A TOOL TO ASSESS CAPACITY TO CONSENT FOR TREATMENT AMONG HOMELESS POPULATIONS WITH PROBLEMATIC SUBSTANCE USE

by

DARLENE LOIS TAYLOR

M.Sc., The University of British Columbia, 2008
B.S.N., The University of Victoria, 2002

A THESIS SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF DOCTOR OF PHILOSOPHY

in

THE FACULTY OF GRADUATE AND POSTDOCTORAL STUDIES

(Health Care and Epidemiology)

THE UNIVERSITY OF BRITISH COLUMBIA
(Vancouver)

September 2014

© Darlene Lois Taylor, 2014
ABSTRACT

BACKGROUND: Individuals who misuse substances and who are homeless or unstably housed (IMSH) are at risk of acquiring communicable diseases such as HIV, sexually transmitted infections and blood-borne infections and have greater medical needs than the general population. However, obtaining informed consent for health care can be challenging as many IMSH have impaired cognition due to the effects of substances. This dissertation describes the development and validation process used to create a psychometric instrument that measures capacity to consent for health care (CTC-HC) among IMSH.

METHODS: Forty-six qualitative interviews were conducted with 19 nurses who deliver care to IMSH and 27 IMSH to identify concepts that should be included in a capacity assessment instrument. A panel of experts reviewed possible items to obtain content and face validity. The instrument was administered to 302 IMSH. Construct and criterion validity were assessed by comparing the results of the new instrument to 1) a psychiatric assessment and 2) scores obtained from the MacArthur Competency Assessment Tool for Treatment. Item analysis was conducted to determine the reliability of the instrument and a confirmatory factor analysis was conducted. The areas under the receiver operating characteristic curves (ROC) were calculated to assess criterion validity. A diagnostic cut-off value was created using the corresponding points on the ROC.

RESULTS: The final Capacity Assessment Instrument for People who misuse Substances (CAIPS) consists of items that address understanding, voluntariness, orientation, ability to communicate, sustained attention, distorted reality, appreciation, reasoning, expression of choice, decision making demands, and physical indication of
substance use. These concepts were incorporated into an 11-item instrument that scores items on a four-point Likert scale. The CAIPS instrument demonstrated good internal reliability (Cronbach’s alpha: 0.861 – 0.893) and inter-observer reliability (weighted kappa statistic of 0.657). The factor analysis confirmed the unidimensionality assumption and the ROC analysis revealed that the CAIPS has a sensitivity of .75 - .81 and a specificity of .63 - .51.

CONCLUSIONS: CAIPS is a reliable tool with moderate validity and is the first validated capacity assessment instrument available for clinicians to assess CTC-HC among IMSH.
PREFACE

This dissertation is original independent work by the author, D. Taylor. The study protocol has been published. For this publication I was the lead author, responsible for the concept formation, data collection and analysis and was the lead writer of the manuscript. The co-authors of the manuscript, Louise Masse, Anita Ho, Michael Rekart, Mark Tyndall, Bonnie Henry, Joanne Clifton, Laurena Peters, Gina Ogilvie and Jane Buxton contributed only as is commensurate with supervisory committee, collegial or co-investigator duties.

Ethical approval was obtained from the University of British Columbia (UBC) Behavioural Research Ethics Board (BREB) (H09-01982) as well as ethics boards from each health authority in BC (Fraser Health Authority: 2011-127; Interior Health Authority: 2011-12-038-E; Northern Health Authority: RR-2011-0044; Vancouver Coastal Health Authority: V09-01982; Vancouver Island Health Authority: H2012-07).
TABLE OF CONTENTS

ABSTRACT ................................................................................................................................................................. ii
PREFACE ................................................................................................................................................................ iv
TABLE OF CONTENTS ......................................................................................................................................... v
LIST OF TABLES ........................................................................................................................................................ x
LIST OF FIGURES ................................................................................................................................................ xii
ACKNOWLEDGMENTS ........................................................................................................................................ xiv
DEDICATION ........................................................................................................................................................ xvi
1 BACKGROUND, RATIONALE AND OBJECTIVES ............................................................... 1
1.1 The Epidemiology of Homelessness ................................................................................................. 2
1.1.1 Definition of Homelessness ........................................................................................................ 2
1.1.2 Prevalence of Homelessness ...................................................................................................... 4
1.1.3 Morbidities Associated with Homelessness .......................................................................... 6
1.2 The Epidemiology of Substance Misuse .......................................................................................... 6
1.2.1 Definition of Substance Misuse ................................................................................................ 6
1.2.2 Prevalence of Substance Misuse ............................................................................................... 7
1.2.3 Morbidities Associated with Substance Misuse ......................................................................... 9
1.3 Health Needs of Those Who Are Homeless and Who Misuse Substances ..................... 10
1.4 Context of Delivering Health Care to IMSH ............................................................................. 12
1.5 Research Rationale .............................................................................................................................. 14
1.6 Conceptual Framework ....................................................................................................................... 15
1.7 Overall Goal ........................................................................................................................................... 22
1.8 Overall Objectives ............................................................................................................................... 22
1.9 Design ...................................................................................................................................................... 22
1.10 Study Setting .......................................................................................................................................... 23
1.11 Dissertation Overview ......................................................................................................................... 26
2 LITERATURE REVIEW OF SUBSTANCE USE, CONSENT AND EXISTING CAPACITY ASSESSMENT INSTRUMENTS ............................................................................................................. 28
2.1 Effects of Substance Misuse ........................................................................................................... 28
2.2 Definitions of Consent ......................................................................................................................... 32
2.2.1 Legal Definition of Consent ......................................................................................................... 32
<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.3.1</td>
<td>Participant Attributes</td>
<td>77</td>
</tr>
<tr>
<td>3.3.2</td>
<td>Results From Interviews</td>
<td>79</td>
</tr>
<tr>
<td>3.4</td>
<td>Discussion</td>
<td>102</td>
</tr>
<tr>
<td>3.4.1</td>
<td>Contextual Factors</td>
<td>104</td>
</tr>
<tr>
<td>3.4.2</td>
<td>Non-Contextual Factors: Measures</td>
<td>109</td>
</tr>
<tr>
<td>3.4.3</td>
<td>Threshold</td>
<td>111</td>
</tr>
<tr>
<td>3.5</td>
<td>Summary and Conclusions</td>
<td>112</td>
</tr>
<tr>
<td>4</td>
<td>INSTRUMENT DEVELOPMENT STAGE</td>
<td>115</td>
</tr>
<tr>
<td>4.1</td>
<td>Introduction</td>
<td>115</td>
</tr>
<tr>
<td>4.1.1</td>
<td>Use of Validated Question From Existing Instruments</td>
<td>115</td>
</tr>
<tr>
<td>4.1.2</td>
<td>Instrument Objectives</td>
<td>116</td>
</tr>
<tr>
<td>4.1.3</td>
<td>Table of Test Specifications</td>
<td>117</td>
</tr>
<tr>
<td>4.1.4</td>
<td>Item Writing</td>
<td>119</td>
</tr>
<tr>
<td>4.2</td>
<td>Panel of Experts</td>
<td>123</td>
</tr>
<tr>
<td>4.2.1</td>
<td>Phase One</td>
<td>124</td>
</tr>
<tr>
<td>4.2.2</td>
<td>Phase Two</td>
<td>135</td>
</tr>
<tr>
<td>4.2.3</td>
<td>Final Instrument</td>
<td>143</td>
</tr>
<tr>
<td>4.2.3.1</td>
<td>Instructions to Clinicians Who Are Administering the Instrument</td>
<td>143</td>
</tr>
<tr>
<td>4.2.3.2</td>
<td>Items That Measure Capacity to Consent</td>
<td>146</td>
</tr>
<tr>
<td>4.3</td>
<td>Cognitive Testing</td>
<td>148</td>
</tr>
<tr>
<td>4.3.1</td>
<td>Methods</td>
<td>148</td>
</tr>
<tr>
<td>4.3.2</td>
<td>Results</td>
<td>149</td>
</tr>
<tr>
<td>4.4</td>
<td>Pilot Testing</td>
<td>149</td>
</tr>
<tr>
<td>4.5</td>
<td>Summary: Description of the Instrument</td>
<td>151</td>
</tr>
<tr>
<td>5</td>
<td>VALIDATION PHASE</td>
<td>152</td>
</tr>
<tr>
<td>5.1</td>
<td>Introduction</td>
<td>152</td>
</tr>
<tr>
<td>5.1.1</td>
<td>Validity</td>
<td>152</td>
</tr>
<tr>
<td>5.1.2</td>
<td>Reliability</td>
<td>153</td>
</tr>
<tr>
<td>5.1.3</td>
<td>Objectives</td>
<td>153</td>
</tr>
<tr>
<td>5.1.4</td>
<td>Sample Size</td>
<td>154</td>
</tr>
<tr>
<td>5.1.5</td>
<td>Inclusion/Exclusion Criteria</td>
<td>154</td>
</tr>
<tr>
<td>5.2</td>
<td>Methods</td>
<td>155</td>
</tr>
<tr>
<td>5.2.1</td>
<td>Partnership with Community Agency</td>
<td>155</td>
</tr>
</tbody>
</table>
APPENDIX H: Consent form for participants of the pilot testing portion of the validation phase

APPENDIX I: Demographic/substance use questionnaire administered to participants of validation phase of this dissertation

APPENDIX J: Consent form for the 302 participants who participated in the validation phase

APPENDIX K: Psychiatric data collection form

APPENDIX L: The CAIPS instrument used in the validation phase of this dissertation

APPENDIX M: Standardized script used for Administration of the MacCAT-T instrument

APPENDIX N: Questions used for the MacCAT-T assessment adapted for use with a hypothetical flu vaccine scenario
LIST OF TABLES

Table 1: Physical and mental effects of substances ................................................................. 29
Table 2: Characteristics of instruments previously published to assess capacity to consent for treatment and research ................................................................. 41
Table 3: Psychometric properties of instruments previously published to assess capacity to consent for treatment and research ................................................................. 43
Table 4: Characteristics of nurses and clients who participated in the qualitative study 78
Table 5: Concepts that were incorporated in the instruction to clinicians and the new instrument ................................................................. 114
Table 6: Table of specifications ................................................................................................ 118
Table 7: First iteration of items ................................................................................................ 121
Table 8: The mean scores for the question ‘How important is the concept to measuring capacity to consent?’ ........................................................................................................ 124
Table 9: Item-response congruency for the first phase of expert review ......................... 125
Table 10: Changes in wording of items before and after Phase 1 of the expert panel consultation ........................................................................................................ 134
Table 11: Mean responses to the question, how important is the concept to assessing capacity to consent: Phase 2 ................................................................. 139
Table 12: Item-objective congruency index after the Phase 2 of expert review .......... 140
Table 13: Items in final instrument .......................................................................................... 146
Table 14: Demographic characteristics of included and excluded participants ............ 168
Table 15: Amount of time that a drug was used prior to study visit ........................................ 170
Table 16: Frequency of participants with and without capacity associated with substance use impairment and/or mental illness ................................................................. 171
Table 17: Number of participants who were rated as having capacity for each of the MacCAT-T domains based on a cut-off score of <4 for understanding, <2 for appreciation and <5 for reasoning ........................................................................................................ 174
Table 18: Mean, median and mode for each item and for each nurse ............................... 181
Table 19: Inter-item correlation matrix ............................................................................... 182
Table 20: Corrected item-total correlation ........................................................................... 182
Table 21: Cronbach’s alpha values under for Nurse LJ and Nurse CM under three conditions ........................................................................................................ 183
Table 22: Cronbach’s alpha and absolute agreement for Nurse LJ and Nurse CM .......... 184
Table 23: The weighted kappa values (quadratic weights) and the intraclass correlation (consistency and agreement) for the composite score under the three conditions .... 184
LIST OF FIGURES

Figure 1: Pathway to possible infringement of right to consent or refuse care ............ 2
Figure 2: Conceptual framework for assessing CTC-HC among IMSH ....................... 21
Figure 3: Flow of research activities ......................................................................... 23
Figure 4: Overarching claim ..................................................................................... 80
Figure 5: Factors from the qualitative study and from the literature ........................... 113
Figure 6: Flow of study activities for validation phase .............................................. 158
Figure 7: Psychiatric assessment framework ............................................................... 160
Figure 8: Frequency distribution of MacCAT-T scores for the appreciation domain ... 173
Figure 9: Frequency distribution of MacCAT-T scores for the reasoning domain ...... 173
Figure 10: Frequency distribution of MacCAT-T scores for the understanding domain ......................................................................................................................................... 174
Figure 11: Frequency distribution of MacCAT-T scores for the expression of choice domain ......................................................................................................................................... 174
Figure 12: Item 1: The client is able to repeat back, in their own words the main side effects/potential complications of the intervention that is being offered to them........ 175
Figure 13: Item 2: The client made their decision about the medical intervention without external pressure or coercion. (i.e. the client is not giving an answer that they feel the clinician wants to hear) ........................................................................................................ 176
Figure 14: Item 3: The client is oriented to person, place, and time (i.e. do they know who they are, where they are and what year it is?) or, if disorientated, it does not a direct bearing on the medical intervention being offered. ........................................................................................................ 176
Figure 15: Item 4: The client can engage in the form of communication that they normally use (e.g., speech, signing writing) excluding a physical difficulty in speaking or use of foreign language not understood by the nurse. ........................................................................................................ 177
Figure 16: Item 5: The client is able to follow simple verbal or written instructions. (i.e. follow at least one instruction) .......................................................................................................................... 177
Figure 17: Item 6: The client is experiencing symptoms of distorted reality (i.e. symptoms hallucinations, delusions, paranoia) and these symptoms have a direct bearing on the intervention proposed ........................................................................................................ 178
Figure 18: Item 7: The client knows that he/she is either at risk of an illness or has an illness and therefore requires clinical care ........................................................................................................ 178
Figure 19: Item 8: The client is able to use the information given to them about the intervention to form a decision about consenting to the intervention or refuse the intervention ........................................................................................................ 179
Figure 20: Item 9: The client is able to verbally or physically (e.g., nodding yes or holding their arm out for a blood test) indicate a choice. ........................................................................................................ 179
Figure 21: Item 10: While offering care to a client he/she seems to be distracted by friends, other activities, and/or symptoms of withdrawal. – reverse coding done........ 180

Figure 22: Item 11: There are physical indications that the client may have recently used drugs or alcohol (e.g., tweaking, nodding head, slurred speech, gyrating). – reverse coding done..................................................................................................................... 180

Figure 23: Structural equation model displaying standardized estimates and residuals. 186

Figure 24: Receiver operator characteristic curve showing accuracy of CAIPS instrument with the psychiatric assessment of capacity used as the gold standard. ......................... 188

Figure 25: Receiver operator characteristic curves showing accuracy of the CAIPS instrument with the MacCAT-T assessment of capacity used as the gold standard....... 190
ACKNOWLEDGMENTS

The research described in this dissertation would not have been possible without the contributions of the participants including the street outreach nurses from BCCDC, other public health nurses around the province, and individuals with problematic substance use and who are homeless or unstably housed around the province. In particular, I am deeply grateful for the collaborative contributions that the members of the Vancouver Area Network of Drug Users (VANDU) made to this research both as co-researchers as well research participants.

I am grateful to the members of my panel of experts, including Elaine Jones, Fiona Gow, James Tigchelaar, Catherine Syms, Michelle Patterson, Mark Tyndall and David Unger for taking time out of their busy lives to review the instrument items. I would also like to thank Natasha Van Borek for assisting with the qualitative interviews and for being the second coder, along with Neville Li, during the qualitative analysis. In addition, I am grateful to Eden Lee who enrolled participants into the validation phase of the research, Dr. Jonathon Fleming for conducting the psychiatric assessments, Deborah Kraus for administering the MacArthur Competency Assessment Tool and Elizabeth James and Christine MacMillian for administering the new instrument developed during this research.

Support for this dissertation was generously provided by the Canadian Institutes for Health Research through an operating grant (RN97807 – 231014). In addition, I deeply thank Dr. Gina Ogilvie who generously provided research grant funding to support my salary during the entirety of my graduate studies.
My heartfelt appreciation goes to my dear colleague, Brenda Sawatzky-Girling who has weathered this dissertation experience alongside me. Her advice and support has proved invaluable throughout the development of this work.

I offer my deepest appreciation and gratitude to my supervisor, Jane Buxton, for the endless support she has provided to me and for her sage advice throughout this work, particularly related to conducting research with vulnerable populations. I am grateful to my other committee members, Dr. Anita Ho and Dr. Louise Masse, whose mentorship in the areas of ethics and psychometric instrument development was invaluable to my research. I also extend my endless thanks and gratitude to Dr. Gina Ogilvie, who has been involved in my studies and career development since the beginning. I deeply value her hard work in helping me develop my capacity to become an independent investigator and never let me settle for mediocrity. I cannot thank her enough for all she has done.

I would like to thank my parents Kathy Taylor and the late Don Taylor as well as my brother Mickey Taylor and sister Colleen Dadd for their love and endless faith in me. Special thanks to Greg Dadd for working his editorial magic. Finally, I thank my daughter, Kate Thomson, who is the sunshine in my life and who has patiently endured having a graduate student mom for 11 years.
DEDICATION

For my daughter, Kate
1 BACKGROUND, RATIONALE AND OBJECTIVES

How do health care professionals deliver care to individuals who have pronounced physical and mental illness needs, are fearful of the health care system due to stigmatization, are marginalized due to a lack of housing, addictions and mental illness, and may have questionable capacity to consent for health care (CTC-HC) due to substance use? This scenario is difficult for both health care providers and the people to whom they deliver care. Health care providers may experience anxiety when faced with the ethical dilemma of whether to treat someone with questionable CTC-HC, especially if they are uncertain about how to assess capacity. Moreover, clients who fit the description above may experience loss of autonomy and self-actualization when seeking or being offered health care and therefore are likely to avoid getting the care they need. Under some circumstances, this may mean increased morbidity among this population (including untreated communicable diseases) and possibly increased spread of disease. Moreover, individuals who misuse substances and are homeless or unstably housed (IMSH) are particularly vulnerable to not having their legal and moral rights to informed consent respected. In addition, they may feel discriminated against if they are not provided with the opportunity to consent or refuse care. This dissertation examines the importance and intricacies of assessing CTC-HC among IMSH.

The following figure displays the pathway to infringement on the right to consent or refuse health care:
This chapter describes the context in which IMSH may lack capacity to consent. Specifically, the epidemiology of homelessness and its associated morbidity as well as the epidemiology of substance misuse and its associate morbidity are described. This is followed by a description of the impact of the convergence of homelessness and substance misuse and the challenges this convergence creates for the delivery of health care and the determination of CTC-HC among IMSH.

### 1.1 The Epidemiology of Homelessness

#### 1.1.1 Definition of Homelessness

Homelessness is a broad term that has been defined differently by many sources. Infocus Consulting Ltd, was contracted by the Greater Vancouver Regional Steering Committee on Homelessness to conduct the Vancouver Homeless Count (a region-wide count of homeless individuals which is conducted every three years). It defines a person who is homeless as (2): someone “not having a place of their own where they could expect to stay for more than 30 days and if they did not pay rent. This includes people:

a. who have no physical shelter (staying on the street, in doorways, in parkades, in parks and on beaches, etc.); or

b. are temporarily accommodated in emergency shelters, safe houses for youth; or

c. transition houses for women and their children fleeing violence;
d. or are staying at someone else’s place, (friend or family) where they did not pay rent; or

e. people with no fixed address found at hospitals or jails.”

Echenberg and Jensen describe homelessness on a continuum based on the types of shelter. At one end of the continuum is ‘absolute homelessness’ defined as “only those living on the street or in emergency shelters.” The middle of the continuum is ‘hidden or concealed homelessness’ which “includes people without a place of their own, who live in care with friends, or in a long-term institution.” The other end of the continuum is ‘relative homelessness’ which is “a broad category that includes those who are housed but who reside in a substandard shelter and/or who may be at risk of losing their homes.” The research in this dissertation includes individuals who fall across the full continuum described by Echenberg and Jensen.

The European Federation of National Associations Working with the Homeless (FEANSTA) defines having a home as the following:

“Having a home can be understood as: having an adequate dwelling (or space) over which a person and his/her family can exercise exclusive possession (physical domain); being able to maintain privacy and enjoy relations (social domain) and having a legal title to occupation (legal domain).”

The FEANSTA framework explains that “homelessness consists of housing situations ranging from rooflessness (living on the street or in emergency shelters), to houselessness (living in various types of shelters or institutions), to insecure housing (living under
threat of eviction or violence), and finally to *inadequate housing* (living in unfit or overcrowded conditions).”

Echenberg and Jensen (3) also highlight the fact that homelessness involves the element of time. They stated that homelessness can be chronic (“long-term or repeated homelessness, often experienced by those with chronic illness or addiction problems”) cyclical (“resulting in a change of circumstances, for example having been released from an institution”), or temporary (“relatively short in duration, sometimes caused by natural disasters or a house fire”).(3)

For the purposes of the research in this dissertation, “homeless” and “unstable housing” are being defined as:

**Homeless:** people who have no physical shelter – staying on the street, in doorways, in parkades, in parks and on beaches, etc.; or, are temporarily accommodated in emergency shelters, safe houses for youth, or transition houses for women and their children fleeing violence; or people with no fixed address found at hospitals or jails.(2)

**Unstable housing:** living under threat of eviction or violence; or living in unfit/overcrowded conditions (including, but not limited to single room occupancy units).(4) It also includes individuals living in drug houses and in assisted living apartments in an impoverished neighbourhood.

### 1.1.2 Prevalence of Homelessness

As homelessness is the first step along the pathway to infringement on the right to consent or refuse health care (Figure 1), it is important to understand the breadth of this
problem. In 2005, it was estimated that 100 million people were homeless around the world with an additional 1.6 billion living without adequate housing.(5) A recent report on homelessness in Canada stated that at least 30,000 Canadians are homeless on any given night and 200,000 Canadians experience homelessness in any given year.(6) In 2007, more than 10,580 people were homeless in British Columbia with the greatest proportion of homeless individuals found in Vancouver (n=2,300), Victoria (n=1,550) and Prince George (n=1,050).(7)

More recent reports indicate that homelessness in Vancouver increased by 17% from 2005 to 2012.(2) This increase occurred in the context of a 10% population increase with a 48% decline in the unsheltered homeless and a 68% increase in sheltered homeless in Vancouver.(2) This same report states that 82% of people who are homeless self-report as having one or more health conditions with 40% self-reporting a mental illness. Low socio-economic status is the main reason for homelessness. Low socio-economic status not only results in poor housing, nutrition, and self-care, it may also lead to stigmatization and discrimination from health care providers.(8-11) Many IMSH are unaware of their personal rights regarding access to health care and, in particular, their right to consent or refuse health care interventions. This leaves them vulnerable to coercion and manipulation, or even worse, reluctant to access health care services completely.(12) Similarly, some people may be aware of their right to consent but feel powerless to exert their will and be respected. This paradigm often results in further morbidity and mortality due to poor social determinants of health such as living in poverty, low levels of education, food insecurity, living in poor housing conditions and social exclusion.(13)
1.1.3 Morbidities Associated with Homelessness

Individuals who are homeless have increased health needs compared to the general population due to poor social determinants of health. As a group, IMSH often suffer from mental illness, communicable diseases, and substance abuse/addiction. The 2012 Vancouver Homeless Count states that 83% of the homeless in Vancouver meet the criteria of having a substance use disorder. A recent study conducted by Vila-Rodriguez et al. found that, among a sample of 293 adults living in single-room occupancy hotels in Vancouver, the point prevalence of psychosis was 47.4% and a neurological disorder was present in 45.8% (28% confirmed by MRI). In addition, previous research has shown a direct link between homelessness and HIV transmission. In a longitudinal study of individuals who inject drugs in Vancouver, researchers found that people living in unstable housing are at elevated risk of HIV infection due to risk behaviours associated with these environments, such as borrowing needles.

These data highlight the vulnerability of people who are homeless or unstably housed. Individuals who misuse substances experience similar vulnerabilities.

1.2 The Epidemiology of Substance Misuse

1.2.1 Definition of Substance Misuse

Substance misuse leading to impaired cognitive functioning is the second stage along the pathway to possible infringement on the right to consent or refuse health care (see Figure 1). The Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) defines substance misuse as “a maladaptive pattern of use indicated by continued use
despite knowledge of having a persistent or recurrent social, occupational, psychological or physical problem that is caused or exacerbated by the use or by recurrent use in situations in which it is physically hazardous.” The definition of ‘addiction’ is somewhat different. Some sources describe individuals who are addicted as having lost all control of their substance use.(19) According to Inaba and Cohen (19), addiction is comprised of four components: 1) loss of control, 2) compulsive drug use, 3) cravings for drugs, and 4) continued use despite increasing negative consequences. For the purposes of this dissertation the terms substance misuse and substance addiction will be used interchangeably as both conditions involve impaired cognitive function.

1.2.2 Prevalence of Substance Misuse

The World Health Organization (WHO) reported that the global prevalence of substance use disorders among adults in 2004 was between 0% - 3% with the highest prevalence rates found in the Eastern Mediterranean region.(20) In 2011, Health Canada surveyed 10,076 individuals, aged 15 and older, across Canada in their ‘Canadian Alcohol and Drug Use Monitoring Survey’ (CADUMS). They reported that 77% of respondents stated they had used alcohol in the past 12 months and 9.4% of respondents stated they had used either cannabis, cocaine (powder or crack), speed, ecstasy, hallucinogens or heroin in the past year.(21) Moreover, 0.7% of all respondents reported abusing non-illicit (prescribed) pharmaceuticals and among these, 3.2% reported abusing pharmaceuticals to “get high”. Among those who reported abusing any drug (illicit or prescribed) in the past year, 17.6% experienced a drug-related harm which included harm to physical health, friendships and social life, financial position, home life or marriage, work, studies, employment opportunities, legal problems, difficulty learning, and/or
Incidence of self-reported drug-related harms was slightly higher in females (19.3%) compared to males (16.0%). Canada is now the highest per capita consumer of high potency opioids and in 2009 was the second highest per capita user of prescription narcotics in the world.(22)

In British Columbia, 1,009 participants were surveyed in the CADUMS survey, 13.8% of which reported using an illicit drug in the past year.(21) A policy paper written by BC Physicians in 2009 reported that 224,000 British Columbians demonstrated a dependency on alcohol, and 33,000 had a severe addiction to illicit drugs. According to the 2009-2013 BC Coroners report (23), there were 279 accidental overdose deaths and 7 suicides from alcohol or drug poisoning in 2013. Moreover, according to the BC Centre for Applied Research in Mental Illness and Addiction, (24) 11,750 British Columbians with severe addiction and/or mental illness are homeless (2,000 – 4,000 from Vancouver’s downtown eastside (DTES)). In 2008, one in ten visits to Vancouver General Hospital’s emergency department was due to misusing substances.(25)

Substance misuse is not limited to adult populations. The 2013 Adolescent Health Survey (26), conducted among a representative sample of youth throughout British Columbia (BC), reported the prevalence of substance use among adolescents 13-17 years old. Forty-five percent of youth reported ever using alcohol. Among the youth that reported ‘ever’ using alcohol, 39% reported binge drinking (>5 drinks within a couple of hours) in the past month. This is particularly concerning as the initiation of drinking alcohol early in life is associated with problematic drinking later in life.(27) Of additional concern, 26% of youth surveyed stated they had ever used marijuana, 11%
stated they had used prescription pills for recreational purposes, and 2% stated they had used amphetamines.

Vancouver, B.C., like other major urban areas, has neighbourhoods that have a large proportion of individuals who are highly economically disadvantaged. Areas such as Vancouver’s downtown east side (DTES), are characterized by a mix of demographic, economic and social factors that can facilitate the rapid spread of infectious diseases in the local and ultimately broader population. In the DTES, there were estimated to be 4000 - 4700 injecting drug users (IDUs) in 2000. A more recent study conducted by Vila-Rodriguez et al. revealed 95% prevalence of substance dependence among 293 adults living in single-room occupancy hotels in the DTES including 61.7% with injection drug use.(16)

1.2.3 Morbidities Associated with Substance Use

Injection drug use is associated with a high prevalence of physical and mental co-morbidities requiring medical care. The Substance Abuse and Mental Health Services Administration (SAMHSA) in the USA report that 28 million “adults receiving treatment for mental health problems may also have substance abuse problems.”(30) In Toronto, people misusing substances have reportedly high rates of mental problems including serious anxiety, serious depression, overdose (31) and have received prescription medication for a mental health problem.(32) In BC, 6.88 persons per 100,000 population died of drug overdose in 2011 and 94.69 persons/100,000 were hospitalized due to morbidities associated with illicit drug use in the same year. Other researchers conducted a study in Vancouver among individuals who are HIV infected. They reported
that the effectiveness of highly active antiretroviral therapy (HAART) is hindered by the high prevalence of alcohol and illicit drug use in the population they studied. (33-36)

Substance misuse, in particular misuse of alcohol and illicit drugs, leads to high rates of communicable diseases, blood borne infections and other serious morbidities such as psychotic symptoms (psychosis), cardiovascular disease, hepatotoxicity, rhabdomyolysis, musculoskeletal disorders, diabetes and other endocrine disorders, pulmonary complications, death, and gynecological complications such as still birth. (37-42) Other health problems associated with injection drug use include abscesses and phlebitis (due to poor injection techniques and injecting with unsterile water) and endocarditis. The use of drugs by injection accounts for an increasing proportion of new HIV infections, likely due to sharing needles. The proportion of reported adult HIV cases attributed to IDU in B.C. is decreasing (12.2% in 2012) (43) but are substantially higher than the rate of 8.9% prior to 1995 (44). Injection drug use is the primary cause of Hepatitis C and, although there has been a dramatic decline in reported cases of Hepatitis C (2882 per 100,000 population in 2007 to 1885 per 100,000 per population in 2012), transmission of Hepatitis C through injection drug use remains a concern. (45)

1.3 Health Needs of Those Who Are Homeless and Who Misuse Substances

The convergence of homelessness and substance misuse has a synergistic effect on the health of those affected. This is third in the pathway (Figure 1) to possible infringement on the right to consent or refusal of health care. The health needs of IMSH are “multiple and complex.” (46) Morbidities experienced my IMSH may be the result of
substance misuse. In some cases, morbidities such as mental illness, result in homelessness.(47)

Misuse of illicit drugs and alcohol has costly health, social and community impacts and is known to be associated with homelessness.(48) Research from outside of Canada reports that 29% to 79% of homeless individuals use alcohol and/or illicit drugs.(49;50) The 2012 Vancouver Homeless Count report states that 83% of the homeless in Vancouver meet the criteria of having a substance use disorder.(51)

According to a survey conducted by the Centre for Addictions Research BC, 70% of adults living on the streets in Vancouver and Victoria in 2012 used crack cocaine in the past month.(52) Tobacco, crack cocaine and marijuana were the top three substances reported to be used by the group they surveyed, followed by alcohol. In addition, many substances including prescription drugs were used and available in Vancouver and Victoria.(52)

Morbidities associated with substance use are compounded by the fact that people who use illicit drugs, particularly if they are further marginalized by homelessness, often avoid going to a primary care provider for their health needs. They are more likely to attend emergency rooms when they require health care, often when their health concern has advanced to a severe state.(14;15;53;54) When IMSH do present for health care, clinicians may feel uncertain about the individual’s CTC-HC leaving the individual even more vulnerable to possible infringement of his/her rights to consent or refuse care (third step along the pathway).
1.4 Context of Delivering Health Care to IMSH

IMSH often have serious health care needs that require the attention of a primary care physician or a tertiary health care provider. However, barriers that IMSH experience related to accessing health care include fear of stigma and provider discrimination. (55-59) According to Link and Phelan, the term stigma is applied “when elements of labelling, stereotyping, separation, status loss, and discrimination co-occur in power situations.” (60)(page 367) The creation of low-threshold clinics and services have helped to reduce access barriers. “Low threshold has to do with the extent of barriers that must be crossed in order to access a health care service.”(55)(page 10)

Street outreach programs are a type of low-threshold service that aims to remove as many barriers as possible to provide care in a non-judgmental manner to hard-to-reach populations, including meeting clients were they live and congregate.(55) Such locations include streets, store fronts, back alleys, hotels, and parks. The goal is to provide “non-judgmental support and strategies to reduce the risk of harm to both the client and the community.”(56)(page 22).

The BC Centre for Disease Control (BCCDC), a provincial specialized public health agency, provides direct patient care to impoverished, marginalized populations through the STI/HIV Street Outreach Program (61) and the Tuberculosis Outreach Program. In this setting, nurse-client encounters are often brief and hurried especially when clients are distracted by the need to find money and/or drugs. While this type of care delivery enables the provision of health care to hard-to-reach populations, the setting introduces challenges to assessing CTC-HC.
The very nature of street outreach creates its own set of challenges. Street outreach involves bringing services to clients, wherever they are, rather than waiting for clients to seek care. However, even under these circumstances, marginalized populations may remain mistrustful of street nurses. Therefore, many street nurses strive to sensitively build rapport and trust among their clients by listening and accepting their clients’ social and economic situations, respecting their clients’ autonomy, and communicating in a manner that is acceptable to this population.

Further challenges to delivering care in street outreach settings include the emotional and psychological status of clients when attempts to deliver care are made, especially among those who may be under the influence of illicit drugs or alcohol. Clients who are cognitively impaired on substances like crack cocaine or methamphetamines are likely to be restless, unable to communicate in a coherent manner, and distracted by the effect of the drug (see Table 1). Similarly, clients who have recently used an opioid, such as heroin, are likely to be sleepy, nodding off, and unable to form coherent sentences. Other clients may experience drug-induced psychosis resulting in hallucinations, and/or paranoia. Clients under the influence of alcohol may display relaxing and dulling of the mind. Additionally, a large majority of clients who are homeless or living in unstable housing have mental illness (such as depression, schizophrenia and other psychoses) making it difficult for nurses to communicate and deliver care. Paranoid ideations are particularly challenging for caregivers who attempt to deliver beneficial care to clients who may believe that government agencies (or other authorities) are trying to harm them.
Distraction can be another barrier to delivering street nursing care. Because clinical care often occurs on the streets, in back alleys, hotels, and parks, (63-65) clients may be engaged in sex-work exchanges, illicit drug deals, or other activities that are viewed (by the client) as a higher priority than health care. Similarly, clients who are experiencing symptoms of withdrawal from substances (“dope sick”) often have moderate to severe symptoms including anxiety/agitation, gastrointestinal discomforts, and diaphoresis which consumes their direct attention. In these situations, street outreach nurses may decide to delay care until the client is less distracted or deliver care in a very short nurse-client encounter. Alternatively, nurses may feel the safety of the client or themselves is at risk and may make the nurse-client encounter brief. Under all of these circumstances, outreach nurses may experience difficulties with discussing options for health care, the risks and benefits, and assessing their clients’ capacity in order to obtain informed consent for care.

1.5 Research Rationale

Delivering care in street outreach settings to IMSH is both important and challenging. Reaching individuals who avoid health care in traditional settings is an effective way to meet the complex needs of this population. However, as noted previously, a street outreach setting often involves interacting with individuals who may lack the CTC-HC due to substance use. Health care providers have an ethical obligation to respect clients and a legal obligation to determine whether their clients have the CTC-HC (or lack capacity to consent) prior to providing interventions. However, these obligations may sometimes conflict with health care providers’ other ethical obligations to beneficence and nonmaleficence, which require clinicians to promote their clients’
well-being and to prevent harm. These obligations will be described further shortly. Faced with such dilemmas, clinicians may adopt a paternalistic approach, erring on the “safe” side by assuming their clients lack capacity, so they can proceed with the intervention. This is most likely to occur when a client is exercising his/her right to refuse care. However, this approach may inadvertently deny individuals of their right to consent or refuse care when health care professionals are mistaken. The risk in this type of scenario is that clients may receive care that they do not want, further embedding their mistrust of health providers. Another risk is that clients may be denied care that they want if the clinician feels the clients have questionable capacity to consent.

Instruments for conducting a capacity assessment exist across a wide range of populations with impaired ability to make decisions. However, capacity assessment instruments among IMSH have not been established and therefore health care providers assess clients in an unstandardized manner. There is a need for an evidence-based instrument that can be used to assess CTC-HC in a standardized way for IMSH.

1.6 Conceptual Framework

The research described in this dissertation is primarily grounded in Faden and Beauchamp’s theory of informed consent (66) and Thompson/Dowding’s decision-making theory.(67) Other theories that address ethical aspects of informed consent for both research and health care have been described by others.

It is important to delineate the difference between clinical interventions that are delivered as part of research from those delivered as part of standard clinical care. According to the Belmont Report (a National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research that was developed in 1979),(68) if the
intervention is experimental (i.e., tests a hypothesis), and contributes to generalizable knowledge, then it is considered research. Conversely, if the intervention is meant to improve the well-being of an individual and is not experimental, then it is considered standard practice. The Belmont Report outlines basic ethical principles for the protection of participants of research studies. These principles include, 1) respect for persons, 2) beneficence, and 3) justice. The first principle, respect for persons, refers to the conviction that “individuals should be treated as autonomous agents” and “persons with diminished autonomy are entitled to protection.” (68) Autonomy refers to the ability to deliberate about a health care intervention (including an understanding of risks and benefits) and be able to act according to their deliberation. The second principle, beneficence, refers to an obligation to maximize possible benefits and minimize possible harms. The final principle outlined in the Belmont Report is ‘justice’. Justice refers to “fairness in distribution”, not denying an entitled person without good reason, and not unduly imposing a burden.(68)

The basic principles provided in the Belmont Report are very similar to those provided by Beauchamp and Childress: (12): 1) respect for autonomy, 2) beneficence, 3) nonmaleficence, and 4) justice.

The Belmont and Beauchamp/Childress principles form an excellent foundation for Western biomedical ethics and were taken into consideration in my research addressing capacity to consent. Respect for person and autonomy are particularly important principles when clinicians are assessing CTC-HC among IMSH. These individuals are accustomed to being disrespected and their opinions and choices are often not considered important. Clinicians can change clients’ assumptions that their opinions and choices
don’t matter by providing respectful care. Beneficence and nonmaleficence are part of clinicians’ professional code of ethics. Clinicians who are offering care to (or receiving a request for care from) IMSH should ensure that a client has the CTC-HC in order to avoid doing harm while attempting to maximize the benefits that client may receive from the clinical intervention. Finally, justice is a critical principle that should be applied to marginalized populations such as IMSH. When assessing capacity to consent, clinicians must ensure that IMSH are provided an equal opportunity to consent to (or refuse) care, if they have capacity. Therefore, it is important that clinicians have the skills required to assess capacity among this population.

Freedman (69) provided a moral theory that, unlike the principles described by the Belmont Report and Beauchamp and Childress, is specific to informed consent. Freedman’s theory encompasses four tenets and are particularly relevant to this dissertation: 1) the provision of adequate and sufficient information to the client (there is a balance between providing too much and too little information), 2) ensuring the client demonstrates ‘responsibility’ in their life in general which enables him/her to make a responsible decision for a specific health intervention, 3) establishing whether the client is voluntarily making a decision or if they may be under duress, and 4) determining if the client has the mental capacity to make a decision. (69) This theory puts assessment of mental capacity as part of the main aspects of informed consent; however, Freedman’s argument about the client demonstrating ‘responsibility’ in their life in general is something that does not align with the experiences of IMSH as some might argue that procuring illicit drugs does not demonstrate ‘responsibility’.
Faden and Beauchamp (66) published comprehensive theory that focuses on informed consent. This theory covers consent for both research and therapeutic interventions and includes: 1) autonomous authorization (including intention, understanding, and non-control [persuasion or coercion]), and 2) effective consent (including disclosure of risks and benefits, competence), and is the theory that has been incorporated into my conceptual framework.

Decision making theory, as described by Muir (70), provides a framework of how clinicians, particularly nurses, make clinical decisions. These methods include analytical and intuitive approaches to making decisions and are described in more detail in Chapter 3.

There are other contributing factors that come into play along the pathway of determining capacity to consent. These include the clinical environment (physical environment) in which that encounter takes place, the therapeutic context (i.e., is the health care intervention associated with high risks of harm), and the availability of a capacity assessment instrument which can be used to guide clinicians in assessing clients who misuse substances.

Factors that impact assessment of CTC-HC among IMSH are described at the macro (policy), meso (community) and micro (individual) levels respectively. At the macro level, factors such as legal rights and obligations, professional obligations, as well as ethical/moral rights and obligations, provide guiding policies and overarching principles related to what ‘ought’ to be done when delivering care to and obtaining informed consent from individuals who may or may not be impaired due to substance use. Within this macro context there are factors at the meso level, such as social norms
that contribute to the presence or absence of stigma, and discrimination against individuals who misuse substances and who are homeless, resulting in health equity or inequity at the community or population level. Other factors that influence assessment of CTC-HC at the meso level include the availability of substances in a community, the type of substances in a community, and legal tolerance toward open substance use. All of these play a role in how impaired individuals may be when accessing health care.

Factors at the micro level that are embedded within the macro and meso level environments, can be divided into two categories: 1) micro level factors at the client level and 2) factors at the clinician level. At the client level, the person’s sense of autonomy, self-determination, and recognition that he/she is an agent of his/her own decision-making are all relevant. In addition, the client’s socio-economic status (SES) and age impact how well they are able to make responsible decisions, and how others (clinicians) view their ability to make decisions that show understanding, appreciation, and rational thought processes. Finally, disorders such as mental illness and substance addiction, as well as the type of substances used, can impact a client’s capacity to consent.

At the same time, factors that clinicians bring to a clinical encounter, such as respect or denial of the client’s personhood, attitudes and beliefs surrounding substance use, and adoption of beneficence and nonmaleficence principles, all influence how each clinician approaches assessing capacity to consent. In addition, the level of competence clinicians have related to performing capacity assessments impacts how well an assessment will be conducted. Finally, the level of experience delivering care to individuals who misuse substances (and are homeless or unstably housed) can either
contribute to better capacity assessment approaches or approaches with pre-conceived negative perspectives.

The following figure illustrates the aforementioned conceptual framework:
Figure 2: Conceptual framework for assessing CTC-HC among IMSH
1.7 Overall Goal

The purpose of the research described in this dissertation is to enhance and extend the current literature in the area of obtaining consent for health care in individuals suffering from addiction and homelessness (or unstable housing), by developing a concise capacity assessment instrument that can assist clinicians who work with that population. The aim is twofold: first, to provide this instrument to public health clinicians for use in determining if their clients who are under the influence of alcohol and/or drugs lack capacity to make health care decisions; and second, to provide an instrument with the least number of questions while maintaining good psychometric properties.

1.8 Overall Objectives
The overall objectives of this study are as follows:

1) To determine the current practice that clinicians in BC use to assess CTC-HC among IMSH.
2) To develop a brief psychometric instrument that clinicians can use to assess whether their clients lack CTC-HC.
3) To determine the psychometric properties (validity and reliability) of the new instrument.

1.9 Design

This dissertation employs a two-phase mixed methods approach. There is a qualitative (formative) phase which informed the development of the quantitative phase.
The development of my psychometric instrument involved multiple phases that are displayed in the following figure:

**Figure 3: Flow of research activities**

1. Literature Review
2. Qualitative inquiry
3. Item Development
4. Cognitive testing of instrument
5. Pilot testing of instrument
6. Validation: Administration of instrument to 302 volunteers
7. Psychometric analysis

### 1.10 Study Setting

This study took place in Vancouver, British Columbia, Canada. This location was selected for the study, not only because of its close proximity to the research team, but also because Canada is the highest per capita consumer of high potency opioids and second highest user of prescription narcotics worldwide.\(^{(22)}\) In addition, Vancouver has been referred to as an epicenter of illicit drug use\(^{(71)}\) making it an ideal environment to recruit IMSH. Vancouver’s DTES is one of the oldest neighbourhoods in Vancouver and is located in the heart of city’s downtown core adjacent to the business section. The DTES is known for its high incidence of poverty, sex trade, low income housing, crime, violence and drug use.\(^{(72)}\) It is also known for its high rates of STIs, hepatitis, and tuberculosis. As mentioned above, this is largely due to the DTES population living with poor determinants of health.

Vancouver’s DTES is known for its community activism which often involves advocacy groups such as the Vancouver Area Network of Drug Users (VANDU).\(^{(73)}\) VANDU was formed in 1998 in response to the HIV/AIDS epidemic and aims to address issues of “poverty, social exclusion, criminalization, and ancillary illness.”\(^{(73)}\) VANDU is funded by the Vancouver Coastal Health Authority and is a self-governing non-profit
organization whose members engage in illicit drug and alcohol use. Through its activism, VANDU has made significant contributions, including successfully challenging Canada’s Controlled Drugs and Substance Act, helping to bring heroin maintenance trials to Vancouver, and advocating for dignified housing and health care for people who misuse substances. VANDU was a major collaborator in the research described in this dissertation in that it provided culturally appropriate suggestions for conducting research within its community, provided peer researchers and study coordinators, provided space to conduct the research, and recruited research participants.

In response to the high medical and social needs of individuals living in the DTES, numerous services have been established to address the unique needs of the population. These include organizations that provide assistance with housing, advocacy support, free or low cost clothing, medical and dental services, detox and emergency services, as well as employment and personal development services. Numerous health clinics exist in the DTES that, apart from delivering standard care, are specialized in addressing issues of addiction, physical and emotional abuse, and mental illness. The provision of specialized services in the DTES is essential to the well-being of the community and staff providing these services are accustomed to working with IMSH. This familiarity may result in less stigmatization from these staff compared to staff of clinics outside the DTES. Stigmatization can result in discrimination including assumptions of lack of CTC-HC when impaired by a substance. This is particularly evident when the people who live in the DTES attempt to access services such as hospital emergency rooms that are outside the DTES.
Over the last 40 years, street outreach programs have emerged in B.C., including Vancouver, to deliver health services to street-involved and otherwise marginalized populations. In 1988, the BC Centre for Disease Control (BCCDC) started a street nurse program in an effort to address the increased incidence of HIV/AIDS and STIs among individuals who misuse substances as well as other populations not accessing traditional primary care such as sex workers, street youth, and individuals who are homeless. (65)

An evaluation of this program revealed that clinical care, education, harm reduction and prevention programs resulted in long-term relationships with clients, particularly individuals who misuse drugs who were previously distrustful of the health care system. These new trusting nurse-client relationships increased opportunities to screen and treat those who may be at risk of acquiring a STI but, until that time, were reluctant to access health care. (74) The partnership and collaboration between the clients and the street nurses also resulted in clients taking steps toward reducing harm and promoting well-being. (75) Research from other jurisdictions has shown that risk-reduction interventions delivered to individuals who misuse illicit drugs as part of outreach programs results in significantly lower levels of drug use and improves readiness for full recovery. (76)

However, risk-reduction interventions and other health care interventions must be conducted with informed consent in order to maintain and further build trust. An assessment of CTC-HC must be conducted prior to implementing any intervention, but little is known about how to assess among IMSH.
1.11 Dissertation Overview

In this Chapter, I provided an introduction to the need for a capacity assessment instrument for use in marginalized populations who misuse substances and who are homeless or living in unstable housing. I also stated the focus (goal and objectives) of my research study.

Chapter 2 offers a literature review including the epidemiology of substance abuse and homelessness, the effects of illicit substances, the context and challenges of delivering health care to individuals who misuse substances and who are homeless or living in unstable housing. I also provide definitions (legal, ethical, and professional) of consent as well as definitions for capacity and incapacity. Finally, I provide a critical review of capacity assessment instruments that currently exist in the medical literature.

Chapter 3 describes the formative research that was conducted to inform the construction of a new instrument to assess CTC-HC among the target population. I provide the theory that informed the construction of the new instrument, as well as the methods and results of qualitative interviews conducted to determine the current practice outreach nurses use to assess capacity to consent amongst their clients and to determine the experiences that the target population have with providing consent (or refusal) while accessing health care.

Chapter 4 describes the process of incorporating concepts from the literature and concepts obtained in the formative research to develop items for the new capacity assessment instrument. I describe the process of engaging content experts and using a modified Delphi process to formulate the new instrument.
Chapter 5 describes the methods and results of a validation study aimed at determining the psychometric properties of the new instrument and assessing content validity by comparing it to both a psychiatric clinical assessment and the results of the MacArthur Capacity Assessment Tool for Treatment (MacCAT-T), which is the most widely used capacity assessment instrument.

Chapter 6 provides the results of the validation phase of the dissertation. This includes a description of the study population, the results of the psychometric analysis and evidence of reliability and validity of the new instrument.

Chapter 7 is the discussion chapter. It provides an interpretation of the research findings as well as limitations of the research that was conducted. Finally, it describes opportunities for future research.
2 LITERATURE REVIEW OF SUBSTANCE USE, CONSENT AND EXISTING CAPACITY ASSESSMENT INSTRUMENTS

The previous chapter outlined the unique challenges that IMSH face when accessing health care. This population is particularly vulnerable to coercion and manipulation due to stigmatization and discrimination as a result of poverty and substance use. In addition, health care workers are challenged when attempting to provide care to this population, especially if individuals attempt to access care while under the influence of drugs or alcohol. Nonetheless, being under the influence of a psychotropic substance does not always mean that individuals lack CTC-HC and it is incumbent upon care providers to carefully assess whether their clients lack capacity to consent for the care they are being offered or seeking.

This chapter describes the effects of substances (alcohol and drugs), defines consent and CTC-HC, reviews the literature related to existing capacity assessment instruments, and highlights concepts that may be important to include in a new capacity assessment instrument for IMSH.

2.1 Effects of Substance Misuse

According to Inaba and Cohen (19) psychoactive drugs can be grouped into three major classifications: 1) stimulants, 2) depressants, and 3) psychedelics. Alcohol fits into the depressant category. Table 1 describes the physical and mental effects of each category.
<table>
<thead>
<tr>
<th>Classification</th>
<th>Examples of Substances in Class</th>
<th>Physical Effects</th>
<th>Mental/Emotional Effects</th>
<th>Withdrawal Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stimulants</td>
<td>Cocaine</td>
<td>Excessive stimulation of the central nervous system (CNS) including energized muscles, increased alertness, insomnia, increased heart rate and blood pressure, and decreased appetite</td>
<td>Feeling of confidence</td>
<td>Inability to feel pleasure</td>
</tr>
<tr>
<td></td>
<td>Amphetamines (Adderall, crystal meth, speed)</td>
<td>Depletion of the body’s energy chemicals causing exhaustion</td>
<td>Excitement</td>
<td>Total lack of energy</td>
</tr>
<tr>
<td></td>
<td>Amphetamine congeners (Ritalin, diet pills)</td>
<td>Rapid respirations and dilation of bronchial vessels</td>
<td>Feeling outgoing</td>
<td>Emotional depression</td>
</tr>
<tr>
<td></td>
<td>Plant stimulants (khat, betel nuts, ephedra, yohimbe)</td>
<td>Heart, blood vessel and seizure problems (enlarged heart, damaged heart muscles, coronary arteries, and other blood vessels)</td>
<td>Feelings of a rush or high</td>
<td>Loss of motivation</td>
</tr>
<tr>
<td></td>
<td>Caffeine (coffee, colas, energy drinks)</td>
<td>Stroke</td>
<td>Anger</td>
<td>Anxiety</td>
</tr>
<tr>
<td></td>
<td>Nicotine</td>
<td>Heart attack</td>
<td>Rapid speech</td>
<td>Craving</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Neonatal death</td>
<td>Aggressiveness</td>
<td>Vivid and unpleasant dreams</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dental erosion</td>
<td>Paranoia</td>
<td>Insomnia</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Gastric ulcerations</td>
<td>Inability to experience pleasure</td>
<td>Increased appetite</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Retroperitoneal fibrosis</td>
<td>Mental confusion</td>
<td>Psychomotor agitation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Impaired ability to be attentive impacting decision making</td>
<td></td>
</tr>
<tr>
<td>Classification</td>
<td>Examples of Substances in Class</td>
<td>Physical Effects</td>
<td>Mental/Emotional Effects</td>
<td>Withdrawal Symptoms</td>
</tr>
<tr>
<td>----------------</td>
<td>--------------------------------</td>
<td>-----------------</td>
<td>--------------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Intestinal ischemia</td>
<td>Lowered inhibition inducing freer behaviour</td>
<td>Mild increases in blood pressure, body temperature, respiration and pupil size</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Crack or meth dancing (involuntary writing, flailing, jerky movements)</td>
<td>Relaxing and dulling the mind</td>
<td>General feeling of unease</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Respiratory problems (pneumonia, crack lung, respiratory failure)</td>
<td>Diminished anxiety</td>
<td>Mood swings</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Slow heart rate</td>
<td>Controlling some neuroses</td>
<td>Sleep disturbances</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sedation</td>
<td>Euphoria (in certain depressants)</td>
<td>Anxiety</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Depressed respiration</td>
<td>Psychological and physical dependence.</td>
<td>Cravings</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Relaxed muscles</td>
<td></td>
<td>Hyperactivity (uncontrollable jerking or kicking)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Decreased coordination</td>
<td></td>
<td>Diaphoresis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Induction of sleep</td>
<td></td>
<td>Gastrointestinal disturbances (stomach cramps, vomiting, diarrhea)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dull senses</td>
<td></td>
<td>Bone, joint, and muscle pain</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Diminished pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nausea</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pinpoint pupils</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Droopy eyelids</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nodding head</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Slowed coordination</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dysmenorrhea</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Constipation</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Slurred speech</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sexual dysfunction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depressants</td>
<td>Opiates (opium, heroin, oxycodone, hydrocondone, methadone, Fentanyl)</td>
<td>Slow heart rate</td>
<td>Lowered inhibition inducing freer behaviour</td>
<td>Mild increases in blood pressure, body temperature, respiration and pupil size</td>
</tr>
<tr>
<td></td>
<td>Sedative-hypnotics (alprazolam, clonazepam, barbiturates, z-hypnotics, ramelteon)</td>
<td>Sedation</td>
<td>Relaxing and dulling the mind</td>
<td>General feeling of unease</td>
</tr>
<tr>
<td></td>
<td>Alcohol (beer, wine, hard liquors)</td>
<td>Depressed respiration</td>
<td>Diminished anxiety</td>
<td>Mood swings</td>
</tr>
<tr>
<td></td>
<td>Others (antihistamines, skeletal muscle relaxants, bromides)</td>
<td>Relaxed muscles</td>
<td>Controlling some neuroses</td>
<td>Sleep disturbances</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Decreased coordination</td>
<td>Euphoria (in certain depressants)</td>
<td>Anxiety</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Induction of sleep</td>
<td>Psychological and physical dependence.</td>
<td>Cravings</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dull senses</td>
<td></td>
<td>Hyperactivity (uncontrollable jerking or kicking)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Diminished pain</td>
<td></td>
<td>Diaphoresis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nausea</td>
<td></td>
<td>Gastrointestinal disturbances (stomach cramps, vomiting, diarrhea)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pinpoint pupils</td>
<td></td>
<td>Bone, joint, and muscle pain</td>
</tr>
<tr>
<td>Classification</td>
<td>Examples of Substances in Class</td>
<td>Physical Effects</td>
<td>Mental/Emotional Effects</td>
<td>Withdrawal Symptoms</td>
</tr>
<tr>
<td>----------------</td>
<td>---------------------------------</td>
<td>-----------------</td>
<td>-------------------------</td>
<td>---------------------</td>
</tr>
</tbody>
</table>
| Psychedelics   | • Indoles (LSD, psilocybin mushrooms  
• Phenylalkylamines (peyote, ecstasy)  
• Anticholinergics (belladonna, mandrake)  
• Cannabinoids (marijuana, hashish, sinsemilla, synthetic marijuana)  
• Others (ketamine, PCP, salvia divinorum, nutmeg, dextromethorphan, bromo-dragonFLY, lion’s tail amanita mushrooms) | • Distorts perceptions  
• Nausea and anorexia  
• Dizziness  
• Dilated pupils, blurred vision, and twitching eyelids  
• Increased or reduced appetite  
• Bloodshot eyes  
• Increased blood pressure and heart rate  
• Cardiac arrhythmia  
• Sweating  
• Palpitations  
• Anesthesia (PSP and ketamine)  
• Jaw clenching  
• Tremors  
• Hyperactivity  
• Headaches  
• Seizures, stroke, coma | • Induces illusions, delusions, or hallucinations  
• Confused perception  
• Synesthesia (crossover or mixing of the senses)  
• Impaired concentration and motivation  
• Loss of judgment  
• Memory impairment  
• Slowed reaction time  
• Anxiety  
• Panic  
• Feelings of grandeur  
• Severe depression | • Tachycardia  
• Muscle cramps  
• Seizures  
• Anger, irritability, anxiety, aggression  
• Aches, pains, chills  
• Depression  
• Inability to concentration  
• Sweating  
• Craving  
• Tremors  
• Sleep disturbances  
• Decreased appetite  
• Stomach pain. |

*Information is from Inaba and Cohen (19)*
As seen in Table 1 (above), all of the above-mentioned substances have physical and mental effects which have the potential to influence a person’s CTC-HC. In addition to these physical and mental effects, substance abuse can have social side effects such as legal problems (including incarceration), problematic relationships, and financial and work difficulties. Inaba and Cohen (19) point out that while the desired effects of psychoactive substances (including alcohol) include getting high, gaining confidence, disinhibition, control of anxiety and getting relief from psychological pain (self-medicating), they are counteracted by “mild, moderate, dangerous, and sometimes fatal side effects.” (page 231) Inaba and Cohen refer to the divergence between the desired effects and side effects as “the Catch-22 of psychoactive drug use.” (19) (page 231)

2.2 Definitions of Consent

2.2.1 Legal Definition of Consent

In 1996, BC enacted the Health Care [Consent] and Care Facility [Admission] Act (hereafter the BC Consent Act) that outlines the rights of adults to consent to health care, as well as the elements of consent. (77) This legislation clearly stipulates that individuals must be capable of making rational decisions about their health and outlines how incapability to consent is determined. (77) The BC Consent Act (77) states that “an adult consents to health care if: (a) the consent relates to the proposed health care, (b) the consent is given voluntarily, (c) the consent is not obtained by fraud or misrepresentation, (d) the adult is capable of making a decision about whether to give or refuse consent to the proposed health care, (e) the health care provider gives the adult the information a reasonable person would require to understand the proposed health care and to make a decision, (f) the adult has an opportunity to ask questions and
receive answers about the proposed health care.” Finally, clients must be capable of making decisions that are consistent with their personal values, preferences and wishes. (78)

It is important to note that capacity is different from competency. Capacity is a clinical status that is judged by a health care professional whereas competency is a legal status of a global state that is judged by a legal professional, usually a judge. (79) Furthermore, competency is assessed as a long term status whereas capacity is thought to be on a continuum judged for a single circumstance. (80)

2.2.2 Ethical Definition of Consent

Throughout history, certain groups of people (racial groups, enemies of war) have been treated as ‘less than’ people and “have often been treated as having no moral status or having a lower moral status” and therefore have no moral rights. (12) Lower moral status refers to an attitude in society that views people with ‘questionable’ morals as being less accepted in the community. Some people may consider individuals who misuse substances and who are homeless (or living in unstable housing) as belonging in a ‘low/no moral status’ group. This perspective is a result of these individuals’ failure to follow a moral norm. A moral norm refers to actions that the general society view morally acceptable. This norm sets the stage of acceptable moral actions and values in the society. What starts as mainstream society’s criticism or disapproval of these individuals may lead to intimidation, manipulation, coercion, or exploitation. (12) Therefore, when planning and delivering care to these individuals it is important to acknowledge them as moral agents who are presumed to be capable of consenting (or refusing) health care.

Ethical discussions of consent, in this dissertation, are limited to biomedical ethics (ethical rights of individuals) rather than public health ethics (ethical rights of populations) as the
focus is on protecting the moral rights of individuals. Principles of biomedical ethics, including beneficence, nonmaleficence, and autonomy are important elements of informed consent. (12) By this, I mean that clinicians acting as moral agents must provide benefits to their clients and refrain from doing harm. In obtaining informed consent for health care, clinicians should communicate how the clients will benefit from the health care intervention and warn them of reasonably foreseeable harms. In providing informed consent for health care, clients should demonstrate autonomy, understanding, rational thinking, and appreciation of their illnesses (to name a few) and expressing a choice to agree or refuse care. Obtaining informed consent can be particularly challenging when dealing with individuals who are thought to be vulnerable to coercion and manipulation.

According to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2), individuals are vulnerable when they are not able to safeguard their own interests. This vulnerability may be “caused by limited capacity” due to substance dependency. (78) (page 97) Others have defined a vulnerable person as, “one whose color, gender, minority status, or condition moves it to the margins of the mainstream of society.” (81) (page 28) Consent must be informed, free, and voluntary and requires the clinician exhibiting what the TCPS calls ‘Respect for Persons’. Although the TCPS relates to various types of research involving humans, the tenets of consent can be transferred to consent for clinical care. These tenets include that consent is both voluntary (not under pressure or undue influence) and informed (the client must understand the purpose of the clinical care including the risks and benefits associated with the health care intervention). Consent occurs when the client communicates agreement or refusal to have the health care intervention. This expression of
choice is viewed as the client expressing autonomy. It is equally important to note that voluntary consent is an ongoing process that may be withdrawn at any time.

Beauchamp and Childress’s ethical principles surrounding informed consent (autonomy, beneficence, nonmaleficence, and justice) were adopted for the TCPS2. The TCPS2 core principles are: respect for persons, concern for welfare, and justice.(78) In the TCPS2 document, respect for persons refers to a recognition that all humans (regardless of their lifestyle) have intrinsic value and that they should be given the respect and consideration that is due to them. This section also talks about capacity; specifically that people who lack capacity may be incapable of exercising their autonomy. Concern for welfare refers to an obligation on the researcher’s part to protect the client’s quality of life. This includes ensuring that clients are given adequate information about risks and benefits, and not incur any unnecessary risk for the purpose of research. Although this principle is described in the context of research ethics, it also applies to informed consent for health care intervention. The third TCPS2 principle is justice, which refers to treating people fairly and equitably. The TCPS2 defines informed consent to treatment as an “individual’s autonomous and voluntary authorization of a medical decision” for which an individual has substantial understanding of the risks and benefits.(12) This is contrasted with an equally important human right to informed refusal or to revoke consent.(12;77).

2.2.3. Professional Definition

Medical codes of ethics require that clinicians obtain informed consent from clients prior to any medical intervention.(82;83) It should be noted that informed consent may be given in writing, verbally, or implied, depending on the situation. When clients enter a clinic requesting medical care, their consent for care is implied. It is then re-established when a health care intervention is offered. In outreach settings, the nurse seeks out clients and therefore the client
must verbalize consent for care. The Canadian Code of Ethics for Registered Nurses (83) lists seven values that inform ethical practice for nurses. These values are, “1) providing safe, compassionate, competent and ethical care, 2) promoting health and well-being, 3) promoting and respecting informed decision-making, 4) preserving dignity, 5) maintaining privacy and confidentiality, 6) promoting justice, and 7) being accountable.” While all of these values contribute to ethical assessments of CTC-HC, it is value #3 that applies directly. The Canadian Nurses Association describes the ethical responsibilities related to informed decision-making. These include providing clients with information required to make decisions about their health and well-being, respecting the wishes of capable people to decline health care, and allowing clients to defer decision to their family. It also speaks about the responsibility that nurses have to be “sensitive to the inherent power differentials between care providers and those receiving care, and that they must not misuse that power to influence decision-making.” (83)(page 11). In addition, nurses have a responsibility to respect the decisions their clients make, including choices related to lifestyles or treatment viewed as not conducive to good health. Finally, nurses have a responsibility to respect the law on capacity assessment and substitute decision-making. The Canadian Medical Association (CMA) outlines virtually the same responsibilities for physicians under the CMA Code of Ethics.(82) Tatarsky (84) has suggested that client engagement in “truly informed consent” is key to a collaborative alliance between substance using clients and caregivers.

2.3 Capacity and Incapacity

The BC Consent Act (77) stipulates that adults who are “capable” have the right to consent to health care. The onus is on the health care provider to assess for incapability rather
than capability. The BC Consent Act states that clients may be assessed as incapable to consent if they lack an understanding of the explanation given to them about the medical treatment they are being offered and that they do not understand that the information explained applies to them and the treatment they are being offered. However, other elements such as reasoning and expression of choice are also considered important. Incapability may be transient or intermittent, and individuals may be able to consent to some things in their life but not to more complex interventions. As noted above, the term ‘capacity’ reflects the ability to make a clinical decision and the term ‘competency’ reflects a legal status typically involving financial matters. This study solely relates to capacity.

The TCPS2 defines capacity as “the ability of prospective or actual participants to understand relevant information presented about a research project, and to appreciate the potential consequences of their decision to participate or not participate. This ability may vary according to the complexity of the choice being made, the circumstance surrounding the decision, or the point in time at which consent is sought.” Although this policy statement relates to consent for research, the elements are the same for consent for clinical care.

Some researchers purport that capacity involves the ability to understand relevant information, the ability to weigh the benefits and risks of the proposed intervention and the ability to reach a reasonable decision but does not necessarily require good recall. “Poor recall may be more indicative of the normal forgetting process rather than of incompetency.”

2.4 Existing Instruments to Assess Capacity to Consent

Although legal documents state that individuals who lack CTC-HC are unable to provide informed consent, the practicalities of assessing capacity are not stipulated by law. Numerous
instruments have been developed to measure capacity to consent both for clinical treatment and research purposes. Many of these instruments, however, require considerable user training and are time consuming to administer. To the best of my knowledge, no instruments have been created to assess CTC-HC among IMSH during brief encounters in outreach settings.

Two systematic reviews (80;86) provide a comprehensive assessment of instruments for determining capacity in adults. These instruments are divided into those that focus on consent for health care and those that focus on consent for research purposes. The most widely-used and highly recognized instrument is the MacArthur Competency Assessment Tool, developed by Paul Appelbaum and others.(87;88) Appelbaum et al. were the forerunners in the development of instruments to assess capacity to consent, and subsequent instruments developed by others built on the legal foundation of the MacArthur tests.(89) Moreover, other psychometricians have used the MacArthur capacity tests as a gold standard against their new instruments. The following is a critical review of the MacArthur capacity tests, other capacity assessment tests, and some cognitive tests from the cognitive psychology field that provide guidance related to measuring constructs important for capacity to consent. Finally, the constructs related to capacity to consent for treatment covered in each of the instruments will be reviewed.

2.4.1 MacArthur Competency Assessment Tests for Clinical Research and Treatment (MacCAT-CR, MacCAT-T and others)

MacArthur competency assessment tests, created by Appelbaum, Grisso and colleagues, are considered the gold standard of capacity assessment instruments and are based on four legal standards of competency originally described by Roth et al.(90). These legal standards were, according to Dennis, based on U.S. case law between 1905 and 1914.(81) The four legal constructs incorporated by Appelbaum et al. into their assessment instruments are: 1)
understanding, 2) reasoning, 3) appreciation, and 4) expression of choice. Understanding is defined as the ability to understand the risks and benefits of the treatment as well as possible alternatives. Reasoning or rational manipulation of information focuses on the manner in which participants utilize information to arrive at a decision. Factors that affect a person’s ability to manipulate information include delusions, hallucinations, thought disorder, panic, anxiety, depression and euphoria. Appelbaum and Grisso consider appreciation of the nature of the situation to be the most important among the capacity assessment criteria. This concept refers to the client’s ability to relate factual understanding to their own situation and includes the client’s awareness of his/her illness or potential risk for an illness and the inability to appreciate the risks and benefits of a health care intervention. Expression of choice refers to a clear indication by the client about their choice to agree to or refuse a health care intervention.

2.4.1.1 Understanding Treatment Disclosures (UTD), Thinking Rationally About Treatment (TRAT), and Perceptions of Disorder (POD)

In developing the MacCAT instruments, Appelbaum et al. treated each of the four legal constructs separately and thus created three separate scales between 1991 and 1995, aimed at measuring understanding (Understanding Treatment Disclosures [UTD]), reasoning (Thinking Rationally About Treatment [TRAT]), and appreciation (Perceptions of Disorder [POD]). The fourth legal construct, expression of choice, was considered a one-item construct and did not require a separate scale. The UTD consists of the assessor giving different medical scenarios (vignettes), and then asking the participant to recall (in their own words) what was said to them about the potential risks and benefits of the medical intervention described in the vignette. The TRAT scale includes vignettes as well as TRAT tasks. Scoring is based on information seeking, consequential thinking, comparative thinking, complex thinking.
and describing consequences. The POD also involves vignettes, with nine stimulus questions. Scoring is based on acknowledgement of the participant’s symptoms, his/her beliefs about the seriousness of his/her symptoms, and his/her acknowledgement of the diagnosis given.

Each of the scales (UTD, TRAT and POD) takes 25 to 30 minutes to administer. They were validated in populations with hospitalized patients with schizophrenia (n=75), hospitalized patients with depression (n=92), as well as in patients hospitalized for ischemic heart disease (n=82). The patients with ischemic heart disease were considered a non-mentally ill comparison group. Another sample of non-hospitalized patients with schizophrenia, depression or ischemic heart disease was included in the study (n=249) for a total of 498 participants. Participants were assessed and scored on each scale by trained researchers. Construct validity was conducted by comparing the researchers’ scores to that of a ‘master scorer’ who was part of the research team. Validity was also established by comparing the scores of clients with mental illness to those without mental illness, which demonstrated that clients with mental illness had less capacity than those without mental illness. Psychometric properties for each scale can be found in Table 2 and 3. As these scales were separate entities, no factor analysis was done but intraclass correlations were calculated to test the correlation of one scale to the other. Test-retest reliability was conducted in a subset of the study population by asking participants to be re-tested two weeks after their first assessment.
<table>
<thead>
<tr>
<th>Instrument</th>
<th>Year</th>
<th>Country</th>
<th>Elements of consent for treatment</th>
<th>Method of Measurement</th>
<th>Number of items</th>
<th>Time to administer</th>
<th>Population validated in</th>
<th>Validation gold standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aid to Capacity Evaluation (ACE)(96)</td>
<td>1999</td>
<td>Canada</td>
<td>Understanding and appreciation</td>
<td>Semi structured interview</td>
<td>7 relevant areas (several questions were suggested for each area)</td>
<td>15 minutes</td>
<td>Medical inpatients (n=100)</td>
<td>Two capacity assessment experts (physicians), a panel of experts and Standardized Mini Mental State Exam (SMME)</td>
</tr>
<tr>
<td>Capacity Assessment Tool (CAT)(97)</td>
<td>2001</td>
<td>United States</td>
<td>Communication, understanding of choices, comprehension of risks and benefits, insight, and judgment</td>
<td>Semi structured interview</td>
<td>10</td>
<td>“Only minutes”</td>
<td>Geriatric primary care patients (n=20) facing major medical treatments or invasive procedures</td>
<td>Independent psychiatric assessment</td>
</tr>
<tr>
<td>Capacity to Consent to Treatment Instrument (CCTI)(98)</td>
<td>1995</td>
<td>United States</td>
<td>Choice, understanding, appreciation, reasoning, and reasonable decision</td>
<td>Hypothetical vignettes</td>
<td>not stated</td>
<td>20-25 minutes</td>
<td>Alzheimer's disease (n=29) and 15 older controls</td>
<td>Scores of Alzheimer's disease were compared to subjects without Alzheimer's disease.</td>
</tr>
<tr>
<td>Competency Interview Schedule (CIS) (99)</td>
<td>1994</td>
<td>Canada</td>
<td>Choice, understanding, appreciation, and reasoning</td>
<td>Structured interview format.</td>
<td>15</td>
<td>Not stated</td>
<td>96 psychiatric inpatients (a mixed sample of patients with schizophrenia, schizoaffective disorder, depression and mania) facing electroconvulsive therapy.</td>
<td>Attending psychiatric physician</td>
</tr>
<tr>
<td>Generic and Specific Capacity Instrument (100)</td>
<td>1996</td>
<td>Canada</td>
<td>Not stated</td>
<td>Not stated</td>
<td>38</td>
<td>Not stated</td>
<td>Older people (mostly women) in retirement homes, and homes for the aged. N=96</td>
<td>Panel of experts including health workers, a lawyer, and an ethicist; a second gold standard of three geriatricians was used</td>
</tr>
<tr>
<td>Hopemont Capacity Assessment Inventory (HCAI) (101)</td>
<td>1999</td>
<td>United States</td>
<td>Understanding, appreciation, and expression of choice</td>
<td>Vignettes</td>
<td>9</td>
<td>30-60 minutes</td>
<td>50 Nursing home residences with and without dementia</td>
<td>Mini Mental State Exam (MMSE)</td>
</tr>
<tr>
<td>Hopkins Competency Assessment Test (HCAT) (102)</td>
<td>1992</td>
<td>United States</td>
<td>Understanding</td>
<td>Structured interview</td>
<td>10</td>
<td>10 minutes</td>
<td>16 medical inpatients and 25 adult geriatric patients from a</td>
<td>Forensic psychiatrist</td>
</tr>
<tr>
<td>Instrument</td>
<td>Year</td>
<td>Country</td>
<td>Elements of consent for treatment</td>
<td>Method of Measurement</td>
<td>Number of items</td>
<td>Time to administer</td>
<td>Population validated in</td>
<td>Validation gold standard</td>
</tr>
<tr>
<td>------------</td>
<td>------</td>
<td>---------</td>
<td>----------------------------------</td>
<td>-----------------------</td>
<td>-----------------</td>
<td>-------------------</td>
<td>-------------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>MacArthur Competence Assessment Tool for Treatment (MacCAT-T) (103)</td>
<td>1997</td>
<td>United States</td>
<td>Understanding, appreciation, reasoning, choice</td>
<td>Semi-structured interview; also utilizes patient charts</td>
<td>10 items; no overall score. Sub-scores for each domain</td>
<td>15-20 minutes</td>
<td>Acutely ill schizophrenia or schizoaffective disorder admitted to hospital. N=40.</td>
<td>Brief Psychiatric rating scale. They also compared psychiatric patients with community non-psychiatric patients</td>
</tr>
<tr>
<td>Perceptions of Disorder (POD) (104)</td>
<td>1992</td>
<td>United States</td>
<td>Appreciation</td>
<td>Vignettes</td>
<td>9</td>
<td>25-30 minutes</td>
<td>Schizophrenia, depressions, and ischemic heart disease</td>
<td>Master scorer</td>
</tr>
<tr>
<td>Structured Interview for Competency/Incompetency Assessment Testing and Ranking Inventory (SICIATRI) (105)</td>
<td>1997</td>
<td>Japan</td>
<td>Choice, understanding, appreciation, and reasoning.</td>
<td>Structured interview</td>
<td>12</td>
<td>20 min</td>
<td>Psychiatric (n=25) and medical (n=23) inpatients</td>
<td>Attending physician</td>
</tr>
<tr>
<td>Telephone Interview for Cognitive Status (TICS)(106)</td>
<td>1988</td>
<td>United States</td>
<td>Working memory, language, attention, and some aspects of executive function orientation, comprehension, attention, verbal abstraction, immediate verbal memory.</td>
<td>Structured interview</td>
<td>11</td>
<td>Not stated</td>
<td>100 patients with Alzheimer’s disease; 33 controls</td>
<td>Mini-mental state examination</td>
</tr>
<tr>
<td>Thinking Rationally About Treatment (TRAT) (94)</td>
<td>1995</td>
<td>United States</td>
<td>Rational manipulation or reasoning</td>
<td>Vignettes</td>
<td>19</td>
<td>25-30 minutes</td>
<td>Schizophrenia, depression, and ischemic heart disease</td>
<td>Master scorer</td>
</tr>
<tr>
<td>Understanding Treatment Disclosures (UTD) (92)</td>
<td>1991</td>
<td>United States</td>
<td>Understanding</td>
<td>Vignettes</td>
<td>Not stated</td>
<td>25-30 minutes</td>
<td>Individuals with schizophrenia, depression, and ischemic heart disease</td>
<td>Forensic psychiatrist</td>
</tr>
<tr>
<td>Research</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3-item questionnaire (107)</td>
<td>2005</td>
<td>United States</td>
<td>Understanding</td>
<td>Structured interview</td>
<td>3</td>
<td>Not stated</td>
<td>Outpatients: schizophrenia, Alzheimer’s disease, and diabetes mellitus</td>
<td>MacCAT-CR. They also compared results of mentally ill participants to non-mentally ill diabetes patients</td>
</tr>
<tr>
<td>Brief Informed</td>
<td>2003</td>
<td>United States</td>
<td>Understanding</td>
<td>Structured interview</td>
<td>11</td>
<td>5-10 minutes</td>
<td>Patients with and</td>
<td>Clinical Dementia</td>
</tr>
<tr>
<td>Instrument</td>
<td>Year</td>
<td>Country</td>
<td>Elements of consent for treatment</td>
<td>Method of Measurement</td>
<td>Number of items</td>
<td>Time to administer</td>
<td>Population validated in</td>
<td>Validation gold standard</td>
</tr>
<tr>
<td>------------</td>
<td>------</td>
<td>---------</td>
<td>----------------------------------</td>
<td>----------------------</td>
<td>----------------</td>
<td>------------------</td>
<td>-----------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>Consent Test (108)</td>
<td></td>
<td>States</td>
<td></td>
<td>interview</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>California Scale of Appreciation (CSA)(109)</td>
<td>2002</td>
<td>United States</td>
<td>Appreciation only - in relation to a &quot;patently false belief&quot;</td>
<td>Structured interview</td>
<td>18</td>
<td>10-20 minutes</td>
<td>Schizophrenia (n=39) and control subjects</td>
<td>Not stated</td>
</tr>
<tr>
<td>Deaconess informed consent comprehension test (DICCT) (110)</td>
<td>1996</td>
<td>United States</td>
<td>Understanding and voluntariness</td>
<td>Structured interview</td>
<td>14</td>
<td>&lt; 10 minutes</td>
<td>Participants of anti-infective trials; n=275 men and women</td>
<td>Wechsler Adult Intelligence Scale-R r=0.44</td>
</tr>
<tr>
<td>Evaluation to Sign Consent (111)</td>
<td>2001</td>
<td>United States</td>
<td>Understanding and voluntariness</td>
<td>Structured interview</td>
<td>34</td>
<td>7 minutes</td>
<td>Subjects with schizophrenia and subjects with HIV; n=297</td>
<td>MacArthur Competency Assessment Tool for Clinical Research (MacCAT-CR)</td>
</tr>
<tr>
<td>University of California Brief Assessment of Capacity to Consent (UBACC) (113)</td>
<td>2007</td>
<td>United States</td>
<td>Understanding, appreciation, reasoning</td>
<td>Structured interview</td>
<td>10</td>
<td>5 minutes</td>
<td>Schizophrenia</td>
<td>Psychiatrist and MacCAT-CR</td>
</tr>
</tbody>
</table>

Table 3: Psychometric properties of instruments previously published to assess capacity to consent for treatment and research

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Internal consistency</th>
<th>Intra-observer reliability</th>
<th>ICC</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Positive Likelihood Ratio (95% CI)</th>
<th>Negative Likelihood Ratio (95% CI)</th>
<th>PCA of factor analysis done?</th>
<th>Test-retest done?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aid to Capacity Evaluation (ACE)</td>
<td>Not stated</td>
<td></td>
<td>Not stated</td>
<td>Not stated</td>
<td>81%</td>
<td>90%</td>
<td>8.5 (3.9-19)</td>
<td>90%</td>
<td>Not stated</td>
</tr>
<tr>
<td>Capacity Assessment Tool (CAT)</td>
<td>Not stated</td>
<td>kappa range from 0.58-1.0</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
</tr>
<tr>
<td>Capacity to Consent to Treatment Instrument (CCTI)(98)</td>
<td>Not stated</td>
<td></td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

43
<table>
<thead>
<tr>
<th>Instrument</th>
<th>Internal consistency</th>
<th>Intra-observer reliability</th>
<th>ICC</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Positive Likelihood Ratio (95% CI)</th>
<th>Negative Likelihood Ratio (95% CI)</th>
<th>PCA of factor analysis done?</th>
<th>Test-retest done?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Competency Interview Schedule (CIS)</td>
<td>0.96</td>
<td>0.43 - 0.98</td>
<td>0.95</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Yes - one dimension identified</td>
<td>0.79</td>
</tr>
<tr>
<td>Generic and Specific Capacity Instrument</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>48 participants underwent test-retest. Intraclass correlation was .77</td>
</tr>
<tr>
<td>Hopemont Capacity Assessment Inventory (HCAI)(101)</td>
<td>alpha 0.94</td>
<td>0.93</td>
<td>0.50- 0.66</td>
<td>Not stated</td>
<td>Not stated</td>
<td>3.8 (1.5 - 9.5)</td>
<td>0.38 (0.21-0.68)</td>
<td>Not stated</td>
<td>0.29</td>
</tr>
<tr>
<td>Hopkins Competency Assessment Test (HCAT) (102)</td>
<td>Not stated</td>
<td>0.95-.99</td>
<td>Not stated</td>
<td>100%</td>
<td>100%</td>
<td>54 (3.5 - 846)</td>
<td>0 (0.0 - 0.52)</td>
<td>Not stated</td>
<td>Not stated</td>
</tr>
<tr>
<td>MacArthur Competence Assessment Tool for Treatment (103)</td>
<td>Not stated</td>
<td>Not stated</td>
<td>.99 for understanding, .87 for appreciation, and .91 for reasoning</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
</tr>
<tr>
<td>Perceptions of Disorder (POD)</td>
<td>0.67 – 0.80</td>
<td>Not stated</td>
<td>0.59 - 0.70</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>FA done with POD, TRAT, and UTD revealed a two factor solution</td>
<td>0.56 – 0.59</td>
</tr>
<tr>
<td>Structured Interview for Competency/Incompetency Assessment Testing and Ranking Inventory (SICIATRI)</td>
<td>Not stated</td>
<td>Evidence of choice kappa=0.14; insight kappa =0.22; The remaining items had a kappa score between .40 - .82</td>
<td>Not stated</td>
<td>0.83</td>
<td>0.67</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
</tr>
<tr>
<td>Telephone Interview for Cognitive Status (TICS)</td>
<td>Not done</td>
<td>ICC = 0.99</td>
<td>Pearson r= 94 (between TICS and MMSE)</td>
<td>94%</td>
<td>100%</td>
<td>Not stated</td>
<td>Not stated</td>
<td>No</td>
<td>Yes; r = 0.965</td>
</tr>
<tr>
<td>Thinking Rationally About Treatment (TRAT)</td>
<td>0.55 – 0.68</td>
<td>kappa 0.85</td>
<td>0.18 – 0.30</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>FA done with POD, TRAT, and UTD revealed a two factor solution</td>
<td>0.60 – 0.68</td>
</tr>
<tr>
<td>Instrument</td>
<td>Internal consistency</td>
<td>Intra-observer reliability</td>
<td>ICC</td>
<td>Sensitivity</td>
<td>Specificity</td>
<td>Positive Likelihood Ratio (95% CI)</td>
<td>Negative Likelihood Ratio (95% CI)</td>
<td>PCA of factor analysis done?</td>
<td>Test-retest done?</td>
</tr>
<tr>
<td>--------------------------------------------</td>
<td>----------------------</td>
<td>----------------------------</td>
<td>-----------</td>
<td>-------------</td>
<td>------------</td>
<td>-----------------------------------</td>
<td>-----------------------------------</td>
<td>---------------------------</td>
<td>--------------------</td>
</tr>
<tr>
<td>Understanding Treatment Disclosures (UTD)(104)</td>
<td>0.55 – 0.77</td>
<td>kappa = 0.84</td>
<td>0.06 – 0.50</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>FA done with POD, TRAT, and UTD revealed a two factor solution</td>
<td>Not stated</td>
</tr>
<tr>
<td><strong>Research</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3-item questionnaire</td>
<td>Not stated</td>
<td>Intraclass correlation coefficient was 0.904</td>
<td></td>
<td>Correlation between the 3 item questionnaire and MacCAT-CR subscales: understanding r=0.74; appreciation R=0.41; reasoning r=0.44; expression of choice r=0.12</td>
<td>100%</td>
<td>77.3%</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
</tr>
<tr>
<td>Brief Informed Consent Test</td>
<td>0.63</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
</tr>
<tr>
<td>California Scale of Appreciation (CSA) (109)</td>
<td>.83-.89</td>
<td>kappa = 0.28 - 1.00</td>
<td>0.85</td>
<td>64-76%</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
</tr>
<tr>
<td>Deaconess informed consent comprehension test (DICCT)</td>
<td>Not stated</td>
<td>r=0.84</td>
<td>r=0.39 compared to the WRAT_R scale</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
</tr>
<tr>
<td>Evaluation to Sign Consent</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Yes: interclass correlation coefficients of .66 for tests of objective understanding and .77 for tests of subjective understanding.</td>
<td>Not stated</td>
</tr>
<tr>
<td>Instrument</td>
<td>Internal consistency</td>
<td>Intra-observer reliability</td>
<td>ICC</td>
<td>Sensitivity</td>
<td>Specificity</td>
<td>Positive Likelihood Ratio (95% CI)</td>
<td>Negative Likelihood Ratio (95% CI)</td>
<td>PCA of factor analysis done?</td>
<td>Test-retest done?</td>
</tr>
<tr>
<td>------------</td>
<td>----------------------</td>
<td>----------------------------</td>
<td>-----</td>
<td>-------------</td>
<td>------------</td>
<td>----------------------------------</td>
<td>---------------------------------</td>
<td>-----------------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) (112)</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Significant correlation between understanding and reasoning (Kendall's tau=0.27, p=.05) but appreciation did not correlate with either understanding or reasoning.</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Retested 8 weeks after: correlation between score 1 and score 2 were not significantly correlated for understanding (Kendall's tau=0.26 p=.08) and reasoning (Kendall's tau=-0.15 p=.97) but was significant</td>
</tr>
<tr>
<td>University of California Brief Assessment of Capacity to Consent (UBACC)</td>
<td>0.77</td>
<td>0.84 - 0.98</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Factor analysis done – 3 factor solution</td>
<td>Not stated</td>
</tr>
</tbody>
</table>
2.4.1.2 *MacCAT-T (clinical settings)*

In 1997, Appelbaum and colleagues recognized that the UTD, POD, and TRAT were too lengthy and not feasible for use in clinical settings. Therefore, they combined these three scales into one instrument that incorporated the constructs of understanding, appreciation, and reasoning with the addition of one question covering the construct of expression of choice. Grisso and Appelbaum validated this 10-item instrument in 40 patients with acute schizophrenia or schizoaffective disorder who were admitted to hospital. They included a comparative group identified from the community who were matched on age, gender, race, education and occupation but who did not have schizophrenia or schizoaffective disorder. They administered both the Brief Psychiatric Rating Scale (BPRS) and the MacCAT-T instruments in both groups, and compared domain scores as well as individual scores between these two instruments. They also compared the MacCAT-T domain scores between the psychiatric group and the non-psychiatric community group using intraclass correlation. Overall, they found that the mean scores for each domain were lower in the psychiatric group than the non-psychiatric group, indicating that the psychiatric group had less capacity to consent (Understanding: mean (SD) 4.33 (1.35) for psychiatric group and 5.60 (.66) in the non-psychiatric community group \(p<.001\); Reasoning: 5.20 (2.42) in the psychiatric group and 6.15 (1.69) in the non-psychiatric community group \(p=0.038\)). No comparison was made for the domain of appreciation as the researchers decided it was not appropriate to ask these questions in the non-psychiatric community group. The intraclass correlation test between the BPRS and the MacCAT-T revealed no significant correlation in scores, although greater symptom severity tended to correlate with lower MacCAT-T ratings. It was assumed that the domains of understanding,
reasoning, appreciation and expression of choice were separate concepts and the scores should not be combined.

2.4.1.3 MacCAT-Clinical Research (MacCAT-CR)

After the MacCAT for treatment (MacCAT-T) was fully developed and validated, Appelbaum and colleagues revised the MacCAT-T so it would be applicable in research settings. The MacCAT-CR is now the most widely used instrument of assessment of capacity to consent to participate in research.(112;115-121) This 21-item scale takes 15 to 30 minutes to administer and uses a semi-structured interview guide to rank each item as: 1) inadequate, 2) partial, or 3) adequate capacity. The MacCAT-CR was validated in patients with depression (n=25), schizophrenia (n=25), Alzheimer’s disease (n=37) and a comparison group of patients with HIV (n=25). Again, scores are calculated for each domain. Intra-class correlation between the understanding and reasoning subscales was significant (Kendall’s tau = .27 p=0.05) but the appreciation subscale did not significantly correlate with understanding or reasoning. Table 3 displays the psychometric properties of the MacCAT-CR instrument. Mean level of MacCAT-CR subscale scores vary across diagnostic groups (e.g., people with Alzheimer’s disease perform more poorly than people with schizophrenia).(122) However, Palmer et al. (122) caution that assessments of capacity to consent cannot be made purely on a person’s diagnosis, and scores also vary within any diagnostic group depending on other factors such as hospitalization. When comparing the MacCAT-CR scores to scores from other instruments, researchers often use a cutoff score of 15 on the understanding subscale of the MacCAT-CR instrument.(122;123)
2.4.1.4 3-Item Questionnaire (research settings)

Appelbaum and others recognized that a capacity instrument that takes 15 to 30 minutes to administer may be prohibitive for many research studies. In an attempt to be more efficient, Palmer et al. (122) designed a highly sensitive 3-item instrument measuring only the understanding construct that could be used to screen potential participants. Individuals identified by this instrument as having reduced capacity would then receive a more comprehensive capacity evaluation using the MacCAT-CR instrument. This 3-Item Questionnaire was validated in three groups of people: 1) those with schizophrenia/schizoaffective disorder (n=35), 2) those with Alzheimer’s disease (n=30), and 3) those with type 2 diabetes mellitus (n=36). By choosing these three groups, Palmer et al. hoped to show that the 3-Item Questionnaire would indicate lower understanding in the Alzheimer’s disease group, moderate scores in the schizophrenia/schizoaffective group, and high scores in the diabetes group. The MacCAT-CR instrument was also administered and used as the gold standard. The 3-Item Questionnaire showed high inter-rater reliability (intraclass correlation = 0.904) and the overall score of the 3-Item Questionnaire correlated well with the subscale scores of the MacCAT-CR instrument with the exception of the ‘expression of choice’ subscale (see Table 3). No test for internal consistency was done. Sensitivity and specificity was calculated using the 3-item total score and the threshold for the MacCAT-CR instrument used by the National Institute of Mental Health-sponsored Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) study. (123) Based on a threshold of 2.5 out of a maximum possible score of six for the 3-Item Questionnaire, the sensitivity of this instrument was 100% and specificity was 77.3%. The authors concluded that the 3-Item Questionnaire was a good screening test to determine if further assessment of capacity should be done.
2.4.2 Other Instruments that Assess Capacity to Consent for Research

The MacCAT-CR and other instruments developed to assess capacity to consent for research, cover the same legal constructs as the instruments to assess capacity to consent for health care. Most concentrate on the construct of understanding and emphasize the alternative options (e.g. other treatments in the case of a pharmaceutical trial) that are available if participants choose not to participate in the research study. The main difference between capacity instruments for research and health care interventions is the context of the questions. For example, when discussing risks and benefits, assessment of capacity to consent to research would involve ensuring the participant understands the risks and benefits of being part of a research study, with an emphasis on the voluntary nature of participating. Research shows that people are often confused about whether they are participating in a study or receiving conventional treatment, because either way, they are receiving a medical intervention.(124;125) These factors (understanding they are in a study; ensuring voluntariness) are not part of assessing capacity in non-study circumstances. In non-study circumstances, when discussing risks and benefits with people being offered treatment, assessment of capacity to consent to treatment would involve ensuring the client understands the risks and benefits of the treatment, with an emphasis on the fact that the client can consent to or refuse the type of treatment being offered. The differences in assessing capacity to consent for treatment or for research are subtle and mainly context driven. While I have described the MacArthur instruments in detail, the remainder of this chapter will concentrate on assessment instruments that assess capacity to consent for treatment or health care. Psychometric properties of instruments that assess capacity for research can be found in Table 3.
2.4.3 Hopkins Competency Assessment Test (HCAT)

The HCAT is an instrument developed by Janofsky et al. (102) in 1992, aimed at assessing capacity to consent for treatment or constructing advance directives. This instrument assesses the construct of understanding only, and is administered by giving the client a short essay (available in three different literacy levels) and then administering six true/false questions and four open-ended questions over 10 minutes. The HCAT was validated in 16 medical inpatients and 25 adult geriatric patients from a psychiatric ward, using a clinical assessment from a forensic psychiatrist as the gold standard. Inter-observer reliability was measured by comparing scores from two independent research team members. The Pearson’s correlation coefficient was 0.95 calculated on 16 consecutive HCAT questionnaires. When compared to the psychiatric assessment and a HCAT threshold of 4/10 (10/10 indicating high capacity) or more, the HCAT is 100% sensitive. It should be noted that this low threshold increases the likelihood of false positives. There is a linear relationship between the HCAT scores and the mini-mental state examination (described on page 65 below). The scale was not tested for internal consistency and no factor analysis was conducted; therefore, unidimensionality was assumed and the scores were summed to create an overall score. This assumption may create spurious overall scores. The authors recognized that one limitation of their validation study was that their participants were not randomly selected. The main limitation of this instrument is that it measures only one of the legal constructs (understanding) necessary for the assessment of capacity to consent. For this reason, I have considered the MacCAT-T instrument to be superior to the HCAT.
2.4.4 **Competency Interview Schedule (CIS)**

The CIS is an instrument developed in 1994 by a group of Canadian researchers. This instrument covers all four legal constructs necessary to assess capacity to consent (choice, understanding, appreciation, reasoning), and consists of 15 Likert-scale type questions (7 points) which are asked during a structured interview. It was validated in 96 psychiatric inpatients (mixture of patients with schizophrenia, schizoaffective disorder, depression and mania) who were facing electroconvulsive therapy. The gold standard against which the CIS was compared was a clinical assessment by an attending psychiatric physician. The CIS is one of the few instruments that had a factor analysis conducted on the data and demonstrated unidimensionality. The Cronbach’s alpha calculated on the validation data was 0.96 which demonstrates good internal consistency. Pearson’s correlation was calculated for each item between two raters, resulting in coefficients ranging from 0.43-0.98. While the psychometric properties of the CIS are good, the sample size used to validate the instrument is relatively small (n=96), especially in comparison to the sample size used to validate the UDT, TRAT, and POD scales from which the MacCAT-T originated (n=498).

2.4.5 **Structured Interview for Competency/Incompetency Assessment Testing and Ranking Inventory (SICIATRI)**

The SICIATRI was developed in Japan in 1997 by Tomoda et al. Like the other instruments that came before the SICIATRI, this 12-item instrument takes 20 minutes to administer and covers the constructs of choice, understanding, appreciation, and reasoning. It has a rather complicated method for scoring. The assessor conducts a structured interview. Each question is rated on a three-point scale, and then the client’s overall capacity is ranked (using the
information from the previous questions) using their Ranking Inventory Competency which consists of five levels (from 0-4), with higher levels indicating greater competency on all of the components. A detailed description of the scoring conducted on this instrument can be found in Tomoda et. al. manuscript.(105) The instrument was validated in 25 psychiatric inpatients and 23 medical inpatients using an assessment of capacity from the attending physician as the gold standard. Inter-rater reliability was calculated by examining the level of agreement between the scores of two interviewers. Low kappa scores were seen in evidence of choice (0.14) and insight (0.22). The remaining items had a kappa score between 0.40 - 0.82. When compared to the gold standard, the SICIATRI had a sensitivity of 0.83 and a specificity of 0.67. Like many of the other instruments, no test for internal consistency, no factor analysis, and no test-retest reliability test was done. A panel of experts involved in creating this instrument stated that some items were more important than others when determining capacity and suggested weighting be applied to the items. Due to the low specificity and complexity of scoring, and the small sample size used to validate the SICIATRI instrument, it was not considered appropriate for use in the validation phase of our study.

2.4.6 Capacity to Consent to Treatment Instrument (CCTI)

The CCTI is an instrument developed in 1995 by Marson et al.(98). This instrument involves hypothetical vignettes aimed at assessing the constructs of choice, understanding, appreciation, reasoning, and reasonable decisions. The literature does not state the number of items included, but does state that this instrument takes 20-25 minutes to administer. It was validated in 29 patients with probable Alzheimer’s disease (15 with mild and 14 with moderate cases) and 15 older controls not diagnosed with the disease. Construct validity was not tested using a gold standard but was tested by comparing scores for subjects with Alzheimer’s disease
to those without. Participants were scored as competent, marginally competent, or incompetent for each construct. Therefore, like the MacArthur tests, one overall score is not created. A cut-off for each construct was calculated using the value of two standard deviations below the control group mean. Subjects with scores falling at the cutoff point were considered as having marginal capacity, and subjects with scores above the cut-off were considered as having acceptable capacity. Marson et al.(126) found that subjects with Alzheimer’s disease were able to demonstrate reasonable choice as well as the non-Alzheimer’s control group. However, participants in the Alzheimer’s disease group were rated as being less capable to appreciate the consequences of their choice, provide rational reasons for their choice, and understand treatment information. No test of internal consistency, inter-observer reliability, factor analysis or test-retest reliability were conducted. Due to the length of time to administer the CCTI and the omission of important psychometric analysis, this instrument was not considered for use as a gold standard for the validation phase of our research study.

2.4.7 AID to Capacity Evaluation (ACE)

The ACE instrument was developed by Etchells et al.(127) to assess understanding of the medical intervention and appreciation of clients’ medical condition. It involves one 15-minute semi-structured interviews that covers seven relevant areas of understanding and appreciation. After the interview, subjects are classified as definitely incapable, probably incapable, probably capable or definitely capable. The ACE was validated in 100 medical inpatients using a combination of two capacity assessment experts (physicians), a panel of experts and the standardized mini-mental state exam (SMMSE) as the gold standard. The SMMSE is described later. The main limitation of the validation study is that the same nurse completed both the SMMSE and the ACE instruments, allowing the introduction of bias. Ideally, the validation of
an instrument should involve a researcher to administer the new instrument that is blinded to the gold standard instrument. Regarding assessment of psychometric properties, no test of internal consistency was done, inter-item correlation was not reported, and no factor analysis or test-retest reliability tests were conducted. Interobserver reliability was assessed by calculating the kappa between the gold standard assessments and outcome from the ACE instrument. A kappa of 0.79 was achieved indicating good agreement. Sensitivity and specificity were also calculated using the gold standard assessments and the outcome from the ACE instrument. Sensitivity was 81% and specificity was 90%. Although the reported interobserver reliability, sensitivity and specificity are acceptable, these statistics may be inflated due to the lack of blinding. Moreover, since no test for internal consistency was done, the items should not be summed to create an overall score. Finally, this instrument only assesses understanding and appreciation. For these reasons, it was decided that the ACE instrument was not appropriate for use as a gold standard in the validation phase of our research study.

2.4.8 Capacity Assessment Tool (CAT)

The CAT instrument was developed by Carney et al. (97) and validated using real informed consent for treatment scenarios with 20 hospital in-patients. This instrument covers the constructs of communication, describing choices, understanding risks and benefits, reasoning, and assessment of capacity for the specific decision at hand. CAT involves the administration of ten items that take “only minutes” to administer. (97)(page 19). An independent psychiatric assessment was conducted as the gold standard. The psychiatric assessment involved determining whether the patient had the ability to make a decision to undergo the medical procedure, whether the patient was able to communicate a decision, whether the patient understood the risks and benefits, and whether the patient communicated a reason for making the
choice that they did. Kappa statistics were calculated for each construct and ranged from 0.58 to 1.00. No tests for internal consistency, inter-item correlation, factor analysis or test-retest reliability were conducted. The validation phase of this study involved a very small sample size and the small number of reported psychometric properties made the CAT instrument inappropriate for the validation phase of our research.

2.4.9 **Hopemont Capacity Assessment Inventory (HCAI)**

The HCAI assessment interview was developed by Edelstein in 1999. This instrument involves two different vignettes and includes nine questions related to the vignettes. It takes 30-60 minutes to administer and covers the constructs of understanding, appreciation, and expression of choice. It was validated with 50 nursing home residents with and without dementia. The gold standard was the Mini Mental State Examination (MMSE). In the validation study, the intraclass correlation (between the gold standard and the HCAI) was 0.66 and the Cronbach’s alpha test for internal consistency was 0.94. Test re-test correlation was low at 0.29. No inter-item correlation or factor analysis tests were reported. Like some of the instruments described above, this instrument was validated with a very small sample size and is time consuming. Although the reported psychometric properties are good, failure to test for internal consistency raises concerns about whether an overall score should be calculated. For these reasons it was decided that the HCAI instrument was not appropriate for the validation phase of our research.

2.4.10 **Telephone Interview for Cognitive Status (TICS)**

The TICS instrument was developed in 1988 by Brandt et al.(106) This instrument assesses the constructs of working memory, language, attention, some aspects of executive
function, orientation, comprehension, verbal abstraction, and immediate verbal memory. It is an 11-item instrument and the amount of time to administer is not reported in the literature. It was validated in 100 patients with Alzheimer’s disease and 33 controls using the MMSE as the gold standard. Intraclass correlation between the MMSE and the TICS is 0.94. No test of internal consistency was reported, nor was a factor analysis done. The test re-test correlation was high at 0.965. Brandt et al. cautioned that the TICS should not be used to diagnose individuals with mild cognitive impairment or to detect dementia. Due to the absence of testing for internal consistency it was decided that the TICS instrument was not appropriate for use in the validation phase of our study.

2.4.11 Generic and Specific Capacity Instruments

The Generic and Specific Capacity instruments were developed in Canada in 1996 by Molloy et al. (100). The purpose of these instruments is to determine capacity to consent to complete an advanced directive. An advanced directive is a legal document that “allows people to nominate proxies and specify treatment wishes for life-threatening illness, resuscitation, and feeding.”(100)(page 661). A health care proxy is someone who makes health care decisions on a person’s behalf, based on the directive, should the person ever be unable to communicate their wishes. The instruments include a total of 38 questions (combined) and were validated against the standardized mini-mental state examination (SMMSE), a panel of experts including health workers, a lawyer, and an ethicist, as well as a second panel of geriatricians. Ninety-six older individuals (mainly women) from retirement homes and homes for the aged were recruited for a validation study. The concepts included in these instruments, and the methods used to administer the instrument, have not been reported in the literature. Furthermore, the only
psychometric properties reported were a test-retest correlation of 0.77 and the area under a receiver operating curve (ROC), which indicated the new instrument was inferior to the SMMSE using the panel of experts as the gold standard. Based on the lack of reported psychometric properties reported, it was decided that these Generic and Specific Capacity instruments are not appropriate for use in the validation phase of our research.

### 2.5 Cognitive Testing

In addition to examining current instruments that were created to assess capacity to consent, numerous instruments have been developed by cognitive psychologists that measure elements that are also important to capacity, such as memory and attention skills. Cognitive testing falls under the scientific field of cognitive psychology and covers a large range of evaluations to measure: 1) basic cognitive operations such as sensation, perception, attention, and memory, 2) the acquisition and use of knowledge and skill (learning, remembering, forgetting), 3) the use of language (speaking, listening, writing and reading), and 4) thinking skills and intelligence (problem solving, reasoning, decision making).(128) The cognitive tests that fall under this discipline are far too numerous to mention here. However, four instruments designed to test cognitive functioning (for purposes other than to test capacity to consent), were examined because they were perceived as potentially useful when considering concepts to include in a new instrument to assess capacity to consent among individuals engaging in substance use. These instruments include the Mini Mental State Examination (used as a gold standard for several of the instruments described above), the Choynowski Memory Scale, the clock drawing test, and the Stroop test.

The Mini-Mental State Examination (MMSE) is a widely used instrument that takes 5 to 10 minutes to administer, and consists of 11 items which measure orientation to place and
time, memorization of three words, attention, language function, and visual-spatial ability. (129) Several of the MMSE items ask the client to perform a task such as subtraction of sevens from 100, or copying a picture of two overlapping pentagons. While the concepts of orientation, memory, and attention seemed relevant to assessing capacity to consent, the validated method of measuring these items is not appropriate in street-outreach settings or low-threshold public health clinics, as they are time consuming and not considered as standard narratives for clinical encounters with marginalized populations who are often suspicious of health care providers. Finally, the MMSE does not take into consideration the important elements of capacity assessment that Appelbaum and others identified, such as expression of choice, understanding appreciation, and reasoning, and for that reason that the MMSE does not discriminate capacity status well. (130)

A standardized version of the MMSE (SMMSE) was developed in 1997 (131) because the MMSE was being adapted by clinicians to accommodate different settings. In addition, the MMSE lacked guidelines about how much time should be allowed for the client to answer, and how to handle answers that are mostly right (compared to fully right). The SMMSE has clear guidelines for dealing with these issues and therefore has higher reliability than the MMSE.

The ability to retain information (memory) is an important element of measuring capacity to consent, and is one of the factors to consider under the UK Mental Capacity Act 2005. (132) Although it is not included in the BC Consent Act (77), or any of the validated capacity assessment instruments, short term memory (as it relates to remembering receiving a health care intervention), is important and should be included in a capacity assessment instrument for individuals who abuse substances, especially since some substances (drugs and alcohol) impair working memory. (133-135) The MMSE includes several items that test memory. The
Choynowski Memory Scale (a scale that measure only memory) was also examined. This scale was developed in Poland and includes measurement of auditory memory (recall of 20 pieces of information from a verbal short story), digit span (repeating back a series of digits frontwards and backwards), picture memory (recall of pictures provided to client), learning speed (memorizing of a sentence read aloud by the examiner), visual retention (memory of visually presented geometric figures), associate pairs (recall of a list of words associated with other cue words) and delayed recall (ability to recall the 20 pieces of information from the previous short story). While the Choynowski Memory Scale is too large to incorporate in full, the concepts are of interest for use in our new CTC-HC instrument.

The clock drawing test, cited as early as 1926, is one of the oldest and most widely used neuropsychological assessment instruments. This simple test (clients are asked to draw the face of a clock and then display a specific time on the face of the clock) is used to assess clients for cognitive impairment and dementia. This instrument tests verbal understanding, memory, and constructive skills. Once again, the concepts of verbal understanding and memory are important for assessing CTC-HC, and were considered when constructing our new instrument. Although the clock drawing test is highly acceptable to clinicians in psychiatric and general medical settings, the method of measuring these concepts (i.e., drawing a clock) is not likely feasible or acceptable in street outreach settings.

The final cognitive test of interest explored for the purposes of this research study is the Stroop test. This test involves giving a client a list of words about colours written in various colours of ink, with many written colours printed in colours that are different from the word that is written. Clients are asked to say the colour of the letters independently of the written word. For example, if the word “red” was written in purple ink the client would correctly
respond by saying “purple”. The Stroop effect is seen when clients take a longer time to correctly identify the colour of ink that the word is printed in when it is not written in the same colour that the printed word means. This has been termed ‘interference in the reaction time of a task’. Interference occurs because the brain automatically determines the semantic meaning of written words. When the word is printed in an alternate colour of ink, the mind takes extra time to consciously (non-automatic) identify the colour of ink that the word is written in. Although this test has only been validated in competing semantic activation of word and colour dimensions, the interference effect is of interest when delivering care to individuals with addictions. The Stroop test spurred an inquiry about whether an automatic addictive stimulus (e.g., craving for a drug) would interfere with an individual’s ability to pay attention to what a clinician is saying about a health care intervention. This concept was considered for inclusion into our new CTC-HC instrument.

2.6 Clinician Assessment of Capacity To Consent

For most clinicians, the assessment of CTC-HC is not a skill that is taught in medical or nursing school, and many clinicians lack practical training in this type of assessment. Forman et al. (142) conducted a study involving 115 clinicians from addiction treatment organizations. Here, 44% of participants were assessed as having a clear understanding of the fundamental elements about the client’s right to informed consent and 24% remained unclear of these elements even after training about informed consent. Additional barriers exist that may impact a clinician’s ability or willingness to assess CTC-HC IMSH. Sugarman (143) suggested that some clinicians feel that the very nature of substance addiction inhibits a client’s ability to provide informed consent for treatment, resulting in clinicians treating this population without
their consent. Similarly, Charland (144) stated that “we should not presume that heroin addicts are competent to consent to heroin prescription. In fact, we should assume they are incompetent unless proven otherwise.” (page 37) This perspective stems from the ideology that individuals who are addicted to heroin have an uncontrollable compulsion to seek heroin and this compulsion disables the ability to make a voluntary choice. Others have challenged this perspective by stating that there is a lack of evidence proving that addiction interferes with a person’s moral agency (i.e. a person’s ability to make moral decisions for himself).(141;145)

As seen in Table 2, the vast majority of instruments that have been developed to assess capacity to consent, use expert opinion (psychiatrist or other clinicians) as the gold standard against which the new instrument is validated. Prior to the development of psychometric instruments that measure CTC-HC, clinical assessment was the only option. Despite the existence of current validated psychometric instruments physician judgment continues to be the clinical standard for determining a patient's CTC-HC. (146-148) However, there is debate in the literature about the reliability of expert/clinical assessment.(148-150) For instance, in 1997, Marson et al.(126) demonstrated that physicians have poor ability to correctly assess capacity to consent. They reported only 56% (kappa 0.14) of physicians deemed patients previously diagnosed with dementia as having capacity to consent.(146) However, a subsequent study (148) demonstrated that physicians who were trained on the legal standards of capacity (understanding, appreciation, reasoning, and expression of choice), had good capacity assessment skills, as they demonstrated good agreement with a validated instrument (Capacity to Consent to Treatment Instrument (98)).
2.7 Gold Standards

When evaluating the rigor of instruments developed to assess CTC-HC over the last three decades, it is important to examine the use of a gold standard with which criterion validity can be measured. Many researchers would argue that there is no perfect gold standard to measure capacity.(100) Molloy et al. provide a good solution to this problem by suggesting “to adduce two credible independent face-valid standards. If these putative reference standards are reproducible and agree closely with one another, our confidence in their validity increases markedly.”(100) (page 660). Based on this recommendation, our validation study will include a combination of clinical assessment and an existing capacity assessment instrument as our gold standard.

2.8 Summary

Delivery of health care services to marginalized populations such as those who misuse substances and who are homeless (or live in unstable housing), in order to control communicable diseases, often requires non-traditional modes of delivery such as street outreach nursing programs. Care providers who deliver health care interventions to this population must acknowledge their clients’ legal and moral right to provide informed consent (or refusal) for any care that is offered to them, without pressure, coercion, or manipulation. A large proportion of this population is addicted to illicit drugs or alcohol, which increases the chances of a client being under the influence of a substance and potentially having impaired cognition during a nurse-client encounter. Clients who are impaired may demonstrate excessive stimulation, anxiety, anger, aggressiveness, mental confusion, inability to be attentive (impacting decision making), drug induced psychosis (hallucination, paranoia), and loss of judgment. It is incumbent
upon the clinician to assess each client for CTC-HC prior to delivery of any health care intervention.

While numerous instruments exist for the purpose of assessing capacity to consent among individuals with psychiatric disorders, there is a dearth of literature and instruments that address the capacity to consent in marginalized individuals who misuse substances. (141) The MacArthur capacity assessment instruments (including the UTD, POD, TRAT, MacCAT-T and MacCAT-CR) were developed and validated for use among people with mental illness such as schizophrenia, dementia, and depression. The MacCAT-T and MacCAT-CR, developed from legal constructs, are the most widely used capacity assessment instruments and have been validated with large sample sizes. The MacCAT-T has good interobserver reliability. Grisso et al. compared their instrument to the Brief Psychiatric rating scale and were able to demonstrate good intra-class correlation (interobserver and between scale correlation). Furthermore, using a control group without psychiatric symptoms, the researchers were able to demonstrate a dose response when examining scale results with psychiatric symptoms. Dimensions of appreciation, understanding, and reasoning were assumed to be separate concepts, and questions related to these concepts were validated separately. Therefore, subscale scores are created when using the MacCAT-T. Most of the other instruments reviewed here used a clinical (psychiatric) assessment as a gold standard, did not test for internal consistency and multidimensionality and have been used less widely than the MacCAT-T. Finally, a number of the other instruments used the same constructs as the MacCAT-T instrument. No instruments, to our knowledge, have been developed and validated to assess CTC-HC among IMSH. This study will develop a capacity assessment instrument for this population using the MacCAT-T instrument in combination with a psychiatric clinical assessment as a gold standard for validation purposes.
The critical review of the literature related to existing capacity assessment instruments and methods indicates that the following 16 concepts should be considered for inclusion in a new instrument aimed at assessing CTC-HC among IMSH:

1) Understanding
2) Reasoning
3) Appreciation
4) Autonomy
5) Beneficence
6) Nonmaleficence
7) Justice
8) Avoidance of misuse of power differential
9) Assumption of capacity
10) Voluntariness
11) Expression of choice
12) Memory
13) Attention
14) Orientation
15) Executive functioning
16) Communication

The next chapter will examine how, if at all, the concepts identified in the literature are used by clinicians to assess CTC-HC, and if there are concepts not identified in the literature that are specific to assessing CTC-HC among IMSH.
3 FORMATIVE PHASE (QUALITATIVE)

3.1 Introduction

This chapter reports the methods and results of the qualitative phase of my sequential exploratory mixed methods inquiry. This involves an initial phase of qualitative data collection and analysis followed by a quantitative inquiry. This method allows for the exploration of the phenomenon of CTC-HC. After reviewing the existing literature and the theory surrounding CTC-HC, the following concepts were considered important to incorporate into a new instrument aimed at assessing CTC-HC for treatment: understanding, reasoning, appreciation, autonomy, beneficence, nonmaleficence, justice, avoidance of misuse of power differential, assumption of capacity, voluntariness, expression of choice, memory, attention, orientation, executive functioning, and communication. Later in the chapter, these concepts will be compared to concepts identified through the qualitative interviews and a final list of concepts will be created for use in writing items for the new instrument.

The goal of this phase of the research was to gather information from clinicians who deliver care to IMSH as well as the clients themselves, to inform the creation of questions for a new capacity assessment instrument. This was done by exploring the current practices for assessing CTC-HC in street outreach settings and in clinic settings where health care services are delivered to IMSH, and by exploring the experiences that the target population have had related to accessing health care and providing or refusing consent for care. Both of these groups had lived experiences with CTC-HC. Streiner and Norman refers to this as key informant interviewing, with key informants referring to a small number of participants who have unique and extensive knowledge of the subject area (e.g., assessing capacity among individuals who misuse substance and who are homeless), and are able to articulate their experiences in
They are also able to provide insight on the nature of the problem of assessing CTC-HC and give recommendations for the concepts that should be included in the instrument. The data from the nurses and clients were analyzed together (rather than in two separate groups), as the perspectives of the nurses and clients complemented each other and the findings from one group’s interviews often validated the findings from the other group’s interviews. This was a form of triangulation in data analysis. However, it was not appropriate for clients to comment on some of the questions (e.g., what professional knowledge the nurses use to inform their decisions surrounding CTC-HC), and therefore triangulation was not possible.

The aim of the qualitative research was to determine if clinicians and clients had perspectives on assessing CTC-HC that were not addressed in existing theory and literature. The objectives of the formative phase of this dissertation were as follows:

1) to examine the decision-making practices that clinicians currently use to assess CTC-HC among IMSH; and

2) to explore the experiences that IMSH have had with accessing health care.

The theories that helped inform the formative inquiry portion of this study include decision-making theory as well as portions of critical social theory.

3.1.1 Decision-Making Theory

At the most basic level, clinical decision-making can be defined as choosing between alternatives. Decision-making theory originated from medical decision-making methods developed for physicians and adopted by the profession of nursing. In the 1970’s, decision-making instruments, such as decision trees, were developed to improve the accuracy of nursing diagnosis. In order for nurses to make accurate and appropriate decisions, they must have the requisite training and ability to incorporate the knowledge gained in their training, along with
cognitive skills. This is what Carper describes as empirical knowledge, and has been described by others as analytical information processing. When providing care to IMSH, nurses will draw on previous knowledge that they gained (or seek new knowledge through reading) related to the effects that substances have on cognition, how the effects of substance use differs between drug classifications, and how poverty and homelessness often create power imbalances between IMSH and medical care, thus potentiating infringement on the rights of IMSH related to providing or refusing consent for care.

Carper also describes ‘moral knowledge’ which focuses on “matters of obligation or what ought to be done.” This informs decision-making through the nurse considering “what is good, what ought to be desired, and what is right” These principles form the foundation of many nurse professional codes of ethics. Rodney et al. refers to nurses as moral agents. This means that they have the ability to make “rational and self-expressive choices, have notions of identity, have social and historical relational influences, and are able to take autonomous action.” This refers to the fact that nurses face daily moral choices which sometimes relate to an ethical dilemma. In making these choices, nurses are expected to act in a morally responsible and defendable way “regardless of directives from others or organizational policy.” When offering care to IMSH, nurses are often required to make ethical decisions surrounding CTC-HC when their clients lack capacity due to substance use, but are experiencing a serious or life-threatening medical condition. These decisions are based on the nurses’ personal moral perspective and the ethical guidelines outline by their professional body (e.g., College of Registered Nurses of BC). This qualitative research aims to explore, to what degree (if any), nurses use their moral agency when assessing CTC-HC among IMSH.
Finally, intuitive-humanistic models, which acknowledge the experiences of the nurses and the knowledge that they gained through these experiences, have been described as a method that nurses use to make clinical decisions. Experience with delivering care to IMSH sharpens a nurse’s intuition and provides “understanding without rationale”(157) when assessing a client’s level of understanding of their medical condition, what is being offered to them and the associated risks and benefits. Intuitive decision-making is reviewed in more detail in the discussion section of this chapter.

The research in this chapter aims to determine how nurses who provide care to IMSH make decisions about their clients’ CTC-HC. Therefore, all of these components of decision-making theory (empirical knowledge, moral knowledge, and intuition) were considered in the qualitative inquiry.

3.1.2 Critical Social Theory

Critical social theory provides a framework for inquiry that describes “distortions and constraints that impede free, equal and uncoerced participation in society.”(158)(page 58) Critical social theory explores a phenomenon by examining the “contextual effects of power, knowledge, and values.”(159)(page 51) At the core of critical social theory is empowerment, which “includes emancipation of individuals from all forms of domination.” (160)(page 821) I am particularly interested in the aspect of critical social theory that examines how power imbalances perpetuate inequity in the provision of health care.(161) In Chapter 1, I discussed the environment that IMSH live in and the effects that a low social economic status compounded by misuse of substances has on stigmatization and vulnerability to coercion and manipulation. Using a critical social theory lens, this qualitative inquiry will determine if power imbalances
impact nurses’ assessment of CTC-HC. It will also determine if clients experience power
differentials in nurse-client clinical encounters.

3.2 Methods

Prior to conducting any research activities, ethical approval was obtained from the
University of British Columbia (UBC) Behavioural Research Ethics Board (BREB) (H09-01982)
as well as ethics boards from each health authority in BC (Fraser Health Authority: 2011-127;
Interior Health Authority: 2011-12-038-E; Northern Health Authority: RR-2011-0044;
Vancouver Coastal Health Authority: V09-01982; Vancouver Island Health Authority: H2012-07). Prior to enrolling participants, an interview guide was developed for interviews with nurses
as well as clients as described below.

3.2.1 Interviews

3.2.1.1 Nurses

A semi-structured guide (Appendix A) was created using the decision-making theories
described above. Semi-structured interviews combine the flexibility of an open-ended
unstructured interview but allow for direction similar to a survey or questionnaire.(162) Creation
of the guide also drew on concepts and theories in the literature related to assessment of capacity,
primarily the four major concepts that have been described by Grisso and Appelbaum (88)
(understanding, appreciation, reasoning, expression of choice), as well as the four main ethical
principles of biomedical ethics outlined by Beauchamp and Childress (respect for autonomy,
nonmaleficence, beneficence, and justice).(12) Moreover, a phenomenological approach to
interviewing was planned, allowing clinicians to describe their lived experiences with assessing
CTC-HC. Phenomenologists believe that people’s perception of what they know and believe to be true about the world is constructed as they interact with other people over time and in different circumstances, rather than by objective external reality. Phenomenological interviewing involves asking participants about their lived experiences with a phenomenon which, in this case, was related to CTC-HC.

The interview guide (Appendix A) posed general questions that allowed participants to describe the environment that they delivered care in, the characteristics of individuals that they delivered care to, factors that they considered when assessing a client’s cognitive status, and how they determined if the client was capable or incapable of providing informed consent. Participants were also encouraged to share any ethical dilemmas that they may have faced when delivering care to individuals with problematic substance use and how they generally resolve these types of dilemmas. Probing was used to further explore complex concepts and to allow the participant to describe their decision-making process. The interview guide was adapted throughout the interviewing phase to allow for deeper exploration into dominant themes emerging from the interviews and to probe for deviant cases.

3.2.1.2 Clients

A separate semi-structured interview guide (Appendix B) was created for interviews with IMSH, in collaboration with my thesis committee (JB LM and AH), using concepts identified in the literature. A phenomenological approach to interviewing was adopted to provide clients the opportunity to describe their lived experiences with providing or refusing consent for care, as well as their experiences with accessing health care while under the influence of alcohol or drugs. Critical social theory informed the creation of questions surrounding the presence
and effect of power differentials between clinicians and clients arising from deviation from social norms due to problematic substance use and homelessness. Participants were encouraged to describe examples of accessing health care and to describe their experience with being asked to provide consent. They were also asked to describe any experiences of refusing care. Probing was used to further explore concepts, particularly related to power differentials between clinicians and clients. As in the case of clinician interviews, the interview guide for clients was adapted throughout the interviewing phase to allow for deeper exploration into dominant themes emerging from the first interviews and to probe for deviant cases.

3.2.2 Study Population and Sampling Frame

Purposive sampling was used for both participant groups (clinicians and clients). Purposive sampling aims to “select information-rich cases to examine meanings, interpretations, processes, and theory” (164) (pg. 46). Criterion-based sampling (cases based on a set of criteria outlined in the inclusions and exclusion criteria below), and snowball sampling (participants were asked to refer others, such as family and friends, for participation) were also used.

The sampling frame was designed to identify participants that have personal experience with assessing CTC-HC (clinicians) or who have had personal experience with providing consent for clinical care (clients). The aim was for participants to provide a rich description of all aspects of CTC-HC including their experiences and meanings. I also focused on the processes involved in assessing capacity, particularly from the clinician’s perspective.

3.2.3 Recruitment

3.2.3.1 Clinicians

Inclusion criteria for the clinician group were pre-determined and included:
1) clinicians who self-identified as providing care to individuals with problematic substance use who are homeless or living in unstable housing;

2) lived in a rural or urban setting; and

3) spoke English.

In order to determine if the current practice to assess CTC-HC differs in geographic areas throughout BC, I aimed to recruit at least two clinicians in each of BC’s health authorities (Vancouver Island Health Authority, Northern Health Authority, Interior Health Authority, Fraser Health Authority, and Vancouver Coastal Health Authority). The Communicable Disease Leader in each Health Authority was approached to obtain permission to conduct research in their Health Authority. The research was explained to them and ethics approvals were obtained. The Communicable Disease Leaders then distributed an advertisement regarding the study to nurses working with individuals who are addicted and homeless. Interested volunteers contacted the research team who established eligibility and enrolled the volunteer.

3.2.3.2 Clients

Inclusion criteria for the client group were pre-determined and included:

1) clients who self-identified as having problematic substance use;

2) self-identified as being homeless or living in unstable housing;

3) lived in a rural or urban setting; and

4) spoke English.

I aimed to recruit at least two clients living in each of BC’s five Health Authorities in order to ensure experiences from around the province (rural and urban) were represented. Clients were recruited through a poster that advertised the study at two community-based organizations.
providing services to individuals with problematic substance use (the Vancouver Area Network of Drug Users [VANDU]) in Vancouver and the BC/Yukon Association of Drug War Survivors [DWS] at their Surrey office). Word of mouth advertisement was also done at the local STI clinics in each of the Health Authorities. Recruitment through the local clinics may have produced a biased sample toward people who are willing to access health care. However, this bias was likely balanced by recruiting from the community-based organizations whose clients consisted of individuals who are reluctant to access conventional health care.

A participatory research approach was taken with VANDU that involved hiring three peer researchers. VANDU is a “grassroots democratic organization of drug users with over 2,000 members who work together to improve the lives of people who use illicit drugs and who work toward impacting public policy and practice related to the use of illicit drugs.”(73) The VANDU peer researchers were trained in qualitative interviewing techniques using training methods described by Funk et al.(165) In addition to conducting peer interviews, these peers facilitated recruitment through word of mouth.

3.2.4 Sample Size

Sample size was determined through standard qualitative methods. Lamputtong and Ezzy purport that “when the researcher is satisfied that the data are rich enough and cover enough of the dimensions they are interested in” (also referred to as ‘thematic saturation’), “then the sample is large enough.”(pg. 49)(164) I sampled according to Lincoln and Guba’s approach. Lincoln and Guba recommend sampling until the researcher recognizes no new data is emerging.(166) However, since I wanted to ensure participation from each of the Health Authorities, I did allow for information redundancy (repetition of findings) if it came from a different geographic location.(166)
3.2.5 Interviews

Interviews were conducted by me, a research assistant (NVB) who was trained in qualitative research methods and the area being researched, and three peer counsellors from VANDU (TM, DH, LS). These peer counsellors conducted interviews at VANDU, and NVB was in the room taking notes. Interviews took place between September 2011 and April 2012 at locations of convenience to the participants. All VANDU participants were interviewed in a private room at the VANDU office. Similarly, participants from the Drug Wars Survivors were interviewed in a private room at the DWS office. Nurses from the Street Outreach Program at the BC Centre for Disease Control (BCCDC) were interviewed in a private office at BCCDC. For the remaining interviews, one of the researchers (I or NVB) went to the STI clinics in the participating Health Authority and interviewed participants in a private room in these clinics. All subjects had the study explained to them and signed a consent form. The consent forms for both the nurses and clients are located in Appendix C and D. Nurse participants were given a $20 gift card and client participants were given $20 cash as an expression of thanks for taking time out of their day to participate. Some may question whether providing cash to IMSH participants is ethical as it may be seen as enabling further substance use. However, I intentionally chose to provide cash to client participants as a sign of respect and to demonstrate a non-paternalistic approach.

All interviews were audio-taped and transcribed verbatim. Development of a coding framework took place at the beginning of the interviewing process. The framework was created by NVB and me independently and then merged together. The coding framework was adapted (after discussion and consensus was reached) as new data were collected. Definitions for ideas and concepts were also developed during this time.
Transcripts were checked for accuracy and then uploaded into NVivo 9. Ideas/concepts/themes were identified as the transcripts were read and were coded into a coding framework using NVivo. Double coding of interviews (conducted by me and a new research assistant (KML)) took place for the first 20 interviews. Transcripts were read to identify recurring, converging and contradictory thematic patterns. In order to determine the level of agreement between my coding and KML’s coding (thus evaluating inter-rater reliability), coded sections of the transcripts were compared and a kappa statistic was calculated for each coded section. The kappa coefficient was derived by NVivo software which calculates a coefficient individually for each combination of node and source. The formula that NVivo uses is 
\[ K = \frac{TA - \sum EF}{TU - \sum EF} \]
where TA= the total units of agreement between the two users, EF is the expected frequency, and TU is the total units. Coded sections that had a kappa statistic of <.80 were identified and discrepancies were discussed until agreement was reached. Double coding of all transcripts took place until 80% of the codes had an agreement of at least .80. Thereafter, double coding took place every five interviews.

Member checking was done by presenting the results (from the interviews conducted with the nurse participants) to a subgroup of nurses from BCCDC who participated and agreed to provide feedback during an informal discussion. These nurses confirmed that the findings from the nurse participants were accurate and therefore no further action was taken. A presentation of the results (of the client interviews) was given to members of VANDU followed by a question and answer period. Both nurses and clients were asked if the findings “rang true” to their experiences.(167) This allowed me to discuss my initial interpretations with participants which either solidified my findings or clarified aspects that I was unsure of.
3.2.6 Analysis

An interpretive description approach, described by Thorne,(167) was used, and data were analyzed using a constant comparative method. Constant comparative analysis involves comparing every piece of data with others that may be similar or different to allow for theorizing about possible relationships among the data.(167) Because the semi-structured interview guides were created using concepts and theories described in the literature, deductive and inductive approaches were used to analyze the data. Data that were similar were grouped together and coded. Data that were contradictory were also identified and coded. Groupings were examined for patterns in the data and patterns were then examined and synthesized. Themes were identified that represented meaningful elements of the phenomenon of assessing CTC-HC, and these themes were used to provide an “interpretive explanation” for assessing capacity.(167) My intention was to gather concepts from nurses and clients that were inter-related and possible overlapped; therefore, the data from the nurses and clients were analyzed together (rather than reporting perspectives from each group).

3.3 Results

3.3.1 Participant Attributes

A total of 46 respondents participated in the study: 19 (41.3%) nurses and 27 (58.7%) clients. Participants were located across B.C., with 28 (62.2%) in the greater Vancouver area and 17 (37.8%) from other parts of the province. Among the nurses, 17 (89%) were female and 2 (11.1%) were male. Among the clients, 13 (48.1%) were female and 14 (51.9%) were male.

Twelve clients out of 27 (44.4%) used drugs only, 13 (48.1%) used both drugs and alcohol, one was not currently using drugs/alcohol, and no participants used alcohol only. This
data was missing for one participant. All 27 clients (100%) had used drugs and/or alcohol for more than 10 years.

Table 4: Characteristics of nurses and clients who participated in the qualitative study

<table>
<thead>
<tr>
<th></th>
<th>Number (%) of Nurse Participants n = 19</th>
<th>Number (%) of Client Participants n = 27*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>2 (10.5%)</td>
<td>14 (51.9%)</td>
</tr>
<tr>
<td>Female</td>
<td>17 (89.5%)</td>
<td>13 (48.1%)</td>
</tr>
<tr>
<td>Health Authority (HA)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PHSA**</td>
<td>9 (47.5%)</td>
<td>0</td>
</tr>
<tr>
<td>Vancouver Coastal HA</td>
<td>2 (10.5%)</td>
<td>15 (55.5%)</td>
</tr>
<tr>
<td>Fraser HA</td>
<td>2 (10.5%)</td>
<td>7 (25.0%)</td>
</tr>
<tr>
<td>Northern HA</td>
<td>2 (10.5%)</td>
<td>3 (11.1%)</td>
</tr>
<tr>
<td>Interior HA</td>
<td>2 (10.5%)</td>
<td>0</td>
</tr>
<tr>
<td>Island HA</td>
<td>2 (10.5%)</td>
<td>2 (7.4%)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>15 (78.9%)</td>
<td>8 (29.6%)</td>
</tr>
<tr>
<td>First Nations</td>
<td>0</td>
<td>11 (40.8%)</td>
</tr>
<tr>
<td>Other</td>
<td>4 (21.1%)</td>
<td>8 (29.6%)</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-20</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>21-30</td>
<td>Not collected</td>
<td>3 (11.1%)</td>
</tr>
<tr>
<td>31-40</td>
<td></td>
<td>6 (22.2%)</td>
</tr>
<tr>
<td>41-50</td>
<td></td>
<td>5 (18.5%)</td>
</tr>
<tr>
<td>51-60</td>
<td></td>
<td>10 (37.1%)</td>
</tr>
<tr>
<td>&gt;60</td>
<td></td>
<td>3 (11.1%)</td>
</tr>
<tr>
<td>Employment Type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Welfare</td>
<td>Not Collected</td>
<td>2 (7.4%)</td>
</tr>
<tr>
<td>Dealing drugs</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Pan handling</td>
<td>1 (3.7%)</td>
<td>0</td>
</tr>
<tr>
<td>Binning***</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disability benefits</td>
<td>5 (18.5%)</td>
<td>0</td>
</tr>
<tr>
<td>Part time employment</td>
<td>3 (11.1%)</td>
<td>0</td>
</tr>
<tr>
<td>Full time employment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unemployed</td>
<td>11 (40.4%)</td>
<td>0</td>
</tr>
<tr>
<td>Volunteer only</td>
<td>1 (3.7%)</td>
<td>1 (3.7%)</td>
</tr>
<tr>
<td>Illegal activity</td>
<td>1 (3.7%)</td>
<td></td>
</tr>
</tbody>
</table>

* Numbers may not add up to 27 when participants chose not to answer the question
** Provincial Health Services Authority
3.3.2 Results From Interviews

The results presented here include the combined findings from the nurses and the clients. Comparative analysis between groups was not conducted. The results from each group were examined and used to validate the findings between nurses and client responses (triangulation). Five major categories emerged from the data: 1) *internal guiding forces* that contribute to the nurses’ assessment, 2) *external guiding forces* that contribute to the nurses’ assessment, 3) *measures* that were identified as important for assessing CTC-HC, 4) *threshold setting* for determining CTC-HC and 5) *context* (physical and interpersonal) in which assessment of CTC-HC takes place.

3.3.2.1 Overarching Conceptual Claim from Nurse and Client Interviews

When delivering care, clinicians incorporate information from internal guiding forces and external influences to measure CTC-HC. This is a complex process that must balance the level of risk that is associated with the intervention and the client’s level of capacity at any given moment. All of this is done within the context of delivering care to clients who bring their personal history with accessing health care to the nurse-client encounter. Figure 4 below displays this overarching claim (a claim that covers all the elements of the findings).
3.3.2.2 Internal Influences

During the interviews with the nurse participants, nurses talked about the knowledge that they bring to the encounter. This includes knowledge gained through professional education,
knowledge of ethical and legal principles that is required by professional development and knowledge gained through years of experience as a nurse, particularly years working with individuals with addictions.

3.3.2.2.1 Previous knowledge of client

The concept of ‘experience as nurse’ is closely linked to the nurse’s previous knowledge of the client. This is useful for both novice nurses and veteran nurses who have had several years of experience delivering care in outreach settings. Nurses talked about getting to know clients who repeatedly access the clinics they practice in, or clients who have been on the streets for more than a couple of months. Nurses talked about knowing what the client’s baseline condition is, which they described as “the best a client would get” in terms of their level of impairment. Having knowledge of the client’s baseline condition informed the nurse’s decision about whether they should delay care until the client was more cohesive.

“A lot of it is having known people a long time, so knowing that this isn’t bizarre behaviour for them because they’re always in this sort of state or this is a pretty good state for them. So um, that kind of thing.” (Nurse 08)

Nurses also talked about having previous knowledge of their client’s attitudes about certain health care procedures or interventions. Some clients want to get tested for HIV or other communicable diseases but are too fearful to actually do it, so they use drugs to get enough courage to have the test. The following quote talks about how a client had to get high in order to have the courage to get a pelvic examination.

“Yeah, they’ll say it’s something I’ve been thinking about for a really long time and I just never seem to have the time to do it and now I’m here and [inaudible] for me. Okay, that’s a valid reason for us. If they’re saying like
I’m always too scared but now I’m not, like maybe they just did coke and they’re not used to doing coke or something then maybe we’ll say like I’d feel more comfortable if we wait until tomorrow.” (Nurse 17)

3.3.2.2 Intuition

Many of the experienced nurses talked about using their intuition when assessing the client. They talked about intuition coming into play when a decision is required but the clients are not able to articulate their rationale for their decision. As one nurse states, “….it’s just what we do” (Nurse 08). This was generally used in combination with using their knowledge of the client from previous encounters or assessing the physical environment for safety and confidentiality issues.

3.3.2.3 Knowledge of ethical and legal principles

The majority of nurses stated that they were aware of the Nurses Code of Ethics but could not articulate clearly the specifics of what is mentioned in this code. Most nurses were familiar with obtaining written informed consent from a patient prior to surgery or other invasive procedures and they drew on this knowledge to guide their thinking about the ethics of getting consent prior to delivering health care. Very few of the nurses were familiar with what is written in the BC Law about the client’s rights to consent with the exception of the legal aspects related to testing for HIV or other infections that are listed as a reportable disease. Nurses expressed that they feel conflicted because they are aware of the legal requirements for capacity consent but they do not want to deny clients care if they are in need while they are impaired.
“Like I say, I don’t know how it would hold up legally because they are technically under the influence of alcohol or drugs, but that’s the legal end. The ethical end is that you can’t leave them, if they’ve consented, even if you know they are impaired.” (Nurse 18)

3.3.2.2.4 Experience as Nurse

The vast majority of nurses talked about the importance that the number of years as a nurse was to assessing clients, especially the number of years delivering care to clients with problematic substance use. Nurses with more than two years of experience delivering care to homeless individuals with addictions talked about ‘just knowing’. Many referred to a ‘gut feeling’ or using their intuition to determine whether the client had been using substances recently and whether they were high or not. Novice nurses, or nurses who had little experience practicing with populations with substance use issues, concurred with what the more veteran nurses said related to the value of having experience in this particular field. Many of the novice nurses expressed feeling uncertain about whether they should deliver care to a client who may be under the influence of a substance, and often referred to a more experienced colleague to help them make a decision.

3.3.2.2.5 Professional knowledge:

Nurses talked about how they use knowledge gained from their nurse training to frame how they approach assessing CTC-HC during an encounter involving a client who may be impaired due to substances. Basic nursing skills such as assessing if the client is orientated to person, place and time was referred to by the majority of nurses. They talked about asking the
patient if they knew who they were, what day or year it was and whether they knew where they were.

“So you basically are assessing, are they oriented, are they making sense, do they know who I am, do they know what I’m asking them.” (Nurse 8)

Nurses also talked about using basic physical assessment skills to assess whether there are physical signs that the client has been using substances recently.

3.3.2.2.6 Risk to public health

The final internal factor that influences the nurse as she/he is assessing the client’s CTC-HC, is the pressure they feel regarding adhering to communicable disease guidelines in order to protect the public from the spread of an infectious disease. Nurses expressed internal conflict as a result of competing interests: the desire to respect the client’s autonomy and the desire to protect the public. In these situations, nurses expressed the need to compromise with one of these two interests.

3.3.2.3 External Influences

External influences, such as safety, timing of the encounter, location, and urgency of care, are elements or concepts that are not necessarily used to assess the client’s CTC-HC but influence the nurse’s ability to make a thorough or accurate assessment. These elements are generally outside the control of the nurse but must be taken into consideration when making their assessment.
3.3.2.3.1 Safety

Safety is an issue that virtually all of the nurses talked about, especially nurses that have experience with street outreach. These nurses talked about their own personal safety in terms of how volatile the client might be (as a result of the drug that the client may be using). In these situations, nurses talked about delaying care until it was safer to engage with the client. In some of these situations, the nurse is able to calm the client down or defuse the situation at which time the nurse will continue to assess the client’s CTC-HC.

Nurses also talked about assessing the environment to determine if there were other people in the immediate environment that may harm the client or the nurse. There was also reference to the client’s emotional safety which refers to whether the client is vulnerable to power imbalances, emotional abuse, or depression. Under these circumstances, it is important to determine if the client is consenting or refusing care in order to escape a potentially dangerous situation.

One nurse talked about how safety is the prime factor that they consider when assessing whether they should deliver care. In the following quote, the nurse talks about how they don’t care which substance the person is on; as long as it’s safe to deliver care and the person can consent, they will provide care.

“I care about the behaviour. As long as this person is breathing and their vitals are okay that’s a whole other issue. But if I’ve got a live person and I’m not going to have them coding on me then I care about the conversation we’re having, not the behaviour.” (Nurse 08)

Finally, safety was referred to in relation to whether delivering care can be done in a safe manner. For example, is the client coherent enough to be able to remember and articulate
whether they have allergies or not, or if they have already had an influenza shot this year?

Nurses talked about assessing the client to determine if they had the capacity to deal with a side effect from the intervention that was delivered. They also talked about the fact that some clients take substances in order to have the emotional strength to get an HIV test. In these situations, nurses pointed out that they need to assess if the client will be able to cope with the test result, especially if the test indicates the client is positive for HIV.

3.3.2.3.2 Timing

Timing is another issue that nurses often have no control over and affects their ability to assess the patient. Nurses expressed that when delivering care in street outreach settings, they may only have a couple of minutes with the client. As a result, the nurse must consider whether they have enough time to assess the client for CTC-HC, or delay providing care (if possible). Timing is particularly important when the nurse is approaching the client (e.g., in a back alley) in the client’s setting. This is particularly important because the interaction between nurse and client may be unwelcomed by the client if they are involved in another activity such as trying to ‘turn a trick’ (in the case of a sex worker), or in the middle of a drug deal. Nurses referred to these situations as the nurse being in the client’s reality, and they need to be mindful and respectful of this.

3.3.2.3.3 Location

Many nurses who were interviewed stated they delivered care in a public health clinic or other medical clinics that provide service to individuals who are homeless or who live in poverty. In these situations, clients present with a specific purpose and therefore there is an element of implied consent. Irrespective, the nurse must still assess the client’s capacity, to ensure the client understands the benefits and harms related to the care they are requesting. However, this is
different than outreach situations where the nurse is the one approaching the client to offer care. Street outreach nurses state that they deliver care in locations such as alleyways, doorways, churches, clients’ homes, hotel lobbies, parking lots, jails, on the street or in restaurants. When nurses approach the client, they are conscious about the importance of being respectful that they are in the client’s environment.

“I think the defining characteristic is that these are mainly folks that won’t come to a clinic, right, so we go to them. So you’re meeting them on their turf that means in their home, on the street, alleyways, doorways” (Nurse 07)

Nurses assess the safety of the environment and whether they can deliver care in these settings and still maintain patient confidentiality. All of these factors impact how well the nurse can interact with the client, how willing the client will be to answer questions, and how quickly the client may consent or refuse care based on their surroundings. All of these factors are taken into consideration when assessing the client’s CTC-HC prior to delivering care.

3.3.2.3.4 Urgency of care

Many nurses talked about having a moral or ethical dilemma when faced with a clinical encounter which requires urgent care. Urgent care was described as a medical situation in which the client’s life was at risk. One nurse described an example of patients who were experiencing signs and symptoms of drug overdose and required oxygen or the administration of drugs to reverse the effects of opioid overdose (e.g., naloxone). An ambulance may also be needed under this circumstance. Nurses stated that many clients who are overdosing often refuse oxygen, naloxone, or assistance from paramedics, mainly because they do not want to lose the effect of the drug they took. In some situations, the client does not want an ambulance to be called because they have had a bad experience with emergency room care and therefore don’t want to
re-experience this. Nurses described how they try to respect the client’s decision under these circumstances and, on occasion, try to persuade the client to accept the intervention. However, if the client’s condition continues to deteriorate, the nurses will then intervene with life-saving measures. Clients who were interviewed confirmed that they expected a health care provider to intervene to save their lives if they were not capable of making a decision in an emergency situation.

3.3.2.4 Measures

The majority of nurses were able to describe the factors that they measure when assessing CTC-HC. This process usually involves a pre-assessment to determine if there are any physical indications of substance use, followed by an investigation about what substances the client may be under the influence of. Similarly, an assessment is done regarding whether the client is withdrawing from a substance, as this state can also influence a client’s CTC-HC. These pre-assessments are followed by measuring understanding, an assessment of the client’s ability to communicate and an assessment of the client’s memory.

3.3.2.4.1 Ability to communicate

Nurses talked about the importance of the client being able to engage in a conversation with the nurse. Clients may be too sleepy or euphoric to be able to engage in a conversation at all, or their speech may be too slurred to be comprehensible. Under these circumstances, the nurse is not able to assess the client’s capacity at all. The following quote demonstrates a nurse’s experience with this phenomenon.

“Well right off the bat if [there is] somebody you’re trying to talk to and you can’t make out a word they’re saying, right off the bat that’s a dead sign.” (Nurse 03)
Alternatively, the client may be able to speak and engage in a conversation, but their conversation is either not rational or has nothing to do with the conversation the nurse is trying to have with them. When faced with these circumstances, nurses said they would offer to talk to the client at another time when ‘it’s better for them’. If the client could look the nurse in the eye and have a coherent conversation, about any topic, they would continue with their capacity assessment and provide care when appropriate.

3.3.2.4.2 Memory

The concept of memory was also frequently raised by the nurses as an important indicator of capacity. This is difficult to assess if nurses have had no prior encounters with the client, but a previous encounter facilitates an assessment of working memory. Nurses talked about asking the client if they remembered meeting them before or if they remembered getting an STI or HIV test in the last couple of weeks (if appropriate).

“if it was a vaccine and somebody was so profoundly drunk and they weren't going to remember it and might not be able to manage it if they have an adverse reaction, then there is no point giving it then, right? So, do they have the capacity to manage any side effects of the care you are going to provide?”

(Nurse 10)

Nurses also spoke about safety implications related to the client’s ability to remember. Some nurses recounted situations when a client would come up to them and ask for a flu shot even though they had been vaccinated for the flu the previous day. These experiences heightened the
nurse’s awareness of the need to assess whether the client will remember that they received care in the following days. As mentioned above, nurses also spoke about the importance of the client being able to remember if they have allergies, in order to prevent the nurse from administering a medication that could be harmful.

3.3.2.4.3 Physical indication of substance use

Physical indication of substance use was a dominant theme that was reported by the vast majority of nurses. It was clear that physical assessments are generally the starting point at which their assessment of capacity occurs. Although it is not sufficient on its own, this assessment provides an initial indication that the client may be under the influence of a substance or may be withdrawing from a substance, and therefore further assessment is required. Nurses described physical indicators of use, including the way the person is walking, other involuntary movements, irregular behaviours, their posture, and the size of their pupils. Rich description was provided about how clients who are under the influence of a substance (such as crack cocaine), may display gyrating movement, an inability to walk normally or evidence that they haven’t slept in days.

“....that are noticeably impaired to the point of being physically, 
they’re sketchy they can’t stop moving or they’re somberlant or 
they’re obviously drunk.” (Nurse 02)

Conversely, nurses look at the client’s posture. Slouching over was frequently mentioned as an indicator of the client being under the influence of an opioid or alcohol. If the client is slouched over and appears to be sleeping, the nurse will try to wake them. One nurse described seeing a client that she was familiar with as being slouched over and could not be woken up. Assuming
the client was overdosing, the nurse called an ambulance. The following quote provides an interesting example of how a client may appear (from their posture) to be impaired, but in actual fact could hear and understand what was going on. In this case, further assessment could be done to determine if this person has CTC-HC.

“It’s interesting because there’s been many times like there was a situation on the (inaudible) block where a client I knew quite well was nodding off in front of a store there and basically she was kind of collapsing. I was a little worried that she’d overdosed. This was a number of years ago. So I went into the store, I tried to kind of rouse her, she was sort of in a heap on the concrete there, and I went into the store, this is before we carried cell phones, I said, ‘Can you call an ambulance?’ and so the guy behind the counter said yeah, yeah. I said, ‘right just in front here’, so he called an ambulance. And I walked out of the store and she raised her head up and she looked at me and goes, [name of nurse] you didn’t call an ambulance did you? So it’s always, and I’ve encountered that time and time again, where people are high they are under the influence but they’re still quite competent to make decisions.”

(Nurse 7)

The nurses described some clients as ‘tweaking’ which is a term used to describe the activity clients do that involves picking at themselves or trying to find something on the ground. Nurses also described looking at the size of the client’s pupils. Dilated pupils may be an indication that the client has been using ecstasy, amphetamines, cocaine, or crack. Excessive alcohol use can
also result in dilated pupils. Heroin and other opioids, on the other hand, makes the pupils look pin point.

“And it’s really through the exchange. I mean, if she’s not – if her eyes look like she’s high, you know, like, she’s not really that focused or the speech is not making sense, it’s pretty rare though.” (Nurse 14)

The following quote from a client participant describes the physical signs that indicate that clients are under the influence of a substance.

“The way the drugs act on people, you know, you get sketchy, you get wobbly-weebly, right? …… You know, you can’t look them [the doctor or nurse] straight in the face. Alcohol, of course, you’re going to be reeking of booze, right? …… And you’re slurring your words and – on a – dilatation of the eyes, right?” (Client 16)

3.3.2.4.4 Assessment of which substances are being used and withdrawal

Nurses reported that it is often helpful to know which substance, if any, the client has been using, as different substances will influence the client’s capacity differently. For example, clients who are using heroin are generally sleepy. Although they appear to not be paying attention to what the nurse is saying, they are actually still listening, able to understand what is being said and able to make and express a sound decision. Other drugs can cause hallucinations which may make the client paranoid. Nurse participants reported that in cases such as these, they would delay care until the drug had worn off. Nurses talked about asking the clients what they have been taking which many clients will happily tell them. Clients frequently talked about how using drugs doesn’t affect their ability to think or make decisions whereas alcohol blurs people’s
ability to think, to understand, to communicate, and to remember events while they are drunk. These effects are likely to limit CTC-HC. Nurses confirmed that clients who are high on alcohol are more likely to lack CTC-HC than those who are under the influence of other drugs.

“I would probably put them off a bit if I felt that they were really drunk or really high. And again, it would depend on the service. I mean someone might come in here absolutely drunk out of their mind ummmm because that's the harder one for me. High is a little bit different because there is more, in my mind, an ability to consent or not. When somebody's high.”

(Nurse 10)

The experience of withdrawing or coming down from substances can affect the clients’ ability to make a rational decision. Nurses refer to this as being ‘dope sick’ which makes the client feel violently ill with flu-like symptoms and joint or muscular pain. Under these circumstances, client’s thoughts are generally disorganized and fixated on getting more drugs to alleviate withdrawal symptoms and therefore their attention span is quite short. Engagement in discussions about delivering health care can be very problematic.

“So I almost feel that people are, you’re screwed either way cause if people are really dope sick then they’re not really consenting. They’re either going to tell you to go away cause you’re in the way of them getting a fix or they’re going to try to please you to get a ride or phone call out of you or if people are high, it’s almost better to talk to people when they’re a little bit high and their like, ‘I’m okay now. I’m feeling better now. I feel like me, now let’s have a conversation’. ” (Nurse 08)
Understanding was also a concept that was raised by the majority of nurses. They referred to making sure that the client understands what the medical intervention is, why they are getting the intervention, and what the risks are. Several nurses talked about making decisions about the minimum critical information that should be understood by the client, since many clinical encounters are quite short.

“Well I think it’s probably about just posing a series of questions and whether how appropriate they can answer them. Or whether they answer them at all; whether they’re actually hearing me. Some of them will be out of it so they can’t respond or if they respond they don’t really know what I’m saying. So it’s a question of answering questions and being appropriate with some kind of response it doesn’t have to be detailed but they at least have to understand my questions.” (Nurse 04)

Understanding is a concept that seems simple on the surface, but in reality can be difficult to measure. Some nurses talked about asking the client to repeat back what the nurse has said to them. They talk about needing to hear certain elements from the client that convinces them that the client has understood what was said to them.

“People are right on the money and they can have a great conversation. They know what they’re doing. They give you the answers. They tell you when unsafe sex last happened. They’ll tell you the 3 or 4 key points that I need. They’ll give you the information. They’ll give you the consent.” (Nurse 01)
3.3.2.4.6 Orientation to person place and time

As mentioned above, assessment of whether the client was orientated to person, place and time, was commonly mentioned by the nurses. If the client can state their name, what is going on around them, and why they have come to the clinic, then many nurses will proceed. For many nurses, this was the bare minimum they required in terms of capacity.

“Well I think if they’re oriented to time, place and date and all that, I think if they think they’re on Mars that’s... I mean it’s obvious they’re not in a place where they can make consent but if they know who they are, they know who you are, they know what you’re talking about, and they can.... you can sense that they can understand what the conversation is about and the risk and benefit, I think that that’s kind of where it comes down to.... if they can repeat to you what you said to them, if they can repeat what they’re understanding of your plan or what the medications are for I think that is enough consent.”

(Nurse 06)

“I would probably just start off with asking them how they’re doing? What’s going on? And then I would take it from there, from what they would respond, which direction I would go in. Exploring whether they’re located to time, place and person. So eventually I’d get that they are oriented, know where they are, what’s going on.” (Nurse 04)

Some nurses talked about how assessing for orientation to person, place, and time was a good
way to evaluate whether the client had any mental illness issues. Knowledge of co-diagnosis (substance addiction and mental health) may influence whether the nurse will proceed with delivering care or assist with getting the client assessed by a physician.

3.3.2.4.7 Signs of mental illness

Nurses expressed cautiousness surrounding delivering care to clients with mental illness. Several talked about the need to refer these patients to a mental health care provider or mental health services rather than delivering care to them directly (especially in street outreach settings). Nurses talked about clients displaying paranoia e.g., feeling like the nurse (or someone else) was trying to harm them or trying to trick them into something. Other nurses talked about clients being suicidal, displaying signs of dementia or schizophrenia, hearing voices, and being out of touch with reality. Many nurses talked about the challenges of telling the difference between chronic mental illness and drug induced mental illness. Either way, if the client demonstrated any of these signs, then care was delayed or the client was referred to a physician.

“We go through and we’re trying to find people so it’s really hard to determine if someone is mentally ill versus they are using too many drugs and they’re tweaking out or they’re doing actions or behaviours that are congruent with what the effects of the drugs should be. It sometimes is pretty obvious especially if they may be talking to themselves or really doing some bizarre behaviours that you haven’t seen before but really it’s very very hard to tell, from my perspective.” (Nurse 1)
3.3.2.5 Threshold: Level of Risk Versus Level of Capacity

Nurses were asked about how they determined what level of incapacity was sufficient to delay care. Many nurses struggled with this question and some were not able to articulate exactly how they determined this threshold. Most agreed that the concept of ‘threshold’ is on a continuum and needs to be balanced against the degree of risk involved with providing or not providing the health care intervention. Some stated that if the client appeared to be impaired (on drugs or alcohol), but they required an intervention with virtually no risk, such as dressing to an open wound, then they would do it unless the client said no. Other nurses talked about the minimum amount of capacity that would be required before care would be provided, such as orientation to person, place and time as mentioned above. The following nurse demonstrates the minimum capacity he/she requires with his/her clients.

“So yeah, I think that consent is a bit different with our population … because I wouldn’t -- I wouldn’t -- I wouldn’t expect them to be necessarily sit through what syphilis actually is and what it can do to the body. [laugh] Or you know, I never -- I don’t -- we -- I would never go in depth of -- of -- you know, sometimes it’s -- you know, they know HIV is bad. But they may -- and -- and we definitely try and talk about the transferability, like, how to protect, but sometimes you don’t even get that far. Sometimes it’s just about the testing -- and that’s all they want and as long as they consent to that, then…. (Nurse 15)

Client participants were able to provide information about the level at which they would likely lack CTC-HC. The following client describes the signs that nurses could use that indicate a lack of CTC-HC.
“Well – well if I’m like, knocked right out cold and, you know, they can’t --- can’t wake me up and talk to me or whatever, or they get a little bit of a response out of me but I’m not me; I’m just so tired or so high on heroin that…” (Client 26)

Nurses talked about the need to intervene (regardless of the client’s CTC-HC) under life-threatening circumstances. They talked about some clients being unhappy if the nurse intervened without the client’s consent. This can create a practice dilemma for some nurses.

“Oh we have … like people get upset with us for even just Narcaning, even though we tell them that ‘you had stopped breathing completely, like you were blue, you’re oxygen levels were like at 10 percent instead of a hundred percent’ or whatever so we had to Narcan them.” (Nurse 17)

The following nurse talked about being faced with an ethical dilemma when delivering care to a client who may never present with full capacity. This requires an assessment about whether the client is the best they are ever going to be and whether it would be acceptable to provide care.

“When you’ve gotten to know some of the people a little bit more then you can say okay, this guy who’s alcoholic all the time, he’s definitely not going to be able to give consent at this level but this is his best functioning level and consent would make sense then.” (Nurse 11)

Up to this point, the data from nurses have been used. However, for the following concepts, the clients also contributed important information.
3.3.2.6 Context: Client’s Past Experiences

Nurses talked about the importance of understanding the context within which the encounter is taking place prior to making a clinical assessment. By context, they were referring to the elements that the client brings to the table that influence how the nurse approaches the encounter. These elements include the client’s perception of being stigmatized, the client’s level of trust with health care workers, reluctance to access health care, and the role these elements play in the clinical encounter. All of these elements can influence how well the client engages with the clinician, and thus impacts the extent to which an assessment can be made. The following findings are from the nurses’ impressions of what the clients experience as well as from the clients’ interviews directly.

3.3.2.6.1 Reluctance to access health care

Clients who have been discriminated against in health care settings are hesitant to access health care. The following quote from a client illustrates this reluctance after having a bad experience.

“Like, say if, like, going to emergency or something. I’ve had really bad experience, just been treated so brutally bad, like, so it prevents me --- obviously, I don’t want to go back there, like.” (Client 26)

As mentioned above, stigmatization and nurse-client trust are two main factors that affect the nurse’s ability to assess CTC-HC in an encounter. Other reasons expressed by clients and nurses include fear of getting a serious diagnosis (such as HIV), and fear of health care processes (mandatory reporting). Both clients and nurses talked about how activities related to the client’s addiction (such as getting money, finding drugs, and using drugs) are a higher priority in the client’s life than taking care of their health. This phenomenon is particularly problematic in
street outreach settings when a nurse is attempting to deliver care in the client’s environment. Nurses stated that the client’s willingness to engage in an encounter under these circumstances greatly affects the nurses’ ability to assess the client for capacity.

3.3.2.6.2 Clients’ assumption of a submissive role

Delivering care to individuals who are addicted to substances and who have a low socio-economic status is challenging, especially if they have a history of assuming a submissive role in society. Nurse participants talked about clients who are naturally submissive in personal or social relationships (such as sex workers), and transfer this way of relating to others to nurse-client relationships. These clients tend to consent to health care, not necessarily because they understand the need for it, but allegedly because they want to please the care provider. One nurse described a situation that involved offering a pap test with a sex trade worker. This nurse expressed a concern about not perpetrating the cycle of abuse in this woman’s life.

“The ones that worry me the most are the really agreeable folks, especially first nations women who say yes to anything despite the fact that they might not want to do it or their background or being female or whatever makes them say yes to everything that would probably worry me the most. In the sense of adding to a burden of pain in their lives.” (Nurse 05)

The concepts described above, by both clients and clinicians, provide important insight into the context with which clinicians deliver care, the pre-existing factors that impact how a clinical encounter is conducted, and the elements that a nurse needs to be aware of when assessing CTC-HC.
3.3.2.6.3 Stigmatization

Many of the client participants talked about how they feel stigmatized by receptionists, nurses and doctors in clinics and emergency rooms. This feeling of stigmatization stems from experiences of having to wait for long periods of time to receive care, (longer than non-addicted individuals), refusal of care (particularly refusal of treatment for pain), and being spoken to in a manner that feels disrespectful to the client. Nurses that were interviewed confirmed that clients are stigmatized while accessing health care and this often results in clients delaying seeking health care, even in serious situations.

“Oh, it’s very clear that the – a lot of service providers have preconceived judgmental ideas about this population………..They don’t understand where they’re coming from and why it’s difficult for them………..They just – and so they make up stories from their perspective about why they’re not keeping their appointments and how they’re wasting professional time and resources.” (Nurse 14)

3.3.2.6.4 Trust or distrust

Trust is a critical component of the nurse-client relationship and provides the foundation on which a clinical encounter occurs. The following quote from a nurse describes how nurses who deliver care to clients with addictions, work hard to develop and maintain relationships of trust with their clients.

“In our clinic we do a lot of listening and our clinic is very relationship based. The success of our clinic is based on building relationship. In the beginning we may not offer anything but a friendly face, a smile, somebody they can talk to and once we build a relationship its easier for
us and we have quite a high success rate in our clinic for even our
treatment for TB once we build a trusting relationship we have a high
success rate.” (Nurse 3)

Clients talked about seeking a primary care provider who has an understanding of addictions; someone they can trust with their addiction problems in a nonjudgmental way. During these type of encounters, clients described that usually they don’t have to wait very long, and can generally get their health needs met. These clients are less reluctant to access health care and are more likely to engage in a discussion of consent for health care. Some, however, described the opposite effect of ‘trust’ in their doctor by assuming a submissive role and relinquishing their right to consent. This is demonstrated in the following quote from a client.

“This one doctor said something about, you know, like, “you’re just here
for drugs so why don’t you get up and make room for somebody who
really needs the bed? Or something like that.” (Client 27)

3.4 Discussion

The results of the qualitative portion of this research study have provided important information about concepts and elements that could be incorporated into the new instrument. These results include information about the internal factors (including previous knowledge of client, intuition, knowledge of ethical and legal principles, experience as nurse, professional knowledge, risk to public health, and innate power differential) and external factors (safety, timing, location, and urgency of care) that are combined with measures that can be used to assess CTC-HC. These measures include the ability to communicate, memory, ability to cope with
adverse effects of a health intervention, physical indication of substance use, and understanding the effects of withdrawal rather than impairment. These elements come into play in the context of the client’s past experiences with health care, which may result in reluctance to access future health care, feelings of stigmatization, and mistrust of the health care system.

The external and internal factors, measures, and context identified by this qualitative study have not been described previously in the literature, nor incorporated into existing instruments. This is mainly due to the unique environment of street outreach nursing, as well as the unique effects that alcohol and drugs have on cognition. As mentioned in Chapter 2, the majority of existing instruments have been developed and validated in patients with mental illness such as schizophrenia, Alzheimer’s disease and dementia. The most widely used concepts incorporated into existing instruments include: understanding, (85;89;90;93;98;99;101;104;105;108;110;111;127;168-176) appreciation of the nature of the situation,(89;93;98;99;101;104;105;109;127;173-176) reasoning (85;89;93;98;99;104;105;170;171;173;175;176), and expression of choice (89;93;98;99;101;104;105;170;171;173;176) The concept that has been cited by virtually all other sources is ‘understanding’. This concept was also a dominant theme among the participants of this qualitative study. It is important to note that, although the intent of this dissertation is to develop an instrument to assess CTC-HC among IMSH, the nurses who were interviewed stated that a large majority of their clients also had mental illness. Therefore, it is reasonable to incorporate the concepts described by other researchers and psychometricians into an instrument designed for assessing CTC-HC among IMSH.

In a recent review of psychometric instruments developed to assess capacity to consent, Dunn (86) highlighted an important gap. He stated that contextual factors are sometimes
referred to in the literature surrounding instrument development for assessing capacity, but these factors are understudied.\textsuperscript{(86;177-182)} The results of my qualitative study have filled this important gap. Nurse participants expressed the view that internal factors influencing nurse decision-making, external influences such as safety, and issues related to the client’s experience with accessing health care, are all important contextual factors.

3.4.1 \textbf{Contextual Factors}

3.4.1.1 \textbf{Internal Factors}

The contextual factors raised by the nurse participants included factors that influence decision-making, but are elements that cannot necessarily be measured. These factors stem directly from the findings of the qualitative portion of this dissertation and are not found in the literature or in other instruments. For instance, a recurrent theme in the interviews was the level of experience that nurses have delivering care to individuals with problematic substance use. As in most professions, years of experience providing care to clients with addition problems enables nurses to recognize signs of impairment or lack of capacity in a way that a novice nurse may not. Banning \textsuperscript{(153)} states that as nurses become more experienced, decision-making becomes easier and they become able to make more intricate decisions. Novice nurses tend to rely on the knowledge they gained in training and take into consideration nursing practice guidelines provided by professional practice organizations. This phenomenon is referred to as analytical decision-making by decision-making theorists.\textsuperscript{(183-185)} O’Neil states that this method of accessing knowledge enables complex decision-making based on rational logic that nurses are required to use on a daily basis.\textsuperscript{(186)} The concept of orientation to person, place and time is an example of analytical decision-making that was highlighted by the nurse participants. Another
example of analytical decision-making that was raised by study participants, was assessing understanding by determining if the client could repeat back what was said to them in their own words.

The concepts of orientation and understanding were included in the first draft of the new instrument. However, the concept of ‘experience as a nurse’ (with or without experience with the target population), is an important contextual factor that cannot be ignored. This contextual factor was incorporated into the first draft of the new instrument, not as something to be measured, but as something nurses will be reminded of in the instructions portion for the new instrument.

Along similar lines, experience as a nurse results in decision-making processes that involve intuition. Nurse participants talked about ‘just knowing’ whether the client was high or not. Intuition is defined as, “understanding without rational thought’, which Benner states is critical to clinical judgment.(157) This form of nursing knowledge is aligned with the theory of Nursing Gestalt developed by Pyles and Stern. They describe Nursing Gestalt as a combination of logic and intuition involving both conceptual and sensory acts. (187) The use of intuition in clinical decision-making in nursing has been viewed critically(188) because it makes use of ‘hunches’ rather than empirical knowledge.(189;190) However, intuition strategies involving ‘gut feelings’ are becoming accepted as part of the pathway of physician diagnostic reasoning in general practice.(191) According to the nurse participants in this qualitative study, the use of intuition in information processing while providing care, is helpful in assessing the client’s CTC-HC, but is also useful in assessing physical safety, as well as emotional safety, during a nursing encounter. Intuitive thought allows the nurse to assess the appropriateness of offering care in certain street outreach settings. Once again, nursing intuition is not a factor that can or should be
measured in the new assessment instrument. The instruction portion of the instrument will encourage nurses to incorporate their clinical intuition while assessing their clients for CTC-HC.

Another important contextual factor that the nurses expressed is the advantage of having previous knowledge of the client. Lukers et al. (192) refers to this as “experiential learning.” Having cared for a client on previous occasions provides nurses an opportunity to compare the client’s current status to their status in previous encounters. Many nurses who were interviewed talked about the importance of developing a trusting relationship with their clients by interacting with them even when the provision of care was not needed. This approach provides an important foundation from which the nurse can base future clinical decisions. Incorporating this factor into the new instrument was not possible because it may not be appropriate for all clients under all circumstances. Therefore, this contextual factor was only included in the instructions of the instrument (nurses will be encouraged to use their previous knowledge of the client to assess the other measurable factors in the instrument).

Many public health nurses are consciously aware of the tension between protecting the ethical rights of individuals (thus providing them with the opportunity to provide informed consent for health care), while doing their job to protect the public against communicable diseases. Nurse participants talked about this as an internal tension that sometimes results in nurses trying to persuade clients to accept an intervention (such as a diagnostic test or treatment) that they don’t want. This concept is closely linked to misuse of innate power differentials between nurses and clients. Vulnerability to coercion is common among individuals with addiction issues or who are homeless. This internal tension is at the core of critical social theory. The new instrument incorporates a question that addresses whether the client’s decision was autonomous or was made under the influence of another person (such as the nurse).
3.4.1.2 External Factors

External contextual factors raised by the nurses included safety, timing, location, urgency of care, and decision-making demands. These environmental factors do not contribute to the client’s CTC-HC, but they influence the nurse’s ability to perform a thorough assessment of the client. This may include a nurse-client encounter in an alley where the client is fearful of violent repercussions if their friends, family members or acquaintances (e.g., their pimp or drug dealer) see the client talking to a street nurse. It may also involve safety for the nurse who may be fearful of the client being aggressive, or fearful of those with an aforementioned relationship to the client, being aggressive toward them. Similarly, the amount of time that the client is willing to interact with a nurse significantly limits the number of factors that can be assessed related to CTC-HC. It also limits the possibility of providing the client an opportunity to reflect on the details of a health intervention before agreeing to or refusing consent. Furthermore, the location of the nurse-client encounter is a factor that influences how thoroughly an assessment can be done. For example, if a nurse attempts to engage a client, such as a sex worker, in a health care encounter on the street while the client is ‘working’, she/he may have confidentiality worries (worried that others around them may hear the discussion between the nurse and client) or worries related to losing business. Under these circumstances, the client may be unwilling to speak to the nurse honestly for any length of time. All of these external factors contribute to what I refer to as decision-making demands. As a rule, nurses do not expect clients to understand detailed information about their medical condition or the intervention (i.e. side effects of a medication), but are satisfied with a basic understanding, so the intervention could be given safely. Nurse participants stated that their expectations of their client’s capacity to understand are lower than their expectations of other populations, due to the brevity of most street outreach
encounters. Furthermore, many clients have a low tolerance for accessing and engaging in medical care, and therefore will not engage in a conversation with a street nurse for very long. Although these factors do not directly measure CTC-HC, they do impact on the quality of the assessment and therefore were incorporated into the instrument as a measure.

Urgency of care was a factor that was raised by many nurses and corresponds with legal and professional discourse surrounding the requirement of consent during emergency situations. This highlights the need for nurses to examine the degree to which the urgency of care impacts their decision to assess the patient’s CTC-HC and whether they feel the circumstances allow (by law) for them to intervene without consent.

3.4.1.3 Clients’ Past Experiences

This final set of contextual factors is related to the client’s past experiences with the health care system. Many client participants talked about negative experiences while accessing health care resulting in mistrust in the system. This was especially true for those who did not have a primary care physician. Repeated exposure to negative experiences that include prejudice and discrimination, naturally results in reluctance to access health care services and is laden with distributive justice ethical concerns. Distributive justice refers to the equal distribution of all rights and responsibilities in society, including rights to respectful health care.(12) It also includes fair distribution of health care resources. This distributive injustice phenomenon creates challenges to nurses providing care to this population and requires sensitivity about the best way to approach clients for a health care intervention.(63) Of greater concern, persistent stigmatization from the health care system creates or perpetuates self-stigmatization which Corrigan (193) refers to as the “Why Try” model. Clients who have an awareness of a stereotype
that fits their own lived experience often agree with the notion of the stereotype, begin to blame themselves for their life circumstances, and begin to assume a submissive role acquiescing to role that others perceive them to have. The nurses who were interviewed for this study expressed concerns about clients who exhibit signs of self-stigmatization when clients are too eager to comply with an intervention that the nurse is offering them. With the concepts of stigmatization, assumption of a submissive role, reluctance to access health care, and trust or mistrust of the health care system, the new instrument incorporates a question which addresses the issue of coercion and submissive attitudes.

3.4.2 Non-Contextual Factors: Measures

The remaining concepts that emerged from the qualitative portion of this dissertation, many of which were also identified in the literature, are non-contextual measures. As mentioned above, the concept of ‘understanding’ was a dominant theme that was identified by all nurses and is consistent with the literature. The majority of nurses who were interviewed stated that they often asked the client to repeat back, in their own words, what was said to them, in order to establish if the client understood. A question about this important concept was incorporated into the new instrument. However, care must be taken to ensure that the ability to simply recall is not mistaken for understanding. Baergen (195) highlighted this concern when he cautioned that patients may repeat or paraphrase details about their treatment even though they have little understanding.

Nurses highlighted the fact that their initial assessment generally involves observing the client to determine if there are physical signs indicating that the client has been using a substance. This may involve the client’s posture, the way that they walk, smell of alcohol or
marijuana, and signs of erratic physical movements. While physical indications of substance use, in and of themselves, do not mean the client lacks CTC-HC, they may trigger the nurse to do a further assessment. The first draft of the instrument includes questions related to physical indication of substance use.

Similarly, the current practice for assessing CTC-HC includes determining if the client is able to communicate in a cohesive manner. During an assessment, nurses look for indications of paranoia or hallucinations or other signs of drug-induced or mental illness induced psychosis. A question related to this concept was included in the first draft of the instrument.

A few nurse participants highlighted the topic of ‘ability to cope with adverse effects of an intervention’. On the surface, this does not directly assess the client’s CTC-HC, but is an important consideration when a nurse is deciding if they should provide care. Although a client may agree to an intervention (e.g., an HIV test), the nurse may question whether the client is making a rational decision if there is an indication that harm may occur as a result of the intervention (e.g., if the client suggests that they will kill themselves if an HIV test comes back positive). Once again, although this concept does not directly measure CTC-HC it is indirectly related and therefore a question was included in the instrument related it.

Memory was another topic that was raised by many of the nurse participants. It is not incorporated into any of the existing instruments and is only included in the consent legislation in the United Kingdom. Nurses expressed a concern about clients who were deemed to be capable of consenting for an intervention (i.e. flu vaccine), but then requested it again the following day because they didn’t remember receiving it the day before. The medical repercussions of this are of concern and the risk of this happening should be minimized.
Therefore, a question related to a client’s short term memory was incorporated into the first draft of the instrument.

Nurses emphasized the fact that clients who are withdrawing from substances are as likely to lack CTC-HC as those who are experiencing the effects of a substance. This is mainly due to a lack of concentration as a result of severe symptoms of withdrawal (nausea, diarrhea, diaphoresis, pain), which often leads to a preoccupation with drug seeking. These individuals likely have the ability to make a decision but are unlikely able to focus on a conversation with the nurse. This concept is related to ‘decision-making demands’ described above and has been incorporated as a question in the first draft of the new instrument.

3.4.3 Threshold

Threshold is described as the minimum level of capacity that is required in order to deem the client capable of consenting. The majority of nurses who were interviewed were unsure about how to ascertain this threshold in their own practice and expressed an interest in having an instrument that could assist with determining a threshold if they were unsure. The purpose of the instrument is to provide an overall score with a cut-off value that suggests whether the client has the capacity to consent for care or not. However, the nurses explained that every situation is different, and therefore the idea of having a number to indicate capacity under all circumstances may be impractical. The issue raised by the nurse participants related to the complexity of assessing clients at different levels of capacity versus different levels of risk, is consistent with comments made by Dunn in his systematic review of capacity to consent instruments. (86) He states, “it is fundamental to the notion of capacity that different contexts may demand different kinds or levels of functional abilities.”(page1323) Therefore, a comment was made in the
instructions portion of the new instrument that encourages nurses to weigh the level of risk with the level of capacity. This is especially important when the nurse may not have enough time to do a full assessment.

### 3.5 Summary and Conclusions

The results of this qualitative study have revealed the important considerations that should be included in a new instrument aimed at assessing CTC-HC IMSH. The major themes include: abilities that can be measured (ability to communicate, memory, ability to cope with adverse effects of an intervention, physical indication of substance use, understanding, and withdrawal); contextual themes such as external influences (safety, timing, location, and urgency of care); internal influences (previous knowledge of client, intuition, knowledge of ethical and legal principles, experience as nurse, professional knowledge, innate power differential, and risk to public health); and clients’ past experiences (reluctance to access health care, assumption of submissive role, stigmatization, and trust/mistrust). All of these factors that come into play while assessing capacity consent should be considered while weighing the level of risk versus level of capacity. The factors that have been raised by the participants of the qualitative portion of this study were combined with the factors that were highlighted in the literature. The following figure shows where the factors from the qualitative study and the factors from the literature were combined.
Figure 5: Factors from the qualitative study and from the literature

<table>
<thead>
<tr>
<th>Concepts from Literature</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Understanding</td>
</tr>
<tr>
<td>- Autonomy</td>
</tr>
<tr>
<td>- Reasoning</td>
</tr>
<tr>
<td>- Appreciation</td>
</tr>
<tr>
<td>- Assumption of capacity</td>
</tr>
<tr>
<td>- Informed</td>
</tr>
<tr>
<td>- Beneficence</td>
</tr>
<tr>
<td>- Non-maleficence</td>
</tr>
<tr>
<td>- Justice</td>
</tr>
<tr>
<td>- Avoidance of misuse of power</td>
</tr>
<tr>
<td>- Opportunities for reflection</td>
</tr>
<tr>
<td>- Voluntariness</td>
</tr>
<tr>
<td>- Concentration</td>
</tr>
<tr>
<td>- Conceptual disorganization</td>
</tr>
</tbody>
</table>

- Previous knowledge of client
- Intuition
- Knowledge of ethical and legal principles
- Experience as nurse
- Professional knowledge
- Risk to public health
- Reluctance to access healthcare
- Assumes submissive role
- Stigmatization
- Trust or distrust
- Safety
- Timing
- Location
- Urgency of care
- Decision Making: Assessment of Capacity to Consent
- Context: Client’s past experiences
- Threshold: Levels of risk versus levels of capacity
- Internal Influences
- External Influences
- Measures: Ability to communicate
  - Memory
  - Physical indication of substance use
  - Which substances are being used and withdrawal
  - Understanding
  - Orientation to person, place, and time
  - Signs of mental illness
The following table displays the concepts that were incorporated into the instructions of the new instrument and those that were incorporated into the instrument itself.

### Table 5: Concepts that were incorporated in the instruction to clinicians and the new instrument

<table>
<thead>
<tr>
<th>Concepts used in the instructions to clinicians</th>
<th>Concepts incorporated into the instrument</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 Assumption of capacity</td>
<td>2.1 Understanding</td>
</tr>
<tr>
<td>1.2 Informed</td>
<td>2.2 Voluntariness</td>
</tr>
<tr>
<td>1.3 Beneficence</td>
<td>2.3 Concentration/Sustained attention</td>
</tr>
<tr>
<td>1.4 Nonmaleficence</td>
<td>2.4 Memory impairment/Recall</td>
</tr>
<tr>
<td>1.5 Justice</td>
<td>2.5 Orientation</td>
</tr>
<tr>
<td>1.6 Respect for autonomy</td>
<td>2.6 Verbal abilities</td>
</tr>
<tr>
<td>1.7 Avoidance of misuse of inherent power differentials</td>
<td>2.7 Conceptual disorganization</td>
</tr>
<tr>
<td>1.8 Opportunities for reflection</td>
<td>2.8 Presence of hallucinations, panic, unusual euphoria</td>
</tr>
<tr>
<td>1.9 Level of risk versus level of capacity</td>
<td>2.9 Appreciation of the nature of the situation</td>
</tr>
<tr>
<td>1.10 Who initiated the clinical encounter?</td>
<td>2.10 Using the information in reasoning</td>
</tr>
<tr>
<td>1.11 Threshold setting</td>
<td>2.11 Expression of choice</td>
</tr>
<tr>
<td>1.12 Previous knowledge of client</td>
<td>2.12 Decision-making demands</td>
</tr>
<tr>
<td></td>
<td>2.13 Client's ability to cope</td>
</tr>
<tr>
<td></td>
<td>2.14 Physical indication of substance use</td>
</tr>
</tbody>
</table>

Overall, the qualitative portion of this study has identified new concepts that have not been identified in the literature. Most importantly, the new instrument incorporates contextual factors that have been lacking in other capacity to consent instruments.
4 INSTRUMENT DEVELOPMENT STAGE

4.1 Introduction

Chapters two and three described the process of identifying concepts that could be included in an instrument to assess CTC-HC IMSH. This chapter will describe the process of evaluating each item to determine if they should be included in the instrument and the process of synthesizing the identified concepts into a single instrument. I will also describe the process used to determining construct and content validity.

Steiner and Norman provide six sources that can be used to contribute to concept and item development. These sources include: focus groups, key informant interviews, clinical observation, theory, research, and expert opinion. Among the sources that Steiner and Norman identified, my work focused on key informant interviews, theory and concepts from existing instruments, research and expert opinion.

4.1.1 Use of Validated Question From Existing Instruments.

Most psychometricians suggest using items that have been previously validated (deemed psychometrically sound) by others. A review of the literature and the existing instruments confirmed that no instruments, to our knowledge, have been previously developed that address the unique needs of nurses who deliver care to individuals who may or may not be impaired by substances at the time of a clinical encounter. This supports the need for a new validated instrument with good psychometric properties that can be administered to this population.

While developing my new instrument, concepts that were relevant, important or discriminating were gleaned from previous instruments, but the exact wording of validated questions were not used, as existing questions do not adequately address issues specific to
individuals who misuse substances. Most importantly, existing validated questions are inappropriate for use in street outreach settings where clinical encounters are brief.

4.1.2 Instrument Objectives

After reviewing the concepts that were identified from the literature and considering the concepts that emerged from the qualitative study, the following instrument objectives were created to guide the development of the new test items:

a) To identify individuals who lack understanding of the health intervention being offered;
b) To identify individuals who do not demonstrate autonomy (decision making without coercion or undue pressure);
c) To identify individuals who do not demonstrate rational decision making;
d) To identify individuals who do not demonstrate an appreciation of the fact that the health intervention applies to them (the client);
e) To identify individuals who do not demonstrate an ability to express a choice;
f) To identify individuals who do not demonstrate an ability to recall information provided (memory);
g) To identify individuals who do not demonstrate an ability to concentrate on the health care interaction;
h) To identify individuals who do not demonstrate being orientated to person, place and time;
i) To identify individuals who do not demonstrate conceptual organization that may interfere with understanding of the health care intervention; and
j) To identify individuals who demonstrate distorted reality.
4.1.3 **Table of Test Specifications**

A table of test specifications (below) was created to use as a blueprint to inform the item writing process. The rows represent the content that is to be evaluated in the new instrument and the columns represent the instrument objectives. The X’s indicate the instrument content for each of the objectives.
### Table 6: Table of specifications

<table>
<thead>
<tr>
<th>Content</th>
<th>Knowledge</th>
<th>Understanding</th>
<th>Appreciation</th>
<th>Reasoning</th>
<th>Expression of Choice</th>
<th>Cognitive Functioning</th>
<th>External Influences</th>
<th>Autonomy</th>
<th>Distorted Reality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease or condition of concern</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risks and benefits of health care intervention</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risks and benefits of not intervening</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alternative treatments</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expression of consent or refusal</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consent or refusal without coercion</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Credibility of content provided</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Orientation to person, place and time</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Distraction from external influences</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Memory and recall</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Concentration on topic at hand</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Presence of hallucinations, delusions, paranoia</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>
4.1.4 Item Writing

The following concepts were used as a basis for writing instrument items. We employed a criterion-reference approach to developing the instrument. Linn and Gronlund (196) define criterion-referenced assessment as “a test or other type of assessment designed to provide a measure of performance that is interpretable in terms of a clearly defined and delimited domain of learning tasks.”(page 42). They go on to clarify that criterion-referenced assessments do not attempt to differentiate abilities or traits against other individuals. Definitions for the concepts chosen for the new instrument (listed below) can be found in Appendix E.

- Understanding
- Reasoning
- Appreciation
- Expression of choice
- Memory
- Attention
- Orientation
- Executive functioning
- Voluntariness
- Concentration/
  Sustained attention
- Verbal abilities
- Conceptual disorganization
- Presence of hallucinations, panic,
  unusual euphoria
- Decision-making demands
- Client's ability to cope
- Physical indication of substance use
- Communication

Many instruments are formatted so the client answers the questions included in the instrument. In my new instrument, the questions were formatted so nurses answer the questions. Although the questions are standardized, they allowed for the clinician to incorporate the questions into a standard clinical encounter and allows for a subjective assessment. Questions were constructed in such a way that higher scores are an indication of higher levels of CTC-HC.
The initial set of items was written as questions with categorical response options that intentionally omitted a neutral option. The reason for leaving out a neutral option was to force the clinician to make a negative or positive judgment. The number of response options varied throughout the instrument. Care was taken to avoid ambiguous and/or ‘double-barreled’ questions, as well as questions that included value-laden words. Experts in the field (e.g., street outreach nurses, clinicians) were consulted to provide input into the structure of the initial set of questions, thus evaluating construct validity. A meeting with these experts was convened during which the concepts (from the literature and qualitative study) were discussed. These experts were also given a list of relevant questions from existing instruments. During this meeting, consensus on the wording for each item was achieved. The following table displays the first iteration of potential questions, the level of capacity each question measures, the first iteration of response options, and comments about interpreting the scores.
Table 7: First iteration of items

<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>Level of Capacity Measured</th>
<th>Score</th>
<th>Response Options</th>
<th>Scoring Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Can the client repeat back the side effects of the intervention you want to give to them?</td>
<td></td>
<td>X</td>
<td>1-4</td>
<td>1 = Very unable to repeat side effects 2= Unable to repeat side effects 3 = Able to repeat side effects 4= Very able to repeat side effects</td>
</tr>
<tr>
<td>2</td>
<td>Did the client make their decision about a medical intervention without external influence such as persuasion or coercion?</td>
<td></td>
<td></td>
<td>1 or 2</td>
<td>1= no ;  2= yes</td>
</tr>
<tr>
<td>3</td>
<td>Show the client the following 4 digit number: 8304 Take the number away and ask them to repeat the number. Did the client recall all of the digits correctly?</td>
<td></td>
<td>X</td>
<td>0 – 4</td>
<td>0 = no digits correct 1 = 1 digit correct 2 = 2 digits correct 3 = 3 digits correct 4 = 4 digits correct</td>
</tr>
<tr>
<td>4</td>
<td>Is the client orientated to person, place and time (i.e. do they know who they are, where they are and what year it is?)</td>
<td></td>
<td>X</td>
<td>1-4</td>
<td>1 = Very disorientated 2 = Disorientated 3 = Orientated 4 = Very orientated</td>
</tr>
<tr>
<td>5</td>
<td>Is the client able to engage in a conversation that is cohesive?</td>
<td></td>
<td>X</td>
<td>1-4</td>
<td>1 = Very unable 2 = Unable 3 = Able 4 = Very Able</td>
</tr>
<tr>
<td>6</td>
<td>Is the client able to follow instructions?</td>
<td></td>
<td>X</td>
<td>1-4</td>
<td>1 = Very unable 2= Unable 3 = Able 4 = Very Able</td>
</tr>
<tr>
<td>7</td>
<td>Is the client experiencing hallucinations, panic or unusual euphoria?</td>
<td></td>
<td></td>
<td>1 or 2</td>
<td>1= no ;  2= yes</td>
</tr>
<tr>
<td>Question</td>
<td>Level of Capacity Measured</td>
<td>Score Options</td>
<td>Scoring Comment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>----------------------------</td>
<td>---------------</td>
<td>---------------------------------------------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ask the client if they think you are trying to hurt or harm them. Did the client demonstrate paranoia by saying yes?</td>
<td>X</td>
<td>1 or 2</td>
<td>1= no ;  2= yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the client know that he/she is either at risk of an illness or has an illness and therefore requires clinical care?</td>
<td></td>
<td>1 or 2</td>
<td>No = low capacity; Yes=high capacity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the client able to give a rational reason for consenting or refusing care?</td>
<td></td>
<td>1-4</td>
<td>1 = Very unable 2 = Unable 3 = Able 4 = Very Able</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the client able to verbally or physically indicate a choice?</td>
<td></td>
<td>1 or 2</td>
<td>1= no ;  2= yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>While offering care to a client, does the client seem</td>
<td></td>
<td>0 or 1</td>
<td>No = low capacity; Yes=high capacity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) distracted by friends around him/her?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) rushed to get back to another activity?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) dope sick?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the client capable of coping with a side effect of an unexpected test result?</td>
<td></td>
<td>1-4</td>
<td>1= low capacity; 4 = high capacity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are there any physical indications that the client may have recently used drugs or alcohol?</td>
<td></td>
<td>1 or 2</td>
<td>1= no ;  2= yes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4.2 Panel of Experts

In order to establish content and face validity, a panel of experts was convened that consisted of an ethicist, a physician with experience delivering care to our target population, two street outreach nurses, a psychologist with experience delivering care to individuals with mental illness and homelessness, two lawyers, and a psychiatrist. Face validity is an indication of whether, on the surface, the instrument is measuring the desired construct (CTC-HC). Face validity is a subjective judgment based on the opinion of experts with content expertise. Content validity is an assessment of whether the instrument covers all the relevant and important elements related to the construct. It also ensures that the instrument has enough items and adequately covers the construct under investigation.

Prior to reviewing the draft instrument, the panel of experts was given a full description of CTC-HC. This included its theoretical definition, its defining characteristics, and the characteristics that distinguish it from other constructs. They were also given a description of the meaning of each concept that items were intended to cover. To conduct a content validity assessment, experts were asked to make two kinds of judgments. They were asked to rate: a) how important each concept was in terms of assessing CTC-HC and b) how well each item addressed the given concept. There was also a space for the experts to provide any comments or suggestions about the wording of the question or anything else they deemed important. A copy of the Expert Panel Review form can be found in Appendix F.
4.2.1 Phase One:

During Phase 1, the panel of experts was provided with an electronic copy of the Expert Panel Review form which included instructions for completing the form. They were asked to complete the form and return it within 2 weeks. Once all of the forms were returned, descriptive analysis (frequency, mean and range scores) was performed.

Summary of Comments for Experts:

Overall, all experts stated that they found the instrument acceptable and they provided useful comments and suggestion. Below is a table that displays the mean scores for the question of ‘How important the concept is to measuring CTC-HC’ (scale of 1-5; 1 being very unimportant and 5 being very important).

Table 8: The mean scores for the question ‘How important is the concept to measuring capacity to consent?’

<table>
<thead>
<tr>
<th>Item #</th>
<th>Concept</th>
<th>Mean score (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Understanding</td>
<td>4.38 (4 – 5)</td>
</tr>
<tr>
<td>2</td>
<td>Voluntariness</td>
<td>4.75 (4 – 5)</td>
</tr>
<tr>
<td>3</td>
<td>Concentration/Sustained attention and memory</td>
<td>3.25 (1 – 5)</td>
</tr>
<tr>
<td>4</td>
<td>Orientation</td>
<td>4.38 (3 – 5)</td>
</tr>
<tr>
<td>5</td>
<td>Verbal abilities and conceptual disorganization</td>
<td>4.00 (3 – 5)</td>
</tr>
<tr>
<td>6</td>
<td>Conceptual Disorganization</td>
<td>4.14 (2 – 5)</td>
</tr>
<tr>
<td>7-8</td>
<td>Presence of hallucinations, panic, unusual euphoria</td>
<td>4.19 (3 – 5)</td>
</tr>
<tr>
<td>9</td>
<td>Appreciation of the nature of the situation</td>
<td>4.38 (3 – 5)</td>
</tr>
<tr>
<td>10</td>
<td>Using the information provided in reasoning</td>
<td>4.50 (3 – 5)</td>
</tr>
<tr>
<td>11</td>
<td>Expression of Choice</td>
<td>4.38 (3 – 5)</td>
</tr>
<tr>
<td>12-14</td>
<td>Decision-making demands</td>
<td>3.46 (2 - 4)</td>
</tr>
<tr>
<td>15</td>
<td>Client’s Ability to Cope</td>
<td>4.38 (3 – 5)</td>
</tr>
<tr>
<td>16</td>
<td>Physical indication of Substance Use</td>
<td>3.67 (3 – 4)</td>
</tr>
</tbody>
</table>

There may have been some misunderstanding about how the individual items were to be used in the instrument during Phase 1. There were several comments about individual items being important in assessing CTC-HC, but not sufficient. In other words, there were concerns that single items did not, in and of themselves, assess all
aspects of capacity. In practice, each item in the instrument covers different aspects of measuring capacity. No single element is meant to measure CTC-HC completely; however, when added to other items, capacity can be measured fully.

In addition, I intentionally included some items in the instrument that are indirectly associated with the concept of CTC-HC (items 12 thru 16). As these items are not directly associated with measuring capacity, the item-response congruency is quite low. Although this was explained in the concept definitions, the experts remained uncertain. The following table shows item-response congruency for the first phase of expert review:

Table 9: Item-response congruency for the first phase of expert review

<table>
<thead>
<tr>
<th>Item</th>
<th>Congruency Index (congruent with Capacity to Consent)</th>
<th>Recommended Congruency (n-1)/n</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The client is able to repeat back the side effects of the intervention that is being offered to them.</td>
<td>0.75</td>
</tr>
<tr>
<td>2</td>
<td>The client made their decision about the medical intervention without external pressure or coercion.</td>
<td>0.88</td>
</tr>
<tr>
<td>3</td>
<td>Show the client the following 4 digit number.</td>
<td>0.38</td>
</tr>
<tr>
<td>4</td>
<td>The client is oriented to person, place, and time.</td>
<td>0.88</td>
</tr>
<tr>
<td>5</td>
<td>The client can engage in a conversation that is cohesive.</td>
<td>0.71</td>
</tr>
<tr>
<td>6</td>
<td>The client is able to follow instructions.</td>
<td>0.71</td>
</tr>
<tr>
<td>7</td>
<td>The client is experiencing hallucinations, panic or unusual euphoria.</td>
<td>0.50</td>
</tr>
<tr>
<td>8</td>
<td>The client is demonstrating paranoia with the belief that you are trying to hurt or harm them despite clear explanation of the intervention proposed.</td>
<td>0.63</td>
</tr>
<tr>
<td>9</td>
<td>The client knows that he/she is either at risk of an illness or has an illness and therefore requires clinical care.</td>
<td>0.63</td>
</tr>
<tr>
<td>10</td>
<td>The client is able to give a rationale for consenting or refusing care.</td>
<td>0.71</td>
</tr>
<tr>
<td>Item</td>
<td>Congruency Index (congruent with Capacity to Consent)</td>
<td>Recommended Congruency (n-1)/n</td>
</tr>
<tr>
<td>------</td>
<td>---------------------------------------------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>11</td>
<td>The client is able to verbally or physically indicate a choice.</td>
<td>0.75</td>
</tr>
<tr>
<td>12</td>
<td>While offering care to a client he/she seemed to be distracted by friends around him/her.</td>
<td>0.63</td>
</tr>
<tr>
<td>13</td>
<td>While offering care to a client he/she seemed to be rushed to get back to another activity.</td>
<td>0.50</td>
</tr>
<tr>
<td>14</td>
<td>While offering care to a client he/she seemed to be dope sick.</td>
<td>0.57</td>
</tr>
<tr>
<td>15</td>
<td>The client is able to cope with an adverse effect of the intervention (i.e. an unexpected test result).</td>
<td>0.50</td>
</tr>
<tr>
<td>16</td>
<td>There are physical indications that the client may have recently used drugs or alcohol.</td>
<td>0.43</td>
</tr>
</tbody>
</table>

The following section describes the expert comments for each item in Phase 1:

**Item 1**: The client is able to repeat back the side effects of the intervention that is being offered to them.

Summary of Importance: 3/8 experts said the item was extremely important and 5/8 stated it was somewhat important

Comments: 4/6 experts stated that the ability to simply repeat back information was not indicative of understanding. A suggestion was made to ask the client to repeat back information given to them using their own words. It was also suggested that not all side effects need to be repeated back, but at least the main side effects should be. Finally, it was suggested that this item should not only include being able to repeat back the side effects, but also other risks (i.e. potential complications) associated with the intervention.
**Item 2:** The client made their decision about the medical intervention without external pressure or coercion.

Summary of Importance: 6/8 experts stated this concept was extremely important and 2/8 said it was somewhat important.

Comments: One person suggested adding an explanation to the item about what is meant by pressure or coercion. One expert asked if this concept refers to negative consequences as a result of refusing. Another expert suggested asking them directly if they are agreeing to the intervention because they want to or because someone told them they should. One expert suggested adding the word “extraordinary”, as many clients need a little coercion.

**Item 3:** Show the client the following 4 digit number.

Summary of Importance: 1/8 experts stated this concept was extremely important, 3/8 said it was somewhat important, 2/8 said they were neutral about whether it was important or not, 1/8 said it was unimportant, and 1 said it was very unimportant.

Comments: Three experts stated that this concept is likely covered with item #1. One expert suggested removing the item all together. Another client expressed concern that the client may suffer from dyslexia. Another expert suggested using a string of words may be better than numbers.

**Item 4:** The client is oriented to person, place, and time.

Summary of Importance: 4/8 experts stated this concept was extremely important, 3/8 said it was somewhat important and 1/8 said they were neutral about whether it was important or not.
Comments: One expert suggested that someone may be disorientated and still be able to provide consent, depending on how well they can process information.

**Item 5:** The client can engage in a conversation that is cohesive.

Summary of Importance: 2/8 experts stated this concept was extremely important, 4/8 said it was somewhat important and 2/8 said they were neutral about whether it was important or not.

Comments: The word ‘cohesive’ was problematic for several experts. They suggested using ‘coherent’ or ‘engage in a conversation that makes sense’. One expert said that some people may not speak in a manner that makes sense, but they understand what they are consenting to. Another expert said that this may be measuring poor verbal ability rather than organized thought (in some cases).

**Item 6:** The client is able to follow instructions.

Summary of Importance: 3/7 experts stated this concept was extremely important, 3/7 said it was somewhat important and 1/7 said this concept is somewhat unimportant. (1 expert left this blank).

Comments: Two experts suggested that the statement is too vague. A suggestion was made to say, ‘follow written or verbal instructions’. One expert suggested adding the word “simple” (simple written or verbal instructions). One expert felt it was important to know how many steps the client would have to follow in order to get a high score.

Another expert suggested using the following words: ‘the client can understand steps
they need to take for their treatment.’ Another person suggested that this item would also
measure understanding. Another person would like this context specific.

**Item 7:** The client is experiencing hallucinations, panic or unusual euphoria.

Summary of Importance: 4/8 experts stated this concept was extremely important, 1/8 said it was somewhat important and 3/8 said they were neutral about whether it was important or not.

Comments: One expert stated that panic doesn’t disable someone from making a sound decision. Three other experts stated that many people can make rational decisions even though they are hallucinating; one of these experts suggested removing this item for that reason. It was decided that if hallucination, panic or euphoria were present, it may be a sign that capacity may be affected and other items should be used to confirm this.

**Item 8:** The client is demonstrating paranoia with the belief that the nurse is trying to hurt or harm them despite clear explanation of the intervention proposed.

Summary of Importance: 2/6 experts stated this concept was extremely important, 3/6 said it was somewhat important and 1/6 said they were neutral about whether it was important or not.

Comments: One expert commented that paranoia may not be directed at the researcher. Another expert suggested rewording the item as follows: “Presence of debilitating psychiatric dysfunction.” Another expert stated that if signs of paranoia were evident then not to proceed with the intervention as it might result in harm. Another expert wondered if item #7 and #8 could be one question instead of two.
Item 9: The client knows that he/she is either at risk of an illness or has an illness and therefore requires clinical care.

Summary of Importance: 4/8 experts stated this concept was extremely important, 3/8 said it was somewhat important and 1/8 said they were neutral about whether it was important or not.

Comments: There were concerns about how the nurse is supposed to measure this. One expert stated this would not apply to everyone because many people are tested for an STI or HIV who are not at risk. Another expert stated, ‘One may be aware of an illness and the need for treatment but still not feel comfortable with the type of treatment offered. This distinction needs to be clear.’

Item 10: The client is able to give a rationale for consenting or refusing care.

Summary of Importance: 5/8 experts stated this concept was extremely important, 2/8 said it was somewhat important and 1/8 said they were neutral about whether it was important or not.

Comments: The word ‘rationale’ was problematic for several experts. One person suggested using the word ‘logical’ instead. One expert suggested adding the word “simple” (simple rationale). It was also noted that the ability to express a rationale is dependent of their education level and sophistication. Another expert stated that some people may have an irrational reason for refusing (fear of needles) and wondered if this type of irrational thought contributes to a negative capacity score. Another person stated
that clients use their intuition to make a decision rather than rational thought, and asked if this should be acceptable.

Item 11: The client is able to verbally or physically indicate a choice.

Summary of Importance: 5/8 experts stated this concept was extremely important, 1/8 said it was somewhat important, and 2/8 said they were neutral about whether it was important or not.

Comments: Some experts asked for suggestions about what a physical indication of consent would be (nodding, holding your arm out). Others talked about the difference between expressing a choice and expressing a choice that truly reflects their autonomy. One expert suggested that assessing a physical indication of choice requires too much interpretation.

Item 12: While offering care to a client, he/she seemed to be distracted by friends around him/her.

Summary of Importance: 0/8 experts stated this concept was extremely important, 6/8 said it was somewhat important and 2/8 said this concept was somewhat unimportant.

Comments: One expert suggested giving examples of what ‘distracted’ means. Two experts suggested that people can make an informed decision even though they may be distracted. One expert didn’t see the relevance of this item because the clinician can always ask for privacy.
Item 13: While offering care to a client, he/she seemed to be rushed to get back to another activity.

Summary of Importance: 0/8 experts stated this concept was extremely important, 5/8 said it was somewhat important, 2/8 said they were neutral about whether it was important or not, and 1/8 said the concept was somewhat unimportant.

Comments: Most experts thought that people who are rushed can be perfectly capable of making a sound decision. I explained to the experts that this question doesn’t measure capacity directly. It measures the likelihood that the client answered honestly and accurately, as well as the nurse’s ability to make an assessment if the client seems rushed. One expert suggested combining items 12 and 13. One expert suggested that if the client doesn’t participate, they don’t appreciate the gravity of a capacity interview.

Item 14: While offering care to a client, he/she seemed to be dope sick.

Summary of Importance: 0/8 experts stated this concept was extremely important, 5/8 said it was somewhat important, 1/8 said they were neutral about whether it was important or not, and 2/8 experts said it was somewhat unimportant.

Comments: One expert suggested using the word ‘withdrawal’ rather that dope sick. Other pointed out that dope sick from opioid withdrawal is very different from stimulant withdrawal. One expert suggested that just because someone is dope sick, doesn’t mean they can’t provide informed consent. One expert suggested wording the statement as ‘the person's dope-sickness impedes their ability to understand and make an informed decision." One expert suggested that the item was not relevant.
**Item 15**: The client is able to cope with an adverse effect of the intervention (i.e. an unexpected test result).

Summary of Importance: 4/8 experts stated this concept was extremely important, 3/8 said it was somewhat important and 1/8 said they were neutral about whether it was important or not.

Comments: One expert stated that this item is really important, while two others stated it doesn’t measure capacity. Two experts were unsure how the nurse can measure this in a standardized way. One expert suggested that the item was not relevant.

**Item 16**: There are physical indications that the client may have recently used drugs or alcohol.

Summary of Importance: 0/6 experts stated this concept was extremely important, 4/6 said it was somewhat important and 2/5 said they were neutral about whether it was important or not. Two experts did not provide a response.

Comments: One expert suggested that the wording of the item was too vague. One expert suggested the following wording, “There are physical indications that the client is intoxicated.” There were similar concerns about the fact that someone may have physical indications of substance use but still be able to consent.

**Summary of comments**: The form that was created for the panel of experts was not clear in a few areas. Firstly, the experts did not understand that no single item was meant to measure capacity on its own. Each item was meant to be only ‘one piece of the puzzle’. Greater explanation was required. Secondly, clarification was needed regarding the items
that measure capacity directly and those that measure it indirectly. Items that measure capacity indirectly include items that interfere with the nurse’s ability to make a complete assessment; the client may not give the nurse very much time or may not want to answer the nurse honestly because their friends are nearby. Items that address the concept of decision-making demands, indirectly impact the nurse’s ability to assess the client and therefore are indirectly related to measuring CTC-HC. Further explanation to the experts related that this was required. There was a request for several experts to provide examples that may be helpful in clarifying what the item means. Numerous suggestions for wording of items were helpful and incorporated into the next version of the instrument.

After reviewing the comments from the experts from Phase 1 of the consultation, the wording for many items was changed. The following table describes the wording before and after the Phase 1 consultation:

**Table 10: Changes in wording of items before and after Phase 1 of the expert panel consultation**

<table>
<thead>
<tr>
<th>Item Number</th>
<th>Before Phase One Consultation</th>
<th>After Phase One Consultation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The client is able to repeat back the side effects of the intervention that is being offered to them</td>
<td>The client is able to repeat back, <strong>in their own words the main side effects/potential complications</strong> of the intervention that is being offered to them.</td>
</tr>
<tr>
<td>2</td>
<td>The client made their decision about the medical intervention without external pressure or coercion</td>
<td>The client made their decision about the medical intervention without external pressure or coercion. (i.e. the client is not giving an answer that they feel the clinician wants to hear)</td>
</tr>
</tbody>
</table>
| 3           | Show the client the following 4 digit number :  

8304

Take the number away and ask them to repeat the number. How many digits did the client recall correctly? | Experts suggested removing this item                                                             |
<table>
<thead>
<tr>
<th>Item Number</th>
<th>Before Phase One Consultation</th>
<th>After Phase One Consultation</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>The client is orientated to person, place and time.</td>
<td>The client is oriented to person, place, and time (i.e. do they know who they are, where they are and what year it is?)</td>
</tr>
<tr>
<td>5</td>
<td>The client can engage in a conversation that is cohesive.</td>
<td>The client can engage in a conversation that makes sense (excluding physically inability to speak or language issue).</td>
</tr>
<tr>
<td>6</td>
<td>The client is able to follow instructions.</td>
<td>The client is able to follow simple verbal or written instructions (i.e. follow at least one instruction).</td>
</tr>
<tr>
<td>7</td>
<td>The client is experiencing hallucinations, panic or unusual euphoria.</td>
<td>The client is experiencing hallucinations, phobia or unusual euphoria.</td>
</tr>
<tr>
<td>8</td>
<td>The client is demonstrating paranoia with the belief that you are trying to hurt or harm them despite clear explanation of the intervention proposed.</td>
<td>The client is demonstrating paranoia with the belief that you are trying to hurt or harm them, despite clear explanation of the intervention proposed.</td>
</tr>
<tr>
<td>9</td>
<td>The client knows that he/she is either at risk of an illness or has an illness and therefore requires clinical care.</td>
<td>The client knows that he/she is either at risk of an illness or has an illness and therefore requires clinical care.</td>
</tr>
<tr>
<td>10</td>
<td>The client is able to give a rationale for consenting or refusing care.</td>
<td>The client is able to give a logical reason for consenting or refusing care (appropriate level of logic for their education level).</td>
</tr>
<tr>
<td>11</td>
<td>The client is able to verbally or physically indicate a choice.</td>
<td>The client is able to verbally or physically (e.g., nodding yes or holding their arm out for a blood test) indicate a choice.</td>
</tr>
<tr>
<td>12</td>
<td>While offering care to a client, he/she seemed to be distracted by friends around him/her.</td>
<td>While offering care to a client, he/she seemed to be distracted by friends around him/her (e.g., watching for their friends).</td>
</tr>
<tr>
<td>13</td>
<td>While offering care to a client, he/she seemed to be rushed to get back to another activity.</td>
<td>While offering care to a client, he/she seemed to be rushed to get back to another activity.</td>
</tr>
<tr>
<td>14</td>
<td>While offering care to a client he/she seemed to be dope sick</td>
<td>While offering care to a client he/she seemed to be dope sick or experiencing symptoms of withdrawal.</td>
</tr>
<tr>
<td>15</td>
<td>The client is able to cope with an adverse effect of the intervention (i.e. an unexpected test result).</td>
<td>The client is able to cope with an adverse effect of the intervention (e.g., an unexpected test result).</td>
</tr>
<tr>
<td>16</td>
<td>There are physical indications that the client may have recently used drugs or alcohol.</td>
<td>There are physical indications that the client may have recently used drugs or alcohol (e.g., tweaking, nodding head, slurred speech, gyrating).</td>
</tr>
</tbody>
</table>

4.2.2 Phase Two:

After reviewing the item-objective congruency index and the comments suggested by the experts, it was decided to have a second phase of expert review. Five out of the original eight experts (a nurse, a lawyer, a psychiatrist, a psychologist, and an ethicist...
who is also a physician) agreed to participate in this phase. To improve understanding surrounding the meaning of the concepts and the intent behind each item, it was decided to conduct the second phase through teleconference. In Phase 1, the experts completed the form and emailed it in and therefore did not interact with one another. However, when experts meet in person, or via teleconference, power imbalances can occur, especially between different professional groups such as doctors and nurses. In order to prevent difficulties with power differentials between experts, they were asked not to provide their name during the teleconference. At the beginning of the teleconference, I provided a summary of some of the problems that were detected in the last phase (e.g., each item not being sufficient by itself to measure capacity, items that measure capacity directly or indirectly). Then, during the teleconference, the experts were given a link to an on-line survey. The survey was essentially the same as the paper version provided in Phase 1 of the expert review process (Appendix F), except that it asked how well the item addressed the construct of CTC-HC and how well the item addressed the concept identified specifically for that item. After a group discussion, each expert was asked to provide the following information for each item:

1) How important is the concept (i.e. of understanding for item 1) to assessing capacity to consent? Response options: extremely important, important, neutral, unimportant, extremely unimportant;

2) How well does this item match the objective of measuring CTC-HC (directly or indirectly)? Response options: poor match, moderate or uncertain match, strong match; and
3) How well does this item match the objective of measure the concept (i.e. understanding for item 1)? Response options: poor match, moderate or uncertain match, strong match).

**Summary of comments for Phase Two**

Item 1: All experts were satisfied with Item one and did not have any wording suggestions.

Item 2: All experts were satisfied with Item two and did not have any wording suggestions.

Item 3: All experts agreed that Item 3 was not practical in an outreach clinical setting, so this item was removed.

Item 4: All experts were satisfied with Item four and did not have any wording suggestions.

Item 5: For Item five, the experts wanted to have an option of considering whether the client could engage in written communication and not just verbal communication. One expert suggested that there may be several ways that a client could communicate (speech, signing, writing). Therefore, the wording has been changed to “The client can engage in the form of communication that they normally use (e.g., speech, signing writing).” They also suggested using the language, “excluding a physical difficulty in speaking or use of foreign language not understood by nurse.”
Item 6: Four experts felt that Item 6 did not measure conceptual disorganization and suggested removing it. However, one expert suggested changing the concept name to “understanding” and “sustained attention”, rather than removing the item. Therefore, the item was retained.

Items 7 & 8: The experts suggested combining Items 7 and 8 (since they seem to measure the same things), with the following language: “The client is experiencing symptoms of distorted reality (i.e. hallucinations, delusions, paranoia).” Therefore, the name of the concept was changed to better reflect the content (e.g., ‘distorted reality’).

Item 9: All experts liked Item 9 and did not have any wording suggestions.

Item 10: After I explained to the experts the intention surrounding Item 10 (that the legal concept is ‘reasoning’, which means that the client uses information that the nurse has given him/her to make their decision), they agreed that the item should remain in.

Item 11: All experts liked Item 11 and did not have any wording suggestions.

Items 12 – 14: The experts felt that Items 12 -14 were too much alike and should be combined into one item: “While offering care to a client, he/she seemed to be distracted by friends, other activities, and/or symptoms of withdrawal.”

Item 15: All experts agreed that Item 15 was an important clinical consideration, but did not measure CTC-HC either directly or indirectly. They suggested this item be removed. Therefore, it was removed

Item 16: All experts liked Item 16 and did not have any wording suggestions.
The following table displays the mean responses to the question of, ‘how important the concept is to assessing CTC-HC’:

**Table 11: Mean responses to the question, how important is the concept to assessing capacity to consent: Phase 2**

<table>
<thead>
<tr>
<th>Item #</th>
<th>Concept</th>
<th>Mean score (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Understanding</td>
<td>5.00 (5 – 5)</td>
</tr>
<tr>
<td>2</td>
<td>Voluntariness</td>
<td>5.00 (5 – 5)</td>
</tr>
<tr>
<td>3</td>
<td>Concentration/sustained attention and memory</td>
<td>2.50 (1 – 4)</td>
</tr>
<tr>
<td>4</td>
<td>Orientation</td>
<td>4.20 (4 – 5)</td>
</tr>
<tr>
<td>5</td>
<td>Verbal abilities and conceptual disorganization</td>
<td>4.80 (4 – 5)</td>
</tr>
<tr>
<td>6</td>
<td>Conceptual disorganization</td>
<td>3.00 (2 – 5)</td>
</tr>
<tr>
<td>7-8</td>
<td>Presence of hallucinations, panic, unusual euphoria</td>
<td>3.80 (1 – 5)</td>
</tr>
<tr>
<td>9</td>
<td>Appreciation of the nature of the situation</td>
<td>4.80 (4 – 5)</td>
</tr>
<tr>
<td>10</td>
<td>Using the information provided in reasoning</td>
<td>4.20 (4 – 5)</td>
</tr>
<tr>
<td>11</td>
<td>Expression of choice</td>
<td>5.00 (5 – 5)</td>
</tr>
<tr>
<td>12-14</td>
<td>Decision-making demands</td>
<td>4.40 (4 – 5)</td>
</tr>
<tr>
<td>15</td>
<td>Client’s ability to cope</td>
<td>1.00 (1 – 1)</td>
</tr>
<tr>
<td>16</td>
<td>Physical indication of substance use</td>
<td>4.40 (4 – 5)</td>
</tr>
</tbody>
</table>

The following table displays the item-objective congruency index (congruent with CTC-HC and congruent with the Item concept) after Phase 2 of the expert review. The congruency index was calculated by taking the number of experts who scored the item as +1 divided by the total number of expert scores.
Table 12: Item-objective congruency index after the Phase 2 of expert review

<table>
<thead>
<tr>
<th>Item (after change of wording per 2nd phase suggestions)</th>
<th>Item-Objective Congruency (congruent with Capacity to Consent) Number of +1 scores/total number of scores</th>
<th>Item-Objective Congruency (congruent with item concept) Number of +1 scores/total number of scores</th>
<th>Recommended Congruency: a least (n-1)/n</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 The client is able to repeat back, <strong>in their own words</strong> the main side effects/potential complications of the intervention that is being offered to them.</td>
<td>1.0</td>
<td>1.0</td>
<td>0.8</td>
</tr>
<tr>
<td>2 The client made their decision about the medical intervention without external pressure or coercion. (i.e. the client is not giving an answer that they feel the clinician wants to hear).</td>
<td>0.6</td>
<td>1.0</td>
<td>0.8</td>
</tr>
<tr>
<td>3 Show the client the following 4 digit number : 8304 Take the number away and ask them to repeat the number. How many digits did the client recall correctly?</td>
<td>All experts agreed to remove this item</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 The client is oriented to person, place, and time (i.e. do they know who they are, where they are and what year it is?).</td>
<td>0.6</td>
<td>1.0</td>
<td>0.8</td>
</tr>
<tr>
<td>5 The client can engage in a conversation that makes sense (excluding physical inability to speak or language issue).</td>
<td>0.6</td>
<td>0.8</td>
<td>0.8</td>
</tr>
<tr>
<td>6 The client is able to follow simple verbal or written instructions. (i.e. follow at least one instruction).</td>
<td>The concept for this item was changed after discussion with the fifth expert therefore item-objective congruency index was not calculated.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Item (after change of wording per 2\textsuperscript{nd} phase suggestions)</td>
<td>Item-Objective Congruency (congruent with Capacity to Consent) Number of +1 scores/total number of scores</td>
<td>Item-Objective Congruency (congruent with item concept) Number of +1 scores/total number of scores</td>
<td>Recommended Congruency: a least ((n-1)/n)</td>
</tr>
<tr>
<td>-------------------------------------------------</td>
<td>-------------------------------------------------</td>
<td>-------------------------------------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>7 The client is experiencing symptoms of distorted reality (i.e. hallucinations, delusions, paranoia) which is directly related to the intervention proposed.</td>
<td>0.6</td>
<td>0.6</td>
<td>0.8</td>
</tr>
<tr>
<td>8 The client is demonstrating paranoia with the belief that you are trying to hurt or harm them despite clear explanation of the intervention proposed.</td>
<td></td>
<td></td>
<td>This item was combined with item 7</td>
</tr>
<tr>
<td>9 The client knows that he/she is either at risk of an illness or has an illness and therefore requires clinical care.</td>
<td>1.0</td>
<td>1.0</td>
<td>0.8</td>
</tr>
<tr>
<td>10 The client is able to use the information given to them about the intervention to form a decision about consenting to the intervention or refuse the intervention.</td>
<td>0.2</td>
<td>0.8</td>
<td>0.8</td>
</tr>
<tr>
<td>11 The client is able to verbally or physically (e.g., nodding yes or holding their arm out for a blood test) indicate a choice.</td>
<td>0.8</td>
<td>1.0</td>
<td>0.8</td>
</tr>
<tr>
<td>12 While offering care to a client he/she seems to be distracted by friends, other activities, and/or symptoms of withdrawal.</td>
<td>0.4</td>
<td>0.4</td>
<td>0.8</td>
</tr>
<tr>
<td>13 While offering care to a client he/she seemed to be rushed to get back to another activity</td>
<td></td>
<td></td>
<td>This item is now combined with item 12</td>
</tr>
<tr>
<td>Item (after change of wording per 2\textsuperscript{nd} phase suggestions)</td>
<td>Item-Objective Congruency (congruent with Capacity to Consent) Number of +1 scores/total number of scores</td>
<td>Item-Objective Congruency (congruent with item concept) Number of +1 scores/total number of scores</td>
<td>Recommended Congruency: a least (n-1)/n</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>14 While offering care to a client he/she seemed to be dope sick or experiencing symptoms of withdrawal.</td>
<td></td>
<td>This item is now combined with item 12</td>
<td></td>
</tr>
<tr>
<td>15 The client is able to cope with an adverse effect of the intervention (e.g., an unexpected test result).</td>
<td></td>
<td>The experts recommended deleting this item</td>
<td></td>
</tr>
<tr>
<td>16 There are physical indications that the client may have recently used drugs or alcohol (e.g., tweaking, nodding head, slurred speech, gyrating).</td>
<td>0.4</td>
<td>0.8</td>
<td>0.8</td>
</tr>
</tbody>
</table>
4.2.3 Final Instrument

After the final consultation (Phase 2), the final instrument included a set of instructions and a set of 11 items that are used to assess CTC-HC. The set of instructions incorporate concepts that could not be measured, but are important to consider during a health care encounter when CTC-HC is important. The final instrument, including instructions for use, is as follows:

4.2.3.1 Instructions to Clinicians Who Are Administering the Instrument

Prior to administering the Capacity Assessment Tool, it is important to think about some ethical considerations. Please take time now, to consider the following items:

   a) (Assumption of Capacity) CTC-HC can vary from time point to time point for individuals. In other words, if someone is capable of making a rational decision in the morning, they may not be capable in the afternoon, depending on their mental status or their substance use practices. It is important to enter into an encounter with a client with the assumption that they have capacity (even though the client may not have been capable in other encounters you may have had with them). Take time to clear your mind of preconceived opinions about their level of capacity.

   b) (Informed) It is important that the client be given the amount of information about a medical intervention that a reasonable person would require to make an informed decision and that the information is delivered in a manner in which the client can understand. Take time to reflect if you have provided the client with
enough information about the medical intervention and whether you have explained it in plain language at a level that you believe is appropriate for that individual.

c) (Beneficence and nonmaleficence) Clinicians have a moral obligation to deliver care to clients with the intention of benefiting the individual and to make a conscious effort to not harm the client in any way. Take time to reflect if the intention behind the care you are offering is to benefit the individual and not to harm the client in any way. (This does not include providing care to benefit society and not the client)

d) (Justice) Clinicians also have a moral obligation to provide equal access to health and resources regardless of their status in society. Take time to reflect about whether you are offering the same level and type of care to the individual that you would offer anyone, regardless of their socio-economic status. Are you treating the person differently because they are poor or homeless?

e) (Autonomy and avoidance of misuse of power differential) All clients have the right to hold views, to make choices, and to act based on their personal beliefs and values. Take time to reflect on whether you are allowing the client to express their own beliefs and opinions about the clinical intervention you are offering, or whether you are listening and respecting the client’s viewpoints, or whether you are trying to influence their decision in order for them to agree to what you are
offering them. Consider whether you are viewing the client as an equal partner in the decision-making process.

f) (Reflection) As you are providing information to the client about the clinical intervention that you are offering, it is important for you to allow the client to ask questions, and ask if they would like time to think about their decision to consent. This may mean providing the care at a different encounter. Factors about whether you feel doubtful that you will see the client again or not, should not come into play when allowing the client time to reflect on their decision.

g) (Level of Risk Versus Level of Capacity) Not all clinical encounters involve the same amount of risk and therefore a lower level of capacity may be required. While offering clinical care to a client, consider whether the risk is low (e.g., dressing a wound) or high risk (e.g., testing for a reportable disease, or providing medication (including a vaccination) that the client could have an allergic reaction to). If risk is low, then care may still be delivered as long the client is able to communicate in a coherent manner. If risk is high, an assessment of full understanding is required. Conversely, if clinical care is urgent and/or life threatening, and the client is not capable, the law allows the delivery of clinical care.

h) (Who Initiated the Clinical Encounter) Clients who enter a clinic or who approach a street nurse, do so with a request for care. Under these circumstances,
an element of implied consent can be inferred. This is contrasted by nurses that approach a client on the street or other areas where the client normally hangs out. In this situation, implied consent cannot be assumed. While offering clinical care under these circumstances, consider whether there is an element of implied consent. Either way, an assessment of capacity may still be required, but implied consent may factor into your final decision.

i) (Threshold setting) Threshold setting means the level of capacity that a clinician deems is required in order to state that the client has CTC-HC. Numerous elements may impact the level which a clinician sets for any given client, such as safety of the environment, the amount of time the client is willing to interact etc. While offering clinical care under these circumstances consider whether you had enough time to make a capacity assessment and whether there were factors in the environment that prevented you from fully assessing the client’s CTC-HC.

4.2.3.2 Items That Measure Capacity to Consent

Table 13: Items in final instrument

<table>
<thead>
<tr>
<th>Item Number*</th>
<th>Score</th>
</tr>
</thead>
</table>
| 1 | 1. strongly disagree  
   2. disagree  
   3. agree  
   4. strongly agree |
| Concept: Understanding | The client is able to repeat back, **in their own words** the main side effects/potential complications of the intervention that is being offered to them. |
| 2 | 1. strongly disagree  
   2. disagree  
   3. agree  
   4. strongly agree |
<p>| Concept: Voluntariness | The client made their decision about the medical intervention without external pressure or coercion. (i.e. the client is not giving an answer that they feel the clinician wants to hear). |</p>
<table>
<thead>
<tr>
<th>Item Number*</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>The client is oriented to person, place, and time (i.e. do they know who they are, where they are and what year it is?) or, if disorientated, it does not have a direct bearing on the medical intervention being offered.</td>
</tr>
<tr>
<td>4</td>
<td>The client can engage in the form of communication that they normally use (e.g., speech, signing writing) excluding a physical difficulty in speaking or use of foreign language not understood by the nurse.</td>
</tr>
<tr>
<td>5</td>
<td>The client is able to follow simple verbal or written instructions. (i.e. follow at least one instruction).</td>
</tr>
<tr>
<td>6</td>
<td>The client is experiencing symptoms of distorted reality (i.e. symptoms hallucinations, delusions, paranoia) and these symptoms have a direct bearing on the intervention proposed.</td>
</tr>
<tr>
<td>7</td>
<td>The client knows that he/she is either at risk of an illness or has an illness and therefore requires clinical care.</td>
</tr>
<tr>
<td>8</td>
<td>The client is able to use the information given to them about the intervention to form a decision about consenting to the intervention or refusing the intervention.</td>
</tr>
<tr>
<td>9</td>
<td>The client is able to verbally or physically (e.g., nodding yes or holding their arm out for a blood test) indicate a choice.</td>
</tr>
<tr>
<td>10</td>
<td>While offering care to a client he/she seems to be distracted by friends, other activities, and/or symptoms of withdrawal.</td>
</tr>
<tr>
<td>11</td>
<td>There are physical indications that the client may have recently used drugs or alcohol (e.g., tweaking, nodding head, slurred speech, gyrating).</td>
</tr>
</tbody>
</table>
4.3 Cognitive Testing

4.3.1 Methods

Cognitive testing took place on 15 November 2013 at VANDU, involving the three nurses that were hired for the validation portion of the study (LJ, CM and YW) and three individuals from the target population (members of VANDU). None of these people were involved in the qualitative study. All three nurses met together and were informed about the purpose of the study. They were given a description about how the items were generated. Then each item was reviewed and the nurses were encouraged to discuss their perceptions of the item (their impression of what the item meant), and the appropriateness of the wording of each item. Results of this discussion are below. Once the cognitive testing for the nurses was complete, they each took turns administering the instrument to a member of VANDU. The VANDU volunteers were assessed by the nurses using a hypothetical flu vaccination scenario. No medical assessment was done and no health care was provided. The purpose of the cognitive testing was explained to each participant and written informed consent was obtained (copy of consent can be found in Appendix G). After each member of VANDU had the Capacity Assessment Instrument for People who misuse Substances (CAIPS) administered to them, they were asked questions about whether any of the items were confusing, whether they understood what the nurse was asking them, and whether they found any of the items offensive in any way. Each of the VANDU participants received $20 for their participation in the cognitive testing.
4.3.2 Results

Nurses: Overall, the nurses were happy that the items were not written in the form of a question, but were constructed in a way that they could use their nursing assessment skills to score the item. They wanted clarification about Item four (“The client can engage in the form of communication that they normally use (e.g., speech, signing writing) excluding a physical difficulty in speaking or use of foreign language not understood by the nurse.”). I emphasized that this item is related to whether the nurse can get the client to engage in communication and that the form of communication was less important.

Clients: All of the three clients that were interviewed felt there were no problems with the CTC-HC items, and they stated they were not offended or confused by what the nurses were saying. Two clients stated, in fact the opposite was true; that they were pleasantly surprised about how the nurses interacted with them.

4.4 Pilot Testing

On 18 November, 2013, cognitive testing was conducted with the full research team except the psychiatrist who was not available on this date. A study coordinator (member of VANDU) recruited 7 people from the target population. Each of these people received $20 for participating in the pilot session. The validation study was explained to each participant by a research assistant (EL) and informed consent was obtained. A copy of the consent form is located in Appendix H. Each participant was interviewed three times by: 1) the peer researcher, 2) the researcher administering the MacCAT-T instrument and 3) the two nurses administering the CAIPS instrument. The
peer researcher, the researcher administering the MacCAT-T instrument and the two nurses administering the CAIPS instrument all used separate, private rooms.

The demographic/substance use questionnaire was administered by a peer researcher from VANDU. A copy of this questionnaire can be found in Appendix I. Hiring a member of VANDU as a peer researcher was important because members of VANDU felt that peers would word the questions in a culturally appropriate way, clients would feel more comfortable with the study, and they would answer the questions more honestly than if the interviewer was part of the UBC research team. Both the study coordinator from VANDU and the peer researcher received $10 per hour for working on the study with the research team. The amount of time it took to administer the demographic/substance use questionnaire was measured. The mean time it took to administer the questionnaire was 7 minutes. During the pilot, it was determined that the response options for the question related to where the participant slept the majority of the time, were inappropriate. Therefore it was decided to leave this question as an open ended question, and it was categorized during the analysis phase.

After the demographic/substance use questionnaire was administered, clients were escorted to the MacCAT-T assessment room. Since this is a previously validated questionnaire, the purpose of piloting the MacCAT-T was not to assess validity. Instead, it was administered to determine the amount of time it would take to complete the questionnaire. However, all three of the participants found the questions included in the MacCAT-T questionnaire to be repetitive. The mean time to administer the MacCAT-T questionnaire during this pilot test was 7.2 minutes.
Finally, clients were escorted to the CAIPS assessment room. During the pilot the two nurses took turns administering the instrument to the client while the other one observed the interview and scored the participant independently. Both nurses were blinded to the MacCAT-T assessment and were instructed not to discuss their scoring for each participant with each other. The nurses recorded how long it took to administer the instrument. The mean time was 14.1 minutes. After administering the instrument to seven participants, the nurses stated that they felt comfortable with the instrument and were ready to begin the validation portion of the study.

4.5 Summary: Description of the Instrument

After the expert review, cognitive testing and pilot testing of the instrument, the CAIPS instrument was ready for validation. This version consisted of instructions for the clinician administering the test, definition of the concepts, and 11 items that were in statement format with four Likert-type response options (1 being ‘strongly disagree’ and 4 being ‘strongly agree’). The concepts covered in the measurement portion of the instrument included understanding, voluntariness, orientation, ability to communicate, sustained attention, distorted reality, appreciation, reasoning, expression of choice, decision making demands, and physical indication of substance use. The intention was for each item to be scored, and then summed across to create a global assessment of CTC-HC. Higher scores are an indication of capacity and lower scores are an indication of lack of capacity. The minimum score that could be obtained is 11 and the maximum score that could be obtained is 44. The following chapter describes the validation process, analysis and results.
5 VALIDATION PHASE

5.1 Introduction

Once the CAIPS instrument was fully developed and pilot tested, it was validated at VANDU with 316 IMSH. Di Iorio states, “Test validation is the process of gathering evidence to support the interpretation of scores and subsequent decisions based on these scores.” (197)(page 212) The validation process involved assessing the CAIPS for construct and criterion validity, and reliability (inter-item correlation, internal consistency and interobserver reliability).

5.1.1 Validity

Construct validity is a necessary step in psychometric instrument development because it ensures the instrument can be used to “make accurate inferences about a person.” (page 258)(151) Construct validity refers to whether a measurement instrument actually measures the construct being investigated, in this case CTC-HC.(198) The previous chapter described how construct validity was determined through examination of the items for face validity by a panel of experts. Face validity refers to whether, on the surface, the instrument measures what it is intended to measure. In the validation phase of this dissertation, the construct of CTC-HC was assessed by comparing the results of CAIPS to two gold standards: a psychiatric assessment and the MacCAT-T assessment. This will be explained in more detail later in the chapter.

Criterion validity is defined as an assessment of whether the score of a new instrument predicts “performance on a task” (151) In the case of CTC-HC, assessment criterion validity examines whether the score can predict CTC-HC. This was determined
by assessing the intraclass correlation between the score from the CAIPS and the scores from the MacCAT-T instrument, and the binary assessment of capacity based on the psychiatric clinical assessment.

5.1.2 Reliability

In order for an instrument to be valid, it must be reliable. Inter-item and item-total correlations are important elements of reliability as they measure internal consistency. An instrument is considered to be internally consistent (and measure a global construct) if all individual items within the instrument correlate with each other and if each item correlates with the total score (omitting that item). (151) Finally, the overall internal consistency between items can be summarized with Cronbach’s alpha measure of internal consistency. Another way to test for reliability is by determining if the scores for individual people are similar when assessed by two of more independent evaluators (interobserver reliability). Although test-retest is another way of assessing reliability, it was not performed in this research as it would be impossible to retest the participant in the exact state of impairment as they were in the previous assessment.

5.1.3 Objectives:

The objective of the validation study was to administer the new instrument to individuals who engage in substance use and who are homeless or who live in unstable housing, in order to:

a) determine the internal consistency of the new instrument;

b) determine inter-rater reliability of the new instrument;
c) determine the dimensionality of the new instrument;

d) determine a threshold score, sensitivity, and specificity of the new instrument; and

e) determine external content validity of the new instrument by comparing it to two
gold standards: i) psychiatric clinical assessment and ii) a MacCAT-T
assessment;

5.1.4 Sample Size

Sample size calculation is typically done to ensure that a research study has
enough power to test a hypothesis. There is debate in the literature about the number of
participants needed to validate an instrument.(199) Some psychometricians suggest that,
in general, having a ratio of person-to-item of 10:1 is sufficient.(200) Others have
suggested that a sample size of 300 is acceptable, especially when confirmatory factor
analysis is employed.(201) I aimed for a sample size of 300 which satisfied both of the
above criteria (using an 11 item scale).

5.1.5 Inclusion/Exclusion Criteria

Inclusion criteria included:

a) Participants who were 19 years of age or older;

b) Participants who self-reported as being homeless or living in unstable housing
defined as:

Homeless: people who have no physical shelter – staying on the street, in
doorways, in parkades, in parks and on beaches, etc.; or, are
temporarily accommodated in emergency shelters, safe houses for
youth, or transition houses for women and their children fleeing
violence; or people with no fixed address found at hospitals or jails.(202).

Unstable housing: living under threat of eviction or violence; living in unfit or overcrowded conditions.(4) It also included individuals living in drug houses and in assisted living apartments in an impoverished neighbourhood;

c) Participants who self-reported as having problematic substance use defined as 1) loss of control over substance use, 2) compulsive drug/alcohol use, 3) cravings for drugs or alcohol, and 4) continued use despite increasing negative consequences.(19)

Exclusion criteria were as follows:

a) People who lived outside of Vancouver’s downtown eastside area whose address is a middleclass residential area AND do not live under the threat of eviction; and/or

b) People who cannot speak and understand English.

5.2 Methods

5.2.1 Partnership with Community Agency

As described in Chapter 2, this study was conducted in partnership with VANDU. VANDU is an organization made up of current or former drug users in Vancouver BC. Our previous working relationship for the qualitative portion of the study facilitated additional collaboration for the validation study.
The process of re-engaging VANDU involved completing their form, “VANDU Involvement in Research Projects” which asks for a description of the study, what the research expects to accomplish and how this will directly benefit drug users, and how the study represents the diversity of drug users dealing with a street drug dependency. All consent forms and questionnaires were also provided. The information was given to VANDU’s Board of Directors (made up of drug users) for review. I then attended a Board meeting where I presented information about the study and answered questions. At a separate meeting, the Board voted in favour of collaborating in the validation study. Three individuals, not previously involved with the study, were identified by the VANDU executive to be paid study coordinators. These individuals were responsible for recruiting participants for the study (advertising the study through word of mouth and booking appointments), and coordinating study activities by directing participants to each of the study stations. In addition, one member of VANDU per week, was hired to administer the demographic questionnaire under the direction of a research assistant from BCCDC.

5.2.2 Training of Nurses and Peer Researchers

Nurses: Three registered nurses (LJ, CM and YW) were trained to administer the CAIPS instrument on 15 November, 2013. This took place at the same time as the cognitive testing. Another nurse (DK) was trained to administer the MacCAT-T instrument. Nurses who were hired to administer the CAIPS instrument were instructed to administer it by simulating a typical nursing encounter. For that reason, comprehensive guidelines for administrating the instrument were not developed. These nurses were taught the meaning of the response options and were instructed to use their
nursing judgment while scoring each participant. Therefore, the instrument was validated in the same way that nurses in the field would be administering the instrument. The nurses who administered the CAIPS were instructed not to discuss their assessment scores with each other. These nurses alternated being the interviewer and the observer.

It should be noted that if participants mentioned that they worried about the flu shot being tampered with “by the government” (to harm people who are poor, homeless and/or who use substances), the nurses were instructed not to consider this as paranoia unless paranoia exhibited itself in some other way. The reason for this is because the idea of government interference with the flu shot is a common urban myth.

5.2.3 Study Recruitment

A convenience sample of participants was recruited through word of mouth and snowball sampling. Interested volunteers were directed to sign up for a study visit with the VANDU study coordinator (JM). Some participants were seen the same day of recruitment and others returned at a later date. All participants received $20 to thank them for the time they spent participating in the study.

5.2.4 Study Activities

The study involved one visit that lasted approximately one hour and included three assessments: 1) a psychiatric assessment, 2) the MacCAT-T assessment, and 3) the CAIPS assessment. Each assessment took place in a separate private room. Assessors in each room were blinded to the assessments occurring in the other rooms. The following figure shows the flow of study activities. It is important to note that we alternated participants going from the psychiatrist to either the CAIPS assessment station or the
MacCAT-T assessment station, as I was concerned about one experience influencing the other.

Figure 6: Flow of study activities for validation phase

5.2.4.1 Station One: Consent and Questionnaire

At the onset of the study visit, each participant went to Station 1 where they met with a BCCDC research assistant and a VANDU peer researcher. The study was explained by the research assistant, and the participant was given ample time to ask
questions. The participant was then asked to provide written informed consent and a copy was offered to the participant. A copy of the consent form can be found in Appendix J. It should be noted that we assumed that all participants had capacity to consent for the study. This assumption was made because no instrument existed at the time to assess capacity to consent for this unique population. Since we did not have other evidence to the contrary, we assumed all of the participants had the capacity to consent to the study. This method of consent was approved by the UBC Behavioural Ethics Board and is consistent with the Health Care (Consent) and Care Facility (Admission) Act.(77)

Once consent was obtained, a VANDU peer researcher administered the demographic/substance use questionnaire (Appendix I). The demographic portion of the questionnaire was designed to capture gender, age, education level, ethnicity (cultural group), type of housing, and type of income. These questionnaires were adopted from the Enhanced Surveillance of Street Youth conducted by the Public Health Agency of Canada. (203) The substance use portion of the questionnaire was designed to capture information about past history of drug and alcohol use, time and date of last drug/alcohol use, self-perception of being high, drunk, or withdrawing from a substance at the time of the study visit, self-perception of being addicted to drugs and/or alcohol, history of treatment or other help for substance dependence (including methadone use), and self-reported mental illness (including medication for mental illness).

5.2.4.2 Station Two: Psychiatric Assessment

Once the demographic questionnaire was complete, each study participant was escorted to a private room where a board-certified, registered psychiatrist (JF), conducted a clinical assessment of CTC-HC based on standard psychiatric principles. The purpose
of this assessment was to provide a gold standard assessment of capacity against which the CAIPS instrument could be compared. The following figure displays the framework that was used by the psychiatrist to assess CTC-HC.

**Figure 7: Psychiatric assessment framework**

![Psychiatric assessment framework](image)

Source: Jonathan Fleming (204)

The psychiatrist completed a data collection form that was designed to collect information about the psychiatrist’s opinion of whether the participant was under the influence of alcohol and/or drugs, whether the participant has a mental illness, and whether the participant was capable of making a decision about consenting or refusing treatment during the study assessment period. Capacity was recorded as a binary outcome (yes or no). A copy of the psychiatric data collection form can be found in Appendix K.
5.2.4.3 Station Three: Nurse Assessment using the CAIPS Instrument

Once the psychiatric assessment was completed, each participant was escorted to either Station 3 or 4 (note, the order of these station assessments was alternated weekly). In Station 3, each participant was assessed for CTC-HC using the CAIPS instrument by two registered nurses who had over ten years of experience delivering care to IMSH. One nurse (Nurse A) conducted the CAIPS assessment by simulating a street outreach nursing encounter that involved offering a flu shot. Participants were reminded that the scenario was hypothetical and that they were not actually being offered a flu shot. The nurse would carry on a health care conversation as they normally would in street outreach settings, making sure they incorporated the elements required to complete the CAIPS assessment form. In other words, the conversation between the nurse and each participant was not always the same for each participant, but the same assessment instrument was used for each participant. The second nurse (Nurse B) sat nearby and conducted the CAIPS assessment independent of Nurse A’s assessment. The nurses were instructed not to discuss their individual assessments with each other. This was done in order to test for intraobserver reliability. The nurses alternated between being Nurse A and Nurse B. A copy of the CAIPS that was used in the validation portion of this dissertation can be found in Appendix L. The amount of time to administer the CAIPS instrument was measured and recorded.

5.2.4.4 Station Four: MacCAT-T Assessment

In Station 4, participants were assessed for CTC-HC using the MacCAT-T instrument. The purpose of this assessment was to provide a second gold standard against which the new CAIPS instrument could be compared. The assessment was
conducted by a psychiatric nurse who was blinded to the psychiatrist’s assessment of capacity as well as the CAIPS assessment. This nurse used a version of the MacCAT-T instrument that was adapted for the particular scenario that we used. In order to assess CTC-HC, the psychiatric nurse created a hypothetical clinical encounter, using a vignette, in which participants were offered flu shots. The use of clinical vignettes has been practiced widely throughout the psychometric instrument development literature related to CTC-HC and has been shown to be an effective and valid means of testing for capacity.(205;206) Each participant was reminded that this was a hypothetical situation, and that they were not being offered a flu shot. A standardized script (found in Appendix M) was used to inform the participant about the flu, the flu shot and the risks and benefits of receiving a flu shot.

Once this vignette was conveyed to the participant, he/she was asked a series of questions (adapted from Grisso and Appelbaum’s MacCAT-T form). If participants were unsure of the answers to the questions, they were prompted further by using the exact words that were used in the vignette. This procedure is recommended by Appelbaum and Grisso. The amount of time it took to administer the MacCAT-T instrument was recorded. Scoring was conducted according the MacCAT-T manual.(103) The questions can be found in Appendix N.

5.2.4.5 Development of gold standard value

The majority of capacity to consent studies use a physician’s assessment as the gold standard against which a new instrument is compared. Several studies use both a physician’s assessment and an existing instrument (to establish convergence validity) resulting in two gold standards. In these situations, the two gold standards are not
combined into one; rather, the new instrument is compared to both gold standards with
two sets of results reported. That is the approach I used in the validation portion of this
dissertation (two gold standards: a psychiatric and the MacCAT-T). The psychiatric
assessment provided a binary judgment of capacity. The MacCAT-T was not developed
to provide a binary assessment of capacity, nor is there consensus on possible MacCAT-T
cut-off scores associated with judgments of incapacity. I used a cut-off score of ≤4 for
understanding, ≤2 for appreciation and ≤5 for reasoning. This method has been used by
Aydin et al. (207) as well as by Grisso and Appelbaum.(208) If the participant scored
below these levels in one of the three dimensions, they were considered lacking in CTC-
HC.

5.2.5 Analysis
5.2.5.1 Descriptive Analysis

Frequency analysis was conducted on all demographic data. Bivariate analyses
were conducted to determine if individuals who were included in the study were
different, in terms of demographics and substance use, from those who were excluded
from the study. Frequency analysis was also conducted on variables included in the
psychiatric instrument, the MacCAT-T instrument, and the CAIPS instrument. For the
CAIPS instrument the mean, median, mode and variance were calculated for each item
and for each nurse.

Bar graphs were drawn to illustrate the frequency of response options for each
item in the new instrument. Items six, ten, and eleven are items that were stated in
reverse wording compared to the other items. It other words responses “strongly
disagree” and “disagree” are indicators of capacity whereas these responses were indicators of lack of capacity for the remaining items. These items were reverse coded for the psychometric analysis.

5.2.5.2 Psychometric analysis

5.2.5.2.1 Internal consistency

First, the inter-item correlation matrix was examined in order to determine how well each item in the new instrument correlates with the remaining items. In addition corrected item-total correlation was constructed to determine how well each item correlated with the total score minus the score of that item. An unstandardized Cronbach’s alpha was calculated to determine the overall correlation among the items using scores from each of the nurses. A composite score for each participant was created by summing the individual scores for items one through 11. The mean and variance of the composite score were calculated.

5.2.5.2.2 Inter-rater reliability

A weighted kappa statistic using quadratic weights was calculated on the composite scores from each nurse in order to evaluate the amount of agreement in CAIPS scores between nurses. Weighted kappa’s are used when the response options are ordinal (with more than two responses). Weighting equalizes the amount of difference (distance) between response option 1 and 4 (for example) and response option 2 and 3. Quadratic
weights take into consideration, not only the levels of agreement (linear) between raters, but also the level of disagreement between raters.

5.2.5.2.3 Dimensionality of the new instrument – confirmatory factor analysis.
A confirmatory factor analysis was conducted, to test our a priori hypothesis that the CAIPS instrument is unidimensional. To test this hypothesis, a one-factor confirmatory factor analysis was conducted with weighted least squares estimation (WLSMV) because the estimation method takes into consideration the ordinal nature of the response options. To assess model fit, I followed Hu’s & Bentler criteria and examined the Root Mean Square Error of Approximation (RMSEA) and Comparative Fit Index (CFI).(209) If the RMSEA was less than 0.06 and the CFI was > 0.95 then the fit of the model was considered good.(209) Post-hoc model modifications, if deemed necessary, examined the modification indices to identify potential weaknesses in the model. The factor analysis was conducted using MPlus ver 7.11 (210).

Once it was determined that the capacity assessment instrument for people who misuse substances (CAIPS) was unidimensional the composite score was used to assess validity was established by comparing the composite scores for participants who were judged by the psychiatrist to be under the influence of alcohol and/or drugs at the time of the study visit, to those who were not under the influence of alcohol and/or drugs at the time of the study visit. This comparison was done by conducting a Student’s t-test.

In addition, validity was assessed by testing a null hypothesis that the composite scores of those who were under the influence of a substance at the time of their study
visit (according to the psychiatric assessment) were the same as those who were not
under the influence of a substance at the time of their study visit.

5.2.5.2.4 Determination of a threshold score, sensitivity and specificity of CAIPS

In order to determine the usability of the CAIPS instrument a receiver operator
curve (ROC) was drawn using the composite CAIPS scores for each patient and the
binary assessment from the psychiatrist. This was repeated for each nurse. The same
analysis was done using the composite CAIPS scores and the binary MacCAT-T
assessment. The area under the curve was calculated and a value of >.75 was an
indication that the instrument had adequate sensitivity and specificity and is considered a
useful test.

The coordinates from the ROC curve were used to determine the ideal threshold
for the CAIPS instrument. The CAIPS score that provided best balance between the
sensitivity and specificity scores provided the diagnostic threshold of CTC-HC.

5.2.5.2.5 Determining external content validity of the new instrument by comparing
it to two gold standards: i) psychiatric clinical assessment and ii) a MacCAT-T
assessment

According to Streiner and Norman (151), criterion validity is established by
examining the correlation of a scale (e.g., CAIPS scale) to a gold standard that has been
used and accepted in the field. In order to determine criterion validity the composite
scores of the CAIPS instrument were compared to the psychiatrist’s assessment of CTC-
HC using an unweighted kappa statistic. The same analysis was done comparing the MacCAT-T binary results to the CAIPS.

In addition, a two-way mixed effect model with absolute agreement was conducted to compare the strength of the intraclass correlation of CAIPS scores recorded by each nurse.

All analyses were conducted using SPSS version 14, MedCalc version 13 and MPlus version 7.11. The following chapter provides the results for the analyses just described.
6 RESULTS OF VALIDATION PHASE

6.1 Descriptive

6.1.1 Demographics

A total of 317 participants volunteered for the study. One participant was excluded prior to providing consent as she was deaf and a reliable interpreter was not available. An additional 14 participants were excluded for the following reasons: 2 were duplicates and 12 were not homeless or unstably housed. One of these 12 signed the consent form but did not complete the demographic questionnaire. A total of 302 remained in the analysis. Table 14 below displays the demographic data for those who were included and those who were excluded. Note that only 11 of the 12 excluded participants were included in this analysis as we did not have data for one person and demographic data were duplicated for two participants. The majority of included participants were men (60%), aboriginal (49%), with low educational levels (58% elementary school), and having disability payments as their main source of income (61%).

Table 14: Demographic characteristics of included and excluded participants

<table>
<thead>
<tr>
<th>Variable</th>
<th>Included Participants (302)</th>
<th>Excluded Participants (11)</th>
<th>p value*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>182</td>
<td>60.3</td>
<td>6</td>
</tr>
<tr>
<td>Female</td>
<td>119</td>
<td>39.4</td>
<td>5</td>
</tr>
<tr>
<td>Transgender</td>
<td>1</td>
<td>0.3</td>
<td>0</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>44</td>
<td>10.1</td>
<td>44</td>
</tr>
<tr>
<td>Min</td>
<td>21</td>
<td></td>
<td>22</td>
</tr>
<tr>
<td>Max</td>
<td>70</td>
<td></td>
<td>60</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elementary/primary school</td>
<td>176</td>
<td>58.30</td>
<td>4</td>
</tr>
<tr>
<td>Secondary/high school</td>
<td>89</td>
<td>29.50</td>
<td>5</td>
</tr>
<tr>
<td>Variable</td>
<td>Included Participants (302)</td>
<td>Excluded Participants (11)</td>
<td>p value*</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>----------------------------</td>
<td>-----------------------------</td>
<td>----------</td>
</tr>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
</tr>
<tr>
<td>College/university (undergraduate)</td>
<td>29</td>
<td>(9.6)</td>
<td>2</td>
</tr>
<tr>
<td>completed graduate education</td>
<td>0</td>
<td>(0.0)</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>8</td>
<td>(2.6)</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aboriginal/First Nations/Metis/Inuit</td>
<td>149</td>
<td>(49.3)</td>
<td>4</td>
</tr>
<tr>
<td>Caucasian</td>
<td>124</td>
<td>(41.1)</td>
<td>6</td>
</tr>
<tr>
<td>Hispanic</td>
<td>1</td>
<td>(0.3)</td>
<td>0</td>
</tr>
<tr>
<td>African/Black</td>
<td>7</td>
<td>(2.3)</td>
<td>0</td>
</tr>
<tr>
<td>Asian</td>
<td>3</td>
<td>(1.0)</td>
<td>0</td>
</tr>
<tr>
<td>South East Asian</td>
<td>1</td>
<td>(0.3)</td>
<td>0</td>
</tr>
<tr>
<td>Mixed</td>
<td>12</td>
<td>(4.0)</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>3</td>
<td>(1.0)</td>
<td>1</td>
</tr>
<tr>
<td>Don't know</td>
<td>1</td>
<td>(0.3)</td>
<td>0</td>
</tr>
<tr>
<td>Prefer not to answer</td>
<td>1</td>
<td>(0.3)</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Housing (Sleep Most Often)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single Room Occupancy</td>
<td>143</td>
<td>(47.4)</td>
<td>0</td>
</tr>
<tr>
<td>Assisted living</td>
<td>51</td>
<td>(16.9)</td>
<td>0</td>
</tr>
<tr>
<td>Shelter</td>
<td>67</td>
<td>(22.2)</td>
<td>0</td>
</tr>
<tr>
<td>House</td>
<td>0</td>
<td>(0.0)</td>
<td>3</td>
</tr>
<tr>
<td>Street/Park/Abandoned building</td>
<td>25</td>
<td>(8.3)</td>
<td>0</td>
</tr>
<tr>
<td>Jail</td>
<td>3</td>
<td>(1.0)</td>
<td>0</td>
</tr>
<tr>
<td>Family or Friends (not paying rent)</td>
<td>11</td>
<td>(3.6)</td>
<td>0</td>
</tr>
<tr>
<td>Recovery House</td>
<td>2</td>
<td>(0.7)</td>
<td>0</td>
</tr>
<tr>
<td>Apartment</td>
<td>0</td>
<td>(0.0)</td>
<td>8</td>
</tr>
<tr>
<td>Source of Income</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social welfare</td>
<td>82</td>
<td>(27.2)</td>
<td>3</td>
</tr>
<tr>
<td>Disability</td>
<td>185</td>
<td>(61.3)</td>
<td>8</td>
</tr>
<tr>
<td>Employment insurance</td>
<td>2</td>
<td>(0.7)</td>
<td>0</td>
</tr>
<tr>
<td>Work - Full time</td>
<td>3</td>
<td>(1.0)</td>
<td>0</td>
</tr>
<tr>
<td>Work - Part time</td>
<td>15</td>
<td>(5.0)</td>
<td>1</td>
</tr>
<tr>
<td>Family/friends</td>
<td>3</td>
<td>(1.0)</td>
<td>0</td>
</tr>
<tr>
<td>Sex work</td>
<td>14</td>
<td>(4.6)</td>
<td>0</td>
</tr>
<tr>
<td>Selling drugs</td>
<td>22</td>
<td>(7.3)</td>
<td>0</td>
</tr>
<tr>
<td>Binning (looking in dumpsters)</td>
<td>9</td>
<td>(3.0)</td>
<td>0</td>
</tr>
<tr>
<td>Pan handling</td>
<td>11</td>
<td>(3.6)</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>22</td>
<td>(7.3)</td>
<td>0</td>
</tr>
<tr>
<td>Prefer not to answer</td>
<td>1</td>
<td>(0.3)</td>
<td>1</td>
</tr>
</tbody>
</table>

* caution should be taken when interpreting p-value as sample of excluded participants is very small.
6.1.2 Substance Use

Among the 302 participants, 300 (99.3%) stated they had EVER used drugs for non-medicinal purposes (prescribed or otherwise). The remaining two had only used alcohol. 254 (84.1%) who had EVER used drugs for non-medicinal purposes, stated they felt they were addicted to drugs. The mean (SD) number of years that participants had been using drugs was 25.2 (11.8). Fifty-eight percent of participants had used one or more drugs within two hours of their study visit. The following table displays the amount of time that a drug had been used prior to the study visit broken down by drug type.

Table 15: Amount of time that a drug was used prior to study visit

<table>
<thead>
<tr>
<th>Drug</th>
<th>&lt;5 min</th>
<th>5.1 – 15 min</th>
<th>15.1 – 60 min</th>
<th>1.1 – 2 hrs</th>
<th>2.1 – 5 hrs</th>
<th>5.1 – 12 hrs</th>
<th>12.1 – 24 hrs</th>
<th>1 – 7 days</th>
<th>&gt; 1 Week</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cocaine</td>
<td>14</td>
<td>17</td>
<td>32</td>
<td>12</td>
<td>4</td>
<td>11</td>
<td>18</td>
<td>15</td>
<td>8</td>
</tr>
<tr>
<td>Crystal Meth</td>
<td>1</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>5</td>
<td>3</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Dilaudid</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Gabapentin</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Heroin</td>
<td>8</td>
<td>6</td>
<td>20</td>
<td>1</td>
<td>4</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Marijuana</td>
<td>2</td>
<td>3</td>
<td>16</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Methadone</td>
<td>1</td>
<td>3</td>
<td>8</td>
<td>9</td>
<td>15</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Morphine</td>
<td>0</td>
<td>0</td>
<td>8</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Unspecified opiate</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Valium</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>26</td>
<td>32</td>
<td>90</td>
<td>29</td>
<td>32</td>
<td>26</td>
<td>27</td>
<td>22</td>
<td>9</td>
</tr>
</tbody>
</table>

One hundred and twenty-five (41.4%) of participants stated they felt they were under the influence of drugs during their study visit and 67 (22.2%) felt they were withdrawing from a substance during their study visit. However, 148 (49%) reported using a drug within one hour of their study visit. Sixty-five (21.5%) had taken a dose of methadone within 12 hours of their study visit; 12 (4.0%) had taken methadone within one hour.

A total of 299 (99%) stated they had EVER drank alcohol and 105 (34.8%) stated they were addicted to alcohol. The mean (SD) length of time drinking was 30 years...
Fourty-four (14.6%) stated that had been drinking the day of the study visit. Among these, one had been drinking for 3-4 days, 2 had been drinking for 13-24 hours and 30 had been drinking within 3 hours of their study visit. Twenty-two (7.3%) participants stated they were drunk during their study visit.

A total of 135 (44.7%) participants stated that they had EVER been told that they had a mental illness. Ninety (29.8%) were currently taking medication for their mental illness.

6.1.3 Psychiatric Assessment

The median (min/max) number of minutes to conduct the psychiatric assessment of CTC-HC was 9 (min:4; max: 26). According to the psychiatrist’s opinion, 120 (39.7%) participants were under the influence of drugs during the study visit, 35 (11.6%) were under the influence of alcohol and 81 (26.8%) had a mental illness. The psychiatrist assessed 259 (85.8%) participants as having CTC-HC at the time of his assessment. The following table displays the breakdown of those with and without capacity at the time of the psychiatric assessment.

Table 16: Frequency of participants with and without capacity associated with substance use impairment and/or mental illness.

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Has Capacity</th>
<th>Lacks Capacity</th>
<th>Missing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol Only</td>
<td>14</td>
<td>11 (79%)</td>
<td>3 (21%)</td>
<td>0</td>
</tr>
<tr>
<td>Alcohol and Drugs</td>
<td>7</td>
<td>6 (86%)</td>
<td>1 (14%)</td>
<td>0</td>
</tr>
<tr>
<td>Alcohol and Drugs and Mental Illness</td>
<td>4</td>
<td>3 (75%)</td>
<td>1 (25%)</td>
<td>0</td>
</tr>
<tr>
<td>Alcohol and Drugs and Mental Illness</td>
<td>4</td>
<td>1 (45%)</td>
<td>3 (75%)</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>N</td>
<td>Has Capacity</td>
<td>Lacks Capacity</td>
<td>Missing</td>
</tr>
<tr>
<td>---------------</td>
<td>-----</td>
<td>--------------</td>
<td>----------------</td>
<td>---------</td>
</tr>
<tr>
<td>Mental Illness</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drugs and Mental illness</td>
<td>42</td>
<td>33 (79%)</td>
<td>8 (21%)</td>
<td>1</td>
</tr>
<tr>
<td>Drugs Only</td>
<td>103</td>
<td>99 (96%)</td>
<td>4 (4%)</td>
<td>0</td>
</tr>
<tr>
<td>Mental Illness Only</td>
<td>30</td>
<td>26 (87%)</td>
<td>4 (13%)</td>
<td>0</td>
</tr>
<tr>
<td>None</td>
<td>52</td>
<td>51 (98%)</td>
<td>1 (2%)</td>
<td>0</td>
</tr>
<tr>
<td>Missing information (any of the three elements missing)</td>
<td>46</td>
<td>29 (63%)</td>
<td>16 (35%)</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Total</td>
<td>302</td>
<td>259 (85.7%)</td>
<td>41 (13.5%)</td>
<td>2 (0.8%)</td>
</tr>
</tbody>
</table>

6.1.4 MacCAT-T Assessment

The scores for the MacCAT-T assessment were grouped into four domains (understanding, appreciation, reasoning, expression of choice) according to the instructions outlined by Grisso and Appelbaum.(88) This was then dichotomized by using the methods described in section 5.2.4.5 in Chapter 5. Overall, the number of participants assessed as having CTC-HC according to the MacCAT-T instrument is 208 (68.9%). The mean (SD) number of minutes it took to administer the MacCAT-T instrument was 7.87 (2.54). The median (interquartile range [IQR]) score for the understanding domain was 6 (0 - 6) (maximum possible score = 6), for the appreciation domain was 4 (0 - 4) (maximum possible score = 4), for the reasoning domain was 8 (0 - 8) (maximum possible score = 8), and for the expression of choice domain was 2 (0 - 2) (maximum score = 2). The following graphs display the distribution of responses for each domain. The number (percentage) of participants who were rated as having capacity for each domain is displayed in Table 17.
Figure 8: Frequency distribution of MacCAT-T scores for the appreciation domain

Figure 9: Frequency distribution of MacCAT-T scores for the reasoning domain
Figure 10: Frequency distribution of MacCAT-T scores for the understanding domain

![Frequency distribution of MacCAT-T scores for the understanding domain](image)

Figure 11: Frequency distribution of MacCAT-T scores for the expression of choice domain

![Frequency distribution of MacCAT-T scores for the expression of choice domain](image)

Table 17: Number of participants who were rated as having capacity for each of the MacCAT-T domains based on a cut-off score of ≤4 for understanding, ≤2 for appreciation and ≤5 for reasoning.

<table>
<thead>
<tr>
<th></th>
<th>Understanding n (%)</th>
<th>Reasoning n (%)</th>
<th>Appreciation n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has capacity</td>
<td>218 (72%)</td>
<td>272 (90%)</td>
<td>277 (92%)</td>
</tr>
</tbody>
</table>
Among the 302 participants, data from 295 participants were included in the psychometric analysis. The remaining seven were excluded due to missing data. The mean (SD) number of minutes it took to administer the test was 7.98 (3.31). The amount of time to administer the CAIPS instrument is not statistically different than the MacCAT-T instrument (p=0.63).

6.1.5.1 Frequency of Response Options

The following figures display the frequency of response options for each item included in the CAIPS instrument. Here we can see that responses “Agree” and “Strongly Agree” are used widely.

**Figure 12: Item 1:** The client is able to repeat back, in their own words the main side effects/potential complications of the intervention that is being offered to them.
Figure 13: Item 2: The client made their decision about the medical intervention without external pressure or coercion. (i.e. the client is not giving an answer that they feel the clinician wants to hear)

Figure 14: Item 3: The client is oriented to person, place, and time (i.e. do they know who they are, where they are and what year it is?) or, if disorientated, it does not a direct bearing on the medical intervention being offered.
Figure 15: Item 4: The client can engage in the form of communication that they normally use (e.g., speech, signing writing) excluding a physical difficulty in speaking or use of foreign language not understood by the nurse.

Figure 16: Item 5: The client is able to follow simple verbal or written instructions. (i.e. follow at least one instruction)
Figure 17: Item 6: The client is experiencing symptoms of distorted reality (i.e. symptoms hallucinations, delusions, paranoia) and these symptoms have a direct bearing on the intervention proposed.

Figure 18: Item 7: The client knows that he/she is either at risk of an illness or has an illness and therefore requires clinical care.
Figure 19: Item 8: The client is able to use the information given to them about the intervention to form a decision about consenting to the intervention or refuse the intervention.

Figure 20: Item 9: The client is able to verbally or physically (e.g., nodding yes or holding their arm out for a blood test) indicate a choice.
Figure 21: Item 10: While offering care to a client he/she seems to be distracted by friends, other activities, and/or symptoms of withdrawal. – reverse coding done

![Bar chart showing responses to Item 10 for Nurse LJ and Nurse CM.]

Figure 22: Item 11: There are physical indications that the client may have recently used drugs or alcohol (e.g., tweaking, nodding head, slurred speech, gyrating). – reverse coding done

![Bar chart showing responses to Item 11 for Nurse LJ and Nurse CM.]

Table 18 displays the mean, variance, median and mode for each of the 11 items.

The CAIPS scale has a possible maximum composite score of 44 (11 items with 4
response options each). The median (IQR) composite score from Nurse LJ assessments is 35 (32-39) and from Nurse CM assessments is 37 (34-39). The following table displays the mean, median and mode scores for each item for each nurse.

Table 18: Mean, median and mode for each item and for each nurse

<table>
<thead>
<tr>
<th>Item</th>
<th>Nurse LJ (interviewer and observer)</th>
<th>Nurse CM (interviewer and observer)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (variance)</td>
<td>Median</td>
</tr>
<tr>
<td>1</td>
<td>3.01 (0.74)</td>
<td>3</td>
</tr>
<tr>
<td>2</td>
<td>3.56 (0.35)</td>
<td>4</td>
</tr>
<tr>
<td>3</td>
<td>3.27 (0.26)</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>3.50 (0.30)</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>3.53 (0.30)</td>
<td>4</td>
</tr>
<tr>
<td>6</td>
<td>3.12 (0.30)</td>
<td>3</td>
</tr>
<tr>
<td>7</td>
<td>3.12 (0.30)</td>
<td>3</td>
</tr>
<tr>
<td>8</td>
<td>3.37 (0.35)</td>
<td>3</td>
</tr>
<tr>
<td>9</td>
<td>3.50 (0.27)</td>
<td>4</td>
</tr>
<tr>
<td>10</td>
<td>2.72 (0.64)</td>
<td>3</td>
</tr>
<tr>
<td>11</td>
<td>2.45 (0.57)</td>
<td>2</td>
</tr>
</tbody>
</table>
6.2 Psychometric Analysis

6.2.1 Internal consistency

The following table displays the inter-item correlation matrix for all 11 items.

Forty six of 55 correlations are greater or equal to 0.30 (83.7%) suggesting the scale has adequate inter-item correlation.

Table 19: Inter-item correlation matrix

<table>
<thead>
<tr>
<th></th>
<th>Item1</th>
<th>Item2</th>
<th>Item3</th>
<th>Item4</th>
<th>Item5</th>
<th>Item6</th>
<th>Item7</th>
<th>Item8</th>
<th>Item9</th>
<th>Item10</th>
<th>Item11</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item1</td>
<td>.1000</td>
<td>.360</td>
<td>.536</td>
<td>.487</td>
<td>.498</td>
<td>.301</td>
<td>.275</td>
<td>.484</td>
<td>.492</td>
<td>.349</td>
<td>.287</td>
</tr>
<tr>
<td>Item2</td>
<td>.360</td>
<td>.1000</td>
<td>.455</td>
<td>.416</td>
<td>.431</td>
<td>.184</td>
<td>.292</td>
<td>.443</td>
<td>.393</td>
<td>.203</td>
<td>.137</td>
</tr>
<tr>
<td>Item3</td>
<td>.536</td>
<td>.455</td>
<td>.1000</td>
<td>.651</td>
<td>.552</td>
<td>.369</td>
<td>.339</td>
<td>.544</td>
<td>.398</td>
<td>.317</td>
<td></td>
</tr>
<tr>
<td>Item5</td>
<td>.498</td>
<td>.431</td>
<td>.552</td>
<td>.667</td>
<td>.1000</td>
<td>.321</td>
<td>.389</td>
<td>.480</td>
<td>.547</td>
<td>.397</td>
<td>.324</td>
</tr>
<tr>
<td>Item8</td>
<td>.484</td>
<td>.443</td>
<td>.544</td>
<td>.517</td>
<td>.480</td>
<td>.346</td>
<td>.473</td>
<td>.1000</td>
<td>.602</td>
<td>.359</td>
<td>.316</td>
</tr>
<tr>
<td>Item9</td>
<td>.492</td>
<td>.393</td>
<td>.480</td>
<td>.546</td>
<td>.547</td>
<td>.326</td>
<td>.448</td>
<td>.602</td>
<td>.1000</td>
<td>.379</td>
<td>.293</td>
</tr>
<tr>
<td>Item10</td>
<td>.349</td>
<td>.203</td>
<td>.398</td>
<td>.389</td>
<td>.397</td>
<td>.386</td>
<td>.314</td>
<td>.359</td>
<td>.379</td>
<td>.1000</td>
<td>.607</td>
</tr>
<tr>
<td>Item11</td>
<td>.287</td>
<td>.137</td>
<td>.317</td>
<td>.371</td>
<td>.324</td>
<td>.417</td>
<td>.233</td>
<td>.316</td>
<td>.293</td>
<td>.607</td>
<td>1.000</td>
</tr>
</tbody>
</table>

The following table displays the item-total correlation for all 11 items.

Table 20: Corrected item-total correlation

<table>
<thead>
<tr>
<th>Corrected Item-Total Correlation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item1</td>
</tr>
<tr>
<td>Item2</td>
</tr>
<tr>
<td>Item3</td>
</tr>
<tr>
<td>Item4</td>
</tr>
<tr>
<td>Item5</td>
</tr>
<tr>
<td>Item6</td>
</tr>
<tr>
<td>Item7</td>
</tr>
<tr>
<td>Item8</td>
</tr>
<tr>
<td>Item9</td>
</tr>
<tr>
<td>Item10</td>
</tr>
</tbody>
</table>
A total of 300 cases were available to calculate the unstandardized alpha for the CAIPS instrument for Nurse LJ and Nurse CM. The following table displays the alphas and composite mean and standard deviation values for Nurse LJ and Nurse CM when they were both interviewer and observer, when they were just the interviewer and when they were just the observer.

Table 21: Cronbach’s alpha values under for Nurse LJ and Nurse CM under three conditions

<table>
<thead>
<tr>
<th>Nurse</th>
<th>Cronbach’s alpha (all Items)</th>
<th>Mean (SD) of composite score</th>
</tr>
</thead>
<tbody>
<tr>
<td>LJ</td>
<td>.893</td>
<td>35.4 (4.8)</td>
</tr>
<tr>
<td></td>
<td>Both interviewer and observer</td>
<td></td>
</tr>
<tr>
<td></td>
<td>.889</td>
<td>35.5 (4.5)</td>
</tr>
<tr>
<td></td>
<td>Just Interviewer</td>
<td></td>
</tr>
<tr>
<td></td>
<td>.896</td>
<td>35.3 (4.9)</td>
</tr>
<tr>
<td></td>
<td>Just observer</td>
<td></td>
</tr>
<tr>
<td>CM</td>
<td>.861</td>
<td>36.1 (4.3)</td>
</tr>
<tr>
<td></td>
<td>Both interviewer and observer</td>
<td></td>
</tr>
<tr>
<td></td>
<td>.872</td>
<td>36.0 (4.4)</td>
</tr>
<tr>
<td></td>
<td>Just Interviewer</td>
<td></td>
</tr>
<tr>
<td></td>
<td>.842</td>
<td>36.5 (4.1)</td>
</tr>
<tr>
<td></td>
<td>Just observer</td>
<td></td>
</tr>
</tbody>
</table>

6.2.2 Inter-rater reliability

In order to test for inter-rater reliability, a weighted kappa statistic was calculated on the composite score using MedCalc ver. 13.0.4.(211). Since the nurses alternated being the interviewer and the observer, a sensitivity analysis was conducted by calculating the weighted kappa under three different circumstances: 1) all of the scores recorded by one nurse (LJ) compared to all of the scores by the other nurse (CM), 2) scores of LJ as interviewer only compared to scores of CM as observer only, and 3) scores of CM as interviewer only compared to scores of LJ as observer only. The
Cronbach’s alpha for the 11-item scale was 0.893 (Nurse LJ) and 0.861 (Nurse CM). The following table illustrates the Cronbach’s alpha and absolute agreement for each nurse.

**Table 22: Cronbach’s alpha and absolute agreement for Nurse LJ and Nurse CM**

<table>
<thead>
<tr>
<th>Nurse</th>
<th>Cronbach’s Alpha</th>
<th>Absolute Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurse LJ</td>
<td>.893</td>
<td>.840</td>
</tr>
<tr>
<td>Nurse CM</td>
<td>.861</td>
<td>.792</td>
</tr>
</tbody>
</table>

In order to determine if the internal consistency was affected by the fact that the nurses alternated between interviewer and observer a sensitivity analysis was conducted. The following table displays the weighted kappa values (quadratic weights) and the intraclass correlation (consistency and agreement) for the composite score under the three conditions.

**Table 23: The weighted kappa values (quadratic weights) and the intraclass correlation (consistency and agreement) for the composite score under the three conditions.**

<table>
<thead>
<tr>
<th></th>
<th>Weighted Kappa</th>
<th>ICC Consistency</th>
<th>Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>LJ and CM all</td>
<td>0.657</td>
<td>.801</td>
<td>.794</td>
</tr>
<tr>
<td>CM Interviewer; LJ observer only</td>
<td>0.693</td>
<td>.824</td>
<td>.820</td>
</tr>
<tr>
<td>LJ Interviewer; CM observer only</td>
<td>0.584</td>
<td>.749</td>
<td>.739</td>
</tr>
</tbody>
</table>

According to Altman (212), a kappa value between 0.41 and 0.60 indicates moderate agreement and a value of 0.61 to 0.80 indicated good agreement. With these
results in mind, the remaining results use the composite scores for both Nurse LJ and Nurse CM.

The results of the one-factor confirmatory factor analysis conducted in MPlus are presented in this section. Results indicated that a single factor solution provided a borderline fit ($\chi^2$ goodness-of-fit test [df = 44] = 386.20, p = <.001; RMSEA = 0.160 with 90% confidence interval = 0.146-0.175; and CFI = 0.952). The RMSEA value is higher than 0.06 which, according to Hu and Bentler (209), is suggestive that the model does not adequately fit the data. However, the value for the CFI was 0.952 which is above the 0.95 suggested an acceptable value of fit.(209) Post-hoc examination of the modification indices did not uncover ways to modify the solution to improve the fit of the model.¹ Furthermore, all items loaded onto one factor in a satisfactory manner (see the unstandardized solution in table 24 the standardized solution in Figure 23). As a result, the 11 items were treated as a unidimensional scale.

Table 24: CFA model unstandardized coefficients and standard error

<table>
<thead>
<tr>
<th></th>
<th>Estimate</th>
<th>S.E.</th>
<th>Est./S.E.</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item 1</td>
<td>1.00</td>
<td>0.00</td>
<td>999.000</td>
<td>999.000</td>
</tr>
<tr>
<td>Item 2</td>
<td>0.89</td>
<td>0.07</td>
<td>13.58</td>
<td>0.000</td>
</tr>
<tr>
<td>Item 3</td>
<td>1.21</td>
<td>0.06</td>
<td>20.28</td>
<td>0.000</td>
</tr>
<tr>
<td>Item 4</td>
<td>1.27</td>
<td>0.06</td>
<td>21.60</td>
<td>0.000</td>
</tr>
<tr>
<td>Item 5</td>
<td>1.16</td>
<td>0.07</td>
<td>16.98</td>
<td>0.000</td>
</tr>
<tr>
<td>Item 6</td>
<td>1.01</td>
<td>0.06</td>
<td>16.32</td>
<td>0.000</td>
</tr>
<tr>
<td>Item 7</td>
<td>1.07</td>
<td>0.06</td>
<td>19.48</td>
<td>0.000</td>
</tr>
<tr>
<td>Item 8</td>
<td>1.28</td>
<td>0.06</td>
<td>21.00</td>
<td>0.000</td>
</tr>
<tr>
<td>Item 9</td>
<td>1.35</td>
<td>0.06</td>
<td>21.62</td>
<td>0.000</td>
</tr>
<tr>
<td>Item 10</td>
<td>1.20</td>
<td>0.06</td>
<td>21.14</td>
<td>0.000</td>
</tr>
<tr>
<td>Item 11</td>
<td>1.14</td>
<td>0.06</td>
<td>19.94</td>
<td>0.000</td>
</tr>
</tbody>
</table>

¹ Exploratory factor analyses were conducted to determine if removing any items (i.e items 2 and 7) would improve the fit of the model. The fit of the model (RMSEA) could not be improved by removing any items.
The following figure displays the structural equation model that was used.

Figure 23: Structural equation model displaying standardized estimates and residuals

![Structural equation model diagram]

\[ e = \text{error} \]
In order to determine if the CAIPS instrument is able to differentiate between participants who were under the influence of alcohol and/or drugs at the time of their study visit and those who were not under the influence of a substance, a Student’s t-test was conducted using the CAIPS composite score. The mean CAIPS composite score (for Nurse LJ) was 35.6 for those who were not under the influence and 35.3 for those who were under the influence (p=0.617). Similar non-significant results were found for Nurse CM. A subgroup analysis was conducted to determine if the mean composite score (from Nurse LJ) for those who were under the influence of alcohol (with or without drugs) was significantly different from the mean composite scores for those who were not under the influence of alcohol. The results showed a significant difference (mean 33.6 vs 35.6 respectively; p=0.022) between these two groups. Similar significant results were seen with the composite scores for Nurse CM. A second subgroup analysis was conducted to determine if participants who had symptoms of mental illness at the time of their study visit had lower composite scores than those without mental illness. This analysis (using composite scores from Nurse LJ) showed no significant difference between those who had mental illness and those who did not (mean 35.7 vs 36.00 respectively; p=0.605). Similar non-significant results were seen using composite scores from Nurse CM.

6.2.3 Determination of a threshold score, sensitivity and specificity of CAIPS

6.2.3.1 Psychiatric Assessment

The following ROC curve illustrates the relationship between the psychiatric assessment of capacity and the CAIPS composite score from Nurse LJ. The area under the curve is 0.763 (95% CI: 0.68 – 0.851) which is above the cut-off of 0.75 indicating a
Using the composite score from Nurse CM, the area under the curve is 0.769 (95% CI: 0.68 – 0.86).

**Figure 24: Receiver operator characteristic curve showing accuracy of CAIPS instrument with the psychiatric assessment of capacity used as the gold standard.**

The following table displays the balance between sensitivity and specificity that can be used to determine a threshold score using the psychiatric assessment as the gold standard. The goal of the new scale is to identify the true negatives (people who truly do not have CTC-HC) while minimizing the number of people who would falsely be identified as lacking capacity (false negatives). In other words we would be willing to have a lower specificity with a higher sensitivity so that if misclassification error occurs,
we would err on the side of not denying people the right to provide consent for themselves. A threshold of 32 or 33 was considered a reasonable cut-off.

Table 25: CAIPS scores and corresponding sensitivities and specificities (psychiatrist as gold standard)

<table>
<thead>
<tr>
<th>Score</th>
<th>Nurse LJ</th>
<th></th>
<th>Score</th>
<th>Nurse CM</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sensitivity</td>
<td>Specificity</td>
<td>Sensitivity</td>
<td>Specificity</td>
</tr>
<tr>
<td>19.0</td>
<td>1.000</td>
<td>.000</td>
<td>21</td>
<td>1.00</td>
</tr>
<tr>
<td>21.0</td>
<td>1.000</td>
<td>.025</td>
<td>22.5</td>
<td>.996</td>
</tr>
<tr>
<td>22.5</td>
<td>1.000</td>
<td>.050</td>
<td>23.5</td>
<td>.996</td>
</tr>
<tr>
<td>23.5</td>
<td>1.000</td>
<td>.100</td>
<td>24.5</td>
<td>.992</td>
</tr>
<tr>
<td>24.5</td>
<td>.996</td>
<td>.175</td>
<td>25.5</td>
<td>.988</td>
</tr>
<tr>
<td>26.0</td>
<td>.996</td>
<td>.200</td>
<td>26.5</td>
<td>.988</td>
</tr>
<tr>
<td>27.5</td>
<td>.988</td>
<td>.300</td>
<td>27.5</td>
<td>.984</td>
</tr>
<tr>
<td>28.5</td>
<td>.969</td>
<td>.350</td>
<td>28.5</td>
<td>.976</td>
</tr>
<tr>
<td>29.5</td>
<td>.965</td>
<td>.400</td>
<td>29.5</td>
<td>.960</td>
</tr>
<tr>
<td>30.5</td>
<td>.922</td>
<td>.450</td>
<td>30.5</td>
<td>.956</td>
</tr>
<tr>
<td>31.5</td>
<td>.845</td>
<td>.575</td>
<td>31.5</td>
<td>.937</td>
</tr>
<tr>
<td>32.5</td>
<td>.756</td>
<td>.625</td>
<td>32.5</td>
<td>.881</td>
</tr>
<tr>
<td>33.5</td>
<td>.674</td>
<td>.650</td>
<td>33.5</td>
<td>.813</td>
</tr>
<tr>
<td>34.5</td>
<td>.605</td>
<td>.750</td>
<td>34.5</td>
<td>.750</td>
</tr>
<tr>
<td>35.5</td>
<td>.535</td>
<td>.775</td>
<td>35.5</td>
<td>.655</td>
</tr>
<tr>
<td>36.5</td>
<td>.484</td>
<td>.850</td>
<td>36.5</td>
<td>.567</td>
</tr>
<tr>
<td>37.5</td>
<td>.422</td>
<td>.850</td>
<td>37.7</td>
<td>.508</td>
</tr>
<tr>
<td>38.5</td>
<td>.329</td>
<td>.850</td>
<td>38.5</td>
<td>.361</td>
</tr>
<tr>
<td>39.5</td>
<td>.256</td>
<td>.875</td>
<td>39.5</td>
<td>.246</td>
</tr>
<tr>
<td>40.5</td>
<td>.182</td>
<td>1</td>
<td>40.5</td>
<td>.163</td>
</tr>
<tr>
<td>41.5</td>
<td>.109</td>
<td>1</td>
<td>41.5</td>
<td>.095</td>
</tr>
<tr>
<td>42.5</td>
<td>.074</td>
<td>1</td>
<td>42.5</td>
<td>.048</td>
</tr>
<tr>
<td>43.5</td>
<td>.043</td>
<td>1</td>
<td>43.5</td>
<td>.012</td>
</tr>
<tr>
<td>45.0</td>
<td>.000</td>
<td>1</td>
<td>45.0</td>
<td>.000</td>
</tr>
</tbody>
</table>

6.2.3.2 MacCAT-T Assessment

The following ROC curve illustrates the relationship between the MacCAT-T assessment of capacity and the CAIPS composite score. The area under the curve using data from Nurse LJ is 0.729 which is below the 0.75 cut-off that indicates a useful test.
The area under the curve using data from Nurse CM is 0.770 which is above the 0.75 cut-off indicating a useful test.

**Figure 25:** Receiver operator characteristic curves showing accuracy of the CAIPS instrument with the MacCAT-T assessment of capacity used as the gold standard.

The following table displays the balance between sensitivity and specificity that can be used to determine a threshold score using the MacCAT-T binary score as the gold standard. According to the table below a threshold of 33 (midpoint between both nurses) was considered a reasonable cut-off.
Table 26: CAIPS scores and corresponding sensitivities and specificities using MacCAT-T as the gold standard.

<table>
<thead>
<tr>
<th>Score</th>
<th>Nurse LJ</th>
<th></th>
<th>Score</th>
<th>Nurse CM</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sensitivity</td>
<td>Specificity</td>
<td></td>
<td>Sensitivity</td>
</tr>
<tr>
<td>19</td>
<td>1.000</td>
<td>.000</td>
<td>21</td>
<td>1.000</td>
</tr>
<tr>
<td>21</td>
<td>1.000</td>
<td>.011</td>
<td>22.5</td>
<td>1.000</td>
</tr>
<tr>
<td>22.5</td>
<td>1.000</td>
<td>.022</td>
<td>23.5</td>
<td>1.000</td>
</tr>
<tr>
<td>23.5</td>
<td>1.000</td>
<td>.043</td>
<td>24.5</td>
<td>1.000</td>
</tr>
<tr>
<td>24.5</td>
<td>1.000</td>
<td>.086</td>
<td>25.5</td>
<td>1.000</td>
</tr>
<tr>
<td>25.5</td>
<td>1.000</td>
<td>.097</td>
<td>26.5</td>
<td>1.000</td>
</tr>
<tr>
<td>26.0</td>
<td>1.000</td>
<td>.161</td>
<td>27.5</td>
<td>.995</td>
</tr>
<tr>
<td>27.5</td>
<td>.990</td>
<td>.215</td>
<td>28.5</td>
<td>.990</td>
</tr>
<tr>
<td>28.5</td>
<td>.986</td>
<td>.237</td>
<td>29.5</td>
<td>.985</td>
</tr>
<tr>
<td>29.5</td>
<td>.942</td>
<td>.290</td>
<td>30.5</td>
<td>.970</td>
</tr>
<tr>
<td>30.5</td>
<td>.870</td>
<td>.409</td>
<td>31.5</td>
<td>.926</td>
</tr>
<tr>
<td>31.5</td>
<td>.797</td>
<td>.516</td>
<td>32.5</td>
<td>.866</td>
</tr>
<tr>
<td>32.5</td>
<td>.729</td>
<td>.602</td>
<td>33.5</td>
<td>.812</td>
</tr>
<tr>
<td>33.5</td>
<td>.667</td>
<td>.699</td>
<td>34.5</td>
<td>.723</td>
</tr>
<tr>
<td>34.5</td>
<td>.589</td>
<td>.731</td>
<td>35.5</td>
<td>.639</td>
</tr>
<tr>
<td>35.5</td>
<td>.531</td>
<td>.774</td>
<td>36.5</td>
<td>.574</td>
</tr>
<tr>
<td>36.5</td>
<td>.459</td>
<td>.785</td>
<td>37.5</td>
<td>.401</td>
</tr>
<tr>
<td>37.5</td>
<td>.367</td>
<td>.839</td>
<td>38.5</td>
<td>.297</td>
</tr>
<tr>
<td>38.5</td>
<td>.295</td>
<td>.892</td>
<td>39.5</td>
<td>.203</td>
</tr>
<tr>
<td>39.5</td>
<td>.208</td>
<td>.957</td>
<td>40.5</td>
<td>.124</td>
</tr>
<tr>
<td>40.5</td>
<td>.130</td>
<td>.989</td>
<td>41.5</td>
<td>.059</td>
</tr>
<tr>
<td>41.5</td>
<td>.087</td>
<td>.989</td>
<td>42.5</td>
<td>.015</td>
</tr>
<tr>
<td>42.5</td>
<td>.048</td>
<td>.989</td>
<td>43.5</td>
<td>.000</td>
</tr>
<tr>
<td>43.5</td>
<td>.000</td>
<td>1.000</td>
<td>44.5</td>
<td>.000</td>
</tr>
<tr>
<td>44.5</td>
<td>.000</td>
<td>1.000</td>
<td>45.0</td>
<td>.000</td>
</tr>
</tbody>
</table>

6.2.4 Determining external content validity of the new instrument by comparing it to two gold standards

The unweighted kappa statistic calculated to determine the correlation between the psychiatrist’s binary decision related to CTC-HC (yes/no) and the binary assessment of capacity using a threshold of 33 was 0.253 (fair agreement) using Nurse LJ’s data and .375 (fair agreement) using Nurse CM’s data.
The unweighted kappa calculated to determine the correlation between the MacCAT-T binary decision related to CTC-HC (yes/no) and the composite score for the CAIPS instrument (with threshold of 33) was 0.316 (fair agreement) using Nurse LJ’s data and 0.378 (fair agreement) using CM’s data.

Finally, the following table displays the number and proportion of participants that were assessed as having capacity and lacking capacity for the MacCAT-T instrument, the CAIPS and the psychiatric assessment.

Table 27: The number and proportion of participants that were assessed as having capacity and lacking capacity for the MacCAT-T instrument, the CAIPS and the psychiatric assessment

<table>
<thead>
<tr>
<th>Psychiatric Assessment</th>
<th>Has Capacity</th>
<th>Lacks Capacity</th>
<th>Missing</th>
</tr>
</thead>
<tbody>
<tr>
<td>MacCAT-T</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Understanding Domain</td>
<td>218 (72%)</td>
<td>84 (28%)</td>
<td>0</td>
</tr>
<tr>
<td>Reasoning Domain</td>
<td>272 (90%)</td>
<td>30 (10%)</td>
<td>0</td>
</tr>
<tr>
<td>Appreciation Domain</td>
<td>277 (92%)</td>
<td>25 (8%)</td>
<td>0</td>
</tr>
<tr>
<td>Overall</td>
<td>208 (68.9%)</td>
<td>94 (31.1%)</td>
<td>0</td>
</tr>
<tr>
<td>CAIPS (11-item; threshold 33)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurse LJ</td>
<td>210 (69%)</td>
<td>90 (35.7%)</td>
<td>2 (.7%)</td>
</tr>
<tr>
<td>Nurse CM</td>
<td>242 (80.1%)</td>
<td>53 (17.5%)</td>
<td>7 (2.3%)</td>
</tr>
</tbody>
</table>

6.3 Summary

The validation portion of this dissertation involved a sample of participants who misused drugs and/or alcohol, half of which (at least) were under the influence of a substance during their study visit. In addition, one fourth of the sample had symptoms of mental illness at the time of their study visit. According to the psychiatric assessment, a large majority (259 [86%]) had the CTC-HC, suggesting that individuals who are under the influence of drugs and/or alcohol may have CTC-HC regardless of their substance
use. According to the MacCAT-T assessment, a slightly lower percentage (69%) of participants had the CTC-HC.

The psychometric analyses were conducted for CAIPS. The weighted kappa values measuring the level of agreement between Nurse LJ and Nurse CM was 0.66 indicating good agreement. Intraclass correlation for consistency and agreement was also good between these two nurses (0.79). An examination of the inter-item correlation indicated good correlation between items and the item-total analysis indicated that each item correlated well with the scale total score. In addition, Cronbach’s alpha was between 0.86 – 0.89 indicating excellent internal consistency. These data suggest that CAIPS has good reliability.

A confirmatory factor analysis revealed a single factor among the 11 CAIPS items. Several tests were conducted to evaluate the validity of CAIPS. The mean score for participants who were under the influence of a substance at the time of the study visit (according to the psychiatrist’s assessment) was not statistically different than those who were not under the influence at the time of their study visit. However, participants who were under the influence of alcohol (with or without drugs and mental illness) (n=29) had a significantly lower CAIPS score than all other participants. This is consistent with what nurses reported in the qualitative phase of this dissertation (IMSH who misuse alcohol are more likely to lack CTC-HC that those who misuse drugs). There was no significant difference in CAIPS score between participants with mental illness (with or without drug and alcohol use) and those without mental illness.

Two ROC curves were constructed to evaluate CAIPS instrument against the two gold standards (psychiatric assessment and MacCAT-T assessment). Three out of the four
area under curve calculations are over the 0.75 cut-off indicating a useful test. The sensitivity and specificity tables associated with the points on each ROC curves were used to examine the best balance between sensitivity and specificity in order to determine a diagnostic threshold. These values varied depending on the gold standard that was used and which nurse the data was collected from. It was decided that a cut-off of 33 on CAIPS was a reasonable threshold that can be used to differentiate individuals who have capacity and individuals who do not. Using this cut-off value the CAIPS assessment identified approximately the same proportion of participants lacking capacity as the MacCAT-T assessment did. However, the kappa statistics that were conducted to determine how well the CAIPS results agreed with both the gold standards showed only fair agreement suggesting that the CAIPS appears to have poor criterion validity.
7 DISCUSSION

The research included in this dissertation has filled an important gap in the literature. The CAIPS instrument that has been developed includes instructions for the clinician, an 11 item scale and definitions of terms. The scale includes the following items:

1. The client is able to repeat back, in their own words, the main side effects/potential complications of the intervention that is being offered to them.

2. The client made their decision about the medical intervention without external pressure or coercion.

3. The client is orientated to person, place, and time or, if disoriented, it does not have a direct bearing on the medical intervention being offered.

4. The client can engage in the form of communication that they normally use excluding a physical difficulty in speaking or use of foreign language not understood by the nurse.

5. The client is able to follow simple verbal or written instructions.

6. The client is experiencing symptoms of distorted reality and these symptoms have a direct bearing on the intervention proposed.

7. The client knows that he/she is either at risk of an illness or has an illness and therefore requires clinical care.

8. The client is able to use the information given to them about the intervention to form a decision about consenting to the intervention or refuse the intervention.
9. The client is able to verbally or physically indicate a choice.

10. While offering care to a client he/she seems to be distracted by friends, other activities, and/or symptoms of withdrawal.

11. There are physical indications that the client may have recently used drugs or alcohol.

Numerous instruments have been developed to assess capacity to consent for both research purposes and treatment among individuals who suffer from psychiatric illnesses such as Alzheimer’s disease, dementia, schizophrenia, depression, etc., particularly in the elderly. The need for an instrument to assess CTC-HC in these populations stems from the fact that mental illnesses often require medical interventions that have significant, associated risks. Clinicians strive to offer care in ethical, moral, and legal ways by respecting their clients’ rights to consent for care. However, they have a responsibility to ensure that their clients have the CTC-HC which is something that many clinicians find challenging. Among instruments available to assist with assessing CTC-HC, the MacCAT-T is psychometrically sound and is the most widely used.

Despite the extensive availability of instruments available to assess capacity to consent in mental illness patients, there is a paucity of instruments available to assess capacity to consent for individuals who may lack capacity for other reasons. To my knowledge, no instrument has been developed that assess CTC-HC among IMSH. While this is important for anyone who uses drugs or alcohol, it is a particularly salient problem among individuals who are homeless or who are unstably housed as this population is particularly vulnerable to coercion and manipulation, making them susceptible to
receiving care that they do not want. They are also vulnerable to being refused care that they are requesting.

Stimulants, such as cocaine and crystal methamphetamine, can affect a person’s CTC-HC as they can cause drug induced paranoia, mental confusion, impaired ability to be attentive (impacting decision making), and poor judgement. Depressants, such as opiates, sedatives, and alcohol can impact CTC-HC as they can lower inhibition and dull the mind, leave people with less ability to comprehend what is being said to them and possibly making them more likely to agree to something they might not agree to if they were not under the influence of a depressant. Finally, psychedelics, such as ecstasy and marijuana can impair capacity, as they can induce confused perceptions, impaired concentration, loss of judgment and impaired memory. While many of these effects are similar to symptoms found in mental illness, they are more transient in nature than most mental illnesses, and therefore CTC-HC can vary in short periods of time. The effects of all of these substances point to the need for a capacity assessment instrument that can be made available to clinicians to assist their clinical judgment about their clients’ CTC-HC.

Through an examination of the existing capacity assessment instruments and the formative (qualitative) phase of this research, concepts were identified for possible inclusion into our CAIPS instrument aimed at assessing CTC-HC among IMSH. The final instrument consists of 11 items, six of which are concepts that were previously described and used in other instruments (understanding, appreciation, reasoning, voluntariness, orientation, and expression of choice), and five items that covered concepts that have not been used in previous instruments (ability to engage in communication, sustained attention, decision making demands, physical indication of
substance use and distorted reality). The latter are unique and particularly useful to nurses practicing in low threshold clinics or areas where IMSH congregate. This may explain why the results of the correlation tests comparing the CAIPS to the MacCAT-T instrument conducted during the validation phase of the research were lower than expected.

The validation phase of this research involved an important collaboration with VANDU. This collaboration provided the opportunity to design the demographic questionnaire and recruitment methods in a culturally appropriate way. In addition, having members of VANDU as part of the research team created a milieu of credibility in which participants felt comfortable with the goals of the research and the study team. Although the involvement of IMSH on the research team created some challenges (e.g., peers not showing up to work, showing up to work while under the influence of a substance), the benefits, such as mutual knowledge sharing, far outweighed the challenges. Finally, while conducting the validation phase of the research, the research team was able to play an important public health role in educating community members of the DTES about the flu and the flu shot. This was especially valuable as the study was being conducted during flu season.

7.1 Interpretation of Findings

The sample of participants in the study was largely male, aboriginal, with low educational levels living on disability income. This is consistent with the demographic described by the Urban Health Research Initiative (UHRI) of the BC Centre for Excellence in HIV/AIDS with the exception of the proportion of Aboriginal participants.
The UHRI report 30% of participants of their four cohort studies are aboriginal (71) where the research in this dissertation consisted of 49% Aboriginal participants. This may have resulted in a study population with increased stigmatization. However, the impact of this over-representation is likely minimal as all of the participants were stigmatized due to their substance use.

Seventy percent of participants using drugs had taken a substance within 5 hours of their study visit. Fifty percent of participants reported using a substance within one hour of their study visit. This was due, in part, to the fact that a number of participants enrolled in the study after using VANDU’s injection room up until January 6, 2014. The injection room was closed down after this point; otherwise the percentage of participants having used drugs within one hour of their study visit may have been higher.

According to the psychiatric assessment, 85% of participants were deemed as having CTC-HC. Twenty-eight percent of participants who were under the influence of alcohol (with or without drugs and/or mental illness), lacked capacity. This is compared to 8.9% lacking capacity while under the influence of drugs (with or without alcohol and/or mental illness) and 18.9% lacking consent among those who had symptoms of mental illness (with or without drug and/or alcohol use). These findings suggest that individuals who misuse alcohol are more likely to lack CTC-HC during a clinical encounter than those who misuse drugs or who have mental illness. These findings also validated what the nurses and the clients talked about during the qualitative phase of the research (see Chapter 3).

According to the MacCAT-T assessments, a lower proportion of participants (68%) lacked CTC-HC during their study visit. Possible reasons for this discrepancy
(between MacCAT-T and the psychiatric assessment) are two-fold. Firstly, the dichotomous allocation of capacity or no capacity for the MacCAT-T instrument was based on a method that was not used in any of the MacCAT-T validation studies and has only been used twice subsequent to the MacCAT-T being validated. Another explanation for the discrepancy may be that the MacCAT-T was designed for and validated in populations with mental illness and therefore may not have been as accurate when using it to measure capacity among people with problematic substance use. In addition, although the majority of capacity assessment instruments used a psychiatrist as their gold standard, it may have been better to use an expert in addictions and mental health as a gold standard.

The CAIPS assessment consisted of administering the instrument via an interview with the participant. An observer sat nearby scoring the participant without interacting with him/her to assess inter-observer reliability. Most studies utilize an observer with only a small subsample of the study population and therefore do not include the observer scores for anything other than reason. However, in my validation study, there was an observer for all participants. This raised questions about whether the remaining psychometric analyses should be done with data just from the interviewer, just the observer or both the interviewer and observer. This complication was compounded by the fact that the nurses alternated between being the interviewer and observer. For this reason, sensitivity analyses were conducted. A sensitivity analysis was conducted to determine if there was a difference in internal consistency under various circumstances (each nurse being interviewer and observer, just interviewer and just observer) (see table 18). The results showed high internal consistency in all cases.
Although the level of agreement and level of consistency were similar in various circumstances, I chose to present the remaining results using the composite score for both Nurse LJ and Nurse CM because mean composite scores were significantly different between nurses.

The factor analysis that was conducted produced a model with questionable fit (the RMSEA indicated poor fit, but the CFI indicated good fit). However, the items loaded onto one factor in a satisfactory manner and the modification indices suggest there were no weaknesses in the model.

It is important to note that this instrument should be used in conjunction with other nursing assessments during the encounter. In addition the threshold of 33 is meant to be a guideline only. Training nurses to use the instrument should involve a discussion about the fact that items with legal and ethical implications may have to be given more weight in their decision making process. For instance, a client may score a “0” on the items involving understanding but score high on all the items. Since understanding is a major element of the legal definition of informed consent, the client should be assessed as not having consent even though the composite CAIPS score is above 33.

7.1.1 Validity

A number of other studies aimed at validating a new instrument (98;101;102;105;106;214) include two groups of participants: one group with participants that have the characteristic being measured and one group without the characteristic. Their reason for doing so was to show that their new instrument was able to differentiate between levels of capacity among participants who had the characteristic and those who did not. For example, Grisso and Appelbaum(92;208) validated the Understanding
Treatment Disclosures (UTD), Thinking Rationally About Treatment (TRAT), and the Perceptions of Disorder (POD) instruments (which ultimately became the MacCAT-T instrument), in a sample of patients with schizophrenia, depression, and ischemic heart disease. By doing this, they were able to demonstrate that participants with ischemic heart disease (without mental illness) had higher scores (indicating higher levels of capacity) than participants with schizophrenia and depression. Not all researchers developing a psychometric instrument used a comparison group.\(^\text{100;113;127}\) to validate their instrument. In the validation portion of the CAIPS instrument, the inclusion criteria allowed for people who were not under the influence of a substance to participate in the study. This provided two groups: those who were under the influence of a substance at the time of their study visit and those who were not under the influence at the time of their study visit (all other factors being relatively equal). However, when the overall CAIPS scores were compared between those who were under the influence (with or without mental illness) and those who were not under the influence (with no mental illness), no statistical significance was detected. This may be because participants may have been suffering from long term (residual) effects of substance use (alcohol, drugs, and methadone) affecting executive functioning, not just when under the influence of a substance, but also when they are not under the influence of a substance.\(^\text{215-220}\) In hindsight, it may have been important to include a comparison group who were had similar socio-economic status but who were did not misuse drugs or alcohol.

In order to examine criterion and convergence validity, the CAIPS composite scores were plotted against each of the two gold standards (psychiatric assessment and MacCAT-T assessment) using an ROC curve. In both cases (CAIPS vs psychiatrist
AUC=0.76; CAIPS vs MacCAT-T AUC=0.72 – 0.77) the areas under the curves were above the standard cut-off of 0.75 indicating a clinically useful test. One possible reason that the CAIPS did not align closer to the gold standards is that it actually measures concepts that relate to substance use rather than mental illness (as in the case in the MacCAT-T which was designed and validated for use in patients with mental illness). Streiner and Norman (151) raise an interesting point. They state that while a new index of a construct should correlate with other measure of the construct, “it should not be overly high if we believe that our new scale covers components of the trait not tapped by the existing ones”(page 262). In other words, it is possible that the CAIPS scale does not correlate well with other measures because it is measuring capacity in populations with substance use, reinforcing the need for my new instrument.

Finally, the correlation values between the gold standards and the CAIPS instrument may have resulted from the diagnostic threshold that I chose based on the best balance between sensitivity and specificity. From an ethical perspective, I chose to have a threshold that would provide higher sensitivity while sacrificing specificity. I did this because I felt it was more ethically sound to minimize the chances of clients being refused the right to consent for themselves, (due to a false negative CAIPS result), while increasing the risk of giving them the chance to consent for themselves when they may not have capacity (false positive CAIPS result). This approach may be satisfactory when the risks associated with the health care intervention are low and the benefits are high (e.g., receiving a flu shot). However, when the risks associated with the intervention are high (with low or high benefits), then it may be better to have lower sensitivity and higher specificity, thus raising the diagnostic threshold (cut-off).
7.2 Limitations

There a number of limitations to the validation phase of this dissertation. First and foremost, study participants mainly lived in the DTES and therefore the findings may not be generalizable and the instrument may not be useful in other settings. However, the instrument was developed utilizing input from nurses and IMSH around the province and therefore I have reason to believe that it would be applicable in other settings. Moreover, there was no way of validating what participants reported to us about whether they were homeless/unstably housed or not. Therefore it is possible we may have included people who did not meet the inclusion criteria.

Secondly, the analyses were complicated by the fact that the nurses took turns being the interviewer and the observer. This is problematic because interacting with the participant may increase the nursing intuition portion of the decision-making process or the observer may have wanted to ask more questions in order to make her decision but was unable to do so because of the “observer” role. Therefore combining all scores from the same nurse into a composite score may have underestimated the CAIPS score. This may have contributed to the disparity between the CAIPS score and the psychiatric assessment of capacity.

Next, the validation study involved a “flu vaccine” scenario. Some may argue that the instrument might only be useable in clinical encounters where the flu vaccine is the intervention being offered. However, numerous other instruments were developed using specific interventions or vignettes. (94;98;101) The CAIPS scale utilizes nursing assessment skills and, although the items were the same for all participants, the wording
of the items was incorporated in a way that mirrored a typical nursing encounter. Therefore, the assessment wasn’t really about the flu and flu shot; it was more about how well participants could demonstrate specific capacities. In addition, validating the CAIPS instrument using a flu vaccine vignette may have produced spurious results. Participants may have scored higher if their ability to pay attention to the description of the risks and benefits would have been higher; for example, if they were discussing a health condition that was of real concern.

In addition, the order in which the participants were assessed may have influenced the participant’s ability to answer questions. I was particularly aware of the fact that the MacCAT-T script involved a flu shot vignette which was similar to what was discussed with the CAIPS assessment. Therefore the order of these assessments was alternated weekly. However, the psychiatric assessment always went first. It is possible that the psychiatric assessment influenced how the participants answered questions in the MacCAT-T and CAIPS assessments, but this was not measureable.

Finally, the mean CAIPS composite score was not different between participants that, according to the psychiatrist’s opinion, were not under the influence of a substance and those who were under the influence of a substance at the time of their study visit for all participants. However, the results showed that participants who were under the influence of alcohol (with or without drugs) had less CTC-HC than participants who were under the influence of drugs or not under the influence of anything. Having said that, the number of participants who used alcohol was smaller than desired, so the ability to feel confident about this finding is limited.
7.3 Future Research

This dissertation has produced a unidimensional capacity assessment scale that can be used to assess capacity among IMSH. However, this scale has been validated with veteran outreach nurses in a population largely from a single community organization (providing services to people who are addicted to substances). Further research is required to determine if this scale maintains good psychometric properties under the following circumstances:

a) using nurses who are new to the profession and/or who are unfamiliar with delivering care to IMSH;

b) using other health care professionals such as physicians and paramedics; and

c) using the instrument in a real-life setting such as a public health clinic providing care to IMSH.
REFERENCES


(10) Stanbrook MB. Addiction is a disease: we must change our attitudes toward addicts. CMAJ 2012 Feb 7;184(2):155.


Ref Type: Online Source


(24) Centre for Applied Research in Mental Illness and Addiction. Housing and supports for adults with severe addictions and/or mental illness in BC. 2007. Available online on 4 Aug. 2014 at


(36) Palepu A, Tyndall M, Yip B, O'Shaughnessy MV, Hogg RS, Montaner JS. Impaired virologic response to highly active antiretroviral therapy associated


Ref Type: Online Source


(64) The Street Outreach Program of the BC Centre for Disease Control, The National Film Board of Canada, Directed by Nettie Wild. Bevel Up: Drugs, users and outreach nursing. Caroline Brunt, Fiona Gold, Liz James, Elaine Jones, Janine Stevenson, editors. 2007. Vancouver, BC.

Ref Type: Motion Picture


(131) Molloy DW, Standish TI. A guide to the standardized Mini-Mental State Examination. Int Psychogeriatr 1997;9 Suppl 1:87-94.


(136) Choynowski M. Skala pomieci (Memory Scale). Warsaw: Polish Academy of Sciences, Psychometric Laboratory; 1959.


(167) Thorne S. Interpretive Description. Walnut Creek, California: Left Coast Press; 2008.


(204) Johnathan Fleming. Psychiatric Assessment Framework. 12-1-2013. Ref Type: Personal Communication


APPENDIX A: Interview guide for qualitative interview with nurses

The purpose of this study is to explore the current methods that clinicians use to assess whether their clients have impaired judgment (due to alcohol use, drug use, ) and thus lack capable to consent for health care.

In this study, consent is being defined as an individual’s ability to verbally express a free choice about whether they agree to or refuse medical care provided they understand the risks and benefits.

This interview will take approximately 30 minutes although you may stop earlier if you would like.

1. Can you describe the clients you provide care to?

*Probes:*
- Approximately what proportion of them use illicit drugs? What proportion abuse alcohol? What proportion have a mental health condition? What proportion of them have a mental health illness and abuse drugs/alcohol? Is there a proportion of people you deliver care to who do not use drugs/alcohol or have mental health issues? This is meant to be your best estimate.

2. Can you tell me some of the things you consider when you would like to offer health care to a client that is street involved (i.e. homeless or in unstable housing)?

*Probes:*
- Can you tell me about any experiences that you may have had where you have provided care to someone who has been under the influence of alcohol and/or drugs? Can you tell me about how you can tell that they are under the influence? Can you give me an example of this?
- Can you tell me about the assessments you make when you are planning to provide care to individuals who may be under the influence of drugs or alcohol?

3. Can you tell me about your understanding about delivering health care and patient consent?
Probes:

- What, if any, are the challenges associated with getting patients’ permission for clinical care with people who are street involved?
- Can you tell me of any experience that you may have had when you were faced with an ethical dilemma regarding getting consent from a client? What factors did you consider? How did you decide what to do? Thinking back would have done anything different?
- Can you tell me if there are any professional guidelines that you consider when you are planning to care for someone who is under the influence of alcohol or drugs?
- Some clinicians may face an ethical dilemma when faced with clients who lack capacity to consent but who may spread a communicable disease to other people in the community. Have you ever experienced this type of dilemma? If so, can you describe the situation and the decision-making process you used to come to a final decision to provide care or not provide care.
- Have you ever had a situation where someone under the influence of alcohol or drugs refused the care you were offering them? Can you tell me about that? How did you handle this?

4. Can you tell me about which of your clients are the most difficult to assess capacity to consent?

Probes:

- Are clients who are high on drugs or alcohol more difficult than those who are withdrawing or coming down from a high?
- Are clients on certain types of drugs easier to assess than those on other types of drugs (i.e. a client on crack compared to a different client on heron)?
- Which of the clients with mental health illnesses are most difficult to assess? Are clients with psychosis more difficult to assess than those with depression?

5. Under some circumstances you may decide that a client has partial impairment but is still capable of providing informed consent. Can you tell me how you decided how much impairment is too much?

6. Is there anything that you can think of that would help you when you are faced with ethical dilemmas about patient consent? Can you describe what guidance would be good and what guidance would not be good?

Is there anything else you would like to say or suggest about this topic?
APPENDIX B: Interview guide for qualitative interview with clients

1. Can you please start by telling me a little about yourself?

   **Probes:**
   - How old are you? Where are you from? How long have you been living in Vancouver? What does a typical day look like for you?
   - Are you currently employed? Do you have a place that you pay rent for? If yes, what kind of accommodation is it? Do you usually sleep there? If no, where do you usually sleep?
   - If you do not have a place you pay rent for, when was the last time that you did?
   - Have you ever been to a health clinic? If yes, what were some of the main reasons you went to this (these) clinics?
   - Have you ever received any assistance for what you would consider to be an addiction? If yes, what type of assistance did you receive?

2. If you feel comfortable discussing this, can you tell me about your current alcohol and/or drug use?

   **Probes:**
   - How often do you use alcohol? How often do you use drugs? (every day, several times a day?) How long have you been using alcohol? How long have you been using drugs? Which, if any, do you use more often? Can you tell me what kind of drugs you use (injection and non-injection drugs).
   - What would you consider to be the main reasons for your use of alcohol and/or drugs? Are there any particular circumstances that might make you drink or do drugs more often than how much you would usually use? Can you please tell me a little more about that?

3. How does your alcohol use affect the way you are able to make decisions about how you take care of yourself if at all? Can you please tell me more about this?

   **Probes:**
   - Can you please tell me about any experience that you have had when you have used alcohol and forgot to do things you would normally do? (i.e. go to get your welfare cheque)
   - Can you please tell me about any experience that you have had when you have used alcohol and lost consciousness when you cannot remember what happened to you?
   - Can you please tell me about any experience that you have had when you used alcohol and it affected the way you have understood what someone has said to you? Can you please tell me about any experience that you have had when
your use of alcohol has affected the period of time you were able to recall what someone has said to you?

4. How does your use of drugs affect the way you are able to make decisions about how you take care of yourself, if at all? Can you please tell me more about this?

**Probes:**
- Can you please tell me about any experience that you have had when you have used drugs and forgot to do things you would normally do? (i.e. go to get your welfare cheque; forget to meet up with a friend)
- Can you please tell me about any experience that you have had when you have used drugs and lost consciousness where you cannot remember what happened to you?
- Can you please tell me about any experience that you have had when you have used drugs and it affected the way you have understood what someone has said to you? Can you please tell me about any experience that you have had when you use of drugs affected the period of time you were able to recall what someone has said to you?

5. Where do you go when you need to access health care? What is that experience like for you?

**Probes:**
- Do you prefer to go to clinics or hospitals or other facilities? Why? Do you access health care from the street nurses? In which parts of the city are the facilities located (where you usually access health care)?
- If you feel comfortable answering this question, what health concerns have you had over the past year? Where did you seek medical treatment for these?
- Can you please tell me about any experiences that you have sought health care when you have been using alcohol and/or drugs?
- When health care providers such as doctors or nurses provide you with health care how much are you able to understand about the care they want to provide to you? How you do feel about the information that is being provided to you? Is it too much, too little? What kinds of information do you think are most important for you to be provided for you to be able to decide if you want any particular medical treatment or not? When health care providers discuss the risks and benefits of any medical treatment with you how much are you able to understand about the care they want to provide you? What, if anything, would you recommend to them in order to improve your understanding of the care they want to provide?
- Are you always able to get the health care that you are wanting to receive? (i.e. Have you ever been refused health care? If yes, can you please tell me more about this experience?)
- Have you ever received medical care that you didn’t really want? If so, can you please describe this situation? Were you asked about whether you wanted
the medical care or not? Have you ever refused medical care but it was still provided for you? What was that like for you?

6. Can you please tell me about any experience that you have had when you were under the influence of drugs or alcohol and were required to undergo a medical procedure:

Probes:

- Can you please tell me if you think that there is a difference in your ability to make sound decisions when you are not using alcohol compared to when you are using alcohol?
- Can you please tell me if you think that there is a difference in your ability to make sound decisions when you are not using drugs compared to when you are using drugs?

7. Can you please tell me a little bit about how you feel when you are seeking health care and communicating with a health care provider, whether it is a doctor or nurse or any other type of health care provider?

Probes:

- In these situations are you able to communicate clearly to the health care providers what it is you need in terms of the health care you want? How responsive are health care providers to your needs?
- How does your use of alcohol and/or drugs affect the way your health care provider (doctor, nurse or other) treats you, if at all? Can you tell me how this affects your ability to make your own decisions about your health care?
APPENDIX C: Consent form for qualitative interview with nurses

Consent Form: Clinician Interview

Research study title: A tool to assess decisional capacity to consent for clinical care

Principal Investigator: Dr. Gina Ogilivie, Medical Director, Clinical Prevention Services, BC Centre for Disease Control

Co-Investigators: Dr. Michael Rekart, Juanita Maginley, Joanne Clifton, Laureonna Peters, Michelle Patterson, Dr. Mark Tyndall, Dr. Bonnie Henry, Dr. Jane Buxton, Dr. Louise Masse, Dr. Anita Ho

Sponsor: Canadian Institutes of Health Research (CIHR)

1. INTRODUCTION

You are being invited to participate in this study because you have told us that you are 19 years of age or older and work with clients that use alcohol and/or drugs and are street-involved – defined for this study as not having a place of residence where you sleep for 3 days or more in the past 6 months. We would like to ask you some questions about the substance use practices of the populations you provide care to, as well as the methods you use to assess whether your clients are capable of providing informed consent at the time of providing healthcare.

2. YOUR PARTICIPATION IS VOLUNTARY

Your participation is entirely voluntary, so it is up to you to decide whether or not to take part in this study. Before you decide, it is important for you to understand what the research involves. This consent form will tell you about the study, why the research is being done, what will happen to you during the study and the possible benefits, risks and discomforts. If you wish to participate, you will be asked to sign this form.
If you do decide to take part in this study, you are still free to withdraw at any time and without giving any reasons for your decision. If you do not wish to participate, you do not have to provide any reason for your decision not to participate nor will your decision affect your employment.

3. WHO IS CONDUCTING THE STUDY?

The study is under the direction of Dr. Gina Ogilvie and funded by the Canadian Institutes of Health Research (CIHR).

4. BACKGROUND

The British Columbia law tells us that every adult who is capable of giving or refusing consent to health care has the right to give or consent to health care for any reason. They also have the right to take back consent (revoking) once it has been given. According to the act, every adult is presumed to be capable of giving, refusing or revoking consent to health care unless they demonstrate that they are not capable. In this study we are interested in hearing about your experiences with making assessment with your clients on whether or not to provide them with health care and their consent for the care provided.

5. WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this research study is to survey care providers who provide service to clients with problematic substance use to determine how clinicians assess their client’s capability to consent for health care interventions. We would also like to find out if clinicians would use a tool that could guide their decision-making processes when determining competency to consent.

6. WHO CAN PARTICIPATE IN THE STUDY?

You can participate in this study if you are 19 years of age or older and a clinician that works with clients that use alcohol and/or drugs and are street-involved – defined for this study as not having a place of residence where you sleep for 3 days or more in the past 6 months.

7. WHO SHOULD NOT PARTICIPATE IN THE STUDY?

You should not participate in this study if you are under 19 years of age and are not a clinician that works with clients that do not use alcohol and/or drugs and are not street-involved - defined for this study as not having a place of residence where you sleep for 3 days or more in the past 6 months.

8. WHAT DOES THE STUDY INVOLVE?

This study is taking place at Insite and Primary Outreach Services. A total of 1 clinician
from each site will be enrolled in this study. Across the province we anticipate enrolling a total of 30 clinicians to participate in this study.

This study involves you participating in an interview that will take approximately 60 minutes and will be audio-taped. The audio-tape will be transcribed omitting any names you may have mentioned. You do not have to answer any questions that you do not feel comfortable answering. We would like to ask you some questions about the substance use practices of the populations you provide care to, as well as the methods you use to assess whether your clients are capable of providing informed consent at the time of providing healthcare.

9. WHAT ARE MY RESPONSIBILITIES?

Your responsibilities for this study, should you want to participate, only involve participating in an interview that will take approximately 60 minutes and will be audio-taped.

10. WHAT ARE THE POSSIBLE RISKS OF HARM AND SIDE EFFECTS OF PARTICIPATING?

There are no known risks associated with this research study.

11. WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

No one knows whether or not you will benefit from this study. There may or may not be direct benefits to you from taking part in this study. We hope that the information learned from this study can be used in the future to benefit other people.

12. WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CONSENT TO PARTICIPATE?

Your participation in this research is entirely voluntary. You may withdraw from this study at any time. If you decide to enter the study and to withdraw at any time in the future, there will be no penalty or loss of benefits to which you are otherwise entitled. If you choose to enter the study and then decide to withdraw at a later time, all data collected about you during your enrolment in the study will be retained for analysis.

13. WHAT HAPPENS IF SOMETHING GOES WRONG?

By signing this form, do you not give up any of your legal rights.

14. CAN I BE ASKED TO LEAVE THE STUDY?

If you are not complying with the requirements of the study or for any other reason, the study investigator may withdraw you from the study.
15. AFTER THE STUDY IS FINISHED

Once the study has ended, if you are interested in receiving the study results, we will share these with you if you provide us with your contact information.

16. WHAT WILL THE STUDY COST ME?

There will be no reimbursement for any personal expenses that you incur as a result of participation, such as parking and/or transit costs. You will however be compensated $20.00 for participating in the interview.

17. WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

Your confidentiality will be respected. However, research records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of the BC Centre for Disease Control and the Fraser Health Research Ethics Board for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a subject in this study. Only this number will be used on any research-related information, including personal data and research data, collected about you during the course of this study, so that your identity [i.e. your name or any other information that could identify you] as a subject in this study will be kept confidential. Information that directly discloses your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique identifier that is used on your research-related information will not be removed or released without your consent unless required by law. The audio recordings from this study will be deleted from the password protected electronic database after 7 years, which is standard protocol for the Provincial Health Services Authority (PHSA).

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected and also give you the right of access to the information about you that has been provided to the research team and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to the Principal Investigator.

18. WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY DURING MY PARTICIPATION?

If you have any questions or desire further information about this part of the study before or during participation, you can contact Dr. Gina Ogilvie (24 hour contact) or Darlene Taylor.
20. SUBJECT CONSENT TO PARTICIPATE

• I have read and understood the subject information and consent form and am consenting to participate in the study [A tool to assess decisional capacity to consent for clinical treatment]

• I have had sufficient time to consider the information provided and to ask for advice if necessary.

• I have had the opportunity to ask questions and have had satisfactory responses to my questions.

• I understand that all of the information collected will be kept confidential and that the result will only be used for scientific objectives.

• I understand that my participation in this study is voluntary and that I am completely free to refuse to participate or to withdraw from this study at any time without effecting my participation in the main study and without changing in any way the quality of care that I receive.

• I understand that I am not waiving any of my legal rights as a result of signing this consent form.

• I understand that there is no guarantee that this study will provide any benefits to me.

• I have read this form and I freely consent to participate in this study.

• I have been told that I will receive a dated and signed copy of this form.

SIGNATURES

<table>
<thead>
<tr>
<th>Printed name of subject</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Printed name of principal investigator/ designated representative</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX D: Consent form for qualitative interview with clients

A Tool to Assess Decisional Capacity for Medical Care in Outreach Settings

Principal Investigator: Dr. Gina Ogilvie, UBC Department of Family Practice
Phone:

Co-Investigators: Dr. Michael Rekart
Dr. Mark Gilbert
Juanita Maginley
Joanne Clifton
Dr. Mark Tyndall
Dr. Bonnie Henry
Dr. Jane Buxton
Dr. Louise Masse
Dr. Anita Ho

Purpose:
The British Columbia law tells us that every adult who is capable of giving or refusing consent to health care has the right to give or consent to health care for any reason. They also have the right to take back consent (revoking) once it has been given. According to the act, every adult is presumed to be capable of giving, refusing or revoking consent to health care unless they demonstrate that they are not capable.

Study Procedures:
The study is under the direction of Dr. Gina Ogilvie and involves being interviewed by the study coordinator and a peer interviewer. You are being invited to participate in this study because you have told us that you do not have a regular home that you sleep in AND that you use alcohol and/or drugs. We would like to ask you some questions about what it is like for you to get medical care, whether you feel you understand the medical care you are being offered, and whether you feel you are given the choice to accept or refuse health care.

This interview will take approximately 60 minutes and will be audio-taped. The audi-tapes will be transcribed omitting any names you may have mentioned. You may refuse to answer any questions you wish to in either of the questionnaires.

Potential Risks:
There are no known risks associated with this research study.

Potential Benefits:
You may or may not personally benefit from participating in this study. You may contribute new information that may benefit people in the future.

As your time and assistance is valued, $20.00 will be made available to you in return for your time.

**Confidentiality:**
Your confidentiality will be respected. No information that discloses your identity will be released or published without your specific consent to the disclosure. The research transcriptions will only identify you by a numerical code. No records which identify you by name or initials will be allowed to leave the Investigators' offices.

**Contact for information about the study:**
If you wish to discuss future questions or concerns you may have about this study, you may contact Dr. Gina Ogilvie (24 hour contact) or Darlene Taylor

**Contact for concerns about the rights of research subjects:**
If you have any concerns about your treatment or rights as a research subject, you may contact the Research Subject Information Line in the UBC Office of Research Services at or if long distance e-mail

**Consent:**
Your participation in this study is entirely voluntary and you may refuse to participate or withdraw from the study at any time with no penalty or loss of benefits to which you are otherwise entitled, and your future medical care will not be affected.

Your signature below indicates that you have received a signed copy of this consent form for your own records.

Your signature indicates that you consent to participate in this study.

___________________________________________________
Participant Signature   Date

____________________________________________________
Printed Name of the Subject or Parent or Guardian signing above

Printed Name of Investigator or Delegate ____________________________

Signature of Investigator or Delegate ________________________________

Date: ___________________________
APPENDIX E: Definitions for the concepts chosen for the CAIPS instrument

1. Ethical Principle Concepts

1.1 Presumption of capacity: (77)

Definition: The ‘HEALTH CARE (CONSENT) AND CARE FACILITY (ADMISSION) ACT’ (Part 1 Section 3) stipulates that:

“(1) Until the contrary is demonstrated, every adult is presumed to be capable of
(a) giving, refusing or revoking consent to health care, and
(b) deciding to apply for admission to a care facility, to accept a facility care proposal, or to move out of a care facility.
(2) An adult's way of communicating with others is not, by itself, grounds for deciding that he or she is incapable of understanding anything referred to in subsection”

This means that when a clinician is entering into a health care encounter with an adult client they should go into the encounter assuming that the client has capacity to consent for health care.

1.2 Informed:

Definition: Consent is deemed to be ‘informed’ if the client is given all the information to be able to make a rational decision in a manner which the client can understand.(12;221) BC Law states that the health care provider must give the adult enough information a reasonable person would require to understand the proposed health care and to make a decision.(77)

1.3 Beneficence:

Definition: Actions that are intended to benefit others.(12) This principle includes a benefit to individuals and, for the purposes of our new instrument, does not refer to benefitting the population.

1.4 Nonmaleficence:

Definition: Not inflicting harm on others.(12) This principle includes not harming individuals and, for the purposes of our new instrument, does not refer to not harming the population.
1.5 Justice:

**Definition:** Fair, equitable, and appropriate treatment in light of what is due or owed to persons. (12) This concept includes the ideas related to distributive justice which refers to the notion that all persons should have equal access to health and resources regardless of their status in society.

1.6 Opportunities for reflection: (222)

**Definition:** According to BC’s Health Care (Consent) and Care Facility (Admissions) Act,(77) individuals who are being asked to consent to health care should be given opportunity to ask questions and be provided with answers. This may take time. Therefore the client should be given ample time to reflect on the information that has been given to them so they can ask questions before providing consent.

1.7 Avoidance of misuse of inherent power differentials: (223)

**Definition:** Power differentials occur when a relationship, such as a clinician-client relationship, involves on person who is perceived as being in a position of authority. This may include clients agreeing to an intervention because they want to please the clinician, or a clinician exerting their will (through persuasion) because they do not appropriately recognize their position of power.

1.8 Level of risk versus level of capacity: (86)

**Definition:** The level of capacity required for consent depends on the seriousness or level of risk (long or short term) associated with the medical intervention being offered or requested.

1.9 Who Initiated the clinical encounter?:

**Definition:** Relationship dynamics between a nurse and a client depends on the client’s mental preparedness to engage in a medical encounter. Mental preparedness may depend on whether the client approaches the clinician or the nurse approaches the client (e.g., as in street outreach).
2. Concepts that measure capacity to consent to be used in the instrument

2.1 Understanding information relevant to the decision:

**Definition:** Understanding involves the client’s ability to process information that is provided to them. It has been defined by others as the “ability to comprehend and recall important facts”. (224) However, the ability to recall information is not, in and of itself, indicative of understanding as a person might be able repeat back words that have been spoken to them without actually knowing what the words mean. However, when combined with other aspects of understanding, ability to recall may be indicative of capacity.

2.2 Voluntariness:

**Definition:** The client’s decision to accept or refuse medical care should be made without being under the control of another’s influence. This does not mean that helpful information should not be provided (12); rather the information should not be provided with the intent of persuading or manipulating the individual.

2.3 Respect for autonomy:

**Definition:** Respecting a client’s autonomy involves recognizing and acknowledging the client’s ‘right to hold views, to make choices, and to act based on their personal beliefs and values’. (12) Beauchamp and Childress (12) expand on this definition by stating that respect involves respectful actions, not just respectful attitudes when a client is expressing autonomy.

2.4 Problems of false belief:

**Definition:** This occurs when an individual is unable to accept that the information given to them is true even though suitable disclosure has been provided and the client understands what was said. This false belief may be a result of mental illness or cultural/spiritual beliefs.(12)

2.5 Concentration/sustained attention:

**Definition:** Concentration is defined as the client’s ability to block out external or internal stimuli (e.g., conversations, hearing internal voices, desire for substances) and focus on the conversation about the health care being offered to them. (225)

2.6 Memory impairment/ Recall: (129;226)
**Definition:** Memory is defined as a person’s ability to retain information. Memory impairment, therefore, is any degree of inability to retain information. Working memory, a person’s ability to retain and manipulate information in the short term in order to solve a problem, is often measured in the realm of cognitive psychology. For the purposes of our new instrument, we are interested in both long term and working memory ability as, for many clinical interventions, it will be important that the client remember that the intervention occurred. (227)

2.7 Orientation:

**Definition:** The client’s ability to know who they are (person), where they are (place), what day or year it is (time).

2.8 Verbal abilities:

**Definition:** The client’s ability to verbalize appropriately by naming items or follow verbal commands. (129) It also involves the client’s ability to engage in a conversation.

2.9 Changes in personality: (226)

**Definition:** Changes in personality are any behaviour, or conversation that is inconsistent with what is already known about the client’s personality. For decision making purposes, this change can be temporary.

2.10 Conceptual disorganization:

**Definition:** An indication that the client is not thinking in an organized way.

2.11 Presence of hallucinations, panic, unusual euphoria: (80;127)

**Definition:** This involves the client stating he/she sees things that are not there (hallucinations), or appears to be unusually fearful or unusually happy.

2.12 Appreciation of the nature of the situation: (89;224;228)

**Definition:** The client’s ability to apply information to their own situation.

2.13 Using the information in reasoning: (89;224;228)
Definition: This involves an assessment of whether the client is able to manipulate information rationally. In other words, is the client able use a logical process when using the information that they were given?

2.14 Expression of choice: (89;90;224;228)

Definition: The client’s ability to indicate a choice, either verbally or physically.

2.15 Decision-making demands:

Definition: Situational and/or social factors that contribute to the client’s decision or interfere with a client’s willingness or capability to make a decision. (88)

2.16 Threshold setting:

Definition: The level of impairment that the nurse uses to differentiate between the client having capacity or not having capacity to consent for health care.

2.17 Client’s ability to cope:

Definition: The clinician’s assessment of whether the client will be able to adequately respond to an adverse event or positive diagnosis if they were to occur.

2.18 Physical indication of substance use:

Definition: Any physical evidence/indicator, including body movements, posture, manner of speech, and odor of alcohol, marijuana, and other substance that indicate that the client has recently used a substance (i.e. may be under the influence of a substance).

2.19 Knowledge of the client’s baseline:

Definition: The clinician’s previous experience with the client and the ability to compare the client’s present behaviour and mental capacity to previous encounters when substance use wasn’t involved.
APPENDIX F: Form completed by the panel of experts during the instrument
development of this dissertation (Phase 1 of Modified Delphi Process)

Expert Panel Review Form: PROPOSED QUESTIONS FOR THE INSTRUMENT

During the validation process of this study, a researcher will present the participant with the following hypothetical consent scenario:

The client is being offered a flu vaccine. The researcher will explain the risks and benefits of the vaccine as well as the alternatives to receiving a vaccine for the flu. While this conversation is going on, the researcher will be making an assessment of capacity to consent.

In the following pages, there is a list of proposed questions that may possibly be used in the new instrument. Can you please provide your comments and suggestions for each question. The section in blue is the proposed question with the response options. The concept has a number beside it that corresponds to the list of concepts mentioned previously (above). The sections in red provide a place for you to rate how important you think the concept is for assessing capacity to consent. Then you will be asked if the proposed question addresses the concept adequately. Finally you will be given some space to provide comments about how the question is worded or any other comments you may have related to the concept or proposed question.
**CONCEPT: Understanding**

<table>
<thead>
<tr>
<th>Question #1</th>
<th>Score</th>
<th>How Important is this Concept to Assessing Capacity to Consent</th>
<th>Does this question address the concept adequately?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can the client repeat back the side effects of the intervention you want to give to them</td>
<td>1</td>
<td>☐ Extremely important</td>
<td>☐ No</td>
</tr>
<tr>
<td>The client cannot repeat back anything you have said to them.</td>
<td>2</td>
<td>☐ Somewhat important</td>
<td>☐ Neutral</td>
</tr>
<tr>
<td>The client can reiterate the side effects you explained to them but not in their own words</td>
<td>3</td>
<td>☐ Neutral</td>
<td>☐ Yes</td>
</tr>
<tr>
<td>The client attempts to repeat back the information you gave them in their own words but their response is not correct.</td>
<td>4</td>
<td>☐ Yes</td>
<td>☐ Yes</td>
</tr>
<tr>
<td>The client can correctly repeat some of the information back in their own words but not completely</td>
<td>5</td>
<td>☐ Yes</td>
<td>☐ Yes</td>
</tr>
</tbody>
</table>

Please provide any comments or suggestions related to the way that the question is worded:
**CONCEPT: Voluntariness**

<table>
<thead>
<tr>
<th>Question #2</th>
<th>Score</th>
<th>How Important is this Question</th>
<th>Does this question address the issue of Assessing Capacity to Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td>State how much you agree or disagree with the following statement:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>‘The client made their decision about a medical intervention without external influence such as persuasion or coercion.’</td>
<td>Strongly disagree</td>
<td>Disagree</td>
<td>Neutral</td>
</tr>
</tbody>
</table>

Please provide any comments or suggestions related to the way that the question is worded:
CONCEPT: False Belief

<table>
<thead>
<tr>
<th>Question #3</th>
<th>Score</th>
<th>How Important is this Question</th>
<th>Does this question address the issue of Assessing Capacity to Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td>If the client is refusing care, are they exhibiting signs of false belief (e.g., denial of a diagnosis, psychotic beliefs)</td>
<td>yes</td>
<td>Not sure</td>
<td>No</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>☐ Extremely important</td>
</tr>
<tr>
<td>☐ Somewhat important</td>
<td>☐ Neutral</td>
<td>☐ Somewhat unimportant</td>
<td>☐ Yes</td>
</tr>
<tr>
<td>☐ Neutral</td>
<td>☐ Yes</td>
<td>☐ Extremely important</td>
<td></td>
</tr>
</tbody>
</table>

Please provide any comments or suggestions related to the way that the question is worded:
CONCEPT: Concentration/sustained attention and memory

<table>
<thead>
<tr>
<th>Question #4</th>
<th>Score</th>
<th>How Important is this Question</th>
<th>Does this question address the issue of Assessing Capacity to Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Show the client the following 5 digit number: 83047</td>
<td>1 digit correct</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Take the number away and ask them to repeat the number. How many digits did they get correct?</td>
<td>2 digits correct</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>3 digits correct</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>4 digits correct</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>5 digits correct</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

How Important is this Question

☐ Extremely important
☐ Somewhat important
☐ Neutral
☐ Somewhat unimportant
☐ Extremely important

Does this question address the issue of Assessing Capacity to Consent

☐ No
☐ Neutral
☐ Yes

Please provide any comments or suggestions related to the way that the question is worded:
## Question #5

If you have delivered care to this person within the last week, do they remember you and what care you provided to them?

<table>
<thead>
<tr>
<th>Score</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unsure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### How Important is this Question

- Extremely important
- Somewhat important
- Neutral
- Somewhat unimportant
- Extremely unimportant

### Does this question address the issue of Assessing Capacity to Consent

- No
- Neutral
- Yes

Please provide any comments or suggestions related to the way that the question is worded:
#6 How Important is this Question

Does this question address the issue of Assessing Capacity to Consent:

- [ ] No
- [ ] Neutral
- [ ] Yes

**CONCEPT: Orientation**

<table>
<thead>
<tr>
<th>Question #6</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>When considering offering clinical care to the client, please indicate how much you agree or disagree with the following statement: 'The client appears to be orientated to person place and time' (i.e. do they know who they are, where they are and what year it is?)</td>
<td>Strongly disagree</td>
<td>Disagree</td>
<td>neutral</td>
<td>Agree</td>
<td>Strongly Agree</td>
</tr>
</tbody>
</table>

Please provide any comments or suggestions related to the way that the question is worded:
**CONCEPTS: Verbal abilities and conceptual disorganization**

<table>
<thead>
<tr>
<th>Question #7</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate how well the client is able to engage in a conversation</td>
<td>1</td>
</tr>
</tbody>
</table>

- Cannot contribute to conversation at all
- Attempts to contribute to the conversation but words are slurred or incomprehensible
- Contributes to the conversation but content of their contribution does not make logical sense
- Contributes to the conversation in a coherent manner but some of content of their contribution does not make sense
- Contributes to the conversation in a fully comprehensible and coherent manner

**How Important is this Question**
- ☐ Extremely important
- ☐ Somewhat important
- ☐ Neutral
- ☐ Somewhat unimportant
- ☐ Extremely unimportant

**Does this question address the issue of Assessing Capacity to Consent**
- ☐ No
- ☐ Neutral
- ☐ Yes

Please provide any comments or suggestions related to the way that the question is worded:
### CONCEPT: Changes in personality and knowledge of client’s baseline

<table>
<thead>
<tr>
<th>Question #8</th>
<th>Score</th>
<th>How Important is this Question</th>
<th>Does this question address the issue of Assessing Capacity to Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td>If you have delivered care to this client in the past: rate whether the client is talking in a manner that is typical of the client?</td>
<td>No</td>
<td></td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Unsure</td>
<td></td>
<td>Neutral</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td></td>
<td>Yes</td>
</tr>
</tbody>
</table>

Please provide any comments or suggestions related to the way that the question is worded:
CONCEPT: Conceptual disorganization

<table>
<thead>
<tr>
<th>Question #9</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Rate how well you think the client is able to follow instructions.</td>
<td>Makes no attempt to follow instructions</td>
</tr>
</tbody>
</table>

Please provide any comments or suggestions related to the way that the question is worded:
CONCEPT: Presence of hallucinations, panic, unusual euphoria

<table>
<thead>
<tr>
<th>Question #10</th>
<th>Score</th>
<th>How Important is this Question</th>
<th>Does this question address the issue of Assessing Capacity to Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the client displaying evidence of having hallucinations, delusional ideas, panic or euphoria?</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Unsure</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>No</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please provide any comments or suggestions related to the way that the question is worded:
CONCEPT: Presence of hallucinations, panic, unusual euphoria

<table>
<thead>
<tr>
<th>Question #11</th>
<th>Score</th>
<th>How Important is this Question</th>
<th>Does this question address the issue of Assessing Capacity to Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ask the client if they think we are trying to hurt or harm them. Did the client demonstrate paranoia by saying yes?</td>
<td>Yes</td>
<td></td>
<td>☐ No</td>
</tr>
<tr>
<td></td>
<td>Unsure</td>
<td>□ Extremely important</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ Somewhat important</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ Neutral</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>□ Somewhat unimportant</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ Extremely important</td>
<td></td>
</tr>
</tbody>
</table>

Please provide any comments or suggestions related to the way that the question is worded:
CONCEPT: Appreciation of the nature of the situation

<table>
<thead>
<tr>
<th>Question #12</th>
<th>Score</th>
<th>How Important is this Question</th>
<th>Does this question address the issue of Assessing Capacity to Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please indicate how much you agree or disagree to the following statement:</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>“The client knows that he/she is either at risk of an illness or has an illness and therefore requires clinical care”</td>
<td>Strongly Disagree</td>
<td>Disagree</td>
<td>Neutral</td>
</tr>
</tbody>
</table>

Please provide any comments or suggestions related to the way that the question is worded:
CONCEPT: Using the information provided in reasoning

<table>
<thead>
<tr>
<th>Question #13</th>
<th>Score</th>
<th>How Important is this Question</th>
<th>Does this question address the issue of Assessing Capacity to Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>If you are offering the client clinical care rate how well he/she is able to give a reason for the decision to want the care or refuse the care</td>
<td>Extremely unable</td>
<td>Unable</td>
<td>Unsure</td>
</tr>
</tbody>
</table>

Please provide any comments or suggestions related to the way that the question is worded:
CONCEPT: Using the information provided in reasoning

<table>
<thead>
<tr>
<th>Question #14</th>
<th>Score</th>
<th>How Important is this Question</th>
<th>Does this question address the issue of Assessing Capacity to Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td>If you have provided information to the client so they can decide whether they want a clinical intervention, ask them to “think out loud” while making their decision to accept or refuse care. Then rate How well the client uses the information that you provided to them to make their decision.</td>
<td>1</td>
<td>Uses none of the information</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Uses a small amount of information (e.g., &lt;25%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Unsure</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>Uses most (e.g., 76%-90%) of information</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Uses all (100%) of the information</td>
<td></td>
</tr>
</tbody>
</table>

Please provide any comments or suggestions related to the way that the question is worded:
## CONCEPT: Expression of choice

<table>
<thead>
<tr>
<th>Question #15</th>
<th>Score</th>
<th>How Important is this Question</th>
<th>Does this question address the issue of Assessing Capacity to Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the client able to talk or physically indicate a choice?</td>
<td>No</td>
<td></td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Unsure</td>
<td></td>
<td>Neutral</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td></td>
<td>Yes</td>
</tr>
</tbody>
</table>

Please provide any comments or suggestions related to the way that the question is worded:
CONCEPT: Decision-making demands

<table>
<thead>
<tr>
<th>Question #16</th>
<th>Score</th>
<th>How Important is this Question</th>
<th>Does this question address the issue of Assessing Capacity to Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td>While offering care to a client, does the client seem</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) distracted by friends around him/her</td>
<td>Yes, at least one of these</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) rushed to get back to another activity</td>
<td>Unsure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) dope sick</td>
<td>No, none of these</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please provide any comments or suggestions related to the way that the question is worded:
While offering care to a client, do you feel you had enough time with the client in order to assess their capacity to consent?

<table>
<thead>
<tr>
<th>Question #17</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>No</td>
<td>Unsure</td>
</tr>
</tbody>
</table>

How Important is this Question

- [ ] Extremely important
- [ ] Somewhat important
- [ ] Neutral
- [ ] Somewhat unimportant
- [ ] Extremely important

Does this question address the issue of Assessing Capacity to Consent

- [ ] No
- [ ] Neutral
- [ ] Yes

Please provide any comments or suggestions related to the way that the question is worded:
**CONCEPT: Threshold setting**

<table>
<thead>
<tr>
<th>Question #18</th>
<th>Score</th>
<th>How Important is this Question</th>
<th>Does this question address the issue of Assessing Capacity to Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td>While offering care to a client, were there factors in the environment that prevented you from assessing the client's capacity to consent</td>
<td>Yes</td>
<td>☐ Extremely important</td>
<td>☐ No</td>
</tr>
<tr>
<td></td>
<td>Unsure</td>
<td>☐ Somewhat important</td>
<td>☐ Neutral</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>☐ Neutral</td>
<td>☐ Yes</td>
</tr>
</tbody>
</table>

Please provide any comments or suggestions related to the way that the question is worded:
CONCEPT: Clients’ ability to cope

<table>
<thead>
<tr>
<th>Question #19</th>
<th>Score</th>
<th>How Important is this Question</th>
<th>Does this question address the issue of Assessing Capacity to Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td>When considering offering clinical care to the client, please indicate how much you agree or disagree with the following statement: ‘The client appears to be capable of coping with a side effect of an unexpected test result’</td>
<td>1 Strongly disagree</td>
<td>☐ Extremely important</td>
<td>☐ No</td>
</tr>
<tr>
<td></td>
<td>2 Disagree</td>
<td>☐ Somewhat important</td>
<td>☐ Neutral</td>
</tr>
<tr>
<td></td>
<td>3 neutral</td>
<td>☐ Neutral</td>
<td>☐ Yes</td>
</tr>
<tr>
<td></td>
<td>4 Agree</td>
<td>☐ Somewhat unimportant</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5 Strongly Agree</td>
<td>☐ Extremely important</td>
<td></td>
</tr>
</tbody>
</table>

Please provide any comments or suggestions related to the way that the question is worded:
CONCEPT: Physical indication of substance use

<table>
<thead>
<tr>
<th>Question #20</th>
<th>Score</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are there any physical indications that the client may have recently used drugs or alcohol? e.g.: smell of alcohol or marijuana, pin point pupils, tweaking, slumping over – sleepiness</td>
<td>Yes</td>
<td>Unsure</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

How Important is this Question

- ☐ Extremely important
- ☐ Somewhat important
- ☐ Neutral
- ☐ Somewhat unimportant
- ☐ Extremely important

Does this question address the issue of Assessing Capacity to Consent

- ☐ No
- ☐ Neutral
- ☐ Yes

Please provide any comments or suggestions related to the way that the question is worded:
CONCEPT: Who initiated the clinical encounter?

<table>
<thead>
<tr>
<th>Question #21</th>
<th>Score</th>
<th>How Important is this Question</th>
<th>Does this question address the issue of Assessing Capacity to Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did the client initiate the encounter? (e.g., did client approach clinician rather than the clinician approaching client)</td>
<td>No</td>
<td></td>
<td>□ No □ Yes</td>
</tr>
<tr>
<td></td>
<td>Unsure</td>
<td>☐ Extremely important □ Somewhat important □ Neutral □ Somewhat unimportant □ Extremely important</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please provide any comments or suggestions related to the way that the question is worded:
APPENDIX G: Consent for participants of the cognitive testing portion of the validation phase

Subject Consent Form
Cognitive Testing - Clients

A Tool to Assess Decisional Capacity to Consent for Clinical Treatment

Principal Investigator: Dr. Gina Ogilvie, PhD, MD
Associate, STI/HIV Prevention and Control, BCCDC
Associate Professor, Family Practice, UBC
Associate Professor, School of Population and Public Health, UBC
Phone:

Co-Investigator(s): Michael Rekart,
Mark Gilbert
Juanita Maginley
Joanne Clifton
Mark Tyndall
Bonnie Henry
Jane Buxton
Louise Masse
Anita Ho

Sponsor:
Funding was granted by the Canadian Institute for Health Research (CIHR). There is no potential for conflict of interest for any of the researchers or sponsors involved in this research study.

Emergency contact (24 hours, 7 days a week): Contact Darlene Taylor

1. INVITATION

You are being invited to participate in this research study because you use alcohol and/or drugs, are homeless or live in unstable housing and are an individual over the age of 19. This form will tell you about this study, why the research is being done, and what will happen during the study.

2. YOUR PARTICIPATION IS VOLUNTARY

Your participation is entirely voluntary. It is up to you to decide whether or not to take part in this study.
If you wish to participate, you will be asked to sign this consent form. If you do decide to take part in this study, you are still free to withdraw at any time and without giving any reasons for your decision.

If you do not wish to participate, you do not have to provide a reason for your decision not to participate. You will not lose the benefit of any medical care to which you are entitled or are presently receiving.

Please take time to read the following information before you make your decision.

3. WHO IS CONDUCTING THE STUDY?

The study is being conducted under the direction of Dr. Gina Ogilvie and is being sponsored by the Canadian Institute for Health Research (CIHR). You may request details of the funding if you wish to do so.

4. BACKGROUND

In British Columbia, Canada, all individuals have the right to consent to medical care or refuse medical that is being offered to them. According to the law, people may consent for themselves unless they show that they are not mentally capable of understanding the risks and benefits for the medical care and therefore can’t make a proper decision for themselves. It is the responsibility of each health care provider to make sure that everyone they deliver care to is capable of consenting for health care or capable of making a decision to refuse health care. It is sometimes difficult to make this assessment in people who use alcohol or drugs. In order to protect the rights of these people, we have designed a questionnaire that clinicians can use to make sure that they are treating people who can consent for care.

5. PURPOSE

The purpose of this pilot study is to try out a list of questions with a small number of people who use alcohol and drugs to determine whether the questions are acceptable. Evaluation of the questions will provide insight to evaluate the questions prior to using them in healthcare settings.

6. WHO CAN PARTICIPATE?

People who use alcohol and/or drugs and who are homeless or don’t have a regular place to sleep may participate in this pilot study. Participants should be 19 years of age or older and can speak English fluently.

7. WHO CANNOT PARTICIPATE?

Subjects should not participate in this study if they are under the age of 19.
8. WHAT DOES THE STUDY INVOLVE?

Study Overview

Clients who consent to participation will meet with a nurse who will ask them 11 questions. The nurse will complete the pilot questionnaire and then you will be asked about your feelings about the questions that the nurse asked you. The questionnaire and follow-up discussion will take approximately 20 minutes.

9. WHAT ARE MY RESPONSIBILITIES?

Participants who have expressed interest in volunteering will be asked to meet with the research coordinator to complete the pilot questionnaire. Following the questionnaire the participants will take part in a discussion to share their thoughts about the questionnaire with the research coordinator.

10. WHAT ARE THE POSSIBLE HARMS AND SIDE EFFECTS OF PARTICIPATING?

No known side effects are associated with this questionnaire. All pilot study data will be stored securely at BCCDC in a locked cabinet in a locked room with only the research study coordinator having key access.

11. WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATING?

You will not directly benefit from this study; however, your participation will help in the creation of a questionnaire that nurses can use in the future which will assist with assessing patient’s capacity to consent for healthcare. You will receive $20 to reimburse you for any travel or other study related expenses you incur by participating in this study.

12. WHAT ARE THE ALTERNATIVES TO THE STUDY TREATMENT?

As this is a simple questionnaire (not involving treatment), there are no alternatives to the study procedure

13. WHAT IF NEW INFORMATION BECOMES AVAILABLE THAT MAY AFFECT MY DECISION TO PARTICIPATE?

If new information arises during the research study that may affect your willingness to remain in the study, you will be advised of this information.

14. WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CONSENT TO PARTICIPATE?
Your participation in this research is entirely voluntary. You may withdraw from this study at any time without giving a reason. If you decide to enter the study and to withdraw at any time in the future, there will be no penalty or loss of benefits to which you are otherwise entitled, and your future medical care will not be affected.

15. WHAT HAPPENS IF SOMETHING GOES WRONG?
Signing this consent form in no way limits your legal rights against the sponsor, investigators, or anyone else associated with the study. If something goes wrong during the study period, you can contact Darlene Taylor at (office) or Dr. Gina Ogilvie. You are not waiving any of your legal rights as a result of signing this consent form.

16. CAN I BE ASKED TO LEAVE THE STUDY?
The study investigator may withdraw you from the study if you are not fulfilling requirements. However, there will be no change to the medical care you may be receiving elsewhere.

17. AFTER THE STUDY IS FINISHED
All pilot study data is stored at BCCDC in a locked cabinet in a secure and locked room with only the research study coordinator having key access.

18. WHAT WILL THE STUDY COST ME?
This study will be of no cost to you.

19. WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?
Your confidentiality will be respected. No information that discloses your identity will be released or published without your specific consent to the disclosure. However, research records and medical records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of the UBC Research Ethics Board for the purpose of monitoring the research. However, no records which identify you by name or initials will be allowed to leave the Investigators' offices.

20. WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY DURING MY PARTICIPATION?
If you have questions about this study at any time, either before or after enrolling, or would like to request more information, you may contact Darlene Taylor at or Dr. Gina Ogilvie.

21. WHO DO I CONTACT IF I HAVE ANY QUESTIONS OR CONCERNS ABOUT MY RIGHTS AS A SUBJECT DURING THE STUDY?
If you have any concerns about your rights as a research subject and/or your experiences while participating in this study, contact the Research Subject Information Line, Office of Research Services at the University of British Columbia by e-mail at RSIL@ors.ubc.ca or by phone.

22. SUBJECT CONSENT TO PARTICIPATE

- I have read and understood the subject information and consent form.
- I have had sufficient time to consider the information provided and to ask for advice if necessary.
- I have had the opportunity to ask questions and have had satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and that the result will only be used for scientific objectives.
- I understand that my participation in this study is voluntary and that I am completely free to refuse to participate or to withdraw from this study at any time without changing in any way the quality of care that I receive.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I have read this form and I freely consent to participate in this study.
- I have been told that I will receive a dated and signed copy of this form.
- I am at least 19 years of age or older

Signatures

<table>
<thead>
<tr>
<th>Subject’s Name (please print)</th>
<th>Subject’s Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator’s (or delegate) Name (please print)</td>
<td>Investigator’s (or delegate)</td>
<td>Date</td>
</tr>
</tbody>
</table>
APPENDIX H: Consent form for participants of the pilot testing portion of the validation phase

PILOT STUDY - Clients

A Tool to Assess Decisional Capacity to Consent for Clinical Treatment

Principal Investigator: Dr. Gina Ogilvie, PhD, MD
Associate, STI/HIV Prevention and Control, BCCDC
Associate Professor, Family Practice, UBC
Associate Professor, School of Population and Public Health, UBC
Phone:

Co-Investigator(s): Michael Rekart,
Mark Gilbert
Juanita Maginley
Joanne Clifton
Mark Tyndall
Bonnie Henry
Jane Buxton
Louise Masse
Anita Ho

Sponsor
Funding was granted by the Canadian Institute for Health Research (CIHR). There is no potential for conflict of interest for any of the researchers or sponsors involved in this research study.

Emergency contact (24 hours, 7 days a week)
Contact Darlene Taylor

1. INVITATION

You are being invited to participate in this pilot research study because you use alcohol and/or drugs, are homeless or live in unstable housing and are an individual over the age of 19. This form will tell you about this study, why the research is being done, and what will happen during the study.

2. YOUR PARTICIPATION IS VOLUNTARY

Your participation is entirely voluntary. It is up to you to decide whether or not to take part in this study.
If you wish to participate, you will be asked to sign this consent form. If you do decide to take part in this study, you are still free to withdraw at any time and without giving any reasons for your decision.

If you do not wish to participate, you do not have to provide any reason for your decision not to participate. You will not lose the benefit of any medical care to which you are entitled or are presently receiving.

Please take time to read the following information before you make your decision.

3. WHO IS CONDUCTING THE STUDY?

The study is being conducted under the direction of Dr. Gina Ogilvie and is being sponsored by the Canadian Institute for Health Research (CIHR). You may request details of the funding if you wish to do so.

4. BACKGROUND

In British Columbia, Canada, all individuals have the right to consent to medical care or refuse medical that is being offered to them. According to the law, people may consent for themselves unless they show that they are not mentally capable of understanding the risks and benefits for the medical care and therefore can’t make a proper decision for themselves. It is the responsibility of each health care provider to make sure that everyone they deliver care to is capable of consenting for health care or capable of making a decision to refuse health care. It is sometimes difficult to make this assessment in people who use alcohol or drugs. In order to protect the rights of these people, we have designed a questionnaire that clinicians can use to make sure that they are treating people who can consent for care.

5. PURPOSE

The purpose of this pilot study is to try out three questionnaires with a small number of people who use alcohol and drugs to determine whether they are acceptable. Evaluation of the questions will provide insight to evaluate the questions prior to using them in healthcare settings.

6. WHO CAN PARTICIPATE?

People who use alcohol and/or drugs and who are homeless or don’t have a regular place to sleep may participate in this pilot study. Participants should be 19 years of age or older and can speak English fluently.

7. WHO CANNOT PARTICIPATE?

Subjects should not participate in this study if they are under the age of 19.
8. WHAT DOES THE STUDY INVOLVE?

Study Overview

Clients who consent to participation will meet with a nurse who will ask them 11 questions. The nurse will complete the pilot questionnaire and then you will be asked about your feelings about the questions that the nurse asked you. The questionnaire and follow-up discussion will take approximately 60 minutes.

Specific Procedures

Volunteers will be recruited from a study recruitment flyer. Participants will contact the research study recruiter by signing a form (list of volunteers) at VANDU or talking to the recruiter directly. The recruiter will then contact the willing participants to arrange a meeting to complete a study consent form and pilot study questionnaire and take part in a follow up discussion to evaluate the questions and how the participant felt when answering each question.

9. WHAT ARE MY RESPONSIBILITIES?

Participants who have expressed interest in volunteering will be asked to meet with the research coordinator to complete the pilot questionnaire. Following the questionnaire the participants will partake in a discussion to share their thoughts about the questionnaires with the research coordinator.

10. WHAT ARE THE POSSIBLE HARMS AND SIDE EFFECTS OF PARTICIPATING?

No known side effects associated with this questionnaire. All pilot study data will be stored securely at BCCDC in a locked cabinet in a locked room with only the research study coordinator having key access.

11. WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATING?

You will not directly benefit from this study; however, your participation will help the research team make sure that the three questionnaires are acceptable. You will receive $20 to reimburse you for any travel or other study related expenses you incur by participating in this study.

12. WHAT ARE THE ALTERNATIVES TO THE STUDY TREATMENT?

As this is a simple questionnaire (not involving treatment), there are no alternatives to the study procedure.
13. WHAT IF NEW INFORMATION BECOMES AVAILABLE THAT MAY AFFECT MY DECISION TO PARTICIPATE?

If new information arises during the research study that may affect your willingness to remain in the study, you will be advised of this information.

14. WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CONSENT TO PARTICIPATE?

Your participation in this research is entirely voluntary. You may withdraw from this study at any time without giving a reason. If you decide to enter the study and to withdraw at any time in the future, there will be no penalty or loss of benefits to which you are otherwise entitled, and your future medical care will not be affected.

15. WHAT HAPPENS IF SOMETHING GOES WRONG?

Signing this consent form in no way limits your legal rights against the sponsor, investigators, or anyone else associated with the study. If something goes wrong during the study period, you can contact Darlene Taylor or Dr. Gina Ogilvie. You are not waiving any of your legal rights as a result of signing this consent form.

16. CAN I BE ASKED TO LEAVE THE STUDY?

The study investigator may withdraw you from the study if you are not fulfilling requirements. However, there will be no change to the medical care you may be receiving elsewhere.

17. AFTER THE STUDY IS FINISHED

All pilot study data is stored at BCCDC in a locked cabinet in a secure and locked room with only the research study coordinator having key access.

18. WHAT WILL THE STUDY COST ME?

This study will be of no cost to you.

19. WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

Your confidentiality will be respected. No information that discloses your identity will be released or published without your specific consent to the disclosure. However, research records and medical records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of the UBC Research Ethics Board for the purpose of monitoring the research. However, no records which identify you by name or initials will be allowed to leave the Investigators' offices.

20. WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY DURING MY PARTICIPATION?
If you have questions about this study at any time, either before or after enrolling, or would like to request more information, you may contact Darlene Taylor or Dr. Gina Ogilvie.

21. WHO DO I CONTACT IF I HAVE ANY QUESTIONS OR CONCERNS ABOUT MY RIGHTS AS A SUBJECT DURING THE STUDY?

If you have any concerns about your rights as a research subject and/or your experiences while participating in this study, contact the Research Subject Information Line, Office of Research Services at the University of British Columbia by e-mail.

22. SUBJECT CONSENT TO PARTICIPATE

- I have read and understood the subject information and consent form.
- I have had sufficient time to consider the information provided and to ask for advice if necessary.
- I have had the opportunity to ask questions and have had satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and that the result will only be used for scientific objectives.
- I understand that my participation in this study is voluntary and that I am completely free to refuse to participate or to withdraw from this study at any time without changing in any way the quality of care that I receive.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I have read this form and I freely consent to participate in this study.
- I have been told that I will receive a dated and signed copy of this form.
- I am at least 19 years of age or older

Signatures

_________________________            ___________________________      _________
Subject’s Name (please print)          Subject’s Signature                      Date

__________________________   ________________________             _______
Investigator’s (or delegate)                    Investigator’s (or delegate) Signature       Date
Name (please print)
APPENDIX I: Demographic/substance use questionnaire administered to participants of validation phase of this dissertation

Demographic and Substance Use Questionnaire

Date: _____________________________ Study Number ________________

Part 1: Demographics

1. What gender are you?
   □ Male
   □ Female

2. What is your age? ________

3. What is the highest level of education you completed?
   □ Elementary/primary school
   □ Secondary/high school
   □ College or university (undergraduate)
   □ Completed graduate education (e.g., Masters, PhD, MD degree)
   □ Other ____________
   □ Prefer not to answer

4. What cultural group do you belong to?
   □ Aboriginal/First Nations / Metis/Inuit
   □ Caucasian
   □ Hispanic
   □ African/Black
   □ South Asian
   □ Asian
   □ South East Asian
   □ Middle Eastern
   □ Mixed
   □ Other ________________
   □ Prefer not to answer

5. Over the past THREE MONTHS, where did you sleep most often?
6. In the past THREE MONTHS, where did the MAJORITY of the money you live on come from?
(choose all that apply)
☐ Social welfare
☐ Disability pension
☐ Employment insurance
☐ Work: _____ full time
        _____ part time
☐ Family/friends
☐ Sex work
☐ Selling drugs
☐ Binning
☐ Pan handling
☐ Other (specify) _______________________
☐ Prefer not to answer

7. Have you EVER used drugs for non-medical purposes (prescribed or otherwise)?
☐ Yes → Length of use (past or present) ____________ years
☐ No
☐ Prefer not to answer

8. When was the last time you had any drugs (including methadone)?

<table>
<thead>
<tr>
<th>Number of Substances</th>
<th>Number of minutes ago last used</th>
<th>Route (Check all that apply)</th>
<th>Used together with other substance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>□ Smoking</td>
<td>□ Not applicable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ Injecting</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ Snorting</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ By mouth</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ Other ________</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ Not applicable</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ Smoking</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ Injecting</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ Snorting</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ By mouth</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ Other ________</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ Not applicable</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ Smoking</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ Injecting</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ Snorting</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ By mouth</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ Other ________</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ Not applicable</td>
<td></td>
</tr>
</tbody>
</table>
9. Have you EVER used alcohol?
   □ Yes  ➔ Length of use (past or present) ____________ years
   □ No
   □ Prefer not to answer

10. Have you been drinking today?
    □ Yes ➔ When did you start
    □ No ➔ When was the last time you had any alcohol
        □ < 1 hour ago  # days ________ ago
        □ 1-3 hours ago # weeks ________ ago
        □ 4-12 hours ago # months ________ ago
        □ 13-24 hours ago # years ________ ago
        □ 1-2 days ago □ never
        □ 3-4 days ago □ prefer not to answer
        □ Other __________

11. Do you think you are high or drunk now?

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Not sure</th>
<th>Prefer not to answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>High on drugs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drunk on alcohol</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

12. Do you think you are withdrawing from a substance right now?
    □ Yes
    □ No
    □ Not sure
    □ Prefer not to answer

13. Do you think you are addicted to drugs?
    □ Yes
    □ No
    □ Not sure
    □ Prefer not to answer

14. Do you think you are addicted to alcohol?
    □ Yes
    □ No
    □ Not sure
    □ Prefer not to answer

15. Have you ever undergone treatment or other help for substance dependence?
    □ Yes: If YES, what? ______________  When? ______________
    □ No
    □ Not sure
    □ Prefer not to answer
16. If you are on a methadone program, when did you take your last dose?
   □ Not applicable
   □ < 1 hour ago
   □ 1-3 hours ago
   □ 4-12 hours ago
   □ 13-24 hours ago
   □ 1-2 day
   □ More than 2 days ago
   □ Not sure
   □ Prefer not to answer

17. Have you ever been told you have a mental illness?
   □ Yes: If YES, what? __________________
   □ No

18. Do you take medication for mental illness?
   □ Yes: If YES, when was your last dose? __________
   □ No
APPENDIX J: Consent form for the 302 participants who participated in the validation phase

Consent Form: Study Participant
A Tool to Assess Decisional Capacity for Clinical Treatment in Public Health Care Settings

Principal Investigator: Dr. Gina Ogilvie, UBC Department of Family Practice
Phone:

Co-Investigator(s): Michael Rekart,
Mark Gilbert
Juanita Maginley
Joanne Clifton
Mark Tyndall
Bonnie Henry
Jane Buxton
Louise Masse
Anita Ho

Purpose:
The purpose of this research study is to develop a set of questions that nurses and other care providers can use to determine if individuals who use drugs or alcohol are capable of consenting for health care interventions. You are being invited to take part in this research study because you are over 19 years old and you experience problematic use of alcohol or drugs. You should not participate in this study if you are younger than 19 years old.

Study Procedures:
The study is under the direction of Dr. Gina Ogilvie and involves the following activities:

1. Being interviewed by two study coordinators who will ask you questions from two different questionnaires. The questions are related to how much you understand about an imaginary situation involving receiving a flu shot. This is an imaginary situation and you will not actually be receiving a flu shot. These interviews will take approximately 45 minutes.

2. Being interviewed by a psychiatrist who will determine if you are capable of making decisions about medical care at the time of your study visit. This may take up to 15 minutes.

You may refuse to answer any questions you wish to in either of the questionnaires. It is important for you to know that this assessment will not affect you legally.
Potential Risks:
There are no known risks associated with this research study.

Potential Benefits:
You may or may not personally benefit from participating in this study. You may contribute new information that may benefit people in the future.

Confidentiality:
Your confidentiality will be respected. No information that discloses your identity will be released or published without your specific consent to the disclosure. The research documents (i.e. the questionnaires) will only identify you by a numerical code. No records which identify you by name or initials will be allowed to leave the Investigators' offices.

Remuneration/Compensation:
As your time and assistance is valued, $20.00 in cash will be made available to you in return for your time. The total amount of time required for this study is approximately 60 minutes.

Contact for information about the study:
If you wish to discuss future questions or concerns you may have about this study, you may contact Dr. Gina Ogilvie or Darlene Taylor.

Contact for concerns about the rights of research subjects:
If you have any concerns about your treatment or rights as a research subject, you may contact the Research Subject Information Line in the UBC Office of Research Services.
**Consent:**
Your participation in this study is entirely voluntary and you may refuse to participate or withdraw from the study at any time without jeopardy to your medical care.

Your signature below indicates that you have received a copy of this consent form for your own records.

Your signature indicates that you consent to participate in this study.

______________________________
Subject Signature                  Date
(or Parent or Guardian Signature)

______________________________
Printed Name of the Subject or Parent or Guardian signing above

Printed Name of Investigator or Delegate ____________________________
Signature of Investigator or Delegate ________________________________
Date: ___________________________
## APPENDIX K: Psychiatric data collection form

### Validation Phase: Data Collection Form – Psychiatrist

<table>
<thead>
<tr>
<th>Date _________________</th>
<th>Study Number: ______________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time when assessment started: ______________</td>
<td></td>
</tr>
</tbody>
</table>

1) **In your opinion is this participant under the influence of alcohol?**
   - □ Yes
   - □ No
   - □ Unsure

2) **In your opinion is this participant under the influence of illicit drugs?**
   - □ Yes
   - □ No
   - □ Unsure

3) **In your opinion does this patient have a mental illness?**
   - □ Yes
   - □ No
   - □ Unsure
   - If yes, what type of mental illness _________________________

4) **Is participant capable of making a decision about consenting or refusing treatment**
   - □ Yes
   - □ No

Time assessment ended: ______________
Total amount of time the assessment took ______________
**APPENDIX L: The CAIPS instrument used in the validation phase of this dissertation**

**Validation Phase: CAIPS Data Collection Form**

<table>
<thead>
<tr>
<th>Item Number</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Script:**  I would you to imagine that I am offering you a flu shot. I will tell you the risks and benefits of getting a flu shot and then I am going to ask you some questions. I would like to remind you that you will not actually be getting a flu shot today.

1. **Concept: Understanding**
   The client is able to repeat back, **in their own words** the main side effects/potential complications of the intervention that is being offered to them.

   1. strongly disagree
   2. disagree
   3. agree
   4. strongly agree

2. **Concept: Voluntariness**
   The client made their decision about the medical intervention without external pressure or coercion. (i.e. the client is not giving an answer that they feel the clinician wants to hear)

   1. strongly disagree
   2. disagree
   3. agree
   4. strongly agree

3. **Concept: Orientation**
   The client is oriented to person, place, and time (i.e. do they know who they are, where they are and what year it is?) or, if disorientated, it does not a direct bearing on the medical intervention being offered.

   1. strongly disagree
   2. disagree
   3. agree
   4. strongly agree

4. **Concept: Ability to communicate**
   The client can engage in the form of communication that they normally use (e.g., speech, signing writing) excluding a physical difficulty in speaking or use of foreign language not understood by the nurse.

   1. strongly disagree
   2. disagree
   3. agree
   4. strongly agree

5. The client is able to follow simple verbal or

   1. strongly
<table>
<thead>
<tr>
<th>Item Number</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>disagree 2. disagree 3. agree 4. strongly agree</td>
</tr>
<tr>
<td>6</td>
<td>The client is experiencing symptoms of distorted reality (i.e. symptoms hallucinations, delusions, paranoia) and these symptoms have a direct bearing on the intervention proposed. 1. strongly disagree 2. disagree 3. agree 4. strongly agree</td>
</tr>
<tr>
<td>7</td>
<td>The client knows that he/she is either at risk of an illness or has an illness and therefore requires clinical care. 1. strongly disagree 2. disagree 3. agree 4. strongly agree</td>
</tr>
<tr>
<td>8</td>
<td>The client is able to use the information given to them about the intervention to form a decision about consenting to the intervention or refuse the intervention. 1. strongly disagree 2. disagree 3. agree 4. strongly agree</td>
</tr>
<tr>
<td>9</td>
<td>The client is able to verbally or physically (e.g., nodding yes or holding their arm out for a blood test) indicate a choice. 1. strongly disagree 2. disagree 3. agree 4. strongly agree</td>
</tr>
<tr>
<td>10</td>
<td>While offering care to a client he/she seems to be distracted by friends, other activities, and/or symptoms of withdrawal. 1. strongly disagree 2. disagree 3. agree 4. strongly agree</td>
</tr>
<tr>
<td>11</td>
<td>There are physical indications that the client may have recently used drugs or alcohol (e.g., tweaking, nodding head, slurred speech, gyrating ). 1. strongly disagree 2. disagree 3. agree 4. strongly agree</td>
</tr>
</tbody>
</table>

Time assessment ended: ________________________
Total amount of time that the assessment took: _____________________
APPENDIX M: Standardized script used for Administration of the MacCAT-T instrument

Script: I would like to talk to you about getting a flu shot. You know that we are not offering a flu shot today, right? You might know that people who use substances and who live in areas such as the DTES are more likely to get the flu than other people. The reason for this is that substances actually lower your immune system and also you are living in close quarters so you are more likely to be exposed to the flu virus. The flu can feel like a cold but it usually involves a sore throat, sore muscles, and a high fever. If you have these three symptoms, that’s how you can tell if you have the “real flu.” General colds or stomach illnesses are not considered the “real flu.” As you probably know, there is a vaccine that may protect you from getting the flu. It is a vaccine that is injected into the muscle in your arm. I have been told that the flu vaccine is 60% effective in preventing the flu. It doesn’t protect you from getting general colds or stomach illnesses. Let’s talk about the risks and benefits of the flu shot. The good thing about getting the flu shot is that there is a good chance that you will not get the flu and if you don’t get the flu you won’t be spreading it to other people around you. There are some side effects to the flu shot. Firstly, the shot is given in your arm so you it may give you a sore arm and redness at the injection site. Also, people who are allergic to eggs should not get the flu shot because the shot is made with egg components. These people may have a very severe allergic reaction. That is why people are asked to wait around for 15 minutes after they have been given the flu shot.
APPENDIX N: Questions used for the MacCAT-T assessment adapted for use with a hypothetical flu vaccine scenario

Validation Phase: MacCAT-T

Date ______________________ Study Number: ____________
Time when assessment started: ______________________

<table>
<thead>
<tr>
<th>Concept</th>
<th>Question</th>
<th>Response</th>
<th>Score 0, 1 or 2 (0=low capacity, 2= high capacity)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Understanding of Disorder</td>
<td>Please explain in your own words what I’ve said about the ‘real flu’?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appreciation of Disorder</td>
<td>I have told you that you may be at higher risk of getting the flu than other people. If you have any reason to doubt that, I’d like you to tell me. What do you think □ disagree (score 0) □ ambivalent (score 1) □ agree</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Understanding – treatment</td>
<td>Now please explain in your own words what I’ve said about the flu vaccine.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Understanding risks and benefits</td>
<td>Now please explain in your own words what I have said about the good things and downsides to getting the flu shot</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appreciation – treatment</td>
<td>You may or may not decide that you want the flu shot – we will talk about that later. But do you think it is possible that the flu shot might be of some benefit to you? – EXPLAIN WHY □ disagree (score 0) □ ambivalent (score 1) □ agree</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reasoning - comparative</td>
<td>Now let’s review the choices you have. You can choose to have the</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concept</td>
<td>Question</td>
<td>Response</td>
<td>Score 0, 1 or 2 (0=low capacity, 2= high capacity)</td>
</tr>
<tr>
<td>-----------------------</td>
<td>---------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
<td>---------------------------------------------------</td>
</tr>
<tr>
<td>Flu shot or choose not to have it. Which of these things seems like the best thing for you? Can you tell me what it is that makes that seem better than the other choice.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reasoning - Generate consequences</td>
<td>I told you about the possible benefits and risks or discomforts about getting the flu shot. What are some of the ways that the benefits or risks might influence your activities? What are some of the good things or bad things that might happen that might influence your activities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reasoning - consequential</td>
<td>Score whether the participant acknowledges that there are consequences to each option</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reasoning - logical consistency</td>
<td>Score whether the participant is consistent with his responses and is articulating in a logical manner</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Final choice</td>
<td>Earlier in our discussion you said you might like to have the flu shot or would not like to have the flu shot. What are your thoughts now?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Time assessment ended: ____________________
Total amount of time the assessment took ______________