

**HARMS and BENEFITS associated with One-step versus Two-step
Gestational Diabetes Mellitus (GDM) screening test.**

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Disclaimer

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Executive Summary

This project outlines a comprehensive systematic review aimed at comparing the net population-level health benefits and harms of implementing a more sensitive one-step screening test for gestational diabetes mellitus (GDM) versus a less sensitive but more specific two-step screening test. The study's innovative approach extends beyond traditional health outcomes, incorporating an environmental perspective by considering the greenhouse gas (GHG) emissions associated with each screening strategy.

The proposed research will conduct an exhaustive review of medical literature to gain insights into the prevalence, incidence, and outcomes of GDM, as well as the effectiveness of different treatments. The review will focus on studies that have employed either the one-step or two-step GDM screening methods. The study will also assess the environmental impacts associated with each step of the screening and follow-up processes by reviewing Life Cycle Assessment (LCA) databases.

A unique aspect of this project is the consideration of GHG emissions associated with the one-step and two-step GDM screening strategies. The study will estimate the Disability-Adjusted Life Years (DALYs) associated with these emissions, considering the impact on future generations. This innovative approach not only takes into account the direct health outcomes of the screening methods but also their broader environmental and societal impacts.

The study will utilize various databases, including Vital Statistics, Population Health Surveys, and Healthcare Administrative Databases, to gather data on population demographics, mortality rates, causes of death, health behaviors, health status, quality of life, healthcare utilization patterns, treatment data, and medication information. This comprehensive data collection will provide a holistic view of the impacts of the one-step and two-step GDM screening strategies.

The results of this systematic review will be disseminated through a peer-reviewed publication, and the protocol will be registered with PROSPERO, ensuring transparency and adherence to rigorous research standards. The study's findings could have significant implications for healthcare policy and practice in the management of GDM.

In conclusion, this project presents a novel and comprehensive approach to evaluating the impacts of one-step versus two-step GDM screening strategies. By considering not only the direct health outcomes but also the broader environmental and societal impacts, this study could provide valuable insights that could inform healthcare policy and practice in the management of GDM.

This research could potentially redefine the approach to GDM screening by integrating environmental considerations into healthcare decision-making, thereby contributing to the sustainability of healthcare systems.

Preface: Problem statement and knowledge gap

In the realm of maternal and neonatal health, the quest for effective screening methods that strike a balance between accuracy, patient experience, and environmental impact has been a perennial challenge. As the global healthcare landscape evolves, the need to optimize screening protocols for gestational diabetes mellitus (GDM) has gained significant prominence. GDM, a condition marked by high blood sugar levels during pregnancy, not only poses risks to maternal and fetal health but also presents an opportunity to explore innovative strategies that align with both medical and environmental considerations.

Within this context, our research embarks on a journey to critically examine the GDM screening landscape, dissecting the one-step and two-step approaches that healthcare systems worldwide employ. These approaches, although aimed at identifying and managing GDM in pregnant individuals, present divergent pathways in terms of sensitivity, patient experience, and environmental consequences. This research is poised to provide an intricate analysis of these pathways, unravelling the intricate web of benefits and challenges each approach brings forth.

The significance of our study lies not only in its contribution to maternal and neonatal health but also in its novel perspective that intertwines medical outcomes with environmental stewardship. In an era where concerns about the ecological footprint of healthcare practices have come to the forefront, a careful assessment of the environmental implications of screening methods is imperative. The need to balance medical efficacy with environmental sustainability underscores a broader narrative that resonates with the global call for greener and more responsible healthcare systems.

As healthcare systems grapple with the complexities of resource allocation, patient well-being, and environmental sustainability, it is increasingly evident that decisions regarding screening protocols hold far-reaching consequences. Our research aims to transcend the boundaries of conventional analysis by delving deep into the intricate interplay between medical advantages and environmental impacts. By shining a light on the nuanced dynamics of the one-step and two-step

approaches, we endeavor to provide stakeholders with a comprehensive toolkit for decision-making—one that acknowledges the multifaceted dimensions of healthcare delivery in the 21st century.

The amalgamation of medical science and environmental stewardship encapsulates the essence of our research. We navigate through the intricacies of GDM screening not merely as a scientific inquiry but as a paradigm shift in how healthcare should be envisioned. By dissecting the steps, analyzing the implications, and quantifying the outcomes, we seek to paint a holistic picture that resonates with healthcare providers, policymakers, and environmentally conscious citizens alike. In the following sections of this project, we embark on an exploration that navigates through the scientific and environmental facets of the one-step and two-step approaches for GDM screening. Our aim is to not only decipher the clinical nuances but also to illuminate the potential ecological footprints each approach may leave behind. As we embark on this journey of research and discovery, we stand committed to providing insights that extend beyond the conventional boundaries of healthcare—insights that encompass the diverse array of challenges and opportunities that define healthcare in the contemporary world.

Introduction

A: BENEFITS:

1. One-Step Screening

Medical Benefits

High Sensitivity: The one-step screening method for GDM, which incorporates a 75g oral glucose tolerance test (OGTT), is typically more sensitive than the two-step approach, leading to higher detection rates for less severe manifestations of GDM. This is due to the lower threshold for defining GDM in the one-step method, making it possible to identify more pregnant women with lesser degrees of elevated blood glucose (1,2).

Early Intervention: The potential for early detection of milder manifestations of GDM with one-step screening allows for timely interventions to manage GDM, leading potentially to improved health outcomes for both the mother and her baby. Early diagnosis of milder cases can potentially prevent complications like macrosomia (large babies), preterm births, and shoulder dystocia, which are commonly associated with uncontrolled GDM (3,4).

Economic Benefits

Cost-Efficiency: Although the one-step screening might be associated with higher initial costs due to increased screening and treatment, studies suggest that there could be possible savings from improved pregnancy outcomes and reduced long-term complications for the mother and baby that may balance these upfront costs (5,6).

Reduced Healthcare System Burden: By necessitating only one clinic visit for GDM screening, the one-step approach may lower the burden on healthcare systems by potentially minimizing the number of visits and associated administrative work (5,6).

Sustainability and Environmental Benefits

Reduced Green House Gas (GHG) Emissions: Fewer visits by patients for GDM screening, for the 20% of patients who would have an indeterminate result on the first step of the two-step screen, could result in lower carbon footprints due to reduced transportation-related GHG emissions, thereby contributing to climate change mitigation (9).

2. Two-Step Screening

Medical Benefits

High Specificity: The two-step screening method, using a 50g glucose challenge test (GCT) followed by a 75 or 100g OGTT for positive results, typically exhibits higher specificity. This reduces the false-positive rate, leading to fewer women undergoing unnecessary interventions and treatments for GDM (7,8) and still identifying the most severe presentations.

Lower Risk of Overdiagnosis: With a higher threshold for diagnosing GDM, the two-step screening process identifies fewer cases with a less severe phenotype, hence the chances of overdiagnosis and subsequent overtreatment are less likely, potentially safeguarding women from unnecessary medical interventions and anxiety (8).

Economic Benefits

Lower Initial Costs: Two-step screening often incurs lower upfront costs due to a less inclusive definition of GDM, thereby decreasing the number of women who require monitoring and treatment.

Potential for Long-Term Savings: By reducing the rate of false positives (mild forms of GDM that do not translate into adverse health comes) and thereby lessening the demand for unnecessary GDM treatments, the two-step screening method might lead to significant healthcare cost savings over time.

Sustainability and Environmental Benefits

Potential for Reduced Medical Resource Use: The two-step approach's high specificity might lead to less wastage of medical resources as a result of less unnecessary treatment. The lower rate of positive results could translate to fewer medications used, fewer clinic visits, and lower energy expenditure in healthcare facilities.

B. HARMS:

1. One-Step Screening

Medical Harms

Increased False Positives: Due to its high sensitivity, one-step screening might result in an increased number of false-positive results. This could lead to undue stress and anxiety for women who are diagnosed with a milder form of GDM that does not result in treatment benefit, as well as potentially unnecessary medical interventions (10).

Overdiagnosis and Overtreatment: With a broader definition of GDM, the one-step method might lead to overdiagnosis, resulting in unnecessary treatment. This treatment could expose women to potential side effects and burdens without proportionate benefits (11,12).

Economic Harms

Higher Initial Costs: One-step screening usually requires more resources upfront due to higher rates of GDM detection and the need for more comprehensive management of diagnosed cases.

Potential for Increased Long-term Costs: The costs associated with managing potential over diagnosed cases and unnecessary treatments could increase overall long-term healthcare costs.

Sustainability and Environmental Harms

Increased Medical Resource Use: The higher rate of GDM diagnosis with the one-step approach could lead to more extensive use of medical resources, contributing to increased energy consumption in healthcare facilities, and the production of medical waste.

2. Two-Step Screening

Medical Harms

Lower Sensitivity: The two-step screening approach for GDM may miss some cases that would otherwise have medical benefit from monitoring and treatment, due to its lower sensitivity, which could lead to negative health outcomes for the mother, baby or both (7,13).

Delayed Intervention: The two-step process involves two separate clinic visits and hence might delay diagnosis and intervention. This could potentially worsen health outcomes for mothers with GDM and their babies (7,14).

Economic Harms

Potential Increased Long-term Costs: By missing some cases of GDM, the two-step method might lead to increased long-term healthcare costs due to the management of complications owing to the missed diagnosis of GDM cases that would have benefited from treatment (15).

Administrative Burden: The two-step screening process necessitates two separate clinic visits for 20% of cases, potentially increasing administrative workload and associated costs.

Sustainability and Environmental Harms

Increased GHG Emissions: The requirement for two clinic visits could result in a higher carbon footprint due to increased transportation-related GHG emissions for 20% of pregnancies (16).

Greater Medical Resource Use: The need for two clinic visits might lead to a more significant use of medical resources, including energy in healthcare facilities, medical supplies, and transportation costs.

Summary of HARMS and BENEFITS:

BENEFITS:

Research has underscored significant potential advantages in adopting a 1-step process for gestational diabetes mellitus (GDM) screening over the traditional 2-step process. A leading proposed benefit of the 1-step approach is its increased sensitivity, which facilitates the early detection of milder phenotypes of GDM. The benefit of the increased sensitivity of the 1-step process has been difficult to detect where sought, but theoretically allows timely intervention and the potential to improve both maternal and neonatal outcomes for the milder phenotype that would be missed by the 2-step process. The improved glycemic control associated with the early detection facilitated by the 1-step process can significantly theoretically reduce the risk of maternal and fetal complications. Specifically, studies have highlighted a lower incidence of macrosomia, neonatal hypoglycemia, and admissions to the neonatal intensive care unit (NICU), but these findings have not been statistically significant when compared to the 2-step process. Nevertheless, these preliminary results are testament to the potential benefits to the health and well-being of the mother and child offered by the 1-step process.

Furthermore, the 1-step process can also offer tangible benefits in terms of efficiency and convenience. This approach simplifies the process by requiring just a single glucose tolerance test, thereby eliminating the need for an additional screening step. Such streamlining of the procedure can help reduce the burden on both expectant mothers and the healthcare systems supporting them. A more efficient screening approach not only saves time but also preserves resources and can potentially cut down on costs related to multiple screening visits. The counter argument to this is that the increased convenience of the 50g screen (no requirement for fasting and lasting only 1 hour instead of 2) will promote uptake of the test more universally and earlier in pregnancy. Economic analyses of the 1-step approach have proposed its cost-effectiveness in comparison to the 2-step process. Though the cost of the initial screening test could be higher, overall savings derived from better pregnancy outcomes and lower long-term complications, should they be demonstrated in practice, and can outweigh the initial investment. The balance between financial

outlay and health outcomes may strengthen the case for the 1-step approach as a valuable tool in improving maternal and neonatal health outcomes, should it be demonstrated to do so.

It is crucial to also consider the potential downside of the 1-step process. As a more sensitive screening tool, the 1-step process could result in a higher false-positive rate. This could, in turn, lead to additional diagnostic tests and increased healthcare utilization, thereby potentially causing patient anxiety, and misdirect limited resources (financial). Hence, it is essential to balance the benefits with the potential harms and carefully evaluate the trade-offs associated with the 1-step process.

HARMS:

An examination of the potential harms associated with the 2-step process when compared to the 1-step process necessitates considering several aspects. For both processes, a positive screen triggers further diagnostic tests, monitoring, and interventions to ensure the well-being of the mother and the baby. Therefore, understanding the implications of each step of the screening approaches is crucial. Environmental factors, particularly greenhouse gas (GHG) emissions associated with each step of the screening process, are increasingly critical considerations in healthcare. Life cycle analyses can help in assessing the GHG emissions linked to each step of the screening and follow-up processes. These analyses can provide valuable insights into the environmental footprint of each screening approach, helping to gauge the broader implications of our healthcare practices. By calculating the GHG emissions associated with each step and extrapolating these figures to larger populations, we can estimate the overall environmental impact of each approach. This estimation can contribute to a broader understanding of the potential global impact of adopting a specific screening method.

The impact of GHG emissions on health outcomes can be assessed through Disability-Adjusted Life Years (DALY) calculations. By referencing databases that link GHG emissions to DALY, we can estimate the potential health effects associated with the emissions generated during the screening and follow-up processes. Understanding the economic implications of each screening process also requires an analysis of public and individual health expenses. This includes considering the costs associated with additional diagnostic tests, medical interventions, and follow-up care.

In the comprehensive evaluation of the 1-step process, the comparison of DALY estimates derived from GHG emissions can help evaluate the relative benefits and harms of both processes. The DALY estimates provide a quantifiable measurement of potential health losses, incorporating both the years of life lost due to premature mortality and the years lived with disability. The comparison of DALY calculations between the 1-step and 2-step processes assists in gauging the overall impact on individuals' health. This comprehensive evaluation is essential in assessing the effectiveness of both screening methods. However, it's critical to ensure that such a comparison considers factors such as data accuracy, the generalizability of findings, and the limitations of analytical methods employed. Therefore, the use of robust, comprehensive, and up-to-date research studies is crucial in providing accurate data on GDM screening outcomes, potential harms, and long-term health impacts.

When considering the environmental and economic impacts of both screening methods, it's critical to understand the potential implications of each. Estimating the GHG emissions associated with each step and understanding the potential DALY calculations derived from these emissions allows us to evaluate the broader environmental and health implications. By comparing the DALY estimates, we can gain a clearer understanding of the potential health impacts of the 1-step and 2-step screening methods. This comprehensive evaluation, taking into account both individual and population-level perspectives, can inform the decision-making processes of healthcare providers, policymakers, and stakeholders regarding GDM screening protocols. Ultimately, the objective is to find the most effective screening strategy that improves maternal and neonatal health outcomes while considering factors like clinical effectiveness, cost-effectiveness, and healthcare resource utilization.

Overview

Gestational Diabetes Mellitus (GDM) may cause significant remediable health concerns in pregnant women, affecting approximately 5-20% of pregnancies globally depending on definition and setting. It carries the potential for a wide range of potentially adverse fetal/neonatal and maternal outcomes such as macrosomia, preterm birth, neonatal hypoglycemia, an increased predisposition to maternal type 2 diabetes mellitus. The importance of GDM diagnosis lies in its capacity to allow for the effective management and prevention of these adverse outcomes. Presently, two primary methods for GDM screening prevail: a one-step process and a two-step process. The Canadian Diabetes Association (CDA) in their 2018 guidelines recommend the two-step process as the preferred option. This approach involves an initial 50-gram glucose challenge test (GCT), succeeded by a diagnostic oral glucose tolerance test (OGTT) if the GCT result is positive (but not so strongly positive that it confirms GDM without the need for the confirmatory test) . Conversely, the CDA 2018 guidelines also list a one-step process as an alternative option, which comprises a single 75-gram OGTT with a lower diagnostic threshold for GDM.

Each of these screening processes carries its unique benefits and challenges. The one-step process's primary benefit lies in its enhanced sensitivity, enabling it to detect a higher number of mild, and also potentially severe, GDM cases. This, in turn, facilitates earlier diagnosis and treatment of more severe cases with a remediable clinical phenotype, potentially improving both maternal and fetal outcomes. In contrast, the two-step process offers higher specificity, thereby reducing the likelihood of false positives and unnecessary interventions such as further testing or treatment.

To evaluate the overall benefits and harms associated with opting for the more sensitive one-step process over the more specific two-step process, we aim to investigate the Disability Adjusted Life Years (DALY) associated with each method. DALY serves as a measure of the total disease burden, integrating both mortality and morbidity considerations. Moreover, DALY is an established and widely used metric in public health and health economics. DALY is a measure that expresses the total burden of disease, encompassing both years of life lost to premature mortality and years of healthy life lost to disability. The use of DALYs to assess harms and benefits provides a comprehensive understanding of the disease's total burden and can be applied universally across various conditions and interventions.

By reviewing existing published analyses on GDM screening programs, we can extract the positive screen rate for both one-step and two-step processes. From this data, we can determine the net

benefits of the more sensitive one-step process. Moreover, this information can be extrapolated to provide global DALY estimates, illuminating the potential implications of global implementation of the one-step process.

Additionally, we can examine the potential harms associated with both screening methods, such as the number of extra hospital admissions for neonates, and the interventions associated with further follow-up. By assessing the greenhouse gas (GHG) emissions related to each step in the screening and follow-up process, a per capita rate for the total BC population can be calculated. If extrapolated to a global scale, this would provide an estimation of GHG emissions under a scenario where all health jurisdictions follow the same practices. DALY associated with such GHG emissions can be established using reference databases, with careful consideration of the impact on future generations.

This research project seeks to delve into the potential population-level harms and benefits associated with the choice between the more sensitive one-step screening test and the less sensitive but more specific two-step test for GDM. Our primary measure for these harms and benefits is DALY, capturing the combined years of healthy life lost due to disability or premature death. Through a comprehensive review and analysis of patient outcomes and test screen positive rates for GDM, gleaned from published analyses on GDM screening programs, we hope to derive global DALY estimates. This process allows us to quantify the potential impact of the one-step process on population health and well-being.

Furthermore, it is crucial to understand the harms accompanying both screening methods. These harms extend from the increased number of minimally to non-beneficial hospital admissions for neonates to the additional interventions and follow-ups needed for mild cases that will not benefit from them, as well as the associated DALYs from anxiety, stress and failure to pursue other health promoting activities that the mother could otherwise pursue. Notably, there's also the consideration of the environmental impacts represented by GHG emissions (and other environmental harms) that are furthered by increasing degrees of medical interventions largely unrewarded by a demonstrable health improvement. Understanding the GHG emissions related to each step in the screening and follow-up processes is essential for an integrated evaluation of the environmental footprint of different screening methods. By leveraging data from published life cycle analysis sources, we will measure the GHG emissions for each step, which will then be multiplied by the number of screens and screen positives in BC. This process will provide a per capita rate for BC, and by

extrapolating it globally, we can project the potential GHG emissions if all health jurisdictions followed the same screening practices.

Beyond the environmental implications, the financial repercussions of both methods will also be addressed. We aim to provide a rough estimation of the annual public and individual health expenses associated with the additional diagnoses resulting from the one-step process compared to the two-step process in BC. This estimation will give us insights into the potential efficacy of climate mitigation, adaptation, and resilience investments that could be achieved with an equivalent financial expenditure. Moreover, we will calculate the DALY prevented by redirecting funds from additional diagnoses associated with the one-step process towards climate-related initiatives, providing valuable insights into the potential health and environmental benefits achievable through resource reallocation. Our comprehensive assessment will include a comparison of the DALY estimates from each screening process, effectively measuring the relative benefits and harms associated with the one-step and two-step approaches. By taking into account the trade-offs between these different factors, we aim to obtain a broad understanding of the overall impact of each screening approach on population health and well-being.

This research project aims to enrich ongoing discussions surrounding GDM screening protocols by systematically assessing the benefits and harms associated with both the one-step and two-step screening processes. Using DALY as a comprehensive measure, our objective is to deliver evidence-based insights, where evidence permits, and reason based extrapolations where evidence is not specifically available, that can guide decision-making processes regarding GDM screening strategies. The implications of our findings are relevant to healthcare providers, policymakers, and researchers involved in maternal and child health. By determining the most beneficial, in a holistic sense, approach to GDM screening, we can help shape guidelines and recommendations, optimize resource allocation, and improve health outcomes for pregnant women and their offspring, now and in the future generations, affected by the interactive twin stresses of climate change and GDM (PMID: 35162797). Moreover, our consideration of environmental impacts and the potential for climate-related investments offers a novel perspective to the evaluation of screening methods, underscoring the critical importance of sustainable healthcare practices.

In summary, the comparison of the one-step and two-step processes for GDM screening necessitates a thorough examination of the benefits and harms associated with each method. By utilizing DALY, we can assess the effect on individual disability and premature mortality.

Furthermore, when we incorporate environmental implications and health expenditures into our consideration, we can gain a fuller understanding of the wider consequences of different screening methods. This project intends to provide an in-depth analysis of the net population harms and benefits associated with one-step versus two-step GDM screening, ultimately informing best practices for maternal and neonatal health outcomes.

Objectives and Data Sources

Objectives:

1. Evaluating the net population-level health benefits of implementing a more sensitive (1-step) screening test for gestational diabetes mellitus (GDM) compared to a less sensitive but more specific (2-step) screening test.
2. Quantifying the benefits of the 1-step process in terms of avoidance of Disability-adjusted life years (DALY) for the individuals screened, by analyzing patient outcomes and test screen positive rates from published analyses on GDM screening programs.
3. Determining the harms associated with both the 1-step and 2-step screening processes, including factors such as extra hospital admissions for neonates and disability-adjusted life years (DALY) associated with additional interventions and follow-up.
4. Assessing the greenhouse gas (GHG) emissions associated with each step of the screening tests and follow-up processes using published life cycle analysis sources and calculating the per capita GHG emissions for the population of British Columbia (BC).
5. Estimating the DALY associated with the GHG emissions using reference databases, considering the impact on future generations.
6. Estimating the annual public and individual health expenses associated with the additional diagnoses resulting from the 1-step process compared to the 2-step process in BC.

Questions:

1. Does the implementation of a more sensitive one-step screening test for GDM result in a significant improvement in net population-level health benefits compared to the less sensitive but more specific two-step screening test.

2. Does the one-step screening process for GDM lead to a substantial reduction in Disability-adjusted life years (DALY) for the individuals screened, indicating a significant health benefit.
3. While both the one-step and two-step screening processes for GDM carry associated harms, does the two-step screening process result in fewer extra hospital admissions for neonates and lower DALY associated with additional interventions and follow-up.
4. Will greenhouse gas emissions associated with each step of the one-step screening test and follow-up processes be more than those associated with the two-step screening test for the population of British Columbia (BC).
5. Will the DALY associated with the greenhouse gas emissions resulting from the one-step screening test be significantly lower than the DALY associated with the emissions from the two-step screening test, reflecting a lower impact on future generations.
6. Will the annual public and individual health expenses associated with the additional diagnoses resulting from the one-step screening process be significantly more than those resulting from the two-step screening process in BC after considering the financial implications of a failure to identify remediable health conditions associated with GDM.

Data Sources:

The primary data source for this study is a GDM screening registry that includes information on pregnant women who underwent GDM screening in a defined population. The registry contains demographic information, screening test results, clinical outcomes, and follow-up data.

Also, in British Columbia, Canada, several databases can provide valuable information for estimating **DALYs** and conducting health-related research. Here are some key databases frequently used in studies conducted in British Columbia:

Medical Literature: A comprehensive review of the medical literature will be conducted to provide insight into the prevalence, incidence, and outcomes of GDM, as well as the effectiveness of different treatments. All of this data will be categorized according to the means by whether the GDM was defined by the more sensitive (namely 1-step) vs more specific (namely 2-step) protocols.

Life Cycle Assessment (LCA) Database: The LCA databases will be reviewed to gather data on the environmental impacts associated with each step of the screening and follow-up processes. This information can be used to estimate the greenhouse gas (GHG) emissions associated with the one-step and two-step GDM screening strategies. The GHG emissions data can then be used to estimate the Disability-Adjusted Life Years (DALYs) associated with these emissions, considering the impact on future generations.

Vital Statistics: The Vital Statistics database includes data on births, deaths, and causes of death in British Columbia. It provides information on population demographics, mortality rates, and causes of death, which are important for estimating disease burden.

Population Health Surveys: Periodic population health surveys, such as the Canadian Community Health Survey (CCHS) and the British Columbia Health Survey, collect self-reported data on health behaviors, health status, and quality of life.

Healthcare Administrative Databases: Administrative databases, such as the Medical Services Plan (MSP) Billing Data and PharmaNet, can provide insights into healthcare utilization patterns, treatment data, and medication information, which can be relevant for estimating YLD.

Methodology

Study Design: This study is a comprehensive systematic literature review conducted to compare the net population harms and benefits of selecting a more sensitive one-step screening test for gestational diabetes mellitus (GDM) compared to a less sensitive but more specific two-step screening test.

Study Population: The study population consists of pregnant women who received prenatal care and underwent GDM screening within the time frame of 2010 – 2023. Inclusion criteria include women with a confirmed pregnancy, availability of GDM screening data, and complete follow-up information. Exclusion criteria include women with pre-existing diabetes or incomplete data.

Outcome Measures: The primary outcome measures for this study will be disability-adjusted life years (DALY). DALY will be used to measure the harm associated with the screening

processes. The harm arising from the screening processes will be determined by estimating the DALY associated with extra interventions and follow-up associated with each screening process.

A:

To determine Disability-Adjusted Life Years (DALYs), we need the following key pieces of information based on literature review around the world:

Years of Life Lost (YLL): YLL represents the premature mortality component of DALYs. It quantifies the number of years of life lost due to premature death. To calculate YLL, we need information on the age at death and a standard life expectancy value for the population under study. The difference between the age at death and the standard life expectancy represents the years of life lost.

Years Lived with Disability (YLD): YLD captures the burden of non-fatal health conditions or disabilities. It considers the impact of these conditions on an individual's quality of life and functioning. To calculate YLD, we need information on the prevalence or incidence of the health condition, the duration or average duration of the condition, and a disability weight that represents the severity or impact of the condition on quality of life. The disability weight is typically obtained through population surveys, expert opinion, or the Global Burden of Disease study.

The calculation for DALYs involves adding the YLL and YLD components:

$$\text{DALYs} = \text{YLL} + \text{YLD}$$

Estimation of Health Expenses and DALY: Annual public and individual health expenses associated with additional diagnoses resulting from the one-step process compared to the two-step process will be crudely estimated. The efficacy of potential investments in climate mitigation, adaptation, and resilience resulting from an equivalent financial expenditure by the province of BC will be assessed. The DALY prevented by redirecting funds from additional diagnoses associated with the one-step process towards climate-related initiatives will also be estimated.

B:

GHGs (Greenhouse Gas Emissions): GHGs are a measure of the environmental impact of a process. To calculate GHGs, we need information on the resources used in each screening process and the associated emissions. This could include:

Energy use: This is the amount of energy used by medical equipment, buildings, and other infrastructure involved in the screening process. Energy use data can be obtained from equipment specifications, utility bills, or other similar sources.

Transportation: This is the emissions associated with patient and staff travel to and from the clinic. Transportation data can be estimated based on the distance traveled and the mode of transportation.

Waste generation: This is the emissions associated with the disposal of medical waste. Waste generation data can be estimated based on the volume and type of waste produced.

Emission factors: These are measures of the GHGs emitted per unit of energy used, distance traveled, or waste generated. Emission factors can be obtained from databases like the Emission Factors Database (EFDB) of the Intergovernmental Panel on Climate Change (IPCC).

GHGs are then calculated by multiplying the resource use data by the corresponding emission factors.

❖ **Systematic Review Protocols (PRISMA-P):**

Eligibility Criteria: Studies that compare one-step and two-step GDM screening methods and report on medical, economic, and environmental outcomes.

Information Sources: Relevant databases such as PubMed, Embase, Cochrane Library, and other related databases. The search will be limited to articles published in English.

Search Strategy: The search strategy will include terms related to GDM, one-step screening, two-step screening, harms, benefits, and related terms. The search strategy will be adapted for each database.

We will search for articles that discuss "Gestational Diabetes Mellitus" or "GDM", specifically focusing on those that mention "Screening" within the context of "Pregnancy". We are

particularly interested in comparing "One-step Gestational Diabetes Mellitus Screening" or "One-step GDM Screening" with "Two-step Gestational Diabetes Mellitus Screening" or "Two-step GDM Screening".

The search will also prioritize articles that discuss "Disability-Adjusted Life Years" or "DALY" and those that mention "Greenhouse gas emissions" or "GHG emissions". We are also interested in the "Environmental Impact" of these screening methods and their implications for "Population health".

In terms of healthcare, we will look for articles that discuss "Healthcare Policy", "Healthcare Costs", "Health expenses", or "Healthcare Utilization". We are also interested in the effects of these screening methods on "Neonatal health outcomes" and "Maternal health outcomes".

Finally, we will also consider articles that discuss the "Environmental footprint" or "Life cycle analysis" of these screening methods.

This strategy will help us find articles that contain all of our keywords. If we want to broaden our search to articles that contain any of our keywords, we can adjust the strategy accordingly. Similarly, if we want to exclude certain terms, we can do so. It is to be noted that the novel element of this study, namely that GHG contributions from the screening, diagnostic, therapeutic and monitoring aspects of gestational diabetes, has not been previously studied. Based on this expected lack of published data, gaps in the literature are expected and their documentation will be a noted outcome of this review. Furthermore, while the collective impact of the GDM testing and management processes will not be identified in previous publications, we anticipate that the individual elements within this process can be estimated from existing publications.

The steps to be specifically labelled and investigated are those associated with:

- a) the gestational screen (Step 1 of the 2-step protocol) that is unique to the 2-step process
- b) the Oral glucose tolerance test (common to the 1-step protocol and the 2nd step of the 2-step protocol) that is performed in 100% of the patients entering the 1-step protocol and approximately 20% of patients entering the 2-step protocol)
- c) positive Oral glucose tolerance test (app 15% of patients in a 1-step protocol or 7-8% of patients in the 2-step protocol) initiated:
 - i) medical appointment transport
 - ii) medical appointment testing

- iii) medical appointment prescription for medications
 - iv) medical appointment recommended patient self-monitoring of glucose
 - v) medical appointment initiated follow-up appointments including pharmacy visit +/- dietician visit
 - vi) neonatal glucose measurements
 - vii) additional hospital stay for management of neonatal hypoglycemia management
- d) False negative screens for severe gestational diabetes mellitus cases that will result in preventable adverse outcomes – including untreated neonatal hypoglycemia, neonatal morbidity, maternal morbidity (obstetrical soft tissue trauma associated with vaginal delivery or caesarean section) due to macrosomia - of which there will be more with the 2-step protocol).

By summing these individual estimates, the total impact on GHG from GDM testing by the 1-step vs 2-step process can be estimated albeit with wide confidence intervals.

Study Selection: Two reviewers will independently screen titles and abstracts, followed by full-text screening of potentially eligible studies. Disagreements will be resolved through discussion or consultation with a third reviewer.

Data Collection Process: Data will be extracted using a standardized form. Two reviewers will independently extract data from each study.

Data Items: Data items will include study characteristics, participant details, details of the one-step and two-step screening methods, outcome measures, and results.

Risk of Bias Assessment: The risk of bias in the included studies will be assessed using the Cochrane Risk of Bias tool.

Data Synthesis: A narrative synthesis of the findings from the included studies will be provided. If appropriate, a meta-analysis will be conducted.

Meta-bias(es): Publication bias will be assessed using funnel plots and Egger's test.

Confidence in Cumulative Evidence: The quality of the evidence will be assessed using the GRADE approach.

Ethics and Dissemination: This systematic review will use publicly available data, so ethical approval is not required. The results will be disseminated through a peer-reviewed publication.

Registration: The protocol will be registered with PROSPERO.

Both the 1-step and 2-step processes for gestational diabetes mellitus (GDM) screening involve specific testing and follow-up steps to ensure accurate diagnosis and appropriate management. (Appendix 1 and 2)

Table 1: Search Strategy according to each database

Database	Search Strategy
PubMed	("Gestational Diabetes Mellitus"[Title/Abstract] OR "GDM"[Title/Abstract]) AND "Screening"[Title/Abstract] AND "Pregnancy"[Title/Abstract] AND ("One-step Gestational Diabetes Mellitus Screening"[Title/Abstract] OR "One-step GDM Screening"[Title/Abstract] OR "Two-step Gestational Diabetes Mellitus Screening"[Title/Abstract] OR "Two-step GDM Screening"[Title/Abstract]) AND ("Disability-Adjusted Life Years"[Title/Abstract] OR "DALY"[Title/Abstract]) AND ("Greenhouse gas emissions"[Title/Abstract] OR "GHG emissions"[Title/Abstract]) AND "Environmental Impact"[Title/Abstract] AND "Population health"[Title/Abstract] AND ("Healthcare Policy"[Title/Abstract] OR "Healthcare Costs"[Title/Abstract] OR "Health expenses"[Title/Abstract] OR "Healthcare Utilization"[Title/Abstract]) AND ("Neonatal health outcomes"[Title/Abstract] OR "Maternal health outcomes"[Title/Abstract]) AND ("Environmental footprint"[Title/Abstract] OR "Life cycle analysis"[Title/Abstract])
Embase	'gestational diabetes mellitus'/exp OR 'gdm'/exp AND 'screening'/exp AND 'pregnancy'/exp AND ('one-step gestational diabetes mellitus screening'/exp OR 'one-step gdm screening'/exp OR 'two-step gestational diabetes mellitus screening'/exp OR 'two-step gdm screening'/exp) AND ('disability-adjusted life years'/exp OR 'daly'/exp) AND ('greenhouse gas emissions'/exp OR 'ghg emissions'/exp) AND 'environmental impact'/exp AND 'population health'/exp AND ('healthcare policy'/exp OR 'healthcare costs'/exp OR 'health expenses'/exp OR 'healthcare utilization'/exp) AND ('neonatal health outcomes'/exp OR 'maternal health outcomes'/exp) AND ('environmental footprint'/exp OR 'life cycle analysis'/exp)
Web of Science	("Gestational Diabetes Mellitus" OR "GDM") AND "Screening" AND "Pregnancy" AND ("One-step Gestational Diabetes Mellitus Screening" OR "One-

	<p>step GDM Screening" OR "Two-step Gestational Diabetes Mellitus Screening" OR "Two-step GDM Screening") AND ("Disability-Adjusted Life Years" OR "DALY") AND ("Greenhouse gas emissions" OR "GHG emissions") AND "Environmental Impact" AND "Population health" AND ("Healthcare Policy" OR "Healthcare Costs" OR "Health expenses" OR "Healthcare Utilization") AND ("Neonatal health outcomes" OR "Maternal health outcomes") AND ("Environmental footprint" OR "Life cycle analysis")</p>
Cochrane Library	<p>"Gestational Diabetes Mellitus" OR "GDM" AND "Screening" AND "Pregnancy" AND ("One-step Gestational Diabetes Mellitus Screening" OR "One-step GDM Screening" OR "Two-step Gestational Diabetes Mellitus Screening" OR "Two-step GDM Screening") AND ("Disability-Adjusted Life Years" OR "DALY") AND ("Greenhouse gas emissions" OR "GHG emissions") AND "Environmental Impact" AND "Population health" AND ("Healthcare Policy" OR "Healthcare Costs" OR "Health expenses" OR "Healthcare Utilization") AND ("Neonatal health outcomes" OR "Maternal health outcomes") AND ("Environmental footprint" OR "Life cycle analysis")</p>
CINAHL (EBSCOhost)	<p>(MH "Gestational Diabetes Mellitus" OR MH "GDM") AND MH "Screening" AND MH "Pregnancy" AND (MH "One-step Gestational Diabetes Mellitus Screening" OR MH "One-step GDM Screening" OR MH "Two-step Gestational Diabetes Mellitus Screening" OR MH "Two-step GDM Screening") AND (MH "Disability-Adjusted Life Years" OR MH "DALY") AND (MH "Greenhouse gas emissions" OR MH "GHG emissions") AND MH "Environmental Impact" AND MH "Population health" AND (MH "Healthcare Policy" OR MH "Healthcare Costs" OR MH "Health expenses" OR MH "Healthcare Utilization") AND (MH "Neonatal health outcomes" OR MH "Maternal health outcomes") AND (MH "Environmental footprint" OR MH "Life cycle analysis")</p>
Scopus	<p>TITLE-ABS-KEY("Gestational Diabetes Mellitus" OR "GDM") AND TITLE-ABS-KEY("Screening") AND TITLE-ABS-KEY("Pregnancy") AND TITLE-ABS-KEY("One-step Gestational Diabetes Mellitus Screening" OR "One-step GDM Screening" OR "Two-step Gestational Diabetes Mellitus Screening" OR "Two-step GDM Screening") AND TITLE-ABS-KEY("Disability-Adjusted Life Years" OR "DALY") AND TITLE-ABS-KEY("Greenhouse gas emissions" OR "GHG emissions") AND TITLE-ABS-KEY("Environmental Impact") AND</p>

	TITLE-ABS-KEY("Population health") AND TITLE-ABS-KEY("Healthcare Policy" OR "Healthcare Costs" OR "Health expenses" OR "Healthcare Utilization") AND TITLE-ABS-KEY("Neonatal health outcomes" OR "Maternal health outcomes") AND TITLE-ABS-KEY("Environmental footprint" OR "Life cycle analysis")
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Statistical Analysis:

For this study, statistical analyses will be performed using statistical software such as R, STATA or SAS, based on the need and suitability. A two-sided p-value of less than 0.05 will be considered statistically significant. The study analysis will be structured to answer the defined objectives.

Objective 1: Evaluating the net population-level health benefits of implementing a more sensitive (1-step) screening test for gestational diabetes mellitus (GDM) compared to a less sensitive but more specific (2-step) screening test.

Where feasible based on published data availability, the comparison of the health benefits between the one-step- and two-step GDM screening methods will be conducted as follows: identify studies which look at an intermediary group, those who have glucose measurements that would qualify them for GDM by the one-step method but not by the two-step method. From this intermediary group, identify the observed health benefit of treating these mothers for GDM. Where there is no statistically significant difference in health outcome attributable to this selective intervention, assume that the trend observed is representative of a significant trend that would be observed in a higher-powered study. Take the median of such estimates as a best case estimate for DALY prevented by the increased sensitivity of the 1-step method.

Objective 2: Quantifying the benefits of the 1-step process in terms of avoidance of Disability-adjusted life years (DALY) for the individuals screened.

Regression analysis (linear or logistic based on the nature of the outcome) will be used to estimate the relationship between the screening process (one-step or two-step) and the DALYs. Both unadjusted and adjusted analyses will be performed, accounting for confounding variables such as age, race, body mass index, and prior history of gestational diabetes.

Objective 3: Determining the harms associated with both the 1-step and 2-step screening processes.

Similar to Objective 1, the harms associated with both processes will be evaluated by selectively looking at the harms attributable to the more sensitive 1-step screening test.

Objective 4: Assessing the greenhouse gas (GHG) emissions associated with each step of the screening tests and follow-up processes.

Descriptive statistics will be used to summarize GHG emissions for each step of the screening tests. An independent sample t-test will be performed to compare the mean GHG emissions associated with the one-step and two-step screening methods. If data are not normally distributed, a Mann-Whitney U test will be used. Moreover, a best case scenario for the GHG emissions associated with the screening process will be used (eg assumption that travel is minimized, electric instead of gas powered energy sources for travel, testing, monitoring and pharmaceutical preparations will be utilized).

Objective 5: Estimating the DALY associated with the GHG emissions.

A regression analysis will be conducted to estimate the association between GHG emissions and the DALYs, controlling for potential confounding variables. The coefficient and its 95% confidence interval will be reported.

Objective 6: Estimating the annual public and individual health expenses associated with the additional diagnoses resulting from the 1-step process compared to the 2-step process in BC.

The health expenses will be calculated for each individual and then averaged for each group. An independent sample t-test or Mann-Whitney U test will be used to compare the mean expenses between the groups.

The correlations between the DALY, GHG emissions, and health expenses will be investigated using Pearson's or Spearman's correlation coefficient, depending on the distribution of the data. These correlation coefficients will offer insights into the relationships between these variables, contributing to a comprehensive understanding of the broader impacts of the different GDM screening methods.

In the case of missing data, multiple imputation or a complete case analysis will be performed based on the extent and nature of the missingness. Sensitivity analyses will be conducted to

assess the robustness of the study findings. Results will be reported in line with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines.

For all statistical tests, a p-value of <0.05 will be considered to indicate statistical significance.

All data will be reported as mean \pm standard deviation for continuous variables and as frequency (percentage) for categorical variables, unless otherwise specified. Assumptions of all statistical tests will be checked and transformations applied or non-parametric alternatives used where necessary. Missing data will be handled by conducting a complete case analysis or using multiple imputation methods as appropriate. The results of the statistical analyses will be visualized using appropriate charts and tables to facilitate interpretation.

As this study involves multiple comparisons, the risk of type I error (false positive) increases. To control for this, a Bonferroni correction will be applied to adjust the level of statistical significance.

A sensitivity analysis will also be performed to assess the robustness of the study results against potential uncertainties in the model parameters. In this analysis, the key parameters of the model will be varied within a reasonable range to see how these changes affect the study results.

All statistical analyses will be conducted following the predefined analysis plan, and any deviations from the plan will be reported and justified. All statistical code and outputs will be stored for review and reproducibility purposes.

Recommendations [Next Steps]

Due to the constraints of the project's timeline and its expansive scope, completion within the specified period was not achievable. The remaining sections, encompassing the results and discussion, are in progress and will be meticulously addressed in the subsequent phases of the project.

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Appendix 1:

Both the 1-step and 2-step processes for gestational diabetes mellitus (GDM) screening involve specific testing and follow-up steps to ensure accurate diagnosis and appropriate management.

Testing Process for the 1-Step Process:

a. Step 1: Diagnostic Oral Glucose Tolerance Test (OGTT)

- All individuals OGTT is performed.
- The woman fasts overnight and then drinks a more concentrated glucose solution (75 grams of glucose).
- Blood samples are taken at different intervals, typically at fasting, one hour, two hours, and sometimes three hours after consuming the glucose solution.
- The blood glucose levels are measured at each interval to assess the woman's glucose metabolism.
- Based on specific diagnostic criteria, the results determine the presence or absence of GDM.

2. Testing Process for the 2-Step Process: a. Step 1: Initial Glucose Challenge Test (GCT)

- Similar to the 1-step process, the pregnant woman drinks a glucose solution containing 50 grams of glucose.
- Blood samples are taken one hour after consuming the glucose solution.
- The blood glucose level is measured to assess the woman's glucose tolerance.
- If the GCT result is above the predetermined threshold, further evaluation is required.

b. Step 2: Diagnostic Oral Glucose Tolerance Test (OGTT)

- Individuals who screen positive on the GCT proceed to the diagnostic OGTT, which is identical to the second step in the 1-step process.
- Fasting overnight, consuming a more concentrated glucose solution (75 grams of glucose), and blood samples taken at specific intervals to assess glucose metabolism.

3. Follow-up Steps for Positive Screens (Applicable to Both Approaches):

a. Step 1: Additional Diagnostic Tests

- Once a positive screen is identified, further diagnostic tests may be performed to confirm the diagnosis and assess the severity of GDM. Testing may be performed

via point of care tests or by referral to a laboratory for phlebotomy and central laboratory testing.

- These tests may include additional blood glucose measurements, such as fasting glucose or postprandial glucose levels, as well as glycosylated hemoglobin (HbA1c) testing.
- Diagnostic criteria may vary, and healthcare providers may consider specific guidelines and protocols for follow-up testing.

b. Step 2: Medical Management and Intervention

- individuals diagnosed with GDM, medical management and interventions are initiated to control blood glucose levels and mitigate associated risks.
- This may involve dietary modifications, exercise recommendations, and, in some cases, insulin therapy For or oral medications to maintain optimal glycemic control.
- Regular monitoring of blood glucose levels, prenatal visits, and communication with healthcare providers are essential components of follow-up care.

4. Perinatal management

- Caesarean section may be performed in the case of Large for gestational age fetuses which are more common in uncontrolled GDM
- Traumatic deliveries are more common in uncontrolled GDM.

5. Neonatal management

- Neonatal testing for hypoglycemia is conducted by a standardized protocol in the case of recognized GDM
 1. Neonatal hypoglycemia is more commonly recognized and treated in diagnosed GDM pregnancies.
- Neonatal hypoglycemia of is more commonly severe in uncontrolled GDM

Appendix 2:

Mapping out all steps and processes involved in both approaches.

1. Manufacturing and Production of Screening Materials:
 - Manufacturing glucose solutions: The production of glucose solutions used in the screening process involves energy-intensive processes, raw material extraction, and the use of chemicals. These activities may contribute to GHG emissions and environmental impacts, including water pollution and waste generation.
 - Manufacturing diagnostic tools: The production of diagnostic tools such as test strips, glucometers, and laboratory equipment involves manufacturing processes, resource extraction, energy consumption, and waste generation.
2. Packaging and Distribution:
 - Packaging materials: The production and disposal of packaging materials, such as glucose solution containers, test strip packaging, and transport packaging, can generate waste and contribute to environmental impacts.
 - Transportation of screening materials: The transportation of screening materials from manufacturing facilities to distribution centers and healthcare facilities involves fuel consumption, emissions from vehicles, and potential impacts on air quality and climate change.
3. Screening Process:
 - Healthcare facility operations: The energy consumption and GHG emissions associated with running healthcare facilities, including electricity usage, heating, cooling, and waste management, should be considered.
 - Use of consumables: The use of disposable materials, such as glucose solution containers, test strips, needles, and syringes, generates waste and contributes to environmental impacts
 - Disposal of medical waste: Proper management of medical waste, including the disposal of used consumables, should follow regulations to minimize environmental risks and emissions.
4. Follow-up and Treatment:
 - Healthcare facility operations: Similar to the screening process, ongoing operations of healthcare facilities for follow-up and treatment involve energy consumption, waste management, and potential GHG emissions.
 - Medication production: If medications such as insulin or oral antidiabetic drugs are prescribed as part of the treatment, it is important to consider the environmental impacts associated with their manufacturing and distribution.

5. Patient Travel and Appointments:

- Patient transportation: The transportation of patients to and from healthcare facilities for screenings, follow-up visits, and treatments contributes to GHG emissions, air pollution, and traffic-related environmental impacts.

By mapping out these steps and considering their associated GHG emissions and environmental aspects, a comprehensive understanding of the environmental impact of both the one-step and two-step approaches for GDM screening can be achieved.

How to quantify greenhouse gas (GHG) emissions associated with each step?

To evaluate and quantify greenhouse gas (GHG) emissions associated with the various steps involved in GDM screening, a comprehensive assessment of each step's environmental impact is necessary. Here are some methods and considerations for evaluating and quantifying GHG emissions:

1. Life Cycle Assessment (LCA):

- Conducting a life cycle assessment allows for a comprehensive analysis of the environmental impact of a product, process, or service throughout its entire life cycle.
- LCA involves assessing GHG emissions and other environmental indicators associated with each stage, including raw material extraction, manufacturing, transportation, use, and disposal.
- By considering the entire life cycle, LCA provides a holistic view of the GHG emissions and environmental burdens of the screening process.

2. GHG Inventory and Accounting:

- Utilizing established GHG inventory and accounting methodologies, such as those outlined by the Intergovernmental Panel on Climate Change (IPCC), can provide a standardized approach for quantifying emissions.
- This involves identifying emission sources, estimating emission factors specific to each source, and calculating the total emissions produced.
- GHG emissions can be categorized into scopes: Scope 1 (direct emissions from owned or controlled sources), Scope 2 (indirect emissions from purchased energy), and Scope 3 (other indirect emissions, including upstream and downstream activities).
- By applying these methodologies, emissions from specific steps in the GDM screening process can be quantified.

3. Data Collection and Analysis:

- Collecting data on energy consumption, material inputs, and waste generation at each step is crucial for accurate GHG quantification.
- This can be achieved through surveys, interviews, and direct measurements in healthcare facilities, manufacturing sites, and distribution centers.
- Collaborating with stakeholders, including manufacturers, healthcare providers, and transportation companies, can help gather relevant data for GHG analysis.

4. Emission Factors and Conversion Factors:

- Emission factors provide conversion ratios to estimate GHG emissions based on the quantity of a specific input or activity.
- Specific emission factors exist for different industries, materials, and processes.
- Utilizing emission factors specific to the GDM screening process, such as energy consumption per unit of glucose solution produced, can help estimate emissions more accurately.
- Conversion factors can also be used to convert other environmental impacts, such as water usage or waste generation, into equivalent GHG emissions for a more comprehensive analysis.

5. Geographic Considerations:

- Accounting for regional variations in energy sources and emission factors is essential for accurate GHG quantification.
- Emission factors may differ based on the electricity grid's carbon intensity, transportation fuel sources, or waste management practices in different regions.
- Regional or country-specific data and emission factors should be incorporated to ensure the evaluation reflects the specific context of the GDM screening process.

By employing these evaluation methods, collecting relevant data, and utilizing appropriate emission factors, it is possible to quantify the GHG emissions associated with each step in the GDM screening process more precisely.