A Case Study of a New Era in Disease Classification: An Investigation of the Socio-technical Requirements for Inclusive Standardization Development

by

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B.Sc., University of Victoria, 2009
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ABSTRACT

Until recently, the development and maintenance of the standard international disease classification for diagnostic, epidemiological and health management purposes has been handled by a closed group of experts with little input from other members of the medical community, interested organizations, or patient groups. The eleventh revision of the World Health Organization's International Classification of Diseases (ICD-11) represents an attempt to involve a much broader stakeholder group in the process of redesigning a standardized classification. Our research is an exploratory case study of this revision effort. We examine the socio-technical ecosystem of the ICD-11 project and produce a set of five recommendations for developing inclusive standardization systems. These recommendations are supported by an analysis of two additional projects in the health information and informatics domain, as well as a varied collection of literature. Our first recommendation implores system designers to consider *technology-readiness and collaboration-readiness*. We also advocate for the support of *articulation and coordination work*, and address the need for a *distinct purpose* and *clearly defined process* surrounding any introduced technology. Finally, we shed light on the need for *incremental openness* when attempting to involve a wide audience of stakeholders in the development process.

Contents

List of Tables

List of Figures

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DEDICATION

To the unknown stakeholders in the ICD-11 revision effort.

Chapter 1

Introduction

The basis of modern human society hinges around classification, in ways both subtle and pronounced [13]. Academics are classified by their highest degree obtained, criminals by their offense, and children by their grade in school. The use of classification extends to fulfilling basic needs, such as medical treatment. Insurance companies may pay for therapeutic massage, but not for a spa treatment.

The eternal challenge of classification systems has been and continues to be centered around meeting the specific needs of many users, while remaining true to the purpose of classification: standardized referencing. In this thesis we focus on the problem of disease classification. Though conceived in its purest form over two hundred years ago, disease classification has yet to reach a satisfactory state. However, the introduction of new technological capabilities and interests in the last decade, such as electronic health records [12, 27, 46], varied health information systems [28], and online social networking, has sparked renewed hope for the future of classification in the health domain. A new push towards inclusive standardization, effectively an oxymoron to date, is underway in the form of the latest revision of the International Classification of Diseases: ICD-11. If successful, ICD-11 will represent a major milestone for disease classification and inclusive standardization development.

In this thesis, we present an exploratory case study of the ICD-11 project. While conducting this study, we provide feedback to ICD-11 project management and the ICD-11 software development team regarding how the tools and process as a whole could be improved. We also describe a set of emergent socio-tehnical requirements for successfully inclusive standardization systems, along with recommendations for meeting these requirements, which we believe will have broader impact on inclusive standardization development outside of the ICD-11 revision. The remainder of this

chapter will begin by setting the stage for this work in the context of the "classification challenge". We then provide a brief history of medical classification systems leading up to the current revision of the ICD. Encompassed in this history are the challenges met and intentions perceived along the way. Finally, we discuss our research objective, list our research questions, and outline the remainder of the thesis.

1.1 The Classification Challenge

It is well understood that the nature of any classification system is determined by the criteria used to develop it [35]. As such, a question that has been on the minds of public health officials, medical experts and practitioners for nearly two hundred years is: *how do we select classification criteria that will allow an international disease classification to serve the individual needs of a multitude of users, while providing a "common basis of classification for general statistical use"[26]?* This problem was well stated in 1856 by William Farr in the Sixteenth Annual Report of the Registrar General of England and Wales [9]:

> The medical practitioner may found his main division of diseases on their treatment as medical or surgical; the pathologist, on the nature of the morbid action or product; the anatomist or physiologist on the tissues and organs involved; the medical jurist on the *suddenness* or the *slowness* of the death; and all of these points well deserve attention in a statistical classification.

In a more recent examination of the impact of classification criteria, Bowker and Star highlight the marginalization capability of classification systems [13]:

> For any individual, group or situation, classifications and standards give advantage or they give suffering. Jobs are made and lost; some regions benefit at the expense of others.

Bringing together the needs of inclusiveness and standardization is not an easy task for any classification system. Technological advances in the last decade, however, have been the catalyst for earnest discussion toward realizing such a goal in the medical domain.

1.2 The Birth of Medical Classification

The nineteenth century was a time of discovery and examination in many domains. People came to understand that they were surrounded by "tiny, invisible things that have the power of life or death: microbes and bacteria" [13]. Communities and societies began to sort and classify nearly everything around them: "animals, human races, books, pharmaceutical products, taxes, jobs, and diseases" [13]. The early impact of globalization made the consideration of international public health an especially "urgent necessity" [13]. During this time, Farr laboured to improve international uniformity in medical statistics. He is quoted in 1839 as stating the following in the first Annual Report of the Registrar General of England and Wales [32]:

> The advantages of a uniform statistical nomenclature, however imperfect, are so obvious, that it is surprising no attention has been paid to its enforcement in Bills of Mortality. Each disease has, in many instances, been denoted by three or four terms, and each term has been applied to as many different diseases: vague, inconvenient names have been employed, or complications have been registered instead of primary diseases. The nomenclature is of as much importance in this department of inquiry as weights and measures in the physical sciences, and should be settled without delay.

Farr's perspective resonated so well at the first International Statistical Congress held in Brussels in 1853, that he and Marc D'Espine of Geneva were asked by the Congress to compile a Uniform Classification of Causes of Death [2]. In 1855, not having agreed on the basis of the classification, Farr and D'Espine submitted two separate lists, both employing different classification systems [2]. D'Espine's list "grouped causes according to their nature, that is, as gouty, herpetic, hematic, etc." [31], while Farr's list was arranged by "etiology [or causation] followed by anatomical site" [31]. These two lists were subsequently combined into a single list, a compromise between the two schemes, with Farr's anatomical principles strongly prevailing [31]. This combined list underwent a number of revisions but did not receive international acceptance [31]. It was, however, the catalyst that influenced the comprehensive development of what is today known as the International Classification of Diseases (ICD), a classification that has moved from "recording a single underlying cause of death to looking for complex causes" [13].

1.3 Development of the International Classification of Diseases (ICD): 1890 - 1990

In Vienna in 1891, nearly forty years after Farr and D'Espine's submissions, a committee was formed to further develop an International List of Causes of Death [2]. Interestingly, this committee was chaired by Jacques Bertillon, the grandson of the man who introduced the 1853 resolution requesting that Farr and D'Espine prepare a Uniform Classification of Causes of Death [2].

The Bertillon Classification of Causes of Death, as it was called, was based on the Classification of Causes of Death used by the City of Paris at the time [2]. The Paris Classification was first created in 1860 during a Congress meeting where a complete statistical layout for classifying hospital cases was adopted [31]. This layout was reportedly based on Farr's 1855 anatomical principles [31]. Since 1860, the Paris Classification was repeatedly revised and by the inception of the Bertillon Classification it represented an amalgamation of English, German, and Swiss classifications [2].

The Bertillon Classification received "general approval and was adopted by several countries, as well as by many cities" [2]. In 1898, during a meeting in Ottawa, Canada, the American Public Health Association recommended the adoption of the Bertillon Classification by Canada, Mexico, and the United States of America [2]. The Association also suggested that revision of the classification take place every ten years [2]. This revision schedule was subsequently adopted by the International Statistical Institute, and in 1900 the French Government held the first International Conference for the Revision of the Bertillon or International List of Causes of Death [2]. The first revision conference was attended by delegates from 26 countries [2]. The Government of France also assumed responsibility for organizing the subsequent four revision conferences in 1909, 1920, 1929, and 1938, respectively [2]. By the Fourth (1929) and Fifth (1938) revisions, the Health Organization of the League of Nations was actively involved due to its interest in vital statistics [2].

The Fifth revision was in use from 1939 to 1948 [31]. World War II spanned six of those years, concluding in 1945, and led to the demise of the League of Nations [31]. Following the war, the Interim Commission of the World Health Organization (WHO) "assumed the functions of the League of Nations on the decennial revisions of the International List" and undertook the preparatory work for ICD-6 [31].

What was lacking in the Fifth revision, and all previous revisions, was some way of classifying non-fatal illnesses. In the absence of such a classification, "many countries found it necessary to prepare their own lists [for statistics of illness]" [2]. In preparation for the Sixth revision, the Interim Commission of the WHO appointed an Expert Committee charged with the responsibility of establishing International Lists of *Morbidity*, to compliment the existing *mortality*-centric classification [2]. Incorporating the resulting work into the existing List of Causes of Death and including the information provided by the United States Committee on Joint Causes of Death, the Expert Committee produced the *International Classification of Diseases, Injuries, and Causes of Death* [2]. This document was circulated for comment and suggestion to national governments preparing morbidity and mortality statistics [2]. All feedback that "appeared to improve the utility and acceptability of the classification" was incorporated [2]. The resulting classification was adopted in 1948 at the International Conference for the Sixth Revision of the International Lists of Diseases and Causes of Death and endorsed at the First World Health Assembly in the same year [2].

Several noteworthy milestones were achieved during the development of the Sixth revision which marked a "new era in international vital and health statistics" [2]. In addition to ICD-6 receiving unprecedented international endorsement for its comprehensive morbidity and mortality classification, the International Conference for the Sixth Revision recommended the adoption of a "comprehensive programme of international cooperation in the field of vital and health statistics," including the establishment of national vital and health statistics committees to serve as a link between the national statistical institutions and the World Health Organization [2].

The Seventh and Eighth revisions "left unchanged the basic structure of the Classification and the general philosophy of classifying diseases" [2]. However, a number of countries had begun expanding ICD for use as a diagnostic index for hospital cases [31]. As such, the International Conference for the Seventh Revision recommended the inclusion of "a note explaining the principles that should be followed in expanding ICD for use as a diagnostic cross-index" [31].

By the time preparations were underway for the Ninth revision in the nineteen sixties, WHO Collaborating Centers had been established in London, Paris, Moscow, and Caracas to serve as "clearinghouses for problems in the use of ICD and for questions on application of the rules for coding the underlying cause of death, and to assist the WHO Secretariat in the development of ICD in a setting where data were available for testing revision proposals" [31].

In 1969, the WHO called a meeting of a Study Group on Classification of Diseases. This Study Group recommended that ICD-9 "serve the needs of hospitals for indexing diagnoses for the storage and retrieval of clinical records" [31]. After seeking the views of consultants, international organizations of medical specialists, heads of WHO Collaborating Centers for the Classification of Diseases, and various program units within WHO, the WHO Secretariat concluded that for practical use in hospitals and medical care programs, "the condition, not the etiologic agent, was of concern" [31]. As such, a system was introduced whereby a disease could be classified twice: once according to etiology and again according to manifestation [31]. This was referred to as the dagger and asterisk system [2].

Two supplementary classifications were also approved for the Ninth revision: *Impairments and Handicaps*, and *Procedures in Medicine* [2]. Additionally, three adaptations, designed for the use of specialists, were developed from the Ninth revision: *Oncology*, *Dentistry*, and *Ophthalmology* [31]. The Oncology adaptation became known as ICD-O and was "designed as an alternative to ICD-9 for use by Cancer centers" [31]. The Dentistry adaptation was produced by the responsible WHO unit, and the Ophthalmology adaptation was developed by the American Academy of Ophthalmology and Otolaryngology [31].

The first one hundred years of explicit effort to develop a functioning international system of disease classification was represented by a progression of intertwining dependencies on work that had previously been conducted or conceived. Moving into the new era of classification heralded by advances in technology requires a global trailblazing effort to discover new directions and options for disease classification.

1.4 ICD-10 and the Beginning of Broader Input

For the Sixth, Seventh, and Eighth revisions of the ICD, an Expert Committee of the WHO undertook most of the preparatory work required [31]. However, due to the "increasing complexity of ICD-9," the heads of the Collaborating Centers on Classification of Diseases assisted the WHO Secretariat in preparing revision proposals [31]. The distributed nature of collaboration around the ICD increased further during preparatory work for the Tenth revision: "draft proposals were twice circulated to member countries before the final draft was presented to the revision conference" [31].

The International Conference for the Tenth Revision of the ICD met in Geneva in September of 1989, and in May of 1990, ICD-10 was endorsed by the Forty-third

World Health Assembly [2]. By this time, the Classification was referred to as the *International Statistical Classification of Diseases and Related Health Problems*. The Tenth version of the Classification was translated into the official languages of the United Nations, and many countries also translated ICD-10 into their own official languages [31].

A new addition to the ICD in the Tenth revision was the introduction of alphanumeric codes, allowing for the use of more than double the number of codes that existed in ICD-9 [31]. Also introduced was the concept of a *Family of Classifications* to encompass the various modifications and adaptations [31]. Additionally, it was decided that an annual update process would be put in place between revisions [31]. This process would be managed by an Update and Revision Committee, comprised of "clinicians, nosologists, and users of statistics," as well as "a balance of mortality and morbidity expertise" [31].

Several attempts were made to include a broader audience of interested organizations, groups, and individuals in the update process of ICD-10. For example, the ICD-10 *Update Platform* was created by the WHO and made public in order to "allow users to propose changes to the current ICD and discuss other proposals"[1]. Some countries had their own mechanisms for soliciting input on the ICD-10 update process. Australia, for example, invited "public submissions for modifications to the International Statistical Classification of Diseases and Related Health Problems, Tenth Revision" through their National Casemix and Classification Centre website [8]. These attempts at broader inclusion were unfortunately lacking in momentum and limited in their success [P2, P3, P17][2].

1.5 ICD-11 and Belief in the Crowd

Currently underway is the Eleventh revision of the ICD. The WHO, still charged with the ownership and maintenance of the ICD, plans to open the ICD-11 revision process to all interested nations, organizations, groups, and individuals. As stated in the project documentation, the belief held by the WHO is that "the overall [ICD-11] revision process will enable participation from the global health community and multiple stakeholders" [4]. The intention is that the "process will be transparent to all users" [4].

[1] ICD-10 Update Platform: https://extranet.who.int/icdrevision

[2] These codes refer to participant pseudonyms that are presented in Chapter 2.

Until ICD-10, the official development and revision of the ICD was carried out solely by specific groups of experts, with little input from other members of the medical community, interested organizations, or patient groups [46]. As we mentioned previously, ICD-10's success at involving a larger stakeholder group was also limited. ICD-11 represents an effort to fully progress from a closed collaboration to the inclusion of a much broader participant group in the development of an international classification.

The ICD-11 revision process consists of two stages: the alpha phase and the beta phase [3]. The *alpha* phase is a collaboration among the many individuals involved with the World Health Organization's Family of International Classifications (WHO-FIC) and several select experts from around the world. This phase has included medical practitioners, researchers, classification specialists, statisticians, members of national agencies, WHO project management, and members of WHO Collaborating Centers, all participating on a volunteer basis. The *beta* phase was envisioned in order to move collaboration around the classification into the public arena. However, the details of this phase are still malleable. Stakeholders identified for this phase include but are not limited to government agencies (e.g., Welfare, Disease Control and Prevention, Health Information, Health Policy), special interest groups, insurance agencies, patient groups, drug companies, and individuals.

The progression from one phase to another has blurred to some degree and the transition has been delayed by one year. The needs of and prerequisites for the beta phase are not yet clearly defined, especially in terms of the software tool support that will be required to facilitate and triage the large amount of public input that is anticipated once the beta phase gains momentum. The collaborative tools envisioned for the beta phase at an abstract level are expected to include mechanisms for accepting and triaging feedback from "everybody who would like to contribute in the development of ICD-11" [3]. An effort resembling the ICD-11 beta phase has never been undertaken in the context of international disease classification. As such, it has implications for the future of disease classification and holds potential consequences in terms of stakeholder perception of the international revision effort.

1.6 Alpha Phase Collaborative Technology

In order to facilitate broad, asynchronous collaboration during the alpha phase of the revision process, the collaborative editing platform, *iCAT* [47] has been created

by the ICD-11 software development team. The software development team is small, consisting of about two to three individuals. It was developed from the web-based ontology editor, *WebProtégé*[3] [48, 47]. The majority of the editing and collaboration work of the alpha phase is meant to take place in the iCAT tool. The tool offers support for browsing and editing of ICD concepts, as well as for threaded notes and comments. Notes and comments may contain any HTML formatted text [46]. iCAT also keeps a history of changes that have occurred in the tool, and supports linkages to other terminologies, such as SNOMED[4] [40].

iCAT currently supports pre-configured access privileges that are set in the iCAT configuration file by the software development team [P18]. These access privileges are not organized by TAG, but simply by group (e.g., the "WHO" group). Providing comments for changes made in the tool is optional except in the case of moving or adding new concepts to the ICD-11 hierarchy [P18].

The development of iCAT has been an evolving process since the first prototype was presented at a project meeting in Geneva, Switzerland in 2009 [45]. Subsequent surveys of iCAT users uncovered several issues with the design of the tool that are being iteratively addressed up to the present in an unstructured manner [46]. A detailed overview of the iCAT tool will be provided in Chapter 3. Developing an understanding of the missing requirements for the iCAT tool is a major contribution of this work, as is exploring the requirements for potential beta phase technology. As stated previously, the process and tool requirements for the beta phase are not yet clearly defined [3]. The beta phase tools may incorporate social media elements, such as wikis and Twitter, and will need to account for the triaging of a large amount of information from various sources.

1.7 Research Objectives

This thesis is an exploratory case study of the ICD-11 revision effort, a project which represents a global turning point in the development of standardization systems. ICD-11 is not the only inclusive standardization system underway. It is, however, the largest and most dependent on technological novelties, such as online social networking. While conducting this study, we provide feedback to project management on how the process as a whole could be improved. We also describe a set of emergent

[3] http://protegewiki.stanford.edu/wiki/WebProtege
[4] http://www.ihtsdo.org/snomed-ct

socio-tehnical requirements for successfully inclusive standardization systems, along with recommendations for meeting these requirements, which we believe will have broader impact outside of the ICD-11 revision. To improve generalizability of the recommendations that emerge from this case study, we examine two smaller-scale standardization systems that also have a focus on community involvement: Orphanet [1] and the NCI Thesaurus [6, 24].

The processes, people, and technology involved in an inclusive standardization system form a complex *socio-technical* [15, 49] ecosystem, the needs and requirements for which need to be understood and managed. Our work looks to identify these requirements and make recommendations for how future standardization systems can best meet them. The lessons learned from the study of ICD-11 will influence the trajectory of inclusive standardization systems in health worldwide.

In order to meet our research objectives, we outline the following four research questions:

- RQ1: How is the introduction of collaborative technology into the development of a standardization system received by participants?
- RQ2: How is the idea of a fully inclusive standardization system received by participants?
- RQ3: What positive and/or negative impacts does the utilization of collaborative technology have on the inclusive nature of a standardization system?
  - Does it seem apparent that technology endows us with the power to overcome the classification challenge[5]?
- RQ4: What are the socio-technical requirements for a successful standardization system that leverages collaborative technology and maintains inclusiveness as a central priority?
  - What are the challenges involved in meeting these socio-technical requirements?

[5]The classification challenge refers to the challenge of selecting classification criteria that will allow a classification to serve the individual needs of a multitude of users, while providing a "common basis of classification for general statistical use" [26] (see section 1.1).

1.8 Thesis Outline

The remainder of this thesis is organized into five chapters. We first outline our research approach, followed by a discussion of our study context. We then provide a summary of our findings, followed by a discussion of the socio-technical recommendations that emerged. Finally, we conclude the thesis with limitations and future work.

Chapter 2

Research Design

This thesis investigates "a contemporary phenomenon within its real-life context" [50]. As such, our research objectives align neatly with case study research. The contemporary phenomenon under study is the renewed and revised attempt at inclusive standardization development within the health domain. The real-life context is the ICD-11 revision effort. Due to the unchartered territory that this research takes us into, we model our investigation around an *exploratory* case study [50]. An exploratory case study is used to build an understanding of a particular concept when there are few or no theories to describe it.

The aim of our data collection dictates our units of analysis: the ICD-11 case itself, and the embedded *socio-technical requirements*. We focus our inquiry on the needs and issues present in the ICD-11 case and not, for example, on the particular individuals involved. In order to understand the socio-technical requirements of the ICD-11 case, we leverage multiple sources of evidence: interviews, direct observation, archival records, documentation, and physical artifacts in the form of software tools. For the analysis of our data, we take a *descriptive* approach that we support with *grounded theory* methods [43, 23].

In the remainder of this chapter, we describe in detail the data that we collect in order to answer our research questions and meet our research objectives. We also describe the grounded theory analysis technique that we employ in our descriptive approach to analyzing the data collected, and provide our method for demonstrating credibility of our findings.

2.1 Data Collection

We conducted semi-structured interviews[1] with 16 participants of the ICD-11 revision process. These participants included an epidemiologist and biostatistician, a chiropractic physician, a medical geneticist, a specialist in bioethics and legal medicine, a health information management specialist, and a medical informatics specialist. The interview participants were sampled from various functional aspects of the project which are outlined in the Reporting of Findings section in this chapter and will be described in more detail in Chapter 3. We also moderated 2 focus groups[2] with a broader group of ICD-11 project participants which are described in Chapter 4.

We limit our data collection to the time period extending from the beginning of the second *iCAMP* event [45] and ending in December of 2011. There have been two iCAMP events to date, the first of which took place in September of 2009, and the second of which took place in September of 2010. The iCAMP events have been week-long conferences where ICD-11 participants meet in person at the WHO headquarters in Geneva, Switzerland to discuss the progress of the project and the plans for moving forward. Both of the focus groups we conducted took place during the second iCAMP event, as did the majority of the interviews. A few interviews were conducted via telephone after the second iCAMP event. Each interview was approximately 30 minutes in duration, and each focus group lasted approximately 90 minutes.

Additionally, we observed participants as they took part in discussion during several meetings on the progression of the revision process. A number of these meetings took place at the WHO headquarters in Geneva, Switzerland during the second iCAMP event. Other meetings took place via teleconferencing software.

For a historical perspective on the ICD, we were able to acquire approximately 5 years worth of archived proposal data from the ICD-10 Update Platform mentioned previously. We obtained this data, with permission from the WHO, in order to learn about the previously employed mechanisms for collaborative editing of the ICD. We were able to mine the data stored in the platform to understand the type of collaboration that has occurred on the platform and examine correlations between

[1] See Figures 2 and 4 in our Appendix for a list of interview questions and the interview consent form.

[2] See Figures 3 and 4 in our Appendix for a list of focus group questions and the focus group consent form.

variables such as the length of time a proposal is open for discussion and the outcome of that proposal.

Finally, we had access to extensive project documentation as well as current and prototyped software tools designed and built by the ICD-11 software development team based out of Stanford University. These additional resources provided context for the information discussed in our interviews and focus groups.

2.2 Data Analysis

We used *grounded theory* [43, 23] techniques to qualitatively analyze our interview and focus group data. Two researchers (the author of this work and a research assistant) individually performed an initial pass over the raw data, employing an *open coding* technique to label each utterance from the interviews and focus groups. A software tool called *Qualyzer*[3] was used to store and organize the codes[4]. Each researcher then collected together utterances with related labels, or *codes*, into *concepts*. Subsequently, the researchers revisited the data a second time through the lens of the main concepts that had emerged. Once the researchers had expanded on and enriched their main concepts by completing the second pass of the raw data, they linked and abstracted their concepts into *themes*. The two researchers then discussed and compared themes, reconciling any differences at this time. This discussion and comparison between the two researchers allowed us to build on and describe our themes in more depth. The themes are described in our findings as project needs and socio-technical requirements.

The interview and focus group data acted as our primary sources of evidence, since they proved to be the most useful and the richest sources of information on the ICD-11 revision effort. Project documentation, observation of project meetings, and exploration of the software tools involved added context and aided with triangulation of our findings.

With the data collected from the ICD-10 Update Platform, we were able to generate social network graphs to illustrate the relationships and degree of interconnectedness between people contributing on the platform. Additionally, we mined the platform data for information such as the number of distinct individuals who submitted proposals to the platform, as well as the percentage of proposals implemented,

[3]http://qualyzer.bitbucket.org/

[4]See Figure 1 in our Appendix for an example of our codes and how they are organized.

accepted, rejected and deleted, along with the respective average time proposals in each category were open for discussion. The analysis of this historical data was conducted to greater distinguish the novelty of the ICD-11 case.

2.3 Demonstrating Credibility of Findings

In order to demonstrate the legitimacy of our findings, we evaluate the internal and external *credibility* of our findings. We present the concept of credibility in detail in Chapter 6, along with an evaluative discussion of our research.

To support *internal* credibility, or contextual dependability, we perform member checking [18], a process that requires researchers to provide study participants with a summary of the research findings. The participants are requested to comment on how well the findings resonate with their experience. A summary of our research findings was emailed to all participants for whom we had contact information. The participant feedback from this stage will be described in Chapter 6.

The analysis of data from multiple sources of evidence (described above) within the ICD-11 revision project also increases the internal credibility of our research [50], as does the diversity of our participant selection.

To support *external* credibility, or generalizability of the recommendations that emerge from this case study, we preliminarily examined two additional projects, separate from ICD-11, that are also complex standardization systems within the health domain that have a focus on community involvement. The first of these projects is *Orphanet*, which specializes in rare diseases. The second project is the *NCI Thesaurus*, which is managed by the National Cancer Institute[5] (NCI) and contains vocabulary for Cancers and related diseases. We conducted semi-structured interviews with two participants from each of these additional projects. In the case of the Orphanet project, both participants were also involved in work on the rare diseases chapter of ICD-11. Interviews with participants from the additional projects were analyzed using the same grounded theory analysis technique that was described for the analysis of the ICD-11 interview and focus group data. However, one researcher, instead of two, analyzed the data obtained from the additional projects. A detailed description of the two additional projects is provided in Chapter 3.

[5]http://www.cancer.gov/

In Chapter 5, we use needed literature from several related domains to aid in the development of our socio-technical recommendations for inclusive standardization systems. Such supporting information from domains outside our own also increases the external credibility of our research.

2.4 Reporting of Findings

We describe our findings in anonymized form. Pseudonyms are assigned to each participant and a pseudonym reference is provided for all supporting evidence. For reference, *P1 through P3* are members of the Revision Steering Group (a governing body for the project to be described in Chapter 3) with *P1* also being a WHO representative; *P4 through P10* are Topic Advisory Group members (members of designated groups of specialists to be described in Chapter 3) with *P9 and P10* also being members of the *Orphanet* project; *P11 and P12* are classification specialists, and *P13 and P14* are WHO employees assigned to the ICD-11 project. *P15 and P16* are editors with the *NCI Thesaurus*, *P17* is the Australian National Representative for ICD-11, as well as an employee of the Australian National Casemix and Classification Centre, and *P18* is a member of the ICD-11 software development team. *F1* and *F2* refer to information or quotations recorded during our first and second focus groups, respectively. *GM* and *CM* refer to information or quotations recorded during general project meetings, and closed project meetings with members of the Revision Steering Group, respectively.

2.5 Chapter Summary

We have presented an exploratory case study methodology as our research approach, with the units of analysis being the ICD-11 case itself and the embedded socio-technical requirements of the case context. We use grounded theory methods in our descriptive approach to analyzing the data. Member checking and examination of data from two additional projects provide support for internal and external credibility in our research. In the next chapter, we describe the context and background of our study.

Chapter 3

Discovering the Study Context

In this chapter, we first present our findings regarding ICD-10 and its update process. A historical perspective on ICD-10 is important for understanding the motivation for transitioning to ICD-11 and a redesigned process. We then provide background on the ICD-11 socio-technical infrastructure, followed by a disclaimer about the internal politics of the large scale ICD-11 revision effort. We also introduce the Orphanet and NCI Thesaurus projects in some detail. Finally, we discuss some of the related work, reserving most related literature for inclusion in the discussion of our findings in Chapter 5.

3.1 Why Move Beyond the ICD-10 Model?

The changes to the International Classification of Diseases underway in the eleventh revision will "affect quite substantially statisticians and other health care professionals" [CM]. However, in the face of massive cost and training barriers to adoption [P1], there are tangible reasons for initiating a redesign of the ICD from version 10 to a more robust version 11: "ICD-10 is behind the medical sciences and it's not technology-ready" [P1]. A total of 4,317 new concepts need to be added to the classification [GM]. There are also the more abstract reasons for refreshing the design and development of the ICD which we mentioned previously, such as the desire for broader representation and input.

As alluded to in Chapter 1, we discovered through interviews with participants who had experience with the update process for ICD-10 that attempts to involve a broader stakeholder group in that initiative lacked widespread success [P2, P3, P17].

As such, we were interested to understand the reasons behind this lack of momentum. We examined the ICD-10 update process by exploring the data stored in the ICD-10 *Update Platform* mentioned in Chapter 1. The ICD-10 Update Platform was created by the WHO and made public in order to "allow users to propose changes to the current ICD and discuss other proposals"[1].

With permission from the WHO, we obtained approximately 5 years of data from the ICD-10 Update Platform from March of 2006, when the platform was created, until March of 2011. This data consisted of 795 *proposals* that were created by various individuals to suggest a change or modification to a particular section of ICD-10. A sample proposal is shown in Figure 3.1. Proposal attributes included the *originator, creation date, ICD section affected, description of proposed modification, date it was last updated, current state of the proposal (under moderation, open for discussion, undergoing closed discussion, implemented, accepted, deleted, rejected)*, and finally, if the proposal had been accepted or implemented, its *approval or implementation date*.

We were able to mine the proposal data for information, such as the average amount of time proposals listed under each state had been open, the number of distinct individuals contributing on the platform and the frequency of their activity. We also generated social network graphs using a tool called *Graphviz*[2] [21] by counting the number of times each pair of individuals contributed to the same proposal. We generated these graphs to illustrate the relationships and degree of interconnectedness between people contributing on the platform.

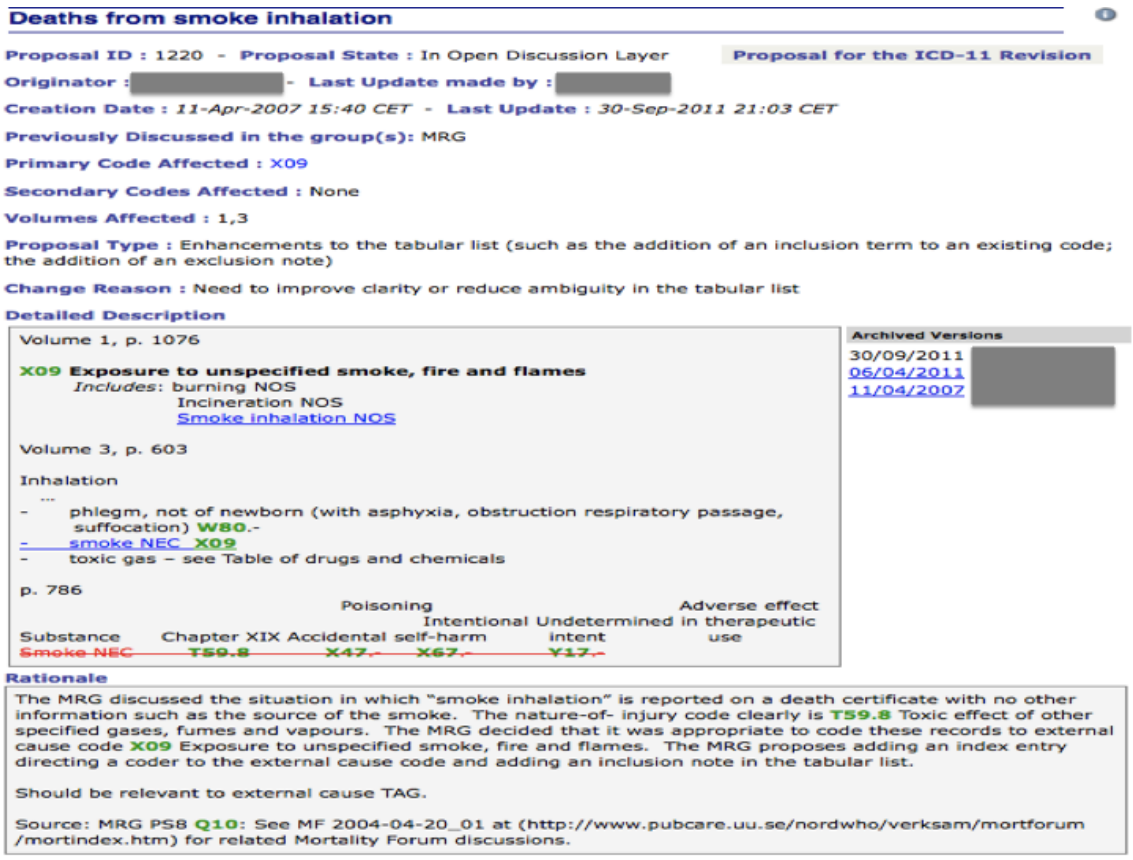
We found that only 69 distinct individuals submitted proposals to the platform in the 5 year span for which we have data. Of the 795 proposals submitted during this time, 70% were submitted by just 5 individuals. These numbers suggest that though the Update Platform was technically open to contribution from any interested individuals, a relatively small group of experts have generated the majority of activity on the platform. Evidence from the interviews we conducted supports this idea: "the [ICD-10 update] process is managed through teleconferences and small numbers of people who know each other well" [P3].

In total, 53% of proposals were accepted within the 5 year time range of our data sample. From the proposal data, we were able to determine the average length of time a proposal was open before being assigned to one of the implemented, accepted, deleted, or rejected states. We found that if a proposal was going to be accepted and

[1]ICD-10 Update Platform: https://extranet.who.int/icdrevision

[2]http://www.graphviz.org

implemented, a decision on that proposal was made relatively quickly, as compared to those proposals that were eventually deleted, or rejected. These numbers are shown in Table 3.1.



Deaths from smoke inhalation

Proposal ID : 1220 - **Proposal State :** In Open Discussion Layer — **Proposal for the ICD-11 Revision**

Originator : [redacted] - **Last Update made by :** [redacted]

Creation Date : *11-Apr-2007 15:40 CET* - **Last Update :** *30-Sep-2011 21:03 CET*

Previously Discussed in the group(s): MRG

Primary Code Affected : X09

Secondary Codes Affected : None

Volumes Affected : 1,3

Proposal Type : Enhancements to the tabular list (such as the addition of an inclusion term to an existing code; the addition of an exclusion note)

Change Reason : Need to improve clarity or reduce ambiguity in the tabular list

Detailed Description

Volume 1, p. 1076

X09 Exposure to unspecified smoke, fire and flames
Includes: burning NOS
Incineration NOS
Smoke inhalation NOS

Volume 3, p. 603

Inhalation
...
- phlegm, not of newborn (with asphyxia, obstruction respiratory passage, suffocation) **W80.-**
- smoke NEC **X09**
- toxic gas – see Table of drugs and chemicals

p. 786

Substance	Chapter XIX	Poisoning Accidental	Intentional self-harm	Undetermined intent	Adverse effect in therapeutic use
~~Smoke NEC~~	~~T59.8~~	~~X47.-~~	~~X67.-~~	~~Y17.-~~	

Archived Versions
30/09/2011
06/04/2011
11/04/2007
[redacted]

Rationale

The MRG discussed the situation in which "smoke inhalation" is reported on a death certificate with no other information such as the source of the smoke. The nature-of- injury code clearly is **T59.8** Toxic effect of other specified gases, fumes and vapours. The MRG decided that it was appropriate to code these records to external cause code **X09** Exposure to unspecified smoke, fire and flames. The MRG proposes adding an index entry directing a coder to the external cause code and adding an inclusion note in the tabular list.

Should be relevant to external cause TAG.

Source: MRG PS8 **Q10**: See MF 2004-04-20_01 at (http://www.pubcare.uu.se/nordwho/verksam/mortforum/mortindex.htm) for related Mortality Forum discussions.

Figure 3.1: A proposal sample from the ICD-10 Update Platform.

Proposal State	Number of Proposals	Mean Time Open (Years)	Standard Deviation (Years)
Implemented	3	0.48	0.15
Accepted	420	0.80	0.50
Deleted	59	2.54	1.10
Rejected	98	3.11	1.14

Table 3.1: This table shows the average (mean) time open for each proposal type on the ICD-10 Update Platform in the 5 year time span we examined.

All of these findings together suggest that a small and familiar group of experts submitting and discussing ICD-10 proposals amongst themselves results in decisions on proposals which are important to implement being made relatively quickly. However, the evidence gathered from our interviews with participants involved in the ICD-11 revision effort indicates that ICD-11 must be a broader classification with more content than ICD-10 [F2]. As such, the ICD-10 Update Platform is unlikely to be able to support the "profoundly different information model of ICD-11" [P2]. Additionally, although officially open to contribution from a wide audience, the ICD-10 update model does not actively support widespread collaboration and input.

3.2 ICD-11 Socio-technical Infrastructure

The socio-technical infrastructure of the ICD-11 revision effort encompasses the people, processes, and technology involved. In this section, we describe the different groups of participants that make up the project, and how they interact with the collaborative technologies they are and will be encouraged to use.

Figure 3.2 depicts the overall structure of the alpha phase of the ICD-11 revision, as well as the progression to the beta phase. Participants in the alpha phase process belong to one or more *Topic Advisory Groups* (TAGs), such as Dermatology, or Rare Diseases. TAGs are responsible for managing the ICD content for their area of specialization. The ICD-11 project plan states that "equitable geographic distribution, expertise, and active leadership are guiding principles for [TAG] membership" [3]. There may also be working groups that operate as subsets of a TAG. Additionally, *horizontal* TAGs function separately from the others and focus on specific use cases of the ICD, such as morbidity and mortality statistics. TAG Managing Editors (MEs) are responsible for leading their TAG and coordinating TAG members to "estab-

lish workgroups and partners to involve," and are expected to "advise in developing various drafts of topic segments" [4]. New drafts of topic segments are commonly referred to as *proposals*, as seen in the ICD-10 update model. The Revision Steering Group (RSG) serves as the planning and steering authority in the update and revision process [5] and is made up of the MEs from each TAG. The RSG, along with the Health Informatics and Modeling TAG (HIM-TAG), are responsible for defining the workflows for each stage in the ICD-11 revision process [46].

An ICD-11 *content model* was created in order to describe the attributes of diseases as well as provide links to external terminologies such as SNOMED CT [45]. The content model for each disease contains several attributes including the ICD-10 Code it refers to, the ICD Title, the Fully Specified Name, and a Short Definition. The iCAT tool reflects the content model structure and provides the ability to populate and edit content model attributes for each disease.

The iCAT tool exists in order to facilitate collaboration around the restructuring and revision of the ICD during the alpha phase, and to some extent the related communication, as depicted in Figure 3.2. As mentioned previously, the requirements for the iCAT tool, in terms of supporting the collaborative development process, have not yet been fully defined or met. Defining these socio-technical requirements is a major contribution of this work, as is exploring the requirements for potential beta phase technology. A step-by-step example of using the current version of the iCAT tool to add comments to the Endocrine, Nutritional and Metabolic Diseases category is shown in Figure 3.3. First the user selects the desired category from the ICD Categories and they are brought to the details screen for the selected category. Then the user selects the field they wish to comment on and enters their comment in the pop-up window provided.

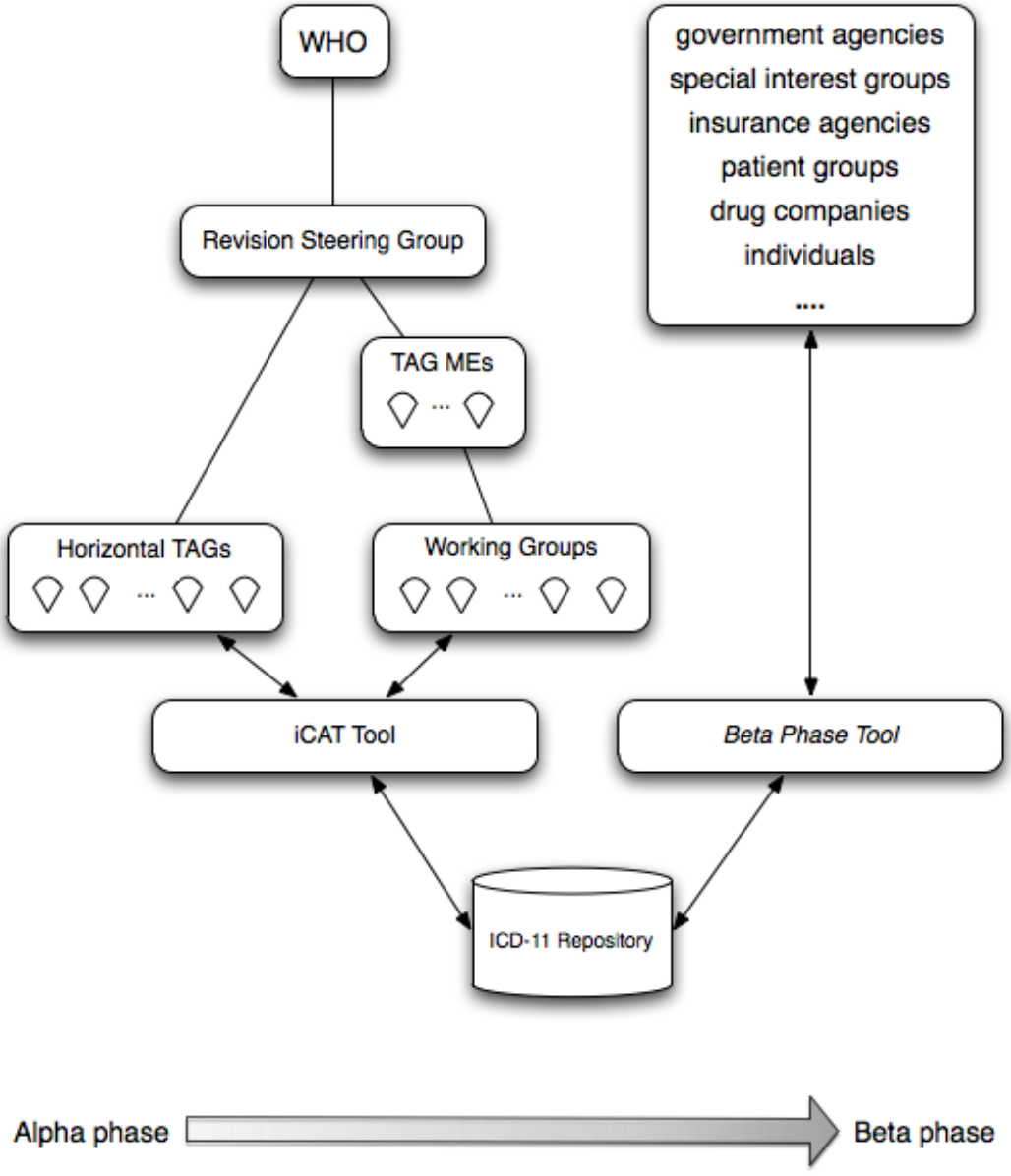


Figure 3.2: The current ICD-11 socio-technical infrastructure.

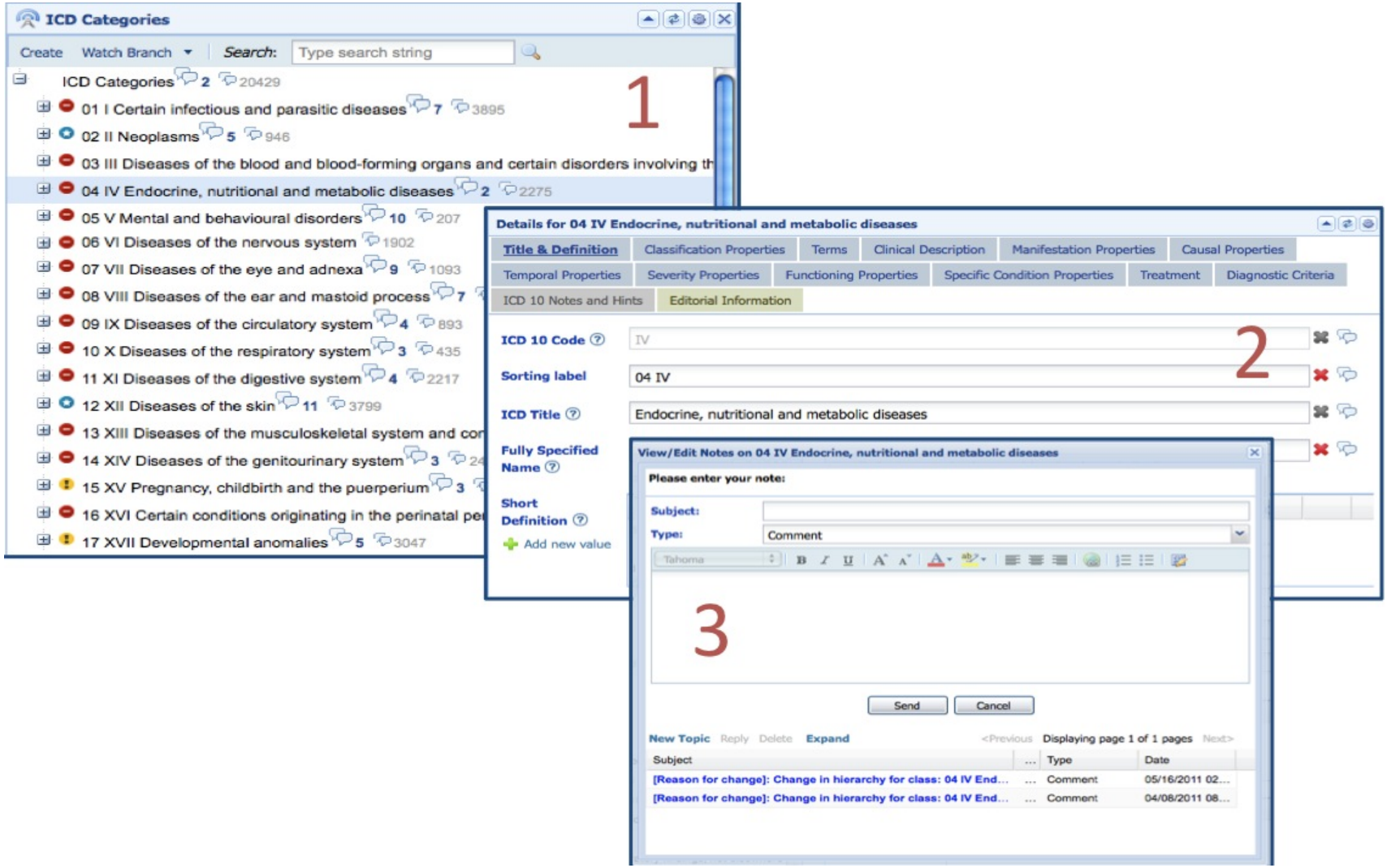


Figure 3.3: Adding a comment to a disease category in the iCAT tool.

3.3 Organizational Landscape

Conducting research on a project which has momentous international impact has been challenging. In a large-scale project such as this, it is easy to see how there may be politically-driven issues and conflict. As such, there has been a need to sift through superficial motivations and interactions in order to discover the core themes and needs of the ICD-11 project. We have attempted to avoid developing a politically-coloured lens when conducting this research. However, we take this opportunity to identify and separate some of the issues that impact the project, but are unrelated to the focus of this research. The ICD-11 project has seen slow progress, with deadlines pushed back significantly. The empirical evidence gathered for this research suggests that there may be political and organizational factors behind these delays.

ICD-11 is a project that has needed to gather support and funding from a variety of sources. In order to accomplish this, it has been necessary to accommodate the requirements and motivations of various resource providers: "to gather resources, you've got to meet the needs of many potential funders" [P3]. As such, the socio-technical requirements of the project have periodically been caught in a multi-way tug-of-war. Additionally, there is uncertainty over who should bear the responsibility of securing funding and to what degree. At the end of data collection for this research, it was not determined what percentage of the funding would be provided by the WHO and what percentage would be supplied by its partners in the project.

Some participants also perceived the project to be lacking in thorough organization: "the whole process has not been organized at all. So we are now paying for that" [P9]. This sentiment is in regards to project planning and scope, as well as the delegation and orchestration of work. Related to organization are the decision-making mechanisms of the project, which participants view as lacking: "there has never been a motion or a vote on a specific decision; we are going to have to make decisions" [GM].

Raising these points is not an attempt to undermine the progress or goals of the ICD-11 revision effort. However, as researchers we feel the need to include a certain amount of reflexivity regarding the context of this research.

3.4 The Orphanet and NCI Thesaurus Projects

To improve generalizability of the recommendations that emerge from this case study, we preliminarily examined two additional projects that are also complex standardization systems within the health domain that have a focus on community involvement. These two projects are separate from ICD-11 and have reached greater maturity, though they are smaller in scale. The first of these projects, *Orphanet*, specializes in rare diseases. The second project is the *NCI Thesaurus*, which contains vocabulary for Cancers and related diseases. The methods we employed for the analysis of these two projects are described in Chapter 2.

Orphanet refers to itself as "the reference portal for information on rare diseases and orphan drugs, for all audiences" [1]. It is an organization that advocates for improved care and treatment of patients with rare diseases. Orphanet consists of 35 paid staff members, 3 of which are assigned to the Rare Diseases chapter of the ICD-11 revision project [P10]. The remaining 32 people are distributed among a variety of projects: an encyclopedia of rare diseases, an inventory of orphan drugs, a directory of specialized services, and several other projects [1]. According to surveys conducted by Orphanet, half of its user base is made up of health care professionals, and one third is patients and their families [1]. Other users of Orphanet services include teachers, students, journalists, industry managers, and other interested individuals [1]. Orphanet issues a bi-weekly community newsletter, called *orphaNews*, that has a readership of approximately 20,000 patients, experts, and interested individuals [P9]. Orphanet also publishes an *internal* newsletter for disseminating information to Orphanet partners.

The *NCI Thesaurus* contains Cancer-related vocabulary for clinical care, basic and translational research, as well as public information and administrative activities. It provides definitions, synonyms, and other information for approximately 10,000 Cancers and related diseases, as well as for therapies and a broad range of other Cancer-related topics [6]. The NCI Thesaurus is published monthly by the NCI and is used in "a growing number of NCI and other systems" [6]. According to P15, there are a total of 12 to 15 dedicated editors working on the NCI Thesaurus on a full-time basis. These editors are paid employees of the NCI and are geographically distributed in five locations: one location at the NCI headquarters in Maryland, two locations in Virginia, one editor in California, and one editor in Michigan. For communication internally, the editors often use email or an internal chat client. However, the NCI

Thesaurus has developed an *application support group* that triages inquiries from external groups.

The Orphanet and NCI Thesaurus projects are significantly smaller in scale than the ICD-11 revision effort. They each focus on a single topic area, rather than an entire ontological classification, and they require fewer collaborators. However, full-time collaborators on both the Orphanet and NCI Thesaurus projects are paid employees, whereas ICD-11 participants are, for the most part, volunteers. By their differences from ICD-11, these additional projects enrich our findings. However, these projects contain much of the same context as the ICD-11 revision and are thus comparable. All three projects are community-minded, with facilities for broad inclusion of interested expert groups, and individuals. They are also standardization systems in the health domain under active curation and each employ varying forms of technological support. The NCI Thesaurus editors use a *Protégé*[3] tool [16] for collaborative editing [P15, P16], whereas members of the Orphanet project leverage varied tools, such as Excel and email [P9, P10]. As described previously, the ICD-11 project currently uses the iCAT tool, which is based on WebProtégé.

3.5 Related Literature

The research group at Stanford University that is responsible for ICD-11 software tool development has produced several papers reflecting on their work and the ICD-11 project as a whole. We discuss two of these papers in this section, as well as related work concerning the adoption of health information systems published by Ludwick *et al.* in 2009. The authors of the latter work discuss the socio-technical factors that impact the adoption process of health information systems.

Tudorache *et al.* published a paper in 2010 that discusses the use of semantic web technologies in the ICD-11 revision process [46]. Several of the authors had direct collaborative experience with the ICD-11 revision effort. The paper depicts the requirements for the latest version of the ICD as falling into two categories: 1) "developing a richer and formal representation for ICD-11 that will support the new goals of the classification," and 2) "designing and implementing an open social development environment to support the richer content acquisition" [46]. Tudorache *et al.* present the lack of a well defined collaboration workflow as a significant concern

[3] http://protege.stanford.edu

and an impediment to meeting requirements in both categories. The paper continues by describing the underlying information representation used for ICD-11 content and the design and use of the *iCAT* tool, which was developed by members of the authors' research group. The results of a web-based survey distributed to users of the tool uncovered concerns about tool complexity and a need for training in order to use it effectively. Part of this complexity may be due to the depth of information that requires representation, rather than solely a result of tool design.

Also in 2010, Tudorache *et al.* [45] published another paper that reported on the results of a more thorough evaluation of the iCAT tool. This evaluation took place during the first iCAMP event in Geneva, Switzerland, and consisted of a survey and a focus group. Eleven medical professionals and nine classification experts participated in the evaluation. The results indicated that iCAT was "a good initial step, but a lot of work needed to be done in terms of supporting an open collaborative process" [45].

In 2009, Ludwick *et al.* surveyed the existing literature on the adoption of health information systems. The motivation for this work was the need to address the "widening health care demand and supply gap," specifically in primary care [29]. According to the authors, health information systems are one solution to the pending problem of an overloaded health care system [29]. A total of "6 databases, 27 journal websites, 20 websites from grey[4] sources, 9 websites from medical colleges and professional associations as well as 22 government/commission websites were searched" in the preparation of their research [29]. The authors aggregated their findings into a concise diagram depicting the risk factors to successful adoption of a health information system in general practice (see Figure 3.4). The diagram includes four "insulating factors" or risk mitigation strategies, and the "fit factor," which the authors believe to be centred around the socio-technical interactions that occur during the adoption process. The authors define these interactions as the way in which the "technical features of a health information system interact with the social features of a health care work environment" [29]. According to the diagram below, the risk factors, such as patient safety, staff anxiety at using a new system, and time constraints, can be offset by the insulating factors of "sound project management, strong leadership, implementation of standardized terminologies and staff training" [29]. The recommendations found in this work have some applicability to the ICD-11 revision project at a high level.

[4]Grey literature refers to works that cannot be found easily through conventional channels, but are usually original and recent.

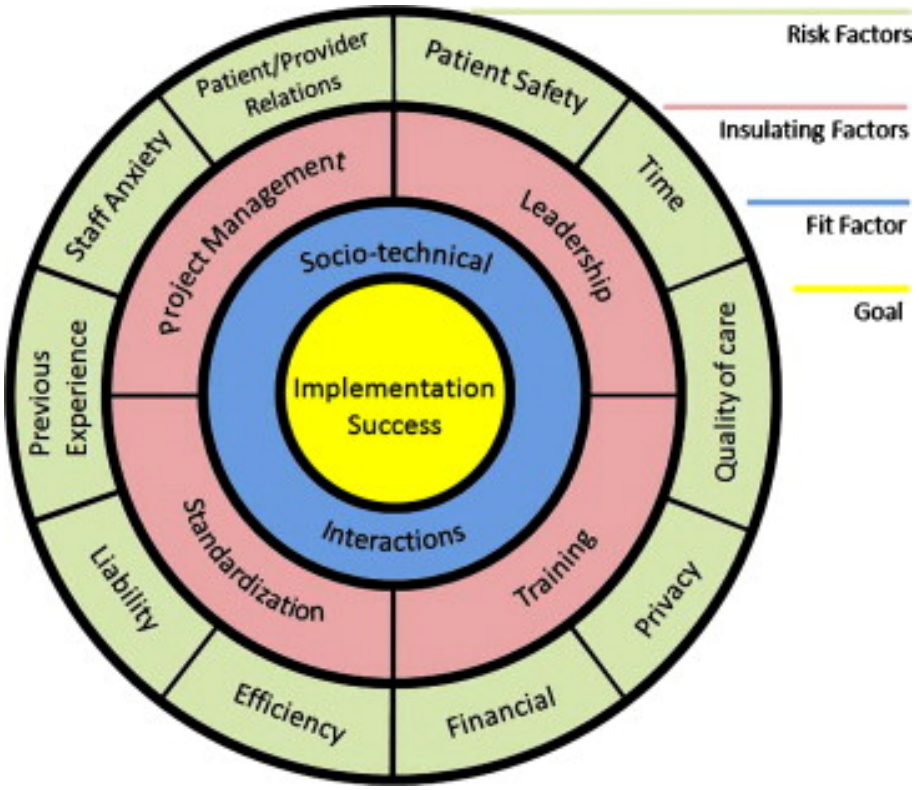


Figure 3.4: The factors for successful adoption of health information systems according to Ludwick *et al.* [29].

3.6 Chapter Summary

This chapter has provided the background for this research. We have set the stage by distinguishing ICD-11 from its predecessor, ICD-10, and delving deeper into the ICD-11 socio-technical infrastructure. We provided insight into a few *behind-the-scenes* factors that have some influence on the ICD-11 project, but are not relevant to this research. We also introduced in some detail the additional projects we examine in order to improve generalizability in this case study, and briefly noted some pertinent prior work.

Chapter 4

Findings and Themes

In this chapter, we present the findings that we uncovered through the use of grounded theory techniques within our exploratory case study. As mentioned previously, pseudonyms were assigned to each participant and a pseudonym reference is provided for all supporting evidence (see Chapter 2). We begin by providing an overview of the sentiments expressed in each of the focus groups, followed by a summary of interesting points from our interviews. Finally, we discuss nine findings which we have abstracted into four themes: *barriers to adopting new technology, participant interactions, resistance to openness*, and *process matters*.

Each of the two focus groups that we conducted during the second iCAMP[1] event in Geneva had a distinct central topic of discussion. For the first focus group, we centred the discussion around participant use and impressions of the collaborative editing software, iCAT, that has been created by the ICD-11 software development team. iCAT[2] is meant to facilitate broad, asynchronous collaboration among participants during the alpha phase of the revision process. In the second focus group, we asked participants to discuss their expectations for the beta phase regarding public feedback and supporting tools. A description of the ICD-11 socio-technical ecosystem as it extends into the beta phase is given in Chapter 3.

For the first focus group, 11 participants were in attendance. These participants included several TAG Managing Editors (also members of the Revision Steering Group[3]) and TAG members, as well as a classification specialist and a WHO representative. A sentiment echoed throughout this focus group was appreciation for the

[1]See Chapter 2 for details about the iCAMP events.
[2]iCAT is discussed in detail in Chapter 3.
[3]See Chapter 3 for a description of the Revision Steering Group.

improvement that had occurred in the usability of the iCAT software since its first prototype a year earlier, though several barriers still exist to fully integrating iCAT into the work of TAGs:

> [I] didnt appreciate the focus on alpha testing of iCAT last year; last year it was so clunky. iCAT had no guidelines about what to do in terms of retiring classes, etc., ...
>
> iCAT was not ready when I tried to use it [last year], so the strategy was to use Excel sheets, but I learned today that we can now do both structure and content at the same time [in iCAT].
>
> The tool [iCAT] is getting better, there are more features now.

In the second focus group there were 14 participants. These participants included several TAG Managing Editors (also members of the Revision Steering Group[4]) and TAG members, as well as two classification specialists, a member of the Health Informatics and Modeling TAG (HIM-TAG),[5] a member of the ICD-11 software development team, and a WHO representative. A large amount of dissension was witnessed in this focus group regarding the expectations for work achieved by the time the beta phase gets underway, the appropriate format for accepting feedback during the beta phase, and the role of TAGs once a broader audience becomes involved:

> If we havent finished alpha phase peer review properly, then we should delay beta phase.
>
> We won't have the content - that's idealistic!
>
> Should we have a tool for internal use or a tool that can be accessed at different levels by anyone?
>
> We need to remember the purpose of this [beta] platform: to allow anyone to form proposals for revision ... At what granularity do we want to consider this?

[4]See Chapter 3 for a description of the Revision Steering Group.
[5]See Chapter 3 for a description of the HIM-TAG.

During participant interviews, we achieved a sense of the distinct roles and experiences of each TAG. For example, members of the Functioning TAG, responsible for aspects of health and disability, have felt a sense of halting progress due to their close integration with all other TAGs:

> From when they constituted our TAG to when we started to be at the point where there was substantive work to be done, [there was] a lag. So now is the time when things are starting to happen. But meanwhile, the other TAGs have met and they've started to use the iCAT as an authoring tool, and there's something in there. But in the meantime, [our TAG doesn't] have a purpose yet. [P5]

Members of the Rare Diseases TAG began work on their ICD-11 chapter long before most other TAGs. As a result, they feel stalled and frustrated with the slow progress of the overall classification:

> We started more than 3 years ago when there was almost no other TAGs designated or starting to work . . . We have excellent relationships with the more active TAGs because we exchange by mail on detailed points and we ask each other who does what, but contacts are very informal and not organized at all as a communication process. [P10]

Our interviews with the NCI Thesaurus editors revealed the flexible use of several communication mediums internally, as well as a dedicated interface for interaction with external groups:

> [We use our] Protégé tool's chat function, email, and phone [to communicate among editors] . . . [We also receive] input from groups that work with common data elements; if concepts are missing, the groups will send an email to NCI Thesaurus that goes through the *application support group* so that there is a record of that request or interaction. [P15]

Through the in-depth analysis of our data, we uncovered nine findings which we abstracted into four themes: *barriers to adopting new technology, participant interactions, resistance to openness*, and *process matters*. We list these themes and the associated findings in Table 4.1 below and describe them in the following sections.

Theme	Associated Findings
Barriers to Adopting New Technology	Organizational Culture Lack of Distinct Purpose Need for Extensive Training
Participant Interactions	Coordination and Awareness Collaboration and Conflict Between Groups
Resistance to Openness	Phased Inclusion Roles and Access Privileges Desire for Ownership over a Stable Product
Process Matters	Need for a Process

Table 4.1: This table shows each of the four themes and the associated findings.

4.1 Barriers to Adopting New Technology

Three findings that emerged from the analysis of our data fall under the theme of "barriers to adopting new technology". The organizational culture of the ICD-11 revision may be an impediment to adoption due to entrenched work practices. Lack of communication regarding the necessity of a new technology may also result in limited adoption. Finally, the training barrier for new technology may be high, especially if the organizational culture resists change, or if the intended users have little experience with technological tools.

4.1.1 Organizational Culture

The adoption of new technology in the context of ICD-11 has been confronted with a well-established organizational culture. Medical "experts have little time and like to focus on what they know" [P9]. As a result, the initial idea of centralizing collaboration efforts using the iCAT tool proved to be difficult to implement in practice: there is a "push against technology; it needs to fit with people's culture" [P9].

At the beginning of the adoption process, many people contributing to ICD-11 were not willing to learn how to use the iCAT tool, rather preferring to stick with tools of widespread use: "you can imagine for people who are used mainly to only email or Internet search, how this is going to be complex and an unfeasible enterprise" [P5]. In other words, "everyone has their own particular format" [F1]. As such, there is a need to articulate work [22] among the different groups and work practices: "a proposal comes in, we give feedback to the TAG that proposed, then they get scared, then we talk, then they agree there is a way to use [iCAT]" [P12].

Within the Orphanet project, similarly entrenched work practices were encountered: "we make a draft which is done in Excel spreadsheets and pdf documents and we just send it by mail. We don't have a collaborative platform to discuss with experts" [P10].

In addition to well established work practices, there is the issue of effort versus gain: "we're all volunteers; if iCAT is easy to use, I'll use it, if not, I'll do everything offline" [F1].

4.1.2 Lack of Distinct Purpose

It has been difficult for project management to convince participants to adapt their work practices to new technology, partly due to a lack of communication regarding the advantages of that adaptation: "whatever iCAT will do, it has to be clear what is the use for it" [P5]. There is clearly confusion around the aims of the new technology being introduced: "until you've decided what the decision rules [for using iCAT] are and articulated them clearly I'm not willing to deal with it" [F1].

4.1.3 Need for Extensive Training

Not surprisingly, training is an essential part of the process of introducing new technology in this setting. Although there has been little training infrastructure developed, a few iCAT training sessions offered during a week-long project meeting in Geneva, Switzerland had a significant impact: "without the iCAT training I wouldn't be able to cope" [P4]. The introduction of the iCAT technology was overwhelming for many people from a usability perspective: "we need to make sure people don't get left behind in terms of understanding [how to use the tool]" [GM].

One participant suggested that the adoption of iCAT should have followed a more gradual process: "[it] would have started smaller, with training sessions on basic concepts ... would have been faster, more effective in the long run" [P9]. However, extensive resources may be required to bring all participants up to speed on the new technology: "[some people] thought you could teach someone to use iCAT in a short period of time, but [they] now realize you can't" [P11]. One participant indicated that working with others helped him to learn the new technology: "[it's] helpful to work together with other people on iCAT to learn" [P12].

The WHO has begun to acknowledge the need for training support by developing training materials, such as step-by-step instructional videos for using the iCAT software [GM].

4.2 Participant Interactions

The second theme that emerged from our findings relates to the interaction of participants within the ICD-11 revision effort. The coordination and awareness that occurs within Topic Advisory Groups became a central finding, as did the concept of cross-

TAG collaboration and conflict. Support for interaction between and among distinct groups within the development of an inclusive standardization system is crucial.

4.2.1 Coordination and Awareness

Coordinating work among TAG members during the alpha phase of ICD-11 proved to be a serious issue. The distributed nature of the work undertaken in the ICD-11 revision requires people to be aware of the activities of others [20]. For instance, P13 revealed a need to know of "people working on the same [ICD] code in the same week". Also, with numerous editors working on the same classification from different parts of the world, there was a need for better informal awareness [25], i.e., a general sense of who is around, what they are doing, and what they are going to do: "we felt if nothing was there, no one was going to do anything" [P12]. Interestingly, as the alpha phase progressed, TAG members were still using informal methods to get their work done, even with increased adoption of the iCAT tool: "[we] discussed any controversy with team members outside of the tool" [P13].

Editors for the NCI Thesaurus also need to manage the challenges of coordination and awareness within their work. They do so by using a variety of communication channels, such as email, phone, and web meetings to coordinate their activities [P16]. Additionally, all changes made to the Thesaurus are brought together at "weekly and monthly intervals" [P16] and any discrepancies are resolved at these times.

The Orphanet project utilizes internal channels for maintaining awareness within the organization. An internal newsletter allows communication "with all the Orphanet partners in order that they know what is going on" [P10].

4.2.2 Collaboration and Conflict Between Groups

Although there seemed to be no formal mechanisms for facilitating communication between TAGs in the ICD-11 revision effort, collaboration and conflict did occur at the TAG level regarding ICD content: "negotiations occur between TAG chairs, proposals are put up, then ready for reviewers" [P6]. Interestingly, *conflict* between TAGs seemed to occur through the introduced technology: "...one TAG will change [the content] one way [in iCAT] and then another TAG will change it back, or change it another way" [P2]. One participant suggested the development and use of a formal proposal-based mechanism to mediate these conflicts: "all changes would be made

as proposals and those proposals would then be compared to each other to form an opinion and then and only then would a change be made to the current version" [P2].

Separate from conflict, *collaboration* seemed to readily occur outside of the new technology: "[we are] working with lots of people and you have so many things to do and you have a tendency to just write on a paper, then you have to put everything together and put it in the [iCAT] tool" [P12]. In some cases, cross-TAG collaboration also occurred outside of the organized *processes*: "[we] might have a separate discussion with TAGs without telling WHO" [P9]. This evidence, as well as a few points mentioned earlier in our findings, suggests that Topic Advisory Groups may be *collaboration-ready*, but not necessarily *technology-ready* [33]. These are topics that we will discuss further in Chapter 5. Additionally, the types of cross-TAG collaboration and conflict observed may reflect a lack of fit between the current processes and tools employed, and the socio-technical needs of the revision effort.

Recent efforts to support cross-TAG communication have been made by the WHO in the form of attempts to organize *TAG2TAG* meetings, monthly teleconferences with members of each TAG [P1]. However, not all TAGs have begun participating in these meetings [P1].

The Orphanet organization has branches all over the world [1]. As such, there is a need to facilitate and orchestrate collaboration among its branches, similar to the need for communication and collaboration between TAGs in the ICD-11 revision effort. In order to manage this collaboration, the Orphanet organization is structured into national teams that are responsible for collecting information about clinical services, research activity and patient organizations at the country level [1]. One team, currently the France national team, is also designated as the coordination team and is responsible for coordinating the national team efforts and implementing quality control [1].

4.3 Resistance to Openness

Our findings indicate that the idea of opening ICD-11 to broad public scrutiny and comment during the beta phase is at this stage too large of a leap for the majority of experts currently involved in the project: "at this point, only the Collaborating Centres, scientific societies and selected groups should be invited to make suggestions, then that would have to be filtered and selected properly through an open process" [P8]. The resistance to sudden and broad openness is representative of the general

sentiment among participants and is related to two additional findings: roles and access privileges, and the desire for ownership over a stable product. We discuss each of these findings below.

4.3.1 Phased Inclusion

One participant expressed his belief that the original project plan for the beta phase had been focused at a different target than is now being realized: "the idea that seemed to take hold later, which is not what we had in mind, of having Joe public or anybody that was interested play a major role in this process was a distortion ... I've no objection to using social networking machinery, but we weren't trying to turn this into a populous Facebook kind of thing ... but rather people would have pride that their very specialized knowledge and ideas would materially influence and shape the representation of that content in the global authority representation of biology and medicine" [P2].

The overwhelming feeling regarding public involvement, however, is that a phased approach should be taken: "the idea is that the previous revisions were made only by the WHO Collaborating Centers, so to extend outside this network is fine, but you must extend to scientific societies, to some very precise organizations" [P7]. P7 also condoned the involvement of user associations and patient groups to some degree, but stated that "to involve individual members of the public is not realistic for the beta phase".

Some TAGs have already planned for an incremental expansion of collaboration by keeping track of the patient groups that are interested in contributing: "we have received many emails from patient organizations saying that they want to be involved in the revision ... so we keep these emails in a book and we will of course send chapters to them for their specialty when they are ready" [P9].

4.3.2 Roles and Access Privileges

Some participants indicated that if the leap to openness were to be made in one jump, there should at least be a "hierarchy of participants" [P2]: "roles are important and we have to define them" [F2]. There may be a need to know "who's commenting" and what their background is [GM].

There is also a common fear among experts involved in the alpha phase that "half baked" [P6] proposals will be revealed to the public, affecting a loss of credibility

and soliciting unnecessary feedback. One participant explained his view that there should be "different layers of commenting [and access] - one level where anyone could come and lobby that certain conditions should not be there, and one "expert level" for proposals that are not yet ready for public view [P3]. Similarly, another participant described his vision of a "web of authority with different roles and different permissions assigned to each of those roles" [P2].

4.3.3 Desire for Ownership over a Stable Product

Related to the idea of access privileges is the need for stability: "for this type of highly technical process, you can consult [the public], but not on the process itself, or on the structure" [P9]. In other words, the classification needs to be in a stable state before input from the public can be handled in a productive way: "at least the major flaws and weaknesses of the proposed product will have been addressed" [P8]. This stance was supported by another participant who stated that "at this stage it is not really the whole public interacting with the [classification] because there are too many issues internal to ICD-11 which need to be [solved]" [P5]. One TAG Managing Editor who has already begun to work with patient organizations indicated that individuals "want to see their disease in the right place," but commented further that it is unlikely they will suggest alterations to the overall structure [P9].

4.4 Process Matters

During our research, we discovered that tool requirements were not the only factor in the success of an inclusive standardization system. As discussed earlier, it is the socio-technical requirements that matter, including the process that surrounds the use of a tool. As such, this fourth theme encompasses the finding that there is a need for more than a tool.

4.4.1 Need for a Process

The ICD-11 revision project has created an ever-changing environment in terms of both process and tool support: the "tool and process [development] of the revision are on going at the same time" [F1]. Some participants have found this lack of structure frustrating: "you must first define the logic you are going to follow and then you

choose the software and unfortunately that was not done in the right timing" [P7]. Other participants considered the changing environment to be an unavoidable aspect of the evolution of a project with limited resources: "what we've got is a very small team of people working with very few resources and we just don't have the time to sit down and think all these things through in a logical way" [P3]. In either case, it is clear that the socio-technical needs of the ICD-11 revision effort cannot be met with a tool alone: "there is a misconception that having a good tool will solve the problem" [P9]. At some point, "the technology and process need to meet to produce an informatics product" [F2].

4.5 Chapter Summary

This chapter has summarized the four themes that encapsulate our nine findings: *barriers to adopting new technology, participant interactions, resistance to openness*, and *process matters*. In the next chapter, we extrapolate from these themes to develop a set of socio-technical requirements for inclusive standardization systems, along with recommendations for meeting these requirements.

Chapter 5

Discussion and Application of the Findings

Technology brings about many new automated and distributed possibilities for information sharing and collaboration. However, without a clear idea of how to best leverage technology in a given context, it can create more havoc than prosperity. The experts involved with the ICD-11 revision effort are in the midst of tackling the centuries-old classification challenge with technology as their new aid. Their mission is to meet the specific needs of an unprecedented number of users, while holding true to the purpose of classification: standardized referencing. It is not yet apparent whether they will in fact succeed. It may take many similar attempts in the context of this or other classifications before we will know. However, we have gained several guiding gems in the process of this exploratory case study. In this chapter, we address each of our first three research questions in the context of our findings. We then provide a set of five recommendations for meeting the socio-technical requirements of an inclusive standardization system, based on our exploratory case study of the ICD-11 revision. Additionally, we think forward to the beta phase explicitly, considering what advice might be taken from previous literature. Finally, we discuss the practical implications and credibility of our findings.

RQ1: How is the introduction of collaborative technology into the development of a standardization system received by participants? The introduction of collaborative technology into the classification development process has been received with trepidation by ICD-11 participants. This is partly due to an existing organizational culture among participants that resists change, and partly due to the way in which the technology was designed and introduced. The intended work process surrounding

the technology is not yet clearly defined, thus appearing disjoint from the technology and reducing the technology's effectiveness. The lack of clearly defined uses and benefits of the technology also contributed to its less than enthusiastic reception among participants.

RQ2: How is the idea of a fully inclusive standardization system received by participants? The idea of a fully inclusive standardization system met with varying levels of concern from ICD-11 participants. The issues raised related to stability of the classification and ownership over topic areas, as well as roles and access privileges. The idea of a phased approach to inclusion, progressing from WHO Collaborating Centres to external expert groups and finally on to patient organizations and the general public, seemed to pacify the uneasiness around the topic of inclusion. Most participants expressed an interest in following through with an extensively collaborative process and the use of technological tools if several significant socio-technical issues are addressed. We outline these issues in the next section when we introduce our five recommendations.

RQ3: What positive and/or negative impacts does the utilization of collaborative technology have on the inclusive nature of a standardization system? Does it seem apparent that technology endows us with the power to overcome the classification challenge? Our findings suggest that the utilization of a technological tool carries little weight without a sound socio-technical system surrounding it, including an appropriate process and workflow. Although carrying the potential to open up new opportunities to meet the classification challenge, technology offers limited assistance without a deep understanding of the socio-technical requirements of the context to which the technology is being introduced. In the remainder of this discussion we describe the socio-technical requirements and associated recommendations that emerged from our findings for producing a successful standardization system that leverages collaborative technology and maintains inclusiveness as a central priority.

5.1 Socio-technical Requirements and Recommendations

RQ4: What are the socio-technical requirements for a successful standardization system that leverages collaborative technology and maintains inclusiveness as a central priority? What are the challenges involved in meeting these socio-technical requirements? In order to address our fourth research question, we present a set of five

socio-technical recommendations (see Figures 5.2, 5.3, and 5.4). These recommendations were derived by the process of abstracting our findings into themes, examining the challenges within these themes, and defining the socio-technical requirements that address these challenges. We also discuss the challenges involved in meeting these socio-technical requirements. Our recommendations incorporate related literature and examples from the Orphanet and NCI Thesaurus projects which have similar objectives to ICD-11. This inductive process is depicted in Figure 5.1.

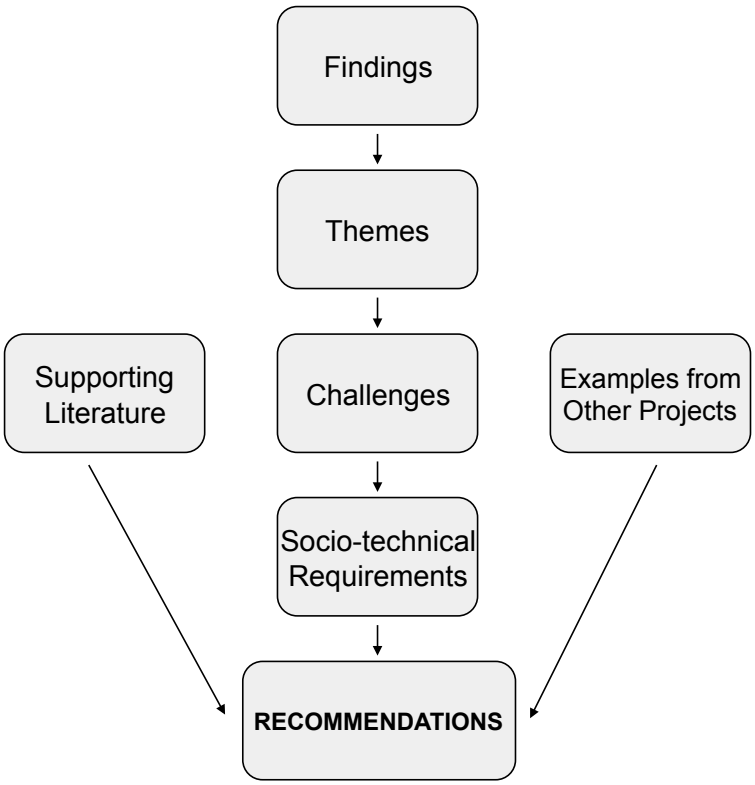


Figure 5.1: Our process for arriving at the five socio-technical recommendations given in this chapter.

CHALLENGE	SOCIO-TECHNICAL REQUIREMENT	RECOMMENDATION	SUPPORTING LITERATURE	EXAMPLES FROM OTHER PROJECTS	ORIGINATING THEMES	ASSOCIATED FINDINGS
Users may not be prepared to collaborate using the technology.	Need to consider technology-readiness and collaboration-readiness.	Assess collaboration-readiness and technology-readiness. If not technology-ready, introduce the technology in baby steps, attempting to match the technology to the setting.	Olson and Olson (2000)	Orphanet – employs flexible and simplistic forms of technology to match the way their collaborative partners work.	Barriers to adoption, TAG interactions	Organizational culture (barrier), need for extensive training (barrier), coordination and awareness within TAGs (TAG interactions), cross-TAG collaboration and conflict (TAG interactions)
Users are not effectively articulating and coordinating work using the technology.	Need to support articulation and coordination work.	1) Have a clearly defined purpose for the technology and make sure the designers work iteratively with end users to design for the work situation and to make articulation work *visible*. 2) Facilitate a shared awareness among users in a system by providing mechanisms for considering both the *content* and the *character* of individual contributions.	Star and Strauss (1999), Strauss (1988), Suchman (1996) 1) Bowker and Star (2000), Bannon (1995), Bannon and Schmidt (1992) 2) Dourish and Belotti (1992)	NCI Thesaurus – distributed team members effectively work towards shared goals using a variety of communication mediums.	Barriers to adoption, TAG interactions	Lack of distinct purpose (barrier), coordination and awareness within TAGs (TAG interactions), cross-TAG collaboration and conflict (TAG interactions)

Figure 5.2: The five socio-technical recommendations for inclusive standardization systems that emerged from our exploratory case study of the ICD-11 revision (continued on next page).

CHALLENGE	SOCIO-TECHNICAL REQUIREMENT	RECOMMENDATION	SUPPORTING LITERATURE	EXAMPLES FROM OTHER PROJECTS	ORIGINATING THEMES	ASSOCIATED FINDINGS
Users are not effectively leveraging the technology because they don't know why they should use it.	Need for distinct purpose of introducing technology.	1) Have clear and persistent aims for the use of the technology, and employ a continuous and strategic reassessment of aims as the project evolves.	Buschmann (2009)	Orphanet, NCI Thesaurus – project mandates are clearly outlined and followed, and technology employed fits with project aims.	Barriers to adoption	Lack of distinct purpose (barrier)
Users cannot effectively leverage the technology because the work process surrounding the technology is incomplete or incompatible.	Need for clearly defined processes surrounding the technology.	1) Design the technology with a clearly defined process in mind. 2) If a process is already in place, integrate the technology into that process.	1) Blog: Tool-leading Processes vs. Process-leading Tools (2011)[1] ➢ "A process must always be the boss and lead the tool to its expectations." 2) Blog: The Big Failure of Enterprise 2.0 Social Business (2011)[2]	NCI Thesaurus – a well-structured and complex process is used to ensure accuracy and coherence[3], and the project employs customizable workflow management software to aid this process.	Process matters	Need for a process (process matters)

[1] http://www.techrepublic.com/blog/tech-manager/tool-leading-processes-vs-process-leading-tools/6864
[2] http://www.lauriebuczek.com/2011/08/23/the-big-failure-of-enterprise-2-0-social-business/
[3] The National Cancer Institute's Thesaurus and Ontology (Golbeck et al., 2011)

Figure 5.3: The five socio-technical recommendations for inclusive standardization systems that emerged from our exploratory case study of the ICD-11 revision (continued on next page).

CHALLENGE	SOCIO-TECHNICAL REQUIREMENT	RECOMMENDATION	SUPPORTING LITERATURE	EXAMPLES FROM OTHER PROJECTS	ORIGINATING THEMES	ASSOCIATED FINDINGS
Users are uncomfortable leveraging the technology to bring in a larger collaborative group, especially all at once.	Need to support incremental openness.	1) Build capabilities for *incremental* openness into the technology, potentially leveraging a role restrictive approach. 2) For wide collaboration, leverage an approach that is as open and *organic as possible*, providing facilities for collaborative sub-communities to self-manage.	Chadwick (2008), Star (1999), Dourish and Belotti (1992) 2) Organizational Wiki Adoption (available online via slideshare), Shirky (2009)	Orphanet – uses separate channels for propagating information internally vs. externally, and utilizes a broadening international network of experts to disseminate information incrementally. NCI Thesaurus – client-centric approach indicates *limited incremental inclusion*, but technological facilities are employed to interact with a broader user group as necessary.	Resistance to openness, barriers to adoption	Security and access (resistance to openness), ownership and stability (resistance to openness), lack of distinct purpose (barrier)

Figure 5.4: The five socio-technical recommendations for inclusive standardization systems that emerged from our exploratory case study of the ICD-11 revision.

5.1.1 Need to Consider Technology-Readiness and Collaboration-Readiness

As discussed by Olson and Olson [33], some organizations collaborate extensively and fairly effectively in their specific context. However, the infrastructure and incentive structure of the organization may not be conducive to the introduction of software-based support, such as change tracking tools, or document repositories. Our empirical evidence suggests that the ecosystem of the ICD-11 revision effort may fall into this category, especially during its beginning stages.

The organizational culture of the ICD-11 project centres around many experts who are very familiar with particular lower-tech tools, such as Excel. These experts are busy individuals who are resistant to changing their work practices, especially given the volunteer context of their involvement in the ICD-11 revision. These experts are, however, quite used to consulting and collaborating with other experts. For instance, several members of the Topic Advisory Groups used informal methods to complete their work with other team members, circumventing use of the iCAT tool.

When use of the iCAT tool was examined, there appeared to be a great deal of conflict occurring *between* TAGs as a result of the flexibility and open edit access offered within the tool. The tool removed the ownership experts previously had over their work when using, for example, a spreadsheet. Members of TAGs were not used to communicating implicitly through a software tool, and so would contact individuals from other TAGs to discuss issues or concerns *outside of the tool*, thus preventing traceability of issues and changes.

For settings where collaboration is abundant, but there exists an inhospitable environment for the introduction of new technology, Olson and Olson prescribe the use of *baby steps*. They suggest that advanced technologies should be introduced in small increments [33]. In the context of iCAT and the ICD-11 revision effort, this would have meant extensive and organized training offered on each functional component of the tool. Additionally, phased introduction of these components as the project progressed and each new component became useful may have aided the adoption process. This step-wise approach allows for the evolution of requirements as each new component is added.

The challenges of accepting the advice of Olson and Olson relate to the amount of time and financial resources an organization has to devote to incremental introduction

of a new technology. Such an approach may require more person hours than a project such as ICD-11 is feasibly able to commit.

As an adaptive example, the Orphanet editors work extensively with numerous expert groups internationally "in order to build a working group representing all the geographic areas in the world" [P10]. Orphanet's policy is to be as accommodating and flexible as possible when working with external experts: "we have a major respect for the expertise of people and I think that's why people accept to work with us; people like that" [P9]. The editors also make an effort to facilitate simplicity: "we make a draft which is done in Excel spreadsheets and PDF documents and we just send it by email" [P10]. In this way, Orphanet naturally caters to the context of their collaborative efforts. The editors have assessed the *collaborative and technological capabilities* of the experts that they partner with and choose to employ simplistic modes of sharing and communicating information, rather than deploy complex technological tools.

5.1.2 Need to Support Articulation and Coordination Work

Articulation work is "work that gets things back 'on track' in the face of the unexpected" [39]. It refers to the "specific details of putting together tasks, task sequences, task clusters and even the work done in aligning larger units such as subprojects, in order to accomplish the work" [42]. As we have seen through participant interviews and observation of participants during project meeting discussions, there has been a great need for articulating work in the progression of the ICD-11 revision effort. With the range of individuals and expertise involved comes a multitude of ingrained processes and styles of work. Navigating obstacles in coupling these different work processes to facilitate smooth collaboration is a major challenge for the socio-technical system being developed around the project. The majority of the work articulation burden thus far has been placed on participants in the project. The currently employed tools and processes are struggling to lighten this load. This gap is partly due to the lack of definition currently offered by the project's processes and aims, and partly due to the fact that articulation work tends to be invisible by nature [44]. Many important low-level socio-technical requirements of the ICD-11 project are likely buried in the unnoticed articulation work undertaken by participants.

Further to its impact on socio-technical requirements, articulation work in the context of international standardization blends with the definition of *categorical work*

given by Bowker and Star [13]. Categorical work refers to the "juggling of meanings" [13] that occurs when the viewpoints of various participants affect the categorical assignments that they make. These assignments in turn affect the outcome of the standardization product and the way it is interpreted. The categorical work is invisible and its effects are therefore overlooked. As such, the first step in supporting articulation work and categorical work is making the work *visible*. However, it is questionable whether "the ongoing dynamic articulation of distributed activities and the cooperative management of the mechanisms of interaction themselves" [10] can be fully captured and made visible. Bannon [11] argues that the best method for shedding light on articulation work and supporting participants in carrying it out is to "ensure that system designers understand the work situation and design for and with end users" [11].

Articulation work is also closely tied to awareness and coordination. In the context of a collaborative authoring project such as ICD-11, both the *content* and *character* of individual contributions are important for participants to consider "with respect to the whole group and its goals" [20]. Facilitating a shared awareness of both of these aspects enables "each individual to make sense of others' activity and tailor their own work accordingly" [20]. Dourish and Bellotti describe three mechanisms for supporting awareness and coordination in collaborative authoring systems [20]. The first of which, referred to as *informational*, facilitates the explicit sharing of information about work being done by each user. Information conduits, such as an integrated e-mail client or an edit log with mandatory explanatory comments for all changes made, are provided in systems with an informational focus. The second mechanism, referred to as *role restrictive*, outlines explicit roles for each user in a system. Each role has a limited set of operations associated with it. For example, an editor may be able to write to a shared artifact and make changes to its structure, while a reviewer may only be able to read specific portions of the artifact. One effect of supporting explicit roles in a collaborative authoring system is the reduction of "uncertainty about the actions an individual might take," thus providing "greater awareness amongst participants" [20].

The third mechanism described by Dourish and Bellotti for supporting awareness and coordination is *shared feedback* [20]. Tools supporting shared feedback "automate collection and distribution of information," and "present it as background information within a shared space" [20]. In a shared feedback setting, there is a shared workspace, or a shared communication channel. This approach allows for fluid and flexible role

assignment since the activities of participants are essentially broadcast, eliminating uncertainty about the actions being taken by each individual. However, mandatory sharing of information with all participants in a system has the potential to be overly invasive in certain contexts.

Within the ICD-11 revision, a shared feedback approach may be appropriate for collaboration among members of Topic Advisory Groups in the context of a *semi-synchronous* system [20], in order to increase awareness within TAGs and incentivize participation. A semi-synchronous system "presents current information on synchronously co-present collaborators, at the same time as representations of past activities by other collaborators who are not synchronously present" [20]. Outside of TAG circles, *informational* mechanisms that facilitate cross-TAG communication and coordination may be helpful. Additionally, leveraging a *role-restrictive* approach as the project moves into the beta phase and includes a wider audience may minimize triaging and editing conflicts.

The iCAT software currently in use by alpha phase participants incorporates some aspects of the three mechanisms described above (see Chapter 3). However, the informational and shared feedback facilities alike are, for the most part, limited to optional commenting and basic change tracking. In addition, the roles and access privileges are not yet clearly defined, and there is no support for modular role assignment based on, for example, membership in a particular TAG.

Due to their geographic distribution, the NCI Thesaurus editors utilize a variety of communication channels, including "[their] Protégé tool's chat function, email, and phone" [P15]. Impressively, these editors "can usually support requests for new terminology within 24 to 48 hours" [P15]. The efficiency with which the NCI Thesaurus editors accomplish their collaborative tasks suggests the presence of effective mechanisms for *managing articulation and coordination work*. The editors work effectively in a distributed manner towards shared goals. This success may be obtained easier in their context due to the small number of editors involved in the project, their flexible use of communication mediums, and the fact that editors are full-time, paid employees of the NCI.

5.1.3 Need for Distinct Purpose of Introducing Technology

Without clearly defining the goals of a project and enumerating the benefits of realizing those goals, it is difficult to sustain a fully functioning socio-technical ecosystem

around the project. A lack of clear and persistent aims has been evident in the unfolding of the ICD-11 revision and in the production of supporting technology. As a result, adoption of the introduced technology has been low because participants don't understand exactly why they should use it, or how it meets the needs of the project.

In a 2009 issue of IEEE Software Magazine, Buschmann discusses some of the mistakes that are often made in software development before architecture of a system even begins. These mistakes most often relate to scoping and requirements. As such, he urges software designers to ask, "where does the system begin," and "*who uses it for what (key) tasks*" [14]? In the context of a dynamic and evolving standardization system such as ICD-11, a continuous and strategic reassessment of aims and key tasks supported by technology may be necessary as the project progresses.

An important commonality between the Orphanet and NCI Thesaurus projects is a distinct *raison d'être*, a *clearly defined purpose*. The project mandates are outlined through online resources, and the processes and technological tools employed match the particular collaborative cultures and the goals set out to be accomplished. These projects are examples that should be considered by other inclusive standardization initiatives, especially in the health domain.

5.1.4 Need for Clearly Defined Processes Surrounding the Technology

There has been divergence between the collaborative steps dictated by the evolving process of the ICD-11 revision and the actions afforded by the supporting technology. Participant confusion and frustration have resulted since effectively leveraging the technology is dependent on a defined and compatible process to surround it.

Contemporary online discourse around the role of processes in successful tool adoption suggests that processes "should always be the boss and lead the tool to its expectations"[1]. This principle is true for minimal disruption and maximized ease of adoption in the case where a new system is being conceived and both the process and tool need to be developed and refined, as well as in the context of improving existing infrastructure. Without providing an "*easy button* with integrated tools that are 'just there' in your workflow,"[2] adoption of new technology into existing infrastructure will likely be difficult.

[1] http://www.techrepublic.com/blog/tech-manager/tool-leading-processes-vs-process-leading-tools/6864

[2] http://www.lauriebuczek.com/2011/08/23/the-big-failure-of-enterprise-2-0-social-business

The NCI Thesaurus is an example of a project that has taken the development and enforcement of its collaborative editing process seriously. The editors follow a well-structured and complex process to ensure accuracy and coherence [24]. Customizable workflow management software is leveraged to aid this process.

As mentioned previously, in the context of a massive international project, it may be challenging to define all goals, processes, and technological requirements ahead of time. Projects of such magnitude naturally and constantly evolve of their own accord. However, a continuous, strategic, and realistic assessment of targets, processes and tools is key to the socio-technical success of a project of this nature.

5.1.5 Need to Support Incremental Openness

We saw the need for incremental openness emerge in our findings in the context of the ICD-11 revision. Participants are not comfortable sharing an artifact they are invested in with others who may not be equally invested, especially while the artifact is fragile during its early stages of production. As such, the incorporation of a *role-restrictive approach* [20], and the ability to flag certain proposals and sections as private or read-only and specify to whom these restrictions apply will likely be necessary as the project progresses into the beta phase. Additionally, the ability to move the artifact through different "layers" of collaborative inclusion at the project planning and tool support levels may be highly pragmatic. Steps in this direction have already been taken in the current tools through the use of symbols denoting the readiness of various chapters for comment by a broader group. *Green* indicates that independent groups and individuals may "go ahead and comment"; *yellow* signals that "work is going on, so [one] may comment, but [TAGs] may change things"; *red* means that work on the chapter has "not started yet" and that one should comment "only if [they] must" [P1].

The notion of a public sphere of deliberation dates back to Athenian times and has at its core an ideal of "rational critical discourse" [17]. In his 2008 paper, Chadwick discusses e-democracy in light of *web 2.0* and asserts that most individuals fall somewhere along a continuum of interest in any issue or artifact they are involved with. As such, he states that "socio-technical environments that have this level of granularity 'designed in' ... are more likely to be successful than those that do not" [17]. Similarly, Star acknowledges the "big, layered, and complex" nature of socio-technical infrastructure and urges that it be constructed in "modular increments" [38], providing support for the idea of incremental inclusion.

Orphanet is a project that is driven by interaction with the whole community of rare disease patients, concerned family members and interested experts, and it has developed well-adopted mechanisms to broadly disseminate information to these groups. For example, their bi-weekly community newsletter, *orphaNews*, has a readership of approximately 20,000 patients, experts, and interested individuals [P9]. Orphanet also issues an *internal* newsletter which communicates with Orphanet partners. These separate channels for internal and external communication embody a form of *incremental inclusion*, similar to the type of access discrimination requested by participants in the ICD-11 revision effort. To obtain the widest reach with information that is ready to be disseminated, and to maintain contact with relevant experts internationally, Orphanet has "contact points in North America, South America, Asia, Australia, etc." [P10]. In this way, they trust their contacts to propagate important information to groups outside of Europe, where Orphanet is based: "we don't have the power to control to who the drafts are disseminated in other parts of the world" [P10].

Similar to Orphanet, the editors of the NCI Thesaurus involve a broad community of experts external to the NCI. They also interact with members of the general public, though only about once or twice per month [P15, P16]. According to P16, the NCI Thesaurus currently has approximately 12 "clients," or regular users. These clients may have information maintained for them within the NCI Thesaurus, or they may have been assigned specific projects by the NCI. A client may also be acquired due to a need for particular vocabulary that they do not have the expertise to produce themselves [P16]. Clients and NCI Thesaurus editors often interact through conference calls, or web meetings [P16].

The client-centric collaborative environment of the NCI Thesaurus suggests a *limited incremental inclusion* approach. However, in order to respond to needs or requests from the general public or user groups outside of their client base, the NCI Thesaurus has a "dedicated front end help desk" [P16], referred to as the *application support group*. The application support group has protocols for forwarding queries about data and available tools to specific editors and ensuring answers are returned for every inquiry. Occasionally, an editor will have direct communication with a member of the public or external user group, usually through email correspondence. Such interaction is "kicked up to the next level if necessary to see if [the request] is okay with everyone" [P16]. In this way, the NCI Thesaurus project provides technological facilities to interact with a broader user group as necessary.

5.2 Thinking Forward to Wide Collaboration During the Beta Phase

Previous literature shows that for successful adoption of wiki-style social authoring tools, there needs to be an organic process with support for emergent behaviour [7]. Evidence for these ideas were seen in the evolution and rapid growth of Wikipedia once the rigid and formal processes of its predecessor, Nupedia, were dropped [37]. As discussed for the overall socio-technical ecosystem of the ICD-11 project, any tools designed for broad collaboration during the beta phase must be designed with a purpose. It should be noted that "to make [everyone] collaborate" is not a purpose [7].

Providing an environment where emergent and organic behaviour is supported works well in the context of Wikipedia, or potentially for informal communication mechanisms within organizational teams [7, 37]. However, such a loosely structured approach may be disconcerting in a setting where millions of people rely on the resulting product for the final word on their well-being.

In order to reconcile the methods that have been shown to work in social authoring contexts with the reliability needs of the ICD-11 project, the purpose, intended processes, and tools of the beta phase will require thorough consideration. A sense of optimism regarding ICD-11 can be found among project participants [P6]. Success for the beta phase may lie in being as open and *organic as possible* by leveraging the idea of incremental inclusion to form "open" communities within a beta phase tool. These distinct communities may be managed by the different Topic Advisory Groups, with the opportunity for cross-community collaboration. Some communities may begin in a fairly restricted manner and progress to open collaboration, whereas other communities may be unrestricted from the beginning. Such attributes would depend on the assessed needs of each community.

5.3 Impact of this Research

The health information and informatics community has been the target audience for the dissemination of findings from this research. As such, we have published a subset of our findings at the Workshop on Interactive Systems in Healthcare[3], collocated

[3]http://wish2011.wordpress.com/accepted-papers/

with the American Medical Informatics Association's 2011 Fall Symposium. We have also been working closely with the software development team for the ICD-11 revision project, in order to communicate the requirements we have elicited. This communication has been structured in two ways: 1) the introduction of *personas* to illustrate likely users of beta phase tools, and 2) the presentation of a diagram depicting our recommendations for phases of technology implementation in the project, along with the users and stakeholders associated with each phase, and the tool features that are likely to be required as the project progresses. Finally, we have given a presentation to the Health Informatics and Modeling Topic Advisory Group (HIM-TAG) for the ICD-11 revision in order to discus our recommendations in a practical sense.

5.3.1 Personas for the ICD-11 Revision

As part of our work, we introduced *personas* [41] to depict a subset of likely users of potential ICD-11 beta phase tools. Personas are "imaginary examples of the real users they represent" [41] and can be of great value in "providing a shared basis for communication" [36]. Through the analysis of our data and an examination of the roles of participants from whom the data was collected, we developed two personas central to the ICD-11 revision: 1) *Rachel*, an experienced and moderately conservative TAG Managing Editor, and 2) *Samuel*, a novice horizontal TAG member. These are only two examples of relevant personas. We recommend that further steps be taken to develop a full set of likely users.

Rachel is a medical expert that has been working with the ICD-11 revision for nearly three years. She has been given the role of Managing Editor for one of the Topic Advisory Groups (TAGs) and has been working closely with the members of her TAG to update and revise the necessary sections of their chapter. She and her TAG members are working on the revision on a voluntary basis. She is a full-time researcher at a large hospital and most of her TAG members also have full-time jobs. She feels a sense of ownership over her work and is aware of her expertise in her area. She is reluctant to support the beta phase of the ICD-11 project because she feels her TAG's chapter is not ready for public exposure. She believes that she and her team of experts are among the most knowledgeable in their area and they are not at a stage where she feels outside input will be helpful. Rather, she expects that fielding outside input from less informed individuals is likely to cause extra work for her team and impede productivity. However, Rachel is not opposed to collaborating with other

TAGs and expert groups. She routinely corresponds with the Managing Editor of a related TAG and occasionally sends draft sections of her TAG's chapter to colleagues in her research network for review. Rachel is also open to allowing public comment on her TAG's chapter at a significantly later date.

Samuel is a member of a *horizontal* TAG (see Chapter 3). He began work with the ICD-11 project about one year ago. His work depends on a partnership with every other TAG. This dependency can be frustrating at times due to coordination challenges, as well as conflicting perspectives and personalities. Samuel tends to feel "out of the loop" in the progression of the ICD-11 revision. He and his TAG members sometimes experience long lags where there is little work for them to do on the project due to the dependent nature of his TAG's role. He completes the majority of his work using spreadsheets rather than a customized electronic tool. Some of his work relates to the actual structure of the ICD, while other tasks relate only to content. There are a few people in his TAG whom Samuel feels comfortable telephoning or emailing when he has questions or concerns. He has thought little about the beta phase since it is unlikely to have a direct impact on his work. As a horizontal TAG, his group's work, though fundamental and important, is largely integrated and interconnected with that of the other TAGs. Any public feedback related to his work will likely be filtered through other TAGs and his TAG's Managing Editor before it reaches him, if it reaches him.

As stated previously, our work in developing personas for the ICD-11 project is preliminary. Further data collection and analysis will be necessary in order to fully develop a set of relevant personas to help guide the development of ICD-11 tools.

5.3.2 Users and Recommended Tool Features for ICD-11 Project Phases

Following the creation of personas, we moved to investigating which specific tools and features might be useful as more groups, organizations, and individuals become involved in providing input to the ICD-11 project. Through a recommendation from the ICD-11 software development team, we consider a specific platform, called *Liferay*[4] [19], as a base for this type of tool development. Liferay is a robust, customizable open source portal platform that has been researched by the ICD-11 software development team. In this section, we describe the features of such a platform that we believe will

[4]http://www.liferay.com

be important for the progression through each stage of incremental openness for the ICD-11 revision effort.

Figure 5.5 illustrates some of the preliminary software tool features our findings have indicated to be important for moving forward in the ICD-11 revision effort. This *tooling map* is overlayed with the respective stages to which each feature would apply, along with the users and stakeholders that are likely to be involved at each stage. There is a fair amount of overlap across stages; the number of stages and the transition points between them have not been clearly defined. However, we believe this diagram gives a sense of the progression of the ICD-11 project through incremental openness and the socio-technical environment that would surround each stage.

The alpha phase depicted in the diagram is comprised of participants who have *expert* contributions to make to the project in some way. This phase includes classification specialists, members of national agencies, WHO project management, WHO representatives, members of WHO Collaborating Centers, and members of statistics agencies. The beta phase depicted in the diagram is comprised of participants who have *experiential* knowledge to contribute to the project. These participants include members of special interest or patient groups, and even insurance agencies or drug companies.

The tooling map illustrated in Figure 5.5 adheres to our fifth recommendation in that it provides capabilities for incremental openness, and supports collaborative processes that are as open and *organic as possible*. The map provides facilities for collaborative sub-communities to self manage, with restricted communities having the opportunity to progress to being more open.

The development of personas and the use of a tooling map may help to move the ICD-11 revision effort forward in a practical sense. The characteristic feature requirements for the incremental opening of ICD-11 have been abstracted away from the specific processes of the project in the tooling map we have developed. Therefore, it is likely that the progressive inclusion of users and stakeholders illustrated here, along with the general tooling features presented at each stage, may be applicable to other inclusive standardization systems with similar objectives.

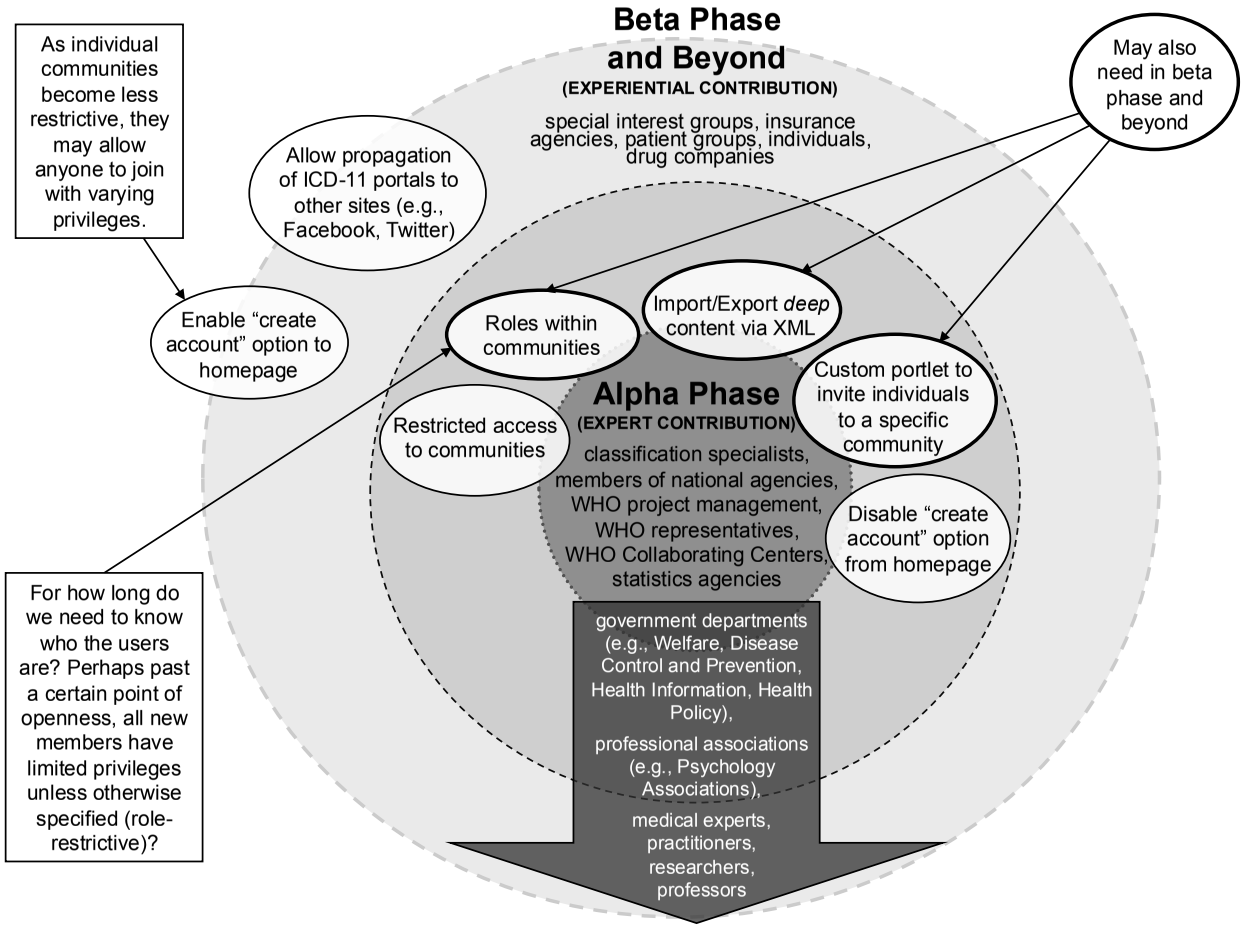


Figure 5.5: ICD-11 project phases, associated users and stakeholders, and recommended tool features.

5.4 Credibility of this Research

In this section, we discuss the internal and external *credibility* of our research. Traditional forms of measuring *validity* in quantitative research do not translate well to assessing the legitimacy of qualitative research where techniques such as grounded theory are applied. Validity is "relative to purposes and circumstances" [30] and is intended to lead to a "dichotomous outcome (i.e., valid vs. invalid)" [34]. Credibility, on the other hand, is used to assess the "truth value of qualitative research" [34].

5.4.1 Internal Credibility

Internal credibility refers to the "consistency, neutrality, dependability, and/or credibility of interpretations and conclusions within the underlying setting or group" [34]. To improve the internal credibility of our research, we analyzed data from multiple sources of evidence within the ICD-11 project, and performed member checking. However, it should be noted that we approached this case study from the perspective of understanding the challenges involved in developing inclusive standardization systems. As such, our lens may be slightly biased in the direction of necessary improvements, potentially overlooking certain positive aspects already present in the project under study.

Member checking allows us to determine whether "the interpretations [of our findings] are fair and representative" [18]. We received responses from four participants (P2, P7, P9, P10) regarding the summary of findings that we provided to them via email. The response from P2 indicated that he was concerned that we had missed a particular point he had made, but did not feel any of the ideas expressed in our findings were misleading. The point in question was revisited and incorporated. P7 approved of the summary of findings and reiterated his strong support for two of the main ideas in particular. P9 commented that the findings in our report may be presented too mildly, but did not object to the points made. P10 was enthusiastically supportive of our findings and indicated her interest in reading the full report once completed.

The *multiple sources of evidence* leveraged in the examination of the ICD-11 case allowed for triangulation of our findings. These sources included interviews, focus groups, and observation of project meeting discussion. We were also given access to project documentation and software tools that have been in use during the course of

the project progression. These additional sources provided context for our findings. Additionally, we were able to interview a diverse set of participants involved in various aspects of the project. These participants included project management, classification specialists, and medical experts.

As discussed in Chapter 3, the scale and broad range of stakeholders involved in the ICD-11 revision created political and organizational issues within the project. Though we made every effort to separate these issues from our findings, they may have influenced participant viewpoints on the socio-technical requirements for the development of the ICD-11 standardization system.

5.4.2 External Credibility

External credibility refers to "the degree that the findings of a study can be generalized across different populations of persons, settings, contexts, and times" [34]. To improve the external credibility of our research, we examined two additional projects, separate from the ICD-11 revision effort. These were the Orphanet and NCI Thesaurus projects. We also used varied supporting literature in the development of our socio-technical recommendations to further applicability outside of our own domain.

Though comparable to ICD-11 in that they are community-minded, with facilities for broad inclusion of interested expert groups and individuals, the additional projects we examined are also quite different from the ICD in terms of their scale, topics of focus, and developmental structure. For example, editors for the Orphanet and NCI Thesaurus projects are paid employees, whereas participants in the ICD-11 revision effort are, for the most part, volunteers. Since our research uncovered similar findings across all three projects, we can expect the external credibility of our research to be high. However, our research objectives focused on *health* information systems. This scope is reflected in our choice of projects to study. As such, the applicability of our socio-technical recommendations may need to be verified outside of the health information and informatics community.

5.5 Chapter Summary

In this chapter, we have presented a set of five recommendations to address the socio-technical requirements of inclusive standardization systems, based on our exploratory case study of the ICD-11 revision effort, and supported by related literature and ex-

amples from the Orphanet and NCI Thesaurus projects. These recommendations include the need to consider technology readiness and collaboration-readiness, and the need to support articulation and coordination work. Additionally, we outlined the need for a distinct purpose for introducing technology into a project, and the need for a clearly defined process surrounding the use of that technology. Our last recommendation discussed the need to support incremental openness so that participants do not feel intimidated by the prospect of broad collaboration efforts. Finally, we considered the beta phase explicitly, drawing on advice from previous literature, and presented the practical implications of our findings as well as the credibility of this research.

Chapter 6

Conclusions

This research set out to answer four research questions, with the over-arching goal of examining the socio-technical requirements of a project which represents a global turning point in the development of standardization systems in the health domain. In this chapter, we discuss the extent to which we have addressed each of these research questions. We also present our evaluation of the credibility of this work. Finally, we discuss a few aspects of potential continuing research and summarize our contributions.

6.1 Research Questions Revisited

In order to address our research questions, we analyzed several sources of evidence, including interviews, focus groups, and project meeting discussion. For additional context, we had access to the tools in use throughout the alpha phase, as well as prototypes of projected beta phase tools. We also reviewed several project planning documents, including those available publicly and those given to us explicitly by project leaders. In this section, we review how completely we have addressed each of our research questions.

RQ1: How is the introduction of collaborative technology into the development of a standardization system received by participants? In order to answer this research question, we aggregated the sentiments of all participants interviewed with the tone of the two focus groups to illustrate the overall stance of project participants toward the introduction of collaborative technology into their collaborative ecosystem. The general feeling among participants was one of trepidation and uncertainty regarding

the impact of technology on their work practices. However, the lack of definition around the uses and benefits of the technology may have contributed to participant concern. As this was an exploratory case study [50], we did not employ surveys with specific questions regarding participant attitudes toward, for example, technology. However, in a next phase, such an approach may enrich our findings on this topic.

RQ2: How is the idea of a fully inclusive standardization system received by participants? Similar to our approach to RQ1, we aggregated participant views on the beta phase of ICD-11 in order to describe participant concerns regarding broad external inclusion in the development of the classification. Though a sudden opening of the classification to the public was generally rejected by participants, many supported a phased approach, allowing for progressive inclusion of WHO Collaborating Centres to external expert groups and finally on to patient organizations and the general public. An in-depth look at *why* participants favour this progression may be appropriate in the context of a follow-up *explanatory* [50] study.

RQ3: What positive and/or negative impacts does the utilization of collaborative technology have on the inclusive nature of a standardization system? Does it seem apparent that technology endows us with the power to overcome the classification challenge? An attempt to overcome the centuries-old classification challenge in light of new and novel technology is commendable. However, our findings suggest that success in such an effort requires more than technology alone. A complex synergy between the people, processes and tools involved would be necessary. This point was explicitly described in our *process matters* finding, as well as implicitly in our *need to consider technology-readiness and collaboration-readiness*, and *need for articulation and coordination work* themes. Further developments in the ICD-11 revision project, or in similar inclusive standardization systems may shed more light on the potential for technology to bring us closer to meeting the classification challenge.

RQ4: What are the socio-technical requirements for a successful standardization system that leverages collaborative technology and maintains inclusiveness as a central priority? What are the challenges involved in meeting these socio-technical requirements? While our first three research questions focused on providing insight into and context for our case, our fourth research question looks to elicit recommendations for the development of future inclusive standardization systems. From our findings and themes, we developed five socio-technical requirements for inclusive standardization systems, along with five recommendations for meeting these requirements. These requirements and recommendations are by no means an exhaustive set. Further in-

vestigation of the ICD-11 revision effort as it progresses into the beta phase would be extremely valuable in expanding on our understanding of the needs of a project of this nature.

6.2 Future Work

In moving forward with the ICD-11 project and in the context of future inclusive standardization systems, we highly recommend the development of sophisticated personas as a precursor to software development. As mentioned in Chapter 3, the inclusion of a multitude of representative stakeholders introduces the potential for conflict and delays. The collaboration around specific personas allows for the creation of a shared project vision. This method is also very cost effective, as it does not require any development work. Further iteration around a beta phase prototype with the help of these personas will also be important. Buschmann argues that *user stories* and scenarios are crucial to "defining a technically sound system scope" [14].

The iteration around a beta phase prototype should include pilot testing with several Topic Advisory groups involved in the ICD-11 revision. An iterative and incremental approach to software development, involving users in the process, allows us to "define an initial system scope and set of requirements in a reasonable time and adjust this big picture step-wise until it has enough focus, substance and clarity" [14]. There is already some project management support for running beta phase pilots with TAGs: "we would like to get a few TAGs to test out *iCAT lite*" [P1].

A major hurdle for progressing into the beta phase will be clearly identifying the *external* users of beta phase tools: "who is the *community*?" [GM]. We may be able to predict usage by experts who are already involved in the project through pilot testing with TAGs, but until we understand the full spectrum of users for these tools, it will be difficult to design appropriate software. This is an important aspect of future work regarding the ICD-11 revision effort and any future large-scale, inclusive standardization systems.

6.3 Concluding Remarks

This thesis has presented the results of an exploratory case study of the ICD-11 revision effort. Regardless of the outcome, the ICD-11 project represents a major milestone for disease classification and inclusive standardization systems in the health

domain. As background for this work, we also examined the context of ICD-10. We discovered that though efforts were made to include a broader audience in this version of the classification, ICD-10 was largely unsuccessful in the aspect of inclusion.

As part of our work, we have communicated a set of socio-technical requirements for developing inclusive standardization systems, along with recommendations for meeting these requirements, to ICD-11 project management and the ICD-11 software development team. Due to the incorporation of findings from two additional projects, as well as supporting literature from varied domains, we believe these recommendations will have broader impact for inclusive standardization systems outside of the ICD-11 revision.

In our recommendations, we have urged the identification of and collaboration with end users. Additionally, we have discussed the next steps for future work relating to the ICD-11 project and other inclusive standardization systems. The creation of personas is a simple, low-cost way to enrich developer understanding of likely system users. However, identifying the full spectrum of end users for large-scale inclusive standardization systems continues to be a challenge and remains as future work.

Over the next few years, ICD-11 will set the direction for standardization systems in the health domain that have inclusiveness as a central priority. As such, the health information and informatics community will be monitoring the progress of the revision with a keen eye.

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Appendix

Figure 1: An example of the data snippets for the code: incremental beta phase feedback.

iCAT User Interview

Consent Form

You are being invited to participate in a research study to help illicit requirements for the future development of the iCAT (International Collaborative ICD Authoring Tool) software system.

Purpose and Objectives

iCAT is a software system developed by Stanford University to support the collaborative development of ICD-11. Our research objective is to help evaluate the iCAT system and the use of social networking approaches for the development of ICD. We also hope to extract new requirements for iCAT that will help better support the development process of ICD-11. Your feedback will be crucial to this process.

The study is being conducted by Dr. Margaret-Anne Storey and Gargi Bougie, researchers in the Department of Computer Science at the University of Victoria. If you have further questions, please contact Margaret-Anne Storey at: mstorey@uvic.ca.

What is Involved

Participation in this study requires that you participate in an interview which will take approximately 30 minutes. You will be audio recorded so that your input can be analyzed later. During the interview, you will be invited to discuss different questions or topics related to iCAT or ICD-11 as instructed by a moderator and you will be asked to express your opinion on the topics.

Voluntary Participation

Your participation is completely voluntary. You may withdraw at any point during the interview session. If you choose to withdraw, at your request, all data from these sessions will be destroyed. To withdraw, you may leave the interview at any time. To withdraw your data, please contact Dr. Margaret-Anne Storey (mstorey@uvic.ca, 250-472-5713).

Anonymity

To protect your anonymity, no identifying information will be associated with the audio recording of the interview. All information will be analyzed by trained researchers and all data will be kept secure and protected at all times in password protected files on a secure server. Study data will be kept for three years. At the end of this time computer data files will be deleted. Furthermore, in any report or published work discussing the results from these studies, you will not be personally identified.

Benefits

This research may lead to improvements in the iCAT software. All participants will be able to examine the dissemination of the study results via a summary report published on the ICD-11 website as well possible scholarly publications. In addition to being able to contact the researchers, you may verify the ethical approval of this study, or raise any concerns you might have, by contacting the Human Research Ethics Office, at the University of Victoria (ethics@uvic.ca).

_____ _____

Participant Date

Figure 2: The consent form for conducting interviews with case study participants.

iCAT User Focus Group

Consent Form

You are being invited to participate in a research study to help illicit requirements for the future development of the iCAT (International Collaborative ICD Authoring Tool) software system.

Purpose and Objectives

iCAT is a software system developed by Stanford University to support the collaborative development of ICD-11. Our research objective is to help evaluate the iCAT system and the use of social networking approaches for the development of ICD. We also hope to extract new requirements for iCAT that will help better support the development process of ICD-11. Your feedback will be crucial to this process.

The study is being conducted by Dr. Margaret-Anne Storey and Gargi Bougie, researchers in the Department of Computer Science at the University of Victoria. If you have further questions, please contact Margaret-Anne Storey at: mstorey@uvic.ca.

What is Involved

Participation in this study requires that you participate in a focus group which will take approximately 1-2 hours. You will be audio recorded so that your input can be analyzed later. During the focus group, you and approx. 6-12 of your peers will discuss different questions or topics as instructed by a moderator and you will be invited to express your opinion on the topics.

Voluntary Participation

Your participation is completely voluntary. You may withdraw at any point during the focus group session. If you choose to withdraw, at your request, all data from these sessions will be destroyed. To withdraw, you may simply leave at any time. To withdraw your data you may contact Dr. Margaret-Anne Storey (mstorey@uvic.ca, 250-472-5713).

Anonymity

To protect your anonymity, no identifying information will be associated with the audio recording of the focus group. All information will be analyzed by the above mentioned trained researchers and all data will be kept secure and protected at all times in password protected files on a secure server. Study data will be kept for three years. At the end of this time computer data files will be deleted. Furthermore, in any report or published work discussing the results from these studies, you will not be personally identified.

Benefits

This research may lead to improvements in the iCAT software. All participants will be able to examine the dissemination of the study results via a summary report published on the ICD-11 website as well possible scholarly publications. In addition to being able to contact the researchers, you may verify the ethical approval of this study, or raise any concerns you might have, by contacting the Human Research Ethics Office, at the University of Victoria (ethics@uvic.ca).

_____ _____

Participant Date

Figure 3: The consent form for conducting focus groups with case study participants.

Interview/Focus Group Questions

Editing and use of iCAT:

1. If you have used iCAT tool to date, do you have some **feedback** on the use of the tool so far?
2. If **others in your group** used it, what were their initial **impressions**? (describe those users)
3. If you have not used it, did you encounter **barriers** to using the tool?
4. Do you have **suggestions** for how it could be improved? For individual editing actions, as well as **collaborative** support?
5. Did you encounter any **overlaps** with other editors or TAGs during your use of the tool? Do you perceive overlap being a significant issue in the future?
6. For those of you that are managing editors for TAGs, how many **TAG members** do you foresee directly using the tool in the near and distant feature?
7. Do you anticipate use of **automated mechanisms** to help automate data entry, such as definitions?

Content Model: (optional)

8. Do you feel you have a good **understanding** of the Content Model?
9. Does the tool provide **sufficient support** for understanding the model?

Peer Review:

10. Can you describe any peer **review processes** you used either for ICD-10 or other versions, as well as peer review you have done so far for ICD-11?
11. How do you envision the **formal peer review process** as we move into the Beta phase?
12. **Who** will your reviewers be? How large is the pool? What are your minimum expectations in terms of their expertise?
13. How do you envision **recruiting** these peer reviewers? What **incentives** do you think they will need to participate?
14. In terms of #**reviews**, do you think 3 will be sufficient?
15. How do you plan to deal with **conflicts** in the reviews? (e.g., will you solicit more reviewers?)

Community Involvement:

16. Can you describe the **characteristics of users** from the community that might provide feedback on ICD-11? What **kind of feedback** do you think they would provide (e.g., do you think they would like to offer specific proposals, or just comment?)
17. What kinds of **incentives** do you think would work for these groups of users?

Closing:

18. Do you have any other input or **comments** you would like to make?

Figure 4: The question guide for conducting focus groups and interviews with case study participants.