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STUDY PROTOCOL

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Optimizing screening practice for gestational diabetes mellitus in primary healthcare facilities in Tanzania: research protocol

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Abstract

Background Tanzania, like most low- and middle-income countries, is facing an increasing prevalence of obesity in the general population, including among women of reproductive age. Excess weight pre-pregnancy is a risk factor for the onset of gestational diabetes mellitus (GDM), which is associated with several poor pregnancy outcomes. Screening for GDM, as a primary preventive measure, is not systematically done in Tanzania. This study aims to explore current practices of screening for GDM during routine antenatal care (ANC), estimate the prevalence of GDM among ANC users and compare the performance of two commonly used GDM screening algorithms. We will then explore the best ways for implementing a functional screening practice for GDM at primary level hospitals using perspectives of health care workers, health managers, and pregnant women.

Methods This will be an observational cross-sectional study design with sequential mixed-methods approach conducted in ANC clinics of two primary level hospitals: Kisarawe District Hospital in Coast region and Mbagala Rangi Tatu Hospital in Dar es Salaam region, Tanzania. Quantitative data will be collected to determine the current structural capacity and screening practices for GDM, the prevalence of GDM among ANC users, and the sensitivity and specificity of the two recommended screening algorithms. Qualitative data will be collected through key informant interviews with health managers and pregnant women and focus group discussions with healthcare workers to understand the rationale, challenges, possible solutions and benefits of the used screening algorithm. We will also explore the meaning of screening/diagnosis to pregnant women, and propose a functional GDM screening algorithm informed by users (i.e. pregnant women, health managers and care workers).

Discussion ANC is an entry point for pregnant women to access preventive services including screening for GDM. When done appropriately, GDM screening would reduce undesired outcomes attributed to GDM also beyond the pregnancy period. Through this study we will understand the bottlenecks and propose evidence to inform feasible ways to overcome them and establish a functional and standardized GDM screening service.

Keywords Gestational diabetes mellitus, Pregnancy, Antenatal care, Women, Screening, Mixed-methods, Sensitivity and specificity, Maternal morbidity

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Background

The global maternal mortality ratio (MMR) remained high at 223 per 100,000 livebirths in 2020 despite the documented decrease by 34.3% between 2000 and 2020 [1]. This high mortality is concentrated in sub-Saharan Africa (SSA) where over 70% of maternal deaths occur [1], with no significant improvements in the past 20 years [2]. In Tanzania, MMR has declined from 556 deaths in 2016 to 104 per 100,000 livebirths in 2022 [3, 4]. This decline could be attributed to several implemented strategies for prevention and improving accessibility to care. However, Tanzania remains far in its contribution for achieving the Sustainable Development Goal target on reduction of national MMR to a target of less than 70 per 100,000 livebirths by 2030 [5, 6].

Globally as well as in Tanzania, maternal deaths are predominantly due to direct causes, which include severe bleeding, anemia, infections, hypertension related complications during pregnancy and unsafe abortion [7, 8]. Indirect causes of maternal deaths, such as cardiometabolic conditions, including diabetes mellitus and specifically gestational diabetes mellitus (GDM), have historically contributed to a small proportion of maternal deaths. The global response to reduce maternal deaths has been focused on controlling the direct causes of death with unmatched efforts on indirect causes to the MMR that are on the rise, a phenomenon known as the obstetric transition [9, 10]. This is highlighting a much-needed urgent attention, to potential indirect causes such as cardiometabolic conditions which prevalence is increasing globally, also among women of reproductive age, inducing adverse and long-lasting outcomes on women during pregnancy and over the life-course [11, 12].

Women developing GDM are at increased risk of early pregnancy loss, fetal macrosomia, onset or exacerbation of hypertensive-related disorders, and urinary tract infections. Childbirth-related complications of GDM include pre-term labor, traumatic birth (due to increased risk for shoulder dystocia to the baby), and post-partum hemorrhage. In the post-partum period, women with GDM are more likely to have infections, experience difficulties in breastfeeding initiation, experience weight retention, and ultimately develop type 2 diabetes mellitus (T2DM) [13]. In-utero, the fetus may develop non-chromosomal congenital malformations and intrauterine fetal death. During labor and immediately following birth, newborns from women with GDM are at increased risk of developing hypoglycemia, hypocalcemia, respiratory distress syndrome and Erb's palsy. Later, complications may also include cardiometabolic syndrome and cardiomyopathy for the newborn [14].

Screening for GDM as primary preventive strategy offers an opportunity to reduce the risks attributed to GDM. In SSA, 87% (97% for Tanzania) of pregnant women receive ANC from a skilled health care worker [3, 15], this could be an area to strengthen for improvement of maternal and newborn wellbeing. The available evidence favors using universal screening for GDM rather than selective screening in low-income countries due to poor medical record structure (for validating the medical history of a client). There is also an existing low ability to ascertain between risk categories among pregnant women, and low awareness of GDM among pregnant women and health care workers [14, 16]. Selective screening not only fails to identify a number of GDM patients due to its lower sensitivity [17, 18], risking those who were missed to be in an advanced stage of the disease at point of diagnosis. This results in additional costs for tests and advanced treatment that will be needed later in pregnancy for further assessment and follow-up [19]. On the other hand, while universal screening could be a better alternative to selective screening in low-resource settings, its implementation modality must be adapted to the contextual health system structure in each country [14].

In Tanzania, screening for GDM is not a standard practice in ANC; neither universal screening nor targeted selective screening (classifying women by risk) is not done fully [20–22]. This could be due to lower priority in addressing prevention of non-communicable diseases within the national health system [23], shortage of testing equipment and supplies or lack of clear algorithms on how to screen for GDM. Two distinct algorithms guiding screening for GDM in Tanzania exist: one is available within the Standard Treatment Guideline (STG) by risk-classifying women (women with any of the features are will undergo OGTT at 24–28 weeks previous history of GDM, previous big baby, poor obstetric history, family history of DM, known impaired glucose tolerance/impaired fasting glucose, grand multipara, glycosuria and BMI > 25 kg/m^2) [24] and the other is in the Tanzania ANC guideline and uses a urine glucose test [25]. This situation creates room for interpretation and suboptimal implementation to either of the available screening guideline [26]. Additionally, little is known about women's, health care workers' and health managers' perceptions toward routine screening for GDM in Tanzania.

Methods

Aim

This study aims to explore the current practices of screening for GDM during routine ANC clinic, estimate the prevalence of GDM in pregnancy, compare the performance of two commonly used GDM screening algorithms, and explore the best ways to develop a functional screening practice for GDM in primary level hospitals

in Tanzania using perspectives of health care workers, health managers, and pregnant women.

Design

This will be an observational, cross-sectional study with a sequential explanatory mixed method approach, [quan + QUAL] → [QUAN] → [QUAL] [27].

The overall study will be organized into four sub-studies. Sub-study one will be a mixed methods study design. The quantitative (quan) strand will be used for the assessment of structural and process components of the provision of screening services. The qualitative (QUAL) strand will be used to assess the current practices of screening for GDM at the two district hospitals by employing structured observation (SO) and focus group discussion (FGD) for data collection. Sub-study two, involves the collection of quantitative data, it will be a cross-sectional study to determine diagnostic accuracy, and calculate sensitivity and specificity comparing the two clinical algorithms recommended by the Tanzanian guidelines (the STG and ANC guideline) [24, 25]. Quantitative data from this sub-study will also be analyzed to estimate GDM prevalence (percentage of screened pregnant women who experience GDM). Sub-study three (QUAL) will be a phenomenological qualitative study to understand women's perceptions of the screening process and how a screening process can be structured to suit women's needs. This will involve doing in-depth interviews (IDI) with a sub-group of women from sub-study two, at least four weeks from the time they were tested at the facilities. Sub-study four (QUAL) will be a case-study adopting a qualitative design of participatory action research [28–31], to explore how managers and healthcare workers can work together in instituting a functional GDM screening practice at the respective facilities. We will employ a series of in-depth interviews (with health district managers and facility managers) and focus group discussions (with health care workers) followed by endorsement meetings with all the participants.

Study setting

Data will be collected from district health managers offices and ANC clinics of two district hospitals, Kisarawe District Hospital (KDH) in Coast region and Mbagala Rangi Tatu District Hospital (MDH) in Dar es Salaam region, Tanzania. The two district-level hospitals were purposively selected to model understanding of GDM screening in a rural (KDH) and urban (MDH) primary health care facility of Tanzania. Selection criteria included—i. Volume of the ANC attendance, ii. presence of full-time gynaecologist and iii. Rural vs urban location of the hospital. Both selected hospitals have two full-time employed Obstetrician and gynaecologists working in the RCH unit of the hospitals.

District hospitals are the referral points for the primary level of health care in Tanzania, have a relatively higher mean daily ANC attendance [32, 33] and they offer the first level where specialized health care services are provided in Tanzania. For this reason, district hospitals are the ideal sites for this research to test the performance of the screening algorithm and considerations for its implementation in the continuum of care for GDM without referring a patient upon diagnosis of GDM.

Description of materials

The overall study will involve 946 pregnant women, 36 health care workers and 22 district health managers at different intervals of the study. Figure 1 shows the order, time and method of data collection for each sub-study and study participants.

Pregnant women enrolled in the study will be those attending ANC at KDH and MDH who are at 24–28 weeks of gestational age. The women should not be on any steroid treatment or with a known diagnosis of diabetes mellitus or be on treatment for diabetes mellitus or have documented active infection or febrile illness.

Health care workers will include doctors (working in the Reproductive and Child Health (RCH) unit of the hospital), nurses (working in the ANC clinic), laboratory personnel and pharmacy personnel. Facility heads will include the medical officer in charge, hospital matron, hospital head of pharmacy, hospital head of laboratory services and the hospital RCH in-charge. District health managers will include the District Medical Officer (DMO), District Reproductive and Child Health Coordinator (DRCHCo), District Pharmacist, and the District head of laboratory services.

Data collection

Data collection techniques

- Quantitative studies:

Sub-study 1:

Assessment of the two hospitals will be done using a structured checklist. A structured checklist will be used by the Principal Investigator (PI), AK, and research assistants to guide assessment of the presence and accessibility of the screening supplies needed (Annex 1).

Sub-study 2:

Using a sensitivity and specificity formulae for sample size calculation [34], n_{Se} = sample size for sensitivity, n_{Sp} = sample size for specificity, $S_{e=}$ Expected sensitivity, $S_{p=}$ Expected specificity, Z = Z-score of the desired confidence level, d = Precision of estimate (maximum

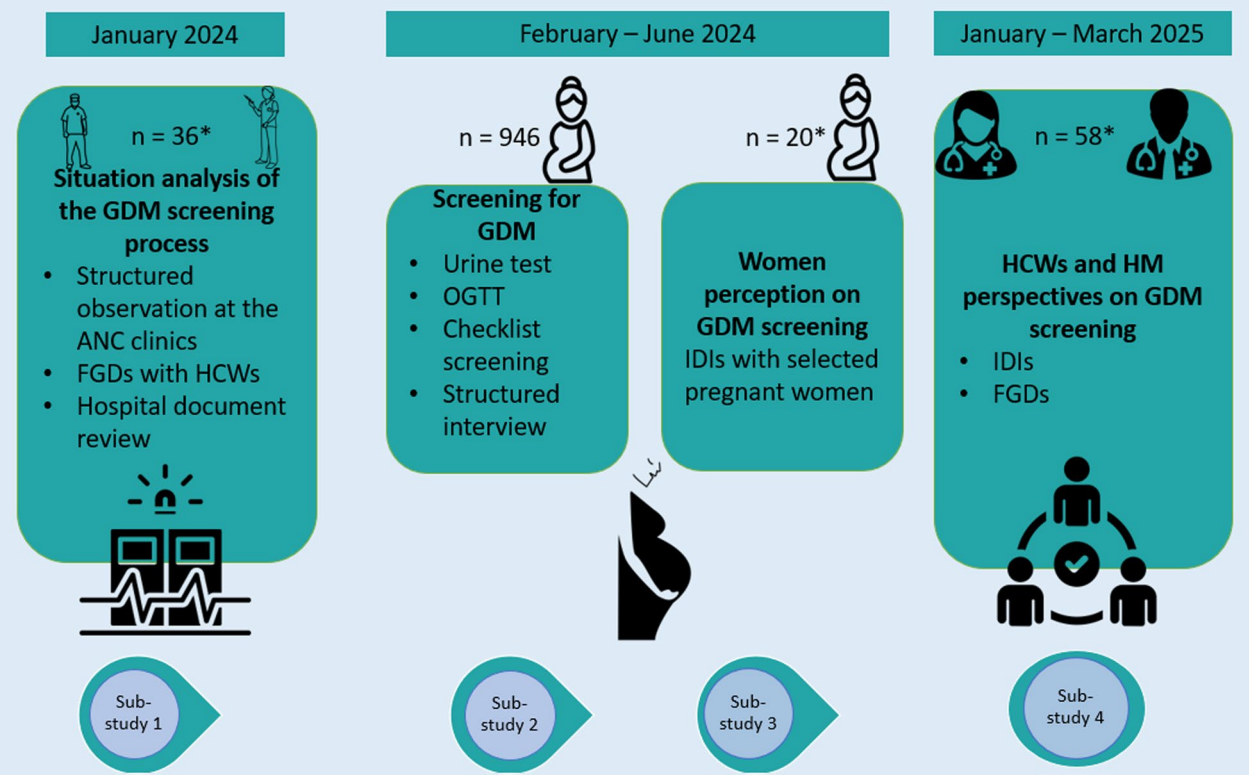

Fig. 1 Methods of data collection, source of data used and timeline for all the sub-studies. *ANC* Antenatal care, *FGD* Focus group discussion, *GDM* Gestational diabetes mellitus, *IDI* In-depth Interview, *HCW* Health care worker, *HM* Health manager, *OGTT* Oral glucose tolerance test and * minimum sample

marginal error), Prev—prevalence of the disease of interest. Se = predetermined value of sensitivity taken as 4.7% for glycosuria [35] and 69% predetermined tested sensitivity of a checklist screening tool [21]; Sp = predetermined value of specificity taken as 97.3% from a study done in Ghana [35]; Prev = predetermined value of prevalence of disease which is 19.5% from a study done in Northern Tanzania [36]; d = Precision of estimate of 7%; z-score of the desired confidence level = 1.96 for 95% confidence. The value that gives the maximum sample size is the sensitivity for a risk scoring tool. Accounting for 10% dropout; final minimal sample size will be 946 women for both facilities, 473 women from KDH and 473 women from MRH.

On a usual clinic visit day, the facilities see about 40–60 pregnant women, (Monday to Friday), assuming that between 20 and 40% of the attending women to be at gestational age 24 -28 weeks, we expect to recruit 10 – 20 women from each facility per clinic visit day.

Women attending ANC clinic with a gestation age of 24–28 weeks will be approached, informed consent for participation in the study will be sought. Those who will agree to participate will be screened using (1) a checklist from the STG [24] and then (2) asked to give a urine sample, and finally (3) an Oral Glucose Tolerance Test (OGTT) will be done Fig. 2. The OGTT test will be done irrespective of the fasting state of the pregnant woman. This was taken to accommodate the documented challenges on having pregnant women to come in a fasting state, where majority have a long travel time and waiting period in the facilities on the day of ANC clinic [37, 38].

1) Screening with STG checklist

For screening with a checklist, every study participant for the sub-study will be interviewed (using a Swahili language interviewer-administered questionnaire). The participant will be asked about socio-demographic characteristics (age, marital status, place of permanent residence, and education status), their anthropometric values (mid-upper arm circumference will be measured at the clinic visit and weight at booking visit will be checked from the ANC card), obstetric characteristics (gravidity, HIV status, history of stillbirth, date of last normal menstrual period and type of pregnancy—single or multiple pregnancy) will be asked from the woman and checked on the ANC card of the participant. The screening tool will use the following variables (via questions and

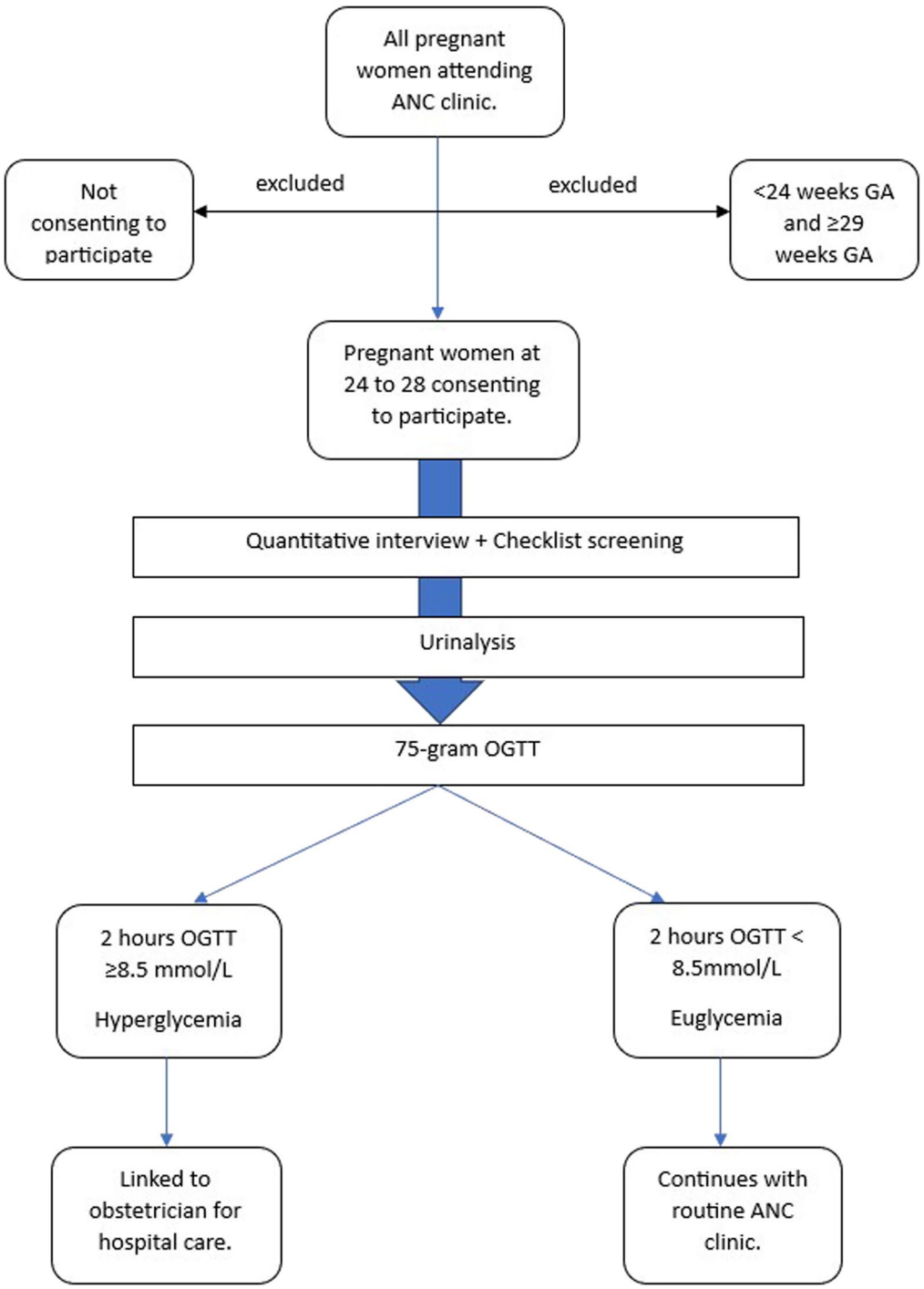

Fig. 2 Recruitment and tests for pregnant women in sub-study two

measurement); weight, height, history of GDM, previous history of having a baby weighing more than 4 kg at birth, history of stillbirth or early neonatal death, family history of diabetes mellitus, grand multiparity and urine in glucose. A woman will be considered screen positive if she has three or more of the risk factors [35].

2) Glucosuria test

For the urine test, women will be informed that the urine sample will be tested for glucose. Women will be given urine collecting containers (60 mls) and instructed to collect their urine (minimum of 10mls) into the container immediately (i.e. before taking the glucose load—75gm oral glucose), and submit the urine sample to the laboratory research assistant for processing. This will be processed directly onsite using CYBOW™ 10 urine reagent strips (DFI co. ltd in South Korea). Color change will be observed after 60 s of immersion of the glucose strip into the urine and compared with the standardized color chart provided with the test strip to determine the glucosuria level. A woman will be considered positive for glucose in urine if she has a trace test result or above ($\geq +1$) [35].

The urine containers will be labeled with the same unique identification number (ID) listed on each woman's questionnaire/checklist and a test request form. The urine will be processed immediately and disposed with the container according to the health facility protocol of handling biomedical waste. A form will be filled out (with woman's unique ID, facility name, date of the test, and space for results of the blood glucose test and urine glucose test) by the laboratory research assistant and attached to the woman's questionnaire once completed.

3) Oral glucose tolerance test

Then, an OGTT will be done: a 75 g dose (we will use the rapilose 75 g OGTT 300mls solution, World Health Organization-approved solution for OGTT) will be given to consenting women while documenting their number (unique ID on the card and request form) and time of taking the glucose load. Following the glucose load ingestion, women will be instructed to wait for two hours as they continue with the clinic proceedings. The research assistants will keep track of the timing and inform women after two hours of to come get their blood glucose level checked. The research assistant will conduct a finger prick blood glucose rapid test after two hours [14] using a pre-calibrated Accu-Chek Active glucometer machine. This machine has met the international clinical test accuracy requirements [39]. The device comes with a calibration strip and control solution to maintain accurate values. The finger prick test will be done by a study laboratory research assistant responsible for processing the blood samples and urine samples.

The results of the urine test and the blood glucose test will be documented in the request form (Annex 2) and the ANC card (RCH card number 4—an antenatal clinic card used in Tanzania) and will be communicated to the pregnant woman and the attending healthcare provider by a member of the research team. For a woman to be classified as GDM positive, the blood glucose level should be $\geq$ 8.5–11.0 mmol/L.

For both, urinalysis and blood glucose test, the facility laboratory personnel will be used as research assistants. Since the hospitals already have functional laboratories, and these tests are routinely done within the hospital setting, orientation to the laboratory RAs on study procedures will be done by the PI.

- Qualitative studies:

Sub-study 1:

1- Structured observations

ANC service provision will be actively observed for two days (in a week), which will be spaced two weeks apart (observed a minimum of four times in total), the days of the week for extended observation will be purposely selected to include a day where women coming to attend clinic for the first time (booking visit)—for KDH Tuesday and for MDH Monday; and another day of the week where follow-up visits are conducted (women who had already attended ANC at least once). The PI will be positioned in such a manner as not to intrude on the services provided but at a place where he can observe the service provision particularly that affects GDM screening. The providers within the units observed, won't be provided with the exact hypothesis for observation but only a general information of the study [40].

A SO guide (Annex 3) and FGD question guide (Annex 4) will be used for sub-study 1. The SO guide aims to capture: Time ANC clinic services starts to end, availability of a topic on GDM screening in the ANC health education guide, availability of the STG screening checklist, availability of the screening algorithm/s on the notice board, the pathway that women have to follow at the ANC clinic (registration to exit of the clinic) and documentation of the screening results, number and cadre of staff attending women for ANC (doctors, nurses, and lab personnel), staff change during the day, and approximate number of women during the day (morning vs afternoon). The observation guide will be in a softcopy format filled in a tablet using kobocollect with additional notes written on a paper-based notebook.

2- Focus group discussions

We will conduct a minimum of three FGDs in each hospital, however, the number may increase as we will follow the concept of information saturation. Each FGD

will have five to eight participants, four nurses/midwives/medical attendants, one doctor/assistant medical officer, and one laboratory personnel responsible for testing samples from the ANC. Purposive sampling for potential individuals will be done, based on cadre, time spent working at the clinic, level of professional training (certificate/diploma/degree/masters training). Those who agree to participate by providing informed consent will be asked for consent and days/times for FGD will be scheduled. Discussions will be audio-recorded, notes will be taken, and images of available guidelines (for example on posters, brochures, printed booklets, etc.) will be taken. The FGDs will be conducted in Swahili and the guide will focus on collective understanding of the existing practice for GDM screening at the facility and why they have chosen the existing practice for GDM screening (facilitators and barriers for implementing guideline recommendations). The FGD guide (Annex 4) will be paper-based, and discussions will be moderated by the PI and research assistants who will be note-takers.

Sub-study 3:

Women who participated in the blood-glucose measurement component of sub-study 2 will be stratified according to their test results (OGTT positive or OGTT negative). Ten women from each stratum, five from each study hospital, will be purposively selected and invited for IDIs at least four weeks from the time the test was conducted. Those who will agree, an informed consent will be signed on the agreed day and place of the interview. The final sample size will be determined iteratively to point of saturation. This will involve the use of an IDI guide (Annex 5) to explore women's perception of the screening process and how best it can be adapted to suit their needs. The interview guide will be paper-based, and discussions will be audio recorded.

Sub-Study 4:

There will be two sets of engagements with the study participants; first one involves IDIs and FGDs with the participants and second one is a findings validation engagement.

Phase 1: The selected participants will be approached following recruitment. This will include DMOs, district pharmacist, DRCHCos, and District laboratory coordinator (from both Kisarawe and Temeke district). In-depth interviews will be done at agreed appointment time and date. Guiding topics for the interviews will be on understanding supplies sustainability relevant to screening for GDM, organization of care (the process a woman is receiving antenatal care during her visit from arrival to the hospital to departure), content of health education provided to pregnant women, on job training on GDM care for health care providers via continuous medical education and other modalities, evidence-based choice of screening algorithm (using results from the sub-study two and merging with contextual factors), and monitoring and evaluation activities for GDM screening services.

Further, FGDs will be conducted with administrators within the hospitals (for both KDH and MDH)—Medical officer in charge, hospital matron, RCH facility in-charge, facility head of pharmacy and facility head of laboratory) to capture facility-specific perspectives in having screening for GDM institutionalized within their hospital setup. Then FGDs with the hospital health care providers will be scheduled to be conducted in the hospital setting. This will involve groups of 6 individuals (per hospital) of the following cadres—nurses/midwives working in the ANC clinic, doctors/assistant medical officers working in the ANC clinic, medical attendants, laboratory personnel, and pharmacy personnel. These will be guided by a discussion guide in Annex 6.

Discussions (FGDs—conducted in Swahili) will be audio recorded using recorders, which will be stored in a secure password-protected folder of the PI's computer. Verbatim transcription and translation of the recordings will be done. Discussion notes from the presentation will be taken as recommendations.

Phase 2: The PI in contact with the study team will analyze the data and develop a report focusing on inputs from the participants on the best ways to have a GDM screening algorithm at the district hospitals. Key messages relating to topics discussed will be developed and summaries to be shared with the participants will be prepared.

Phase 3: The PI will arrange another series of appointment at all levels from the district health administrators (who were involved in the interviews) to the level of the hospitals. The developed summaries will be shared and discussed with the members individually and in groups in the order it was done in phase 1. Discussions at all levels will be conducted to validate the summarized findings to point of agreement. The summary of the results will be shared with the participants a week prior the meeting to give ample time to process the findings noted and get valuable insights during the discussion.

The discussions for this phase will be audio recorded to comprehensively capture the insights from the respondents.

Data analysis

Quantitative data analysis

The PI will lead the analysis process throughout the study using StataSE (StataCorp. 2015. Stata Statistical Software: Release 14. College Station, TX: StataCorp

LP). Collected data will be checked daily for completion, data entry errors, outliers, and entries will be verified to the best possibility. The unit of analysis will be women attending ANC clinics at the respective facilities and the facilities.

Sub-study 1:

Descriptive statistics will be used to summarize quantitative data, which will be presented in tables and aggregated to means and proportions, by each facility. For each attribute required in a screening facility, will be scored and a composite score summing to 100% (according to the component being available or not available) will be used to score the facility capacity for screening GDM. The components assessed will be; 1. Presence and accessibility of the screening guidelines/algorithm at the ANC, 2. Availability of screening supplies (urinalysis test strips, blood glucose test kits, weighing scale, BP machine, height board, biochemistry analyzer, and its reagents, gloves, swabs, lancets) in the ANC clinic and in the requisition order (procurement) to maintain supply duration in-between time of order, 3. What blood test/s is/are done (fasting/random/OGTT), 4. Which glucometer is used (hemocue/biochemistry analyzer), 5. Availability of a checklist used for screening, 6. Availability of a manual for urine glucose level to consider test positive or negative, 7. Availability of glucose load (75gm for OGTT) and 8. Payment method for GDM screening (out of pocket or free), 9. Available staff at ANC with their; cadre/designation, years of work, and if training on screening was done in the past year. Each of the first two components with the addition of five, six, and seven, will have a score of 1(when available) and 0 (when not available), with a total score of 23 as the maximum score and minimum being zero. Components three, four, eight and nine will inform on the supporting information for the capacity of the facility and will be reported descriptively.

Sub-study 2:

The prevalence of GDM among screened women will be calculated, where the numerator will be the number of women who are OGTT positive, and the denominator will be all women screened by OGTT for GDM during the study and stratified by facilities. Frequency distribution tables will be used to show the proportionate distribution of women's characteristics and the screening test results. OGTT results will be used as the gold standard, and the checklist and urine analysis results will be compared to it. A 2×2 table will be used to determine the sensitivity and specificity of each screening test compared to the OGTT. Participants whose values for blood glucose test or a urinalysis (glucosuria) or a checklist score is/are not available, will be excluded from the sensitivity/specificity final analysis.

Qualitative data analysis

After each day of data collection, there will be debriefing meetings to troubleshoot and provide solutions to the data collection process; discuss newly generated themes from the interviews to guide the restructuring of the question guide for subsequent interviews to point of saturation. Audio data will be transcribed and translated, then pseudonymized and coded then analyzed in Nvivo.

For sub-study one, triangulation of SO information and FGD information with the QUAN data will be done after the development of themes from the FGDs. Outcomes of interest will be the practice of screening for GDM at the facilities (through SO), facilitators and barriers of screening practice of choice, and reasons for the choice of the screening algorithm at the facilities (through FGDs).

Sub-study 3

Information from the IDI will be used to develop themes to explain the main outcomes—perception of the screening process, whether is it important to do the screening, what components should be included to have more women screened and what it implied after having a positive screening result (care after the positive screening test).

Sub-study 4

From the IDIs and FGDs, information will be analyzed to develop themes on the following outcomes—what is the best approach in implementing a functional screening practice within the facility, what adjustments need to be done to institute routine screening for GDM, what is the best way to sustain supplies for screening of GDM, what will it imply to screen pregnant women (extra job, extra facility cost, something that has to be done). These will be complemented with the notes and recommendations taken from the validation stakeholders' meetings.

Discussion

The prevalence of GDM varies across different regions of the world. In Europe and Asia, it ranges from 5.4 to 14.8% [41–45]. In Africa, higher prevalence has been reported, 13.9% [46, 47], higher in the Sub-Saharan Africa region, 14.3% [48]. An even higher burden is documented in West-African nations of Cameroon and Nigeria, where more than a fourth of the studied population had GDM [49, 50]. In Tanzania, where there is no nationally representative data on GDM, the prevalence estimates by smaller studies show it is high, ranging between 19.5 and 39% [36, 51]. Tanzania national data shows the prevalence

of overweight or obesity among women of reproductive age increased from 14.2%, in 2004 to 23.8% in 2016 [52]. This high prevalence of obesity in Tanzania highlights the problem at hand, considering the strong links between obesity, GDM and T2DM [53].

Measures of assessing the performance of a screening test particularly for conditions of public health importance are variable [54]. Universally, sensitivity and specificity of screening tools tend to give more guidance on choice and even sequence of the screening algorithm, where necessary [55]. The available screening options for GDM in Tanzania include the clinical risk factors assessment and the glucose challenge tests which would guide for performance or non-performance of the diagnostic test, OGTT [56]. This is guided by the sensitivity and specificity patterns of the tests but cost and context applicability of any of the screening algorithm also varies from country to country [56]. Results from sub-study two will generate evidence for the need to synchronize and update the screening recommendations by comparing the approved national screening algorithms to the gold standard. One of the limitations for this sub-study is that due to the logistical and financial need to keep the screening study in high-patient volume facilities (primary-level hospitals), we will not recruit a sample of pregnant women which is representative at the community level. This limitation is well described in the methods section, and the choice was made because we prioritized the objective on assessing the sensitivity and specificity of the screening tools above the estimation of GDM prevalence which is representative of a population.

From the service provision perspective, there are health care providers, from whom a collective multidisciplinary effort is needed to care for women diagnosed with GDM. This includes health cadres with skills in exercise and nutrition counselling, midwives/nurses, obstetricians, internal medicine specialist with endocrinology expertise, laboratory and radiology (for ultrasound) personnel. A facilitative working environment for them to provide the service including a functional algorithm, and supplies for screening and management of GDM. In Morocco, among the cadres, nurses and midwives had relatively less capacity in caring for women diagnosed with GDM [57]. Similarly, majority of the health care providers across all levels of health facilities were more conversant in managing communicable diseases than non-communicable diseases in Tanzania [23]. Through this work, we will gather perspectives from health care providers', health managers' together with pregnant women's views and build on them to recommend a better facilitative GDM screening environment in primary healthcare level facilities.

In the management of GDM, while medical therapy (use of oral or injectable medications) forms the base of primary management, other lifestyle adaptions are recommended to ensure a positive pregnancy experience for a woman diagnosed with GDM. These adaptations range from a woman putting personal expectations on herself to get a healthy baby to some of practices she has to get adapted to including lifestyle changes (exercise) and blood glucose checks and possibly more ANC visits [58], of which all these adaptations will come with financial implications and adaptations to family lifestyle (due to need for preparing and eating a different diet from the rest of the family). Adapting well to all these changes depends on the social support she receives at home and her individual health literacy supported by a well functional health care system [59]. This will not only determine the pregnancy outcome, but also the psychological wellbeing of the woman, during and after childbirth but also compliance to the suggested care plan [60, 61].

Abbreviations

ANC	Antenatal care
DM	Diabetes mellitus
DMO	District medical officer
DRCHCo	District reproductive and child health coordinator
FGD	Focus group discussion
GDM	Gestational diabetes mellitus
IDI	In-depth interview
IRB	Institutional review board
MUHAS	Muhimbili University of Health and Allied Sciences
OGTT	Oral glucose tolerance test
PI	Principal investigator
RCH	Reproductive and child health
SO	Structured observation
STG	Standard treatment guideline
T2DM	Type 2 diabetes mellitus

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Not applicable.

Author contributions

A.K—Conceptualized the study and wrote the first draft of the manuscript; NS, K.R, J.P, A.B.P, and L.B—study design and manuscript revision. All authors reviewed the manuscript.

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Availability of data and materials

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

The study has received ethical approval from the Institute of Tropical Medicine, Antwerp—Institutional Review Board (Reference number 1687/23), Muhimbili University of Health and Allied Sciences ethics review committee—Tanzania (Senate Research and Publication Committee—Reference number DA 282/298/01.C/1834) and the Tanzanian National Institute of Medical Research ethics review sub-committee (Reference number NIMR/HQ/R.8a/Vol.IX/4457). A written informed consent will be sought from all study participants in all the four sub-studies.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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References

1. WHO, UNFPA, WORLDBANK. Trends in maternal mortality 2000 to 2020: estimates. Sexual and Reproductive Health. 2023; 12.
2. World Health Organization (WHO). Maternal mortality. 2019. https://www.who.int/publications/i/item/9789240068759
3. Ministry of Health, Community Development, Gender E and C (MoHCDGEC)[Tanzania M, Ministry of Health (MoH)[Zanzibar], National Bureau of Statistics (NBS), Office of the Chief government Statistician (OCGS), ICF. Tanzania Demographic and Health Survey and Malaria Indicator Survey (TDHS-MIS). 2015–2016. Dar es salaam, Tanzania and Rockville, Maryland, USA; 2016. https://dhsprogram.com/pubs/pdf/FR321/FR321.pdf
4. Tanzania Demographic and Health Survey and Malaria Indicator Survey (TDHS-MIS). 2022.
5. MoHCDGEC. Tanzania Health Sector Strategic Plan 2021–2026. 2021; 2026.
6. SDG Target 3.1 | Maternal mortality: By 2030, reduce the global maternal mortality ratio to less than 70 per 100 000 live births. https://www.who.int/data/gho/data/themes/topics/sdg-target-3-1-maternal-mortality. Accessed 5 Oct 2023.
7. Say L, Chou D, Gemmill A, Tunçalp Ö, Moller AB, Daniels J, et al. Global causes of maternal death: a WHO systematic analysis. Lancet Glob Health. 2014;2(6):e323–33. https://doi.org/10.1016/S2214-109X(14)70227-X.
8. Makuwani AM, Sospeter PF, Subi L, Nyamhagatta MA, Kapologwe N, Ismael H, et al. Baseline data on trend of maternal mortality in tanzania using administrative data and its policy implication. 2018 Report. Glob J Med Res. 2020;20:5.
9. Graham W, Woodd S, Byass P, Filippi V, Gon G, Virgo S, et al. Diversity and divergence: the dynamic burden of poor maternal health. Lancet. 2016;388:2164–75.
10. Boerma T, Campbell OMR, Amouzou A, Blumenberg C, Blencowe H, Moran A, et al. Maternal mortality, stillbirths, and neonatal mortality: a transition model based on analyses of 151 countries. Lancet Glob Health. 2023;11(7):e1024–31.
11. Hussein J. Non-communicable diseases during pregnancy in low and middle income countries. Obstet Med. 2017;10(1):26.
12. Barnes SB, Ramanarayanan D, Amin N. The unseen side of pregnancy: non-communicable diseases and maternal health. The Wilson Centre, maternal health initiative; 2020. https://www.wilsoncenter.org/publication/unseen-side-pregnancy-non-communicable-diseases-and-maternal-health
13. Hod M, Kapur A, Sacks DA, Hadar E, Agarwal M, Di Renzo GC, et al. The International Federation of Gynecology and Obstetrics (FIGO) Initiative on gestational diabetes mellitus: a pragmatic guide for diagnosis, management, and care. Int J Gynaecol Obstet. 2015;131:S173-211.
14. Hod M, Kapur A, Sacks DA, Hadar E, Agarwal M, Di Renzo GC, et al. The International Federation of Gynecology and Obstetrics (FIGO) Initiative on gestational diabetes mellitus: a pragmatic guide for diagnosis, management, and care #. Int J Gynecol Obstet. 2015;131:S173-211.
15. Antenatal care - UNICEF DATA. https://data.unicef.org/topic/maternal-health/antenatal-care/. Accessed 5 Oct 2023.
16. Utz B, Kolsteren P, De Brouwere V. Screening for gestational diabetes mellitus: are guidelines from high-income settings applicable to poorer countries? Clin Diabetes. 2015;33(3):152–8.
17. Nwali SA, Onoh RC, Dimejesi IB, Obi VO, Jombo SE, Edenya OO. Universal versus selective screening for gestational diabetes mellitus among antenatal clinic attendees in Abakaliki: using the one-step 75 gram oral glucose tolerance test. BMC Pregnancy Childbirth. 2021;21(1):1–8.
18. Idris N, Che Hatikah C, Murizah M, Rushdan M, Bahiyah S, Setar A, et al. Universal versus selective screening for detection of gestational diabetes mellitus in a Malaysian population. Malays Fam Phys. 2009;4(2–3):83.
19. Minsart AF, Lescrainier JP, Vokaer A. Selective versus universal screening for gestational diabetes mellitus: an evaluation of Naylor's model. Gynecol Obstet Invest. 2009;68(3):154–9.
20. Mukuve AM, Mgonja ML, Sendagire I, Noorani M. Magnitude of screening for gestational diabetes mellitus in an urban setting in Tanzania; a cross-sectional analytic study. 2020 Jan 16.
21. Nombo AP, Mwanri AW, Brouwer-Brolsma EM, Ramaiya KL, Feskens EJM. Gestational diabetes mellitus risk score: a practical tool to predict gestational diabetes mellitus risk in Tanzania. Diabetes Res Clin Pract. 2018;145:130–7.
22. Wendelin Mwanri A. Gestational diabetes mellitus in Tanzania-public health perspectives. https://research.wur.nl/en/publications/gestational-diabetes-mellitus-in-tanzania-public-health-perspecti.
23. Ramaiya KL, Swai AM, Mutabingwa TK, Mwanri AW, Kagaruki GB. Capacity and capability of Tanzania health facilities to diagnose and manage diabetes mellitus in pregnancy. Diabetes Res Clin Pract. 2018;145:119–29. https://doi.org/10.1016/j.diabres.2018.05.003.
24. Ministry of Health Tanzania. Standard Treatment Guideline and National Essential Medicines List Tanzania Mainland. 2021. https://hssrc.tamisemi.go.tz/storage/app/uploads/public/5ab/e9b/b21/5abe9bb216267130384889.pdf
25. Ministry of Health, Tanzania Mainland. The Antenatal Care Guideline. 2018. https://platform.who.int/docs/default-source/mca-documents/policy-documents/guideline/tza-mn-21-01-guideline-2018-eng-anc-guidelines.pdf
26. Miller S, Abalos E, Chamillard M, Ciapponi A, Colaci D, Comandé D, et al. Beyond too little, too late and too much, too soon: a pathway towards evidence-based, respectful maternity care worldwide. The Lancet. 2016;388(10056):2176–92.
27. Tashakkori A, Johnson RB, Teddlie C. Foundations of mixed methods research. California: SAGE; 2024. 404 p. https://uk.sagepub.com/en-gb/eur/foundations-of-mixed-methods-research/book252072
28. Conklin J, Kothari A, Stolee P, Chambers L, Forbes D, Le Clair K. Knowledge-to-action processes in SHRTN collaborative communities of practice: a study protocol. Implement Sci. 2011;6(1):1–11. https://doi.org/10.1186/1748-5908-6-12.
29. Cornwall A, Jewkes R. What is participatory research? Soc Sci Med. 1995;41(12):1667–76.
30. Glasson JB, Chang EML, Bidewell JW. The value of participatory action research in clinical nursing practice. Int J Nurs Pract. 2008;14(1):34–9.
31. Tetui M, Coe AB, Hurtig AK, Bennett S, Kiwanuka SN, George A, et al. A participatory action research approach to strengthening health managers' capacity at district level in Eastern Uganda. Health Res Policy Syst. 2017. https://doi.org/10.1186/s12961-017-0273-x.
32. Kapologwe NA, Kengia JT, van Praag E, Killewo J, Kalolo A. Primary health care in Tanzania through a health systems lens: a history of the struggle for universal health coverage. Wallingford: CABI; 2023. p. 1–265.
33. Ramaiya KL, Swai AM, Mutabingwa TK, Mwanri AW, Kagaruki GB. Capacity and capability of Tanzania health facilities to diagnose and manage diabetes mellitus in pregnancy. Diabetes Res Clin Pract. 2018;145:119–29.
34. Negida A, Fahim NK, Negida Y. Sample size calculation guide - part 4: how to calculate the sample size for a diagnostic test accuracy study based on sensitivity, specificity, and the area under the ROC curve. Adv J Emerg Med. 2019;3(3):e33.
35. Agbozo F, Abubakari A, Narh C, Jahn A. Accuracy of glycosuria, random blood glucose and risk factors as selective screening tools for gestational diabetes mellitus in comparison with universal diagnosing. BMJ Open Diabetes Res Care. 2018;6(1):e000493.

36. Njete HI, John B, Mlay P, Mahande MJ, Msuya SE. Prevalence, predictors and challenges of gestational diabetes mellitus screening among pregnant women in northern Tanzania. Trop Med Int Health. 2018;23(2):236–42.
37. Hod M, Kapur A, Sacks DA, Hadar E, Agarwal M, Di Renzo GC, et al. The International Federation of Gynecology and Obstetrics (FIGO) Initiative on gestational diabetes mellitus: a pragmatic guide for diagnosis, management, and care. Int J Gynaecol Obstet. 2015;131:S3.
38. Anjalakshi C, Balaji V, Balaji MS, Ashalata S, Suganthi S, Arthi T, et al. A single test procedure to diagnose gestational diabetes mellitus. Acta Diabetol. 2009;46(1):51–4.
39. Choukem SP, Sih C, Nebongo D, Keunmoe P, Kengne AP. Accuracy and precision of four main glucometers used in a Sub-Saharan African Country: a cross-sectional study. Pan Afr Med J. 2019;32:118.
40. Goodwin MA, Stange KC, Zyzanski SJ, Crabtree BF, Borawski EA, Flocke SA. The Hawthorne effect in direct observation research with physicians and patients. J Eval Clin Pract. 2017;23(6):1322–8.
41. Eades CE, Cameron DM, Evans JMM. Prevalence of gestational diabetes mellitus in Europe: a meta-analysis. Diabetes Res Clin Pract. 2017;129:173–81.
42. Nguyen CL, Pham NM, Binns CW, Van DD, Lee AH. Prevalence of gestational diabetes mellitus in Eastern and Southeastern Asia: a systematic review and meta-analysis. J Diabetes Res. 2018;2018:1–10.
43. Lee KW, Ching SM, Ramachandran V, Yee A, Hoo FK, Chia YC, et al. Prevalence and risk factors of gestational diabetes mellitus in Asia: a systematic review and meta-analysis. BMC Pregnancy Childbirth. 2018;18(1):494.
44. Gao C, Sun X, Lu L, Liu F, Yuan J. Prevalence of gestational diabetes mellitus in mainland China: a systematic review and meta-analysis. J Diabetes Investig. 2018;10(1):154.
45. Paulo MS, Abdo NM, Bettencourt-Silva R, Al-Rifai RH. Gestational diabetes mellitus in Europe: a systematic review and meta-analysis of prevalence studies. Front Endocrinol. 2021;12:691033.
46. Macaulay S, Dunger DB, Norris SA. Gestational diabetes mellitus in Africa: a systematic review. PLoS ONE. 2014;9(6):e97871. https://doi.org/10.1371/journal.pone.0097871.
47. Zhu Y, Zhang C. Prevalence of gestational diabetes and risk of progression to type 2 diabetes: a global perspective. Curr Diab Rep. 2016;16(1):7.
48. Muche AA, Olayemi OO, Gete YK. Prevalence and determinants of gestational diabetes mellitus in Africa based on the updated international diagnostic criteria: a systematic review and meta-analysis. Arch Public Health. 2019;77(1):36.
49. Egbe TO, Tsaku ES, Tchounzou R, Ngowe MN. Prevalence and risk factors of gestational diabetes mellitus in a population of pregnant women attending three health facilities in Limbe, Cameroon: a cross-sectional study. Pan Afr Med J. 2018. https://doi.org/10.11604/pamj.2018.31.195.17177.
50. Onyenekwe BM, Young EE, Nwatu CB, Okafor CI, Ugwueze CV, Chukwu SN. Prevalence of gestational diabetes in south East Nigeria using the updated diagnostic guidelines. Int J Diabetes Metab. 2019;25:26–32.
51. Grunnet LG, Hjort L, Minja DT, Msemo OA, Møller SL, Prasad RB, et al. High Prevalence of gestational diabetes mellitus in rural Tanzania—diagnosis mainly based on fasting blood glucose from oral glucose tolerance test. Int J Environ Res Public Health. 2020;17(9):3109.
52. Kikula AI, Semaan A, Balandya B, Makoko NK, Pembe AB, Peñalvo JL, et al. Increasing prevalence of overweight and obesity among Tanzanian women of reproductive age intending to conceive: evidence from three Demographic Health Surveys, 2004–2016. J Glob Health Rep. 2023. https://doi.org/10.29392/001c.87443.
53. Hossain P, Kawar B, El Nahas M. Obesity and diabetes in the developing world—a growing challenge. N Engl J Med. 2009;356(3):213–5.
54. Oleske DM. Screening and surveillance for promoting population health. In: Oleske DM, editor. Epidemiology and the delivery of health care services. New York, NY: Springer; 2009. p. 131.
55. Wilson JMG, Jungner G, World Health Organization. Principles and practice of screening for disease. World Health Organization. https://iris.who.int/handle/10665/37650
56. White SL, Ayman G, Bakhai C, Hillier TA, Magee LA. Screening and diagnosis of gestational diabetes. 2023. http://www.bmj.com/. Accessed 9 Jul 2023.
57. Utz B, Assarag B, Essolbi A, Barkat A, Delamou A, De Brouwere V. Knowledge and practice related to gestational diabetes among primary health care providers in Morocco: Potential for a defragmentation of care? Prim Care Diabetes. 2017;11(4):389–96.
58. Craig L, Sims R, Glasziou P, Thomas R. Women's experiences of a diagnosis of gestational diabetes mellitus: a systematic review. BMC Pregnancy Childbirth. 2020;20:1–15.
59. Wazqar DY, Evans MK. Socio-cultural aspects of self-management in gestational diabetes. J Diabetes Nurs. 2012;16(2):62–7.
60. Lawson EJ, Rajaram S. A transformed pregnancy: the psychosocial consequences of gestational diabetes. Sociol Health Illn. 1994;16(4):536–62.
61. Parsons J, Sparrow K, Ismail K, Hunt K, Rogers H, Forbes A. Experiences of gestational diabetes and gestational diabetes care: a focus group and interview study. BMC Pregnancy Childbirth. 2018;18(1):25.

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