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Therapist Perception Of The Clarity And Implementability Of Relevant Recommendations From American Academy Of Orthopedic Surgeon's Distal Radius Fracture Clinical Practice Guidelines

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A thesis submitted in partial fulfillment of the requirements for the Doctor of Philosophy degree in Health and Rehabilitation Sciences

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Abstract

Fractures of the distal radius are common and can cause substantial transient or permanent impairment and disability.

Clinical practice guidelines (CPGs) are systematically developed statements or recommendations based on the best available evidence and aimed at assisting health care practitioners in clinical decision-making. Many professional organizations have developed practice guidelines for common clinical conditions. The overall objective of this thesis is to evaluate the therapist's perception of the clarity and implementability of rehabilitation relevant recommendations from The American Academy of Orthopaedic Surgeons (AAOS) CPG for distal radius fractures (DRF) and to identify the quality of CPG related to DRF. To address my study objective, first, I categorized the AAOS DRF CPG using the International Classification of Functioning Disability and Health (ICF) and International Classification of Diseases ICD-10 using linking procedures and compare the content codes of the CPG with the ICF hand core sets as the reference standard. Then I conducted a cognitive interview study to understand the therapist's perceptions of the clarity and implementability of the recommendations.

To further understand the implementability of the AAOS DRF CPG, I conducted a cross-sectional survey on the implementability of the AAOS DRF guidelines using the guideline implementability appraisal tool (GLIA). And we conducted a systematic literature review to identify and appraise CPGs relevant to the management of DRF s using the AGREE II tool.

The results of the thesis indicate that the AAOS DRF CPG focuses on surgical interventions and has minimal linkage to the constructs of the CF constructs (activity or participation) and the ICF Hand Core Set. In my qualitative study, I found that eight of ten recommendations sampled from the AAOS DRF CPG were considered vague and unimplementable by therapists in their clinical practice, due to the lack of clarity and information on what to implement, how to implement, and how to measure the adherence and outcomes of the recommendation. In the systematic review I found that for the selected CPGs developed by professional organizations in the UK, Canada, USA, Denmark, and Norway, the AGREE score for the scope and purpose domain ranged from 61% to 94% and the stakeholder involvement domain ranged from 13% to 97%. The rigor of the development domain score ranged from 38% to 95%, and the clarity of the presentation domain score ranged from 63% to 83%. Scores were lowest on the domain of applicability and ranged from 18% to 60%, and the score for the editorial independence domain ranged from 54% to 79%.

This work implies that CPG that focus on rehabilitation after DRF are needed and improving the implementability of the CPG recommendations by making them more specific and actionable while providing resources would assist with the implementation. Therapists need to be aware and understand variability existing in quality, the rigor of development, and the applicability of these guidelines. Future guidelines should consider implementation during development including ready access to the details about the level recommended in intervention reporting guidelines.

Summary for Lay Audience

Clinical practice guidelines (CPG) are tools that are used to help patients and health professionals to manage health conditions using the best available research evidence. A broken wrist, called a distal radius fracture, is the most common broken bone that requires patients to attend an emergency clinic. From this initial visit through to rehabilitation, many decisions must be made. Clinical practice guidelines should assist with those decisions and help to keep patients informed about whether they are getting best care. However, this is dependent on ensuring that the recommendations within such guidelines are evidence-based, easy to interpret, provide clear guidance and can be reasonably implemented. An international group of orthopedic surgeons (American Academy of Orthopaedic Surgeons) has developed a guideline for how these injuries should be managed. It is important that we understand whether this guideline is understood and used.

In this thesis work I interviewed the health professionals involved in helping patients recover from these fractures and found out detailed information about how they interpret the recommendations, their intention on implementing them and the barriers and facilitators to doing so. In one study in this thesis work, I found that eight of ten recommendations sampled from the American Academy of Orthopaedic Surgeons guidelines to treat the broken wrist were considered vague and difficult to implement by therapists in their clinical practice, as they are not easy to understand and information on what to implement, how to implement were not clearly informed. This thesis finds that CPG that focus on rehabilitation after broken wrist are needed and improving the applicability of the CPG recommendations by making them more specific and actionable while providing resources would assist with the implementation.

Co-Authorship Statement

This thesis contains one published manuscript and three manuscripts awaiting submission. The conceptual ideas for the research, study design, data collection, statistical analysis, and writing were all performed by me, with valuable assistance and direction from my supervisor, Dr. Joy C. Macdermid, and my thesis advisory committee members, Dr. Dave Walton and Dr. Ruby Grewal.

The unique contribution and co-authors of each chapter are as follows:

CHAPTER 1: Introduction

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Dr. Joy C. Macdermid – Supervised work of trainee (ES), revised multiple versions manuscript,

Dr. Dave Walton – Advice on design and conduct of work, revised manuscript

Dr. Ruby Grewal – Advice on design and conduct of work, revised manuscript

CHAPTER 2: Linking of the American Academy of Orthopaedic Surgeons Distal Radius Fracture Clinical Practice Guidelines to the International Classification of Functioning, Disability, and Health; International Classification of Diseases; and ICF Core Sets for Hand Conditions.

Saravanan Esakki - Study design, data collection, primary author, data analysis

Dr. Joy C. Macdermid –Study design, supervised work of trainee (ES), revised multiple versions manuscript,

Dr. Dave Walton – Advice on design and conduct of work, revised manuscript

Dr. Ruby Grewal – Advice on design and conduct of work, revised manuscript

CHAPTER 3: Therapist perceptions of the clarity and implementability of relevant recommendations from the AAOS clinical practice guideline for distal radius fracture.

Saravanan Esakki - study design, data collection, primary author, data analysis

Dr. Joy C. Macdermid – Study design, supervised work of trainee (ES), revised multiple versions manuscript,

Dr. Dave Walton – Advice on design and conduct of work, revised manuscript

Dr. Ruby Grewal – Advice on design and conduct of work, revised manuscript

Dr. Tara L. Packham – Advice on design, data collection and revised manuscript

CHAPTER 4: Survey on implementability of the American Academy of Orthopaedic Surgeons Distal Radius Fracture Clinical Practice Guideline using GuideLine Implementability Appraisal

Saravanan Esakki - study design, data collection, primary author, data analysis

Dr. Joy C. Macdermid – Study design, supervised work of trainee (ES), revised multiple versions manuscript,

Dr. Dave Walton – Advice on design and conduct of work, revised manuscript

Dr. Ruby Grewal - Advice on design and conduct of work, revised manuscript

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CHAPTER 5: Clinical practice guidelines relevant to rehabilitation of DRF of distal radius fracture: a systematic review

Saravanan Esakki - study design, data collection, data analysis and primary author.

Dr. Joy C. Macdermid – Study design, supervised work of trainee (ES), revised multiple versions manuscript,

Dr. Dave Walton – Advice on design and conduct of work, revised manuscript

Dr. Ruby Grewal – Advice on design and conduct of work, revised manuscript

CHAPTER 6: Discussion and Conclusion

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Acknowledgements

I would like to thank the Almighty for all the blessings and love that he has showered upon me throughout my life, the opportunity he gave me in this life to refine myself and to become a person I am today.

I would like to thank Dr. Joy C. Macdermid, for all her support over my education. Words cannot describe how thankful I am to Dr. Joy for her continued unwavering support and guidance that has brought me to where I am today in my academic life. In addition to her contribution to the manuscripts held within this thesis; she has spent many hours over the course of my course work and this thesis work reviewing research methods and writing style, elevating the quality of the subject matter found within. Dr. Joy has become my mentor over the past seven years, and I hope we will continue to collaborate professionally on many projects in the future.

I would like to acknowledge the contributions of my thesis advisory committee, Dr. Dave Walton and Dr. Ruby Grewal. They have provided guidance and assisted with editing of manuscripts published within this thesis. They were both excellent committee members, with honest, timely feedback when editing and revision of papers was needed. Sincere thanks to Dr. Tara L. Packham, who helped immensely with data collection, and assisted with editing of Chapter 3.

Last, but not least, I would like to thank my family. To my wife, Dr. Saipriya Vajravelu Saravanan, who is the love of my life. She has supported me in my personal life and in my professional career. She is my best friend and the person to whom I share everything. My sons, Rakshan Saravanan and Rishaan Saravanan, who brighten my life every day and bring me joy and laughter every minute. To my parents, who supported me in all my activities

Contents

Abstract.....	i
Summary for Lay Audience.....	iii
Co-Authorship Statement	iv
Acknowledgements	vii
CHAPTER 1.....	1
1.1a. Introduction.....	1
1.1b Fracture Classification	2
1.1c Management for distal radius fracture	2
1.1d Clinical Practice Guidelines:.....	4
1.1e Barriers and facilitators for guideline implementation	5
1.1f Health Frameworks.....	7
1.1g ICF core set for Hand conditions.....	8
1.1h Cognitive interviewing:	9
1.1i AGREE and GLIA Tool.....	11
CHAPTER 2.....	20
2.1 Linking of the American Academy of Orthopaedic Surgeons Distal Radius Fracture Clinical Practice Guidelines to the International Classification of Functioning, Disability, and Health; International Classification of Diseases; and ICF Core Sets for Hand Conditions	20
2.1a Abstract.....	20
2.2 Introduction.....	21
2.3 Methods.....	24
2.3a Linking to ICF.....	24
2.4 Analysis	25
2.4a CPG to ICF linkage.....	25
2.5 Results	27
2.6 Discussion.....	28
2.7 Conclusion	30
CHAPTER 3.....	38
3.1 Therapist perceptions of the clarity and implementability of relevant recommendations from the AAOS clinical practice guideline for distal radius fracture.	38
3.1a Abstract:	38
3.2 Background	40

3.3 Methodology	42
3.3a Research Design	42
3.3b Ethics and Consent	44
3.3c Participants	44
3.3d Sampling and Sample Size	45
3.3e Recruitment	45
3.3f Setting	46
3.3g Data Collection & Management	46
3.3h The Guideline Sampled	47
3.3i Interview Format & Guides	47
3.3j Participant Demographics	47
3.4 Data Analysis	48
3.5 Results	49
3.5a Cognitive interview analysis:	49
3.5b Interpretive description method to understand the factors influencing the guideline implementation	55
3.6 Discussion:	60
3.7 Limitations:	64
3.8 Conclusion:	64
CHAPTER 4	78
4.1 Survey on implementability of the American Academy of Orthopaedic Surgeons Distal Radius Fracture Clinical Practice Guideline using GuideLine Implementability Appraisal	78
4.1a Abstract	78
4.2 INTRODUCTION	81
4.3 METHOD	82
4.3a Ethics and Consent	82
4.3b DRF Clinical practice guideline	82
4.3c Appraisal instrument	82
4.3d The global dimension:	84
4.3e Participants and mailing procedure:	84
4.4 RESULTS:	86
4.5 DISCUSSION	90
4.6 Limitations of the study	93
4.7 Conclusions	94

CHAPTER 5.....	105
5.1 Clinical practice guidelines relevant to rehabilitation of DRF of distal radius fracture: a systematic review	105
5.1a Abstract.....	105
5.2 INTRODUCTION.....	107
5.3 Methods.....	109
5.3a Search strategy	109
5.3b Inclusion and exclusion criteria.....	110
5.3d Evaluation of Quality of Clinical Practice Guidelines Using AGREE II.....	111
5.4 Results	112
5.5 Discussion.....	118
5.6 Conclusion	Error! Bookmark not defined.
CHAPTER 6.....	128
6.1 DISCUSSION AND CONCLUSION	128
6.1a Contextual Overview	128
6.1.b Overall summary of the thesis results.....	129
6.1.c. Contribution of the thesis to the literature and clinical practice	133
6.1. d. Limitations.....	134
6.2 Conclusions.....	135

TABLES AND FIGURES AND APPENDIX

CHAPTER 2

Linking of the American Academy of Orthopaedic Surgeons Distal Radius Fracture Clinical Practice Guidelines to the International Classification of Functioning, Disability, and Health; International Classification of Diseases; and ICF Core Sets for Hand Conditions

1. Table 1. ICD-10 Conditions Used in the AAOS Guidelines. -----p23
2. Table 2. ICF Codes Used in the AAOS Guidelines. -----p24
3. Table 3. AAOS DRF Recommendations That Are Not Codable in ICF -----p24

4. Table 4 ICF Linkage Indicators to Define the Linkage Between AAOS DRF CPG Recommendations and the ICF Core Sets. -----p25

CHAPTER 3

Therapist perceptions of the clarity and implementability of relevant recommendations from the AAOS clinical practice guideline for distal radius fracture.

1. Figure 1: Determinants of behavior as described in the TPB-----p36
2. Appendix:1 Recommendations pertaining to rehabilitation-----p56
3. Appendix 2: Cognitive interviewing (CI) - to identify sources of interpretation dissonance in patient-reported outcome measures (PRO)-----p59
4. Table:1 Codes and Themes-----p60

CHAPTER 4

Survey on implementability of the American Academy of Orthopaedic Surgeons Distal Radius Fracture Clinical Practice Guideline using GuideLine Implementability Appraisal

1. Table 1: The global dimension included 9 questions-----p75
2. Table 2: Participants Demographics-----p77
3. Table 3: GLIA response options-----p78
4. Table 4: Glia response for the AAOS DRF CPG-----p79
5. Figure:1 Global considerations questions-----p86
6. Figure 2: Executability: Is the recommended action stated? -----p86
7. Figure 3: Executability: Detail provided about how to do it? -----p87
8. Figure 4: Measurability: Can adherence be measured? -----p87
9. Figure 5: Measurability: Can the outcome be measured? -----p88

10. Appendix1: AAOS DRF CPG Recommendation with the corresponding number--p88

CHAPTER 5

Clinical practice guidelines relevant to rehabilitation of DRF of distal radius fracture: a systematic review

1. Figure 1: Selection of guidelines-----p103
2. Table 1: The Appraisal of Guidelines for Research and Evaluation II (AGREE II) Instrument-----p106
3. Table 2: Appraisal of Guidelines, Research, and Evaluation II domain-standardized scores-----p107
4. Table 3: Clinical guideline recommendations regarding the rehabilitation care of DRF -----p109

CHAPTER 6

Discussion and Conclusion

1. Appendix 1: HAMILTON INTEGRATED RESEARCH ETHICS BOARD (HIREB) RENEWAL FORM FOR REB APPROVED STUDIES-----p129
2. Appendix 2: LETTER OF INFORMATION / CONSENT-----p135
3. Appendix 3: HIREB: General Research Application-----p142

CHAPTER 1

1.1a. Introduction

Epidemiology:

Distal radius fractures (DRF) are one of the most common fractures of the upper extremity(1). DRF is the cause for one-sixth of all ortho trauma department visits and constitutes 26-46% of all fractures treated in the health care setting(1,3). A common mechanism of injury is falling on the outstretched palm with the wrist in 40°-90°of extension(4). Amongst older adults, DRF is often a low-energy fall-related fracture and indicates a risk of subsequent falls(5). It has been reported that elderly women are at five times higher risk of DRF than men due to menopause-related secondary bone loss(3,6). There has been a gradual increase in the incidence of distal radius fractures in recent years. Nellans et al. reported that the rates of DRF have increased by up to 17% in the past 40 years(1). This alarming rate of DRF is attributed to the increasing number of people with osteoporosis, obesity, and lifestyle(7). In Canada, the average cost per fall leading to a visit of a patient to the emergency department is \$11,408 and the average cost per fall requiring hospital admission is \$30,000(8). This creates a high economic burden on the health care system(8).

1.1b Fracture Classification

DRF are commonly classified into three main types: intra articular fracture where the rest of the metaphysis is intact, metaphyseal fracture characterized by the volar angulation of the distal fragment, and metaphyseal fracture characterized by the dorsal angulation of the distal fragment(9,10). Majority of DRFs were often the metaphyseal type, which is also called as Colles' fracture(11). Fracture instability in the Colles' fracture is determined by the degree of dorsal displacement of the distal fragment, the degree of comminution of the dorsal cortex close to the fracture, and the degree of radial shortening(12). Another common classification of the DRF describes three main types of fractures: extraarticular, partial intraarticular, and complete intraarticular(13). Each of these main types further has subgroups that describe the in-depth character of the fracture type. Another common classification of the DRF is based on the mechanisms of the injury as described by Frykman(14). This classification categorizes the DRFs into intraarticular or extra-articular fractures, with or without associated distal ulna fracture(14). Another commonly used classification based on the mechanisms of injury is the Fernandez classification, ranging from compression, shearing, bending, avulsion/fracture-dislocation to combined/high-velocity injury(15). However, all classification systems have notable low Intra- and interobserver reliability, so it is highly difficult to choose a treatment strategy based only on the DRF classifications(6).

1.1c Management for distal radius fracture

In addition to being one of the most common injuries seen in orthopedics, fractures of the distal radius have also proven to be one of the most difficult to treat(14). This difficulty arises in part from the heterogeneous nature of the injuries but is also related to the difficulty in regaining

anatomic and functional normalcy following the injury(16). The consequences of an inadequately treated distal radius fracture can be devastating. Several authors have noted that malunion following treatment of a distal radius fracture results in physical deformity, weakness, stiffness, and frequent pain of the wrist(17–22). A correlation has been made to the severity of the initial injury and both anatomic and functional outcomes. It has been shown that those with extensive comminution and intra-articular involvement with associated soft tissue injury are at risk for having a poorer outcome than those who sustain fractures of the distal radius without these characteristics(10). The technique for the treatment of these injuries is open to debate but is directed at attaining the best anatomic and functional outcomes while minimizing complications(13).

In the acute stage, the DRF can be treated either conservatively or surgically. Once the fracture was fixed, DRF patients are referred for rehabilitation. Rehabilitation aims to improve functions and relieve pain(23). Factors such as age, sex, mode of injury, pre and post-reduction radial shortening, and complexity in joint involvement influence the recovery of the patient with DRF(23).

Irrespective of either conservative or surgically managed DRF, patients should regain an optimal range of motion, muscle strength, and functional movement within three to six months(19,24,25). However, complications such as complex regional pain syndrome, hand stiffness, fracture malunion, and delayed functional movement may delay recovery(25). More than 18% of the patients with DRF reported having persistent pain and loss of functional movement, mal or non-union, joint stiffness, complex regional pain syndrome resulting in disability(24).

Patients with DRF can experience a wide spectrum of disabilities including pain, swelling, decreased range of motion, and functional disabilities. DRF management is based on factors not

limited to the fracture type, patient's age and physical condition, quality of the bone, the clinical experience of the clinicians(19). As far as fracture fixation is considered, there is a variety of surgical techniques for DRF and there is not any single gold standard treatment approach(26). The rehabilitation management of DRF aims at pain management and improving the range of motion, grip strength, and hand function(27). In the acute immobilization phase, the rehabilitation goals focus on reducing the edema and maintaining/improving the range of motion in digits. During the mobilization phase, the rehabilitation goals include controlling the pain and edema, restoring range of motion in the forearm, hand, and wrist, and to improve the handgrip strength and hand function(23,27). The overall aim of rehabilitation is to restore hand function to the pre-fracture functional levels. Due to the high incidence of these fractures, patients are often seen by physiotherapists/occupational and hand therapists for rehabilitation(27).

1.1d Clinical Practice Guidelines:

To assist therapists in providing care that is aligned with evidence-based practice (EBP) in the treatment of DRF, clinical practice guidelines should be implemented. These guidelines attempt to locate, review, and summarise the best available scientific evidence and are said to be vital tools for clinicians(28).

Clinical practice guidelines (CPGs) are the evidence-based information available to assist and inform the clinicians and patient decisions about appropriate healthcare for definite clinical situations(29). Good CPGs synthesize the best available evidence to aid the clinician and patient decision-making. Guidelines are one way to transfer research evidence to health care processes, help in standardizing care by reducing variation in care, improve health care practices, produce

better patient care outcomes, and reduce health care costs(29–31). Health professional associations and other groups help with guideline development to a nominated group of motivated experts who engage in the process of translating research evidence into clinical recommendations(29). CPG contains recommendations with varying levels of research evidence and statements based on clinical expertise. CPG may include expert and clinical knowledge, stakeholder feedback, and address practical concerns with regards to the feasibility of guideline use(29). There is a wide range of perceptions around the utility of CPGs in medicine(32).

Some clinicians consider the practice guidelines as a way of minimizing instinctual, unscientific, and potentially biased treatment decision making(34). But surprisingly, evidence shows that in countries such as Canada, the United Kingdom, and The USA, more than 30% of patients do not receive care in terms of the current scientific evidence(35). Considering the epidemiology and the extent of the disability experienced by the patients with DRF around the world(1), it is important for the clinicians, researchers, policymakers, and the DRF patients to have a reliable and implementable evidence-based CPG. Implementation of CPG is the process of translating the evidence from CPGs into practice(36). Implementation is a strenuous process as it involves bringing changes at the individual, organizational, or health system levels. For the successful guideline implementation, it is important to identify the factors influencing the implementation of the recommendations, that is the barriers and facilitators in the guideline implementation(37).

1.1e Barriers and facilitators for guideline implementation

Practice guidelines on fracture management have been developed in many countries. However, the integration of these guidelines by clinicians appears problematic(38). Despite the availability of

guidelines, several studies carried out with physicians and physical therapists have demonstrated significant gaps in knowledge and practice related to fracture management(28). To explain these gaps, research recommends identifying the barriers to guideline use. This allows predicting guideline use, to better understand why guidelines are used or not, and to develop implementation strategies aimed at the barriers to facilitate guideline use(39,40).

Barriers to the use of evidence related to fracture management have been studied with physicians and physical therapists, with one of the main barriers being the required shift of clinical management from pathophysiology to the prevention of persistent disability(41). However, no study has been done on the perceptions of rehabilitation professionals regarding the use of evidence-based guidelines on the management of DRF. It is therefore not known how these health professionals perceive current evidence related to DRF management or the barriers they encounter when using this evidence.

Barriers and facilitators related to the use of several guidelines related to conditions like low back pain, stroke rehabilitation, neck pain, and whiplash injury have been previously studied with rehabilitation professionals(42–45). To our knowledge, this is the first study that focuses on the barriers and facilitators related to the use of DRF clinical practice guidelines.

Understanding guideline use can contribute to the development of an implementation strategy targeting improved care of patients with DRF, we explored the barriers and facilitators for the implementation of CPGs in the clinical areas of rehabilitation using Guideline Implementability Appraisal (GLIA) and Appraisal of Guidelines for Research and Evaluation (AGREE) instrument.

1.1f Health Frameworks

Health frameworks help clinicians and health researchers in describing and understanding the aspects of the health needs of an individual(46). International Classification of Functioning Disability and Health (ICF) is one of the common frameworks relevant to rehabilitation, which helps clinicians/researchers to understand and describe functioning and disability(47).

The World Health Organization officially endorsed the ICF in 2001. The ICF has two major components: a conceptual model and a coding system. The conceptual model helps to recognize the relationship between an individual's health condition and other contextual factors(47). The conceptual model comprises 2 major categories such as functioning and disability: and contextual factors. The functioning and disability part have three domains: body structures/ functions, activities, and participation. The body structure/function represents the functioning at the level of body parts; activities – represent functioning at the level of the person as a whole; and finally, participation – represent the functioning of a whole person in their complete environment. The contextual factors part consists of two factors; the environmental factors and the personal factors(47). The ICF coding system is a hierarchical system, which has a total of 1440 alphanumeric codes. The alphanumeric codes were sectioned into four main domains of Body Functions ('b' codes - 493), Body Structures ('s' codes - 310), Activities, and participation ('d' codes - 384), and Environmental factors ('e' codes - 253). The codes are arranged into components, that includes chapters (1st level) and categories on 2nd, 3rd, and 4th level(48).

1.1g ICF core set for Hand conditions

ICF core sets were developed for some specific health conditions to make the ICF more applicable for everyday use in clinical practice and health research(49). These core sets are a subset of ICF categories that provides the lists of important categories that are relevant for specific health conditions(50).

There are two types of core sets such as comprehensive and brief core sets. The comprehensive core set consists of a list of comprehensive ICF categories that helps to make a typical spectrum of problems in the situation functioning of patients with a specific condition(51). While a brief ICF Core Set consists of a list of ICF categories with a few categories which are sufficient to be used in clinical situation and research(52). There are currently 34 core sets that have been developed for various conditions including hand conditions, osteoarthritis, chronic pain, rheumatoid arthritis, amputees, osteoporosis, ankylosing spondylitis, etc. (52).

The ICD-10 is the standard disease classification tool(53). The ICD-10 can be used in epidemiology, health management, and clinical purposes, such as describing and analyzing the general health of the population group(54). One of the main advantages of ICD-10 includes the fact that its coding structure is adapted in such a way that it allows future expansion and hence allows the coding of in-depth clinical information of the condition(53,54). The ICD-10 has been used by many European countries for coding mortality and/ or morbidities. The flexibility of the ICD-10 helped countries such as Australia, Canada, and the United States to build upon the ICD-10 by adding new codes and have developed their versions of ICD 10(55).

The first manuscript analyzes and describes the scope and focus of the American Academy of Orthopaedic Surgeons (AAOS) DRF CPG using the ICF and ICD-10 as a basis for content

analysis, and to compare the content of the CPG with the ICF hand core sets as the reference standard. This guideline was selected as being the only one coming from a major North American professional association, and so considered the most likely to be considered for implementation in this context.

CPGs must be developed with involvement from their target users to identify what is meaningful and applicable from their perspective to enhance implementability and clinical utility(56). Cognitive interviewing (CI) can be utilized to understand the perspective of the target users of the CPGs. CI has been posited as a technique to ensure recommendations included in CPGs have precision and relevance to potential respondents(57).

1.1h Cognitive interviewing:

Cognitive interviewing (CI) is a psychologically oriented technique for empirically studying the participant's cognitive process when responding to a survey questionnaire(57). This technique was comprehensively implemented in research studies to gain insight into participant's understanding and interpretation of specific questions(58–60). CI aims to understand the decision processes of the respondent made while responding. This is of importance since people understand and interpret the meaning of the words in different ways(61). Traditionally, the CI process has in-depth, semi-structured interviews with a small sample of approximately 8–25 respondents(62). During CI, participants first answer the evaluated question and then are probed for their interpretation of recommendation or item content and response formats to help determine potential problems or concerns associated with each recommendation or item(62). The CI aims to prompt how the

respondent interprets and understands the question, the process used by the respondent to recall pertinent information from the respondent's memory while answering the questions(57).

In CI techniques "think aloud" and verbal probing are the two approaches generally implemented to receive the required information from the participants. "Think-aloud" approach is based on methods from psychology and memory testing adapted from the work of Ericsson and Simon in the 1970s. In this method, the interviewer reads each question, and respondents are requested to "think aloud" about the process that goes on in their minds while they try to answer. In this think-aloud process, the interviewer aims to understand the cognitive process that participants go through while formulating an answer(57). The interviewer also aims to reveal possible misconceptions or misunderstandings about the purpose/meaning of the question. When the interviewer asks the question, participant were encouraged to think aloud and to verbalize the thoughts(62). The interviewer typically must teach the participant how to think aloud and includes a think-aloud practice question, as most participants may be unfamiliar with verbalizing the thought processes while answering the question(63). The practice question can be something similar to ask the participant to visualize the place where they live, and then to mentally count up the number of rooms, doors, or windows in the place. Then the participant is instructed to verbalize what they see and think about while counting the rooms, doors, or windows(63).

The second manuscript indicates therapist perceptions of the clarity and implementability of relevant recommendations from the AAOS clinical practice guideline for distal radius fracture using the cognitive interview approach. Even though CPG intends to bridge the research evidence and clinical practice gap by providing definitive recommendations for clinical practice, issues regarding their use and implementation remain questionable(56). To improve the use of the CPG's and subsequent improvement in patient care largely depends on the rigor of their development and

dissemination and implementation strategies. However, in reality, numerous guidelines have no clear implementation plans and have not been rigorously developed, and therefore it could be difficult for practitioners to follow their recommendations(64). Therefore, a highly methodological quality development process for CPGs is more likely to yield a CPG that contains relevant and appropriate recommendations(65). Many instruments have been developed to evaluate the methodological quality and implementability of the CPG(37).

1.1i AGREE and GLIA Tool

To improve the methodological quality of guidelines several tools were developed since late 1990 such as AGREE, ADAPTE, and national and local handbooks or checklists. These tools help the guideline developers and users to assess the quality of guidelines(66). The Appraisal of Guidelines for Research and Evaluation (AGREE) instrument was developed by an international group of researchers in 2003, further, this guideline was revised in 2009 as AGREE II(67). The main utility of the AGREE tool is in developing new guidelines and to report the quality of the existing CPGs(68). The AGREE Instrument has 23 questions organized under six domains (1) scope and purpose; (2) stakeholder involvement; (3) rigor of development; (4) clarity and presentation; (5) applicability; (6) editorial independence and one overall assessment item, to judge whether the guideline can be recommended for its use in clinical practice(67). AGREE instrument has also been used in research and policy(66). The sharing of the standard tool across countries will facilitate international comparison of guidelines and can provide a framework for studies aimed at developing guidelines. This can also help to understand the similarities and differences in recommendations across the developed guidelines for a similar health condition(56). As the

number of clinical practice guidelines submitted for publication increases, there is a need to ensure the quality of the developed CPGs(67). The AGREE tool can be adopted by editors of peer-reviewed journals as a framework to assess the quality of clinical guidelines in the same way that CONSORT (Consolidated Standards of Reporting Trials) is used to judge the quality of randomized controlled trials and meta-analyses(66).

The focus on guideline development methods can lead to “science or evidence-driven” guidelines rather than evidence-based but “consumer-driven” resources(28). Several studies reported that the development of a quality guideline does not automatically result in more successful implementation, it is essential to understand the guideline implementability for the successful utilization of the guidelines in clinical settings(28,46,69,70). The objective of the Guideline Implementability Appraisal (GLIA) is to provide a tool for the appraisal of the implementability of clinical guidelines(71). Implementability can be defined as a set of guideline characteristics that predict potential challenges to effective implementation(56). Tools like GLIA helps with identifying the potential barriers at both an individual and organizational level for guideline implementation(36). The GLIA tool was specifically developed to assist to identify and understand the implementation barriers related to intrinsic factors of the guideline itself (eg, inconsistencies, ambiguity, and incompleteness) along with the extrinsic factors related to the specific healthcare provider or organization(71).

The third manuscript summarizes the cross-sectional survey on the implementability of the AAOS DRF guidelines using the guideline implementability appraisal tool (GLIA). These three study results show that AAOS DRF CPG does not provide meaningful and implementable recommendations for the rehabilitation professionals working with DRF patients. We conducted a

systematic review to identify the available CPGs on the treatment of DRF and its recommendations relevant to the DRF rehabilitation.

The first and 2nd manuscript of this thesis were planned as part of a master's degree. When I transitioned to a PhD program, I wanted to extend my investigations beyond the AAOS CPG. There is a CPG for DRF in development by the American Physical Therapy Association (APTA), but it was not completed in time to be included in this thesis. Therefore, I undertook a systematic literature review to find, appraise and synthesizes other CPGs relevant to the management of DRF, using the AGREE II appraisal tool. This review also identifies the extent to which these guidelines address rehabilitation since this is a focus of this thesis, and our prior work on the AAOS guideline had indicated that guideline had a very medical focus. Thus, the systematic review did not direct the focus on the AAOS CPG in the 1st 3 manuscripts, but rather determined whether the state of the evidence was different when looking at other guidelines that might exist external to North America.

Overall, this thesis examined in detail the usability and relevance to rehabilitation of the AAOS DRF practice guideline and situated that in the context of international CPG across 4 manuscripts.

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CHAPTER 2

2.1 Linking of the American Academy of Orthopaedic Surgeons Distal Radius Fracture Clinical Practice Guidelines to the International Classification of Functioning, Disability, and Health; International Classification of Diseases; and ICF Core Sets for Hand Conditions

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2.1a Abstract

Background: American Academy of Orthopaedic Surgeons (AAOS) distal radius fracture (DRF) clinical practice guidelines (CPG) are readily available to clinicians, patients, and policymakers. International Classification of Functioning, Disability, and Health (ICF) provides a framework for describing the impact of health conditions. The International Classification of Diseases–10th Revision (ICD-10) is a classification system to classify health conditions as specific diseases or disorders. This study aims to analyze and describe the scope and focus of the AAOS DRF CPG using the ICF and ICD-10 as a basis for content analysis, and to compare the content of the CPG with the ICF hand core sets as the reference standard.

Methods: Established linking rules were used by 2 independent raters to analyze the 29 recommendations of the AAOS DRF CPG. ICD-10 codes were assigned in the same process. Summary linkage statistics were used to describe the results for ICF and the hand core sets.

Results: Among the 29 recommendations of the AAOS DRF CPG, 5 meaningful concepts were linked to the ICF codes. Of these, 5 codes appeared on the comprehensive ICF core set and only 3 codes appeared in the brief ICF core set, and 7 conditions were covered in ICD-10 codes.

Conclusions: The AAOS DRF CPG focuses on surgical interventions and has minimal linkage to the constructs of the ICD-10 and ICF. It does not address activity or participation (disability) and is not well linked to key concepts relevant to hand conditions.

2.2 Introduction

Distal radius fracture (DRF) is one of the most common types of fracture (7,25,31) that can cause substantial pain, disability (6,14,24,37) and health care burden.⁶ Study shows that more than 640 000 cases of DRF were reported during 2001 in North America (14) and nearly 372 000 individuals age 65 years and older sustain DRF every year in the United States (35). Many studies describe the extent of impairments and disabilities experienced by patients with DRF. Appropriate and effective treatment is essential to manage the DRF and to minimize the disability experienced by the patients with DRF (30). Evidence-based practice guidelines help the health care professionals in clinical decision making on effective treatment (4) Clinical practice guidelines (CPG) are defined as “Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances” (25). Evidence-based CPG is developed by identifying high-quality evidence to facilitate more rational and efficient clinical practice and better health care outcomes (21,25). Many professional organizations have developed evidence-based CPG that plays a significant role in initiating the quality of health care (16). The American Academy of Orthopaedic Surgeons (AAOS) is the largest professional group that provides professional support to orthopedic surgeons and other allied health care professionals

who work in orthopedics (2). The AAOS has invested substantial effort in developing clinical practice guidelines, for a variety of common orthopedic conditions including DRF (1). The CPG was developed using a process where orthopedic surgeons develop priority clinical questions and the best evidence was identified to locate the best available evidence to address the issues raised (1), (<http://www.aaos.org/research/guidelines/DRFguideline.asp>). Considering the epidemiology of the DRF and the extent of disability experienced as the result of DRF around the world (6,13,19, 40) it is important for the clinicians, policymakers, researchers, and public, including people with disability, to have a uniform language/terminology to describe the disability. The International Classification of Functioning, Disability, and Health (ICF) is the World Health Organization's (WHO) initiative that provides a unified framework for the description of health constructs (45). It was approved by World Health Assembly in 2001(8). The International Classification of Diseases–10th Revision (ICD-10) is the standard diagnosis based classification system that describes diagnoses for epidemiology, health management, and clinical purposes, including analyzing the general health of the population group (44) It is used universally in linking the mortality and morbidity statistics and indexing of hospital records (44). As described by ICF, disability is a universal human experience that occurs through the complex interaction between a person's health condition and personal factors and environmental contextual factors, resulting in functioning at various levels: body structures and functions, activities, and participation (15,43). ICF and ICD-10 are the international language for describing health and disability and can be used for content analysis in evaluating outcome measures (38,43) or disability experiences (2) to understand the content of the outcome measures, treatment program, and disability experiences (15). ICF can enhance patient-centeredness and goal setting (11,12,33). For these reasons, the International Guidelines Network recommended ICF and ICD-10 to be incorporated into guideline

development (42), and the American Physical Therapy Association (17) has adopted ICF as a framework for recent and future guidelines. The ICF core set for hand conditions was developed in 2009 to comprehensively describe the functioning and disability of individuals with hand conditions (23,36). A total of 117 ICF codes were included in the comprehensive ICF core set for hand conditions. These codes can be taken into account when conducting a comprehensive, multidisciplinary assessment (36). The brief ICF core set has 23 ICF codes and it can be used in assessing any patient with hand conditions irrespective of the health care setting and can be used by the individual health care professionals even when not a multidisciplinary team is involved (23,36). The process for developing CPG and the available pool of evidence determine the nature and scope of the resulting recommendations. Understanding the quality and content of the CPG is needed for potential users to consider their usefulness in practice. Although there has been much development of a methodology to determine the quality of CPG (1,29) and the quality of guidelines in the hand therapy has been evaluated (27), there has been less focus on understanding the content or comprehensiveness of the CPG recommendations. For guidelines to be useful, they should do the following: provide recommendations that are evidence-based providing clear direction on the strength of the supporting evidence, recommend clear and specific actions to be taken under specific circumstances, provide a clear indication of the expected outcomes, and potential complications with different treatment options, and provide a sufficient range of options so that users can provide comprehensive care. As ICF is recommended as a framework for CPG, the purpose of this study is to examine the linkage of the AAOS DRF CPG for the ICF and ICD-10.

The purpose of this study is to

1. classify the content addressed in the recommendations of the AAOS CPG for distal radius fracture using ICF and ICD-10 codes, and

2. determine the extent to which the recommendations represent important areas of function and disability by comparing content with the ICF hand core sets.

2.3 Methods

The AAOS DRF clinical practice guidelines consist of 29 recommendations (<http://www.aaos.org/research/guidelines/DRFguideline.asp>); each recommendation was directly linked to the ICF separately by 2 health professionals (physiotherapists). The linking process was based on the 10 linking rules for ICF developed by Cieza et al. (8). All 29 recommendations were linked to the most precise ICF and ICD-10 category; items that were not codable in ICF were assigned as not covered (nc). To get the most appropriate linkage, after some calibration of codes, raters evaluated the set of recommendations independently and met to review and discuss codes until consensus between the 2 reviewers was reached. In the case of disagreement, a third rater who was well trained in ICF arbitrated. As a final stage, the linked ICF categories were compared and analyzed with the comprehensive ICF core set for the hand conditions.

2.3a Linking to ICF

The ICF is a bio-psycho-social model and hierarchically organized linking system divided into conceptual units such as functioning and disability and contextual factors (22,43,45). Functioning and disability concepts have been subdivided into body structure (s), body function (b), and activity and participation (d). The contextual factor consists of an environmental factor (e) and personal factors (pf) (22,45). The linking is an alphanumeric hierarchical linking system, starting with broad concepts at the chapter or first level and progressing to more detail across the second to fourth levels. A letter signifies whether the code relates to impairments in a body structure (s) or body function (b) or activity/participation (d) or environmental factors (e), and the number

added to the right indicates an increasing precision of description (45) Concepts that were not defined by the ICF were marked not defined (nd), and concepts that represent the personal factors were marked as (pf) as they are not linkable in ICF (45).

2.4 Analysis

ICF linkage indicators. Raters established the content of the CPG using the instructions/training and established linking rules⁸ and any further updates established by the ICF branch to select the ICF codes that best represent the content of the CPG. Individual codes were compared with the ICF core sets for the hand conditions (<https://www.icf-research-branch.org/icf-core-sets-projects2/other-health-conditions/development-of-icf-core-sets-for-hand-conditions>) summarized using summary statistics that describe ICF linkage (26). We described the number of codes and the distribution, for example, by chapters or domains. Summary statistics that describe how the linkage to ICF in a broad sense more specifically to hand core and even more specifically to the disability codes within the core sets were obtained using previously proposed summary statistics as listed below(http://srs-mcmaster.ca/wp-content/uploads/2015/04/ICF-linkageindicators_Final-to Post.pdf).

2.4a CPG to ICF linkage.

This is the percentage of items from the CPG that can be linked to ICF codes. This represents the extent to which content of the CPG can be expressed in ICF codes:

$$\text{CPG to ICF linkage} = \frac{\text{No.of recommendations linked to at least 1 ICF code}}{\text{Total No.of recommendaion on the CPG}} \times 100$$

$$\text{AAOS DRF CPG to ICF Linkage} = \frac{11}{29} \times 100 = 38\%$$

CPG to a (comprehensive or brief) core set absolute linkage. This is the percentage of items from the CPG that could be linked to ICF codes that appear on a relevant brief or comprehensive core

$$\text{set} = \frac{\text{No.of recommendations linked to a code appearing in the core set}}{\text{Total No.of recommendations on the CPG}} \times 100$$

$$\text{The comprehensive core set absolute linkage} = \frac{11}{29} \times 100 = 38\%$$

$$\text{The brief core set absolute linkage} = \frac{8}{29} \times 100 = 28\%$$

CPG to the (brief or comprehensive) core set unique linkage: It is the percentage of the CPG's items that could be linked to unique ICF codes and represents the extent to which the items of the CPG represent different content indicated by the core set. Once an item is linked to a core set item, additional items that code to that same code are not counted again:

$$= \frac{\text{No.of recommendations that are linked to unique codes in the core set}}{\text{Total No.of recommendations on the CPG}} \times 100$$

$$\text{Comprehensive core set unique linkage} = \frac{5}{29} \times 100 = 17\%$$

$$\text{Brief core set unique linkage} = \frac{4}{29} \times 100 = 14\%$$

Core set unique disability representation. It is the percentage of the unique core set disability codes that are covered when the CPG's items are linked to ICF codes. It represents the extent to which the disability codes defined by the core sets are represented on the CPG. Once an item is linked to a core set disability code, additional items that code to the same code is not counted again:

$$\frac{\text{No. of unique codes (d) from the recommendation that appear in the core set}}{\text{Total no. of disability codes in the core set brief or comprehensive}} \times 100$$

$$\text{Comprehensive core set unique disability representation} = \frac{0}{37} \times 100 = 0\%$$

$$\text{Brief core set unique disability representation} = \frac{0}{37} \times 100 = 0\%$$

2.5 Results

The AAOS guidelines on the treatment of DRF covered 7 different conditions that were codable in ICD-10 (Table 1). Only 11 recommendations were linkable in ICF giving it a percentage score of 38%. Two concepts were linked to the component of body structure (s), 2 concepts were linked to the components of body function (b), one concept was linked to the components of environmental factors (e), and no concept was linked to the component of activity and participation (d; Table 2). Among the 29 recommendations, 18 recommendations (62%; Table 3) did not have a meaningful concept that could be linked to ICF.

CPG to the (Comprehensive or Brief) Core Set Absolute Linkage and Unique Linkage

Of the 29 recommendations of AAOS DRF treatment guidelines, 11 recommendations with the meaningful concept were linked to the comprehensive core set for hand conditions resulting in the absolute linkage score of 38%, and 5 recommendations were linked to the brief core set for the hand conditions (28%). The unique linkage of the AAOS DRF treatment guideline recommendation to the unique codes (5 codes) in the comprehensive core set was 17% (Table 4) and in the brief core set (4 codes) was 14% (Table 4).

Unique Core Set Disability Representation

Surprisingly, using the linking procedure, none of the AAOS DRF guideline recommendations represented the activity and participation (d) ICF category and we were unable to link any of the meaningful concepts of the AAOS DRF guidelines to the disability codes on either comprehensive

or brief core set for the hand conditions. It has 0% representation scores when linked to the unique core set disability content.

2.6 Discussion

This study indicates that the AAOS DRF recommendations have minimal linkage to ICF and ICD-10; also, they address little of the content of the hand core set. Only a few of the meaningful concepts from the CPG were directly linked to the ICF categories, for example, pain (b280, sensation of pain), casts and splints (e115, products, and technology for personal use in daily living), and ligaments of the forearm (s73013, ligaments of the forearm). Concepts like wrist motion and finger motion exercises were linked to the ICF by codes that were relatively imprecise. For example, “active finger motion exercise” and “early wrist motion” were linked to b7100 (b7100, mobility of single joint). The AAOS recommendations mainly focused on surgical interventions that are not represented by the ICF categories and have been coded as not codable “nc.” This focus aligns well with the target audience being orthopedic surgeons. Health policymakers, funders, and clinicians should be aware that as the guidelines do not address function (14), they are not appropriate for rehabilitation professionals or other groups who are focused on functional outcomes. CPG may be developed by multidisciplinary teams and should address comprehensive management or be very focused on a specific intervention or target user. As long as the scope and target audience are specified as recommended by the Appraisal of Guidelines for Research and Evaluation (AGREE) (10,28), this is acceptable. AAOS CPG recommendations use a development strategy where the evidence search is driven by the questions of an expert clinician team who were predominantly surgeons. The lack of focus on function in the recommendations might reflect deficiencies in the evidentiary pool with respect to

rehabilitation. This concern was raised in previous systematic reviews of exercise for upper limb fractures⁵ and a 2007 Cochrane review of rehabilitation in DRF (19). A 2011 systematic review focused on fractures of the upper extremity finding that most studies addressed proximal humerus fractures or distal radius fractures and found conflicting studies about the relative benefits of home versus supervised exercise or combinations of these (5). The most comprehensive Cochrane review was performed by Handoll et al and published in 2006 (19). They found weak evidence of improved hand function for hand therapy in the days after plaster cast removal, with some beneficial effects continuing 1 month later (one trial). They also found a lack of differences in the outcome between supervised and unsupervised exercises during mobilization based on one small trial. For interventions started post immobilization, there was weak evidence of a lack of clinically significant differences in outcome in patients receiving formal hand therapy (4 trials), passive mobilization (2 trials), ice or pulsed electromagnetic field (1 trial), or whirlpool immersion (1 trial) compared with no intervention. There was weak evidence supporting the short-term benefit of continuous passive motion (post external fixation; 1 trial), intermittent pneumatic compression (1 trial), and ultrasound (1 trial). This review suggested weak evidence of better short-term hand function in participants given physiotherapy than in those given instructions for home exercises by a surgeon based on 1 trial. A recent systematic review addressed therapist supervised versus home program exercise following DRF and found a small pool of evidence to recommend between these 2 approaches but suggested both were beneficial (41). More recent systematic reviews on other aspects of DRF have not concurred and would benefit future CPG efforts. Although the available evidence is weak, it does not directly align with the recommendations of the AAOS, which suggests that the method of posing questions to drive the literature search may miss relevant evidence. A search strategy that looks for all evidence on rehabilitation is advisable for future

guidelines that wish to address rehabilitation of distal radius fractures. We found that the wording of the AAOS guidelines rarely specified a specific outcome of treatment. This is a notable departure from the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach for guideline recommendations that suggest that it should be clear what the strength of the evidence is for different outcomes, as the risk of bias in the evidentiary pool may be different for different outcomes (18). Furthermore, as treatments can have different effects on different outcomes, and different risk parts of the informed consent process involve providing a clear summary of this information to patients, CPG ideally should provide a clear indication of the nature and strength of the evidence and the balances of costs, risks, and benefit across different outcomes if they are to assist patients and clinicians in choosing among treatment options. None of the guideline recommendations addressed how to optimize activities and participation outcomes following DRF or referred to this outcome. This is an important gap because activity and participation is a primary focus in rehabilitation and is more related to health status recovery (38) and patient satisfaction (40). The potential limitation of our study can be the use of 2 raters that have affected the selection of the codes and agreement in linking. However, we have limited the potential linking error by consulting with the third rater (MacDermid) who was the part of the expert group that approved the core set for hand conditions the international ICF consensus conference.

2.7 Conclusion

The biomedical approach evident in the AAOS guidelines may anticipate that improvements in surgical approach and radiographic outcomes may translate to better functional outcomes, although this is not explicitly stated. Conversely, a rehabilitation guideline should consider

multiple aspects of the ICF that affect patient outcomes, as rehabilitation tends to take on a broader focus. Rehabilitation guidelines may need to incorporate theoretical frameworks (34) and empirical evidence (41) to provide algorithms by which patients are allocated less or more intensive therapy, or different therapeutic paradigms depending on different injury, psychological, social, or physical factors. The comprehensive and brief ICF core set for the hand conditions was developed to describe the functioning and disability of the hand conditions (22). The core sets were established through evidence-informed multidisciplinary international consensus. Participants of the consensus panel included surgeons. As the hand core set forms a reference standard for the core issues in hand conditions (22), a gap between a CPG and these concepts reflects a lack of attention to important domains of hand function. Future guidelines that focus on rehabilitation are needed and should consider using the ICF hand core sets when developing search strategies and recommendations.

Table 1. ICD-10 Conditions Used in the AAOS Guidelines.

ICD-10 codes	Health conditions
S52.5	Fracture of the lower end of radius
S63.0	Dislocation of the radioulnar joint
S52.7	Fracture and dislocation of radius and ulna
S63.3	Traumatic rupture of the ligament of wrist
Z46.7	Fitting and adjustment of orthopedic devices
Z45	Adjustment and management of the implanted device
Z47.8	Other orthopedic follow-up care

Table 2. ICF Codes Used in the AAOS Guidelines.

Description	ICF codes	Comprehensive core set for hand conditions	Brief core set for hand conditions
Spinal cord and related structures	s120 •	s120 •	s120 •
Ligaments and fasciae of the forearm/structures of the forearm	s 73013 □	s7301 Θ	X
Sensation of pain	b280 •	b280 •	b280 •
Mobility of a single joint	b7100 •	b7100 •	b710 Θ
Products and technology for personal use in daily living	e115 •	e115 •	e1 *

Note. • represents the same level, □ represents the fourth level, Θ represents the third level, * represents the chapter level, and X is an absent code.

Table 3. AAOS DRF Recommendations That Are Not Codable in ICF.

AAOS recommendations:

We suggest operative fixation for fractures with post reduction radial shortening of >3 mm, dorsal tilt >10°, or intraarticular displacement or step-off >2 mm as opposed to cast fixation.

We are unable to recommend for or against any one specific operative method for fixation of distal radius fractures.

We are unable to recommend for or against operative treatment for patients older than 55 years with distal radius fractures.

We are unable to recommend for or against locking plates in patients older than 55 years who are treated operatively.

Arthroscopic evaluation of the articular surface is an option during operative treatment of intraarticular distal radius fractures.

We are unable to recommend for or against the use of supplemental bone grafts or substitutes when using locking plates

We are unable to recommend for or against the use of bone graft (autograft or allograft) or bone graft substitutes for the filling of a bone void as an adjunct to other operative treatments.

In the absence of reliable evidence, it is the opinion of the work group that distal radius fractures that are treated nonoperatively be followed by ongoing radiographic evaluation for 3 weeks and at cessation of immobilization.

We are unable to recommend whether 2 or 3 Kirschner wires should be used for distal radius fracture fixation.

We are unable to recommend for or against using the occurrence of distal radius fractures to predict future fragility fractures.

We are unable to recommend for or against concurrent surgical treatment of distal radioulnar joint instability in patients with operatively treated distal radius fractures.

We suggest that all patients with distal radius fractures undergo a post reduction true lateral X-ray examination of the carpus to assess DRUJ alignment.

To limit complications when using external fixation, it is an option to limit the duration of fixation.

We are unable to recommend for or against over distraction of the wrist when using an external fixator.

Ultrasound and/or ice are options for adjuvant treatment of distal radius fractures.

We are unable to recommend for or against fixation of ulnar styloid fractures associated with distal radius fractures.

We are unable to recommend for or against using external fixation alone for the management of distal radius fractures where there is depressed lunate fossa or 4-part fracture (sagittal split) of Functioning, Disability, and Health.

Table 4. ICF Linkage Indicators to Define the Linkage Between AAOS DRF CPG Recommendations and the ICF Core Sets.

Linkage indicator	Comprehensive core set (%)	Brief core set (%)
1. Measure to core set absolute linkage	38	28
2. Measure to core set unique linkage	17	14
3. Unique core set disability representation	0	0

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CHAPTER 3

3.1 Therapist perceptions of the clarity and implementability of relevant recommendations from the AAOS clinical practice guideline for distal radius fracture.

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Acknowledgments: Joy MacDermid was supported by a Canadian Institutes of Health Research Chair in Gender, Work and Health, and the Dr. James Roth Chair in Musculoskeletal Measurement and Knowledge Translation.

3.1a Abstract:

Background: Clinical practice guidelines (CPG) can support the best practice by providing clear recommendations based on the synthesis of the highest quality literature available on any specific clinical problem. Given the high incidence of Distal Radius Fractures (DRF), guidelines supporting best practices are important. The American Academy of Orthopaedic Surgeons (AAOS) has produced one of the few available clinical practice guidelines (CPG) for DRF.

Purpose: To describe how therapists understand recommendations related to rehabilitation within the AAOS DRF CPG, and to identify potential factors that influence the implementation of recommendations.

Methods: This study used a Cognitive Interview process to elicit therapists' perceptions and interpretations of recommendations. An interpretive description methodology was also utilized to understand the factors that influenced the implementation of recommendations.

A total of fifteen participants from Canada and the USA who had experience with DRF rehabilitation were interviewed. Textual data from interview transcripts were coded and analyzed to find themes.

Results: All participants unanimously expressed that AAOS DRF guideline lacked clarity. Most of the participants (94%) reported that the guideline did not provide specific intervention parameters which limited implementation. A majority of the participants (87%) did not agree with the applicability of individual recommendations based on their clinical experience. Participants perceived that there was inadequate evidence to justify the recommendations. Lack of leadership, limited availability of resources, and unsupportive organizational culture were identified as factors that influenced their implementation of recommendations.

Conclusion: This study found that eight of ten recommendations sampled from the AAOS DRF CPG were considered vague and unimplementable by therapists experienced in managing DRF. There was a lack of specific information needed for implementation such as targeting criteria, dosage or timing of interventions. A CPG specifically designed to inform rehabilitation of DRF with clear and specific recommendations is needed.

3.2 Background

Clinical practice guidelines (CPGs) are systematically developed statements or recommendations based on the best available evidence, and aimed at assisting health care practitioners in clinical decision-making(1,2). CPGs are intended to improve the consistency and quality of healthcare delivery with expected improvements in patient outcomes. CPGs can help to: a) translate research evidence into health care practice, b) aid in standardizing healthcare by attenuating practice variation, c) improve the reliability of medical decisions by use of standardized criteria, d) produce better patient care outcomes, and e) reduce health care costs (3). CPGs contribute to overcome an enormous task of searching and appraising literature that evidence-based practitioners would otherwise need to engage in if knowledge synthesis tools were not available.

Health professional associations and other groups delegate the responsibility of guideline development to a selected group of motivated experts/specialists who engage in the process of converting research evidence into clinical recommendations (4). Extensive resources have been invested in the development and implementation of CPGs over the past two decades (5,6). Despite these efforts, not all guidelines are consistently successful in improving health care (7). Unsuccessful implementation has been reported, resulting in a substantial waste of time and resources (8,9). To understand why health care professionals do or do not use CPG, it is important to explore the factors influencing the implementation of specific CPG (10,11).

Distal Radius Fractures (DRF) are the most common type of fractures in the upper extremity (12) and the incidence appears to be increasing worldwide (13). Typically, a DRF is characterized by a low-energy fracture occurring approximately 2 cm above the distal articular surface of the radius where the cortical bone becomes thinner and is reinforced by the trabecular bone network (13,14).

It is most commonly caused by a fall on an outstretched hand from a standing height or lower, among people older than 50 years (15). A fracture of the distal radius may be described as a Colles, Smith, Barton, or Hutchinson fracture depending on the characteristics of the injury(15).

Many studies (13,16–18) describe the extent of impairments and disabilities experienced by patients with DRF. Appropriate and effective treatment including interventions provided by physiotherapists and occupational therapists is essential to manage DRF and to minimize the disability experienced after these injuries (20). Evidence-based practice guidelines can help health care professionals in clinical decision making to provide effective treatment (1).

The American Academy of Orthopaedic Surgeons (AAOS) is the largest professional group in North America providing professional support to orthopedic surgeons and other allied health care professionals who work in orthopaedics (19). The AAOS has invested substantial effort in developing CPGs for a variety of common orthopedic conditions including DRF (19). The DRF CPG was developed using a process where an expert panel of orthopedic surgeons developed priority clinical questions and the best evidence was compiled and appraised by professionals for review by the expert panel (19): a process thoroughly described on their website (<http://www.aaos.org/research/guidelines/DRFguideline.asp>). The guidelines were subsequently reviewed by multiple professional groups that were considered relevant to the guideline implementation. Given the considerable investment in the development of these guidelines, it is important to understand their impact on practice, including rehabilitation care provided by therapists.

The purposes of this study were to understand the following in the context of guidelines for DRF, using the AAOS CPG as an exemplar:

1. How do therapists understand and implement specific recommendations?
2. What are the factors influencing the implementation of the recommendations?

3.3 Methodology

3.3a Research Design

A cross-sectional qualitative design was adopted to explore therapists' understanding of the AAOS DRF CPG, and the factors influencing the implementation of the recommendations in their clinical practice. This approach was selected because it facilitates an understanding of experiences and behaviors in context "from the perspective of those being studied" (20 p.78) (21). Two different qualitative methodologies were used to best match the individual research objectives. Cognitive interviewing (22) was used to explore and describe how therapists understand individual recommendations. Interpretive description (23) methodology was also utilized to understand the factors that influenced the implementation of recommendations.

While cognitive interviewing is typically used to explore comprehension of self-reported questionnaires and surveys (22), we posited it would be a useful technique to gain insight into how potential guideline users understand and interpret specific recommendations. We employed two types of techniques in cognitive interviewing: a think-aloud strategy and verbal probing. The think-aloud strategy (16,18) was intended to get the individual to verbalize everything he/she is thinking when reading the recommendations. In the verbal probing strategy (16,18), participants were probed for their interpretation of recommendations to help determine potential benefits, problems, or concerns associated with each recommendation (22,24). Thus, to understand the therapists'

understanding of the specific recommendations from the AAOS DRF CPG, we included the cognitive interview technique in this study.

An interpretive description approach is most useful when the purpose of a study is to generate findings that are relevant to clinical practice (25,26). According to Thorne interpretive description legitimizes the process of drawing on multiple research traditions, and "...offers a framework within which the design decisions that work for your particular questions can be effectively set forth" (25 pages .103) (23). This approach was selected for the present study to understand the factors influencing the implementation of the AAOS DRF recommendations, with a lens towards informing the next steps for supporting implementation at the point of care in hand rehabilitation settings.

Themes from the semi-structured interviews were constructed through a thematic framework to understand and predict intention and clinical behavior (28–30). Using a theoretically informed framework is also one of the reasons to choose the interpretive description for this study. Several theories have been proposed to describe, explain, and predict human behavior. The Theory of Planned Behavior (TPB) has been used in several studies as a framework to investigate the behavior change of health care providers (31–33).

In this study, the TPB was used in developing an interview guide and to analyze the determinants of behavior of therapists as described in the TPB (Figure 1). This allows us to understand the influences such as intention, attitude, subjective norm, and perceived behavior control of the therapists towards the implementation of the CPG.

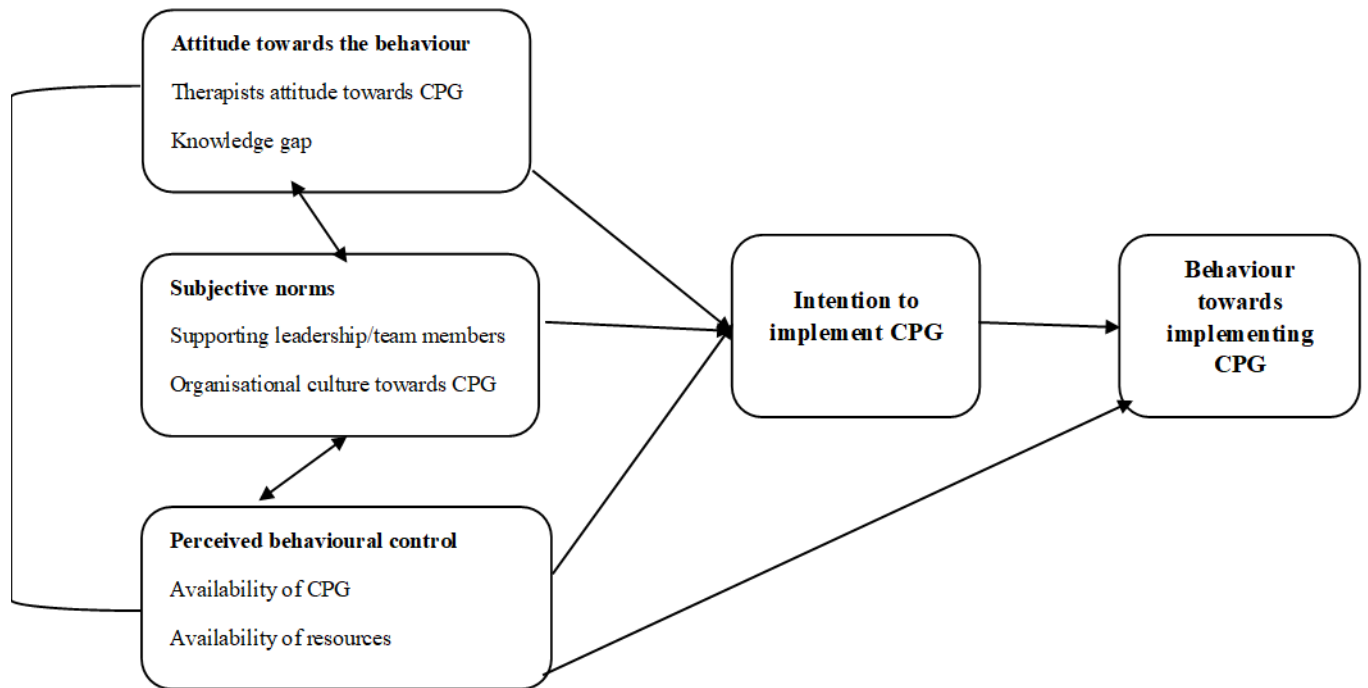


Figure 1: Determinants of behavior as described in the TPB., Ajzen, I. (1985)

3.3b Ethics and Consent

Ethical approval was received from the local responsible agency (Hamilton Integrated Research Ethics Board, HiREB # 15-285-5). Therapists were contacted according to the approved recruitment plan (described below) and written informed consent was obtained from each participant before conducting the interviews.

3.3c Participants

This study focused on physiotherapists and occupational therapists who had clinical experience with DRF rehabilitation. To be included, the participants (a) were a licensed physical or occupational therapist (Canada or USA), (b) had a minimum of 5 years of clinical experience with

or were currently working in DRF rehabilitation, (c) were able to read, write and talk in English. and (d) were able to provide informed consent.

3.3d Sampling and Sample Size

Purposive sampling was used to recruit physiotherapists and occupational therapists from diverse practice settings and a range of practice experiences from Canada and the USA. The original sample size estimate for the purpose of ethical approval was twenty participants in total, with considerations to stop data collection if data saturation was obtained. Morse defined the concept of data saturation as “collecting data until no new information is obtained” (28 p.148) (34). The recruitment of participants was stopped at fifteen participants, as we achieved the data saturation. After the thirteenth interview, there were no new themes generated from the interview data. Therefore, it was considered that the data collection had reached a point of data saturation. However, we continued the data collection for two more interviews to confirm no new themes were inspired.

3.3e Recruitment

Electronic notices about the study were sent to professional associations and alumni of the School of Rehabilitation Sciences at McMaster University through professional networks and list-serves (list of followers or contacts). These included: Hamilton Health Sciences, Canadian Society for Hand Therapists (Hamilton, London and Toronto chapters), Ontario Society of Occupational Therapists, Ontario Physiotherapy Association, and School of Rehabilitation Sciences graduate students at McMaster University, and School of Rehabilitation Science graduate trainees at Western University, London Ontario.

Participants who completed interviews were also encouraged to invite their colleagues to participate (a strategy known as snowball sampling). Further, a poster presentation was given at the national meeting of the Canadian Society for Hand Therapists: eligible attendees (from USA and Canada) who met the study criteria were invited to participate. Interviews were conducted in a period from November 2015 through April 2016.

3.3f Setting

Literature in the area of qualitative interviewing suggests researchers thoroughly consider the location of face-to-face interviews (35–37). Given the personal nature of the research, it was important that a familiar, confidential, and quiet setting be selected. All interviews with the Canadian participants were conducted face-to-face in their workplace in a private room. Participants from the USA were interviewed over Skype (Microsoft corporations) as it allowed researchers to reach a geographical spread of participants more economically and quickly (38). All the Skype interviews were conducted in a quiet private room at the primary investigator's graduate office, while the participants were in their convenient private place

3.3g Data Collection & Management

Consistent with the interpretive description methodology, a semi-structured interview approach was adopted (23). Semi-structured interviews elicit rich descriptions, allowing researchers to verify statements and probe for additional information (37). In-person interviews were conducted by an occupational therapist experienced in cognitive interviewing and upper limb rehabilitation (TP) and the Skype interviews were conducted by the primary investigator (SE).

3.3h The Guideline Sampled

The AAOS DRF CPG has twenty-nine recommendations aimed to inform professionals treating DRF patients. Given our intent to conduct an in-depth analysis of individual recommendations, we selected ten recommendations pertaining to rehabilitation (See Appendix 1). This relevant subset also permitted an in-depth exploration of the content during interviews.

3.3i Interview Format & Guides

The sampling strategy and interview guide were approved in advance by the ethics committee. Prior to the commencement of interviews, informed consent was provided. Participants were encouraged to share their opinions freely and were reminded that the purpose of the interview process was not to test their knowledge or adherence but to understand the clarity of the recommendations.

During cognitive interviewing, more follow-up probes were used to elicit detail on issues raised by the participants and to iteratively explore ideas raised by previous participants. All questions were open-ended, to prompt participants to speak freely about their understanding of the AAOS DRF CPG recommendations. Interview questions addressing factors influencing the guideline implementation were designed to encourage the sharing of individual perspectives with minimal prompting from interviewers.

3.3j Participant Demographics

A total of fifteen therapists were interviewed for the present study. Seven were occupational therapists and eight were physiotherapists. Eleven therapists were recruited from Canada and four

therapists from the USA. The therapists varied in age, with the youngest falling within the thirty to the thirty-nine-year-old range and the oldest falling within the fifty to the fifty-nine range. There was variability concerning the length of time employed as a therapist. For example, the shortest employment period was five years and the longest employment period was twenty-five years. Each participating therapist had experience working in DRF rehabilitation.

3.4 Data Analysis

Textual data from interview transcripts were coded and analyzed to find themes using NVivo 11. The interview transcript was independently coded by the principal investigator. Following coding of the first transcript, the principal investigator developed a codebook using NVivo 11. Although the initial codebook was used to guide the coding of the remaining interviews, codes that evolving from each subsequent interview were added. Multiple meetings between the principal investigator and the co-authors took place during analysis to discuss the emerging codes and to deepen the understanding to co-construct the codes, categories, and themes.

Codes of the cognitive interview data were categorized into different constructs as proposed by MacDermid (39) for classification purposes. Five themes allowed us to identify issues with the clarity and actionability of individual guideline recommendations.

Similarly, the codes of the interpretive description methodology (semi-structured interview) were analyzed using thematic analysis. There were five overall themes emerged related to therapists' understanding, intention, and behaviors around guideline use, as well as contextual influences.

3.5 Results

3.5a Cognitive interview analysis:

This interview with the fifteen therapist found that eight of ten recommendations sampled from the AAOS DRF CPG were sufficiently vague that therapists did not consider them implementable. Participants shared challenges with guideline interpretation that was categorized into five of the areas using a priori framework identified by MacDermid (appendix 2) to understand the clarity and precision of the recommendations.

Comprehension/clarity

The most common issue reported by all the participants was lack of clarity (See Appendix1 for a full listing of the recommendations). For example, the terminology used in recommendation #1 (Rigid immobilization) was felt to be confusing and vague. Therapists wanted a definition for terms such as ‘rigid immobilization’ and ‘displaced’. They highlighted the potential utility of a clear classification system for type and amount of displacement to inform clinical decision-making using this recommendation, such as *‘the amount of displacement, shortening, or dorsal tilt’*. The words ‘displaced DRF’ used in the recommendation lacked definition as to what was meant by the term ‘displaced’.

“It doesn’t describe what is classified as displaced DRF, I don’t see any meaning here”
(participant 3)

The participants also considered the words used as ambiguous, leading to variable interpretations by respondents. More than eighty percent of the participants called for more clarity on the focus and responsibility for re-evaluation, and guidance for decision-making, when analyzing, for example, the recommendation #5 (Follow-up for unremitting pain).

“They haven’t specifically mentioned what type of re-evaluation, is it medical? Or for pain? There could be potentially a lot of sources that could contribute to pain. I think they need to be more precise”. (participant 7)

Another example of lack of clarity was Recommendation # 6 [Home exercise program] also considered confusing for more than eighty-five percent of the participants. They felt it was not clear whether the recommendation was for or against rehabilitation services. Further, they reported the recommendation did not give any clear information about what action is to be undertaken.

“It sounds like patients don't need therapy after just three days of post-fracture”.
(participant 1)

Participants reported that recommendations from the AAOS DRF CPG find to be very vague and difficult to understand. For example, a participant commented on the recommendation#8 as

“Not defined (what they meant by) early, for me 2 to 3 weeks is early. but we could also start motion at day1 too”. (participant 4)

Language ambiguity is commonly reported by the participants, they find the recommendation difficult to interpret due to ambiguous language, hence not very positive to implement in their practice. For example, in the recommendation on early wrist mobilisation (recommendation 8)

“what is early? Is early a day two or day twenty-two?”. (participant 2)

More than seventy-five percent of the participants perceived the lack of clarity in recommendation 10, they reported that it was very unlikely that they follow this guideline as any unclear recommendation could mislead their clinical practice.

“To me, that's again a very bland statement.” (participant 4)

“Well, I think they can separate ultrasound and ice because they are completely different. You can't say ultrasound and or ice” (participant 8)

Inadequate definition of intervention

From the participants' perspectives, the guideline lacked in providing sufficient information to support the clinical decision and their practice. They found that recommendation #2 [Removable splints] did not have enough information to utilize in their practice. Participants voiced some terms were confusing and lacked clear specifications. Participants reported that the recommendation doesn't state any clear boundaries for implementation (e.g. time interval, context, or other parameters).

“what do they recommend here? Using removable splint for how long? What type of removable splints? I couldn't see any specific parameters of the intervention required for implementing this recommendation” (participant 9)

Participants explicitly reported that no recommendation in this CPG is clear on targeting criteria and dosage or timing of interventions. More than ninety-four percent of the participants reported having difficulty in identifying their role and course of action. When asked about Recommendation #6 [Home exercise program], they reported that it was not clear from the recommendation of what was meant by a home program.

“Does this mean no referral to rehab and the surgeon gives instructions? Does this mean seen only once by a therapist and given home exercise program? Or does it mean most therapy is done at home but with regular follow-ups for adjusting the program as the client progresses?” (participant 6)

Also, the participants believe that the recommendation is useful only in specific cases.

“I don’t think that all patients with DRF require the therapy, they might be more beneficial from the home program” (participant 13)

Participants also reported that the CPG shows unclear boundaries for implementation in the context of the time interval. One of the therapists commented on the recommendation (#8)

“This recommendation does not provide any clear time interval because early is day 0 to week 3. If they have said that the patient does not need to begin wrist motion before week 4 then that makes more sense to me.” (participant 15)

Inadequate definition of clinician role/ responses /actions

Within all the ten-recommendation about rehabilitation, Recommendation#9 [Vitamin C] arose different perspectives on the participants. More than eighty-seven percent of the participants found it to be new and useful. However, participants had very minimal pre-existing knowledge about this recommendation.

“I don't know that for sure though, I've read somewhere that it's helpful to do but I don't know the research behind Vitamin C interventions for pain control?” (participant 14)

Participants showed interest in implementing this recommendation but felt unsure about their role.

“There is no risk of taking Vitamin C, but I don’t have a strong comment, it's not something I recommend and it's not something in my practice” (participant 12)

Some participants reported that they have been recommending Vitamin C in their clinical practice, however, they were not recommending it consistently and were uncertain about the specifics about how to do so.

“yes, I do actually, I do recommend that patients use Vitamin C, but I'm not sure of the dosing. So, I tell them to use what's on the label. I have recommended Vitamin C. But I don't recommend it routinely”. (participant 5)

Cognitive Dissonance (CD)

Participants also seemed to doubt the applicability of some recommendations. More than eighty percent of the participants could not agree with recommendation # 3 [Immobilization of the elbow]. Participants responded that this recommendation cannot be used clinically since elbow immobilization along with casting may further restrict elbow movements.

“I wouldn't personally recommend elbow immobilization, as it restricts lots of early movements in the elbow” (participant 3)

While discussing the Recommendation #6, [Home exercise program] participants expressed concern the recommendation directly affects the therapist's practice.

“When the recommendation says that home exercise as an option, rather than proper rehabilitation with the help of therapists, then most of the surgeons will not refer their patient for the therapy.” (participant 13)

Similarly, participants felt that this recommendation might reduce the quality of care.

“Because when they say do this, do that and come back and see me after one month. I don't see any quality there. I would love to see every DRF patient, goes to see the therapist at least once, and get the proper stuff to do.” (participant 1)

Participants also had difficulty in value the 'Recommendation #10' [Ultrasound and/or ice] and the role of ice therapy in treating DRF.

“I generally don't recommend ice, unless someone is having more of like a neuropathic burning kind of sensation” (participant 8)

Practice culture differs between the participants, regarding ultrasound and ice, participants do acknowledge that they use either or both of them in treating DRF patients depending on the need.

“For ice, it's been shown in lots of literature. Both ice and heat reduce pain and swelling. I would use ice at initial stages, maybe two weeks of surgery and after that heat. I recommend cold, but not necessarily as a regular practice.” (participant 10)

Evidence Uncertainty (EU)

More than seventy-five percent of the participants reported that there was not enough supporting evidence for Recommendation#4 [Predict future fragility fractures]. Although evidence shows that DRF elevates the risk of fragility fracture, participants reported that DRF cannot predict the future fragility fracture in a pediatric, young, or younger adult population. For instance, a participant reported,

“We cannot predict future fragility fracture for a young patient with DRF due to road traffic injury or a young athlete with DRF due to a fall” (participant14)

Few participants expressed that this recommendation does give meaningful information associated with the aging, fragility fracture, and DRF. This recommendation may apply to the older population but not in other populations.

“I have seen geriatric patients with fragility wrist fracture who had the history of DRF, but I don't think this recommendation can be generalized to all age groups.” (participant8)

3.5b Interpretive description method to understand the factors influencing the guideline implementation

A thematic analysis of the factors influencing the guideline implementation was evaluated based on the components of the theory of planned behavior: attitudes, subjective norm, and perceived behavioral control. From our participants' discussion of guideline implementation, there were five overall themes identified related to therapists' understanding, intention, and behaviors around guideline use, as well as contextual influences.

Attitudes and perceptions towards CPG

Attitudes and perceptions were the most frequently identified theme representing factors influencing the therapists' use of clinical practice guidelines.

All the participants indicated having the necessary skills to be able to interpret and understand the CPG. However, seventy-four percent of the therapists reported not using CPGs in their practice for a variety of reasons including their attitude, beliefs, and disagreement with recommendations. Lack of reliable evidence influence their attitudes and perception towards CPG that negatively affected the implementation of the guideline recommendations

“I don't follow a specific set of guidelines because of the insufficient and inconclusive evidence” (participant 4).

“I know there is some evidence for ultrasound, but I do not go near ultrasound ever. No ultrasound in any of my treatment protocol for me, in my 20 years of experience, it never gave me any good results.” (participant 12)

An additional factor that affects the guideline implementation identified by therapists included their reluctance to use clinical practice guidelines because they were perceived to reduce clinicians' autonomy.

“Sometimes they can suggest certain recommendations, that I have found clinically do not work. You better have to tailor your plan based on your own experience” (participant 6)

Knowledge gap

Therapists in this study reported general knowledge of clinical practice guidelines. However, they lacked familiarity or awareness of the specific clinical practice guideline (AAOS DRF CPG) to be able to incorporate into their practice. For some participants, the guidelines' recommendations are similar and compatible with their professional training and current practice. Although considering important, few participants reported attending one or two continuing education courses with similar approaches to the guidelines.

“I would say updating yourself with new guidelines and updated versions of existing guidelines is very important as a part of professional development, I always motivate my team members to attend any formal or informal courses to equip themselves” (participant3)

Availability of CPG and therapist perception towards them

Interestingly, one of the most common themes was the characteristics of the CPG themselves such as usability, format, contents, and easy access to CPG. The participants reported that they were more likely to use CPG in their care plans if they are available on the intranet or internet.

“We do have a list of CPG recommendation in our system here, we do follow them as it is readily available to refer, also all our colleagues know about them, so it is easy for unanimous implementation” (participant 12)

Disagreement with CPGs contents was reported by the therapists as one of the factors that affected the guideline implementation. Participants reported that recommendations in CPG sometimes were rigid and conflicted with the accepted practice of therapists or goals for individual patient’s care.

“All they [the guideline prescribers] are doing is extrapolating data from studies with inconclusive evidence. And yet we are expected to use these guidelines as something meaningful” (participant 5)

Most of the participants agreed that they do follow CPGs, but they were not convinced with the AAOS DRF CPG.

“Personally, Yes, I do practice evidence-based medicine, but these AAOS DRF guideline recommendations? Not a lot, because they are neither clear nor focusing therapy”.
(participant 13)

Availability of resources

The most frequently identified factors that affected the use of CPG were time, staffing, supplies, and equipment.

“We don’t have many therapists here. Most of the time I work on my own. I wish I have more time to follow all these guidelines and recommendations” (participant 10)

The participants reported time constraints during their work hours as one of the factors that affect guideline implementation. When the workload was too heavy due to limited staffing or patient

acuity, therapists faced challenges in completing tasks and were less likely to consider CPG as a part of their essential tasks.

“You know, this is a private clinic, they (clinic owner) have a strict budget for pay. We always have a shortage of staff and I don’t have time to look at any guidelines or recommendations, rather I go with my experience” (participant 9)

The availability of the required equipment in their practice settings also played a major role among therapists to implement guideline recommendations.

“We don’t have an ultrasound machine in this clinic what can I say? I can’t comment anything about this recommendation since we don’t use any ultrasound at all” (participant 1)

Supporting leadership and Organizational culture

Another important factor that influenced the implementation of the CPG was the presence of leadership. Leadership in this study was described by the therapist as either provided by referring surgeons or a multidisciplinary team that supported and led the implementation of clinical practice guidelines or the in-charge/owner of the private clinics. Leaders had the power to direct care and limit therapist autonomy and choice.

“Our doctors send patients with the prescription marked with the treatment plan, like IFT or ultrasound, traction, etc, we can’t make our own choices here” (participant 7)

Further, disagreement among leaders on the need for CPG, and lack of administrative support from private clinic managers were also reported as a factor that impacted the implementation of the CPG in their clinical practice.

In contrast, some therapists identified that the presence of formal leaders and administrators with positive attitudes towards CPG made a difference and also identified as a factor that enhanced the guideline implementation.

“We’ve got a wonderful team here; our manager encourages us to implement the guidelines and advance practitioners educate the other therapists here.” (participant 11)

An organization with a culture of resistance to change or a lack of peer endorsement of clinical practice guidelines and a lack of clear communication among different disciplines (surgeons and therapists) negatively impacted the use of CPGs. Even when a therapist had a positive attitude and believed that CPGs could improve workflow and patient outcomes, she/he would be discouraged to use them if the work culture/environment was not supportive.

“None of us use any kind of particular recommendations here. We do have an assessment chart, but the treatment protocol is entirely up to the therapist and patients” (participant 4)

“We see different patient conditions here. We don’t follow any CPG to be very open, at the end of the day it’s the treatment outcome that we are concerned about, so we do what is good for our patients”. (participant 10)

On the contrary, some participants claimed that organizations that supported and used multidisciplinary approaches to encourage the use of CPG in their practice were more likely to have most therapists using CPG.

“My previous workplace was very particular in practicing evidence-based, we had training and classes, it was an excellent place, this place (workplace) doesn’t care about anything like that, they care only on patient volumes” (participant 5)

3.6 Discussion:

Two key messages were elucidated from the major themes of the study. The first key message was that the AAOS DRF CPG may not be relevant and precise to all aspects of DRF rehabilitation. The second message was that therapists face multiple intrinsic and extrinsic factors that influence the implementation of the CPG; however, most of them are modifiable with appropriate strategies. To our knowledge, this is the first study to evaluate the factors that influence the implementation of evidence-based recommendations in DRF rehabilitation.

Findings from the in-depth exploration of cognitive interviewing helped us to understand how therapists viewed individual recommendations, whereas previous studies (40,41) have tended to focus on overall perspectives of practice guidelines. Further, we triangulated the information since we used the existing framework to organize the potential sources of dissonance independently developed by one of the authors (JM) based on cognitive interviewing literature and interview experience; while a second author (SE) independently evaluated the responses and themes.

The only *a priori* cognitive interview construct that was not subsequently identified in the interview-driven content analysis was ‘calibration across recommendations, where the actions inferred by one recommendation alter or modify the interpretation of another (39). While this issue did not appear in this particular CPG, it is important to retain in the taxonomy as it may be relevant for future evaluations. Using a consistent taxonomy of sources of dissonance across these types of evaluations can facilitate an understanding of consistent themes. The cognitive interviews of fifteen therapists yielded useful data to gain an understanding of the therapist’s interpretation and perception of the AAOS DRF CPG.

Issues raised about relevance in this study may reflect the fact that the guideline is not specifically designed for therapists. Nevertheless, we did evaluate ten recommendations that specifically addressed aspects of therapy; therefore, it could be assumed that if these recommendations were clear and implementable that they would be relevant to therapists.

Despite therapists' ability to interpret and understand the guideline recommendations, they do have factors that influence implementing them in their practice. Participants in this study have expressed positive attitudes, desires, and willingness to participate in education sessions on CPG and increase their use in clinical practice.

Regarding the factors influencing the guideline implementation, therapists face challenges such as resource availability including referral sources, staffing, and equipment availability. In a systematic review of factors that influence the physicians' use of CPG, Cabana et al (42) found that awareness, familiarity, self-efficacy, agreement with CPG, and outcome expectancy, were the major factors that influence their guideline implementation. Similarly, in another study of physicians identified that lack of awareness, concerns for the loss of autonomy and individualized care, and potential conflict with existing care, were identified as common factors influencing guideline implementation (43). Our study finds the factors influencing the guideline implementation within rehabilitation professionals and the results reinforce the existing literature (44–49)

This study found that the therapist's negative attitudes towards CPGs and lack of motivation in using CPGs appeared to decrease the utilisation of CPGs. Janssen et al (2011) reported that healthcare professionals who verbalized a lack of motivation and commitment toward the use of CPG or those who were resistant to change were less likely to use CPG(47). Our findings also align with the current literature which states that clinician's perception of CPG use could cause

stagnation of critical thinking, affect individualized care for patients, and may lead to negative consequences (47). Therapists work experience may also play an important role because therapists with several years of work experience felt a higher level of autonomy and were less likely to use CPG (47).

Attitudes, perceptions, and knowledge were bidirectionally influenced therapists in the utilization of CPG and served as factors that influence the CPG implementation. However, changing attitudes and influencing perceptions of therapists may be difficult (50). To increase uptake of CPG, concerted knowledge translation and implementation efforts targeting increasing motivation were needed, as the benefits of CPG depend on moving evidence into practice(51,52)

According to literature reviews, the most commonly reported formats of CPGs were online resources, paper formats such as journal articles, summary sheets, and tables (53,54). However, therapists perceived that these CPG formats were not readily available, or easily accessible when they needed to use them. Similar results were reported in studies conducted on understanding the factors that influenced the implementation of CPG (45,53). This study result shows that easy electronic availability of recommendations may be helpful in successful implementation for the CPG. Despite online resources like magicAPP (<https://app.magicapp.org/>) were available, still not all the recommendations were available in their content.

A successful implementation can happen when CPG are integrated with the therapist's workflow, and with continuing education to increase knowledge among a community of healthcare providers who share the same goals (55). Education at the start of implementation and continuing education throughout the implementation process of CPG are recommended by the healthcare providers to increase the use of CPG (56–58).

Other implementation strategies are identifying target indicators and developing a team leadership action plan(59). Factors that enhance and affect the guideline implementation, although interrelated, are not simply the mirror images of each other. For example, lack of time for the therapist was identified as a factor that affects the guideline implementation, however, increasing the number of staff alone may not be sufficient enough to increase the use of CPG (32,56,59). A supportive and positive environment needs to be created by having multidisciplinary discussions for plans of care for patients, fostering open communication among different team members, and sharing clear goals for patients (59).

Private clinic administrators and managers can improve their therapist's use of CPG by creating a supportive environment that facilitates communication between therapists and with other disciplines. As point-of-care rehabilitation providers, therapists are more likely to implement CPG in individual clinical encounters. Their active involvement with development and implementation is much needed in ensuring that patients receive quality care (10,60,61).

To successfully implement guidelines, feasible, simple, and logically formatted CPG from respected sources needs to be readily accessible. Appropriate supplies, equipment, and staffing should also be provided under strong leadership with the organizational commitment to the use of CPG. A practice guideline that was specifically designed to address rehabilitation of distal radius fractures might provide more comprehensive recommendations concerning therapy. However, important considerations for such a document would be a) clear recommendations, b) recommendations provided specific actions with sufficient information to support implementation, and c) identified subsets of the clinical population to be targeted, with appropriate tailoring of the recommended course of action.

3.7 Limitations:

A potential limitation of our study could be most of our participants were recruited from a single province in Canada, and there were only four participants from the USA. We selected ten recommendations from the guidelines pertaining to rehabilitation, therefore the study results cannot be generalized to the guideline as a whole. Other limitations in this study could be the variability across interviewers and interview formats: while most of the interviews were taken in person face to face, a few interviews were conducted over Skype, where we might have missed any nonverbal cues as the participants can see themselves in the video which gives them a room for altering their nonverbal cues or it might be a distraction during the interview. However, the perceived lack of clarity in the selected recommendations and uncertainty about what specific actions should be implemented were consistent findings that arose across recommendations.

3.8 Conclusion:

This study found that eight of ten recommendations sampled from the AAOS DRF CPG were sufficiently vague that therapists did not consider them implementable. There was a lack of specific information needed for implementation such as targeting criteria and dosage or timing of interventions. Other factors that influence the guideline implementation identified in this study included: recommendations perceived to be irrelevant, availability of resources, lack of supporting leadership, and organizational culture.

Appendix:1

Link to AAOS DRF CPG:

<https://www.aaos.org/research/guidelines/drfssummary.pdf>

Recommendations pertaining to rehabilitation:

1. We suggest rigid immobilization in preference to removable splints when using non-operative treatment for the management of displaced distal radius fractures.

Strength of Recommendation: Moderate

Description: Evidence from two or more “Moderate” strength studies with consistent findings, or evidence from a single “High” quality study for recommending for or against the intervention. A **Moderate** recommendation means that the benefits exceed the potential harm (or that the potential harm clearly exceeds the benefits in the case of a negative recommendation), but the strength of the supporting evidence is not as strong.

Implications: Practitioners should generally follow a **Moderate** recommendation but remain alert to new information and be sensitive to patient preferences.

2. The use of removable splints is an option when treating minimally displaced distal radius fractures.

Strength of Recommendation: Limited

Description: Evidence from two or more “Low” strength studies with consistent findings, or evidence from a single “Moderate” quality study recommending for or against the intervention or diagnostic. A **Limited** recommendation means the quality of the supporting evidence that exists is unconvincing, or that well-conducted studies show little clear advantage to one approach versus another.

Implications: Practitioners should exercise clinical judgment when following a recommendation classified as **Limited**, and should be alert to emerging evidence that might negate the current findings. Patient preference should have a substantial influencing role.

3. We are unable to recommend for or against immobilization of the elbow in patients treated with cast immobilization.

Strength of Recommendation: Inconclusive

Description: Evidence from a single low-quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence that has resulted in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in following a recommendation labeled as **Inconclusive**, exercise clinical judgment, and be alert for emerging evidence that clarifies or helps to determine the balance between benefits and potential harm. Patient preference should have a substantial influencing role.

4. We are unable to recommend for or against using the occurrence of distal radius fractures to predict future fragility fractures.

Strength of Recommendation: Inconclusive

Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An **Inconclusive** recommendation means that there is a lack of compelling evidence that has resulted in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in following a recommendation labeled as **Inconclusive**, exercise clinical judgment, and be alert for emerging evidence that clarifies or helps to determine the balance between benefits and potential harm. Patient preference should have a substantial influencing role.

5. In the absence of reliable evidence, it is the opinion of the work group that all patients with distal radius fractures and unremitting pain during follow-up be re-evaluated. Strength of Recommendation: Consensus

Description: The supporting evidence is lacking and requires the work group to make a recommendation based on expert opinion by considering the known potential harm and benefits associated with the treatment. A **Consensus** recommendation means that expert opinion supports the guideline recommendation even though there is no available empirical evidence that meets the inclusion criteria of the guideline's systematic review.

Implications: Practitioners should be flexible in deciding whether to follow a recommendation classified as **Consensus**, although they may give it preference over alternatives. Patient preference should have a substantial influencing role.

6. A home exercise program is an option for patients prescribed therapy after distal radius fracture.

Strength of Recommendation: Limited

Description: Evidence from two or more "Low" strength studies with consistent findings, or evidence from a single "Moderate" quality study recommending for or against the intervention or diagnostic. A **Limited** recommendation means the quality of the supporting evidence that exists is unconvincing, or that well-conducted studies show little clear advantage to one approach versus another.

Implications: Practitioners should exercise clinical judgment when following a recommendation classified as **Limited**, and should be alert to emerging evidence that might negate the current findings. Patient preference should have a substantial influencing role.

7. In the absence of reliable evidence, it is the opinion of the work group that patients perform active finger motion exercises following diagnosis of distal radius fractures.

Strength of Recommendation: Consensus

Description: The supporting evidence is lacking and requires the work group to make a recommendation based on expert opinion by considering the known potential harm and benefits associated with the treatment. A **Consensus** recommendation means that expert opinion supports the guideline recommendation even though there is no available empirical evidence that meets the inclusion criteria of the guideline's systematic review.

Implications: Practitioners should be flexible in deciding whether to follow a recommendation classified as **Consensus**, although they may give it preference over alternatives. Patient preference should have a substantial influencing role.

8. We suggest that patients do not need to begin early wrist motion routinely following stable fracture fixation.

Strength of Recommendation: Moderate

Description: Evidence from two or more "Moderate" strength studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention. A **Moderate** recommendation means that the benefits exceed the potential harm (or that the potential harm clearly exceeds the benefits in the case of a negative recommendation), but the strength of the supporting evidence is not as strong.

Implications: Practitioners should generally follow a **Moderate** recommendation but remain alert to new information and be sensitive to patient preferences.

9. We suggest adjuvant treatment of distal radius fractures with Vitamin C for the prevention of disproportionate pain.

Strength of Recommendation: Moderate

Description: Evidence from two or more “Moderate” strength studies with consistent findings, or evidence from a single “High” quality study for recommending for or against the intervention. A **Moderate** recommendation means that the benefits exceed the potential harm (or that the potential harm clearly exceeds the benefits in the case of a negative recommendation), but the strength of the supporting evidence is not as strong.

Implications: Practitioners should generally follow a **Moderate** recommendation but remain alert to new information and be sensitive to patient preferences.

10. Ultrasound and/or ice are options for adjuvant treatment of distal radius fractures.

Strength of Recommendation: Limited

Description: Evidence from two or more “Low” strength studies with consistent findings, or evidence from a single “Moderate” quality study recommending for or against the intervention or diagnostic. A **Limited** recommendation means the quality of the supporting evidence that exists is unconvincing, or that well-conducted studies show little clear advantage to one approach versus another.

Implications: Practitioners should exercise clinical judgment when following a recommendation classified as **Limited**, and should be alert to emerging evidence that might negate the current findings. Patient preference should have a substantial influencing role.

Appendix 2:

Cognitive interviewing (CI) - to identify sources of interpretation dissonance in patient-reported outcome measures (PRO)

By: JC MacDermid, PhD

Interview approaches in cognitive interviewing can be studied in the literature,^{1–4} and variations exist. This is a framework for one approach for CI-PRO.

Cognitive interviewing: sources of dissonance in interpreting CPG recommendations

Clinicians use clinical practice guidelines to guide practice. This requires understanding specific recommendations and what actions they are suggesting. Clinicians can have difficulty acting on recommendations for a variety of reasons. Using cognitive interviewing we can identify issues with the clarity and actionability of individual guideline recommendations. The following is a list of major categories of issues that can arise that can be used for classification purposes.

Comprehension/Clarity (C)

Refers to when the terms/words used in the recommendation are ambiguous and/or incorrectly interpreted by respondents.

Relevance (R)

Refers to when a recommendation is not relevant to specific clinicians (e.g. recommendation is not possible or important in their circumstances). This includes when the infrastructure or personnel required are not available, they do not have the skills/equipment required, the recommendation is not permitted due to scope of practice or institutional restrictions, or the recommendation does not apply to the patient population or context of their practice.

Inadequate definition intervention (ID-I)

Refers to when clinicians are unable to identify the specific parameters of the intervention required for

implementation. This could include lack of definition of the components of the intervention, indications or contraindications; dosage or other unclear boundaries for implementation (e.g. time interval or context).

Inadequate definition of clinician role/ responses /actions (ID-C)

Refers to when responses or actions required by the clinician are not specifically identified within a recommendation. This includes lack of definition of competency or skill requirements, where there is no definition of what the clinician does to implement a skill-based intervention, or if specific clinical reasoning is needed to implement (screening, triaging).

Evidence Uncertainty (EU)

Refers to when clinicians doubt the validity or applicability of a recommendation because they do not think there is sufficient evidence to justify the recommendation.

Cognitive Dissonance (CD)

Refers to when clinicians doubt the validity or applicability of a recommendation because their clinical experience/judgement is that the risks/downsides outweigh the potential benefits, or their experience with implementation of that recommendation has been negative. This also includes where clinicians accept recommendations even though the evidence is unclear, due to positive experiences/judgements.

Calibration Across Recommendations (CAI)

Refers to when the actions inferred by one recommendation would affect or modify the interpretation or implementation of another recommendation. This includes when there are multiple recommendations for the same issue, without clarity on which recommendation has priority i.e. has a better treatment effect or level of evidence.

Perspective Modifiers (PM)

Perspective modification occurs when the actions recommended are interpreted differently based on a personal factor, attitude/, belief role, scope of practice, clinical/life experience or environmental factor.

Table:1 Codes and Themes (*CI Cognitive interview *TPB Theory of Planned Behavior)

Codes	Themes	
Unclear, lack of definition, difficulty understanding, lack of clarity, unclear information	Comprehension/Clarity	CI
Confusing terminology, lack of definition of intervention, lack of information about intervention	Inadequate definition of intervention	CI
Unsure about the recommendation, Vitamin-C, benefits of Vitamin-C	Inadequate definition of clinician role/response/actions	CI
Agreement with the recommendation, acceptance of CPG, approval of the recommendation	Cognitive dissonance	CI
No evidence, lack of support, lack of meaningful information	Evidence uncertainty	CI
Personal experience, compliance with own experience, clinical appropriateness, availability of CPG, accessibility of CPG	Attitude and perceptions towards CPG	TPB
Knowledge of CPG, training, familiarity with CPG	Knowledge gap	TPB
Short of staff, short of time, work hours, time constraints, equipment availability	Availability of resources	TPB
Work environment, work culture, organizational culture	Organizational culture	TPB

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CHAPTER 4

4.1 Survey on implementability of the American Academy of Orthopaedic Surgeons Distal Radius Fracture Clinical Practice Guideline using GuideLine Implementability Appraisal

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Acknowledgments: Joy MacDermid was supported by a Canadian Institutes of Health Research Chair in Gender, Work and Health, and the Dr. James Roth Chair in Musculoskeletal Measurement and Knowledge Translation.

4.1a Abstract

Background:

Clinical practice guidelines (CPG) have the potential to reduce the variation in clinical care and improve outcomes if implemented. This study evaluated the implementability of the American Academy of Orthopaedic Surgeons (AAOS) Distal Radius Fracture (DRF) Clinical Practice Guideline (CPG)

Methods:

A cross-sectional survey was conducted using components of the guideline implementability appraisal tool (GLIA) and a sample of physiotherapists and occupational therapists with clinical experience in DRF rehabilitation recruited from hospitals across Canada and the United States through convenience sampling and snowball sampling. Participants completed the nine questions in the global dimensions part and two questions in executability (what to do ? and how to do?)

dimension, and two questions in measurability (measuring adherence and outcomes) dimensions of the GLIA. Participants evaluated 10 recommendations from the guideline pertaining to rehabilitation.

Results:

A total of 173 responses were received, 103 were physiotherapists (78 from Canada and 25 from the USA) and 70 were occupational therapists (56 from Canada and 14 from the USA). In the global question dimension, 64% of the participants reported that the guideline did not address the “strategies on guideline implementation” and 79% reported that the guideline is not clear on “what sequence the recommendations should be applied?”

In the executability dimension questions, 80% of the participants reported that there is no information on the “recommended action” or on “how to execute the recommendations”. In the measurability dimension questions 81% of the participants reported that the guideline does not provide sufficient information on the “adherence measurement” or on “how to measure the outcomes” for recommendations R7(Rigid immobilization), R8(Removable splints), R9(Immobilization of the elbow), R17(Future fragility fractures), R20(Unremitting pain re-evaluation), R23(Early wrist motion) and R26 (Vitamin C). Only 3 out of 10 selected recommendations, R21(Home exercise), R22(Active finger motion exercise), R27(ultrasound and/or ice) were considered implementable by a minimum of 70% of the participants. The remaining 7 recommendations were reported to be difficult to implement due to lack of information on either or both the executability dimensions and measurability dimensions on the GLIA tool.

Conclusion:

Most therapists found the AAOS DRF CPG was not implementable Due to the lack of clarity and information on what to implement, how to implement, or to measure measuring the adherence and outcomes of the recommendation. The future guideline should consider implementation during development including ready access to the details about the level recommended in intervention reporting guidelines.

4.2 INTRODUCTION

Clinical practice guidelines (CPG) are systematically developed statements or recommendations based on the best available evidence aimed at assisting health care practitioners in clinical decision-making(1–4). The role of CPG is to support clinician and patient decision-making to decrease variation and improve outcomes (5,6). Implementation of CPG's in clinical practice enhances the guideline-recommended clinical care and, ultimately, improves the treatment outcomes(7–9).

However, adherence to CPG is poor in most healthcare settings(7,10–13). Implementation of guidelines requires 'turning changes in attitude, belief, and knowledge into changes in medical practice'(5). To improve guideline adherence and thereby improve healthcare, the implementability of the guidelines should be studied (8). Understanding the implementability of guidelines requires considering the barriers that interfere with implementation(7). Successful guideline implementation is dependent on the acceptance of the guidelines by the target audience(13). Identifying barriers to guideline acceptance is one of the key factors in the success of implementation strategies(12).

The American Academy of Orthopaedic Surgeons (AAOS) is the largest professional organization that provides professional support to orthopaedic surgeons and affiliated professionals who work in orthopaedics (14). The AAOS has invested substantial effort in developing clinical practice guidelines, for a variety of common orthopaedic conditions including distal radius fracture (DRF) (14). The CPG was developed using a process where an expert panel develops priority clinical questions, a formal process is used to locate and evaluate the quality of the evidence addressing those questions and the final recommendations are constructed in consultation with the expert panel. This process is thoroughly described on their website

<http://www.aaos.org/research/guidelines/DRFguideline.asp>).

4.3 METHOD

A cross-sectional survey methodology was used to seek input from the target users of the DRF CPG, therapists delivering hand and upper limb rehabilitation.

4.3a Ethics and Consent

Ethical approval was received from the local responsible agency (Hamilton Integrated Research Ethics Board, HiREB # 15-285-5). Therapists were contacted according to the approved recruitment plan.

4.3b DRF Clinical practice guideline

The AAOS DRF CPG has 29 recommendations aimed to inform the professionals treating the DRF patients(15). After a review of the full guideline, we selected 10 of the 29 recommendations which, pertained to rehabilitation (See Appendix 1) for review by therapists. We sent the full AAOS DRF CPG along with the appraisal instrument (GuideLine Implementability Appraisal - GLIA) appraisal instrument to the participants and requested an evaluation of the selected items.

4.3c Appraisal instrument

The GLIA instrument is an appraisal tool that is completed by potential users of a guideline after review of the guideline documents to identify the barriers to CPG implementation(16). The first part of the GLIA instrument consists of nine global dimensions questions that relate to the

guideline as a whole. The second part is evaluating items that relate to individual recommendations, focusing on 8 dimensions or intrinsic factors 1) executability, 2) decidability, 3) validity, 4) flexibility, 5) the effect on the process of care, 6) measurability, 7) novelty/innovation, and 8) computability)(16).

Two GLIA dimensions are of particular importance because failure to address them adequately will result in inconsistent implementation(17,18). Any recommendation that does not clearly communicate what to do (i.e., it fails executability criteria) or measuring adherence and outcome (i.e., fails measurability criteria) is not fully ready for implementation(18).

To address the purpose of this study while managing response burden, the participants were asked to answer the global dimensions questions (n=9) for the entire CPG, and two items from the 8 possible dimensions in the second part of the GLIA, executability (n = 2), and measurability (n = 2) dimensions were evaluated for each of the 10 rehabilitation-related recommendations (Appendix 1). The participants evaluated the guideline on each item or dimension using a dichotomous scale, with yes being a favorable response and no being a negative response for all of the items.

4.3d The global dimension:

Table 1: The global dimension included 9 questions

Table: 1 Global dimension
(i) Does the CPG clearly define the target population?
(ii) Does the CPG clearly define its intended audience?
(iii) Are the settings in which the CPG to be used clearly described?
(iv) Do the organization(s) and author(s) who developed the CPG have credibility with the intended audience of the CPG?
v) Does the CPG suggest strategies for the implementation of tools for application?
(vi) Is it clear in what sequence the recommendations should be applied?
(vii) Is the CPG internally consistent?
(viii) Are all recommendations easily identifiable?
(ix) Are all recommendations concise?

4.3e Participants and mailing procedure:

The present study focuses on therapists including physiotherapists and occupational therapists who have clinical experience with DRF rehabilitation. The potential users of the AAOS guidelines were recruited through convenience sampling(19) and snowball sampling(20) Potential participants were recruited from diverse practice settings and a range of practice experiences from Canada and the USA. To be included, the participants (a) were a licensed physical or occupational therapist

(Canada or USA), (b) had a minimum of 5 years of clinical experience or currently working in DRF rehabilitation, and (c) were able to read, write and speak English.

Recruitment methods included the use of professional service providers lists from the provincials Ministry of Health and Ministry of Long-Term Care, professional contact lists from the Canadian Physiotherapy Association, and Canadian Association of Occupational Therapists, American Physical Therapy Association, American Occupational Therapy Association and The American Society of Hand Therapists. Recipients were encouraged to forward the survey to other potentially eligible participants in their facility; thus, the total number of potential recipients is unknown.

The GLIA questionnaire and the 10 specific recommendations from the AAOS guidelines were sent to the participants through their email with instructions on how to complete the GLIA evaluations. Participants were provided with the primary investigator's email, to return the completed questionnaire or to contact the investigator if they needed any further clarification. Reminders through email were sent to the participants at an interval of one month.

All the participants answered the nine questions in the global dimension part (Table 1). Extracted data were tabulated in an Excel table. Items with the answer 'yes' were coded in green color and items with the answer 'no' were coded in red color and were interpreted as the recommendation does not meet the criterion for implementation.

Table 2: Participants Demographics

Number of responses	Participants of the occupation	Country of practice	Experience upper limb rehabilitation
173 (after excluding responses with missing data)	103-PT 70- OT	78 -Canada 25 – USA 56 - Canada 14- USA	Median \bar{x} 20 (5-35 years)

Table 3: GLIA response options

Y (yes)	The recommendation meets this criterion fully
N (no)	The recommendation does not meet this criterion
NA	The criterion does not apply to this recommendation

4.4 RESULTS:

One hundred and seventy-three responses were received over 24 months (May 2016- June 2018). Among them, 103 were physiotherapists (78 from Canada and 25 from the USA) and 70 were occupational therapists (56 from Canada and 14 from the USA) (Table 2). Demographics of participants were summarized using descriptive statistics, including means and standard deviations for continuous data, and frequencies and percentages for categorical data. Four responses (2.2%)

were identified for data missing completely or random, responses with missing data for any variables were excluded from the analysis as suggested by Briggs et al.,2003 and Nakai & Weiming, 2011(21,22).

All the questions except Q5 (strategies for implementation) and Q6 (sequence of recommendation implication) in the global dimension part of the GLIA were reported as “YES” (they met the criteria for the guideline implementation) by 156 participants (90.5%) (Figure 1). One hundred and ten of the participants (63.5%) reported for Q5(strategies for implementation), that the guideline did not address the strategies for implementing the recommendations. Similarly, for the Q6 (sequence of recommendation implication) 137 participants (79.1%) reported that the guideline does not provide any information on what sequence the recommendations should be applied.

In the executability dimension questions, 65% of the participants answered that the guideline does not provide sufficient information on the recommended action there are insufficient details on how to execute the recommendations. On average, more than 80% (139 of 173 participants) of the participants reported that the recommendations R7(Rigid immobilization), R8(Removable splints), R9(Immobilization of the elbow), R17(Future fragility fractures), R20(Unremitting pain re-evaluation), R23(Early wrist motion) and R26 (Vitamin C) lack information to support the executability of the guideline. (Table 2).

In the executability questions, more than 60% of the participants responded in GLIA that recommendations R21(Home exercise), R22(Active finger motion exercise), R27(ultrasound and/or ice) has sufficient information on "what to do" which are considered as the factors that support the implementation of this guideline recommendation. (Figure 3)

Table 4: Glia response for the AAOS DRF CPG

Recommendation	Executability		Measurability	
	What to do? (recommended action stated?)	How to do it?	Measuring adherence?	Measuring outcomes?
	No	No	No	No
[R7] Rigid immobilization	n=130 75.1%	n=166 95.9%	n=165 95.3%	n=159 91.9%
[R8] Removable splints	n=130 75.1%	n=120 69.3%	n=148 85.5%	n=155 89.1%
[R9] Immobilization of elbow	n=143 82.6%	n=149 86.1%	n=139 80%	n=150 86.7%
[R17] Future fragility fracture	n=165 95.3%	n=168 97.1%	n=161 93%	n=156 90.1%
[R20] Unremitting pain	n=110 63.5%	n=112 64.7%	n=120 69.3%	n=118 68.2%
[R21] Home exercise	n=47 26.6%	n=75 43.4%	n=67 38.8%	n=60 34.7%
[R22] Active finger motion exercise	n=5 2.9%	n=3 1.8%	n=23 13.3%	n=11 6.4%
[R23] Early wrist motion	n=117 67.6%	n=120 69.3%	n=101 58.3%	n=110 63.5%
[R26] Vitamin C	n=159 91.9%	n=164 94.7%	n=131 75.7%	n=53 30.7%
[R27] Ultrasound and/or Ice	n=43 24.9%	n=108 62.4%	n=78 45.1%	n=74 42.8%

In the measurability dimension questions, more than 80% (140 of 173 participants) of the participants reported that the recommendations R7(Rigid immobilization), R8(Removable splints), R9(Immobilization of the elbow), R17(Future fragility fractures), R20(Unremitting pain re-evaluation) and R23(Early wrist motion) lack information to support the measurability of the guideline (Table 2). Measurement of adherence requires information on both the actions performed and the circumstances under which the actions are performed. Similarly, measurement of the outcome should include such things as changes in health status, mortality, costs, and satisfaction. For all these six recommendations, participants reported that the recommendation lacks enough information in both the adherence measurement and outcome measurement and these six recommendations were barriers for the guideline implementation (Figure 4).

Participants responded positively (“Yes”) for the recommendation R21(Home exercise), R22(Active finger motion exercise), R27(ultrasound and/or ice) in the measurability part. Mean of μ :120.8 participants (69.8%) responded in GLIA that these three recommendations have information on the measurability of the adherence and the outcomes of the recommendations, and they are considered as positive for the implementation of this guideline. For recommendation R26 (Vitamin C), 75.7% (131 of 173 participants) (Table 2) reported that this recommendation is not clear or lack information on both the actions performed and the circumstances under which the actions are performed, whereas, on the measurement of the outcome (pain), 69.3% (120 of 173 participants) reported that R26 (Vitamin C) provides the sufficient details on outcomes measurement. (Figure 5).

4.5 DISCUSSION

To the best of our knowledge, this is the first study to assess the quality of AAOS DRF CPG using the GLIA tool. This study result indicates that barriers to implementation exist even in guidelines that are developed by a large professional group like AAOS with experts and professional guidelines developers using the best evidence synthesis. The major limitation in the process appears to be that implementability was not considered during development, and the specific information needed to implement is lacking. Only 3 of the 10 recommendations relevant to rehabilitation from AAOS DRF CPG were considered to meet the criterion for implementation.

This study identifies that the majority (70%) of the rehabilitation related recommendation from the AAOS guideline presented executability (exactly what to do under the circumstances defined) and measurability (degree to which the guideline identifies markers or endpoints to track the effects of the implementation of the recommendation) problems. It is generally recognized that CPG guidelines should be clear and action-oriented(23). Failed executability and measurability are often the results of vagueness in the description of the actions involved in a recommendation(24). This vagueness results in application inconsistencies that go against the standardization purposes of a CPG(24,25).

This study identified that the phrases such as “is an option” and “unable to recommend for or against” in some of the recommendations did not provide the clinician what specific action should be taken. The literature shows that in practice, vague recommendations are significantly less utilized than recommendations that clearly state what to do(25). These types of recommendations may serve to protect clinicians from malpractice accusations(clinicians can defend themselves as following the guidelines), but do not accomplish either of the goals of CPG which are to reduce variation and improve outcomes(26).

Strength of CPG recommendations is often classified according to a specific “grading system,” (27) which usually considers only levels of evidence but also focus on other aspects that might impact the strength of the recommendation, such as the significance of the therapeutic risk reduction and possible harms and benefits for possible outcomes(23). The GRADE (Grading of Recommendations, Assessment, Development, and Evaluation)(28) system classify the evidence “quality” at 1 of 4 levels — very low, low, moderate or high for an individual recommendation based on an appraisal of overall benefits, including whether the benefits are positive, negative or uncertain(27). Guidelines developed with insufficient quality of evidence risks inappropriate recommendations that may lead clinicians to the detriment of their patient’s health(29). AAOS DRF CPG recommendations were mostly supported by “low” to “moderate” evidence quality in the GRADE, thus jeopardizing the guideline users to make inferences that may not always be correct.

Despite the limited (consensus-based) strength of recommendations and the lack of specifics in dosage or progression, clinicians in this study viewed 3 recommendations [R21(Home exercise program), R22(Active finger motion exercises) and R27(Ultrasound and/or ice)] as executable and measurable. This may reflect their compatibility with the existing attitudes and beliefs of the therapists working with DRF(25,30). However, there can be wide variation in-home programs in terms of the exercises selected, dosage, progression, etc. therefore when a lack of detail is present, CPG may support confirmation bias where therapists think that they are providing best practice, and may not reduce variation and practice(24).

Issues identified in the executability dimensions show that the guideline lacks clarity and detail in the recommendations. Solutions for such concerns have been proposed by other authors.(8,31,32) For better CPG adherence, recommendations should be in highlighted or stand-alone text (i.e.,

independent from headings) and language should be brief, unambiguous, and as clear as possible(24,33). The AAOS guidelines do have identified recommendations and have provided the detailed guideline document with all relevant studies included/excluded for each of the questions addressed within the guideline. It is possible that therapists wanting to implement recommendations could backtrack to primary studies to find additional details. The AAOS also provides summary versions of the document which is recognized as an important means of communicating the key findings. However, the strategy of creating vague recommendations where the evidence is not clear does little to advance practice(25). A clear description of each recommendation about who does, what for, whom, when, and how should be specified in CPG recommendations (5,8,34). A simple restructuring of the AAOS DRF CPG recommendations with clear and unambiguous language can potentially result in an improvement in guideline utilization, thus improve the quality of care for people with DRF.

Measuring treatment outcomes provides a reliable and credible rationale for treatment on an individual patient level and is a critical component of clinical practice(35). The results from treatment outcome may also be grouped for aggregated analysis focused on determining the quality of care(36). Clinicians reported that they find difficulty with adherence to guideline recommendations which doesn't meet the criterion for the measurability of outcomes(37–39). Our study results show that more than 60% of the selected recommendations from the AAOS DRF CPG failed to meet the measurability criterion in the GLIA tool, which indicates that therapist will find difficult in implementing these recommendations in their clinical practice.

Our study result adds to the existing literature that insists on considering the target audience while developing the guidelines for a better acceptance rate(26,38,40,41). Despite the AAOS claim of rehabilitation professionals as one of the potential users of the guideline, it doesn't provide

sufficient informative recommendations for the rehabilitation professionals working with DRF patients. From the perspective of rehabilitation practitioners, these recommendation needs further modification to be useful in their clinical practice. Our participants had a minimum of five years of clinical experience, still they find the AAOS DRF CPG recommendation ambiguous, suggesting it would be quite difficult for the novice practitioner to interpret. Several studies reported that a practice guideline should inform the best available knowledge to support novice professionals with limited experience, limited exposure to appropriate patients, and low confidence with their clinical decision making(41–43). Considering the steady increase in the incidence of DRF throughout the world and its repercussion contributing to medical, social and economic burden(44–48), the implementability issues reported in this study suggest there is a need for a revised version of the present CPG or a new guideline focusing on the rehabilitation aspect of the DRF.

4.6 Limitations of the study

Most of the participants in this study did not have any experience with the GLIA tool. Even though all the participants had a minimum of 5 years of clinical experience, most of them are novices in appraising a CPG recommendation using GLIA. However, as target users of this guideline, we felt they represented a critical viewpoint to understand the barriers to implementation in practice. In this study, we investigated global consideration and intrinsic factors as such executability and measurability dimensions in the GLIA tool. External factors that affect the implementation of such as organizational factors and environmental factors (e.g., availability of resources and lack of time) were not considered in this study. A future study should focus on these factors, possibly with individual interviews of rehabilitation professionals is suggested.

4.7 Conclusions

This study identifies that the AAOS DRF CPG recommendations have major barriers to implementation that primarily relate to a lack of clear and specific recommended actions that could be implemented. These barriers could be overcome by clearer and less ambiguous phrasing of the recommendations, and by the development of implementation resources that contain details of interventions recommended. Taking implementability issues into account while updating or developing new CPG might increase their uptake and impact on practice.

Figure:1 Global considerations questions

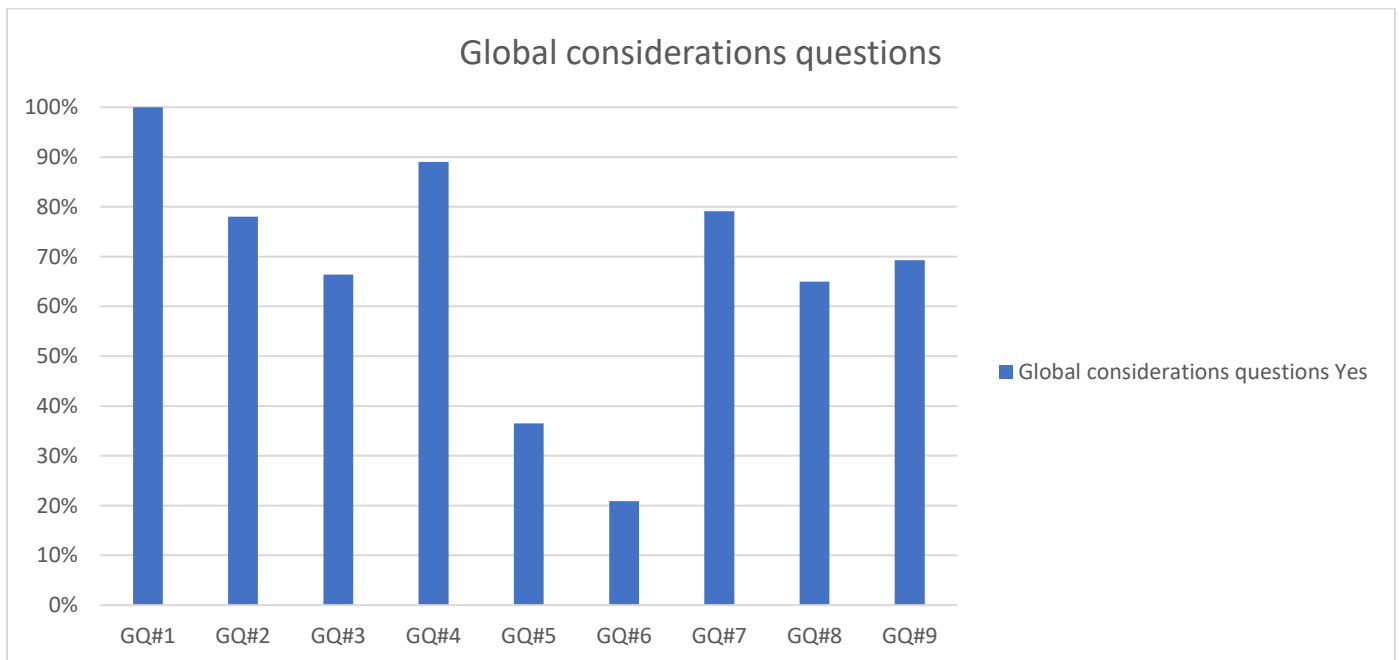


Figure 2: Executability: Is the recommended action stated?

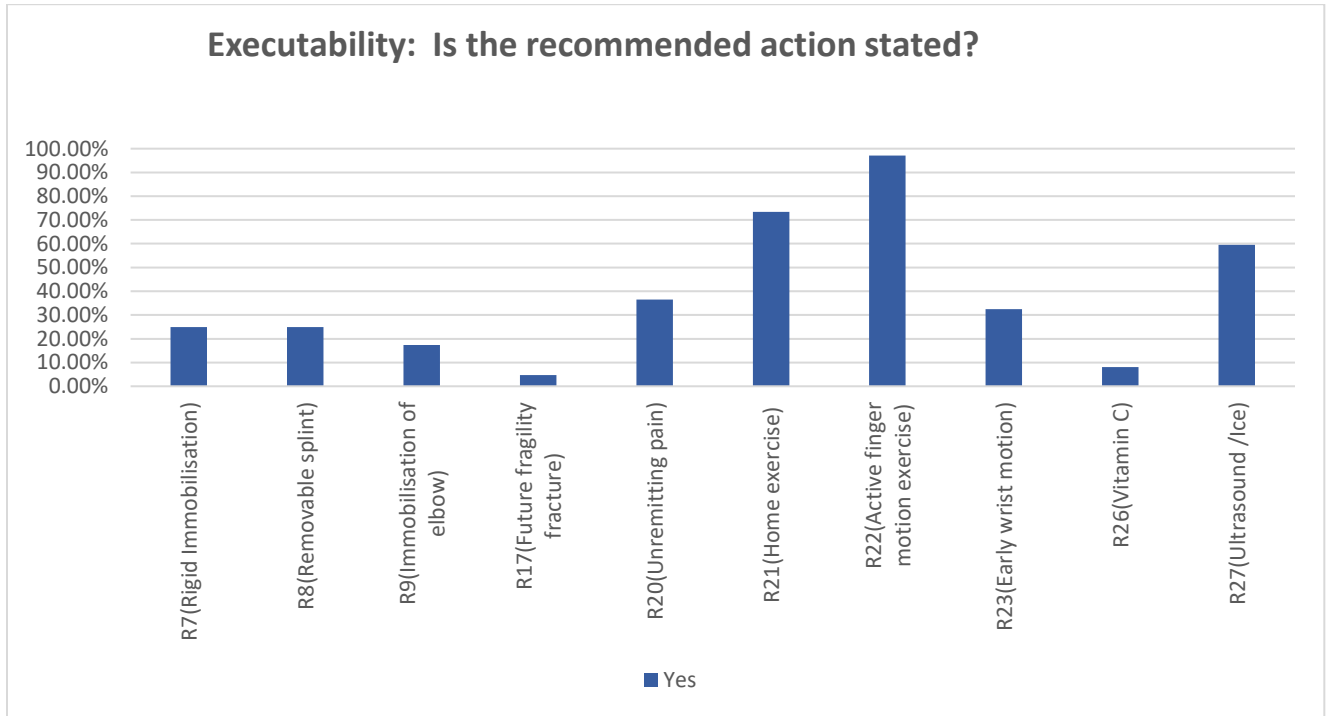


Figure 3: Executability: Detail provided about how to do it?

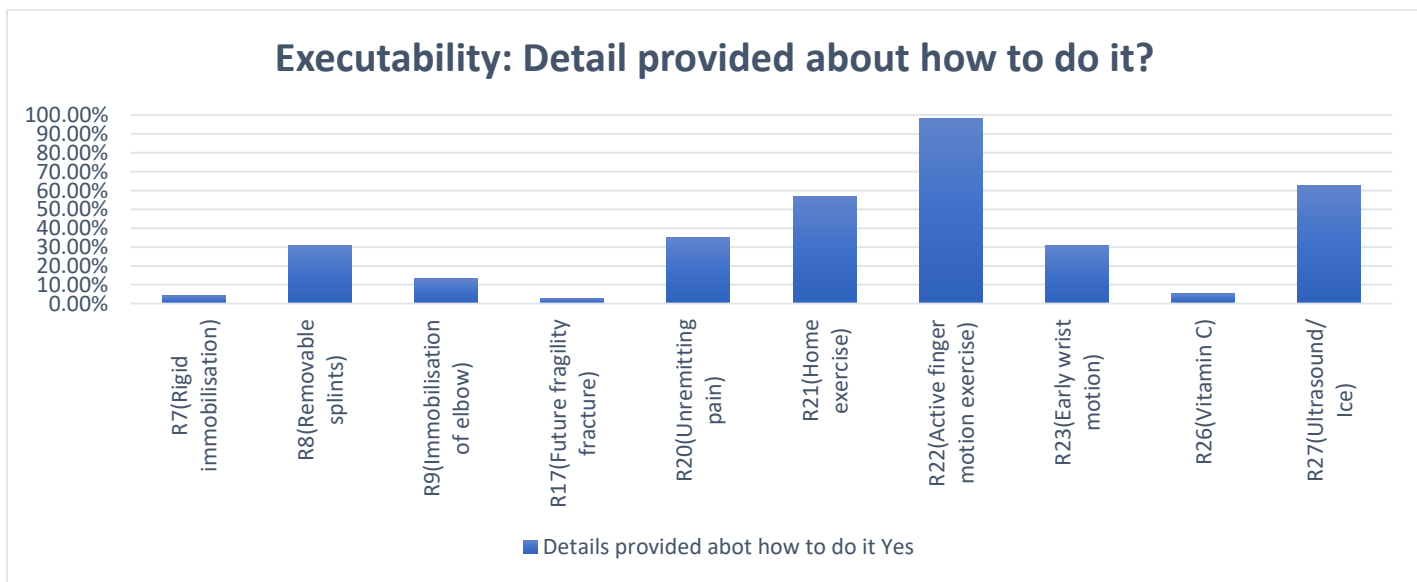


Figure 4: Measurability: Can adherence be measured?

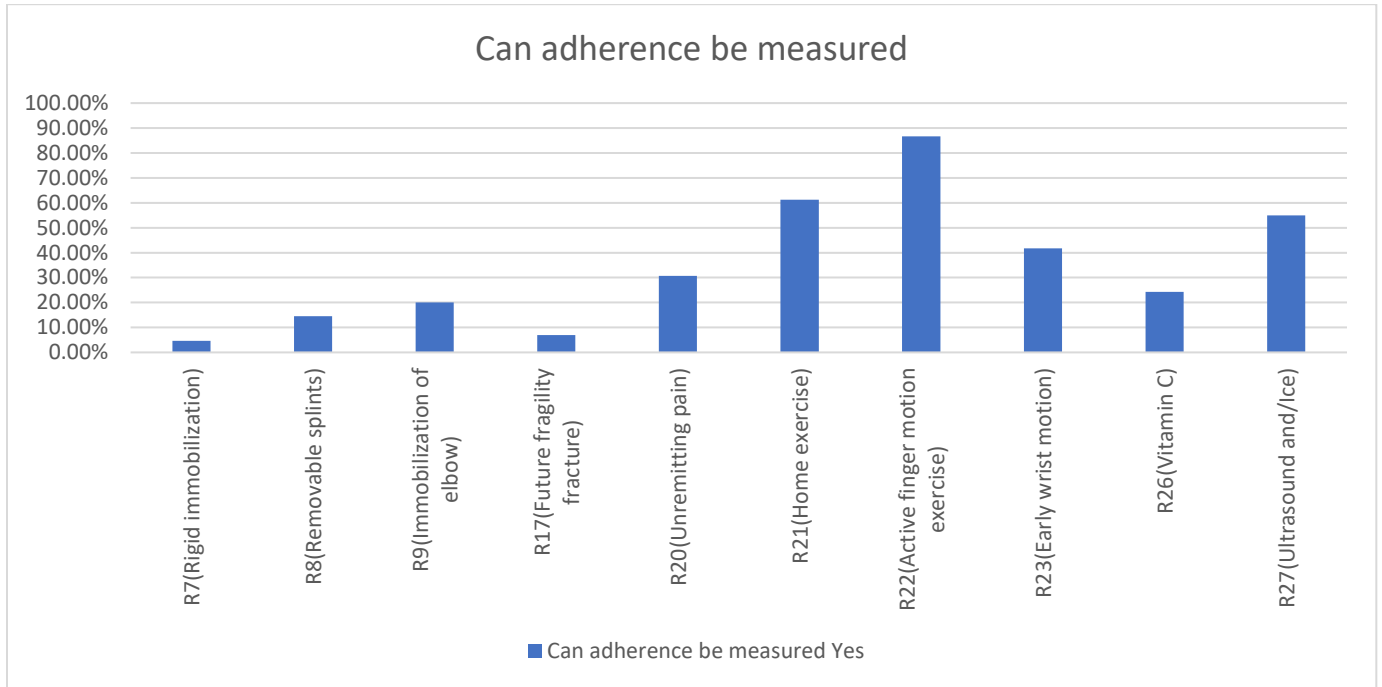
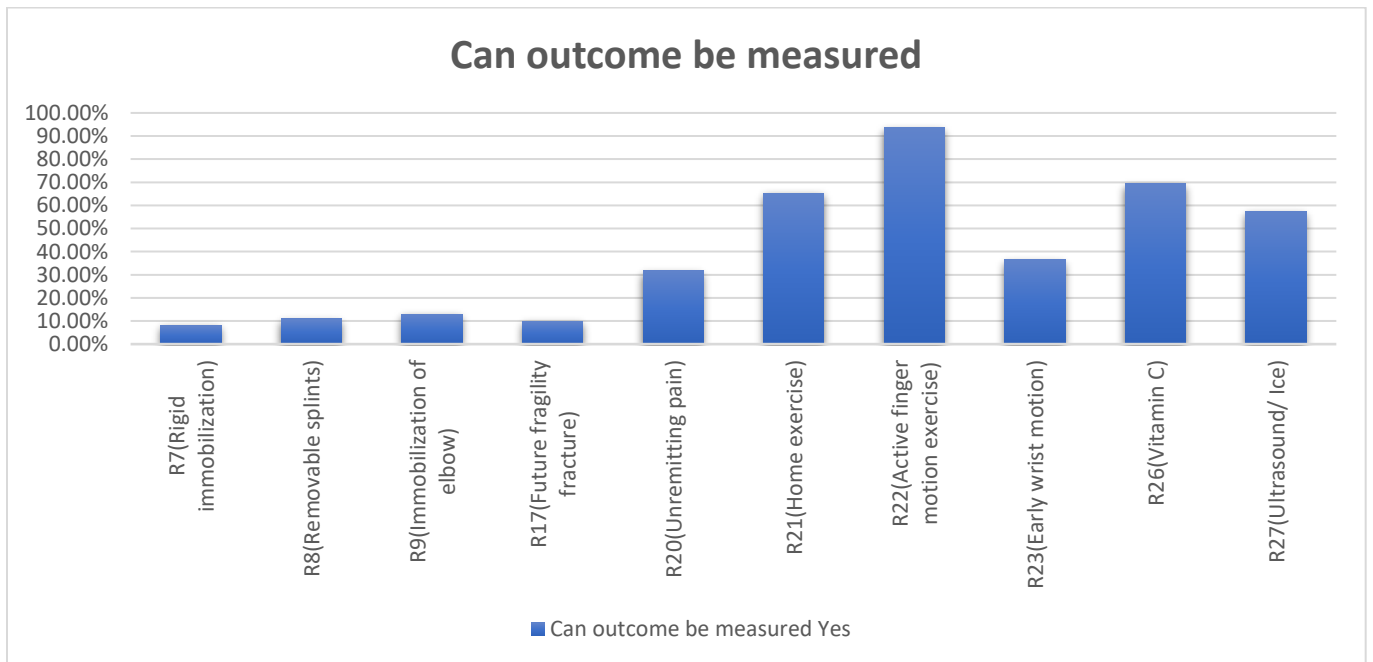


Figure 5: Measurability: Can the outcome be measured?



Appendix1: AAOS DRF CPG Recommendation with the corresponding number:

- 7. We suggest rigid immobilization in preference to removable splints when using non-operative treatment for the management of displaced distal radius fractures.
- 8. The use of removable splints is an option when treating minimally displaced distal radius fractures.
- 9. We are unable to recommend for or against immobilization of the elbow in patients treated with cast immobilization.
- 17. We are unable to recommend for or against using the occurrence of distal radius fractures to predict future fragility fractures.
- 20. In the absence of reliable evidence, it is the opinion of the work group that all patients with distal radius fractures and unremitting pain during follow-up be re-evaluated.
- 21. A home exercise program is an option for patients prescribed therapy after distal radius fracture.
- 22. In the absence of reliable evidence, it is the opinion of the work group that patients perform active finger motion exercises following diagnosis of distal radius fractures.
- 23. We suggest that patients do not need to begin early wrist motion routinely following stable fracture fixation.
- 26. We suggest adjuvant treatment of distal radius fractures with Vitamin C for the prevention of disproportionate pain.
- 27. Ultrasound and/or ice are options for adjuvant treatment of distal radius fractures.

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CHAPTER 5

5.1 Clinical practice guidelines relevant to rehabilitation of DRF of distal radius fracture: a systematic review

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Acknowledgments: Joy MacDermid was supported by a Canadian Institutes of Health Research Chair in Gender, Work and Health, and the Dr. James Roth Chair in Musculoskeletal Measurement and Knowledge Translation.

5.1a Abstract

Background:

Distal Radius Fractures (DRF) are the most common fractures of the upper extremity, potentially lead to persistent disability and are variably managed. The purpose of this review was to conduct a systematic review of CPGs relevant to the management of DRF, to identify the quality of CPGs using the AGREE II tool, and to identify if these guidelines include specific recommendations for the rehabilitation of the patient with DRF.

Methods:

A standard systematic review methodology was conducted. Electronic databases including grey literature search (including the National Guideline Clearing House), Cochrane central, CINAHL, Medline, Embase, and PubMed were searched from 2000 -to November 2019 to identify CPGs for

the management of DRF. Two reviewers independently evaluated all citations, using the AGREE II, and a third reviewer resolved any disagreements. Data were extracted about CPG purpose and clinical recommendations.

Results:

From 308 articles available for screening, a total of 5 CPGs met the inclusion criteria. The CPGs were aimed at a variety of clinicians that included physiotherapists, occupational therapists/ hand therapists, chiropractors, and surgeons/physicians. Selected CPGs were developed by professional organizations in the UK, Canada, USA, Denmark, and Norway. The AGREE score for the scope and purpose domain ranged from 61% to 94% and the stakeholder involvement domain ranged from 13% to 97%. The rigor of the development domain score ranged from 38% to 95%, and the clarity of the presentation domain score ranged from 63% to 83%. Scores were lowest on the domain of applicability and ranged from 18% to 60% and the score for the editorial independence domain ranged from 54% to 79%.

Conclusion:

AGREE results suggest that none of the clinical guidelines was of overall satisfactory quality to apply in clinical practice. Guidelines that address DRF rehabilitation and a more comprehensive manner are needed.

5.2 INTRODUCTION

Distal Radius Fractures (DRF) are the most common fractures of the upper extremity(1,2). They are also the most common fracture overall under the age of 75(3). The incidence rate of DRF distinctly varies between different countries and is known to be dependent on the geographical area(4). In Canada, DRF account for more than 20% of all fractures seen in the emergency department, where these numbers do not include those treated by medical practitioners in the community(5) The higher incident rate of low energy DRF was reported due to the icy or snowy weather in Canada.

Evidence shows a gradual increase in the incidence of DRF in recent years(3,4,6–9). The extent of impairments and disabilities experienced by DRF patients were described in several studies(9–13). Disabilities such as reduced hand function due to hand stiffness, complex regional pain syndrome, mal-union, future fragility fracture, and osteoporosis were reported as the poor outcomes in the longer term in the DRF patients. To minimize the disability experienced by the patients with DRF, evidence-based effective, and appropriate treatment is essential. Practice guidelines developed based on high-quality evidence help health care professionals in clinical decision making to provide effective treatment(14).

Clinical Practice Guidelines

Clinical practice guidelines (CPG) are systematically developed statements or recommendations based on the best available evidence aimed at assisting health care practitioners in clinical decision-making(15,16). CPG aims to improve the quality of health care delivery and strengthen the position of the patient. CPG are also described as “boundary objects” that “act to accommodate divergent trends by providing a focus of attention for negotiations on controversial issues”(17).

These knowledge tools contribute to overcoming the enormous task of searching and appraising literature that individuals would otherwise need to engage in as evidence-based practitioners if knowledge synthesis tools were not available(18). Health professional associations and other groups accredit the responsibility of guideline development to a selected group of motivated experts/specialists who involve in the process of converting research evidence into clinical recommendations.

Appraisal instrument

The AGREE II instrument was developed by an international group of researchers and guideline developers from 13 countries and has accepted reliability and the instrument is endorsed by the World Health Organization (19). It is widely accepted in the guideline development community as the international standard for guideline evaluation and has been used in numerous medical areas to evaluate CPGs(20). The instrument assesses the reporting of not only the quality of the development process but also the quality of documentation about the guideline development. It consists of 23 items organized in six domains followed by one final question rating willingness to recommend. Each item is ranked on a 4-point Likert scale based on an agreement with the item. A standardized score is calculated for each of the six domains by summing all the scores of the individual items in a domain and by standardizing the total as a percentage of the maximum possible score. According to the AGREE II instructions, the standardized domain scores are not combined into a single quality score(21).

Though there are several CPGs available for the clinicians, it is important to identify the quality of the existing CPGs relevant to the DRF care. Further, CPG recommendations relevant to DRF rehabilitation is unknown. Hence, the purpose of this study is:

1. To identify and evaluate the quality of CPGs relevant to the treatment of DRF using the AGREE II
2. To identify the extent to which the recommendations related to rehabilitation and the content of the rehabilitation related recommendations

5.3 Methods

5.3a Search strategy

The literature search was conducted to identify relevant CPGs using the following sources:

1. National Guideline Clearinghouse ([https:// www.guideline.gov/index.asp](https://www.guideline.gov/index.asp)): (separately hand therapy, physiotherapy, occupational therapy, hand, and wrist)
2. Cumulative Index to Nursing and Allied Health Literature (CINAHL)—A search was conducted using the terms [Clinical Practice Guidelines] and [wrist or hand] and [fracture] and [hand therapy or physiotherapy or occupational therapy or conservative management or rehabilitation]
3. PubMed—A search was conducted using the terms [Clinical Practice Guidelines] and [wrist or hand] and [fracture] and [hand therapy or physiotherapy or occupational therapy or conservative management or rehabilitation]
4. The Canadian and Ontario Physiotherapy Association’s web sites, which contain a database of relevant CPGs.
5. Medline, National Institute of Health and Clinical Excellence (NICE) Guidance, Canadian Medical Association, the American College of Physicians Clinical Recommendations, and the World Health Organization (Appendix: 1 search terms).

5.3b Inclusion and exclusion criteria

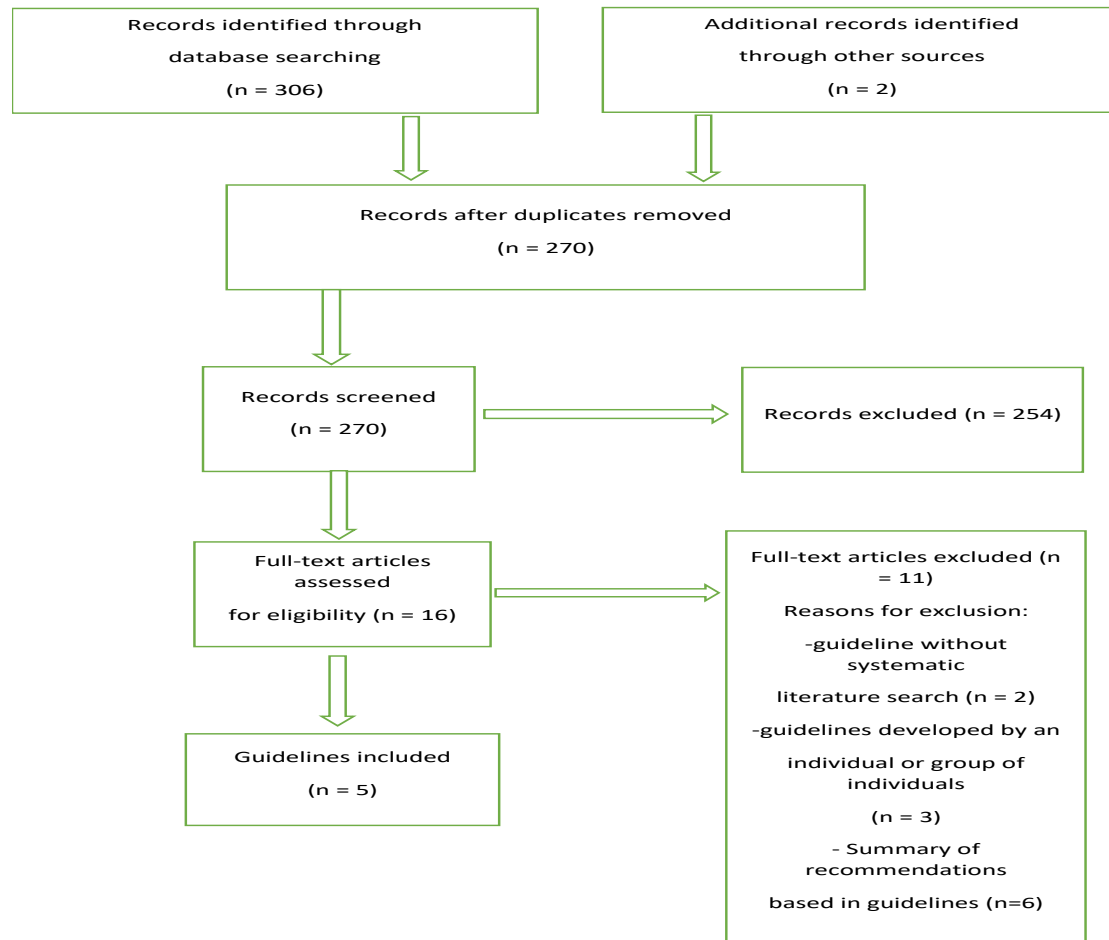
CPGs developed by the professional group and published in English were included. Guidelines only with evidence-based and contained clearly defined specific clinical recommendations were included in this study.

CPGs related to a single treatment modality including surgery, massage, or manipulation were excluded, also CPGs related to traditional healing/medicine (e.g. traditional Indigenous medicine) and Systematic reviews, which were not developed into CPGs, were not included.

Each study was evaluated for inclusion in the review at three separate stages: title, abstract, and article level. Articles retrieved from each database were assessed at the title level by both the reviewers. Studies remaining after title elimination were randomized to two different reviewers by drawing numbers out of a box. Each abstract was assessed for inclusion independently by each reviewer.

This study was conducted in congruence with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement. The PRISMA statement provides instruction to ensure a clear presentation of what was proposed, performed, and found in a systematic review, and guide with clear reporting of all key information.

Figure 1: Selection of guidelines



5.3d Evaluation of Quality of Clinical Practice Guidelines Using AGREE II

Several tools are available for evaluating the quality of CPGs (22). The Appraisal of Guidelines for Research and Evaluation (AGREE II) collaboration has been predominantly utilized in evaluating the quality of the CPG (20). The version of the AGREE II scale used in this study was published in 2002 by the AGREE II collaboration (www.AGREE IIcollaboration.org) and can be downloaded with an accompanying manual that defines the interpretation of items. The subscales

covered include scope and purpose, stakeholder involvement, the rigor of development, clarity, and presentation, and applicability of the guideline. Previous authors have demonstrated that the instrument is valid as compared with other appraisal instruments in terms of its scope and content(19,23,24). The AGREE II instrument is composed of a total of 23 items, which are scored from 1 to 7. A score of 1 (Strongly Disagree) is given when there is no information that is relevant to the AGREE II item or if the concept is very poorly reported. A score of 7 (Strongly Agree) should be given if the information is exceptional and the full criteria and considerations required in the User's Manual have been met. A score between 2 and 6 is assigned when the reporting of the AGREE II item does not meet the full criteria or considerations. A final item, a subjective question, asks the reviewer "Would you recommend these guidelines for use in practice?" The reviewers select "strongly recommend, recommend with provisions or alterations, would not recommend or unsure."

5.4 Results

Selection of guidelines

As shown in Figure1, the database search identified 306 documents. After two reviewers independently screened titles, abstracts, and full-texts according to the inclusion and exclusion criteria, five guidelines were selected for inclusion. The five guidelines included in the review were, American Academy of Orthopaedic Surgeons "The treatment of Distal Radius Fractures- (AAOS DRF CPG)(25) developed in the USA, National Clinical Guidelines Centre (NICE Guidelines)(26) and the British Society of Surgery and Hand (BSSH) Best practice for the management of DRF(27) were developed in the United Kingdom, Danish Health Authority

National Clinical Guidelines on the treatment of DRF(28) developed in Denmark, and Norwegian Orthopaedic Association and Medical Association, treatment of DRF(29) in adult was developed in Norway. All the guidelines were published in English.

Quality assessment

Each guideline was independently assessed by two appraisers using AGREE II. The appraisers did not have previous experience of using the AGREE II instrument. Both the appraisers first read the AGREE II manual and watched the online overview tutorial. The appraisers were free to discuss the appraisal process or the guidelines' content but were requested not to share their scores to each other. For every guideline we calculated the standardised domain and overall quality scores. To examine the performance of AGREE II in our use case, we performed several analyses. The AGREE II scores for each domain for each guideline are provided in Table 1. An evaluation of inter-rater reliability was performed for the AGREE II ratings and the intraclass correlation coefficient was 0.97 (95% confidence interval=0.94–0.98), showing a high level of reliability.

Scope and purpose

The score for the scope and purpose domain ranged from 61%(BSSH) to 94%(AAOS and Danish). All guidelines described their overall objectives, health questions, and target populations.

Stakeholder involvement

The score for the stakeholder involvement domain ranged from 13%(BSSH) to 97%(Danish). All but BSSH best practice guidelines had at least a score of 60% of the maximum possible score in this domain. Many guidelines lacked a description of how they included the views and preferences of patients or had not performed a test among target users.

Rigor of development

The score for the rigor of the development domain ranged from 64%(NICE) to 95%(Danish). All five guidelines scored more than 50% of the maximum possible score in this domain. Danish and Norwegian Orthopaedic Association guidelines clearly described systematic methods of searching for evidence and they described its procedures for updating guidelines.

Clarity of presentation

The score for the clarity of the presentation domain ranged from 63%(BSSH) to 83% (Danish Health Authority Guidelines and Norwegian Orthopaedic Association). All five guidelines scored more than 70% of the maximum possible score in this domain.

Applicability

Scores were lowest on the domain of applicability and ranged from 18% (NICE and BSSH) to 60%(Norwegian). Only the Norwegian Orthopaedic Association guideline scored more than 50% described the facilitators and barriers of its applications.

Editorial independence

The score for the editorial independence domain ranged from 54% (BSSH and Danish) to 79% (AAOS). All the five guidelines scored 50% of the maximum possible score in this domain and gave information on editorial independence and described possible conflicts of interest.

Table:2 Appraisal of Guidelines, Research, and Evaluation II domain-standardized scores

Guideline	Scope and purpose (%)	Stakeholder involvement (%)	Rigor of development (%)	Clarity of presentation (%)	Applicability (%)	Editorial independence (%)	The overall quality of the guideline
American Academy of Orthopedic Surgeons	94%	66%	71%	72%	22%	79%	57.1%
National Institute for Health and Care Excellence Guidelines (NICE)	86%	63%	64%	75%	18%	66%	64%
British Society for Surgery of the Hand (BSSH) Best practice for the management of distal radial fractures (DRFs)	61%	13%	71%	63%	18%	54%	57.1%
Danish Health Authority National clinical guideline on the treatment of distal radial fractures (DRFs)	94%	97%	95%	83%	45%	54%	71.4%
Treatment of distal radius fractures in adults - Norwegian Orthopaedic Association - The Norwegian Medical Association	72%	88%	86%	83%	60%	75%	78.5%

Rehabilitation intervention recommendation:

None of the guidelines has specific recommendations on rehabilitation intervention for the DRF. These guidelines recommended actions on the rehabilitation were inconclusive (Table 2). The Danish Health Authority Guideline and the Norwegian Orthopaedic Association guideline explicitly recommended that patient with DRF doesn't need any formal physiotherapy and occupational therapy interventions under the direct supervision of the therapists unless it is a complex nature of the injury. These two guidelines recommend independent self-rehabilitation based on a written training plan following a single instruction as a good practice.

BSSH's best practice for management of DRF considered the rehabilitation interventions during and after the immobilisation period for both surgically and non-surgically managed DRF patients. They have also considered the type of rehabilitation intervention, mode of delivery, and the discipline of the rehabilitation provider. Their recommendation as the best practice for the management of DRF is that patients who experience disproportionate levels of pain, edema, loss of motion or delayed functional recovery should be referred to physiotherapy or occupational therapy after clinical assessment for further instruction and treatment. They are also inconclusive to suggest anyone rehabilitation intervention as superior to others to restore function following an acute DRF. The choice of intervention should be provided by rehabilitation professionals (physiotherapist / occupational therapist) considering patients' requirements as well as physical impairments.

AAOS DRF CPG recommended the home exercise program as an option for the patients prescribed therapy after DRF. They recommend patients to perform active finger motion exercise following the DRF, but they do not recommend early wrist mobilisation routinely following stable

fixation of DRF. They also recommend ultrasound and ice as limited recommendations (inconclusive) as the option for treating DRF patients(25).

Table 3: Clinical guideline recommendations regarding the rehabilitation care of DRF

Guidelines	Rehabilitation Care	Rehabilitation Relevant Recommendation	Evidence and Strength of recommendation	Conclusion
AAOS DRF CPG	Considered in 4/29 recommendations	Home exercise program Active finger motion exercises Early wrist mobilisation Ultrasound/ Ice	RCT and systematic reviews	Inconclusive recommendations
NICE Guidelines	Considered in 0/44 recommendations	-	-	-
BSSH Best practice for the management of DRF	Considered in 5/19 recommendations	Wrist and fingers mobilisation during the casting period Rehabilitation after removal of the cast	RCT and systematic reviews	Inconclusive recommendations Inconclusive recommendations Inconclusive recommendations
Danish Health Authority Guidelines	Considered in 1/11 recommendation	Independent home-based therapy and Supervised therapy for more complex DRF patients.	RCT and systematic reviews	Recommended Independent self-rehabilitation following DRF and Supervised rehabilitation only for the complex patient.
Norwegian Orthopedic Association	Considered in 1/13 recommendations	Independent home-based therapy and Supervised therapy for more complex DRF patients.	RCT and systematic reviews	Recommended Independent self-rehabilitation following DRF and supervised rehabilitation only for the complex patient.

5.5 Discussion

Clinical practice guidelines are used by healthcare professionals to improve quality in patient care. Pool of scientific evidence supports better treatment outcomes when guidelines that have been rigorously evaluated are implemented in clinical practice(30-35). Despite an increasing volume of guidelines during the last two decades, evidence shows gross failings in their implementation due to the guideline developing methods and limited improvement in quality with time. This systematic review identified five CPGs on DRF that are not likely to benefit physical therapy practice standards since the attention to rehabilitation issues was limited.

There are three main factors that highlight why these five guidelines received high scores across many of the AGREE II domains. First, in all the selected five CPGs, systematic methods were used to search for evidence, strengths and limitations of available studies were highlighted, and methods for formulating recommendations were performed repeatedly in a systematic way. Furthermore, each guideline explicitly linked the recommendations to the supporting evidence, guidelines all were reviewed externally. Despite these strengths, these guidelines fail to explicitly describe the procedure for updating the guideline. Most common criticisms of these five CPGs are that they fail to cite high levels of evidence and recommendations are often inconclusive.

The second reason that these guidelines scores well in 'rigor of development' domain in the AGREE II was because large and representative bodies supported their development. This was evident from their scores in the 'Stakeholder involvement' domain. The AAOS guidelines, NICE, Danish, and Norwegian guideline recommendations were peer reviewed by large healthcare bodies that represented different areas in clinical medicine. Patients with DRF are managed by various healthcare professionals during the course of their treatment, hence, a broad range of specialists to contribute to the guideline review process is essential because some aspects of patient care may

not be confined to one group of specialists. The third reason why all the five CPGs included in this study performed well (54% (BSSH and NICE) to 79% - AAOS) is that conflicts of interest of all the study authors and reviewers were documented in all these five CPGs. It is not uncommon for the guideline developers to be associated with the funding body (33–35), but the guideline must demonstrate editorial independence without any influential bias from the funding bodies. All the five guidelines did report their funding sources and any competing interests of their developers. BSSH scores on the 'Stakeholder involvement' domain were modest; this indicates room for improvement, especially as regards the participation of multidisciplinary team and patient population. In addition, given the socioeconomic dimensions of DRF, guideline developers should actively seek and consider the preferences of the working and patient population.

The health benefits, side effects, and risks of implementing the recommendations should be explicitly detailed for the successful implementation of guidelines(30,32). The Norwegian Orthopaedic Association mentioned the “benefits and harms” for each recommendation as the “key info” in their guideline handbook. Similarly, Danish Health Authority Guidelines specifically mentioned the “Balance between beneficial and adverse effects” for each of their recommendations. It is important that both risk and benefits of treatment be considered in practice, and hence in practice guidelines to support decision-making for both the clinicians and patients (17).

The “applicability” domain is key to assessing the translational capacity of each guideline and had a great effect on the implementation of CPGs (22). Barriers and facilitators of each recommendation should be explicitly mentioned in the CPG for the better guideline applicability (20,33,37). However, in our study, 'applicability' domain for all the five CPGs had the lowest score in our appraisal, this suggests that guideline developers do not pay sufficient attention to

factors affecting the practical implementation of their recommendations. Similar findings have been also noted in guideline appraisals from other clinical areas (30,32,33,35). Notably none of the included guidelines described the facilitators and barriers of implementation into clinical practice, potentially limiting their applicability.

NICE is well known for its quality of guidelines (38), but in this study, it scored low in the “applicability” domain because the guideline does not describe the facilitator and barriers to its application. Also, there is no information on how the guideline can be implemented in clinical practice. Similar results were reported by Parikh et al 2019 on AAOS and NICE neck pain management CPGs failed to identify barriers and facilitators to implementation and strategies to improve the implication guideline (39). Similarly, Patricia et al 2017 reported that AAOS and NICE guidelines for vertebral fracture scored low in the applicability domain in the AGREE tool due to the lack of information on barriers and facilitators, and information on guidelines implementability(40). Similar results were reported by Pincus et al 2017, on AAOS CPG for Achilles tendon scored very poor in the AGREE tool for the applicability(32). Guideline developers must consider providing the required information on barriers and facilitators while developing new CPGs or updating the existing guidelines.

All the guidelines except the NICE guideline highlighted recommendations on rehabilitation (e.g. therapy intervention under the trained professional, and home-based self-supervised interventions), however, it is essential to further improve the identification of priority questions for research (30). Future guideline developers should consider the identification of priority questions focusing on rehabilitation and should consider the coverage of rehabilitation relevant evidence, including the current practice, differences in practice, topics covered in the ongoing trials, and should involve patients as to their choices and beliefs in treatment.

Strengths and limitation of the study

The strengths of our work include the systematic search and the use of the AGREE, a recognized tool that has been used for evaluating the quality of CPG in other reviews. Potential weaknesses of this review are that we may have missed guidelines since these may have been published in sources other than those we searched, also we might have missed the guidelines that were not published in English. Also, we may have missed some details about the CPG process if these were not documented in the publication and that none of the CPG were specifically designed to address rehabilitation.

Conclusion

The lack of comprehensive recommendations and low applicability scores in current CPG's indicates that they are inadequate to guide the rehabilitation of DRF. Most of the CPGs related to the rehabilitation care of DRF cannot be implemented as such in the clinical practice as assessed by the AGREE II. Variability existed in quality, the rigor of development, and applicability of these guidelines, and it is important for the clinicians to be aware and understand these variabilities to implement the highest quality guidelines in the rehabilitation of DRF.

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CHAPTER 6

6.1 DISCUSSION AND CONCLUSION

This chapter provides the summary of the content covered in the thesis, reviews the main findings from each manuscript presented in this thesis and integrates the work within the larger problem. The specific contribution of individual study findings has been described within the manuscript chapters. In this section, the overall thesis contribution to the existing literature and clinical practice is discussed along with the potential limitations and future research recommendations.

6.1a Contextual Overview

Distal radius fracture (DRF) is the most common fractures of the upper extremity and common fracture overall in patients under the age of 75(1). In Canada, DRF is the cause for one-sixth of all emergency department visits in hospital and they comprise 26-46% of all fractures treated in the health care setting(2,3). The rates of DRF have increased by up to 17% in the past 40 years(4). In the acute stage, the DRF can be treated either conservatively or surgically. DRF can lead to limitations in range of motion (ROM), increased swelling, pain, and ultimately reduced function(5,6). Due to the high incidence of these fractures, patients are often seen by hand therapists for rehabilitation. Once the fracture has healed, DRF patients are referred for rehabilitation to improve function and relieve pain(5). To minimize the disability experienced by the patients with DRF, appropriate and effective treatment is essential. Evidence-based practice guidelines help the health care professionals in clinical decision making on effective treatment(7,8). Clinical practice guidelines (CPG) are defined as “Systematically developed

statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.”(9)

Extensive resources have been invested in the development and implementation of CPGs by the health professional associations and other groups of motivated experts/specialists who engage in the process of converting research evidence into clinical recommendations(9–11). Implementation of CPG’s in clinical practice enhances the guideline-recommended clinical care and, ultimately, improves the treatment outcomes. However, evidence shows that adherence to CPG is very poor in most healthcare settings(12–15). Implementation of guidelines requires ‘turning changes in attitude, belief, and knowledge into changes in medical practice’(14). This thesis result highlights the importance of guideline adherence and implementability. Understanding the implementability of guidelines requires considering the barriers that interfere with implementation(15). Our study results show that guideline implementation depends on the acceptance of the guidelines by the target audience. This study identified barriers to guideline acceptance and the quality of the available CPGs relevant to DRF care.

6.1.b Overall summary of the thesis results

The results presented in this thesis were derived from four independent manuscripts. The order of the manuscripts was determined by the staging of the work as I transitioned from a Master's degree to a PhD. Hence the systematic review was a concluding piece of work to place prior work in context , rather than directing the focus to the AAOS guideline. The first manuscript analyzes and describes the scope and focus of the American Academy of Orthopaedic Surgeons (AAOS) DRF CPG using the ICF and ICD-10 as a basis for content analysis, and to compare the content of the CPG with the ICF hand core sets as the reference standard. Among the 29 recommendations of the AAOS DRF CPG, 5 meaningful concepts were linked to the ICF codes. Of these, 5 codes appeared

on the comprehensive ICF core set and only 3 codes appeared in the brief ICF core set, and 7 conditions were covered in ICD-10 codes. This study informs that the AAOS DRF recommendations have minimal linkage to ICF and ICD-10; also, they address little of the content of the hand core set. Only a few of the meaningful concepts from the CPG were directly linked to the ICF categories. A rehabilitation guideline should consider multiple aspects of the ICF that affect patient outcomes, thus patients can allocate less or more intensive therapy, or different therapeutic paradigms depending on different injury, psychological, social, or physical factors. Thus, this paper focused on the content of the CPG using ICF linking as an international transdisciplinary language and was able to conclude that there was insufficient focus on rehabilitation in this CPG. Despite this limitation, there were recommendations for practice and it was considered important to investigate the usability of these. A novel aspect of this paper was the adaptation of summary indicators developed by my thesis supervisor for outcome measure linkage to ICF, to this application of linking content to CPG recommendations.

The second manuscript indicates therapist perceptions of the clarity and implementability of relevant recommendations from the AAOS clinical practice guideline for distal radius fracture using a cognitive interview approach. The study found that the guideline did not provide specific parameters for the intervention required for implementation. A majority of the participants (87%) did not agree with the applicability of individual recommendations based on their clinical experience and they perceived that there was inadequate evidence to justify the recommendations. We identified that lack of leadership, limited availability of resources, and unsupportive organizational culture as factors that influenced the implementation of recommendations. This paper integrated two qualitative techniques. Cognitive interviewing is a structured process with an intended purpose that focused on understanding how respondents understand and interpret

content, usually an item on an outcome measure. We adapted this approach and summary statistics, developed by my supervisor, to fit the exploration of CPG recommendation interpretation. We used , interpretative description, which a qualitative approach to describing content with a clinical purpose to focus on implementability. Integrating these 2 techniques provided greater insights into why the CPG were not easily implemented since it addressed issue with the recommendations and the context.

The third manuscript summarizes the cross-sectional survey on the implementability of the AAOS DRF guidelines using the guideline implementability appraisal tool (GLIA). A total of 173 responses were received, 103 were physiotherapists (78 from Canada and 25 from the USA) and 70 were occupational therapists (56 from Canada and 14 from the USA). This study identified that the AAOS DRF guideline did not address the “strategies on guideline implementation” and are not clear on “what sequence the recommendations should be applied?”. In the executability dimension questions, this study report identified that there is no information on the “recommended action” or on “how to execute the recommendations”. In the measurability dimension questions, our participants reported that the guideline does not provide sufficient information on the “adherence measurement” or on “how to measure the outcomes” for recommendations. The study result indicates that most therapists found the AAOS DRF CPG was not implementable due to the lack of clarity and information on what to implement, how to implement, or to measure measuring the adherence and outcomes of the recommendation. In some ways the findings of this results were not unexpected given the results of the prior study. However, this design was initially chosen thinking that GLIA is a very different process and might come to different conclusion, or at least gain additional insights. Although the findings were similar, this can be considered a validation of the findings, and increases our confidence that these are major issues with current CPG. Application

of GLIA by survey was challenging given the volume of responses that must be made. When evaluating the two approaches we can see different strengths and weaknesses. The cognitive interviewing approach being qualitative used a smaller sample and allowed interviewers to explore the reasons for answers. GLIA represented a larger sample and so may have been more representative but did not allow for exploration of the reasons for answer and there are concerns about how it respondents interpreted or engaged, given the survey format. An approach where GLIA is completed during an interview might be useful in future studies. However, we did find GLIA to be burdensome for respondents, even though we did not fully implement all aspects. Users may need to focus on key recommendations when implementing GLIA by survey .

The fourth manuscript is a systematic literature review that synthesizes the CPGs relevant to the management of DRF and identifies the quality of this CPGs using the AGREE II tool and identifies if these guidelines include the rehabilitation care for the patient with DRF. CPGs included in this study were developed by professional organizations in the UK, Canada, USA, Denmark, and Norway. The AGREE score for the scope and purpose domain ranged from 61% to 94% and the stakeholder involvement domain ranged from 13% to 97%. The rigor of the development domain score ranged from 38% to 95%. and for the clarity of the presentation domain score ranged from 63% to 83%. Scores were lowest on the domain of applicability and ranged from 18% to 60% and the score for the editorial independence domain ranged from 54% to 79%. The study results suggest that none of the guidelines was of overall satisfactory quality to apply in clinical practice. This systematic review was conducted after the detailed review of the AAOS was completed, to see if there might be better options outside of the North American context. Although it might seem biased to focus on the AAOS guideline initially, we know that context is very important in CPG implementation and that the endorsement of AAOS and the large initiative to translate their CPG

into practice would be a major influencing factor in North America. By addressing gaps in the AAOS guideline, we demonstrated that despite the large effort put forward by AAOS, these CPG do not support better DRF rehab. This leaves room for existing DRF CPG or newly developed ones to take a more predominant role. This review concluded that gaps in DRF rehabilitation exists beyond the AAOS DRG and suggested the need for a rehabilitation specific CPG. This work is in progress by APTA.

6.1.c. Contribution of the thesis to the literature and clinical practice

The four manuscripts included in this thesis provide deeper insight on AAOS DRF CPG linkage to ICF and ICD-10, the extent to which the recommendations represent important areas of function and disability by comparing content with the ICF hand core sets, how therapist understand and interpret the AAOS DRF CPG recommendations, barriers to the implementation of the recommendations and the quality of guidelines focusing the DRF rehabilitation. This thesis highlights that AAOS DRF CPG recommendations relevant to rehabilitation lacked clarity and reported that this guideline did not provide any specific parameters of the intervention required for implementation. There was a lack of specific information needed for implementation such as targeting criteria and dosage or timing of interventions. A CPG specifically designed to inform rehabilitation of DRF with clear and specific recommendations is needed. Future guidelines should consider implementation during development including ready access to the details about the level recommended in intervention reporting guidelines.

This thesis work contributes to the literature by providing the first systematic literature review that synthesizes the CPGs relevant to the management of DRF and identifies the quality of this CPGs using the AGREE II tool and also identifies if these guidelines include the rehabilitation care for the patient with DRF. AGREE results suggest that none of the clinical guidelines was of overall

satisfactory quality to apply in clinical practice. Guidelines that address DRF rehabilitation and a more comprehensive manner are needed.

6.1. d. Limitations

The limitations specific to individual studies have been discussed in each of the manuscript chapters. In this section, we describe the overall methodological limitation of our thesis work. A potential limitation of the cognitive interview methodology could be most of our participants were recruited from a single province in Canada, and there were only four participants from the USA. Also, in the cognitive interview as well as in the survey study, we selected ten recommendations from the AAOS DRF guidelines pertaining to rehabilitation, therefore the study results cannot be generalized to the guideline as a whole. In our survey, most of the participants did not have any experience with the GLIA tool. Even though all the participants had a minimum of 5 years of clinical experience, most of them are novices in appraising a CPG recommendation using GLIA. In further work, these limitations can be overcome by either including the participants from a wide geographical location and to educate the participants in-depth on the AGREE tool before appraising the CPG.

Several limitations exist for the thesis overall. Our early focus on AAOS may have led us to not direct enough focus on international CPG, although as we explained the rationale for this was predominance of AAOS as an influential body in North America. We had hoped to study the APTA guideline, but guidelines take time to complete and it was not ready when this PhD work was completed, we understand that work will be published soon which may provide a better option for therapists. However, rigorous examination of APTA guidelines is also needed. Finally, while we criticized existing CPG, we did nothing to improve them through this thesis. Highlighting

problems is an important step but contributing to better CPG is where true impact on clinical practice will be achieved.

We understand and acknowledge that there is an updated version of AAOS DRF CPG published in 2020 December (16), available for the clinicians. Therefore, some of our findings might appear to be outdated. CPG are regularly updated. In the updated version, the guideline developers have reduced the number of recommendations from twenty-nine to seven recommendations, in which only one recommendation focusing on the DRF rehabilitation which was concluded based on the "low" to "moderate" quality studies. The overall approach to this CPG is similar to their prior CPG. This update on AAOS DRF CPG further strengthens our study results which strongly indicates the need for the rehabilitation focused CPG for the patient with distal radius fracture.

6.2 Conclusions

This thesis established that existing CPG for DRF do not sufficiently focus on rehabilitation. The statement is often too generic/vague to direct specific actions or be implemented consistently across different practitioners/contexts. their value in affecting the quality of practice was questionable. this work concludes there is a need for rehabilitation specific DRF CPG that provide detail on the what specific assessments, prognostic variables, interventions, and outcome measures are best supported by evidence and should be implemented in practice.

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13. Brand C, Landgren F, Hutchinson A, Jones C, Macgregor L, Campbell D. Clinical practice guidelines: barriers to durability after effective early implementation. *Intern Med J.* 2005 Mar;35(3):162–9.
14. Leentjens AF, Burgers JS. What factors are important for the successful implementation of guidelines? *Tijdschr Psychiatr.* 2008;50(6):329–35.
15. Francke AL, Smit MC, de Veer AJ, Mistiaen P. Factors influencing the implementation of clinical guidelines for health care professionals: a systematic meta-review. *BMC Med Inform Decis Mak.* 2008 Sep 12;8:38.
16. American Academy of Orthopaedic Surgeons/American Society for Surgery of the Hand Management of Distal Radius Fractures Evidence-Based Clinical Practice Guidelines. www.aaos.org/drfcpg Published December 5, 2020.

Appendix 1



HAMILTON INTEGRATED RESEARCH ETHICS BOARD (HIREB) RENEWAL FORM FOR REB APPROVED STUDIES

Complete the form in NO smaller than 10 point font; handwritten submissions are NOT acceptable

Sections that are left blank will be interpreted as negative answers.

Use this form only if data are being collected or participants are still being followed. If all data collection and participant follow-up has ended and the study is either completed or cancelled, submit a Study Completion Report.

A. IDENTIFYING INFORMATION

1. Name of Local Principal Investigator: [REDACTED]

2. Email for Local Principal Investigator: [REDACTED]

[REDACTED] Co-Investigators (Please highlight additions/deletions): [REDACTED]

4. Research Project Title: Understanding the clarity and implementability of Orthopaedic Surgeons Distal Radius Fracture treatment guidelines

5. REB Project #: 15-285-S

B. CURRENT STATUS OF THE STUDY

Progress of study: Not Activated Active Enrollment
(Check all that apply) On Hold Closed to Enrollment
 Interim Analysis Final Analysis in progress
 Abstract(s)/Manuscript(s) attached Health Chart/Databases only
 Tissue Study for Study Complete (see website

Study Completion form)

At THIS site:

Specify #

Number of participants enrolled to-date.

Number of participants currently receiving intervention
N/A

Number of participants currently in follow-up
N/A

Number of participants withdrawn due to AE
-

Number of participants withdrawn due to other reasons

Please specify reason(s):

Number of participants who have completed study
8

Target number of participants
20

NOTE: For chart research, state # of charts under enrolled field

C. STUDY PROGRESS TO-DATE

1. Please list all published abstracts or manuscripts arising from this study since the last renewal/approval. -

2. Changes in the Investigators
Have there been any changes in investigators since the last approval? YES
 NO

If YES, has the REB been notified? YES
 NO

If NO, submit changes on an Amendment Form now.
ATTACHED

3. Institutional Resources Required
Have there been increases in the institutional resources required to support the study? YES
 NO

If YES, submit changes on an Amendment Form now.
ATTACHED

4. Is your research study funded by a commercial sponsor? YES
 NO

What is the current funding for the project? \$ _____

Have there been any changes in funding status since the last approval? YES
 NO

If YES, has the REB been notified? YES
 NO

If NO, submit changes on an Amendment Form now.
ATTACHED

5. Has your relationship with the study sponsor changed? YES
 NO

If YES, include a description of any potential conflict of interest issues arising from the changes, e.g. indirect/direct financial interest including patent and/or stocks, honorarium or other benefits from sponsor, and explain how it is being managed to ensure that participant rights and welfare are protected.

NOTE: If a Conflict of Interest was not reported initially and should have been, you are obligated to declare it now.

6. Is there anything new in the literature that may affect the study design or information provided in the consent forms?
 YES NO

Please state the source and comment:

7. What is your latest REB-approved protocol version date? March 26th 2015

8. What is your latest REB-approved consent form version date(s)? May 3rd 2015
9. Please confirm that any study amendments proposed in the past year have been submitted for REB approval; otherwise submit proposed amendments on a separate amendment request form.
 Already submitted to the REB Office N/A ATTACHED
10. Does this study have a Data Safety Monitoring Committee? YES
 NO
 If YES, please attach the most recent report(s) if they have not already been submitted to the REB Office.
 Already submitted to the REB Office ATTACHED
11. Please confirm that all unexpected or adverse events have been submitted to the REB for follow-up or submit on a separate adverse event report form.
 Already submitted to the REB Office N/A ATTACHED
- Have these events changed the assessment of risk for participants? YES
 NO
12. If you are still recruiting participants, do the consent forms conform to the current requirements as posted on the REB website? Please note that you should consult the REB website for the latest templates and submit an Amendment Request Form separately to update your consent forms.
 YES NO
- If NO, please attach an Amendment Request Form and a revised consent form.
 ATTACHED

D. PRIVACY AND DATA SECURITY

1. To comply with Ontario privacy legislation, the following mandatory privacy attestation is required for all studies:
 Identifying information de-linked
- Use of study participant names, initials, patient numbers, and other identifying information is strictly prohibited on data collection forms, adverse event reports, and other research participant-specific documents. Participants must be assigned a unique identification code. The code-breaking information must be kept separate from the data extraction files. It is the responsibility of the Principal Investigator to ensure that the code-breaking information is totally inaccessible to individuals who are not on the research team. All identifying information must be stored separately, either in a locked cabinet or on computer with encryption software separate from the computer used for data files or on an institutional server without data.

Data collection sheet for any data not collected as part of study instruments is attached.

Records/computers secured

- Method:
- Participants coded
 - Files/folders pass worded
 - Computer pass worded
 - Computer encrypted
 - Computer in locked office only
 - Other (specify):

Chart/Computer Access limited to research team

- Method:
- Cabinet/Office keys ONLY with research personnel
 - Computer passwords ONLY with research team
 - Other (specify):

2. Data Sources & Storage

- a) Identify all sources of data (e.g. database, registry, health record, clinic files, physician office files, etc.):
- b) Where will the data be stored? Locked cabinet in locked institutional office
- c) How will the data be stored and protected while in storage? Password protected computer on a secure network
- d) For how long will the data be stored? Until the study completed
- e) Who will have access to these data in the future? PI and LPI
- f) How will the data be returned and/or destroyed? Data will be destroyed once the study is completed
- g) Will data be sent outside of the institution?

NO

YES – Please specify where and how the data will be sent, noting any security measures and strategies for protecting study participant privacy.

3. Do you plan on linking locally collected data with any other data set (e.g. OHIP data)?

NO

YES – If so, identify the data set, why these linkages are required, identify how linkage will occur, and provide a list of data items contained in it.

4. PRIVACY AND SECURITY ACKNOWLEDGEMENT:

On behalf of all members of my research team, I recognize the importance of maintaining the confidentiality of personal health information and the privacy of individuals with respect to that information. I will ensure that the personal (health) information is used only as necessary, to fulfill the specific research objectives and related research questions described in the application approved by the REB. This includes all conditions and restrictions imposed by the REB governing the use, security, disclosure, return or disposal of the research participants' personal health information. I agree to take any further steps required by the REB or HHS and/or SJHH to ensure that the confidentiality and security of the personal health information is maintained in accordance with the Personal Health Information Protection Act (PHIPA), its accompanying regulations and the Tri-Council Policy Statement.

Signature of Local Principal Investigator

Date

Submit one (1) copy of the Study Completion Report and supporting documentation to the Research Ethics Board:

[Redacted address information]

Appendix 2



LETTER OF INFORMATION / CONSENT

Understanding the clarity and implementability of Orthopaedic Surgeons Distal Radius Fracture treatment guidelines

Local Principal Investigator:

Student Investigators:

[Redacted names and contact information for the Local Principal Investigator and Student Investigators]

macderj@mcmaster.ca

esakkis@mcmaster.ca

What is the purpose of the study?

The purpose of this study is to understand how does rehabilitation professionals interpret the recommendations made within the American Academy of Orthopaedic Surgeons (AAOS) Distal Radius Fracture (DRF) Clinical Practice Guidelines (CPG)? What is their intention to implement these recommendations; and what barriers and facilitators affect this intention?

Procedures involved in the Research

You will be asked to answer some questions in an open structured interview to explain your personal experience in dealing with AAOS DRF CPG. The interview will be audio taped with your consent and interview will take 20-30 minutes.

After the interview, you will be asked to evaluate the AAOS DRF CPG using Guideline Implementation Appraisal (GLIA) to help explain the issues regarding the guideline implementation.

Are there any risks to doing study?

You may feel uncomfortable about answering some questions. Apart from that there is no risk in this study. You may not answer any question that you feel discomfort.

Are there any benefits to doing this study?

You might learn about the AAOS DRF CPG and the benefits of their implementation in your daily clinical practice. Also, your participation in this study will provide information to researchers and clinicians to better understand which guideline is highly suggested to use based on the Guideline Implementation Appraisal (GLIA) evaluation for such guideline.

Payment or Reimbursement?

You will be given parking passes, if needed, for your interview.

Confidentiality:

Every effort will be made to protect (guarantee) your confidentiality and privacy. We will not use your full name or any information that would allow you to be identified.

The information/data you provide will be kept in a locked desk/cabinet where only the research team will have access to it. Information kept on a computer will be protected by a password. Once the study has been completed and the results published, the data will be destroyed.

What if I change my mind about being in the study?

Your participation in this study is voluntary. It is your choice to be part of the study or not. You can decide to stop (withdraw), at any time, even after signing the consent form or part-way through the study. If you decide to withdraw, there will be no consequences to you. You have the option of removing your data from the study OR information provided up to the point where you withdraw will be kept unless you request that it be removed.

If you do not want to answer some of the questions you do not have to, but you can still be in the study.

How do I find out what was learned in this study?

The results of the study will be published in a scientific journal. If you would like to receive the paper personally, please let me know how you would like me to send it to you.

Questions about the Study

If you have any questions about the research now or later, please contact the local PI:

macderj@mcmaster.ca

This study has been reviewed by the Hamilton Integrated Research Ethics Board (HIREB). The REB is responsible for ensuring that participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please call The Office of the Chair, [REDACTED]

CONSENT

I have read the information presented in the information letter about a study being conducted by [REDACTED]
[REDACTED]

I have had the opportunity to ask questions about my involvement in this study and to receive additional details I requested.

I understand that if I agree to participate in this study, I may withdraw from the study at any time. I have been given a copy of this form. I agree to participate in the study.

1. I agree that the interview can be audio recorded. Yes No

2. I would like to receive a summary of the study's results. Yes No

If yes, where would you like the results sent:

Email: _____

Mailing address: _____

3. I agree to be contacted about future research and

I understand that I can always decline the request. Yes No

Please contact me at: _____

Name of Participant (Printed) Signature Date

Consent form explained in person by:

Name and Role (Printed) Signature Date

Instructions

1. This form is used to apply for initial REB review of most new research projects (except for studies listed in point 2)
2. Do not use this form for Chart reviews, Prospective databases, or Human tissue research. Specialized forms are available on our website.
3. Please answer all questions. If your application is incomplete it cannot be reviewed. Guidance on specific topics is available on the [Guidelines](#) section of our website.
4. Most researchers should submit their application to: (see 5. for exceptions)
[Hamilton Integrated Research Ethics Board](#)

mazzedeb@hhsc.ca

Requirements:

- Three (3) paper copies of your application and all supporting documents. One copy must have original signatures.
- Electronic copy in **Word format (not PDF)** of your application and consent forms **ONLY**

The deadlines for submissions are the second and the last Tuesday of every month (4.00 pm). The REB meets on the first Wednesday and the third Tuesday of every month. Researchers can expect to receive the results of the review within 10 days of the REB meeting.

5. If you are an **Undergrad or Master's student** at McMaster University doing minimal risk health science research, please submit your application to:
[Student Research Committee \(SRC\)](#)

sancan@hhsc.ca

Requirements:

- Three (3) paper copies of your application and all supporting documents. One copy must have original signatures.
- Electronic copy **in Word format not PDF** of your application and all supporting documents.

There is no deadline for submission. The SRC is a subcommittee of the HIREB and in some cases an application may be referred to the HIREB for additional review. The approval process generally takes 4-5 weeks.

6. **Good Clinical Practice (GCP) and Tri-Council Policy (TCPS) Training Requirements :**

All local principal investigators (LPIs) involved in clinical trials, as defined by the Tri-Council Policy Statement on the Ethical Conduct for Research Involving Humans (TCPS), are required to provide proof of GCP training when submitting an application to the Hamilton Integrated Research Ethics Board. **Refer to Section 2-Question 1.**

For all other (non-clinical trial) research, the LPI will be required to provide proof of completion of either the TCPS2: CORE (Course of Research Ethics <http://tcps2core.ca/welcome>) online training or of GCP training by appending their certificate to the REB application.

7. If you have any questions about REB forms, requirements or processes, please contact:
Research Ethics Officer: sancan@hhsc.ca

Appendix 3

HIREB: General Research Application

1. General Information

1. Title of Study:
Understanding the clarity and implementability of Orthopaedic Surgeons Distal Radius Fracture treatment guidelines
2. Keywords (list up to five):
Clinical practice guidelines, American Academy of Orthopaedic Surgeons, Distal radius fracture, Cognitive interview
3. What is your expected study period?
Start: 03/10/2015 (m/d/y) End: 12/01/2015 (m/d/y)
4. Has this study undergone a formal scientific review? Yes No
If yes, please attach the approval letter
5. Has this study been submitted to any other REB? Yes No
If yes, please attach the approval letter (or relevant correspondence)
6. Has this study been denied approval by any other REB? Yes No
If yes, please attach the REB letter
7. Is this an industry sponsored study? Yes No
If yes, who is the sponsor? _____
8. Is this an investigator-initiated study? Yes No
9. Is this a student project? Yes No
If yes, please specify: Resident/Fellow MD Post-doc PhD Master's Undergrad
10. Is this a multi-site study? Yes No

11. Do you plan on conducting this study at SJHH and HHS? Yes No

If yes, you must name a Local Principal Investigator at each site and obtain the necessary signatures with regard to resource utilization at both hospitals.

12. How will you make the results of this study public?

Peer reviewed publication Clinical trial registry Thesis Presentation

Report to participants (Please explain):

Other (specify):

13. How would you explain this study to a lay person (max. 10 lines)?

Clinical practice guidelines are tools that are used to help patients and health professionals how to manage health conditions using the best available research evidence. A broken wrist, called a distal radius fracture, is the most common broken bone that requires patients to attend an emergency clinic. From this initial visit through to rehabilitation, many decisions must be made. Clinical practice guidelines should assist with those decisions and help to keep patients informed about whether they are getting best care. However, this is dependent on ensuring that the recommendations within such guidelines are evidence-based, easy to interpret, provide clear guidance and can be reasonably implemented. An international group of orthopedic surgeons has developed a guideline for how these injuries should be managed. It is important that we understand whether this guideline is understood and used. This study will interview the health professionals who involved in helping patients recover from these fractures and find out detailed information about how they interpret the recommendations, whether they intend to implement them and the barriers and facilitators to doing so.

2. Investigators

1. Who will serve as the Local Principal Investigator (LPI) for this study? If the study will be conducted at more than one site, specify the LPI for **each** site:

For studies conducted at HHS, the LPI must have an appointment at HHS or McMaster University.

For studies conducted at SJHH, the LPI must have an appointment at SJHH. The LPI cannot be a student.

If the study is being conducted at both HHS and SJHH, you must name an LPI at each site.

[REDACTED]		
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

GCP/TCPS Training

Is this a clinical trial? Yes No

- a. **If yes**, please complete the CITI-GCP Tutorial (<https://www.citiprogram.org/>) and attach your certificate (see Section 24). If you completed another accredited GCP training instead of the CITI-GCP tutorial, please append the program outline with the completion certificate for the other training (see Section 24).
- b. **If no**, please attach a copy of either your TCPS2 (CORE) tutorial certificate or GCP certificate (see Section 24).

2. Is the LPI the Principal Investigator (PI) of this study? Yes No

If No, please complete this section. If this is a student project, please name one student as PI.

[REDACTED]		
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

3. Does this study have a Coordinator? Yes No
 If Yes, please complete this section

First: [redacted]	Last: [redacted]	Degree: [redacted]	Student <input type="checkbox"/>
Institution: [redacted]	Dept: [redacted]	Program: [redacted]	
Address: [redacted]	City: [redacted]	Province: [redacted]	PC: [redacted]
Tel: [redacted]	Ext: [redacted]	Fax: [redacted]	Email: [redacted]

4. Does this study have any Co-investigators? Yes No
 If Yes, please complete this section. To list additional researchers, please include a separate page with your paper submission

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

3. Study locations

1. Where will this study take place? (Please check all that apply)

St. Joseph's Healthcare
Hamilton

Hamilton Health Sciences

Setting

St. Joseph's Hospital

Chedoke

Emergency

Centre for Mental Health
Services

Hamilton General

ICU

Centre for Ambulatory
Services

Juravinski Hospital and
Cancer Centre

Inpatient

MUMC

Outpatient

St. Peter's Hospital

McMaster University (specify Building OR Dept/School, i.e. School of Nursing):

Other (specify location):

4. Description of Research

1. Is this a clinical trial? Yes No

A clinical trial is "...any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc." (WHO)

2. Is this an observational study? Yes No

An observational study monitors change over time without introducing an intervention

3. Does this study include human tissue collection or analysis? Yes No

If yes, please specify: Retrospective Prospective

4. Does this study include genetic testing? Yes No

If yes, please attach a separate Genetic Consent form

5. Does this study require access to existing records? Yes No
If yes, please specify the source of the records:

Health Records (specify):

Electronic Database (specify):

Outside Institution (specify):

Educational Records (specify):

Other (specify):

6. Does this study involve qualitative methods? Yes No
If yes, please specify: Questionnaire/Survey Focus Group Interview Other (specify):

[Please attach a copy of all study questions and interview guides](#)

7. Does this study involve any other types of research? Yes No
If yes, please explain:

5. Clinical Trials

- If this is not a clinical trial, please go to section 6.

1. What type of clinical trial is this study? (Please check all that apply)

- Pilot Phase 1 Phase 2 Phase 3 Phase 4
 Randomized Double Blind Single Blind Open Label
 Other (specify): _____

2. Will this trial use an Active comparator? Yes No

If yes, please justify that this treatment is standard care and that clinical equipoise exists (max 5 lines):

3. Will this trial use a Placebo control? Yes No

[Please see TCPS Section 7.4 for limits on the use of placebos](#)

If yes, please justify that a placebo is necessary and that clinical equipoise exists with respect to this treatment (max 5 lines): _____

4. Does this trial involve a new investigational drug, device, or natural health product? Yes No

5. Does this trial involve a drug, device or natural health product used for an indication outside of the Health Canada Notice of Compliance (NOC) or Drug Identification Number (DIN) application or Medical Device License? Yes No

6. Does this trial require Health Canada approval? Yes No

If yes, who submitted the Clinical Trial Application to Health Canada?

LPI PI Sponsor (specify): _____ Other (specify): _____

7. Have you received a No Objection Letter (NOL) from Health Canada? Yes No

The NOL must be submitted to the REB before the study may begin

8. Has this study been registered on a clinical trial registry? Yes No

Registry name: _____ Registration number: _____

All clinical trials must be registered before they begin

6. Methodology

- This section is intended to be a summary. Please submit a study protocol detailing the research that you plan to conduct.
1. What is the rationale for this study (i.e., why are you doing this study; max 5 lines)?
Evidenced based Clinical Practice Guidelines (CPG) are developed by identifying high quality evidence to facilitate more rational and efficient clinical practice and better health care outcomes. Understanding the clarity and implementability of treatment guidelines is essential for the effective implementation of CPG in clinical practice.
 2. What are the objectives of this study (i.e., what do you hope to show; max 5 lines)?
To understand how do rehabilitation professionals interpret the recommendations made within the AAOS DRF CPG? What is their intention to implement these recommendations; and what barriers and facilitators affect this intention?
 3. Please specify your study design (e.g., RCT, cohort; max 5 lines):
This is a cross-sectional study using cognitive interviewing and qualitative methods.
 4. Please specify your study population (e.g., diagnosis, age, gender; max 5 lines):
Rehabilitation professionals (Physical and occupational therapists) from multiple sites, in Canada who were working or experienced with hand conditions.
 5. Please specify your study procedures (max 5 lines):
Stage 1: Rehabilitation professionals who manage DRF will be interviewed using a cognitive interviewing approach to investigate their interpretation of each of the rehabilitation relevant recommendations within the AAOS DRF.

Stage 2: A standardized implementability tool (GLIA) will be completed by practitioners and implementation issues will be identified from the questionnaire.
 6. What is your primary outcome and how will it be measured (max 5 lines)?
This research will determine whether the AAOS DRF CPG provides necessary guidance for rehabilitation professionals and determine whether a future guideline is needed specific to rehabilitation.
 7. What are your secondary outcomes and how will they be measured (max 5 lines)?
It will identify barriers and facilitators that affect the guidelines implementation.

8. What is your sample size?

Local: Total (for multi-site studies): 20-30; until data saturation attained

9. How did you determine your sample size (max 5 lines)?

Sample size were determined based on the data saturation results from similar type previous qualitative studies.

10. How will you analyze your data (max 5 lines)?

The results will be synthesized using a qualitative description approach; and data analyses prescribed for cognitive interviewing.

7. Study Interventions

1. Does this study involve any diagnostic testing? Yes No
 If yes, please specify: Imaging Lab Other (specify):

2. Does this study involve any of the following interventions? Yes No
 If yes, check all that apply:

- Chemotherapy Drugs Observation Exercise
- Radiotherapy Natural health product Questionnaire/Survey
- Gene therapy Surgery Focus group
- Cognitive/Behavioural therapy Medical Device Interview
- Other (specify):

3. Does this study require any drugs? Yes No
 If yes, list all drugs identified in the protocol

Investigational	Generic	Brand	Manufacturer	Dose	Freq	Route	Duration
<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

8. Safety and Monitoring

- All studies must be monitored to ensure participant safety and confidentiality, and to ensure the integrity of data collection and analysis

1. How will you monitor the conduct of this study (max 5 lines)?

Student's Supervisor will monitor the conduct of this study.

If this is a minimal risk Undergraduate/Master's study, the student's Supervisor should serve as monitor.

2. Does this study have a formal steering committee? Yes No

If yes, please explain: [REDACTED]

3. Will an interim data analysis be done? Yes No

If yes, please explain: [REDACTED]

4. Will you use a data safety monitoring board (DSMB)? Yes No

If yes, is it independent of the sponsor? Yes No

9. Risks and Benefits

1. What are the risks to participants in this study (e.g. pain, distress, privacy breach, social implication; max 5 lines)?
[redacted]
2. How will you minimize and manage the risks (max 5 lines)?
At the beginning of the interview, a participant will be noticed that they can stop the interview at any time or they can refuse to answer any questions also they can withdraw from the study at any point throughout the study. Their data will be destroyed.
3. Will participants receive any other benefits from participating in this study (e.g. continued access to new drug)? Yes No
If yes, please explain: [redacted]
4. Will participants be reimbursed for study related expenses (e.g. parking)? Yes No
If yes, please explain: [redacted]
5. Will participants receive any compensation (e.g. money for time)? Yes No
If yes, please explain: [redacted]
6. How will the scientific community and society benefit from this study (max 5 lines)?
DRF is one of the most common of all fractures. While many recover well, it has been estimated that 16% of Canadians with DRF will experience some degree of disability which contributes to the substantial economic burden. Understanding the facilitators and barriers to the implementation of the AAOS DRF treatment guidelines can address the issues regarding the implementation process on individual or organizational level.

10. Participants

1. Does this study focus on any of these vulnerable groups? Yes No
If yes, check all that apply:

People with cancer

Children

People with incurable disease

Elderly people

People in medical emergencies

Aboriginal people

People in long-term care

People in poverty

People with mental health issues

People in prison

People who are unable to consent

Other (specify):

2. Do you have any age, ethnicity, language, gender or race-related inclusion or exclusion criteria?
Yes No

If yes, please explain:

11. Recruitment

1. How do you plan to recruit participants?

- Investigators will approach their own patients/students
- Investigators will receive referrals from other Healthcare providers
- Decision support services (DSS) will prepare a list of potential participants. [DSS signature required \(for HHS\)](#)
- Advertising (e.g., poster, email, web-based). [Please submit a copy of all advertisements](#)
- Database of people who consented to future contact. Please explain:
- Direct approach (e.g. random digit dialing). Please explain:
- Educational records (e.g. information from Registrar). Please explain:
- Other (specify):

[Patients may not be approached by a researcher until someone in the patient's circle of care has asked the patient if they are interested in hearing about a study.](#)

2. Do you need to screen Personal Health Information (PHI) of patients to identify potential participants? Yes No

If yes, please describe your screening process (max 5 lines):

[Researchers must destroy all information collected during screening in a secure manner, as soon as screening is complete.](#)

3. Does your recruitment plan require you to contact potential participants by:

Telephone Yes No

Email Yes No

Letter Yes No

[If yes, please attach a copy of all telephone scripts and correspondence](#)

12. Consent

1. Will you be seeking written consent from participants (i.e. age 16+)? Yes No

If yes, please attach a [Consent form for Participants](#)

If no, please explain:

2. Will any participants be minors (i.e. age 0-15)? Yes No

If yes, please attach a [Consent form for Parents](#), and an [Assent form for children age 7-15](#).

3. Will all participants be competent to consent? Yes No

If no, please attach a [Consent form for Substitute Decision Makers](#)

4. Do you need to request a waiver of consent? Yes No

Please see [TCPS Section 2](#) for conditions under which consent can be altered or waived

If yes, please explain:

5. Who will obtain consent to participate?

The interviewer

6. When and where will this be done?

Prior to interview at the school of rehabilitation science.

7. Will any of the investigators have a position of authority or power over the participants? Yes No

If yes, how will you manage and minimize any undue influence?

8. How will you ensure continuing consent during the study?

Importance of compliance will be addressed through out the study.

9. Will participants have the option to withdraw from this study? Yes No

If yes, what do they have to do to withdraw?

13. Collection of Personal Information

Categories of information (TCPS2e)

- Identifying information identifies a participant through direct identifiers (e.g. Full name, Medical record number)
- Identifiable information could identify a participant through a combination of indirect identifiers (e.g. DOB plus address)
- De-identified/coded information: identifiers are removed and replaced with a code; the code can be used to re-identify participants
- Anonymized information: all identifiers are removed and no code is kept
- Anonymous information: no identifiers were collected

Personal Health Information (PHI)

- The collection, use and disclosure of PHI are regulated by the Personal Health Information Protection Act (PHIPA) 2004. Researchers must comply with this legislation
- Collection of participant SIN is prohibited, unless payments to participant exceed \$500/yr (required for tax purposes)
- PHI should be collected at the lowest level of identifiability possible (e.g. initials instead of a name, age instead of DOB)

1. Do you need to record any identifiers for this study? Yes No
If yes, check all that apply:

<u>PERSONAL IDENTIFIERS</u> <i>(check all that apply)</i>	Y	How will this item be stored?		Justify why each item is required
		<i>Paper</i>	<i>Electroni -cally</i>	
Full Name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Address	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Telephone Number	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Ontario Health Card Number	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Gender	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Initials	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Date of Birth (day/month/year)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Age or year of birth	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Full Postal Code	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
First 3 digits of Postal Code	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Email address	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Fax number	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Healthcare Provider	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Admission Date	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Discharge Date	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Service Date	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Medical Device Identifier	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Certificate/License number	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Vehicle Identification	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Medical Record Number	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Account Number	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Full face photograph	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
OTHER (specify):	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	only if they request interview by Skype
OTHER (specify):	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

2. How will you record study data?

Case report form. CRFs must not include direct identifiers. Please attach the first 2 data pages.

Other (specify):

PHIPA requirements

- Paper files with identifiable information must be kept in a locked cabinet within a locked office (but not at home)
- Electronic files with identifiable information may be stored on a password protected computer on a secure network (i.e., virus protection, file backup, firewall) or they must be encrypted.
- Electronic files with identifiable information may be stored on mobile devices (e.g. laptop, CD, USB, PDA), but only if there is no alternative method of storage; these files must be encrypted.
- Identifying and/or identifiable PHI cannot be transmitted by email unless it is encrypted

Coding

- Identifying and/or identifiable PHI should be protected by a coding system
- The code (study ID and identifiable PHI) must be isolated from study data and stored in a secure manner

1. Will you use a coding system to protect identifiable information? Yes No
 If No, please explain:

2. How will you store and protect the study code (or other data with identifiers)?

Type of record	Required protection	Location (i.e., bldg, room)
Paper file	<input checked="" type="checkbox"/> Locked cabinet in locked institutional office	<input type="text"/>
Electronic file	<input checked="" type="checkbox"/> Password protected computer on a secure network	<input type="text"/>
Electronic file	<input type="checkbox"/> Encrypted (specify software used): <input type="text"/>	
AV tapes	<input checked="" type="checkbox"/> Locked cabinet in locked institutional office	<input type="text"/>

3. How will you store and protect data without identifiers?
 Transcript will have only numbers and no personal informations will be stored.

4. Do you plan to anonymize the study data? Yes No
 If yes, when?

You are required to destroy identifiers or links at the earliest possible time.

5. How long will you keep the study data?
Until the study completed

If this study requires Health Canada approval, records must be retained for 25 years. For all other studies the REB recommends 10 years. Sponsors and institutions may set other requirements.

6. What will you do with the study data after this period?
Data will be destroyed.

15. Transmission of Data

1. Does this study require you to send data outside of the institution where it is collected? Yes No

No

If No, go to section 16

2. Does this data include identifiers? Yes No

If No, go to section 16

If yes, a data transfer agreement is necessary (contact your institutional Agreements/Contracts official in the Research Administration office for details)

3. Where will the data be sent?

█

Data sent to the US is open to access by US Regulatory Bodies. Researchers must inform study participants of this possibility.

4. Please list the names and affiliations of persons outside of your research team who will have access to the identifiable data.

Name	Institutional affiliation
█	█
█	█
█	█

5. How will the data be transmitted?

Fax

Email Encryption protocol must be attached

Private Courier Delivery must be traceable

Canada Xpresspost Regular mail may not be used

Other (specify): █

1. Will you link the locally collected data with any other data sets? Yes No

If yes:

Identify the dataset: [redacted]

Explain how the linkage will occur: [redacted]

Provide a list of data items contained in the dataset: [redacted]

2. Will the data be entered into a database for future use? Yes No

If yes, please specify:

Where it will be stored? [redacted]

Who will be the custodian? [redacted]

Who will have access to the database? [redacted]

What security measures will be in place? [redacted]

[Any secondary analysis must be approved by the REB.](#)

17. Funding

1. Does this study require any financial or in-kind support? Yes No

If No, go to section 18.

If yes, please identify the sources (include all internal, external, public or private sources)

Funding Source	Sponsor funding reference no. <i>(For funding from a granting agency, enter the award number; for funding from a commercial sponsor, enter the study protocol number.)</i>	Status	Local Budget	Total Budget
[Redacted]	[Redacted]	<input type="checkbox"/> Applied <input type="checkbox"/> Pending <input type="checkbox"/> Received <input type="checkbox"/> In-kind specify): [Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	<input type="checkbox"/> Applied <input type="checkbox"/> Pending <input type="checkbox"/> Received <input type="checkbox"/> In-kind specify): [Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	<input type="checkbox"/> Applied <input type="checkbox"/> Pending <input type="checkbox"/> Received <input type="checkbox"/> In-kind specify): [Redacted]	[Redacted]	[Redacted]

2. Where will the funds be administered?

SJHH HHS McMaster Faculty of Health Sciences Other (specify):

[Redacted]

Did the research proposal for this funded project originally include human participants (or use of their biological material and/or access to their records)? Yes No

If 'No' and you did not need ethics approval for your research at the time the funding was originally awarded, inform the appropriate research administration office above about this emerging ethics requirement, and once you have received final ethics approval, advise them of the HIREB file number (e.g. 13-021) assigned to your study.

3. Will there be a signed contract/agreement with a study-related funding source? Yes No
 If yes, will it limit your access to the research data, or your right to publish the study results? Yes No

If yes, please explain:

[Agreements must be reviewed and signed by authorized institutional officials](#)

4. For industry sponsored studies, the HIREB Office will generate an invoice for the \$3000 review fee; the invoice will be e-mailed to the Sponsor immediately following the monthly HIREB meeting. Please note that payment will be 'due on receipt' and final approval of the study may be contingent on payment of this invoice. Please provide Sponsor contact information for billing of HIREB review fee; if not the Sponsor, please provide the contact information as outlined in the contract/agreement:

Salutation: <input type="text"/>		First Name:: <input type="text"/>	Last Name: <input type="text"/>	
Company: <input type="text"/>			Address1: <input type="text"/>	
Address2: <input type="text"/>		City: <input type="text"/>	Province/State: <input type="text"/>	PC: <input type="text"/>
Country:: <input type="text"/>	Phone: <input type="text"/>	Fax: <input type="text"/>	Email: <input type="text"/>	
	Ext.: <input type="text"/>			

18. Conflict of Interest

1. Will any investigators, members of the research team, and/or their partners or immediate family members:

- Function as an advisor, employee, officer, director or consultant for a study-related sponsor or funding source? Yes No
- Have a direct or indirect financial interest (including patents or stocks) in the drug, device or technology employed in this research study? Yes No
- Receive any personal benefit (apart from fees for service) as a result of, or connected to this study? (e.g., remuneration, intellectual property rights, rights of employment, consultancies, board membership, share ownership, stock options, honorariums). Yes No

2. If you answered yes to any of the above, please describe the conflict of interest:

Please explain how you will manage the COI to ensure that participant rights and welfare are not affected:

19. Budget

Services	A (Unit cost)	B (# per participant)	C (# of participants)	(AxBxC) = Subtotal
<input type="checkbox"/> X-ray	█	█	█	█
<input type="checkbox"/> Ultrasound	█	█	█	█
<input type="checkbox"/> Bone Scan	█	█	█	█
<input type="checkbox"/> CT Scan	█	█	█	█
<input type="checkbox"/> MRI/PET	█	█	█	█
<input type="checkbox"/> ECG	█	█	█	█
<input type="checkbox"/> Endoscopy	█	█	█	█
<input type="checkbox"/> Labs	█	█	█	█
<input type="checkbox"/> Pharmacy (e.g. drugs, fees)	█	█	█	█
<input type="checkbox"/> Other (specify): █	█	█	█	█
Personnel (for this section only, if personnel costs cannot be calculated on a per participant basis, please enter the total cost in the Subtotal column.)				
<input type="checkbox"/> Investigator (e.g. history, physical)	█	█	█	█
<input type="checkbox"/> Nurse/coordinator	█	█	█	█
<input type="checkbox"/> Other staff (specify): █	█	█	█	█
Participants				
<input checked="" type="checkbox"/> Reimbursement (e.g. parking)	█	1hour max	40	320
<input type="checkbox"/> Payment (e.g. money for time)	█	█	█	█
Equipment (specify): █				
Administration (specify): █				
Other (specify): █				
Industry Studies (add 30% overhead)				
Industry Studies (add \$3000 REB fee)				
Total				320

- Please check all services required in your study and enter amounts where possible
- If you have a detailed study budget, please include it as a supporting document
- If you report your budget as cost per participant, please provide a list of services/costs per participant
- Payments to investigators should not exceed accepted standards (e.g., OHIP)
- Investigators may not accept any payments for enrolling participants

Note: for studies being conducted at McMaster University or one of the Hamilton Health Sciences sites, complete Sections 20 and 21 below on pages 17 and 18; for studies being conducted at St. Joseph's Healthcare Hamilton, complete Sections 20, 21, 22 and 23 on pages 19-22. If you are applying for approval to conduct the study at both McMaster/HHS and SJHH, you will need to complete the Resource Authorization sections for both hospitals.

20. Resource Authorization – HHS/FHS

1. Does your study require resources from any of these areas? Yes No

If yes, please obtain the necessary approvals

Area	Name of Authorized Official	Signature
<input type="checkbox"/> Decision Support	[Redacted]	
<input type="checkbox"/> Health Records	[Redacted]	
<input type="checkbox"/> HHS Chief Privacy Officer	[Redacted]	
<input type="checkbox"/> Laboratory Services	[Redacted]	
<input type="checkbox"/> Pharmacy	[Redacted]	
<input type="checkbox"/> Radiology/Diagnostic Imaging	[Redacted]	
<input type="checkbox"/> Nuclear Medicine	[Redacted]	
<input type="checkbox"/> Radiation Safety	[Redacted]	
<input type="checkbox"/> EMROC (Emergency Med Research)	[Redacted]	
<input type="checkbox"/> PEMROC (Pediatric Emergency Med Research)	[Redacted]	
<input type="checkbox"/> Information Technology	[Redacted]	
<input type="checkbox"/> Centre for Simulation Based Learning	[Redacted]	
<input type="checkbox"/> Critical Care ICU	[Redacted]	
<input type="checkbox"/> Infectious agents	[Redacted]	
<input type="checkbox"/> Biosafety hazards	[Redacted]	
<input type="checkbox"/> Medical directives	[Redacted]	
<input type="checkbox"/> Other (specify):	[Redacted]	

2. Does your research involve patients at HHS? Yes No
 If yes, please obtain approvals from nursing and clinical care in each area

Inpatient area	Name of Authorized Official	Signature
Outpatient area	Name of Authorized Official	Signature

3. Does your research involve University students as participants? Yes No
 If yes, please obtain approvals from Dept/Program where students will be recruited as this research could affect teaching/in-class time.

Dept/Program	Name of Authorized Official	Signature

1. **Confirmation of Responsibility:** Local Principal Investigator

- I assume full responsibility for the scientific and ethical conduct of the study as described in this REB application and submitted protocol.
- I agree to conduct this study in compliance with the Tri-Council Policy Statement (TCPS) and any other relevant regulations and guidelines.
- I certify that all researchers and other personnel involved in this project at this institution are appropriately qualified and experienced or will undergo appropriate training to fulfill their role in this project.
- I certify that any and all conflicts of interest have been declared
- I have obtained all necessary resource utilization signatures, and all costs associated with the use of these resources have been declared.
- On behalf of my research team, I recognize the importance of maintaining the confidentiality of all personal information, including personal health information, and the privacy of individuals with respect to that information. I will ensure that the personal information is used only as necessary, to fulfill the specific research objectives and related research questions described in this application and approved by the REB. This includes all conditions and restrictions imposed by the REB governing the use, security, disclosure, return or disposal of the research participants’ personal information. I agree to take any further steps required by the REB and/or the institution to ensure that the confidentiality and security of the personal information is maintained in accordance with the Personal Health Information Protection Act (PHIPA), its accompanying regulations and the TCPS.

██████████

Name of LPI	Signature	Date (m/d/y)
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██████████

Name of PI (if different from LPI)	Signature	Date (m/d/y)
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██████████

Name of Supervisor (if PI is an Undergrad/Masters student)	Signature	Date (m/d/y)
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2. **Confirmation of Resources:** Clinical Director (or) Manager (or) Chair (or) Vice President
Please obtain the signature of the person who is responsible for the Department, School or Programme where this study is being done.

- I have reviewed this study and considered any research which is planned or already in progress
- I confirm that the necessary resources are available

Sarah Bouma, Director of Administration, School
of Rehabilitation Sciences

Name & title	Signature	Date (m/d/y)
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3. **Confirmation of LPI Qualifications:** Chief (or) Chair of Department
For the Schools of Nursing and Rehab Science the designated Research representative may sign on behalf of the Chair.

- I confirm that the LPI has the credentials and expertise to conduct this research
- I confirm that the LPI is a member in good standing at HHS and/or McMaster University

[Redacted Name & Title]
[Redacted Signature]

Name & title	Signature	Date (m/d/y)
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4. Does your study require resources from any of these areas? Yes No
 If yes, please obtain the necessary approvals

Area	Name of Authorized Official	Signature
<input type="checkbox"/> Health Information Services	██████████	
<input type="checkbox"/> Chief Privacy Officer	██████████	
<input type="checkbox"/> Laboratory Services	██████████	
<input type="checkbox"/> Pharmacy	██████████	
<input type="checkbox"/> Radiology/Diagnostic Imaging	██████████	
<input type="checkbox"/> Nuclear Medicine	██████████	
<input type="checkbox"/> Radiation Safety	██████████	
<input type="checkbox"/> Imaging Research Centre	████████████████████ ██████	
<input type="checkbox"/> Information Technology	██████████	
<input type="checkbox"/> Infectious agents	██████████	
<input type="checkbox"/> Biosafety hazards	██████	
<input type="checkbox"/> Medical directives	██████████	
<input type="checkbox"/> Other (specify): ██████	██████	

5. Does your research involve patients at SJHH? Yes No
 If yes, please obtain approvals from nursing and clinical care in each area

Inpatient area	Name of Authorized Official	Signature
[Redacted]	[Redacted]	
[Redacted]	[Redacted]	
[Redacted]	[Redacted]	
[Redacted]	[Redacted]	
[Redacted]	[Redacted]	
[Redacted]	[Redacted]	
Outpatient area		
[Redacted]	[Redacted]	
[Redacted]	[Redacted]	
[Redacted]	[Redacted]	
[Redacted]	[Redacted]	
[Redacted]	[Redacted]	
[Redacted]	[Redacted]	

21. Confirmation of Responsibility (LPI) - SJHH

- I assume full responsibility for the scientific and ethical conduct of the study as described in this REB application and submitted protocol.
- I agree to conduct this study in compliance with the Tri-Council Policy Statement (TCPS) and any other relevant regulations and guidelines.
- I certify that all researchers and other personnel involved in this project at this institution are appropriately qualified and experienced or will undergo appropriate training to fulfill their role in this project.
- I certify that any and all conflicts of interest have been declared
- I have obtained all necessary resource utilization signatures, and all costs associated with the use of these resources have been declared.
- On behalf of my research team, I recognize the importance of maintaining the confidentiality of all personal information, including personal health information, and the privacy of individuals with respect to that information. I will ensure that the personal information is used only as necessary, to fulfill the specific research objectives and related research questions described in this application and approved by the REB. This includes all conditions and restrictions imposed by the REB governing the use, security, disclosure, return or disposal of the research participants' personal information. I agree to take any further steps required by the REB and/or the institution to ensure that the confidentiality and security of the personal information is maintained in accordance with the Personal Health Information Protection Act (PHIPA), its accompanying regulations and the TCPS.

Name of LPI	Signature	Date (m/d/y)
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Name of PI (if different from LPI)	Signature	Date (m/d/y)
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22. Confirmation of Qualifications - SJHH

- Please obtain the appropriate signature to confirm that the LPI is qualified to conduct the study

Chief of Department

If the LPI is a member of the Medical, Dental, Midwifery and Special Professional staff, please obtain this signature:

- I have reviewed this protocol
- I confirm that the LPI is a member in good standing of the medical staff of SJHH
- I confirm that s/he has the credentials/expertise to conduct the research being proposed in this application

Name & title	Signature	Date (m/d/y)
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(or)

Professional Practice Leader

If the LPI is a member of an allied health profession, please obtain this signature:

- I have reviewed this protocol.
- I confirm that the LPI is a member in good standing of the discipline of _____ SJHH
- I confirm that s/he has the credentials/expertise to conduct the research being proposed in this application.

Name &title	Signature	Date (m/d/y)
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23. Confirmation of Resources - SJHH

- Please obtain the appropriate signature for each clinical department, program or service involved in this study.

Director, Clinical Services

If a program, clinic or service (e.g. Emergency, CTU, OPD) reports to a Director, Clinical Services, please obtain this signature:

(Hamilton Regional Laboratory Medicine Program only requires the signature of the Chief of Laboratory Medicine)

- I have reviewed the attached protocol
- I confirm that the Department/Program of [redacted] has the resources needed to conduct this study (e.g. space, funding, patient population)
- I have taken into consideration any research which is planned or already in progress in the Department/Program

[redacted]

Name & title	Signature	Date (m/d/y)
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(or)

Vice President (and) Director/Manager

If a diagnostic/therapeutic service (e.g. Pharmacy, Social Work) and/or institute/centre (e.g. CMAS, CEM) reports directly to a Vice-President, please obtain these two signatures:

- I have reviewed the attached protocol
- I confirm that the Service/Institute/Centre of [redacted] has the resources needed to conduct this study (e.g. space, funding, patient population)
- I have taken into consideration any research which is planned or already in progress in the Department/Program

[redacted]

Name (Vice President)	Signature	Date (m/d/y)
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[redacted]

Name (Director/Manager)	Signature	Date (m/d/y)
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24. Supporting Documents

- Please assign (or report) a version date for all supporting documents (this is how the REB tracks changes)

Document	Version date (m/d/y)	Comments
<input checked="" type="checkbox"/> Protocol (Required)		
Consent forms		
<input checked="" type="checkbox"/> Participant		
<input type="checkbox"/> Parent		
<input type="checkbox"/> Assent		
<input type="checkbox"/> Genetic		
<input type="checkbox"/> Other		
Clinical trial documents		
<input type="checkbox"/> Investigator brochure		
<input type="checkbox"/> Product monograph		
<input type="checkbox"/> Health Canada NOL	Date:	Control Number:
General documents		
<input type="checkbox"/> REB correspondence		
<input type="checkbox"/> Advertisement		
<input type="checkbox"/> Telephone script		
<input type="checkbox"/> Sample email		
<input checked="" type="checkbox"/> Interview guide		
<input checked="" type="checkbox"/> Questionnaire		
<input type="checkbox"/> Case report form		
Training documents		
<input type="checkbox"/> CITI GCP training	Date:	Certificate Number:
<input type="checkbox"/> Other GCP training (append program outline)	Date:	Certificate Number:
<input checked="" type="checkbox"/> TCPS2 CORE Certificate	Date:	
Other (specify)		

CURRICULAM VITA

Name: Saravanan Esakki
Post Secondary Education: Bachelor of Science: Physiotherapy
Degrees: 1997-2003, BPT
The Tamil Nadu Dr. M.G.R. Medical University 2004
Chennai, TN, India

Related Work: Teaching Assistant

London, ON

Western University/ Jan 2014 to June 2020

- Reviewing MSc OT/PT student's assignment, marking, and documenting.
- Helped with Invigilating.

Teaching Assistant

Hamilton, ON

McMaster University/ Jan 2013 to Sep 2013

- Reviewing MSc OT/PT student's assignment, marking, and documenting.
- Helped with Invigilating.

Publications:

Saravanan Esakki, PT¹, Joy C. MacDermid, PT, PhD² . Saipriya Vajravelu PT, MSC, PhD³.

"Linking

of the American Academy of Orthopedic Surgeons Distal Radius Fracture Clinical Practice Guidelines to the International Classification of Functioning Disability and Health (ICF) and ICF Core Sets for Hand Conditions".

Status: Published. - "Hand" Journal

Saravanan Esakki, PT¹, Joy C. MacDermid, PT, PhD² . Joshua I. Vincent³, Tara L. Packham³,

Dave Walton³, Ruby Grewal³, "*Rasch analysis of the Patient-Rated Wrist Evaluation questionnaire*".

Status: Published. - Archives of Physiotherapy.

Saravanan Esakki, PT¹, Joy C. MacDermid, PT, PhD². "*Appraisal of: Role of physical therapists in the management of individuals at risk for or diagnosed with venous thromboembolism: Evidence-based clinical practice guideline*"

Status: Published. - Journal of physiotherapy

Saravanan Esakki, PT¹, Joy C. MacDermid, PT, PhD². "*Appraisal of: Management of neck pain and associated disorders: A clinical practice guideline from the Ontario Protocol for Traffic Injury Management (OPTIMA) Collaboration*"

Status: Published. - Journal of physiotherapy

Saipriya Vajravelu MSc, PT¹, Patricia Solomon PT, PhD², Joy C. MacDermid, PT, PhD²,

Saravanan Esakki³, Rahul Mota³, Fatmah Hasani³. "*Measuring Health Related Quality Of Life (HRQOL) in HIV positive individuals - content analyses of measures based on the International Classification of Functioning, Disability*"

Status: Published. - Critical Reviews in Physical and Rehabilitation Medicine.

Conference Poster Presentation:

Saravanan Esakki, Joy C. MacDermid, Saipriya Vajravelu. (May 22 & 23, 2015) "Linking of the American Academy of Orthopedic Surgeons Distal Radius Fracture Clinical Practice Guidelines to the International Classification of Functioning Disability and Health (ICF) and ICF Core Sets for Hand Conditions". CSHT Annual Meeting in Montreal, Quebec.

Saravanan Esakki, Joy C. MacDermid, Saipriya Vajravelu. (May 5-7 2015) "Linking of the American Academy of Orthopedic Surgeons Distal Radius Fracture Clinical Practice Guidelines to the International Classification of Functioning Disability and Health (ICF) and ICF Core Sets for Hand Conditions". McMaster University Faculty of Health Sciences Research (FHS) Plenary. (*Awarded Excellence in Poster Presentation Award*)

Saravanan Esakki, Joy C. MacDermid., Saipriya Vajravelu. (January 15, 2015) "Linking of the American Academy of Orthopedic Surgeons Distal Radius Fracture Clinical Practice Guidelines to the International Classification of Functioning Disability and Health (ICF) and ICF Core Sets for Hand Conditions". McMaster University School of Rehabilitation Science, Student Poster Presentation

Saravanan Esakki, Joy C. MacDermid, Saipriya Vajravelu. (October 22, 2015) (*Accepted*) "Linking of the American Academy of Orthopedic Surgeons Distal Radius Fracture Clinical Practice Guidelines to the International Classification of Functioning Disability and Health (ICF) and ICF Core Sets for Hand Conditions". ISOQOL 22nd Annual Conference in Vancouver, BC, Canada.

