

HWHB EVALUATION PROTOCOL

DESIGNED BY

DIVISION OF PUBLIC HEALTH
DELAWARE HEALTH & SOCIAL SERVICES

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HWHB Evaluation Protocol

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PART I. EVALUATING THE COMPARATIVE CAPABILITY OF THE HWHB MODULE

A multidimensional approach was taken when designing the evaluation plan for the HWHB program. The first part of this analysis centers on the overall comparative capability of the HWHB module, the data collection instrument. This is essential as the HWHB program and module may be applied to settings outside of the State of Delaware. This part of the evaluation protocol answered the following questions:

- *Does the HWHB program feature services that align with current best/suggested practices?*
- *Does the HWHB program feature services that have been clinically shown to improve preconception/prenatal health?*
- *Does the HWHB program feature services that can be measured on a consistent basis?*

Through careful assessment, it was determined that the framework for evaluating the HWHB program should coalesce the recommendations and guidelines suggested by thoughtleaders in the field, namely: the American Academy of Pediatrics (AAP), the American College of Obstetricians and Gynecologists (ACOG), the Centers for Disease Control and Prevention (CDC), and the United States Preventive Services Task Force (USPSTF). **Figure 1** displays how the final HWHB evaluation protocol combines the guidelines and recommendations from three diverse yet well-respected sets of thoughtleaders.

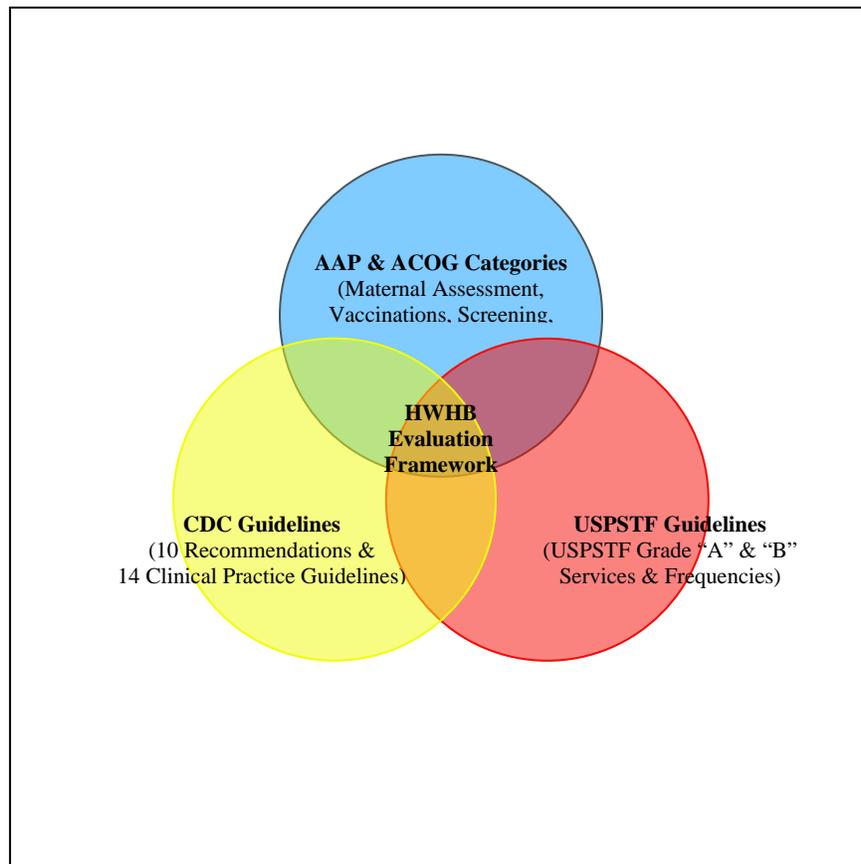


Figure 1: Foundation for HWHB Evaluation Framework

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The questions posed above are answered by each of these sets of thoughtleaders in the following manner:

AAP & ACOG Categories

Answers: Does the HWHB program feature services that align with current best/suggested practices?

The AAP and ACOG have assembled the main components of preconception care under four categories: Maternal Assessment, Vaccinations, Screening, and Counseling.¹ The intended composition of these categories is as follows:

- *Maternal Assessment.* Family History, Behaviors, Obstetric History, General Physical Exam.
- *Vaccinations.* Rubella, Varicella, Hepatitis B.
- *Screening.* HIV, STDs, Genetic Disorders.
- *Counseling.* Folic Acid Consumption, Smoking and Alcohol Cessation, Weight Management.

The evaluation framework organizes all of the HWHB services into these categories. It is anticipated that organizing the services in this manner will allow for future comparisons in content between the HWHB program and related programs throughout the nation.

CDC Guidelines

Answers: Does the HWHB program feature services that have been clinically shown to improve preconception/prenatal health?

The CDC outlines ten recommendations relevant to improving preconception care.^{2,3} These recommendations and the HWHB services that correspond to these recommendations are provided in **Table 1**. The CDC indicates fourteen clinical practice guidelines for which scientific evidence has demonstrated success in enhancing pregnancy outcomes.^{2,4} These fourteen clinical practice guidelines and the HWHB services that align with these guidelines are listed in **Table 2**.

Given the vast clinical research underpinning these practice guidelines and the fact that the HWHB module answers to all of them, many of the services presented in the HWHB module have been shown to improve preconception and prenatal health.

USPSTF Guidelines

Answers: Does the HWHB program feature services that are measured on a consistent basis?

The USPSTF maintains a list of services that should be offered to patients based on the patient's age, sex, family history, pregnancy status, and other characteristics.⁵ A "grade" that establishes whether or not the service should be performed is then assigned to each of these services based on well-documented standards of care and respected clinical research. These grades are defined as follows:

- "A". USPSTF recommends the service. There is high certainty that the net benefit is substantial.
- "B". USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.

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- “C”. USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small.
- “D”. USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.
- “I”. The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

The USPSTF also indicates the frequency for when each of these services should be performed. **Table 3** displays the recommended services (i.e., grades “A” and “B”) for the HWHB target population and the frequency when these services should be provided. All of the services listed in **Table 3** are found in the HWHB module. Accordingly, the HWHB module features services that are measured on a well-documented and consistent basis.

PART II. EVALUATING THE EFFECTIVENESS OF THE HWHB MODULE

The second part of this evaluation process focuses on how to best evaluate the effectiveness of the HWHB module. This part of the evaluation protocol has two components:

- **Lead Measurement Evaluation**: Appraisal of how lead measures change over time in the HWHB target population. Lead measures are those indicators that are more easily measured in the clinical practice setting and are linked to maternal well-being and/or birth outcomes. Examples of lead measures include Gonorrhea status and Family Planning/Reproductive Life Plan discussion.
- **Lag Measurement Evaluation**: Appraisal of how lag measures change over time in the HWHB target population. Lag measures are those indicators that are not easily controlled in the clinical practice setting and often take more time to measure. Examples of lag measures include infant deaths and premature births.

Lead Measurement Evaluation

It is important to remember that women enter the HWHB program in either the preconception care or prenatal care setting and the services listed under each of these settings have slight differences. Moreover, women coming to participating clinics may either be new members or existing members to the HWHB program. As a result, four different lead measurement evaluations must take place:

- *Baseline Preconception Lead Evaluation*: Conducted on preconception women coming into a participating clinic for a first visit. This evaluation provides baseline data.

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- *Pair Preconception Lead Evaluation*: Conducted on preconception women coming into a participating clinic for a subsequent visit. This evaluation shows changes in measurement results compared to the previous visit.
- *Baseline Prenatal Lead Evaluation*: Conducted on prenatal women coming into a participating clinic for a first visit. This evaluation provides baseline data.
- *Pair Prenatal Lead Evaluation*: Conducted on prenatal women coming into a participating clinic for a subsequent visit. This evaluation shows changes in measurement results compared to the previous visit.

Conceptual Framework for Lead Measurement Evaluation

Figure 2 displays how many of the HWHB women fit into each of these four lead measurement groups starting at Time 2. The dashed bold line in the center of the figure separates the preconception evaluations (above line) from the prenatal and pregnancy evaluations (below line). The italicized letters are variables assigned to cohorts of women based on their pregnancy status at the time of evaluation. Subscript 1 indicates non-pregnant women and subscript 2 indicates pregnant women.

The conceptual framework indicates the cohort of women who came in for preconception care by *Time 1* (cohort *a*) will have their baseline services measured through *Baseline Preconception Lead Evaluation*. The cohort of women who came in for prenatal care by *Time 1* (cohort *m*) will have their baseline services measured through *Baseline Prenatal Lead Evaluation*. During the six months between *Time 1* and *Time 2*, some of the women who came in for preconception care (cohort *a*) may have become pregnant (subcohort a_2) while the remainder did not become pregnant (subcohort a_1). Therefore, at *Time 2*, a *Pair Preconception Lead Evaluation* can take place that compares the service measurement results between *Time 1* and *Time 2* for women who remained in preconception care (subcohort a_1). The women who became pregnant (subcohort a_2) are joined by women who became pregnant again after completing their pregnancy between *Time 1* and *Time 2* (subcohort $(m_1)_2$). Both subcohort a_2 and subcohort $(m_1)_2$ will join women who enter the HWHB program for the first time in prenatal care at *Time 2* (cohort *n*) for *Baseline Prenatal Lead Evaluation*. Meanwhile, some of the women who came in for prenatal care (cohort *m*) may have completed their pregnancy and are not pregnant at the time of evaluation (subcohort m_1) while the remaining did not complete their pregnancy yet (subcohort m_2). Therefore, at *Time 2*, a *Pair Prenatal Lead Evaluation* can take place that compares the service measurement results between *Time 1* and *Time 2* for women who remained in prenatal care (subcohort m_2). The women who completed their pregnancy and are not pregnant at the time of evaluation (subcohort m_1) will join women who enter the HWHB program for preconception care at *Time 2* (cohort *b*) for *Baseline Preconception Lead Evaluation*. The same process is replicated between *Time 2* and *Time 3*, the point in time six months after *Time 2*.

It is important to remember that many service measurements are recommended to be performed once annually. As a result, many women may not have had a subsequent visit within six months when this service measurement would take place again. With that said, it is anticipated that some paired evaluation can be conducted as early as *Time 2* but assuredly at *Time 3* as well as *Time 4* (the point in time six months after *Time 3*).

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In addition, although both women who become pregnant after receiving preconception care at *Time 1* (subcohort a_2) and women who become pregnant after having completed a pregnancy between *Time 1* and *Time 2* (subcohort $(m_1)_2$) are not new HWHB members at *Time 2*, these women will have their service measurement results evaluated in the *Baseline Prenatal Lead Evaluation* along with women coming in for prenatal care who are new HWHB members at *Time 2* (cohort n). Having paired service measurements for these existing HWHB members (subcohorts a_2 and $(m_1)_2$) would not be appropriate at *Time 2* because these women are pregnant at *Time 2* but were either not pregnant at *Time 1* or were in a different pregnancy, and therefore, may have considerably different service measurement results. A set of exceptions to this condition is described in the last paragraph of the *Service Measurements for Lead Measurement Evaluation* section below.

Furthermore, although women who complete their pregnancy after receiving prenatal care at *Time 1* (subcohort m_1) are not new HWHB members at *Time 2*, these women will have their service measurement results evaluated in the *Baseline Preconception Lead Evaluation* along with women coming in for preconception care who are new HWHB members at *Time 2* (cohort b). The exception referenced above does not apply to this scenario.

Service Measurements for Lead Measurement Evaluation

Table 4 and **Table 5** list the service measurements adopted from the HWHB module services for the *Baseline Preconception Lead Evaluation* and *Pair Preconception Lead Evaluation*, respectively. **Table 6** and **Table 7** outline the service measurements taken from the HWHB module services for the *Baseline Prenatal Lead Evaluation* and *Pair Prenatal Lead Evaluation*, respectively. Note that the main difference between the non-pair and pair evaluation processes lies with the style of measurement; that is, the *Baseline Preconception Lead Evaluation* and *Baseline Prenatal Lead Evaluation* tend to measure baseline data whereas the *Pair Preconception Lead Evaluation* and *Pair Prenatal Lead Evaluation* measure changes in baseline data. As discussed in PART I of the evaluation process, the service measurements are grouped by the four AAP and ACOG categories. For emphasis, the service measurements in both tables that align with the CDC's fourteen clinical practice guidelines are highlighted in yellow.

Figure 3 defines eight different groups that will be used while evaluating part of the *Family Planning & Reproductive Life Plan* service. Women in these eight groups are all sexually active but differ in whether or not they use contraception as well as in their plans for becoming pregnant. As of now, three service measurements will be evaluated. Two of these service measurements examine the change in women who state that their plans to be pregnant are "Unknown". These two service measurements differ only on whether the woman is using contraception (Group 4) or not (Group 8). It is expected that the percentage of women with an "Unknown" plan to be pregnant will decrease in both groups based on proper implementation of the *Family Planning & Reproductive Life Plan* service. The third service measure focuses on the change in women who claim that they "Never" plan to be pregnant yet are sexually active and not using contraception (Group 5). It is anticipated that effective use of the *Family Planning &*

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Reproductive Life Plan service will encourage these women to adopt contraception while maintaining a plan of “Never” becoming pregnant (Group 1).

As mentioned in the previous section, a set of exceptions exists for women who, after having service measurement results evaluated for HWHB preconception care at a point in time, become pregnant and have service measurement results evaluated for prenatal services at the subsequent evaluation point in time. In **Figure 2**, these are women who are in subcohort a_2 at *Time 2* and subcohort $(a_1 + b + m_1)_2$ at *Time 3*. The set of exceptions is located in the *Prenatal Care Assessment* segment in **Table 7** and each service measurement in the set is denoted as “[Exception Subset]”. These service measurements center on evaluating how well the preconception lead measures ultimately align with future prenatal lead measures. The first of these seven service measures assesses how well the *Family Planning & Reproductive Life Plan* service succeeds in encouraging women to seek care during their first trimester of pregnancy. Using the group definitions provided by **Figure 3**, the other six of these seven service measures address how well providers are gauging whether their patients are accurately stating their plans to be pregnant (Group 2, Group 3, Group 5, and Group 6) or not (Group 1 and Group 5).

Lag Measurement Evaluation

The Lag Measurement Evaluation consists of two different evaluations:

- *Baseline Lag Evaluation*: Conducted on the first pregnancy outcomes for women in the HWHB program. These women may have or may not have completed at least one pregnancy prior to being an HWHB member. This evaluation provides baseline data.
- *Pair Lag Evaluation*: Conducted on the subsequent pregnancy outcomes for women in the HWHB program. These women must have completed a pregnancy while being an HWHB member. This evaluation shows changes in outcomes compared to the previous pregnancy.

Conceptual Framework for Lag Measurement Evaluation

Figure 2 presents how HWHB women enter into the lag measurement evaluation process (see first three paragraphs in the *Conceptual Framework for Lead Measurement Evaluation* section for how variables are defined). At *Time 2*, the pregnancy outcomes for women who have had prenatal care through the HWHB program and have completed their pregnancy (subcohort m_1) are evaluated in the *Baseline Lag Evaluation* (listed as $m_{1outcomes}$). At *Time 3*, the pregnancy outcomes for those women who have completed their pregnancy and either become pregnant while in the HWHB program or have entered prenatal care in the HWHB program between *Time 1* and *Time 2* and (subcohorts $(a_2 + n + m_2)_1$ and $((m_1)_2)_1$) are also assessed in the *Baseline Lag Evaluation* (listed as $((a_2 + n + m_2)_1 + ((m_1)_2)_1)_{outcomes}$).

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At *Time 2*, it is possible to pair women who have had a prior pregnancy* before entering the HWHB module (*PPreg*) and have had prenatal care through the HWHB program and completed their pregnancy (subcohort m_1). This *Pair Lag Evaluation* (listed as m_{1out} & $PPreg_{out}$) consists of comparing the birth outcomes for the same women in these sets. The same method of paired evaluation can occur at *Time 3* with women who have had a prior pregnancy before entering the HWHB module (*PPreg*) and have had prenatal care through the HWHB program and completed their pregnancy (subcohort $(a_2 + n + m_2)_{1out}$). In this case, the *Pair Lag Evaluation* is listed as $(a_2 + n + m_2)_{1out}$ & $PPreg_{out}$. Finally, a slightly different method of paired evaluation can take place at *Time 3* with women who have had prenatal care through the HWHB program and have completed their pregnancy (subcohort m_1) and who became pregnant again and completed their pregnancy while in the HWHB program (subcohort $(m_1)_2$). In this case the *Pair Lag Evaluation* is listed as m_{1out} & $((m_1)_2)_{1out}$.

Service Measurements for Lag Measurement Evaluation

Table 8 and **Table 9** list the outcome measurements for both the *Baseline Lag Evaluation* and *Pair Lag Evaluation*, respectively. These outcome measurements are adopted from the pilot evaluation of the Interpregnancy Care Program of Grady Memorial Hospital in Atlanta, Georgia and Delaware Health Statistics.^{6,7} Unlike the lead measurements which rely upon data collected directly from the HWHB module, most of the lag measurement data is collected by Delaware Health Statistics. In order to conduct proper analysis for each of the outcome measurements, the following fields will need to be accessed from the birth cohort dataset, fetal death registry, and medical records:

- Ectopic/Molar Pregnancy. Medical Records: ICD-10 coding for ectopic and molar pregnancy.
- Fetal Death. Fetal Death Registry: primary cause of death. ICD-10 coding will then be applied.
- Preterm Birth. Birth Cohort Dataset: gestational weeks [*gest*].
- LBW/VLBW. Birth Cohort Dataset: birth weight in grams [*gramsx*].
- Infant Death. Birth Cohort Dataset: age at death in days [*dage*].

Similar to the *Lead Measurement Evaluation* process, the main difference between the non-pair and pair evaluation processes lies with the style of measurement; that is, the *Baseline Lag Evaluation* tends to measure baseline data whereas the *Pair Lag Evaluation* measures changes in baseline data in pregnancy outcomes. The *Pair Lag Evaluation* can be separated into two components: evaluation of pregnancy outcomes with pregnancies before HWHB (outcome measurement codes A1-A10 in **Table 9**) and evaluation of pregnancy outcomes with pregnancies during HWHB (outcome measurement codes B1-B10 in **Table 9**). Applying the cohort definitions in **Figure 2**, outcome measurement codes A1-A10 would be performed on any comparisons that involve outcome data for pregnancies occurring before the HWHB program ($PPreg_{out}$) whereas outcome measurement codes B1-B10 would be used for all other comparisons (e.g., m_{1out} & $((m_1)_2)_{1out}$). Using this two-fold approach, it will be possible to evaluate the

* The data on whether a woman had a previous pregnancy before HWHB and the resultant birth outcome can be found in the data collected in the *Program Eligibility* section of the *HWHB Identifiers, Demographics, and Eligibility* screen in the HWHB module.

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impact of the HWHB program on the set of women who had a previous pregnancy before joining the HWHB program as well as women in the HWHB program who did not have a previous pregnancy before joining the HWHB program.

Study Group Design for Lead Measurement Evaluation & Lag Measurement Evaluation

Differing demographics and medical history may have a substantial impact on the overall service measurement results. Accordingly, it is suggested that all the service measurement percentages are adjusted by the following six factors for the four *Lead Measurement Evaluation* and two *Lag Measurement Evaluation* reports:

- Age Group. Field: *magex*. Categories: “Under 16”; “16-19”; “20-25”; “Over 25”.
- Race/Ethnicity Group. Field: *detracem*. Categories: “White Non-Hispanic”; “Black Non-Hispanic”; “Hispanic”; “Other”.
- Health Care Coverage. Field: *payment2*. Categories: “Medicaid”; “Private Insurance”; No Insurance/Patient Pay.
- Non-Pregnancy Risk Factors. Field & Categories: To be decided based on available birth cohort dataset fields and the CDC Clinical Practice Guidelines listed in **Table 2**.
- Pregnancy Risk Factors. Field & Categories: To be decided based on available birth cohort dataset fields and the CDC Clinical Practice Guidelines listed in **Table 2**.
- Zip Code Cluster. Field: *tract*. Categories: To be defined.

Comprehensive statistical analysis will reveal whether any differences in service measurement results for each of these factors are significant. For baseline analyses (i.e., *Baseline Preconception Lead Evaluation*, *Baseline Prenatal Lead Evaluation*, and *Baseline Lag Evaluation*) statistically significant results may provide insight on what factors should be more proactively examined in different segments of the target population. For example, if the *Age Group* category “20-25” has a lower percentage of distinct women who have had a risk assessment performed in the last year compared to the other three *Age Group* categories and this percentage is statistically significant, it may be prudent to examine the underlying reasons why this difference occurred and what should be carried out to have a more favorable result in the subsequent evaluation.

For pair analyses (i.e., *Pair Preconception Lead Evaluation*, *Pair Prenatal Lead Evaluation*, and *Pair Lag Evaluation*) statistically significant results may suggest that discrepancies exist in how the effectiveness measures are being addressed over time. For example, if the net percentage change of women who have had BP measured in the last year was much larger for “White Non-Hispanic” compared to “Black Non-Hispanic” and the difference was statistically significant, it may be wise to investigate what made the increases in screening prevalence differ significantly between the two race/ethnicity groups over this period of time.

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As shown in **Table 10**, the number of pregnancies in Delaware is approximately 10,000 annually.[†] The HWHB program will capture a subset of these women. At this time, the number of women in this subset is unknown since the actual number of pregnant women as well as the number of women enrolled in the preconception program have yet to be reported. Once these numbers are known, it will be possible to estimate the number of women measured in the baseline and pair evaluations. Knowing these numbers will also help elucidate the overall effect the HWHB program has on the State of Delaware's pregnancy statistics.

PART III. EVALUATING THE EFFICACY OF THE HWHB MODULE

This process – the *Comparative Evaluation* – will demonstrate the efficacy of the HWHB program. The *Comparative Evaluation* will compare lag outcome measurements between HWHB women and non-HWHB women.

As of now, the method by which *Comparative Evaluation* will take place has not been decided. **Table 11** offers three viable options that should be considered to best review the HWHB program's efficacy in reducing overall poor birth outcomes. Unlike the *Lead Measurement Evaluations* and *Lag Measurement Evaluations*, the *Comparative Evaluation* will occur at an undetermined point in the future. Based on similar evaluation designs,^{6,8,9} the *Comparative Evaluation* will most-likely be conducted 3 to 5 years after the implementation of the HWHB module (i.e., sometime between 2012 and 2015).

The design of the favored comparative option – *Retrospective Comparison to Non-Treatment Group* – is provided in **Figure 4**. In this design, a multi-year collection of HWHB birth outcomes in the *Pair Lag Evaluation* cohort (see **Figure 2**) would be split into two cohorts: women who have had both HWHB preconception and prenatal services (Cohort A) and women who have had only HWHB prenatal services (Cohort B). Each of these cohorts is then linked to the Delaware Health Statistics' birth cohort dataset. The MOMID algorithm will be used to establish this link.[‡] Once each of the HWHB women is identified through their respective MOMID, the HWHB women can be “matched” to those women in the birth cohort dataset who are not in the HWHB program to create a control for Cohort A and a control for Cohort B. The women are matched using the following fields:

- Age Group. Field: *magex*. Categories: “Under 16”; “16-19”; “20-25”; “Over 25”.
- Race/Ethnicity Group. Field: *detracem*. Categories: “White Non-Hispanic”; “Black Non-Hispanic”; “Hispanic”; “Other”.
- Health Care Coverage. Field: *payment2*. Categories: “Medicaid”; “Private Insurance”; No Insurance/Patient Pay.

[†] The total number of pregnancies here refers to those pregnancies that resulted in live births only. Since this does not include ectopic/molar pregnancies or pregnancies that resulted in fetal deaths, this number is an underestimate.

[‡] Delaware Health Statistics has the code for this algorithm and will be able to supply the matching MOMID when given certain demographic information about women in the HWHB program.

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- Non-Pregnancy Risk Factors. Field & Categories: To be decided based on available birth cohort dataset fields and the CDC Clinical Practice Guidelines listed in **Table 2**.
- Pregnancy Risk Factors. Field & Categories: To be decided based on available birth cohort dataset fields and the CDC Clinical Practice Guidelines listed in **Table 2**.
- Previous Pregnancies. Fields: *lalive*, *ldead*, and certain fields from the fetal death registry. Categories: To be defined.
- Zip Code Cluster. Field: *tract*. Categories: To be defined.

After matching a “short list” of non-HWHB women to each HWHB woman, the “short list” of non-HWHB women should be randomized to account for differences in preconception history;[§] the end result of this randomization process will be one non-HWHB woman matched to each HWHB woman. After matching and randomization, a retrospective comparison of *Pair Prenatal Lead Evaluation* results may be possible for Cohort A and for its control. This analysis (*Comparison A₁*) will answer:

- Do any differences exist in the quality and type of clinical services provided to women in the HWHB program and women not in the HWHB program over a period of time?

For example, if the net percentage change of women who have had a Chlamydia Screening in the last year was much larger for Cohort A compared to its control and the difference was statistically significant, it may be possible to conclude that the HWHB program has a significantly greater impact in providing this clinical service for women in the program compared to other clinics/programs. *Comparison A₁* will also list the services offered by the HWHB program that are not offered elsewhere in Delaware, and conversely, the preconception/prenatal services offered elsewhere in Delaware that are not supplied by the HWHB program.

In addition to *Comparison A₁*, two retrospective comparisons of *Pair Lag Evaluation* results will be performed: *Comparison A₂* (between Cohort A and its control) and *Comparison B* (between Cohort B and its control). Both comparisons will answer the question:

- Is there a difference in the number of poor pregnancies and poor birth outcomes in the HWHB program and women not in the HWHB program over a period of time?

As an example, if the net percentage change of total pregnancies resulting in a live-born infant born before 32 weeks (preterm birth) was much smaller over the last year for Cohort B compared to its control and the difference was statistically significant, it may be possible to conclude that the HWHB program has a significantly greater reduction in the number of preterm births compared to other clinics/programs.

[§] This randomization process will ultimately lead to a woman in the control having the less, more, or a similar preconception history compared to HWHB match. The exact definition of preconception history will have to be established.

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The method of retrospective comparison is the same for *Comparison A₂* and its control and *Comparison B* and its control. Note, however, that the cohorts for the two comparisons are different since *Comparison A₂* examines women who have had both preconception and prenatal care in the HWHB program (Cohort A) while *Comparison B* examines women who have had only prenatal care while enrolled in the HWHB program (Cohort B). As a result, it is possible to conduct *Comparison C*, a comparison of these two cohorts. This comparison will answer the question:

- Is there a difference in the number of poor pregnancies and poor birth outcomes between women who have had preconception and prenatal care in the HWHB program (Cohort A) compared with women who have only had prenatal care in the HWHB program (Cohort B)?

For example, if the net percentage change of total pregnancies resulting in a live-born infant weighing less than 1500 grams (low birth weight) was much smaller over the last year for Cohort A compared to Cohort B and the difference was statistically significant, it may be possible to conclude that women enrolled in the HWHB program for both preconception and prenatal care tend to have a reduced number of infants with low birth weight compared to women enrolled in the HWHB program for prenatal care only.

END TEXT

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Table 1: CDC Recommendations

Recommendation	HWHB Correlate
<i>Recommendation 1. Individual Responsibility Across the Lifespan.</i> Each woman, man, and couple should be encouraged to have a reproductive life plan.	Family Planning & Reproductive Life Plan
<i>Recommendation 2. Consumer Awareness.</i> Increase public awareness of the importance of preconception health behaviors and preconception care services by using information and tools appropriate across various ages; literacy, including health literacy; and cultural/linguistic contexts.	Family Planning & Reproductive Life Plan
<i>Recommendation 3. Preventive Visits.</i> As a part of primary care visits, provide risk assessment and educational and health promotion counseling to all women of childbearing age to reduce reproductive risks and improve pregnancy outcomes.	Depression Counseling, Folic Acid Discussion & Supplementation, Healthy Diet & Physical Activity Discussion, Risk Assessment, Sexually Transmitted Infections
<i>Recommendation 4. Interventions for Identified Risks.</i> Increase the proportion of women who receive interventions as follow-up to preconception risk screening, focusing on high priority interventions (i.e., those with evidence of effectiveness and greatest potential impact).	Risk Assessment
<i>Recommendation 5. Interconception Care.</i> Use the interconception period to provide additional intensive interventions to women who have had a previous pregnancy that ended in an adverse outcome (i.e., infant death, fetal loss, birth defects, low birthweight, or preterm birth).	Postpartum/Interconception Care Services
<i>Recommendation 6. Pre-Pregnancy Checkup.</i> Offer, as a component of maternity care, one pre-pregnancy visit for couples and persons planning pregnancy.	Family Planning & Reproductive Life Plan
<i>Recommendation 7. Health Insurance Coverage for Women with Low Incomes.</i> Increase public and private health insurance coverage for women with low incomes to improve access to preventive women's health and preconception and interconception care.	[Overall] HWHB Program
<i>Recommendation 8. Public Health Programs and Strategies.</i> Integrate components of preconception health into existing local public health and related programs, including emphasis on interconception interventions for women with previous adverse outcomes.	[Overall] HWHB Program
<i>Recommendation 9. Research.</i> Increase the evidence base and promote the use of the evidence to improve preconception health.	[Overall] HWHB Evaluation Plan
<i>Recommendation 10. Monitoring Improvements.</i> Maximize public health surveillance and related research mechanisms to monitor preconception health.	[Overall] HWHB Evaluation Plan

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Table 2: CDC Clinical Practice Guidelines

Clinical Practice Guideline	HWHB Correlate
<u>Alcohol Misuse</u> . No time during pregnancy is safe to drink alcohol, and harm can occur early, before a woman has realized that she is or might be pregnant. Fetal alcohol syndrome and other alcohol-related birth defects can be prevented if women cease intake of alcohol before conception.	Alcohol Misuse
<u>Anti-Epileptic drugs</u> . Certain anti-epileptic drugs are known as teratogens. Before conception, women who are on a regimen of these drugs and who are contemplating pregnancy should be prescribed a lower dosage of these drugs.	Anti-Epileptic Drug Use
<u>Diabetes</u> . The three-fold increase in the prevalence of birth defects among infants of women with type 1 and type 2 diabetes is substantially reduced through proper management of diabetes.	Insulin-Dependent & Non-Insulin Dependent Diabetes
<u>Folic Acid</u> . Daily use of vitamin supplements containing folic acid has been demonstrated to reduce the occurrence of neural tube defects by two thirds.	Folic Acid Discussion & Supplementation
<u>Hepatitis B</u> . Vaccination is recommended for men and women who are at risk for acquiring hepatitis B virus (HBV) infection. Preventing HBV infection in women of childbearing age prevents vertical transmission of infection to infants and eliminates risk for infection and sequelae, including hepatic failure, liver carcinoma, cirrhosis, and death.	Hepatitis B Status & Immunization
<u>HIV/AIDS</u> . If HIV infection is identified before conception, timely treatment can be administered and women (or couples) can be given additional information that can influence the timing of the onset of pregnancy.	HIV Screening
<u>Hypothyroidism</u> . The dosages of Levothyroxine TM required for treatment of hypothyroidism increases in early pregnancy. Levothyroxine TM dosage needs to be adjusted for proper neurologic development.	Hypothyroidism
<u>Isotretinoin (Accutane)</u> . Use of isotretinoin in pregnancy to treat acne results in miscarriage and birth defects. Effective pregnancy prevention should be implemented to avoid unintended pregnancies among women with childbearing potential who use this medication.	Isotretinoin Use
<u>Maternal Phenylketonurea (PKU)</u> . Women diagnosed with PKU as infants have infants with mental retardation. However, this adverse outcome can be prevented when mothers adhere to a low phenylalanine diet before conception and continue it throughout their pregnancy.	Maternal Phenylketonuria
<u>Obesity</u> . Adverse perinatal outcomes associated with maternal obesity include neural tube defects, preterm delivery, diabetes, cesarean section, and hypertensive and thromboembolic disease. Weight loss before pregnancy reduces these risks.	BMI Screening, Healthy Diet & Physical Activity Discussion
<u>Oral Anticoagulant</u> . Warfarin, which is used for the control of blood clotting, has been demonstrated to be a teratogen. To avoid exposure to warfarin during early pregnancy, medications can be changed to a nonteratogenic anticoagulant before the onset of pregnancy.	Oral Anticoagulant

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Clinical Practice Guideline	HWHB Correlate
<u>Rubella Seronegativity</u> . Rubella vaccination provides protective seropositivity and prevents the occurrence of congenital rubella syndrome.	Rubella Status & Immunization
<u>Smoking</u> . Preterm birth, low birthweight, and other adverse perinatal outcomes associated with maternal smoking in pregnancy can be prevented if women stop smoking during early pregnancy. Because only 20% of women successfully control tobacco dependence during pregnancy, cessation of smoking is recommended before pregnancy.	Tobacco Use
<u>STD</u> . <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoea</i> have been strongly associated with ectopic pregnancy, infertility, and chronic pelvic pain. STDs during pregnancy might result in fetal death or substantial physical and developmental disabilities, including mental retardation and blindness.	Chlamydia, Gonorrhoea, Sexually Transmitted Infections

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Table 3: USPSTF Guidelines

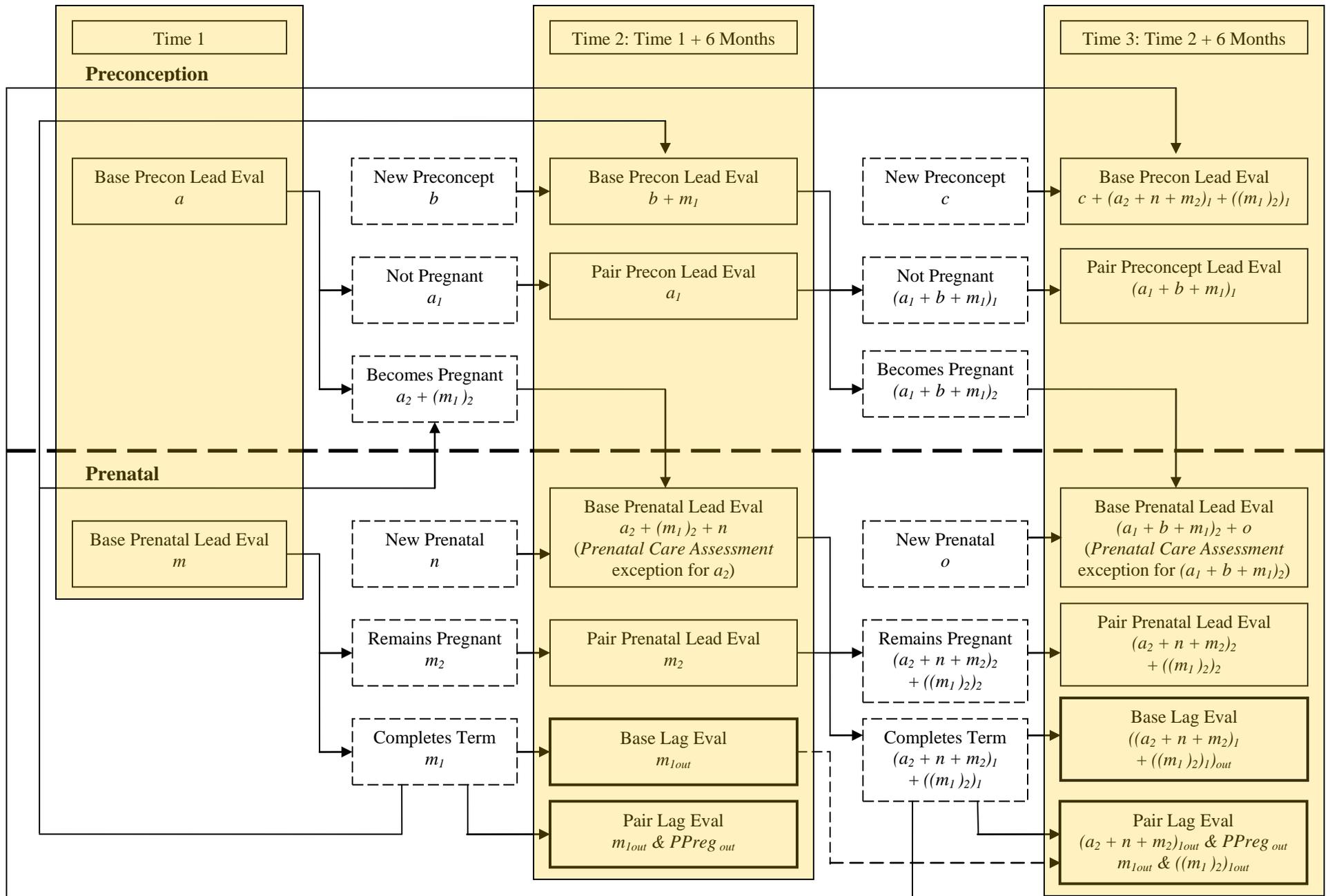
Service	USPSTF Grade	USPSTF Frequency Recommendation
<u><i>Asymptomatic Bacteriuria</i></u>	A	Once at 12 to 16 weeks' gestation or at the first prenatal visit, if later.
<u><i>Blood Pressure</i></u>	A	Last Screening Date must be in the measurement year if Systolic BP between 120 to 139 mm Hg or Diastolic BP between 80 to 90 mm Hg. Last Screening Date must be in the measurement year or in year prior if Systolic BP/ Diastolic BP is less than 120/80 mm Hg.
<u><i>Chlamydia Screening</i></u>	A	Last Screening Date must be in the measurement year.
<u><i>Hepatitis B Screening</i></u>	A	First prenatal visit.
<u><i>Rh Status</i></u>	A	First prenatal visit.
<u><i>Syphilis Screening</i></u>	A	Last Screening Date must be in the measurement year or at the first prenatal visit (if pregnant). For women in high-risk groups, many organizations recommend repeat serologic testing in the third trimester and at delivery.
<u><i>Tobacco Use</i></u>	A	Last Discussion Date must be in measurement year.
<u><i>Cervical Cancer Screening</i></u>	A	Last Pap Test must be in the measurement year or the two years prior to the measurement year.
<u><i>Folic Acid Discussion & Supplementation</i></u>	A	Folic Acid Discussion & Supplementation should take place at every visit.
<u><i>HIV Screening</i></u>	A	Last Screening Date must be in the measurement year.

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Service	USPSTF Grade	USPSTF Frequency Recommendation
<u>Alcohol Misuse</u>	B	Last Discussion Date must be in the measurement year.
<u>BMI Screening</u>	B	Last Screening Date must be in the measurement year.
<u>Depression Counseling</u>	B	Last Screening Date must be in measurement year.
<u>Gonorrhea Screening</u>	B	Last Screening Date must be in the measurement year or at the first prenatal visit (if pregnant).
<u>Healthy Diet & Physical Activity Discussion</u>	B	Last Screening Date must be in measurement year.
<u>Lipid Disorders in Adults</u>	B	Last Screening Date must be in the measurement year.
<u>Sexually Transmitted Infections</u>	B	Last Discussion Date must be in measurement year.

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Figure 2: Conceptual Framework for Evaluating HWHB Measures



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Table 4: Baseline Preconception Lead Service Measurements

MATERNAL ASSESSMENT
Risk Assessment
Percentage of distinct women who have had a risk assessment performed in the last year.
Percentage of distinct women who have a PSS greater than or equal to 25.
Percentage of distinct women who have at least one box scored in the Partner Violence Screen.
Percentage of distinct women who have at least one box scored in the Environmental Tox Screen.

VACCINATIONS
Immunizations
Percentage of distinct women who have had a dTap performed.
Percentage of distinct women who have had a Hepatitis B vaccination.
Percentage of distinct women who have had an HPV vaccination.
Percentage of distinct women who have had an Influenza vaccination.
Percentage of distinct women who have had an MMR vaccination.
Percentage of distinct women who have had a Varicella vaccination.

SCREENING
BMI Screening
Percentage of distinct women who have had a BMI Screening performed in the last year.
Percentage of distinct women who have a BMI greater than 30.
Percentage of distinct women who have a BMI greater than 30 and are in Bundle D.
Blood Pressure [BP]
Percentage of distinct women who have had BP measured in the last year.
Percentage of distinct women who have a BP greater than 120/80 mmHg.
Percentage of distinct women who have a BP greater than 120/80 and are in Bundle D.
Cervical Cancer Screening
Percentage of distinct women who have had a Pap Test within the last three years.
Percentage of distinct women who have tested positive for Cervical Cancer.

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Chlamydia Screening
Percentage of distinct women who have had a Chlamydia Screening within the last year.
Percentage of distinct women who have tested positive for Chlamydia.
Dental Visit
Percentage of distinct women who have had a Dental Visit within the last year.
Gonorrhea Screening
Percentage of distinct women who have had a Gonorrhea Screening within the last year.
Percentage of distinct women who have tested positive for Gonorrhea.
HIV Screening
Percentage of distinct women who have had an HIV Screening within the last year.
Percentage of distinct women who have tested positive for HIV.
Lipid Disorders in Adults
Percentage of distinct women who have had lipid levels measured within the last year.
Percentage of distinct women who have a HbA1c greater than or equal to 6.5%. ¹⁰
Percentage of distinct women who have a HbA1c greater than or equal to 6.5% and are in Bundle D. ¹⁰
Percentage of distinct women who have a LDL-c greater than or equal to 130 mg/dL. ¹¹
Percentage of distinct women who have a LDL-c greater than or equal to 130 mg/dL and are in Bundle D. ¹¹
Syphilis Screening
Percentage of distinct women who have had a Syphilis Screening within the last year.
Percentage of distinct women who have tested positive for Syphilis.
Trichomoniasis Screening
Percentage of distinct women who have had a Trichomoniasis Screening within the last year.
Percentage of distinct women who have tested positive for Trichomoniasis.

COUNSELING

Alcohol Misuse

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Percentage of distinct women who have had a discussion on alcohol use within the last year.
Percentage of distinct women age 20 and under who use alcohol.
Percentage of distinct women age 21 and over who use alcohol.
Percentage of distinct women who misuse alcohol (at least two boxes checked in CAGE questionnaire)
Depression Counseling
Percentage of distinct women who have had a discussion on depression and had a PHQ administered within the last year.
Percentage of distinct women who have scored a "None" on the PHQ-9.
Percentage of distinct women who have scored a "Mild" on the PHQ-9.
Percentage of distinct women who have scored a "Moderate" on the PHQ-9.
Percentage of distinct women who have scored a "Moderately Severe" on the PHQ-9.
Percentage of distinct women who have scored a "Severe" on the PHQ-9.
Mean score on the PHQ-9 on all distinct women.
Mean score on the PHQ-9 on all distinct women in Bundle B.
Drug Abuse
Percentage of distinct women who have had a discussion on drug abuse within the last year.
Percentage of distinct women who have abused drugs in the past.
Percentage of distinct women who currently abuse drugs.
Family Planning & Reproductive Life Plan [Group Definitions in Figure 3]
Percentage of distinct women who have had a discussion within the last year on the Family Planning & Reproductive Life Plan.
Percentage of distinct women who have been given a DHMIC Reproductive Life Plan.
Folic Acid Discussion & Supplementation
Percentage of distinct women who use vitamins regularly.
Percentage of distinct women who have been given DHMIC vitamins.
Healthy Diet & Physical Activity Discussion
Percentage of distinct women who have had a discussion on healthy diet and physical activity and had a HDPQ administered within the last year.
Percentage of distinct women who have scored an "Unhealthy" on the HDPQ.
Percentage of distinct women who have scored a "Moderately Unhealthy" on the HDPQ.
Percentage of distinct women who have scored a "Borderline Unhealthy" on the HDPQ.

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Percentage of distinct women who have scored a "Moderately Healthy" on the HDPQ.
Percentage of distinct women who have scored a "Healthy" on the HDPQ.
Mean score on the HDPQ on all distinct women.
Mean score on the HDPQ on all distinct women in Bundle D.
Sexually Transmitted Infections
Percentage of distinct women who have had a discussion on sexually transmitted infections within the last year.
Percentage of distinct women who are "aware" of STIs.
Tobacco Use
Percentage of distinct women who have had a discussion on tobacco use within the last year.
Percentage of distinct women who have used tobacco in the past.
Percentage of distinct women who currently use tobacco.

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Table 5: Pair Preconception Lead Service Measurements

MATERNAL ASSESSMENT
Risk Assessment
Net change [over designated period] in percentage of distinct women who have had a risk assessment performed in the last year.
Net change [over designated period] in mean PSS score.
Net change [over designated period] in number of distinct women who have at least one box scored in Partner Violence Screen.
Net change [over designated period] in number of distinct women who have at least one box scored in Environmental Tox Screen.

VACCINATIONS
Immunizations
Net change [over designated period] in percentage of distinct women who have had a dTap performed.
Net change [over designated period] in percentage of distinct women who have had a Hepatitis B vaccination.
Net change [over designated period] in percentage of distinct women who have had an HPV vaccination.
Net change [over designated period] in percentage of distinct women who have had an Influenza vaccination.
Net change [over designated period] in percentage of distinct women who have had an MMR vaccination.
Net change [over designated period] in percentage of distinct women who have had a Varicella vaccination.

SCREENING
BMI Screening
Net change [over designated period] in percentage of distinct women who have had a BMI Screening performed in the last year.
Net change [over designated period] in BMI among women who have a BMI greater than 30.
Net change [over designated period] in BMI among women who have a BMI greater than 30 and are in Bundle D.
Blood Pressure [BP]
Net change [over designated period] in percentage of distinct women who have had BP measured in the last year.
Net change [over designated period] in BP among women who have a BP greater than 120/80 mmHg.
Net change [over designated period] in BP among women who have a BP greater than 120/80 and are in Bundle D.
Cervical Cancer Screening
Net change [over designated period] in percentage of distinct women who have had a Pap Test within the last three years.
Net change [over designated period] in percentage of distinct women who have tested positive for Cervical Cancer.

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Chlamydia Screening
Net change [over designated period] in percentage of distinct women who have had a Chlamydia Screening within the last year.
Net change [over designated period] in percentage of distinct women who have tested positive for Chlamydia.
Dental Visit
Net change [over designated period] in percentage of distinct women who have had a Dental Visit within the last year.
Gonorrhea Screening
Net change [over designated period] in percentage of distinct women who have had a Gonorrhea Screening within the last year.
Net change [over designated period] in percentage of distinct women who have tested positive for Gonorrhea.
HIV Screening
Net change [over designated period] in percentage of distinct women who have had an HIV screening within the last year.
Net change [over designated period] in percentage of distinct women who have tested positive for HIV.
Lipid Disorders in Adults
Net change [over designated period] in percentage of distinct women who have had lipid levels measured within the last year
Net change [over designated period] in HbA1c among women who have a HbA1c greater than or equal to 6.5%. ¹⁰
Net change [over designated period] in HbA1c among women who have a HbA1c greater than or equal to 6.5% and are in Bundle D. ¹⁰
Net change [over designated period] in LDL-c among women who have a LDL-c greater than or equal to 130 mg/dL. ¹¹
Net change [over designated period] in LDL-c among women who have a LDL-c greater than or equal to 130 mg/dL and are in Bundle D. ¹¹
Syphilis Screening
Net change [over designated period] in percentage of distinct women who have had a Syphilis Screening within the last year.
Net change [over designated period] in percentage of distinct women who have tested positive for Syphilis.
Trichomoniasis Screening
Net change [over designated period] in percentage of distinct women who have had a Trichomoniasis Screening within the last year.
Net change [over designated period] in percentage of distinct women who have tested positive for Trichomoniasis.
COUNSELING
Alcohol Misuse
Net change [over designated period] in percentage of distinct women who have had a discussion on alcohol use within the last year.

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Net change [over designated period] in percentage of distinct women age 20 and under who use alcohol.
Net change [over designated period] in percentage of distinct women age 21 and over who use alcohol.
Net change [over designated period] in percentage of distinct women who misuse alcohol (at least two boxes checked in CAGE questionnaire)
Depression Counseling
Net change [over designated period] in percentage of distinct women who have had a discussion on depression and had a PHQ administered.
Net change [over designated period] in mean score on the PHQ-9 on all distinct women.
Net change [over designated period] in mean score on the PHQ-9 on all distinct women in Bundle B.
Drug Abuse
Net change [over designated period] in percentage of distinct women who have had a discussion on drug abuse within the last year.
Net change [over designated period] in percentage of distinct women who have abused drugs in the past.
Net change [over designated period] in percentage of distinct women who currently abuse drugs.
Family Planning & Reproductive Life Plan [Group Definitions in Figure 3]
Net change [over designated period] in percentage of distinct women who have had a discussion on the Family Planning & Reproductive Life Plan.
Net change [over designated period] in percentage of distinct women who have been given a DHMIC Reproductive Life Plan.
Net change [over designated period] in percentage of women in Group 4.
Net change [over designated period] in percentage of women in Group 8.
Percentage of women in Group 5 who shifted to Group 1.
Folic Acid Discussion & Supplementation
Net change [over designated period] in percentage of distinct women who use vitamins regularly.
Net change [over designated period] in percentage of distinct women who have been given DHMIC vitamins.
Healthy Diet & Physical Activity Discussion
Net change [over designated period] in percentage of distinct women who have had a discussion on healthy diet and physical activity.
Net change [over designated period] in mean score on the HDPQ on all distinct women.
Net change [over designated period] in mean score on the HDPQ on all distinct women in Bundle D.
Sexually Transmitted Infections
Net change [over designated period] in percentage of distinct women who have had a discussion on sexually transmitted infections.
Net change [over designated period] in percentage of distinct women who are "aware" of STIs.

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Tobacco Use
Net change [over designated period] in percentage of distinct women who have had a discussion on tobacco use within the last year.
Net change [over designated period] in percentage of distinct women who have used tobacco in the past.
Net change [over designated period] in percentage of distinct women who currently use tobacco.

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Table 6: Baseline Prenatal Lead Service Measurements

MATERNAL ASSESSMENT
Risk Assessment
Percentage of distinct women who have had a risk assessment performed in the last year.
Percentage of distinct women who have a PSS greater than or equal to 25.
Percentage of distinct women who have at least one box scored in the Partner Violence Screen.
Percentage of distinct women who have at least one box scored in the Environmental Toxin Screen.
Prenatal Care Assessment
Percentage of distinct women who entered prenatal care in their first trimester of pregnancy.
Percentage of distinct women who claim that their pregnancy was planned.
Pregnancy Risks
Percentage of distinct women who are using anti-epileptic drugs before pregnancy.
Percentage of distinct women who are using anti-epileptic drugs during pregnancy.
Percentage of distinct women who have dental disease before pregnancy.
Percentage of distinct women who have dental disease during pregnancy.
Percentage of distinct women who have depression/mental illness before pregnancy.
Percentage of distinct women who have depression/mental illness during pregnancy.
Percentage of distinct women who have insulin-dependent [Type I Diabetes] before pregnancy.
Percentage of distinct women who have insulin-dependent [Type I Diabetes] during pregnancy.
Percentage of distinct women who have non-insulin dependent [Type II Diabetes] before pregnancy.
Percentage of distinct women who have non-insulin dependent [Type II Diabetes] during pregnancy.
Percentage of distinct women who have folic acid deficiency (less than 0.4 mg/day) before pregnancy.
Percentage of distinct women who have folic acid deficiency (less than 0.4 mg/day) during pregnancy.
Percentage of distinct women who have hypertension before pregnancy.
Percentage of distinct women who have hypertension during pregnancy.
Percentage of distinct women who have hypothyroidism before pregnancy.
Percentage of distinct women who have hypothyroidism during pregnancy.
Percentage of distinct women who are using isotretinoin before pregnancy.
Percentage of distinct women who are using isotretinoin during pregnancy.
Percentage of distinct women who are using oral anticoagulants before pregnancy.

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Percentage of distinct women who are using oral anticoagulants during pregnancy.
Percentage of distinct women who had seizures before pregnancy.
Percentage of distinct women who had seizures during pregnancy.
Percentage of distinct women who have gestational diabetes.
Percentage of distinct women who have maternal phenylketonuria (PKU).
Percentage of distinct women who have placental disorders.
Percentage of distinct women who have preeclampsia.
Postpartum/Interconception Care
Percentage of distinct women who are breastfeeding.
Percentage of distinct women who have their baby sleep on his/her back.
Percentage of distinct women who have their baby sleep in a separate bed/crib.
Percentage of distinct women who are planning to have more children.
Percentage of distinct women who are planning on using pregnancy contraception.
First Prenatal Visit Measures
Percentage of distinct women who tested positive for cytomegalovirus.
Percentage of distinct women who tested positive for Hepatitis B.
Percentage of distinct women who tested positive for Herpes Simplex.
Percentage of distinct women who tested positive for rubella.
Percentage of distinct women who tested positive for toxoplasma.

VACCINATIONS

Immunizations
Percentage of distinct women who have had a dTap performed.
Percentage of distinct women who have had a Hepatitis B vaccination.
Percentage of distinct women who have had an HPV vaccination.
Percentage of distinct women who have had an Influenza vaccination.
Percentage of distinct women who have had an MMR vaccination.
Percentage of distinct women who have had a Varicella vaccination.

SCREENING

BMI Screening

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Percentage of distinct women who have had a BMI Screening performed in the last year.
Percentage of distinct women who have a BMI greater than 30.
Percentage of distinct women who have a BMI greater than 30 and are in Bundle D.
Blood Pressure [BP]
Percentage of distinct women who have had BP measured in the last year.
Percentage of distinct women who have a BP greater than 120/80 mmHg.
Percentage of distinct women who have a BP greater than 120/80 and are in Bundle D.
Cervical Cancer Screening
Percentage of distinct women who have had a Pap Test within the last three years.
Percentage of distinct women who have tested positive for Cervical Cancer.
Chlamydia Screening
Percentage of distinct women who have had a Chlamydia Screening within the last year.
Percentage of distinct women who have tested positive for Chlamydia.
Dental Visit
Percentage of distinct women who have had a Dental Visit within the last year.
Gonorrhea Screening
Percentage of distinct women who have had a Gonorrhea Screening within the last year.
Percentage of distinct women who have tested positive for Gonorrhea.
HIV Screening
Percentage of distinct women who have had an HIV Screening within the last year.
Percentage of distinct women who have tested positive for HIV.
Lipid Disorders in Adults
Percentage of distinct women who have had lipid levels measured within the last year.
Percentage of distinct women who have a HbA1c greater than or equal to 6.5%. ¹⁰
Percentage of distinct women who have a HbA1c greater than or equal to 6.5% and are in Bundle D. ¹⁰
Percentage of distinct women who have a LDL-c greater than or equal to 130 mg/dL. ¹¹

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Percentage of distinct women who have a LDL-c greater than or equal to 130 mg/dL and are in Bundle D. ¹¹
Syphilis Screening
Percentage of distinct women who have had a Syphilis Screening within the last year.
Percentage of distinct women who have tested positive for Syphilis.
Trichomoniasis Screening
Percentage of distinct women who have had a Trichomoniasis Screening within the last year.
Percentage of distinct women who have tested positive for Trichomoniasis.

COUNSELING

Alcohol Misuse
Percentage of distinct women who have had a discussion on alcohol use within the last year.
Percentage of distinct women age 20 and under who use alcohol.
Percentage of distinct women age 21 and over who use alcohol.
Percentage of distinct women who misuse alcohol (at least two boxes checked in CAGE questionnaire)
Depression Counseling
Percentage of distinct women who have had a discussion on depression and had a PHQ administered within the last year.
Percentage of distinct women who have scored a "None" on the PHQ-9.
Percentage of distinct women who have scored a "Mild" on the PHQ-9.
Percentage of distinct women who have scored a "Moderate" on the PHQ-9.
Percentage of distinct women who have scored a "Moderately Severe" on the PHQ-9.
Percentage of distinct women who have scored a "Severe" on the PHQ-9.
Mean score on the PHQ-9 on all distinct women.
Mean score on the PHQ-9 on all distinct women in Bundle B.
Drug Abuse
Percentage of distinct women who have had a discussion on drug abuse within the last year.
Percentage of distinct women who have abused drugs in the past.
Percentage of distinct women who currently abuse drugs.
Percentage of distinct women who indicate having a partner who has abused drugs in the past.
Percentage of distinct women who indicate having a partner who currently abuses drugs.

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Family Planning & Reproductive Life Plan [Group Definitions in Error! Not a valid bookmark self-reference.]
Percentage of distinct women who have had a discussion within the last year on the Family Planning & Reproductive Life Plan.
Percentage of distinct women who have been given a DHMIC Reproductive Life Plan.
Folic Acid Discussion & Supplementation
Percentage of distinct women who use vitamins regularly.
Percentage of distinct women who have been given DHMIC vitamins.
Healthy Diet & Physical Activity Discussion
Percentage of distinct women who have had a discussion on healthy diet and physical activity and had a HDPQ administered within the last year.
Percentage of distinct women who have scored an "Unhealthy" on the HDPQ.
Percentage of distinct women who have scored a "Moderately Unhealthy" on the HDPQ.
Percentage of distinct women who have scored a "Borderline Unhealthy" on the HDPQ.
Percentage of distinct women who have scored a "Moderately Healthy" on the HDPQ.
Percentage of distinct women who have scored a "Healthy" on the HDPQ.
Mean score on the HDPQ on all distinct women.
Mean score on the HDPQ on all distinct women in Bundle D.
Sexually Transmitted Infections
Percentage of distinct women who have had a discussion on sexually transmitted infections within the last year.
Percentage of distinct women who are "aware" of STIs.
Tobacco Use
Percentage of distinct women who have had a discussion on tobacco use within the last year.
Percentage of distinct women who have used tobacco in the past.
Percentage of distinct women who currently use tobacco.
Percentage of distinct women who indicate having a partner who has used tobacco in the past.
Percentage of distinct women who indicate having a partner who currently uses tobacco.

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Table 7: Pair Prenatal Lead Service Measurements

MATERNAL ASSESSMENT
Risk Assessment
Net change [over designated period] in percentage of distinct women who have had a risk assessment performed in the last year.
Net change [over designated period] in mean PSS score.
Net change [over designated period] in number of distinct women who have at least one box scored in Partner Violence Screen.
Net change [over designated period] in number of distinct women who have at least one box scored in Environmental Toxin Screen.
Prenatal Care Assessment [Group Definitions in Figure 3]
Percentage of distinct women who did not enter prenatal care in their first trimester of pregnancy and had a Family Planning & Reproductive Life Plan discussion in their most recent preconception care lead evaluation. [Exception Subset]
Percentage of distinct women who claimed that their pregnancy was planned and were in Group 1 in their most recent preconception care lead evaluation. [Exception Subset]
Percentage of distinct women who claimed that their pregnancy was planned and were in Group 2 in their most recent preconception care lead evaluation. [Exception Subset]
Percentage of distinct women who claimed that their pregnancy was planned and were in Group 3 in their most recent preconception care lead evaluation. [Exception Subset]
Percentage of distinct women who claimed that their pregnancy was planned and were in Group 5 in their most recent preconception care lead evaluation. [Exception Subset]
Percentage of distinct women who claimed that their pregnancy was planned and were in Group 6 in their most recent preconception care lead evaluation. [Exception Subset]
Percentage of distinct women who claimed that their pregnancy was planned and were in Group 7 in their most recent preconception care lead evaluation. [Exception Subset]
Pregnancy Risks
Net change [over designated period] in percentage of distinct women who are using anti-epileptic drugs during pregnancy.
Net change [over designated period] in percentage of distinct women who have dental disease during pregnancy.
Net change [over designated period] in percentage of distinct women who have depression/mental illness during pregnancy.
Net change [over designated period] in percentage of distinct women who have insulin-dependent [Type I Diabetes] during pregnancy.
Net change [over designated period] in percentage of distinct women who have non-insulin dependent [Type II Diabetes] during pregnancy.
Net change [over designated period] in percentage of distinct women who have folic acid deficiency (less than 0.4 mg/day) during pregnancy.
Net change [over designated period] in percentage of distinct women who have hypertension during pregnancy.
Net change [over designated period] in percentage of distinct women who have hypothyroidism during pregnancy.
Net change [over designated period] in percentage of distinct women who are using isotretinoins during pregnancy.
Net change [over designated period] in percentage of distinct women who are using oral anticoagulants during pregnancy.
Net change [over designated period] in percentage of distinct women who had seizures during pregnancy.
Net change [over designated period] in percentage of distinct women who have gestational diabetes.
Net change [over designated period] in percentage of distinct women who have maternal phenylketonuria (PKU).
Net change [over designated period] in percentage of distinct women who have placental disorders.

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Net change [over designated period] in percentage of distinct women who have preeclampsia.
Postpartum/Interconception Care
Net change [over designated period] in percentage of distinct women who are breastfeeding.
Net change [over designated period] in percentage of distinct women who are having their baby sleep on his/her back.
Net change [over designated period] in percentage of distinct women who are having their baby sleep in a separate bed/crib.
Net change [over designated period] in percentage of distinct women who are planning to have more children.
Net change [over designated period] in percentage of distinct women who are using pregnancy contraception.

VACCINATIONS

Immunizations
Net change [over designated period] in percentage of distinct women who have had a dTap performed.
Net change [over designated period] in percentage of distinct women who have had a Hepatitis B vaccination.
Net change [over designated period] in percentage of distinct women who have had an HPV vaccination.
Net change [over designated period] in percentage of distinct women who have had an Influenza vaccination.
Net change [over designated period] in percentage of distinct women who have had an MMR vaccination.
Net change [over designated period] in percentage of distinct women who have had a Varicella vaccination.

SCREENING

BMI Screening
Net change [over designated period] in percentage of distinct women who have had a BMI Screening performed in the last year.
Net change [over designated period] in BMI among women who have a BMI greater than 30.
Net change [over designated period] in BMI among women who have a BMI greater than 30 and are in Bundle D.
Blood Pressure [BP]
Net change [over designated period] in percentage of distinct women who have had BP measured in the last year.
Net change [over designated period] in BP among women who have a BP greater than 120/80 mmHg.
Net change [over designated period] in BP among women who have a BP greater than 120/80 and are in Bundle D.
Cervical Cancer Screening
Net change [over designated period] in percentage of distinct women who have had a Pap Test within the last three years.
Net change [over designated period] in percentage of distinct women who have tested positive for Cervical Cancer.

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Chlamydia Screening
Net change [over designated period] in percentage of distinct women who have had a Chlamydia Screening within the last year.
Net change [over designated period] in percentage of distinct women who have tested positive for Chlamydia.
Dental Visit
Net change [over designated period] in percentage of distinct women who have had a Dental Visit within the last year.
Gonorrhea Screening
Net change [over designated period] in percentage of distinct women who have had a Gonorrhea Screening within the last year.
Net change [over designated period] in percentage of distinct women who have tested positive for Gonorrhea.
HIV Screening
Net change [over designated period] in percentage of distinct women who have had an HIV screening within the last year.
Net change [over designated period] in percentage of distinct women who have tested positive for HIV.
Lipid Disorders in Adults
Net change [over designated period] in percentage of distinct women who have had lipid levels measured within the last year
Net change [over designated period] in HbA1c among women who have a HbA1c greater than or equal to 6.5%. ¹⁰
Net change [over designated period] in HbA1c among women who have a HbA1c greater than or equal to 6.5% and are in Bundle D. ¹⁰
Net change [over designated period] in LDL-c among women who have a LDL-c greater than or equal to 130 mg/dL. ¹¹
Net change [over designated period] in LDL-c among women who have a LDL-c greater than or equal to 130 mg/dL and are in Bundle D. ¹¹
Syphilis Screening
Net change [over designated period] in percentage of distinct women who have had a Syphilis Screening within the last year.
Net change [over designated period] in percentage of distinct women who have tested positive for Syphilis.
Trichomoniasis Screening
Net change [over designated period] in percentage of distinct women who have had a Trichomoniasis Screening within the last year.
Net change [over designated period] in percentage of distinct women who have tested positive for Trichomoniasis.
COUNSELING
Alcohol Misuse
Net change [over designated period] in percentage of distinct women who have had a discussion on alcohol use within the last year.

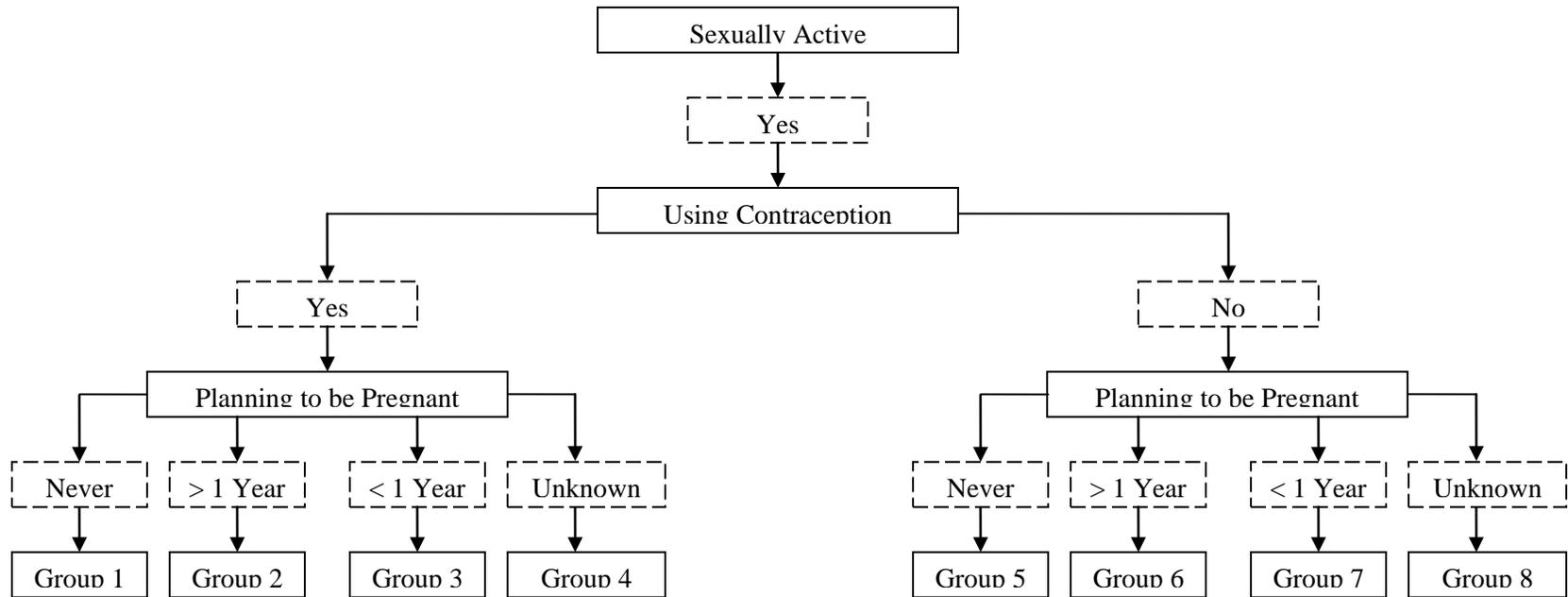
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Net change [over designated period] in percentage of distinct women age 20 and under who use alcohol.
Net change [over designated period] in percentage of distinct women age 21 and over who use alcohol.
Net change [over designated period] in percentage of distinct women who misuse alcohol (at least two boxes checked in CAGE questionnaire)
Depression Counseling
Net change [over designated period] in percentage of distinct women who have had a discussion on depression and had a PHQ administered.
Net change [over designated period] in mean score on the PHQ-9 on all distinct women.
Net change [over designated period] in mean score on the PHQ-9 on all distinct women in Bundle B.
Drug Abuse
Net change [over designated period] in percentage of distinct women who have had a discussion on drug abuse within the last year.
Net change [over designated period] in percentage of distinct women who have abused drugs in the past.
Net change [over designated period] in percentage of distinct women who currently abuse drugs.
Family Planning & Reproductive Life Plan [Group Definitions in Figure 3]
Net change [over designated period] in percentage of distinct women who have had a discussion on the Family Planning & Reproductive Life Plan.
Net change [over designated period] in percentage of distinct women who have been given a DHMIC Reproductive Life Plan.
Net change [over designated period] in percentage of women in Group 4.
Net change [over designated period] in percentage of women in Group 8.
Percentage of women in Group 5 who shifted to Group 1.
Folic Acid Discussion & Supplementation
Net change [over designated period] in percentage of distinct women who use vitamins regularly.
Net change [over designated period] in percentage of distinct women who have been given DHMIC vitamins.
Healthy Diet & Physical Activity Discussion
Net change [over designated period] in percentage of distinct women who have had a discussion on healthy diet and physical activity.
Net change [over designated period] in mean score on the HDPQ on all distinct women.
Net change [over designated period] in mean score on the HDPQ on all distinct women in Bundle D.
Sexually Transmitted Infections
Net change [over designated period] in percentage of distinct women who have had a discussion on sexually transmitted infections.
Net change [over designated period] in percentage of distinct women who are "aware" of STIs.

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Tobacco Use
Net change [over designated period] in percentage of distinct women who have had a discussion on tobacco use within the last year.
Net change [over designated period] in percentage of distinct women who have used tobacco in the past.
Net change [over designated period] in percentage of distinct women who currently use tobacco.

Figure 3: Family Planning & Reproductive Life Plan Group Definitions



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Table 8: Baseline Lag Outcome Measurements

Percentage of total pregnancies resulting in poor birth outcome (ectopic/molar pregnancy, fetal death, preterm birth, LBW/VLBW, infant death).
Percentage of total pregnancies resulting in ectopic/molar pregnancy.
Fetal Death: Percentage of total pregnancies resulting in late spontaneous abortion (12-20 weeks' gestation).
Fetal Death: Percentage of total pregnancies resulting in stillbirth (20+ weeks' gestation).
Preterm Birth: Percentage of total pregnancies resulting in live-born infant born before 32 weeks.
Preterm Birth: Percentage of total pregnancies resulting in live-born infant born before 37 weeks.
LBW/VLBW: Percentage of total pregnancies resulting in live-born infant weighing between 1500 and 2499 g.
LBW/VLBW: Percentage of total pregnancies resulting in live-born infant weighing less than 1500 g.
Infant Death: Percentage of total pregnancies that ultimately result in neonatal death (from 1 hour after birth to 27 days after birth).
Infant Death: Percentage of total pregnancies that ultimately result in postneonatal death (from 28 days after birth to 365 days after birth).

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Table 9: Pair Lag Outcome Measurements

A1	Percentage of total pregnancies resulting in poor birth outcome (ectopic/molar pregnancy, fetal death, preterm birth, LBW/VLBW, infant death) compared to previous birth outcome (before HWHB).
A2	Percentage of total pregnancies resulting in ectopic/molar pregnancy compared to previous birth outcome (before HWHB).
A3	Fetal Death: Percentage of total pregnancies resulting in late spontaneous abortion (12-20 weeks' gestation) compared to previous birth outcome (before HWHB).
A4	Fetal Death: Percentage of total pregnancies resulting in stillbirth (20+ weeks' gestation) compared to previous birth outcome (before HWHB).
A5	Preterm Birth: Percentage of total pregnancies resulting in live-born infant born before 32 weeks compared to previous birth outcome (before HWHB).
A6	Preterm Birth: Percentage of total pregnancies resulting in live-born infant born before 37 weeks compared to previous birth outcome (before HWHB).
A7	LBW/VLBW: Percentage of total pregnancies resulting in live-born infant weighing between 1500 and 2499 g compared to previous birth outcome (before HWHB).
A8	LBW/VLBW: Percentage of total pregnancies resulting in live-born infant weighing less than 1500 g compared to previous birth outcome (before HWHB).
A9	Infant Death: Percentage of total pregnancies that ultimately result in neonatal death (from 1 hour after birth to 27 days after birth) compared to previous birth outcome (before HWHB).
A10	Infant Death: Percentage of total pregnancies that ultimately result in postneonatal death (from 28 days after birth to 365 days after birth) compared to previous birth outcome (before HWHB).
B1	Net change in percentage of total pregnancies resulting in poor birth outcome (ectopic/molar pregnancy, fetal death, preterm birth, LBW/VLBW, infant death).
B2	Net change in percentage of total pregnancies resulting in ectopic/molar pregnancy.
B3	Fetal Death: Net change in percentage of total pregnancies resulting in late spontaneous abortion (12-20 weeks' gestation).
B4	Fetal Death: Net change in percentage of total pregnancies resulting in stillbirth (20+ weeks' gestation).
B5	Preterm Birth: Net change in percentage of total pregnancies resulting in live-born infant born before 32 weeks.
B6	Preterm Birth: Net change in percentage of total pregnancies resulting in live-born infant born before 37 weeks.
B7	LBW/VLBW: Net change in percentage of total pregnancies resulting in live-born infant weighing between 1500 and 2499 g.
B8	LBW/VLBW: Net change in percentage of total pregnancies resulting in live-born infant weighing less than 1500 g.
B9	Infant Death: Net change in percentage of total pregnancies that ultimately result in neonatal death (from 1 hour after birth to 27 days after birth).
B10	Infant Death: Net change in percentage of total pregnancies that ultimately result in postneonatal death (from 28 days after birth to 365 days after birth).

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Table 10: Historic Data on Pregnancies, Live Births, and Infant Deaths in Delaware

	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
Pregnancies Resulting in Live Births	9988	10061	10391	10468	10842	10541	10852	11107	11147	11732
All Live Births	10148	10246	10574	10666	11046	10747	11083	11337	11358	11603
All Infant Deaths	77	81	103	81	102	114	96	107	97	104

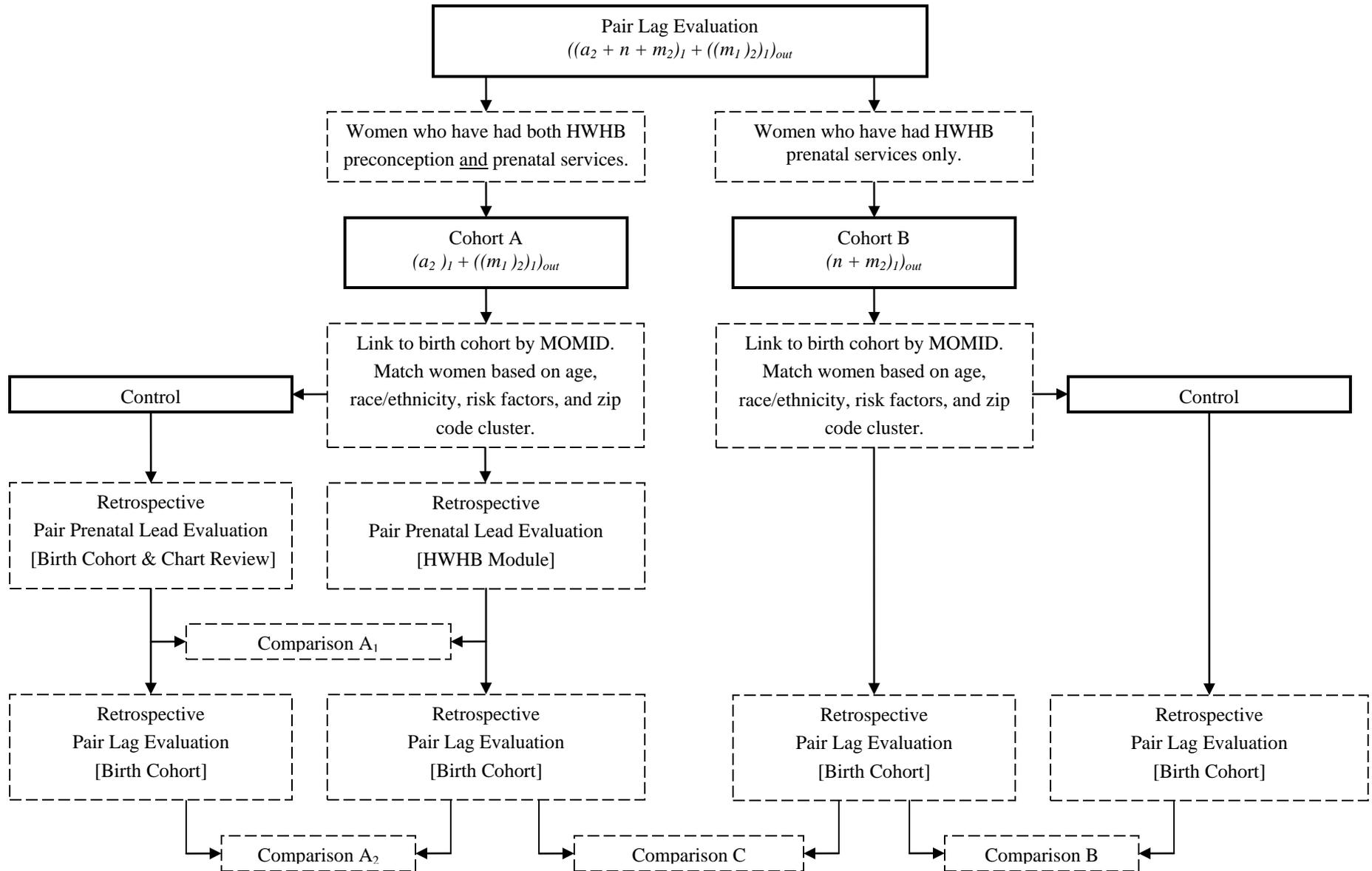
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Table 11: Comparative Evaluation Options

	Study Design	Advantages	Disadvantages
Retrospective Comparison by Time	Matched comparison of performance measures on the target population before the implementation of the HWHB program and after implementation. The comparison would be similar to previous work conducted by Dunlop <i>et al</i> and Ehrental & Kroelinger. ^{6,8}	<ul style="list-style-type: none"> Fairly easy analysis using the Birth Cohort Dataset/Delaware Health Statistics Data and the HWHB Measures. 	<ul style="list-style-type: none"> Difficult to truly claim causal relationships from implementing the HWHB program. Differences in clinical staff and case management practices at the varied sites over time makes comparison between time frames tenuous. Some complex chart review may need to take place.
Retrospective Comparison to Henrietta Johnson	Matched comparison of performance measures on the target population between the HWHB program and Henrietta Johnson, a non-participating clinic.	<ul style="list-style-type: none"> Clear control and treatment group allows for simple retrospective design. 	<ul style="list-style-type: none"> Differences in clinical staff and case management practices at Henrietta Johnson over time makes for a weak comparison. Necessary buy-in from Henrietta Johnson may hard to acquire especially since the results may be unfavorable to either Henrietta Johnson or HWHB.
Retrospective Comparison to Non-Treatment Group	Matched comparison of performance measures on the target population between the HWHB program and women presenting with similar demographic/risk factors but are not in the HWHB program. The comparison would be similar to previous work conducted on the Magnolia Project. ⁹	<ul style="list-style-type: none"> Clear control and treatment group allows for simple retrospective design. Fairly easy analysis using the Birth Cohort Dataset/Delaware Health Statistics Data and the HWHB Measures. Possibility of claiming causal relationships from implementing the HWHB program. 	<ul style="list-style-type: none"> Population size of non-HWHB participants may be fairly small. Non-HWHB participants are most-likely seeking similar care to HWHB participants. Some complex chart review may need to take place.

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Figure 4: Comparative Evaluation, Retrospective Comparison to Non-Treatment Group Design



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