Evidence-based Practice Center Systematic Review Protocol

Systematic Review of Maternal and Childhood Outcomes associated with the Special Supplemental Nutrition Program for Women, Infants and Children (WIC)

November 20th, 2020

Amendment Date(s) if applicable: May 14th, 2021

(Amendments Details–see Section VII)

I. Background

The Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) was established in 1974 to safeguard the health of low-income women, infants, and children up to age five who are at nutritional risk, by providing nutritious supplemental foods, nutrition education, breastfeeding support, and referrals to other health and social service programs. WIC is administered by the U.S. Department of Agriculture (USDA) Food and Nutrition Service (FNS) through 89 State agencies, and in 2018 served 7.8 million people.[1] To be eligible for WIC, a person must be pregnant, up to 12 months postpartum, an infant up to age 1, or a child between ages 1 and 4. Applicants must be considered "at nutritional risk" and have household income less than or equal to 185 percent of the Federal Poverty Guidelines issued annually by the U.S. Department of Health and Human Services. Applicants may also be adjunctively income-eligible for WIC if they participate in Medicaid, the Supplemental Nutrition Assistance Program (SNAP), or Temporary Assistance for Needy Families (TANF). Applicants must live in the State or Territory in which they apply or meet the residency requirements established by an Indian Tribal Organization (ITO). In 2017, about 14.1 million people in the U.S. were eligible to receive WIC benefits; program coverage (those receiving benefits of those eligible) was 45% for pregnant women and 79% for infants, and declines with age among children (figures for children from 1-4 are: 58%, 44%, 40% and 25%, respectively).[2]

WIC has been the subject of numerous studies of its impact on maternal and child outcomes, and over time WIC has evolved to better and more efficiently address program goals and maintain consistency with the latest dietary guidelines (see **Figure 1** for key changes). In 2004, USDA[3] published a review of the effectiveness of WIC as one of several federal assistance programs and included published studies from the 1970s through 2002. A second review, published by USDA in 2012, covered studies from 2002 to 2010 and unpublished studies from 1999 to 2002 (i.e., going beyond the 2004 review[3]), while also explicitly evaluating the quality of the evidence.[4] The 2012 review[4] found evidence that WIC participation was associated with improved birth outcomes and child diet quality. The review identified weaker quality evidence, subject to selection bias, suggesting that WIC participation was associated with a lower likelihood of breastfeeding and mixed findings on infant or child anthropometric outcomes (e.g., weight-for age, length-for-age, overweight, failure-to-thrive). The 2012 review also found that no clear conclusions could be drawn with respect to outcomes for child health and development. The time period for the review[4] focused on the evaluation of outcomes prior to the 2009 change in the WIC food package. The 2009 change was the first major change in the food package and was designed to address weaknesses in the package for breastfeeding promotion, improved diet quality, and child obesity prevention.[5] In the years since the 2009 food package change, new studies have evaluated outcomes for women, infants, and children associated with WIC participation. Our review coincides with the timeline for re-evaluation of the package (Figure 1)

as well as the anticipated Dietary Guidelines for Americans (DGA) 2020-2025 which will include guidelines for pregnancy, and birth to 24 months. In the review, we intend to synthesize evidence on the effectiveness of WIC that is pertinent to decision making at both the clinical and policy levels. Clinicians (including pediatricians, obstetricians, nutritionists, and public health professionals) as well as WIC participants themselves need reliable information about the overall effectiveness of WIC. Policy makers at the state and federal levels need such information to determine whether changes should be made in WIC programming to further improve dietary and health outcomes for women, infants, and children.

Changing policies and program

WIC provides many services including supplemental nutritious foods, nutrition education, breastfeeding support and support of and referral to other services, which are thought to lead to improved intermediate outcomes and nutrition and health outcomes. The WIC timeline (Figure 1) shows changes in service provisions over time, most notably revision of the supplemental food package in 2009. The food package changes were made to align with recommendations from the Institute of Medicine (IOM, renamed as National Academy of Medicine in 2015) review of the WIC food package[6] the American Academy of Pediatrics (AAP) recommendations regarding breastfeeding, and the Dietary Guidelines for Americans 2005[7] for chronic disease prevention. The changes included adding more fruits, vegetables and whole grains, a switch to low-fat milk (at age 2 years), reductions in amount of 100% juice, and enhanced provisions for exclusive breastfeeding women, all of which were considered important for child outcomes, including breastfeeding, nutrient intake, diet quality, growth, and obesity prevention. The transition from using paper food instruments for WIC purchases to the use of electronic benefit transfer (EBT) technology has also presented a substantial change to the Program over the last decade. The Healthy Hunger-Free Kids Act of 2010[8] mandated that by October 1, 2020 all WIC State agencies would have established statewide EBT systems for all WIC food redemption.

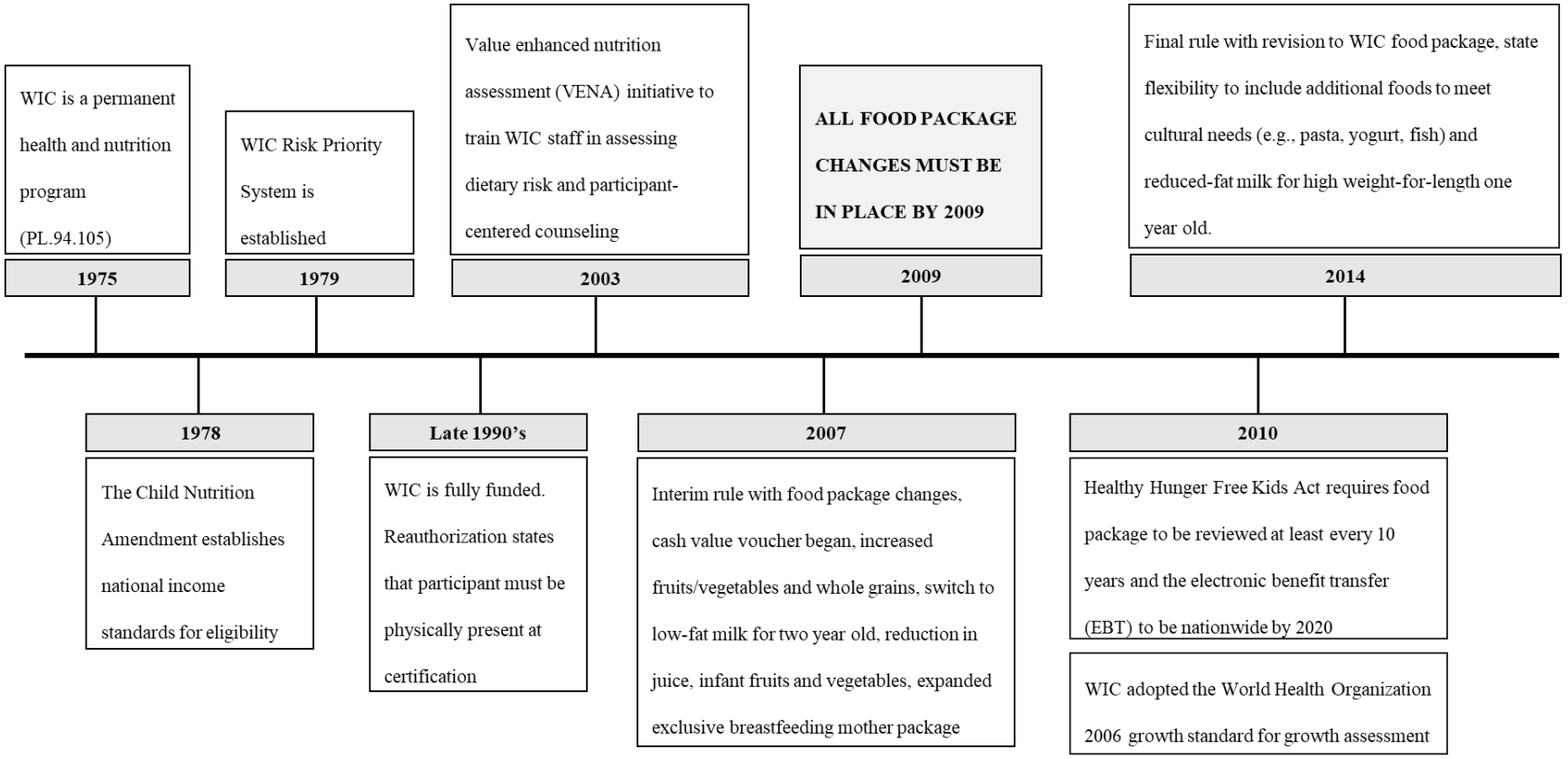
Participation in WIC and limited causal evidence problem

WIC is a federal program administered by 89 State agencies in accordance with federal regulations. Causal evidence of impact through randomized controlled trials is limited/non-existent. Studies have used non-experimental designs and "natural experiment approaches" to assess effects, e.g. use of propensity scores to reduce bias due to participant and other antecedent factors which influence participation. As noted in the 2012 evidence review[4], studies have used innovative strategies (e.g., propensity matching methods) to enhance the causal inference regarding the effectiveness of WIC for women and child outcomes.

Purpose of the Review

This systematic review will summarize the evidence on how participation in WIC is associated with outcomes for women and children. This review will be inclusive in its consideration of study designs utilized to evaluate WIC participation and maternal and child outcomes, but also evaluate the quality of evidence provided by studies, and consider how studies have characterized participation of women and/or children in WIC, to best inform what is known and what are the evidence gaps to be addressed in future research. Because the questions for the review seek evidence among sub-groups of WIC participants, the review will indirectly address whether WIC participation addresses inequities in outcomes for women and children.

Figure 1.WIC timeline with selected key program changes



II. The Key Questions (KQ)

Key Question 1: Among women who are eligible to participate in WIC, how is WIC participation during pregnancy associated with maternal and infant birth outcomes?

a. Does the association vary by gestational age at WIC enrollment or duration of mother's WIC participation?
b. Does the association vary by participant factors such as:
    i. Age of the mother at delivery
    ii. Race/ethnicity of mother
    iii. Geographic location (e.g. region, urban vs. rural)
    iv. Education of the mother
    v. Employment status of the mother
    vi. Marital status
    vii. Housing (e.g. public), homelessness

Key Question 2: Among infants and children eligible to participate in WIC, how is WIC participation associated with dietary and health outcomes in childhood?

a. Does the association vary by age or duration of WIC participation?
b. Does the association vary by participant factors such as:
    i. Age of the mother at delivery
    ii. Race/ethnicity of child
    iii. Geographic location (e.g. region, urban vs. rural)
    iv. Education of the mother
    v. Employment status of the mother
    vi. Marital status of the mother
    vii. Housing (e.g. public, private), homelessness

PICOTS Inclusion Criteria

A brief overview of the PICOTS inclusion criteria is provided here:

Table 1. PICOTS

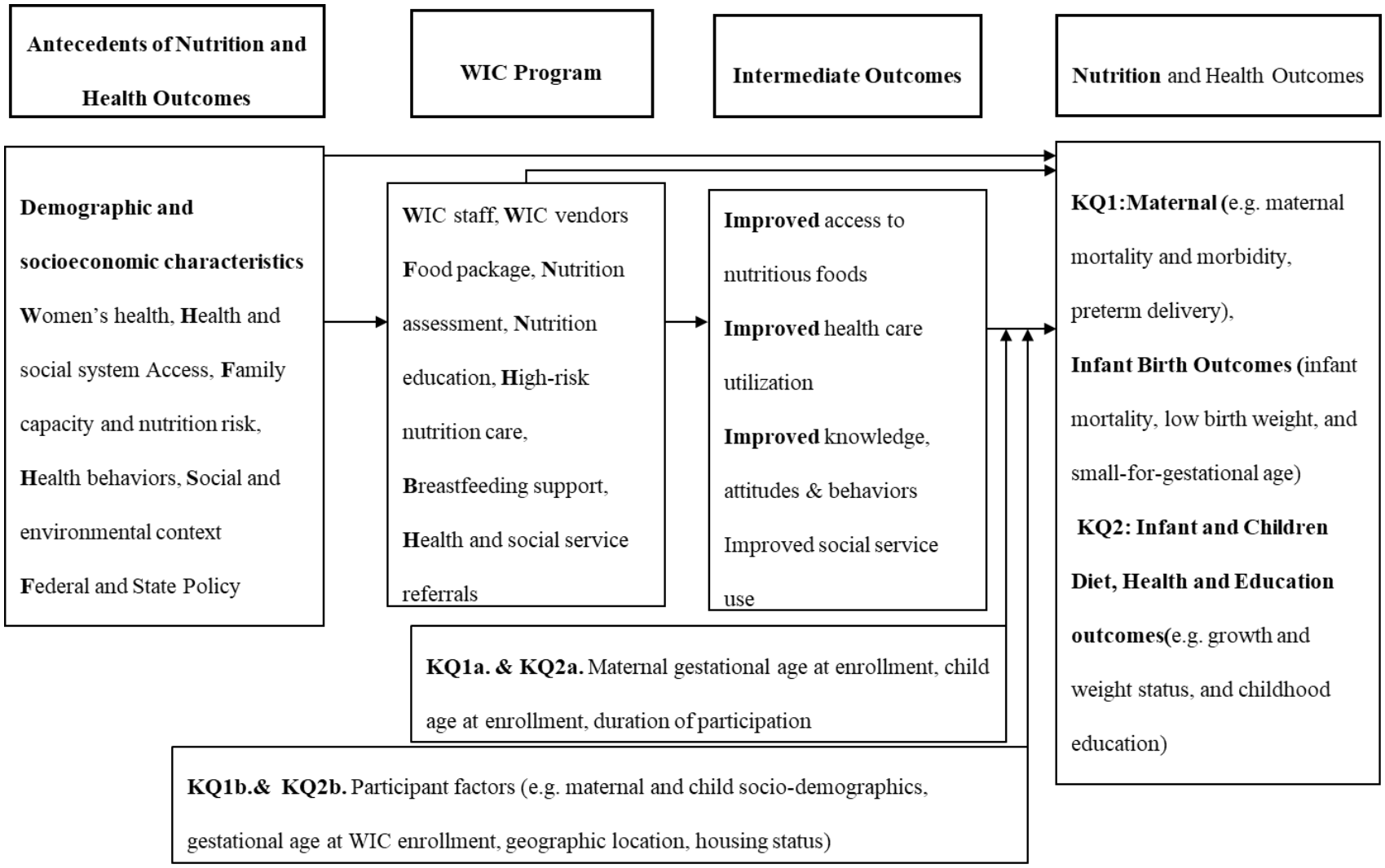
PICOTS elements	KQ 1	KQ 2
Population	Women who participated in WIC during pregnancy and their infants at birth up to 28 days **Participant factors include;** age of mother at delivery, race/ethnicity of mother, geographic location, education of mother, employment status of mother, marital status of mother, housing, parity, and maternal nutritional status at enrollment	Infants/children who participated in WIC (age from 29 days up to age 5) **Participant factors include;** age of mother at delivery, race/ethnicity of child (or mother), geographic location, education of mother, employment status of mother, marital status of mother, housing, parity of mother, and maternal and/or child nutritional status at enrollment
Intervention	Participation in WIC with service provisions from 2009 onwards (year and location), defined at a minimum as enrolling in WIC for one month or more	Participation in WIC with service provisions from 2009 onwards (year and location), defined at a minimum as enrolling in WIC for one month or more
Comparison	Women who were eligible for WIC, but did not participate during pregnancy, and their infants at birth up to 28 days; duration of WIC participation	Infants/children who were eligible for WIC, but did not participate at the age studied (ages from 29 days up to 5 years); duration of WIC participation
Outcomes*	**Dietary practices** of infants and mothers, diet quality, household food security, food purchasing **Anthropometric status**: weight status (e.g. BMI, underweight, obesity) **Maternal**: e.g. anemia, weight gain, health care utilization (prenatal, postpartum), mode of delivery, intra- and post-partum complications, morbidity and mortality **Infant birth outcomes**: e.g. gestational age, birth weight, small/large for gestational age, birth complications such as preterm delivery, hospitalization	**Dietary practices** of infants and children, diet quality, household and child food security, food purchasing **Anthropometric status**: e.g. weight-for-age, length- or height-for-age, weight-for-length, or weight-for-height percentile or Z-score, BMI-for-age percentile or Z-score, underweight, and obesity), growth velocity **Infant and child outcomes**: anemia, iron deficiency anemia, iron deficiency, primary health care utilization, immunization status, morbidity and mortality **Child development/school performance** (e.g., cognitive development, behavioral development, educational performance, school-related factors (e.g. attendance, behavior))
Timing**	Studies published 2009 onwards	Studies published 2009 onwards
Setting	Any jurisdiction served by a WIC State or Local Agency	Any jurisdiction served by a WIC State or Local Agency
Study Design	Intervention trials (randomized and non-randomized), observational studies, quasi-experimental, before-after, interrupted time series	Intervention trials (randomized and non-randomized), observational studies, quasi-experimental, before-after, interrupted time series

* Please see appendix A for the detailed list of outcomes

** Only for specific key outcomes (maternal mortality, infant mortality, child development/school performance) will studies prior to 2009 be included

III. Analytic Framework

Figure 2. Draft analytic framework for assessing the association of WIC participation with outcomes



KQ=Key Question

IV. Methods

A. Criteria for Inclusion/Exclusion of Studies in the Review: The criteria for inclusion and exclusion of studies for the systematic review will be based on the Key Questions and are briefly described in the previous PICOTS section and below in Table 2 & 3.

Table 2. PICOTS: Inclusion and exclusion criteria for quantitative studies

Criteria	Inclusion	Exclusion
Population	KQ1: Women who participated in WIC during pregnancy and their infants up to age 28 days KQ2: Infants/Children who participated in WIC (ages 29 days up to age 5)	• Animal studies
Interventions	Intervention as defined by KQ1-2*	• No intervention of interest
Comparisons	Comparison as defined by KQ1-2*	• Studies that do not report a comparison group KQ1-2 *
Outcomes	All studies must evaluate an outcome of interest as defined by KQ1-2*	• Studies that do not report any of the outcomes of interest.
Type of Study	As defined by KQ1-2*	• Studies published before 2009 for all the outcomes except maternal mortality, infant mortality, child development/school performance • Publications with no original data (e.g., editorials, letters, comments, reviews) • Full text not presented or unavailable, abstracts only • WIC program materials, brochures, and training manuals • Descriptions of WIC participation levels and participant characteristics without outcome data • Descriptive research on WIC implementation, operations, and program costs

*Please see PICOTS inclusion criteria

Table 3. Additional inclusion and exclusion criteria for qualitative and mixed-methods studies

Criteria	Inclusion	Exclusion
Comparison	No comparison group needed	
Type of study	Qualitative or mixed-methods studies (e.g., interviews, focus group) that assess perceptions/experiences of WIC participants and/or staff, or barriers/facilitators relevant to outcomes of interest	Studies of barriers/facilitators related to WIC participation but not linked to outcome

B. Searching for the Evidence: Literature Search Strategies for Identification of Relevant Studies to Answer the Key Questions: We will search the following databases for relevant original studies: PubMed, Embase®, CINAHL, ERIC, SCOPUS, PsycINFO, and the Cochrane Central Register of Controlled Trials. Since we are focusing on outcomes associated with the WIC Program and current service provisions (considered from 2009 in terms of the food package) we will search primarily for original studies published since 2009, the earliest year we would expect to find a published study relevant to the WIC Program with the current food package. For most of the outcomes of interest, we do not plan to include studies before 2009 because it would be very difficult to determine whether effects from older studies apply to the WIC Program with the current food package, especially with concomitant concerns about secular changes, differences in participant characteristics, differences in analytic methodologies for covariate adjustment, and the effects of the economic recession of 2007-2008.

For selected outcomes less likely to be affected by the change in the food package than by other elements of the WIC Program, such as maternal mortality, infant mortality, and child development/school performance, we will include studies before or after 2009. To facilitate identification of relevant studies on these outcomes that were published before 2009, we plan to use the prior review (USDA 2012) which focused on WIC participation and outcomes prior to the 2009 changes.[4] We will search for original studies on these outcomes that were published before 2009, but were not included in the 2012 USDA review. We also will search for studies published since 2009 but with data on pre-2009 changes in WIC. We will search for the studies in the following manner:

a) **Original studies published since 2009:** We will search and include studies published since 2009 for all the outcomes except for the outcomes listed in b below

b) **Original studies published before or after 2009 for the selected outcomes:** We will conduct a targeted search for the studies published since 2000 on the following selected key outcomes that were not likely to be impacted by the 2009 food package changes or that are likely to have very limited data:
   I. Infant mortality;
   II. Maternal mortality;
   III. Child development/school performance.

c) **Original studies published since 2009 that compare results before and after 2009:** We will also identify original studies published since 2009 which compare or contrast outcomes before and after the 2009 changes in the WIC program.

d) **Systematic reviews published since 2009:** We will search the reference list of relevant reviews for articles that our search might have missed.

It is important to consider and capture the experiences and perceptions of WIC participants and WIC staff with respect to current WIC service provisions, including the new food package. Such information is likely to come from qualitative studies involving focus groups or in-depth interviews. Important insights regarding WIC effectiveness for specific outcomes or for specific sub-groups of participants (as per KQ1b and KQ2b) may come also from qualitative studies or the qualitative component of multiple- or mixed-method studies. Therefore, we plan to identify and consider high quality qualitative studies that provide insights about the association of WIC with outcomes.

We will develop a search strategy for PubMed, based on an analysis of the medical subject headings (MeSH) for all potentially relevant publications and text words of key articles identified *a priori* (Appendix B). The searches will be updated during the peer review process. We will hand search the reference lists of all newly included articles. Our search strategy should yield quantitative, mixed-method and qualitative studies.

Additionally, we will search grey literature (2009 to present) for unpublished evaluations, white papers and USDA reports, and make a public call for quantitative and/or qualitative study reports/papers through professional organizations (e.g., Health Policy Reference Center, the National WIC Association (NWA), American Society for Nutrition (ASN), Academy of Nutrition and Dietetics (AND), and the National Association of County and City Health Officials (NACCHO)).

Manufacturers and other stakeholders of included drugs and devices will be informed about submitting Supplemental Evidence and Data for Systematic review (SEADS) information relevant to this review using a Federal Register notification. A portal about the opportunity to submit information will be made available on the EHC website.

We will use DistillerSR (Evidence Partners, 2010) to manage the screening process. Distiller SR is a web-based database management program that manages all levels of the review process. All applicable citations identified by the search strategies will be uploaded to the system and reviewed in the following manner:

i. Abstract screening: Two reviewers will independently review abstracts, which will be excluded if both reviewers agree that the article meets one or more of the exclusion criteria listed in Table 1. The articles will not be excluded based on the study design and outcome at this level. Differences between reviewers regarding abstract eligibility will be tracked and resolved through consensus adjudication. Relevant reviews, including systematic reviews and meta-analyses, will be tagged for a references list search.

ii. Full-text screening: Citations promoted based on abstract review will undergo another independent parallel review using full-text of the articles to determine if they should be included in the final qualitative and quantitative systematic review and meta-analysis. The differences regarding article inclusion will again be tracked and resolved through consensus adjudication.

C. Data Abstraction and Data Management: We will use a systematic approach to extract all data to minimize the risk of bias in this process. We will use standardized forms for data extraction and pilot test them. Each article will undergo double review for data abstraction. The second reviewer will confirm the first reviewer's data abstraction for completeness and accuracy. A third reviewer will audit a random sample of articles by the first two reviewers to ensure consistency in the data abstraction of the articles. Articles referring to the same study will be abstracted on a single review form if reporting the same data or on separate forms if necessary, with clear information that the results should be interpreted as from the same study.

For all articles, reviewers will extract information on general study characteristics (e.g., study design, study period, data source, geographic location, and time period), WIC program characteristics (national, state agency, local agency), study participant characteristics, eligibility criteria (with respect to WIC and the exposure), WIC program exposure for intervention and comparison/contrast, including duration, intensity and components of the intervention, outcome measures and the results of each outcome, including measures of variability. We will compile time and place information about WIC services, and link it with extracted studies to inform about

contextual factors that may influence the effectiveness of the WIC Program, including how components of the WIC Program may vary within and across state agencies, and over time. Reviewers will abstract data when available by subgroups relevant to answer KQ1b and KQ2b (e.g., race/ethnicity, housing status, maternal or child age). We will complete the data abstraction process using forms created in Excel (Microsoft, Redmond, WA). The Excel files will be used to maintain the data and to create detailed evidence tables and summary tables.

Data Abstraction for Qualitative and Mixed-Methods (i.e. both quantitative and qualitative components) Studies: We intend to identify and summarize 1) qualitative results extracted from quantitative or mixed methods studies; 2) stand-alone qualitative studies capturing WIC participant or staff perceptions/experiences that link to specific participant characteristics or an outcome. These would include a) perceptions of the new food package and breastfeeding, maternal and child dietary outcomes, and child growth outcomes; b) perceptions of WIC services for participants with housing instability, of specific race/ethnic groups, or who are non-English speaking; c) explorations of why/how services lead to differential impacts among participants. We are particularly interested in understanding the role of WIC on mitigating or exacerbating health disparities.

As with quantitative studies, we will extract information on general study characteristics (e.g., study design, reason for doing the study, theoretical framework, study period, data source/methods, geographic location, and time period, author relationship with WIC), WIC program characteristics (national, state agency, local agency), study participant characteristics, sampling, WIC program exposure, relevant outcome measures.

D. Assessment of Methodological Risk of Bias of Individual Studies: We will use the EPHPP (Effective Public Health Practice Project) tool to assess the risk of bias in studies addressing our outcomes of interest.[9] The domains include assessment of study selection bias, confounders, blinding, data collection methods, withdrawals and drop-outs. Two reviewers will independently evaluate the risk of bias of each study. Differences between reviewers will be resolved by consensus adjudication.

We will not assess bias per se in individual qualitative studies. However, two reviewers will assess the quality of studies using qualitative or mixed methods approaches using the JBI Critical Appraisal Checklist for Qualitative Research.[10]

E. Data Synthesis

E.1. Overview of Approach to Data Synthesis: We anticipate identifying a wide range of study designs, including observational studies (often with comparison groups) and quasi-experimental studies. We will also conduct a separate synthesis of the qualitative results. We plan to use a mix of methods for summarizing and displaying the types of evidence available on the topic, including evidence tables, bar graphs, flow charts and other plots, all guided by the framework shown in **Figure 2** and considering the pathways (e.g., supplemental nutritious food, nutrition education, breastfeeding support, and referral services) through which WIC participation may lead to the outcomes.

For each KQ, evidence tables will display summary information about study designs and characteristics, characteristics of WIC participants, and outcomes. When possible, we will stratify our findings by population, study design, and intervention (e.g. nature or duration of WIC participation, as well as rigor of assessment of WIC as the exposure of interest). We will also use

visual displays of outcomes and evidence, such as infographics, to help communicate key results with policymakers.

E.2. Principles for Pooling Quantitative Data: Randomized controlled trials and nonrandomized studies will be analyzed separately. Statistical significance (will be set at a two-sided alpha of 0.05). When we have sufficient data (at least two studies) and studies are adequately homogenous with respect to key variables (population characteristics, data source, study duration, intervention (comparison), and outcome measures), we will conduct meta-analyses. We will evaluate statistical heterogeneity among studies using an I^2 statistic, and because of heterogeneity in study approaches, we anticipate finding substantial statistical heterogeneity. For continuous outcomes, when possible, we will calculate a standardized mean difference using a random-effects model with DerSimonian and Laird formula.[11] In a situation where dichotomous outcomes are presented; we will calculate a pooled effect estimate of relative risk between comparison groups of observational studies or study arms using a random-effects model with the DerSimonian and Laird formula. For sparse data meta-analysis, we will employ the Peto odds ratio method when event rates are less than 1 percent. When event rates are between 5-10%, there are substantial differences between the N of two comparison groups or arms, or effect size is large, dichotomous data will be meta-analyzed using the Mantel-Haenszel method without continuity correction.[12] We will use Cohen's classification to categorize effect sizes as small, medium or large. Dichotomous data with zero values in both arms will not be included in meta-analyses. All meta-analyses will be conducted using STATA (College Station, TX).

All studies, including those that are not amenable to pooling, will be summarized qualitatively. Results will be presented as structured by the Key Questions, and any prioritized outcomes will be presented first.

E.3. Synthesis of Qualitative Results: The qualitative evidence synthesis will provide contextual factors focused on participant and staff perspectives/experiences related to the WIC program and inform answers to Key Questions 1b and 2b. We believe that the synthesis of qualitative data from qualitative and mixed-methods studies will be informative for policymakers and other stakeholders. We are planning to integrate the qualitative evidence synthesis into the systematic review. Because the methods for qualitative evidence synthesis are complex and continuing to develop we plan to follow standard guidance provided by Cochrane and other commonly used guides.[10, 13]

F. Grading the Strength of Evidence (SOE) for Major Comparisons and Outcomes:
At the completion of our review, we will grade the strength of evidence from quantitative studies on each of the outcomes for each comparison of interest by using the grading scheme recommended by the Agency for Healthcare Research and Quality Methods Guide for Conducting Comparative Effectiveness Reviews.

Following this standard EPC approach, for each key outcome, we will assess the number of studies, their study designs, the study limitations (i.e., risk of bias and overall methodological quality), the directness of the evidence relative to the Key Questions, the consistency of study results, the precision of any estimates of effect, the likelihood of reporting bias, and the overall findings across studies. Based on these assessments, we will assign a strength of evidence rating as being either high, moderate, or low, or there being insufficient evidence to estimate an effect. Investigators writing each section will complete the strength of evidence grading.

The team members will review the assigned grade for key outcomes and conflicts will be resolved through consensus.

G. Assessing Applicability: We will consider elements of the PICOTS framework when evaluating the applicability of evidence to answer our key questions as recommended in the Methods Guide for Comparative Effectiveness Reviews of Interventions. We will consider important contextual factors, including population characteristics (e.g., WIC program and WIC participant related factors) and intervention (and comparison group) characteristics that may cause heterogeneity and affect the generalizability of the findings.

V. References

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VI. Definition of Terms

VII. Summary of Protocol Amendments

Date	Section	Original Protocol	Revised Protocol	Rationale
May 14th, 2021	IV. Methods A. Criteria for Inclusion/Exclusion of Studies in the Review	Exclusion criterion: Studies published before 2009 for all the outcomes except maternal mortality, infant mortality, child development/school performance	Studies published before 2009 or that only use data collected before 2009 for all the outcomes except maternal mortality, infant mortality, child development/school performance	This exclusion criterion was not fully explained (publication date and data used in the studies) in the original protocol
May 14th, 2021	IV. Methods A. Criteria for Inclusion/Exclusion of Studies in the Review		We will include studies of dietary outcomes of women whose children participate in WIC	This criterion is added to report dietary outcome evidence collected from women who are not beneficiary of WIC[not pregnant, postpartum, breastfeeding] but caregivers of children in WIC, to more completely capture the nature of the dietary data available(i.e. from intake studies to benefit redemption studies at the household level).
May 14th, 2021	IV. Methods A. Criteria for Inclusion/Exclusion of Studies in the Review	We will include studies published since 2009 that compare results before and after 2009 change	We will include studies published since 2009 that compare results before and after the 2009 WIC food package change	This criterion was only in the text not in the PICOTS table

VIII. Review of Key Questions

IX. Key Informants

Not Applicable for the systematic review

X. Technical Experts

Technical Experts constitute a multi-disciplinary group of clinical, content, and methodological experts who provide input in defining populations, interventions, comparisons, or outcomes and identify particular studies or databases to search. The Technical Expert Panel is selected to provide broad expertise and perspectives specific to the topic under development. Divergent and conflicting opinions are common and perceived as healthy scientific discourse that fosters a thoughtful, relevant systematic review. Therefore, study questions, design, and methodological approaches do not necessarily represent the views of individual technical and content experts. Technical Experts provide information to the EPC to identify literature search strategies and suggest approaches to specific issues as requested by the EPC. Technical Experts do not do analysis of any kind; neither do they contribute to the writing of the report. They do not review the report, except as given the opportunity to do so through the peer or public review mechanism.

Members of the TEP must disclose any financial conflicts of interest greater than $5,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals are invited to serve as Technical Experts and those who present with potential conflicts may be retained. The AHRQ TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

XI. Peer Reviewers

Peer reviewers are invited to provide written comments on the draft report based on their clinical, content, or methodological expertise. The EPC considers all peer review comments on the draft report in preparing the final report. Peer reviewers do not participate in writing or editing of the final report or other products. The final report does not necessarily represent the views of individual reviewers.

The EPC will complete a disposition of all peer review comments. The disposition of comments for systematic reviews and technical briefs will be published 3 months after publication of the evidence report.

Potential peer reviewers must disclose any financial conflicts of interest greater than $5,000 and any other relevant business or professional conflicts of interest. Invited peer reviewers with any financial conflict of interest greater than $5,000 will be disqualified from peer review. Peer reviewers who disclose potential business or professional conflicts of interest can submit comments on draft reports through the public comment mechanism.

XII. EPC Team Disclosures

EPC core team members must disclose any financial conflicts of interest greater than $1,000 and any other relevant business or professional conflicts of interest. Related financial conflicts of interest that cumulatively total greater than $1,000 will usually disqualify EPC core team investigators.

XIII. Role of the Funder

This project was funded under Contract No. xxx-xxx from the Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services. The AHRQ Task Order Officer reviewed the EPC response to contract deliverables for adherence to contract requirements and quality. The authors of this report are responsible for its content. Statements in the report should not be construed as endorsement by either the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.

XIV. Registration

This protocol will be registered in the international prospective register of systematic reviews (PROSPERO).

Appendix A: Detailed list of outcomes by key question

Key Question 1: Among women who are eligible to participate in WIC, how is WIC participation during pregnancy associated with ***maternal and infant birth outcomes***?

Outcomes		Measures
Maternal health outcomes [health risk] in: ➢ **Pregnancy** ➢ **Postpartum**	Anemia Iron deficiency Iron-deficiency anemia Nutritional anemias	
	Gestational weight gain	Total gestational weight gain; IOM rec by BMI: under, within, over
	Weight status (e.g. BMI, underweight, overweight, obesity)	Pregnancy, Postpartum obesity Postpartum weight retention
	Health care utilization	Utilization of recommended prenatal care, postpartum care and other health maintenance recommendations Inter-pregnancy interval
	Morbidity	GDM Pre-eclampsia Gestational hypertension Mental Health (symptoms) Smoking, alcohol, risk behaviors
	Mode of delivery	Cesarean/Vaginal
	Intra- and post-partum complications	Prolonged labor, PROM, Postpartum hemorrhage, transfusion
	Mortality	Fetal death (stillbirth), pregnancy-related death (while pregnant or within a year of the pregnancy ending)
Dietary outcomes	Diet intake, practices and quality (infant and mother) (Diet quality measure Dietary intake (method) Diet quality score)	Breastfeeding (intention, initiation, and duration of any breastfeeding) Dietary intake (nutrient intake); diet quality measures (HEI, AHEI, DASH/Medical); glycemic load; servings of food groups, variety, adequacy and moderation components, SSB, sodium/salt, EFA); nutrient density (% fat, and by type; %CHO)
	Food purchasing behavior at the participant level	Benefit redemption, purchasing surveys
	Household food security	e.g., 18-item USDA Household Food Security Scale
Infant birth outcomes	Gestational age	Preterm, late preterm, early term, term and late term
	Birth weight	Very low birth weight Low birth weight, Normal birth weight High birth weight
	Small for gestational age Large for gestational age	
	Birth complications	preterm delivery, hospitalization, NICU stay, congenital malformations, neonatal (live birth and death within 28 days) or infant (within first year of life after live birth) death

BMI=Body mass index; GDM=Gestational diabetes mellitus; PIH=pregnancy-induced hypertension; PROM =Prelabor rupture of the membranes; USDA =United States Department of Agriculture; AHEI=Alternative Healthy Eating Index; DASH =Dietary Approaches to Stop Hypertension; HEI =Healthy Eating Index; SSB =sugar-sweetened beverage; EFA=Essential Fatty Acids; CHO= Carbohydrates; NICU= Neonatal Intensive Care Unit; WIC = Special Supplemental Nutrition Program for Women, Infants and Children

Key Question 2: Among ***infants and children eligible*** to participate in WIC, how is WIC participation associated with dietary and health outcomes in childhood (to age 17 years)?

Outcomes		Measures
Health outcomes	Anemia Iron deficiency anemia, nutritional anemias, iron deficiency	
	Child growth, anthropometric status	weight-for-age, length- or height-for-age, weight-for-length, or weight-for-height percentile or Z-score, BMI-for-age percentile or Z-score, underweight, overweight, obese; growth velocity (change in size/status or z-score over time)
	Healthcare Utilization	Well child visits Immunization status
	Morbidity	otitis media, allergies, gastrointestinal respiratory infections, asthma, immunization status, Pre-diabetes, Diabetes mellitus, elevated blood pressure/hypertension, hyperlipidemia
	Mortality	Infant mortality Child mortality
Dietary outcomes	Dietary practices of infants and children	Infants: maternal intention to breastfeed; Ever breastfed or any breastfeeding; Exclusive breastfeeding (initiation and duration); Duration of any breastfeeding; introduction of formula (timing); timing of solids introduction (< 4 months, < 6 months); cereal in the bottle; timing of cow's milk introduction (< 12 months); food group servings; nutrient intakes Children (1-2): food group servings, groups for variety, adequacy and moderation; added sugars, SSB, type of milk; fruit juice; dietary diversity; nutrient intakes, nutrient density measures (iron, zinc, calcium, %fat (total and by type)) energy density
	Diet quality	Children 2-5: [HEI, AHEI, food group servings (adequacy and moderation, added sugars, SSB), type of milk; fruit juice] Nutrient intakes and nutrient density measures (iron, zinc, calcium, %fat (total and by type)) energy density
	Food purchasing behavior at the participant level	Benefit redemption, purchasing surveys
	Household and child food security	18-item USDA Household Food Security Scale
Child development/school performance	Academic development	Pre-school or Head Start (e.g., attendance, behavior) K-12 educational performance, school-related factors (e.g. attendance, behavior) ADHD, conduct disorders, mental health
	Child development (behavioral development, cognitive development; cognitive performance)	BSID II/III; WPPSI, WISC, other standardized measures or specific constructs

ADHD =Attention deficit hyperactivity disorder; AHEI=Alternative Healthy Eating Index; HEI =Healthy Eating Index; SSB =sugar-sweetened beverage; WISC=Wechsler Intelligence Scale for Children; BSID =Bayley Scales of Infant Development; WPPSI = Wechsler Preschooland Primary Scale of Intelligence

Appendix B. PubMed Search Strategy

(WIC program [mh] OR WIC [tiab] OR "Women, Infants, and Children"[tw] OR "WIC program"[All Fields] OR "WIC programs"[All Fields] OR "Special Supplemental Nutrition Program"[All Fields])

AND

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