ARSI UNIVERSITY

COLLEGE OF HEALTH SCIENCE AND MEDICINE

DEVELOPMENT AND VALIDATION OF RISK SCORE PREDICTION MODEL FOR STILL BIRTH AT ASELLA TEACHING REFERRAL HOSPITAL, OROMIA, ETHIOPIA,2024

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ACRONYM AND ABBREVIATION

ANC	Antenatal Care
ATRH	Asella Teaching and Referral Hospital
AUROC	Area Under Receiver Operating Curve
CS	Cesarean Section
DCA	Decision Curve Analysis
ENAP	Every Newborn Action Plan
JSTRH	Jimma Specialized Teaching Referral Hospital of Incidence
PNC	Postnatal Care
PROM	Premature Rupture of Membrane
PTSD	Post Traumatic Stress Disorder
RH	Rhesus status
STB	Stillbirth
STI	Sexually Transmitted Infection
SSA	Sub Sahara Africa
TD	Tetanus Diphtheria Vaccine
UtA-PI	Uterine artery pulsatility index
UN IGME	United Nations Inter-agency Group for Child Mortality Estimation

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Abstract

Back ground: - stillbirth is defined as the death of the fetus after 28 weeks of gestation or weight more than 1000 g before extraction from the uterus. A grave public health concern, stillbirth was claiming the lives of over 1.9 million children; 83.6% of all stillbirths occurred in low-income countries in 2021. The silent tragedy of stillbirth devastates women's lives, families' lives, and even nations. Even though a number of studies have been done to predict the risk of stillbirth but the problem is still underestimated. In a limited resource country like Ethiopia, the development and validation of risk score prediction is quite substantial to take further meaningful action.

Objective: - To develop and validate of risk score prediction model for stillbirth at Asella Teaching and Referral Hospital, Oromia, Ethiopia. 2024G.C

Methodology: - A retrospective follow-up study was conducted at Asella Teaching and Referral Hospital from 1 October 2022 to 1 October 2024. Every expectant mother giving birth at Asella Teaching and Referral Hospital served as the source population. 1,008 participants were recruited in the study by a computer-generated random sampling technique. Data were collected using kobo tool box. The logistic regression analysis used to develop the model. To assess performance, the model discrimination and calibration of the model were done. Lastly, the model was validated by the bootstrapping method. Decision curve analysis was used to evaluate clinical implication model.

Result: The study found incidence of stillbirth at Asella Teaching and Referral Hospital were 10.3% and those maternal characteristics like history of stillbirth, history of anemia, history of abortion, abruptio placenta, preeclampsia, and cord accident predictors of stillbirth, with a ROC of 0.767, and a well-calibrated model. It was internally validated and has optimism of 0.0007999. the model was found to have clinical benefit.

Conclusion and Recommendation: - The developed risk-score has excellent discrimination performance and clinical benefit. It can be used in the clinical settings by healthcare providers for early detection, timely decision making, and improving care quality. Utilization of model is helpful to prevent incidence of stillbirth by 10.3%. The study reveals obstetric and gynecological issues predict stillbirth, recommending Hospital's maternal health team to consider these predictors and

Key words:- *development, validation, stillbirth, risk score prediction*

1. INTRODUCTION

1.1 Background

There are differences in the thresholds used to define stillbirth. According to the World Health Organization, a stillbirth is defined as fetal death (i.e., death before to the full extraction or expulsion of a conceived product from its mother) occurring during the third trimester (≥28 completed weeks of gestation) or with a birth weight ≥1000 g [1]. In United Kingdom, it is defined as a death at 24 weeks or later, whereas in the US, it is loss of a baby at or after 20 weeks of pregnancy[2]. In Ethiopia, it is defined as a fetus born dead at 28 weeks of gestation or more with a birth weight of 1000 g or more[3][4].

In 2021, there were around 1.9 million stillbirths worldwide at 28 weeks or older. That indicates that 1 in 72 babies were stillborn 13.9 stillbirths per 1,000 total births. This resulted in almost 77% of stillbirths for mothers in Southern Asia and Sub-Saharan Africa, while approximately 45% of all stillbirths occurred in Sub Sahara Africa (SSA). Africa's stillbirth rate is rising, both in terms of total number and percentage of stillbirths [5]. Countries differ greatly in the probability of stillbirth: In 2021, the highest national stillbirth rate was twenty times higher than the lowest national rate [6].

Since 2018, UN IGME (United Nations Inter-Agency Group for Child Mortality Estimation) has been working on estimating stillbirth indicators. Stillbirths are a marker of maternal health, as well as access to quality care during pregnancy and around the time of birth[5] Despite the vast burden, stillbirths are underestimated in many settings[6][7].

Every Newborn Action Plan (ENAP) has set a stillbirth target of 12 per 1000 births or less by 2030 To achieve this goal, a clear knowledge of the distribution of perinatal mortality across Sub Sahara Africa (SSA) countries is essential to inform prioritization of regional initiatives, which focus on encouraging national-level advocacy and effective interventions that strengthen the health system of high burden countries[8]. this may be seen as unrealistic to achieve since the documented reduction during the Millennium Development Goal (MDG) was only from 24.7 to 18.4 per 1000 births[9].

Developing an easily accessed clinical decision support system is essential for early detection of high-risk pregnancies that end in stillbirth, as recommended by specialists in maternal and child health. The apparent model performance (i.e., in the development dataset) was not found in any of the models developed in our nation for use later in pregnancy that included sociodemographic factors, maternal features, medical and surgical factors, ultrasonography, and biochemical variables. However, few attempts in countries like Uganda to test these models internally and none were evaluated externally[10].

1.2 Statement Of Problem

Globally, the stillbirth rate was 13.9 per 1000 births in 2019, accounting for an estimated 2.9 million stillbirths at 28 weeks or more of gestation worldwide. South Asia, eastern and southern Africa, and West and central Africa had the next highest rates, at 22.8 per 1000 births. The greatest percentage, 33.1%, was seen in South Asia. Africa and South Asia accounted for the majority of the highest point estimates of stillbirths. In 2019, 83.6% of all stillbirths occurred in lower-middle-class and low-income countries[11].The quiet tragedy of stillbirth destroys women's lives, families' lives, and even nations [12].

Pregnancy care and obstetric management have advanced, yet stillbirth prediction and prevention are not entirely certain. There have been missed opportunities for early intervention due to the lack of specificity and sensitivity in existing risk assessment systems, which have demonstrated different degrees of accuracy[13].

More preventable perinatal mortality and morbidity are happening in medical facilities, despite an increase in the number of institutional deliveries. This can be explained by the low caliber of care given at the hospital during delivery. Ending avoidable maternal and neonatal death and morbidity requires improving the standard of care provided in healthcare institutions[2]. Conversely, stillbirths are closely associated with unfavorable social and economic factors. The issue of stillbirths cannot be fully resolved by health system-related factors alone. Socioeconomic status, reproductive health, environmental health, personal habits, and health care infrastructures were identified as the common predictors[14].

The study highlights Europe's social inequalities in stillbirth risk, highlighting the impact of social disadvantage[15].Social inequalities contribute to distal determinants of stillbirth risk, affecting parental health, behaviors, and knowledge. Stillbirths perpetuate health disparities, creating disease, maternal depression, and long-term risks for mothers, so improving pregnancy outcomes is crucial[16].

Parents who experience perinatal loss during pregnancy are profoundly affected, and pregnancy itself may exacerbate psychological suffering such as sadness, anxiety, PTSD, and grieving. Because of the worry about experiencing another loss, the second pregnancy could also be seen as more stressful[17].

Poor healthcare system response to maternal and fetal medical conditions, illiteracy, poverty, and low educational status are risk factors for stillbirth. Poverty and low education affect family decisions, access to care, and the effectiveness of life-saving interventions in resource-poor countries[18].

Ethiopia is home to one of the highest rates of stillbirths globally[19]. The country has reduced the rate of stillbirth from 35.8 per 1,000 LBs in 2000, with an ARR of 2.0%, to 24.6 per 1,000 LBs in 2019[20]. One of the main issues in poor nations, such as Ethiopia, is stillbirth, which is a negative birth outcome. Understanding the stillbirth predictors is essential for creating effective interventions and keeping an eye on public health initiatives in order to reduce the high stillbirth rate and newborn morbidity.

To guarantee the risk prediction model's generalizability and dependability, validation is also essential. To evaluate the effectiveness of the model in various contexts and with various populations, validation studies ought to be carried out in a variety of demographics[21][22]. In addition, external validation with separate datasets is required to validate the predicted accuracy of the model and evaluate its therapeutic value[23].

To sum up, the development and verification of a prognostic risk prediction model for stillbirth is necessary in order to enhance prenatal care and avert this catastrophic consequence. The model ought to take into account several parameters linked to stillbirth and go through a rigorous validation process to guarantee its precision and suitability for use in a range of demographics. As a result, it is critical to create and verify a prognostic risk prediction model that can reliably stratify pregnant women's stillbirth risk, thereby improving outcomes and lowering the incidence of stillbirth.

Only a few attempts have been made to develop a decision-making tool for early detection of pregnancies with a high risk of stillbirth, but these models cannot be applied to low-resource settings[24]. In the present study, we used routine clinical and non-clinical profiles of pregnant women receiving care at ATRH to construct a prediction model to be applied to pregnancy to identify pregnancies at high risk of stillbirth.

1.3Significance of study

Stillbirth remains one of the major worldwide health concerns, and Ethiopia is one of the low- and middle-income countries that experience it. This study's findings, which provide a simple and easily usable prognostic tool, was help anticipate stillbirth early upon admission, thereby relieving Mather's headache. Therefore, public health experts and clinicians working on maternal and child health units (especially obstetric and gynecologic specialists, midwives, and neonatologists) can use the risk prediction score that was be developed, using easily measurable and accessible maternal variables, to predict stillbirth at admission and help inform decisions about further prevention that doctors and pregnant women can make together. Apart from guaranteeing that patients at high risk have the necessary care and support, this is facilitate healthcare systems in allocating resources. The finding of this study will also serve as the baseline data for the researchers who want to conduct further investigation.

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2. OBJECTIVE

2.1General objective

- ❖ Development and Validation of risk score prediction model for stillbirth at Asella Teaching and Referral Hospital, Oromia, Ethiopia, 2024

2.2 Specific objective

- ➢ To develop a risk score prediction model for stillbirth at Asella Teaching Referral Hospital.
- ➢ To validate a risk score prediction model for stillbirth at Asella Teaching Referral Hospital.

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3. LITERATURE REVIEW

3.1 Factors associated with stillbirth

The Chinese retrospective cohort study reveals significant differences in the stillbirth rate between migrant and permanent populations. Although making up 87% of the population, migrant women had a higher stillbirth rate than those in the permanent population. The stillbirth rate was highly associated with the GDP per capita of the maternal birthplace[24].

The 2016 study in Danish showed Pregnancy-related maternal smoking has been linked to a higher chance of stillbirth. After controlling for potential confounders, a logistic regression model was used to analyze the relationship between maternal smoking and the risk of stillbirth overall as well as separately for antepartum and intrapartum stillbirths. But there was no increased risk of stillbirth for women who stopped smoking by the start of the second trimester at the latest[25].

A statewide study conducted in England found that high levels of prenatal alcohol exposure are linked to poor obstetric and birth outcomes as well as high rates of mental illness, low maternal educational attainment, and risky lifestyle choices[26]. Alcohol consumption during pregnancy was associated with increased rates of stillbirth and antepartum hemorrhage according to a study done in the Amhara regional state[27].

The Swedish study aimed to investigate the relationship between older mothers and the risk of stillbirth. It discovered that the rates of stillbirth rose with maternal age, reaching 0.27% for 25–29 years, 0.31% for 30–34 years, 0.40% for 35–39 years, and 0.53% for 40 years or beyond. In first-time mothers, the risk of stillbirth rose with age. This rise was almost 25% higher at ages 30-34 and doubled at ages 35–36 when compared to 25–29 years old[28].

Maternal age ≥35 years prior to eclampsia/eclampsia, diabetes during pregnancy, stillbirth in prior pregnancies, interpregnancy interval >2 years, referral from another hospital, and gestational age <37 were the factors of stillbirth detected in the case control study conducted in Douala General Hospital, Cameroon[29].

a prospective study investigating the relationship between the risk of stillbirth after sexually transmitted diseases during pregnancy in Kenya in 2019. Genital infections and STIs were widespread, often asymptomatic, and in some cases linked to stillbirth or infant death. Vaginal yeast (25%), bacterial vaginosis (22%), Trichomonas vaginalis (6%), Chlamydia trachomatis (5%), Neisseria gonorrhea (2%) and syphilis (1%), as well as genital diseases, were found in

55% of the population. Of the 592 women who had STIs or vaginal infections, 34% had symptoms.[30]. Pregnancy-related STIs are highly prevalent, and their effects on the developing fetus highlight the necessity of screening and treatment programs to reduce perinatal death[31].

The cross-sectional study at Nepal in 2019 on factors associated with stillbirth showed maternal age, maternal education, place of residence, and sub-region remained significantly associated with having experienced stillbirth[32][28].

A cross-sectional study assesses Plasmodium/intestinal helminth infection in pregnancy and other risk factors for stillbirth in Ghana. When compared to women with no malaria, women with malaria had increased risk of stillbirth. Other factors associated with stillbirth were severe anemia, low serum folate concentration, past induced abortion, and history of stillbirth[33].

Retrospective cohort study based on data from five hospitals in South West Ethiopia found that dietary counseling during pregnancy, length of labor, place of residence, age at first marriage, educational status, weight of the newborn, and bad obstetric history were significant predictors of stillbirth. Additionally, logistic regression demonstrated these factors[34].

In 2019, a study was conducted to determine the factors that contribute to stillbirths at the North-West Ethiopian Felege Hiwot Comprehensive Specialized Referral Hospital. The factors associated with stillbirth that raise the chance of fetal death included illiteracy, STDs, premature rupture of the membrane, congenital defects, and a history of perinatal deaths. Conversely, it was discovered that using a partograph and receiving at least two doses of the tetanus toxoid vaccine protected against stillbirth[35].

3.2 Prediction model for stillbirth

A tertiary referral center in the Midwest of the United States developed and internally validated a clinical prediction model to measure stillbirth risk. The final score for stillbirth risk took into consideration variables such as pre-gestational diabetes, body mass index, smoking, chronic hypertension, nulliparity, black race, and mother age. There was no difference in the overall performance between the tools for the stillbirth simple risk score (AUC 0.66), with a sensitivity of 59% and a specificity of 65%. The score showed modest discrimination but clinically significant performance[36].

In order to predict all antepartum stillbirths in 2022, a study integrating maternal risk factors and the uterine artery pulsatility index (UtA-PI) was conducted. The results revealed placental malfunction, a lower BMI, a history of preeclampsia, and smoking. The results show strong discrimination between affected and unaffected pregnancies, with an AUC of 0.838 that was consistent with the dataset used to create the algorithm. In a similar vein, there was good agreement between the predicted risk and observed incidence of placental dysfunction-related antepartum stillbirth, with the calibration slope being 1.029 and the intercept being 0.009.[37].

According to Uganda's predictive study, the country has a 2.5% stillbirth incidence. Abortion history, bilateral end-diastolic notch, preeclampsia history in the individual, and hemoglobin levels between 9.5 and 12.1 g/dL were all predictive of stillbirth. With 68.1% accuracy, 69.1% sensitivity, and 67.1% specificity, the models' AUC was 75.0%[10].

The retrospective cohort study created a prediction model for stillbirth in Nigeria, which demonstrates that the basic and extended models' calibration and discriminative performance were both excellent (i.e., the C-statistic for the basic model is 0.80, and for the extended model is 0.82, but sensitivity and specificity are not assessed [20].

predicted perinatal death in pregnancy with hypertension demonstrates Symptoms, maternal age, and dipstick proteinuria are used to identify pregnancies at risk of perinatal mortality. With an AUC ROC of 0.75, the model demonstrated decent discriminating ability. Model optimism was assessed at 0.01 following 500 iterations of bootstrapping, suggesting that the model had little overfitting to the data. This model has an enormous amount of potential for identifying pregnant women with hypertension who are most at risk of perinatal death [38].

Conceptual framework

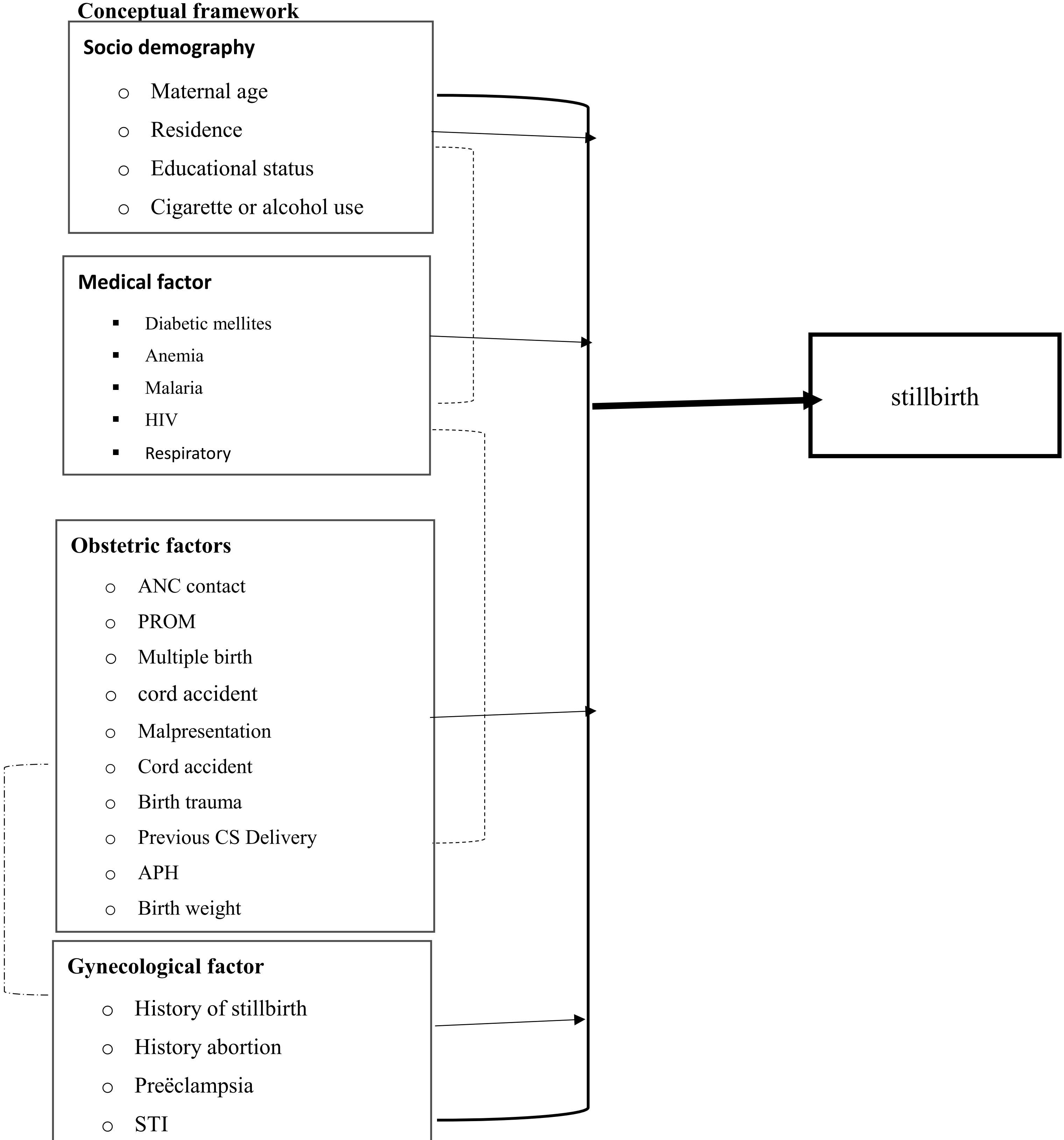

Figure 1 conceptual framework on development and validation of risk score prediction stillbirth adopted from[39][40][41]

4. METHOD AND MATERIAL

4.1Study setting and period

The study was conducted at Asella Teaching and Referral Hospital from 1 October 2022 to 1 October 2024; data was extracted from September 2024 to October 2024. Asella is the zonal town of the Oromia regional state and is 171 km away from Addis Ababa, the capital city of Ethiopia. The hospital operates as a referral center and offers preventative, curative, palliative, and diagnostic services to Asella town and the surrounding community of 4.25 million people. There have been 510 health care professionals working at ATRH. Gynecology and obstetrics is one of the major departments in the hospital. Antenatal care and delivery services are among the services provided in the hospital. The institution has 10 obstetrics and gynecology specialists, 76 midwives, and 9 emergency surgeons.

4.2 Study design

A retrospective follow-up study was conducted at Asella Teaching and Referral Hospital (ATRH) in Ethiopia to develop and validate risk score for stillbirth among pregnant women who had delivery in ATRH.

4.3 Source population

All pregnant women who delivered at Asella teaching and referral hospital

4.4 Study population

All women’s delivered at Asella teaching and referral hospital during study period

4.5 Sample size determination

Ten to twenty occurrences per predictor are recommended as a general guideline for creating a prediction model. For each predictor, a minimum of 10 events are needed in the sample size when developing a prediction model[42].

The necessary sample size can be calculated using the formula

N = (n×10)/I, where N is the sample size, n is the number of candidate predictor variables and

I is the estimated event rate in the population.

For this study the following 12 predictors were been considered including number of antenatal care visits, multiple gestations, hypertension, birth interval of >3 years, history of perinatal death, maternal wealth index, basic education, advanced maternal age, grand multiparity of ≥5, antepartum hemorrhage, infection, and maternal HIV. taking into account study done incidence 12.5%[43].

N= (12×10)/0.125

= **960** Adding 5% non-response rate the final sample size was 1,008

4.6 Sampling techniques

Using a computer-generated simple random sampling procedure, 1,008 records (charts) of study delivered women were selected.

4.7 Inclusion and Exclusion criteria

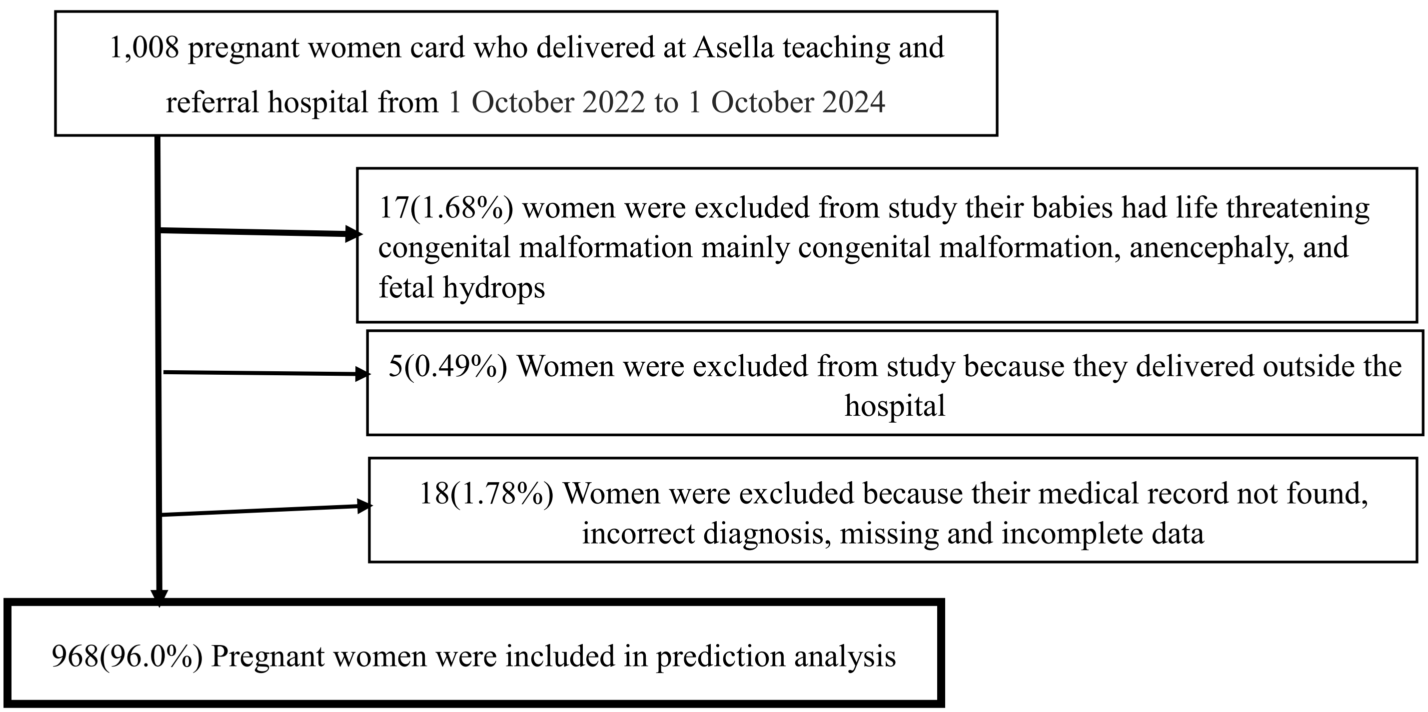

Figure 2 inclusion and exclusion criteria on development and validation of risk score prediction model on stillbirth at ATRH, Asella, Oromia, Ethiopia,2024

4.8 Variables of the study

4.8.1 Dependent variable

Stillbirth(yes/no).

4.8.2Independent variables

Sociodemographic factors: - Age, marital status, educational status, maternal weight, place of residence,

Obstetric factor: -gravidity, hemoglobin level, pregnancy status, timing of ANC initiation, timing of iron folate initiation, premature rupture of membrane (PROM), antepartum hemorrhage (APH)

Gynecological factor: - History of still birth, History abortion, Preëclampsia, Cervical incompetency, Umbilical cord pathology, Small for gestational age

Medical factor: -Sexually transmitted infection (STI) comorbidities (such as pulmonary: history of asthma or COPD (chronic obstructive pulmonary disease); cardiac: history of heart failure or ischemic heart disease; and renal diseases),

4.9 Operational definition

Stillbirth: when baby die in womb after 28 weeks of pregnancy[41].

model is a coherent set of formal elements describing something built for some purpose that is amenable to a particular form of analysis[44].

Discrimination:- distinguish between pregnant women who give alive birth and those who do not(stillbirth)[45].

Area under curve(AUC): - setting the area represents the probability that a randomly chosen stillbirth subject is (correctly) rated or ranked with greater suspicion than a randomly chosen live birth subject[46].

Calibration:- an assessment of how closely the predictions of the model match the observed outcomes in the data [47]**.**

Clinical utility of the investigations performed as defined by usefulness in contributing to identification of the cause of death[48].

Risk scores: -are a way of stratifying a population for targeted screening. They use data from risk factors to calculate an individual's score; a higher score reflects higher risk[49].

Predictive model:- is a statistical technique used to predict the outcome of future events based on historical data[50].

Late initiation of ANC:- Pregnant women who start antenatal care visit after 12 weeks of gestation[51] .

4.10 Data collection procedure and tool

Data was be collected using structured checklists prepared from studies that have been conducted on related topics. To collect data from the mother's medical records, a data extraction checklist was be created on the web-based Kobo Toolbox application. The checklist would be organized according to the sociodemographic traits of the expectant mothers, ailments, previous and current obstetric features.

.4.11 Data quality control and assurance

In order to collect data, an English data extraction checklist was created. Preceding the commencement of data collection, the principal investigator was recruiting 4 (four) BSc midwife data collectors and provided one day of training to the data collectors regarding the Kobo Toolbox, checklist components, protocol, and possible obstacles they could face. There was frequent and scheduled supervision of data collectors. While gathering data, the lead researcher confirmed that the information is accurate and comprehensive.

4.12 Data processing and analysis

The gathered information was exported to STATA 14 software for data analysis and processing. Multiple imputation, which assumes missing values at random, was manage missing data. To create and report the prediction model, the Transparent Reporting of a multivariable Prediction model for Individual Prognosis or Diagnosis (TRIPOD) guideline was be follow [52]. The characteristics of the study participants are shown in tables and figures.

Using a logistic regression analysis, the most influential variables for stillbirth prediction were assessed. To learn more about how each possible factor is related to stillbirth and to be included in a multivariable regression analysis, a bivariable regression analysis was performed. In the multivariable regression analysis, variables from the bivariable analysis with a p-value of ≤0.25 were fitted. The likelihood ratio tests were used to evaluate each predictor's contribution to the multivariable analysis following the application of a stepwise backward elimination strategy. Fitting the simplified model was done using a p-value ≤0.15 for the likelihood ratio test, in an attempt to be more liberal [53].

All variables that showed association in the bivariate model were entered into multivariable logistic regression. After variance inflation factor (VIF) was performed, candidate predictors with VIF > 5 were selected to fit the model to multivariable logistic regression. History of anemia, history of stillbirth, history of abortion, abruptio placenta, preeclampsia, and cord accident were shown to have a statistically significant association at P-value < 0.05.

4.13 model development and performance

The study's hypothetical design was proposed as follows: the incidence of stillbirth at a future time "t" is a function of various prognostic determinants measured at a time point before the occurrence of stillbirth or during pregnancy, "t_0."which is moment of prognostication The study's domain included pregnant women who had delivery in ATRH.

$$(STB(t_0+1) = f\{x_1(t_0) + x_2(t_0) + x_3(t_0) \ldots\ldots\})$$

The discrimination power and calibration of the model were used to evaluate its performance. When a model is used to distinguish between pregnant women who give live births and those who do not (stillbirth), it is referred to as discrimination. In this, we assess the discriminating power of using the area under the receiver operating characteristic curve (AUROC). Good discriminating power is indicated by an AUROC of 0.7 to 0.9, while exceptional discrimination power is indicated by an AUROC of >0.9, indicating excellent discrimination power [46]. Model calibration is the agreement between the observed proportions of stillbirth and predicted probabilities. Calibration was assessed using a calibration plot and a value of p to ensure the reliability of the prediction model, with the calibration plot falling along a 45° line or an insignificant statistical test, such as the Hosmer-Lem show test [54]. The internal validation was carried out using the bootstrap approach, which duplicated the sample 1,000 times. This method is especially useful for evaluating prediction quality and the stability of particular predictors [46].

The optimal cutoff point for classifying pregnant women's risk of stillbirth into high and low categories was determined using the Youden index [53]. The prediction's effectiveness was evaluated using sensitivity, specificity, accuracy, positive likelihood ratio, and negative likelihood ratio. The therapeutic benefit of the model was evaluated using decision curve analysis (DCA). Using DCA, the benefit of a true-positive classification was compared to the possibility of a false-positive classification [55]. A graphical depiction was created to provide a simple, individually applicable clinical prediction of stillbirth.

4.14Ethical clearance

The Institutional Review Board of Arsi University's midwifery department was provided ethical clearance. Additionally, a letter of authorization from the administration office of Asella Specialized Hospital was required in order to carry out the study. To ensure patients' privacy, personal information was eliminated by giving each questionnaire a unique number. All information was gathered from the register, which was securely stored, and all information has been completely anonymized before being accessed. Following data collection, all patient cards and documents were to be returned to a safe location. For ethical concerns, data was not to be shared with anybody beyond the writers. All information was input into a computer that requires a password. The data was only accessible to the investigators.

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5. RESULT

5.1 sociodemographic variable

A total of 1,008 pregnant women participated in the study, about 96% (968) indivual were fit for this study. From a total of 279 respondents, 28.28% are in the age range of 25-29, with a mean age of 28.93 and a standard deviation of 6.27 (28.93 ± 6.27). more than half: Sixty-six percent of mothers had completed higher education. Most of the mothers lived in cities, and about a quarter were housewives (Table1).

Table 1:-sociodemographic variable to development and validation of risk score prediction of stillbirth at ATRH, Asella Ethiopia, 2024

5.2 Medical factors

Out of a total of study participants, over half, 579 (59.81%) of the women, ever had a history of anemia, and the 913 (94.32%) were negative for HIV status. Regarding the history of high blood pressure, 68 (7.02%) were exposed to hypertension, and almost 299 (30%) experienced a urinary tract infection, followed by 190 (19.63%) with a history of STI at some point in their life. Additionally, the history of kidney and heart issues was found to be 91 (9.59%) and 128 (13.49%), respectively (Table2).

Variable	**Category**	**Frequency**	**Percentage (%)**
Age category	Less than 20	76	7.85
	21-24	173	17.82
	25-29	279	28.82
	30-35	228	23.55
	Above 35	212	21.90
Educational status	Can't read and write	9	0.93
	Can read and write	43	4.43
	Primary school	269	27.79
	Secondary school	379	39.15
	Collage and above	268	27.69
Occupation	House wife	244	25.21
	Government employee	189	19.52
	Self-employee	288	29.13
	Merchant	147	15.19
	Others	106	10.95
Residence	Urban	657	67.87
	Rural	311	32.13
Alcohol, cigarette	Yes	933	96.78
	No	31	3.22

Table 2:- medical history of women on development and validation of risk score prediction of still birth at ATRH, Asella Ethiopia, 2024 GC

Variable	Category	Frequency	Percentage (%)
HIV Status	Yes	55	5.68
	No	913	94.32
History of DM	Yes	70	7.23
	No	898	92.77
History of anemia	Yes	579	59.81
	No	389	40.19
History of hypertension	Yes	68	7.02
	No	900	92.98
Obesity	Yes	62	6.4
	No	906	936
History of STI	Yes	190	19.63
	No	778	80.37
History of UTI	Yes	299	30.89
	No	669	69.11
History of respiratory problem	Yes	98	10.19
	No	864	89.81
History of heart problem	Yes	128	13.49
	No	821	86.51
History of kidney problem	Yes	91	9.59
	No	858	90.41

5.3 Obstetric and gynecological history

This study result showed that about 75 (7.75%) have an abortion history. 68 (7.42%) ever had a history of cesarean section. 87 (8.99%) of research participants had experienced postpartum bleeding, and 118 (12.19%) had suffered a loss with a history of stillbirth. The history of congenital anomaly was found in 51 (5, 30%) (table3).

Table 3:- obstetric and gynecological history on development and validation of risk score prediction of still birth at ATRH, Asella Ethiopia, 2024

Variable	Category	Frequency	Percentage(%)
History of abortion	Yes	75	7.75
	No	893	92.25
History of cesarean section	Yes	68	7.42
	No	849	92.58
History of post-partum hemorrhage	Yes	87	8.99
	No	881	91.01
History of low birth weight	Yes	166	18.26
	No	743	81.74
History of stillbirth	Yes	118	12.19
	No	850	87.81
History of ectopic pregnancy	Yes	72	7.48
	No	890	92.52
History of congenital Anomaly	Yes	51	5.30
	No	911	94.70

5.4 Current obstetric and gynecological factors

This study showed that 685 (67.98%) were multigravida. The majority of the population had early ANC 719 (75.45%), and 25 (2.67%) had very low birth weight; additionally, 150 (15.5%) had gestational diabetes. Most of the women's 615 deliveries (63.65%) were vaginal. The data indicates about 50 (5.17%) of RH status and 108 (11.16%) chorioamnionitis, while conditions like 243 (25.10%) preeclampsia, 289 (29.86%) oligohydramnios, 116 (11.98%) abnormal presentation, 47 (4.86%) abruptio placenta, 141 (14.57%) twin pregnancy, and 127 (14.48%) cord accident. The majority of labor was induced rather than spontaneous, and oxytocin was predominantly administered multiple times during labor management (Table 4).

Table 4:- current obstetric and gynecological factors to development and validation of risk score prediction of still birth at ATRH, Asella Ethiopia, 2024

Variable	**Category**	**Frequency**	**Percentage(%)**
Gravidity	Primigravida	310	32.02
	Multigravida	658	67.98
Parity	Primipara	33 5	34.61
	Multipara	633	65.39
ANC contact	Yes	939	97
	No	14	3
Timing ANC	Early	719	75.45
	Late	220	23.08
RH status	Positive	50	5.17
	Negative	918	94.83
Birth weight	Above 2.5 kg	719	76.82
	Between 1.5-2.5	192	20.51
	Below 1.5kg	25	2.67
Preeclampsia	Yes	243	25.10
	No	725	74.90
Gestational DM	Yes	150	15.50
	No	818	84.50
PROM	Yes	325	36.15
	No	574	63.85
Chorioamnionitis	Yes	108	11.16
	No	860	88.84
Oligohydramnios	Yes	289	29.86
	No	679	70.14

Abnormal presentation	Yes	116	11.98
	No	852	88.02
Abnormal position	Yes	134	13.84
	No	834	86.16
Abruption placenta	Yes	47	4.86
	No	921	95.14
Cord accident	Yes	127	14.48
	No	750	85.52
Twin pregnancy	Yes	141	14.57
	No	827	85.43
Onset of labour	Spontaneous	451	46.59
	Induced	517	53.41
Mode of delivery	Vaginal	615	63.53
	Instrumental	207	21.38
	c/s	146	15.08

5.5 Prognosis model development and validation for stillbirth

5.5.1 Predictor selection for prediction of stillbirth

The incidence of preterm birth was 10.3%. sociodemographic, medical, obstetric, and gynecological related conditions of mothers were considered for the development of a prognosis risk score model for stillbirth. In the bivariable binary logistic regression analysis. Age, history of hypertension, history of anemia, history of UTI, history of stillbirth Cord accident, Abruptio placenta, Preeclampsia, PROM, Chorioamnionitis, Oligohydramnios and had a p-value ≤ 0.25 and were considered for the multivariable binary logistic regression analysis. However, underlying age, history of hypertension, history UTI, PROM, chorioamnionitis, and oligohydramnios were excluded in multivariable binary logistic regression analysis using the likelihood ratio test at a p-value > 0.15(table 5).

Table 5:- Bivariate and multivariate logistic regression model on development and validation of risk score prediction model on stillbirth Asella, Ethiopia 2024G.C

		Bivariate analysis		Multivariate analysis	
Variable	**Category**	**OR (95% CI)**	**P-Value**	**AOR (95% CI)**	**p-value**
Age	**<20**	1.56(.91923 - 2.6667)	0.099	1.38(.7116 -2.685)	0.339
	21-24	1			
	25-29	.818(.3589314-1.86830)	0.635	.876(.3160 2.4268)	0.799
	30-34	.5231(.2544292-1.07520)	0.078		
	>35	.472(.0468123-4.76798)	0.525	.049(.00265-.89579)	0.042
History of DM	**Yes**	.470(1.119134-4.03885)	0.021	.69(.29159 - 1.633)	0.399
	No	1			
History of anemia	**Yes**	.273(.1593327 .46807)	0.000	.365(.18401 .72746)	0.004**
	No	1			
History of HTN	**Yes**	.407(.2173798 -.763942)	0.005	.480(.21644-1.066)	0.072
	No	1			
History of STI	**Yes**	.448(.28551- .7039798)	0.000	.746 (.4078 - 1.3665)	0.440
	No	1			
History of UTI	**Yes**	.5056(.33213 -.7696935)	0.001	.8348(.4868-1.4316)	0.512
	No	1			

History of abortion	**Yes**	.349(.19459 - .62806)	0.000	.281(.13570 .5838)	0.001 **
	No	1			
History of ectopic	**Yes**	.713(.428441-1.187091)	0.194	1.327(.50947 3.4343)	0.566
	No	1			
History of stillbirth	**Yes**	.263(.1627063 - .42591)	0.000	.359(.197617.65321)	0.001**
	No	1			
History of low birth wt,	**Yes**	.608(.3086 - 1.199)	0.151	.756(.40856 -1.4002)	0.374
	No	1			
Abruptio placenta	**Yes**	.242 (.12505 - .471300)	0.000	.273(.11835-.63262)	0.002 *
	No	1			
Preeclampsia	**Yes**	.248(.16257 .37988)	0.000	.311(.17370 .55634)	0.000**
	No	1			
PROM	**Yes**	.491(.31873- .75606)	0.001	.776 (.45003 -1.3388)	0.362
	No	1			
Chorioamnionitis	**Yes**	.419(.246724- .71177)	0.001	0.33(.232667-.9285)	0.030
	No	1			
Oligohydramnios	**Yes**	.549(.359599 - .838976)	0.006	.717(.41361-1.2426)	0.236
	No	1			
Cord accident	**Yes**	.302(.186101-.4889492)	0.000	.414(.22334-.7686)	0.005*
	No	1			

Multivariable logistic regression coefficients and risk score for variables retained in the final reduced model for prediction

We used the results of a multivariable logistic regression analysis to find the factors about the mother and the pregnancy that significantly and independently predicted the risk score for stillbirth. history of Anemia, history of abortion, history of stillbirth, preeclampsia, abruptio placenta and cord injuries all increased the risk of stillbirth This model also classifies predictors of stillbirth into high risk and low risk. It shows a history of anemia and preeclampsia as high risk and a history of abortion, history of stillbirth, abruptio placenta, and cord accident were low risk for stillbirth.

Table 6:- multivariable binary logistic regression coefficient and risk score retained in the final reduced model for prediction.

Prediction	category	Multivariable		Reduced		
		β (95% CI)	**P- value**	**β (95%CI)**	**P- value**	**Risk score**
History of anemia	Yes	.858(-1.45 -.273)	0.004	.9072(.32746 - 1.486)	0.002	3
	No	1				
History of abortion	Yes	1.018(-1.683-.3531)	0.003	.3033(.08370 - .5229)	0.007	1
	No	1				
History of stillbirth	Yes	.862(-1.407-.31758)	0.002	.422(.153739-.6907)	0.002	1
	No	1				
Abruptio placenta	Yes	1.346(-2.08 -.60466)	0.000	.336(.15116-.5218)	0.000	1
	No	1				
Preeclampsia	Yes	1.08(-1.548-.6056)	0.000	1.067(.6012-1.5327)	0.000	4
	No	1				
Cord accident	Yes	.836(-1.363 -.3095)	0.002	.418(.1547-.68135)	0.002	2
	No	1				
Constant		9.70(7.8862-11.516)	0.000	-2.84(-3.262-2.4249	0.000	
						12

5.5.2 Development of model

The theoretical design of this study was found to be:

STB (t_{0+1}) = f (history of anemia (t_0) +history of abortion(t_0) + history of stillbirth(t_0) + preeclampsia(t_0) + abruptio placenta (t_0) + cord accidents (t_0)

where Y = 1 means having stillbirth and Y = 0 means alive birth.

STB (Y = 1) = f (βo + β1history of anemia+ β2 history of abortion + β3history of stillbirth+ β4preclampsia+ β5 abruption placenta+ β6cord accident).

Risk prediction model(stillbirth) = 9.70+0.42cord accident+1.067preeclampsia+0.422history of stillbirth+0.3033 history abortion +0.9072 history of anemia

Risk score development using simplified risk score

Using the final reduced model or significant β coefficients, we constructed a simplified risk score to facilitate practical application. A simplified prediction score was obtained by dividing the significant β coefficients by the lowest significant β coefficient and rounding to the closest integer. There is a range of 0 to 12 for the possibility of the lowest and greatest risk scores of stillbirths and alive

Simplified risk score(stillbirth)= (2*cord accident+ 4*preeclampsia+ 1*history of stillbirth+ 1*history abortion + 3* history of anemia)

5.5.3 Performance of Model

Discrimination is the ability of the model to distinguish stillbirth and alive birth and is measured with the area under the receiver operating curve (AUROC). This study reveals that with the initial beta coefficients, the final reduced model with six predictors had an area under the ROC of 0.767, indicating that it was 76.7% successful in distinguishing between live birth and stillbirth. This suggests that the model has a high degree of discrimination (figure3).

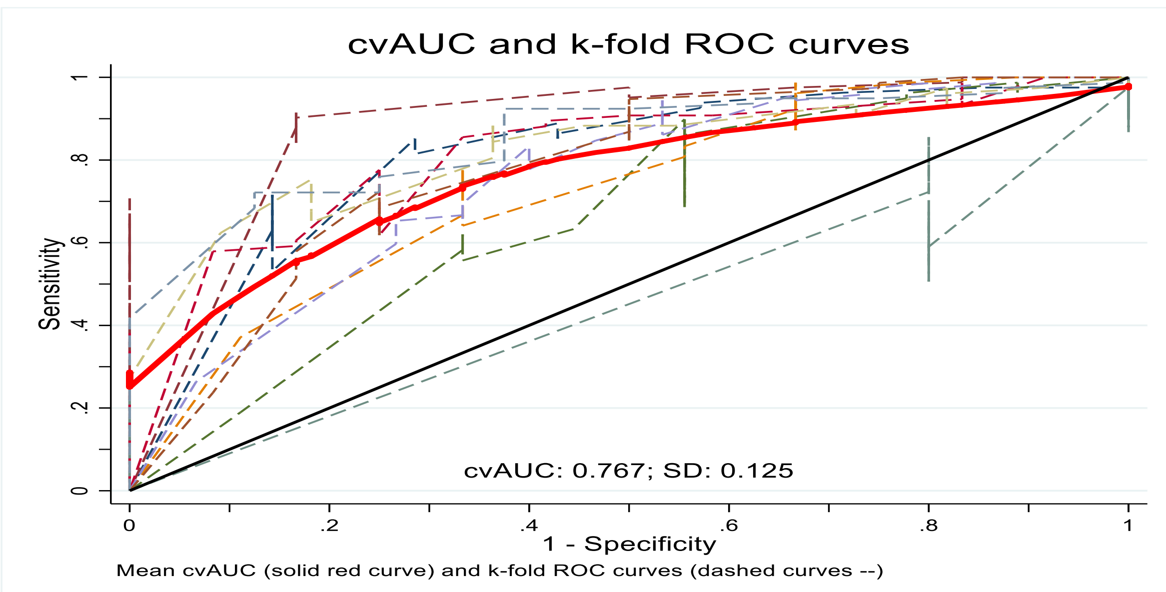

Figure 3 Overall discrimination performance of predictive model d of stillbirth on development and validation of risk score prediction model on stillbirth, Asalla, Oromia, Ethiopia 2024G.C

Calibration characterizes the model's performance in terms of the agreement between predicted risk and observed risk reported using a calibration plot. The intercept of zero and the ratio of expected to observed equal (O/E=1) define the best calibration. The developed model was well calibrated with the Hosmer-Lemeshow test ($p = 0.974$) and the calibration plot falling along a 45° line. This indicates that the model well represented the data. (figure 4).

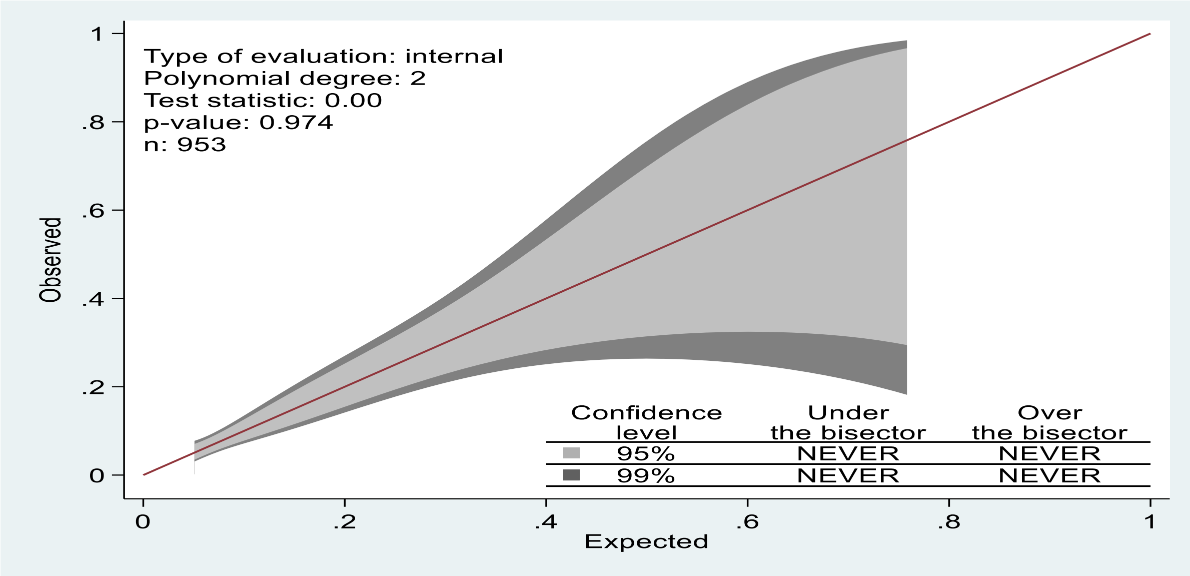

Figure 4:-calibration performance of the model on development and validation of risk score prediction model on stillbirth, Asella, Ethiopia-2024E.C

5.6 Validation of Model

The bootstrap technique was employed to validate the proposed model in order to assess its optimism and bias. With full information on every predictor, 1,000 random bootstrap samples with replacement were selected from the data set. Following bootstrapping, the model's predictive performance is regarded as the performance that may be anticipated when the model is used on comparable future populations. Additionally, actual performance less expected performance yielded the optimism correction estimate, which came out to be 0.000799.

The prognostic model's bootstrap statistics display the bias in each of the predictor's initial beta coefficients. Each estimate's discrimination power was reassessed once the bias was subtracted. An optimism coefficient (pooled bias) of 0.0007999 (0.892–0.957) indicated that the bias-corrected beta-coefficients performed similarly to the model prior to internal validation, with an AUC of 0.7339 (95% CI: 0.6729–0.7948) (figure 5).

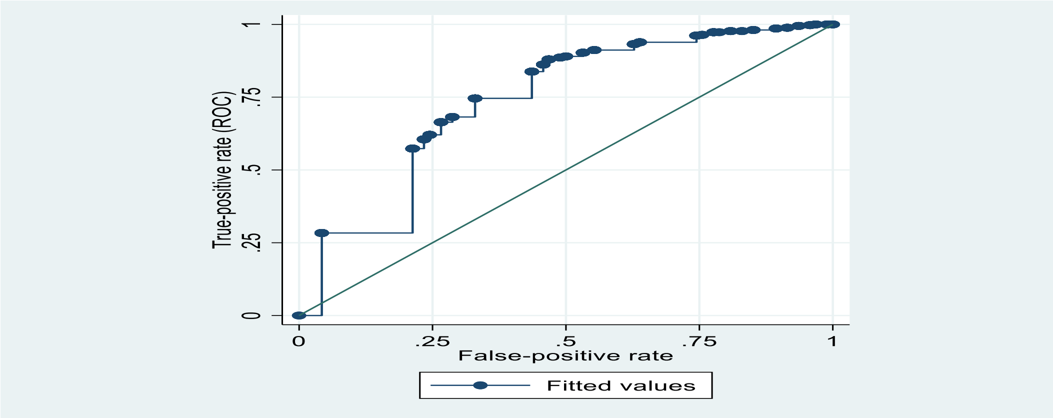

Figure 5 bootstrapping technique on development and validation risk score prediction model on stillbirth at Asella, Ethiopia, 2024EC

Decision curve analysis

As long as the goal of creating this risk score model is to identify stillbirth children early on and provide them with the necessary care and attention to receive the best possible treatment. The developed model (model) has highest net benefit ratio starting from threshold probability > 0.01 compared to not treating all (horizontal green line) and treating all regardless of their risk (vertical line nearly blue lines). With the highest net benefit ratio, the model is more significant from a clinical and public health standpoint. Therefore, regardless of the prediction probability, the prognosis model should be the major focus because it has a larger cost-benefit ratio than not treating anyone or treating everyone.

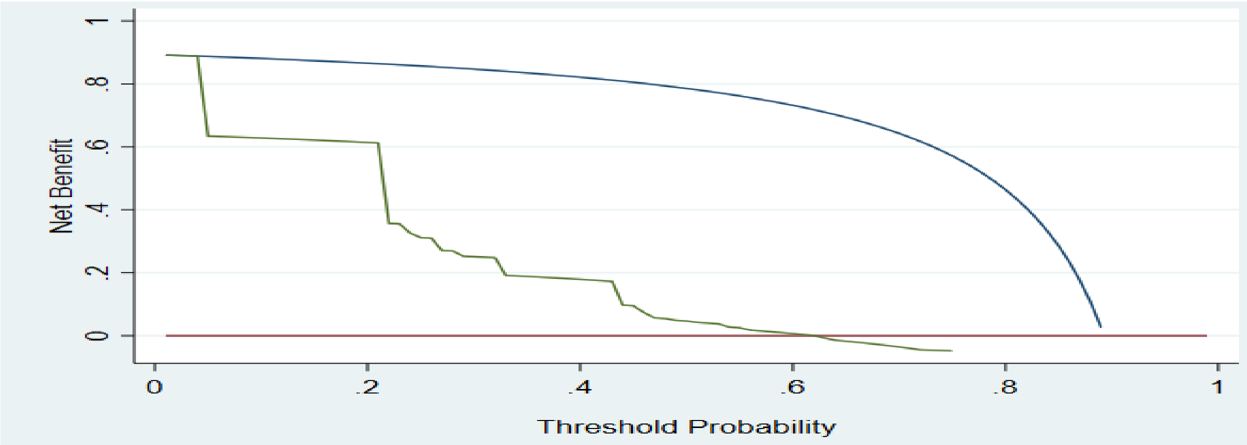

Figure 6 decision curve analysis graphical representation on development and validation of stillbirth at Asella Teaching and Referral Hospital 2024G.C

6. DISCUSSION

The risk prediction model resulting from this study helps to identify potentially relevant maternal characteristics that have adverse outcomes on live birth. This model uses 4 (four) clinical and non-clinical variables that can be obtained routinely on hospital admission and that can be incorporated into clinical practice as a tool for pregnant women that can benefit from interventions aimed at reducing bad obstetric and gynecological outcomes.

The final model contains 6 predictors, including preeclampsia, cord accident, anemia history, stillbirth, abruptio placenta, and abortion history, according to this study. This model shows an acceptable level of fit and discrimination performance; therefore, using this strategy, pregnant women who are at high and low risk of stillbirth would be classified, and additional care and appropriate procedures would be done as needed.

This study found that incidence of stillbirth was about 10.3%.was higher than 4.05% Nigeria[52] 2.9% Sweden[53] 8%Jimma[54] southern Ethiopia 3.68%[54] this might be due quality of obstetric and gynecological problem and Sociodemographic variation. but lower than nation level study12.93%[55]

History of anemia was the independent risk factor for stillbirth, according to this study. The results are corroborated by eastern Ethiopia[56] Shashamane [39], Swedish [52], and Sudanese [53]. This could be explained scientifically by anemia (<11g), which results in hypoxia that stresses both the mother and the fetus. Another possible explanation for this could be the mother's poor nutritional status and lack of extra meals throughout pregnancy, which could result in a micronutrient shortage during pregnancy, which has been linked to major consequences for the fetus's health. Consequently, the risk of stillbirth was higher for moms who had low hemoglobin or anemia [52].

The data provide a clear understanding of the risk of stillbirth associated with a history of abortion. Suggesting that the mother who experience abortion has higher chance to stillborn finding is comparable with Danish[57] Kersa [53] Debre Markos [35] Jimma [34] Bahir Dar [54] This may be due to uterine scarring or cervical insufficiency from prior procedures and underlying health conditions.

The other notable finding of this study is that the history of stillbirth episodes is another predictor of stillbirth, as confirmed by both bivariate and multivariate analyses of this study. Similar study conducted in the United Kingdom [55] Wolaita [56], Wollo [57], and Addis Ababa [52] reveal something. Parents entering into subsequent pregnancies following stillbirth face a risk of stillbirth occurrence, alongside increased risk of the other adverse pregnancy outcomes and psychosocial challenges.

This study demonstrates fetal risk of death associated with preeclampsia begins when preeclampsia becomes clinically apparent. The comparable study at Harar [3] Woldia [58] This might be due to a maladaptive placenta that is failing to provide adequate oxygen and nutrients to the growing fetus, leading to both adverse obstetric sequelae and fetal programming.

The result of this study shows that there is association between stillbirth and cord accident. comparable studies done on finding predictors of stillbirth shows America[58] eastern shoe[59]shows there is association between stillbirth and cord accident this might be due to when cord blood flow is compromised, preventing fetus from getting enough oxygen and nutrients.

The model that was developed demonstrated strong discriminating power for pregnant women at risk of stillbirth. The model's discriminative power was 0.767 using an AUROC based on the coefficient (β), and its performance was 0.73336 with internal validation (bias-corrected). 0.73336 was the performance-predicting model based on the risk score. Thus, 76.7% of pregnant women with a simplified risk score were able to be discriminated against based on their risk of stillbirth.

The model's accuracy lines up with prospective cohort research in Europe to predict stillbirth outcomes, which found that a combination of placental malfunction, uterine doppler at mid-trimester, and clinical risk factors had AUROC (0.75) [37]. However, predictors require specialized imaging technology, which is frequently unavailable in low-resource environments. As a result, such predictors are difficult to find in routine clinical and public health practice, rendering the model less effective. Which is greater than (AUROC=0.70) Australia [52] and 57%

(AUROC=0.57) Nigeria [53], Even while those established models performed well, they outperformed our model due to less exact estimation. This could be because the predictors utilized in model construction contributed less to risk discriminating capacity and the consequent inclusion criterion.

The simplified risk score developed from the regression model is easier to use in routine clinical and public health practice and had comparable discrimination power and well calibrated. Development of this risk score prediction model has potential important implication for clinical practice and research.by using this model, law risk pregnant women's managed as less extensive whereas high risk pregnant women's managed with highly extensive intervention.

7. CLINICAL PRACTICE IMPLICATION

With variables that are widely accessible without requiring a sophisticated clinical evaluation of expectant mothers, the created risk score model is simple to use in clinical settings. The prediction score will assist in identifying pregnant women who are at a higher risk of stillbirth and in risk stratification. High-risk groups can then receive more care and attention, or women who are more likely to give birth early can be identified so that preventative measures can be provided and prenatal care decisions can be guided.

Our prediction model includes variables that are easily obtained and have a high enough accuracy to be used by both mid-level and lower-level health professionals in primary care settings. Six of the maternal characteristics included in our model can be easily identified through from history of pregnant women's. As a result, this feasible prognosis risk score would provide a chance to reduce prenatal complications associated with stillbirth, thereby improving overall maternal and child healthcare. The model is critical to preventing the devastating personal, economic, and health consequences of stillbirth.

8. CONCLUSION AND RECOMMENDATION

CONCLUSION

This research aimed at developing and validating a risk score prediction model on stillbirth. Based on secondary data from patient cards. The following predictors were found to be significant to predict stillbirths, including history of abortion, history of anemia, history of stillbirth, preeclampsia, abruptio placenta, and cord accident. These variables predict stillbirth by 76.6% AUC. This indicated that the model has very good predictive ability with accuracy. The developed model was well calibrated ($p = 0.974$) to conclude that bad obstetric and gynecological problems of mothers are associated with stillbirth. Model optimism was assessed at 0.00079 following 1000 iterations of bootstrapping, suggesting that the model has a good fit.

RECOMMENDATION

The study revealed that bad obstetric and gynecological problems are predictors of stillbirth. So that the investigator recommends to Arsi University Teaching Referral Hospital's maternal health team to consider highly those predictors with great risk score and moderate attention for lower risk score mainly while providing care for their client. Additionally, to better understand the implications of the study results, future studies should focus on the development and validation of a risk score prediction model using prospective cohort study design that is best to prevent stillbirth.

9.STRENGTHS AND LIMITATION

This study was a baseline study in Asella, Ethiopia, to find out the development and validation of risk score predictors of stillbirths and to pave the way for more research. I was included in a large number of sample sizes; this makes the study powerful to detect the most common predictors of stillbirth in the study area, and good model performance might indicate reliability to use in a clinical setup.

The study was not without limitations, secondary collected data, some variables for the prediction of stillbirth might have been missed and problem of documentation. However, models developed using retrospectively collected data are still important in resource-limited settings like Ethiopia. However, internal validation was done, It would have been better if it had gone through external validation to ensure its prediction capability when applied to other contexts.

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ANNIX

English Version Questionnaire

Interview Record for Quantitative Data **Identification Number** ☐

Questionnaire Development and validation of risk score predictors on stillbirth at Asella Teaching and Referral Hospital Ethiopia, 2024G.C

Sociodemographic data

code	Questions	Response	Skip
101	Age	__________ years old	
102	Marital status	1. Single 2. Married 3. Divorced 4. widow	

103	Educational status	1. Can't read and write 2. Read and write 3. Primary school 4. Secondary school 5. College and above	
104.	Occupation	1. House wife 2. government employee 3. Self employed 4. merchant 5. others (specify)	
105.	Residence	1. Urban 2. Rural	

Medical factors

Code	Question	Response	skip
201.	HIV sero status	1. Negative 2. Positive	
202.	History of DM	1. Yes 2. No	
203.	History of Anemia	1.Yes 2.No	
204.	History of HTN	1. Yes 2. No	
205.	History of STI	1.Yes 2.No	

Obstetric history

Code	Question	Response	skip
301.	History of abortion	1.Yes	If No skip

		2.No	to 303
302.	If yes how many times	_______________	
303.	History of cesarean delivery	1.Yes 2.No	If No skip to 305
304.	If yes how many times	_____________	
305.	History of postpartum hemorrhage	1.Yes 2.No	
306.	History of still birth	1.Yes 2.No	
307.	Current birth outcome is stillbirth	1.Yes 2.No	

Current obstetric history

Code	Question	Response	Skip
401.	Gravida	____________	
402.	Parity	___________	
403.	Gestational age (weeks)	____________	
404	ANC contact	yes	
		No	
405	If yes timing of ANC	Early	
		Late	
404.	Abruption placenta	1.Yes 2.No	
405.	Placenta previa	1.Yes 2.No	
406.	Antepartum hemorrhage (vasprevia,…)	1.Yes 2.No	
407	Has preeclampsia	1.Yes 2.No	
408.	Has gestational DM	1.Yes 2.No	
409.	Polyhydramnios	1.Yes 2.No	

410	Onset of labour	1. Spontaneous 2. Induced	
411	Labour augmented	1.Yes 2.No	
412.	Obstructed labour	1.Yes 2.No	
413.	Prolonged labour	1.Yes 2.No	
414.	Has cephalopelvic disproportion	1.Yes 2.No	
415.	Mode of delivery	1. Vaginal 2. Instrumental 3. Cesarean	
416.	Has episiotomy	1.Yes 2.No	If 2 skip to 421
417.	If yes is there extension > 2 degree tear	1. Yes 2. No	
418.	Genital trauma other than episiotomy	1. Vaginal wall laceration 2. Perineal tear 3. Cervical tear 4. Absent	
419.	Uterine atony	1.Yes 2.No	
420.	Coagulopathy	1.Yes 2.No	

Declaration of Investigator

I, the undersigned student of Master of maternity and reproductive health declare that this research paper is my original work in partial fulfillment of the requirement for the degree of Master of maternity and reproductive health to my best knowledge.

Name of investigator: ___________________________________

Signature: _______________ Date__________________

Declaration of Advisors

We, the undersigned Advisors and département, declare that this proposal is our original work in partial fulfillment of the requirement for the degree of Master of maternity and reproductive health for the stated student above to our best knowledge. We confirmed that this proposal is ready for defense with our approval as the university advisor(s).

Date of Submission: ______________________________

Name of primary Advisors:	Signature	Date
______________________	______________	__________
Name of secondary Advisors:	Signature	Date
______________________	______________	__________
Name of département	signature	Date
______________________	______________	__________
Name of examiners	signature	Date
______________________	______________	__________