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Developing the Language and Tools to Address Food Insecurity

Submitted to the Faculty
Yale University School of Nursing

In Partial Fulfillment
of the Requirements for the Degree
Doctor of Nursing Practice

Sarah C. DeSilvey

March 31, 2020

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This DNP Project is accepted in partial fulfillment of the requirements for the degree
Doctor of Nursing Practice.

Dr Jane K Dixon

Date here March 31, 2020

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Signed:

March 31, 2020

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This work is principally dedicated to my kids,
my ethical copilots in everything.

Second, deep thanks to my wonderful advisor, Dr Jane Dixon.

Lastly, to the friends and colleagues who made the Gravity Project happen;

May the good work continue.

Abstract

There is vast literature indicating associations of food insecurity with concerning health outcomes, and clinic and community settings now regularly partner to address food insecurity as it is assessed. However, there is scarce health terminology to use in the care of patients experiencing food insecurity. This presents challenges as clinicians seek to define food insecurity as a risk for their patients, order interventions to address it, and study the effect of interventions in individual and population settings. Furthermore, there is no published food insecurity diagnostic criteria to employ as clinicians listen to the histories of their patients and try to support them in being well. This project endeavored to complete three aims: apply for ICD-10-CM terminology for food insecurity and related health concerns, apply for SNOMED CT terminology for key interventions, and forge initial considerations for a food insecurity diagnostic criteria. The author initially proceeded independently, but their efforts soon became embedded in the national consensus social determinant of health (SDOH) data initiative, the Gravity Project. The author served as one of two food insecurity subject matter experts. The Gravity Project worked collaboratively with data standard organizations to identify a comprehensive data set of 24 screening tools, six goals of care, eight diagnoses, and 109 interventions. In tandem, the author worked with key national content experts to develop diagnostic criteria considerations and a pathway for criteria development.

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List of Common Abbreviations

AAP- American Academy of Pediatrics

AAFP- American Academy of Family Physicians

ANA- American Nurses Association

CDC- Centers for Disease Control and Prevention

EHR- Electronic Health Record

FRAC- Food Research & Action Center

ICD-10-CM- International Statistical Classification of Diseases and Related Health Problems,
10th Edition, Clinical Modification

NCHS- National Center for Health Statistics

NHIS- National Health Interview Survey

NLM- National Library of Medicine

USDA- United States Department of Agriculture

SIREN- Social Intervention and Research and Evaluation Network

SNAP- Supplemental Nutrition Assistance Program

SNOMED CT- Systematized Nomenclature of Medicine Clinical Terms

Chapter One: Introduction and Statement of the Problem

Introduction

It is estimated that greater than 37 million Americans live in food insecure households (Coleman-Jensen, Rabbitt, Gregory, & Singh, 2019). Over the last decades there has been a proliferation of literature on the health risks and diagnoses associated with food insecurity. Food insecurity is associated with poorer reported health status in adults (Alvarez, Lantz, Sharac, & Shin, 2015), caregivers (Cook et al., 2013), children (Cook et al., 2004), and disabled adults (Brucker, 2017). It is associated with maternal and adolescent mental health concerns (Alaimo, Olson, & Frongillo, 2001; Casey et al., 2004; Whitaker, Phillips, & Orzol, 2006) and adolescent suicidality (Alaimo, Olson, & Frongillo, 2002). A recent study from the United States Department of Agriculture (USDA) demonstrated that, even when poverty is controlled, food insecurity has increased associations with each of the Center for Disease Control and Prevention (CDC) top 10 diseases of concern (hypertension/high blood pressure, coronary heart disease (CHD), hepatitis, stroke, cancer, asthma, arthritis, chronic obstructive pulmonary disease (COPD), chronic kidney disease, and diabetes) (Gregory & Coleman-Jensen, 2017). Furthermore, food insecurity is estimated to be associated with additional individual health costs of more than \$1,800 a year per person (Berkowitz, Basu, Meigs, & Seligman, 2017).

Armed with these statistics, United States (US) professional organizations and government agencies have drafted policy, ethical, and practical guidelines for addressing food insecurity in clinical practice. The American Academy of Pediatrics (AAP), and the Academy of Nutrition and Dietetics each have policy statements on the significance of food insecurity assessment (American Academy of Pediatrics, 2015; Holben & Marshall, 2017). In their *Code of Ethics for Nurses*, the American Nurses Association (ANA) states that food security is a facet of

“health as a human right” (American Nurses Association, 2015, p. 31), and nurses have an ethical obligation to address food insecurity (American Nurses Association, 2015). Assessment of food insecurity is further detailed in clinical recommendations by major provider organizations such as the recently updated AAP Bright Futures Guidelines (Hagan & Shaw, 2017), an AAP authored food insecurity toolkit (American Academy of Pediatrics & Food Research and Action Center, 2017) and the recent release of the American Academy of Family Physicians (AAFP) “Everyone Project” which includes valid food insecurity screening (American Academy of Family Physicians, 2018). Food insecurity screening and assessment was also chosen as a key facet of the Center for Medicaid and Medicare Services Accountable Health Communities project (Center for Medicare & Medicaid Services, 2018).

Furthermore, in line with the National Quality Strategy (Agency for Healthcare Research and Quality, 2017) and goals for population health, states and health systems are taking population health approaches to address food insecurity. In 2016 the Oregon Health Authority, in partnership with the state primary care organization, chose food insecurity screening as a clinical priority (Oregon Primary Care Organization, 2017). In Vermont, addressing food insecurity is now part of statewide maternal and child health initiatives (State of Vermont, 2017) and health system community health needs assessment (University of Vermont Medical Center, 2017). Lastly, in 2018 North Carolina launched a universal social risk screening program, including food insecurity screening, to broad acclaim (North Carolina Department of Health and Human Services [NCDHHS,] 2018).

Concerns to be Addressed

Despite the widely recognized need to assess and address food insecurity, there are several concerns that complicate clinicians' ability to care well for patients with food insecurity within the principles of evidenced based, precise care.

The standard of evidenced based care.***Lack of consistent, valid measurement.***

The validity of food insecurity screening instruments in US practice is based upon the gold standard USDA Food Security Module (United States Department of Agriculture, 2017d). Although there are select brief validated tools for food insecurity assessment used in US clinical practice (Hager et al., 2010; Kleinman et al.; Lane, Dubowitz, Feigelman, & Poole, 2014), they do not cover the full operational definition of food insecurity of the USDA tool: worry about and/or actually not having enough money for food, and an ensuing effect on the “quality, variety or quantity” (United States Department of Agriculture, 2017a, p. para 2) of food. Furthermore, there are many widely distributed tools that are not validated and still aim to screen for food insecurity (National Association of Community Health Centers, 2017). In other instances the USDA Food Security Module answers (“often true, sometimes true...”) have been adapted to “yes, no” in the name of brevity (Pediatrics, 2015; NCDHHS, 2018) but this detracts from sensitivity (Makelarski, Abramsohn, Benjamin, Du, & Lindau, 2017). The use of non-validated or low sensitivity screening instruments limits the ability to accurately screen for food insecurity and assess our interventions within the context of the literature. Developing the scientific base of social needs screening through psychometrics has been identified as a key challenge in national social determinant strategy (National Alliance to Impact the Social Determinants of Health, n.d.)

Furthermore, the development and dissemination of invalid and incomplete tools to assess food insecurity reveals a unique bias. Clinicians would not be content to use invalid tool to screen for diabetes. Clinicians would not be content if a mental health screen missed a swath of clinical depression. The same rigor must apply to social concerns. Employing valid tools to identify food insecure patients is both a scientific requirement and a moral requirement; we must correctly identify patients that might need further care.

Lack of diagnostic criteria.

The correct identification of patients with food insecurity is further complicated by the lack of clear disseminated diagnostic criteria. In the evidence-based practice of health care, the clinician marries information from screening and patient history and exam within the diagnostic process to create a final assessment. Without diagnostic criteria to give conceptual framing to food insecurity assessment, it is difficult to clearly interpret screening outcomes, or simply listen to patient story, and define the concern of food insecurity in a manner that is consistent and equivalent across settings (National & Academies of Sciences Engineering and Medicine, 2015).

The standard of precision in care.

The national health focus on food insecurity is set within an era where caring with precision requires discrete language. In the age of the electronic storing and transfer of health information, if we cannot name the concern of food insecurity and define our interventions, we cannot easily document, follow and collaborate on the care of food insecure patients. This limits our ability to care for patients over time, to share care of patients with other practitioners, to care for whole populations, and to study the outcomes of our interventions.

Lack of diagnostic language.

The primary language for diagnoses in US clinical practice is the International Statistical Classification of Diseases, 10th Edition, Clinical Modification (ICD-10-CM) (Center for Disease Control and Prevention National Center for Healthcare Statistics, 2017). The encoded ICD-10-CM diagnoses are used to represent diagnoses in all claims driven quality analysis for private and federal insurers, accountable care organizations, and health systems. However, although food insecurity is a concept with clear operational and conceptual definitions affecting 11.1% of US households, we do not have clear ICD-10-CM language to represent this concern (DeSilvey et al., 2018; World Health Organization, 2016).

The current ICD-10-CM assessment language used for food insecurity is *Z59.4 Lack of adequate food and safe drinking water*. It does not convey the socioeconomic root of food insecurity. It couples water and food adequacy into one concept, blurring both. It also does not convey the worry that is part of the food insecurity continuum and the source of much of its associations with poor mental health (United States Department of Agriculture, 2017a). Thus, it does not clearly represent the concern of food insecurity as it is conceptually and operationally defined (United States Department of Agriculture, 2017a).

Again, this lack of clarity is unique to social concerns. The recent update to ICD-10-CM was largely an evolution of precision (World Health Organization, 2016). Diabetes is now divided into its subtypes and refined by stating the presence of complications. Cellulitis is defined by its location. Pneumonia is defined by the pathogen (World Health Organization, 2016). The intent of the 10th revision of ICD was to foster clarity- clarity in laterality, origins, stages of healing. However, it left largely unaddressed concepts within the economic social determinants of health, including food insecurity.

Lack of intervention language.

Lack of clarity in diagnosis is further complicated by the inability to represent many of the US interventions for food insecurity within clinical practice. Clinicians currently cannot document the presence of common food resources such as food prescriptions, the Supplemental Nutrition Assistance Program (SNAP), or the Women Infants and Children's (WIC) program. Although clinicians can specify counseling for many concerns, there is no encoded language for counseling for socioeconomic factors. Clinicians are unable to clearly and discretely name the common interventions that originate in the clinical setting. This further complicates the ability to care with clarity and precision and share this care across settings (DeSilvey et al., 2018; World Health Organization, 2016).

The Problem in Summary

The clinical significance of food insecurity is clear, and there is broad professional and even federal consensus that addressing food insecurity is important for health. However, there is no specific encoded assessment language for food insecurity within claims. There are few intervention codes to define the ways providers address food insecurity in US health care. And, even with a professional requirement for evidenced based assessment, there are no published diagnostic criteria to ground food insecurity assessment in the presence of either validated or even non-validated screens. Each of these concerns complicate our ability to care for patients, to share our care across settings, and to study the effects of our care in population research and quality analysis.

Chapter Two: Background and Aims

Contextual Background

Food insecurity definitions and tools.

Understanding the problem, setting, and literature requires a brief review of the definitions and prevalence of food insecurity and food insecurity severity within households. Food insecurity is defined by the USDA as economically or socially driven “limited or uncertain availability of nutritionally adequate and safe foods or limited or uncertain ability to acquire acceptable foods in socially acceptable ways” (Bickel, Nord, Price, Hamilton, & Cook, 2000).

In US practice, the gold standard for food insecurity conceptual and operational definition has been established by expert consensus to be the USDA Food Security Module. The Food Security Modules contain adult 6-item and 10 item tools (United States Department of Agriculture, 2012a), a longer 18-item household with children tool (United States Department of Agriculture, 2012b), and a tool adapted for use in adolescent populations (Connell, Nord, Lofton, & Yadrick, 2004). A continuum of food security status ensues from the modules and within the USDA conceptual definition- from food security, to mild, moderate, and severe food insecurity- as reports of worry devolve into reports of effect on food quality and finally effects on quantity and missed or skipped meals. Note, the operational definition for the modules are crafted for the purposes of the Current Population Survey. They state that two positive answers are an outcome of marginal food security not food insecurity. However, in conceptual discussions of food insecurity any question indicating worry to effect on quantity places one on the food insecurity spectrum. (See Table 1).

Table 1: USDA Definitions of Food Security Status

Two-category food insecurity status	Food secure		Food insecure	
Four-category food insecurity status	High food security Households have no problems or anxiety about consistently accessing adequate food	Marginal food security Households had problems, at times, or anxiety about acquiring adequate food, but the quality, variety, and quantity of their food intake were not substantially reduced.	Low food security At times households reduce the quality, variety, and desirability of their diets due to a lack of resources for food, but the quantity of food intake and normal eating patterns were not substantially disrupted.	Very low food security At times eating patterns of one or more household members were disrupted and food intake reduced because the household lacked money and other resources for food.
Number of Module Questions Answered Positive	<i>none</i>	<i>1-2</i>	<i>3 or more</i>	
Severity of food insecurity	Less severe -----> More severe			

(Gregory & Coleman-Jensen, 2017, p. 2)

To make clinical assessment more efficient, over the last 10 years a few brief screens have been validated for use in clinical practice. The most common is the 2-item Hunger Vital Sign™ (HVS™). It consists of the first two questions of the USDA module and thus includes questions of worry about not having enough food, and food not lasting and there is no money to buy more. (See Table 2 for a detailing of the full 18-item USDA module and how it relates to the 6-item short form of the module and the Hunger Vital Sign™.) The one item Kleinman et al.

(2007) tool asks about experiences of hunger in the past month. The SEEK tool utilizes the first “worry” question of the USDA module and Hunger Vital Sign™ but with “yes/no” answers as opposed to the “often true/sometimes true/never true/don’t know, refused” of the USDA module. The sensitivity of the SEEK tool, when compared to the gold standard USDA module, is only 59%. Concepts of food insecurity are also addressed through non-validated questions about economically driven food access (Jernigan et al., 2017; National Association of Community Health Centers, 2017).

Table 2: The USDA Food Security Modules and the Hunger Vital Sign™

USDA 18-item Food Security Module Adult and Household Questions	USDA 6-item	HVS™
“We worried whether our food would run out before we got money to buy more.” Was that often, sometimes, or never true for you in the last 12 months?		✓
“The food that we bought just didn’t last and we didn’t have money to get more.” Was that often, sometimes, or never true for you in the last 12 months?	✓	✓
“We couldn’t afford to eat balanced meals.” Was that often, sometimes, or never true for you in the last 12 months?	✓	
In the last 12 months, did you or other adults in the household ever cut the size of your meals or skip meals because there wasn’t enough money for food? (Yes/No	✓	
(If yes to question 4) How often did this happen—almost every month, some months but not every month, or in only 1 or 2 months?	✓	
In the last 12 months, did you ever eat less than you felt you should because there wasn’t enough money for food? (Yes/No)	✓	

In the last 12 months, were you ever hungry, but didn't eat because there wasn't enough money for food? (Yes/No)	✓	
In the last 12 months, did you lose weight because there wasn't enough money for food? (Yes/No)		
In the last 12 months did you or other adults in your household ever not eat for a whole day because there wasn't enough money for food? (Yes/No)		
(If yes to question 9) How often did this happen—almost every month, some months but not every month, or in only 1 or 2 months?		
USDA 18-item Food Security Module Child Questions Age 0-17		
“We relied on only a few kinds of low-cost food to feed our children because we were running out of money to buy food.” Was that often, sometimes, or never true for you in the last 12 months?		
“We couldn't feed our children a balanced meal, because we couldn't afford that.” Was that often, sometimes, or never true for you in the last 12 months?		
“The children were not eating enough because we just couldn't afford enough food.” Was that often, sometimes, or never true for you in the last 12 months?		
In the last 12 months, did you ever cut the size of any of the children's meals because there wasn't enough money for food? (Yes/No)		
In the last 12 months, were the children ever hungry but you just couldn't afford more food? (Yes/No)		
In the last 12 months, did any of the children ever skip a meal because there wasn't enough money for food? (Yes/No)		
(If yes to question 16) How often did this happen—almost every month, some months but not every month, or in only 1 or 2 months?		

In the last 12 months, did any of the children ever not eat for a whole day because there wasn't enough money for food? (Yes/No)		
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Food insecurity prevalence and patterns.

Every year the USDA publishes a report on the state of food insecurity in the US the year prior based on data from administration of the full 18-item Food Security Module in a December supplement of the monthly Current Population Survey (Coleman-Jensen, Rabbitt, Gregory, & Singh, 2019; United States Census Bureau, 2015, 2018; United States Department of Agriculture, 2017c). In the most recent report (for year 2018), more than 37 million Americans were estimated to be food insecure. There are a few important food insecurity trends detailed in this report to consider in the presentation of the problem and in the ensuing analysis of the literature. In food insecure households, children are often spared direct food insecurity themselves by caregivers sacrificing their own intake; thus, when children are personally food insecure it is largely indicative of more severe food insecurity of the household. There are markedly increased rates of food insecurity in African American and Hispanic households compared to Caucasian households (21.2%, 16.2% and 8.1%, respectively). Lastly, rates of food insecurity in single female and single male parent households are significantly higher than in dual parent households (27.8%, 15.9%, and 8.3% respectively) (Coleman-Jensen et al., 2019).

United States assessment and intervention terminology.

The problem at hand is in part a problem of language. To understand the context, it is important to discuss briefly the primary terminologies used in US clinical practice. Although there are many terminologies employed in US healthcare, there are two primary sets of encoded language that apply to addressing food insecurity: the International Statistical Classification of

Diseases and Related Problems, 10th Revision (ICD-10), and the Systematized Nomenclature of Medicine- Clinical Terms (SNOMED CT).

ICD-10 is an international product of the WHO. In the US it is modified by a division of the Center for Disease Control and Prevention (CDC) called the National Center for Health Statistics (NCHS) into a clinical modification called International Classification of Diseases, 10th revision, Clinical Modification, (ICD-10-CM) (Center for Disease Control and Prevention National Center for Healthcare Statistics, 2017; National Library of Medicine, 2017). ICD-10-CM is principally a terminology of assessment. It is used to establish and refine diagnoses, the causes of injury, counsel, and factors that influence health (such as body mass index or social risks).

SNOMED CT are a product of an international non-profit called SNOMED International, licensed in the US by the National Library of Medicine (NLM). The full SNOMED CT terminology set includes a broad range of codes that cover nearly all aspects of health care including screening, diagnosis, intervention, pathogen, environments of care, elements of patient and family history, and parts of the body (National Library of Medicine, 2017). Within the US, SNOMED CT are primarily seen in their assessment role as correlates of ICD-10-CM in a section of the EHR called the problem list as part of meaningful health record use (National Library of Medicine, 2017; SNOMED International, 2017a).

Although some US EHRs allow clinicians to assess with SNOMED CT as part of problem-based assessment, ICD-10-CM are still the most broadly employed diagnostic set of codes. ICD-10-CM are, furthermore, the only set employed in US claims to define the diagnoses driving referrals and orders and justify billing (Center for Disease Control and Prevention

National Center for Healthcare Statistics, 2017). As diagnoses in the e-bill, ICD-10-CM are used for claims-based analysis of quality and population health.

Interventions to address health problems classically fall into three categories: referrals to specialists; orders (such as prescription of medications or in office therapies;) and counseling. Each of these common interventions are encoded in a set terminology. Prescriptions of medications in the US are encoded with a set called RxNorm (U.S. National Library of Medicine, 2012). Billable orders are encoded with codes defined by the American Medical Association called Current Procedural Terminology (CPT®) (American Medical Association, 2018). The interventions for food insecurity, such as SNAP, home-delivered meals, or food prescription do not fall into one of these pre-existing terminologies. However, SNOMED CT terminology can be employed to create discrete terms (DeSilvey et al., 2018; SNOMED International, 2017a).

A brief review of the role of diagnostic criteria.

In *Improving Diagnosis in Health Care* the Committee on Diagnostic Error in Health Care detail the role of criteria, within the diagnostic process, for establishing clear diagnoses and appropriate intervention (National & Academies of Sciences Engineering and Medicine, 2015). In health care, across the spectrum, clinicians employ criteria crafted by content experts, to ensure that the core commonly defined elements of a condition are met. There are criteria that are composed of laboratory results, such as the diagnostic criteria for diabetes (American Diabetes Association, 2018). Hypertension and its stages are defined by specific results of vital signs (James, Oparil, Carter, & et al., 2014). Criteria can also be based on patient history taking such as those for mental and behavioral health (American Psychiatric Association, 2013) and the functional bowel disorders (The Rome Foundation, 2006).

Clinicians use criteria to establish equivalence across settings. By establishing and following clear criteria it is ensured, as much as possible, that the named condition (ex. diabetes, hypertension, depression, or irritable bowel syndrome) is similar in meaning and measurement across settings regardless of the observer. However, although the USDA has a clear definition for food insecurity, there is no diagnostic criteria. This means concepts of financial strain can be interpreted as food insecurity as with the CARDIA screen (Vijayaraghavan et al., 2013), and desiring food resources can be considered food insecurity as with the We Care tool (Garg, Toy, Tripodis, Silverstein, & Freeman, 2015).

A Review of the Literature

The purpose of the literature review was to demonstrate the clinical significance of food insecurity, and to detail existing assessment language within clinical practice. If there is sufficient evidence that food insecurity has clinical significance, this supports the need for specific clinical language to assess and address food insecurity, to aid in diagnosis, patient and population management, and research. Furthermore, a body of evidence detailing the clinical significance of food insecurity solidifies the needs for clear diagnostic criteria to create equivalent diagnosis across settings.

Method for searching the literature for evidence.

There were two domains of literature review. The first search was for associations between food insecurity and health and utilization outcomes. A subsequent search was conducted regarding the limited literature on food insecurity assessment language. Because the literature on food insecurity is shared by many disciplines, the food insecurity and health and utilization outcomes review was conducted in biomedical databases such as SCOPUS and PubMed, in social science databases such as ProQuest Social Science and Agricultural and Environmental,

and in the grey literature of government and non-governmental organizations. The following search terms were applied: *food insecurity, health status, chronic disease, diabetes, obesity, mental health, depression, development, utilization, access, and hospitalizations*. To make sure the breadth of literature was discovered, key author searches were conducted to cross check findings. The sample, the region of the sample, the tools employed and whether they were valid, the primary variables, and the variables controlled for were defined for each piece of literature. The literature was further organized into domains of health outcomes, health access and utilization to aid in synthesis. The steps researchers employed to control for income were highlighted in order to disentangle effects of financial difficulty on food insecurity associations. There was then a subsequent database search for the following search terms: *food insecurity, social determinants, ICD, SNOMED, interoperability, and health IT*.

Food insecurity and associated health outcomes.

Much of the literature on food insecurity and associated health outcomes comes through the study of broad national health surveys such as the National Health and Nutrition Examination Survey (NHANES) (Seligman, Bindman, Vittinghoff, Kanaya, & Kushel, 2007; Seligman, Laraia, & Kushel, 2010), the National Health Interview Survey (NHIS) (Brucker, 2017; Gregory & Coleman-Jensen, 2017), the Medical Expenditure Panel Survey (MEPS) (Brucker, 2017), and the Early Childhood Longitudinal Study (ECLS) (Jeong-Hee & Bartfeld, 2012). States have also begun to look to food insecurity and clinical implications through population studies such as the California Health Interview Survey (Allen, Becerra, & Becerra, 2017; Smith, Colon-Ramos, Pinard, & Yaroch, 2016) and the Survey of the Health of Wisconsin (Saiz et al., 2016). Beyond the national studies, much of the literature on food insecurity comes from the non-profit research

and policy network Children's HealthWatch and their urban research settings (Chilton et al., 2009; Cook et al., 2013; Cook et al., 2004; Rose-Jacobs et al., 2016).

Food insecurity has associated poor health outcomes across the age spectrum. Many studies query for concepts of health status based on the NHANES question ("Would you say |your/SP's| health in general is... excellent, very good, good, fair, or poor?") (Center for Disease Control and Prevention, 2013) Household food insecurity has associations with fair and poor child health as reported by caregivers in both settled (Cook et al., 2013; Cook et al., 2004; Drennen et al., 2019) and New American families (Chilton et al., 2009). Increasing food insecurity severity strengthens this association (See Table 1) (Cook et al., 2004; Cook et al., 2006). Furthermore, early childhood food insecurity was associated with future poor reported health in 8th grade students as part of the ECLS-Kindergarten Cohort (Jeong-Hee & Bartfeld, 2012).

The associations of food insecurity and poor reported health status persist into adulthood. In a large (n=4,562) study of community health center patients, Alvarez, Lantz, Sharac, and Shin (Alvarez et al., 2015) found women in food insecure households had increased rates of fair and poor self-reported health. This supports the extensive findings of Children's HealthWatch, that have demonstrated that mothers in food insecure households have increased rates of fair/poor health along with their children (Cook et al., 2013). Brucker (2017) demonstrated that food insecurity is associated with poor health status in adults with disabilities. This is of particular concern given the increased rates of food insecurity in young adults with disabilities (Brucker & Nord, 2016).

The risks associated with food insecurity extend into specific health concerns. Infants from food insecure households have been found at increased developmental risk when measured

by a validated tool after controlling for child and caregiver variables (Cook et al., 2013; Drennen et al., 2019; Rose-Jacobs et al., 2008). Children from food insecure households have increased rates of asthma and iron deficiency anemia (Thomas, Miller, & Morrissey, 2019; Mangini, Hayward, Dong, & Forman, 2015; Skalicky et al., 2006). The recent USDA report of adult NHIS data demonstrated increased rates of each of the 10 CDC critical diseases of concern when controlled for poverty. Increasing severity of food insecurity is associated with increased rates and number of the chronic diseases in question (Gregory & Coleman-Jensen, 2017). This work supported previous studies that detailed associations with chronic disease (Jernigan et al., 2017; Seligman et al., 2010), cardiovascular disease (Saiz et al., 2016), diabetes (Seligman et al., 2007), and diabetes poor control (Berkowitz, Baggett, Wexler, Huskey, & Wee, 2013; Mayer, McDonough, Seligman, Mitra, & Long, 2016; Seligman, Jacobs, Lopez, Tschann, & Fernandez, 2012).

The research on food insecurity and overweight/obesity is complex. The national data on children and food insecurity and overweight/obesity conflicts depending on child age and whether the child is food insecure (child-level food insecurity). Household food insecurity was not associated with overweight/obesity in a national analysis of NHANES data for children age 9-11 (Nguyen, Ford, Yaroch, Shuval, & Drope, 2017). However, in a different NHANES data analysis, Kaur, Lamb and Ogden (2015) found an association between household food insecurity and overweight/obesity for children age 6-11, but not children age 2-5. This same study found no association between food insecurity and overweight/obesity for child-level food insecurity for all ages (Kaur et al., 2015). In a national study of NHIS data, Hernandez, Reesor, and Murillo (2017) reported that food insecurity was associated with obesity only in Caucasian and Hispanic women. When regional and local analysis were conducted the association of food insecurity and

obesity is moderated by gender, urban/rural, and ethnic variables (Ryan-Ibarra, Sanchez-Vaznaugh, Leung, & Induni, 2017; Smith et al., 2016; Vedovato et al., 2016). Ryan-Ibarra et al. (2017) recently demonstrated that in immigrant families, increased duration of time in the US increased the association between food insecurity and obesity.

There are vast mental and behavioral concerns associated with food insecurity. There are increased rates of behavior concerns among children from food insecure households (Nagata, Gomberg, Hagan, Heyman, & Wojcicki, 2019; Whitaker et al., 2006). Mothers and adolescents demonstrate increased rates of mood and anxiety disorders (Alaimo et al., 2001, 2002; Whitaker et al., 2006). Recent studies from the California Health Interview Study demonstrate increased rates of moderate to severe psychological distress related to food insecurity severity in African American and Hispanic adults (Allen et al., 2017; B. J. Becerra, Sis-Medina, Reyes, & Becerra, 2015). Finally, numerous studies detail associations with depression across the age spectrum. There are multiple studies detailing an association between food insecurity and maternal depression (Casey et al., 2004; Cook et al., 2013; Nagata, Gomberg, Hagan, Heyman, & Wojcicki, 2019). Whitaker, Phillips and Orzol (2006) demonstrated not only an association between food insecurity and maternal depression, but that increasing severity of depression was correlated with increasing severity of food insecurity. Finally, Alaimo et al. (2002) demonstrated that adolescents in food insecure households have increased rates of depression, suicidality, and “desire to die” even when outcomes were controlled for household income.

Food insecurity and associated utilization outcomes.

The studies on food insecurity and health access and utilization raise additional concerns. Food insecurity is associated with decreased ambulatory care and postponed care for children and adults (Kushel, Gupta, Gee, & Haas, 2006; Ma, Gee, & Kushel, 2008; Thomas, Miller, &

Morrissey, 2019). Food insecurity is associated with cost-related medication underuse and medication “scrimping” (Berkowitz, Seligman, & Choudhry, 2014; Herman, Afulani, Coleman-Jensen, & Harrison, 2015; Knight, Probst, Liese, Sercye, & Jones, 2016). Studies of increased acute care utilization demonstrate an association for adults, but not children (Kushel et al., 2006; Palakshappa, Khan, Feudtner, & Fiks, 2016). Food insecurity has associations with increased adult and childhood emergency room visits and lifetime hospitalizations (Cook et al., 2013; Cook et al., 2004; Cook et al., 2006; Ma et al., 2008; Peltz & Garg, 2019; Thomas, Miller, & Morrissey, 2019). Studies on food insecurity and emergency room use and hospitalizations persist when examining specific diagnoses such as type 2 diabetes (M. B. Becerra, Allen, & Becerra, 2016). In a recent study of NHIS and MEPS data it was reported that adults with food insecurity had an average extra \$1,863 in health care costs per year when adjusted for age, gender, race/ethnicity, education, income, insurance, and residence area. When multiplied by the current estimated prevalence of food insecurity in the US, this represents a \$77.5 billion dollar increase in total national health care costs (Berkowitz et al., 2017).

Existing assessment and intervention language for food insecurity.

The literature on food insecurity encoded language is slim. In 2017, I successfully applied for a specific SNOMED CT code for food insecurity (733423003) so that the concern could be placed in patient problem lists (DeSilvey et al., 2018; SNOMED International, 2017b). The ICD-10-CM code currently employed in the US for food insecurity assessment is Z59.4 “Lack of adequate food and safe drinking water” (American Academy of Pediatrics & Food Research and Action Center, 2017; Arons, DeSilvey, Fichtenberg, & Gottlieb, Manuscript in preparation; Gottlieb, Tobey, Cantor, Hessler, & Adler, 2016). In international ICD-10 this concept is divided into Z59.4 “Lack of adequate food” and Z58.6 “Inadequate drinking water

supply” (World Health Organization, 2016). Although there are SNOMED CT intervention codes for “referral for socioeconomic factors: 41920009” and “provision of food: 710925007,” there are no codes for food prescription, SNAP benefits, WIC, counsel for socioeconomic factors, home delivered meals, school meals, and the other resources clinicians use to assist food insecure individuals and families (Arons et al., Manuscript in preparation; SNOMED International, 2017b).

Critique of the literature.

There are a few key limitations in the literature. All studies cited examined association, not causation. The strength of each study depends largely on the degree to which there was control for confounding variables and whether valid tools were used to measure food insecurity.

All but a few studies controlled for income as a variable, but different methods were used. In some Children’s HealthWatch studies, because of their focus on young children, they use a public insurance inclusion criteria as they consider private insurance a proxy for high income in the age group of young children (Cook et al., 2013; Rose-Jacobs et al., 2008). More recent Children’s HealthWatch studies have limited the sample to just public insured young children in an effort to control for confounding variables (Chilton et al., 2009). Alaimo et al. (2002) and Seligman et al. (2012) used stratified annual income data. Brucker (2017) separated respondents into below the poverty line (<100%), low income (100-200% of the federal poverty level), middle income (200-300% of the federal poverty level) and >400%. Poverty-to-income ratio (the ratio of a household’s income to the poverty threshold given the number of household members (United States Census Bureau, 2017)) is used in multiple studies, but it is stratified differently across studies (Cook et al., 2004; Kaur et al., 2015; Whitaker et al., 2006). However, in each study that uses poverty-to-income ratio, consideration was made to reflect eligible cutoff

for federal nutrition support so this concept could be used in analysis (Cook et al., 2004; Kaur et al., 2015; Whitaker et al., 2006). In an analysis of ECLS data, mean income and number of years with income below the federal poverty line were both used to ensure that “food insecurity impacts were differentiated from poverty impacts” (Jeong-Hee & Bartfeld, 2012, p. e51).

Another important consideration is the validity of the tools used to measure both food insecurity and associated health outcomes. All researchers but Saiz et al. (2016) and Jernigan et al. (2017) used validated tools to measure food insecurity. All studies used validated tools to measure depression, anxiety, and developmental risk when these were variables of concern.

Lastly, because many studies excluded non-English speakers, the experience of immigrants and New Americans is underrepresented. Furthermore, broad national surveys can dilute regional and ethnic variations in food access and food preferences. In contrast, NHANES data does include a wide array of languages. Emerging studies seek to address both of these concerns through ethnicity focused research as demonstrated by the work of Allen et al. (2017), Chilton et al. (2009), Nagata et al. (2019), Ryan-Ibara et al. (2017), and Smith et al. (2016).

Summary of the evidence.

In 2018, it was estimated that there were 14.3 million food insecure households in the US (Coleman-Jensen et al., 2019). Food insecurity has been shown to have associations with negative physical, mental, and behavioral health outcomes for adults and children, across ethnicities, even when great effort is made to control for the effect of poverty (Alaimo et al., 2002; Allen et al., 2017; Chilton et al., 2009; Gregory & Coleman-Jensen, 2017; Jeong-Hee & Bartfeld, 2012; Ryan-Ibarra et al., 2017; Smith et al., 2016). Furthermore, food insecurity has concerning associations with health care access including decreased preventative care and cost-related medication underuse, even in the presence of critical chronic disease (Kushel et al., 2006;

Ma et al., 2008; Seligman et al., 2012). Lastly, this literature review clearly demonstrates troubling associations of food insecurity with health care utilization for all ages, including increased emergency room visits, increased hospitalizations, and increased total cost of care (Berkowitz et al., 2017; Cook et al., 2006).

Despite this evidence, clinicians do not have clear diagnostic criteria to aid in evidenced based assessment. The only ICD-10-CM code clinicians have to employ, “Lack of adequate food and safe drinking water,” is not specific to the economic and social drivers of food insecurity, is not specific to food access, and does not include concepts of worry that are inherent in both the conceptual and operational definition of food insecurity (United States Department of Agriculture, 2017a, 2017d). Lastly, there is little specific encoded language available to document the most common food insecurity interventions.

Theoretical Framework

The framework that gives context and direction for this project is the World Health Organization Commission on the Social Determinants of Health’s “Conceptual Framework for Action on the Social Determinants of Health” (World Health Organization, 2010). The Commission’s intent was to model both the origins of health differences among social groups and the paths that lead from these origins to “the stark health differences in health status on a population level” (World Health Organization, 2010, p. 9). They then sought to frame a way to address these origins of health differences in the name of health equity. I chose this framework because first, I share the values that ground the framework: health equity, human rights, and distribution of power. Second, my project can be considered a direct response to the end goal of the framework; action on the social determinants within an understanding of socially and politically constructed health inequities.

Core values.

The Commission explicitly stated the “core values” that grounded the framework development: health equity, human rights, and distribution of power (World Health Organization, 2010, p. 12). The Commission described *health equity* as the “explicit ethical foundation” of the work and *human rights* as the “framework for social mobilization and political leverage to advance the equity agenda” (World Health Organization, 2010, p. 12). They defined *health equity* as the “absence of unfair and avoidable or remediable differences in health among population groups defined socially, economically, demographically, or geographically” (World Health Organization, 2010, p. 12).

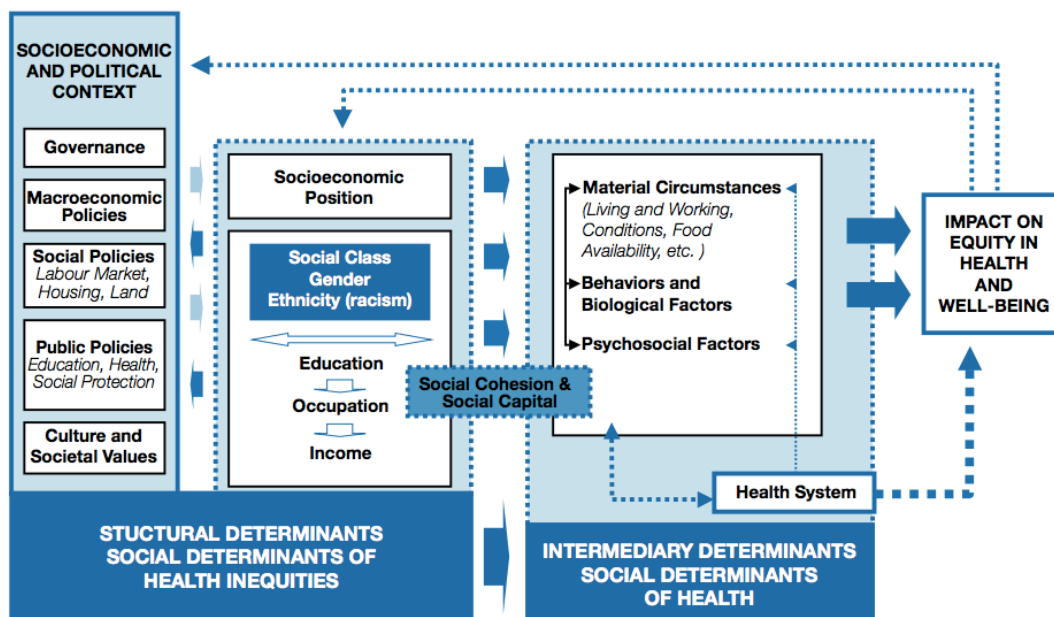
The Commission’s approach to human rights was in keeping with the “1948 Universal Declaration of Human Rights” which holds that “Everyone has a right to a standard of living adequate for the health and well-being of himself and his family, including food, clothing, housing and medical care, and necessary social services” (The United Nations, 1948, p. 12). The Commission further detailed the capacity for the health sector to push for transformative policy in the pursuit of health equity, because the human rights perspective creates an obligation that “requires consideration of poverty and social disadvantage” (World Health Organization, 2010, p. 13). Lastly, the Commission described the role of empowerment and power within the pursuit of human rights. They spoke to the full embodiment of empowerment being peoples’ effective freedom to “decide what the meaning of their life will be” (World Health Organization, 2010, p. 13). They detailed that if a right to health is based on empowerment, then the voice of those whose health status is at risk must be the source of decision making. They further discussed that the concepts of power within the framework can be seen outside of the classic “power over” definition. They positioned the power at the heart of health equity within feminist literature and

aimed to foster “power to” (power to organize and change existing hierarchies) and “power with” (the power of collective action) (World Health Organization, 2010, p. 21).

The framework.

The framework groups all determinants by levels of influence and divides social determinant concepts into fundamental structural determinants and ensuing intermediary determinants. The structural determinants are comprised of the socioeconomic and political context, social hierarchies and social position. The socioeconomic and political context includes governance, macroeconomic policy, social policies, public policy, culture and societal values, and epidemiologic conditions (Figure 1).

Figure 1: Final Form of the Committee on Social Determinants of Health Conceptual Framework



(World Health Organization, 2010)

Within culture and societal values, the Commission took care to discuss the difference in the cultural value placed on health and how this shapes public policy. It named the welfare state and the presence (or lack thereof) of redistributive policies as the contextual factor most

powerfully affecting health. The inclusion of the socioeconomic and political context in the framework was unique, but the authors felt it necessary to include because “the structural, cultural, and functional aspects of social system... exert a powerful formative influence on patterns of social stratification and, thus, on people’s health opportunities” (World Health Organization, 2010, p. 25). In essence, they are the root of inequity.

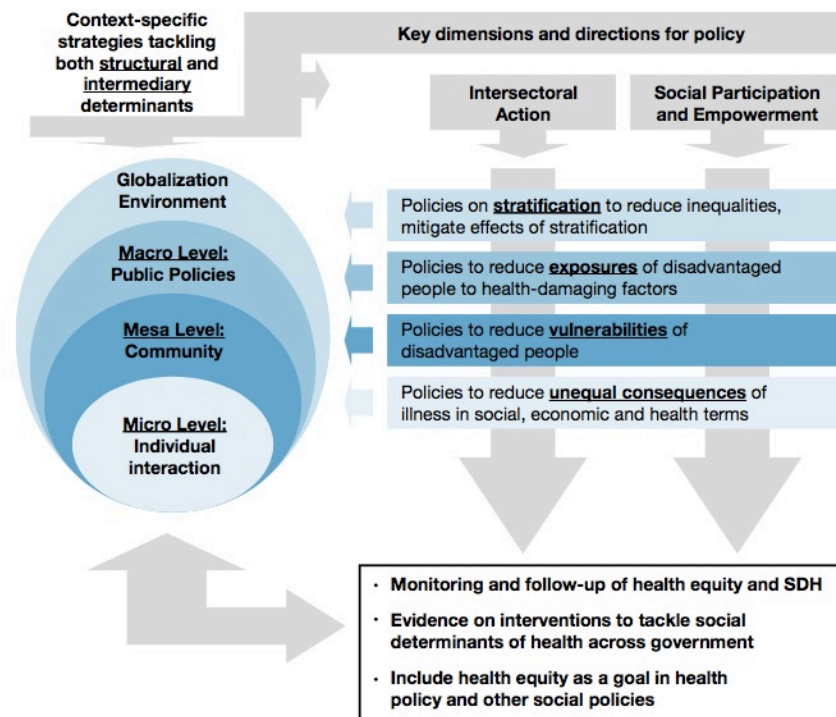
The framework next addresses social hierarchies of power and access to resources and the socioeconomic position issuing from gender, income, class, education, race, and occupation. It then models how each of the structural determinants relate to each other; socioeconomic position and hierarchies are modified by structural mechanisms, within the socioeconomic and political context, to generate and reinforce social stratification. Because the structural determinants create marked differences in distribution and access to resources and power, the Commission collectively named these *the social determinants of health inequities* (societal determinants of inequalities in health.)

The final level in the framework details the intermediary determinants, simply named the social determinants of health. The social determinants of health comprise material goods (including food access), behavior and biology, and psychosocial factors (including stress, negative life events, and strain). The framework models the way these intermediary determinants “flow from the configuration of underlying social stratification” (World Health Organization, 2010, p. 37) to impact health equity and well-being.

The framework includes the health system itself as an intermediary social determinant. It does so in part because of how health access can influence health equity. However, it also does so because the Commission conceptualized that the health system “can directly address differences in exposure and vulnerability not only by improving equitable access to care, but also

in the promotion of intersectoral action to improve health status” (World Health Organization, 2010, p. 40). The Commission gave examples of food supplementation through the health system and transportation programs to tackle geographic access issues. In a supplemental model of action, the Commission detailed micro and macro levels of intervention and policy to reduce exposures and vulnerabilities of disadvantaged peoples and unequal consequences of illness (Figure 2).

Figure 2: Framework for Tackling Social Determinant of Health Inequities



(World Health Organization, 2010)

The framework’s alignment with my project.

The role of the health system in effecting change is where my project is most directly aligned with the framework. I state above that I orient myself within the same core values of health equity, human rights, and distribution of power. I agree with the statement that the human rights perspective “requires” (World Health Organization, 2010, p. 13) the health sector to

consider poverty and social disadvantage. I concur with the framework's demonstration of how socioeconomic and political structure, ensuing social stratification, and the social determinants of health impact outcomes in health. However, what is unique with this framework is the health system detailed as a determinant itself, for this is true to my experience and ethical compass. I am furthermore inspired to see directly named the role clinicians must have in addressing the social and political structures that affect the vulnerabilities and health inequities of our patients. I am also emboldened to see a detailed path for action through both micro and macro clinical care and policy.

The heart of my project is the knowledge that there is a clinical and moral duty to make systems level change in how we address the social determinants. My action is addressing the lack of language and diagnostic criteria. However, underlying the project is the fact that I wholly accept the responsibility to challenge the structural determinants inherent in current cultural values of health and cultural perceptions of poverty to effect real change. I am not just working to alleviate food insecurity for one patient or one community. I am working to change the way our culture speaks clinically about the social determinants and food insecurity, by clarifying, highlighting and destigmatizing. I do this in the bold hope that action on food insecurity in the clinical domain will foster our ability to advocate in the political domain. Because, as noted in the framework, it is the political and social context that are the root of the inequities we see in our daily practice.

A Threefold Aim

The literature clearly indicates the cultural and clinical significance of food insecurity, a dearth of diagnostic criteria to commonly assess it, the lack of language to specifically diagnose and document it, and the absence of the language to name the interventions employed in caring

for food insecure families. The goal of my project is to create the diagnostic criteria and encoded language needed to assess and address food insecurity with evidence, precision, and care. The aim of my project is threefold:

1. Apply for International Statistical Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) language for the following concepts; food insecurity, lack of adherence to prescribed nutrition therapy secondary to financial hardship, and counseling for socioeconomic factors.
2. Apply for Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) language for priority food insecurity interventions.
3. Develop key criteria considerations and initial diagnostic criteria for food insecurity.

Chapter 3: Methods

Introduction

The work of this threefold project is unique. The setting is, in essence, a national system of allies and organizations. The methods are distinct for each aim. The whole project is supported by the close alliance of longtime colleagues and content experts. This section begins with description of the allies that form the core advisory group for the project as a whole. Then, the setting (including contacts and organizations) and methods for each aim will be addressed in turn. Because there are many partners in this project, discussion of each aim includes a table with key contacts and roles to assist the reader. In all cases, the work of this project is built upon the analysis of existing food insecurity terminology and explication of the process for terminology development detailed in “An Overview of Food Insecurity Coding in Health Care Settings: Existing and Emerging Opportunities,” a brief I authored with colleagues from the core advisory group (DeSilvey et al., 2018).

The Community of Labor

Addressing the concerns of poverty in clinical practice has been an area of focus throughout my career. Over the course of many years I have developed a close set of national colleagues who are experts on food insecurity and medical and social care integration, and we collaborate on many projects. The support of this collective takes two forms in the work to be done. The first aim, application for ICD-10-CM language for food insecurity and related concepts was only possible because of the loose collaboration of my longest standing allies. Subsequently, after aim one was complete, in the spring of 2019 the national support for social determinant language synthesized around my work into a formal initiative called the Gravity

Project, spearheaded by the same longtime colleagues. I will detail the longtime allies individually in turn, and then describe the makeup of the Gravity Project as it remains today.

Longstanding colleagues.

1. Children's HealthWatch is a non-profit, national coalition of pediatricians, researchers and policy experts (Children's HealthWatch, 2016). Their aim is to improve the health of children in the United States (US) through research and policy advocacy. I met the team seven years ago when my thesis was the first use of their validated brief food insecurity screen, the Hunger Vital Sign™, in inpatient pediatrics. Within this organization my contacts are Executive Director, Stephanie Ettinger, De Cuba, MPH, and Deputy Director of Innovative Partnerships, Richard Sheward, MPP, and John Cook PhD.
2. The Food Research & Action Center (FRAC) is a non-profit leading the charge to end poverty-related hunger and undernutrition in the United States (Food Research & Action Center, 2018). My contacts within the Food Research & Action Center are Alex Ashbrook, JD, the Director of Special Projects and Initiatives, and Heather Hartline-Grafton, RD, DrPH, Senior Nutrition Policy and Research Analyst.
3. The Social Interventions Research and Evaluation Network (SIREN) is a nationally renowned center for social determinant research. SIREN is a leader in medical and social care integration research, including analyzing current health information technology's (HIT) capacity to address the social determinants. Laura Gottlieb, MD, MPH, Director, and Caroline Fichtenberg, PhD, Acting Director (SIREN, 2017).

A new community: The Gravity Project.

As stated above, SIREN is a national leader in social determinant research and in this role they spearhead the discussion on how the capacity to address social needs in clinical settings is limited by a lack of data. In the spring of 2019, supported by the Robert Wood Johnson Foundation and extensive federal, professional, and industry support, they kicked off the Gravity Project with the help of the American Academy of Family Physicians, Blue Cross Blue Shield and HL7 FHIR (a health care data standard organization.) The Gravity Project is a national initiative to build consensus data sets and data standards for three initial social risks: food insecurity, housing, and transportation. SIREN enlisted the help of health information experts, EMI advisors to manage the project and MaxMD to assist with standard development. Food insecurity was the first concept addressed. I was tapped to partner with the Academy of Nutrition and Dietetics to co-lead the food insecurity build. The core food insecurity data set initiative was tasked with collating and developing data requirements for conceptually matched screening tools, goals of care, diagnoses, and interventions through consensus process. The methods for the second aim and third aim (and refinement of the first) were henceforth grounded in this community and the shared labor. The community has at present more than 600 members. All members are able to contribute data elements and the final set is endorsed by consensus. Again, the success of the aims, rests largely upon the depth and expertise of the collective. I will detail key members of the Gravity community below. The model, the consensus process description, all meeting materials, and the master data set are available at the Gravity confluence page (The Gravity Project, 2019.)

1. The Steering Committee Organizations: American Academy of Family Physicians (AAFP), National Committee for Quality Assurance, HHS Agency for Healthcare

- Research and Quality, Academy Health/National Interoperability Collaborative, AmeriHealth Caritas, American Medical Association, CMS Office of Minority Health, CMS Innovation Office, Center for Disease Control and Prevention, MyHealth Network, McKinsey, Department of Veteran's Affairs, HHS Office of the National Coordinator, American Hospital Association and the American Hospital Association Institute for Diversity and Health Equity, National Association of Community Health Centers, United HealthCare, Blue Cross Blue Shield Association.
2. EMI Advisors- Program Management- Evelyn Gallego, Project Management- Lynette Elliott, and Coding Specialist- Linda Hyde
 3. MaxMD- FHIR Technical Lead- Lisa Nelson
 4. SIREN- Program Direction: Laura Gottlieb and Caroline Fichtenberg
 5. Academy of Nutrition and Dietetics Food Insecurity and Terminology Subject Matter Experts: Donna Pertel MEd and Constantina Papoutsakis PhD, RD

Gravity process.

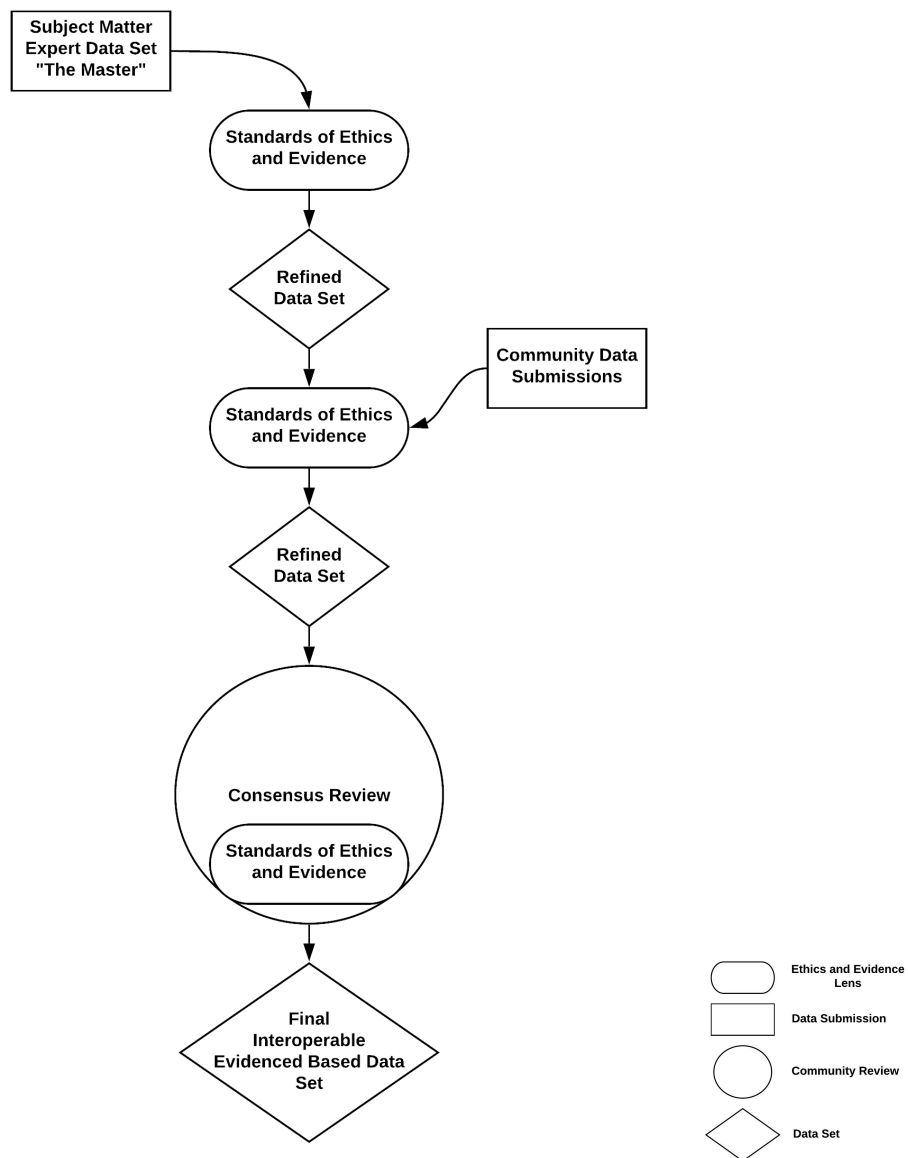
Data set development.

It is important to briefly detail the Gravity data and data standard development process. Initially, the subject matter experts, in this case myself and the AND, crafted a core data set based on known existing food insecurity code and crucial needs. We then adjudicated with evidence and ethics in mind to ensure alignment with the concept of food insecurity. The community then offered submissions. Each code suggestion was further adjudicated and if matched, it was added to the set. This process was continued in an iterative manner until a full set was developed. Key choices points for broad build were presented to the community and reviewed and refined until consensus was found. An example of this intervention framework

will be discussed below. Once a full set was on hand, there was a many week process of end to end review to publicly address any concerns in the set. Then, there was a final consensus vote.

(See figure 3)

Figure 3: Gravity Project Data Submission and Adjudication Process



Data standard development.

In the presence of the final data set, the data standard development work begins. This work is outside of the scope of this doctoral project, but it informs the diagnostic criteria work so it will be briefly detailed here. The aim of a data standard is to create logical consistency, not just in the terms used, but in how they are used. The Gravity Project is partly an initiative of a standards development organization called Health Level Seven (HL7). As an HL7 project, each data element is used to construct a web based computable logic model that any user can employ to share and interpret the food insecurity data. This ability to share and consistently interpret data is contained in a concept called interoperability. The logic of the model depends on every element having a clear definition that forms its relationship to other data elements.

Data recommendations dissemination.

The Gravity Project has extensive federal support. One final key deliverable of the Gravity Project is a white paper commissioned by the Office of the National Coordinator for Health Information Technology (ONC). At the close of each domain the ONC commissions a gap analysis paper that details the code needing to be built to complete the data set. This paper then serves as a government reference for all necessary data build.

Aim 1: Apply for ICD-10-CM Language**General application process.**

Applications for new ICD-10-CM language are made to the National Center of Health Statistics (NCHS), a division of the Centers for Disease Control and Prevention (Centers for Disease Control and Prevention, 2018b) – with two deadlines yearly. Broadly, NCHS is the house of US population health statistics. However, within the NCHS there is a division called the Classifications and Public Health Data Standards Division that is responsible for ICD-10-CM

(Centers for Disease Control and Prevention, 2018a). The acting chief of this division is Donna Pickett, MPH, RHIA. The ICD-10 Coordination and Maintenance Committee of the Classification and Public Health Data Standards Division reviews applications for new ICD-10-CM content twice yearly in September and March. Applications are submitted two months prior (July and January) via email. Although there is no template for ICD-10-CM requests, there are examples of past requests on the ICD-10-CM Coordination and Maintenance Committee website (Centers for Disease Control and Prevention, 2018a).

Drafting the application.

The first step was to draft the ICD-10-CM application (See Appendix A). This was necessary to develop understanding of the aim among key partners prior to submission. I extensively reviewed samples of previous applications and enlisted the help of two key coding specialist: Chris Denis, of VT BCBS and Kathy Giannangelo, of the American Health Information Management Association (AHIMA.) All applications must suggest the proposed codes and represent the logic of how any new code stems from the existing taxonomy. For instance, food insecurity will be built from the same root as “Lack of adequate food and safe drinking water,” Z59. Kathy Giannangelo took great care to further model how the application would affect the full ICD taxonomy. The initial goal was to craft language just for food insecurity itself. And, a specific code for food insecurity was part of the application. However, in discussion with certified coders, US professional organizations, and food insecurity content experts, the application was fleshed out to include two additional needed codes. The original application requests Z91.110 “patient non-compliance with dietary regimen due to financial hardship” built off of “patient non-compliance to dietary regimen code Z91.11. This code is crafted as a correlate to an existing code Z91.120 “patients intentional underdosing of medication

due to financial hardship.” The application also requested a code for “counseling for socioeconomic factors” build off the counseling root Z71.8.” (See Appendix A)

Sponsorship and letters of support.

The development of specific ICD-10-CM language for food insecurity is a novel concept, and it was clear in my conversations with NCHS a good case would need to be made. Building on my work with Chris Denis, VT BCBS offered to sponsor the application in line with their mission to address social needs. The BCBS Association is familiar with the ICD application process. To justify the build in the eyes of NCHS the BCBS team, my national colleagues, and myself reached out to broad key stakeholders to for letters of support or co-sign status. The response was significant (detailed in the full application, Appendix A)

Table 3: ICD-10-CM Core Contacts

Organization Title	Organization Purpose	Organization Contact	Role
National Center for Health Care Statistics, ICD-10 Coordination and Maintenance Committee	Agency responsible for new ICD-10-CM development	Donna Pickett, MPH, RHIA- acting Chief of Classification and Public Health Data Standards	Head of the ICD-10 Coordination and Maintenance Committee
Food Research and Action Coalition	National non-profit focusing on policy and practice solutions for poverty-related hunger and undernutrition	Core Advisory Group Members: Alex Ashbrook, JD, Director of Special Projects and Initiatives, and Heather Hartline-Grafton, RD, DrPH, Senior Nutrition Policy and Research Analyst	Helpful to initiate contact with professional organizations

Blue Cross Blue Shield Vermont	Insurer	Medical Director- Josh Plavin, MD Medical and Clinical Coding Specialist- Chris Denis, RCP, CCS-P, CUC, CPC, EFPM, RCAPPM	Leverage of national BCBS ICD-10-CM coding advocacy
AHIMA	Health information professional organization	Kathy Giannangelo, MA, RHIA, CCS, CPHIMS, FAHIMA	Health information expert familiar with ICD taxonomy and application process

Submitting the application to NCHS.

The final step was to submit the application to NCHS. The application was submitted via email on July 13th 2018. This marked the completion of aim one.

Next steps.

Although the aim was to simply apply, the mission was to develop the code and I will briefly detail the next steps here. Because of the novel nature of the build, the submission was just the beginning of a many long phone conversations with Donna Pickett on the methods of food insecurity screening and assessment in US clinical practice. We reviewed the AAP toolkit and the Accountable Health Communities model among others. We edited the application slightly to better mesh with the existing ICD taxonomy. She personally presented the application to the committee at the March 2019 gathering (CDC, 2019). (See Appendix B).

It was right at this time that the Gravity Project took hold. We agreed that it would be best to ground the application in the will of the Gravity Project's national consensus and the decision on the application was paused until the Gravity process was complete. At the close of

the Gravity food insecurity data set recommendations, the community not only recommended the basic codes for food insecurity ICD codes as originally presented, they advocated for the addition of specific codes to represent the strata of food insecurity severity. These will now go back to NCHS for review at the September 2020 Coordination and Maintenance Committee Meeting as an amendment to the original application.

Aim 2: SNOMED CT Intervention Language Build

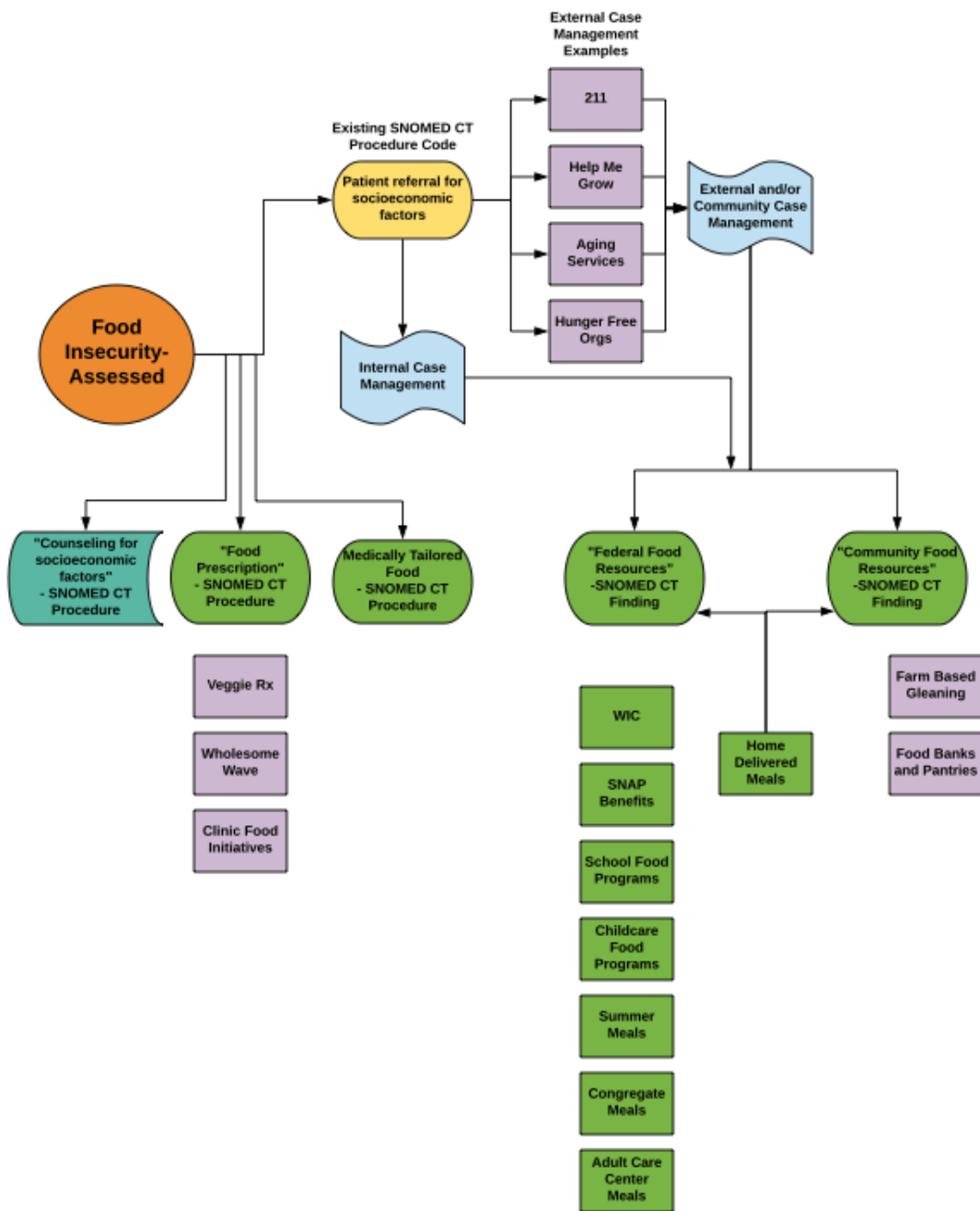
General application process.

New US SNOMED CT content are vetted through the National Library of Medicine SNOMED CT content request system (National Library of Medicine, 2017). Head of Terminology is Jim Case, DVM, MS, PhD.

Pre-Gravity intervention modeling.

Prior to Gravity, to make sure that the intervention language developed reflects practice, I leveraged the insight and wisdom of core advisors and colleagues to craft a draft of proposed codes based on the process of addressing food insecurity in clinical settings and began a rough mapping to existing SNOMED CT terminology (Figure 3). Through this work I met Donna Pertel and Constantina Papoutsakis of the Academy on Nutrition and Dietetics. Shortly after this work, the Gravity Project commenced, and I asked them to help spearhead the work. We then used this as a template for our conversations on food insecurity data development.

Figure 4: Flow of Suggested Food Insecurity Intervention Codes



Gravity Project intervention build.

The build of food insecurity intervention language proved far more complicated than expected. There were a few key issues at play. First, the aim of the Gravity Project was not just

to develop “some” data recommendations it was to develop “all” data recommendations. This meant doing an extensive review of federal, state, and local food insecurity programming to create a set of program concepts and definitions that were distinct from each other. The goal was to say what was needed to be said in the simplest way possible. Toward this end, some smaller programs were grouped into larger parent concepts. All program definitions were crafted in consult with the Gravity community but key support was offered by the AND, FRAC, and key Gravity member, Melissa Cannon of California Food Policy Advocates (CAFPC). Of note, through end to end review a few key programs, such as the Food Distribution Program on Indian Reservations (FDIPR) program, initially contained within the food pantry were brought forward as their own data point. The reason was that the communities served by the programs felt the specific code was required to differentiate FDIPR from general pantries in care and research. In the final set there were 23 specific program types at the heart of the intervention build.

The second area of complexity occurred in the syntactic structure of the data suggestions. As mentioned in the introduction, there is no open taxonomy for social programs themselves. Thus, in order to build into SNOMED CT, we needed to craft a structure of activities to surround the programs. One cannot just say SNAP, one needs to say “Referral for, Education about, Evaluation of eligibility for... SNAP.” The aim again was to say things as simply as possible so I conducted an extensive review of clinical, care management, and social work literature to arrive at a basic activity structure to ground the intervention build that could hopefully be employed by any provider or worker in clinic and community settings.

Gravity Project intervention structure.

- Referral. A type of order wherein clinicians/providers request services and/or assessment from other professionals and/or programs.

- Provision. For the purposes of the project, provision covers any concrete support that is able to be given to the patient directly at the point of service.
- Counseling. Psychosocial procedure that involves mental/behavioral strategies such as listening, reflecting, etc. to facilitate recognition of course of action/solution.
- Education. Procedure that is synonymous with those activities such as teaching, demonstration, instruction, explanation, and advice that aims to increase knowledge and skills, change behaviors, assist coping.
- Assessment. The process of both provider clinical observation and interpretation, and the application of assessment tools. In both activities the aim is to arrive at outcomes that define the status of the patient in order to guide further care.
- Evaluation of eligibility. Chosen to mark the activities prior to determination of eligibility. (Crucial for federal assistance programs).
- Assistance. Non-clinical aid with the tasks of care such as applications and setting up appointments.
- Coordination. Organizing activities and sharing information.

Final steps.

This structure was then matched practically to each of the programs. For example, “Evaluation of eligibility for ____” only for programs where eligibility was required. This marrying resulted in a full set of 109 interventions with 97 needing to be built. The set was published in the final master data set. From here, the Gravity Project’s position within the national conversation changes the application the standard process, as detailed above. Because of the Gravity Project’s close relationships with the ONC, SNOMED, and the AND, and standing as an HL7 FHIR Accelerator Project, the regular NLM process for SNOMED CT application

does not apply. The Gap Analysis paper, was submitted to the ONC, on February 3rd with the ANA and AMA as partners (See Appendix C). This commenced an open dialogue with all partners about necessary build. The SNOMED team has been present for every step of the Gravity data set development. As a HL7 FHIR Accelerator Project there is a unique process with direct lines of communication with SNOMED CT. With the data set in hand, the Gravity team has met with the SNOMED CT team to streamline build. This completed Aim 2.

Aim 3: Diagnostic Criteria Build

The diagnostic criteria build is a process apart from the other aims. Diagnostic criteria are, by convention, drafted by a representative panel of content experts and thus a full criteria are outside the scope of this project. The work of diagnostic criteria development is complex. It is also new to social determinant experts as the literature and knowledge of social needs has classically been in the public health, rather than clinical space. Therefore, the aims of this project were simply to work with content experts to craft baseline understanding of the need for criteria and agreement on criteria fundamentals prior to a formal convening. In the early spring of 2019 this worked commenced by reaching out to content experts at both the AND and the USDA. The original plan was to form an independent planning group to spearhead further work. However, shortly after these early meetings the work was integrated into two other paths of work: The Gravity Project (described above) and the National Quality Forum (NQF) Food Insecurity Quality Measure Technical Expert Panel that I participated in with Matthew Rabbit of the USDA. The role each of the initiatives played in the development of diagnostic criteria considerations will be described below.

Table 4: Diagnostic Criteria Organizations and Contacts

Organization Title	Organization Purpose	Organization Contact	Role
United States Department of Agriculture	Author of the gold standard Food Security Module and content expert on food insecurity research	Alisha Coleman-Jensen, social science analyst, PhD Christian Gregory, PhD, economist Mathew Rabbitt, PhD economist	Content and measurement experts
Children's HealthWatch	Author of the validated 2-item brief food security screener, the Hunger Vital Sign™ and content expert on food insecurity research	Stephanie Ettinger De Cuba, MPH Richard Sheward, MPP John Cook, PhD, MAEd	Content experts
Food Research & Action Center	National non-profit focusing on policy and practice solutions for poverty-related hunger and undernutrition	Heather Hartline-Grafton, RD, DrPH, Senior Nutrition Policy and Research Analyst	Nutritionist and food insecurity content expert
Academy of Nutrition and Dietetics		Donna Pertel and Constantina Papoutsakis	Content and coding experts
Feeding America		Dr Hilary Seligman	Content expert

Development of criteria considerations.

As stated above, initially the plan was to develop a novel group and the work of developing criteria considerations proceeded within this vein. For the purposes of this project,

criteria considerations are understood to be the variables that need to be considered when building an eventual criteria. This work occurred through a series of conversations in the spring (April and May) of 2019 with both the AND and Dr Christian Gregory of the USDA. The AND has an extensive history in nutrition criteria development and the USDA are the authors of the gold standard measure. It was agreed upon that considerations would be as follows: core concepts, severity stratification, temporality, including duration of time per incidence, acuity versus chronicity, and cyclic patterns of recurrence.

Definitions, measurement, and initial criteria concepts.

With the above considerations in hand, the aim of diagnostic criteria development paused briefly as Gravity Project work commenced. However, soon the aims would merge. The process of using the food insecurity data set to build a data standard, and the key role of definitions, were briefly described above. In June of 2019 as Gravity was developing needed data elements, it came to light that the existing USDA definitions for food insecurity presented a logical challenge. First, the posted definitions were population definitions rather than individual definitions (USDA, 2017a). Second, the food security and food insecurity definitions were not logically inverse and thus incompatible with computable logic (USDA, 2017a). Lastly, there was a conflict between the conceptual definitions of food security and insecurity and their operational definitions in the USDA module literature. The USDA employs the conceptual definition of food insecurity developed by the Life Sciences Research Office in 1990, as published in the “Guide to Measuring Household Food Security:”

Access by all people at all times to enough food for an active, healthy life. Food security includes at a minimum: (1) the ready availability of nutritionally adequate and safe foods, and (2) an assured ability to acquire acceptable foods in socially acceptable ways (e.g.,

without resorting to emergency food supplies, scavenging, stealing, or other coping strategies) (Bickel et al., 2000, pg 6)

However, the operational definition within the USDA food security modules (as detailed above) defines food insecurity as answering positively to three or more questions on the tool. This allows worry about not having enough money for food (question one of the module) and food not lasting (question two) to be deemed marginal *food security*, not *food insecurity*. This conflicts with the conceptual definition of food security above that requires “assured ability” to enough food (Bickel et al., 2000, pg 6). The presence of each of these concerns, population definitions, not logically inverse, and incongruent USDA conceptual and operational definitions all required that the Gravity Project develop a working group of food insecurity subject matter experts to create new definitions to ground the data standard development. This definitions work is again outside of the current project scope and will be detailed elsewhere. However, crafting new computable definitions required an extensive review of the literature of food insecurity measurement, distillation of essential measurable concepts, and iterative refinement through consult with experts. This is essentially the same work of diagnostic criteria development. Thus, it was agreed as the definitions were crafted, the core criteria would be defined as well.

The base criteria concepts issue from the seminal qualitative work of Radimer, Olson, and Campbell (1990). From their research with rural women in Northern US, it was understood that the experience of food insecurity and hunger lie along a continuum from worry to missing meals. These core criteria are included in every standard measurement of food insecurity including the USDA Food Security Modules (USDA, 2017d), the WHO Food Insecurity Experiences Scale (FIES) (Ballard, Kepple, & Cafiero, 2013), and the Household Food Insecurity Access Scale (HFIAS) (Coates, Swindale, & Bilinsky, 2007). Further review of more

recent literature revealed a concept of cultural acceptability (Coates, 2013). Thus, the base criteria concepts are:

1. Worry about not having enough food (Radimer, Olson, and Campbell, 1990)
2. Lack of cultural acceptability (Coates, 2013)
3. Decrease in quality of food (Radimer, Olson, and Campbell, 1990)
4. Reductions in portion sizes (Radimer, Olson, and Campbell, 1990)
5. Skipping meals (Radimer, Olson, and Campbell, 1990)
6. Not eating for one or more days (Radimer, Olson, and Campbell, 1990)

Quality measurement and time.

The base concepts in hand the final element to consider for initial criteria was time. A key issue surrounded the time look-back for the gold standard USDA modules, 12-months. This span was chosen to match with the calendar year, as the tool is employed as a look-back from December. It was not chosen to align with a critical duration of time akin to true criteria (such as the DSM-V criteria for depression (American Psychiatric Association, 2013) or the Rome Criteria for Irritable Bowel Syndrome (The Rome Foundation, 2006)). Thus, it would need to be revised for criteria development. The consideration of time merged into the work of the NQF Food Insecurity TEP. The directives of the TEP are to assist with development of three distinct food insecurity measures representing food insecurity screening, appropriate clinical action in the presence of positive screens, and change in food insecurity severity after intervention. I sit on the TEP with Richard Sheward of Children's HealthWatch and Matthew Rabbitt of the USDA among others. The work of the TEP itself is again outside the scope of this project, however, it became crucial to consider the element of time when constructing a practical measure for change in severity. For, if we maintained the 12-month look-back, it would complicate re-assessment of

severity that occurred in any shorter span. It was thus agreed, based on the literature, that any duration of time qualified for food insecurity initial assessment and that temporality would be used only to further delineate acuity, chronicity, and cyclic patterns.

Final and future steps.

With the considerations, core concepts, and temporality considerations in hand, the USDA, the AND and myself will now embark to craft a unique TEP to refine the criteria. The aim is to secure funding over the next months and commence this work the summer of 2020.

Human Subjects Disclosure

The project works solely within the structural realms of health care long before patient contact. There is no direct patient involvement of patients or other human subjects. Participants in the project are involved as experts. Therefore, there is no need for IRB approval.

Chapter 4: Results, Evaluation, and Implications

Results

This project has both practical and conceptual results. On the practical side it crafted a pathway for vastly expanded terminology and tools to address food insecurity. In addition, the work itself, because it was novel, because it required consistent advocacy for right process, because it asked me to often consider why as a nurse I was right for the job, prompted deep reflection. What made the work whole? From this reflection, and discussion with my advisor, issued an initial model of the role of the nurse leader in addressing social needs. This model in process will be described later in this section.

ICD-10 terminology.

The project resulted in two phases of ICD-10-CM requests. The first was through the joint BCBS and YSN application heard at the March 2019 ICD-10 Coordination and Maintenance Committee Meeting. This met the criteria for the first aim. However, the second was a refinement of this initial request through the consensus of the Gravity Project in collaboration with the Office of the National Coordinator and the CDC. The complete concepts are detailed in the table below.

Table 5: Comparison of Existing ICD-10-CM, Initial BCBS and YSN Request, and Gravity Request

Existing Code	BCBS and YSN Request	Gravity Request
Lack of adequate food and safe drinking water	Lack of adequate food Inadequate drinking water supply	(no edits)
	Food Insecurity	Food Insecurity, NOS

		Mild Food Insecurity Moderate Food Insecurity Severe Food Insecurity
	ADD- Patient's noncompliance with dietary regimen due to financial hardship	(no edits)
Patient's noncompliance with dietary regimen	ADD- Counseling for socioeconomic factors	(no edits)

Intervention terminology.

Because of the Gravity Project's development, the terminology suggestions resulting from this project far exceeded initial expectations. The collective power of the Gravity Project community and the collaboration of SNOMED CT and the Office of the National Coordinator, created an intervention concepts request that was by nature comprehensive, as opposed to representative. The intent was not to just name essential things. It was to name all of the things that need to be said. This included every federal, state, and tribal food program. This included concepts for farmers market programs through both the Older Americans Act and the Special Supplemental Nutrition Program for Women, Infants and Children Program. This resulted in 109 concepts. Of these, ninety-seven would need to be built into data standards. (A further description of this process and the outcomes are included in the ONC Gap Analysis Paper, Section 6.4, Appendix C)

As stated above, the project also created a necessary framework for all intervention build, and this alone is significant. In the open source development of SNOMED CT, there can be a

cacophony of code. The aim of the Gravity Project was to foster not just syntactic consistency (code that is constant across settings) but semantic consistency (language that conveys what needs to be said and is understood). The collectively crafted and agreed upon intervention structure and definitions were the framework for this.

Diagnostic criteria considerations.

The results of the diagnostic criteria work were intended to be a template for future labor. This remains the case. The core criteria considerations are in hand: core concepts, severity stratification, temporality, including duration of time per incidence, acuity versus chronicity, and cyclic patterns of recurrence. The core concepts will be built off of Radimer, Olson, and Campbell (1990) and Coates (2013). The concept of time has been liberated from the 12 month look back of the USDA module. The TEP to come will have the benefit of resting upon the agreements already in hand.

Evaluation

Evaluation of adherence to project aims occurred externally through a regular updates with my advisor, Dr Jane Dixon. This included essential tasks, key milestones, and project partners. Evaluation of the content and necessity of the aims of the project were fundamentally part of the process; the national community vetted every deliverable. The only adaptation was to add content. The end results were more ICD-10-CM and intervention codes than initially conceived and diagnostic criteria suggestions aligned with the deliverables of national TEPs.

Implications and Dissemination

The implications of this project are many. First, it aims to create discrete codes to document food insecurity within ICD-10-CM and food insecurity intervention within SNOMED CT. This will allow care providers, insurers, and private and government agencies to document,

share, and evaluate the care of food insecure individuals and families. Furthermore, by building diagnostic criteria it will ground the assessment of food insecurity in a common, evidenced based, conceptual understanding. Therefore, the eventual employment of discrete terms to name and address food insecurity will be built upon equivalent diagnostic assessment.

In addition to the concrete aims of the food insecurity elements of the project, the extensive labor of this initial Gravity Project domain is already being folded into a project plan for future domain work to address housing, transportation, social isolation, adverse childhood experiences (ACEs) and protective factors. The work has just begun.

Dissemination will occur on many fronts. First, all participating members of the Gravity Project are asked to commit to dissemination of the data and employment of the data standards. Given that members include the AMA, AAFP, VA, AHA, BCBS, UHC, Epic, Cerner, the NACHC, and many more... this is extensive. Furthermore, as a government sponsored initiative, the Office of the National Coordinator (ONC) Gap Analysis, detailing the key findings of the food insecurity build, will be in the public domain and the data recommendations will be integrated into future data standards. The project has already been included in key federal recommendations including a November 2019 HHS social determinant data roundtable (US Office of the Chief Technology Officer, Center for Open Data Enterprise, 2019).

Statement of Relation to Leadership Immersion

This project represents a novel and necessary integration of advocacy, ethics, public health and policy, social determinant content expertise, evidence, nursing informatics, inter-professional collaboration and leadership, as well as the science of advanced clinical practice. As such, it fundamentally reflects the perspective of the doctoral prepared nurse practitioner (American Association of Colleges of Nursing, 2006). Initially, the concept for Leadership

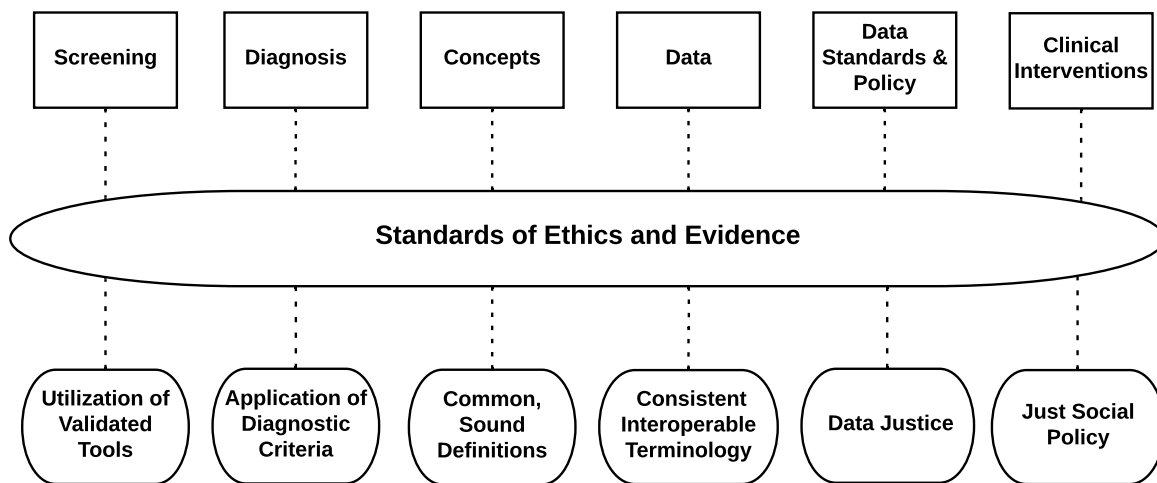
Immersion was to partner with nurse informatics scholars to develop a model for the role of the nurse leader in SDOH informatics. The Gravity Project changed that as well. The Gravity Project became a practicum of leadership itself. Over the course of the last year I have had to employ each of the DNP essentials to enable the project to succeed. The scientific underpinnings of practice were evident in the role of literature as my guide for definitions, crucial interventions, and diagnostic criteria. Systems thinking and systems leadership were evident as I evolved from being the food insecurity subject matter expert, to the clinical lead of the initiative, through my capacity to shape project priorities and direction and integrate content expertise, clinical practice, and informatics. The role of information systems in this initiative is clear. The project also required that I collaborate with the Office of the National Coordinator to integrate the initiative into data policy. The Gravity Project by design is a beautiful example of interprofessional collaboration toward a common goal- a community of thought representing the breadth of care required to address social needs. The intent to build language and tools to address SDOH is grounded in a public and population health orientation. This is enhanced by the project collaboration with US HHS, CMS, and state departments of health. Lastly, the project required thinking as a nurse at the top of my scope. If I had a concept of what advanced practice nursing was prior to this work, it has certainly evolved.

Although, I did not propose that an aim of the project was to develop a conceptual model, a beginning model has indeed evolved out of, and formed the basis for the Gravity work. I am grateful for the wisdom of my advisor. The model depicts how a lens of nursing ethics and evidence helps evolve the core activities of caring for social needs into their better selves. Screening become the application of validated tools. Diagnosis becomes the application of diagnostic criteria. Concepts are based on common sound definitions. Data evolves into

consistent interoperable terminology. Data standards and data policy become based on principles of data justice- person centered, with minimal bias, employed only for the good of the person. Lastly the interventions to heal the person, broaden to become activities, aligned with the WHO model, aiming to create just social policy. (See Figure 5)

Figure 5: The Transformative Lens of Ethics and Evidence in Addressing the Social

Determinants of Health



Conclusion

This project is best imagined as a set of interdependent outcomes. First, there are the three practical aims, all completed because of the camaraderie, expertise, and conviction of a broad set of national allies. Then, there is the evolution of the author, who started three years ago with an idea of how to make small but significant change as a lone architect and evolved into the leader of a national collective. Finally, both the labor of the aims and in some sense, the evolution of the person are conceptualized in the model in development which offers an ethical and scientific frame for the work. The common threads are that there is an imperative to act to

address inequity with all tools on hand, including the language to name what we see, that nurses are uniquely positioned to do this work, and that the work is good.

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Appendix A: ICD-10-CM Application as Submitted



**BlueCross BlueShield
of Vermont**

An Independent Licensee of the Blue Cross and Blue Shield Association.

Specific ICD-10-CM for Food Insecurity and Its Sequelae

BACKGROUND:

There is broad national consensus that assessing the social determinants of health (SDH) is a key facet of improving both individual and population health outcomes. This is represented first in the policy aims of government programs such as Healthy People 2020 (Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2020, 2010) and the Center for Medicaid and Medicare Services Accountable Health Communities Project (Alley, Asomugha, Conway, & Sanghavi, 2016; Center for Medicare and Medicaid Innovation, 2017).

Within the social determinants, food insecurity is an established concept of concern. The United States Department of Agriculture publishes a yearly report on the state of food insecurity (Coleman-Jensen, Rabbitt, Gregory, & Singh, 2017). Professional organizations such as the American Academy of Family Physicians (AAFP), the American Academy of Pediatrics (AAP) and the Academy of Nutrition and Dietetics have policy statements on the need for social determinant and food insecurity screening and assessment (American Academy of Family Physicians, 2012; American Academy of Pediatrics, 2015; Holben & Marshall, 2017). To aid clinicians in practice, both the AAFP and the AAP have toolkits with specific steps for SDH and food insecurity screening and assessment (American Academy of Family Physicians, 2018; American Academy of Pediatrics & Food Research and Action Center, 2017)

CURRENT ICD-10-CM TABULAR LIST:

Although ICD-10-CM has a code for food and water insufficiency (Z59.4: Lack of adequate food and drinking water), the concepts are joined, which makes tracking of each individual issue impossible. In addition, Z59.4 does not specifically represent the social and economic conditions that are inherent in the United States Department of Agriculture 2017 conceptual and operational definition of food insecurity. Lastly, there is no code to represent when patients with prescribed dietary needs are unable to follow a dietary regimen because of cost.

As we work toward more sensitive and specific screening and assessment for the social determinants of health in clinical practice, specific language for the mature concept of food insecurity is a necessary step.

PROPOSAL:

What we request, to aid patient and population care and study, is to divide Z59.4 into food and water concepts, add a specific Z59 code for the concern of food insecurity, and add a further code in the Z91 series to represent lack of compliance to dietary regimen due to financial hardship, a sequela of food insecurity.

P.O. Box 186 • Montpelier, VT 05601-0186
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BlueCross BlueShield of Vermont

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PROPOSED TABULAR MODIFICATIONS:

Z59.4	Add 5 th digit	Lack of adequate food and safe drinking water
		Z59.4x Inadequate food
		Z59.4x Food insecurity
		Z59.4x Inadequate drinking water supply
Z91.1		Patient's noncompliance with medical treatment and regimen
Z91.11	Add 6 th digit	Patient's noncompliance with dietary regimen
		Z91.110 Patient's noncompliance with dietary regimen due to financial hardship
Z71.8		Other specified counseling
	Add	Z71.8x Counseling for socioeconomic factors

SUBMITTED BY:

BlueCross BlueShield Vermont

Joshua Plavin, MD, MPH, MBA
Vice President and Chief Medical Officer

Yale School of Nursing

Sarah C. DeSilvey, MSN, FNP-C



BlueCross BlueShield of Vermont

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SUPPORTED BY:

AAPC Burlington Chapter of Professional Coders (80201)

Academy of Nutrition and Dietetics

Center for Promotion of Child Development Through Primary Care

Children’s HealthWatch

Colorado Prevention Alliance

Community Servings, Inc

Connecticut State Medical Society

Department of Vermont Health Access, (Vermont Medicaid) J. Scott Strenio, MD Chief Medical Officer

Excellus (BlueCross Blue Shield New York)

Feeding America

Food is Medicine Coalition

Food Research and Action Center (FRAC)

Fresh Advantage LLC

Fredric Garner, M.D., Burke Pediatrics LLC

Greater Lawrence Family Health Center

Health Begins

Raman Nohira, MD

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OneCare Vermont, Norman Ward, MD Chief Medical Officer

Oregon Primary Care Association

Regence (BlueCross BlueShield Oregon and Utah)

The Root Cause Coalition

Social Interventions, Research and Evaluation Network (SIREN)

South Boston Community Health Center

The South End Community Health Center

St Louis University College for Public Health and Social Justice/PHASE Program at SSM Health Cardinal Glennon Children’s Hospital

University of Vermont Children’s Hospital, Lewis First, MD Chief of Pediatrics



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Appendix B: ICD-10-CM Application as Presented

ICD-10 Coordination and Maintenance Committee Meeting
March 5-6, 2019

Food Insecurity

The Blue Cross Blue Shield of Vermont and the Yale School of Nursing are requesting new ICD-10-CM codes related to food insecurity. They note that there is broad national consensus that assessing the social determinants of health (SDH) is a key facet of improving both individual and population health outcomes. BCBS of Vermont notes that this is represented first in the policy aims of government programs such as Healthy People 2020 (Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2020, 2010) and the Center for Medicaid and Medicare Services Accountable Health Communities Project (Alley, Asomugha, Conway, & Sanghavi, 2016; Center for Medicare and Medicaid Innovation, 2017).

Within the social determinants, food insecurity is an established concept of concern. The United States Department of Agriculture publishes a yearly report on the state of food insecurity (Coleman-Jensen, Rabbitt, Gregory, & Singh, 2017). Professional organizations such as the American Academy of Family Physicians (AAFP), the American Academy of Pediatrics (AAP) and the Academy of Nutrition and Dietetics have policy statements on the need for social determinant and food insecurity screening and assessment (American Academy of Family Physicians, 2012; American Academy of Pediatrics, 2015; Holben & Marshall, 2017). To aid clinicians in practice, both the AAFP and the AAP have toolkits with specific steps for SDH and food insecurity screening and assessment (American Academy of Family Physicians, 2018; American Academy of Pediatrics & Food Research and Action Center, 2017)

Although ICD-10-CM has a code for food and water insufficiency (Z59.4, Lack of adequate food and drinking water), the concepts are joined, which makes tracking of each individual issue impossible. In addition, Z59.4 does not specifically represent the social and economic conditions that are inherent in the United States Department of Agriculture 2017 conceptual and operational definition of food insecurity. Lastly, there is no code to represent when patients with prescribed dietary needs are unable to follow a dietary regimen because of cost.

The submitter states that as we work toward more sensitive and specific screening and assessment for the social determinants of health in clinical practice, specific language for the mature concept of food insecurity is a necessary step.

The Blue Cross Blue Shield of Vermont and Yale School of Nursing request to aid patient and population care and study, is to divide Z59.4 capture food and water concepts separately, add a specific code at subcategory Z59.4 for the concern of food insecurity, and add a unique code at Z91.1 and Z71.8 to capture lack of compliance to dietary regimen due to financial hardship, a sequela of food insecurity.

This proposal is supported by a number of organizations and individuals including: the Academy of Nutrition and Dietetics, Colorado Prevention Alliance, Connecticut State Medical Society Blue Cross Blue Shield New York, and the Oregon Primary Care Association.

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ICD-10 Coordination and Maintenance Committee Meeting
 March 5-6, 2019

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TABULAR MODIFICATION

	Z59	Problems related to housing and economic circumstances
New subcategory	Z59.4	Lack of adequate food and safe drinking water Inadequate drinking water supply Excludes1: effects of hunger (T73.0) inappropriate diet or eating habits (Z72.4) malnutrition (E40-E46)
New code	Z59.41	Lack of adequate food Inadequate food Lack of food
New code	Z59.42	Food insecurity
New code	Z59.43	Lack of safe drinking water Inadequate supply of drinking water
	Z71	Persons encountering health services for other counseling and medical advice, not elsewhere classified
New code	Z71.8	Other specified counseling
	Z71.85	Counseling for socioeconomic factors
	Z91	Personal risk factors, not elsewhere classified
	Z91.1	Patient's noncompliance with medical treatment and regimen
	Z91.11	Patient's noncompliance with dietary regimen

ICD-10 Coordination and Maintenance Committee Meeting
March 5-6, 2019

New code

Z91.110 Patient's noncompliance with dietary
regimen due to financial hardship

Appendix C: ONC Gap Analysis Manuscript



**Gravity Project: Social Determinants of Health
(SDOH) Coding Gap Analysis
776-01280-000-04**

Deliverable 1.6.1: SDOH Data Gap Analysis Report

March 11, 2020

Prepared for:

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Deliverable 1.6.1: SDOH Data Gap Analysis Report



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- Donna Pertel, MEd, RD, Gravity Food Insecurity Co-Lead, Academy of Nutrition and Dietetics
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2.0 Executive Summary

The Gravity Project seeks to identify coded data elements and associated value sets to represent social determinants of health (SDOH) data documented across the following four clinical activities: screening, diagnosis, goals, and interventions. The Project is a direct response to the growing evidence of strong links between social risk and an individual's health and health care utilization. It focuses on identifying, developing, and validating 1) the data elements needed to document SDOH data across all four clinical activities, and 2) national standards to support the electronic capture and exchange SDOH data across a variety of systems and settings of care and social services. This paper summarizes the gaps in coding terminologies and data standards available to represent and exchange the data elements identified through the Project.

The following table summarizes the scope of the data content gaps by activity area and reflects the scope of work that will be required to improve these coded content gaps.

Table 1: Scope of Gaps in Data Content by Activity Area

Activity	Total # of Concepts	# Current Codes	# Requiring Codes
Screening	24 Screeners	2 Screeners	22 Screeners
	77 Questions	6 Questions	71 Questions
Diagnosis	8	5	3
Goals	6	0	6
Interventions	109	12	97

The data interoperability gap can be addressed through the development of standardized guidance for how data should be exchanged. This standardized guidance will be provided through a new SDOH focused [Fast Healthcare Interoperability Resources \(FHIR®\)](#) Implementation Guide (IG). FHIR® is a next generation standards framework created by the standards development organization, Health Level Seven (HL7). FHIR® leverages the latest web standards to build a base set of tested and validated resources that address a variety of use cases.

The Gravity Project became an HL7 FHIR® Accelerator project in August 2019. The HL7 FHIR® Accelerator Program is designed to assist implementers across the health care spectrum in the creation of FHIR® IGs, reference implementations, and other informative documents that assist with creating standardized applications to support and promote data interoperability. The Gravity Project is currently developing a FHIR® IG to support the capture and exchange of SDOH data.

3.0 Introduction

Initiated by the Social Interventions Research and Evaluation Network (SIREN) with funding from the Robert Wood Johnson Foundation and in partnership with EMI Advisors LLC (EMI), the

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Gravity Project is a multi-stakeholder public collaborative of 800+ participants focused on developing, testing, and validating standardized SDOH data for use in patient care, care coordination between health and human services sectors, population health management, public health, value-based payment, and clinical research.¹ The Gravity Project team includes representatives from SIREN, EMI, MaxMD, and the Academy of Nutrition and Dietetics.

The Gravity Project addresses the needs for both semantic and structural level interoperability of SDOH electronic data. It is executed as a public collaborative process using an HL7 Confluence website and online meeting platform. The first phase of the Gravity Project is focused on data interoperability of the following three key SDOH domains: food insecurity, housing instability and quality, and transportation access. The technical approach consists of five task areas represented in Figure 1 below.

The first task set the stage for the public collaboration and the scope of the project. The second task engaged the public collaborative in the identification of a consensus approved use case which specified the functional requirements for collecting and exchanging SDOH data in a clinical setting. The third task focused on developing data element definitions for three key SDOH domains: Food Insecurity, Housing Instability and Quality, and Transportation Access. As part of this task, the team established and refined a process to gather, review, and adjudicate robust data definitions for SDOH data documentation across four clinical activities of screening, diagnosis, goals, and interventions.

Other recognized SDOH domains will be prioritized and addressed in future phases of the Gravity Project.² Food insecurity was selected as the first SDOH domain to execute on based on the maturity of the work already done in this area and the availability of existing concepts in the key coding terminologies. In the fourth task, the team will conduct a coding gap analysis and develop coding recommendations to address the coding gaps identified for the data elements defined in task three.

This report presents the findings from the gap analysis conducted for the food insecurity data elements identified as part of Task 3 from July to December 2019 (see Figure 1). This report describes the process of achieving consensus on the most important data concepts, discusses how that data can best be shared across organizations, and identifies the gaps that need to be addressed in order to achieve interoperability.

The fifth task for this project involves the development, testing, and balloting of an HL7 FHIR Implementation Guide based on the use cases and coded data elements defined in tasks three and four.

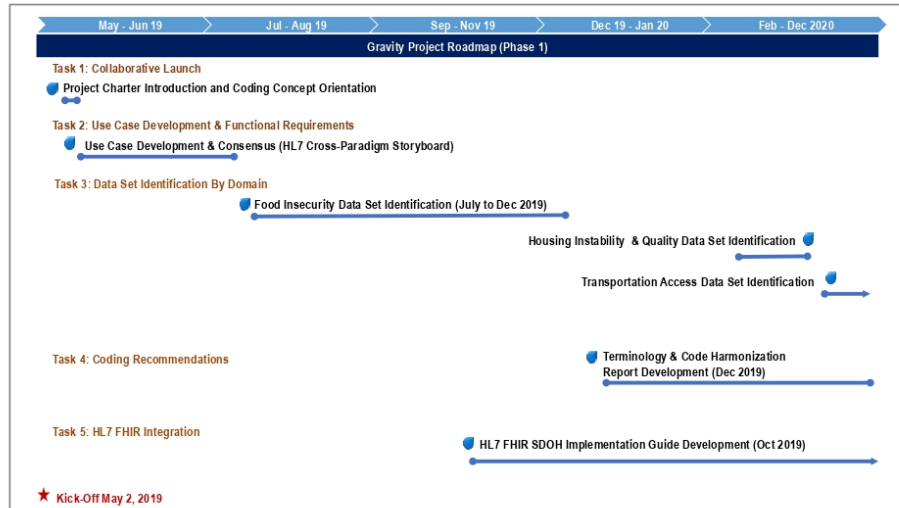
¹ Gallego, Evelyn. Why Data Standards Matter for SDOH Integration in Clinical Care: A Trajectory of the Gravity Project. December 16, 2019. <https://www.emiadvisors.net/2019/12/16/why-data-standards-matter-for-sdoh-integration-in-clinical-care-a-trajectory-of-the-gravity-project/>

² A total of 20 social risks domains were identified in Arons A, DeSilvey S, Fichtenberg C, Gottlieb L. [Documenting social determinants of health-related clinical activities using standardized medical vocabularies](https://doi.org/10.1002/jam2.10001). JAMIA Open. 2018;2(1):81-88. (<http://sirennetwork.ucsf.edu/tools-resources/mmi/compendium-medical-terminology-codes-social-risk-factors>)

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Figure 1: Gravity Project 2019 to 2020 Roadmap



References to the Food Insecurity Master List are made throughout this report. The Master List contains the adjudicated concepts for each of the care activity areas (screening, diagnosis, goals, interventions). The adjudication process involved the following steps:

1. The Gravity Project Food Insecurity Leads created an initial Master List based on their experience in the food insecurity domain.
2. The Gravity community was invited to review the Master List and submit recommendations for additions based on the data elements used in their organizations. These submissions were reviewed by the Leads and, if accepted, were added to the Master List. Submissions were returned to their respective organizations with the dispositions for each element submitted. The latest version of the Master List was published after each Gravity Public Collaborative meeting for everyone to review.
3. An end-to-end review period was held at the end of the submission period for community review and feedback. During the review period, additional updates were made to the Master List based on feedback. This feedback included but was not limited to clarifying definitions, creating more specific terms such as severity levels of food insecurity, and determining the appropriate CPT concepts to include for interventions.
4. A final consensus vote was held in December 2019. Committed Members of the Gravity community were asked to vote on acceptance of the Master List. "Yes with Comments" votes have been reconciled and all consensus voting results are available on the Gravity Confluence:

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<https://confluence.hl7.org/pages/viewpage.action?pageId=55938680#FoodInsecurityDomain-FinalFoodInsecurityConsensusVotingCommentsandDispositions-Published31January2020>

The Master List includes concepts that have codes in one of the following code systems: Current Procedural Terminology (CPT), Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT), Healthcare Common Procedure Coding System (HCPCS), Logical Observation Identifiers Names and Codes (LOINC®), and International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10). It also included concepts that will need to have codes added. The final published version of the Master List based on consensus voting reconciliation is available on the Gravity Project Confluence:

<https://confluence.hl7.org/pages/viewpage.action?pageId=55938680#FoodInsecurityDomain-FinalFoodInsecurityMasterList-Published31January2020>

4.0 Compendium Analysis

The work of the Gravity Project rests upon a prior work to collate and develop interoperable coded concepts to address social risk. The beginning of this effort can be traced to November 8th, 2017 when SIREN convened a gathering in Washington, D.C. of health industry leaders and stakeholders to review the rationale for integrating social concepts into interoperable data exchanges, to examine gaps in data, and to design a collaborative process to address these gaps. To ground this work, the team at SIREN and Sarah DeSilvey, one of the subject matter experts (SMEs) for the Gravity Project, performed a comprehensive search to create a compendium of existing social risk codes. The findings were published in the online spreadsheet, “Compendium of Medical Terminology Codes for Social Risk Factors”³ and then analyzed in the paper “Documenting Social Determinants of Health-Related Clinical Activities Using Standardized Medical Vocabularies.”⁴

This analysis clearly revealed large gaps in coded data that made it difficult to adequately document social risk. It also acknowledged a limitation of the collected terminology. The codes gathered as part of this work were based on a simple search without expert panel adjudication, so the quality of the collected codes themselves could not be determined. These findings, coupled with the investment of the November 8th gathering, catalyzed a national consensus project to build interoperable data sets to address social risk, which was stood up as the HL7 Gravity Project on May 2, 2019.

The Gravity Project addresses both the data gaps and the data quality concerns of the original compendium. It directly addresses gaps in data. To tackle the data gaps, the Gravity Project team asked the community to name not just what exists in data already, but what needs to exist to deliver quality care. The result was the discovery of a comprehensive set of missing

³ <https://sirenetwork.ucsf.edu/tools-resources/mmi/compendium-medical-terminology-codes-social-risk-factors>

⁴ Arons, A., DeSilvey, S., Fichtenberg, C., & Gottlieb, L. (2019). Documenting social determinants of health-related clinical activities using standardized medical vocabularies. *JAMIA Open*, 2, 81-88. doi: <https://doi.org/10.1093/jamiaopen/ooy051>

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food insecurity data elements in each of the following activities: screening, diagnosis, goals, and interventions. These data gaps will be more thoroughly detailed in later sections of the paper.

The project addressed data quality concerns by vetting every data element and every data definition identified through the process. All data submissions were thoroughly reviewed and discussed by both internal and external SMEs to ensure conceptual fit. The Gravity Project employed a collaborative review process to address data concept and quality issues.

The first facet of the approach involved constructing an adjudication criterion for each activity. For screening, screeners were only included if the primary outcome of the screen was the concept of food insecurity status. For example, screeners for food access, malnutrition, and financial strain were not added. Diagnosis criteria included only primary diagnoses of food insecurity, its strata of severity, and any linked concept that could not exist without food insecurity also being present. An example of the latter is the proposed ICD-10-CM code “patients non-compliance to dietary regimen secondary to financial hardship.” All other secondary diagnoses were excluded, regardless of the strength of evidence documenting association with food insecurity. Because of this process, some of the elements in the compendium were excluded as they were not a conceptual match to food insecurity even though they contained the search terms “food” and aligned with alternate social risks. Goals needed to be relevant to the domain and be measurable. To investigate interventions, the team gathered definitions for the various programs that support food insecurity and developed a framework to standardize intervention concepts. These aspects of the intervention work are described in more detail in the Intervention Gap Analysis section. Table 2 below identifies concepts in the compendium that were not included in the Food Insecurity Master List for the reasons noted above.

The second facet of the approach was driven by the need to assess semantic usefulness and consistency. The work to address the many gaps in intervention activities revealed that there are challenges with the existing concepts in the compendium. Some terms conflated discrete clinical concepts (such as “food education, guidance and counseling”). Others were not clearly defined, such as “arrange meals on wheels.” Given the breadth of concept gaps in the realm of intervention, it was necessary to create a framework to represent all core interventions, along with clear definitions for each. Performer roles and billing requirements were both considerations in the structure of the framework. The team conducted an extensive review of available literature and created an evidenced-based framework for all identified intervention activities, along with applicable SNOMET CT codes and definitions. All further data elements were built into this framework. As a result of using this framework to assess intervention concepts, some of the elements represented in the compendium were not added—even if they may have been a conceptual match, compendium concepts were excluded if their meanings were unclear and needed refinement.

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Table 2: Food Concepts in the Compendium That Were Not Added Due to Concept and Quality Adjudication

Activity	Concept	Reason
Screening	PhenX-Healthy food environments (Perceived Availability of Healthy Foods Scale)	Food Access concept
Diagnosis	Z73.8 Other problems related to life management difficulty	Not specific to food insecurity
	286442003 Unable to obtain food	Not specific to food insecurity
	286445001 Difficulty obtaining food	
Interventions	384811003 Meals on wheels program management	Administrative role, non-clinical
	410293007 Food education, guidance and counseling	Combines concepts that are discrete
	385766001 Meals on wheels provision assessment	Did not match intervention structure
	183681001 Arrange meals on wheels	
	410388007 Food surveillance	Not specific to food insecurity

5.0 Food Insecurity Definitions

During the course of this phase of the project, the team did an extensive review of the literature on food insecurity measurement, resulting in new working definitions for food insecurity that establish the foundation for a clinical finding that could be represented using a FHIR® Observation Resource build. These new definitions are:

- **Food Security:** Certain and stable access to food that is adequate in quantity and in nutritional quality; culturally acceptable; safe and acquired in socially acceptable ways.
- **Food Insecurity:** Uncertain, limited, or unstable access to food that is adequate in quantity and in nutritional quality; culturally acceptable; safe and acquired in socially acceptable ways.

This work started with reviewing the food insecurity definition of the United States Department of Agriculture (USDA), which can be found on the USDA website.⁵ This review identified three significant concerns:

1. Published definitions were population level rather than person level;
2. Definitions for food security and food insecurity were not inverse and, thus, did not allow for the computable logic of value sets; and
3. Definitions did not include more recent concepts of food insecurity, such as cultural acceptability.

⁵ <https://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-us/>

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- **Food Insecurity:** Uncertain, limited, or unstable access to food that is adequate in quantity and in nutritional quality; culturally acceptable; safe and acquired in socially acceptable ways.

These new working definitions include all of the primary dimensions for food insecurity: quantity, quality, cultural acceptability, safety and being acquired in socially acceptable ways. They address all of the status modifiers of food insecurity: uncertainty in the present, limitation, and stability (which allows for fluctuations over time). They also establish logically inverse concepts that support computable inferencing.

6.0 Care Activity Gap Analysis

The Gravity Project Co-Leads and SMEs for the Food Insecurity Domain were Sarah DeSilvey, FNP-C, University of Vermont, Larner College of Medicine and Yale School of Nursing and Donna Pertel, MEd, RD representing the Academy of Nutrition and Dietetics. They developed an initial list of concepts for the following four activities: screening, diagnosis, goals, and interventions.

- **Screening:** This refers to activities where SDOH data from individual patients are initially captured, whether through a self-administered, provider-administered, or health plan-administered questionnaire. These activities may also be repeated at certain intervals to monitor changes in social risks. The primary code set for these tools is LOINC®.
- **Assessment/Diagnosis:** These include activities where providers (clinical and community-based) and health plans analyze the data obtained through screening to determine a patient's social risks and needs. SNOMED CT and ICD-10-CM are the code sets for diagnosis, health status and other clinical findings.
- **Goals:** These refer to the intention of care—the “why” of treatment/intervention. Goals can be both patient and population specific. Patient goals are best made collaboratively with the patient and care team aligned with principles of person-centered care. Goals will be coded using LOINC®.
- **Interventions:** These refer to actions undertaken by providers (clinical and community-based) and health plans to help address identified social needs. These include referrals, case management, care planning, counseling and education, and provision of services and orders. SNOMED CT is the primary terminology for interventions with CPT and HCPCS as secondary code sets.

The Master List was introduced at the start of the Gravity Project public meetings and refined during the course of the project based on submissions from community members, discussions in the Gravity Project community meetings, and reviews with external SMEs.

This section of the report describes the coded concept gaps that were identified during the review of each of these care activities and the examination of concepts within several of the nationally recognized terminologies routinely captured using electronic health records and other technology in the course of care. These terminologies represent concepts used in other

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areas of health care and are catalogued in the Office of the National Coordinator for Health Information Technology’s (ONC’s) Interoperability Standards Advisory (ISA).⁶

Each of the following sections includes a table of the adjudicated food insecurity concepts. Each table shows concepts with currently existing codes in green and concepts without a code in red.

6.1 Screening

Table 3 presents the twenty-four screening tools that were submitted by Gravity public collaborative participants for review and adjudication. Each screening tool was reviewed against the following three criteria: validation against the USDA screener, whether the tool was part of a multi-domain screener, and applicable LOINC® Panel code and LOINC® Panel name for those that are currently in the LOINC® system. Validation status is included as an important part of the screening tool evaluation process in order to indicate whether each screening tool has been proven to actually measure what it was intended to measure. Validated tools were considered to be more appropriate for the purposes of capturing SDOH data.

Screening tools can be specific to food insecurity or they can have a multi-domain focus, meaning they can be used across all the social determinant domains, including food insecurity. For multi-domain tools, only those questions related to food insecurity were included in the Master List. Several of the tools are copyrighted, such as the KAISER YCLS and Kleinman, so permission would be required to add them to LOINC®. The complete list of screening tools, their component questions and answers, as well as reference information are in the Master List.

Table 3: Gravity Food Insecurity Master List Screening Tools

KEY:

X - validated against the USDA screener

O - low sensitivity when compared to the Hunger Vital Signs (HVS)

Validation Status	Relevant Screening Tool	Multi-domain	LOINC® Panel Code	LOINC® Panel Name
X	Hunger Vital Sign		88121-9	Hunger Vital Sign (HVS)
X	AHC (Accountable Health Communities Health Related Social Needs Screening Tool)	Yes		
	Medicare THA (Total Health Assessment)	Yes		
	IHELP	Yes		
	PRAPARE	Yes	93025-5	Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences [PRAPARE]
X	US household food security six item			

⁶ <https://www.healthit.gov/isa/sites/isa/files/inline-files/2019ISAResponseEdition.pdf>

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Validation Status	Relevant Screening Tool	Multi-domain	LOINC® Panel Code	LOINC® Panel Name
X	US household food security ten item			
X	US household food security 18 item			
X	FIES-SM (Food Insecurity Experience Scale)			
X	SWYC (Survey of Well Being of Young Children)	Yes		
X	Health Leads	Yes		
	We Care	Yes		
X	HFIAS (Household Food Insecurity Access Scale)			
	Kaiser YCLS (Your Current Life Situation)	Yes		
X	Household Food Security Survey Module (HFSSM) (NOTE: Canadian survey adapted from the US food security measurement method)			
X	USDA Youth			
	Health Information National Trends Survey			
O	SEEK (Safe Environment for Every Kid)	Yes		
X	Kleinman			
	Community Connect Social Needs Screening Tool	Yes		
	Community Health of Central Washington (CHCW) Internally developed SDOH Tool	Yes		
	Total Health Quick Check (CHC Sno)	Yes		
X	AAFP Social Needs Screening Tool	Yes		
O	North Carolina SDOH	Yes		

6.1.1 Screening Data Concept Gaps

Analysis of the screening data elements revealed an additional type of data element that is not a “question and answer”—the information is not solicited from the patient in the form of a question to be populated with the patient’s answer to that question. This other type of data element is defined solely within the context of the screening tool, and its definition is a derivation expression based on the answers associated with the questions posed in the questionnaire. This type of derived data element can be a score (such as summing the numbers assigned to the questions), or a more complex expression that evaluates the responses into an interpretation. These are both considered post-coordinated in that the value is determined after the screening answers have been collected but before the screening is considered to be “completed.”

The organization responsible for creating the screening tool defines these derived data elements as part of the tool. The definition of the element describes how to compute the data

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element based on the other collected variables. The rules for interpreting a screening tool are prescriptive and are part of what is standardized and validated when the screening tool undergoes validation.

Historically, interpretation data elements have been completed by the person administering or interpreting the screening by following the instructions supplied with the screening tool. As screening tools become available as questionnaires, logic describing how to derive an interpretation will need to be supplied and well-formed as a computable expression that can be executed programmatically. These post-coordinated interpretations may be completed by a computer system prior to completing the screening instrument. The current gap is how the automated creation of the QuestionnaireResponse resource in FHIR⁷ handles interpreting the derived data elements correctly. LOINC[®] codes with a property of “Imp” (meaning implied) are used for these types of data elements, rather than “Find,” which indicates that a question needs to be asked.

The following Figure 2 shows an interpretation data element (Food Insecurity Risk LOINC[®] 88124-3)⁸. This interpretation data element is defined as, “An answer of ‘often true’ or ‘sometimes true’ to either or both of the Hunger Vital Sign™ (HVS) questions identifies a patient as at risk for Food Insecurity (FI).”

Figure 2: Hunger Vital Sign (HVS) LOINC[®] Code 88121-9

LOINC CODE	LONG COMMON NAME	LOINC STATUS
88121-9	Hunger Vital Sign [HVS]	Active
Term Description		
The Hunger Vital Sign™ identifies individuals and families as being at risk for food insecurity. A positive screen is either question answered with "often true" or "sometimes true." Source: Regenstrief LOINC		
Panel Hierarchy		
Details for each LOINC in Panel LHC:Forms		
LOINC	Name	Example UCUM R/O/C Cardinality Units
88121-9	Hunger Vital Sign [HVS]	
88122-7	Within the past 12 months we worried whether our food would run out before we got money to buy more [U.S. FSS]	
88123-5	Within the past 12 months the food we bought just didn't last and we didn't have money to get more [U.S. FSS]	
88124-3	Food insecurity risk [HVS]	

⁷ <https://www.hl7.org/fhir/questionnaire.html>

⁸ This material contains content from LOINC[®] (<http://loinc.org>). LOINC is copyright © 1995-2019, Regenstrief Institute, Inc. and the Logical Observation Identifiers Names and Codes (LOINC) Committee and is available at no cost under the license at <http://loinc.org/license>.

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The HVS screening tool includes only two questions. The third data element in the panel is a derived data element. The derived data element in the panel, 88124-3 (see Figure 3 below), has a property of Imp and a method of HVS. The question data elements in the panel, 88122-7 (see Figure 4 below) and 88123-5 (not shown), have a property of Find and a method of U.S. Food Security Survey.

Figure 3: Example Derived Data Element LOINC® Code 88124-3

LOINC CODE 88124-3	LONG COMMON NAME Food insecurity risk [HVS]	LOINC STATUS Active
Term Description		
An answer of "often true" or "sometimes true" to either or both of the Hunger Vital Sign™ questions identifies a patient as at risk for food insecurity (FI). Source: Regenstrief LOINC		
Fully-Specified Name		
Component	Food insecurity risk	
Property	Imp	
Time	Pt	
System	^Patient	
Scale	Ord	
Method	HVS	

Figure 4: Example Question Data Element LOINC® Code 88122-7

LOINC CODE 88122-7	LONG COMMON NAME Within the past 12 months we worried whether our food would run out before we got money to buy more [U.S. FSS]	LOINC STATUS Active
Fully-Specified Name		
Component	Within the past 12Mo we worried whether our food would run out before we got money to buy more	
Property	Find	
Time	Pt	
System	^Patient	
Scale	Ord	
Method	U.S. Food Security Survey	

Existing FHIR® IG and Form Creation Tools need to offer more mature expression definition language to include these elements in questionnaires. The LOINC® code system may need additional refinements to distinguish and document the derivation rules associated with interpretation elements of a LOINC® panel code established to express the definition of the screening tool.

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The current standard expression language or syntax defined for expressing the relationship between a screening interpretation element and the other data elements collected within a screening tool needs to be evaluated to determine if it can address the more complex of these interpretation elements that will be needed in the future. More work is necessary to establish a machine processable language for describing how to compute the derived data elements (for example, application of the Clinical Quality Language (CQL) employed to define logical expressions used in quality measure definition).

Another gap area to address with Regenstrief, the entity responsible for curating LOINC®, concerns the use of similar questions across multiple screening tools. For example, there are several ways to ask if meals were skipped due to food insecurity in several screeners. If they are unique questions, they should each have a different LOINC® code assigned. To facilitate accurate workflows and proper data aggregation, discussions should be held with Regenstrief to look at practical solutions for handling semantically equivalent observations expressed using different question/answer representations. The association of multiple question/answer pairs to a single clinical finding may offer useful processing patterns that help code systems and computers identify semantically equivalent screening question/answer pairs.

6.1.2 Household Representation Gap

Representation of an observation about a household versus an individual patient was identified as a necessary data concept during the data element collection and Use Case creation phase of the project. This need was also submitted in community comments during the consensus voting period as an item for future consideration. It will be discussed further when planning begins for version 2.0 of the SDOH-CC IG planned for the 2021 development cycle. Addressing this need will involve the owners and users of the respective screening tools.

6.2 Diagnosis

Table 4 represents the Diagnosis tab in the Master List, including the diagnosis, diagnosis type (primary or secondary) and for those concepts in either SNOMED CT or ICD-10-CM (or both), the code and description. ICD-10-CM Code Status identifies those codes in the current version of ICD-10-CM and those “proposed,” which have been presented to the ICD-10 Coordination and Maintenance Committee for inclusion in a future release of ICD-10-CM.

As mentioned earlier in this report, only primary diagnoses were included in the Diagnosis Master List. This includes any linked concept that could not exist without food insecurity also existing. In addition, diagnoses that represent severity of food insecurity (mild, moderate and severe) are also listed. When both a SNOMED and ICD-10-CM code are on the same row, this indicates how they are presently mapped between the two systems.

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Table 4: Current and Proposed ICD-10-CM Codes

Key
Green – identifies concepts with codes that currently exist
Red – identifies concepts without a code

Diagnosis / Assessed Need	Diagnosis Type	SNOMED CT Code	SNOMED Fully Specified Name	ICD-10-CM Code	ICD-10-CM Description	ICD-10-CM Code Status
Food Insecurity	Primary	733423003	Food insecurity (finding)	Z59.4	Lack of adequate food and safe drinking water	Current
Food Insecurity	Primary			Z59.42	Food insecurity	Proposed
Food Insecurity	Primary	706875005	Insufficient food supply (finding)	Z59.4	Lack of adequate food and safe drinking water	Proposed
Food Insecurity	Primary			Z59.41	Lack of adequate food	Proposed
Food Insecurity	Primary	445281000124101	Nutrition impaired due to limited access to healthful foods (finding)	E63.9	Nutritional deficiency, unspecified	Current
Food Insecurity	Primary	445271000124104	Nutrition impaired due to limited access to nutrition related supplies (finding)	E63.9	Nutritional deficiency, unspecified	Current
Food Insecurity	Primary	129832003	Noncompliance with dietary regimen (finding)	Z91.11	Patient's noncompliance with dietary regimen	Current
Food Insecurity	Primary			Z91.110	Patient's noncompliance with dietary regimen due to financial hardship	Proposed
Mild Food Insecurity	Primary					
Moderate Food Insecurity	Primary					
Severe Food Insecurity	Primary					

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The work on defining food insecurity diagnoses also revealed a gap in the Care Activity Framework. In addition to the screening, diagnosis, goal, and interventions data elements, it was determined that a fundamental clinical assessment observation needs to be developed and tied to the definition of food insecurity developed by the Gravity community. In a clinical care setting, between screening being performed and a diagnosis being made, a clinician documents his or her observation of the situation to establish the evidence upon which a diagnosis can be made. These simple assertions of present or absent observables are documented as the clinician’s clinical finding (observation). A simple assertion such as “food insecurity present” may be based on screening information and other information gathered from speaking with and examining the patient. A clinical finding such as food insecurity may require the severity of the food insecurity to be observed. Having well-formed definitions for terms such as Mild Food Insecurity, Moderate Food Insecurity, and Severe Food Insecurity makes it possible for these finer-grain notions to be represented as discrete data elements. The definitional work done by the Gravity Project in the area of diagnoses (conditions) needs to be applied to the representation of the clinical finding that is the evidence for the diagnosis.

Review of the existing SNOMED CT concepts uncovered some issues that will need to be addressed with the steward of SNOMED CT. These issues include updates to definitions, such as the one for the food insecurity concept, and review of the hierarchy placement. Future work with stakeholders will allow the Gravity Project to propose appropriate modeling of the concept “food insecurity” in SNOMED CT.

6.3 Goals

Six goals were identified for food insecurity (see Table 5). Goals were included if they were relevant to the domain and were measurable. Two of these are patient defined goals and the remainder are organizational goals. Organizational goals may be assessed by reviewing patient-level data or they may only be assessable by examining organization-level data. It is important to note that the use cases in scope for this phase of the Gravity Project focus only on patient-centered goals. None of the goals in the Master List are currently coded concepts. Requests will need to be made for their inclusion in LOINC®.

Table 5: Current and Proposed LOINC® Codes

Key
Red – identifies concepts without a code

Goal	Goal Type	LOINC® Code	LOINC® Long Name
Food security	Patient		
Intervention for food insecurity	Organization		
Decrease in severity of food insecurity	Patient		
Decline in prevalence of food insecurity	Organization		
Screening for food insecurity	Organization		
Access nutrition and food support program resources	Organization		

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6.4 Interventions

A significant amount of work revolved around the development of intervention concepts in the Master List. This included development of program definitions and creation of a framework for defining interventions.

6.4.1 Intervention Program Definitions

During the course of this project the Food Insecurity Leads gathered information on program definitions to assist in the creation of interventions related to the various local, state, and federal programs available to address food insecurity issues. Table 6 reflects the current definitional work completed for this project. Note that this is a work in progress and there will be updates in the future based on community feedback and further discovery.

Table 6: Current Definitional Work Completed by Gravity To-Date

Program	Definition	Includes, but Not Limited To
Benefits enrollment assistance	A program that coordinates cross sector benefit eligibility, assessment and application.	
Child and Adult Care Food Program (CACFP)	A government program that provides CACFP reimbursements for nutritious meals and snacks to eligible children and adults who are enrolled for care at participating childcare centers, day care homes, and adult day care centers. The program also provides reimbursements for meals served to children and youth participating in afterschool care programs, children residing in emergency shelters, and older adults or living with a disability and enrolled in day care facilities.	
Community action agency	Non-profit private and public organizations established under the Economic Opportunity Act of 1964 with the aim of helping people achieve self-sufficiency. https://www.hud.gov/states/california/homeless/commaction	
Community Meal Program	Meals for a target group.	Congregate meals
Community resource assistance	Help connecting individuals with available community resources to address identified social needs.	
Food and nutrition incentive program	Financial incentives or matching programs to promote consumption of healthful foods including produce via community supported agriculture and other initiatives.	Gus Schumacher Nutrition Incentive program Senior farmers market
Food Distribution Program on Indian Reservation (FDPIR)	Provides USDA Foods to income-eligible households living on Indian reservations and to Native American households residing in designated areas near reservations or in Oklahoma. USDA distributes both food and administrative funds to participating Indian Tribal Organizations and state agencies to operate FDPIR.	

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Program	Definition	Includes, but Not Limited To
Food pantry program	A community based supportive food and nutrition program offering food to individuals for consumption. https://www.feedingamerica.org/our-work/food-bank-network https://www.fns.usda.gov/fdpir/food-distribution-program-indian-reservations	FDIPR (Food Distribution Program on Indian Reservation) School based pantry
Food prescription program	Prescription from a health care provider to access foods recommended, which also includes vegetables, fruits, and prescriptions for other foods.	Food Prescription Produce Prescription Veggie Prescription
Food provision program	Food offered when a support need is identified. Examples include groceries as part of an education opportunity (e.g., cooking class), commodity food program, food rescue or gleaning program (e.g., produce brought to a clinic), or weekend food backpack program.	
Garden programs	Actions to plant gardens to produce foods for consumption.	
Home delivered meal program	Meals delivered to a client's place of residence supported or subsidized by a charitable, social, or government agency.	Meals on wheels
Meals on wheels program	A specific home delivered meal program for eligible older adults and household members with demonstrated social and/or economic need.	
Medically tailored meal program	Meals delivered to individuals, living with assessed illness, tailored to the medical needs of the recipient by a Registered Dietitian Nutritionist (RDN). http://www.fimcoalition.org/our-model	
Nutrition and food support programs	Support programs that provide food and/or nutrition resources.	
School meal and snack program	Meals and snacks that meet specific nutrition standards and are available to school-aged children throughout the year. https://www.fns.usda.gov/school-meals/faqs	
Senior congregate meal program	Meals offered in community settings for eligible older adults, and along with eligible supportive individuals.	
Senior farmers market program	Financial incentives or matching programs to promote consumption of produce by older adults. https://www.fns.usda.gov/sfmnp/senior-farmers-market-nutrition-program	
SNAP education	Nutrition curriculum, a facet of the SNAP program.	
Special Supplemental Nutrition Program for Women, Infants, and Children (WIC)	Supplemental foods, health care referrals, and nutrition education for low-income pregnant, breastfeeding, and non-breastfeeding postpartum women, and to infants and children up to age five who are found to be at nutritional risk. https://www.fns.usda.gov/wic	WIC farmers market program
Summer meal and snack program	A program that reimburses program operators who serve free healthy meals and snacks to children and teens in low-income areas. https://www.fns.usda.gov/sfsp/summer-food-service-program	

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Program	Definition	Includes, but Not Limited To
Supplemental Nutrition Assistance Program (SNAP)	A government-based nutrition benefit program to supplement the food budget of qualified families for purchasing food. The US program is currently call the Supplemental Nutrition Assistance Program (SNAP). https://www.fns.usda.gov/snap/supplemental-nutrition-assistance-program	
WIC Farmer's Market program	Coupons for participants of the WIC program to purchase food at farmers markets. https://www.fns.usda.gov/fmnp/wic-farmers-market-nutrition-program	

6.4.2 Interventions Framework

There are both structural and terminology-related constructs that influence standardized representations of interventions within the clinical space (e.g., procedures, medication administration, immunizations, referrals to other programs, providers, and specialties). Presently, interventions to address the SDOH do not fit neatly within these existing terminologies. The following framework was developed to establish consistency across settings and roles within multiple communities. It was used to construct the Intervention section of the Food Insecurity Master List:

- **Referral.** A type of order wherein clinicians/providers request services and/or assessment from other professionals and/or programs.
- **Provision.** For the purposes of the project, provision covers any concrete support that is able to be given to the patient directly at the point of service.
- **Counseling.** Psychosocial procedure that involves mental/behavioral strategies such as listening, reflecting, etc. to facilitate recognition of course of action/solution.
- **Education.** Procedure that is synonymous with those activities such as teaching, demonstration, instruction, explanation, and advice that aims to increase knowledge and skills, change behaviors, assist coping.
- **Assessment.** Assessment includes both the process of provider clinical observation and interpretation and the utilization of assessment tools. In both activities the aim is to arrive at outcomes that define the status of the patient in order to guide further care.
- **Evaluation of eligibility.** Chosen to mark the activities prior to determination of eligibility. (Crucial for federal food assistance programs).
- **Assistance.** Non-clinical aid with the tasks of care such as applications and setting up appointments.
- **Coordination.** Organizing activities and sharing information.

It is important to note that this framework distinguishes “assessment” from “evaluation of eligibility.” These separate notions of assessment and evaluation are not distinguished in

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SNOMED CT. The Gravity Project will need to engage with SNOMED CT to understand the implications of this framework and determine whether or not it can be supported.

Several comments received from the Gravity Community indicate that further refinement of this framework may be needed in order to reach the level of clarity required to model the complex referral and intervention concepts present in clinical care when addressing a patient’s social determinants of health.

6.4.3 Interventions Master List Gaps

The Master List includes over 100 data elements for Interventions. Table 7 provides a snapshot of food insecurity interventions and identifies those that currently have a code in SNOMED CT, which is the primary terminology to document interventions.

Table 7: Snapshot of Interventions Data Concepts in the Food Insecurity Master List

Key
Green – identifies concepts with codes that currently exist
Red – identifies concepts without a code

Intervention	SNOMED CT Code	SNOMED CT Fully Specified Name
Assessment for food insecurity		
Assessment of nutritional status	1759002	Assessment of nutritional status (procedure)
Assistance with application for Food Pantry Program		
Assistance with application for nutrition and food support programs		
Community Action Agency education		
Coordination of care plan		
Counseling for barriers to goals		
Counseling for readiness for goals		
Education about nutrition and food support programs		
Evaluation of eligibility for Food and Nutrition incentive program		
Evaluation of eligibility for Home Delivered meals		
Evaluation of progress toward goals		
Education about food and nutrition incentive program		
Education about meals on wheels program	385767005	Meals on wheels provision education (procedure)
Nutrition counseling	441041000124100	Counseling about nutrition (procedure)
Nutrition education	61310001	Nutrition education (procedure)
Provision of food	710925007	Provision of food (procedure)
Provision of medically tailored meals		
Referral to community health worker		
Referral to community meal program	713109004	Referral to community meals service (procedure)

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Intervention	SNOMED CT Code	SNOMED CT Fully Specified Name
Referral to Dietitian Nutritionist	103699006	Patient referral to dietitian (procedure)
Referral to Food and nutrition incentive program		

As noted in the analysis of the diagnoses data elements, there are a few intervention data elements that will need further review with the stewards of the SNOMED CT Code System, including definitions of concepts such as “education” and concepts that conflate multiple interventions such as “food education, guidance and counseling.”

6.4.4 CPT/HCPCS Classification System Gaps

The coding gap analysis activities revealed additional gaps in existing applicable CPT and HCPCS coding. The Gravity Project team applied a similar adjudication approach, akin to the approach applied for screening tools, to assess HCPCS and CPT concepts applicable to food insecurity. Codes for “health risk assessment and intervention” and “medical nutrition assessment” were included because they are more closely aligned with food insecurity interventions. “Non-specific professional evaluation and management (E&M)” CPT codes were not included because they are used for a wide variety of purposes and thereby cannot be directly applied to food insecurity. One clear gap identified was coding for “Medically tailored nutrition”—defined by the *Food is Medicine Coalition*⁹ as distinct from home delivered meals. “Medically tailored meals (MTM)” are delivered to individuals living with severe illness through a referral from a medical professional or healthcare plan. Meal plans are tailored to the medical needs of the recipient by a Registered Dietitian Nutritionist (RDN), and are designed to improve health outcomes, lower cost of care, and increase patient satisfaction.¹⁰ Given the extensive use of MTM codes for both Centers for Medicare & Medicaid Services (CMS) and private insurance reimbursement, it is critical to address this gap within the Gravity Project.

The List of CPT/HCPCS concepts can be found in the Master List. The gaps identified for CPT and HCPCS codes will be addressed by the end users of these code systems.

6.4.5 Human Services Data Collaboration Gap

The consolidation of intervention data concepts yielded additional gaps outside the scope of the Gravity Project, both of which involve data mapping to other taxonomies and integration with community data approaches. The first is described in this section and the second is described in the following section 6.4.6.

⁹ <http://www.fimcoalition.org/>

¹⁰ <http://www.fimcoalition.org/our-model>

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6.4.5.1 2-1-1- Taxonomy

The 2-1-1 Taxonomy is a classification system describing types of human services and the associated types of populations served. It is in use by “Information-and-Referral” providers certified by the Alliance of Information and Referral Systems (AIRS), as well as key federal programs operated by the Department of Housing and Urban Development. It is the protected intellectual property of 2-1-1 Los Angeles.

When it comes to aggregated and verified information about programs available to address social needs, the 2-1-1 Taxonomy is likely the most detailed and authoritative body of knowledge. The 2-1-1 Taxonomy has been cross-walked to some other existing taxonomies, such as the National Center for Charitable Statistics’ National Taxonomy of Exempt Entities (NTEE) and ICD-10. The intellectual property restrictions, however, limit its use in various settings, including broad public interoperability initiatives.

Gravity revealed a key need to employ or develop a services/program taxonomy to define the programs themselves in records and enable the identification of services in FHIR syntax. Opportunities exist to work with 2-1-1 Los Angeles, AIRS, stakeholders, and standards organizations such as SNOMED and Regenstrief, to plot an open interoperable solution. This project relates to the second gap that is also out of scope for the Gravity Project, which involves eligibility and enrollment panels as described in the following section 6.4.6. This is relevant for activities where a panel identifies enrollment in a program and will need to be mapped to the defined program taxonomy code.

6.4.5.2 Syntactic Interoperability for Data About Services

The Human Services Data Specification (HSDS) and API protocols, a.k.a. the Open Referral format, is a data interchange format that specifies types information about organizations, the services they provide, and locations at which they are offered to facilitate exchange of this data among heterogeneous information systems and institutional contexts. It is analogous to FHIR for information about services. (HSDS does not specify types of services or types of people, but rather provides instructions for how such taxonomies can be linked with the underlying data about the services’ location, accessibility, etc.) The Alliance of Information and Referral Systems has formally endorsed HSDS as a standardized method of exchanging resource directory data.

We recommend that future iterations of relevant FHIR modules (perhaps specifically the HealthcareService module - <https://www.hl7.org/fhir/healthcareservice.html>) evolve in alignment with this industry standard, ideally through field implementations that can yield replicable mapping and translation tools.

6.4.6 Eligibility and Enrollment Panel Gap

Through the consolidation and definition of programs and clinical activities of care, the Gravity Project identified a need for a LOINC® panel to represent both eligibility for and enrollment in programs. Eligibility and enrollment are both out of scope; however, the community strongly believes these are crucial elements for supporting Gravity use cases across a variety of settings.

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The team engaged in initial communications with Regenstrief for development of a rolling panel that could include all key programs across social need domains.

6.4.7 Data Element Definition Process Gap

When new codes are identified for use in standards-based information exchange, the code system owner requires assurances that the proposed concepts are properly defined and are fit for the intended purpose before agreeing to create them. The HL7 Connectathon¹¹ testing and balloting process ensures that codes proposed for use in an IG are properly defined and fit for purpose. This permits the creation of new coded concepts to proceed without introducing unneeded or poorly defined codes that do not aid efforts in achieving interoperability.

The Office of the National Coordinator (ONC) United States Core Data for Interoperability (USCDI)¹² has established a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange. New USCDI data elements will be proposed through an open, collaborative process through a publicly available submission and promotion system. The Gravity Project intends to use the USCDI promotion model to advance the interoperability of SDOH data elements.

7.0 Interoperability Gap Analysis

It is true that coded data is required to allow organizations to effectively use information in today's computerized environment; however, a list of codes (with their associated meanings) is insufficient for interoperability that supports specific, meaningful, and consistent use of the coded information. In order to support and promote meaningful and consistent use of coded information, it is imperative to provide clear guidance that defines the syntax, structure, codes, and transport protocols expected to facilitate information exchange among disparate systems.

The Gravity Project has identified three critical use cases¹³ to enable valuable exchange of SDOH information between clinical and community-based systems and other systems supporting organizations that supply human services intended to address SDOH issues, as well as systems that perform secondary analysis on SDOH information (e.g. researchers). Those use cases are as follows:

1. Document SDOH Data in Conjunction with the Patient Encounter;
2. Document and Track SDOH Related Interventions to Completion; and
3. Gather and Aggregate SDOH Data for Uses Beyond the Point of Care.

The Master List of concepts relevant to these use cases does not provide the level of instruction that implementers need in order to be able to exchange information in a standardized way using these codes. To attain interoperability, more detailed guidance must be developed, tested, and adopted as an agreed upon standard.

¹¹ <http://www.hl7.org/events/fhir-connectathon/index.cfm>

¹² <https://www.healthit.gov/uscdi>

¹³ <https://confluence.hl7.org/display/GRAV/Gravity+Use+Case+Package>

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An HL7 Implementation Guide (IG)¹⁴ provides comprehensive instructions and testable expectations that implementers can use to design and deploy systems that communicate needed information in standard ways. The HL7 Connectathon testing and balloting process ensures that the instructions in a published IG effectively address the use case transactions and meet community expectations for sharing the needed information. The Gravity Project connects the necessary technical steps of developing an IG and testing data sets with the overarching community engagement and education necessary to achieve the desired interoperability.

8.0 Conclusion

The food insecurity domain phase of the Gravity Project achieved several milestones. The team established and refined a process to gather, review, and adjudicate robust data definitions for SDOH data documentation across four clinical activities of screening, diagnosis, goals, and interventions. The ability to engage key stakeholders through the Gravity public collaborative established a method to achieve multi-stakeholder consensus on data concepts and to identify coding gaps that need to be addressed through the HL7 standards development process. Initial Gravity FHIR IG development activities acknowledge the significant progress made by HL7 to-date to standardize the exchange of data across disparate systems and multiple users of data. The next phases of the Gravity Project will build on these efforts and identify the priorities needed to close the gaps that have been identified in this report.

¹⁴ HL7 Implementation Guides explain how to use HL7 standards such as FHIR, CDA, and V2 to facilitate information exchange among disparate systems.