DISSERTATION

DEVELOPMENT, VALIDATION, AND IMPLEMENTATION STRATEGIES FOR THE <u>EX</u>ERCISE IN <u>CANCER EVALUATION AND DECISION SUPPORT</u> (EXCEEDS) ALGORITHM

Submitted by

Kelley R. Covington

Department of Occupational Therapy

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Doctoral Committee:

Advisor: Anita Bundy Co-Advisor: Mackenzi Pergolotti

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ABSTRACT

DEVELOPMENT, VALIDATION, AND IMPLEMENTATION STRATEGIES FOR THE <u>EX</u>ERCISE IN <u>CANCER EVALUATION AND DECISION SUPPORT</u> (EXCEEDS) ALGORITHM

Background: Clinical practice guidelines recommend referral to cancer rehabilitation or exercise services (CRES) to optimize survivorship. Yet, ability to connect the *right survivor* with the *right* CRES at the *right time* is an ongoing challenge and barrier to utilization of these services.

Objective: I aimed to develop a CRES decision support algorithm and used Delphi methodology to systematically: (1) evaluate the algorithm's acceptability and utility; and (2) establish consensus for implementation priorities including key stakeholders, platforms and strategies.

Method: I performed a literature review and synthesis, then convened a multidisciplinary expert stakeholder group to participate in algorithm development. We worked iteratively and collaboratively until consensus was reached for content and format of the Exercise in Cancer Evaluation and Decision Support (EXCEEDS) algorithm and conceptual model. Then I recruited international clinical and research experts to participate in the two-part (three survey) online modified Delphi study. In Part 1, participants completed one survey including: (1) CRES recommendations for two randomized case studies in two conditions (using EXCEEDS vs. without EXCEEDS); (2) the Acceptability of Implementation Measure (AIM); and (3) open-ended feedback on the algorithm. Following this survey, I compared decision efficiency (accuracy and duration) between conditions (EXCEEDS vs. independently) for each case study using frequencies (*hypothesis* \geq 75% accurate) and paired samples *t*-test (*p* <.05), then calculated consensus for each AIM domain ("meets approval", "is appealing", "welcome in my field/practice"; *hypothesis* \geq 70% agreement) and overall score (*hypothesized mean* \geq 4.0). These results were reported to participants in Part 2. I also performed inductive thematic analysis of open-ended feedback. In Part 2 of the Delphi study, participants completed a series of two surveys including ranking the following items using curated lists: (1) stakeholder group (1 -most likely to 7- least likely to benefit), (2) platform (1 most likely to 6- least likely to be beneficial) and, implementation strategies (1 - most important to 15least important for successful implementation). I performed preliminary analysis of each ranking using measures of central tendency (median and IQR), then calculated the proportion of participants who ranked each option as a high priority. Ten implementation strategies were ranked as high priority and returned to participants for the final survey where they rated each strategy in terms of *effort* associated with using the strategy (1 - low effort to 4 - high effort) and potential *impact* of the strategy on successful implementation of the EXCEEDS algorithm (1 - low impact to 4 - high impact). Following the Eisenhower Urgent-Important Matrix Method, I plotted the effort/impact scores in four quadrants representing effort and impact for each strategy to determine implementation priorities. Results: The final EXCEEDS algorithm combines biomedical and individual characteristics associated with need for supervised skilled CRES into 11 risk-stratified dichotomous (yes/no) questions, organized into two sections: (1) pre-exercise medical clearance recommendation, and (2) CRES triage recommendation. Delphi study participants (N=133) represented all CRES stakeholder groups (oncology, physical medicine and rehabilitation, exercise science, etc.). Loss to follow up between surveys ranged 28% (survey 3) to 43% (survey 2). When using the EXCEEDS algorithm, decision accuracy improved in six (of eight) conditions (75%) and duration improved in all conditions (N=4, p < .05). Consensus was achieved in three AIM domains (75%); overall AIM score was $M=3.90 \pm 0.473$ (range = 1.0 - 5.0). Qualitative themes from participant feedback include: (1) algorithm strengths (n = 123, 40.9%), (2) implementation considerations (n=93, 30.5%), and (3) areas for revision (n=87, 28.5%). Oncology clinicians and administrators were the highest-ranked stakeholder group (Median=2.0, IQR=1.0 - 3.75, 75.0% agreement) and the only one to achieve consensus. Open-access internet was the highest-ranked implementation platform (*Median* = 2.0, IQR= 1.0 - 3.5, 72.4% agreement) and the only one to achieve consensus. Consensus was achieved for eight of the ten highest-ranked implementation strategies (80%, inter-rater agreement range = 93.4% - 71.1%). Two strategies were categorized as urgent/important:

"develop educational materials" and "remind clinicians". Seven strategies were categorized important/not urgent. One strategy, "model and simulate change", was categorized as not important/not urgent. Conclusion: The EXCEEDS algorithm is an acceptable and efficient evidence-based solution to identify and connect the *right survivor*, with the *right* CRES, at the *right time*. Thus, implementation of the EXCEEDS algorithm guided by the consensus-based priorities identified in the Delphi study has the potential to improve CRES coordination and utilization. Future hybrid studies will be used to determine prospective efficacy and best practices for implementation.

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DEDICATION

To the survivors who taught me the "occupational power of exercise" and said, "I wish I would have known about this (CRES) sooner".

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Chapter 1: Introduction

More than 16.9 million individuals in the United States are living with or beyond cancer (i.e., cancer survivors) (American Cancer Society, 2021). It is estimated an additional 1.9 million new cases will be diagnosed in 2021 (American Cancer Society, 2021). With advances in detection and treatment, cancer death rates have decreased markedly since peaking in 1991 (Siegel et al., 2021). For all cancers, the latest data show an average 5-year relative survival rate of 67% with specific cancer types ranging 98% (prostate) to 10% (pancreas) (Siegel et al., 2021). As a result, a paradigm shift is underway in oncology care and research with focused efforts to optimize cancer survivorship (i.e., time from diagnosis until end of life) for this growing population (Institute of Medicine & National Research Council, 2006; Levit et al., 2013; Stuver et al., 2020).

For cancer survivors, the deleterious effects of cancer treatment on health and functioning can be acute, late and/or lasting, and often negatively impact quality of life, ability to participate in important activities and life roles. Up to 10 or more years following treatment completion, researchers show high prevalence of treatment effects in survivors of the most common cancer types (i.e., breast, gynecological, prostate, and colon/rectal), including depression/anxiety, difficulty sleeping, fatigue, pain, and limited physical, cognitive and sexual functioning (Harrington et al., 2010).

Regardless of pre-cancer exercise history, systematic reviews (Cormie et al., 2017; Patel et al., 2019) and meta-analyses (Li et al., 2016; Morishita et al., 2020) show individuals who achieve the recommended 90-150 minutes of exercise (during and/or following cancer treatment) have significantly lower risk of functional decline, morbidity, cancer recurrence and mortality. Cancer-specific evidence-based exercise guidelines, led by the American College of Sports Medicine (ACSM), were published in 2019 and endorsed by 14 international multidisciplinary organizations, including the World Health Organization (WHO) (Campbell et al., 2019). The guidelines include exercise prescription recommendations for common cancer treatment effects and recommend survivors "avoid inactivity" and work up to the exercise guidelines of 90-150 minutes of moderate intensity aerobic exercise per week

(Campbell et al., 2019). However, up to 90% of survivors are insufficiently active to receive these health benefits (Avancini et al., 2020). Thus, participation in cancer rehabilitation or exercise services (referred to here on as CRES) may be key to proactively addressing survivors' functional needs, promoting habitual physical activity, and optimizing length and quality of survivorship (Alfano & Pergolotti, 2018; Cheville et al., 2017; Covington et al., 2019; Schmitz et al., 2020; Turner et al., 2018).

Cancer Rehabilitation and Exercise Services (CRES)

In the United States, CRES exist in diverse forms. Using a stepped care framework, CRES levels include outpatient cancer rehabilitation; clinically supervised exercise; supervised, cancer-specific community-based exercise; and generic or unsupervised community-based exercise (Alfano et al., 2016; Cheville et al., 2017). In the stepped care framework, each step/level down indicates progressively lower risk of exercise-related adverse events and lower need for specialized care. See Figure 1.1 for an overview of each level of care and a depiction of the continuum of relative risk/need as described by the stepped care model (Alfano et al., 2016).

Growing research evidence (Covington et al., 2019; Hunter et al., 2017a, 2017b; Piscione et al., 2017; Scott et al., 2013) supports the benefits of each level of CRES on key patient outcomes including physical activity level, physical, mental and social functioning. Specifically, systematic reviews (Brayall et al., 2018; Hunter et al., 2017a, 2017b; Scott et al., 2013; Spence et al., 2010) demonstrate the benefits of cancer rehabilitation services (including PT and OT) for a variety of cancer-related impairments (e.g., neuropathy, pain, myopathy, lymphedema) and mental, physical, cognitive and sexual functioning. Participation in clinically supervised exercise has been associated with improved patient outcomes including increased muscular strength, endurance, physical functioning, and aerobic capacity and decreased anxiety/depression and fatigue (Beidas et al., 2014; Kirkham et al., 2016; H. J. Leach et al., 2018; Marker et al., 2018; Santa Mina et al., 2019).

Level of care	Supervision characteristics	Patient characteristics	Relative risk/need
Outpatient cancer rehabilitation	 Supervisor(s): Occupational therapists (OT), Physical therapists (PT), Physiatrists, Speech and language pathologists (SLP), or rehabilitation nurses. Setting: Medically-based facility or community-based clinic 	 Preparing for surgery or other treatment (i.e., prehabilitation) Function-related impairment (physical, mental, social, sexual, etc.) Difficulty managing cancer-related sequela that interfere with activities of daily living (following medical management) – for example: fatigue, pain, neuropathy, etc. High risk for exercise-related adverse event Medically complex or frail ^a Transitioning from inpatient care to the community ^a 	HIGH Risk of adverse event
Clinically supervised exercise	 Supervisor(s): Master's-level exercise physiologist/kinesiologist with relevant cancer-specific certifications and training, Rehabilitation therapist (OT/PT/SLP), ^b rehabilitation nurse, ^b or other advanced care clinician affiliated with medical center or university.^b Setting: Medically-based facility or outpatient clinics (like rehabilitation) 	 Difficulty managing cancer-related sequela that do not interfere with activities of daily living (following medical management) – for example: fatigue, pain, neuropathy, etc. Difficulty managing cancer-related sequela that interfere with activities of daily living and no access to rehabilitation due to insurance or other factors Moderate-high risk for exercise-related adverse event Preparing for upcoming high-risk treatment (e.g., major surgery, transplant, chemotherapy, etc.)^a Medically complex or frail^a Transitioning from inpatient care to the community^a 	
Cancer-specific community- based exercise	 Supervisor(s): Exercise professional(s) with a Bachelor's-level degree in exercise physiology/kinesiology (or related field), relevant exercise certification(s) (e.g., exercise physiologist or personal trainer), and cancer-specific certification or training Setting: Variety of community settings, including fitness/wellness center, municipal building, university- based clinic or gym, worksite, and outdoor locations 	 Low-moderate risk for an exercise-related adverse event Do not have a functional impairment that precludes activities of daily living May have functional limitations(not impairments) that restrict full participation in exercise or life roles Low-moderate exercise self-efficacy Preparing for upcoming high-risk treatment (e.g., major surgery, transplant, chemotherapy, etc.)^a Transitioning from inpatient care to the community^a 	cialized, stepped care
Generic or unsupervised community- based exercise	 Supervisor: None (self-directed), or Exercise professional without relevant certification or training Setting: Community-based settings as described above 	 Low risk for an exercise-related adverse event No functional impairments or Low-moderate exercise self-efficacy Transitioning from inpatient care to the community^a 	Need for Spe

Figure 1.1

Overview of each level of stepped care and corresponding level of risk for exercise-related adverse event and need for specialized care

Existing reviews of cancer-specific community-based exercise programs (Covington et al., 2019; Musanti & Murley, 2016) conclude that while more research is needed, in general, these services are safe and effective to improve quality of life and physical function (Swartz et al., 2017). While unsupervised, home-based exercise is often preferred by survivors (Karvinen et al., 2007; Nicole Culos-Reed et al., 2017; Rogers et al., 2009; Trinh et al., 2012), research has demonstrated only mixed effects of unsupervised exercise on function, cancer-specific outcomes, and quality of life (Cheng et al., 2017; Schmitz, Troxel, et al., 2019; Swartz et al., 2017).

A Common Language to Enhance Understanding and Decision Making for CRES

More than 60 different oncology clinical practice guidelines recommend participation in CRES to optimize functioning and well-being of cancer survivors (Stout et al., 2020). However, these recommendations lack the specificity and consistency needed to align with the levels of stepped care described in Figure 1.1. For example, many National Comprehensive Cancer Network (NCCN) and American Society of Clinical Oncology (ASCO) guidelines specify the need for "qualified exercise supervision and intervention" but do not specify that a rehabilitation clinician is required, or which rehabilitation discipline is most appropriate. Medical status, function, and patient goals vary widely between and within individuals throughout the cancer continuum but play an important role in the safest/most efficacious CRES and the best qualified person to supervise or provide care (Coletta et al., 2020). For example, researchers indicate survivors with functional impairment or high risk for exercise-related adverse events should be supervised by a cancer rehabilitation specialist with communication to the oncology care team (Maltser et al., 2017). Thus, connecting patients to CRES is a multi-component and time-consuming process involving understanding of the most effective, safe, and feasible intervention for a given patient, facilitating a referral, and empowering patients to participate.

Lack of shared understanding of patient needs across levels of care is a major barrier to care coordination. The International Classification of Functioning, Disability and Health Framework (ICF) has been recommended (but not widely adopted) to guide rehabilitation care assessment and delivery in oncology care (Alfano & Pergolotti, 2018; Campbell et al., 2012; Cheville et al., 2017; Gilchrist et al.,

2009; Stout et al., 2012; Weis & Giesler, 2018). First created by the World Health Organization in 2001 (*International Classification of Functioning, Disability and Health: ICF*, 2001), the ICF (Figure 1.2) provides a common language for clinicians and researchers to understand the multifactorial and transactional influence of a health condition on an individual. Thus, the ICF is a practical framework to understand cross-discipline and support initiatives to enhance interpersonal, patient-centered communication about care needs. I chose the ICF as a guiding conceptual framework to foster multidisciplinary shared understanding by accounting for the myriad medical, personal, behavioral, and environmental factors that can influence exercise safety and stepped care need for cancer survivors. I believe multidisciplinary shared understanding facilitated by the biopsychosocial perspective of the ICF is critical to improve care coordination for CRES.

Health Condition



(disorder or disease)

Figure 1.2

The International Classification of Functioning, Disability and Health Framework (ICF). Reproduced from (*International Classification of Functioning, Disability and Health: ICF,* 2001)

Statement of the problem

CRES can attenuate declines associated with cancer treatment and enhance patient functioning and quality of life (Brayall et al., 2018; Covington et al., 2019; Hunter et al., 2017b). However, the right exercise environment is an important factor for participation in exercise and a common barrier due to lack of accessible information and individualized recommendations/referrals (Blaney et al., 2013; Cantwell et al., 2020; Fitzpatrick J., 2011; Hardcastle, Maxwell-Smith, et al., 2018; Midgley et al., 2018). As a result, CRES are vastly underutilized by survivors (Cheville et al., 2009; Pergolotti et al., 2015; Stubblefield, 2017).

Researchers show fewer than half of oncology clinicians discuss exercise with their patients due to lack of education or awareness of cancer exercise guidelines, perceived social norms (e.g., belief that exercise discussion is not part of oncologist role), and low confidence (Hardcastle, Kane, et al., 2018; Nadler et al., 2017). Furthermore, researchers show only 2-9% of survivors with identified functional decline are referred to CRES by an oncology clinician (Cheville et al., 2009; Pergolotti et al., 2015; Stubblefield, 2017). Widespread low rates of exercise participation during and following cancer treatment and oncology clinicians' awareness of the importance of exercise participation for their patients (Nadler et al., 2017) are evidence that survivors and clinicians have little practical understanding of the *meaning* of exercise during survivorship.

Up to 80% of oncology clinicians report little-to-no awareness of exercise guidelines for survivors or how to provide exercise advice (Nadler et al., 2017). Without guidance from a trusted clinician, the majority of survivors (30-93%) report uncertainty about exercise safety, and low confidence to overcome barriers including fatigue, access to local CRES, side effect management, and financial toxicity (Avancini et al., 2020; Awick et al., 2017; Ferri et al., 2020; Hardcastle, Maxwell-Smith, et al., 2018). Exercise promotion and care coordination are especially challenging because we rely on oncology clinicians to lead care coordination. To promote the care coordination and utilization of CRES, oncology clinical organizations (Alfano, Mayer, et al., 2019; Mayer & Alfano, 2019; Mohile et al., 2018) and research representatives from rehabilitation and exercise organizations (Schmitz, Campbell, et al., 2019;

Stout, Brown, et al., 2020) have called for the development and implementation of evidence-based, personalized, risk-stratified care pathways, including algorithms to guide multidisciplinary understanding and decision making (Alfano, Jefford, et al., 2019). Such pathways must be able to account for the medical, physical, functional, behavioral and environmental factors that influence a survivor's needs for exercise safety and specialized vs. non-specialized intervention, and be easily integrated into existing clinical workflows and clinical care pathways. Thus, an Occupation and Rehabilitation science perspective is needed to improve understanding of survivors' needs and the most appropriate rehabilitation or exercise program to meet those needs.

Personal Bias/Positionality

Development of the EXCEEDS algorithm is the culmination of my educational, clinical, research and professional experiences. My educational background in Health and Exercise Science, Occupation Science and Rehabilitation Science has prepared me with a breadth of knowledge in cancer exercise physiology, a unique perspective on exercise as a meaningful occupation, and a pragmatic research approach. As such, I believe exercise self-efficacy is a right of all individuals living with and beyond cancer (i.e., survivors), and that inability to support the exercise-related needs of cancer survivors is a form of occupational injustice leading to inequities in health and wellbeing (Stadnyk, 2007). In my clinical experiences as a certified Clinical Exercise Physiologist and Cancer Exercise Trainer, I have witnessed this phenomenon firsthand when coaching and counseling community-based survivors at various stages of treatment and survivorship. In this context, I have found that I can leverage the "occupational power" of exercise by helping survivors to understand exercise is a means and an end to improved health, functioning and quality of life. Likewise, in my research, I have sought to better understand the experiences of survivors who participate in CRES (H. J. Leach et al., 2018, 2019; Pergolotti, Covington, Lightner, et al., 2020; Pergolotti, Covington, Stubblefield, et al., 2020) and the lived experience of common cancer-related sequelae (e.g., falls, cancer-related cognitive decline, distress) that are barriers to participation in exercise and other meaningful activities (Covington, Atler, et al., 2021; Pergolotti, Bailliard, et al., 2020; Pergolotti, Battisti, et al., 2020). In addition, I have purposely sought out

experts in the fields of oncology and cancer rehabilitation to better understand expert perception of the same sequalae and impact on participation (Covington et al., 2020).

As the Research Manager for a national cancer-rehabilitation company, I have learned about and witnessed the many limitations of our current cancer care system that often preclude the integration of supportive care services. In this role, I use my unique skills to understand the needs of oncology and CRES providers across the country, and drive research efforts to develop innovative approaches to improve the implementation and coordination of evidence-based care for cancer survivors. From these experiences, I strongly believe that lack of common understanding and ability to communicate survivors' needs for CRES across disciplines (e.g., oncology to community CRES) are the crux of care coordination. In addition, I believe a pragmatic approach drawing from concepts in implementation science must be leveraged *a priori* to develop and study novel approaches to address barriers to CRES care coordination. Dissertation Objectives and Overview

To lessen care coordination barriers and support exercise promotion and referrals to CRES, I designed and completed a two-phase dissertation project. The overarching goals of this work are to develop and validate an algorithm that can serve as a common language/framework to understand need for CRES and, once implemented, serve as a pragmatic tool to guide CRES decision making. In phase 1, I synthesized existing literature and cancer exercise guidelines (described in Chapter 2) to (1) define each level of CRES, (2) conceive a conceptual model guided by the ICF, and (3) develop a risk stratified algorithm to guide personalized referrals and exercise promotion, called the <u>Exercise in Cancer</u> <u>Evaluation and Decision Support (EXCEEDS) Algorithm</u>. Phase 1 is described in Chapter 3 along with the resulting EXCEEDS algorithm.

For Phase 2, I conducted an online International Delphi study to accomplish two discrete aims: (1) validate the algorithm via expert consensus for utility and acceptability, and (2) determine expert consensus for implementation priorities (key stakeholders, platforms, and strategies). Accordingly, I report, the design and results of the Delphi study separately in Chapters 4 and 5. Finally in Chapter 6, I

summarize the key findings as they pertain to future initiatives to advance care coordination and relevance of the EXCEEDS algorithm to the fields of occupation and rehabilitation science.

Chapter 2: Literature review, Synthesis and Critique

To develop an evidence-based algorithm that will be acceptable and useful to support preexercise clearance and triage decision making for multidisciplinary stakeholders (e.g., oncology, rehabilitation or exercise clinicians, survivors), I conducted a literature review and critical synthesis of existing pre-exercise medical clearance and triage recommendations published in research literature and by leading research groups or clinical organizations and relevant to the CRES levels described in Chapter 1. I searched PubMed and MEDLINE databases for articles published in English using key phrases including "neoplasm" or "cancer;" "patient" or "survivor;" "exercise," "physical activity" or "rehabilitation;" "medical clearance," "risk," or "safety;" and "guidelines" or "perspectives;" "decision making," or "prescription." In addition, I searched the websites of leading oncology, rehabilitation and exercise clinical organizations including NCCN, ASCO, ACSM, American Occupational Therapy Association (AOTA) and the American Physical Therapy Association (APTA) for the latest clinical practice recommendations and resources. From these searches, I identified and reviewed 49 published resources including exercise pre-participation risk-screening recommendations, relevant peer-reviewed research, and clinical practice or exercise participation guidelines. I excluded articles (*n* = 29, 59.2%) that did not describe explicit recommendations for pre-exercise medical clearance or triage.

From my literature review, I identified 20 publications by expert research or clinical groups that described 15 unique approaches to guide pre-exercise medical clearance or triage decision making for CRES, referred to here-on as frameworks. To inform development of the EXCEEDS algorithm, I abstracted information pertaining to the following domains from each resource: (1) type of framework (i.e., pre-exercise medical clearance only *or* hybrid triage and medical clearance); (2) level(s) of CRES described; (3) endorsing clinical organization (if applicable); (4) point of triage (i.e., trigger for referral or recommendation); (5) framework objective (i.e., determine suitability for supervised vs. unsupervised exercise); and (6) contextual limitations. I summarized information pertaining to each domain in Table

2.1, Each resource had strengths and weakness that are important to inform development of the EXCEEDS algorithm.

Type of recommendation(s)

All 15 frameworks were published between 2011-2019; most (n=9, 60%) were published 2016 or later. Each provided at least one triage recommendation to the CRES levels described in Table 1.2 (e.g., cancer rehabilitation, clinically supervised exercise, cancer-specific community-based exercise, and generic/unsupervised community-based exercise). Mohile et al. (2018) and McNeely et al. (2016) provided only triage recommendations. The remaining thirteen (86.6%) provided recommendations for pre-exercise participation medical clearance in addition to triage; thus, I categorized these resources as "hybrid" in Table 2.1.

Level(s) of CRES included with triage recommendations

All resources recommended criteria for supervised or unsupervised care; however, three resources (20%) did not provide information necessary to categorize the recommended level CRES into one of the four levels defined in Figure 1.1 (Bredin et al., 2013; Burr et al., 2012; Riebe et al., 2015). The remaining 80 percent (*n*=12) provided triage recommendations including the following levels of CRES: cancer rehabilitation, clinically supervised exercise, and community-based cancer-specific exercise. See Table 2.1. Seven (58.3%) recommended additional criteria for triage to unsupervised or generic community-based exercise, each of these had been published since 2016 (Alfano et al., 2016; Cheville et al., 2017; Dalzell et al., 2017; Macmillan Cancer Support, 2018; McNeely et al., 2016; Santa Mina et al., 2018; Schmitz, Campbell, et al., 2019).

Table 2.1

Key domains of published frameworks for exercise pre-participation risk-screening and/or triage to outpatient rehabilitation or community-based exercise services, used to inform development of the Exercise in Cancer Evaluation and Decision Support (EXCEDS) Algorithm.

Name or model title	Year/Reference	Country	Endorsing Organization	Point of Triage	Framework objective	Туре	Level(s) of CRES	Major limitation(s)
Physical Activity Readiness Questionnaire (PAR-Q & PAR-medX)	2011 (Bredin et al., 2013; Warburton et al., 2011, 2018)	CAN	PAR-Q	Questionnaire or medical provider	Determine eligibility for supervised vs. unsupervised	Hybrid	Not specified, supervised or unsupervised	Limited cancer- specific factors and triage recommendations
Exercise Preparticipatio n Health Screening Questionnaire for Exercise Professionals	2015 (Magal & Riebe, 2016; Riebe et al., 2015; Whitfield et al., 2017)	USA	American College of Sports Medicine (ACSM)	Exercise professional	Determine need for medical supervision	Hybrid	Not specified, supervised or unsupervised	No cancer- specific factors
Tailored framework for identifying appropriate PA/exercise programming for cancer survivors	2017 (Alfano et al., 2016; Basen- Engquist et al., 2017)	USA	American Cancer society	Oncology clinician	Differentiate "risk level" (levels 1-4) and corresponding intervention type	Hybrid	 Cancer rehabilitation Clinically supervised Cancer- specific, supervised CB Generic/unsup ervised CB 	 Reliance on oncology clinician Lack of detail on safety and triage criteria

Name or model title	Year/Reference	Country	Endorsing Organization	Point of Triage	Framework objective	Туре	Level(s) of CRES	Major limitation(s)
Geriatric- Assessment (GA) Guided Interventions	2018 (Mohile et al., 2018)	USA	American Society of Clinical Oncology	Oncology clinician	Determine impairment- related need for supervision using geriatric assessment	Triage only	 Cancer rehabilitation Clinically supervised 	 Specific to older adults Reliance on oncology clinician
ActivOnco Model of Care	2017 (Dalzell et al., 2017)	CAN	Hope and Cope; Segal Cancer Center, Montreal	Physiotherapis t with cancer training	Differentiate "Complex" and "non- complex" patients	Hybrid	 Cancer rehabilitation Clinically supervised Cancer- specific, supervised CB Generic/unsup ervised CB 	• Limited generalizability to U.S.
Macmillian Cancer Rehab guidelines	2018 (Macmillan Cancer Support, 2018)	UK	Macmillan Cancer Care	"Allied Health Professionals"	-	Hybrid	 Cancer rehabilitation Cancer- specific, supervised CB Generic/unsup ervised CB 	• Limited generalizability to U.S.
NCCN - Physical Activity Assessment	2019/2020 (National Comprehensive Cancer Network, 2021)	USA	National Comprehensi ve Cancer Network	Oncology clinician	Determine "risk for physical activity- induced adverse events"	Hybrid	 Cancer rehabilitation Clinically supervised Cancer- specific, supervised CB 	 Reliance on oncology provider

Name or model title	Year/Reference	Country	Endorsing Organization	Point of Triage	Framework objective	Туре	Level(s) of CRES	Major limitation(s)
Oncology Clinician's Guide to Referring Patients to Exercise	2019 (Schmitz, Campbell, et al., 2019)	USA	ACSM ^a	Oncology clinician	Determine "specific needs" or "likelihood of needing assessment"	Hybrid	 Cancer rehabilitation Clinically supervised Cancer- specific, supervised CB Generic/unsup ervised CB 	 Reliance on oncology provider
Model of Care Supporting Survivor Return to Exercise	2016 (McNeely et al., 2016)	USA	N/A	Nurse	Differentiate risk level: low (stable), moderate, or high	Triage only	 Cancer rehabilitation Clinically supervised Cancer- specific, supervised CB Generic/unsup ervised CB 	• Lack of detail on safety and triage criteria
Connecting people with cancer to physical activity and exercise programs: A pathway to create accessibility and engagement	2018 (Santa Mina et al., 2018)	CAN	The Cancer Care Ontario	"Health care providers"	Differentiate risk level: low, moderate, high	Hybrid	 Cancer rehabilitation Clinically supervised Cancer- specific, supervised CB Generic/unsup ervised CB 	 Lack of detail to clearly define & operationalize safety and triage criteria Limited generalizability to U.S.

Name or model title	Year/Reference	Country	Endorsing Organization	Point of Triage	Framework objective	Туре	Level(s) of CRES	Major limitation(s)
Clinical decision tree for assessing the risk of adverse events during physical activity in cancer patients	2012 (Burr et al., 2012)	CAN	The PAR-Q Collaboration	"Family physician"	Differentiate risk level: low, intermediate, high	Hybrid	Not specified, supervise or unsupervised	• Lack of detail to clearly define & operationalize safety and triage criteria
Incremental levels of specialization and resource intensity that characterize cancer rehabilitation.	2018 (Cheville et al., 2017)	USA	N/A	Not specified	Determine levels needed for specialization and resource intensity	Hybrid	 Cancer rehabilitation Clinically supervised Cancer- specific, supervised CB Generic/unsup ervised CB 	• Lack of detail to clearly define & operationalize safety and triage criteria
Model for prescribing exercise in breast cancer survivors	2011 (Schmitz, 2011)	USA	N/A	Oncology clinician	Determine need for pre- participation referral and service needs	Hybrid	 Cancer rehabilitation Clinically supervised Cancer- specific, supervised CB 	 Lack of detail to clearly define & operationalize safety and triage criteria Specific to breast cancer
Breast cancer rehabilitation model	2011 (Hayes et al., 2011)	AUS, USA, SWE	N/A	"appropriate medical professional", nurses suggested	Determine need for surveillance, education and exercise supervision	Hybrid	 Cancer rehabilitation Clinically supervised Cancer- specific, supervised CB 	 Specific to breast cancer Lack of detail to clearly define & operationalize safety and triage criteria

Name or model title	Year/Reference	Country	Endorsing Organization	Point of Triage	Framework objective	Туре	Level(s) of CRES	Major limitation(s)
ESSA position statement: Exercise medicine in cancer management	2019 (Hayes et al., 2019)	AUS	Exercise and Sports Science Australia (ESSA)	"Accredited exercise physiologists"	Determine need for physiotherapy	Hybrid	 Cancer rehabilitation Clinically supervised Cancer- specific, supervised CB 	• Lack of clear triage criteria; not generalizable to U.S.

Note. Hybrid indicates the resource provided recommendations for pre-exercise participation medical clearance in addition to triage. ^a Lead by the ACSM and officially endorsed by 13 additional organizations: American Academy of Physical Medicine and Rehabilitation, American Cancer Society, American College of Lifestyle Medicine, American Physical Therapy Association, Canadian Society for Exercise Physiology, Commission on Accreditation of Rehabilitation Facilities, Exercise and Sports Science Australia, German Union for Health Exercise and Exercise Therapy, Macmillan Cancer Support, National Comprehensive Cancer Network, Royal Dutch Society for Physical Therapy, Society for Behavioral Medicine, and Sunflower Wellness

Endorsing clinical organization

Most authors (*n*=11, 73.3%) reported endorsement by clinical organizations including: The PAR-Q Collaboration (Schega et al., 2015), ACSM (Riebe et al., 2015; Schmitz, Campbell, et al., 2019), ACS (Basen-Engquist et al., 2017), ASCO (Mohile et al., 2018), NCCN (National Comprehensive Cancer Network, 2021), Macmillan Cancer Care (Macmillan Cancer Support, 2018), Cancer Care Ontario (Santa Mina et al., 2018), and Exercise and Sports Science Australia (Hayes et al., 2019). Researchers and clinical expert authors represented the following countries: the United States (*n*=9, 60.0%) (Alfano et al., 2016; Cheville et al., 2017; Hayes et al., 2011; McNeely et al., 2016; Mohile et al., 2018; National Comprehensive Cancer Network, 2021; Riebe et al., 2015; Schmitz, 2011), Canada (*n*=4, 26.7%) (Bredin et al., 2013; Burr et al., 2012; Dalzell et al., 2017; Santa Mina et al., 2018), Australia (*n*=2, 13.3%) (Hayes et al., 2011, 2019), the UK (Macmillan Cancer Support, 2018) or Sweden (Hayes et al., 2011). *Point of Triage*

Informed by my literature review, I defined point of triage as the party responsible for recommendation decisions (i.e., oncology or other clinician). Of the 15 articles, five (33.3%) recommended an oncology clinician (Alfano et al., 2016; Mohile et al., 2018; National Comprehensive Cancer Network, 2021; Schmitz, 2011; Schmitz, Campbell, et al., 2019), six (37.5%) recommended another healthcare provider or clinician (typically nurse) (Bredin et al., 2013; Burr et al., 2012; Hayes et al., 2011; Macmillan Cancer Support, 2018; McNeely et al., 2016; Santa Mina et al., 2018), and three (20.0%) specifically recommended a rehabilitation or exercise clinician (Dalzell et al., 2017; Hayes et al., 2019; Riebe et al., 2015).

Framework objective

I abstracted the goal of each publication's recommendations, then summarized into one statement (see Table 2.1, Framework objective). I reviewed each framework objective then categorized the goals into three major themes following established guidelines for inductive content analysis approach (Kyngäs, 2020). Inductive content analysis is a multi-step process including: (1) choosing a unit of analysis (e.g., framework objective), (2) open-coding data, (3) consolidating initial codes into sub-concepts or themes,

and (4) describing the resulting themes (Kyngäs, 2020). The resulting three major themes were: (1) determine level of risk for exercise-related adverse event (low/moderate/high); (2) determine eligibility for unsupervised exercise; or (3) guide CRES intervention needs (e.g., exercise prescription, education, self-monitoring). Most goal themes described by the authors included: determining exercise-related risk (Goal 1; n=6, 40%) and guiding intervention needs (Goal 3; n=6, 40%); only 20% aligned with determining eligibility for unsupervised exercise (Goal 2; n=3). For the aims of this synthesis, I grouped each framework into the emerging theme that most accurately represented the authors' original description.

Major limitations

I abstracted, summarized, and grouped the major limitations into four categories: (1) not generalizable to the general population of cancer survivors; (2) reliance on oncology clinician as point of triage, (3) lack of operational criteria for decision making , and (4) not generalizable to the United States healthcare system/CRES levels (see Figure 1.1). Limitations were not mutually exclusive. I categorized each framework based on limitations described by the authors, and my own experience as a certified clinical exercise physiologist, cancer exercise trainer and research manager for a national cancer rehabilitation company. In summary, Limitation 1 (Bredin et al., 2013; Hayes et al., 2011; Mohile et al., 2018; Riebe et al., 2015; Schmitz, 2011) and Limitation 2 (Alfano et al., 2016; Mohile et al., 2018; National Comprehensive Cancer Network, 2021; Schmitz, 2011; Schmitz, Campbell, et al., 2019) each applied to five (33.3%) of the reviewed frameworks. Limitation 3 (Bredin et al., 2013; Burr et al., 2012; Cheville et al., 2017; Hayes et al., 2011, 2019; Riebe et al., 2015; Santa Mina et al., 2018; Schmitz, 2011) applied to eight frameworks (53.3%%), and Limitation 4 applied to four (26.7%) (Dalzell et al., 2017; Hayes et al., 2019; Macmillan Cancer Support, 2018; Santa Mina et al., 2018).

Limitation 1: Limited generalizability to cancer survivors

I classified non-cancer specific resources and those specific to one oncology sub-group (e.g., older adults or breast cancer) as having low generalizability to the general population of cancer survivors. Non-cancer specific resources included the Physical Activity Readiness Questionnaire (PAR-Q) (Bredin et al., 2013; Warburton et al., 2018) and ACSM's Preparticipation Health Screening Questionnaire (Magal & Riebe, 2016; Riebe et al., 2015). Although not cancer specific, these resources were important to include in my critique because they have been widely implemented in fitness-based settings in North America over the past 10 years in the form of a simple flow diagram or open-access online survey that can be used by fitness professionals or individuals to guide decision making for pre-exercise medical clearance.

The PAR-Q collaboration is a leading international group dedicated to reducing barriers to physical activity and exercise for those with and without chronic disease (Bredin et al., 2013; Warburton et al., 2011). Their two-phase system, uses two simple algorithm-based questionnaires (the PAR-Q+ and the ePARmed-X+) to determine need for pre-participation medical evaluation then provides broad exercise recommendations (i.e., unrestricted vs. restricted and supervised vs. unsupervised exercise) (Warburton et al., 2018). High reliability, sensitivity, and specificity have been demonstrated in the general population (Warburton et al., 2011). The PAR-Q algorithm includes cancer but is not sensitive enough to capture cancer-specific needs for intervention; using PAR-Q system, pre-participation medical evaluation is recommended for all individuals receiving treatment (e.g.., chemotherapy, immunotherapy, radiotherapy) or diagnosed with lung/bronchogenic, multiple myeloma, and head and/or neck cancer.

The ACSM's Exercise Pre-participation Health Screening Questionnaire for Exercise Professionals is a screening questionnaire based on ACSM's Pre-participation Health Screening algorithm (Magal & Riebe, 2016; Riebe et al., 2015). Following the algorithm, the questionnaire is designed for exercise professionals to use with clients to determine need for pre-exercise medical clearance based on current activity level and desired activity level (e.g., high, moderate or low intensity), the presence/absence of chronic disease (e.g., cardiovascular, metabolic, renal), and the presence/absence of signs or symptoms of chronic disease (Magal & Riebe, 2016; Riebe et al., 2015). It was developed by a multidisciplinary, scientific expert panel and informed by review of literature and roundtable discussion and was updated in 2018 to reflect the latest research evidence on exercise-related risk for the general population (American College of Sports Medicine, 2018). However, cancer-specific considerations have not yet been incorporated and, like PAR-Q, the tool is not designed to differentiate recommendations beyond the level of supervised vs. unsupervised exercise.

Several research groups retrospectively evaluated the potential utility of the ACSM algorithm for cancer survivors, with various survivor cohort groups. These studies estimate 65%–75% of breast (Igwebuike et al., 2017), 39% of head and neck (Bauml et al., 2017), 20% of colorectal (Brown & Schmitz, 2014), and 15% of endometrial survivors (Zhang et al., 2015) could be prescribed a community or home-based exercise program *without* pre-exercise medical clearance or specialized supervision. These numbers are concerning because many large research studies show that upwards of 60% of cancer survivors have one or more long-term health and functional needs (Alfano et al., 2007; Harrington et al., 2010; Schmitz et al., 2012) and up to 90% of survivors do not achieve exercise levels associated with health benefits (Avancini et al., 2020). Despite high utility in the general population, neither the PAR-Q nor ACSM algorithm captures the potential elevated risk and need for specialized CRES due to complex cancer-related sequelae or late/long-term cancer-related impairments (Brown et al., 2015; National Comprehensive Cancer Network, 2021).

Pre-exercise clearance and triage recommendations currently exist for two cancer subgroups: older adults with cancer (Mohile et al., 2018) and individuals with breast cancer (Hayes et al., 2011; Schmitz, 2011). Recommendations specific to older adults were developed and published in 2018 by clinical and research leaders in the field of geriatric oncology as an ASCO clinical practice guideline (Mohile et al., 2018). These recommendations are important because the majority of individuals living with cancer are 65 years old or older and receiving community-based care (Bluethmann et al., 2016). Older adults are often more medically complex, sedentary, and often have high prevalence of functional disability (Bluethmann et al., 2016; Pergolotti et al., 2015). These recommendations are also applicable to many individuals younger than 65 due to the accelerated aging effects of cancer treatment on human physiology and risk of frailty, especially those who have experienced multiple lines of cancer treatment over time (Wang et al., 2021).

Breast-cancer-specific recommendations were developed by an international research group including leaders from the ACSM and other organizations in 2011 based on growing research evidence supporting safety and benefits of exercise for breast cancer survivors (Hayes et al., 2011; Schmitz, 2011). Breast-cancer-specific guidelines are important because it is the most commonly diagnosed cancer type in women and has an average 10-year survival rate of 84% (Siegel et al., 2021). Breast cancer survivors account for a large proportion of all survivors and the effects of exercise in this population have been studied extensively. However, research evidence specific to breast cancer may not be generalizable to other cancer types because breast cancer survivors tend to be a more easily accessible, have fewer comorbid conditions, and are often a more homogeneous and motivated sample to participate in exercise research. Therefore, breast cancer-specific guidance provided by Hayes, Schmitz and colleagues (2011) cannot be generalized to a non-breast cancer population. In addition, neither of these publications included recommendations for triage to unsupervised, or generic, community-based exercise.

Limitation 2: Reliance on oncology clinician as point of triage.

Oncologists have been historically viewed as the ideal point of decision making and triage for all aspects of a patient's care; however, more recently researchers have suggested other clinicians may be better suited to facilitate rehabilitation or exercise stepped care triage; for example, a nurse navigator or rehabilitation clinician (Coletta et al., 2020; Stout et al., 2019). One third of the reviewed frameworks (*n*=5) relied on an oncology clinician as the point of triage (Alfano et al., 2016; Mohile et al., 2018; National Comprehensive Cancer Network, 2021; Schmitz, 2011; Schmitz, Campbell, et al., 2019). However, it is worth noting that 60% of these publications were specifically developed or endorsed by clinical oncology organizations in the United States, including ASCO, NCCN and ACS (Alfano et al., 2016; Mohile et al., 2018; National Comprehensive Cancer Network, 2021). Therefore, each of these were specifically designed to be used by an oncology clinician. In addition, recommendations provided by Mohile et al., (2018) were specific to older adults and recommendations by Schmitz et al., 2011 were specific to individuals with breast cancer (previously described in Limitation 1).

Schmitz et al.'s (2019) three-step framework ("Assess, Refer, and Advise") called: "*Oncology clinician s'guide to referring patients to exercise*", is the only framework developed by an organization outside of oncology that relies on oncology clinicians as point of triage (Schmitz, Campbell, et al., 2019). Development was led by Dr. Kathryn Schmitz (ACSM past president and founder of the Move Through Cancer Initiative (Schmitz et al., 2020) and co-authors from the second International ACSM Cancer and Exercise Roundtable conference (Schmitz, Campbell, et al., 2019). As stated by the authors, the goal of this framework is to support oncology clinicians to motivate their patients to be active by showing the range of programming available during and following treatment. In alignment with ASCO, NCCN and ACS recommendations, ACSM's "*Oncology clinician's guide*" provides a broad framework to guide triage decision making for referral to cancer rehabilitation or community-based exercise programs.

When using the framework, Schmitz et al. (2019) recommend oncology clinicians "assess" patients' needs for rehabilitation or exercise using the Eastern Cooperative Oncology Group Performance Status (ECOG-PS) scale (Schmitz, Campbell, et al., 2019). ECOG-PS was developed over 50 years ago, and is still widely used by oncologists to evaluate suitability for systemic cancer treatment based on the performance status from fully ambulatory (grade 0) to dead (grade 5) (Datta et al., 2019; Oken et al., 1982). ACSM's "Oncology clinicians' guide" framework recommends a grade 3 benchmark ("capable of only limited self-care, confined to bed or chair more than 50% of waking hours" (Oken et al., 1982) for referral to outpatient cancer rehabilitation vs. community-based exercise (Schmitz, Campbell, et al., 2019). Following their recommendations, individuals graded higher than 3 should be referred to outpatient rehabilitation, while grade 2 ("Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours") or less should be referred to community-based exercise (Schmitz, Campbell, et al., 2019). Use of ECOG-PS to guide CRES triage decision making it a highly problematic recommendation to oncologists because ECOG-PS has been shown to miss critical information important to patients (Kelly & Shahrokni, 2016) and is prone to bias and high inter-observer variability. Furthermore, research shows clinician-rated performance status is often inaccurate (Datta et al., 2019) and underestimates adverse events related to cancer treatment (Basch

et al., 2017). Oncology clinicians who follow ACSM's framework and rely on ECOG-PS are likely to overgeneralize survivors' needs for CRES and elevate individuals' risk for exercise-related adverse events.

Limitation 3: Lack of operational criteria for decision making.

Six frameworks (including the ACSM's framework for oncology clinicians described in limitation 2) provided little detail other than cancer type and treatment status to define criteria for preexercise medical clearance or triage to one or more CRES intervention levels (Burr et al., 2012; Cheville et al., 2017; Hayes et al., 2019; McNeely et al., 2016; Santa Mina et al., 2018; Schmitz, Campbell, et al., 2019). Both Cheville et al. (2017) and Hayes et al. (2019) provided detailed information pertaining to rehabilitation or exercise intervention content (i.e., intervention modalities and modifications) and safety (i.e., how to monitor for red/yellow flags), but criteria for triage to each level of intervention was less clear; each recommends following ACSM general pre-exercise screening guidelines (Cheville et al., 2017; Hayes et al., 2019).

In collaboration with the PAR-Q group, Burr et al., (2012) developed a cancer-specific decision tree to categorize risk of exercise-related adverse events into high, intermediate, or low. Like the PAR-Q+ and PARmed-X, this decision tree is designed to be used by individuals and by community-based exercise professionals. Using this decision tree, an individual's level of risk is determined by responses to a maximum of 5 questions: (1) *What type of cancer do you have*?" (lung/bronchogenic, multiple myeloma or head/neck); (2) "*Have you recently visited your oncologist and discussed becoming more active*?" (yes/no), (3) "*During your last visit did your oncologist indicate that your test results were negative*?" (yes/no); (4) "*Are you currently receiving treatment*" (yes/no); and (5) "*Did you receive chemotherapy as part of your previous cancer treatment*" (yes/no).

Santa Mina and colleagues from Cancer Care Ontario Exercise for People with Cancer Guidelines Working Group (2018), developed a *"clinical pathway"* for triage to each level of CRES described in Chapter 1 based on high, moderate or low risk of exercise-related adverse events (Santa Mina et al., 2018). However, the framework lacked detail on the criteria to differentiate need for one level of CRES

vs. another. Instead, they recommended using other previously established tools, including the decision tree developed by Burr and colleagues (2012) and exercise-related guidelines from the NCCN (Brown et al., 2015; Burr et al., 2012; National Comprehensive Cancer Network, 2021). While each of these tools provides valuable information that could be used to support decision making for participation in rehabilitation or exercise, they do not account for many important factors known to influence risk for physical activity adverse events during and after cancer treatment, including: presence of comorbid conditions; recent fall(s); catheter or recent major surgery; metastasis to bone, brain or other major organ; current physician activity level; and physical, mental or cognitive functioning limitations (Brown et al., 2015; Hayes et al., 2019; Maltser et al., 2017; National Comprehensive Cancer Network, 2021).

Limitation 4: Limited generalizability to the United States health care.

In the U.S., we are almost entirely reliant on medical providers to refer individuals to rehabilitation and provide clearance for exercise in community-based settings. Each of the five (33.3%) publications that recommended an oncology clinician as point of triage were U.S.-based (Alfano et al., 2016; Mohile et al., 2018; National Comprehensive Cancer Network, 2021; Schmitz, 2011; Schmitz, Campbell, et al., 2019). Even in states where patients can self-refer to outpatient rehabilitation, insurance adds an additional layer of complexity and is often a barrier. Many insurers require medical approval; care is often subject to therapy caps; and out-of-pocket costs can be overwhelming for patients and their families (Pergolotti et al., 2018). These barriers contribute to slow adoption of published guidelines into routine clinical practice. To my knowledge, the PAR-Q and ACSM's Exercise Pre-participation Health Screening Questionnaire for Exercise Professionals are the only published frameworks that are routinely used to guide decision making in community-based exercise, and none of the reviewed frameworks is consistently used in oncology practice.

In Australia and Canada, qualified exercise professionals (i.e., minimum of bachelor's degree and relevant certifications), have expanded roles in health care that are recognized across health care sectors, especially in oncology. The ActivOnco Model of Care developed by Dalzell et al. (2017), and Santa Mina et al.'s (2018) Pathway to Connect Individuals with Cancer to Exercise Programs, both include nuances

specific to Canadian healthcare (e.g., role of exercise professionals, setting of care, reimbursement). Models developed by Hayes and colleagues (2019) are based on Australian health care. Specifically, Hayes and colleagues' 2019 publication is the Exercise and Sports Science of Australia (ESSA) position statement on "Exercise Medicine in Cancer Treatment" (Hayes et al., 2019), which provides a detailed framework for accredited exercise physiologists in Australia to prescribe exercise for individuals with cancer. In this statement, the ESSA warned that *"endorsing a blanket requirement for medical clearance for all cancer patients creates additional barriers."* Instead they recommended that exercise physiologists communicate with medical providers for any patients receiving active treatment on an individual basis to determine any contraindications the patient may not be aware of (Hayes et al., 2019) Across publications, the primary limiting factor for generalization in the U.S. is the role and qualifications of exercise professionals. For example, in each of the publications by Dalzell et al. (2017), Hayes et al. (2019) and Santa Mina et al. (2018), a qualified exercise professional can provide clearance for exercise, often without additional medical oversight.

Conclusion

Systematic reviews and meta-analysis demonstrate the benefits of exercise for functioning, quality of life, and survival (Mctiernan et al., 2019; Patel et al., 2019) and support participation in outpatient rehabilitation for individuals with functional decline or participation restrictions (Brayall et al., 2018; Hunter et al., 2017a, 2017b). Yet, connecting survivors to exercise and rehabilitation interventions is a multi-component process, involving understanding the most effective, safe, and feasible intervention for a given patient, facilitating that referral, and activating and empowering patients to participate in the exercise program. Taken together, the limitations and inconsistencies of the reviewed frameworks (summarized in Table 2.1) preclude ability to establish consensus for how to triage the right patient to the right CRES level at the right time. Lack of consensus can lead to overgeneralized recommendations and may contribute to growing disparities in access to and quality of care and the high prevalence of unmet functional needs. In addition, the amount and variety of published frameworks that have been developed in the past 10 years without evidence of dissemination into clinical practice demonstrates a clear gap

between research-derived recommendations and real-world clinical practice that must be closed to improve decision making and participation in CRES.

It is clear that care coordination between oncology and CRES is a critical barrier that must be addressed to optimize survivorship for the almost 20 million survivors living in the U.S. Overgeneralized recommendations reliant on busy oncology clinicians must be replaced with prescriptive and proactive, risk-stratified, data-driven methods for care pathway delivery that can be integrated into various levels of clinical workflow and technology platforms (Alfano, Jefford, et al., 2019). Targeted efforts are needed to develop a detailed, cancer-specific framework and decision support tool that can be easily understood and used by a variety of individuals (i.e., oncology, rehabilitation or exercise clinicians, and individuals with cancer) and used to connect the right patient, to the right CRES, at the right time.

Chapter 3: Development of the EXCEEDS Algorithm

Introduction

Despite high levels of research evidence (Mctiernan et al., 2019; Patel et al., 2019) and calls to action spanning four decades, knowledge of, access to, and utilization of exercise and rehabilitation services for cancer survivors remains limited (Pergolotti et al., 2015). As a result, inactivity and disability are prevalent and contribute to high rates of long-term cancer-related burden and high health care costs (Avancini et al., 2020; Pergolotti et al., 2015). Leading researchers and clinical organizations agree survivors should 'avoid inactivity,' and they call for oncology clinicians to screen patients and refer to exercise or rehabilitation services based on individual needs (Alfano, Mayer, et al., 2019; Schmitz, Campbell, et al., 2019; Stout, Brown, et al., 2020; Stout, Santa Mina, et al., 2020).

Individualized referral to exercise or rehabilitation services is a complex process that requires ability to understand a survivor's needs and goals, then match with recommendations from numerous sources — often during busy clinical encounters. Heterogeneity in medical status, functional level, and goals throughout the continuum of care play an important role in determining the safest and most efficacious service, and the best qualified person to supervise and prescribe exercise. For example, survivors having trouble with activities of daily living are likely to benefit most from rehabilitation, while supervised or unsupervised community-based exercise may be more appropriate for those who have few daily restrictions but seek to maintain or improve endurance or fitness. At least 69 oncology clinical practice guidelines include exercise or rehabilitation recommendations to support screening and referral, yet only approximately 20% of oncologists are aware of these recommendations (Nadler et al., 2017). Thus, practical ability to understand individual needs across the continuum of care and coordinate the *right* exercise or rehabilitation *service*, for the *right survivor*, at the *right time* is an ongoing challenge in oncology and survivorship care. International colleagues have specifically called for development of a practical decision support algorithm to improve knowledge of individual needs and care coordination at point of care or point of need (Alfano, Jefford, et al., 2019).
In this article I describe development of the <u>Exercise in Cancer Evaluation and Decision Support</u> (EXCEEDS) Algorithm and our next steps for validation and implementation. To promote knowledge and understanding of existing services, we first define the core elements of exercise and rehabilitation services using a stepped care model (Alfano et al., 2016). To promote common understanding of survivors' individualized needs, we provide a conceptual model of cancer-related disability and subsequent need for exercise or rehabilitation services.

Methods

Literature Review

I searched PubMed and MEDLINE databases for articles published in English using key phrases including "neoplasm" or "cancer;" "patient" or "survivor;" "exercise," "physical activity," or "rehabilitation;" "medical clearance," "risk," or "safety;" "guidelines" or "perspectives;" and "decision making," or "prescription." From these searches, I identified and reviewed 49 publications including exercise pre-participation risk-screening recommendations, relevant peer-reviewed research, and clinical practice or exercise participation guidelines.

Literature Synthesis

From each article I abstracted: (1) characteristics used to differentiate each level of stepped care, and (2) criteria associated with need for pre-exercise medical clearance or need for specialized care (e.g., rehabilitation intervention vs. exercise supervision). I synthesized and grouped characteristics into eight defining features to differentiate four stepped care service levels: cancer rehabilitation; clinically supervised exercise; supervised, cancer-specific community-based exercise; and unsupervised, or generic, community-based exercise (Table 3.1). Next I drew upon a multidisciplinary conceptual framework, the International Classification of Disability and Functioning (ICF) (*International Classification of Functioning, Disability and Health: ICF*, 2001), to model cancer-related disability and subsequent need for specialized services across the continuum of care (Figure 3.1).

Table 3.1

Defining features of Cancer Exercise and Rehabilitation Stepped Care Services

	Cancer Rehabilitation	Clinically Supervised Exercise	Supervised, Cancer-Specific	Generic or Unsupervised
			Community-Based	Community-Based
Level of care (Alfano	"Impairment-driven	"Impairment-directed care,	"General conditioning	"General conditioning,
et al., 2016)	care, complicated"	uncomplicated"	activities, specialized"	unspecified"
Delivery personnel	Rehabilitation	Exercise clinician with	Exercise	Generic:
(minimum	clinician(s) with	a master's-level degree and	professional(s) with a	Exercise professional(s)
requirements)	cancer-specific training	relevant clinical certification	Bachelor's-level degree in	with high school degree
(Alfano et al., 2016;	or experience/master's-	(preferably cancer-specific) ^{b,c} or	Exercise Physiology (or	and site-required
Basen-Engquist et al.,	level clinical degree	training. Supervision or	related field), relevant	certification.
2017; Cheville et al.,	(minimum) and board	evaluation may be led by	certification(s) from ACSM ^d	Unsupervised:
2017; Coletta et al.,	certification. May	rehabilitation therapist, or other	(or comparable organization),	Exercise prescription/
2020; Covington et al.,	include occupational or	clinician(s). ^{<i>a</i>}	and cancer-specific	support may be provided
2019; McNeely et al.,	physical, or other		certification or training.	by 3 rd party via
2016; Santa Mina et	therapist/clinician. ^a			asynchronous platform
al., 2018; Schmitz,				(e.g., educational
Campbell, et al., 2019)				

	Cancer Rehabilitation	Clinically Supervised Exercise	Supervised, Cancer-Specific	Generic or Unsupervised
			Community-Based	Community-Based
				resource, peer support,
				mobile application).
Facility	Outpatient rehabilitation	Outpatient location; typically	Community sites, not typically	Home-based or any
(Cheville et al., 2017;	clinic	affiliated with university,	affiliated with medical	community-based
Covington et al., 2019;		cancer center or other medical	institution	setting
McNeely et al., 2016;		clinic		
Santa Mina et al.,				
2018; Schmitz,				
Campbell, et al., 2019)				
Focus of service	Interdisciplinary	Discipline-specific assessment	Individualized and supervised	Guideline concordant
(Alfano et al., 2016;	assessment and	and intervention to address	exercise prescription or	physical activity and
Basen-Engquist et al.,	therapeutic exercise to	specific clinical outcomes	instruction including aerobic,	improved fitness ^e
2017; Cheville et al.,	address specific clinical		resistance, flexibility and	
2017; McNeely et al.,	outcomes (i.e.,		balance/coordination exercise	
2016; Schmitz,	impairment, functional			
Campbell, et al., 2019)	limitations, side effects)			

	Cancer Rehabilitation	Clinically Supervised Exercise	Supervised, Cancer-Specific	Generic or Unsupervised
			Community-Based	Community-Based
Goals of service	Short term: Improve	• Short term: Improve fitness,	• Short term: Improve fitness,	• Short term: continue to
(Basen-Engquist et al.,	physical function	participation in life activities,	ability to complete	improve fitness,
2017; Cheville et al.,	(ability to complete	physical activity level and	ADL's/IADLS, and self-	function, exercise self-
2017; Covington et al.,	daily activities), reduce	exercise self-efficacy;	efficacy. Minimize exercise	efficacy and QOL.
2019; Hayes et al.,	symptom burden,	symptom management;	barriers. Find enjoyable	Reduce barriers
2011; Marshall et al.,	maximize	improve exercise knowledge	types/modalities of exercise.	associated with center-
2018; Santa Mina et	independence and	and expectations via	• Long-term: transition to	based exercise
al., 2018; Schmitz,	improve QOL.	education and reflection.	unsupervised, build	• Long term: maintain or
2011)	Improve exercise	• Long-term: Ability to self-	guideline-accordant physical	enhance guideline-
	knowledge via	monitor during exercise and	activity/exercise habits. ^e	accordant physical
	education.	set/achieve exercise goals.		activity/exercise
	• Long-term: Enhanced	Transition to less specialized		habits. ^e
	functional status and	service.		
	quality of life to			
	support transition to			

	Cancer Rehabilitation	Clinically Supervised Exercise	Supervised, Cancer-Specific	Generic or Unsupervised
			Community-Based	Community-Based
	less specialized			
	service.			
Cost/funding	Services covered by	Not typically subsidized by 3 rd	Not typically subsidized by 3 rd	Not typically subsidized
(Basen-Engquist et al.,	most 3 rd party payers;	party payers. May be offered at	party payers. May be	by 3 rd party payers
2017; Carvalho et al.,	may be subject to patient	no additional charge to the	subsidized alternatively (e.g.,	(except Silver Sneakers).
2017; Cheville et al.,	copayments and payer	patient in some cancer care	workplace wellness,	May be subsidized
2017; Covington et al.,	medical necessity	settings.	scholarships or donations)	alternatively.
2019; Pergolotti et al.,	criteria.			
2018)				
Caveats	• Limited availability or	• Limited accessibility and	Limited availability or	• May increase risk of
(Basen-Engquist et al.,	accessibility due to	reimbursement	accessibility due to cost,	exercise-related
2017; Covington et al.,	costs, location, 3 rd	• Challenging for health care	location, 3 rd party	adverse event for those
2019; Pergolotti et al.,	party reimbursement,	providers to recognize need	reimbursement, etc.	with more serious
2019)	etc.	and make referral	(especially in rural areas)	health conditions or
	• Likely not			those at risk for
	reimbursable for			moderate-to-severe

 Cancer Rehabilitation	Clinically Supervised Exercise	Supervised, Cancer-Specific	Generic or Unsupervised
		Community-Based	Community-Based
 survivors without	Insufficient workforce of	Lack of sustainable funding	cancer treatment-
diagnosable	clinicians with cancer-specific	model and program	related impairments
impairments	training	accreditation standards	• Generic exercise
Insufficient workforce	• Cost for services may be high	Insufficient workforce of	programs and self-
of rehabilitation	• Services may not be cancer-	exercise professionals with	guided resources are
clinicians with cancer	specific (e.g., combined with	cancer-specific training	widely available but
specific training	cardiac rehabilitation or other	• Services vary in eligibility	rarely evidence-based
• Growing, but limited	services)	criteria, participant fees,	or delivered with
evidence of efficacy	• Growing, but limited evidence	design, content and ability to	clinical expertise
and effectiveness	of efficacy and effectiveness	provide specialized care.	• Individuals must be
	• Recommended (Marshall et	• Growing, but limited	motivated to maintain
	al., 2018), but lack of agreed	evidence of effectiveness	activity and seek
	upon and mandated minimal		out/use additional
	standards for implementation		resources (i.e., high
			self-efficacy)

	Cancer Rehabilitation	Clinically Supervised Exercise	Supervised, Cancer-Specific	Generic or Unsupervised
			Community-Based	Community-Based
General patient	• Presence (or	• Presence (or signs/symptoms)	• No health condition (or	• No health condition (or
qualifiers (synthesized	signs/symptoms) of a	of a health condition that	signs/symptoms) that	signs/symptoms) that
from literature review)	health condition that	indicates moderate risk for an	indicate greater than low risk	indicate greater than
	indicates high risk for	exercise-related adverse	of an exercise-related	low risk of an exercise-
(Campbell et al., 2019;	exercise-related	during unsupervised exercise,	adverse during supervised	related adverse during
Coletta et al., 2020;	adverse event, or need	or need for specialized clinical	exercise, or need for	unsupervised exercise
Maltser et al., 2017;	for specialized	care during exercise (e.g.,	specialized clinical care	• High exercise self-
National	rehabilitation care	weakened immune system,	during exercise	efficacy
Comprehensive	(e.g., difficultly	bowel or gastrointestinal	• Presence of a catheter	• May have completed
Cancer Network,	managing	issues, history of falls)	• Low exercise self-efficacy	cancer rehabilitation,
2019; Schmitz,	lymphedema;	• Difficulty completing some	• May have completed cancer	clinically supervised
Campbell, et al., 2019)	lung/bone/brain	ADL independently	rehabilitation or clinically	intervention, or
	diagnosis or	Functional limitations or	supervised intervention	community-based
	metastasis)	conditions that require clinical		
		supervision and/or		
		professional exercise		

Ca	ancer Rehabilitation	Clinically Supervised Exercise	Supervised, Cancer-Specific	Generic or Unsupervised
			Community-Based	Community-Based
· 1	Inability to complete	guideline to address specific		
1	most ADL/IADL	needs (e.g., impaired balance		
i	independently	due to neuropathy, mild		
• I	Functional limitations	fatigue, managing treatment		
C	or conditions that	side effects)		
I	require a specialized			
1	rehabilitation program			
t	to address specific			
I	needs (e.g., ataxia,			
S	surgical restrictions,			
S	severe pain or fatigue,			
1	myopathy)			

Note. ACSM= American College of Sports Medicine (ACSM), QOL = Quality of Life, IADL= Instrumental Activity of Daily Living; ADL = Activity of Daily Living.

^{*a*} Other rehabilitation clinicians include: dietician/nutrition, psychology, social work, lymphedema or pelvic floor specialists, etc.

^b Certifications: Clinical Exercise Physiologist (CEP; <u>https://www.acsm.org/get-stay-certified/get-certified/cep</u>) or Registered Clinical Exercise Physiologist

^{*c*} Certification: ACSM/American Cancer Society Cancer Exercise Specialist (<u>https://www.acsm.org/get-stay-certified/get-certified/specialization/cet</u>)

^d Certifications: Exercise Physiologist (<u>https://www.acsm.org/get-stay-certified/get-certified/health-fitness-certifications/exercise-physiologist</u>), Personal Trainer (<u>https://www.acsm.org/get-stay-certified/get-certified/health-fitness-certifications/personal-trainer</u>), Group Exercise Instructor (<u>https://www.acsm.org/get-stay-certified/get-certified/health-fitness-certifications/gei</u>)



Figure 3.1

EXCEEDS Algorithm Conceptual Model

Note. Appropriate navigation of the levels of exercise and rehabilitation stepped care (b) is a function of multidimensional factors (a), described previously by the International Classification of Function, Disability and Health (*International Classification of Functioning, Disability and Health: ICF*, 2001), and Alfano & Pergolotti et al. 2018 (Alfano & Pergolotti, 2018). Throughout the continuum of care these factors interact to increase or decrease risk of exercise-related adverse event and need for specialized care. Figure (a) used with permission from Alfano and Pergolotti (2018).

Algorithm Development

To develop the EXCEEDS algorithm, I synthesized criteria associated with need (or no need) for pre-exercise medical clearance, then grouped all criteria according to domain (i.e., activity level, disease, or symptom). In each domain, I organized criteria by associated level of risk for exercise-related adverse events. For example, I grouped criteria associated with high level of exercise-related adverse event together (e.g., angina, shortness of breath, recent injury, or treatment). Next, I synthesized criteria associated with need for specialized care and aligned each criterion with a level of stepped care as defined in Table 3.1. Guided by the ICF, I grouped criteria into broad domains (e.g., disease side effects, functional factors, and behavioral factors). Finally, I sorted each domain by decreasing need for specialized care. For example, I grouped cancer-specific side effects associated with high need for specialized care.

Final criteria and stepped care triage recommendations for each domain (Table 3.2) were established through an iterative consensus-building process with a multidisciplinary team of expert stakeholders representing the following disciplines: exercise physiology, nursing, occupational therapy, physiatry, physical therapy, behavioral science, medical oncology, and patient-advocacy (G.C., G.W., J.F., T.K., N.H., C.A., & M.P.). Each stakeholder reviewed and provided feedback on the rationale for proposed criteria and recommendations (i.e., pre-exercise medical evaluation and level of stepped care). Based on stakeholder feedback to further differentiate triage recommendations for each level of stepped care, we stratified side effect and functional domains into two levels: Level 2 (i.e., need for rehabilitation) and Level 1 (i.e., need for clinical supervision). In these domains, all criteria associated with need for rehabilitation vs. clinically supervised exercise were categorized as "Level 2" vs. "Level 1." For example, fatigue is a common side effect of cancer treatment. Our literature review indicated cancer rehabilitation is the most appropriate level of service for survivors with moderate-to-high levels of fatigue interfering with daily activities (i.e., Level 2), while those with mild or controlled fatigue (i.e., Level 1) are likely to benefit equally from clinically-supervised exercise, or unsupervised exercise if they have no additional risk factors. Through ongoing consultation with reviewed literature and among the stakeholder team, I

refined the EXCEEDS algorithm until stakeholder consensus was reached for all algorithm factors and triage recommendations.

Results

Defining Characteristics of Exercise and Rehabilitation Stepped Care Services

Using a stepped care framework, exercise and rehabilitation services recommended for cancer survivors include four levels, from the highest specialized care to the lowest: cancer rehabilitation; clinically supervised exercise; supervised, cancer-specific community-based exercise; and unsupervised, or generic, community-based exercise (Alfano et al., 2016; Cheville et al., 2017). Table 1 summarizes characteristics that differentiate each level of stepped care including: level of care as described previously by Alfano (Alfano et al., 2016); minimum requirements of delivery personnel; facility characteristics; focus of service; short and long term goals of service; cost and functioning considerations; caveats; and general patient qualifiers synthesized during our literature review.

Conceptual Model

Guided by the International Classification of Function, Disability and Health (ICF) (*International Classification of Functioning, Disability and Health: ICF*, 2001) and the work of Alfano and Pergolotti (Alfano & Pergolotti, 2018), Figure 3.1 depicts the multidimensional factors that can influence a survivor's need for exercise or rehabilitation stepped care services at any point along the continuum of care. Throughout the continuum of care, ICF factors interact to increase or decrease risk of exercise-related adverse events and need for specialized care (Figure 3.21). For example, the negative effects of radiation on body structures and function increase risk for exercise-related adverse event and may lead to activity restriction without rehabilitation intervention. Accordingly, the EXCEEDS algorithm is designed to be used at any time to guide triage decision making based on an individual's risk of exercise-related adverse events and need for specialized care.

Table 3.2

EXCEEDS algorithm domains, criteria, and supporting references

Algorithm	Criteria	Reference(s)
Domain		
Section 1: Medical	Clearance Recommendation	
Physical activity	Yes or No: currently meeting exercise guidelines (Guidelines: ≥30 minutes of	(American College of Sports
level	moderate intensity exercise on ≥ 3 days per week for ≥ 3 months) ^a	Medicine, 2018; Dalzell et al., 2017)
Chronic disease	Yes or No: presence of ≥ 1 chronic disease or related complications, including:	(American College of Sports
	• heart failure	Medicine, 2018; Brown et al., 2015;
	• kidney failure (or other renal disease)	Macmillan Cancer Support, 2018;
	• diabetes	National Comprehensive Cancer
	• metastatic cancer to bones or brain, or another major organ	Network, 2021; Warburton et al.,
	• Unstable angina	2018)
	• Dizziness resulting in loss of balance or consciousness	
	• Major surgery with restrictions in past 3 months	
	History of cardio toxic treatment	

	Yes or No: New, worsening or difficulty managing any of the following	(Dalzell et al., 2017; Macmillan
	conditions: lymphedema, ostomy, significant weight fluctuations, infection,	Cancer Support, 2018)
	ataxia, malnourishment, severe fatigue, bone/back/neck pain and unusual	
	weakness	
High risk	Yes or No: presence of ≥ 1 complication or high-risk signs/symptoms associated	(Brown et al., 2015; Dalzell et al.,
signs/symptoms	with the following diseases:	2017; Macmillan Cancer Support,
	Cardiovascular or respiratory disease	2018; National Comprehensive
	• Previous stroke, neurological condition, or spinal cord injury	Cancer Network, 2021; Warburton et
	• Musculoskeletal injury or degenerative conditions	al., 2018)
	• Recent steroid injection and potential for steroid-induces myopathy	
	• Uncontrolled diabetes mellitus	
Section 2: Triage R	Recommendations	
Cancer-specific	Yes or No, presence of ≥ 1 of the following factors:	(Dalzell et al., 2017; Macmillan
factors	• Cancer Type (Head & Neck, Lung Myeloma, sarcoma, or metastasis to	Cancer Support, 2018; Maltser et al.,
	bones, brain or other organ)	2017; McNeely et al., 2016; National
	• Fracture risk or severe osteoporosis or osteopenia	Comprehensive Cancer Network,
	• History of blood clot, deep vein thrombosis, or pulmonary embolism	2021)
	• Lymphedema high risk or difficulty managing	

Level 2 functional	Yes or No, presence of ≥ 1 of the following factors:	(Brown et al., 2015; Dalzell et al.,
factors	• Mobility aid required to complete daily activities	2017; Macmillan Cancer Support,
	• Able to mobilize 1 block of less	2018; McNeely et al., 2016; Mohile et
	• Limited upper extremity range of motion	al., 2018; National Comprehensive
	• ADL or IADL dependency	Cancer Network, 2020, 2021;
	• Moderate-severe general mobility pain (hip knee, back, etc.)	Pergolotti, Battisti, et al., 2020;
	• Ataxia or unusual weakness	Schmitz, Campbell, et al., 2019)
	• Moderate cognitive declines that impair function	
	• Peripheral neuropathy that is painful or limits function	
Level 2 side	Yes or No, presence of ≥ 1 of the following factors:	(Dalzell et al., 2017; Macmillan
effects	• Moderate to severe fatigue (4+)	Cancer Support, 2018; McNeely et
	• Neurological symptoms (dizziness/lightheaded; disorientation)	al., 2016)
	• Blurred vision	
	• Dyspnea	
Level 1 functional	Yes or No, presence of ≥ 1 of the following factors:	(Macmillan Cancer Support, 2018;
factors	• Fall in previous six months	McNeely et al., 2016; Mohile et al.,
	• Other mobility issues including: decreased balance, decreased gait speed,	2018; Schmitz, Campbell, et al.,
	mild bodily pain when moving, difficulty with ADL/IADL	2019; Wildes et al., 2018)

Level 1 side	Yes or No, presence of ≥ 1 of the following factors:	(Dalzell et al., 2017; Macmillan
effects	• Active treatment or surgery in past 3 months	Cancer Support, 2018; McNeely et
	• Treatment side effects, including:	al., 2016; National Comprehensive
	• Daily mild fatigue	Cancer Network, 2021)
	• Mild neuropathy	
	Occasional cognitive difficulty	
	Orthostatic hypotension	
	• Gastrointestinal (severe nausea; vomiting/diarrhea; dehydration;	
	inadequate food/fluid intake)	
	• Urinary or fecal incontinence	
	• Managed lymphedema	
	• Weakened immune system: thrombocytopenia (low platelets), anemia	
	(low hemoglobin) or neutropenia (low white blood cell count)	
Presence of a	Yes or No, current or planned upcoming presence of catheter (Including, but not	(Macmillan Cancer Support, 2018;
catheter	limited to, peripherally Inserted Central Cather (PICC), intraperitoneal catheter, or	National Comprehensive Cancer
	ostomy)	Network, 2021)

Exercise self-	Yes or No, high confidence in ability to exercise at least 3 times per week for at	(Macmillan Cancer Support, 2018;
efficacy	least 30 minutes per day over the next 3 months without support from an exercise	McNeely et al., 2016; National
	professional.	Comprehensive Cancer Network,
		2021)

Note. ^a Measure: Physical Activity Vital Sign (PAVS) (Ball et al., 2016)

The EXCEEDS Algorithm

The EXCEEDS algorithm is a two-part tool designed to identify exercise-related risk and provide appropriate triage recommendations. In the EXCEEDS algorithm, risk-stratified branching logic is used in each section and domain to minimize the amount of information necessary to make medical clearance and triage recommendations. Figure 3.2 illustrates the EXCEEDS algorithm flow chart. Survivors should be re-evaluated at each stage of the continuum of care (Courneya & Friedenreich, 2007) as part of prospective surveillance (Stout et al., 2012; Watson et al., 2012) and in the presence of any adverse event, change in health status, or exercise motivation.





EXCEEDS Algorithm Flow Chart Diagram

Section 1 of the algorithm includes three domains (Physical Activity Level, Presence of Chronic Disease, and Medical Follow-Up) that determine need, or no need, for pre-participation medical clearance. Pre-exercise medical clearance is indicated only for individuals who are insufficiently active

(i.e., <30 minutes moderate intensity exercise, 3x per week for 3 months (American College of Sports Medicine, 2018)) and answer yes to any question in the chronic disease or medical follow-up domains. Section 2 includes seven domains: cancer-specific factors; functional factors (level 1 & 2); side effects (level 1 & 2); presence of catheter; and exercise self-efficacy. Stop logic is used in each domain to immediately provide a recommendation when a risk/specialized care need is identified. For example, if a survivor answers yes to any question in the cancer-specific factors domain, referral to cancer rehabilitation is immediately recommended and no additional questions are prompted. Table 2 provides additional detail on the criteria and references for each domain.

Justification of Triage Recommendations for Each Stepped Care Level: Highest Specialized to Lowest

Cancer Rehabilitation. Cancer rehabilitation services are delivered by licensed healthcare professionals with expertise in therapeutic interventions to maintain or restore function, reduce symptom burden, improve quality of life, and maximize independence by improving a survivor's ability to participate fully in work, leisure, and other life roles (Alfano et al., 2016; Alfano & Pergolotti, 2018). Randomized trials and practice-based evidence have demonstrated many of these benefits throughout the continuum of care, including enhanced physical health or functioning (Scott et al., 2013; Spence et al., 2010), reduced symptom burden (Spence et al., 2010), and enhanced quality of life and participation (Hunter et al., 2017b; Mewes et al., 2012; Pergolotti et al., 2019; Spence et al., 2010). Physical and occupational therapists (PT/OT) are the primary recipients of triage recommendations from the EXCEEDS algorithm due to the exercise-related nature of the tool and fall within PT/OT scope of practice. However, additional members of the cancer rehabilitation team are included in Table 1 because many survivors will have needs outside the PT/OT scope of practice. Using the EXCEEDS algorithm triage to cancer rehabilitation is recommended for all individuals who have one cancer-specific factor, one level 2 functional factor, or one level 2 side effect.

Clinically Supervised Exercise Services. Clinically supervised exercise services may be a pragmatic and accessible supplement to cancer rehabilitation for some individuals with comorbidities (e.g., a survivor with cardiac instability but no other functional limitations) or for those with limited

accessibility to rehabilitation for geographic or financial reasons (e.g., no local cancer-specific rehabilitation clinicians; no or limited insurance; or high out-of-pocket costs). Intervention is typically led by an exercise clinician with oversight from a rehabilitation or other clinical specialist including nursing. Although the effectiveness of these programs has not been reviewed exclusively, many studies have demonstrated positive effects and impacts for cancer survivors, including decreased fatigue (Kirkham et al., 2016; H. J. Leach et al., 2018; Santa Mina et al., 2017) and improved function (Cheville et al., 2019; Kirkham et al., 2016; H. J. Leach et al., 2018; Santa Mina et al., 2019), quality of life (Kirkham et al., 2016), symptom management (Cheville et al., 2019), fitness (Kirkham et al., 2016), physical activity level (Santa Mina et al., 2017), and health-care utilization (Cheville et al., 2019). However, we recommend a minimum requirement of an evaluation by a qualified cancer rehabilitation practitioner prior to initiating exercise programs to ensure the survivor's safety and maximum benefit. Clinically supervised exercise is the minimum level of care recommended for individuals who are currently inactive and who have at least one response in the chronic disease or medical follow-up domains. Using Section 2 of the EXCEEDS algorithm, we recommend triage to clinically supervised exercise for individuals with one level 1 functional factor or one level 1 side effect.

Supervised, Cancer-Specific Community-based Exercise. Many cancer-specific and supervised programs exist across the U.S. (Table 1) and the American College of Sports Medicine (ACSM) has recently led efforts to consolidate information about these programs into a publicly available database for clinician and individual use. The reach, effectiveness, implementation, impact (on quality of life) and maintenance of cancer-specific community-based programs have been recently summarized (Covington et al., 2019). In general, these programs are safe and effective to improve quality of life (Covington et al., 2019; Musanti & Murley, 2016) and physical function (Swartz et al., 2017). Many individual programs have demonstrated improvements in cancer-specific outcomes (Hsieh et al., 2008; Marker et al., 2018) and long-term sustainability (Haas et al., 2012; Heston et al., 2015; Irwin et al., 2017; Noble et al., 2012; Santa Mina et al., 2017), including the Livestrong® at the YMCA program (Irwin et

al., 2017), which was available in 791 YMCAs across the US (April 2020).¹ Supervised, cancer-specific community-based exercise is the minimum level of care recommended for individuals who are currently active and have a positive response in the medical follow-up domain. Using Section 2 of the EXCEEDS algorithm, I recommend that individuals who either have a catheter (National Comprehensive Cancer Network guidelines (National Comprehensive Cancer Network, 2021) or have low exercise self-efficacy² should be triaged to supervised, cancer-specific community-based exercise interventions.

Unsupervised or Generic, Community-Based Exercise. Unsupervised community-based exercise includes self-directed exercise in any setting, often community- or home-based. I include generic (i.e., non-cancer specific) community-based services in this category because they lack cancer-specific supervision. Generic exercise includes traditional fitness classes, SilverSneakers®, worksite wellness, and personal training with a non-specialized trainer. Evidence suggests that supervised exercise is superior to unsupervised exercise for cancer survivors (Westphal et al., 2018); therefore, I have based triage recommendations on a survivor's level of exercise self-efficacy. Although home-based exercise is often preferred by survivors (Karvinen et al., 2007; Rogers et al., 2009; Trinh et al., 2012), research has demonstrated mixed effects on function, cancer-specific outcomes, and quality of life (Cheng et al., 2017; Schmitz, Troxel, et al., 2019; Swartz et al., 2017). Recommendations for home-based exercise should be made with caution, based on the needs of the survivor, and accompanied by personal support and local resources. The EXCEEDS algorithm recommends that individuals with high exercise self-efficacy and no other concerns can start or continue independent or generic community-based exercise.

¹ <u>https://www.livestrong.org/what-we-do/program/livestrong-at-the-ymca</u>

² Exercise self-efficacy as defined in the EXCEEDS tool is an individual's level of confidence in their ability to perform moderate intensity exercise at least 30 minutes per day, at least three times per week, for three months.

Survivors may be encouraged to participate in independent or generic community-based exercise as a complement to specialized services at the discretion of the appropriate rehabilitation or exercise professional.

Discussion

The EXCEEDS algorithm is an innovative tool that can be used at point of care or point of need to determine the safest and most efficacious exercise and rehabilitation interventions and facilitate patient-centered referrals in alignment with current recommendations. Through our collaborative development effort led by multidisciplinary stakeholders, I have closed critical gaps, enhanced clinical decision making, and integrated exercise and rehabilitation into a routine component of cancer care. To maximize the utility and adaptability of the EXCEEDS algorithm, I combined risk stratification³ and health-care need decision-making processes⁴ (Watson et al., 2012) into one step-by-step evidence-based decision-making process. Watson, Stout, and colleagues (Stout et al., 2012; Watson et al., 2012) previously emphasized the importance of this dual approach for surveillance during cancer survivorship and provided a prospective surveillance framework to guide the timing of evaluation that can be integrated into clinical pathways (Stout, Brown, et al., 2020).

Limitations and Next Steps

This manuscript presents the current version of the EXCEEDS algorithm; the tool is not yet widely available and additional research and validation are required prior to widespread dissemination. A Delphi study is currently underway to gain consensus for the EXCEEDS algorithm's acceptability and strategic implementation, including needs for adaptation and integration with existing digital and clinical

³ Risk stratification is "the process of quantifying the probability of a harmful effect to individuals resulting from a range of internal and external factors."(Watson et al., 2012)

⁴ Health-care need is "the capacity to benefit from health care" (Watson et al., 2012)

platforms. The development team will adapt the EXCEEDS algorithm using an iterative process similar to the one described earlier. Finally, validation and clinical implementation effectiveness trials of the algorithm will be formulated, based on results from the Delphi study. The sensitivity and specificity of the algorithm will be determined through comparison to current recommendations. I plan to test the efficacy of the algorithm retrospectively in a large clinical registry sample and compare EXCEEDS algorithm recommendations to those made by the ACSM and PAR-Q collaboration (Igwebuike et al., 2017; Warburton et al., 2011; Whitfield et al., 2017). Although beyond the scope of this article, additional work is needed to further understand the role of various types of supervision, such as indirect or direct supervision and synchronous or asynchronous virtual platforms.

Conclusion

The EXCEEDS algorithm is designed to address current barriers to exercise and rehabilitation care coordination by providing a common language to understand and differentiate levels of care, a practical model to conceptualize individualized needs, and an evidence-based guide to support point of care or point of need decision making. Implementation of the final version of the EXCEEDS algorithm is planned for both clinician-facing and survivor-facing platforms, including electronic medical records, patient portals, smartphone applications, and print materials. Thus, implementation of the EXCEEDS algorithm has potential to optimize survivorship care through improved ability to connect the *right survivor*, to the *right service*, at the *right time*.

Chapter 4: Consensus-Based Validation of The EXCEEDS Algorithm: Part 1 of an International Modified Delphi Study

Introduction

Risk-stratified clinical pathways that can be initiated at point of care (i.e., during routine clinical encounter/procedure) or point of need (i.e., any other time a patient has needs) are required to improve CRES coordination (Alfano, Mayer, et al., 2019; Howell et al., 2020; C. R. Leach et al., 2020; Mayer & Alfano, 2019). Specifically, a clinical decision support tool that can integrate biomedical information and individual characteristics is needed to support equitable and efficient care coordination between oncology and Cancer Rehabilitation or Exercise Services (CRES) (Alfano, Jefford, et al., 2019). However, systematic review of evidence (Khairat et al., 2018) and a recent study by Knoerl and colleagues examining the impact of a chemotherapy-induced peripheral neuropathy screening algorithm (Knoerl et al., 2021), show that simply developing a clinical decision support tool and implementing it is insufficient to enhance care coordination. In these studies, lack of *a priori* stakeholder engagement to validate the tool's efficiency and acceptability was a critical barrier to successful implementation. Therefore, targeted efforts are needed to engage oncology and CRES stakeholders (i.e., clinicians, survivors, researchers, administrators) in the development, pragmatic validation and implementation of a CRES clinical decision support tool.

I conducted a modified Delphi study to engage international stakeholders to validate the <u>Ex</u>ercise in <u>Cancer Evaluation and Decision Support (EXCEEDS) algorithm. The EXCEEDS algorithm (Figure 3.2 and Table 3.2) is a two-part cancer-specific decision support tool that combines biomedical and individual characteristics associated with risk of exercise-related adverse events and need for supervised skilled CRES, into a two-section risk-stratified guide. Section 1 can be used to identify exercise-related risk (i.e., need for pre-exercise medical clearance), and Section 2 can be used to provide appropriate triage recommendations at point-of-care or point-of-need (Covington, Marshall, Campbell, et al., 2021).</u>

In this chapter I report the primary aims of the Delphi Study: to evaluate (1) decision making efficiency and (2) consensus for acceptability of the EXCEEDS Algorithm. I also report analyzed participant open-ended feedback to inform pre-implementation revisions or adaptations to optimize efficiency and acceptability. Secondary aims of the Delphi Study were to elucidate pragmatic implementation priorities for the EXCEEDS algorithm and are reported separately (*see Chapter 5*). Procedures

Delphi methodology was selected to validate the EXCEEDS algorithm because it is ideal to engage a large audience of geographically diverse expert stakeholders without in-person contact (Trevelyan & Robinson, 2015); appropriate to establish consensus in health research (Trevelyan & Robinson, 2015); and used previously to validate a variety of clinical support tools or frameworks (Boyer et al., 2020; Chang et al., 2010; Hagen et al., 2008). To validate the EXCEEDS Algorithm, I modified the traditional first "round" of a Delphi study to encourage focused feedback on utility and acceptability of the EXCEEDS algorithm (vs. idea generation). Otherwise, the study was conducted following established guidelines (Birko et al., 2015; C. C. Hsu & Sandford, 2007; Trevelyan & Robinson, 2015), and reported in accordance with recommendations to improve rigor and transparency (Sinha et al., 2011). The current study was deemed exempt from review by the Institutional Review Board at Colorado State University (20-10145H).

Recruitment and enrollment

I recruited experts in the fields of oncology, cancer rehabilitation or exercise oncology via study advertisement posted online and list serv emails. Experts meeting minimal inclusion criteria (i.e., clinician, researcher or administrator with Bachelor of Science degree and experience in oncology, cancer rehabilitation or exercise) completed an online consent form and provided their email address to be recontacted. I allowed participants three weeks to complete the survey and sent two reminder emails. Incomplete surveys were considered lost to follow up. The consent and survey were conducted online, facilitated by Qualtrics Software, Version XM.(Qualtrics, 2020)

Participants

Of the 228 individuals who accessed the online consent form, 206 (90.4%) were eligible and consented to participate. Of those, 133 (64.6%) completed the survey and were included in the analysis for this study. Participant characteristics are described in Table 4.1.

Table 4.1

Characteristics of	f participants	included in anal	lysis (N=133)
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Characteristic	n	%
Sex		
Male	30	22.6
Female	102	76.7
Prefer not to answer	1	0.8
Age group		
21-34 years old	38	28.6
35-44	48	36.1
45-54	47	35.3
Race ^a		
White	112	84.8
Asian	14	10.6
Black/African American	3	2.3
Native Hawaiian or other pacific	3	2.3
islander		
Spanish/Latino ethnicity (yes)	8	6.0%
Country		
USA	97	72.9

Characteristic	n	%
Canada	23	17.3
Aus	3	2.3
Israel	3	2.3
Other (Italy, Costa Rica, Denmark,	8	6.0
Japan)		
Highest degree		
B.S.	26	19.5
Masters-level	27	20.3
Clinical doc.	33	24.8
PhD or ScD	22	16.5
MD	23	17.3
Other	2	1.5
Primary discipline ^b		
PT	58	43.6
Oncology	33	24.8
Ex Science	23	17.3
Research	15	11.3
ОТ	18	13.5
Physiatry	10	7.5
Nursing	6	4.5
Other ^c	4	3.0
Has cancer rehabilitation or exercise clinical	73	54.9
certification (yes)		

Years of experience

Characteristic	n	%
1-3 years	10	7.5
3-10 years	41	30.8
10-20 years	41	30.8
Over 20 years	41	30.8
Stakeholder group		
Health care admin	19	14.3
Licensed rehab professional	72	54.1
Certified exercise professional	17	12.8
Other health care provider	62	46.6
Policy maker	1	0.8
Research	41	30.8
Other ^d	6	4.5
Current role		
Clinician	83	62.4
Researcher	24	18.0
Admin	16	12.0
Educator	5	3.8
Other ^e	4	3.0
Missing	1	0.8

Note. ^a Race not reported by 1 participant. ^b Could select multiple. Do not add to 100%.

^c Other discipline included: psychology, internal medicine, speech language pathologist.

^d Other stakeholder groups included: consultant, survivor advocate, health care education professional, cancer previvor, business development, nonprofit director.

^e Other current role included: advocate, mentor, non-profit founder, program development.

Survey

I randomized participants to review two (out of four) case studies (Appendix 4.1) to make two recommendations in series. They recommended: (1) yes/no pre-exercise medical clearance is necessary, and (2) the most appropriate level of intervention for triage (options: cancer rehabilitation, clinically supervised, cancer-specific community-based, generic/unsupervised community-based). Next, the EXCEEDS algorithm (Figure 3.2 and Table 3.2) was provided as a downloadable interactive PDF and participants repeated each case study using EXCEEDS to guide decision making. After using the algorithm, participants rated acceptability using the validated 4-item, Acceptability of Intervention Measure (AIM) (Weiner et al., 2017), then had the option to provide open-ended feedback algorithm format and content.

Statistical analysis

Case study decision making efficiency. Efficiency when using the EXCEEDS algorithm was evaluated in terms of decision accuracy (correct/incorrect) and the number of seconds required to make the triage decision (decision duration) for each case study. To determine accuracy, I coded each medical clearance and triage decision as correct or incorrect, then calculated and descriptively compared the proportion of correct responses between conditions (Individual vs. EXCEEDS). I established an *a priori* benchmark of 75% to indicate acceptable decision accuracy, meaning the absolute proportion of correct responses when using the EXCEEDS algorithm must increase and equal 75% or greater to be considered an "acceptable" improvement in accuracy. Decision duration (seconds) was collected during each survey by Qualtrics software. To address potential outliers due to unlimited survey length, I plotted average duration using histograms then removed outliers greater than three standard deviations above the mean. Then I used paired samples *t*-tests to compare triage decision duration (seconds) between individual and EXCEEDS conditions for each case study. The significance level was set to p<.05.

AIM consensus for algorithm acceptability. Using the AIM, participants rated acceptability in four domains (*"meets approval," "appealing," "like using*" and *"welcome in practice/discipline*") on a 5-

point Likert scale (1 = completely disagree, 5 = completely agree). Higher average scores indicated greater acceptability of each domain and overall acceptability (Weiner et al., 2017). Test-retest reliability of the AIM has been established previously (Weiner et al., 2017). Quantitative (AIM) and qualitative (open-ended feedback) acceptability outcomes were evaluated using sequential mixed method analysis (Teddie & Tashakkori, 2007). To establish consensus for acceptability in each AIM domain, I calculated descriptive statistics (mean and standard deviation, median and interquartile range [IQR]), then calculated the proportion of participants who responded "agree" (4) or "strongly agree" (5). To evaluate overall acceptability, I followed AIM scoring instructions and calculated descriptive statistics (mean and standard deviation) (Weiner et al., 2017). Cut off scores indicating "high" acceptability have not yet been validated for AIM overall acceptability score, therefore I established an *a priori* mean of 4/5 points (i.e., "agree") as a benchmark. I defined consensus as 70% or more participants "agree" or " strongly agree," with each AIM domain, based on the definition of consensus used in previous Delphi studies (Kleynen et al., 2014; Vogel et al., 2019).

Following guidelines for inductive qualitative analysis (Savin-Baden & Major, 2013), I reviewed all open-ended responses, then re-read each response while recording key terms and themes described by the participants (e.g., "flow diagram", "criteria detail", "terminology"). I repeated this process until a preliminary list of codes was established, then performed line-by-line coding of all responses using NVivo software (QSR International, 1999). After initial coding, I reviewed all coded data and organized into major themes as appropriate. All committee members reviewed the final coding mechanisms and resulting themes. Data triangulation was performed by consulting AIM scores for each participant to enhance rigor and credibility(Savin-Baden & Major, 2013). Qualitative outcomes include description and frequency of major themes, description and frequency of sub-themes, and corresponding participant quotes (Appendix 4.2).

Results

Case study decision making efficiency

Comparative decision efficiency favored the EXCEEDS algorithm in terms of accuracy and decision duration (Table 4.2). In all case studies, medical clearance decision accuracy improved and achieved the benchmark of 75% accuracy when using the EXCEEDS algorithm. Medical clearance decision accuracy ranged 76.6% to 91.5% when using EXCEEDS, compared to 59.4% to 71.8% accuracy without. In three of four (75%) cases, triage level decision accuracy improved when using EXCEEDS, and two cases achieved the 75% accuracy benchmark. Triage level accuracy when using EXCEEDS ranged 28.1% to 83.1%, compared to 28.1% to 71.8% accuracy without. For all case studies, triage level decision duration (seconds) was significantly shorter when using the EXCEEDS algorithm (p<.05). Average improvement in triage decision duration ranged from 15.03 ± 31.91 seconds ("Greg", t(65)=3.83, p = .00) to 32.6 ± 53.21 seconds ("Anna", t(62)=4.86, p = .00).

Table 4.2

Decision accuracy and	l duration,	individual 1	vs. EXCEEDS	condition f	or eacl	h case stud	!y
							~

Individual

EXCEEDS

Case	Medical	Triage	Triage level	Medical	Triage level	Triage level
	clearance	level (n , %	duration, sec	clearance	(n, % correct)	duration, sec
	(n, % correct)	correct)	$(M \pm SD)$	(n, % correct)		$(M \pm SD)$
Anna	51 (71.8%)	51 (71.8%)	74.64 ± 50.96	71 (91.5%) ^a	59 (83.1%) ^a	42.04 ± 35.31 ^b
Bob	43 (67.2%)	26 (40.6%)	52.22 ± 45.43	49 (76.6%) ^a	30 (46.9%)	35.50 ± 28.70 ^b
Dianne	38 (59.4%)	18 (28.1%)	57.73 ± 48.16	51 (79.7%) ^a	18 (28.1%)	27.29 ± 21.25 ^b
Greg	45 (67.2%)	41 (61.2%)	33.05 ± 29.93	58 (86.6%) ^a	55 (82.1%) ^a	18.02 ± 17.27 ^b

Note. Correct medical clearance decisions according to EXCEEDS: Anna (yes), Bob (no), Dianne (no), Greg (no). Correct triage level decisions according to EXCEEDS: Anna (rehabilitation), Bob (rehabilitation), Dianne (clinically supervised), Greg (unsupervised or generic community-based). ^a Compared to Individual condition, accuracy improved in the EXCEEDS condition and achieved hypothesis of \geq 75% accuracy

^b Compared to Individual condition, triage level decision duration was shorter in EXCEEDS condition, p < .05.

AIM consensus for algorithm acceptability

Consensus for acceptability was achieved in three out of four acceptability domains: "*meets approval*" (72%), "*is appealing*" (86%) , and "*welcomed in my practice/discipline*" (78%), see Table 4.3 for all domain scores and inter-rater agreement. AIM overall score was $M=3.90 \pm 0.473$ (range = 1.0 – 5.0). Most participants (n = 111, 82.7%) provided open-ended feedback, resulting in 305 comments related to the content and format of the algorithm. Three major themes arose during analysis: (1) perceived strengths of the existing algorithm (n = 123, 40.9%; e.g., flow chart visual, organization, and content), (2) considerations for implementation (n = 93, 30.5%; e.g., key populations, stakeholder groups and use-cases for implementation), and (3) areas to consider for revision (n = 87, 28.5%; e.g., readability of risk factors, domain terminology, some components of flow chart). Each major theme is summarized in Appendix 4.2 including sub-themes and participant quotations.

Table 4.3

Expert-rated acceptability of the EXCEEDS algorithm and inter-rater agreement by domain

AIM domain question ^a	Average	Median rating,	Inter-rater
	rating,	(IQR)	agreement, ^b
	$Mean \pm SD$		n (%)
"The EXCEEDS algorithm meets my approval"	3.79 ± 0.79	4.0 (3.0 – 4.0)	96 (72.2%)
"The EXCEEDS algorithm is appealing to me"	4.05 ± 0.81	4.0 (5.0 - 5.0)	113 (85.5%)
"I like using the EXCEEDS algorithm"	3.76 ± 0.92	4.0 (3.0 – 4.0)	90 (67.7%)
"I welcome the EXCEEDS algorithm in my	4.02 ± 0.78	4.0 (4.0 - 5.0)	103 (77.5%)
discipline or practice"			

Note. AIM = Acceptability of Intervention Measure, average rating reflects individual level agreement with each domain.

^a Domain rating scale: 1 (complete disagree) to 5 (completely agree)

^b Proportion of participants who rated the domain \geq 4 ("agree")

Discussion

In this study, I used Delphi methodology to engage real-world CRES stakeholders to evaluate efficiency and establish consensus for acceptability of the EXCEEDS algorithm to guide CRES decision making. Use of the EXCEEDS algorithm resulted in enhanced CRES decision efficiency (decision accuracy and duration) in most conditions, and consensus for acceptability was achieved in 75% of domains. Stakeholder-rated acceptability of the EXCEEDS algorithm was higher (*Mean score*= 3.90 ± 0.47 , domain range = 3.76 - 4.05, n=133) than reported in the study by Knoerl and colleagues (2021) (*Mean score* = 3.21, domain range= 2.89 - 3.95, n=19) (Knoerl et al., 2021) Furthermore, the lowest rated acceptability domain reported by Knoerl and colleagues (2021) pertained to utility of the algorithm at point of care (*Mean score* = 2.89 ± 1.29). In the present study, the two highest-rated acceptability domains were related to utility at point of care, and each achieved consensus (86% and 76% agreement). Because lack of pre-implementation evaluation of algorithm clinician perceptions was a barrier to successful implementation in the study by Knoerl et al. (2021), the results of this study provide promising evidence that the EXCEEDS algorithm could be successfully implemented to improve CRES decision making.

To our knowledge, EXCEEDS is the first algorithm of its kind to be validated as an efficient and acceptable decision support tool prior to implementation. Online recruitment and data collection methods were a strength of this study that enabled participation from a diverse group of experts representing each CRES discipline. Stakeholder engagement and retention were higher than reported by previous Delphi studies recruiting clinical experts, including oncology clinicians.(T. Hsu et al., 2020; Schneider et al., 2017) Traditionally the ideal sample size for a Delphi study is 6-50 [9], however a large sample was especially important in this study to optimize rigor to evaluate algorithm efficiency (via randomized case studies), and to establish consensus for acceptability from the perspectives of real-world stakeholders. In addition, most participants elected to provide open-ended feedback to further inform our understanding of algorithm acceptability.

Limitations

Although the EXCEEDS algorithm is designed for point-of-care or point-of-need use, the present study only simulates use at point of care. Thus, the findings of this study cannot be extrapolated to efficiency and acceptability at point of need. In addition, lack of purposeful sampling due to online-enrollment methods allowed for any individual who met the minimum inclusion criteria to enroll in the study. The wide range in experience and perspectives of participants in this study is practical for the aims, but likely contributed to variability in participant responses, particularly for CRES decision efficiency. *Future directions*

The algorithm development team (Covington, Marshall, Campbell, et al., 2021) will use the results of this study to systematically revise the EXCEEDS algorithm. Specifically, each of the three qualitative themes will be considered a priority area for pre-implementation revision and future adaptation. Implementation priorities (e.g., key stakeholders, platforms, and strategies) will be determined by the Development team following evaluation of the Delphi study secondary aims (i.e., determine consensus for implementation priorities) and corresponding surveys (*n*=2). Future validation of the algorithm will build from the results of this study and use similar methodology (including stakeholder engagement & mixed method analysis) to evaluate utility at point of need. In addition, pragmatic validation of the algorithm is planned using retrospective cohort and case-series study designs to establish prescriptive utility. Hybrid study designs will be used to simultaneously study implementation strategies associated with optimal adoption and utilization of the EXCCEDS algorithm, and effectiveness to improve decision making in real-world point-of-care and point-of-need scenarios.

Conclusion

The results of this study provide compelling evidence that the EXCEEDS algorithm may be an efficient, acceptable, and pragmatic tool to support real-world CRES decision making for multidisciplinary stakeholders. Thus, implementation of the EXCEEDS algorithm could be a novel and pragmatic solution to improve care coordination for CRES at point of care or point of need during survivorship.

Chapter 5: Consensus-Based Implementation Priorities for The EXCEEDS Algorithm: Part 2 Of An International Modified Delphi Study

Introduction

Since 2007, the American Medical Informatics Association (AMIA) has recommended clinical decision supports to enhance screening and clinical care coordination at point of care or point of need (Osheroff et al., 2007). Decision supports exist in a variety of forms (e.g., clinical guidelines, algorithm, clinical pathways) and have been integrated into a variety of health care platforms (e.g., computerized alerts/reminders, patient data dashboards, disease-specific order sets/templates) to integrate biomedical information, individual characteristics, and evidence-based reasoning for patient-centered clinical recommendations (Osheroff et al., 2007; Sittig et al., 2008). In cancer care, use of decision supports is associated with reduced prescriber error rates and enhanced adherence to clinical practice guidelines (Pawloski et al., 2019), including disease risk factor screening and referral for preventative or follow up care clinical sets or treatments (Mazo et al., 2020). However, lack of decision support to address the functional (vs. medical) sequelae of cancer treatment by identifying those likely to benefit from CRES is an important gap in research and a barrier to equitable, guideline concordant cancer care (Alfano, Jefford, et al., 2019; Alfano, Leach, et al., 2019).

Evidence from systematic reviews show that developing a decision support tool is merely the first step — strategic selection and utilization of stakeholders (i.e., users who will adopt and champion the tool), platforms (i.e., media and methods to access/use the tool) and strategies (i.e., techniques to promote integration and adoption) are critical for successful implementation of decision supports in clinical practice (Damschroder et al., 2009; Osheroff et al., 2012; Powell et al., 2015; *Using Prioritization Matrices to Inform UX Decisions*, 2018). In cancer care specifically, low stakeholder buy in, impractical platform selection, and lack of *a priori* use of implementation strategies have been associated with low integration and adoption of existing decision supports and minimal impact on clinical guideline adherence (Khairat et al., 2018; Knoerl et al., 2021). International multidisciplinary leaders in clinical oncology,

rehabilitation, and exercise warn lack of efficient communication between disciplines is a critical barrier to CRES care coordination, and that future models of care will require "synergy" between disciplines (Coletta et al., 2020) and a precision-based medicine approach to identify the *right* patients and match them with the *right* CRES at the *right* time (Alfano, Jefford, et al., 2019; Covington, Marshall, Campbell, et al., 2021). Dynamic use and iterative evaluation of implementation strategies targeted at the individual (i.e., stakeholder or user) and organizational levels (i.e., clinic or health care organization) are critical for successful health care innovations (Damschroder et al., 2009). In addition, tremendous growth in digital engagement and consumerism of digital patient health information is creating increased pressure on health care systems to utilize digital platforms (Dicker & Jim, 2018; Fisch et al., 2016; Gonzalez, 2018).

The Exercise in Cancer Evaluation and Decision Support (EXCEEDS) algorithm (Figure 3.2 and Table 3.2) combines biomedical and individual characteristics associated with risk of exercise-related adverse event and skilled need for supervised CRES with evidence-based reasoning for patient-centered recommendations. The EXCEEDS algorithm is specifically designed to support multi-user (oncology, general practice, rehabilitation, exercise, survivors) clinical decision making in a variety of platforms (e.g., electronic medical record, open-access internet, application technology, patient handout). However, there are no established best practices to guide practical selection of the *right stakeholder group, the right platform*, or the *right strategy* for implementation.

In "Part 1" of this modified international Delphi study (Chapter 4), the EXCEEDS algorithm was associated with improved CRES decision making efficiency and consensus was established for algorithm acceptability. The aims of this study were to establish expert consensus for implementation priorities for a CRES decision support algorithm in three domains: (1) stakeholders, (2) platforms, and (3) implementation strategies. I used a modified Delphi methodology to achieve these aims.

Procedures

I selected Delphi methodology to accomplish the aims of this study because it is an effective means to gain and measure consensus from a group of expert stakeholders (Holey et al., 2007), and
important for development and implementation of new technology and innovations in healthcare (Birko et al., 2015; Trevelyan & Robinson, 2015). Traditional Delphi methodology can be modified, while maintaining the key features of participant anonymity, controlled feedback provided to participants, aggregate group response statistics, and expert feedback (Trevelyan & Robinson, 2015). With that in mind, I designed two surveys to determine expert consensus via repeating surveys where content is informed by results of the preceding survey, and consensus is determined over iterative examination (Trevelyan & Robinson, 2015). I invited all participants who completed Part 1 of the Delphi study (*N*=133) to participate in Part 2 via email. Participants were given three weeks to complete each online survey, and two reminder emails were sent out. After 3 weeks, I considered incomplete surveys lost to follow up. All consent and survey procedures were conducted online, facilitated by Qualtrics Software, Version XM (Qualtrics, 2020). This study was exempt by the Institutional Review Board at Colorado State University #20-10145H.

Participants

Seventy-six participants completed the first survey (57.1%) and 55 (72.4%) completed the second survey. See Table 5.1 for a description of the characteristics of participants in each survey.

Table 5.1

Characteristics of participants in EXCEEDS Delphi study, Round/Survey 2 & 3

Characteristic		Round 2, N=76 (n, %)	Round 3, N=55 (n, %)	
Sex				-
	Male	21 (27.6)	14 (25.5)	
	Female	55 (72.4)	41 (74.5)	
Age group				
	21-34 years old	21 (27.6)	15 (27.3)	
	35-44	25 (32.9)	17 (30.9)	
	45-54	30 (39.5)	23 (41.8)	

White	66 (88.0)	47 (87.0)
Asian	5 (6.70)	5 (9.09)
Black/African American	2 (2.63)	1 (1.82)
Native Hawaiian or other	2 (2.63)	1 (1.82)
Pacific islander		
Country		
USA	49 (64.5)	33 (60.0)
Canada	18 (23.7)	14 (25.5)
Australia	2 (2.63)	2 (3.64)
Japan	2 (2.63)	2 (3.64)
Israel	2 (2.63)	1 (1.82)
Other (Italy, Costa Rica,	3 (3.95)	3 (5.45)
Denmark)		
Highest degree		
B.S.	16 (21.1)	11 (20.0)
Masters-level	13 (17.1)	10 (18.2)
Clinical doc.	18 (23.7)	12 (21.8)
PhD or ScD	14 (18.4)	12 (21.8)
MD	13 (17.1)	10 (18.2)
Other	2 (2.63)	11 (20.0)
Primary discipline		
PT	33 (43.4)	11 (20.0)
Oncology	23 (30.3)	26 (47.3)
Ex Science	18 (23.7)	7 (12.7)

Research	11 (14.5)	4 (7.27)
OT	8 (10.5)	4 (7.27)
Physiatry	6 (7.89)	8 (14.5)
Nursing	4 (5.26)	15 (27.3)
Other	1 (1.32)	0 (0.0)
Has cancer rehabilitation or	41 (53.6)	30 (54.5)
exercise clinical certification (yes)		
Years of experience		
1-3 years	5 (6.60)	4 (7.27)
3-10 years	23 (30.3)	15 (27.3)
10-20 years	23 (30.3)	17 (30.9)
Over 20 years	25 (32.9)	19 (34.5)
Stakeholder group		
Health care admin	8 (10.5)	6 (10.9)
Licensed rehab	41 (53.9)	31 (56.4)
professional		
Certified exercise	15 (19.7)	9 (16.4)
professional		
Other health care provider	33 (43.4)	23 (41.8)
(i.e., non-rehab or exercise)		
Policy maker	1 (1.3)	1 (1.82)
Research	27 (35.5)	21 (38.2)
Other	6 (7.90)	5 (9.09)
Current role		
Clinician	43 (56.6)	28 (50.9)

Researcher	16 (21.1)	13 (23.6)
Admin	10 (13.2)	7 (12.7)
Educator	5 (6.60)	5 (9.09)
Other	2 (2.60)	2 (3.64)

Note. Race not reported by one participant. Participants could select multiple responses for primary discipline, percentages do not add to 100%.

Surveys

This part (Part 2) of the Delphi study included two online surveys. Each survey began with consolidated feedback from the previous survey (Trevelyan & Robinson, 2015). The goal of the first survey was to establish consensus-based ranking for key stakeholders, platforms, and strategies, then use these rankings to establish a list of "Top" implementation strategies to continue to the second survey for further evaluation. The second survey builds upon the results of the first via prioritization of strategies using the Eisenhower Urgent-Important Matrix Method (Jyothi & Parkavi, 2016; *Using Prioritization Matrices to Inform UX Decisions*, 2018).

Survey 1: Rank key stakeholders, platforms and strategies. The first survey began with an established list of implementation stakeholders, platforms and strategies that I selected *a priori* following extensive literature review of existing clinical decision support in oncology (Mazo et al., 2020; Pawloski et al., 2019) and barriers to real-world CRES decision making (Avancini et al., 2020; Ferri et al., 2020; Hardcastle, Kane, et al., 2018; Nadler et al., 2017; Yang et al., 2017). The seven key stakeholder groups included: oncology clinicians and oncology administrators; specialized and non-cancer specialized rehabilitation clinicians; specialized and non-cancer specialized exercise clinicians; cancer survivors; and researchers in related fields (Appendix 5.1). Next, participants ranked the ability for each group to benefit from the EXCEEDS algorithm, from 1 (most likely to benefit) to 7 (least likely to benefit).

Next, I provided participants with descriptions of six decision support platforms: open-access internet, restricted access internet, electronic medical record networks, handheld device application, clinical print materials, patient-facing print materials (Appendix 5.2). For each of the seven key

stakeholder groups (Appendix 5.1), participants ranked the likelihood of benefit for implementation of the EXCEEDS algorithm, from 1 (most likely to be beneficial) to 6 (least likely to be beneficial).

Finally, I provided participants with an overview of 15 discrete implementation strategies, see Appendix 5.3. I selected each strategy from Powell et al.'s (2015), *"Refined Compilation of Implementation strategies"* to reflect algorithm implementation goals (Covington, Marshall, Campbell, et al., 2021), implementation barriers reported by similar clinical decision support initiatives (Khairat et al., 2018), and key areas of effective CDS medication management programs as described by Sittig and Osheroff (Osheroff et al., 2012). Participants considered potential implementation-related needs of each stakeholder group and platform, then ranked the importance of each strategy for successful implementation from 1 (most important for successful implementation) to 15 (least important for successful implementation).

Survey 2: Prioritize key strategies for implementation. I provided participants with a brief background on the Eisenhower Urgent-Important Matrix Method and the definition of "successful implementation" established *a priori: "the degree to which the EXCEEDS algorithm is established in a practical, sustainable process (or interface) that is efficient, promotes equitable access to all potential users, and minimizes barriers to care coordination.*" Next, I gave participants an overview of the 10 discrete implementation strategies that resulted from ranking analysis of Survey 2 (Appendix 5.4). Participants rated each strategy in terms of *effort* associated with using strategy (1 - low effort to 4 - high effort) and potential *impact* of the strategy on successful implementation of the EXCEEDS algorithm (1 – low impact to 4 - high impact).

Statistical Analysis

To accomplish Aim 1 (consensus for key stakeholder, platforms, and implementation strategies), I calculated central tendency (median and IQR) for all participant rankings collected during the first survey, then sorted (high-low) by median rank (see Tables 5.2, 5.3 and 5.4). I then reviewed individual rankings and coded as "yes" (numerical value 1) if the participant ranked the item as a priority (defined as 1-3 ranking for stakeholders or platforms or 1-10 ranking for strategies). To determine inter-rater agreement (consensus), I calculated the proportion of participants who ranked each option as a priority. I established a 70% benchmark *a priori* to indicate consensus (Kleynen et al., 2014; Vogel et al., 2019). Implementation strategies that did not achieve the a priori benchmark 10 (out of 15) ranking (based on median) or 70% agreement were considered low priority and were eliminated for subsequent analysis in the second survey to facilitate a focus prioritization of the remaining strategies.

To address Aim 2 (prioritize key implementation strategies), I followed Eisenhower prioritization methodology (Jyothi & Parkavi, 2016; *Using Prioritization Matrices to Inform UX Decisions*, 2018) to prioritize each of the 10 discrete implementation strategies. I calculated central tendency (mean and standard deviation) of *effort* and *impact* ratings for each implementation strategy. Using mean effort (x) and mean impact (y) ratings as coordinates, I plotted each of the Top 10 strategies onto the "Eisenhower matrix" (Figure 5.1) (*Using Prioritization Matrices to Inform UX Decisions*, 2018). Finally I used the matrix plot and corresponding 2.50 median cut-offs, to categorize each strategy in terms of urgency and importance using the following previously established prioritization categories (ordered from greatest to least priority): "*Do now*" (low effort/ high importance), "*Decide*" (high effort, high importance), "*Delegate*" (low effort, low importance), and "*Delete*" (high effort/low importance) (Bratterud et al., 2020; Using Prioritization Matrices to Inform UX Decisions, 2018).

Results

In Aim 1, oncology clinicians and administrators were the highest-ranked stakeholder group and achieved consensus (Table 5.2). Cancer-specialized rehabilitation clinicians were ranked second but did not achieve inter-rater agreement (Table 5.2). The remaining stakeholder groups did not achieve 50% inter-rater agreement (Table 5.2). Open-access internet and electronic medical record networks were the highest-ranked implementation platforms and achieved consensus (Table 5.3). The remaining platforms groups were ranked as follows but attained <55% inter-rater agreement: handheld device application, clinical print materials, restricted access internet, patient-facing print materials (Table 5.3). Consensus was achieved for eight of the ten highest-ranked implementation strategies (80%, inter-rater agreement range = 93.4% - 71.1%). "Identify and prepare champions" (*Median*=4.0, IQR= 1.25 - 9.25, 78.9%

agreement), "capture and share local knowledge" (*Median*=5.0, IQR= 2.0 - 7.0, 93.4% agreement), and "develop educational materials" (Median=6.0, IQR = 4.0 - 11.0, 72.4% agreement) were the three highest-ranked strategies (Appendix 5.4). Level of agreement achieved consensus for the remaining 10 highest ranked implementation strategies that were carried on to the second survey, except "use advisory boards and workgroups" (rank = 7, Median 7.5, IQR = 3.0 - 11.0, 69.7% agreement) and "remind clinicians" (rank = 9, Median 8.0, IQR = 4.25 - 11.0, 67.1% agreement). See Appendix 5.4 for the ranking results of all implementation strategies determined in Aim 1.

For Aim 2, the average *effort* and *impact* ratings for each implementation strategy are presented in Table 5.4 and plotted using the Eisenhower Urgent-Important Matrix (Figure 5.1). Two strategies were categorized as urgent/important: "develop educational materials" and "remind clinicians." Seven strategies were categorized important/not urgent. No strategies were categorized as urgent/not important. One strategy, "model and simulate change," was categorized as not important/not urgent.

Table 5.2

Key stakeholder group ranking results reported as consensus-based rank, median rank, and inter-rater agreement

Consensus-	Stakeholder group	Median rank	Inter-rater agreement,
based rank		(IQR)	n, %
1	Oncology clinicians and administrators	2.0 (1.0 - 3.75)	57, 75.0 ^a
2	Rehabilitation clinicians	3.0 (2.0 - 5.0)	43, 56.6
	(cancer-specialized)		
3	Rehabilitation clinicians	4.0 (2.25 - 5.0)	34, 44.7
	(non-cancer specialized)		
4	Exercise clinicians	4.0 (2.0 - 5.0)	30, 39.5
	(cancer-specialized)		
5	Cancer survivors	4.0 (1.0 - 6.0)	30, 39.5

6	Exercise clinicians	4.5 (3.0 - 6.0)	30, 39.5
	(non-cancer specialized)		
7	Researchers in related fields	7.0 (5.0 - 7.0)	4, 5.30

Note. N = 76. Consensus-based rank determined by average rank in ascending order. Average rank determined from Likert scale item: 1 = most likely to benefit, to 7 = least likely to benefit from using the EXCEEDS algorithm. Inter-rater agreement calculated as the proportion of participants who ranked the stakeholder group in as a high priority (1-3).

^a Consensus achieved, $\geq 70\%$ inter-rater agreement

Table 5.3

Key platforms ranking results reported as consensus-based rank, median rank, and inter-rater agreement

Consensus-	Platform type	Median rank	Inter-rater agreement
based rank		(IQR)	n, %
1	Open-access internet	2.0 (1.0 - 3.5)	55, 72.4% ^a
2	Electronic medical record networks	2.5 (1.5 – 3.5)	53, 69.7%
3	Handheld device application	3.0 (2.5 – 4.0)	41, 53.9%
4	Clinical print materials	3.5 (2.5 – 4.5)	31, 40.8%
5	Restricted access internet	5.0 (3.0 - 6.0)	21, 27.6%
6	Patient-facing print materials	5.0 (3.5 - 5.5)	11, 14.5%

Note. N = 76. Consensus-based rank determined by average rank in ascending order. Average rank determined from Likert scale item: 1 = most likely to be beneficial, to 6 = least likely to be beneficial for key stakeholders to use the EXCEEDS algorithm. Inter-rater agreement calculated as the proportion of participants who ranked the platform type in as a high priority (1-3). ^a Consensus achieved, $\geq 70\%$ interrater agreement.

Table 5.4

Implementation strategy prioritizes as categorized by the Eisenhower matrix, effort and impact ratings

reported as mean, standard deviation (1-10 rank).

Eisenhower matrix	Implementation strategy	Effort rating	Impact rating
category		M, SD	M, SD
"Do now"	Develop educational materials	2.51, 0.94	2.87, 0.88
(urgent, important)	Remind clinicians	1.93, 0.90	2.76, 0.90
"Decide"	Identify and prepare champions	2.78, 0.88	3.42, 0.69
(important, not urgent)	Capture and share local knowledge	3.05, 0.76	3.44, 0.69
	Conduct ongoing training	2.82, 0.70	3.04, 0.82
	Stage implementation scale up and tailor	3.38, 0.76	3.38, 0.71
	strategies		
	Use advisory boards and workgroups	2.65, 0.89	2.62, 0.81
	Conduct cyclical small tests of	3.05, 0.76	2.71, 0.76
	adaptations to physical structure		
	Adapt physical structure	3.07, 0.98	2.75, 0.78
"Delegate"	N/A	N/A	N/A
(urgent, not important)			
"Delete"	Model and simulate change	2.62, 0.83	2.49, 0.79
(not important, not			
urgent)			

Note. All ratings based on 4-point Likert scales effort, 1 (low effort) to 4 (high effort) and impact, 1 (least impact) to 4 (most impact). All rankings determined by ordering mean rating #1 (low effort or high impact) to #10 (high effort or low impact)



Figure 5.1.

Implementation strategy effort and impact ratings plotted onto the Eisenhower matrix for prioritization.

Note. Each implementation strategy is represented by an "X". Plot coordinates were determined by effort (x) and impact (y) ratings. Each quadrant ("do now", "decide", "delegate", and "delete") is defined by a boundary of 2.50 x 2.50 points.

Discussion

Enhanced CRES decision making is needed to improve survivorship care via improved ability to identify survivors experiencing functional decline or inactivity and match them with CRES service most appropriate to optimize functioning, well-being and survival (Alfano, Jefford, et al., 2019; Covington, Marshall, Campbell, et al., 2021). I previously demonstrated the EXCEEDS algorithm is an acceptable CRES decision support tool and associated with improved decision-making accuracy and efficiency (*See Chapter 4*). Yet, there are no established best practices to guide practical selection of the *stakeholders, platforms, or strategies* to successfully implement the EXCEEDS algorithm. In this study, I established expert consensus for key stakeholders (oncology stakeholders and administrators), platforms (open-access internet), and implementation strategies for the EXCEEDS Algorithm.

Stakeholders

Oncology clinicians and administrators were the highest-ranked stakeholder group, and only one to achieve the *a priori* consensus benchmark of 70% agreement. These results are consistent with cancer rehabilitation and exercise clinical practice guidelines (Schmitz, Campbell, et al., 2019; Stout, Santa Mina, et al., 2020) and previously developed decision support tools (Fong et al., 2021; Schmitz, 2011; Schmitz, Campbell, et al., 2019). However, some researchers argue oncology clinicians may not be the best suited to guide CRES decision making due to limited knowledge CRES clinical guidelines (Hardcastle, Kane, et al., 2018; Nadler et al., 2017). Cancer specialized rehabilitation clinicians received the second highest average rating in this study, but consensus was not achieved (57% agreement). These results reflect emerging literature supporting the role of clinical navigators with rehabilitation expertise/experience to enhance coordination of care and promote early screening and detection of functional needs (Stout et al., 2019). In certain care models, research shows navigation led by a clinician experienced in oncology and rehabilitation may lead to high patient satisfaction with care, improved adherence to clinical practice guidelines, and expansion of cancer rehabilitation services to diagnosis-specific programs (Stout et al., 2019).

To learn how to leverage the EXCEEDS algorithm to address these barriers I specifically included oncology clinicians in the EXCEEDS algorithm development team and as participants in the Delphi study. In Part 1 of the Delphi study, oncology clinicians' CRES average decision accuracy and efficiency improved significantly when using the EXCEEDS algorithm, and 73% agreed they would welcome implementation in their discipline or practice (Covington, Marshall, Sharp, et al., 2021). Because EXCEEDS algorithm will be implemented following the consensus-based priorities established in this study, I believe it has enormous potential to lessen CRES decision making barriers for oncology clinicians by improving their understanding of CRES guidelines and providing an evidence-based step-by-step tool to guide referrals. Furthermore, level of agreement was the same for cancer survivors, cancer-specialized and non-cancer specialized exercise clinician stakeholder groups and there was little-to-no difference between median rankings. Thus, the EXCEEDS algorithm may be able to serve as a bridge between disciplines to improve care coordination and communication.

Platforms

In this study, open-access internet was the highest-ranked implementation platform and the only one to achieve consensus. EMR networks were the second-ranked platform and negligibly missed consensus (69.7% agreement). The results of this study align closely with previous calls to use digital platforms to develop clinical decision support repositories (Sittig et al., 2008), and reflect the well-documented growths in digital engagement and consumerism of digital patient health information due to technology advances over the past 10 years (Dicker & Jim, 2018; Fisch et al., 2016; Gonzalez, 2018). EMR networks are the most frequently cited platform in the oncology clinical decision support literature, however limitations of existing studies prevent ability to conclude effectiveness of EMR-based clinical decision support in cancer care (Pawloski et al., 2019). In addition, because cross-discipline communication is a prominent barrier to CRES coordination, reliance on EMR may contribute to communication barriers between disciplines (e.g., oncology and community-based exercise).

As indicated by participants in this study, implementation of the EXCEEDS algorithm using open-access digital platforms may be most appropriate to capitalize on growth in technology capabilities

and consumerism. The EXCEEDS could be integrated into existing open-access internet resources for cancer survivors, for example, the American College of Sports Medicine's (ACSM) *Moving Through Cancer* website.⁵ The *Moving Through Cancer* website is curated by the ACSM's special interest group (Schmitz et al., 2020) and hosts the latest evidence-based science for CRES, a variety of clinical resources, and an international registry of CRES programs and resources. To our knowledge, this is the only comprehensive registry of all levels of cancer-specific CRES, thus integration of the EXCEEDS algorithm has the potential create a "one-stop-shop" for survivors or providers seeking CRES guidance. *Implementation strategy priorities*

I established consensus for 10 theory-based implementation strategies, then prioritized using the Eisenhower method. Two implementation strategies were categorized as highest priority: "*develop educational materials*" and "*remind clinicians*". Only one ("model and simulate change") was categorized as not important and not urgent (i.e., "Delete), indicating the original list of implementation strategies I selected were practical for the EXCEEDS algorithm. In addition, these findings align with previously identified barriers to decision support system adaptation and sustainability, including lack systems to facilitate alerts or reminders when integrated into electronic medical record networks (Khairat et al., 2018).

High-ranked implementation strategies also reflected many qualitative themes that emerged from prior analysis of participant open-ended feedback on the EXCEEDS algorithm (collected during Part 1of the Delphi study, see Chapter 4). For example, many participants suggested strategies to improve implementation of EXCEEDS algorithm, including: multidisciplinary educational materials, physical structure adaptations to improve clarity and utility, and the need to consider local or population-specific factors that may influence CRES decision making (ex. availability of specific services, financial concerns, insurance restrictions, etc.).

⁵ https://www.exerciseismedicine.org/support_page.php/moving-through-cancer/

Strengths

To foster pragmatic elucidation of implementation priorities for the EXCEEDS algorithm, I drew from widely accepted implementation science (Powell et al., 2015) and prioritization theory (Jyothi & Parkavi, 2016) to develop all survey questions. Similarly, I drew from existing systematic reviews of clinical decision supports in cancer care (Mazo et al., 2020; Pawloski et al., 2019) and barriers to CRES decision making (Hardcastle, Kane, et al., 2018; Nadler et al., 2017; Yang et al., 2017) to ensure the stakeholder groups, platforms and implementation strategies provided to participants for ranking were relevant to real-world CRES decision making. Utilization of modified Delphi methodology with online recruitment and data collection was a strength of this study that enabled us to engage a diverse but relevant group of expert stakeholders to accomplish the study aims. Stakeholder engagement was high; loss to follow up for each survey was 43% and 28%, respectively and similar to other previous Delphi studies including clinical experts where there was no compensation for participants (C. R. Leach et al., 2020; Lyons et al., 2017).

Limitations

The findings of this study must be considered with caution as they represent the opinions of the experts who participated in this study and may not be representative of all CRES stakeholders. Specifically, additional research is needed to understand survivors' perspectives of acceptability and implementation priorities of the EXCEEDS algorithm when used at point of need.

Future directions

Guided by the results of the Delphi study, the EXCEEDS Algorithm development team (Covington, Marshall, Campbell, et al., 2021) will develop a strategic plan for implementation. Two implementation strategies ("*develop educational materials*" and "*remind clinicians*") were categorized as urgent/important and will become the primary priorities for implementation of the EXCEEDS algorithm. Seven strategies were categorized important/not urgent will be reviewed and vetted by the Algorithm development team to determine appropriate use. Future studies will follow the implementation priorities established in this study and use hybrid implementation-effectiveness study designs to understand how

test each of the platforms and strategies that resulted as priorities in this study may/may not contribute to successful implementation of the EXCEEDS algorithm. Once successfully implemented, research is needed to evaluate impact of the EXCEEDS algorithm on clinical decision making and outcomes including: compliance with clinical practice guidelines or accreditation standards, individual-level compliance with exercise guidelines, costs, and patient reported outcome measures. Currently little is known about the impact of decision supports on these important clinical outcomes (Pawloski et al., 2019). Conclusion

I established consensus for key stakeholders, platforms and implementation strategy priorities for the EXCEEDS algorithm. These results will be used to guide strategic implementation of the EXCEEDS algorithm in cancer care clinical pathways at point of care and point of need, including clinical implementation and research initiatives. Thus, stakeholders at the individual- and organizational-levels should consider adoption of the EXCEEDS algorithm as an innovative and pragmatic strategy to optimize cancer survivorship via improved oncology and CRES coordination.

Chapter 6: Discussion

For this dissertation, I led development of the EXCEEDS algorithm then conducted an international modified Delphi study to validate the algorithm and establish consensus for acceptability, decision making efficiency, and key implementation strategies. In this chapter, I will integrate findings from each phase of my dissertation to demonstrate the EXCEEDS algorithm's potential to address limitations of existing CRES clinical decision supports (described in Chapter 2). Specifically, I will (1) demonstrate EXCEEDS' ability to address existing CRES care coordination barriers by highlighting strategic decisions and key findings during each major phase of the dissertation; (2) explain how this work draws from and contributes to the fields of occupational and rehabilitation science; and (3) discuss limitations and future directions for the EXCEEDS algorithm.

EXCEEDS' potential to address CRES coordination barriers

As described in Chapter 2, limitations of existing CRES clinical decision supports (limited generalizability, reliance on an oncology clinician as point of triage, and lack of operational criteria for decision making) preclude consensus for how to connect the *right patient* to the *right CRES* at the *right time*. I sought to address each of these limitations via development and validation of the EXCEEDS algorithm. Specifically, I integrated the highest levels of exercise oncology research evidence with the strengths of non-cancer specific CRES clinical decision support tools that have been successfully implemented in the United States and Canada: the ACSM's Preparticipation Health Screening Questionnaire (American College of Sports Medicine, 2018; Riebe et al., 2015) and the Physical Activity Readiness Questionnaire (PAR-Q) tools (Bredin et al., 2013; Warburton et al., 2018). From my synthesis, I identified common strengths that I believe contribute to successful implementation of these tools including: engagement from large groups of multidisciplinary stakeholders (i.e., ACSM and PAR-Q leadership groups vs. individual research groups), organization of risk factors into domains or groups (vs. a long list of discrete factors), use of clear and simple language that can be understood by users with

varying clinical knowledge (vs. medical jargon) and open-accessibility (vs. closed-access). I systemically integrated each of these strengths into the EXCEEDS algorithm during the development process. In the Delphi study, I sought to understand acceptability, utility and implementation needs for the EXCEEDS algorithm, including if these "strengths" may contribute to successful implementation. In the following paragraphs I discuss strategic decisions and key findings during each major phase of this project (i.e., formation of development team, algorithm development, and Delphi study) and evidence supporting EXCEEDS' ability to address existing CRES care coordination barriers

Phase 1: Formation of the development team

Previous researchers have shown lack of a priori stakeholder engagement during the development of clinical decision supports is a critical barrier to successful implementation with oncology clinicians or in oncology-related workflows (Knoerl et al., 2021; Pawloski et al., 2019). Both the ACSM and PAR-Q decision support tools began with formative research (i.e., literature review and survey studies), followed by an iterative development and review process performed by a group of multidisciplinary expert leaders selected from each organization. Selected leaders at each organization worked together to develop and establish consensus for the content of each tool and broad strategies for implementation. In addition, each organization has maintained these leadership groups to regulate implementation of the tool and perform continuous content reviews and updates as new research evidence emerges (PAR-Q+ Collaboration, 2020; Riebe et al., 2015). Likewise, EXCEEDS stakeholder engagement began prior to algorithm development and was instrumental to each step of the development process. Following literature review, I recruited multidisciplinary colleagues from the American Congress of Rehabilitation Medicine - Cancer Rehab Networking Group (ACRM-CRNG; referred to hereon as the "development team" [Covington, Marshall, Campbell, et al., 2021) to participate in an iterative, consensus-building review and algorithm development process. The ACRM-CRNG was the most appropriate stakeholder group to develop the EXCEEDS algorithm because members are diverse, including individuals with a wide range of clinical, academic, and research experience in the fields of oncology, cancer rehabilitation and exercise oncology.

ACRM-CRNG members who participated in the development team (*n*=6) represented the following disciplines: exercise physiology, nursing, occupational therapy, physiatry, physical therapy, and behavioral science. To ensure all disciplines were represented, I recruited two additional members to represent medical oncology, and patient-advocacy. Each member of the development team was also instrumental to recruitment for the Delphi study by advertising the study with various professional groups and colleagues.

Phase 2: Algorithm development

Over a 6-month period (August 2019 – February 2020), I led the development team in an iterative process until consensus was reached for algorithm content and format. Informed by my literature synthesis (Chapter 2) and the above-discussed strengths of successfully-implemented non-cancer specific CRES decision supports (ACSM & PAR-Q), we made three decisions to optimize utility of the algorithm for multidisciplinary users: (1) divide into two major sections with independent aims (medical clearance vs. triage), (2) use dichotomous (yes/no) criteria to simplify information necessary for decision making, and (3) depict the algorithm using a flow chart visual diagram. We hypothesized splitting the algorithm into two sections would enhance generalizability of the algorithm across cancer populations and environments via the maximal number of possible use-cases. The resulting EXCEEDS algorithm contains a risk-stratified series of 11 dichotomous (yes/no) questions, organized in ten domains across two sections (Covington, Marshall, Campbell, et al., 2021). Development team members agreed the flow chart diagram (Figure 6.1) had the highest cross-discipline utility and potential for implementation. Specifically, the flow chart (including key and legend) was thought to be explicit enough to demonstrate the EXCEEDS logic for CRES decision making, while flexible enough that the user could openly interpret how the logic could be integrated into existing platforms that they may encounter during daily workflow/decision making (ex. electronic medical record, patient portal, other digital or print material).



Refer to supervised, concer-specific exercise



EXCEEDS Algorithm Flow Diagram

Design of EXCEEDS enables dual or discrete use of each section and the dichotomous (yes/no) criteria and organization of domains (i.e., descending order of risk/need for specialized care) provides easy-to-follow logic that prevents the user from answering unnecessary questions. Depending on the setting (e.g., oncology clinical encounter, community-based program assessment) and the user's needs (e.g., triage to CRES or determine if medical clearance necessary prior to participation), Section 1 (Medical clearance), Section 2 (CRES triage), or both, can be used. Section 1 could be used independently by survivors or community-based exercise specialists to determine if medical clearance is warranted due to change in health status or activity level. Similarly, section 2 could be integrated into electronic health record systems for clinicians to use as a checklist to guide care transition between CRES levels. A simple checklist version of the algorithm is one example of how the specific design of the EXCEEDS algorithm enables it to be easily adapted for a variety of uses or existing platforms. For example, many existing clinical organization-sponsored webpages provide general recommendations but lack a method for survivors to receive individualized recommendations at point of need: ACSM Moving Through Cancer,⁶ Cancer.net "Physical Activity Tips",⁷ Breast Cancer.org "Exercise Resource Guide".⁸ A checklist could be easily integrated to these websites to provide more accurate and patient-centered recommendations that account for local environmental factors and common barriers to CRES participation (e.g., accessibility of local cancer-specific programs, cost, etc.)

Phase 3: Delphi Study

Lack of stakeholder engagement and a priori implementation strategies are frequently cited barriers to successful implementation of clinical decision supports (Knoerl et al., 2021; Pawloski et al., 2019). The Delphi study provided a means to engage stakeholders to evaluate the EXCEEDS algorithm

⁶ https://www.exerciseismedicine.org/support_page.php/moving-through-cancer/

⁷ https://www.cancer.net/survivorship/healthy-living/physical-activity-tips-survivors

⁸ https://www.breastcancer.org/tips/exercise/resources

prior to implementation and provide feedback on acceptability, utility and needs for implementation. Ultimately the results of the Delphi study provide: (1) preliminary evidence that the algorithm is acceptable and useful to a variety of CRES stakeholders, (2) consensus for stakeholder, platforms and strategies key to successful implementation, and (3) valuable insight into how strengths adopted from the ACSM and PAR-Q non-cancer specific tools (stakeholder engagement, organization of risk factors, use of clear and simple language, and open accessibility) may contribute to successful implementation.

Stakeholder engagement. In the Delphi study, I sought to engage a large diverse group of stakeholders to comprehensively pilot test and understand the algorithm's potential real-world utility and acceptability. Ultimately, more than 200 multidisciplinary experts representing each discipline of CRES and 13 unique professional organizations enrolled in the Delphi study. Participant retention across the Delphi study was moderate to high (shown in Figure 6.2). Retention to the Round 1 survey was high (65%) for an open-access survey, indicating most of those who enrolled were engaged in the survey and appropriate to participants. Furthermore, 83% of participants who completed the Round 1 survey provided at least one open-ended comment on the Algorithm. The diversity and retention of Delphi study participants demonstrate the EXCEEDS algorithm is an appealing solution to a common issue for a variety of stakeholders.



Figure 6.2

EXCEEDS Delphi Study Participant Enrollment and Retention Flow Diagram

Algorithm acceptability and utility. Results of the Delphi study provide strong preliminary evidence that the EXCEEDS algorithm is an acceptable and useful CRES decision support. Compared to independent decision making, use of the EXCEEDS algorithm resulted in improved CRES decision accuracy (according to clinical practice guidelines) in a shortened amount of time in most case vignettes (75%). In Round 1 of the Delphi study (Chapter 4), participants described the content underlying each

algorithm domain (i.e., list of risk factors/criteria) and the flow chart format to be major strengths of EXCEEDS. Specifically, participants described the organization of content into risk-stratified domains was "appropriate," "clear," "logical" and "easy to understand/follow." Many also commented the "layout" and "organization" of the flow diagram, made it "visually appealing," "intuitive" and "easy to use". Overall, the flowchart was described as a "comprehensive and logical decision tree." Participant-rated acceptability of the algorithm was higher than reported in similar studies (Knoerl et al., 2021), and a sub-analysis of oncology clinicians revealed little difference in oncology-rated acceptability and overall scores (Covington, Marshall, Sharp, et al., 2021). Consensus for acceptability was achieved in most domains (75%), including "The EXCEEDS algorithm meets my approval;" "I like using the EXCEEDS algorithm;" and "The EXCEEDS algorithm is welcomed in my practice/discipline."

Implementation priorities. Although reliance on oncology providers was a limitation of existing CRES decision supports identified and discussed in Chapter 2, oncology clinicians and administrators were the highest-ranked stakeholder group in the Delphi study and the only one to achieve consensus (\geq 70% agreement). Cancer specialized rehabilitation clinicians received the second highest average rating in this study, but consensus was not achieved (57% agreement). However, because EXCEEDS algorithm will be implemented following the consensus-based priorities established in this study, it has the potential to lessen CRES decision making barriers for oncology clinicians (e.g., low awareness of guidelines, limited time and confidence for personalized recommendations). In addition, because the EXCEEDS algorithm is designed *a priori* for multidisciplinary users, it is likely that adoption by oncology clinicians will drive downstream adoption by rehabilitation and exercise clinicians who seek to communicate and share patient case information with their patients' oncology provider(s).

Open-access internet, defined as "any publicly accessible website, including those owned and managed by organizations, health care systems, universities or fitness centers," was the highest ranked platform and only platform (of 6) to achieve consensus. Follow these results, I will lead the development team to prioritize implementation of the EXCEEDS algorithm in open-access online platforms like the

ACSM and PAR-Q tools. The highest prioritized implementation strategies for the EXCEEDS algorithm included "develop educational materials," "remind clinicians" reflect many barriers to successful implementation of decision supports reported by existing systematic reviews (Khairat et al., 2018; Pawloski et al., 2019) and qualitative themes that emerged from prior analysis of participant open-ended feedback on the EXCEEDS algorithm. For example, strategies suggested by participants to improve implementation of EXCEEDS algorithm during Part 1 of the Delphi study included: multidisciplinary educational materials, physical structure adaptations to improve clarity and utility, and the need to consider local or population-specific factors that may influence CRES decision making (e.g., availability of specific services, financial concerns, insurance restrictions). Lack of practical educational materials or consideration of local factors that may influence care coordination are known barriers to adoption of clinical decision supports in oncology (Khairat et al., 2018; Pawloski et al., 2019).

Occupation and Rehabilitation Science: Applied Concepts and Contributions

This dissertation was completed towards achievement of a PhD in Occupation and Rehabilitation Science. Development of the EXCEEDS algorithm was the culmination of my research experience in cancer rehabilitation, clinical expertise as an exercise physiologist, and my doctoral studies in Occupation Science (OS) and Rehabilitation Science (RS). In addition, the EXCEEDS algorithm contributes a patient-centered and biopsychosocial perspective on CRES needs during cancer treatment and survivorship that can be pragmatically used to enhance exercise participation for individuals living with and beyond cancer.

Adopting an OS perspective to unlock the "occupational power" of exercise

Occupations, or how individuals occupy their time and expend energy, can exist in a variety of forms, physical and social environments, and for a variety of purposes (e.g., self -care, leisure, productivity, play) (Larson et al., 2003; Rudman, 2010). Typically, occupations are described in one of eight groups: activities of daily living (ADL), instrumental ADL, sleep and rest, work, education, play, leisure and social participation (Braveman et al., 2017). From Occupational Science, we understand all

humans have an innate desire to perform occupations, and the ability to do so in a meaningful way is an important determinant of health, well-being and justice (Townsend et al., 2007; Wilcock & Townsend, 2009). The nature of human occupation, is typically understood in three dimensions: *form* (the physical/mental ways in which occupation is performed), *function* (how occupation influences development, adaptation, health and quality of life), and *meaning* (the subjective experience of participation in an occupation). The bulk of existing research evidence is focused on how various *forms* of exercise (e.g., aerobic, resistance, yoga) serve as a *function* to improve physical and mental health and functioning for cancer survivors (Beebe-Dimmer et al., 2020; Kim et al., 2020; Loh et al., 2020). However, widespread low rates of exercise participation during and following cancer treatment [up to 90% (Avancini et al., 2020)] and oncology clinicians' awareness of the importance of exercise participation for their patients (Nadler et al., 2017) are evidence that survivors and clinicians have little practical understanding of the *meaning* of exercise during survivorship.

OS researchers show that meaning is associated with improved participation in occupations, better health behaviors, and enhanced quality of life (Henriksson et al., 2020; Loh et al., 2020). Therefore, lack of understanding of the meaning of exercise may be an important and understudied barrier to exercise participation for cancer survivors and CRES referral for clinicians. In a recent qualitative study including 49 cancer survivors who participated in a community-based exercise program, survivors described exercise provided a "*vehicle for recovery*" that enabled a sense of "*self-power*" over their health and well-being (Cantwell et al., 2020). However, in the same study, participants reported environmental, individual and treatment-related barriers to exercise participation and recommended regular fitness assessments and a home exercise program to support long-term participation (Cantwell et al., 2020). The conclusions of Cantwell and colleagues (2020) are in agreement with previous quantitative investigations of physical activity participation behavior and determinants (Avancini et al., 2020; Hardcastle, Maxwell-Smith, et al., 2018; Sturgeon et al., 2018) and reflect many of the health benefits of routine physical activity reported by multiple meta-analysis (Friedenreich et al., 2020; Kohler et al., 2016; Li et al., 2016;

Swartz et al., 2017). Together, these studies demonstrate a missed opportunity to capitalize on (what I like to call) the "occupational power" of exercise. The "occupational power" of exercise is my conceptual means of explaining the phenomena that a survivor's ability to exercise in a meaningful way is an important and powerful determinant of exercise participation and mediator for functional, survival and quality of life outcomes. I believe the key to unlocking the "occupational power" of exercise is to: (1) use research evidence and anecdotal experiences to demonstrate *meaning* of exercise to survivors and clinicians and (2) reduce barriers to CRES via patient-centered recommendations at point of care and point of need. Thus, implementation of the EXCEEDS algorithm could help catalyze the "occupational power" of exercise for individuals and health care systems by connecting the right survivor, with the right CRES, at the right time.

Adopting an RS perspective to model disability and guide patient-centered decision making

RS includes basic and applied health and social sciences that pertain to the restoration of human functioning via enhanced interaction with the surrounding environment (Brandt & Pope, 1997). In the medical model, disability is often articulated as the "absence of ability" due to an individual's physical or mental decline or impairment (Kielhofner, 2005). However, in RS, disability is the product of factors external to the individual that lead to "activity restrictions" and "participation limitations" (Brandt & Pope, 1997; Kielhofner, 2005). Contrary to the static deficit-accumulation view of disability from the medical model, in RS, disability and ability are viewed on a wide and dynamic continuum and influenced by a variety of factors (e.g., health, personal/behavioral, environmental). RS applies this biopsychosocial and dynamic view of disability to study the health, behavioral, environmental and societal factors that interact to influence disability/ability experienced by individual's with a health condition with the goal to optimize participation functioning throughout the lifespan (Seelman, 2000). As originally demonstrated in the Enabling Disabiling Model (Brandt & Pope, 1997) and more recently in the International Classification of Functioning, Disability and Disease (*International Classification of Functioning, Disability and Health: ICF*, 2001), if the environment "fits" the needs of the individual the experience of

disability is lessened, and participation in occupations is more likely to occur and contribute to meaning and quality of life. However, when the environment is not congruent with an individual's needs (e.g., physical, psychosocial, financial, spiritual), disability may be experienced by any individual (regardless of medical or functional status).

In parallel, CRES can attenuate declines associated with cancer treatment and enhance patient functioning and quality of life (Brayall et al., 2018; Covington et al., 2019; Hunter et al., 2017b). However large cohort survey and descriptive studies have demonstrated the right exercise environment is an important factor for participation in exercise and a common barrier to survivors due to lack of accessible information and individualized recommendations/ referrals (Blaney et al., 2013; Cantwell et al., 2020; Fitzpatrick J., 2011; Hardcastle, Maxwell-Smith, et al., 2018; Midgley et al., 2018). Various research and clinical groups have recommended application of the ICF to guide clinicians' understanding of patients' needs for CRES (Alfano & Pergolotti, 2018; Gilchrist et al., 2009; Weis & Giesler, 2018), but has not been widely adopted outside of academic settings. We (EXCEEDS development team) adopted the ICF as a conceptual framework for the EXCEEDS algorithm that could be equally understood and used by clinicians as a conceptual model for the interaction among factors likely to influence an individuals' CRES-needs and for RS researchers studying the efficacy and implementation of CRES. As shown in Figure 6.3, appropriate navigation of the levels of exercise and rehabilitation stepped care (b) is a function of multidimensional factors (a), described previously by the ICF, and depicted by Alfano and Pergolotti (2018). Throughout, the continuum of care these factors interact to increase or decrease risk of exercise-related adverse event and need for specialized care.





EXCEEDS Algorithm Conceptual Model.

Reproduced from (Covington, Marshall, Campbell, et al., 2021). Figure (a) used with permission from Alfano and Pergolotti 2018 (Alfano & Pergolotti, 2018).

Limitations

There are many limitations that must be acknowledged with the findings of this dissertation. First, we hypothesized decision efficiency when using the EXCEEDS algorithm would improve significantly in all cases and consensus would be achieved in all domains of acceptability. However, the *a priori* hypothesis for improve decision making efficiency was achieved in six of eight conditions, and acceptability achieved hypothesized levels of consensus in three out of four domains. These results indicate EXCEEDS is acceptable, but improvements are needed to enhance efficiency and acceptability. In addition, although we made every effort to recruit a diverse but representative group of participants in the algorithm development team and Delphi study, open-access and snowball recruitment strategies used in the Delphi study precluded ability to determine participation rate (i.e., proportion who consented out total who were exposed to recruitment) and may have contributed to some response bias. While the

Delphi study enabled simulated pilot testing of the algorithm, these results cannot be directly extrapolated to real-time clinical decision.

Future directions

Guided by the results of the Delphi study, I will convene and lead the development team to adapt the algorithm and establish a strategic plan for implementation evaluation and dissemination. Participant open-ended feedback collected during the Delphi study provided clear and actionable themes that will be used by the development team to revise elements of algorithm prior to implementation. Because many of these themes align closely with previously described elements of successfully implemented non-cancer specific decision support tools (e.g., organization and clarity of language), we believe that pre-implementation revisions to the EXCEEDS algorithm guided by these themes will enhance efficiency and acceptability. As part of strategic planning, we will seek opportunities to integrate the algorithm with open-access web-based platforms, specifically those frequently used by oncology clinicians and the open-access patient-facing online platforms described previously. As the algorithm is adapted to various platforms and implemented, I will use hybrid implementation-effectiveness study designs to prospectively evaluate implementation and impact of the EXCEEDS algorithm in real-world settings with real-life cases. Testing with additional stakeholders, especially cancer survivors, is needed to further understand efficiency and acceptability of the algorithm to facilitate survivors' decision making at point of need.

Positionality

During this dissertation I began working full time as the research manager for the Cancer Rehabilitation sub-company (ReVital) of a for-profit health care company (Select Medical). This position has afforded be tremendous first-hand experience to learn about real-world barriers and facilitators of CRES access and utilization, including oncology clinician beliefs behavior regarding exercise. From these experiences I believe I have a very unique perspective on the research needed to improve access and utilization of these services. In addition, I have the practical understanding and resources needed to develop a program of research around the EXCEEDS algorithm. Together, my experiences and resources

have greatly prepared me to take this work to the next level where it has the potential to have real-world impacts on access to and utilization of CRES.

Conclusion

The EXCEEDS algorithm is an acceptable evidence-based CRES decision support tool that combines the strengths of existing decision supports with cancer-specific research evidence and clinical guidelines to provide a common language to describe exercise/rehabilitation services, a practical model to understand individualized needs, and step-by-step decision support guidance. To my knowledge, EXCEEDS is the first decision support algorithm to be systematically developed, evaluated and validated prior to implementation via consensus from two groups of real-world expert stakeholders. Thus, future, implementation of the EXCEEDS algorithm has the potential to advance survivorship care by lessening existing CRES care coordination barriers associated with identifying the *right survivor* and connecting them with the *right CRES* at the *right time*.

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Case studies developed by the authors, then randomly selected for EXCEEDS Algorithm Delphi study Round 1 Survey

Case study A: Anna

Anna was diagnosed with Stage II breast cancer approximately 9 months ago. She completed active treatment (mastectomy and chemotherapy) and takes Tamoxifen daily. She has had Type 2 Diabetes for 10 years, which caused mild neuropathy-related sensations in her toes prior to cancer. Prior to her cancer diagnosis, Anna went to the gym twice per week and walked her dogs 1 hour every day for exercise. However, since her cancer diagnosis (i.e., for the last 9-months), she has been mostly sedentary. Recently, she began to experience lymphedema symptoms in her right arm. *She has no additional medical diagnoses, signs/symptoms of chronic disease or disability.*

Anna's goals are to manage lymphedema so she can return to her job as a dental hygienist and to get back to exercising regularly. She is also seeking help for the tingling sensation in her toes because she sometimes has difficulty staying balanced during daily activities.

Question/item		Answer
Medical clearance		Yes
	Reason	Inactive, chronic disease, high risk s/s (lymphedema)
Triage level		Rehab
	Reason	Cancer-specific factors (lymphedema)

Case study B: Bob

Bob completed radiation treatment for prostate cancer approximately one year ago. He is being treated with Androgen Deprivation Therapy (ADT) and experiences some side effects, including difficulty with memory, multitasking, and giving/following directions. Bob was recently seen by his oncologist who ruled out the possibility of recurrence. He has a BMI of 30.0 and has been recently diagnosed with pre-diabetes. Bob commutes to work on his bicycle 5 days per week (30 minutes

roundtrip) and plays Frisbee golf with friends for at least 1 hour every Saturday. *He has no additional medical diagnoses, signs/symptoms of chronic disease or disability.*

Bob has concerns about these cognitive difficulties due to ADT, which sometimes interfere with his ability to work and complete other daily tasks. He also wants to learn how to lessen risk for diabetes by improving his diet and exercise routine.

Question/item	Answer
Medical clearance	No
Reason	Active
Triage level	Rehab
Reason	Moderate cognitive decline (functional)

Case study D: Dianne

Dianne had a lumpectomy 1 year ago and is currently receiving chemotherapy treatment. She is on medical leave from an active job in the construction industry. Dianne walks 2-3 miles each day (moderate intensity) to stay active. She has no surgical weight limit restrictions. *She has no additional medical diagnoses, signs/symptoms of chronic disease or disability.*

Dianne wants to increase her exercise intensity to improve strength and endurance. Her goals are to return to work and to participating in exercise classes with her friends soon after completing treatment.

Question/item	Answer
Medical clearance	No
Reason	Active
Triage level	Clinically supervised
Reason	Current chemotherapy (lvl 1 side effect)

Case study G: Greg

Greg completed cancer treatment 3 years ago for localized colon cancer. He walks 2 miles every morning before work, and lifts weights at the gym (moderate intensity) twice each week. He has coronary artery disease (CAD) and had a stent put in 5 years ago. He takes Statin daily, but experiences no related symptoms or issues and has no additional *medical diagnoses, signs/symptoms of chronic disease or disability*.

Greg wants to continue to exercise on his own and at the gym so that he can stay healthy and active.

Question/item	Answer
Medical clearance	No
Reason	Active, CVD- medicated
Triage level	Generic or unsupervised
Reason	High exercise self-efficacy

Qualitative themes identified from participant open-ended feedback on EXCEEDS algorithm content and format. A total of 305 discrete comments were identified, thematically coded and analyzed.

Theme 1: Perceived strengths of the EXCEEDS algorithm.

Participants described the content underlying each algorithm domain (i.e., list of risk factors/criteria) and the flow chart format to be major strengths of EXCEEDS. Algorithm content was described as "*comprehensive*" and "*thorough*". Specifically, participants described the organization of content into risk-stratified domains was "*appropriate*", "*clear*", "*logical*" and "*easy to understand/follow*". Many also commented the "*layout*" and "*organization*" of the flow diagram, made it "*visually appealing*", "*intuitive*" and "*easy to use*". Overall, the flowchart was described as a "comprehensive and logical decision tree".

Theme 2: Considerations for implementation

Participants commented on a variety of considerations for implementation of the algorithm — sub-themes include: (1) stakeholder groups most likely to find the tool useful (n=24, 64.9%), (2) features to enhance utility of the existing flowchart (n=22, 23.7%), and (3) ways to clarify algorithm directions for in specific clinical situations (n=12, 12.9%). Many commented that individuals "*not particularly experienced in cancer rehab[ilitation]*" may benefit most from using the tool, including oncology and rehabilitation clinicians. Yet, many noted the tool would be a useful in provider-to-provider or patient-to-provider conversations about exercise. For example, one participant commented: "*I love the idea of showing this to patients and physicians to better help explain when to refer patients to OT/ST/PT*". The addition of four features were suggested to enhance utility of the algorithm: (1) a "*red flag section to warrant follow up with oncologist*"; (2)"*a legend*" to clarify level 1 vs. 2 side effects; (3) definition or examples of each level of supervised exercise (as provided in the study); and (4) "*specific tests/measures*" to evaluate risk factors (e.g., validated assessment tools or scales). Participants commented that directions to use the algorithm in the following circumstances should be clarified: (1) "*when you need to flow back up the algorithm*" (i.e., when a patient becomes higher risk or has greater

specialized need), (2) when specific levels of intervention or cancer-specific clinicians are not available in a geographic area (ex. local cancer-specific rehabilitation therapist unavailable), and (3) *"when cancer treatment details are limited"*.

Theme 3: Areas to consider for revision

Participants commented on five specific areas of the algorithm that warrant consideration for revision, from most to least frequent, the areas include: (1) description of specific risk factors (n=26, (29.9%); (2) readability of risk factors within a domain (n=20, 23.0%); (3) visual aspects of the flow diagram (n=16, 18.4%); (4) domain terminology (n=13, 14.9%); and (5) operational definition of medical clearance (n=11, 29.7%). In general, participants provided feedback that "some definitions/terminology is unclear". Specifically, criteria used to identify presence of "chronic disease", and criteria to differentiate "level l" from "level 2" in the 'functional factors' and 'side effect' domains. Some commented the presentation of risk factors in each domain was challenging because the algorithm and factors were presented as a two-page downloadable PDF in the Delphi study. They suggested adding a "quick reference" list of risk factors on the 1-page flow chart, especially for 'functional factors' and 'side effect' domains which have two distinct levels of factors. Regarding visual aspects of the flow diagram, "some of the arrows and keys were confusing", and participants suggested the following edits to clarify: (1) more clearly elucidate use of symbols via the key, and (2) simplify the number and orientation of arrows in Section 2 (Triage Recommendation). Domain terminology edits were suggested to clarify level 1 vs level 2 for 'side effects' and "functional factors' domains, one participant suggested: "change to something more immediately understandable (mild vs moderate...)". In section 1, few participants suggested updating "medical clearance" language to "medical referral", clarifying the necessity of medical referral for outpatient cancer rehabilitation, and defining the level of clearance needed (i.e., referral vs., evaluation).

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Stakeholder groups and corresponding potential benefits of using the EXCEEDS algorithm in an adapted form, evaluated by participants in Survey #2 of the Delphi study.

Group	Included professions	Potential benefits
Oncology	Medical oncologist	• Reduced time and burden
clinicians and	Surgical oncologist	• Improved knowledge and confidence for
administrators	Radiation oncologist	rehabilitation and exercise recommendations
	• Oncology nurses and nurse	• Evidence-based 'conversation starter' to engage
	navigator	patients
	• Oncology social worker	• Improved workflow
	• Clinical manager and other	• Enhanced continuity of care
	administrators	• Enhanced fulfillment of value-based care
	• Residency mentor and other	survivorship requirements
	educators	
Rehabilitation	Any of the following who have	• Enhanced understanding of safety considerations
clinicians	completed cancer-specific	that indicate medical referral
(cancer-	residency, board certification or	• Improved knowledge and confidence to refer
specialized)	other licensure/certification:	patients to community-based services upon
	• Physiatrist	discharge
	• Rehabilitation Nurse	• Evidence-based 'conversation starter' to engage
	Physical Therapist	patients and support self-monitoring
	Occupation Therapist	• Easy-to-use functional screening tool to evaluate
	• Speech language Pathologist	safety for independent exercise
	• Rehabilitation psychologist	
	• Nutrition	

Exercise	Any of the following who have	•	Enhanced understanding of safety considerations
clinicians	completed cancer-specific training		that indicate medical referral or rehabilitation
(cancer-	and/or certification:		evaluation.
specialized)	• Certified/Registered Clinical	•	Improved knowledge and confidence to ensure
	Exercise Physiologist		patient safety and intervention effectiveness in
	• Certified Exercise Physiologist		community-based settings
	• Cancer Exercise Trainer	•	Evidence-based 'conversation-starter' to engage
			patients and support self-monitoring
		•	Easy-to-use functional screening tool to evaluate
			safety for independent exercise
Rehabilitation	Any of the following who do not	•	Enhanced understanding of safety considerations
clinicians	have cancer-specific training or		that indicate medical referral or specialized cancer
(non-cancer	certification:		rehabilitation evaluation
specialized)	• Physiatrist	•	Evidence-based 'conversation starter' to engage
	• Rehabilitation Nurse		patients and support self-monitoring
	• Physical Therapist	•	Easy-to-use functional screening tool for evaluated
	Occupation Therapist		safety for independent exercise
	• Speech language Pathologist		
	• Rehabilitation psychologist		
	• Nutrition		
Exercise	Any of the following who do not	•	Enhanced understanding of safety considerations
clinicians	have cancer-specific training or		that indicate medical referral, rehabilitation
(non-	certification:		evaluation or other specialized care/supervision
cancer	· Certified/Registered Clinical		
specialized)	Exercise Physiologist		

	Certified Exercise Physiologist	•	Improved knowledge and confidence to ensure
	• Athletic trainer		patient safety and intervention effectiveness in
	• Personal trainer		community-based settings
	• Group fitness instructor	•	Evidence-based 'conversation-starter' to engage
			patients and support self-monitoring
		•	Easy-to-use functional screening tool to evaluate
			safety for independent exercise
Cancer	Anyone living with or beyond a	•	Enhanced knowledge of safety considerations that
survivors	cancer diagnosis		warrant evaluation or clearance
		•	Improved confidence to self-monitor for risk
			factors and participate in care decision making
		•	Improve continuity of care between oncology,
			outpatient rehabilitation and exercise service.
		•	Enhanced functioning, exercise self-efficacy,
			activity level, and well-being.
		•	Enhanced knowledge and self-efficacy for self-
			monitoring across the cancer continuum
Researchers	Individuals performing research in	Ev	idence-based and consensus-based guidelines can be
in related	clinical, academic, or industry	use	ed to:
fields	settings. Included but not limited	•	inform inclusion criteria for intervention studies
	to the following fields:	•	provide a common language for supportive care
	• Oncology care (including sub-		needs during treatment and survivorship in
	disciplines)		research literature
	• Cancer survivorship	•	provide a framework for health services research
	• Rehabilitation science		and policy

Occupational science

•

- Exercise science
- Health services and policy

support implementation science research on

clinical practice guideline implementation

Platforms under consideration for adaptation of the	e EXCEEDS algorithm and evaluated by participants
in Survey #2	

Platform	Description and examples	
Open-access	Any publicly accessible website, including those owned and managed by organizations,	
internet	health care systems, universities or fitness centers.	
	Examples:	
	<u>ACSM Move Through Cancer Website</u>	
	• Websites for local outpatient rehabilitation clinics and medical- or gym-based	
	fitness programs (for digital screening and appointment scheduling)	
	• Stand-alone website dedicated to EXCEEDS project (similar to the <u>PAR-Q</u>	
	collaboration website)	
Restricted access	Any web-based location where membership, payment or other conditions are required to	
internet	access.	
	Examples:	
	• <u>NCCN Website</u> (clinical and patient/caregiver resources)	
	• Stand-alone patient portal system (i.e., not integrated with EMR)	
Electronic	Any applications integrated with EMR, EHR and PHR.	
medical record	Examples:	
networks	• Active <u>clinical decision support systems (CDSS)</u> : alert, reminder, corollary orders,	
	and guidelines	
	Passive CDSS	
	• Documentation forms and templates in EMR	
	• Patient portal system integrated with EMR	
	• Patient intake kiosks available in waiting rooms	

Handheld device	Smartphone, tablet or other computer application that must be downloaded from IOS or	
application	Android. Including but not limited to general health and fitness applications and cancer-	
	specific support applications.	
	Top relevant apps in the App/Play Store:	
	· General health and fitness: FitBit®, MyFitnessPall®, Google Fit®, Samsung	
	Health ®	
	· Cancer-specific: Cancer.net Mobile®, BELONG®, Cancer Therapy Advisor®,	
	Breast Cancer Healthline®	
Clinical print	Any printed materials intended to be used as a resource by clinicians and/or	
materials	administrators.	
	• Referral/script pads	
	• Informational brochure, rack card, or other handout	
	• Printed posters to display in waiting rooms and exam rooms	
Patient-facing	Any printed materials intended to be easily understood and used by patients, caregivers	
print materials	or other lay persons.	
	• Stand-alone informational brochure, rack card, or other handout	
	• Printed materials integrated with other diagnosis and treatment information (ex.	
	diagnosis or chemo teach info packet)	

Discrete implementation strategy	Description (Powell et al., 2015)
Capture and share local knowledge	Capture local knowledge from implementation sites/platforms
	on how implementers and clinicians made something work in
	their setting and then share it with other sites
Adapt physical structure	Evaluate current configuration and adapt the physical structure,
	as needed, to best accommodate stakeholder and/or local needs
Model and simulate change	Model or simulate the change that will be implemented prior to
	implementation
Conduct cyclical small tests of	Implement physical adaptations in a cyclical fashion using small
adaptations to physical structure	tests of change before taking changes system-wide. Tests of
	change benefit from systematic measurement, and results of the
	tests of change are studied for insights on how to do better. This
	process continues serially over time, and refinement is added
	with each cycle
Remind clinicians	Develop reminder systems designed to help clinicians to recall
	information and/or prompt them to use the clinical innovation
Stage implementation scale up and	Phase implementation efforts by starting with small pilots or
tailor strategies.	demonstration projects and gradually move to a system wide
	rollout. Tailor the implementation strategies to address barriers
	and leverage facilitators that were identified through earlier data
	collection

Overview of 15 discrete implementation strategies (strategically selected from Powell et al 2015)

Use advisory boards and workgroups	Create and engage a formal group of multiple kinds of
	stakeholders to provide input and advice on implementation
	efforts and to elicit recommendations for improvements
Promote adaptability	Identify the ways a clinical innovation can be tailored to meet
	local needs and clarify which elements of the innovation must be
	maintained to preserve fidelity
Use mass media	Use media to reach large numbers of people to spread the word
	about the clinical innovation
Conduct ongoing training	Plan for and conduct training in the clinical innovation in an
	ongoing way
Develop academic partnerships	Partner with a university or academic unit for the purposes of
	shared training and bringing research skills to an implementation
	project
Develop educational materials	Develop and format manuals, toolkits, and other supporting
	materials in ways that
	make it easier for stakeholders to learn about the innovation and
	for clinicians to
	learn how to deliver the clinical innovation
Develop and organize quality	Develop and organize systems and procedures that monitor
monitoring systems	clinical processes and/or outcomes for the purpose of quality
	assurance and improvement
Facilitate relay of clinical data to	Provide as close to real-time data as possible about key
providers	measures of process/outcomes using integrated modes/channels
	of communication in a way that promotes use of the targeted
	innovation

Identify and prepare champions	Identify and prepare individuals who dedicate themselves to
	supporting, marketing, and driving through an implementation,
	overcoming indifference or resistance that the intervention may
	provoke in an organization

Consensus-	Implementation strategy	Median rank (IQR)	Inter-rater
based rank			agreement, n, %
1	Identify and prepare champions	4.0 (1.25 – 9.25)	60, 78.9 ^a
2	Capture and share local knowledge	5.0 (2.0 - 7.0)	71, 93.4 ^a
3	Develop educational materials	6.0 (4.0 - 11.0)	55, 72.4 ^a
4	Conduct cyclical small tests of adaptations to	6.5 (4.0 -10.0)	60, 78.9 ^a
	physical structure		
5	Stage implementation scale up and tailor	7.0 (3.25 – 10.0)	60, 78.9 ^a
	strategies		
6	Adapt physical structure	7.0 (3.0 – 11.0)	55, 72.4 ^a
7	Use advisory boards and workgroups	7.5 (3.0 – 11.0)	53, 69.7
8	Model and simulate change	8.0 (4.0 - 10.0)	60, 78.9 ^a
9	Conduct ongoing training	8.0 (4.25 - 11.0)	54, 71.1 ^a
10	Remind clinicians	8.0 (5.0 - 12.0)	51, 67.1
11*	Promote adaptability	9.0 (6.0 - 12.0)	48, 63.2
12*	Facilitate relay of clinical data to providers	10.0 (7.0 - 13.75)	42, 55.3
13*	Develop and organize quality monitoring	11.0 (7.0 – 13.0)	33, 43.4
	systems		
14*	Develop academic partnerships	12.0 (5.0 -13.75)	35, 46.1
15*	Use mass media	14.0 (9.25 - 15.0)	23, 30.3

Key implementation strategy results reported as consensus-based rank, median rank, and inter-rater agreement

Note. N = 76. Consensus-based rank determined by average rank in ascending order. Average rank determined from Likert scale item: 1 = most important, to 15 = least important for successful implementation the EXCEEDS algorithm. Inter-rater agreement calculated as the proportion of

participants who ranked the stakeholder group in as a high priority (1-10). *Excluded from prioritization evaluation in Round 3.

^a Consensus achieved, $\geq 70\%$ inter-rater agreement

List of Abbreviations

Abbreviation	Explanation
ASCO	American Society of Clinical Oncology
ACSM	American College of Sports Medicine
ΑΟΤΑ	American Occupational Therapy Association
APTA	American Physical Therapy Association
CRES	Cancer rehabilitation or exercise services
ECOG-PS	Eastern Cooperative Oncology Group Performance Status
EXCEEDS	Exercise in Cancer Evaluation and Decision Support
ICF	International Classification of Functioning, Disability and Health Framework
PAR-Q	Physical Activity Readiness Questionnaire
NCCN	National Comprehensive Cancer Network