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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

#### Supplemental Evidence and Data Request on Maternal and Childhood Outcomes Associated With the Special Supplemental Nutrition Program for Women, Infants and Children (WIC)

**AGENCY:** Agency for Healthcare Research  
and Quality (AHRQ), HHS.

**ACTION:** Request for supplemental  
evidence and data submissions.

**SUMMARY:** The Agency for Healthcare  
Research and Quality (AHRQ) is seeking  
scientific information submissions from  
the public. Scientific information is  
being solicited to inform our review on  
*Maternal and Childhood Outcomes  
Associated with the Special  
Supplemental Nutrition Program for  
Women, Infants and Children (WIC)*,  
which is currently being conducted by  
the AHRQ's Evidence-based Practice  
Centers (EPC) Program. Access to  
published and unpublished pertinent  
scientific information will improve the  
quality of this review.

**DATES:** Submission Deadline on or  
before January 15, 2021.

**ADDRESSES:** Email submissions: [epc@ahrq.hhs.gov](mailto:epc@ahrq.hhs.gov).

Print submissions:

Mailing Address: Center for Evidence  
and Practice Improvement, Agency for  
Healthcare Research and Quality,  
ATTN: EPC SEADs Coordinator, 5600  
Fishers Lane, Mail Stop 06E53A,  
Rockville, MD 20857.

Shipping Address (FedEx, UPS, etc.):  
Center for Evidence and Practice  
Improvement, Agency for Healthcare  
Research and Quality, ATTN: EPC  
SEADs Coordinator, 5600 Fishers Lane,  
Mail Stop 06E77D, Rockville, MD  
20857.

#### FOR FURTHER INFORMATION CONTACT:

Jenae Benns, Telephone: 301–427–1496  
or Email: [epc@ahrq.hhs.gov](mailto:epc@ahrq.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The  
Agency for Healthcare Research and  
Quality has commissioned the  
Evidence-based Practice Centers (EPC)  
Program to complete a review of the  
evidence for *Maternal and Childhood  
Outcomes Associated with the Special  
Supplemental Nutrition Program for  
Women, Infants and Children (WIC)*.  
AHRQ is conducting this systematic  
review pursuant to Section 902 of the  
Public Health Service Act, 42 U.S.C.  
299a.

The EPC Program is dedicated to  
identifying as many studies as possible  
that are relevant to the questions for  
each of its reviews. In order to do so, we  
are supplementing the usual manual  
and electronic database searches of the  
literature by requesting information  
from the public (e.g., details of studies  
conducted). We are looking for studies  
that report on *Maternal and Childhood  
Outcomes Associated with the Special  
Supplemental Nutrition Program for  
Women, Infants and Children (WIC)*,  
including those that describe adverse  
events. The entire research protocol is  
available online at: [https://  
effectivehealthcare.ahrq.gov/products/  
outcomes-nutrition/protocol](https://effectivehealthcare.ahrq.gov/products/outcomes-nutrition/protocol).

This is to notify the public that the  
EPC Program would find the following  
information on *Maternal and Childhood  
Outcomes Associated with the Special  
Supplemental Nutrition Program for  
Women, Infants and Children (WIC)*  
helpful:

- A list of completed studies that  
your organization has sponsored for this  
indication. In the list, please indicate  
whether results are available on  
[ClinicalTrials.gov](https://clinicaltrials.gov) along with the  
[ClinicalTrials.gov](https://clinicaltrials.gov) trial number.

- For completed studies that do not  
have results on [ClinicalTrials.gov](https://clinicaltrials.gov), a  
summary, including the following  
elements: Study number, study period,  
design, methodology, indication and  
diagnosis, proper use instructions,  
inclusion and exclusion criteria,  
primary and secondary outcomes,  
baseline characteristics, number of  
patients screened/eligible/enrolled/lost  
to follow-up/withdrawn/analyzed,  
effectiveness/efficacy, and safety results.

- A list of ongoing studies that your  
organization has sponsored for this

indication. In the list, please provide the  
[ClinicalTrials.gov](https://clinicaltrials.gov) trial number or, if the  
trial is not registered, the protocol for  
the study including a study number, the  
study period, design, methodology,  
indication and diagnosis, proper use  
instructions, inclusion and exclusion  
criteria, and primary and secondary  
outcomes.

- Description of whether the above  
studies constitute *ALL Phase II and  
above clinical trials* sponsored by your  
organization for this indication and an  
index outlining the relevant information  
in each submitted file.

Your contribution is very beneficial to  
the Program. Materials submitted must  
be publicly available or able to be made  
public. Materials that are considered  
confidential; marketing materials; study  
types not included in the review; or  
information on indications not included  
in the review cannot be used by the EPC  
Program. This is a voluntary request for  
information, and all costs for complying  
with this request must be borne by the  
submitter.

The draft of this review will be posted  
on AHRQ's EPC Program website and  
available for public comment for a  
period of 4 weeks. If you would like to  
be notified when the draft is posted,  
please sign up for the email list at:  
[https://  
www.effectivehealthcare.ahrq.gov/  
email-updates](https://www.effectivehealthcare.ahrq.gov/email-updates).

The systematic review will answer the  
following questions. This information is  
provided as background. AHRQ is not  
requesting that the public provide  
answers to these questions.

#### Key Questions (KQs)

**KQ 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

**KQ 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 (Populations, Interventions, Comparators, Outcomes, Timing, Settings)

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. <i>Anthropometric status:</i> Weight status ( <i>e.g.</i> BMI, underweight, obesity). <i>Maternal:</i> <i>E.g.</i> anemia, weight gain, health care utilization (prenatal, postpartum), mode of delivery, intra- and postpartum complications, morbidity and mortality. <i>Infant birth outcomes:</i> <i>E.g.</i> 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. <i>Anthropometric status:</i> <i>E.g.</i> 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. <i>Infant and child outcomes:</i> Anemia, iron deficiency anemia, iron deficiency, primary health care utilization, immunization status, morbidity and mortality. Child development/school performance ( <i>e.g.</i> , cognitive development, behavioral development, educational performance, school-related factors ( <i>e.g.</i> 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.

### 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 ( <i>e.g.</i> , 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 .....	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).
Diet intake, practices and quality (infant and mother) (Diet quality measure, Dietary intake (method), Diet quality score).	
Food purchasing behavior at the participant level .....	Benefit redemption, purchasing surveys.
Household food security .....	<i>E.g.</i> , 18-item USDA Household Food Security Scale.

Outcomes	Measures
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 .....	<i>Infants:</i> 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. <i>Children (1–2):</i> 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. <i>Children 2–5:</i> [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.
Diet quality .....	
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. BSID II/III; WPPSI, WISC, other standardized measures or specific constructs.
Child development (behavioral development, cognitive development; cognitive performance).	

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 Preschool and Primary Scale of Intelligence.

Dated: December 10, 2020.

**Marquita Cullom,**

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