

# Audit of Early and Late Maternal Deaths in Georgia: Potential for Improving Substandard Obstetric Care

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**Introduction:** Quality of care is an important factor in reducing preventable maternal deaths, yet it is a significant challenge in many countries. Substandard and poor quality of care is the leading factor in two-thirds of maternal deaths in European countries. Our study investigated the deaths of all women of reproductive age in 2012 in Georgia. The aim was to define the underlying causes of maternal deaths and to identify the factors in women's care which contributed to the fatal outcomes.

**Methods:** A national Reproductive Age Mortality Survey was conducted in Georgia in 2014–15. Data from multiple sources was triangulated to identify all deaths of women of reproductive age. This was followed by verbal autopsy diagnoses. Each case of early and late maternal death was investigated through interviews and medical record reviews at the last medical facility providing care for the deceased woman. A specialist panel reviewed and assigned underlying causes of death, assessed the management of each woman's condition, and identified elements of suboptimal care.

**Results:** We identified a total of 23 maternal deaths, including 15 (65%) early and eight (35%) late deaths. The maternal mortality ratio was 26.3 per 100 000 live births. The four leading causes of early maternal deaths were: sepsis, hemorrhage, embolism, and pregnancy-induced hypertension. Embolism and sepsis were the direct causes of the eight late maternal deaths. Cancer, tuberculosis, and postpartum suicide constituted the indirect causes of death. Improvements in care which would have made a difference to the outcomes were identified in 87% of early maternal deaths and 67% of late maternal deaths due to direct obstetric causes.

**Discussion:** Delayed recognition and inappropriate management of maternal complications were common across almost all cases studied. The findings from Georgia highlight the conclusion that most maternal deaths were preventable and that improvement in obstetric care is urgently required.

**Keywords:** maternal mortality, late maternal death, cause of death, quality of care, maternal death preventability

## Introduction

Although maternal mortality has declined globally by 38% over the past two decades,<sup>1</sup> the dominant and most common direct causes of maternal death remain postpartum hemorrhage, hypertensive disorders and maternal sepsis.<sup>2</sup> Still, indirect causes have been playing an increasing role in maternal mortality, globally.<sup>3,4</sup> These causes include cardiovascular disease, cancer, mental health disorders, infectious diseases and non-genital sepsis.<sup>3,4</sup>

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While the maternal mortality ratio in Europe is relatively low in comparison with other regions of the world, there is a wide variation in the European Region<sup>1</sup> (As defined by the World Health Organization (WHO), the European Region comprises 53 countries, covering a vast geographical region from the Atlantic to the Pacific oceans.) across countries both in terms of mortality rates and causes of maternal deaths.<sup>1</sup> Importantly, low-income countries have higher levels of maternal deaths from direct obstetric causes in contrast to high-income countries, which are experiencing increasing levels of maternal mortality from indirect causes. This is likely due to the rise in non-communicable diseases (NCDs).

The “three delays” model of maternal care identifies three time points when appropriate interventions can prevent an emergency condition from progressing toward a maternal death. These delays are: (1) in seeking care; (2) in reaching a care facility; and (3) in receiving appropriate care.<sup>5</sup> This model is commonly applied to evaluate factors that may impede women from receiving appropriate medical care. It is estimated that 50–70% of maternal deaths can be prevented simply by assuring that women have access to appropriate and good quality of care.<sup>6,7</sup> Thus, quality of care is an important factor in reducing preventable maternal deaths and a significant challenge in many countries. As shown by confidential enquiries, substandard and poor quality of care is the leading factor in two thirds of maternal deaths in European countries.<sup>8</sup>

The factors influencing quality are complex and interconnected. They include: the availability of infrastructure and supplies; level of training of health care personnel; preparedness of facilities to provide required levels of specialized care when complications arise; adequate and rapid referral systems; and provider-patient relationships.<sup>9,10</sup> Other factors include leadership, governance and accountability for quality. In low- and middle-income countries, maternal mortality reduction is slow due to the limited quality of services provided, combined with poor health system capacity to timely identify and adequately manage pregnancy complications.<sup>11</sup>

Monitoring and clinical auditing of individual maternal deaths, both early and late, can provide insights into different aspects of the quality of services provided and then help define the elements of delay and substandard care which need to be addressed. This process is central for detecting gaps in the health system and recommending policies and improvements to health care decision makers.<sup>12</sup> In addition, many countries focus efforts solely on prevention of early

maternal death and too often fail to link late maternal death with missed opportunities in care during pregnancy or after delivery.<sup>13</sup> A late maternal death is defined as death of a woman from direct or indirect causes more than 42 days but less than one year after the end of pregnancy. It has been introduced in the International Classification of Diseases (ICD) 10<sup>th</sup> Revision because of the current advancements in medical care potentially delaying death after life-threatening complications of pregnancy.<sup>14</sup> Despite its importance, reporting and examining of late maternal deaths has to date been insufficient.

A Reproductive Age Mortality Survey (RAMOS) was conducted in Georgia in 2014 (RAMOS14) in order to ascertain the accuracy of routine statistics and to understand the epidemiology of maternal mortality and its determinants. RAMOS used retrospective data from 2012<sup>15</sup> and assessed the magnitude of maternal mortality and its causes, enabling a comparison to a similar survey conducted in 2008, based on 2006 data. In this study, we assessed each maternal death and identified the main causes of death as well as contributing factors. We also assessed the elements of substandard medical care, including timely identification of risks or complications, adequate and timely referral to the appropriate level obstetric facility, evidence-based management of severe maternal conditions, and timely interventions. Importantly, the study also addresses late maternal deaths, contributing to the knowledge base around these deaths.

## Materials and Methods

### Study Population

The national RAMOS was conducted between March 2014 and January 2015. The study’s target population included all women aged 15 to 49 who were permanent residents in Georgia, and who died in 2012. The year 2012 was selected as the most recent year for which full and error-checked databases were available at the time the study began.

### Standard Definitions

In this study we used the World Health Organization (WHO) ICD-Maternal Mortality (ICD-MM) definition of maternal death and underlying causes of death classification and applied these definitions to all reviewed maternal deaths:

A maternal death is the death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and the site of the pregnancy, from any

cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes.

We also applied the definition of late maternal deaths as “delayed deaths occurring between full six weeks (more than 42 days) and one year postpartum”.<sup>16</sup> All maternal deaths were included and classified based on their causes as either direct or indirect. Direct obstetric deaths were standardly defined as

those resulting from obstetric complications of the pregnancy state (pregnancy, labor and the puerperium), from interventions, omissions, incorrect treatment, or from a chain of events resulting from any of the above.

Indirect obstetric deaths were those resulting from previous existing disease or disease which developed during pregnancy and which was not due to direct obstetric causes, but which was aggravated by physiologic effects of pregnancy.<sup>16</sup>

## Data Collection

The triangulation of data from multiple sources was applied to identify potentially eligible women of reproductive age (WRA). Data sources included: 1) the civil registration and vital statistics (CRVS) mortality electronic dataset; 2) routine health statistics and surveillance data from the National Center for Disease Control and Public Health (NCDC&PH) of Georgia; 3) hospital and ambulance service registers and electronic datasets; 4) regional death registers; and 5) community informants contacted during the field investigations. The 2012 number of live births (57,002) reported in the official statistics, CRVS and NCDC &PH data sources, was used to yield maternal deaths per 100,000 live births.

Of the 913 eligible deaths of WRA in 2012 in Georgia, 36 were identified as pregnancy-related deaths (Figure 1). A multidisciplinary panel of medical experts reviewed the medical records of all 36 women who died during pregnancy or within 1 year of termination of their pregnancy, categorized the pregnancy-related deaths as maternal deaths (“direct” or “indirect”) or as “co-incident”. The review identified 13 deaths as co-incident. For the 23 deaths categorized as maternal, a panel of experts conducted additional in-depth reviews of the treatment and care provided to the women and commented on the quality of care and preventability of the death.

The review team considered the existing Georgian national guidelines and clinical care protocols as the

reference standard of care for evaluating timely recognition and treatment, appropriate management and referral. Where local guidelines were lacking, we applied guidelines from the Royal College of Obstetricians and Gynecologists (RCOG),<sup>17,18</sup> American College of Obstetricians and Gynecologists (ACOG),<sup>19</sup> and WHO.<sup>20–22</sup> Categorization of the quality of care was made based on the United Kingdom’s (UK) scoring system<sup>3</sup> as follows: 1 - good care, 2 - improvements to care which would have made no difference to the outcome, and 3 - improvements to care which would have made a difference to the outcome.

## Statistical Analyses

The SPSS version 21.0 (IBM, Armonk, NY, USA) was used to analyze mortality data. We applied univariate, stratified analyses, constructed frequency tables and performed cross tabulation to investigate patterns of maternal mortality in Georgia. The overall MMR was calculated as number of all maternal deaths per 100 000 live births.

## Ethical Approval

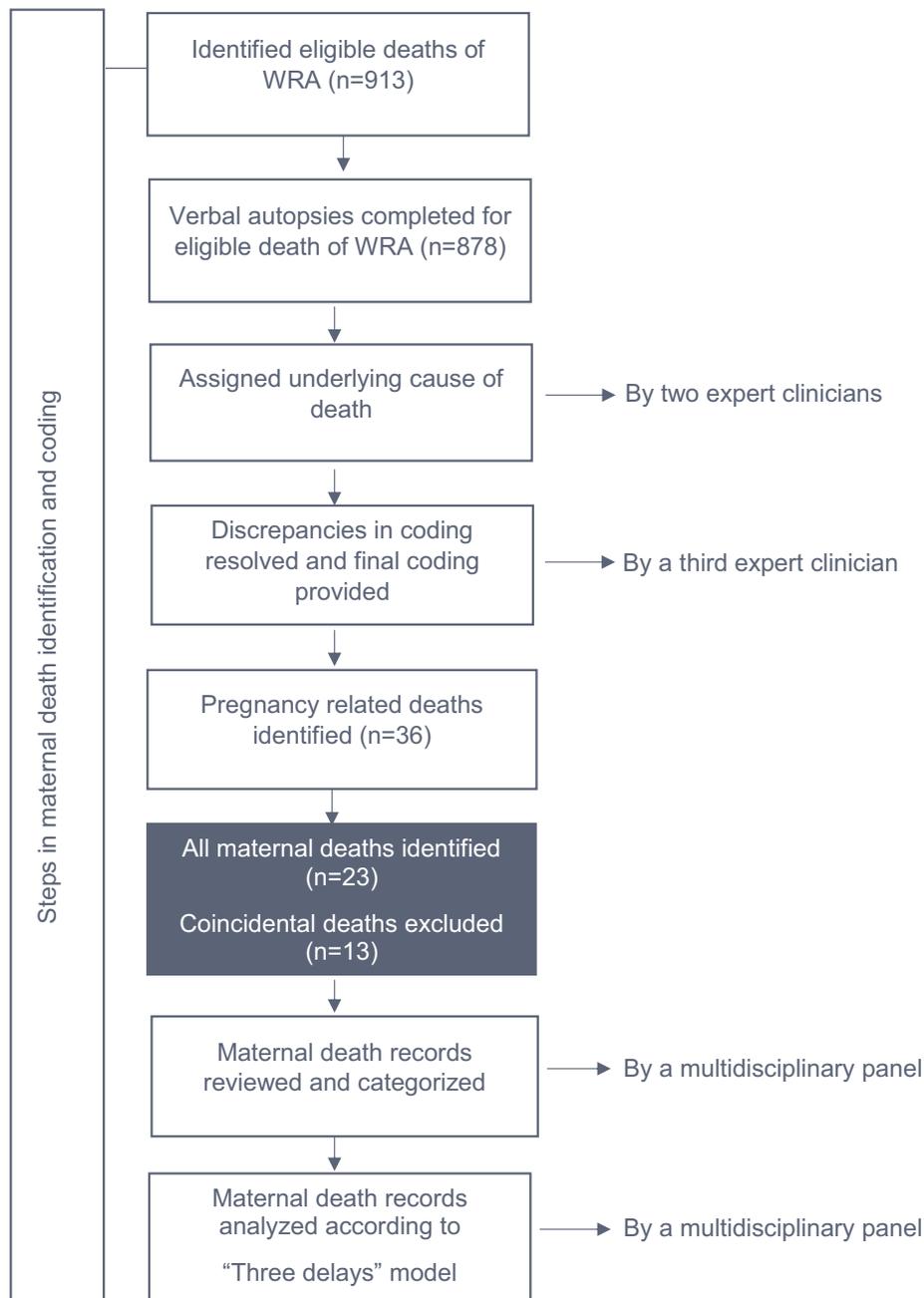
The study protocol was approved by the Georgian Institutional Review Boards of NCDC & PH (IRB 2017–035 and 2019–013) and the Regional Committees for Medical and Health Research Ethics South East Norway (2015/1352). Written informed consent was obtained from all respondents (family members or caretakers of the deceased women) prior to the interviews.

## Results

The study identified a total of 23 maternal deaths during 2012, including 15 (65%) early and eight (35%) late maternal deaths. The overall MMR was 40.3 per 100 000 live births, early MMR was 26.3 per 100 000 live birth. Of the fifteen early maternal deaths, 14 (93%) were direct and one (7%) indirect.

## Causes of Maternal Death

The leading causes of maternal deaths were sepsis (n=5), hemorrhage (n=3), pregnancy-induced hypertension (PIH) (n=2) and embolism (n=1). In other direct causes category, sudden death, unanticipated complication of anesthesia during delivery and complication following intrauterine fetal death, were one death in each (Figure 2). Direct causes of the late maternal deaths were: embolism (n=2) and sepsis (n=1). Indirect causes were cancer (n=3), tuberculosis (n=1), and postpartum suicide (n=1). Coincidental



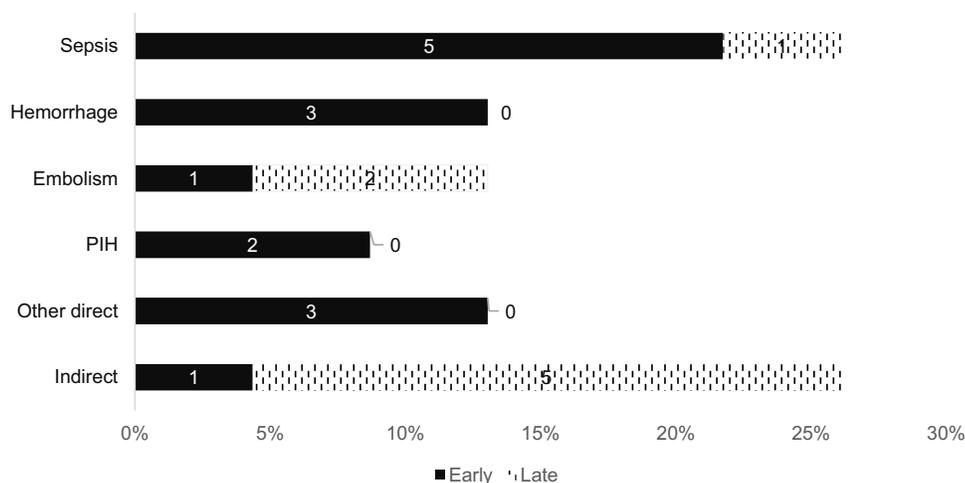
**Figure 1** Maternal death identification and coding, Georgia, 2012.

causes (13), unrelated to pregnancy, were due to transport and other accidents (n=6), cancer (n=6) and liver cirrhosis.

### Selected Characteristics of Women in Relation Causes of Mortality

The study showed that the majority (over 50%) of maternal deaths were among women aged 21–30 years. Importantly, the number of deceased women delivered by cesarean

section was twice as high compared to vaginal deliveries (eight and four, respectively). As many as 26% (n=6) of deaths occurred post-abortion or from ectopic pregnancy. These included early fetal loss (three miscarriages) and two induced abortions, one from a self-attempted termination. Finally, 13% (n=5) of women were still pregnant at the time of death. Women who died from sepsis and embolism tended to deliver by cesarean section and were younger (range 21–30) as compared to the older age groups (Table 1).



**Figure 2** Causes of maternal deaths by time of death, Georgia, 2012.

## Overview of Care

Overall, we found that suboptimal care was provided in 13 (87%) out of 15 early maternal deaths. Similarly, improvements in care which would have made a difference to the outcome in two (67%) of the three late maternal deaths due to direct obstetric causes.

## Early Recognition and Appropriate Management

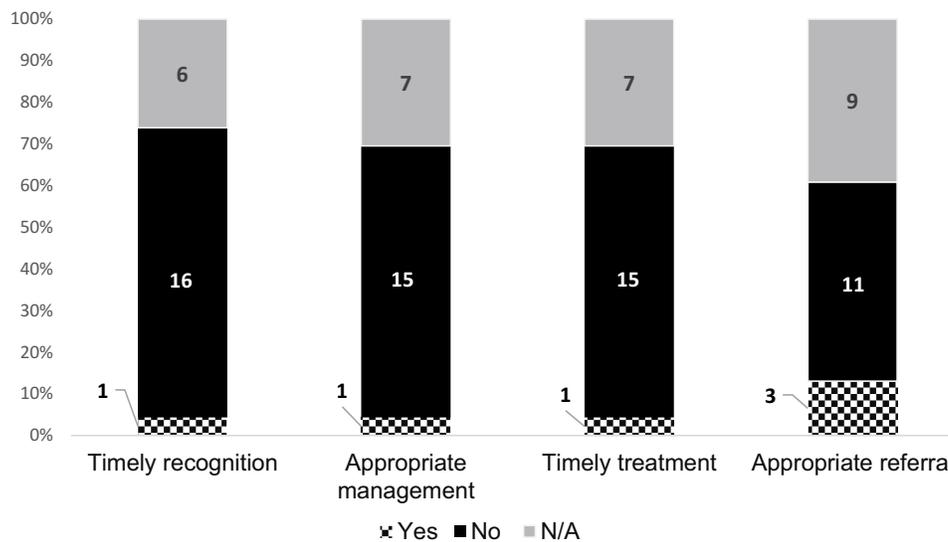
Our study found that delayed recognition of a severe or life-threatening condition was a significant problem. Out of the 23 cases of maternal death, only one (4%) was identified in a timely way. The other 16 (70%) were detected with delays

and for six (26%) indirect deaths, timely identification of the problem was not a relevant factor. Along with delayed recognition, deficiencies were evident in the management of complications in many death cases (65%) (Figure 3).

There were delays in recognizing all sepsis cases (five were early and one was a late death). A significant problem identified was timely recognition of the clinical signs suggestive of infection (Table 2: case 4, case 9 and case 16). Some of the cases (eg case 16, Table 2) evidenced a delay in both timely recognition and treatment of sepsis. Medical records were deficient in half of the sepsis cases, which were missing a full set of vital parameters on day

**Table 1** Selected Characteristics of 23 Maternal Deaths by Main Cause of Death (in Columns), Georgia, 2012

Characteristics	Sepsis/Septic Shock (n=6)	Obstetric Hemorrhage (n=3)	Embolism (n=3)	Preeclampsia/Eclampsia (n=2)	Other Direct (n=3)	Indirect (n=6)	All (n=23)
Age, years							
21–30	4	1	2			3	12
31–40	2	1	1	1		2	7
≥ 40		1		1	1	1	4
Delivery mode							
Miscarriage/ectopic pregnancy	1	2				1	4
Induced abortion	1					1	2
Vaginal delivery	1	1	1			1	4
Caesarean delivery	3		2		1	2	8
Undelivered/pregnant				2	2	1	5
Time of death							
Antepartum				2	2	1	5
Post-abortion	2	2				2	6
Postpartum	4	1	3		1	3	12



**Figure 3** Evaluation of care provided to 23 deceased women by key characteristics, Georgia, 2012.

preceding to or at a time when the diagnoses of infection was made. Additionally, gaps were documented in timing and spectrum of laboratory testing. No blood or other samples were drawn for bacterial culture for presumed infection in five out of six sepsis cases. Although antibiotic therapy was initiated in most cases on the same day as infection was suspected, the delays and use of a proper antibiotic regimen was a significant problem.

Poor management was identified in all three fatal cases of obstetric hemorrhage. The management did not follow any of three basic principles of patient safety: the right patient, the right place, and the right procedure (case 3, Table 2). Although the uterine perforation was detected on time, the curettage was initially performed in a facility where complications could not be properly managed. The woman was transported to another specialized facility without prior stabilization. Her condition deteriorated during transportation. Stabilization measures also were inadequate in the referral hospital. A total hysterectomy was then performed instead of repairing the hole in the posterior wall of the uterus.

In one case of hemorrhage after a spontaneous abortion at mid-pregnancy (case 5, Table 2), the team misinterpreted the clinical signs as bleeding from a cervical laceration. A hysterectomy was conducted too late and failed to save the woman's life.

Similarly, we identified inadequate management of postpartum uterine atony (case 11, Table 2). Initial blood loss was underestimated. Surgical management and hysterectomy were delayed, and insufficient blood transfusion

was applied, despite hemodynamic instability (with a hemoglobin of 50 g/L, and hematocrit of 6.8%).

Poor prophylaxis and management were evident in two of three cases of thromboembolic maternal deaths but had probably no association with the last case due to the time lag of 133 days (case 2 and case 17, Table 2).

Finally, in-depth clinical audit disclosed substantial deficiencies in preeclampsia management. Two women who died from severe preeclampsia had inadequate monitoring of blood pressure and lack effective antihypertensive treatment. Conversely, another woman (case 6, Table 2) received a loading intravenous overdose of magnesium sulfate (10g instead of the recommended 4g). This woman's condition deteriorated within one hour after the toxic dose suggestive of hypermagnesemia.

### Maternal Referral

Along with deficiencies in early recognition and management of maternal complications, the study documented inappropriate and/or delayed referral in 11 (79%) out of 14 cases requiring referral (Figure 2). In six cases of early maternal deaths, the women were not referred in a timely manner or were referred to inappropriate level facilities.

## Discussion

Our study is among the first analyzing the magnitude and pattern of both early and late maternal deaths in Georgia during 2012. Of the eight late maternal deaths identified in the present study, most (7/8: 88%) were unrecognized by the official statistics as maternal deaths. Direct cause of

**Table 2** Individual Overview of Maternal Deaths (n=23), Georgia, 2012

Case #	Timing of Death	Brief History*	Cause of Death	Timely Recognition	Appr. Management	Timely Treatment	Appr. Referral	Quality of Care**
1	Early Maternal	31–40 years old, P1. Admitted to hospital at 18 GW, incomplete abortion. Self-administration of 10 tablets of Misoprostol (Cytotec®) to terminate pregnancy. Refused hospitalization, later due to aggravation of clinical condition, self-referred to the hospital. Curettage of uterine cavity 15 minutes after admission; antibiotics and saline infusion initiated. Developed septic shock, resuscitation started, hysterectomy performed. Condition deteriorated rapidly during the surgery, and she died.	Sepsis/septic shock	No	No	No	No	3
2	Early Maternal	21–30 years old, P0. Admitted to maternity hospital: 39 GW, severe preeclampsia, obesity, uterine fibroids, intrauterine fetal growth restriction, cephalic presentation, in the first stage of labor. CS performed 7 hours after admission upon woman's request. Discharged on the 4 <sup>th</sup> day after delivery in satisfactory condition. On the 5 <sup>th</sup> day after delivery, sudden death at home.	Embolism	No	No	No	Yes	3
3	Early Maternal	≥ 40 years old, P2. Admitted to hospital at 14 GW, incomplete abortion. Curettage of the uterine cavity. Postoperative hemorrhage - suspected uterus perforation. Saline infusion started. Woman transported to the district hospital. At admission acceptable circulation, mentally altered, Hb-52 g/L, Ht-7.6%. Total hysterectomy performed 20 minutes after admission. Infusion with 9000 mL Crystalloids, 2 packs of fresh-frozen plasma. At the end of the surgery: Hb-36g/L, Ht-3.5%. Woman died despite resuscitation performed.	Obstetric hemorrhage	Yes	No	No	No	3
4	Early Maternal	21–30 years old, P0. Admitted to maternity hospital: 38 GW, cephalic presentation, first stage of labor, pre-labor rupture of membranes. CS performed 50 minutes after admission upon woman's request. Antibiotic therapy initiated immediately after CS. Two days postpartum fever, no laboratory tests performed, antibiotic therapy continued. On day five fever persisted, laboratory tests performed, antibiotic regimen changed. Septic shock developed on day eight; patient died shortly after the shock.	Sepsis/septic shock	No	No	No	No	3

(Continued)

Table 2 (Continued).

Case #	Timing of Death	Brief History*	Cause of Death	Timely Recognition	Appr. Management	Timely Treatment	Appr. Referral	Quality of Care**
5	Early Maternal	31–40 years-old, P2. Admitted to hospital at 18 GW, spontaneous abortion. Treatment initiated with Oxytocin, macerated fetus spontaneously delivered. Curettage of the uterine cavity performed, bleeding started during the procedure. 10 IU of Oxytocin administered I/M. Bleeding continued. Transfusion of saline solution along with 20 IU Oxytocin. Fresh and frozen plasma transfused. Bleeding continued, hysterectomy performed after 5 hours. Post-operatively condition deteriorated, despite resuscitation measures died 12 hours post-surgery.	Obstetric hemorrhage	No	No	No	No	3
6	Early Maternal	≥ 40 years old, P4. Admitted to maternity hospital at 32 GW, essential hypertension. At admission: blood pressure (BP) 200/120 mmHg, proteinuria +2. No other laboratory tests performed. Bolus dose of Magnesium sulfate therapy started. One hour after Magnesium Sulphate injection, condition worsened. Overdose suspected. Patient died despite resuscitation measures.	Preeclampsia	No	No	No	Yes	3
7	Early Maternal	21–30 years old, P1. Admitted to maternity hospital at 39 GW, fetus in cephalic presentation, first stage of labor. Elective CS performed. Postoperative period uncomplicated. Discharged home in satisfactory condition. Re-admitted to hospital on day 5 after discharge with fever: 38.9°C, Pulse-124. Blood tests and abdominal ultrasound performed. Peritonitis diagnosed. Antibiotic therapy started. Hysterectomy performed. After the surgery, condition deteriorated further; she died 2 days later.	Sepsis/septic shock	No	No	No	No	3
8	Early Maternal	21–30 years old, P1. Admitted to maternity hospital at 16 GW, spontaneous abortion, fever 39°C; cervical dilatation. Fetus expelled, curettage of uterine cavity performed. Antibiotic therapy initiated. After curettage condition worsened, septic shock diagnosed, and resuscitation initiated. Two days later the patient died.	Sepsis/septic shock	No	No	No	No	3

9	Early Maternal	31–40 years old, P3 Admitted postpartum to maternity hospital with fever (39° C). On day 9 after CS, discharged home, despite fever. Ultrasound examination performed, no laboratory tests. Antibiotic therapy prescribed and patient discharged home. Woman's condition worsened, re-admitted to hospital 8 days after discharge. Blood and urine tests performed, surgical site infection suspected; wound drainage conducted, but condition worsened further. Hysterectomy performed; the patient died shortly thereafter.	Sepsis/septic shock	No	No	No	No	No	3
10	Early Maternal	31–40 years old, P2. Self-referral at 33 GW to outpatient clinic with difficulty breathing and chest pain. BP 200/110 mmHg, no laboratory tests performed. Woman referred to district hospital within 1-hour after admission, condition deteriorated, and died despite resuscitation measures.	Preeclampsia/ Eclampsia	No	No	No	No	No	3
11	Early Maternal	21–30 years old, P0. Admitted in active labor, 41 GW, following an uncomplicated pregnancy. Normal progress in labor and delivery of a 4200-gram neonate. After placenta expulsion, 1 hour after delivery the patient developed atonic uterine bleeding. Uterotonics administered: Oxytocin 5 IU bolus dose and 10 IU diluted in 500 mL saline. BP 100/70, pulse 90. Transfusion of crystalloids commenced. After a short pause, the bleeding continued. Hysterectomy and resuscitation measures performed. Woman died shortly after surgery.	Postpartum Hemorrhage	No	No	No	No	N/A	3
12	Early Maternal	21–30 years old, P0. Admitted at 23–24 GW to referral hospital unconscious. Reportedly woman had not felt fetal movements in a week. IUFD confirmed at the first point of contact, at the district hospital. Antibiotic treatment initiated. Induction of labor. Four hours later, the patient's condition deteriorated. Pulse 120, BP 90/60, she developed respiratory distress. Woman transported to referral hospital and died shortly afterward.	Complication following intrauterine death.	No	Yes	Yes	No	No	2
13	Early Maternal	21–30 years old, P0. Elective CS at term. Esophageal intubation, final peri-arrest intubation. The patient suffered a cardiac arrest and died.	Complication of anesthesia/Failed Intubation	No	No	No	No	Yes	3
14	Early Maternal	>40 years old, multipara. Sudden death at home whilst 8 weeks GA. No autopsy.	Undefined(Sudden death at home)	N/A	N/A	N/A	N/A	N/A	N/A
15	Early Maternal	21–30 years old, P0. Admitted at 24 GW to referral hospital in altered mental status, fever, preceding otitis media with outpatient antibiotic treatment. Cranial CT on admission, laboratory tests, and antibiotic treatment initiated, developed coma and died within 24 hours.	Bacterial meningoencephalitis	No	No	No	No	Yes	3

(Continued)

Table 2 (Continued).

Case #	Timing of Death	Brief History*	Cause of Death	Timely Recognition	Appr. Management	Timely Treatment	Appr. Referral	Quality of Care**
16	Late Maternal	21–30 years old, P0. Admitted to referral hospital, 54 days postpartum after vaginal delivery, unconscious, transferred from district hospital with diagnosis of septic shock. Two admissions and discharges prior to transfer to referral hospital. Antibiotic therapy, hysterectomy performed in district hospital. Despite resuscitation measures, the woman died three days later.	Sepsis	No	No	No	Yes	3
17	Late Maternal	31–40 years old, P2. Died at home, 133 days after CS.	Embolism	N/A	N/A	N/A	N/A	3
18	Late Maternal	21–30 years old woman, P0. Died at home, 116 days after vaginal delivery.	Embolism	N/A	N/A	N/A	N/A	N/A
19	Late Maternal	21–30 years old, previous parity unknown. Admitted at 8 GW to hospital for vaginal bleeding, incomplete abortion. Vacuum aspiration performed. Re-admitted after 2 days with abdominal pain, ultrasound investigation confirmed ruptured ectopic pregnancy. Surgery performed and discharged from hospital in satisfactory condition. Died 69 days afterwards in intensive care unit treated for leukemia.	Myeloid leukemia	N/A	N/A	N/A	N/A	N/A
20	Late Maternal	21–30 years old woman, P1. Died 46 days after CS, in the ambulance during transfer to hospital. Prior to pregnancy, treatment of active tuberculosis. Three weeks of complaints: shortness of breath and fatigue.	Tuberculosis	No	No	No	N/A	3
21	Late Maternal	31–40 years old. Diagnosed with breast cancer during pregnancy. Initiated treatment after delivery, died in the hospital 186 days postpartum.	Breast cancer	N/A	N/A	N/A	N/A	N/A
22	Late Maternal	Woman ≥ 40-years old, previous parity unknown. Died at home 90 days after an abortion. Curettage performed at 12 weeks of gestation. History of breast cancer treatment. Diagnosed with recurrent breast cancer during pregnancy.	Breast cancer	N/A	N/A	N/A	N/A	N/A
23	Late Maternal	31–40 years old, Previous parity unknown. Died 167 days after vaginal delivery. Committed suicide, no known history or treatment for mental health disorders.	Suicide	No	N/A	N/A	N/A	N/A

**Notes:** \*For the purpose of anonymization, only previous parity (not gravidity) and age categories are provided. \*\*1 – good care; 2 – improvements of care which would have made no difference to the outcome, and 3 – improvements of care which would have made a difference to the outcome.

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**Abbreviations:** P0, nulliparous prior to present pregnancy; P1 - 1, delivery prior to present pregnancy; CS, cesarean section; GW, gestational weeks; Hb, hemoglobin; Ht, hematocrit; CT, computer tomography; IUFD, intrauterine fetal death; N/A, not available.

one officially reported late maternal death following ectopic pregnancy was reclassified as indirect only after the comprehensive case review, while other late maternal deaths were misclassified in other ICD-10 chapters.

With the introduction of an electronic notification system, it is noteworthy that the remarkable progress has been achieved in Georgia in death registration coverage, and the death certification process has improved. However, despite well documented improvements, the quality of cause-of-death certification and coding has still been overlooked by Georgia's vital registration system. Most pregnancy check-boxes remain empty within one year postpartum following a maternal death. This study's association between death and pregnancy was made possible only through data matching or birth records linkage. The coupling of pregnancy and female deaths is particularly challenging with deaths occurring during pregnancy, after abortion, or any deaths due to indirect obstetric causes. Official statistics systems have not captured late maternal death in many countries who have conducted confidential enquiries, including Denmark, Ireland, Finland, and the UK.<sup>23</sup> Our study confirms that the complications of pregnancy and birth may surpass 42 days postpartum. It underscores the importance of monitoring, proper classification and the integration of late maternal death into official statistics.

Most of the late maternal deaths documented in our study were indirect, with the leading cause being malignant neoplasms. This finding is in line with a prior study from Italy, where cancer was a leading cause of late maternal deaths, occurring in 38.8%.<sup>13</sup> Another indirect cause of late maternal death was tuberculosis. The outcome for pregnant women with tuberculosis is poorer, with a six-fold increase in the risk of maternal mortality.<sup>24</sup> Treatment adherence in previous treatment episodes was the cause of an ensuing maternal death from tuberculosis in our study. While the proportion of successfully treated patients with tuberculosis has improved markedly among new cases, Georgia still has a high percentage (27%) of clinical failure or poor treatment adherence in previous tuberculosis treatment episodes.<sup>25</sup> Overall, critical aspects of care among the late maternal deaths were indicative of deficiencies in preconception care in Georgia, where an improvement might have prevented or limited some maternal deaths. Preconception care provides critical opportunities to detect and manage chronic diseases and other health risks, and better protect the health of women with non-communicable as well as communicable diseases and their offspring.

In addition to identifying the causes of maternal death, the individual death audits provide important insights into the organization and delivery of maternal health services in Georgia. Overall, the study showed deficiencies and delays at all stages of provision of care. While analyzing a third delay (ie delivery of adequate care within the health facility), we assessed the care at the first admission to a facility and at the referral hospital, including timely recognition, appropriate management and treatment delay, and any delays in transfer to another higher-level facility. Lack of effective and timely care at any of these time points may aggravate a patient's condition and result in a poor outcome.<sup>26-29</sup> In most of the reviewed cases, we found either delays in referral, referral to a facility not capable of providing the required level of care, or both. For example, facilities that managed the miscarriages and related complications, such as bleeding and uterus perforation leading to maternal death, were basic maternity units with limited capacity to handle such complications or to stabilize the patient before referring to another facility.

We found substandard care in which improvements would have made a difference to the outcome in 13 (87%) of early and two (67%) of the three late maternal deaths from direct obstetric causes. The findings are in line with UK confidential enquiries to maternal deaths and studies from Netherlands which identified that improvements in care would have made a difference to outcomes for over 90% of women who died.<sup>30,31</sup>

Sepsis or septic shock was the most common underlying direct cause of maternal deaths in Georgia in 2012. Substandard care wherein improvements could have made a difference to the outcome was found across all sepsis cases. Delay in recognition and diagnosis of sepsis was responsible for majority of maternal deaths from sepsis documented by our study. This agrees with findings from other countries.<sup>32</sup> Achieving a low sepsis-associated mortality is based on rapid triage using a risk-scoring system and early therapy, including appropriate antibiotic treatment within one hour of a suspected diagnosis.<sup>33,34</sup> As such, obstetricians should maintain a higher level of alert and provide information to pregnant and postpartum women on the importance of seeking timely medical care. Moreover, the best care for sepsis is multidisciplinary; that is, where different specialists are involved in case management at early stage of case identification.<sup>17</sup> A multidisciplinary approach should become a standard of care for Georgia as well, in addition to wide-scale adherence to basic principles of patient care; namely,

regular measuring, monitoring and recording of full spectrum of vital parameters, and strict infection control. In line with some other studies,<sup>35,36</sup> we found more maternal sepsis among younger women and in women delivered by caesarean section. Post-operative infection was the source of sepsis in our study, while respiratory infections were dominant sepsis cases in the maternal health studies from the high-income countries.<sup>3</sup>

Inadequate antibacterial prevention and/or timely treatment was the main element of substandard care we found by our study. Routine antibiotic use prior to the initiation of or during caesarean section is recommended for women undergoing caesarean section.<sup>20</sup> No antibiotic prophylaxis was provided in either of the three women who delivered via caesarean section and who died from sepsis or septic shock. The medical records review of these women does not provide evidence of clinical signs of sepsis prior to the surgery. Our data point to the fact that sepsis represents a major threat to maternal health in Georgia, and that there is frequently late recognition then suboptimal care. Thus, improvements in this area are urgent.

Whilst the number of women who died from pregnancy induced hypertension was low in our study, substandard care was evident for these women. Important opportunities are present to further improve care, prevent deaths and reduce morbidity from pregnancy induced hypertension. Identifying women with risk factors<sup>21</sup> is important for early recognition as well as proper antenatal care, referral, and appropriate management. In our study, risk factors were present in both cases of preeclampsia. However, no increased schedule of antenatal care for these women with pre-existing hypertension was provided, and no visits were scheduled between 28 and 33 weeks of gestation. This is too long a time period without medical contact for the high-risk women.

In Georgia, a full assessment for pre-eclampsia or HELLP syndrome, including a spectrum of blood tests, is strongly recommended in women presenting with symptoms or signs of this syndrome. Yet, in our study, neither woman received proper laboratory tests, imaging investigations or treatment, according to the national clinical practice guidelines. Poor compliance with evidence-based clinical practice guidelines and protocols, as demonstrated by our study, remains a challenge in Georgia and across many countries. Multi-faceted, tailored solutions, going beyond simple dissemination of guidelines/protocols should be extensively implemented by Georgia to increase compliance with existing evidence-based protocols. Some

European countries, such as UK and Norway, which began implementing targeted interventions to lower avoidable maternal mortality over the last decade, have reached 10-fold reductions in deaths from pre-eclampsia and eclampsia or have achieved a zero level of maternal deaths from preeclampsia. Maternal death inquiries of previous years in these countries identified substandard care of hypertensive complications.<sup>4,37,38</sup>

Pregnancy and particularly the delivery mode by caesarean section increases the risk of thromboembolism, further aggravated in the immediate postpartum period. Thromboembolism was the third major cause of maternal deaths in our study. We identified substandard care in at least two of the three maternal deaths due to thromboembolism. Suggested preventive interventions include early pregnancy and postpartum risk assessment for thromboembolism and thromboprophylaxis with low-molecular weight heparin after caesarean delivery in women with risk factors (other than previous venous thromboembolism or thrombophilia).<sup>18,19</sup> Most importantly, timely referral is recommended for all pregnant or postpartum women who complain of newly emerged dyspnea, for evaluation of thromboembolism or pulmonary embolism.<sup>18</sup>

Delay in the diagnoses and adequate management of maternal hemorrhage are important substandard care factors that may lead to severe maternal morbidity or death.<sup>39</sup> Several studies have found that most deaths from hemorrhage are preventable.<sup>7,40,41</sup> Early recognition and adequate assessment of blood loss in the management of obstetric hemorrhage is the cornerstone of care. In our study, blood loss was significantly underestimated in all three maternal deaths from hemorrhage. In addition, the clinical management did not comply with the national clinical practice guidelines. In the case of major obstetric hemorrhage, there should be no delay in surgical management. While no other surgical management procedures were used before opting for hysterectomy, all three women in our study underwent delayed hysterectomy. The strategies for blood transfusion also were inadequate. Furthermore, the risk of postpartum hemorrhage can be reduced by 60% with active management of the third stage of labor and routine administration of prophylactic uterotonic drugs immediately after delivery.<sup>22</sup> Despite strong recommendations in force, there is still a significant variation in uterotonic drug practices in Georgia.

The bundle approach<sup>42-44</sup> recently has been proposed as an intervention to address suboptimal adherence to hemorrhage and other clinical practice guidelines and to

improve the quality of care. Further, staff education and simulation exercises could help to improve accuracy of the blood loss measurement.<sup>45,46</sup> Unfortunately, no quality of care improvement strategies or continuous medical education and audits with multidisciplinary morbidity and mortality reviews were required or implemented by health facilities in Georgia at the time of the study period.

Our findings from Georgia highlight the need for improvements in quality of obstetric care to reduce maternal deaths. Since 2015, several initiatives have been implemented to reduce avoidable maternal deaths. These initiatives include in-service training courses for obstetrician-gynecologists, midwives and intensive care specialists and the updating of national clinical practice guidelines. Health systems improvements have been implemented. They aim to regionalize specialized maternal and newborn care services and create a coordinated system of care between different facility levels. These efforts led to improvements in facility infrastructures, scope of practice and definition of competencies at each level along with a greatly strengthened referral system. Further acceleration of these initiatives and systemic changes to improve the quality of care offer a strong hope of decreasing in preventable maternal mortality.

One of the strengths of our study lays in the opportunity to interview family members to get the details of each patient's case and thus providing a reliable clinical timeline prior to the maternal death. The study was also strengthened by a comprehensive methodology likely to include all deaths within a year of abortion and non-facility deaths, with no or less likely missing number of deaths of WRA within a year following delivery. The study also had the advantage of being able to access and use data from hospitalizations during pregnancy and one year before the fatal event. However, the study did not include a detailed review of medical records or characteristics of care for late maternal deaths due to indirect causes. Additionally, postmortem autopsies -important to examine the cause and factors that contribute to death<sup>47</sup> - were not performed in any of the 23 maternal death cases, due mainly to cultural challenges related with postmortem autopsy practices in Georgian society.

## Conclusions

Most maternal deaths which were analyzed in this study were potentially preventable. The clear implication is that improvements in the quality of care are necessary to

reduce maternal mortality. While we recognize that evaluation of substandard care may lack robustness, the cases of maternal mortality in our study illustrate the presence of failures in quality of care such as delayed and misdiagnoses, inadequate treatment, failure to follow national protocols and delays or inappropriate referrals to manage obstetric emergencies. Comprehensive, multi-dimensional, proactive strategies are of paramount importance to implement efforts to address these challenges and to minimize preventable maternal deaths. Recommended actions include: (1) routine periodic national analyses and monitoring of maternal deaths; (2) establishing an internal (facility-based) clinical audit system to guide the design of obstetric interventions and policies; (3) enhancing active surveillance for identification and registration of late maternal deaths; (4) improving routine postpartum care focusing on early recognition of complications to reduce late maternal deaths; (5) introducing a mandatory continuous medical education system; (6) implementing quality improvement initiatives to address modifiable risk factors; and (7) introducing mechanisms to reward quality and safety of maternity care, including financial incentives for measured quality of care and public reporting of healthcare quality data.

## Ethics

The study was conducted in accordance with the Helsinki Declaration.

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## Author Contributions

All authors made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; took part in drafting the article or revising it critically for important intellectual content; agreed to submit to the current journal; gave final approval of the version to be published; and agree to be accountable for all aspects of the work.

## Disclosure

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