.

3. Chemotherapy associated GI complications: Diarrhea, nausea, vomiting and abdominal pain is common during chemotherapy.

4. Chemotherapy associated alopecia: Hair loss is common due to chemotherapy.

5. Oxaliplatin-associated neuropathy: Neurotoxicity is a common adverse effect of oxaliplatin that usually presents as a peripheral neuropathy.

6. Oxaliplatin-associated pulmonary fibrosis: Pulmonary fibrosis is not common, it only occurs in <1% of patients and presents with dry cough, dyspnea, basal crepitations, and pulmonary infiltrates on CXR or CT chest.

7. Bladder dysfunction after rectal excision: Bladder dysfunction is not common and it occurs as a result of damage to the pelvic nerves during surgery for rectal cancer.

8. Erectile dysfunction after rectal excision: Erectile dysfunction is not common, it can occur due to pelvic nerve damage.

9. Other complications due to radiation (not related with this specific case).

Patient Education:

In CPG-PE ontology, surgical treatment options for CRC such as Polypectomy, Colectomy, Total Mesorectal Excision etc. are encoded as Surgery, which is an instance of class cpg:Treatment_Choice_Step, which has an instance of cpg: Intervention_For_Treatment. Each individual surgery option has patient education in term of pem:TherapeuticProcedure to explain about the surgical procedure, for example Colectomy (see Figure 29 in Appendix). For all surgery options, there is patient education in term of pem:Pre-Post-OpCare and pem:DecisionMaking-Counseling to explain patients about pre and post-operative care and counsel them about the complications and outcomes of the surgery for CRC (see Figure 30 in Appendix).

In CPG-PE ontology, chemotherapeutic options for CRC such as 5-Fluorouracil (5-FU), Bevacizumab etc. are encoded as Chemotherpy, which is an instance of class cpg:Treatment_Choice_Step, which has an instance of cpg: Intervention_For_Treatment. Each individual chemotherapeutic option has patient education in term of pem:Radition-Chemotherpy to explain about the chemotherapeutic drug and its adverse effects, for example 5-Fluorouracil (5-FU) (see Figure 31 in Appendix). For all chemotherapy options, there is patient education in term of pem:DecisionMaking-Counseling to counsel patients about the complications and outcomes of the chemotherapy for CRC (see Figure 32 in Appendix).

In CPG-PE ontology, radio-therapeutic options for CRC are encoded as Radiotheraphy, which is an instance of class cpg:Treatment_Choice_Step, which has an instance of cpg: Intervention_For_Treatment and has also an instance of cpg:Radiotherpy. Radiotherapy has patient education in term of pem:Radition-

Chemotherpy to explain about the chemotherapeutic drug and its adverse effects, and pem:DecisionMaking-Counseling to counsel patients about the complications and outcomes of the radiotherapy for CRC (see Figure 33 in Appendix).

15. **Prevention:**

Lifestyle modifications may reduce risk for colorectal cancer:

- Smoking cessation [136]
- Avoid excessive alcohol use [136]
- Avoid obesity [136]
- Avoid diets high in red meat [136]
- Diets high in fruits and vegetables [136], specially onion and garlic [137, 138]
- Regular moderate exercise and physical activity [136, 139].

16. **Prognosis:**

5-year survival after surgical resection as follows [128]:

- 85%-95% for stage I
- 60%-80% for stage II
- 30%-60% for stage III, but 26% if > 4 lymph nodes involved

Survival rate varies by country, region and ethnicity; however the approximate 5-year survival rate for colorectal cancer patients in the United States (all stages included) is 65%. Survival is inversely related to stage; patients with stage I have a 95% 5-year survival rate, and those with stage III have only a 60% survival rate. For patients with metastatic, stage IV disease, the 5-year survival rate is estimated at approximately 10% (see Staging).

17. **Follow-up:**

Pooled analysis form several large adjuvant trials reported that 85% of colon cancer recurrences occur within 3 years from after resection of primary tumor. Therefore, those patients who had resection for stage II and III colon cancer undergo regular follow up for at least 5 years after resection. With physical examinations every 3-6 months for first

three years, every 6 months during year 4 and 5 as recommended by American Society of Clinical Oncology (2005).

Serum CEA level should be checked every 3 months in patients with stage II or III disease for at least 3 years and every 6 months in years 4 and 5. Computerized tomography (CT) of the chest and abdomen should be performed annually for at least 3 years after primary tumor resection. All patients with colon cancer should have preoperative or postoperative colonoscopy. In the absence of any suspected high-risk pathology on the first colonoscopy, follow-up colonoscopy should be performed at 3 years after surgery and then, if normal, once every 5 years thereafter.

Patient education:

In CPG-PE ontology, follow-up visit for CRC is encoded as Follow_Up, which is an instance of class cpg:Visit_Step, has patient education in term of pem:Follow-up to explain about the follow up monitoring after the management of CRC (see Figure 34 in Appendix).

5.2.2. Vignette 2: Preeclampsia

A 38-year-old woman presents at 37 weeks' gestation with severe headache and acute abdominal pain. She had a routine prenatal visit 4 days previously with no signs or symptoms reported or observed. On examination, her BP is 165/110 mmHg and urinalysis reveals proteinuria (3+). She is admitted to hospital and is started on labetalol.

1. **Highlights:**

Preeclampsia is an hypertensive syndrome that occurs in pregnant women after 20 weeks' gestation, consisting of new-onset, persistent hypertension (defined as a BP of ≥140 mmHg systolic and/or ≥90 mmHg diastolic, based on at least 2 measurements taken at least 4 hours apart) with proteinuria (defined as urinary excretion of ≥0.3 g protein/24 hours). Delivery is the definitive treatment; the decision about when and how to deliver should only be made after a thorough assessment of the risk and benefits to the mother and the baby. Other mainstays of management include antihypertensive therapy, seizure control, and fluid restriction. It can occur in subsequent pregnancies; therefore, women should be counseled about the risk. Figure 19 gives a brief summary of the diagnosis and management of Preeclampsia as follows:

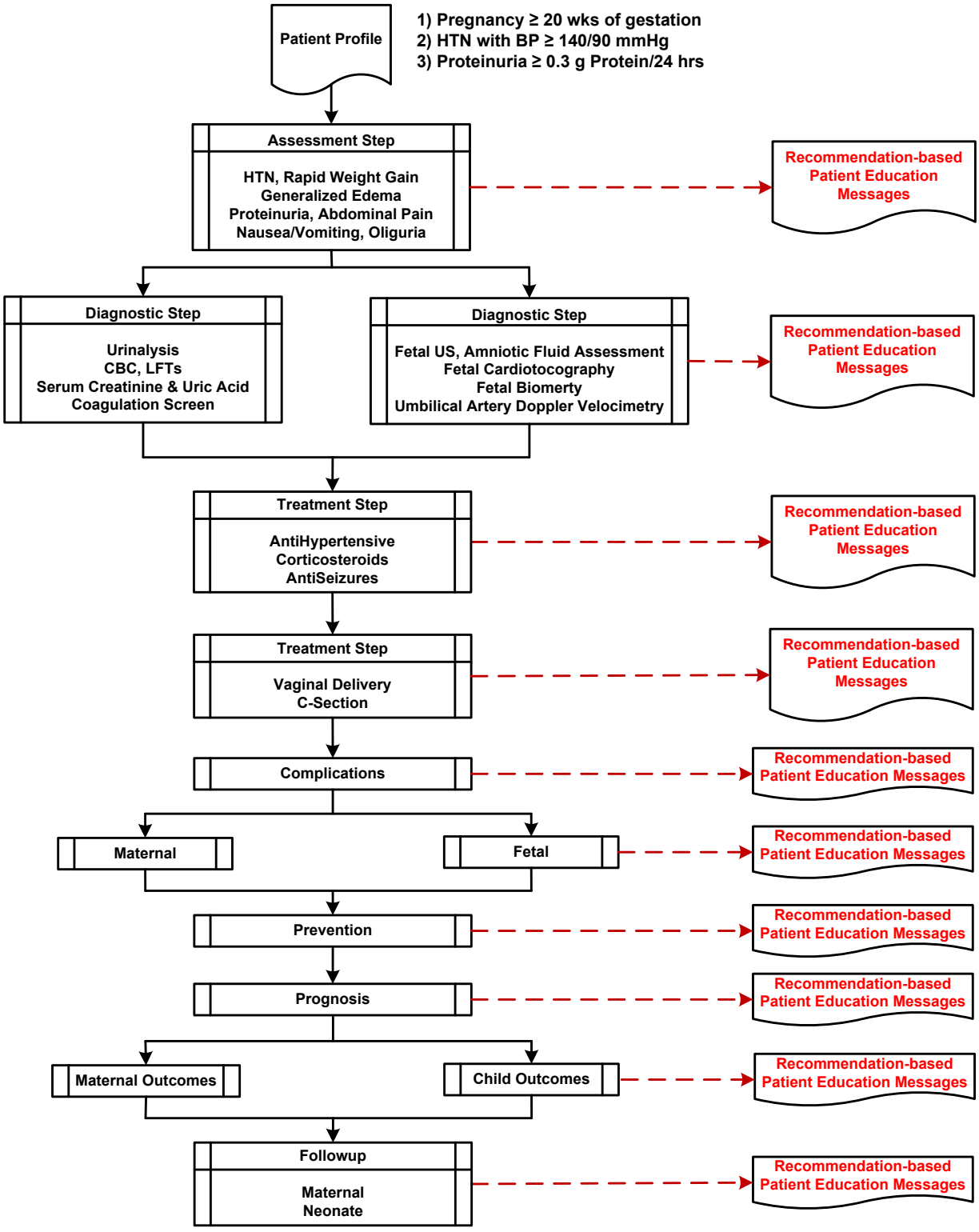

Figure 19: Diagnosis and management of Preeclampsia

2. Presenting Complaint:

- Severe headache for 2 days
- Acute Abdominal pain for 2 days
- Face and hands numbness and swelling
- Nausea and vomiting

3. History of Presenting Complaints and Examination:

A 35-year-old woman at 37 weeks of pregnancy comes with the complaints of severe headache and acute abdominal pain for last 2 days. She also reported face and hands numbness and swelling since yesterday. She also reported decreased frequency of urine in last 24 hours. Earlier, she had a routine prenatal visit 4 days ago with no signs or symptoms reported or observed. She observed these symptoms worsen during nights. As far as her past medical, surgical and obstetric history is concerned; it is her fourth pregnancy. In previous three times, she had this complaint of increase blood pressure in two of them, at 36 weeks and 32 weeks of gestations respectively. Her previous pregnancy was 13 months ago, in which she had the same complaints at 32 weeks of gestation. She had no history of pre-existing hypertension, renal diseases, liver diseases and diabetes mellitus. However, she had a history of preeclampsia and she is obese for last 5 years with a BMI of 37.2 35 kg/m^2. She has been using contraceptive methods, and the average interval between her pregnancies was 20 months. She moderately consumes alcohol and had a history of methamphetamine use. As far as her family history is concerned, her mother had a history of preeclampsia and diabetes, and her father had a history of heart disease (ST segment Elevation Myocardial Infarction, STEMI). On examination, her BP was 165/110 mmHg and there was a generalized edema (especially in face and hands). However, fetal movements and heart sounds were normal, and the rest of the general physical and systemic examination was normal. She immediately admitted to the hospital and her urine specimen was sent for quantitative protein measurement, and she was started on labetalol for severe increase in blood pressure.

4. Differential Diagnoses:

- Preeclampsia
- Eclampsia
- Chronic hypertension
- Gestational hypertension
- Antiposholipid antibody syndrome
- HELLP Syndrome
- Thrombotic Thrombocytopenic Purpura (TTP)
- Hemolytic Uremic Syndrome (HUS)
- Renal Disease
- Liver disease

Patient Education:

In CPG-PE ontology, all these concepts such as presenting complain, history of presenting complain, and differential diagnoses are encoded in Assessment_1 which has the instance of cpg:Assessment class. They are presented as instance of cpg:Assesment_Items. It gives patient education material about the possible reasons for these sign and symptoms i.e. possible diagnoses, and their associated clinical presentation in a simple language as pem:DiseaseConditionDiscription, as shown in Figure 35 (see Appendix). Moreover, cpg:Clinical_Guideline encoded the concept Diagnosis_and_Management of Preeclampsia, has patient education in terms of pem:DiseaseConditionDescription as shown in Figure 36 (see Appendix).

5. Criteria for Evaluation:

Society of Obstetricians and Gynecologists of Canada (SOGC) recommendations for classification of hypertensive disorders of pregnancy [140]:

- hypertension in pregnancy defined as diastolic blood pressure ≥ 90 mm Hg, based on average of at least 2 measurements using same arm (SOGC Grade II-2B)
- severe hypertension defined as systolic blood pressure ≥ 160 mm Hg or diastolic blood pressure ≥ 110 mm Hg (SOGC Grade II-2B)
- for diagnosis of clinically significant proteinuria

    - strongly suspect proteinuria when urinary dipstick proteinuria ≥ 2+ (SOGC Grade II-2A)
    - proteinuria defined as ≥ 0.3 g/day in 24-hour urine collection or ≥ 30 mg/mmol urinary creatinine in spot (random) urine sample (SOGC Grade II-2B)
    - insufficient evidence for recommendations on accuracy of urinary albumin:creatinine ratio (SOGC Grade II-2I)
- definitions of preeclampsia
    - in women with pre-existing hypertension - resistant hypertension, new or worsening proteinuria, or ≥ 1 of other adverse conditions (SOGC Grade II-2B)
    - in women with gestational hypertension - new-onset proteinuria or ≥ 1 of other adverse conditions (SOGC Grade II-2B)
- severe preeclampsia defined as preeclampsia with onset before 34 weeks gestation, with heavy proteinuria or with ≥ 1 adverse conditions (Grade II-2B)
- adverse conditions include:
    - maternal symptoms of hypertension such as headache, visual changes, abdominal pain
    - maternal signs of end-organ dysfunction
    - abnormal maternal laboratory testing
    - elevated aspartate aminotransferase (AST), alanine aminotransferase (ALT), lactate dehydrogenase (LDH) with symptoms
    - platelet count < 100 × 109/L
    - albumin < 20 g/L
    - fetal morbidity

American College of Obstetricians and Gynecologists (ACOG) criteria for Preeclampsia [141]:

Preeclampsia is defined as hypertension (blood pressure ≥ 140/90 mm Hg) and proteinuria (> 300 mg/24 hours) after 20 weeks gestation, with proteinuria (defined as

urinary excretion of ≥0.3 g protein in 24 hours). Disease severity is based on the BP measurement, and whether there are signs of systemic involvement.

(a) ***Mild-moderate:***

Preeclampsia is considered as mild to moderate, if BP is 140 to 159 mmHg systolic and/or 90 to 109 mmHg diastolic.

(b) ***Severe:***

Preeclampsia is considered severe, if one or more of the following criteria are present:

- blood pressure ≥ 160/110 mm Hg on 2 occasions at least 6 hours apart during bed rest
- proteinuria ≥ 5 g/24 hours or ≥ 3+ on 2 random urine specimens at least 4 hours apart
- cerebral or visual disturbances
- epigastric or right upper quadrant pain
- fetal growth restriction
- impaired liver function
- oliguria < 500 mL/24 hours
- pulmonary edema
- thrombocytopenia
- cyanosis

Patient Education:

In CPG-PE Ontology, criteria for evaluation of Preeclampsia is encoded as Condition_1, which is an instance of cpg:Condition, has patient education in terms of pem:DiseaseConditionDescription of Preeclampsia, as shown in Figure 37 (see Appendix).

6. Common Clinical Presentation:

Common clinical presentations are as follows [140, 142, 143]:

- rapid weight gain
- generalized edema (affecting face and hands)

- visual disturbances (for example, blurred vision, scotomata, and cortical blindness [rarely])
- severe headache
- nausea and/or vomiting
- epigastric or right upper quadrant pain
- oliguria
- hyperreflexia
- chest pain
- dyspnea

7. Risk Factors:

More important risk factors for preeclampsia are as follows [140, 142]:

- maternal age ≥ 40 years [144-146]
- medical, family and social history
    - previous preeclampsia, especially if severe or before 32 weeks gestation [144-148]
    - family history of preeclampsia (mother or sister) [145, 146, 149, 150]
    - antiphospholipid antibody syndrome [144-146, 151]
    - pre-existing hypertension or diastolic blood pressure ≥ 90 mm Hg at first antenatal visit [144-146, 152]
    - pre-existing renal disease or proteinuria at first antenatal visit [144-146, 151]
    - pre-existing diabetes mellitus [144-146, 151]
    - obesity (body mass index ≥ 35 kg/m2) [144-146, 153, 154]
- risk factors in current pregnancy
    - multiple pregnancy [144-146, 151, 155]
    - first ongoing pregnancy (Primiparity or nulliparity) [144-148, 156, 157]
    - interpregnancy interval ≥ 10 years [144, 145, 150, 156, 158]
    - blood pressure ≥ 130 mm Hg systolic or ≥ 80 mm Hg diastolic at first antenatal visit [144-146, 152]

Less important risk factors for preeclampsia are as follows [140, 142]:

- demographic risk factors
    - lower socioeconomic status
    - Nordic, Black, South Asian, or Pacific Island ethnicity
- medical, family and social history
    - heritable thrombophilias
    - non-smoking (based on observational studies)
    - increased pre-pregnancy triglyceride levels
    - family history of early-onset cardiovascular disease
    - cocaine and methamphetamine use
- risk factors in current pregnancy
    - inter-pregnancy interval < 2 years
    - use of reproductive technologies
    - new partner
    - gestational trophoblastic disease
    - excessive weight gain in pregnancy
    - infection during pregnancy (for example, urinary tract infection, periodontal disease)
- possible risk factors occurring in second or third trimester of current pregnancy
    - elevated blood pressure
    - abnormal maternal serum screening
    - abnormal uterine artery Doppler velocimetry
    - cardiac output > 7.4 L/minute
    - elevated uric acid

8. Assessment:

Based on above mentioned evaluation criteria, common clinical presentations and risk factors for Preeclampsia, the assessment of patient's condition as follows:

1. Greater than 20 weeks of gestation—Yes, 37 weeks of gestation.
2. Advance maternal age—Yes, 37 years
3. Preeclampsia in previous pregnancy—Yes, In previous three times, she had this complain of increase blood pressure in two of them at 36 weeks and 32 weeks of gestations respectively.

4. Family history of preeclampsia—Yes. Her mother had a history of preeclampsia.
5. Obesity—Yes. She is obese for last 5 years with a BMI of 37.2 35 kg/m^2.
6. Headache—Yes. Severe headache for last 2 days.
7. Epigastric or right upper quadrant pain—Yes. Acute abdominal pain for last two days.
8. Increase Blood Pressure—Yes. Presented with BP 165/110 mmHg.
9. Generalized Edema—Yes. There was a generalized edema (especially in face and hands).
10. Nausea and/or vomiting—Yes. For last 2 days.
11. Oliguria—Yes. Decrease frequency of urine in last 24 hours (400ml/24 hours)
12. Reduced Fetal Movements—No. Fetal movements were normal.
13. Fetal growth restriction—No.
14. Cerebral and visual disturbances—No.
15. Weakness or malaise—Yes.

Patient Education:

Detailed assessment of having risk factors are encoded in Assessment_1 (see Figure 38 and 49 in Appendix), which is an instance of Class cpg:Assessment, has patient education in terms of pem:DiseaseCondition Description, pem:DecisionMaking-Counseling and pem:RiskFactorsModification-Prevention, which gives patient education about Preeclampsia, counsel them about the of the possible outcomes of the condition or prognosis, and risk factors, their modification and prevention (see Figure 39 in Appendix).

9. Criteria for Diagnosis:

Criteria for Diagnosis for Preeclampsia are as follows:

(a) ***Maternal testing:***

- Monitor blood pressure
- *American College of Obstetricians and Gynecologists (ACOG)* recommendations [141]:

- initial testing in preeclampsia (perform weekly in mild preeclampsia, more often if disease progression suspected)
    - renal function
    - liver enzymes
    - platelet count
    - 12-24 hour urine collection for protein
- consider invasive hemodynamic monitoring in preeclamptic women with severe cardiac disease, renal disease, refractory hypertension, pulmonary edema or unexplained oliguria (ACOG Level B)

- *Society of Obstetricians and Gynecologists of Canada (SOGC)* recommendations for women with Preeclampsia/suspected preeclampsia [140]:
    - hemoglobin (higher in women with preeclampsia unless microangiopathic hemolytic anemia)
    - white blood cell (WBC) count and differential (higher in preeclampsia)
    - platelet count (lower in preeclampsia)
    - blood film (shows microangiopathy with red blood cell fragments in preeclampsia)
    - serum creatinine (Cr) (higher in preeclampsia)
    - serum uric acid (higher in preeclampsia)
    - glucose (Glu)
    - aspartate aminotransferase (AST) and alanine aminotransferase (ALT) (higher in preeclampsia)
    - lactate dehydrogenase (LDH) (higher in preeclampsia)
    - albumin (lower in preeclampsia)
    - bilirubin (higher in preeclampsia)
    - urinalysis (routine and microscopy)
    - proteinuria (assessed by urinary dipstick, spot or 24-hour) (higher in preeclampsia)
    - coagulation tests if presence of thrombocytopenia or placental abruption
        - INR and activated partial thromboplastin time (aPTT)
        - fibrinogen (lower in preeclampsia)

(b) ***Fetal monitoring:***

- *Society of Obstetricians and Gynecologists of Canada (SOGC)* recommendations for fetal testing in women with suspected preeclampsia (SOGC Grade II-IB) [140]:
    - fetal movement count (lower in preeclampsia)
    - non-stress test (non-reassuring fetal heart rate in preeclampsia)
    - biophysical profile (lower score in preeclampsia)
    - deepest amniotic fluid pocket (lower in preeclampsia)
    - ultrasound (US) for fetal growth (usually asymmetrical intrauterine growth in preeclampsia)
    - umbilical artery Doppler (increased resistance, absent or reversed end-diastolic flow in preeclampsia)
    - umbilical artery Doppler velocimetry may support placental origin for intrauterine fetal growth restriction (SOGC Grade II-2B)
- fetal monitoring during expectant management of mild preeclampsia [142]:
    - non-stress test twice weekly
    - amniotic fluid index once or twice weekly
    - biophysical profile may be done weekly as substitute for 1 twice weekly nonstress test and amniotic fluid index
    - ultrasound for fetal growth every 3-4 weeks
- fetal monitoring in severe preeclampsia [142]:
    - continuous fetal heart rate monitoring
    - non-stress test on admission
    - ultrasound for estimated fetal weight
    - amniotic fluid volume
    - umbilical artery Doppler measurements

10. Diagnostic Step:

(a) ***Diagnostic Laboratory Tests:***

1. Urinalysis:

- 24 hours quantitative protein measurement: 1.5 g/24 hours

- Urine dipstick: 2+

A urinary excretion of ≥0.3 g protein in 24 hours or 2+ or greater on 2 random urine samples collected at least 4 hours apart is diagnostic in Preeclampsia [152].

2. CBC
    - Hemoglobin: Increased
    - White Blood Cells (WBCs) Count: Increased

    Hemoglobin and WBC count is higher in Preeclampsia [140].
3. Liver Function Tests (LFTs):
    - Aspartate aminotransferase (AST): Elevated
    - Alanine aminotransferase (ALT) Elevated
    - Lactate dehydrogenase (LDH) Elevated
    - Albumin: Slightly decreased
    - Bilirubin: Elevated

    Liver enzymes are higher in preeclampsia [140].

    4. Serum Creatinine and Uric Acid: Both are in normal range.

    Serum Creatinine and Uric acid are elevated in Preeclampsia [140].

5. Coagulation Screen
    - Platelet count: Decreased
    - INR: Increased
    - Prothrombin Time (PT) and activated partial thromboplastin time (aPTT): Increased
    - Fibrinogen: Decreased
    - d-dimer: Increased

    Coagulation tests/ screening may be abnormal in Preeclampsia [140].

Patient education:

In CPG-PE ontology, diagnostic laboratory tests such as CBC, LFTs, urinalysis, serum creatinine and uric acid etc. are encoded as Diagnostic_Lab_Test, which is an instance of class cpg:Diagnostic_Step, also has an instance of cpg: Laboratory_Exam. For all diagnostic lab tests there is patient education in term of pem:DiagnosticProcedure to explain about the laboratory test, pem:DecisionMaking-Counseling to explain about the

actions and step if the results will be abnormal or not in a normal physiological range (see Figure 40 in Appendix).

(b) ***Diagnostic Procedures and Imaging***

1. Fetal Ultrasound: Normal
2. Fetal Cardiotocography: Normal
3. Fetal Biometry: Normal
4. Umbilical Artery Doppler Velocimetry: Normal
5. Amniotic Fluid Assessment: Normal

Patient education:

In CPG-PE ontology, diagnostic imaging and procedures such as fetal ultrasound, fetal biometry, amniotic fluid assessment etc. are encoded as Diagnostic_Imaging_and_other_Procedures, which is an instance of class cpg:Diagnostic_Step, also has an instances of cpg: Procedure_To_Diagnose, cpg: Intervention_For_Diagnosis, cpg: Group_Of_Diagnostic_Processes, and cpg: Diagnostic_Imaging. For all diagnostic imaging and procedures, there is patient education in term of pem:DiagnosticProcedure to explain about the diagnostic imaging and procedures, pem:DecisionMaking-Counseling to explain about the actions and step if the results will be abnormal (see Figure 41 in Appendix).

11. Diagnosis:

Patient is diagnosed as severe preeclampsia, with normal viable fetus with mature lungs.

12. Therapeutic Procedures:

Society of Obstetricians and Gynecologists of Canada (SOGC) recommendations are as follows [140]:

- Hospitalize the patient, if severe hypertension or severe preeclampsia (SOGC Grade II-2B), preeclampsia remote from term, signs of disease progression or compliance difficulties (including logistic barriers)
- Delivery indicated if:

- Preeclampsia and mature fetus (gestational age ≥ 37 weeks) (SOGC Grade III-B)
- Gestational age ≥ 34 weeks and maternal or fetal distress
- Consider vaginal delivery unless cesarean section required for usual obstetric indications (SOGC Grade II-2B)

- Antihypertensive medications for acute severe hypertension (doses in different guidelines vary)
  - Hydralazine 5-10 mg IV every 20 minutes as needed
  - Labetalol 20 mg IV bolus, then 40 mg in 10 minutes if needed, then 80 mg every 10 minutes (maximum 220 mg)
  - Nifedipine 10-30 mg orally, repeat in 45 minutes if needed
  - Last resort - sodium nitroprusside 0.5-10 mcg/kg/minute (risk of fetal cyanide toxicity if used > 4 hours)

The management plan for this patient would be as follows:

- Regular BP monitoring
- Antihypertensive Therapy
- Delivery

(a) ***Medication:***

1. Labetalol:

Intravenous: 20 mg intravenous bolus initially, followed by 40 mg bolus 10 minutes later, then 80 mg bolus every 10 minutes until desired response, maximum 220 mg total dose.

Oral: 200 mg orally every hour until desired response, maximum 1600 mg/day; chronic: 200-400 mg orally three to four times daily, maximum 1600 mg/day.

Other options are:

- Hydralazine: 5-10 mg intravenously every 15-20 minutes until desired response.
- Nifedipine: 10 mg orally (immediate-release) every hour until desired response, maximum 120 mg/day; chronic: 10-60 mg orally (sustained-release) twice daily, maximum 160 mg/day.

2. Corticosteroids: Indicated before 34 weeks of gestation to mature fetal lungs, but in this case, i.e. 37 weeks of gestation, the fetal lungs are already mature.

3. Magnesium Sulfate: Indicated only in cases with seizures.

Patient Education:

All antihypertensive medications such as labetalol, hydralazine, and nifedipine etc. are encoded as Antihypertensive_Medications, which is an instance of class cpg: Prescription, which is an instance of class cpg: Treatment_Step. For all antihypertensive medications, there is patient education in term of pem:DrugInformation-AdverseReaction to give information about the drug and its adverse effects and pem: SelfManagement to explain patients how to manage their own illness by taking medication properly (see Figure 42 in Appendix).

For optional medications for epilepsy are encoded as Antiseizures_Drugs, which is an instance of class cpg: Treatment_Choice_Step, has Antiseizure drug Magnesium_Sulfate, which is an instance of class cpg: Prescription. It has patient education material in terms of pem:DrugInformation-AdverseReaction to give information about the drug and its adverse effects (see Figure 43 in Appendix). Likewise, there is patient education in terms of pem:DrugInformation-AdverseReaction for corticosteroids, which is another optional medication if the baby is immature for delivery (see Figure 44 in Appendix).

(b) ***Delivery:***

1. Vaginal Delivery: Patient is planned for normal vaginal delivery.

2. Cesarean Section (C-Section): If indicated due to any obstetric complications [140].

13. Complications:

(a) ***Eclampsia:***

Eclampsia (generalized seizures) is a convulsive stage of preeclampsia and may be life-threatening [140, 142, 143]. The incidence rate of eclampsia in Canada from 1991 to 2001, based on 973 cases is 0.38 per 1,000 deliveries [159].

(b) ***Maternal Complications:***

Possible maternal complications are as follows [140, 142, 143]:

1. Stroke or cerebrovascular accident: Stroke may occur at systolic blood pressure of 160 mm Hg and over the years, this has been the main cause of maternal death and morbidity, caused by the elevation of BP [160].
2. Pulmonary edema: It is mainly a postpartum event indicated by breathlessness, but can be diagnosed early with the use of a pulse oximeter (O2 saturation monitor), which is the best measure of fluid overload [160].
3. Acute respiratory distress syndrome (ARDS): ARDS can also be a complication in preeclampsia.
4. Placental abruption: Placental abruption is the most serious complication of preeclampsia, as it can bring sudden fetal demise and severe complications to the mother; its incidence has been falling over the last 30 years [160].
5. Renal manifestations: Different renal manifestations can also be the complication of preeclampsia [160].
6. Liver manifestations and coagulation abnormalities: are also possible maternal complications of preeclampsia.

(c) ***Fetal/Childhood Complications:***

Following are the possible fetal complications [140, 142, 143]:

1. Intrauterine growth restriction (IUGR) may complicate up to 30% of preeclampsia pregnancies
2. Oligohydramnios
3. Preterm birth
4. Fetal death or still birth.

Patient Education:

In CPG-PE ontology, vaginal delivery is encoded as Normal_Delivery, which is an instance of cpg:Treatment_Step, also has an instance of cpg: Procedure_For_Treatment. It has patient education in terms of pem: TherapeuticProcedure and pem:DecisionMaking-Counseling, to provide patient education about the procedure and possible outcomes in terms of complications and outcomes of the preeclampsia (see Figure 45 in Appendix).

For optional mode of delivery i.e. Caesarean section are encoded as Caesarean_Section, which is an instance of class cpg: Treatment_Choice_Step, has concept C-Section, which is an instance of class cpg: Procedure_For_Treatment. It has patient education in terms of pem: TherapeuticProcedure and pem:DecisionMaking-Counseling, to provide patient education about the procedure and possible outcomes in terms of complications and outcomes of the preeclampsia (see Figure 46 in Appendix).

14. Prevention:

There are following efforts could be made to prevent preeclampsia:

1. Low-dose Aspirin (75-80 mg/day orally starting at 12-14 weeks' gestation) [140, 144-146]
2. Weight reduction [144]

Some of the strategies, which are not preventive for preeclampsia, but have a beneficial effect, are as follows:

1. Abstain from alcohol [140]
2. Periconceptual use of folate-containing multivitamin [140]
3. Smoking cessation [140]
4. Avoiding inter-pregnancy weight gain [140]
5. Increased rest at home in third trimester [140]
6. Reducing workload or stress [140]

15. Prognosis:

Preeclampsia is a self-limiting condition of pregnancy, which usually worsens with time but resolves after delivery [161]. Worldwide, preeclampsia and eclampsia are estimated to be responsible for approximately 14% of maternal deaths per year (50,000-75,000). Among other causes of deaths, stroke and pulmonary edema are the most common causes of maternal death in preeclampsia [140].

The maternal and child outcomes are as follows:

- ***Maternal Outcomes:***

- Preeclampsia may be associated with future maternal risk of cardiovascular disease [162].

- Hypertension in pregnancy associated with increased risk of maternal death and major morbidity [163].
- Preeclampsia associated with 3.6 times risk of fatal stroke in later life [164].
    - ***Child Outcomes:***
- Severe preeclampsia before 24 weeks gestation associated with very low perinatal survival [140].
- Severe early-onset maternal hypertensive disorder may be associated with moderate delays in mental and psychomotor development at age 1 year [165].

16. Follow-up:

Following are the recommendations for maternal and neonate follow-up:

1. *Society of Obstetricians and Gynecologists of Canada (SOGC)* recommendations for maternal follow-up [140]:

- For care during first 6 weeks postpartum
    - Measure blood pressure during time of peak postpartum blood pressure at 3-6 days after delivery (SOGC Grade III-B)
    - Antihypertensive medication can be restarted postpartum, especially in women with severe preeclampsia and women who delivered preterm (SOGC Grade II-2I)
    - Antihypertensive medications acceptable for use in breastfeeding include (SOGC Grade III-B)
        - Nifedipine extended-release
        - Labetalol
        - Methyldopa
        - Captopril
        - Enalapril
    - Confirm resolution of end-organ dysfunction (SOGC Grade III-I)
    - Nonsteroidal anti-inflammatory drugs (NSAIDs) should NOT be given postpartum if any of following criteria present (SOGC Grade III-I)
        - Hypertension difficult to control
        - Oliguria

        - Elevated creatinine
        - Platelets < 50 × 109/L
    - Consider postpartum thromboprophylaxis in women with preeclampsia, especially after antenatal bed rest for > 4 days or after cesarean section (SOGC Grade III-I)
    - Low-molecular-weight heparin should NOT be given postpartum until ≥ 2 hours after epidural catheter removal (SOGC Grade III-B)
- For care beyond 6 weeks postpartum
    - For women with history of severe preeclampsia, especially those who presented or delivered before 34 weeks gestation, screen for
        - Pre-existing hypertension (SOGC Grade II-2B)
        - Underlying renal disease (SOGC Grade II-2B)
        - Thrombophilia (SOGC Grade II-2C)
    - Advise women that intervals between pregnancies < 2 or ≥ 10 years associated with recurrent preeclampsia (SOGC Grade II-2D)
    - Encourage overweight women to attain healthy body mass index (BMI) for decreasing risk in future pregnancies (SOGC Grade II-2A) and for long-term health (SOGC Grade I-A)
    - Consider assessing traditional cardiovascular risk markers in normotensive women with hypertensive disorders of pregnancy (SOGC Grade II-2B)
    - Advise all women with history of hypertensive disorder of pregnancy to pursue healthy diet and lifestyle (SOGC Grade I-B)

2. Follow-up neonate for hematologic screening as there is a chance of neutropenia or thrombocytopenia in infants born to hypertensive mothers [166].

Patient education:

In CPG-PE ontology, follow-up visit for Preeclampsia is encoded as Follow_Up, which is an instance of class cpg:Visit_Step, has patient education in term of pem:Follow-up to explain about the follow up monitoring of the patient after delivery of the baby (see Figure 47 in Appendix).

5.3. Systematic Evaluation

We will also evaluate our CPG-PE framework by comparing it with different patient education systems and other frameworks discussed in chapter 2, that are intended for providing patient education in healthcare. Some of them are intended to provide patient education, while others focus more on decision making and counseling during the course of patient illness or disease condition(s) i.e. how to cope with disease condition(s) itself as well as stress, distress, and anxiety caused during this duration. Some of them managed to address both i.e. patient education and decision making and counseling. We will evaluate our CPG-PE framework by comparing it with these systems and framework for patient education on the following parameters:

- *Evidence-based guidelines:* Use of CPGs or evidence-based guidelines as a source of recommendation to deliver patient education. As we discussed in Chapter 1, there are already over 10 000 health related websites exist, and more than one third of internet users access the World Wide Web to retrieve health and medical information [18] (See Section 1) (Chapter 1). Unfortunately, much of this material is inaccurate or misleading to the patients [19, 20] (See Section 1) (Chapter 1). Sometimes, physicians do not use evidence based guidelines frequently in clinical practice, which restrict physicians to deliver that education and information to the patients, which are important for the behavioral modification [17]. We argue that, if evidence-based guidelines will be used to provide patient education then we can avoid this problem i.e. scarcity of the resources and bases of patient education. We discussed earlier, if computerized and computer interpretable then CPG has the potential to develop guideline-based clinical decision support system, which can give recommendations tailored for individual patients at the point of care, and also serve as the bases for providing patient education [37, 73].
- *Personalized patient education:* Delivery of personalized or tailored patient education, specific to the patient disease condition(s) and/ or co-morbidities. Studies have shown that generic, lengthy, and non-relevant information has negligible impact on patients and health outcomes or sometimes even deteriorates the condition(s) [16]. Studies suggest that, impersonal, general, and decontextualized information has negligible impact on patients and health outcomes

as compared to the selective and patient-specific information and educational interventions [33, 34]. Tang and Newcomb [35] conducted a research study to examine, understand and address patients' need for information in the process of clinical care. In their study, participants preferred to receive information tailored to their own health condition(s) [35].

- *Patient education at each step:* Patient education regarding each step during the care process at the point and time of care i.e. when a recommendation comes (action or decision step), there should be a simultaneous patient education related to that recommendation. Studies have shown that, provision of appropriate and timely available information in a suitable form is crucially important [16]. Sometimes due to unavailability and lack of time, handing out lengthy descriptions of different illnesses and possible treatments to the patients deteriorate the condition [16]. Therefore, we argue that, it is more appropriate to give patient education on step-by-step, rather than giving the whole information regarding patient disease condition(s) and/ or co-morbidities at a glance to overwhelm the patient.
- *Psychosocial and behavioral factors:* Addressing psychosocial, environmental, behavioral, and other factors, which have a role in etiology of the disease condition as well as their prognosis and outcomes within patient education. Another parameter on the basis of which patient education materials can be personalized to the specific patient other than the "disease specific" and "demographic factors", is the "*psychosocial and behavioral factors*" A study by Brug et al [167] addressed psychosocial, behavioral, and motivational factors, that can be used to tailor patient information material or provide personalized patient education materials. These factors are named as "*psychological determinant of health behavior*" which includes: an individual's attitudes, social influences, personal norms, perceived behavior control, and intentions. Brug et al [167] argue that, these psychosocial factors related to each individual are more proximal or more important determinants of health behavior than the demographic factors or variables, as the determinant of health behavior in clinical care.
- *Shared decision making (SDM) and patient preference:* Encouraging shared decision making (SDM) and patient preference during the process of clinical care.

As we discussed in Chapter 2 (See Section 2.1.6.1), majority of the patient wanted to collaborate with their doctors in the process of decision making (shared decision making), and opt for any diagnostic and therapeutic modality according to their preference, after discussing with their doctors [68, 69].

- *Comprehensiveness to incorporate multiple diseases:* Ability to address and incorporate multiple disease conditions in terms of providing patient education related to various disease conditions from different medical disciplines and specialities.

We will assess and evaluate different patient education systems and our CPG-PE framework on these parameters mentioned above in detail.

5.3.1. Evidence-based Guidelines

GEM-based CPG generated tailored patient education materials [17, 73]; use evidence-based guideline i.e. Canadian guideline for managing dyslipidemia, to provide tailored patient education materials. In GEM paper-based Canadian guideline for managing dyslipidemia is converted into the XML-based GEM (Guideline Elements Model) formalism, so the GEM-based CPG can be used as the basis for generating tailored education materials.

The LEAF (Layman Education and Activation Form) [74, 45], which is an important component of the PEAS (Patient Education and Activation System) project [74], that aims to improve medical care by using an artificial intelligence system to educate patients. The LEAF project consists of a patient history form that explains itself and addresses patients' questions concerns in the process of care. LEAF does not use any evidence-based guideline to provide patient education. LEAF was an intelligent medical history form that provides patients a relevant set of questions, gives detailed explanations about filling those questions, suggests relevant health topics that the patient might want to pursue, and educates patients on general health issues and conditions. So the information or education material given to the patient is based on their answers to those questions rather than any decision criteria by the physician or guideline recommendations.

The PULSE [76, 77] (Personalisation Using Linkages of SCORE and behaviour change readiness to Web-based Education) do not follow and evidence-based guidelines,

but there is an electronic patient data capture template (DCT), which inherently comprises a set of evidence-based parameters for patient disease description evaluation and management. Healthcare professional enters patient data in the system, and it creates patient profile, and delivers patient education based on patient profile.

Migraineur [78] do not use evidence-based guidelines to provide patient education about migraine headaches. The prototype system consists of two major components (See Figure 8): i) an interactive history taking module and ii) an intelligent explanation module. The history taking module collects the information and data from the patients through a set of 104 questions, which are asked to the patient during clinical encounter based on their health status. The intelligent explanation module produces an interactive information sheet, which contains explanations in simple language that are tailored to individual patients, and responds logically to follow-up questions about the topics covered in the information sheet. So the information or education material given to the patient is based on their answers to the set of those 104 questions rather than guideline recommendations.

HealthDoc [79] do not follow any evidence-based guideline to provide information and education to the patients. The patient education is delivered based on patient profile and psychosocial parameters. CHESS (Comprehensive Health Enhancement Support System) [80-82] do not follow any evidence-based guideline to deliver information and education to the patient. It has different sections i.e. Question and Answer, discussion group, and personal stories etc. which provides patient education about their disease condition(s) in the form of healthcare literature about various disease conditions. Personalised Healthcare Information Delivery System (PHIDS) [84] do not follow evidence-based-guidelines to provide patient education. It works on the generation of patient health profile from the EMR, and composition of Patient Health Information (PHI) document based on patient health profile, in order to deliver education to the patients.

Our CPG-PE framework use evidence-based guidelines, in order to provide education to the patients based on their disease condition(s) and/ or co-morbidities. We have used CPG ontology [37] to encode Clinical Practice Guidelines, and PE Ontology encodes

Patient Education Materials. We augmented these two ontologies as CPG-PE ontology, which is a part of our CPG-PE framework. Upon execution, CPG-PE can deliver personalized patient education materials specific to their disease condition(s) and/ or co-morbidities, behavioral and psychosocial factors.

5.3.2. Personalized Patient Education

GEM-based CPG generated tailored patient education materials [17, 73], provides personalized or tailored patient education materials by using an evidence-based clinical practice guideline using Guideline Element Module (GEM). It provides personalized patient education to those patients who have dyslipidemia. The patient education material created, are tailored to patients based on their specific profile driven by CPGs. The patient specific profile is used to direct the selection of education materials specific to the patient. Layman Education and Activation Form (LEAF) [74, 75] provides customized or personalized education materials to the patients. The LEAF (Layman Education and Activation Form) project consists of an intelligent medical history form, that provide patients a relevant set of questions, acquire information about the patient's medical history, and customized medical information to the patients and gives detailed explanations to those questions which were answered by the patient in medical history form. It also suggests relevant health topics that the patient might want to pursue, and educate patients on general health issues and conditions.

The PULSE [76, 77] (Personalisation Using Linkages of SCORE and behaviour change readiness to Web-based Education) is a Web-based personalised educational intervention for the management of cardiovascular diseases risk. PULSE is a web-based adaptive hypermedia system, which delivers the personalized education material to the patient based on a patient profile created by combining an electronic patient data capture template (DCT) , the Systematic COronary Risk Evaluation (SCORE) algorithm for ten-year risk assessment for fatal cardiovascular disease, and a Stage of behaviour Change readiness model. Migraineur [78] created by Buchanan et al., is an intelligent interactive system for delivering customized or personalized information to patients suffering from chronic or acute migraine headaches. Its interactive history taking module has set of 104 questions, which are asked to the patient during clinical encounter,

and the intelligent explanation module generates an interactive information sheet, which contains explanations (based on their answers) that are tailored or personalized to the individual patients.

HealthDoc [79] offers customized information and health-education materials to patients, highly specific to the disease condition and personal characteristics of the individual patient. It provides customized education material on a particular topic, which is produced from a master document on that topic. The master documents contain all the information including illustrations and annotations. CHESS (Comprehensive Health Enhancement Support System) [80-82] is a computer-based support system, which provides information and support to people facing different health problems. It does not provide personalized patient education materials to the patients. It provides generalized patient education materials i.e. it provides generic information about different disease conditions in terms of terms of health articles and literature related to various disease conditions. Personalised Healthcare Information Delivery System (PHIDS) [84] is an intelligent info-structure to provide personalized health information to the patients. It ensures that, on one hand the healthcare content must be disseminated to an individual is specifically focused on his or her healthcare needs, and on the other hand the PHI should be periodically pushed to the individual to ensure the timely consumption of the up to date PHI.

Our CPG-PE framework is also intend to provide personalized patient education materials based on CPG(s) recommendations specific to patient's disease condition(s) and/ or co-morbidities, motivational status, behavioral and psychosocial factors. As we discussed earlier in Chapter 4 (section 4.5), the personalization will take place upon execution of CPG-PE framework through a computerized decision support system (CDSS), CPG(s) will give recommendations based on patients profile generated through electronic patient record (EPR), for the given disease condition(s) and/or co-morbidities. Based on the clinical recommendations provided by CPGs, CPG-PE can offer information to patients related to their disease condition(s) during clinical care process regarding disease condition description, risk factor modification and prevention, clinical examination, diagnostic and therapeutic procedures, medications, prognosis, and complications etc. at each recommendation step of CPG(s), in the form of PEMs. For an

example, CPG is recommending surgical procedure i.e. *Trans-urethral resection of prostate* (TURP) for a patient having *Benign Prostatic Hyperplasia* (BPH) , but the patient is at high risk or not suitable for any surgical procedure due to any co-morbidities i.e. uncontrolled hypertension, diabetes, bleeding disorders, or history of recent Myocardial Infarction (MI), so CPG will recommend alternative therapy for this patient in terms of medication i.e. *Alpha Adrenergic Blocker* (e.g. Prazosin). Simultaneously PEM related to the use, benefits, indications, contraindications, and adverse effects will be delivered to the patient as "***DrugInformation-AdverseReactions***" through CPG-PE ontology in our CPG-PE framework. We also demonstrated this feature i.e. providing personalized patient education, of our CPG-PE framework in two comprehensive clinical cases: colorectal cancer (See Section 5.1.1) and preeclampsia (See Section 5.1.2).

5.3.3. Patient Education at Each Step

This is a unique feature of our CPG-PE framework, which none of the patient education system provides i.e. delivery of patient education at each recommendation step during the clinical care process in the course of the management of patient disease condition(s). Upon execution, CPG-PE will offer PEMs at each recommendation step by the CPG(s) i.e. clinical examination, risk factors, diagnostic interventions, therapeutic interventions, surgical procedures, medications, complications etc. Where and when CPG(s) will recommend any action or decision step in the process of clinical care, the PEMs related to that specific recommended step or action will be generated through merged CPG-PE ontology.

For an example, CPG is recommending Serum *Prostate Specific Antigen* (PSA) for suspected Prostate Cancer to a patient; PEM related to this specific test will be delivered to the patient as "***DiagnosticProcedure***" through CPG-PE ontology in our CPG-PE framework. This PEM will explain and educate patient about the serum PSA, its indication, normal and pathological values etc. Now CPG is recommending the next step following the result of previous step i.e. Serum PSA results, is *Trans-rectal ultrasound guided biopsy* (TRUS Biopsy). Based on the CPG recommendation of TRUS Biopsy on this step, another PEM will be delivered to the patient related to this specific procedure as "***DiagnosticProcedure***" through CPG-PE ontology in our CPG-PE framework. This PEM will provide patient information about TRUS biopsy: i) What is the procedure all about;

ii) For which condition(s) this procedure is indicated; iii) What will happen during the procedure; iv) If any preparation is required for the procedure; v) What are the complications can occur after this procedure; etc. Following the next step, CPG is recommending *Brachytherapy*; PEM related to *Brachytherapy* will be delivered to the patient as "***Radiation-Chemotherapy***". This PEM will provide patient education regarding the need, role, procedure description, outcome, and complications etc. of brachytherapy. Alternatively, if the patient is not suitable for brachytherapy, then CPG will recommend for surgery i.e. *Radical Prostatectomy* for this specific patient. PEM related to Radical Prostatectomy will be delivered to the patient as "***TherapeuticProcedure***" through CPG-Ontology in our CPG-PE framework. This PEM will provide information and education to the patient regarding *Radical Prostatectomy* i.e. procedure description, indication, outcome, and possible complications etc. This will go step-by-step and on each step CPG(s) will give some recommendation(s) and the corresponding PEMs will be generated through CPG-PE ontology deliver to the patient during the process of clinical care, regarding recommendation(s) at each step by the CPG(s). We already demonstrated it earlier in our clinical case study: colorectal cancer (See Section 5.1.1) and preeclampsia (See Section 5.1.2).

5.3.4. Psychosocial and Behavioral Factors

GEM-based CPG generated tailored patient education materials [17, 73] do not address psychosocial and behavioral parameters or factors, which have an influence and a role in disease etiology, progression, and its outcomes. GEM does not use these parameters or parameters, which Brug et al [167] named as "*psychological determinant of health behavior*", that can be used to tailor patient information material or provide personalized patient education materials. Layman Education and Activation Form (LEAF) [74, 75] also do not address psychosocial, behavioral and motivational parameters or factors. It provides personalized or tailored patient education based on disease specific condition, but does not use psychosocial and behavioral parameters or factors to personalize or tailor information to the patients.

The PULSE [76, 77] (Personalisation Using Linkages of SCORE and behaviour change readiness to Web-based Education), address psychosocial, behavioral, and

motivational factors in order to provide personalized education materials to the patients for the management of cardiovascular diseases risk. . The system framework based on a patient profile created by combining an electronic patient data capture template (DCT) , the Systematic Coronary Risk Evaluation (SCORE) algorithm for ten-year risk assessment for fatal cardiovascular disease, and a Stage of behaviour Change readiness model. The system is designed to address both medical and psychosocial aspects of risk management for cardiovascular diseases. Electronic patient data capture template (DCT), comprises a set of evidence-based parameters for evaluation and management of patient disease condition. These parameters included: age, gender, personal and family health history related to CVD, smoking status, amount of regular exercise, eating habits, alcohol consumption, weight control values, stress, depression, lipid values, blood pressure (BP) values, glycemic control values, and behaviour change readiness.

Migraineur [78] do not address psychological and behavioral factors. It does not use psychosocial and behavioral parameters to personalize information to the patient. It personalizes education materials on disease-specific parameter, in order to provide customized information to patients suffering from chronic or acute migraine headaches. HealthDoc [79] address psychosocial and behavioral factors in order to provide personalized education materials to the patients in the process of clinical care. It offers customized information and health-education materials highly specific to the disease condition and personal characteristics of the individual patient. CHESS (Comprehensive Health Enhancement Support System) [80-82] also address psychosocial and behavioral parameters, but do not use these parameters to provide personalized patient education. It consists of an integrated set of services to provide information, referral, skills training, decision support and social support to its users. CHESS provide generalized education to the patients in general about their health condition(s), through patient educational literature on various disease conditions in general. It has social support component which address psychosocial and behavioral factors and also encourage social networking and share information between patients suffering from similar disease condition(s) in a group discussion. Personalised Healthcare Information Delivery System (PHIDS) [84] do not address psychosocial and behavioral factors in patient education materials. It personalizes

education materials on disease-specific parameter, but does not use psychosocial and behavioral parameters or factors to personalize information to the patients.

Our CPG-PE framework address these psychosocial and behavioral parameters or factors, which are address by Brug et al [167] and the psychodynamic model [31], in providing personalized education material to the patients. Upon execution, CPG-PE will offer personalized education materials to the patient based on CPG(s) recommendations specific to patient's disease condition(s) and/ or co-morbidities, psychosocial, motivational and behavioral factors, in the process of clinical care. We encoded these parameters or factors which are addressed by psychodynamic model as:

1. Applied_Psychosocial_Aspects:
    a. applied_behavioural_factors,
    b. applied_motivational_factors,
    c. applied_demotivation_factors,
    d. applied_educational_status,
    e. applied_living_conditions,
    f. applied_socioeconomic_conditions.
2. Applied_Religious_Cultural_Aspects:
    a. applied_cultural_obligations,
    b. applied_emotional_factors,
    c. applied_moral_considerations,
    d. applied_religious_obligations.

We have already discuss how these factors and parameters will be used in CPG-PE ontology upon execution of CPG-PE framework, in order to provide personalized education materials to the patients based on CPG(s) recommendations specific to patient's disease condition(s) and/ or co-morbidities, psychosocial, motivational and behavioral factors, in the process of clinical care in Chapter 4 (See Section 4.5).

5.3.5. Shared Decision Making (SDM) and Patient Preference

GEM-based CPG generated tailored patient education materials [17, 73] do not encourage shared decision making between the patient and the physician, while providing

patient education materials. It does not give patients choices regarding different management options and other modalities during the clinical care process. Layman Education and Activation Form (LEAF) [74, 75] encourage shared decision making between the patient and the physician, while providing patient education materials. It gives patient different choices and options during the course of management of their health condition(s) regarding different management modalities. The main objective of LEAF [74, 75] was to create more informed, activated and educated patients, so they should have better understanding about medical terminologies and doctors' vocabulary. LEAF intends to reduce the communication gap between the patients and the physicians, and to improve doctor-patient communication during health care process through shared decision making between them.

The PULSE [76, 77] (Personalisation Using Linkages of SCORE and behaviour change readiness to Web-based Education) do not facilitate patient preference and shared decision making between the patient and the physician, while providing personalized patient education materials for the management of cardiovascular diseases risk. Migraineur [78] encourage shared decision making between the patient and the physician and facilitates patient preferences, while providing customized or personalized information to the patients suffering from acute or chronic migraine headaches. The main objective of this project is to increase the overall effectiveness of physicians' time, and the quality of healthcare, by improving interaction and the information exchange between the physicians and the patients for effective management of patients' condition in clinical care settings. HealthDoc [79] do not encourage shared decision making between the patient and the physician during the process of clinical care. It does not facilitate patient preferences and does not provide patient choices regarding different diagnostic and therapeutic modalities, while providing education to the patient during the course of management of their health condition(s) in clinical care process.

CHESS (Comprehensive Health Enhancement Support System) [80-82] encourage shared decision making and provides patient preferences. CHESS [80-82] is a decision support system, which provides information and support to help patients to monitor their health condition/status and risk behaviors, share in important decisions, and plan how to

implement their decisions. It provides information, skills training, decision support, and social support to the patients to improve their decision making and coping skills during the course of their illnesses and its management during the process of clinical care. Personalised Healthcare Information Delivery System (PHIDS) [84] do no encourage shared decision making between the patient and the physician, and also do not provide patient preference, while providing personalized patient education for the management of their health condition(s) during the process of clinical care.

As we mentioned earlier, one of our objective is to improve shared decision making between the patient and the physician during clinical encounters by producing much informed and educated patients. CPG-PE framework encourages shared decision making between the patient and the physician in the process of clinical care. Upon execution, CPG-PE will offer PEMs at each recommendation step by the CPG(s) i.e. clinical examination, risk factors, diagnostic interventions, therapeutic interventions, surgical procedures, medications, complications etc. The idea is that, patient will have some information about the next step or action which their physician is planning for them during the course of management of their disease condition(s), in the process of clinical care. If the patient is well informed about the next step which they are going through in the process of care, it will allow patients to discuss about that specific step i.e. laboratory test, imaging tests, diagnostic procedure, surgery etc. and it will promote shared decision making between the patient and their physician during the clinical encounters.

For an example, if CPG(s) is recommending TRUS Biopsy to a patient after serum PSA results, PEM will be delivered to the patient related to this specific procedure as "***DiagnosticProcedure***" through CPG-PE ontology in our CPG-PE framework, to aware and inform patient about TRUS biopsy. In this way, when they will see their physicians, they will be much more informed about this procedure, and they can discuss the pros and cons of this procedure with their physicians to come to a mutual decision which will be best in benefit of the patient as well as patient will be fully compliant for this procedure.

Our CPG-PE framework facilitates patient preferences and offer patient different choices and options based on their preferences. For an example, CPG is recommending *Brachytherapy* for a patient and the patient is not suitable for brachytherapy or if the

patient is not willing to go for brachytherapy due to some cultural barriers or personal preference, the psychodynamic model will indicate about those barriers using properties Applied_Psychosocial_Aspects and Applied_Religious_Cultural_Aspects to the physician and they will try to find out another alternative procedure for therapy, then CPG will recommend for an alternative therapeutic procedure in terms of surgery i.e. *Radical Prostatectomy* for this specific patient. PEM related to Radical Prostatectomy will be delivered to the patient as "***TherapeuticProcedure***" through CPG-Ontology in our CPG-PE framework. This PEM will provide information and education to the patient regarding *Radical Prostatectomy* i.e. procedure description, indication, outcome and possible complications etc. In this way CPG-PE framework will offer different options regarding diagnostic and therapeutic regimen, for the patients to choose one based on their personal preference during the course of management of their disease condition(s) in the process of clinical care. It will also satisfy patient's wish, as shown by research studies, majority of the patient want to collaborate with their doctors in the process of decision making (shared decision making), and opt for any diagnostic and therapeutic modality according to their preference after discussing with their doctors [123, 124].

5.3.6. Comprehensiveness to Incorporate Multiple Diseases

GEM-based CPG generated tailored patient education materials [17, 73], intended to provide personalized patient education to those patients who have dyslipidemia. However, it can convert different guidelines to incorporate multiple disease conditions in order to provide tailored patient education materials. Layman Education and Activation Form (LEAF) [74, 75] incorporates multiple disease conditions while providing personalized education materials to the patients. It consists of an intelligent medical history form, which is not disease specific and can be used for any disease. The medical history form provides patients a relevant set of questions, acquires information about the patient's medical history and customized medical information to the patients related to their disease condition(s).

The PULSE [76, 77] (Personalisation Using Linkages of SCORE and behaviour change readiness to Web-based Education) is a Web-based personalised educational intervention for the management of cardiovascular diseases risk. It cannot incorporate

multiple disease conditions to provide personalized education material to the patients. Migraineur [78] is an intelligent interactive system for delivering individualized information to the patients suffering from chronic or acute migraine headaches. It cannot incorporate multiple disease conditions or provide personalized patient education materials for any other disease condition.

HealthDoc [79] incorporate multiple disease conditions in order to provide customized information and health-education materials to patients. Its master document is written by health professional and domain experts on different topics on various disease conditions containing all formations including illustrations and annotations. CHESS (Comprehensive Health Enhancement Support System) [80-82] is a computer-based support system, which provides information and support to the patients related various disease conditions. It incorporates multiple disease conditions in order to provide generalized information and education to the patients regarding different disease conditions. Personalised Healthcare Information Delivery System (PHIDS) [84] is an intelligent info-structure to provide personalized healthcare information to the patient. It can incorporate multiple disease conditions through multiple TD (Topic-specific Document), in order to provide personalized healthcare information to the patients based their Health Profile (HP).

Our CPG-PE framework can incorporate multiple disease conditions from different medical disciplines and specialties. As we discussed in chapter 4 (See Section 4.1) analyzed numerous PEMs related to various diseases and specialty from different resources i.e. American College of Family Physicians, A.D.A.M., Inc., British Medical Journals (BMJ) patient education leaflets, Ferri's Netter Patient Advisor etc. for modeling the knowledge within PEMs. We identified key concepts and knowledge elements within PEMs related to different diseases from various medical discipline and specialties. We modeled those knowledge elements/ structure and develop a knowledge model for PEMs as CPG-PE ontology in our CPG-PE framework. We have modeled all the possible key concept and knowledge elements within the PEMs related to different disease conditions from various medical discipline and specialties, so CPG-PE ontology can incorporate multiple disease conditions and co-morbidities in our CPG-PE framework.

The overall summary of the Systematic evaluation on comparison of CPG-PE framework with other related Patient Education Systems on different parameters is listed in Table 5 below:

Table 5: Systematic Evaluation: Comparison of CPG-PE framework with other patient education systems on different parameters

	GEM	LEAF	PULSE	Migraineur	Health -Doc	CHESS	PHIDS	CPG-PE Framework
Evidence-based guidelines	x							x
Personalized patient education	x	x	x	x	x		x	x
Patient education at each step								x
Psychosocial and behavioral factors			x		x	x		x
SDM and patient preference		x		x		x		x
Comprehensiveness to incorporate multiple diseases	x	x			x	x	x	x

We evaluated our CPG-PE framework based on three approaches: 1) Consistency checking of PEO: by running Pellet 1.5.2 reasoner on our ontology; 2) An extensive case study: by two comprehensive clinical vignettes i.e. colorectal cancer and preeclampsia; and 3) Systematic evaluation: by comparison of CPG-PE framework with other related patient education systems on different parameters. Our CPG-PE framework is capable of providing personalized education materials to the patients, based on CPG(s) recommendations related to their disease condition(s) and/or co-morbidities, motivational, psychosocial and behavioral factors, in order to improve shared decision making between the patient and the physician during the process of clinical care. In the Chapter 6, we will conclude our research work with some working limitations along with future research directions.

Chapter: 6

6. Conclusion and Future Directions

6.1. Conclusion

In this research work, studies have shown that patient education have been an extremely important and critical issue, in improving health outcomes in clinical practice in past few decades. Clinical practice based on Evidence Based Medicine (EBM), and patient self-education about their personal health is necessary to achieve patient compliance and better health outcomes. Patient compliance requires efficient communication between the patients and the physicians. Physicians typically do not have much time to explain the rationale behind the diagnoses and treatment of the disease conditions to their patients, which creates a lot of confusion and chaos in the minds of the patients, regarding the options of management of their disease conditions. It leads to patients' non-compliance and undesirable health outcomes. Studies have shown that, patient compliance and better health outcomes are strongly related to the patients' understanding of their disease conditions, its prescribed treatment, and the management options. It requires the need of better communication between the patients and the physicians, and shared decision making between them. The psychodynamic model encourages shared decision making between the patients and the physicians to choose the desired and most appropriate diagnostic and therapeutic modalities in the process of care, to achieve desirable and better health outcomes. We used this model as the basis of patient education for our research work.

In this research work, we proposed a CPG based Patient Education framework (CPG-PE) using Semantic Web technologies. Upon execution of CPGs, it will give recommendation(s) based on patient specific profile, using those patient specific recommendations, it can deliver patient education message highly specific to the individual patient according to their disease condition(s) and associated co-morbidities. Our patient education (PE) approach for CPG-PE framework to promote shared decision making is based on psychodynamic model, to deliver personalized patient education materials in order to produce more informed patients and improve clinical decision

making. Our main objective is to promote shared decision making between physicians and patients during clinical encounters at the point of care. Our PEMs also have decision making and counseling parts, which will help patient to deal with tense situation related to or during their disease condition(s), psychodynamic model flexibly allow us to do so, because it covers emotional, psychological, cultural values, family pressure, and personal esteems etc. along with the management of disease condition at the point of care.

We have defined a methodology to develop Personalized Patient Education System as our CPG based Patient Education Framework (CPG-PE Framework) as follows (See Section 3.4):

1. *Step 1*: Computerization of CPGs
2. *Step 2*: PEM Knowledge Modeling
3. *Step 3*: Development of PE Ontology
4. *Step 4*: Merging CPG and PE Ontologies
5. *Step 5:* Representing PEMs in CPG-PE Ontology
6. *Step 6*: Personalization of PEMs
7. *Step 7*: Evaluation of CPG-PE framework

We have modelled a number of PEMs from several specialties related to various diseases from different resources i.e. American College of Family Physicians, A.D.A.M., Inc., British Medical Journals (BMJ) patient education leaflets, Ferri's Netter Patient Advisor etc. in our CPG-PE ontology to be used by our CPG-PE framework, to provide personalized educational materials to the patients based on CPG(s) recommendations related to their disease condition(s) and/ or co-morbidities, psychosocial, and behavioral factors, during the process of clinical care. For representing PEMs in the PE ontology, we defined concepts in terms of 6 Classes i) pem: **PEMaterial**, ii) pem: **Conditions**, iii) pem: **Factors**, iv) pem: **Considerations**, v) pem: **Obligations** and vi) pem: **Status.**

1. Class **PEMaterial** is further classified into 27 sub-classes (See Section 4.2.4).
2. Class pem: **Conditions**, is further classified into sub-class: Living_Conditions.
3. Class pem: **Factors**, is further classified into sub-classes: i) Behavioural_Factors ii) Demotivational_Factors iii) Emotional_Factors iv) Motivational_Factors.

4. Class pem: **Considerations**, is further classified into sub-classes: Moral_Considerations.
5. Class pem: **Obligations**, is further classified into sub-classes: i) Cultural_Obligations ii) Religious_Obligations
6. Class pem: **Status**, is further classified into sub-classes: i) Educational_Status ii) Socio-economic_Status.

We defined 17 properties as the basis of patient education which can be the key concepts and knowledge elements in the PEMs related to various diseases related to different medical disciplines and specialties (See Section 4.2.5)

These sub-classes and properties cover a broad range of diseases conditions under different fields of medicine, and can incorporate any disease condition (s) or co-morbidities for patient education purposes. We made this CPG-PE framework generic enough to incorporate any disease condition(s) or co-morbidities. Irrespective of the fact that, which guideline is in use, our CPG-PE frame work is generic and comprehensive to incorporate multiple diseases related to various medical disciplines and specialties. We covered all those aspects of CPG/physicians recommendations which have patient education potential in CPG-PE ontology, so it can generate PEMs specific to patient disease condition(s) and/ or co-morbidities, behavioral and psychosocial factors for any disease condition(s)/co-morbidities, based on CPG(s) recommendations upon execution of CPG(s) of our CPG-PE framework, during the process of clinical care.

CPG-PE framework aims to improve the clinical discussion and shared decision making between a patient and their physician. As clinical management is a step-by-step, back and forth process, in the process of clinical care. A patient will come with their presenting complains, and the EPR will generate patient profile based on their disease condition(s) and/ or co-morbidities, behavioral attitude and psychosocial factors. The patient-specific case profile can be used to select CPG or multiple CPGs, and CPG(s) will recommend some action or decision step. At each and every recommendation step, PEMs will also be delivered to the patients explaining that recommendation step. The first recommendation would be possibly the best option in the favor of the patient, but one of our research objective is to promote patient preferences as well, so the given

recommendation can be altered by the CPG(s) if any alternative is available, based on patient own preferences. Physicians will provide all the options to the patient as recommended by CPG(s), and leave it to the patient to choose one based on their own personal preferences. Our CPG-PE framework will help the patient in this aspect, as it will give PEMs at each and every recommendation step by CPG(s), as suggested by their physician. In this way, patient would be more knowledgeable and well-informed about the diagnostic and therapeutic modalities, which they have to go through during the course of the management of their health condition(s) during the process of clinical care. It will improve clinical shared decision making, and patient will actively participate in the management of their health condition(s) during the process of clinical care.

In our research work we demonstrated that, the computerized CPG or CPG ontology can be used to generate patient education materials, if incorporated in our CPG-PE framework. On one hand, it would serve as CDSS to the physicians and on the other hand, patient education materials would be generated for the patients based on their disease condition(s), and co-morbidities. Both of these functions will be driven by CPG(s) based recommendations, so they will be based on recent evidence-based medicine, and suitable for patient disease condition(s) and co-morbidities for best possible outcomes. However, there are risk in adopting CPGs and computerizing it. Studies have shown that, evidence based CPGs are not freely disseminated or fully fitted into the specific clinical settings. Even after dissemination, evidence based guidelines are not used [14], and there are serious deficiencies in the adaptation of CPGs in clinical practice [15]. Also proper use of guidelines is a more complex problem than the failure to adapt CPGs for practice [11-13]. The rapid proliferation of clinical practice guidelines (CPGs) has made computerization increasingly useful to clinicians [93]. However, representation of clinical practice guidelines in a computer-interpretable format has been a critical issue for guideline development, dissemination, implementation and evaluation. The CDSS based on our CPG-PE framework is intended to work with CPGs and computerization of those CPGs. It is not useful for clinical pathways or any other institution-based pathways, for the management of disease conditions in the process of clinical care.

This research work also demonstrated that, it is possible to generate personalized patient education materials from already written patient education documents (in word and PDF format) i.e. American College of Family Physicians, A.D.A.M., Inc., British Medical Journals (BMJ) patient education leaflets, Ferri's Netter Patient Advisor etc., using knowledge modeling which we have discussed in chapter 4 (See Section 4.1). We identified key concepts and knowledge elements within PEMs after analyzing numerous PEMs from several specialties related to various diseases from different resources i.e. American College of Family Physicians, A.D.A.M., Inc., British Medical Journals (BMJ) patient education leaflets, Ferri's Netter Patient Advisor etc. to develop a knowledge model for PEMs. Based on knowledge modeling of PEMs, we develop an ontology-based knowledge model for PEMs i.e. "Patient Education Ontology" (PEO), to be used by our CPG-PE framework. PEO represents the knowledge elements within already written patient education documents from these resources PEMs, and CPG-PE ontology can deliver personalized patient education materials to the patients based on their disease condition(s)/ co-morbidities psychosocial and behavioral factors, upon execution of our CPG-PE framework, in order to improve shared decision making between the patient and the physician during the process of clinical care.

We re-visited our research objective, and analyzed what we have accomplished in this research. We developed a comprehensive knowledge model in terms of CPG-PE framework which can provide the following as shown by evaluation of our CPG-PE framework in Chapter 5:

1. Delivers patient-specific education based on CPG(s) recommendations related to their disease condition(s) and co-morbidities, as we mentioned in our evaluation that CPG-PE framework can provide patient-specific education based on their health profile.
2. Addresses and highlights psychosocial and behavioral aspects of disease condition etiology and their impact on the patient health condition(s) outcomes.
3. Encourages patients' preference and choices among different modalities and options of diagnostics and therapeutics, during the course of the management of their disease condition(s), as shown by our evaluation of CPG-PE framework.

4. Improves shared decision making between patients and physicians during the process of clinical care. We were unable to evaluate it in this time frame; it can be a potential future work.
5. Produces more knowledgeable and well-informed patients, so they can actively participate in the management of their disease condition(s) during the process of clinical care. We were unable to evaluate it in this time frame, and it can be evaluated in future.
6. Comprehensive enough to address and incorporate multiple disease conditions, in order to provide patient education related to various disease conditions from different medical disciplines and specialities, as shown by our evaluation of CPG-PE framework.

6.2. Limitations

Consider limited technical expertise of the author, our CPG-PE frame work needs more technical work to be done, in order to make this framework semantically executable. There is a need to use this CPG-PE frame work to be used by a rule-based engine, so it can act as a decision support system (CDSS) for the physicians and decision aid and counselling system for the patient to improve shared decision making between the patient and the physician during the process of clinical care, and improve patients compliance and health outcomes. Unfortunately, usually guidelines do not address those psychosocial, motivational, cultural, environmental, and behavioral factors address by the psychodynamic model, which have significant role in the etiology, risk, progression and prognosis of the disease. These are the factors/ parameters, on the basis of which patient education materials can be personalized to the specific patient other than the "disease condition specific". We modeled major factors/ parameters address by the psychodynamic model in our PEO, so if there is a need to personalize these factors in patient education materials, then CPG-PE ontology can incorporate these factors/ parameters, in order to deliver personalized patient education materials based on these factors/ parameters along with disease condition(s) specific CPG(s) recommendations during the process of clinical care, upon execution of our CPG-PE framework.

Currently, it is our contention that in patients' health profile, there is demographic data/information which can be connected to psychodynamic model, i.e. age, gender,

address, ethnicity, socio-economic status, religious believes, neighborhood information etc. So psychodynamic model will help us to incorporate these aspects such as patients' self-esteem, emotion, religious, and cultural beliefs etc., along with psychosocial, motivational, behavioral, and environmental factors, which have a strong influence on their lives and have role in the etiology, risk, progression and prognosis of the disease.

6.3. Future Directions

Still, significant scientific work can be done on this domain "Computerized Patient Education". Our CPG-PE framework using semantic web technology is one of the steps in this process. Our CPG-PE framework can be executed and implemented as a fully functional CDSS for the physicians, and an interactive computer web-based program as Patient Education and Counselling System (PECS) or to the mobile devices through Spontaneous Messaging System (SMS). Clinical Pathways (CP) and other institution-based pathways can be included in our CPG-PE framework, which are used in different institutional and clinical settings during the course of management of patient's disease condition(s) and/ or co-morbidities during clinical care process. Further, there is a need to evaluate how our CPG-PE framework improves shared decision making between patients and physicians by a clinical trial during the process of clinical care.

Our CPG-PE framework can be used by "*CarePlan*", which has a framework, based on innovative knowledge management approaches particularly Semantic Web, for patient-centric healthcare tools [88]. This framework comprises (1) patient information stored in online records, (2) CPGs, (3) Clinical Pathways, and (4) a semantic web of heterogeneous medical knowledge resources [88]. So our CPG-PE framework could be a fifth component of the *CarePlan*. Other patient education models and theories could also incorporate in CPG-PE framework, to develop a Comprehensive Care Plan for patient-centric healthcare tool or Patient Education and Counselling System (PECS) in future.

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Appendix

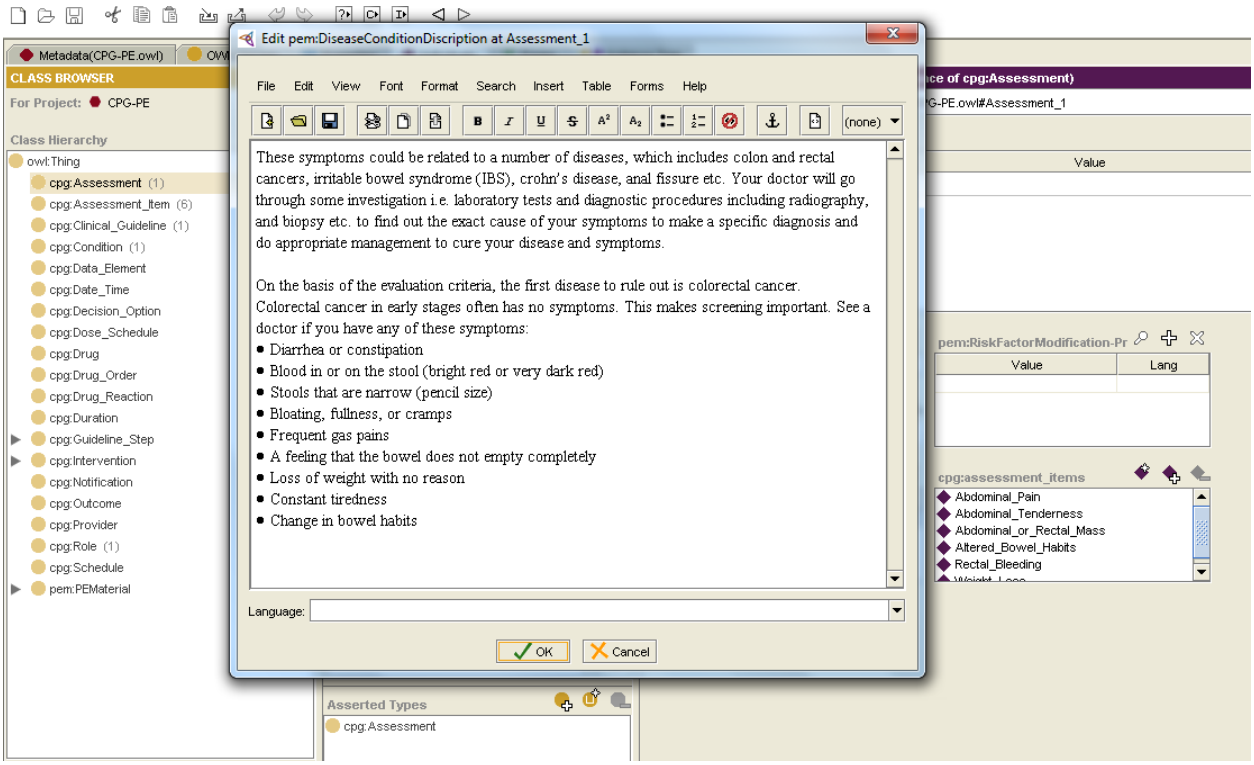

Figure 20: PEM about the initial assessment of the patient's condition

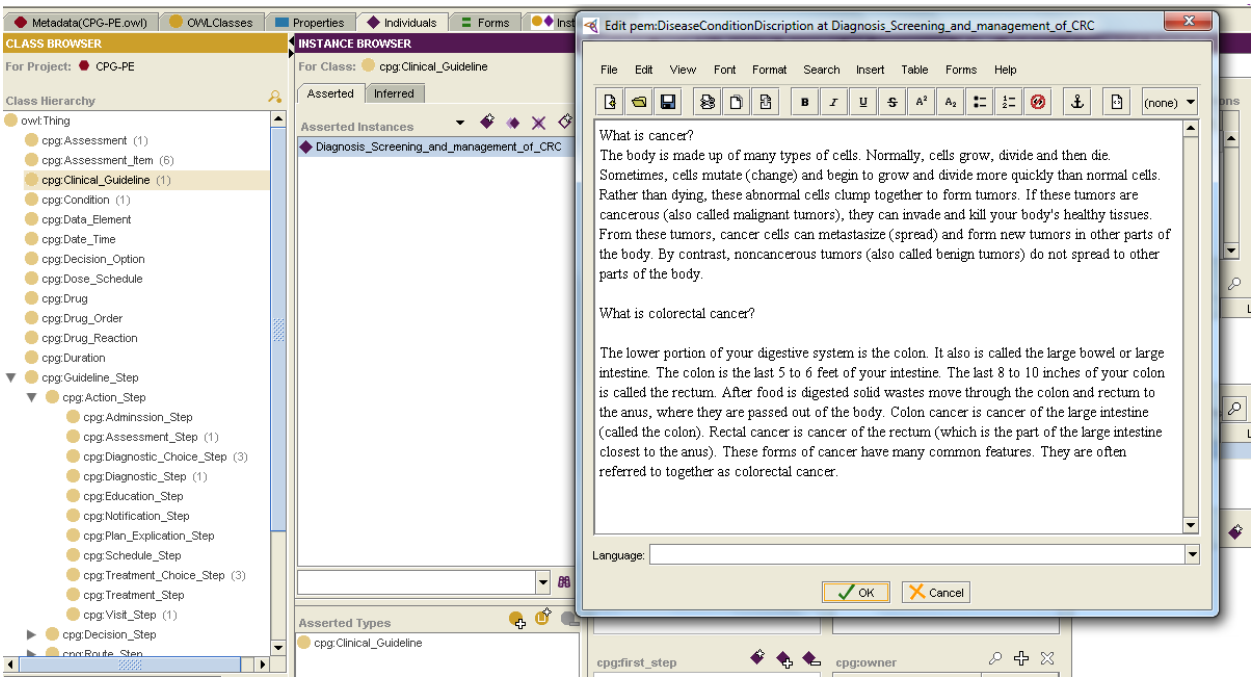

Figure 21: PEM about CRC (disease condition description)

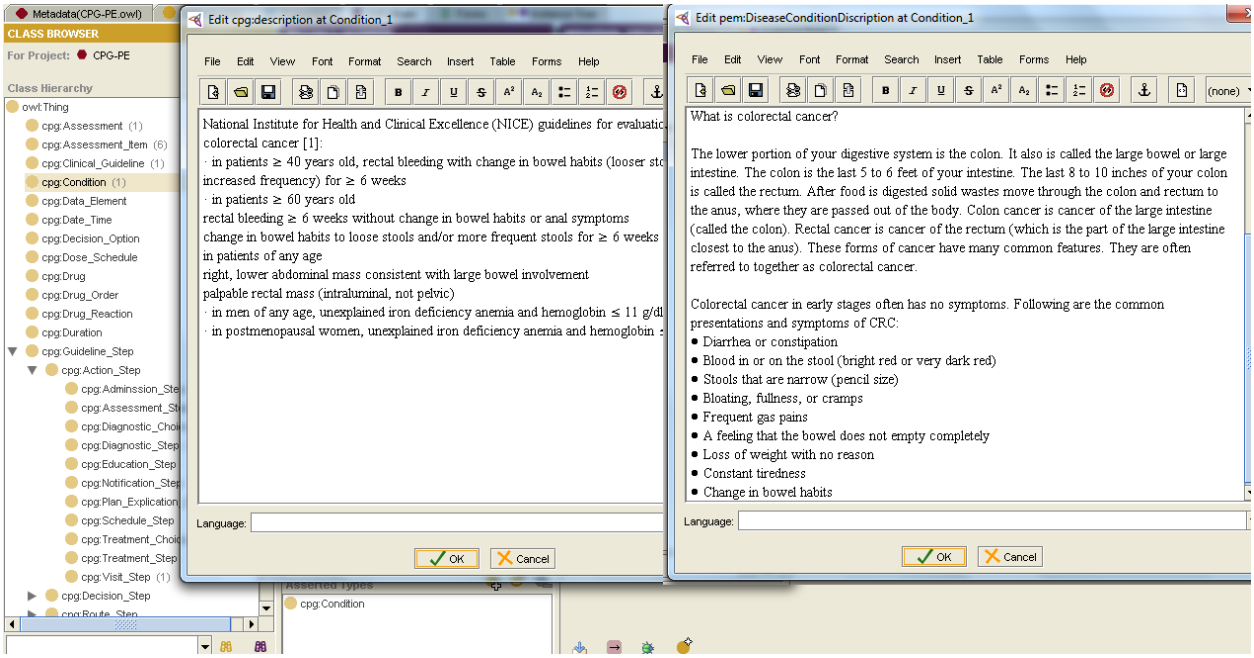

Figure 22: Evaluation criteria of CRC and Disease Condition Description

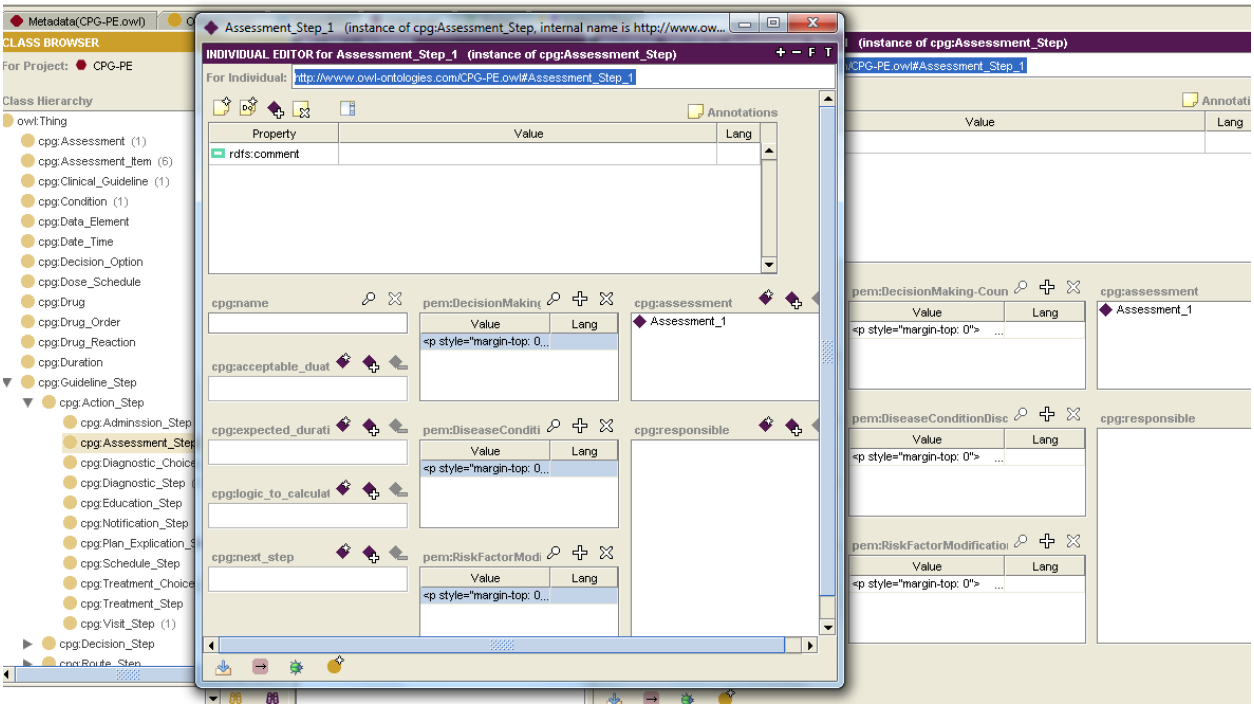

Figure 23: Assessment of the risk factors of CRC

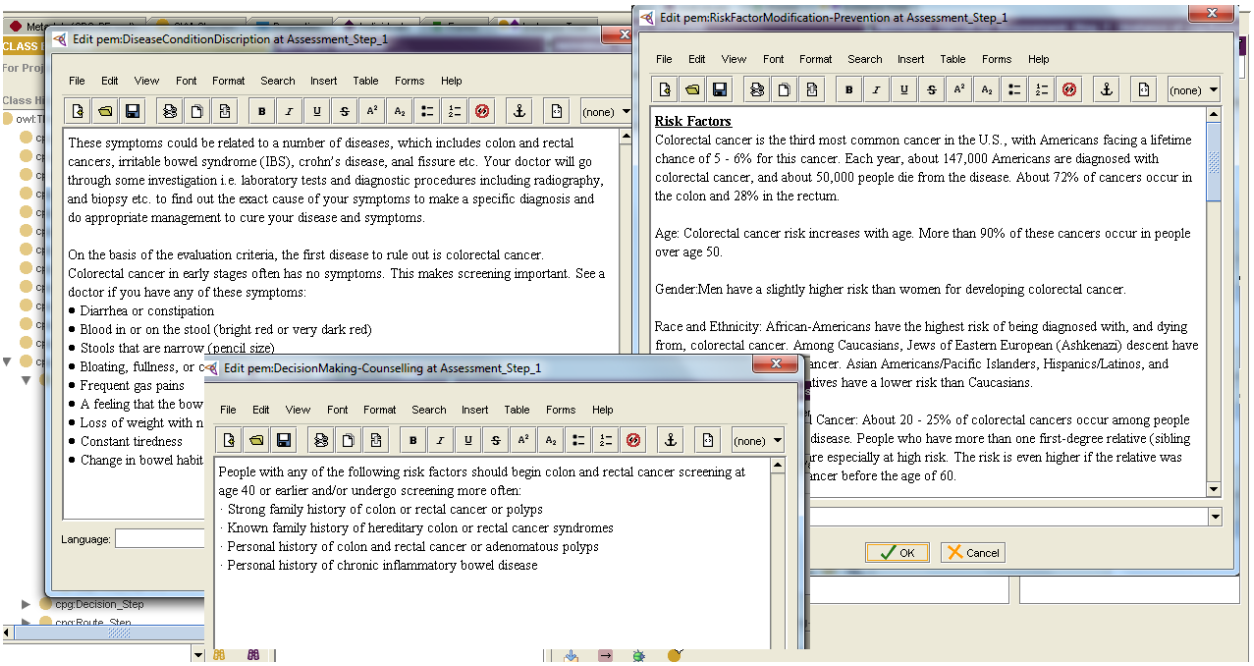

Figure 24: Description of CRC, risk factor modification-prevention and counseling

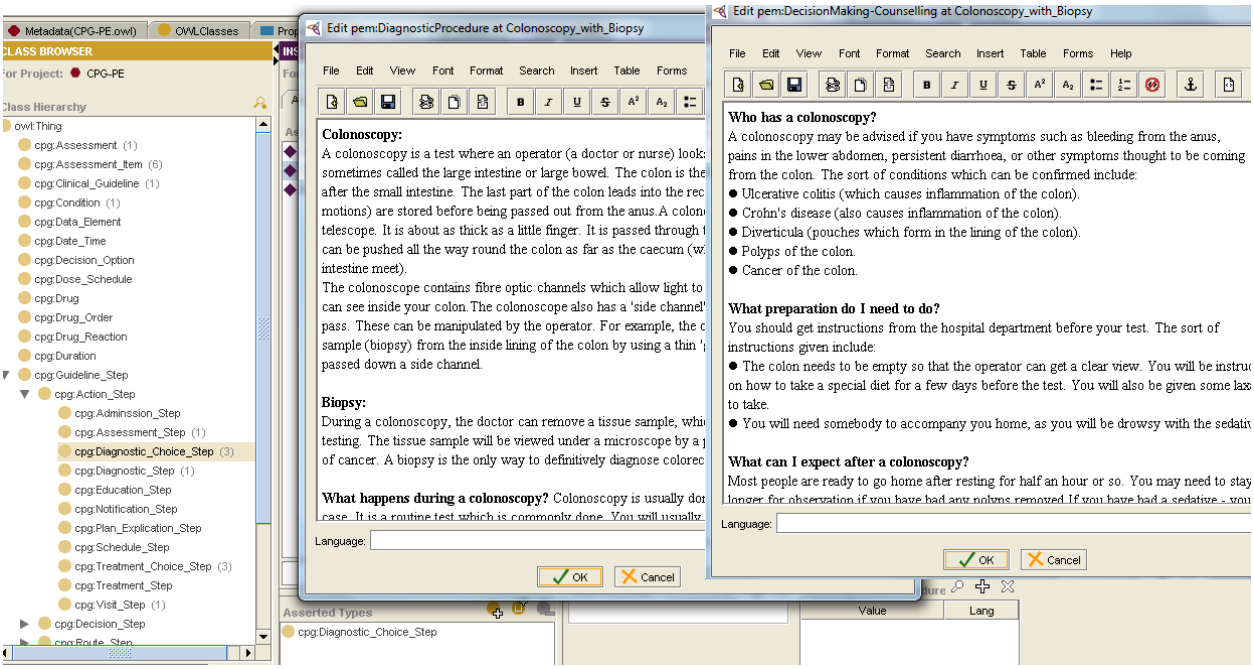

Figure 25: PEM about diagnostic procedure and counseling regarding CRC

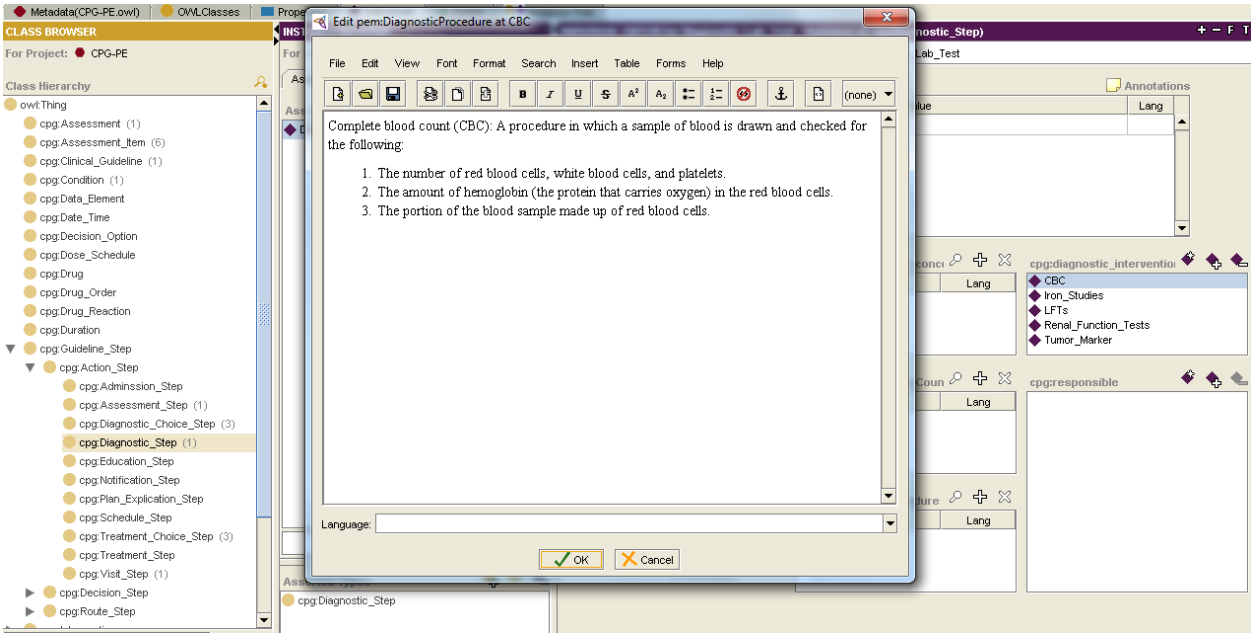

Figure 26: PEM about diagnostic procedure-diagnostic laboratory test for CRC

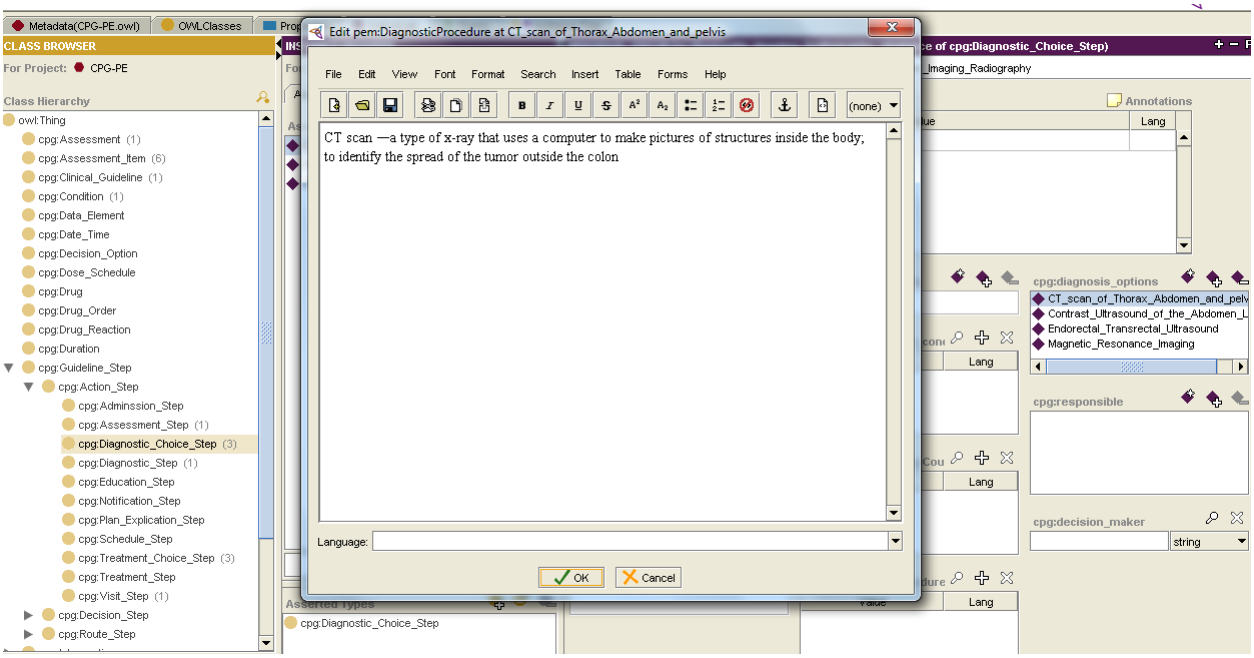

Figure 27: PEM about diagnostic procedure-diagnostic imaging and radiography

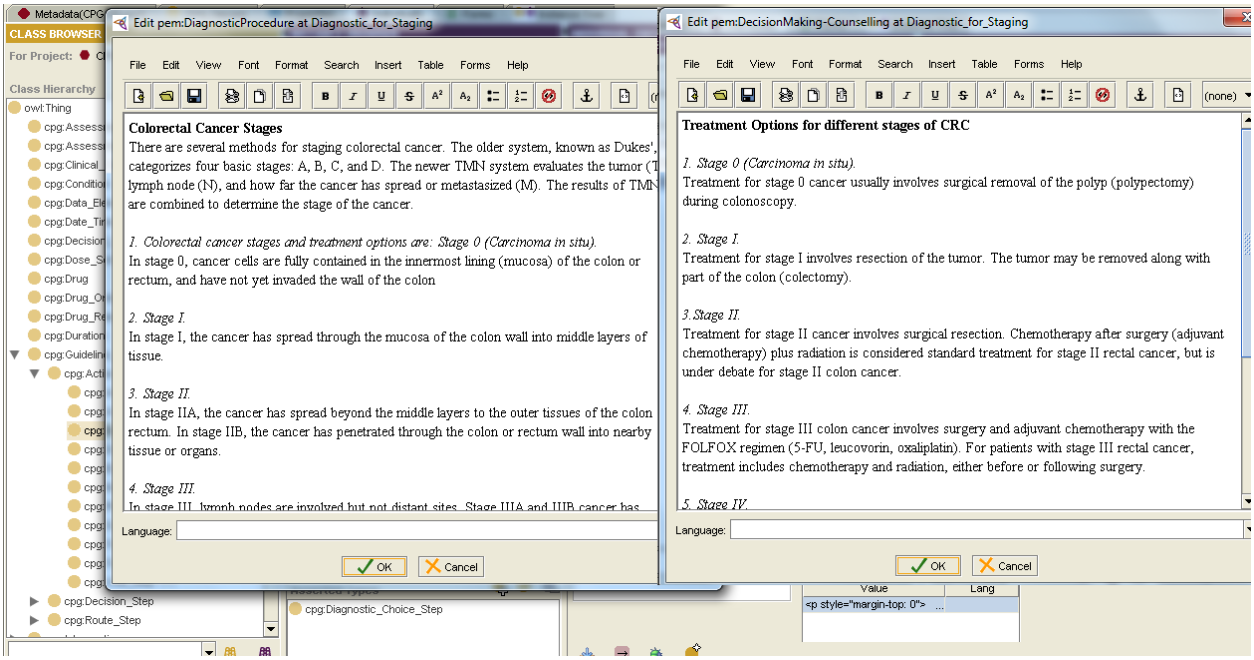

Figure 28: PEM about diagnostic procedure-CRC staging and counseling about the treatment options

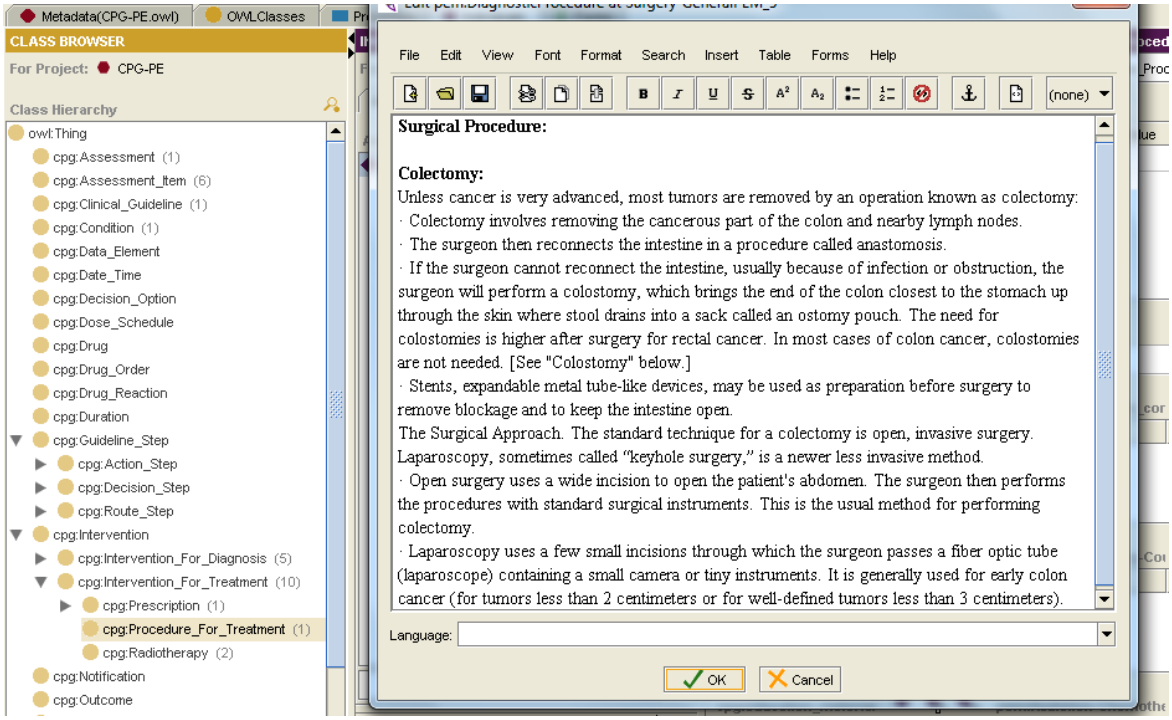

Figure 29: PEM for therapeutic procedure-surgery

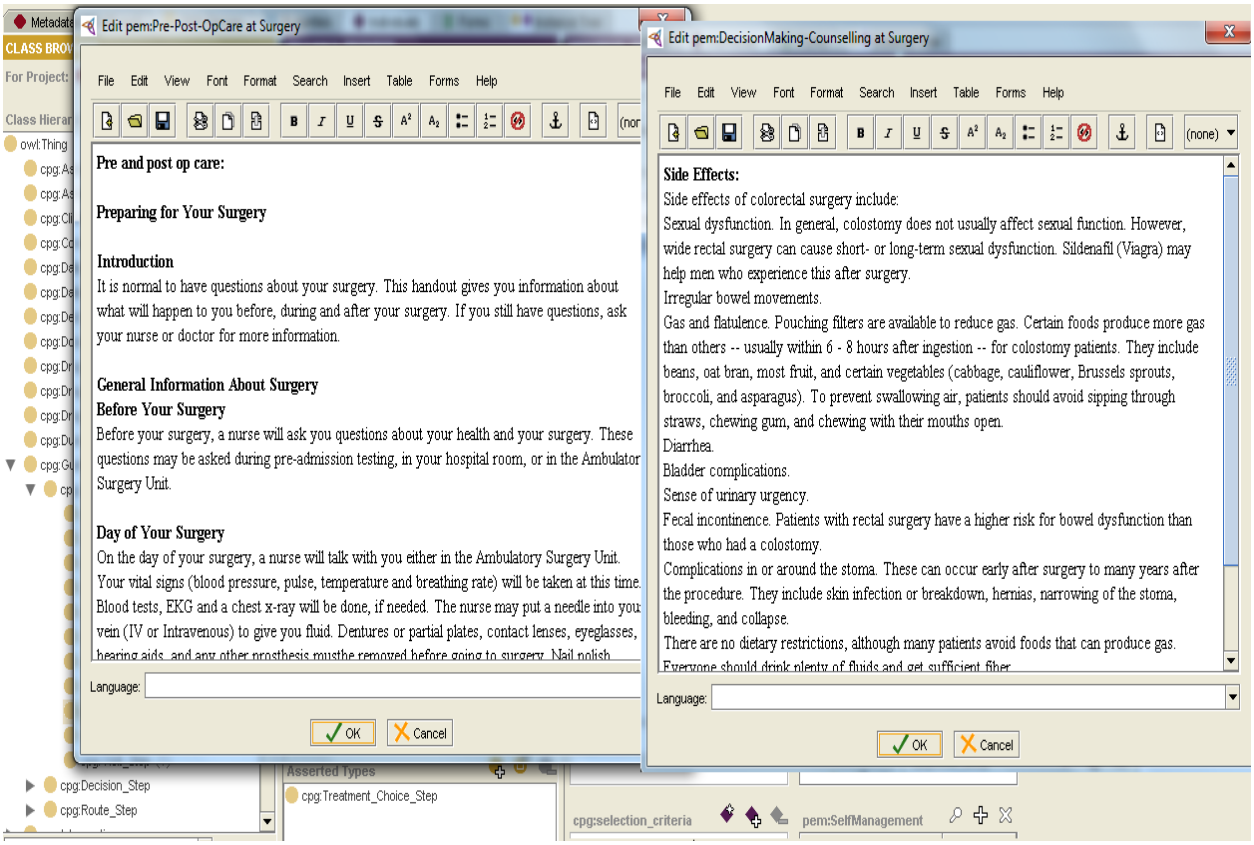

Figure 30: PEM pre and post-op care and counseling for the proposed outcome of Colorectal Cancer surgery

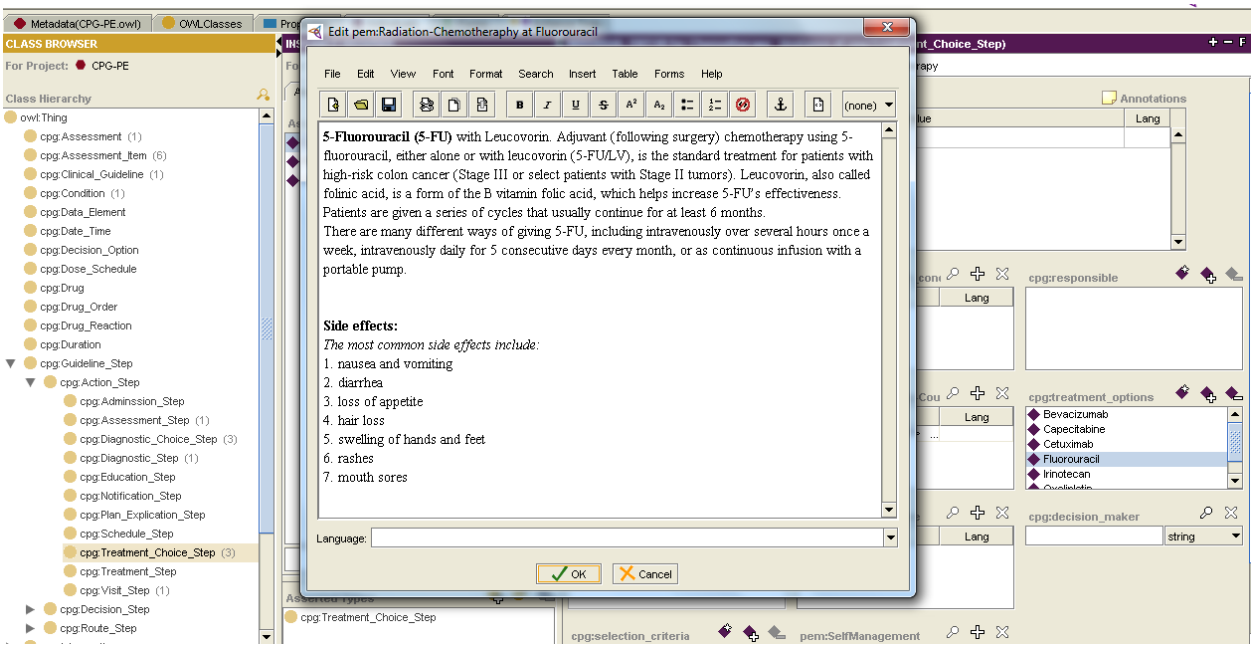

Figure 31: PEM for Chemotherapy and its adverse effects as Radiation-Chemotherapy

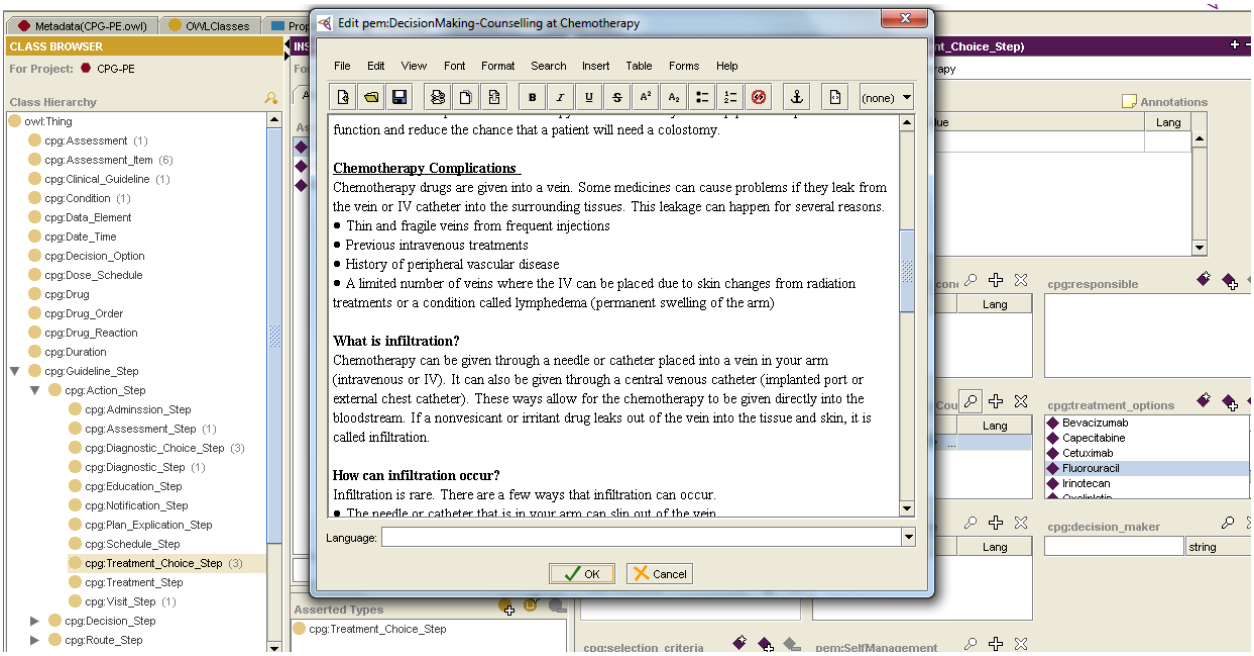

Figure 32: PEM about counseling for complications and outcomes of Chemotherapy for CRC

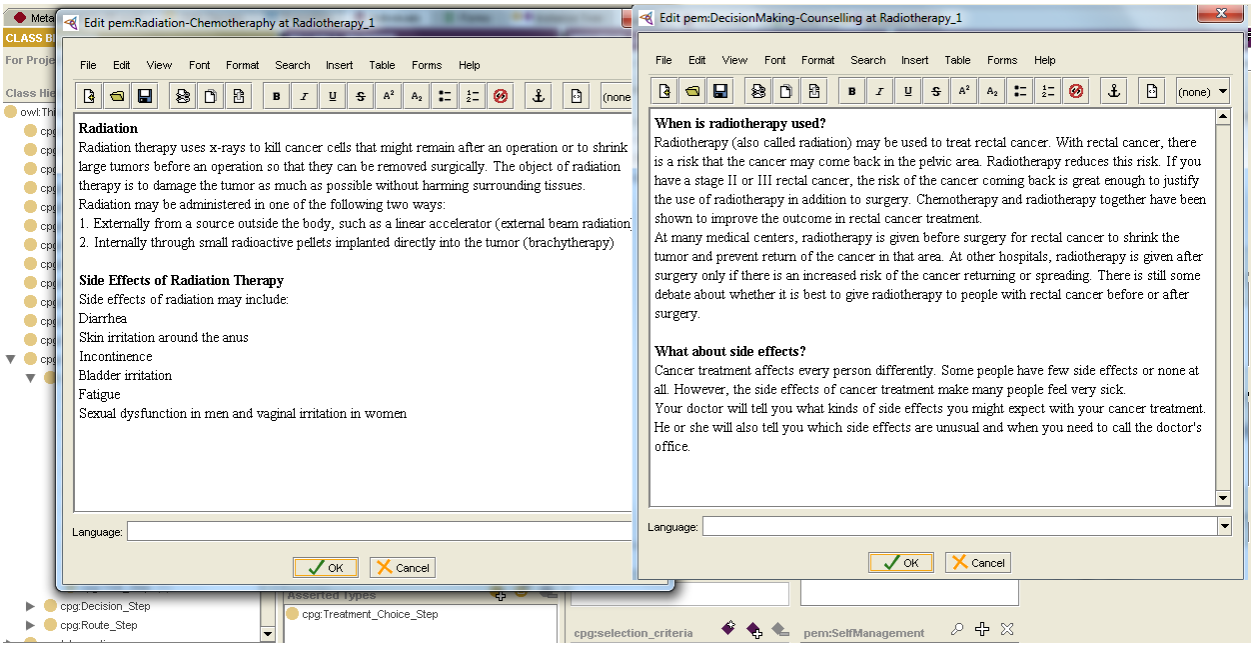

Figure 33: PEM about radiation therapy and counseling for its complications and outcomes

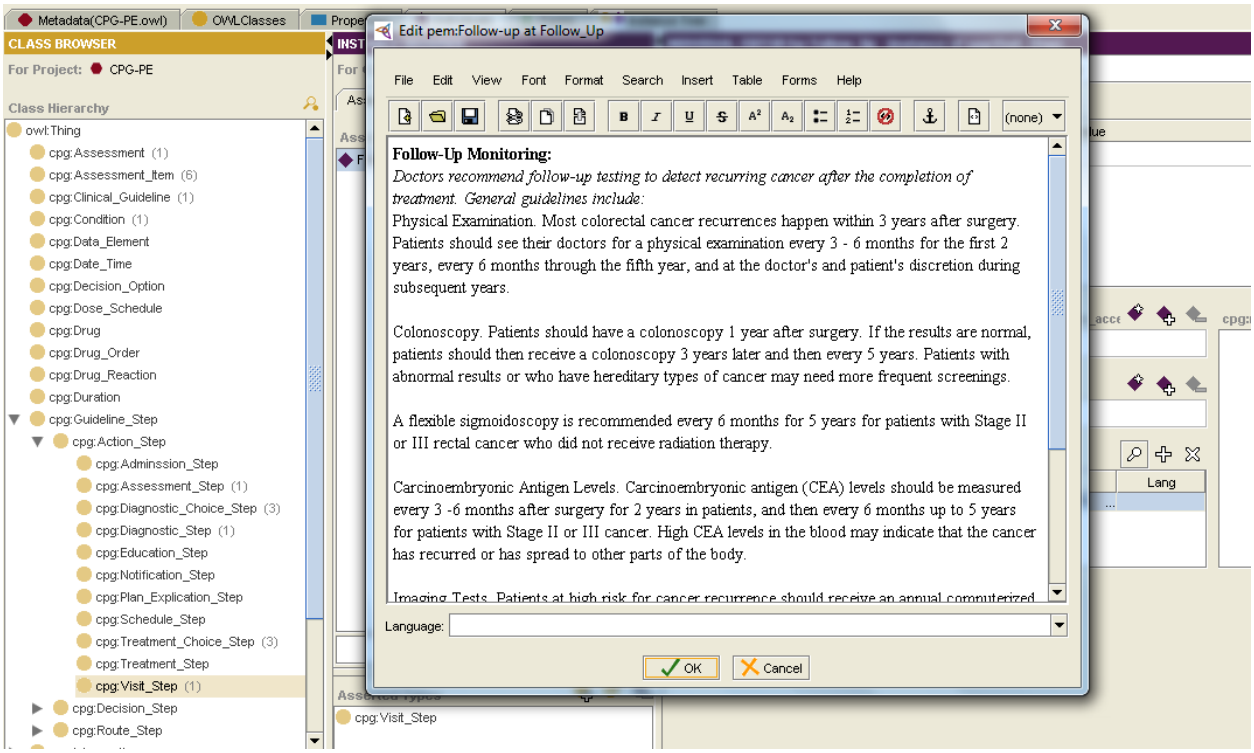

Figure 34: PEM about follow-up of CRC

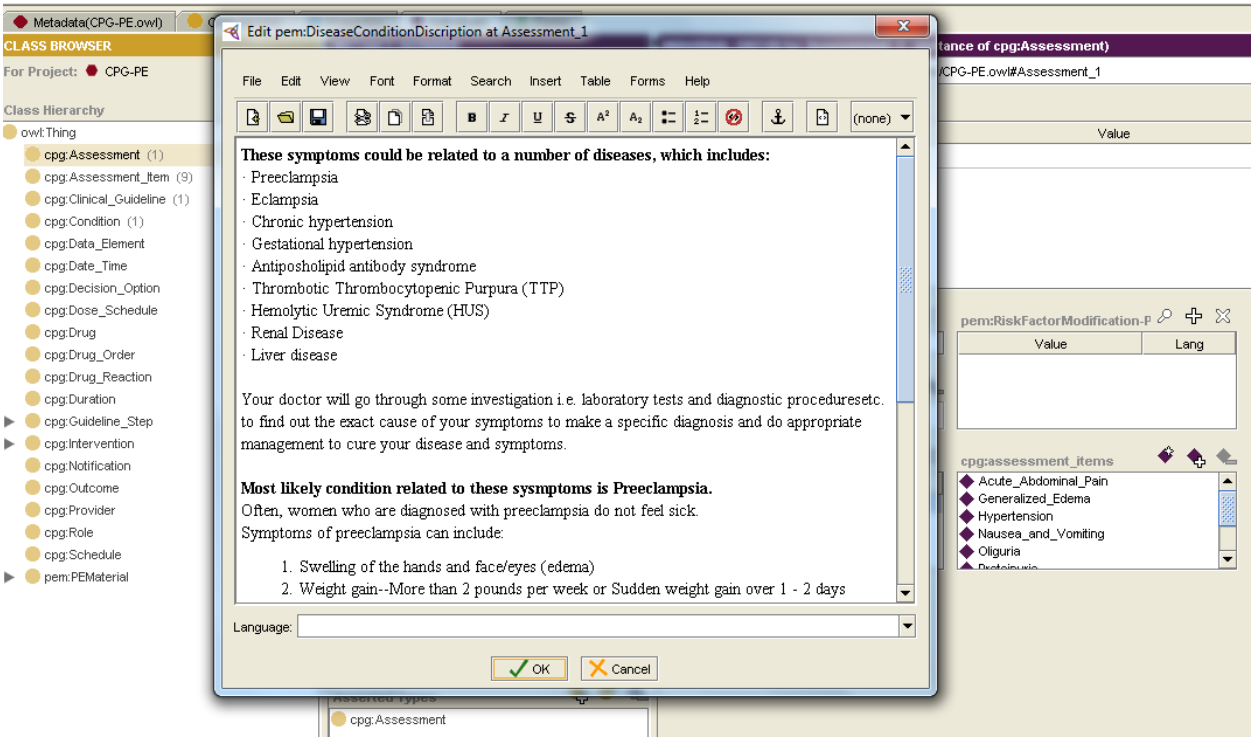

Figure 35: PEM about the initial assessment of the patient's condition

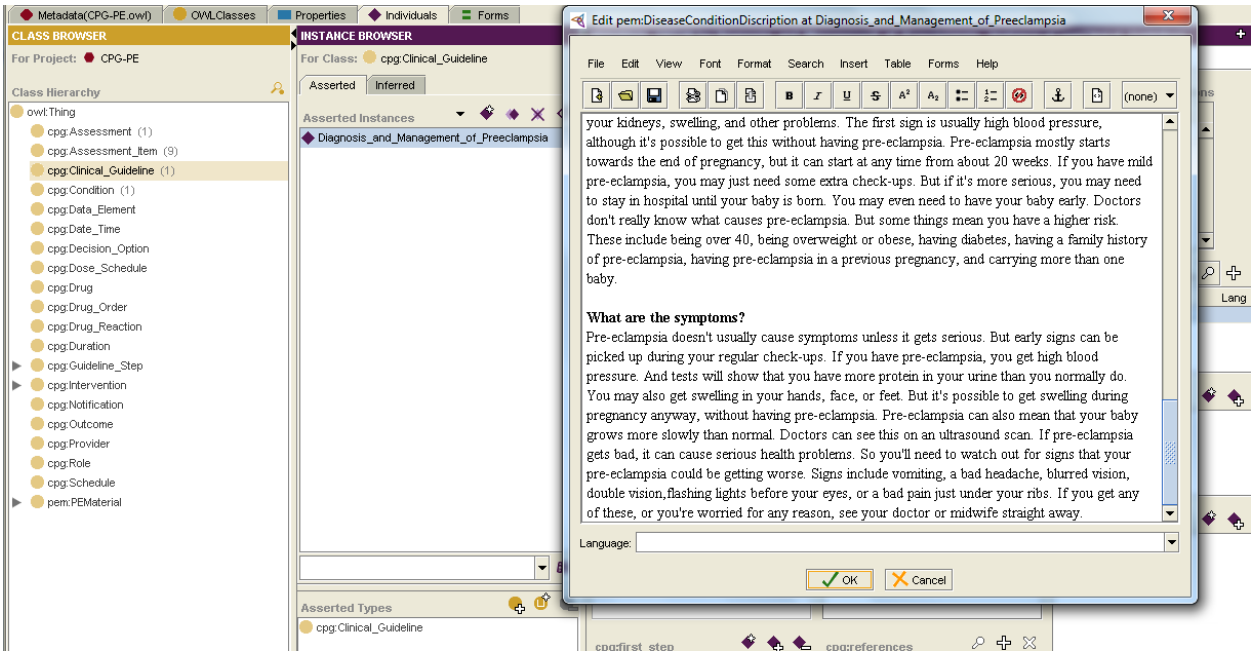

Figure 36: PEM about Preeclampsia (disease condition description)

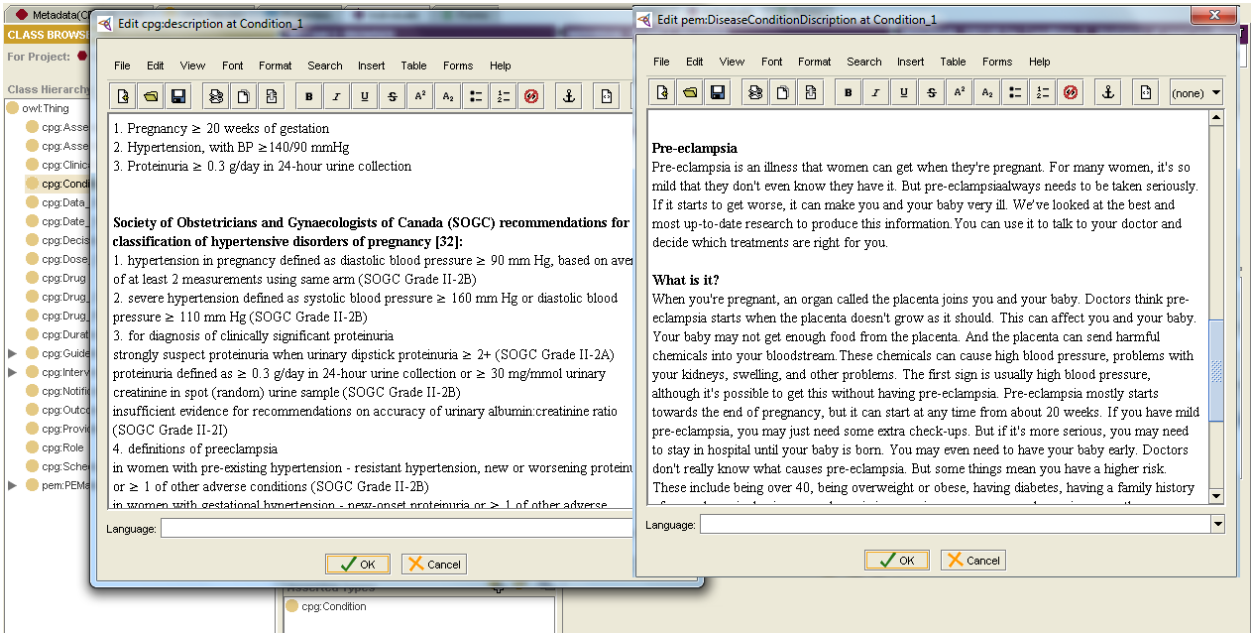

Figure 37: Evaluation criteria of Preeclampsia and Disease Condition Description

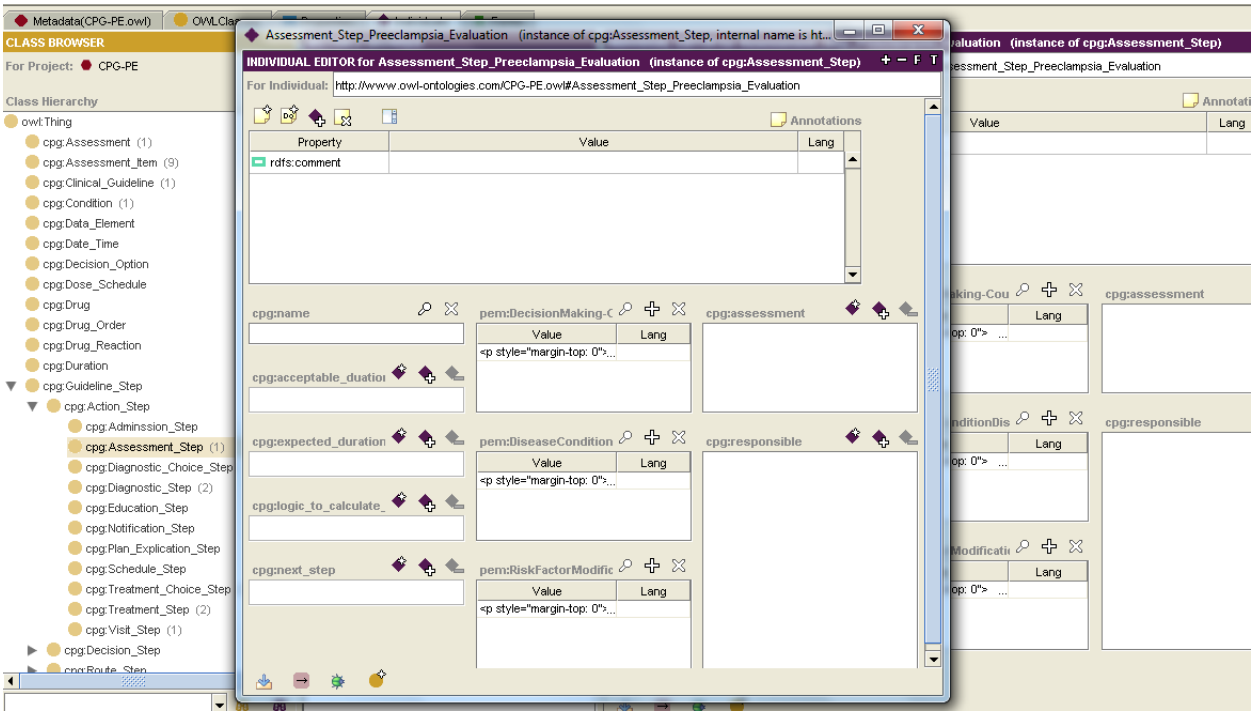

Figure 38: Assessment of the risk factors for Preeclampsia

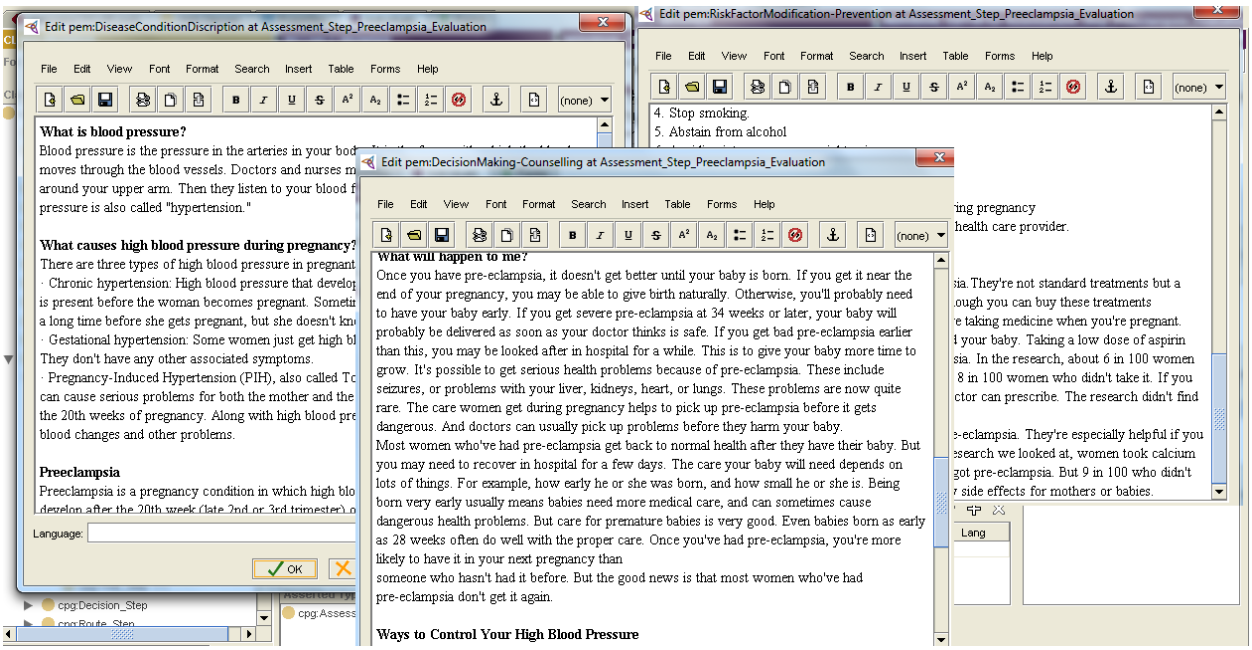

Figure 39: Description of Preeclampsia, risk factor modification-prevention and counseling

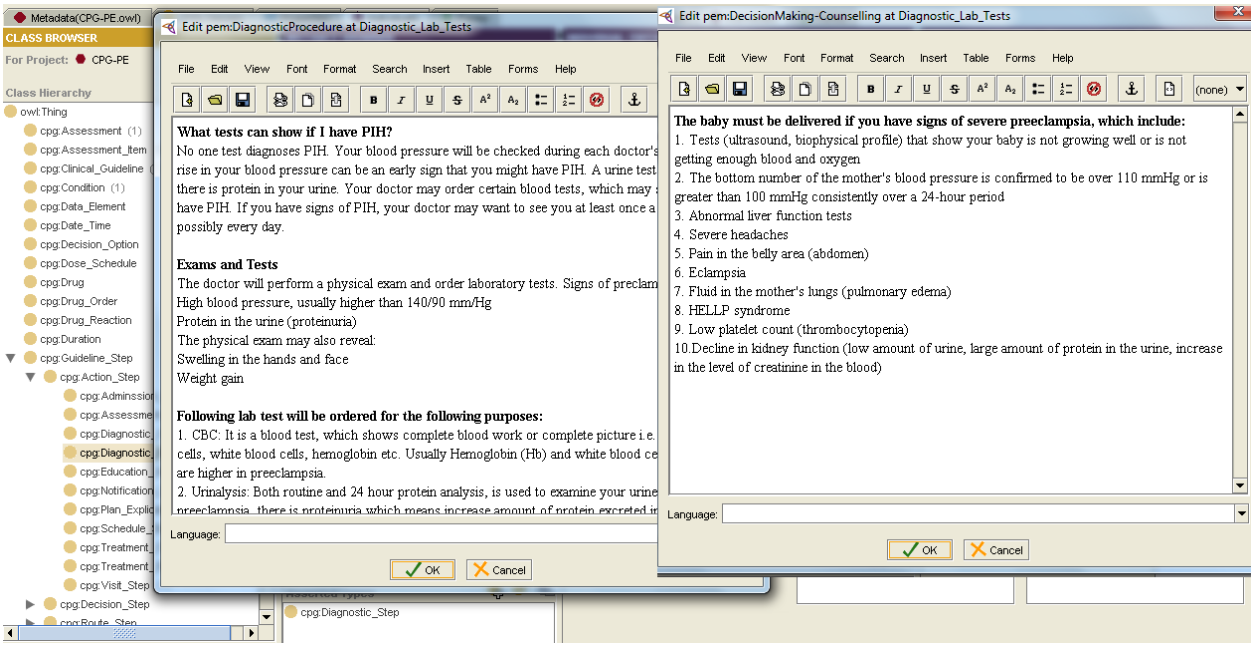

Figure 40: PEM about diagnostic procedure-diagnostic laboratory test and counseling

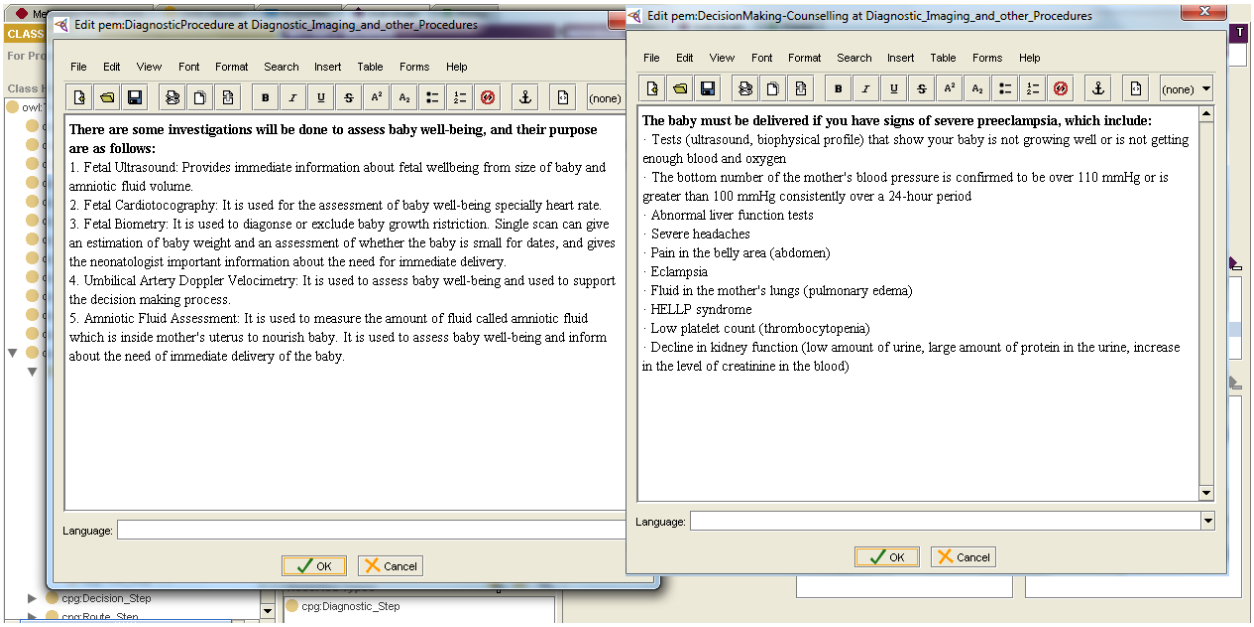

Figure 41: PEM about diagnostic procedure-diagnostic imaging/procedures and counseling

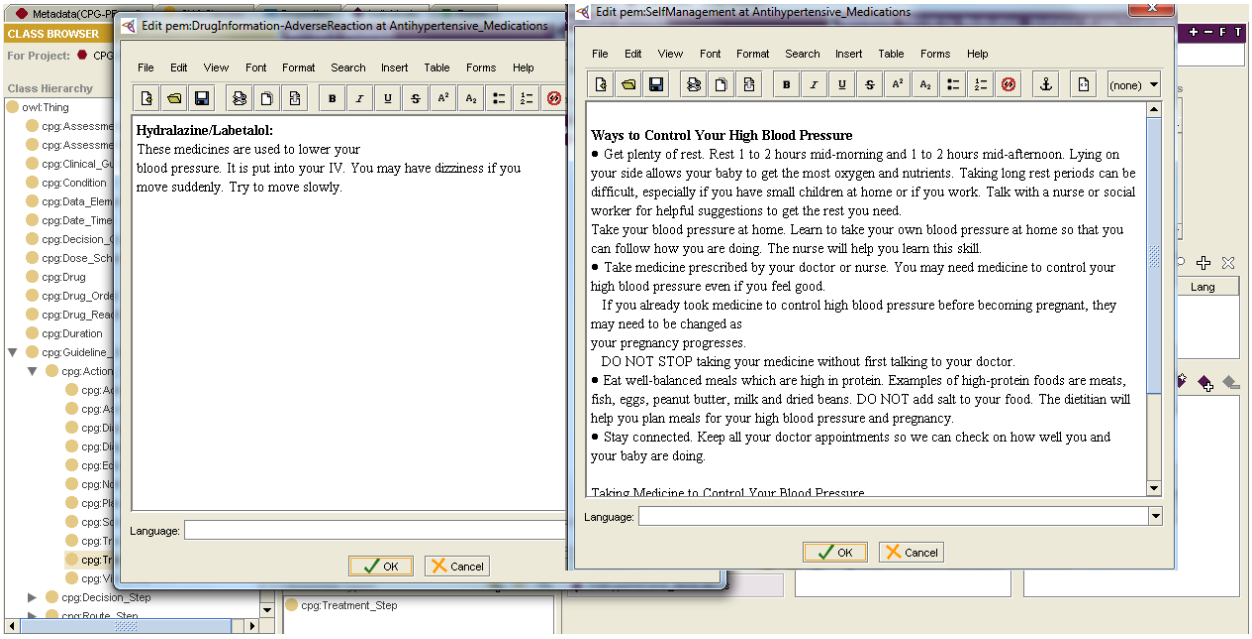

Figure 42: PEM for Drug Information/adverse reaction and self-management (antihypertensive)

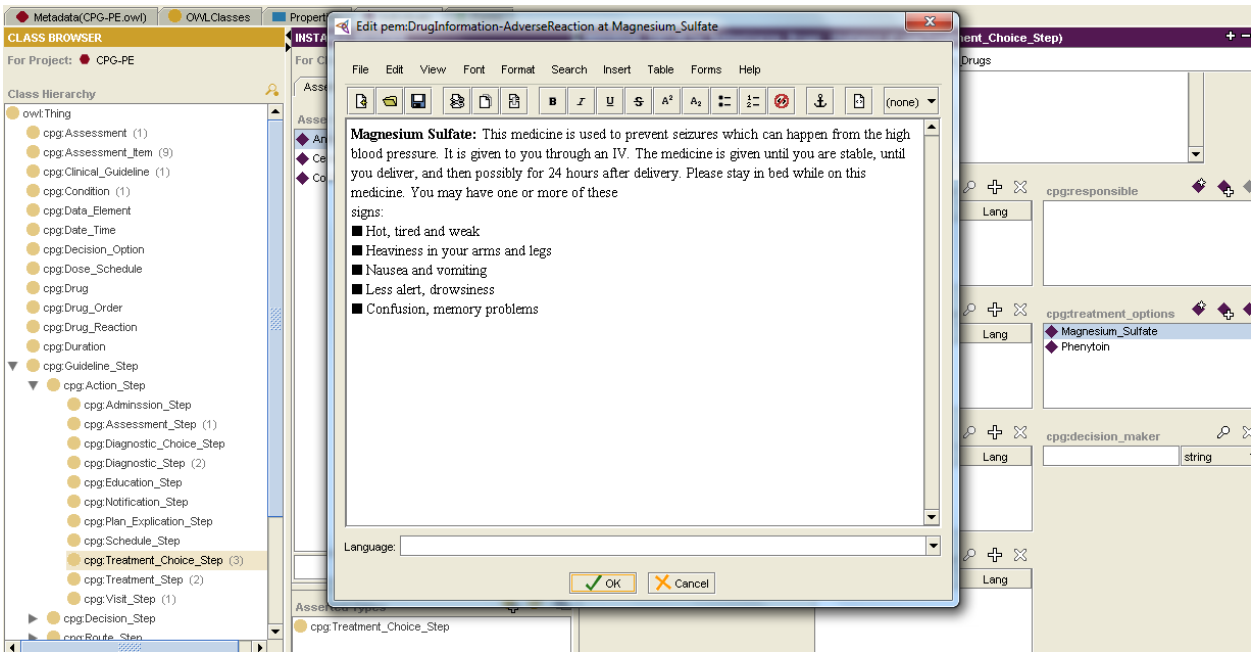

Figure 43: PEM for Drug Information/adverse reaction (Antiseizures)

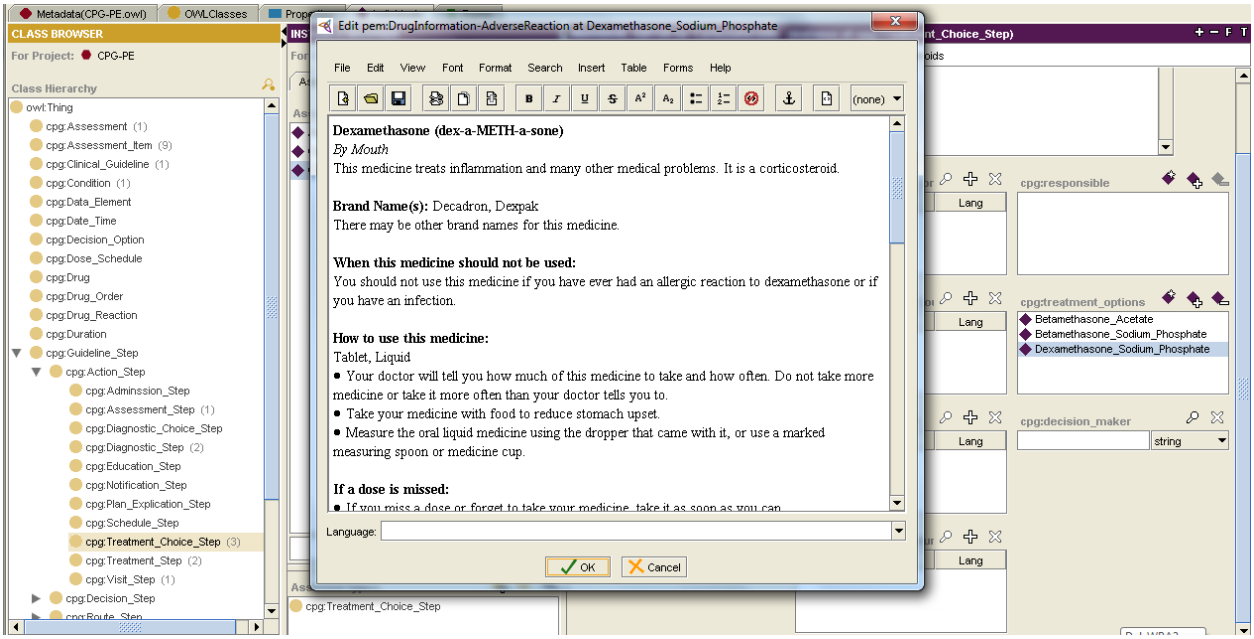

Figure 44: PEM for Drug Information/adverse reaction (Corticosteroids)

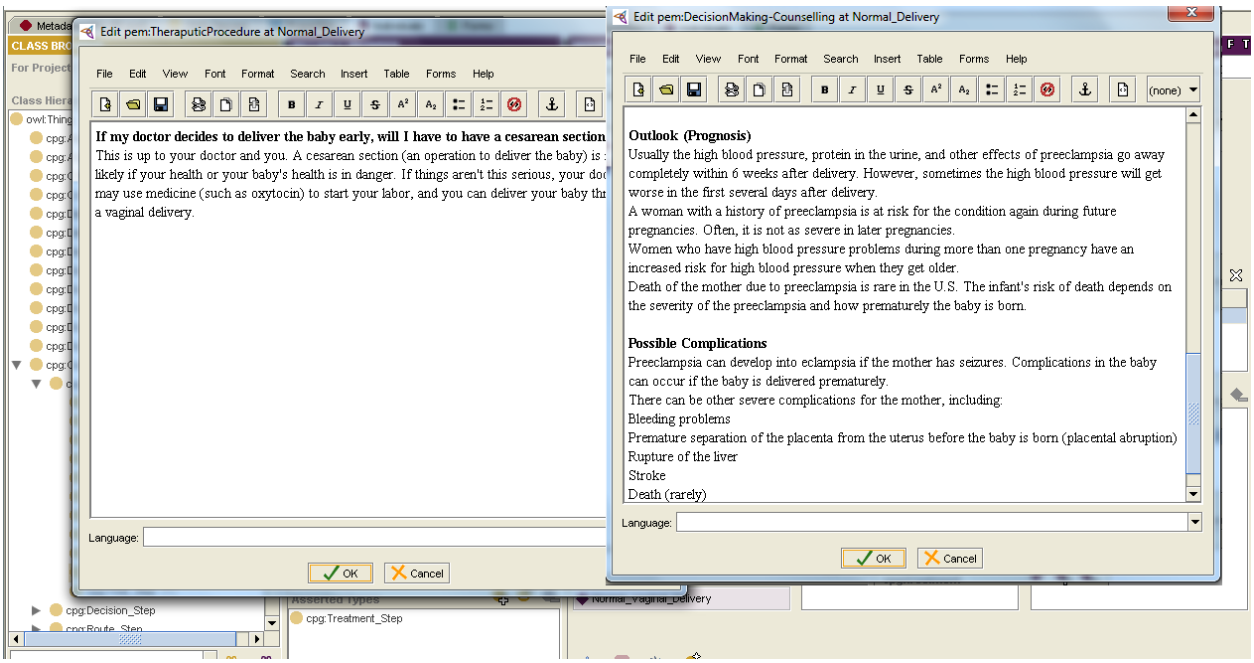

Figure 45: PEM therapeutic procedure-delivery and possible outcomes of preeclampsia

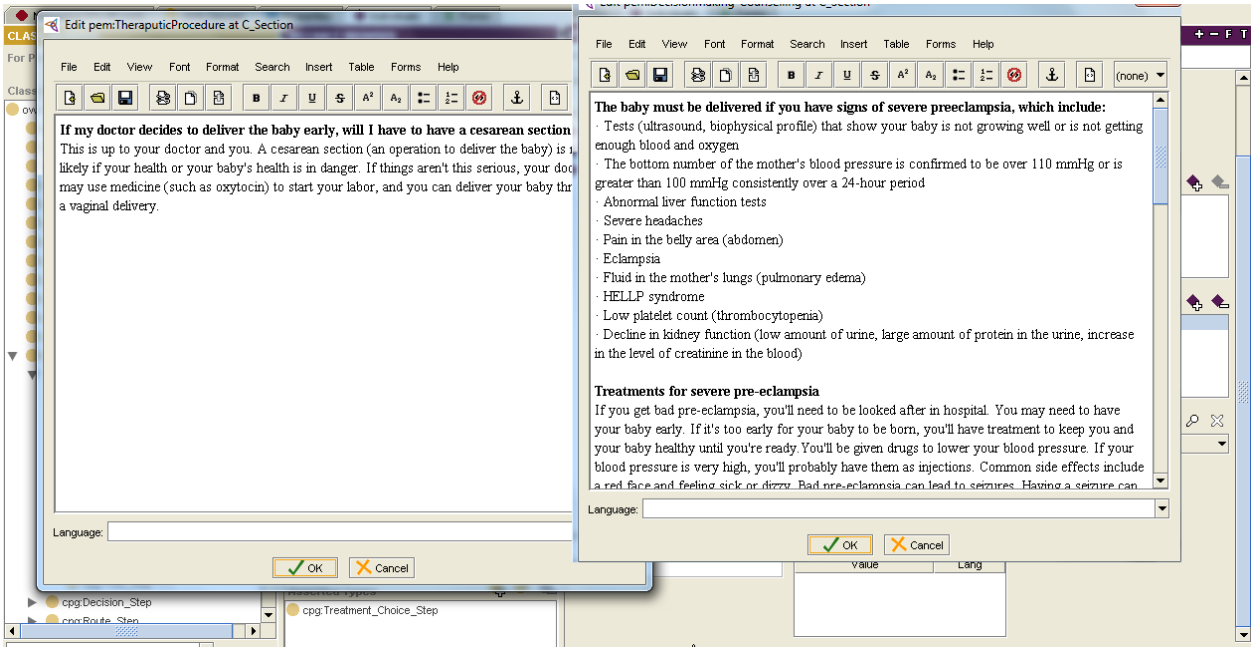

Figure 46: PEM therapeutic procedure-C section and possible outcomes of preeclampsia

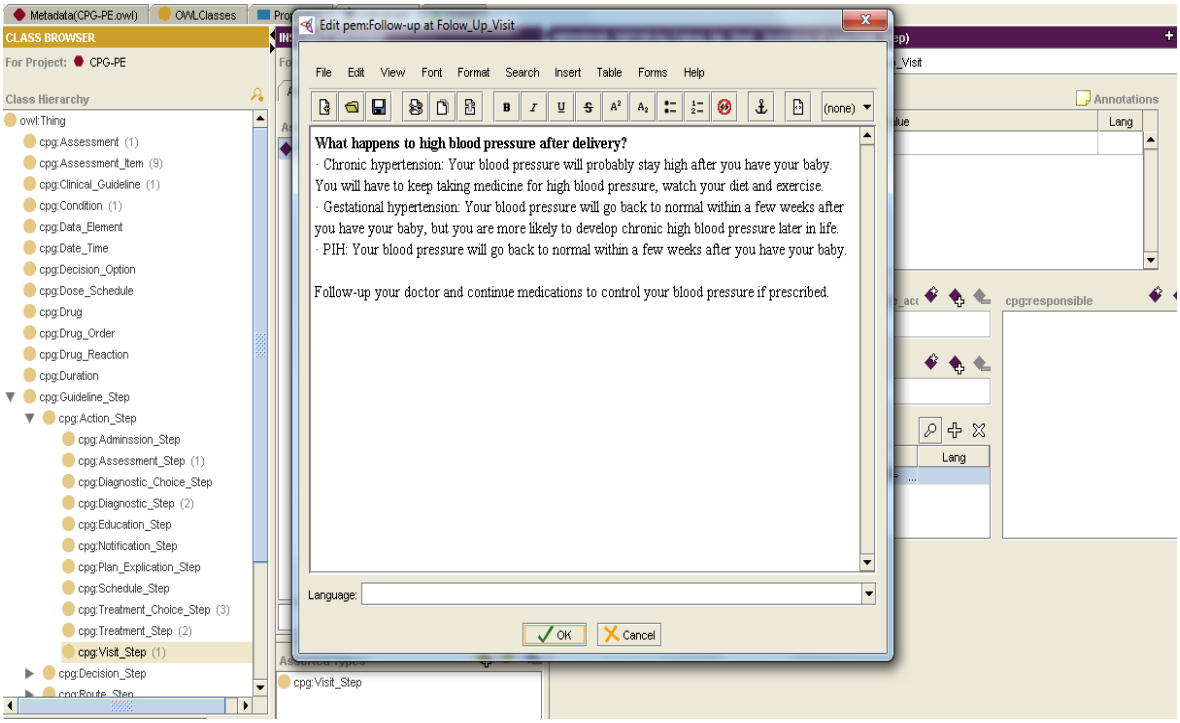

Figure 47: PEM about follow-up of Preeclampsia

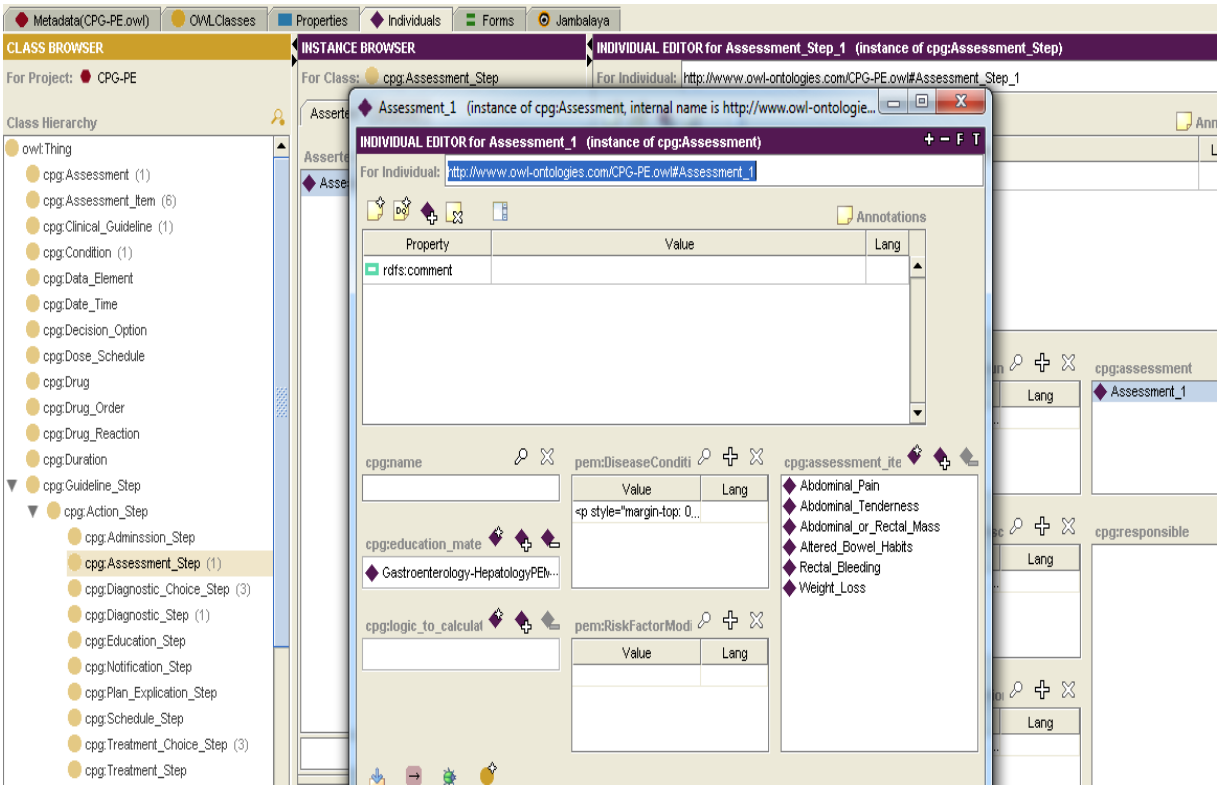

Figure 48: Assessment of the risk factors for CRC by CPG

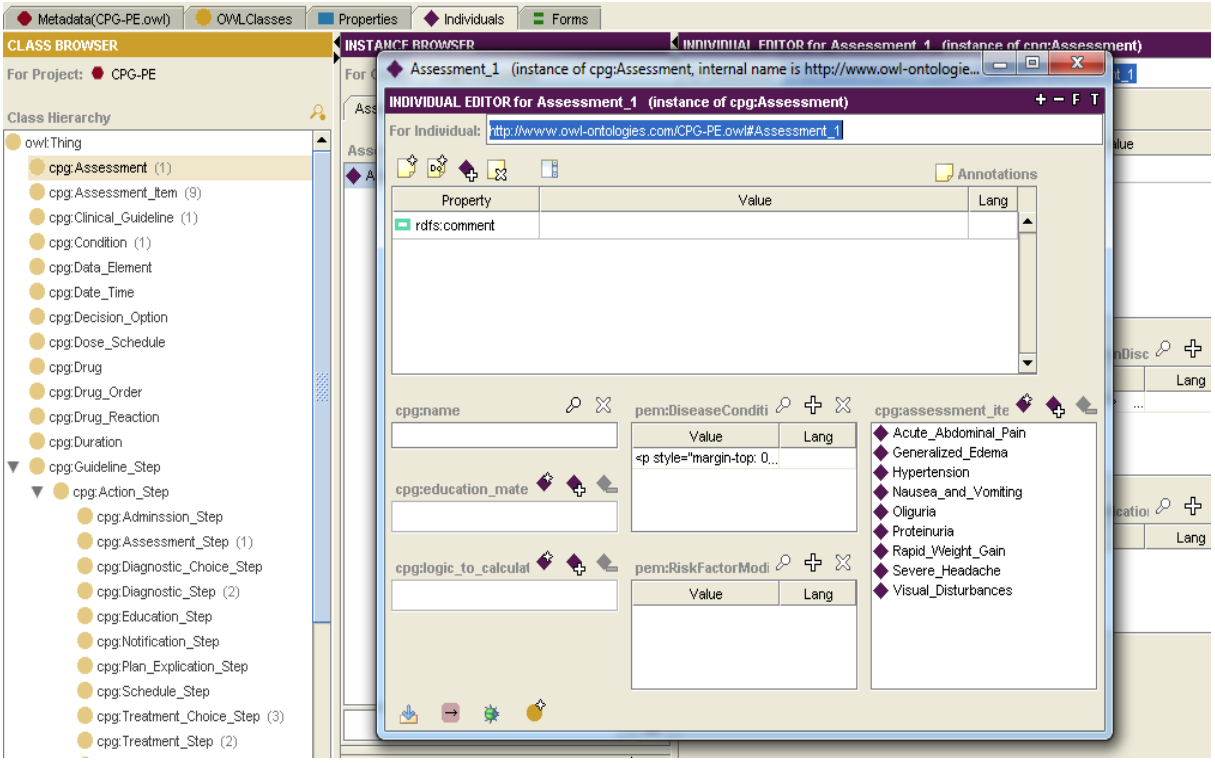

Figure 49: Assessment of the risk factors for Preeclampsia by CPG