Taxonomy for Guidelines of Healthcare

by

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ABSTRACT

The Institute of Medicine has defined Clinical Practice Guidelines (CPGs) to be systematically developed statements to help physicians and patients make decisions about appropriate healthcare for specific clinical circumstances. (Field, Lohr, 1992) There is a move towards representing all types of health care guidelines, not just clinical guidelines. During a time of increased volume and complexity of medical research, economic pressures, and a demand for a reduction in practice variations, there has been a greater emphasis on the production of computer-based guidelines to support medical practice. The expectation is that guidelines shared by computers can be centrally updated, made widely available, and facilitate decision support. These advantages, however, are contingent on a clear understanding of all factors affecting the development, updating, dissemination, use and the purpose of guidelines.

A taxonomy of guidelines has been developed to systematize such issues. The taxonomy could organize and make guidelines more accessible; it could serve to index them. This thesis identifies the context and issues surrounding the potential for a taxonomy and presents a version of the taxonomy. The taxonomy is represented using an entity-relationship conceptual model. During the development of this work, GEM (Guideline Elements Model) and a few other projects in this field were published with similar purpose in mind. A comparison of our model to these other initiatives concludes this work.

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To My Family. For your encouragement and faith.

CHAPTER 1: INTRODUCTION

The Institute of Medicine has defined Clinical Practice Guidelines (CPGs) to be "systematically developed statements to help physicians and patients make decisions about appropriate health care for specific clinical circumstances." (Field, Lohr, 1992) The Canadian Medical Association states that guidelines have been proposed as a way to assist physicians in the clinical decision-making process and hence improve the quality of care. Guidelines have the potential to improve outcomes, minimize risks, and enhance efficiency. (Woolf, Grol, Eccles, Grimshaw, 1999) During a time of increased volume and complexity of medical research, economic pressures, and a demand for a reduction in practice variations, there has been a greater emphasis on the production of computer based practice guidelines to support medical practice. The expectation is that practice guidelines shared by computers can be centrally updated and made widely available. A further expectation is that they could be integrated into computer-based approaches for decision support. However, the extent to which these expectations are justified hinges on a number of factors, such as the application domain, purpose, type of author, stage of maturity, etc., of a guideline. This project aims to understand the current context of health care guidelines and to further create a classification that establishes the structure of a quality guideline. There is a movement to extend the evidence-based approach beyond the clinical practice. We intend to create a taxonomy that can accommodate all health care guidelines, not just clinical guidelines. The work is based on a survey from Europe, which is a more heterogeneous and culturally diverse environment than North America. As a consequence, it is expected that the results will be more generally applicable than if they had been obtained from material solely collected in North America.

Based on an analysis of relevant documents collected from the Internet and library resources, an overview of the concepts of guidelines and the context in which they exist will be presented in Chapter 1: Introduction. A more detailed literature review of specific identified issues, such as computer-based representations of guidelines, will be included in this chapter. Chapter 2 describes and defines Clinical Practice Guidelines, their current context, and the Taxonomy classification system. Chapter 3 covers the methodology used to create the taxonomy. Chapter 4 presents the taxonomy itself by first revealing specific literature and examples that lead to the creation of the taxonomy. Secondly, an overview diagram of the taxonomy is depicted in Figure 1 and described in detail throughout several tables. Chapter 5 then compares the taxonomy with the state of the art developments found in recent literature. Key conclusions and summarised findings comprise Chapter 6.

Quality of Health Care

Health care, in every global arena, is moving towards one with both accountability and sustainability. There is great pressure politically and from the people at large to provide accessible quality health care. Whether health care is considered a right or a privilege, a movement that includes quality improvement and overall management, is beginning to emerge.

American national health care expenditures have shaped questions about quantity of health care versus quality of health care and whether patient needs are being met in the best way possible. (Darby, 1992) Research by Darby (1992), a National Health Policy Forum consultant, has shown that up to one third of all health care interventions and procedures

had little impact on patients' health or were potentially harmful to patients. In Canada, problems such as long wait lists for treatment, crowded emergency departments, diagnostic testing delays and shortages of doctors and nurses in rural communities are becoming more and more common. (British Columbia Medical Association, 2000) (Canadian Medical Association, 2000) Public opinion polls are showing that Canadians feel that their expectation of access to health care is not being met. (Rawlin, 2001)

There is also considerable evidence that indicates that medical errors are a leading cause of death and injury. (Kohn, Corrigan, Donaldson, 2000) Findings from this Institute of Medicine's report include:

- Two studies (1984 and 1992) in New York and Colorado and Utah respectively, found that the proportion of adverse events caused by errors was 58 percent in New York and 53% in Colorado and Utah.
- After extrapolating these study results to over 33.6 million admissions in the United States in 1997, it was determined that these preventable adverse events are a leading cause of death in the United States. More specifically, 44,000 to 98,000 Americans die in hospitals each year due to medical errors.
- National costs related to these deaths (lost income, lost household production, disability, health care costs) are estimated between $17 billion and $29 billion annually.
- One study conducted at two teaching hospitals established that almost 2% of admissions experienced a preventable adverse drug event, resulting in an average

increased hospital cost of $4,700 per admission or about $2.8 million annually for a 700-bed teaching hospital. Generalized to the entire nation, the cost would be about $2 billion dollars annually.

- In 1998 approximately 2.5 billion prescriptions were dispensed by U.S. pharmacies at a cost of about $92 billion dollars. Several studies found errors in prescribing medications, dispensing by pharmacists, and unintentional non-adherence on the part of the patient. (Kohn, Corrigan, Donaldson, 2000)

The population demographics are changing and thus the needs are changing within Canadian communities. Major restructuring of the Canadian health care system and greater attention to processes and management of the health care delivery system are taking place.

The British Columbia Medical Association (2000) has defined their principles of providing health care within "Patient Care Objectives" and "Management Objectives." The Patient Care Objectives postulate the health care to be patient focused, available, timely, continuous (seamless over the entire treatment regime) and of a high level of quality. The Management Objectives propose that the management philosophy include long term planning, sustainability and accountability. (Thomson, 2000)

Long term planning of the health care system includes a multi-year time horizon plan that would be continuously monitored and reviewed using information assessing the public demand, need and expectation, and capacity. Sustainability suggests that the public health

care expenditures must reflect government's ability to pay. There is a balancing scheme between government priorities and the array of treatment applications and services. Sustainability motivates researchers to find more efficient and different ways to provide services while still maintaining (or increasing) quality. Accountability ensures that the health care system provides for the right service, at the right time, by the right individual, at the right place. Providers may be held accountable in areas such as professional competence, legal and ethical conduct, financial performance, accessibility, public health promotion and community benefit. Additional activities such as government sanctions, approval or denial of accreditation applications, report cards and purchasing selections may be used to establish accountability. (Darby, 1992) This principle lends itself to practice guidelines in particular. By appropriately defining quality guidelines that are either integrated into the delivery system or accessible at the point of care to a diverse audience, we are ensuring the above principle.

ProGuide Material

This work originates from a project called ProGuide in the European Union, lead by a research group in Munich, Germany. ProGuide stands for PROmoting the development, dissemination, and evaluation of GUIDElines of clinical practice. (Engelbrecht, R., Courte-Wienecke, S., Moser, W., Balint, J., Fox, J., Thomson, R., Humber, M., Pisanelli, D.M., Renaud-Salis, J.L., der Lei, J., & Talmon, J., 1998) ProGuide's goal is "to provide state of the art information services to organizations involved in the development, dissemination, implementation, and measurement of evidence based CPGs." (Engelbrecht et al., 1998) Their mission is "to collect and make available this information at the

European and International levels." (Engelbrecht et al., 1998) The project hopes to achieve and provide guideline relevant information to the European Union. The ProGuide project is conceived in four phases:

1. Description of the state of the art development, dissemination and implementation of (computer based) guidelines, and description of user requirements for information services;

2. The development of relevant scenarios for developing and implementing computer-based guidelines;

3. Evaluation of those scenarios; and

4. Construction of a World Wide Web server based approach on the results of this research.

ProGuide accomplished the first phase of their project by sending out a survey to health care organizations of European countries and one survey to the University of Texas in the United States. Twelve out of the twenty countries sampled returned the survey. Out of the 292 questionnaires sent out, 34 were returned completed for evaluation. The survey was aimed at assessing who was involved during guideline development, dissemination, and implementation. It further addressed issues of compliance, financing, quality assurance, user requirements, and Internet server features. The comments of the participants are

mostly in a qualitative format, but there were also several "yes/no" choices throughout the ten-topic survey. Open-ended questions help to understand the reflections of the subjects, however more probing may be required.

A review of the ProGuide survey material showed that a wide variety of institutions and persons, with a variety of professional backgrounds and competencies, contribute to guideline development in Europe. The guidelines serve a broad spectrum of purposes. A taxonomy of guidelines, guideline development, and an interpretation of its implications, which is currently not available, is relevant to the developers of practice guidelines, as well as to the designers and implementers of computer support systems for such.

Rationale for Taxonomy

A taxonomy to represent practice guidelines would supplement ProGuide's work in a number of ways. First of all, the taxonomy would organize and systematize the guidelines represented in any form (e.g. text based, computer based, algorithms, flow charts etc.). A taxonomy could serve as an index creating greater accessibility to the user since a guideline would be easier to find. However, making the guidelines more accessible is only one aspect of uptake. Secondly, the guidelines must also be accepted and considered reliable and valid before a health care practitioner, administrator, or patient will use them. It is therefore desirable that a taxonomy not only ensures the quality of the guideline, but also assists in assessing a guideline.

Thirdly, provided the taxonomy could systematically organize the practice guidelines, it could also promote a standard for guideline developers. A taxonomy with such features could represent the desired qualities of guidelines that would promote uptake. If the developer were to consider the axes of the taxonomy and understand the user requirements, it would be more likely that a good quality guideline will be developed and used.

Fourth, a taxonomy could also decrease duplicate work. It is time consuming for any health care organization to go through the process of developing a guideline. If a guideline was easily available, considered reliable, and met the criteria of the organization, it should be possible to save time and provide better quality of care to the patient. This however should not prevent organizations from investing the time to locally adapt the practice guidelines if need be. It is important to try and prevent unnecessary duplication but still at the same time, facilitate local adaptation.

Lastly, a taxonomy would enable us to decide what kinds of guidelines, roles in guideline development, dissemination, and implementation are required and which of these should be supported in which way by computer technology.

Other Initiatives

There are several initiatives along guideline authoring and dissemination that are taking place by key organizations throughout the world. The National Guideline Clearinghouse, the National Institute for Clinical Excellence (NICE), the Royal College of General

Practitioners, the Canadian Medical Association, the National Health and Medical Research Council (NHMRC) from Australia, and the New Zealand Guidelines Group are examples of such groups.

The National Guideline Clearinghouse (NGC) (2000) is "an internet Web site intended to make evidence-based clinical practice guidelines and related abstract, summary, and comparison materials widely available to health care professionals." NGC is operated by the U.S. Department of Health and Human Services, Agency for Health Care Policy and Research (AHCPR) in partnership with the American Medical Association (AMA), and the American Association of Health Plans (AAHP). (National Guideline Clearinghouse, 2000) Guidelines are submitted to the site. The criteria for inclusion of Clinical Practice Guidelines in NGC are: the guideline must fall within the Institute of Medicine's definition of clinical practice guidelines; the guideline must be produced by a medical specialty association such as relevant professional societies, public or private organizations, government agencies at the Federal, State, or local level, or a health care organization or plans; corroborating documentation must be produced and verified that a systematic literature search and review of existing scientific evidence published in peer reviewed journals was performed during the guideline development; and, the guideline must be written in English, current and the most recent version produced in the last five years. (National Guideline Clearinghouse, 2000) Once submitted for review and accepted, the guideline is organized in a searchable database. The National Guideline Clearinghouse collects and catalogues guidelines for the public to access. It does not appear that the

purpose of this database was to create a taxonomy for authoring, however, it does help with dissemination of the information.

The National Institute of Clinical Excellence (NICE) (1999) is part of the National Health Service (NHS). NICE's role is to provide patients, health professionals and the public with authoritative, robust and reliable guidance on current "best practice." (Rawlin, 2001) The Department of Health and the National Assembly for Wales commissioned this group to author clinical guidelines on specific disease areas or conditions and to disseminate them within the National Health Service. Currently they do not have any guidelines available in their database. Some guidelines have already been started but others still must be commissioned. Only a few topics such as different types of diabetes and a few specific cancers are being studied. (Rawlin, 2000)

The Royal College of General Practitioners (RCGP). The RCGP is the academic organization in the UK for general practitioners. "Its aim is to encourage and maintain the highest standards of general medical practice and act as the 'voice' of general practitioners on education, training and standards issues." (The Royal College of General Practitioners, 2001) One program created by this group is called the Clinical Practice Evaluation Programme (CPEP). CPEP aims to develop a flexible, multi-level, evidence-based evaluation and feedback system to enable general practice teams to evaluate and compare their quality of care for patients. In 1996 the College developed a national clinical guideline for the management of acute low back pain. This is the only guideline that they have currently published. It is available on the world-wide-web

(http://www.rcgp.org.uk/rcgp/clinspec/guidelines/backpain/index.asp). The presentation of the guideline is in a text-based format. The guideline includes a description of the developers, evidence review and recommendation, and charts and algorithms. Other future initiatives include guidelines on asthma, type 2 diabetes, CHD, and depression.

One major initiative in Canada is through the Canadian Medical Association (CMA). The CMA has developed the CPG Infobase for referencing and educational purposes for guideline dissemination. (Canadian Medical Association, 1998) Currently, CPG Infobase holds over 750 guidelines. One can search for these guidelines by medical specialty or by title only. Once a guideline is found, a link is provided to the original web based document. The criteria for inclusion of a CPG in the CPG Infobase are similar to that of the National Guideline Clearinghouse. There is no standard, other than the criteria for inclusion in which the guideline is presented. The provincial medical associations across the country have their own practice guideline committees. However, the CMA has organized these efforts in such a way that CPG Infobase collects and shares this information across the provinces. Future directions for this database include the creation of a user-friendly web-based search engine. (Canadian Medical Association, 1998)

The objective of the National Health and Medical Research Council (2001) of Australia is to advise the Australian community on the achievement and maintenance of the highest practicable standards of individual and public health, and to foster research in the interests of improving those standards. This group currently has approximately 40 clinical practice

guidelines available on the World Wide Web and through their publication catalogue. There is a charge to access many of these guidelines.

The National Health Committee of New Zealand established The New Zealand Guidelines Group (NZGG) in 1996. The purpose of NZGG is to train health and disability professionals and consumers in the development and implementation of evidence-based best practice guidelines. (New Zealand Guidelines Group, 2001) They currently have over forty guidelines available over the World Wide Web organized by specialty of medical field.

Computer Based Approach

There are a number of factors influencing a computer-based approach to represent practice guidelines. These include: Increased volume and complexity of medical research; Economic pressures; Demand for a reduction in practice variations; and finally, the Expectation that practice guidelines shared via computers can be centrally updated and made widely available. The advantages to a computer based approach and the associated obstacles to these advantages will be presented.

Perceived Advantages

An Internet server can potentially support guidelines and improve dissemination in various ways. The suggested advantages of computer-based dissemination of guidelines are as follows:

Computer Embedded Algorithms: In order to facilitate dissemination and implementation of guidelines, it is possible to embed the guidelines within the facilities' computer system. Suggestions to the physician can be presented on a case-by-case scenario.

Accessible: Many times health care practitioners are unaware of current quality guidelines in their field. It is desirable to have accessible practice guidelines. If the health care practitioner is unaware that a guideline exists, it is unlikely that they would search for one. A computer-based collection of guidelines could be accessible if a comprehensive, accepted, and known taxonomy was developed.

Faster Retrieval of Information: Reading through an immense amount of text is time consuming. The Internet provides great utility search engines that can help the user find information in a timely manner. However, search engines are also too unspecific and they do not reduce the amount of text one would have to read. A taxonomy will aid the user in finding specific information in formats other than text, which would reduce the amount of literature one must read.

Easier to update and disseminate the new information: If the information is centrally located, the update will only have to be performed at one location. This definitely makes the process more efficient. A designated authority could administer and maintain the database since the information could come from all over the world.

Cost effective: In the long run, it is thought that a computer based approach will save resources such as paper, printing, and man power to disseminate the information.

Anyone with authorization and any computer, with any platform, can access the information: The same software is not needed across establishments. The only knowledge one would need is how to use the Internet and the taxonomy once it is available.

Perceived Obstacles

There are many obstacles that must be overcome before computer based guidelines will be used.

Lack of resources: It is important to note that there are many facilities in the world that do not have access to the Internet, nor even a computer. Therefore, the need for paper-based guidelines cannot be ignored. The proposed taxonomy should be able to facilitate all formats of guidelines including text based and computer algorithms.

Representation Format: Practice guidelines may be represented in many different forms such as text, tables, flow charts and specialized representations. Some formats may be more appropriate than others depending on the purpose of the guideline, the institution's environment, and resource availability. There are several computer-based formats that are being developed and are becoming available.

Incentives to use the equipment to access Practice Guidelines: Practitioners may think that they know the guideline but are unaware that it has been updated. In this case the need to assess the guidelines may not be apparent. Embedding the guidelines into practice algorithms could avoid this problem. However, the equipment needed to access the information may not be available at the appropriate time or place.

Ability to find the guideline: The practitioner may not have the skill to use the search engine or be familiar with the taxonomy and thus may have a difficult time finding the guideline. Additionally, the search engine may not be specific enough to be able to locate the proper information.

Dependency on the computer: Elson and Connelly (1998) acknowledge findings that physicians exposed to computer support become at least partially dependent on it. If these same physicians move on to environments without this computer support, it is possible that their practice could deteriorate.

CHAPTER 2: BACKGROUND

In order to systematize and logically represent clinical practice guidelines, it is important for all those involved to use a common vocabulary. In working towards this, the definition of practice guidelines along with its uses, outcomes, gaps in quality and appraisal methods will first be presented. Secondly, the lifecycle of a practice guideline and desirable attributes of a "good" guideline will be discussed. Lastly, taxonomy and entity-relationship model will be defined and described.

Definition of Clinical Practice Guidelines

CPGs are defined to be "systematically developed statements to help physicians and patients make decisions about appropriate health care for specific clinical circumstances." (Field, Lohr, 1992) Throughout the literature reviewed this definition of the Institute of Medicine (IOM), of the United States of America, seems to be widely accepted and used. ProGuide and the National Institute for Clinical Excellence also use this definition. The mission of the Institute of Medicine is to advance and disseminate scientific knowledge to improve human health. The Institute provides objective, timely, authoritative information and advice concerning health and science policy to government, the corporate sector, the professionals, and the public. (National Academy of Sciences, 1999)

The Royal College of General Practitioners believe that the purpose of national guidelines is two fold. Firstly, it is to use national resources to bring the evidence together and to draw on a wide network to construct appropriate recommendations. Secondly, it is to provide easily accessible evidence-based recommendations. (Hutchinson, 2001)

The Canadian Medical Association states that CPGs are tools to help health care practitioners deliver high quality care by outlining the best practices based on available evidence and expert opinion. (Canadian Medical Association, 1997a) Practice guidelines have also been defined to be written statements that describe preferable courses of clinical action, ranges of acceptable medical practice, or required clinical responses. (Berger, Rosner, 1996)

Basic Terminology

Clinical practice guidelines are referred to by many different terms. CPGs have been designated: practice parameters, practice protocols, practice standards, practice options, practice guidelines, clinical guidelines, clinical pathways, and clinical algorithms. Distinction between these terms is often lost and debate about issues surrounding CPGs is often a result of different terminology usage. (Elson, Connelly, 1998) Berger and Rosner (1996) believe that the lack of standardization of CPGs is partially caused by the absence of a nomenclature.

A practice guideline is a recommendation. It is a framework that is not intended to ignore or supersede the professional knowledge of medical staff. The National Institute of Clinical Excellence believes that the objective of clinical guidelines is to improve the quality of clinical care by making available to health professionals and patients well-founded advice on best practice. They additionally consider guidelines to be only advisory. (Rawlin, 2000) In order to better define what a guideline is intended to be, and not to be, several words have been defined in Table 1 using the Merriam-Webster

Collegiate Dictionary (1993). The definitions for guideline, option, protocol, parameter, algorithm, procedure and standard all contribute to what is meant by a practice guideline. However, a guideline is not a policy, regulation or a law.

Table 1: Definition of possible synonyms to the word "guideline"

Guideline:	An indication or outline of policy or conduct
Recommendation:	Something that has been endorsed as fit, worthy, or competent
Option:	Something that may be chosen
Protocol:	A detailed plan of a scientific or medical experiment, treatment, or procedure
Parameter:	A characteristic element
Algorithm:	A step by step procedure for solving a problem or accomplishing some end
Procedure:	A series of steps followed in a regular definite order
Standard:	Something established by authority, custom, or general consent as a model or example
Policy:	A high-level overall plan embracing the general goals and acceptable procedures
Regulation:	An authoritative rule dealing with details or procedures
Law:	A rule of conduct or action prescribed or formally recognized as binding or enforced by a controlling authority

Purpose

Originally, CPGs were anticipated to improve quality of care. Now, there are further expectations. They are used to: (Berger, Rosner, 1996)

- improve efficiency of health care;
- reduce liability risk;
- provide medical education;
- assist in utilization review and quality assurance activities;
- help in determining physician suitability for employment; and
- support the determination of legal standards of care.

Depending on the kind of user of a particular CPG, each user may have a different purpose associated with the guideline's use. Different users are likely to vary with respect to the importance they associate with differing purposes of guidelines.

Do Clinical Practice Guidelines Affect Processes or Outcomes of Care?

Despite the increased popularity and interest in guidelines, there is still some doubt whether clinical practice guidelines are effective. (Cluzeau, Littlejohns, Grimshaw, Feder, Moran, 1999) Some of these doubts are raised because of the cost of widespread introduction of clinical practice guidelines, the uncertainty about their effectiveness, and the concerns about side-effects. (Grimshaw, Russell, 1993) However, a study performed by Grimshaw and Russell (1993) identified 59 published guidelines that met defined criteria for scientific rigour. After following implementation of the guideline, it was found

that 55 out of the 59 guidelines did indeed change the process of care in the direction of the proposed guideline. Out of the 59 studied guidelines, 11 guidelines assessed the outcome of care. 9 out of the 11 studied guidelines of patient outcome found some significant improvement. These rigorous evaluations are not always found in the guideline itself. It is also difficult to assess the increased quality of care because patients, physicians, payers and managers define quality differently and because current evidence about the effectiveness of guidelines is incomplete. (Woolf et al., 1999)

Other issues related to practice guidelines include the fear that they may become sanctioned, mandatory forms of practice. Guidelines that are inflexible also can harm the patient by leaving no room for tailoring the guideline to suit the patient based on their medical history and personal circumstances. (Woolf et al., 1999) Milliman & Robertson Inc. (2001) is an international firm of actuaries and consultants that have been evaluating risks and opportunities related to individual healthcare, benefits, and insurance. This group has developed a nine publication series that spans the continuum of patient care and describes the best practices for treating common conditions in a variety of care settings. They do state that the guidelines are "not meant to be a substitute for medical judgement." (Milliman & Robertson Inc., 2001) These guidelines are written by their own clinicians and are sold to other healthcare establishments. They can be integrated into the delivery of care. It is not known whether an appraisal or evaluation is performed on the guideline.

There is also concern that guidelines will erode clinical abilities, diminish clinical judgment, and reduce medical practice to cookbook medicine. (Hurwitz, 1999) Potentially

medical staff can become dependent on them, and not use their own innovativeness and creativity to look at a problem. In a Canadian study, greater than one fifth of the physician participants had concerns about loss of autonomy, the rigidity of guidelines and decreased satisfaction with medical practice. (Hayward, Guyatt, Moore, McKibbon, Carter, 1997)

Gaps in Quality of Clinical Practice Guidelines

Two major studies have been published that concluded that guidelines are in need of critical appraisal.

The first study looked at 431 guidelines that were developed by medical speciality societies between January, 1988 and July, 1998. (Grilli, Magrini, Penna, Mura, Liberati, 2000) Of the 431 guidelines, 67% did not report any description of the stakeholders, 88% gave no information on searches for published studies, and 82% did not give any explicit grading of the strength of the recommendations. Between 1988 and 1998, there was an improvement in including the searches for published studies and the explicit grading of evidence. However, overall, only 5% of the 431 guidelines met all three criteria. (Grilli et al., 2000)

The second study concluded that guidelines published in the peer-reviewed medical literature during the past decade do not adhere well to established methodological standards. (Shaneyfelt, Mayo-Smith, Rothwangl, 1999) This group performed a structured review of peer-reviewed guidelines published from 1985 through June 1997. 279 guidelines produced by 69 different developers were evaluated. Despite the improvement

in adherence to established methodological standards over the years, the average overall adherence to standards by each guideline was 43.1%. More specifically, the adherence to methodological standards on guideline development and format was 51.1%, on identification and summary of evidence, 33.6%, and on the formulation of recommendations, 46%. (Shaneyfelt et al., 1999) Perhaps before guidelines are accepted into a collection of approved guidelines, they must go through an appraisal process as described in the next section.

Appraisal of Practice Guidelines

Two appraisal methodologies are in the development stage to assess the quality of guidelines.

Researchers from the Health Care Evaluation Unit, St. George's Hospital Medical School in London, the Health Services Research Unit, University of Aberdeen, United Kingdom, the Department of General Practice and Primary Care, St. Bartholomew's and the Royal London School of Medicine and Dentistry, London England have combined efforts to develop a generic methodology to assess the quality of clinical guidelines. (Cluzeau et al., 1999) The purpose of their developed appraisal instrument is to assess whether developers have minimized the biases inherent in creating guidelines, and address the requirements for effective implementation.

Thirty-seven elements describing predictors of guideline quality were grouped into three dimensions (rigour of development, clarity of presentation, and implementation issues).

Responses to the questions are typically 'yes' or 'no.' The ease of use, reliability, and validity of the instrument was tested on a national sample of guidelines for the management of asthma, breast cancer, depression, and coronary heart disease with 120 appraisers. It was determined that this tool has acceptable reliability, some evidence of validity and that the instrument could differentiate between national and local guidelines. The authors concluded that they hope that the use of this instrument would encourage guideline developers to create guidelines that reflect relevant research evidence more accurately. At present the questions are not scored, however, research is taking place to develop a methodology to quantify the performance of guidelines for each dimension and to devise standardised scores for comparison between guidelines. The National Health Service Executive is using the instrument to assist in deciding which guidelines to recommend to the UK National Health Service. (Cluzeau et al., 1999)

The second initiative is through the German Guidelines Clearinghouse (2001). As of March 1999 there are more than 700 German clinical practice guidelines available via the internet. However the clearinghouse has identified a few major roadblocks to uptake. Only a few of the guidelines mention the recommendations' evidence, contain information regarding the development process, sponsorship, implementation and cost-benefit. The Agency for Quality in Medicine (1999) (Joint Institution of the German Medical Association and the National Association of the Statutory Health Insurance Physicians) has created the Appraisal Instrument of the German Guidelines Clearinghouse. In this appraisal form there are 41 questions that cover the dimensions of the quality of the

guideline development, the content and the format of the guideline, and the applicability of the guideline. (Agency for Quality in Medicine, 1999)

Lifecycle

The lifecycle of a practice guideline is a time consuming process that requires many resources (researchers, trial studies, subjects, and multi-disciplinary team group work). ProGuide distinguishes three main phases of guidelines in their report: development, dissemination, and implementation.

ProGuide states that the **development** of guidelines is a process guided by different groups who enjoy the trust of the medical profession (such as scientific bodies and research institutes). Their task is to read and interpret the complexity of scientific information and to evaluate it critically according to principles shared within the medical profession. (Engelbrecht et al., 1998)

Dissemination is defined as communication of information to clinicians to improve their knowledge or skills. It is a more active process than simply distributing information and it targets a specific clinical audience. (Canadian Medical Association, 1997b) Guidelines are distributed in a broad range of ways such as publication in professional journals, postal distribution to relevant groups, incorporation within continuing medical education, educational initiatives that focus specifically on guidelines, discussions with peers and the senior physician which all may include the use of new media such as the internet and CD Rom. (Engelbrecht et al., 1998) (Canadian Medical Association, 1997b)

Implementation is putting a guideline into place. It is more active than dissemination, involves effective communication strategies, and identifies and overcomes barriers by using administrative and educational techniques that are effective in the practice setting. (Canadian Medical Association, 1994)

There are several ways to help facilitate implementation of practice guidelines. Factors that affect acceptance of guidelines include qualities of the guideline, characteristics of the health care professional, characteristics of the practice setting, incentives, regulation and patient factors. (Davis, Taylor-Vaisey, 1997) Ownership of the guideline is more readily achieved by those who participated in the development of the guideline as opposed to those who were not involved. (Thomson, Lavender, Madhok, 1995)

Davis and Taylor-Vaisey (1997) did a review of guideline implementation strategies. The relatively strong intervention methods that they found included reminder systems, academic detailing and multiple interventions. Reminder systems can be as simple as displaying information on posters and pocket-sized laminated cards to aid in the dissemination of the information. Reminder systems can also be more complex and be integrated into a computerized decision support system. Academic detailing are educational, one on one effort, for the investigators of the study to meet with the proposed users of the guidelines. A combination of interventions appeared to have more impact on physician behaviour and health care outcomes as opposed to single interventions. Moderately effective interventions include audit and feedback performed concurrently by

peers or opinion leaders (educationally influential and respected clinicians identified by their own colleagues). (Davis, Taylor-Vaisey, 1997)

Desirable attributes of Practice Guidelines

A study was performed to assess Canadian physicians' confidence in, attitudes about and preferences regarding clinical practice guidelines. 3000 Canadians were physicians were mailed a self-administered survey. 1878 (62.6% responded). The finding revealed that:

- 52% of the respondents reported using guidelines at least monthly;
- Most of the respondents expressed confidence in guidelines issued by various physician organizations, but over 50% were not confident in guidelines issued by federal or provincial health ministries or by health insurance plans;
- Respondents felt that endorsement of the guideline by respected colleagues (78%) or a major organization (62%) was very important;
- 62% of the respondents thought that user friendliness of the guidelines format was very important.; and
- Short pamphlets, manuals summarizing a number of guidelines, journal articles and pocket cards summarizing guidelines were preferred formats by more than 50% of the group.

By providing choices for different ways to present the guideline and displaying endorsers for the guidelines, perhaps Canadian physicians may be more interested in using the guideline.

The Institute of Medicine outlines nine desirable attributes of clinical practice guidelines. (Field, Lohr, 1992) These were also mentioned in the ProGuide report. The nine attributes will first be presented. An additional attribute arising from the ProGuide survey will also be suggested.

Validity: a guideline is valid when it results in the benefit expected.

Reproducibility: a guideline is reproducible when, starting from the same scientific evidence and using the same method, diverse experts arrive at the same conclusions.

Given a defined set of specific evidence, a defined guideline results with respect to the application and understanding of the guideline. However, a concern would be how one would compare the results of different people to determine that they are in fact the same interpretations of the guidelines.

Reliability: a guideline is reliable if, given the same clinical circumstances, another health professional interprets and applies it in the same way.

This attribute may be difficult to ensure since not every clinical circumstance is the same for every person. The patient could have multiple health problems and may not be exactly the same type of patient the guideline was developed for and/or tested on to begin with.

Another problem is that as scientists, we attempt to run controlled trials, when in reality people's health experiences do not manifest in a controlled environment.

Reliability is difficult to enforce since health care professionals have different backgrounds and different areas of expertise. In a McGill University study (Wilkins, 1999) it has been shown that a generic expert (general practitioners) strictly followed the guideline recommendations. However, a domain specific expert did not follow the guideline recommendations precisely but added additional steps to the guideline. Instead of following the guidelines precisely, the guidelines served as a memory aid, which helped to make implicit knowledge explicit. (Wilkins, 1999)

Representative Development: a guideline must be produced with a process of involvement of the diverse persons interested in the problem.

This requirement is mentioned in almost all the literature produced on this topic. (Basinski, 1995) (Engelbrecht et al., 1998) (Canadian Medical Association, 1994) (Hayward et al., 1997) (Lewis, 1995) Though consensus may be laborious and time consuming, it is important to reflect on the experience and policy requirements of all those involved. It is, however, also important to make sure that CPGs are not made so that the patient is ignored and thus dis-serviced. This is the ideal intention but can be difficult to achieve. Perhaps involvement of the patient in the components of the lifecycle could help achieve this.

Clinical applicability: a guideline must be applicable to definite populations of patients in accordance with scientific evidence and clinical experience.

The population for the specific guideline must be defined in detail so that the health care practitioner can determine whether their patient is an example of this population and will benefit from the guideline. Also, the defined population will flag the physician to notice discrepancies between their own live patient and the theoretical patient.

Clinical flexibility: a guideline must make clear which clinical situations constitute an exception.

Clarity: a guideline must be written in clear language and be presented in the most suitable form for use in clinical practice.

It was not stated how clarity would be achieved. This attribute is most suitable for guidelines described as written text. However, guidelines can be represented in a variety of formats (diagrams (Wilkins, 1999) or computer embedded algorithms (Shiffman, Brandt, Liaw, Corb, 1999)), which do not use written text. Therefore this attribute may be too limiting and prescriptive for alternative forms of representation. Clarity of the guideline would depend on the format used. In general, clarity may be trying to achieve a representation that is concise and easily understood.

Documentation: a guideline must indicate those who have taken part in its production, the method utilized, and the scientific evidence taken into consideration.

There must be a well-documented reference, process, design, and procedure for the development of the guideline. Additionally, the date of final composition should be presented so that users know the age of the guideline. An update log for each guideline could help with achieving this attribute.

Scheduled Review: a guideline must state in what circumstances updating is necessary.

It is obvious that a review should take place whenever there is quality counter-evidence available. Furthermore, additional supportive evidence should be displayed as new research occurs to further substantiate the guideline.

The authors of ProGuide suggested another desirable attribute:

Strength of Recommendation: a guideline must signal the quality of the scientific evidence on which the recommendations expressed are based; must represent a categorized criterion of the recommendations; according to the type of scientific evidence supporting a particular recommendation on clinical practice, this will be defined as supported by evidence based on good quality reading-matter (random clinical studies, meta-analysis), of medium quality (other non-random studies) of the simple opinion of experts. (Engelbrecht et al., 1998)

This attribute is concerned with the methods used to generate the scientific insights on which the guideline is based. The strength of recommendation can also depend on whether a trustworthy body developed the guideline.

Taxonomy

Definition and Attributes of Taxonomy

The need for classification has always existed. It is a process that humans instinctively carry out to identify food, predators, mates, fuel, building materials and now many more entities. (Varol, 1999) It can be considered a process that is essential for survival. When one groups, one begins to sort and understand the extensive array which exists.

Taxonomy is the theoretical study of classification, including its bases, principles, procedures, and rules. (Sneath, Sokal, 1973) (Cummins, 1999) Classification refers to ordering entities into groups on the basis of their similarities. One objective of the taxonomy is to serve as the key to an information storage system. An example of such is a library. Libraries classify books to allow users to locate their selection. The general purposes of a taxonomy are as follows: (Friesen, 1999)

- To serve as an index to stored information.
- To allow for predictions and interpolations.
- To permit the making of generalizations.
- To provide a basis for explanation.

The definition of taxonomy is derived from ordering physical entities. For example, when we are classifying the animal kingdom, we group vertebrates in one category and invertebrates in another. Whether vertebrae are present or not would be a characteristic for grouping. We call such a characteristic an "axis" or "taxon." The taxon or axis is any

taxonomic grouping that can be used to indicate the rank of a group as well as the items that are contained within that group. (Varol, 1999) The taxonomic description is a statement of the taxon's characters. The taxon's characters are necessary to distinguish a taxon from the other taxa. (Varol, 1999)

Attributes of a good taxonomy would include: high information content, stability, ease of use, and a balanced classification. (Friesen, 1999)

Information content relates to the number of characteristics that one could deduce from the classification itself. One could try to maximize the information content by creating a classification system that contains groupings that are as homogenous as possible. (Friesen, 1999) Secondly, an individual item should be organized into a group which it shares the most attributes with. Finally, different degrees of likeness between entities can be presented by arranging the groups into a hierarchy of levels. Each level should represent entities with a similar level of distinctness. (Friesen, 1999)

The second attribute, stability, is important to ensure that the classification system serves as an effective medium of communication. It is desirable for the taxonomy to remain the same unless there is a fundamental change in the underlying topology. (Friesen, 1999)

Convenience, the third attribute, refers to the ease of use of the system. A taxonomy with few categories at each level (optimum level of subdivision is 2 to 5 taxa at each new level) is easily remembered and therefore more likely to be applied. (Friesen, 1999)

Finally, balance is an important attribute. Many times, classifications systems have both deeply nested groups in the crown group (main category) and shallow nesting groups in the stem groups. It is advantageous to have a more balanced taxonomic hierarchy, with a more equal distribution of groups and levels. As was learned in computer science, balanced trees are more efficiently searched than non- balanced trees. (Friesen, 1999)

An Example: SNOMED

The principles for grouping are artificial and depend on the purpose one pursues. An example of a taxonomy introduced in 1993 is: SNOMED a (Systematized NOmenclature of Human MEDicine). (SNOMED International Authority, 2000) SNOMED is a comprehensive, multiaxial nomenclature created for indexing the entire medical record. The developers of SNOMED took into consideration what the users of the medical record would want to know. SNOMED is an artificial language used to express medical fact, but it has a small classification portion to it that is described below and can be applied to the building of our taxonomy.

The system used for classification is often controlled in a hierarchical manner. This is often complicated if there are potentially several parents to a child node. Hierarchical classification systems are therefore a compromise. In order to decrease this type of problem, it is desirable to separate different classification principles -- such as morphology and topography -- which can be maintained as comparatively pure hierarchies. We call these different principles "logical axes." SNOMED has 11 logical axes. An example of how one can find a diagnosis in the hierarchy is as follows:

Searching for Iron Storage Disease *(D-11120 or F-10363)*

D- - Diagnostic term

D-10000 - Metabolic/Nutritional disorder

D-11000 - Disorder of mineral metabolism

D-11100 - Disorder of iron metabolism

D-11120 - Iron storage disease

However, Iron Storage Disease can also be found under the Function axis:

F-10363

F- - Function

F-10000 - Unit of metabolism

F-10300 - Element, ion, simple compound

F-10360 - Iron

F-10363 - Iron, increased

Iron Storage Disease can be independently retrieved following separate paths of logic. This will account for the fact that different users will come to the same conclusion differently.

The principles above give us a good idea of what a taxonomy is and how to classify entities. We can now look at applying this information to the creation of the taxonomy.

Health care practice guidelines are abstract entities. In this case, a taxonomy of guidelines and roles in their development, dissemination, and application would allow us to decide such questions as what kind of guidelines and what kind of roles in their life cycle should be supported by a WWW based server. We could then assess what functional components the server should have.

There are three considerations in developing a taxonomy: (Cummins, 1999)

1. Separation of logical axes;

2. Scale of representation: (free text, cardinal metric scales, nominal scale, existential scale); and

3. Practicality: one goal of classification is complete representation of the available information at the desired level of precision. Striving for maximum precision could result in the loss of practicality of the taxonomy.

The above description of taxonomy provides details on how one would classify a single guideline. The goal here of this taxonomy is to describe what a guideline should consist of

and what it should be. The entity-relationship model, as described below, could provide some direct assistance on creating a conceptual framework to represent this reality.

Entity-Relationship Model

The Entity-Relationship model is a conceptual framework. It is a detailed (logical) model that captures the overall structure of organizational data. (Palinski, 1997) It focuses on the data structure and it separates the functional modeling. The model consists of the entity type or class, the entity instance itself, the relationship between the entities and the attributes of the entity type. (Palinski, 1997) Since we are not trying to define and classify an individual guideline, the entity instance or the primary key of the entities are not required.

The Entity type or class, categorizes people, things or events that share a common set of attributes. They are characterized by the relationships with other types or classes. The relationship is the association among entities. It will specify both the degree (number of participating entity types), and the cardinality (number of instances in one entity type associated with instances in another). It will also define the modality between the entities. Attributes are the property or characteristics of the entity type. (Palinski, 1997)

The entity, relationship and attributes will all be used and defined in the result and discussion sections. We will be using this form to represent the framework for the taxonomy.

CHAPTER 3: METHODOLOGY

Proposed Research Tasks

There are three steps to the proposed research.

1. Analysis of relevant documents collected from the Internet, library resources, and ProGuide will be completed to understand the context and environment of practice guidelines.
2. Development of a framework for a taxonomy.
3. Critical comparison of this taxonomy with recently published materials.

Taxonomy Framework

A framework for the taxonomy has been created based on a literature review and ProGuide's comments. The literature review helped to develop the principles that should be represented in the taxonomy. Several iterations of the taxonomy have taken place as current literature and studies have been found. The framework has been represented using an Entity-relationship diagram.

Testing and Refinement

Once the framework has been refined, it will be compared to other recently published framework ideas. It is desirable to create a taxonomy that reflects such a diverse environment as depicted throughout ProGuide's work. In doing so, the taxonomy has a greater opportunity for use internationally.

CHAPTER 4: RESULTS

Practice guidelines are attractive for numerous reasons, a central one being that they can potentially standardize clinical practice around an appropriate norm and thus promote "best practice." (Haycox, Bagust, Walley, 1999) (West, Newton, 1997) However, there are several concerns regarding guidelines which include the amount of time, effort, resources and skills required to create, produce and update a guideline, (Feder, 1999) (Haycox et al., 1999) (West, Newton, 1997) the inconsistent quality of existing guidelines, (Cook, Giacomini, 1999) (Jackson, Feder, 1999) (West, Newton, 1997) and the suppression of creative patient centred care by the imposition of nationally developed external standards. (McKee, Clarke, 1995) (West, Newton, 1997) (Williams, 1999) (Williamson, 1995) This section focuses on these particular concerns in greater detail. With the following understanding of the problems surrounding health care guidelines and a further analysis on the principles of taxonomy, the framework for the taxonomy is presented in the results and discussion sections.

Guidelines for Guidelines

Despite the sheer amount of guidelines on numerous topics and the variability in quality, guidelines generally have several common elements. These elements include: (Thomson et al., 1995)

- Guidelines can help patients and professional make appropriate decisions about health care;

- They can describe suitable care based on scientific evidence and broad consensus, although allowing legitimate variations in practice;

- They can focus on specific factors while taking into account both organizational and community characteristics and influences on health care;

- And, guidelines can play a role in quality assurance and improvement.

In order to fulfill many of these expectations of guidelines, they must have particular attributes. Three main attributes that were found throughout the literature and should be reflected in the taxonomy are as follows:

1. Guidelines should identify the key decisions and their specific consequences. (Feder et al., 1999) (Jackson, Feder, 1999) (West, Newton, 1997) (Williams, 1999) (Thomson et al., 1995) Clear statements regarding the recommended practice within specific circumstances should be provided.

2. Detailed review of the relevant evidence base on the benefits, risks, and costs of the clinical decision and alternatives should be identified. (Cook, Giacomini, 1999) (Haycox et al., 1999) (Jackson, Feder, 1999) (West, Newton, 1997) (Williams, 1999)

3. Presentation of the evidence in a simple algorithm that displays the sequence of steps that should be followed for the physician and the patient. This should be in an approved format that is flexible to the stakeholder preferences. (Cook, Giacomini, 1999) (Feder et al., 1999) (Haycox et al., 1999) (Thomson et al., 1995) (West, Newton, 1997) (Williams, 1999)

All three of these recommendations will be included in the taxonomy along with several other contributing attributes which relate to the above three points.

One study looked into finding a flexible approach to model guidelines. (Tu, Musen, 1999) The goal of this study was to analyze the dimensions along which guidelines may vary and to describe a task-oriented approach to guideline modeling. The authors found six dimensions along which modeling requirements of a guideline can be analyzed: (Tu, Musen, 1999)

1. Provider behaviours that a guideline influences (behaviours that a guideline tries to influence as):

    - Setting goals or constraints;
    - Choosing an alternative among competing options;
    - Sequencing a set of actions;
    - Interpreting data.

Within the proposed taxonomy, the goals could be represented by the category and specialty of the guideline. Secondly, the constraints could refer to the patient population that the guideline is intended for. It is also important to provide preventive, diagnostic, or therapeutic options. This will be reflected by the different categories in the taxonomy. The suggested set of actions refers to the specific recommendation itself. Finally, the interpretation of the data (evidence) would include the outcomes associated with the guideline and the resource requirements.

2. Temporal dimensions of actions and data.

This dimension could refer to the time line of the evidence as well as the temporal order of steps in which the guideline should be executed. Flow charts could potentially represent the sequencing of the guideline.

3. Abstractions.

Abstractions are the conclusions and concepts that the guideline committee will come to when developing the guideline. However, when a physician is reading a guideline, it is important for him to understand how this conclusion came to be and whether or not they would be using the guideline appropriately and for the proper patient population. A guideline can be perceived as an argument. Using Toulmin's argument structure, the guideline can be considered a claim in an argument. All claims should have data, warrant, backing, qualifiers, and a rebuttal. (Shankar, Musen, 1999) Thus, to support and provide a quality guideline these issues should be addressed. The data and backing refer to the evidence that was used to formulate the guideline. The warrant deals with the category of

the guideline while the qualifier could represent the population being considered. Finally, the rebuttal could be found in options available and the outcomes associated with the guideline. Patient preferences could also be involved here.

4. Degrees of Uncertainty

It is also always important to know whether the evidence supporting the guideline is of a high standard. A taxonomy can also help to gauge the evidence in which a guideline is based. Comments by the developer of the guideline support could assist in this area.

5. Point of View

If the developer to the guideline was identified, the point of view will be realized. The purpose of the guideline, the organization type and the funding source will also aid in understanding the point of view.

6. Normal Case and Exceptions

Within the identification of the patient population, the normal cases and exceptions should be revealed. Further insight into adaptation of the guideline could be found when discussing the flexibility of the guideline.

Quality of Guidelines

A major critique of guidelines is that they do not consistently describe the methodology for collecting the evidence, the quality of the evidence, nor how the diverse sources of evidence resulted in a particular interpretation. (Cook, Giacomini, 1999) This concern has

motivated the guideline community to discuss and improve the methods for developing guidelines. (Cook, Giacomini, 1999) (Haycox et al., 1999) (West, Newton, 1997) (Williams, 1999)

One of the fundamental contributions in this respect is the suggestion by Archie Cochrane, noted British epidemiologist, to base conclusions on systematic, comprehensive reviews of all randomized controlled clinical trials (RCTs) relevant to a defined problem. This led to the Cochrane Collaboration. Cochrane emphasized that reviews of research evidence must be prepared systematically and they must be kept up-to-date to take account of new evidence. (Cochrane, 1972) The Cochrane Collaboration is an international effort to facilitate this process across all areas of health care. (Chalmers, 1993) The taxonomy will have to reflect the use of methodologies of this nature.

Another initiative is through the National Health Services (NHS). The NHS is an organization whose purpose is "to secure through the resources available the greatest possible improvement in the physical and mental health of the people of England." (National Health Service Executive, 1997) The executive of this service has created a multidisciplinary Clinical Outcomes Group to be responsible for endorsing suitable guidelines that the executive can safely promote. However, they will only approve CPGs based on randomized controlled trials. Two assumptions must be made in order to accept RCTs. The first being that outcomes identified during the trial should be reproducible in normal practice settings and, secondly, adoption of an effective guideline leads to optimal

treatment for the whole population. (Haycox et al., 1999) There are a few dangers in only considering RCTs as quality evidence.

One problem identified was that clinical topics that are not the current priority could be neglected in terms of funding and attention. (West, Newton, 1997) Secondly, clinical areas such as rehabilitation and learning disability do not suit this type of research design. (West, Newton, 1997) Lastly, real life clinical circumstances do not necessarily replicate the controlled environment where the RCT was tested. (Haycox et al., 1999) There are restrictions and limitations on resources, patient compliance, and patient compatibility uncertainties. Perhaps other kinds of evidence should be considered acceptable. These other methodologies will also have to be reflected in the taxonomy.

Nationally developed guidelines are generally considered to be more firmly based on empirical quality research while locally developed guidelines are more related to use. (West, Newton, 1997) Those guidelines issued by national bodies could potentially hamper local attempts to adapt the guideline to their specific community or patient centred circumstance. (Haycox, et al., 1999) If the guideline is locally adapted, there could be a greater sense of ownership and uptake. Flexibility of the recommendation was addressed throughout the literature (Cook, Giacomini, 1999) (West, Newton, 1997) (Williams, 1999) and in the ProGuide survey results. (Engelbrecht et al., 1998)

Computer Aids for Guideline Representation and Implementation

Dodek and Ottoson (1996) state "the purpose of CPGs is to improve patient outcomes by changing physician behaviour" (p. 82). We can broaden the scope of the taxonomy to include all guidelines in general having to do with health care. Guidelines could be recommendations of practice for management (staff hours), pharmaceutical supplies, and many other health care functions. It is worthwhile then to create a taxonomy that could handle the diverse purposes and topics of practice guidelines.

Embedding Guidelines into Work Flow

Even once a guideline has been approved, and considered reliable, it is often difficult to influence change. Implementation can be defined as "an iterative process in which ideas expressed as policy, are transformed into behaviour, and expressed as social action."(Dodek, Ottoson, 1996, p.82) Dodek and Ottoson (1996) found that in order to facilitate implementation of guidelines, personal, interactive approaches are more effective than formal, indirect method and that the technical design of guideline implementation plans should involve a more creative and practical approach. It is thus easy to conclude that embedding guidelines into workflow could potentially improve uptake and adherence and therefore promote use of the guideline and change behaviour.

A study performed by Chin & Wallace (1999) illustrated two distinct ways in which guidelines were embedded into a computer based patient record at the decision making point during the ordering process. In each case, the quality of care improved. A radiology guideline was embedded into the computerized patient record. This guideline provided

information about appropriate indications for a test to the clinician at the time of order. The clinician could choose to read the information or ignore it. Compliance to this recommendation increased from 55% to 86% to 90% when this guideline was embedded into the workflow. (Chin, Wallace, 1999) A second guideline was related to the prescribing of medication. When a clinician is about to prescribe and order a drug for therapy, different cost-effective drug alternatives are presented. This guideline supports cost effective prescribing habits. A costly drug was prescribed almost 50% less often when the embedded guideline took affect. (Chin, Wallace, 1999)

It is important and desirable to maintain physician autonomy. If guidelines are to improve efficiency, then they should do that in forms of flexible efficiency aids and not as sanctioned norms. (Cook, Giacomini, 1999) (Fairfield, Hunter, Mechanic, Rosleff, 1997) (Grol, Dalhuijsen, Thomas, Veld, Rutten, Mokkink, 1998) (Shaneyfelt, Mayo-Smith, Rothwangl, 1999) Physicians should have the opportunity to accept or dismiss the recommendation. It is also advantageous to maintain the simplicity and ease of use of the guideline. Several new initiatives and studies are currently under way to promote ease of use and acceptance of computer embedded guidelines.

If a guideline is embedded into the workflow, there is the possibility that the explanation for this procedural change may not be displayed. An example of an explanation-based analysis is currently under way by Shon and Musen (1999). This group is studying the kinds of explanations that are required by physicians to accept the guideline and further make confident decisions regarding health care. This is a web-based study where the

participants (clinicians) are presented with three cases in random order. Within each scenario 1) They are presented a case and are asked to choose a clinical decision; 2) They are presented the guideline recommendation and are asked to choose the clinical decision again; 3) They are presented a randomly chosen evidence-based explanation for the guideline recommendation and are asked to choose the clinical decision. At each step, they are asked how confident they are about their decision. During the evidence-based explanation portion, one of the four explanations was presented to the physician: 1) Guideline knowledge alone; 2) Guideline knowledge with patient data and abstractions; 3) Guideline knowledge with guideline validity data; 4) Guideline knowledge with patient and validity data. This study is in progress and should reveal what kind of information is required by the physician to make confident decisions while using guidelines.

Forms of Representation for Guidelines

Guidelines can be represented, disseminated and implemented in a number of ways. The most common way is text based formats. The main advantage to this form is that internationally there are still many organizations that do not have access to computers at the appropriate time and place for guideline use. It is therefore appropriate to maintain this form of representation. However, for other organizations, computers are becoming central to patient care, if not the operation of the institution. If guidelines are created in a structured computer interpretable format, implementation of guidelines on a large scale can be accomplished. Structured guidelines provide a variety of applications such as decision support during the care of patients, workflow management support, quality assurance evaluations (measured by compliance to the guideline), protocols in clinical

trials, and structured guidelines which may also be used in simulation programs for educational purposes. (Boxwala, Greenes, Deibel, 1999)

The following section identifies several alternatives for representation of guidelines in a computer compatible format. The ideas below are organized in a hierarchical fashion which could potentially lend itself to an axis within the taxonomy. The alternatives are systematized in the following groupings: clinical algorithms, graphical representation, decision support systems and other.

Clinical Algorithms

Clinical algorithms are the decision making and action sequencing aspects of a guideline. (Tu, Musen, 1999) An algorithm should include the scenario, decision, sequence of actions, goal and specifications of the activity and action. (Tu, Musen, 1999) If it was possible to represent a guideline in a computer algorithm, then one does not have to remember the specifics of the guideline because the computer may automatically ask the physician particular questions and recommend certain procedures. It requires however, that the care process is comprehensively supported by computer-based documentation.

Algorithms can be used in different ways. Wang, Jenders, and Dasgupta (1999) translated national childhood immunization guidelines to a computer-based reminder recall system. The decision support system incorporated several reminders and recalls at the point of care. These were based on the Centers for Disease Control and Prevention recommendations. The system presented reminders and questions on screen to the patients' family and care providers. These reminders and questions included such things as vaccine due dates, allergies and contraindications that apply to the patient, and recalls to health care providers and patient parents via e-mail, fax or regular mail. (Wang et al., 1999)

In another study, an algorithm was created to parse through a clinical trial (which has been converted to XML) and match patients using specific patient criteria. (Ohno-Machado, Wang, Mar, Boxwala, 1999) A patient or a practitioner can enter information about themselves (condition related criteria) and find clinical trial matches. There are two

versions of this application, one for the patient and one for the practitioner. A major concern regarding the searching mechanism was that each of the criteria were given equal importance and were all considered independent in the ranking process. In reality, some criteria will have more importance than others will or the criteria may overlap. Lastly, the algorithm does take patient preferences (e.g. modality of treatment, potential toxicity, potential for cure, and geographic constraints) into consideration when ranking the clinical trials.

A specific example of a clinical algorithm is a specialized programming language called Arden Syntax.

Arden Syntax

The Arden Syntax for Medical Logic Modules (MLMs) is a language for encoding medical knowledge. Each MLM contains sufficient logic to make a single medical decision. MLMs are a series of procedural instructions that work like an "if then" rule. (Jenders, 2000) Each unit can chain to and can call others. This helps with multiple states and decision points. MLMs have been used to generate clinical alerts, interpretations, diagnoses, screening for clinical research, quality assurance functions, and administrative support. (Jenders, 2000) With an appropriate computer program (known as an event monitor), MLMs run automatically, generating advice where and when it is needed. For example, one MLM warns physicians when a patient develops new or worsening kidney failure. Thus it monitors events or data that are uploaded to the database and attempts to figure out which procedures are related.

The syntax is flexible. Due to institution specific mapping, however, it is becoming more of a programming language instead of a simple easy to read English like syntax. Arden Syntax is not often used to share or represent complex guidelines. Most sharing to date involves simple MLMs. In the future, the syntax will have more guideline constructs, structured output statements, and it will work across populations instead of on a single patient focus. (Jenders, Gordon, Boxwala, Tu, 1999)

Graphical Representation

A graphical representation of a guideline attempts to display the guideline in a concise, user-friendly pictorial format. Examples of such would include flow charts, conceptual models and other diagrams. The example presented here is the Guideline Interchange Format.

Guideline Interchange Format (GLIF)

An example of a graphical representation of a guideline is Guideline Interchange Format (GLIF). GLIF specifies an object-oriented model for guideline representation and a syntax for guideline transport that would facilitate computer-based clinical guideline sharing. (Boxwala et al., 1999) (Greenes, Boxwala, Sloan, Ohno-Machado, Deibel, 1999) (Patel, Allen, Arocha, Shortliffe, 1998) This representation is given in a flow chart type format. The tool suite includes tools for the guideline repository, guideline authoring, guideline viewing, and guideline execution. These tools are solely for computer implementation and usage. (Greenes et al., 1999) The repository stores clinical guidelines, classifies and

indexes them, and maintains and controls their access over a network. It does not appear that explanations of the guideline are presented. However, Greenes et al. (1999) states that they will be conducting ethnographic studies with potential guideline developers to better define the user interface requirements of these tools.

A guideline execution engine for GLIF was developed and tested by Boxwala et al. (1999). The goal of this engine is to traverse the guideline by evaluating logic conditions specified in the guideline against patient data values. The results of the evaluation are used to generate patient-specific recommendations from the guideline. The engine was used in three major applications: 1) To manage referrals: the guidelines will help select the therapy option, and in some cases to decide whether the therapy should be delivered at the medical centre or at the referring institution, and to guide the delivery of the selected therapy. 2) To guide the primary care physician in the assessment and management of the problem. When a referral to the specialist is necessary, the system will recommend the referral and assist in setting it up via a Tele-medicine system. 3) To develop a simulation program: this program generates patient management options from a guideline based on a patient profile. The user-selected option is compared to the correct recommendation of the guideline for that patient.

Decision Support Systems

A decision support system is a computer program application that analyzes data and presents it so that users can make decisions more easily. Such a system may present information graphically and may include an expert system or other artificial intelligence

approach. An example of a decision support system is EON (Enhanced Middleware for Automation of Protocol-Directed Therapy). To work with decision support systems such as EON, WOZ was created as an explanation framework. Both can be summarised as follows.

Enhanced Middleware for Automation of Protocol-Directed Therapy

The Stanford Medical Informatics group has developed an evolving set of components that together help to automate various aspects of protocol-based care. (Musen, Shankar, O'Connor, Advani, 1999) Enhanced Middleware for Automation of Protocol-Directed Therapy (EON) has now undergone major enhancements so that it is more able to accommodate a wider class of guidelines and protocols. There are three main modules within EON 2.0. The first module includes problem-solving methods that address tasks such as customizing the guidelines to specific patient cases and determining protocol eligibility. The second module includes an electronic knowledge base that contains descriptions of the guidelines. The third module includes a database mediator, named Tzolkin, which can function as the medium for all queries between the problem-solving components and a patient database. (Musen et al., 1999) These components will provide an opportunity to measure not only the quality of the system's advice, but also the usability of new features.

WOZ

WOZ is an explanation framework that justifies the conclusions of a clinical decision-support system. (Shankar, Musen, 1999) This multi-agent framework explains the claims

of EON. It uses explicit models that abstract the explanation strategy and the agent architecture. The argument structure uses Toulmin's argument model. The WOZ framework includes 1) identifying the distinct elements of the explanation space that are required to satisfy user's explanatory query, 2) obtaining the required information from the appropriate agents, and 3) presenting the explanation in a coherent manner. (Shankar, Musen, 1999)

Other

This category includes other computer executable formats that do not fit into the above noted categories.

Extensible Markup Language (XML)

Extensible markup language reduces a document to words in a known context-free grammar through a process of markup. This tool can help with the dissemination of a guideline by making it available on the web. An XML-based semi-automated process was developed and Lukoff, Dolin, McKinley, Fuller & Biron (1999) were able to use the MS Word authoring template to automatically generate both an XML and HTML representation of the guideline. The HTML version can then be installed onto the internet. Searching a database to find relevant information can be made easier if the guideline is encoded into the markup language. (Lukoff et al., 1999)

The next portion of the Result section includes a conceptual framework for the taxonomy and a detailed description of the framework. Figure 1 depicts a model of the taxonomy.

It is believed that this framework alleviates numerous concerns for practice guidelines as stated earlier. The Discussion section will provide an analysis of the framework, a comparison to the Guideline Element Model and other current research in this field, and ideas for future work.

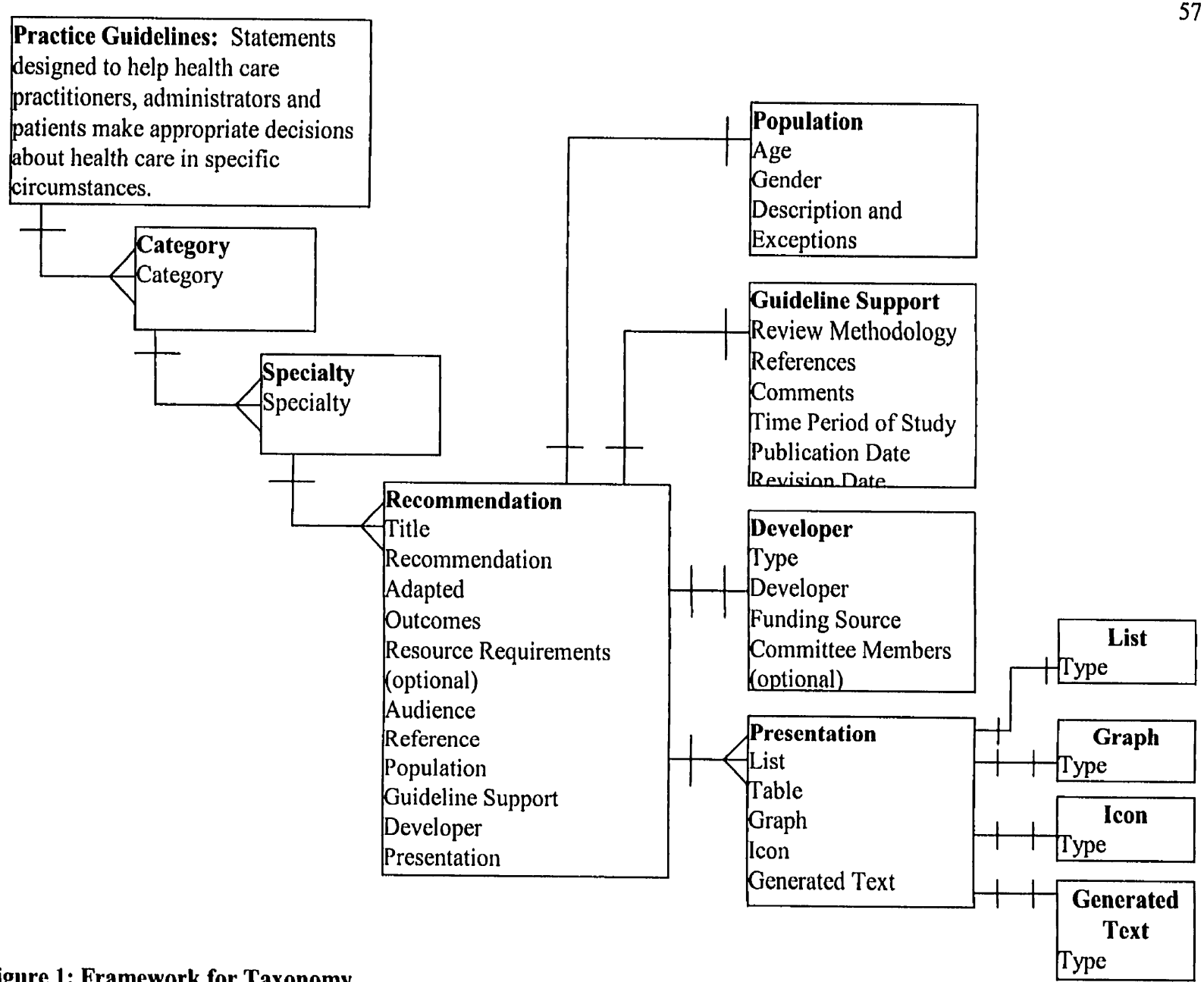

Figure 1: Framework for Taxonomy

Presentation of Guidelines

Previously in this taxonomy, the computer aspect of guidelines was defined using the form of representation of the guideline. Starren and Johnson (2000) state that representation is "the internal (person or computer) form of perceptual and prepositional information utilized for inference, computation, and internal storage." However, the term "representation" does not always characterize the sensory manifestation of the computer. So, it is now proposed to differentiate the guidelines by their presentation. Presentation has been defined by Starren and Johnson (2000) to be "a sensory manifestation of information." This may be in any form – tactile, auditory, or visual. It may be static or dynamic. This external manifestation may be used for external storage or transmission. (Starren, Johnson, 2000)

Description of the Framework

The results of Figure 1 will be described in this section flowing from the left of the diagram to the right. This framework is based upon the background research presented above and several other significant articles. (Eccles, Clapp, Grimshaw, Adams, Higgins, Purves, Russell, 1999) (Hongsermeier, 1997) (Shaneyfelt et al., 1999) (Shekelle, Woolf, Eccles, Grimshaw, 1999) Following the description, an analysis of the framework will be presented.

The diagram is in the form of an entity relationship diagram in a hierarchical representation. Each segment is a singly parented segment. This is not a complete or best

representation of reality. Primary keys have not been identified, however, the entities, the attributes and their relationships have been described below.

The left most box in Figure 1 allows for only guidelines to enter this classification system. Practice guidelines are statements designed to help health care practitioners, administrators, and patients make appropriate decisions about health care in specific circumstances.

1. Category

The Category entity refers to the differing purposes of guidelines. There are several purposes noted throughout the literature. These include: (Agency for Health and Policy Research, 1998) (Canadian Medical Association, 1997b) (Berger, Rosner, 1996) (Lewis, 1995)

- Limiting variations in practice that may signal problems in the quality of service;
- Eliminating or reducing unnecessary costs associated with the variations in practice;
- Providing a basis for educating the public on the value, risks, and benefits of diagnostic and therapeutic procedures;
- Empowering patients and giving them a sense of autonomy in dealing with their health care situation;

- Making more informed health care benefits purchasing decisions; and
- Incorporate the information into educational curricula and continuing education efforts.

Each purpose is not equally important to all prospective guideline audiences, whose responses will be conditioned by their own ranking and ordering. For this reason, the purpose of the guideline is important for the audience to know.

Table 2: Category Entity

Entity	Relationship	Attribute	Optional?	Attribute Type
Category	1:M to the Specialty Entity	Category: This attribute defines the category of the guideline.	Mandatory	Choice of the following; Drop down list with multiple choices. (National Guideline Clearinghouse, 1999) 1. All 2. Assessment of Therapeutic Effectiveness 3. Counselling 4. Diagnosis 5. Evaluation 6. Management 7. Prevention 8. Rehabilitation 9. Risk Assessment / Prognosis 10. Screening 11. Technology Assessment 12. Treatment

2. *Specialty*

This entity defines the health care specialty that the guideline falls into. It is possible that a guideline may be involved in more than one specialty.

Table 3: Specialty Entity

Entity	Relationship	Attribute	Optional?	Attribute Type
Specialty:	1:M to the Recommendation Entity	Specialty: This attribute defines the health care specialty that the guideline falls into.	Mandatory	Choice of the following; Drop down list with multiple choices. (National Guideline Clearinghouse, 1999) 1. All 2. Adolescent Health 3. Allergy and Immunology 4. Anaesthesiology 5. Behavioural Health 6. Cardiology 7. Cardiothoracic surgery 8. Cardiovascular nursing 9. Chiropractic 10. Clinical Laboratory 11. Clinical Pathology – Blood Bank and Transfusion Medicine 12. Colon and Rectal Surgery 13. Critical Care 14. Critical Care Nursing 15. Dentistry 16. Dermatology 17. Emergency Medicine 18. Endocrinology

Entity	Relationship	Attribute	Optional?	Attribute Type
				19. Epidemiology and Public Health 20. Family Practice 21. Fetal and Maternal Medicine 22. Gastroenterology 23. General Surgery 24. Geriatrics 25. Gynecology Oncology 26. Gynecology 27. Hematology 28. Infectious Diseases 29. Internal Medicine 30. Medical Genetics 31. Medical Oncology 32. Mental Health and Substance Abuse 33. Microbiology 34. Neonatology 35. Nephrology 36. Neurological Surgery 37. Neurology 38. Nuclear Medicine 39. Nursing 40. Nutrition 41. Obstetrics 42. Occupational Medicine 43. Oncology 44. Ophthalmology 45. Optometry 46. Orthopedic Surgery 47. Orthopedics 48. Otolaryngology 49. Pathology 50. Pediatric Cardiology 51. Pediatrics 52. Perinatology 53. Pharmacology 54. Physical Medicine

Entity	Relationship	Attribute	Optional?	Attribute Type
				and Rehabilitation 55. Plastic Surgery 56. Podiatry 57. Preventive Medicine 58. Primary Care 59. Psychiatry 60. Pulmonary Medicine 61. Radiation Oncology 62. Radiology 63. Rheumatology 64. Sleep Medicine 65. Social Services 66. Speech-Language Pathology 67. Sports Medicine 68. Surgical Pathology 69. Thoracic Surgery 70. Urology 71. Vascular Surgery

3. Recommendation

The third entity refers to the formulation of recommendation. There are several attributes under this entity. Due to the different types of "Presentations" of the guideline, the "Resource Requirement" attribute is important to define, for example, what type of hardware, software, amount of financial resources and skills are needed to implement the guideline.

Table 4: Recommendation Entity

Entity	Relationship	Attribute	Optional?	Attribute Type
Recommendation		Title: This attribute refers to the title of the guideline.	Mandatory	Free entry text based.
		Recommendation: This attribute refers to the specific recommendation that the audience will follow.	Mandatory	Free entry text based.
		Adapted: This attribute refers to whether this particular guideline has been adapted from a previous guideline. The source can be included here.	Mandatory	Yes/No choice and include reference if the answer is "Yes"
		Outcomes: This attribute	Mandatory	Free entry text based.

Entity	Relationship	Attribute	Optional?	Attribute Type
		refers to the clinical benefits and harms related to the guideline recommendation. Both relative and absolute risks should be included.		
		Resource Requirements: This attribute refers to the resource requirements needed to implement this guideline. An economic analysis can be present.	Optional	Free entry text based.
		Audience: This attribute refers to the intended audience of the guideline. A guideline may be written for different stakeholders.	Mandatory	Choice of the following; Drop down list with multiple choices. (National Guideline Clearinghouse, 1999) 1. All 2. Allied Health Care Practitioners 3. Chiropractors 4. Clinical Laboratory Personnel 5. Dentists

Entity	Relationship	Attribute	Optional?	Attribute Type
				6. Dietitians 7. Health Care Providers 8. Health Plans 9. Hospitals 10. Managed Care Organizations 11. Nurse Practitioners 12. Nurses 13. Occupational Therapists 14. Pathology Assistants 15. Patients 16. Pharmacists 17. Physical Therapists 18. Physician Assistants 19. Physicians 20. Psychologists 21. Public Health Departments 22. Respiratory Care Practitioners 23. Social Workers 24. Speech Language Pathologists 25. Students 26. Substance Use Disorder Treatment Providers 27. Utilization Management
		Reference: This attribute refers to the	Mandatory	Free entry text based.

Entity	Relationship	Attribute	Optional?	Attribute Type
		reference of the guideline. It can be a hyperlink to a web based document or the text based location of the document.		
	1:1 to the Population entity.	Population: This attribute refers to the population that the guideline is intended for.	Mandatory	** See the Population Entity for Details**
	1:1 to the Guideline Support entity.	Guideline Support: This attribute refers to the research and support that is the basis for the guideline.	Mandatory	**See the Guideline Support Entity for Details**
	1:1 to the Developer entity	Developer: This attribute refers to acknowledging and making accountable the developers of the guidelines.	Mandatory	**See the Developer Entity for Details**
	If the Presentation option is selected there is a 1:M relationship to the	Presentation: This refers to the sensory manifestation of the guideline. It is what the human eye sees and it is	Mandatory	**See the Presentation Entity for Details**

Entity	Relationship	Attribute	Optional?	Attribute Type
	Presentation entity.	different from the internal representation of the guideline.		

4. Population

The fourth entity refers to the population that the guideline is intended for.

Table 5: Population Entity

Entity	Attribute	Optional?	Attribute Type
Population	Age: This attribute refers to the age group of the population that the guideline is to be used upon.	Optional: This category is optional due to such examples as the nurse population or the clerks in a HIV ward as the targeted population.	Choice of the following; Drop down list with multiple choices. (National Guideline Clearinghouse, 1999) 1. All 2. Infant Newborn (to 1 month) 3. Infant (1 to 23 months) 4. Child (2 to 12 years) 5. Adolescent (13 to 18 years) 6. Adults (19 to 44 years) 7. Middle Age (45 to 64 years) 8. Aged (65 to 79 years) 9. Aged, 80 and over
	Gender: This attribute refers to the gender of the population that the guideline is to be used upon.	Mandatory	Choice of the following. May only choose one: 1. All 2. Female 3. Male 4. Other
	Description and Exceptions: This attribute refers to a	Mandatory	Free entry text based.

Entity	Attribute	Optional?	Attribute Type
	description of the intended population. Exceptions and flexibility considerations can be made here.		

5. Guideline Support

The fifth entity refers to the details of the support and basis of the recommendations.

Table 6: Guideline Support Entity

Entity	Attribute	Optional?	Attribute Type
Guideline Support	Review Methodology: refers to how the support and basis for the recommendations was collected.	Mandatory	Choice of the following; Drop down list with multiple choices. (Shekelle et al., 1999) 1. Evidence for meta-analysis of Randomized controlled trials; 2. Evidence from at least one RCT; 3. Evidence from at least one controlled study without randomization; 4. Evidence from at least one other type of quasi-experimental study; 5. Evidence from non-experimental descriptive studies such as comparative studies, correlation studies, and case-controlled studies; 6. Evidence from expert committee reports or opinions or clinical experience of respected authorities, or both;
	References: This attribute refers to the references of the support provided.	Mandatory	Free entry text based.
	Comments: This attribute refers to the comments	Mandatory	Free entry text based.

Entity	Attribute	Optional?	Attribute Type
	that the developers provide on the support listed.		
	Time Period of Study: This attribute refers to the time period of the support and recommendation basis gathering.	Mandatory	Free entry text based (dates).
	Publication Date: This attribute refers to the date in which this guideline was published.	Mandatory	Free entry text based (dates).
	Revision Date: This attribute refers to the anticipated revision / update date.	Mandatory	Free entry text based (date).

6. Developer

The sixth entity refers to acknowledging and making accountable the developers of the guidelines. The credentials and history of the developer could potentially influence guideline usage.

The developers of guidelines and the users of guidelines could potentially be the same groups of people. It is important to distinguish the two for the taxonomy so that the user is aware of who the developer is. For example, a physician may create the guideline for the patient to use. Guidelines meant for patients and those for physicians may be written in different degrees of medical terminology. What a patient may be interested in knowing could be very different than what a physician would need to know. Health care professionals and associations who may do the research and present findings in specific clinical areas are classified here.

Table 7: Developer Entity

Entity	Attribute	Optional?	Attribute Type
Developer	Type: This attribute refers to the organization type of the developer.	Mandatory	Choice of the following; Drop down list with multiple choices. (National Guideline Clearinghouse, 1999) 1. Other 2. Academic Institution 3. Disease Specific Society 4. Federal Government Agency [US] 5. Hospital/Medical Center 6. International Agency 7. Managed Care Organization 8. Manufacturer 9. Medical Specialty Society 10. National Government Agency [Non US] 11. Nursing Home/Extended Care facility

Entity	Attribute	Optional?	Attribute Type
			12. Private for Profit Organization 13. Private non profit organization 14. Private non profit research organization 15. Professional Association 16. Public for profit organization 17. State/Local government agency [Non US] 18. State/Local government agency [US]
	Developer: This attribute refers to the identification of the developer.	Mandatory	Free entry text based.
	Funding Source: This attribute refers to the funding source for the developers of this guideline.	Mandatory	Free entry text based.
	Committee: This attribute refers to the committee member's names and designation.	Mandatory	Free entry text based.

7. Presentation

The seventh entity refers to the sensory manifestation of the information. (Starren, Johnson, 2000) There is currently research on different ways to represent and present guidelines so that they can be integrated into work flow (see Forms of Representation in the Result Sections). As guidelines become more and more specific to their presentation, it is important to distinguish them on this basis. One of the many desires of guidelines is that they are user friendly. Other forms of presentation other than the conventional text-based guideline could aid in this endeavour.

Table 8: Presentation Entity

Entity	Relationship	Attribute	Optional?	Attribute Type
Presentation	1:1 to the List entity.	List: (Starren, Johnson, 2000) This attribute refers to items, typically textual, arranged in a uni-dimensional sequence.	Optional	**See the List Entity for Details**
		Table: (Starren, Johnson, 2000) This attribute refers to the items arranged in an n-dimensional grid. Column and row location conveys information.	Optional	Option box: Yes/No choice.
	1:1 to the Graph	Graph:	Optional	**See the Graph

Entity	Relationship	Attribute	Optional?	Attribute Type
	entity.	(Starren, Johnson, 2000) This attribute refers to spatial arrangement of points, lines, and labels that convey information.		Entity for Details**
	1:1 to the Icon entity..	Icon: (Starren, Johnson, 2000) This attribute refers to small stylized pictorial symbols.	Optional	**See the Icon Entity for Details**
	1:1 to the Generated Text entity.	Generated Text: (Starren, Johnson, 2000) This attribute refers to the computerized creation of text from coded data.	Optional	**See the Generated Text Entity for Details**

8. List

The eight entity refers to items that are typically textual and arranged in a uni-dimensional sequence. (Starren, Johnson, 2000)

Table 9: List Entity

Entity	Attribute	Optional?	Attribute Type
List	Type: This attribute refers to the list type of the guideline presentation.	Mandatory	Choice of the following; Drop down list with multiple choices. (Starren, Johnson, 2000) 1. Simple List: all items at same logical level, sequence may convey information 2. Nested List: items may contain sublists with additional information.

9. Graph

The ninth entity refers to spatial arrangement of points, lines, and labels that convey information. (Starren, Johnson, 2000)

Table 10: Graph Entity

Entity	Attribute	Optional?	Attribute Type
Graph	Type: This attribute refers to the list type of the guideline presentation.	Mandatory	Choice of the following; Drop down list with multiple choices. (Starren, Johnson, 2000) 1. Simple Chart: Location of points and lines with respect to axes conveys information. 2. Simple Chart – Annotated Template: Labels and icons overlaid on schematic background graphic. Location on template conveys information. 3. Configural Chart: Creates a "shape." Explicit display of configural data relations through emergent features. 4. Configural Chart - Configural Icon: Alterations (shape, color, etc.) of icon convey information. 5. Graph Notation: Nodes connected by edges. Information conveyed by labels and by topology of connections. 6. Graph Notation – Annotated Graph: Information about nodes conveyed by adding icons or symbols to nodes.

10. Icon

The tenth entity refers to small stylized pictorial symbols. (Starren, Johnson, 2000)

Table 11: Icon Entity

Entity	Attribute	Optional?	Attribute Type
Icon	Type: This attribute refers to the Icon type of the guideline presentation.	Mandatory	Choice of the following; Drop down list with multiple choices. (Starren, Johnson, 2000) 1. Atomic Icon: Each icon has unique meaning independent of context 2. Atomic Icon – Annotated Template: Atomic_Icons overlaid on schematic background graphic. Location on template conveys information. 3. Atomic Icon – Configural Icon: Alterations (shape, color, etc) of icon convey information. 4. Atomic Icon – Annotated Graph: Information about nodes conveyed by adding icons or symbols to nodes. 5. Iconic Language: Visual languages where each sentence is a spatial arrangement of icons. 6. Iconic Language – Notational Text: Sentences contain icons, abbreviations and conventional text.

11. Generated Text

The eleventh entity refers to the computerized creation of text from coded data. (Starren, Johnson, 2000)

Table 12: Generated Text Entity

Entity	Attribute	Optional?	Attribute Type
Generated Text	Type: This attribute refers to the generated text type of the guideline presentation.	Mandatory	Choice of the following; Drop down list with multiple choices. (Starren, Johnson, 2000) 1. Full-Text Natural Language Generation: Generation of complete and "natural-sounding" sentences and paragraphs. 2. Notational Text: Sentences contain icons, abbreviations and conventional text.

Numerical Representation According to Figure 1

Figure 1 could potentially be numerically coded so that one could map an application problem, such as a clinical case, to the guideline taxonomy. With this feature, one would then have the ability to retrieve guideline(s) to apply to that case. This would further mean that the computer would "abstract" a clinical case with respect to the guideline taxonomy, and then retrieve guideline(s) that apply (with respect to some defined measure of similarity). This computer supported numerical representation would accomplish the difficult task of guarding a human user against thinking that he or she uses the latest guideline when in fact the guideline has been updated. The emphasis here would not be on creating a catch-all representations for guidelines on computers, but on mapping a problem case accurately enough to the purpose or capabilities of guidelines to find a match that can further be analyzed by a human. Please see Figure 2 for illustration.

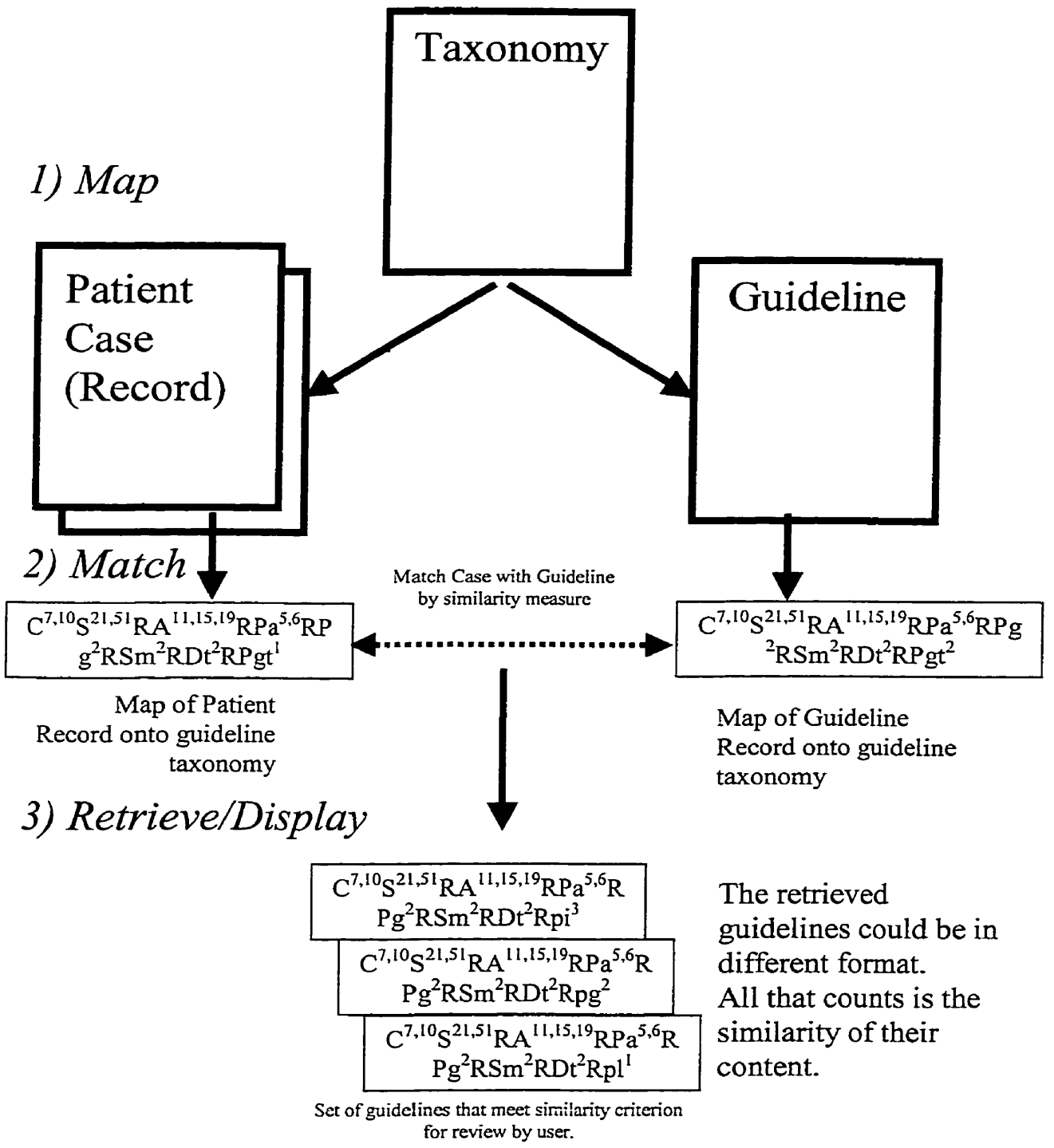

Figure 2: Guideline Mapping, Matching and Retrieval

Several attributes within the entities of Figure 1 are free text-based, others have specific choices that the user can select. These include the following:

Category – **C**ategory

Specialty – **S**pecialty

Recommendation – **A**udience

Recommendation – **P**opulation – **a**ge

Recommendation – **P**opulation – **g**ender

Recommendation – Guideline **S**upport – Review **m**ethodology

Recommendation – **D**eveloper – **t**ype

Recommendation – **P**resentation – **l**ist

Recommendation – **P**resentation – **t**able

Recommendation – **P**resentation – **g**raph

Recommendation – **P**resentation – **i**con

Recommendation – **P**resentation – **g**enerated **t**ext

The bold letters in this list can be used for alphanumeric representation of the guideline. Each of the above attributes has a number of specific choices. These choices have been numbered and can be found above within the "Description of the Framework." Table 13 condenses this information.

Table 13: Alphanumeric Representation of the Taxonomy

Entity Abbreviation	Numbered Choices
C	1-12
S	1-71
RA	1-27
RPa	1-9
RPg	1-4
RSm	1-6
RDt	1-18
RPl	1-2
RPt	If RPt is present in the coding then there is a table, if it is not then there is not a table.
RPg	1-6
RPi	1-6
RPgt	1-2

We can now use Table 13 to map a guideline to the taxonomy.

For example the alphanumeric code: $C^{7,10}S^{21,51}RA^{11,15,19}RPa^{5,6}RPg^{2}RSm^{2}RDt^{2}RPgt^{1}$

This code would translate into:

Table 14: Mapping Guideline to Taxonomy

Code	Translation
$C^{7,10}$	Category: Prevention and Screening
$S^{21,51}$	Specialty: Fetal and Maternal Medicine and Pediatric
$RA^{15,19,21}$	The Recommended audience for the guideline is: Patients, Physicians and Public Health Departments
$RPa^{5,6}$	The Recommended Population Age group is: Adolescent and Adults
RPg^{2}	The Recommended Population Gender that the guideline applies to is Female.
RSm^{2}	The Recommendation's support is from evidence of at least one RCT.
RDt^{2}	The organization type that developed this guideline is an Academic Institution.
$RPgt^{1}$	The presentation of the guideline is in the form of generated text (full-text natural language generation).

CHAPTER 5: DISCUSSION

This taxonomy was created based on relevant research in the field but independent of other initiatives. Literature searches one year ago did not reveal several state of the art projects such as the Guideline Elements Model (GEM). These new developments give great opportunity to assess the work presented here. A comparison will be made between this taxonomy for guidelines of healthcare and GEM. The authors of the GEM used XML (Extensible Markup Language) to represent their classification system. First a description of GEM will be presented. Secondly a description of XML in the context of a guideline will be described. Thirdly, similarities and differences between the two models will be discussed. Several other initiatives related to this field are also underway. Fourthly, a few of these initiatives will be presented. Ideas for improving the taxonomy based on the comparison to GEM and other projects will conclude this section.

Guideline Element Model Description

Shiffman, Karras, Agrawal, Chen, Marenco & Nath (2000) sought to develop a guideline document model that included a sufficiently broad set of concepts to be useful throughout the guideline life cycle. This work was supported by a grant from the National Library of Medicine and a grant from the National Institute of Standards and Advanced Technology. The authors of this work consist of a group of medical doctors with affiliations to Yale University, New Haven, Connecticut.

The Guideline Element Model (GEM) was constructed for the same reasons our taxonomy was created. However, particular emphasis was placed on developing a model to "better

represent the heterogeneous knowledge contained in practice guidelines." (Shiffman et al., 2000) Extensible Markup Language (XML) was used to represent the constructs of the framework. XML helped to make the GEM a flexible, comprehensible, shareable and reusable knowledge representation that can both be read by humans and processed by computers.

GEM was derived from extensive literature review using the Institute of Medicine's Guideline Appraisal Instrument for assessing clinical guidelines, the National Guideline Clearinghouse, and the augmented decision table model (concepts for implementing guidelines from a variety of sources, those that have multiple topics, and those using evidence based and consensus methodologies).

Extensible Markup Language (XML)

XML is a meta-language that is used to describe other languages. It is similar to HTML (hypertext markup language) in that one would code, markup or highlight the document for mapping and retrieval for use on the World Wide Web. However, HTML has a predefined markup system while XML does not. HTML has tag semantics that are fixed. XML provides the capability to define the tags and the structural relationships between them. (Walsh, 1998) Therefore, XML is flexible and can be customized to suit the application. (World Wide Web Consortium's XML Special Interest Group, 2000)

XML is a language used to markup structured information. Structured information includes both content and the role that the content plays. XML identifies the structure in documents. (Walsh, 1998)

Comparison between the Taxonomy and GEM

The taxonomy presented in this thesis has 35 attributes that one would use to help structure and define the guideline. The GEM's hierarchy include over 100 elements. Just by sheer number one could predict that the GEM's work is more comprehensive and inclusive than the work presented here.

The hierarchy in both the GEM and this taxonomy begins with the guideline itself. GEM breaks up the guideline into 9 equal entities (identity of the guideline, purpose, developer, intended audience, target population, method of development, testing, revision plan, and knowledge components). Generally speaking, all these areas are included in the "Recommendation" entity of the taxonomy proposed here. However, the GEM has included further attributes and constructs to help define and structure the guideline even more. This certainly makes the framework far more specific but it also loses its simplicity. A classification system is more likely to be used if it is easily remembered and has only 2-5 axes per level. GEM has greater than 10 axes at some levels. Balance in the design is another attribute of a good taxonomy. Out of the 9 equal entities, there appears to be balance among 8 entities. However, the knowledge component entity is extensive therefore not making this an overall balanced structure. This may prove to be a disadvantage for a computer to search through the document efficiently. In addition to the

greater specificity of the GEM and the overall structure, five other major differences exist with the taxonomy proposed here. Table 15 gives an overview of the similarities and differences between the GEM and the taxonomy. A discussion of the major differences follows.

Table 15: Comparison between GEM and the Proposed Taxonomy

All attributes that are specific to the Taxonomy Proposed here.	**All attributes that are common to both GEM and the Taxonomy Proposed here.**	**All attributes that are specific to GEM.**
	Category	
	Specialty	
Recommendation Entity: Resource Requirements	*Recommendation Entity:* Title Recommendation Adapted Reference Audience	*Recommendation:* Rationale Objective Available Options Implementation Strategy Exceptions Health Care Setting
Population Entity: Descriptions and Exceptions	*Population Entity:* Age Gender	
Guideline Support Entity: Comments	*Guideline Support Entity:* Review Methodology References (Source documents) Time Period of Study Publication Date Revision Date	*Method of Development:* Evidence Grading Specification and Quantification of Harm/Benefit Value Judgment Patient Preferences Cost Analysis
		Knowledge Component: Action, Logic, Reason for recommendation Strength of Recommendation

All attributes that are specific to the Taxonomy Proposed here.	**All attributes that are common to both GEM and the Taxonomy Proposed here.**	**All attributes that are specific to GEM.**
		Evidence Quality Cost Algorithm
		Testing: External Review Pilot Testing
		Revision: Scheduled Review
Presentation Entity: List Table Graph Icon Generated Text		*Format:* Paper Electronic

GEM (XML) Compared to the Proposed Taxonomy (Entity Relationship Model)

The most obvious discrepancy is that the taxonomy presented here is using an entity relationship model to provide framework for the taxonomy. GEM uses XML. The advantage of using the entity relationship model is that it can provide a form for a developer to fill in when designing a guideline. Although both frameworks provide information structural constructs to develop a quality guideline, the entity relationship model can go a step further by providing database designed form to enter the data. The entity relationship model can also be used on the World Wide Web. Currently the National Guideline Clearinghouse is using a database design. XML in essence takes a document and "tags" specific GEM designed details (title, user, purpose etc.). The document therefore remains intact. XML can then be used for searching and retrieving information from the document.

A trained XML individual would "markup" the guideline for the GEM model. There is a great possibility that many of these attributes will not be found within the document. In order to overcome this loss of information, a method of guideline authoring could be devised by the creators of GEM for the developer to use.

Method of Development Axis

In the taxonomy presented in this thesis, there are only a few attributes that relate to the methodology. They are found under the entity Guideline Support. The GEM has additional attributes such as cost analysis, benefits and harm, rating schemes and patient preferences.

Knowledge Component Axis

The knowledge components in GEM describe the actual recommendation in a lot more detail. The taxonomy presented in this paper identifies the recommendation but does not structure it. The GEM arranges the recommendation into action statements, certainty, strength, quality, value, sensitivity, specificity, predictive value, algorithms and many more other identifiable attributes. It appears that in the GEM, the recommendation is the central key area of attention. This is quite possibly the best way to encourage uptake of the guideline. As was stated in the Background section, one of the major desires of guidelines is to have accurate and comprehensive evidence that will prove there will be a change to outcome.

Presentation of Guideline

The taxonomy proposed here identifies in great detail different approaches for presenting guidelines. The advantage of this is so that a variety of users with differing technical expertise can identify and use guidelines that suit their environment. The GEM does not identify modes of guideline presentation. Since guidelines are shared in a variety of formats and are not as often found in paper text form, it is important to identify and compare the presentation and representation of the guideline. As health care institutions become more technologically advanced, other forms of presenting guidelines can make the guideline user-friendly.

Other Projects related to Clinical Practice Guidelines

During the latter part of the year 2000, several projects related to clinical practice guidelines emerged and were presented at the American Medical Informatics Association Conference. These projects will be described here to illustrate the growth and development in this field. HGML (hypertext guideline markup language) is similar to XML and can be used to translate existing documents into a machine-operable form. Three decision support systems, which integrate guidelines into the current computer operating system in the organization, show great promise. An updated version of the Guideline Interchange Format (GLIF3) has recently been published. And finally, a proposed expansion and reconstruction of the National Guideline Clearinghouse (NGC) is in progress.

Hypertext Guideline Markup Language (HGML)

Most existing guidelines are in text format. They do not contain algorithms or easy ways to incorporate the guideline into a database system. The advantage of maintaining the guideline in its original text format helps to keep the integrity of the guideline and avoid possible ambiguity and misinterpretation. HGML seeks to be XML compliant, however, it is more specific to guideline representation. As in XML, tags are identified throughout the document. (Hagerty, Pickens, Kulikowski, 2000) The difference here is that HGML has already specific tags identified such as recommendation and references. Therefore, HGML is an application of XML to guidelines.

Decision Support Systems

At the 2000 Annual American Medical Informatics Association (AMIA) conference, several papers were presented on decision support systems. The first decision support system helped to identify patients with community-acquired pneumonia who are eligible for a computerized pneumonia guideline. (Aronsky, Haug, 2000) The guideline was integrated into the diagnostic tracking system. Therefore, the patient statistics and laboratory results are used to help compute the probability of the patient having pneumonia based on twenty clinical variables. However, it still remains the clinician's responsibility to initiate the computerized evaluations and furthermore the clinician is still ultimately responsible for identifying the eligible patients. During this 9 week study, the probability of pneumonia was computed on 4,361 patients. At the 95% sensitivity level 894 patients were incorrectly classified as pneumonia patients and also 6 pneumonia patients were incorrectly identified as being pneumonia-free. (Aronsky, Haug, 2000) Despite the fact that this system is not perfect, it does help alert physicians on possible pneumonia cases. The next step would be to integrate computerized processes in providing care to those pneumonia patients based on a quality guideline for treatment.

IMM/Serve is a program that looks at a patient's vaccination history and projects recommendations of vaccinations that are due and produces a forecasting schedule. (Miller, Frawley, Sayward, 2000) This group of researchers faced several challenges when installing this program into 75 sites within the US Indian Health Services. The challenges included local customization demands due to practice preferences within the 75 sites, accommodation of different local hardware and software environments, and incorporation

of national recommendation changes. To solve some of these problems, the authors are looking at an alternative approach to dissemination, which would be to run IMM/Serve at a single central location and have all the sites access the central location remotely via the Internet. (Miller et al., 2000)

The final project involves computer-assisted instruction (CAI). CAI is thought to enhance learning by custom designing the information displayed based on the individual's needs. (Bell, Mangione, 2000) Bell and Mangione (2000) have constructed a web-based instruction system called SAGE (Self-study Acceleration with Graphic Evidence). SAGE was created to teach knowledge important for care after myocardial infarction. The program features a pre-test and an overview that coordinates studying resources for a set of learning objectives. After taking the pre-test the 79 resident users, on average, accessed less than half of the guideline passages and very little graphic evidence. The authors believe that further research is needed to learn how to motivate workers more through self-study and to integrate this information into clinical practice. (Bell, Mangione, 2000)

GLIF3

The Guideline Interchange Format (GLIF), a language for structured representation of guidelines, was introduced earlier in this thesis. It has gone through several changes in the past year. GLIF3 is the latest and newest version. GLIF3 now allows for guideline coding at three levels: a conceptual flowchart, a computable specification that can be verified for logical consistency and completeness, and a specification that can be integrated into informational systems. (Peleg, Boxwala, Ogunyemi, Zeng, Tu, Lacson, Bernstam, Mork,

Ohno-Machado, Shortliffe, Greenes, 2000) GLIF3 is to support guidelines that differ in four major ways: medical purposes, intended uses, intended users, and utilization sites. Additionally, the authors are creating macros within these specifications. These macros are similar to the attributes in the taxonomy presented in this thesis. However, there are two major disadvantages to GLIF3. One is that this method involves extensive expert encoding in a formal language. Second is that GLIF does not maintain the relationship of the procedural component to the original published document. (Hagerty, Pickens, Kulikowski, 2000)

National Guideline Clearinghouse

The National Guideline Clearinghouse (NGC) has been previously mentioned throughout this paper. The database went online to the public in January 1999 with over 260 guidelines. It has grown to contain over 700 guidelines as of March 2000. A group of researchers are currently analysing the infrastructure of NGC to improve upon it. They have found several new ways to improve the design. They have added several sub-axis: "usage mode" which refers to implementation, "encounters" which refers to when one would retrieve the information, "setting" which refers to clinical facility, "time frame" which refers to whether the condition is within emergency, acute or chronic purposes, "format" which refers to the guideline representation language, "distribution by originator" which refers to where the guideline is published, and "computability" which refers to implementation and retrieval. (Bernstam, Ash, Peleg, Tu, Boxwala, Mork, Shortliffe, Greenes, 2000) These are all significant proposed improvements to the current database. The most significant addition to NGC is the format. We call it "Presentation" in our

taxonomy. The National Guideline Clearinghouse is on its way to becoming a widely used system.

Improvements on Taxonomy

In retrospect and after careful consideration of all the new research in the field, there are several areas in which this taxonomy can be improved.

Entity Relationship Diagram

The entity relationship diagram was used to design this taxonomy. It was additionally thought to be more conducive to a database design. Perhaps either XML (used in GEM) or, HGML are more appropriate for guideline classification and retrieval. The reason being that by "tagging" the information in the guideline document, the original text is kept intact. This will help maintain the integrity and clarity of the document while allowing the user to specify specific areas in the guideline. Additionally, XML and HGML are conducive to a central web-based server.

Flexibility and Adaptation

Within the axes of this taxonomy it is possible to have many more attributes. The benefit of an entity relationship diagram is that it is fairly simple to add attributes. For instance, the Population Entity could actually have more attributes than just "age", "gender", and "description and exception." It could be possible to locally adapt this entity to contain more attributes such as "ethnicity" or even "blood-type." Only the main population dimensions of a medical population were included here. Other dimensions, such as

"ethnicity" were not found in any of the research. It is therefore recommended that these attributes be added after further findings or local adaptation.

Despite the ease of entering new attributes into this taxonomy, creating new entities could be more challenging. One would have to restructure the entire design based on relationships and cardinality between the entities.

Adapting guidelines to local circumstances and cases is just as important as adapting this taxonomy. Potentially, other cultures may either run their health care system differently or have differing requirements. As stated above, it is relatively easy to add new attributes to help define the entities to local specifications.

Language

One of the most significant obstacles within the guideline field is the lack of a standardized language. As was shown earlier, our taxonomy used the word "Presentation" while the National Guideline Clearinghouse used the word "Format" to describe an entity. Agreement and clear definitions of what is meant by the entities and attributes is fundamental for any taxonomy to function appropriately. A further suggestion would be to use SNOMED CT (Systematized NOmenclature of Human MEDicine for Clinical Terms) for defining the medical conditions. SNOMED RT (Systematized NOmenclature of Human MEDicine Reference Terminology) will facilitate the health care field's transition from paper records to electronic records. Perhaps many of the attributes in this taxonomy could fall under these two nomenclatures. It will create an international approach for

computerizing scientific terms that all health care professionals can use for management of patient records and medical communication. (SNOMED International Authority, 2000)

Evolution of the Taxonomy

Any model created for the purpose of classifying guidelines would require consistent monitoring, updating and reviewing. A well recognized group throughout the world could take on this challenge, retrieve feedback from several agencies world wide, and develop a comprehensive system. Several groups are working on this same project. If a collaborative approach took place, perhaps the classification system will be more widely used and accepted. The creator of the model would have to monitor the system, and update it every time a new guideline has been authored according to some standardized policy. The model would also have to be reviewed continually for new ways of enabling uptake and accessibility of the guidelines.

CHAPTER 6: SUMMARY AND CONCLUSIONS

There are many advantages and uses for practice guidelines. If we can ensure that the guidelines are of superior quality, using appropriate standards in methodology, and that they are current up-dated versions, there is then opportunity to use them as a shared resource both nationally and internationally. There are a number of difficulties in achieving this; however a taxonomy would enhance and support uptake by users of these guidelines. An appropriate taxonomy is a prerequisite to consistent development, representation and dissemination of guidelines, particularly when integrated with a computer based information systems. There are already multitudes of guidelines on the Internet. If the guidelines are organized according to the taxonomy, there will be greater ease for users to find and accept what they are looking for.

This thesis presented a taxonomy for guidelines of healthcare. It was created to assist and support guideline accessibility, authoring, development, dissemination and update. A recent surge in research related to this field has been reviewed and compared to the taxonomy proposed here.

The methods and procedures used in designing the taxonomy included extensive literature review from the Internet, library resources and ProGuide to help develop the principles that should, and should not be, represented in the taxonomy. The framework was formulated, using an Entity-Relationship model, and then underwent numerous revisions based on further literature review. A final analysis between the proposed taxonomy and other recent advancements in the field concluded the work.

The taxonomy features 35 attributes within 9 entities. Relationships and cardinality were identified between the entities. It is believed that the most significant demands for a quality guideline were acknowledged and integrated into this system.

When this project began, there were no other known published initiatives directed at systematizing and logically representing guidelines. This thesis identified the context of guidelines and specifically described a format for guideline representation. Developers can use the taxonomy to help them author quality guidelines. Disseminators can use the taxonomy to produce a web-based publication of the guidelines. And implementers can use the information to assist them in applying the recommendations to their specific health care setting.

The taxonomy presented here was compared to the Guideline Elements Model (GEM). Most of the attributes within the taxonomy can be found within GEM. However, the taxonomy presented here is much more specific regarding the presentation and format of the guideline. This information can prove to be especially useful to the implementers of guidelines. GEM excelled at the Knowledge Components and Method Development of the guideline. GEM appears to be a comprehensive effort at establishing a clear, flexible and shareable representation.

Other initiatives are underway in the field to collect and disseminate quality guidelines. However, it was noticed that these initiatives (National Guideline Clearinghouse and the Canadian Medical Association) do not have a specific format for authors to submit

guidelines. The taxonomy could lend itself to creating detailed inclusion criteria for guidelines based on the required attributes.

Several key areas for improving this taxonomy were identified in the thesis. These areas include using XML or HGML to structure the taxonomy instead of the Entity Relationship model; allowing for flexibility and adaptation of the taxonomy locally by adding new attributes; standardizing the language used within the taxonomy; and building in a way for the taxonomy to evolve and continually be updated and maintained.

The intention of the taxonomy was to meet the needs of all stakeholders involved in the guideline lifecycle. It is clear from the research, and the popularity of guidelines, that a taxonomy is a necessity. There are many projects underway to build this classification system. Perhaps by uniting these projects internationally, a structured, standardized representation can be constructed and shared throughout the world.

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