Running heading:

Self-management Common Data Elements

Title:

Recommendations of Common Data Elements to Advance the Science of Self-management of Chronic Conditions

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Abstract

Purpose: Common data elements (CDEs) are increasingly being used by researchers to promote data sharing across studies. The purposes of this article are to (a) describe the theoretical, conceptual, and definition issues in the development of a set of CDEs for research addressing self-management of chronic conditions; (b) propose an initial set of CDEs and their measures to advance the science of self-management; and (c) recommend implications for future research and dissemination.
Design and Methods: Between July 2014 and December 2015 the directors of the National Institute of Nursing Research (NINR)-funded P20 and P30 centers of excellence and NINR staff met in a series of telephone calls and a face-to-face NINR-sponsored meeting to select a set of recommended CDEs to be used in self-management research. A list of potential CDEs was developed from examination of common constructs in current self-management frameworks, as well as identification of variables frequently used in studies conducted in the centers of excellence.
Findings: The recommended CDEs include measures of three self-management processes: activation, self-regulation, and self-efficacy for managing chronic conditions, and one measure of a self-management outcome, global health.
Conclusions: The self-management of chronic conditions, which encompasses a considerable number of processes, behaviors, and outcomes across a broad range of chronic conditions, presents several challenges in the identification of a parsimonious set of CDEs. This initial list of recommended CDEs for use in self-management research is provisional in that it is expected that over time it will be refined. Comment and recommended revisions are sought from the research and practice communities.

Clinical Relevance: The use of CDEs can facilitate generalizability of research findings across diverse population and interventions.

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Body of article:

The science of self-management is focused on the need for strategies to help individuals with chronic conditions and their caregivers better understand and manage their illnesses, control their symptoms, and improve their health behaviors (Intercultural Cancer Council, 2011). Self-management encompasses both the maintenance of wellness and the management of chronic conditions (Grady & Gough, 2014). Self-management research, including research supported by the National Institutes of Health (NIH)–National Institute of Nursing Research (NINR), supports the development, testing, translation and dissemination of interventions that help individuals from diverse backgrounds and their families use self-management to live with chronic conditions to improve health outcomes, while reducing the burden for caregivers and the healthcare system.

Use of common data elements (CDEs), which are fundamental logical units of data pertaining to one kind of information that are clearly conceptualized (Warzel et al., 2003), promotes effective leveraging of resources by facilitating data sharing across studies within and across institutions (Cohen, Thompson, Yates, Zimmerman, & Pullen, 2015; Redeker et al., 2015). CDEs facilitate generalizability of research findings across diverse populations and interventions, and their use may reduce the cost and complexity of conducting self-management studies. Researchers in a number of disciplines, including nursing (Cohen et al., 2015; National Cancer Institute, 2014; National Institute of Neurological Diseases and Stroke, 2014; National Institute on Drug Abuse, 2014; Redeker et al., 2015), are increasingly using CDEs. To date, however, CDEs have not been developed or extensively used to support self-management science. The NINR currently supports four exploratory (P20) and six centers of excellence (P30) designed to advance the science of self-management and symptoms (Table 1). This article is a report of the consensus of the NINR Center Directors (July 2014 to August 2015); the purposes are to (a) describe the theoretical, conceptual, and definition issues in the development of a set of CDEs for research addressing self-management of chronic conditions; (b) propose an initial set of CDEs and their measures to advance the science of self-management; and (c) recommend implications for future research and dissemination.

Insert Table 1 about here

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Self-Management Definitions and Frameworks Influencing the Development of Common Data Elements

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Definitions

For the purposes of this article, self-management is considered either or both a process or an outcome. Definitions of self-management have varied widely, but these definitions generally describe processes that are often complex in chronic conditions, usually occur on a daily basis, and require confidence to regulate and take action that result in specific self-management behaviors and health. Definitions have evolved from early definitions by Creer, Renne, and Christian (1976), who described self-management as the patient's ability to actively participate in his or her treatment or care, and Corbin and Strauss (1988), who expanded the definition to include specific content areas such as medical, behavioral, role, or emotional management. More recently, Lorig and Holman (2003) emphasized self-management processes (self-efficacy, skill building, emotional management), and Grey, Schulman-Green, Knafl, and Reynolds (2015) posited that individual and family self-management were interactive in influencing outcomes for chronic conditions.

The terms self-management, self-care, and self-regulation have been used interchangeably, and as a result, the definitions are blurred and often inconsistent. Self-care definitions share similar conceptual overlap with self-management. For example, Levin and Idler (1983) described self-care as "Those activities individuals undertake in promoting their own health, preventing their own disease, and limiting their own illness and restoring their own health without the assistance of a health professional" (p. 181). Lawson, Bundy, Lyne, and Harvey (2004) described the medical perspective of self-care as management of treatment and disease, with specific aspects of care being the responsibility of the patient. Psychologists, on the other hand, have defined self-care in terms of the internal processes of health that include self-concept, health belief, and cognitive behaviors (Penning & Keating, 2000). From a nursing perspective, Orem (McLaughlin Renpenning & Taylor, 2003) described self-care as being either universal (essential demands of daily living that included air, fluids, food, elimination, rest, active, solitude, interactive relationships with others, and protections from hazards) or a health deviation. More recently, Riegel, Dickson, and Faulkner (2015) described a self-care framework in which self-management is a subset of activities within the overarching concept of self-care.

Similarly, the term self-regulation has emerged over the past several decades within the fields of psychology and health. The discipline of psychology definitions of self-regulation have several common elements, including the importance of being goal-directed and changing attitudes and behaviors through supportive mechanisms and deliberate processes (e.g., using problem solving and motivation; Karoly, 1993; Leventhal, Leventhal, & Contrada, 1998). Bandura (2005) expanded the definition of self-regulation by relating the construct to health promotion through self-monitoring of health behaviors and social support.

Self-efficacy is another term closely related to self-management. Bandura (1977) first introduced the term self-efficacy as a critical component of social cognitive theory related to motivation and defined it as the personal judgment of one's capability to organize and to execute a plan of action geared toward attaining a selected goal. He indicated that self-efficacy referred to an individual's performance capabilities and that the levels of self-efficacy were based on the difficulty of a particular task or behavior ranging from the simplistic to the more complex of a selected task. A similar but different concept closely related to self-efficacy is patient activation, the definition

of which also includes one's judgments regarding capability to perform a set of self-management activities, but also includes judgment about skill building and actual execution of those behaviors. Thus, there is some conceptual overlap in the definitions of self-efficacy and patient activation.

Heading level 2:

Self-Management Frameworks

The most frequently used contemporary self-management frameworks are summarized in Table 2. One or more of these frameworks undergird the current NINR-funded self-management centers. Although these frameworks use a variety of terms, they share many commonalities, such as antecedents or predisposing factors or contexts, processes, and outcomes related to the individual's or family's management of the chronic condition. For example, context sometimes comprises risk and protective factors (Ryan & Sawin, 2009), facilitators and barriers (Grey et al., 2015), or sociocultural context (Knafl & Deatrick, 2003). Self-management processes (Grey et al., 2015; Ryan & Sawin, 2009) are also called self-management tasks and core self-management skills (Lorig & Holman, 2003). Processes, tasks, and skills include some actions and factors related to taking actions. Lorig and Holman (2003) use tasks and skills but focus on how individuals apply these in ways that are appropriate for them. Grey et al. (2015) include integration into one's lifestyle, "ownership" of the need, using resources. Ryan and Sawin (2009) include many elements of action taking and regulating or modifying action. Knafl and Deatrick (2003) identify behaviors and approaches ("management styles") that indicate the type of engagement of the parent or family in management and the characteristics that define those engagement styles.

Insert Table 2 about here

Several factors commonly associated with self-management are present in these contemporary frameworks as either context or process. The most common individual-level psychological factors include self-efficacy, attitudes, health beliefs, and perceptions about the severity of chronic condition or risk factors (Grey et al., 2015; Lorig & Holman, 2003; Ryan & Sawin, 2009). Knowledge or skills is another factor known to improve self-management processes and outcomes; however, it is well known that level of knowledge often is not sufficient to translate to the desirable self-management behaviors or outcomes (Dickson & Riegel, 2009). Depressive symptoms are another individual factor that has been shown to influence both the self-management process and self-management outcomes (Chew, Shariff-Ghazali, & Fernandez, 2014). There also are family- or community-level factors that influence self-management, including perceived social support (Graven & Grant, 2014), family support (Kara Kaşıkçı & Alberto, 2007), social isolation (Wada, Akiyama, Takeda, Nakamura, & Takizawa, 2014); neighborhood factors such as food insecurity, safe walking environment, and violence (Merom et al., 2015); and cultural values and practices (Lemacks, Wells, Ilich, & Ralston, 2013). These factors are identified either directly or indirectly in the Grey et al. (2015) and the Ryan and Sawin (2009) frameworks and can be inferred from Lorig and Holman (2003) and Knafl and Deatrick (2003).

Our review of self-management frameworks showed that all included outcomes. In two frameworks (Grey et al., 2015; Ryan & Sawin, 2009), outcomes are categorized as proximal (usually short-term) outcomes, such as self-management behaviors specific to the condition or recommended treatment regimen, or distal (long-term) outcomes, such as health status (Grey et al., 2015; Lorig & Holman, 2003; Ryan & Sawin, 2009) and quality of life (Grey et al., 2015; Ryan & Sawin, 2009). Since these frameworks primarily focus on management of chronic conditions, health status outcomes are often reported as disease- or condition-specific variables such as improvement in HbA1c for people with diabetes. In addition, an improved overall or global health status, sense of well-being, or improved health-related quality of life are also identified distal outcomes of self-management (Grey et al., 2015; Ryan & Sawin, 2009). Utilization of health care and costs are included as outcomes in most frameworks (Grey et al., 2015; Lorig & Holman, 2003; Ryan & Sawin, 2009). Family-specific outcomes are identified in Grey et al. (2015) and Knafl and Deatrick (2003). The mechanisms for achieving the outcomes are portrayed as linear models with potential moderating or mediating factors (Grey et al., 2015; Ryan & Sawin, 2009).

The frameworks propose varied mechanisms of action to achieve self-management behaviors and outcomes. For example, Lorig et al. (1999) have relied heavily on Social Cognitive Theory and self-efficacy, arguing that it is the increase in one's confidence to carry out a given behavior or skill that explains the change in self-management behavior. Others have suggested that motivation—or self-regulation—is a mechanism driving self-management behavior. More recently, patient activation has been shown to be a primary mechanism in the self-management process (Hibbard, Mahoney, Stockard, & Tusler, 2005). In addition, self-management itself can be considered a mechanism for improving health. For example, Grey and colleagues (2013) found support for self-management as a mediator of the relationship between family functioning and depression and HbA1c and quality of life among adolescents with type 1 diabetes.

The work of Lorig and colleagues (Lorig, Ritter, Laurent, & Plant, 2006; Lorig, Sobel, Ritter, Laurent, & Hobbs, 2001; Lorig et al., 1999) illustrates an approach to self-management of chronic illness more broadly through their Chronic Disease Self-Management Program. By focusing on processes or mechanisms, in this instance, self-efficacy and problem solving, decision-making and confidence building, these authors do not limit self-management to a specific condition or population, but rather view overall health status as the major outcome of chronic illness self-management. Although not all centers use the same unifying framework, there were sufficient commonalities across the self-management perspectives to identify elements that were deemed important and were common to all centers.

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Process to Develop Common Data Elements for Self-Management Science

We developed a systematic process for choosing CDEs for use in self-management research by following the best practices outlined in previous work done by the P20 and P30 center directors (Redeker et al., 2015). Our process started in July 2014 with a series of monthly conference calls among center directors and NINR staff. Within each

NINR-funded center, investigators had developed common measures that each pilot project was using in order to harmonize data across center studies. These measures are internal to each self-management and symptom center. Each center has a different focus (see Table 1), making the list of measures diverse and quite lengthy. The iterative process began with an initial list of over 80 measures that were used across centers and considered possible candidate self-management CDEs, duplicates were removed, and a list of 50 was agreed upon in preparation for the annual Center Directors meeting in May 2015. During this meeting the Directors held discussions, using a consensus process, to work through a theoretical analysis of self-management with the aim to develop conceptual consistency between chosen data elements, measures of the concepts, and self-management theoretical positions. At the 2015 meeting, Directors divided into small working groups to delve into issues related to operationalization of three areas of self-management science: outcomes associated with self-management, basic self-management behaviors and processes, and mediators and moderators of self-management. Each working group produced a draft list of concepts, variables, and measures, and this list was further reduced during a series of cross-center telephone conference calls after the annual meeting. Criteria used to make the selection of the initial set of four recommended CDEs included parsimony, cost, subject burden, potential for use across different chronic conditions, and consistency with measures from the symptom science CDEs (Redeker et al., 2015).

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Recommended Common Data Elements for Use in Self-Management Studies

The list of proposed CDEs, their recommended measures for use in self-management studies, and information of where to access the measures is provided in Table 3. Although a lengthy list of possible candidate CDEs was originally considered, it was decided to limit the number of recommended CDEs to only a few. With the recent development of the CDEs for symptom science, we realized that the total set of CDEs for nursing science potentially could be quite large. In general, the acceptance and use of CDEs by researchers in a scientific field is more successful if the list of recommended CDEs is parsimonious (Redeker et al., 2015); thus, we decided to constrain our proposed CDEs for self-management science to four CDEs that are frequently used in self-management studies across multiple populations and chronic conditions and where expanded use of these measures has the potential to advance self-management science. The CDEs selected represent core constructs across existing self-management frameworks. All measures selected have good psychometric properties and have been used in multiple adult populations. The recommended CDEs include measures of three self-management processes: activation, self-regulation, and self-efficacy for managing chronic conditions, and one measure of a self-management outcome, global health.

Insert Table 3 about here

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Activation

Activation is a recommended CDE because it includes the broad range of elements involved in self-management, including the knowledge, skills, beliefs, and behaviors that a person needs to manage a chronic illness (Hibbard et al., 2005; Hibbard, Stockard, Mahoney, & Tusler, 2004). Activated individuals also have better health outcomes and lower rates of emergency department use and hospitalizations (Hibbard et al., 2005). We recommend that activation be measured using the 10-item Patient Activation Measure® (PAM®; Hibbard et al., 2004), a self-report scale that predicts self-management behaviors, including self-monitoring, goal setting, medication management, health information seeking, and healthy living behaviors (e.g., healthy diet and being physically active). A total score can be obtained using the PAM® and it also can be used to segment people into one of four progressively higher levels of activation. Advantages of the PAM® include its applicability across a broad range of chronic conditions, its availability in multiple languages, and the availability of a version to assess caregiver activation. There currently is not a version for assessment of activation in children. A major limitation of the PAM® is that there is a cost for its use in large studies. For healthcare researchers, however, it can be obtained at a reduced fee for use in large studies, and there is no fee for use in studies of less than 250 unique participants (with a signed agreement). Permission to use the PAM® must be obtained exclusively at Insignia Health® located in Portland, OR (see Table 3).

Heading level 2:

Self-Regulation

Another recommended CDE for self-management research is self-regulation. Although there are numerous definitions and measures of self-regulation in the literature, we selected the Index of Self-regulation (IRS; Fleury, 1998; Yeom, Choi, Belyea, & Fleury, 2011) because it assesses an individual's effort to make behavioral changes and modulate thoughts, emotions, and behaviors to achieve goals. The IRS can be used to assess general behavior change or specific changes. This nine-item self-report scale has been tested across several populations and is available in Spanish. There currently is not a version for assessment of self-regulation in children.

Heading level 2:

Self-Efficacy for Managing Chronic Conditions

Although numerous instruments exist to assess self-efficacy for specific self-management behaviors (e.g., self-efficacy for exercise; self-efficacy for medication adherence), we recommend that studies of

the self-management of chronic illness include a measure that addresses the management of chronic conditions in general, the Self-efficacy for Managing Chronic Illnesses Scale (Lorig et al., 2001). This brief, six-item self-report measure can be used in addition to a measure of self-efficacy specific to a condition or behavior (e.g., self-efficacy for healthy living behaviors in persons with human immunodeficiency virus infection). Thus, with little increased subject burden, the role of self-efficacy in self-management studies can be assessed across studies of adult populations and numerous chronic conditions. The Self-efficacy for Managing Chronic Illnesses Scale is available in numerous languages and has been used in studies of numerous cultural groups and chronic conditions (Lorig et al., 2001). It has not been used with children.

Heading level 2:

Global Health

The recommended CDE outcome measure for self-management research is global health as measured by the Patient Reported Outcomes Measurement Information System (PROMIS) Global Health short form. This 10-item instrument assesses an individual's perception of health over the past 7 days in multiple domains. Measures of both global physical health and global mental health are obtained. Similar to other PROMIS measures, it can be administered and scored electronically if desired. Another advantage of using this PROMIS measure is that it is widely used across scientific disciplines. It is recommended for use only in adults.

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Relationship Between Common Data Elements for Self-Management and Common Data Elements for Symptom Management

As the NINR Center Directors represented both self-management and symptom management centers, it was quickly acknowledged that the constructs of self-management and symptom management have overlapping, complementary, and synergistic attributes and processes that would be helpful to consider in identifying and using self-management CDEs. Specifically, symptom management can be conceptualized as a task of self-management (part of the process; Grady & Gough, 2014; Ryan & Sawin, 2009), as a moderator of the self-management process (Disler, Gallagher, & Davidson, 2012), or even as an outcome (Grey et al., 2015).

Chronic symptoms are prevalent in people with chronic conditions. Symptoms can occur that are signs of progression or exacerbation of a health condition, side-effects of treatment, or chronic effects of a health condition and its treatment (e.g., cancer, chronic obstructive pulmonary disease). The relationship between symptom management and self-management can change depending on their respective roles. One example of symptom management as a critical task in the process of self-management can be illustrated in people with chronic heart failure. Changes in the severity of dyspnea or fatigue (key symptoms) often herald the need for self-management regarding adherence to medication regimens and management of fluids and sodium, which then directly improve the management of the disease.

On the other hand, when the disease is not active but long-term symptoms persist as a sequelae of the disease, such as cancer-related fatigue in long-term survivors, the self-management of the specific symptom may be the objective. For example, fatigue can be a long-term symptom resulting from cancer treatment, being present in some survivors up to 10 years after anticancer therapy (Bower et al., 2006). Learning to monitor fatigue levels, understand the context in which fatigue is exacerbated, increase activity, and practice energy conservation strategies when needed can reduce fatigue levels (Barsevick et al., 2004). In this instance, self-management may be the mediator through which fatigue is lessened.

Finally, symptoms can moderate the ability of a client to successfully self-manage. In diabetes mellitus, a goal of self-management is diet and exercise to keep insulin and glucose well balanced and improve circulation. Sleep disturbance or pain could negatively impact a person's ability to exercise, either because of being in too much pain or too sleepy to engage in exercise behavior. In this example, successful management of the symptom (pain or sleep) could then lead to the ability to exercise and thereby keep the diabetes mellitus appropriately controlled.

Given the complex but intertwined relationships among symptoms, symptom management, and self-management, improved understanding of the concepts and mechanisms underlying self-management (e.g., self-efficacy, motivation, activation, self-regulation) through careful use and selection of self-management CDEs is likely to enhance understanding of symptom management. A broad view of self-management and its interrelationships with symptom management will provide a more comprehensive approach than a singular focus on self-management without considering the role of symptoms (and vice versa).

When evaluating behavioral interventions to improve symptom management, understanding adherence to the behavior and reasons for lack of adherence to the behavior can provide insight into how an intervention may be working, or if not found to be effective, why it may not have been helpful. Concepts related to self-management would contribute to understanding behavior adherence. Also, symptoms can affect the ability to self-manage. For examples, fatigue, sleep disturbance, and cognitive dysfunction may influence the ability to self-manage. Therefore, the use of a parsimonious list of CDEs from both self-management and symptom management fields can advance both fields.

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Implications for Future Research and Dissemination

Several considerations should be taken into account in the future use of these recommended CDEs for self-management research. First is the context in which these recommendations were formulated. As described, the selection of the CDEs was done by the directors of the NINR-funded self-management and symptom management centers. Each of these centers has a different self-management or symptom management research focus (see Table 1) and currently uses its own set of CDEs. Thus, the full range of possible CDEs for self-management research may not be represented in this recommended list. Although the existing literature on self-management is well known by this group of center directors, it may be that representation on the development team of

more and different types of self-management research foci may have resulted in a different set of CDEs. This list of CDEs is considered provisional in that it is expected that over time the list will be refined by the larger self-management scientific and practice communities. To facilitate this "vetting" process, a series of sessions have been convened at upcoming regional and will be presented at national nursing research conferences to share the recommended CDEs and invite comments from the nursing research and practice communities. The vetting and revision activities of a CDE set, however, are an ongoing process in which multiple venues for comment and recommended revisions are sought from the scientific and practice communities.

Another important consideration as investigators begin to use the CDEs is the limitations in their conceptual and practical applications. Consistent with the literature, we are aware that there is some conceptual overlap among the three self-management process CDEs (activation, self-regulation, and self-efficacy for managing chronic illness). We decided, however, that each of these three variables represents sufficiently different and important dimensions of self-management processes. There also were other constructs associated with self-management that were considered but are not included on this list, such as patient use of and reliance on healthcare services and the predisposing factors influencing self-management. We also did not include CDEs and measures for specific self-management behaviors, such as exercise, eating behaviors, and medication taking. This was primarily because the goal was to recommend a set of CDEs that could be used across a wide range of self-management studies addressing different populations, chronic conditions, and behavioral targets. It is noted that our focus in this set of CDEs is on the self-management of chronic illness and does not take into full account the self-management of wellness promotion. There is likely a considerable overlap in a set of CDEs for self-management of chronic illness and CDEs for self-management of wellness promotion. The focus to develop the CDEs for self-management of wellness may be a next step in the advancement of the use of CDEs for self-management science. Lastly, biologic markers of self-management are not included in this initial set of proposed CDEs. This is in part because of the current lack of knowledge about common biological markers of self-management, as well as our decision to limit ourselves to only four CDEs. The development of biological CDEs for self-management research is an important area for future development of CDEs to advance the science of self-management.

To date, measures of the CDEs selected have not been designed for use with children. Given the need for the development of self-management skills in children with chronic conditions, CDEs of relevant constructs of self-management in children are needed. In addition to their usefulness in different age groups, a general limitation of the CDEs is a lack of information about their appropriateness for use in studies of different cultures, ethnic or racial groups, and sexual identities.

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Summary and Conclusions

The use of CDEs in self-management research can advance the science of self-management in several ways. The use of common

constructs and their measures in self-management research studies can facilitate data sharing across studies and increase generalizability of research findings across diverse populations and interventions. Their use may reduce the cost of conducting self-management studies as well as speed up knowledge production. The four recommended CDEs for self-management research (activation, self-regulation, self-efficacy for managing chronic conditions, and global health) described herein represent a first step in the design and use of CDEs for self-management research. Several steps and processes in the development and subsequent use of a final set of CDEs are yet to be completed. Next steps include submitting the CDEs for public review and then revising the CDEs based on the feedback from this review, education of nursing scientists regarding their use, and developing protocols for CDE collection, use, and management. The availability of infrastructure to support CDE use, including a national data repository for sharing study data that includes the CDEs and links to other CDEs developed in other institutes at the NIH, is needed. These recommendations, therefore, include a call to action from the nursing scientist community to use, add to, and help refine the proposed CDEs for self-management of chronic conditions.

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Clinical Resources[JC3]

- Available common data elements. https://www.ninr.nih.gov/researchandfunding/available-cdes# (includes progress of the National Institute of Nursing Research to develop a set of common data elements for use in nursing research)
- Common data elements for use in neuroscience clinical research. https://commondataelements.ninds.nih.gov
- National Collaborative on Childhood Obesity Research measures registry. http://tools.nccor.org/measures/ (a registry of dietary behavior and physical activity measures suggested by the National Collaborative on Childhood Obesity Research)
- PROMIS: Dynamic tools to measure health outcomes from the patient perspective. http://www.nihpromis.org (a system of item banks measuring patient-reported health status for various domains of physical, mental, and social health across clinical populations; i.e., not disease-specific)
- Summary table for National Institutes of Health common data element tools and resources. https://www.nlm.nih.gov/cde

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