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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published and unpublished pertinent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*.

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 Bennis, Telephone: 301–427–1496
or Email: *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 along with the
ClinicalTrials.gov trial number.*

- *For completed studies that do not
have results on 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 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:
 - iii. Geographic location (e.g. region, urban vs. rural)
 - vi. Marital status of the mother
- i. Age of the mother at delivery
 - iv. Education of the mother
 - vii. Housing (e.g. public, private), homelessness
- ii. Race/ethnicity of child
 - v. Employment status of the mother

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 (e.g. BMI, underweight, obesity). <i>Maternal:</i> E.g. anemia, weight gain, health care utilization (prenatal, postpartum), mode of delivery, intra- and postpartum complications, morbidity and mortality. <i>Infant birth outcomes:</i> 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. <i>Anthropometric status:</i> 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. <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 (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.

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: <ul style="list-style-type: none"> > Pregnancy. > Postpartum. Anemia, Iron deficiency, Iron-deficiency anemia, Nutritional anemias. Gestational weight gain Weight status (e.g., BMI, underweight, overweight, obesity). Health care utilization Morbidity Mode of delivery Intra- and post-partum complications Mortality 	Total gestational weight gain; IOM rec by BMI: under, within, over. Pregnancy, Postpartum obesity, Postpartum weight retention. Utilization of recommended prenatal care, postpartum care and other health maintenance recommendations Inter-pregnancy interval. GDM, Pre-eclampsia, Gestational hypertension, Mental Health (symptoms), Smoking, alcohol, risk behaviors. Cesarean/Vaginal. Prolonged labor, PROM, Postpartum hemorrhage, transfusion. 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).	Benefit redemption, purchasing surveys.
Food purchasing behavior at the participant level	E.g., 18-item USDA Household Food Security Scale.
Household food security	

Outcomes	Measures
Infant birth outcomes: Gestational age Birth weight Small for gestational age. Large for gestational age. Birth complications	Preterm, late preterm, early term, term and late term. Very low birth weight, Low birth weight, Normal birth weight, High birth weight. 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 Healthcare Utilization Morbidity Mortality Dietary outcomes: Dietary practices of infants and children Diet quality Food purchasing behavior at the participant level Household and child food security Child development/school performance: Academic development Child development (behavioral development, cognitive development; cognitive performance).	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). Well child visits, Immunization status. Otitis media, allergies, gastrointestinal respiratory infections, asthma, immunization status, Pre-diabetes, Diabetes mellitus, elevated blood pressure/hypertension, hyperlipidemia. Infant mortality. Child mortality. <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. Benefit redemption, purchasing surveys. 18-item USDA Household Food Security Scale. 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.

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.

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Associate Director.

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