

U.S. Department of Health and Human Services
Office of Inspector General



Instances of IHS Labor and Delivery Care Not Following National Clinical Guidelines or Best Practices

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December 2020, OEI-06-19-00190





Why OIG Did This Review

During a review of medical records for the Office of Inspector General (OIG) study *Incidence of Adverse Events in Indian Health Service Hospitals* (OEI-06-17-00530), our clinician-reviewers identified instances in which labor and delivery patients received care that did not follow national clinical guidelines or best practices. We conducted this companion study because most of these instances, although concerning, did not result in patient harm, and therefore do not appear in our main report about adverse events. Due to the small number of labor and delivery patients included in this review and our sample design, these instances are not projectable to all labor and delivery patients in Indian Health Service (IHS) hospitals.

How OIG Did This Review

We reviewed medical records associated with 48 labor and delivery patients to identify instances in which providers did not follow national clinical guidelines or best practices. For each record, an obstetrics nurse and an obstetrician-gynecologist—each with specialized experience in patient safety—assessed whether the care met national clinical guidelines for diagnosing and treating postpartum hemorrhage, induction of labor, delivery via Caesarean section, and diagnosis and treatment of severe hypertension/preeclampsia. In addition, our reviewer examined whether the diagnosis of postpartum hemorrhage incorporated the best practice of quantitative estimation of blood loss.

We also asked IHS hospitals to describe training for providers of maternal care, and their implementation of the Alliance for Innovation on Maternal Health (AIM) “bundles” of maternal-safety best practices.

Instances of IHS Labor and Delivery Care Not Following National Clinical Guidelines or Best Practices

Key Takeaway

Slightly more than half of the 48 IHS labor and delivery patients in our sample received care that did not follow national clinical guidelines or best practices. For about half of these patients, providers did not use the best practice of quantitative estimation of blood loss during a postpartum hemorrhage.

What OIG Found

We found that 27 of 48 labor and delivery patients (56 percent) had some aspect of care that did not follow national clinical guidelines (13 patients), did not use best practices for blood loss estimation (8 patients), or included both concerns (6 patients) during their stays at IHS hospitals.

Postpartum hemorrhage is one of the most severe maternal health complications and is rare nationally, affecting about 1 to 3 percent of deliveries. Among the 48 IHS labor and

delivery patients in our sample, 16 patients (33 percent) experienced a postpartum hemorrhage. Most of these patients—14 of the 16—received care related to the hemorrhage that did not follow national clinical guidelines or best practices. For some patients, IHS hospital staff did not diagnose the hemorrhage in a timely manner, resulting in delays in treatment that could have reduced the excessive bleeding. Other instances of care included IHS providers not following national clinical guidelines when inducing labor. Of the 13 patients in our sample with induced labor, providers did not follow national clinical guidelines for 10 patients. Most of these cases were related to inappropriate doses of induction medication.

IHS has also taken steps to directly address improvement in labor and delivery services via its ongoing implementation of maternal-safety best practice “bundles,” or sets of maternal-safety best practices, developed by AIM. Yet at the time of our review, 3 of the 10 IHS hospitals with labor and delivery units had yet to implement any of the AIM best practice bundles as requested by the IHS Chief Medical Officer.

What OIG Recommends and How the Agency Responded

OIG recommends that IHS comprehensively assess its labor and delivery practices and consider changes based on the results of this assessment. Specific to postpartum hemorrhage, OIG recommends that IHS provide guidance to its hospitals and training to clinicians focused on diagnosing and treating postpartum hemorrhage. Finally, OIG recommends that IHS encourage and support its hospitals in adopting AIM’s maternal-safety best practices. IHS concurred with our recommendations and described actions it has already taken toward implementation. These efforts include facility site visits and expanded training. IHS also reported that all IHS hospitals that provide planned childbirth services have implemented the AIM guidance for postpartum hemorrhage and severe hypertension.

TABLE OF CONTENTS

BACKGROUND	1
Methodology	6
FINDINGS	9
Slightly more than half of the IHS labor and delivery patients in our sample received care that did not follow national clinical guidelines or best practices	9
Postpartum hemorrhages were unusually common in our sample and were sometimes associated with delays in diagnosis	10
Other instances of care that did not follow national clinical guidelines in our sample were related to induction of labor and medication management	12
Three of the 10 IHS hospitals with labor and delivery units did not implement any of the AIM “bundles” of maternal-safety best practices as requested by IHS headquarters	15
RECOMMENDATIONS	16
IHS should assess its labor and delivery practices and consider practice improvements based on the findings of this assessment	16
IHS should take steps to ensure that IHS providers employ best practices in diagnosing and treating postpartum hemorrhage	16
IHS should encourage and support greater adoption of AIM bundles of maternal-safety best practices	17
AGENCY COMMENTS AND OIG RESPONSE	18
APPENDICES	19
A. Summary of Methodology for Companion Study <i>Incidence of Adverse Events in Indian Health Service Hospitals</i> (OEI-06-17-00530)	19
B. Glossary of Selected Terms	22
C. Sample Counts by Stratum	24
D. Agency Comments	26
ACKNOWLEDGMENTS AND CONTACT	29
ABOUT THE OFFICE OF INSPECTOR GENERAL	30
ENDNOTES	31

BACKGROUND

Objectives

To describe care provided to a sample of Indian Health Service labor and delivery patients that did not follow national clinical guidelines or best practices.

This study is a companion to *Incidence of Adverse Events in Indian Health Service Hospitals* (OEI-06-17-00530), a study that identified patient harm caused by medical care. During the process of reviewing medical records for the study of adverse events, our clinician-reviewers identified instances in which labor and delivery patients experienced care that did not follow national clinical guidelines or best practices. Most of these instances did not result in patient harm and therefore do not appear in our main report about adverse events.

Quality of Maternal Care in Hospitals

Morbidity (illness and/or disease) and mortality (death) in labor and delivery are a significant public health challenge, with U.S. rates markedly higher than those in other industrialized countries. This has led to growing concern from the public about the quality of maternal care in U.S. hospitals.^{1,2} Research has found that most severe maternal morbidity and most pregnancy-related deaths are preventable and could be the result of substandard care.^{3,4}

The Centers for Disease Control and Prevention (CDC) defines pregnancy-related mortality as the “death of a woman while pregnant or within 1 year of the end of a pregnancy.”⁵ Studies suggest that American Indian and Alaskan Native (AI/AN) women are 2.5 to 4.5 times more likely to suffer pregnancy-related mortality than their white, non-Hispanic counterparts.^{6,7} During our study period, IHS reported that no maternal deaths occurred in its hospitals. In fiscal year (FY) 2017, about 6 percent of AI/AN deliveries nationally occurred in IHS hospitals.⁸

The CDC defines severe maternal morbidity as including “unexpected outcomes of labor and delivery that result in significant short- or long-term consequences to a woman’s health.”⁹ Severe maternal morbidity is also more likely to afflict AI/AN women, with this group experiencing severe maternal morbidity at a rate 1.7 times higher than that of non-Hispanic white women.¹⁰ The reasons for this disparity are unclear but may be partly explained by differences in how AI/AN women receive care. For example, AI/AN women are more than twice as likely to report late prenatal care or no prenatal care (12 percent of births) than are non-Hispanic white women (5 percent of births).¹¹

Postpartum Hemorrhage

Postpartum hemorrhage is a potentially serious complication that occurs during a small proportion of deliveries (between 1 and 3 percent) and accounts for 11 percent of the pregnancy-related deaths in the United States.^{12, 13, 14} Postpartum hemorrhage is excessive bleeding immediately following birth and is characterized by a decrease in blood pressure, an increase in heart rate, and a decrease in red blood cell count.¹⁵ Effective diagnosis of postpartum hemorrhage requires an accurate estimate of the amount of blood lost, with treatment ranging from administration of medication to, in more severe cases, surgical interventions to tie off or seal blood vessels in the uterine wall.¹⁶

Prompt diagnosis minimizes the impact of postpartum hemorrhage on a patient because it enables the delivery of timely and appropriate treatment.¹⁷ There are two methods of diagnosing postpartum hemorrhage: visual estimation of blood loss; and quantitative estimation of blood loss. With visual estimation, providers estimate the amount of blood lost based on the amount of blood they can see, such as blood on laparotomy pads or on surfaces in the labor and delivery room.¹⁸ With quantitative estimation, providers physically collect blood, such as via the use of a drape when the blood drains into a measuring pouch or via the use of sponges that can be weighed to determine the amount of blood lost.¹⁹ Research conducted over the past few decades has shown that visual estimation tends to underestimate the amount of blood loss caused by postpartum hemorrhage, which in turn could delay the response to the postpartum hemorrhage.^{20, 21, 22, 23} Although the benefits of quantitative estimation are well established in research, one study in 2018 was unable to demonstrate that the improved accuracy of this practice was associated with better patient outcomes.²⁴ The American College of Obstetricians and Gynecologists (ACOG) officially endorsed quantitative estimation of blood loss as a best practice beginning in December 2019.²⁵

For this study, we included quantitative estimation of blood loss as a “best practice.” Notably, the sample of patients reviewed for this study received services during 2017, when support for quantitative estimation was not as widespread as it is today.

Induction of Labor

Induction of labor is the use of medication (such as synthetic oxytocin) and devices to facilitate labor sooner than it would occur naturally.²⁶ Labor may be induced on either an elective basis or when concerns arise about the health of the mother or infant.²⁷ A provider might schedule an elective induction to avoid an unattended delivery if a patient lives far from a hospital.²⁸ The health-related reasons for inducing labor include the following: the pregnancy is approaching 2 weeks past the due date and labor has yet to begin; there is a uterine infection; there is not enough amniotic fluid surrounding the fetus; the growth of the fetus has stalled; or the mother has diabetes.²⁹ Risks associated with induction include a deceleration of the infant’s heart rate caused by medication; an increased risk of infection for mother and infant; and

increased risk that uterine muscles will not properly contract after delivery, which can lead to postpartum hemorrhage.³⁰ The prevalence of labor induction nationally increased substantially from 1990 to 2018. In 1990, labor was induced for about 10 percent of deliveries, compared to nearly 27 percent of deliveries in 2018.^{31, 32}

Quality of Care

The Institute of Medicine defines national clinical guidelines as “recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.”³³ Medical providers and clinicians are not required by the Centers for Medicare & Medicaid Services (CMS) or other authorities to adhere to these guidelines and practices, but the absence of them might indicate that providers delivered substandard care.

In a national review of hospitalized Medicare patients, OIG found that many adverse events and temporary harm events were the result of substandard care, including instances in which national clinical guidelines or best practices were not followed.³⁴ An adverse event refers to patient harm from medical care or within a health care setting, and includes failure to provide needed care. An adverse event indicates that the care resulted in an undesirable clinical outcome not caused by underlying disease. Temporary harm represents an outcome that did not cause lasting harm and is often less severe than an adverse event.

Adverse events and temporary harm events are not always the result of substandard care and are not always preventable. For example, providers may not be able to prevent an allergic reaction if they do not have prior knowledge that the patient is allergic. Also, not all instances of substandard care result in patient harm.

Indian Health Service

IHS provides health care services directly to AI/ANs through IHS-operated facilities, and provides financial support for Tribes to operate their own health care facilities.³⁵ IHS manages its services through 12 Area Offices. Each Area Office is managed by an Area Director and provides support and oversight for the health care delivery sites located within the corresponding geographic area. Each Area Office also includes clinical leadership working alongside the Area Director. IHS health care delivery sites include hospitals, health stations, and other types of facilities.

Indian Health Service Hospitals

Currently, IHS directly operates 24 acute-care hospitals, many of which are in remote locations. During the period we examined in this study—FY 2017—IHS operated 26 hospitals. (Since the end of FY 2017, two Tribes have assumed operating responsibility for two hospitals.) IHS acute-care hospitals are typically small, with most having fewer than 30 beds each in FY 2017. In that same year, the total number

of inpatients across all IHS-operated hospitals on any given day was approximately 158. The average daily census for individual IHS hospitals was approximately six inpatients per hospital, and the average length of stay for these patients was 3.9 days.³⁶

Labor and Delivery Units at Indian Health Service Hospitals

IHS requires each labor and delivery unit at its hospitals to be staffed by at least one registered nurse who has had advanced clinical preparation and experience in obstetric nursing.³⁷ Ten hospitals reported having an active labor and delivery unit during FY 2017. IHS also requires labor and delivery units to have clerical support and technicians to assist with the labor and delivery process.³⁸ IHS requires that an obstetrician-gynecologist (OB/GYN) and a certified nurse midwife be present at each facility that performs at least 200 deliveries per year.³⁹ In FY 2017, providers at 6 IHS hospitals performed altogether at least 200 deliveries.

Quality and Safety at Indian Health Service Hospitals

IHS instructs its hospitals to “meet the requirements of a nationally recognized accrediting or certifying body.”⁴⁰ The accrediting organizations that IHS uses must support the reimbursement requirements established by CMS.⁴¹ Among these are requirements included in the Medicare Conditions of Participation (CoPs), which is a set of minimum standards for quality and safety. One of the CoPs requires that hospitals develop and maintain Quality Assessment and Performance Improvement programs.⁴² As part of such a program, a hospital must “track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital.”⁴³

Indian Health Manual

The Indian Health Manual (IHM) is the reference for policy and procedural instructions specific to IHS, and it includes a chapter dedicated to maternal and child health. For example, the IHM has rules and requirements that IHS facilities should follow specific to standing orders issued by the physician and the conduct of labor and delivery.⁴⁴ The IHM also lists guidelines from professional organizations that IHS facilities should use to best inform their procedures in the delivery of maternal care.⁴⁵ Additionally, IHS directs all its health care facilities to follow the standards and recommendations of ACOG and the Joint Commission (an accrediting body) with respect to delivery by emergency Caesarean section.⁴⁶

Implementation of AIM Bundles of Maternal-Safety Best Practices

In August 2017, the IHS Chief Medical Officer sent an email to all Area Directors requesting that IHS hospitals with labor and delivery units implement at least 1 of the 12 “bundles” of maternal-safety best practices issued by the Alliance for Innovation

on Maternal Health (AIM).⁴⁷ AIM is a national initiative including several prominent organizational stakeholders in the field of maternal health, such as ACOG. Each of the 12 AIM bundles for maternal safety is a collection of best practices regarding a particular aspect of maternal care and cover a variety of maternal health topics including hemorrhage; severe hypertension/preeclampsia; postpartum care access and standards; and reduction of peripartum racial disparities.⁴⁸ The IHS Chief Medical Officer request to its hospitals specifically focused on the AIM bundles related to hemorrhage and severe hypertension.

Recent IHS Efforts To Improve Quality

IHS has also developed plans in recent years to improve hospital management and performance, including creating a new Office of Quality and implementing a framework for improving quality and establishing a 5-year strategic plan as well as steps focused specifically on maternal care.

ACOG Recommendations to IHS. Since 2014, IHS has taken some steps to begin implementing recommendations that ACOG made to IHS to improve maternal care.⁴⁹ For example, the IHS Chief Medical Officer made hiring a national maternal and child health coordinator a top priority in FY 2020 for the Office of Clinical and Preventive Services.⁵⁰ The Chief Medical Officer also appointed a Chief Clinical Consultant for Obstetrics and Gynecology for issues related to maternal health. IHS has also designated its hospitals using the ACOG classification system for levels and complexity of maternal care.⁵¹ Moreover, individual facilities have started their own initiatives to train their current obstetric unit nurses and staff to help fill vacancies while improving the quality of maternal care.⁵²

Quality Framework. In December 2018, IHS announced the final provisions of a Quality Framework, including the establishment of a new Office of Quality, effective January 2019.⁵³ The Quality Framework seeks to centralize several IHS functions related to quality of care, such as physician credentialing, patient surveys, standards for wait times, and quality metrics.⁵⁴

IHS Strategic Plan. In February 2019, IHS released its *IHS Strategic Plan FY 2019-23*, the first such document since its previous strategic plan ended in 2011.⁵⁵ This updated strategic plan specifically references IHS hospitals in several of its provisions, including goals for compliance with CoPs and plans to address longstanding issues with staffing at hospitals and Area Offices.⁵⁶

Other Quality Improvement Efforts. Additionally, IHS hospitals participate in improvement initiatives through the Partnership for Patients and other CMS programs. In 2017, CMS and IHS reported to OIG that IHS hospitals were receiving support for Quality Assessment and Performance Improvement programs through two types of collaboratives: Quality Innovation Network-Quality Improvement Organizations; and Hospital Improvement and Innovation Networks. Both types of collaboratives are dedicated to preventing patient harm in hospitals.⁵⁷

Methodology

Scope

To identify care that did not follow national clinical guidelines or best practices, we reviewed medical records associated with all 48 labor and delivery patients included in the stratified sample of patients selected for the study *Incidence of Adverse Events in Indian Health Service Hospitals* (OEI-06-17-00530). (See Appendix A for more information about the methodology for the main study.) These 48 labor and delivery patients were admitted to 11 of the 26 hospitals operated by IHS during FY 2017. Our inquiry focused on whether IHS hospitals followed the national clinical guidelines in the following circumstances: (1) inducing labor; (2) performing delivery via Caesarean section; (3) diagnosing and treating severe hypertension/preeclampsia; and (4) diagnosing and treating postpartum hemorrhage. In addition, we determined whether the estimate of the amount of blood lost during a postpartum hemorrhage incorporated the best practice of quantitative estimation of blood loss. Because of the stratified sampling design and the small number of labor and delivery patients in our sample, these data are not projectable to the broader population of all IHS labor and delivery patients.

Sample Selection

We identified 48 labor and delivery patients within the sample of 400 IHS patients selected for the study *Incidence of Adverse Events in Indian Health Service Hospitals* (OEI-06-17-00530). We included all 48 of these labor and delivery patients in this review. The sampling frame included patients admitted to any of the 26 IHS-operated hospitals during FY 2017. If a patient had multiple admissions to one or more IHS hospitals during FY 2017, we included all admissions in our review. For each admission, we requested complete medical records from the associated IHS hospital.

Data Collection and Data Sources

Medical Record Review To Identify Adverse Events and Temporary Harm Events.

We reviewed medical records to identify adverse events and temporary harm events for the study *Incidence of Adverse Events in Indian Health Service Hospitals* (OEI-06-17-00530). The first stage of the medical record review was a screening process using a modified version of the Global Trigger Tool methodology designed by the Institute for Healthcare Improvement to identify patients who may have experienced harm events.⁵⁸ A registered nurse with expertise in obstetrics and patient safety performed this screening of medical records for all labor and delivery patients.

In the second stage of the medical record review, an OB/GYN reviewed records for labor and delivery admissions that the nurse had identified as likely to include adverse events or temporary harm events. This physician examined medical records using a structured data collection instrument and assigned a degree of severity using a nationally recognized index for harm. Events were considered “adverse events” when

they resulted in one of four serious outcomes: prolonged hospital stay; permanent harm; harm that required life-sustaining intervention; or harm that contributed to death. Events were considered “temporary harm” when the event required intervention but did not result in any of these four serious outcomes. The physician also determined whether the event could have been prevented if the care had been better. (See Appendix A for more information about this methodology.)

Medical Record Review To Determine Whether Care Followed National Clinical Guidelines and Best Practices. An OB/GYN with specialized experience in obstetrics and patient safety used a structured data collection instrument to review medical records of the 48 labor and delivery patients in our sample. The physician-reviewer assessed whether the care met national clinical guidelines for the following: (1) diagnosing and treating postpartum hemorrhage; (2) induction of labor; (3) delivery via Caesarean section; and (4) diagnosing and treating severe hypertension/preeclampsia. National clinical guidelines are evidence-based frameworks that support clinical decisionmaking with the goal of optimizing patient care.⁵⁹

For diagnosis and treatment of postpartum hemorrhage, this physician-reviewer also assessed whether the care included the best practice of quantitative estimation of blood loss.⁶⁰ See Exhibit 1 for the number of patients who experienced maternal health conditions, as determined by our physician-reviewer. Some patients experienced more than one maternal health condition.

Exhibit 1: Number of patients who experienced selected maternal health conditions (n=48 patients)

Maternal health conditions	Applicable patients
High-risk pregnancy	26
Postpartum hemorrhage	16
Induction of labor	13
Caesarean section	6
Severe hypertension/preeclampsia	3

Source: OIG analysis of FY 2017 medical records for a sample of 48 patients in labor and delivery units at IHS hospitals, 2019.

We refer to each determination of care not following national clinical guidelines or best practices as an “instance,” and patients could experience more than one instance during their labor and delivery admissions. These instances could be the result of commission (actions taken by the providers, such as providing care that did not follow clinical guidelines or was not clinically indicated), or the result of omission (providers not taking action that was needed, such as failing to diagnose and intervene to address a problem in a timely manner).

In addition to determining whether a patient experienced care that did not follow national clinical guidelines or best practices, the physician-reviewer abstracted contextual information about the pregnancy, such as whether labor was induced and whether the pregnancy included any high-risk factors. Following our physician-reviewer's assessment of the care provided to each labor and delivery patient, we reviewed the assessments for logic and consistency with guidance used in the adverse events study.

Hospital Questionnaire. We asked all 26 IHS hospitals in operation in FY 2017 to complete a short questionnaire describing their labor and delivery services, including the following: labor and delivery unit staffing; training provided to staff specific to maternal health outcomes of interest (such as postpartum hemorrhage); and the extent to which the hospital had implemented the AIM bundles of maternal-safety best practices. Of the 26 IHS hospitals that received the questionnaire, we received responses from 25 hospitals.⁶¹

Limitations

We cannot provide projectable rates of care that did not follow national clinical guidelines or best practices, or otherwise generalize the findings of this report to the population of IHS labor and delivery patients. As such, when describing the care provided to the 48 patients in our sample, we present unweighted sample percentages. Also, it is possible that our physician-reviewer did not identify all instances of care that did not follow national clinical guidelines or best practices within our sample of labor and delivery patients. We did not identify these instances of care likely because documentation in the medical records was incomplete. Conversely, the medical record may not have documented care that did not follow national clinical guidelines or best practices.

Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

Slightly more than half of the IHS labor and delivery patients in our sample received care that did not follow national clinical guidelines or best practices

We found that 27 of the 48 labor and delivery patients we reviewed (56 percent) had instances of care that did not follow national clinical guidelines or best practices during their stays in IHS hospitals in FY 2017. Of these 27 patients, 6 patients received care that did not follow one or more national clinical guidelines and *also* did not use the best practice of quantitative estimation of blood loss associated with a postpartum hemorrhage. Of the remaining 21 patients, 13 received care that did not meet one or more national clinical guidelines and 8 received care that did not use the best practice of quantitative estimation of blood loss.

Among these 27 patients were 41 unique instances of care not following national clinical guidelines or best practices, with 9 patients experiencing more than 1 instance during labor and delivery admission. Most commonly, care that did not follow national clinical guidelines or best practices involved diagnosing and treating postpartum hemorrhage, which affected 14 patients (29 percent of our sample) with 17 distinct instances. The next most common type was care associated with labor inductions. Our review found that providers did not follow national clinical guidelines for inducing labor for 10 patients (21 percent of our sample) with 11 distinct instances in which providers did not adhere to guidelines.

More than half of the patients in our sample had one or more or characteristics that put their pregnancies at high-risk

Among the 48 labor and delivery patients in this review, 26 patients (54 percent) had high-risk pregnancies. For reference, between 6 and 8 percent of pregnancies nationally are considered high-risk.⁶² Among the 27 patients who received care that did not follow national clinical guidelines or best practices, the proportion of high-risk pregnancies was similar to that in our overall sample, with 17 of these pregnancies (63 percent) determined by our review to be high-risk. Risk factors in our sample included diabetes, maternal asthma, active substance abuse disorder, and evidence that the expectant mother had a history of complicated births.

Our review determined that in 22 of 26 high-risk pregnancies (85 percent), the IHS hospitals had appropriate personnel and services to accommodate these patients' risk factors. Of the four remaining patients with high-risk pregnancies, three patients were admitted to hospitals that did not have adequate resources to accommodate the patients' risk factors. For the fourth patient, our physician-reviewer was unable to determine whether the admitting hospital had adequate resources.

For two of the three patients who were admitted to hospitals without adequate resources, the hospitals attempted to transfer the patients to other hospitals. For one of these patients, the potential transfer hospitals were too busy to accept the patient; for the other patient, labor progressed too rapidly for a transfer to occur. The third patient who was admitted to a hospital without adequate resources did not receive a needed cardiology consultation because the hospital did not have that specialty care available.

A quarter (7 of 27) of the patients who received care that did not follow national clinical guidelines or best practices experienced temporary harm

Of the 27 labor and delivery patients who received care that did not follow national clinical guidelines or best practices at IHS hospitals, the care contributed to patient harm for 7 patients. Two of the seven patients harmed had two harm events each, for a total of nine harm events among patients in our sample. Our review classified all nine events as “temporary harm events,” meaning that the harm was not extensive enough to result in prolonging the hospital stay, requiring life-sustaining intervention, or other more serious consequences. The most common type of harm (involving four of the nine harm events) was excessive bleeding due to postpartum hemorrhage.

Our physician-reviewer determined that the care that these seven patients received contributed to the harm. For example, two patients had delays in providers’ diagnosing postpartum hemorrhage because in each case the staff relied on visual estimation of blood loss, which yielded an inaccurate assessment of bleeding and condition. Had the IHS hospital staff diagnosed the hemorrhages earlier, the staff may have been able to reduce bleeding using medication. One of these two patients ultimately required a blood transfusion.

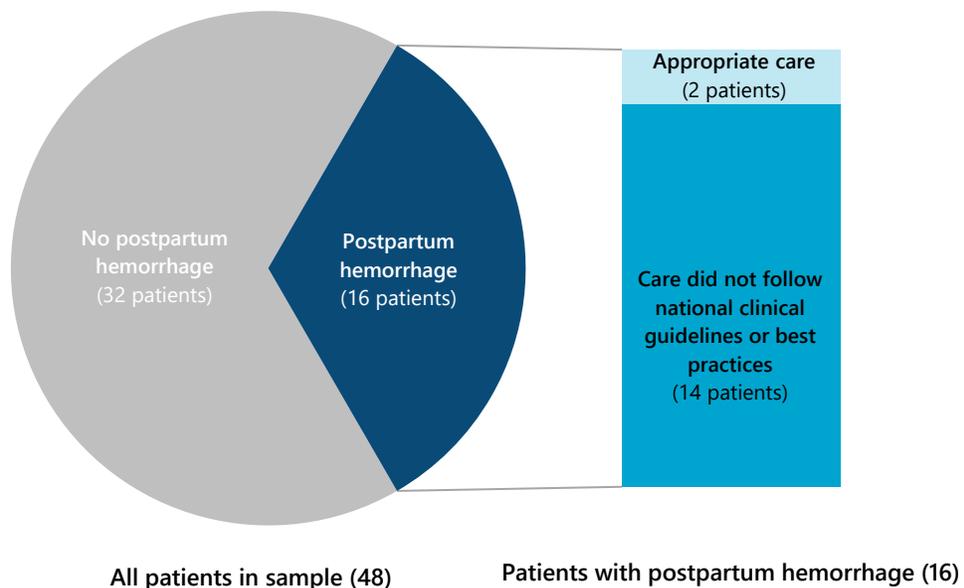
It is important to note that most of these harm events had multiple contributing factors, including issues that were unrelated to national clinical guidelines or best practices. For example, one patient who had a postpartum hemorrhage had severe hypertension/preeclampsia during labor, necessitating induction of labor. The IHS hospital staff induced labor appropriately, but the induction contributed to the subsequent hemorrhage. Our review found that the staff could not have prevented the excessive bleeding, given all factors present.

Postpartum hemorrhages were unusually common in our sample and were sometimes associated with delays in diagnosis

Postpartum hemorrhage is one of the most severe maternal health complications and is also rare, affecting between 1 and 3 percent of deliveries nationwide.^{63, 64} However, 16 of the 48 IHS labor and delivery patients we reviewed (33 percent) had a hemorrhage. Although these numbers are not projectable to all IHS labor and delivery patients, the high proportion within our sample raises concerns.

Providers did not follow national clinical guidelines or best practices related to diagnosing and treating hemorrhages for 14 of the 16 patients who had a postpartum hemorrhage (see Exhibit 2 on the next page). This care involved a range of shortcomings, from the use of visual estimation to assess blood loss (all 14 patients) to the administration of a medication that was inappropriate given the patient’s medical history. A few of these 14 patients experienced multiple instances of care that did not follow national clinical guidelines or best practices, with a total of 17 instances of such care related to diagnosing and treating postpartum hemorrhage (14 instances of not following best practices and 3 instances of not following national clinical guidelines).

Exhibit 2: One-third of sampled patients had a postpartum hemorrhage, and nearly all of these patients received care that did not follow national clinical guidelines or best practices (n=48 patients)



Source: OIG analysis of FY 2017 medical records for a sample of 48 patients in labor and delivery units at IHS hospitals, 2019.

Of the 16 patients who had a postpartum hemorrhage, 14 patients (88 percent) had high-risk pregnancies. Similar to the other labor and delivery patients in our sample, patients with hemorrhages had a range of risk factors, from active substance abuse problems to a history of complicated births.

Several IHS hospitals did not consistently use quantitative estimation of blood loss, a best practice for diagnosing postpartum hemorrhage that can lead to quicker treatment

As this report explained previously, quantitative estimation of blood loss enables providers to obtain more accurate and timely estimates of the amount of blood lost during a postpartum hemorrhage, allowing for quicker diagnosis and treatment and

potentially less impact to patients. The alternative method—visual estimation of blood loss—may underestimate blood loss such that providers do not diagnose a postpartum hemorrhage until they observe changes in vital signs, such as a drop in blood pressure or decreased red blood cell count.⁶⁵ Research supports quantitative estimation of blood loss as a best practice, and ACOG endorsed the use of quantitative estimation in 2019. (As mentioned previously, the sample of patients reviewed for this study received services in 2017, which was prior to this endorsement and when support for quantitative estimation was not as widespread as it is today.)

Among the 11 IHS hospitals with labor and delivery patients in our sample, only 1 hospital reported solely using quantitative estimation, the more accurate method of estimating blood loss. This hospital had seven labor and delivery patients in our sample, one of whom had a postpartum hemorrhage. This hemorrhage was diagnosed and treated according to national clinical guidelines, including the use of quantitative estimation of blood loss.

Among the other 10 hospitals with labor and delivery patients in our sample, 8 reported relying on a mix of quantitative estimation and visual estimation of blood loss, and the remaining 2 reported relying solely on visual estimation of blood loss. Of the patients in our sample who had postpartum hemorrhages, most patients (15 of 16) were treated in hospitals that relied, at least in part, on visual estimation of blood loss.

Another factor associated with a risk of hemorrhage is induction of labor. Of the 13 patients in our sample for whom labor was induced, 7 patients (54 percent) had a postpartum hemorrhage. In assessing the care provided to these seven patients, we found that providers used visual estimation of blood loss for five patients.

Other instances of care that did not follow national clinical guidelines in our sample were related to induction of labor and medication management

Of the 48 labor and delivery patients in our sample, 13 had an induced labor (27 percent) and most of these patients (10 of 13) received care that did not follow national clinical guidelines related to their inductions. For reference, the national rate of induced births was 27 percent in 2018.⁶⁶ Inductions in our sample sometimes involved patients with complex conditions that can lead to inductions; for example, our review included two inductions in which patients were diagnosed with gestational diabetes and one induction in which the patient had pregnancy-induced hypertension/preeclampsia. Eight of the 13 induced patients (62 percent) in our sample had at least 1 risk factor associated with their respective pregnancies.

Most care that did not follow national clinical guidelines related to induction of labor involved the use of induction medications. Among the 10 patients who received such care related to their inductions, there were 11 instances of not following national clinical guidelines. All 11 of these instances included inappropriate medication

regimens (problems with the timing and dosage of medications), including 6 instances in which misoprostol (a medication used to induce labor) was administered at a starting dose that was double the recommended starting dose.

We identified additional instances of care that did not follow national clinical guidelines unrelated to postpartum hemorrhage and induction of labor. These included other inappropriate medication regimens and the use of medical devices that were not clinically indicated.

IHS providers placed five patients on inappropriate medication regimens (with the wrong dosage or timing of medications). One of these patients was given medication intended to advance labor after the patient was already in active labor and experiencing tachysystole (excessive contractions). For another patient, IHS providers administered medications to treat preterm labor after the start of active labor. In addition to inappropriate timing, the combination of medications given to this patient can increase the risk of patient morbidities, including pulmonary edema (excess fluid in the lungs).

Our review also identified three instances in which medical devices were used on patients when use of the devices was not clinically indicated. Two of these instances involved the use of indwelling catheters; the other involved the insertion of fetal scalp electrodes. Use of these devices is known to put patients at higher risk of infection. (See Exhibit 3 on the next page for all instances of care at IHS hospitals that did not follow national clinical guidelines or best practices for labor and delivery patients in our sample.

Exhibit 3: Care that did not follow national clinical guidelines or best practices for labor and delivery patients in our sample (n=27 patients)

Type of care	Number of instances
Best Practice Not Followed	
Postpartum hemorrhage (PPH) not properly diagnosed and treated	14
Visual estimation of blood loss; no delay in diagnosis of PPH	6
Inaccurate visual estimation of blood loss; no delay in diagnosis of PPH	4
Inaccurate visual estimation of blood loss; delay in diagnosis of PPH	3
Visual estimation of blood loss; delay in diagnosis of PPH	1
National Clinical Guidelines Not Followed	
Induction of labor not performed properly	11
Inappropriate starting dose of induction medication	6
Inappropriate administration of induction medication during active labor	4
Missed diagnosis of tachysystole (excessive contractions) leading to continued, potentially harmful administration of induction medication	1
Other inappropriate medication regimens	5
Medication administered for PPH without a diagnosis of PPH ¹	2
Medication normally used to induce labor administered to noninduced patient and medication continued after tachysystole (excessive contractions) diagnosed	1
Medications to treat preterm labor administered after patient was in active labor	1
Medication for strep prevention not administered despite history of strep	1
PPH not properly diagnosed and treated	3
Signs and symptoms present consistent with PPH but not diagnosed	1
Medication administered to treat PPH contraindicated for hypertensive patient	1
Medication administered to treat PPH contraindicated for patient with asthma	1
Use of medical devices without clinical indication	3
Use of indwelling catheter not clinically indicated	2
Insertion of fetal scalp electrode not clinically indicated	1
Other improper diagnoses	2
Misdiagnosis of severe hypertension/preeclampsia given details in medical record	1
Missed diagnosis of hypotension leading to failure to treat hypotension	1
Severe hypertension/preeclampsia not properly diagnosed and treated	2
Lack of treatment for severe hypertension/preeclampsia	1
Inappropriate blood pressure monitoring of patient with severe hypertension/preeclampsia	1
Unattended, precipitous delivery	1
Total instances of care	41

OIG analysis of FY 2017 medical records for a sample of 48 patients in labor and delivery units at IHS hospitals, 2019.

¹ The IHS hospital may have administered the medication prophylactically in these two instances, but such use is inconsistent with current national clinical guidelines.

Three of the 10 IHS hospitals with labor and delivery units did not implement any of AIM's bundles of maternal-safety best practices as requested by IHS headquarters

At the time of our review, 3 of the 10 IHS hospitals with labor and delivery units had not implemented any of the AIM bundles of maternal safety best practices, despite the request by the IHS Chief Medical Officer that these hospitals adopt at least 1 bundle. The bundles are a collection of best practices for maternal care and cover a variety of topics related to the safety and quality of labor and delivery care. The other 7 hospitals reported that they had satisfied the IHS Chief Medical Officer's request to implement at least 1 AIM maternal-safety bundle, and 3 of these 7 hospitals reported that they had implemented all 12 bundles of maternal-safety best practices. Among hospitals that implemented only some of the AIM bundles, all implemented the bundle related to postpartum hemorrhage and most implemented the bundle related to severe hypertension.

Among the 13 IHS hospitals that did not have labor and delivery units, we found that 4 had implemented 1 or more AIM bundles of maternal-safety best practices. These hospitals perform deliveries only on an emergency basis and therefore are not subject to the IHS Chief Medical Officer's request to implement at least one AIM bundle of maternal-safety best practices. Of the four hospitals that implemented at least one of the bundles, two hospitals implemented the bundle focused on postpartum hemorrhage and one hospital implemented the bundle focused on severe hypertension. None of these hospitals reported that they had implemented all 12 of the bundles.

RECOMMENDATIONS

Our review of sampled medical records from FY 2017 identified instances of care provided to IHS labor and delivery patients that did not follow national clinical guidelines or best practices. IHS implemented changes in calendar years 2018-19 designed to improve the quality of care provided in its hospitals, including the development of a new Quality Framework and Office of Quality. IHS has also taken steps to directly address improvement in labor and delivery services via its ongoing implementation of ACOG recommendations and AIM bundles of maternal-safety best practices. However, work remains to be done to ensure that IHS labor and delivery patients receive safe care that is driven by current standards and best practices. As IHS implements these improvements, it should consider the findings within this report and work to ensure that national clinical guidelines and best practices are followed.

We recommend that IHS:

Assess its labor and delivery practices and consider practice improvements based on the findings of this assessment

IHS should undertake a comprehensive assessment of its labor and delivery practices and consider revising policies and providing additional clinician training related to national clinical guidelines and current best practices. This assessment should also consider opportunities to improve staff training and approaches for ameliorating patient risk factors.

Take steps to ensure that IHS providers employ best practices in diagnosing and treating postpartum hemorrhage

Given the prevalence of postpartum hemorrhage in our sample of labor and delivery patients and that diagnosis and treatment of these hemorrhages often involved care that did not follow national clinical guidelines or best practices, IHS should provide guidance and technical information to hospitals regarding diagnosing and treating this condition. This information could be added to the IHM and include best practices in diagnosing and treating postpartum hemorrhage, such as the use of quantitative estimation of blood loss to minimize delays in diagnosing a hemorrhage. IHS should also provide training for IHS hospital clinicians to adopt national clinical guidelines and best practices related to this condition, and track postpartum hemorrhage incidents by hospital and provider to identify recurring problems.

Encourage and support greater adoption of AIM's bundles of maternal-safety best practices

The IHS Chief Medical Officer requested that all IHS hospitals that provide labor and delivery services implement at least one of the AIM maternal-safety bundles. The AIM maternal-safety bundles are designed to focus hospitals on best practices in maternal care, and some IHS hospitals have already implemented the bundles. Still, of the 10 hospitals that responded to our survey and provide labor and delivery services, 3 hospitals reported that they had yet to implement any of the AIM maternal-safety bundles. IHS should work with these hospitals to encourage them to implement one or more of the AIM bundles. Additionally, IHS should work with all its hospitals to encourage further implementation of the AIM bundles and provide any technical or other guidance to further highlight the importance of this implementation.

AGENCY COMMENTS AND OIG RESPONSE

IHS concurred with our recommendations. In its response, IHS described actions already taken to implement the recommendations and planned actions for further implementation. OIG values the steps that IHS has taken and will monitor progress as IHS continues its efforts to improve the care provided during labor and delivery at IHS hospitals. (For the full text of IHS's comments, see Appendix D.)

To assess labor and delivery practices and consider opportunities for practice improvements, IHS described its collaboration with ACOG and participation in several efforts to improve maternity safety. IHS reported that a committee within ACOG conducts quality benchmarking site visits at IHS facilities and routinely addresses maternity safety measures during these reviews. In 2020, this group surveyed the 10 IHS hospitals that provide planned childbirth services about their implementation of the AIM bundles related to postpartum hemorrhage and severe hypertension. IHS plans to use these results to provide any additional guidance needed. IHS facilities also participate in State Perinatal Collaboratives and Maternal Mortality Review Committees, as well as in the national AIM program. IHS also implemented training on Advanced Life Support in Obstetrics. In addition to these efforts, IHS should conduct a comprehensive assessment of its labor and delivery practices and use the results of the assessment to identify practice improvements.

To ensure that IHS providers employ best practices in diagnosing and treating postpartum hemorrhage, IHS reported that it engaged in a series of webinars in 2017 reviewing the AIM bundles, with a focus on postpartum hemorrhage management. IHS also described its ongoing oversight of quality of care and adverse events. As IHS continues its efforts to implement best practices, it should work to formalize these processes and provide technical assistance on changes in best practices, such as following the practice of quantitative estimation of blood loss when diagnosing postpartum hemorrhage.

To encourage and support greater adoption of the AIM bundles of maternal-safety best practices, IHS explained that it has a longstanding affiliation with the AIM program. Although IHS cannot officially "join" AIM, IHS reported that the 10 Federal sites that provide planned childbirth services have successfully implemented the AIM bundles for both postpartum hemorrhage and severe hypertension. IHS should continue to encourage its hospitals that provide childbirth services to adopt the AIM bundles, including hospitals that only provide childbirth services on an emergency basis.

APPENDIX A

Summary of Methodology for Companion Study *Incidence of Adverse Events in Indian Health Service Hospitals* (OEI-06-17-00530)

The labor and delivery patients whose records we reviewed were selected as part of a larger sample for the companion study *Incidence of Adverse Events in Indian Health Service Hospitals* (OEI-06-17-00530). Medical record reviews to identify adverse events revealed examples of care that did not follow national clinical guidelines or best practices among labor and delivery patients. This care did not always cause patient harm and therefore is not included in the adverse events report. Although we subsequently conducted a dedicated medical record review to assess national clinical guidelines and best practices, some aspects of the original review for adverse events are included in this report. The summary below describes the methodology for the adverse events report.

Scope

The companion study *Incidence of Adverse Events in Indian Health Service Hospitals* (OEI-06-17-00530) provides a nationally representative estimate of the incidence of adverse events and temporary harm events in IHS hospitals during FY 2017 (October 2016 through September 2017). The study population included all eligible patients admitted to IHS hospitals in FY 2017, and contained pediatric and older patients as well as labor and delivery patients. The incidence rates are composed of all patient harm events regardless of whether they were preventable.

Sample Selection

Using encounter data extracted from the IHS National Data Warehouse, we selected a stratified random sample of 400 patients from those admitted to 1 or more of the 26 IHS-operated hospitals during FY 2017. We selected this sample from the general population of inpatients—from newborns to older adults—who had IHS hospital stays. We excluded 15 of these patients from the review because they did not have a conventional inpatient stay for acute-care services.⁶⁷ In addition, a hospital was unable to locate the medical record for one patient, so we excluded that patient from our analysis. The final sample we used for analysis consisted of 384 patients.

To ensure that the sample included the smallest hospitals, and to limit the data-collection burden on certain hospitals, we used a stratified sample design composed of six strata chosen by hospital size and geographic area. Of the 384 patients included in our analysis, 48 had more than one stay at an IHS hospital

during FY 2017. We reviewed all stays for these patients. Sampled patients had a combined total of 457 stays in our analysis file with an average length of stay of 3.5 days.

Data Collection

We requested complete medical records from IHS hospitals for the sampled patients' hospital stays. We reviewed the medical records for completeness and made additional requests for missing components of the record.

Identification of Adverse Events and Temporary Harm Events. We conducted a two-stage review to identify adverse and temporary harm events among sampled patients. The first stage of review consisted of nurses screening the sampled medical records. Nurses then referred cases meeting certain criteria to physicians for the second stage of review, as described below.

Nurse Screening. The first stage of the review process consisted of nurses screening medical records using one of two trigger tools. For adult patients, nurses used an OIG-modified version of the Institute for Healthcare Improvement's Global Trigger Tool to perform their reviews. The Global Trigger Tool requires screeners to look for "triggers" that indicate possible harm. A trigger is a clue that may be the result of an event, such as a transfer to a higher level of care. In addition to triggers for adult patients, we included triggers for both labor and delivery patients and for any patients who remained in IHS hospitals after they no longer required inpatient acute care. For pediatric patients (aged 17 and younger), nurses reviewed medical records using the Global Assessment of Pediatric Patient Safety Trigger Tool.⁶⁸

Physician Review. In the second stage of review, one of six physicians reviewed the medical records for each patient flagged by a nurse during the screening process, as well as additional cases flagged during quality assurance reviews. Physicians examined the records to identify events and then described these events using a structured data-collection instrument. Physicians used a guidance document to ensure consistency across reviewers. We also held a series of "consensus calls" during which physicians were encouraged to discuss complex or questionable cases, or seek the opinion of a physician with a different area of specialization. We also identified certain types of cases (e.g., deaths) as requiring consensus call discussion.

We report all harm events identified by the physician-reviewers. When an initial event caused a series of related events, we collapsed the events into a "cascade event" and counted it as a single event. For labor and delivery adverse events, we counted events that occurred in the delivery room as applying to the mother and not the newborn.

Assessment of Severity. As in prior OIG studies, physician-reviewers assigned each event to one of five levels of harm using an OIG-modified version of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Index of Categorizing Medication Errors. We distinguish between "adverse events" (levels F through I on the index) and "temporary harm events" (level E on the index) to

separately identify events that were more likely to affect cost and length of stay. Both types of events represent harm to patients resulting from medical care. See Exhibit A-1 for the complete NCC MERP index as modified by OIG.

Exhibit A-1: OIG-modified version of the NCC MERP index for categorizing errors

Event type	Level	Description
Adverse event	I	Harm occurred that may have contributed to or resulted in the patient's death.
	H	Harm occurred that required intervention to sustain the patient's life.
	G	Harm occurred that contributed to or resulted in permanent patient harm.
	F	Harm occurred that contributed to or resulted in prolonged facility stay, elevation in level of care, or transfer to another facility.
Temporary harm	E	Harm occurred that caused temporary harm that required intervention.

Source: Adapted from the NCC MERP Index for Categorizing Errors. Revised February 20, 2001.

Assessment of Preventability. The physician-reviewers classified each event into one of five preventability classifications: clearly preventable; likely preventable; likely not preventable; clearly not preventable; or unable to determine. Physicians also selected a rationale for each preventability determination from a list of options. Physicians had the option of using an OIG-developed algorithm as guidance for difficult preventability decisions.

APPENDIX B

Glossary of Selected Terms

Adverse event—Harm to a patient as a result of medical care or in a health care setting, including failure to provide needed care.

Amniotic fluid—Liquid that surrounds and protects a fetus within the uterus.

Caesarean delivery—A surgical procedure during which an infant is delivered via an incision through the mother's abdomen and uterus.

Clinically indicated—Advisable for treatment based on a patient's current condition.

Epidural—An injection of local anesthetic into the space outside the dura mater of the spinal cord in the lower back, commonly used in childbirth.

Hypertension—Abnormally high blood pressure.

Hypotension—Abnormally low blood pressure.

Induction of labor—The use of medication and procedures to facilitate labor sooner than labor would occur naturally.

Indwelling catheter—A device inserted inside the bladder used to drain urine into an external vessel.

Laparotomy pad—A pad made from several layers of gauze folded into a rectangular shape and used as a sponge or packing material in abdominal operations.

Medication regimen—The dose and frequency of medication administered to a patient.

Misoprostol—A medication used to induce labor and treat postpartum hemorrhage.

Objective/quantitative estimation of blood loss—A quantitative estimation of the blood lost during a postpartum hemorrhage in which providers rely on medical equipment, such as a drape with a measuring pouch, to physically measure blood loss.

Oxytocin—A hormone used to induce labor and treat postpartum hemorrhage.

Peripartum—Occurring around the time of childbirth, typically from a month before to a few months after.

Postpartum hemorrhage—Excessive bleeding immediately following birth, characterized by a decrease in blood pressure, an increase in heart rate, and a decrease in red blood cell count.

Precipitous delivery—A rapid delivery occurring within less than 3 hours of the start of regular contractions.

Preeclampsia—A pregnancy complication characterized by unusually high blood pressure and protein in the urine.

Standing Orders—Written protocols approved by a medical director that authorize designated members of the health care team (e.g., nurses or medical assistants) to complete certain clinical tasks without having to first obtain a physician order.

Tachysystole—Excessive contractions of the uterus during labor and delivery.

Temporary harm—Harm to a patient that required intervention but did not cause lasting harm, which is classified as level E on the patient harm index.

Visual estimation of blood loss—A qualitative approximation of blood loss through which providers visually estimate the amount of blood lost during a postpartum hemorrhage.

APPENDIX C

Sample Counts by Stratum

Our sample numbers are based on a stratified sample of 48 labor and delivery patients admitted to IHS hospitals during FY 2017. Stratification was based on hospital size and location, and was designed to ensure inclusion of small hospitals and not unnecessarily burden larger facilities. Below are the sample frequencies by the six strata (numbered from 1 to 6). Exhibit C-1 presents the number of labor and delivery patients with selected maternal health conditions. Exhibit C-2 shows the number of labor and delivery patients who had any instances of care that did not follow national clinical guidelines or best practices. Exhibit C-3 shows the number of instances for these patients.

Exhibit C-1: Number of labor and delivery patients with selected maternal health conditions by stratum (n=48 patients)

Maternal health condition	Total patients	(1)	(2)	(3)	(4)	(5)	(6)
High-risk pregnancy	26	4	4	2	0	6	10
Postpartum hemorrhage	16	2	1	3	0	4	6
Induction of labor	13	0	2	0	0	2	9
Caesarean section	6	2	0	0	0	1	3
Severe hypertension/preeclampsia	3	1	0	0	0	0	2
Total labor and delivery patients	48	11	9	4	0	6	18

Source: OIG analysis of FY 2017 medical records for a sample of 48 patients in labor and delivery units at IHS hospitals, 2019.

Note: Some patients had multiple maternal health conditions.

Exhibit C-2: Number of patients with care that did not follow national clinical guidelines or best practices by stratum (n=48 patients)

Type of care	Total patients	(1)	(2)	(3)	(4)	(5)	(6)
Postpartum hemorrhage not properly diagnosed and treated	14	2	1	3	0	4	4
Induction of labor not performed properly	10	0	2	0	0	0	8
Caesarean section not performed properly	0	0	0	0	0	0	0
Severe hypertension/preeclampsia not properly diagnosed and treated	2	1	0	0	0	0	1
Labor and delivery patients with more than one instance of care that did not follow national clinical guidelines or best practices	9	1	2	1	0	0	5
Labor and delivery patients whose instances of care that did not follow national clinical guidelines or best practices contributed to harm	7	0	2	1	0	1	3
Total labor and delivery patients with instances of care that did not follow national clinical guidelines or best practices	27	4	4	3	0	5	11

Source: OIG analysis of FY 2017 medical records for a sample of 48 patients in labor and delivery units at IHS hospitals, 2019.

Note: Some patients had multiple instances of care that did not follow national clinical guidelines or best practices.

Exhibit C-3: Number of instances of care that did not follow national clinical guidelines or best practices for labor and delivery patients by stratum (n=27 patients)

Type of care	Total instances	(1)	(2)	(3)	(4)	(5)	(6)
Postpartum hemorrhage not properly diagnosed and treated	17	2	1	5	0	4	5
Induction of labor not performed properly	11	0	2	0	0	0	9
Other inappropriate medication regimens	5	2	2	0	0	0	1
Use of medical devices without clinical indication	3	0	2	0	0	0	1
Other improper diagnoses	2	0	1	0	0	0	1
Severe hypertension/preeclampsia not properly diagnosed and treated	2	1	0	0	0	0	1
Unattended, precipitous delivery	1	0	0	0	0	1	0
Total instances of care that did not follow national clinical guidelines or best practices	41	5	8	5	0	5	18

Source: OIG analysis of FY 2017 medical records for a sample of 48 patients in labor and delivery units at IHS hospitals, 2019.

APPENDIX D

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 10 2020

Indian Health Service
Rockville, MD 20857

TO: Inspector General

FROM: Director

SUBJECT: IHS Response to Draft OIG Report OEI 06-19-00190 "*Instances of IHS Labor and Delivery Care Not Following National Clinical Guidelines or Best Practices*" dated September 2020

We appreciate the opportunity to provide our official comments on the Draft OIG Report, OEI 06-19-00190, "*Instances of IHS Labor and Delivery Care Not Following National Clinical Guidelines or Best Practices*," dated September 2020. Our responses and planned actions to the three OIG recommendations are discussed below.

Recommendation Number 1: The IHS concurs with the recommendation.

IHS should assess its labor and delivery practices and consider practice improvements based on the findings of this assessment.

Planned and completed actions:

The Indian Health Service (IHS) has a long-standing relationship with the American College of Obstetricians and Gynecologists (ACOG) Committee on American Indian and Alaska Native Women's Health. This committee conducts quality benchmarking site visits to IHS Federal, Tribal, and Urban Indian sites on a rotating basis, and routinely addresses maternity safety measures in their program reviews. Since 2017, this has included attention to the Alliance for Innovation on Maternal Health (AIM) bundle implementation. At national IHS training sessions we have featured content on the AIM, including several presentations and sessions on implementation of the bundles on Obstetric Hemorrhage, Hypertension, Venous Thromboembolism, and Substance Use Disorder.

In 2020, the ACOG surveyed the 10 Federal hospitals currently providing planned childbirth services on implementation of the Obstetric Hemorrhage and Severe Hypertension bundles. The IHS anticipates receiving this report early in 2021 and will utilize the ACOG assessment to reinforce AIM work at any sites that would benefit from additional guidance.

IHS sites participate in a variety of quality improvement efforts as applicable to their size and location. These efforts include participation with State Perinatal Collaboratives and Maternal Mortality Review Committees, as well as the national AIM program. IHS participation is well-established with the New Mexico Perinatal Collaborative and the Arizona Perinatal Trust, as well as the New Mexico and Arizona Maternal Mortality Review Committees. The IHS Great Plains MCH Coordinator is working closely with State stakeholders in North Dakota and South Dakota, as those states develop their Perinatal Collaboratives and Maternal Mortality Review Committees.

The IHS implemented widespread Advanced Life Support in Obstetrics (ALSO) training. ALSO training provides team-based, hands-on learning to assure prompt and appropriate responses to obstetric emergencies. The Navajo Area IHS held their annual ALSO training course most recently in September 2020. Additional ALSO courses have been combined with other national trainings on a rotating basis, including centrally located trainings in Phoenix, Oklahoma City, and Salt Lake City attended by Indian Health clinician staff from across the country. In addition to providing ALSO training to staff at our Labor and Delivery units, many staff in our rural Emergency Departments are ALSO trained.

Recommendation Number 2: The IHS concurs with the recommendation.

IHS should take steps to ensure that IHS providers employ best practices in diagnosing and treating postpartum hemorrhage.

Planned and completed actions:

The IHS employs best practices in diagnosing and treating postpartum hemorrhage. In 2017, in response to the IHS Chief Medical Officer directive, the IHS conducted a series of webinars reviewing implementation of the AIM bundles, with Obstetric Hemorrhage (PPH) management as the primary focus. AIM PPH content is included in all appropriate ACOG and IHS maternity care educational events and in the ALSO courses.

The IHS has a robust system of debriefing, case review, peer review, and event tracking at the facility level, overseen both by the Maternity Care teams and by our Quality Assurance/Process Improvement programs. This assures identification of, and the opportunity to address any unusual patterns.

Recommendation Number 3: The IHS concurs with the recommendation.

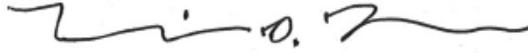
IHS should encourage and support greater adoption of the AIM bundles of maternal-safety best practices.

Planned and completed actions:

The IHS has actively promoted implementation of the AIM patient safety bundles and has a long-standing affiliation with the national AIM program. While the IHS is not able to officially “join” the AIM, due to required data sharing agreements, efforts have included each of the other aspects of implementation. Utilizing the AIM bundles enables each facility to improve performance with respect to each of the four key areas: Readiness; Recognition; Response; and Reporting. Internal queries reveal that all 10 Federal sites have successfully implemented both of the Obstetric Hemorrhage and the Hypertension bundles. We anticipate that this will be confirmed by the ongoing, independent ACOG program review discussed above.

Page 3 – Inspector General

Thank you for the opportunity to review and comment on this draft report. Please refer any follow-up questions you have regarding our comments to Ms. Athena Elliott, Chief Compliance Officer, IHS, by e-mail at athena.elliott@ihs.gov.



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ACKNOWLEDGMENTS AND CONTACT

Acknowledgments

Jesse Valente served as the team leader for this study, and Demetrius Martinez served as the lead analyst. Others in the Office of Evaluation and Inspections who conducted the study include Jennifer Hagen. Office of Evaluation and Inspections staff who provided support include Joe Chiarenzelli, Althea Hosein, Christine Moritz, and James Ortmann.

This report was prepared under the direction of Ruth Ann Dorrill, Regional Inspector General for Evaluation and Inspections in the Dallas regional office, and Amy Ashcraft, Deputy Regional Inspector General.

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To obtain additional information concerning this report, contact the Office of Public Affairs at Public.Affairs@oig.hhs.gov. OIG reports and other information can be found on the OIG website at oig.hhs.gov.

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ENDNOTES

- ¹ Tavernise, S., "Maternal Mortality Rate in U.S. Rises, Defying Global Trend, Study Finds," *New York Times*, Sept. 2016. Accessed at <https://www.nytimes.com/2016/09/22/health/maternal-mortality.html> on Sept. 11, 2019.
- ² Martin, N. and Montagne, R., "U.S. Has The Worst Rate Of Maternal Deaths In The Developed World," *NPR and ProPublica*, May 12, 2017. Accessed at <https://www.npr.org/2017/05/12/528098789/u-s-has-the-worst-rate-of-maternal-deaths-in-the-developed-world> on Sept. 30, 2019.
- ³ Petersen, E.E., et al., "Vital Signs: Pregnancy-Related Deaths, United States, 2011-2015, and Strategies for Prevention, 13 States, 2013-2017," *Morbidity and Mortality Weekly Report*, May 2019, 68:423-429. Accessed at <https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6818e1-H.pdf> on Sept. 11, 2019.
- ⁴ Geller, S.E., et al., "The continuum of maternal morbidity and mortality: Factors associated with severity," *American Journal of Obstetrics & Gynecology*, Sept. 2004, pp. 939-944. Accessed at <https://www.sciencedirect.com/science/article/abs/pii/S0002937804009020> on May 19, 2020.
- ⁵ CDC, *Pregnancy Mortality Surveillance System*, last reviewed Aug. 2018. Accessed at <https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pregnancy-mortality-surveillance-system.htm> on May 20, 2019.
- ⁶ Petersen, E.E., et al., "Vital Signs: Pregnancy-Related Deaths, United States, 2011-2015, and Strategies for Prevention, 13 States, 2013-2017," *Morbidity and Mortality Weekly Report*, May 2019, 68:423-429. Accessed at <https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6818e1-H.pdf> on Sept. 11, 2019.
- ⁷ Urban Indian Health Institute, *Community Health Profile: National Aggregate of Urban Indian Health Program Service Areas*, Oct. 2016, p. 37. Accessed at <https://www.issuelab.org/resource/community-health-profile-national-aggregate-of-urban-indian-health-program-service-areas.html> on Sept. 11, 2019.
- ⁸ IHS Analysis of Data from IHS Data Warehouse. Prepared for inclusion in "Talking Points: IHS Maternal Morbidity and Mortality Efforts" submitted to House Committee on Energy and Commerce on July 15, 2019.
- ⁹ CDC, *Severe Maternal Morbidity in the United States*. Accessed at <https://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidity.html> on June 14, 2019.
- ¹⁰ Howell, E.A., "Reducing Disparities in Severe Maternal Morbidity and Mortality," *Clinical Obstetrics and Gynecology*, June 2018, 61(2), pp. 387-399.
- ¹¹ Child Trends, *Late or No Prenatal Care*, May 2019. Accessed at <https://www.childtrends.org/indicators/late-or-no-prenatal-care> on May 21, 2019.
- ¹² CDC, *Reproductive Health: Data on Selected Pregnancy Complications in the United States*. Accessed at <https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pregnancy-complications-data.htm#post> on July 12, 2019.
- ¹³ Callaghan, W.M., et al., "Trends in postpartum hemorrhage: United States, 1994-2006," *American Journal of Obstetrics and Gynecology*, vol. 202, issue 4, 2010.
- ¹⁴ Neggers, Y., "Trends in maternal mortality in the United States," *Reproductive Toxicology*, vol. 64, 2016, p. 76.
- ¹⁵ University of Rochester, *Postpartum Hemorrhage*. Accessed at <https://www.urmc.rochester.edu/encyclopedia/content.aspx?ContentTypeID=90&ContentID=P02486> on Aug. 19, 2019.

¹⁶ Ibid.

¹⁷ Evensen, A., et al., *Postpartum Hemorrhage: Prevention and Treatment*. Accessed at <https://www.aafp.org/afp/2017/0401/p442.pdf> on July 8, 2019.

¹⁸ Schorn, M.N., "Measurement of Blood Loss: Review of the Literature," *Journal of Midwifery & Women's Health*, vol. 55, no. 1, Jan.-Feb. 2010.

¹⁹ Ibid.

²⁰ Lertbunnaphong, T., et al., "Postpartum blood loss: visual estimation versus objective quantification with a novel birthing drape," *Singapore Medical Journal*, 2016. Accessed at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4971452/pdf/SMJ-57-325.pdf> on July 8, 2019.

²¹ Brant, H.A., "Precise Estimation of Postpartum Haemorrhage: Difficulties and Importance," *British Medical Journal*, vol. 1, 1967.

²² Duthie, S., et al., "Discrepancy between laboratory determination and visual estimation of blood loss during normal delivery," *European Journal of Obstetrics & Gynecology and Reproductive Biology*, vol. 38, 1990.

²³ Stafford, I., et al., "Visually estimated and calculated blood loss in vaginal and cesarean delivery," *American Journal of Obstetrics and Gynecology*, vol. 199, no. 519, Nov. 2008.

²⁴ Diaz, V, et al., "Methods for blood loss estimation after vaginal birth," *Cochrane Database of Systematic Reviews*, 2018, issue 9, art. no.: CD010980.

²⁵ ACOG, "Quantitative Blood Loss in Obstetric Hemorrhage," *Committee Opinion Number 794, Dec. 2019*. Accessed at <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/12/quantitative-blood-loss-in-obstetric-hemorrhage> on July 9, 2020.

²⁶ ACOG, *Labor Induction: FAQ 154, Sept. 2017*. Accessed at a now-outdated link on Sept. 9, 2019; page is now located at <https://www.acog.org/patient-resources/faqs/labor-delivery-and-postpartum-care/labor-induction>.

²⁷ Mayo Clinic, *Inducing labor: When to wait, when to induce*. Accessed at <https://www.mayoclinic.org/healthy-lifestyle/labor-and-delivery/in-depth/inducing-labor/art-20047557> on Oct. 31, 2019.

²⁸ Ibid.

²⁹ Ibid.

³⁰ Ibid.

³¹ Osterman, M. and Martin, J., "Recent Declines in Induction of Labor by Gestational Age," *NCHS Data Brief No. 155*, June 2014. Accessed at <https://www.cdc.gov/nchs/data/databriefs/db155.pdf> on Sept. 9, 2019.

³² Martin, J.A., et al., "Births: Final Data for 2018," *National Vital Statistics Reports*, vol. 68, no. 13, Nov. 2019. Accessed at https://www.cdc.gov/nchs/data/nvsr/nvsr68/nvsr68_13-508.pdf on Feb. 4, 2020.

³³ Institute of Medicine, "Clinical Practice Guidelines We Can Trust," *National Academies Press*, 2011, p. 4. Accessed at https://www.ncbi.nlm.nih.gov/books/NBK209539/pdf/Bookshelf_NBK209539.pdf on Sept. 11, 2019.

³⁴ OIG, *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries*, OEI-06-09-00090, Nov. 2010.

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- ³⁵ Pursuant to the Indian Self-Determination and Education Assistance Act, P.L. No. 93-638, IHS contracts and compacts with tribes or tribal organizations to deliver services.
- ³⁶ IHS, Internal Memorandum, *Fiscal Year 2017 Hospital Inpatient Statistics for IHS and Tribal Sites With Prior Fiscal Year Comparisons (FY 2016)*, July 13, 2018.
- ³⁷ IHS, *Indian Health Manual*, 3-13.2F(2)d1.– Personnel. Accessed at <https://www.ihs.gov/ihm/pc/part-3/p3c13/#3-13.2F2> on Nov. 4, 2019.
- ³⁸ IHS, *Labor and Delivery*. Accessed at <https://www.ihs.gov/dper/planning/rrm-references/inpatient-nursing-labor-and-delivery/> on June 14, 2019.
- ³⁹ IHS, *Obstetrics and Gynecology*. Accessed at <https://www.ihs.gov/dper/planning/rrm-references/obstetrics-and-gynecology/> on June 14, 2019.
- ⁴⁰ IHS, *Circular No. 97-01*. Accessed at http://www.ihs.gov/ihm/index.cfm?module=dsp_ihm_circ_main&circ=ihm_circ_9701 on Jan. 22, 2014.
- ⁴¹ Social Security Act §§ 1880(a) and 1865 (a)(1).
- ⁴² 42 CFR § 482.21.
- ⁴³ 42 CFR § 482.21(c)(2).
- ⁴⁴ IHS, *Indian Health Manual*, 3-13.4F(1)c and 3-13.2F(2)b4. Accessed at <https://www.ihs.gov/IHM/pc/part-3/p3c13/> on Oct. 3, 2019.
- ⁴⁵ IHS, *Indian Health Manual*, 3-13.2. Accessed at <https://www.ihs.gov/ihm/pc/part-3/p3c13/#3-13.2> on Aug. 23, 2019.
- ⁴⁶ IHS, *Indian Health Manual*, Part 3, Chapter 13: Manual Appendix 3-13-A. Accessed at <https://www.ihs.gov/ihm/pc/part-3/p3c13-ap-a/> on Sept. 9, 2019.
- ⁴⁷ Email from IHS Chief Medical Officer to all Area Directors on Aug. 7, 2017.
- ⁴⁸ ACOG, *Alliance for Innovation on Maternal Health*. Accessed at <https://web.archive.org/web/20190831191921/https://www.acog.org/About-ACOG/ACOG-Departments/Patient-Safety-and-Quality-Improvement/What-is-AIM?IsMobileSet=false> on May 19, 2019.
- ⁴⁹ ACOG, *Committee on American Indian/Alaskan Native Women's Health Recommendations to the IHS from the Rural Maternal Safety Meeting, 2014*. Accessed at https://www.acog.org/-/media/AIAN-Womens-Health/Rural-Maternal-Safety-Final-wlogo_right.pdf?dmc=1&ts=20190615T0318074009 on June 14, 2019.
- ⁵⁰ IHS, *Fiscal Year 2020 Justification of Estimates for Appropriations Committees*, op. cit., p. CJ-221. Accessed at https://www.ihs.gov/sites/budgetformulation/themes/responsive2017/display_objects/documents/FY2020CongressionalJustification.pdf on May 19, 2020.
- ⁵¹ IHS, *Indian Health Manual*, 3-13.2D(3). Accessed at <https://www.ihs.gov/IHM/pc/part-3/p3c13/#3-13.2D> on Oct. 3, 2019.
- ⁵² IHS, *Navajo Area IHS Quarterly Report To Tribal Leaders*, Oct. 2018, p. 5. Accessed at http://www.nnols.org/uploads/FileLinks/0c2f4964b67c4994bc29904aa0296ed2/10_15_2018_FINAL_Council_Report_w_attach.pdf on June 14, 2019.
- ⁵³ IHS press release, "Indian Health Service Announces Office of Quality," Dec. 21, 2018. Accessed online on Jan. 16, 2019. Original link no longer works; for an archived version, see

https://web.archive.org/web/20190614222230/https://www.ihs.gov/newsroom/includes/themes/responsive2017/display_object/s/documents/PressRelease-IndianHealthServiceAnnouncesNewOfficeofQuality_122118.pdf.

⁵⁴ Testimony of Rear Admiral Chris Buchanan, IHS Deputy Director, before the U.S. House of Representatives Committee on Natural Resources, Subcommittee on Indian, Insular, and Alaska Native Affairs, June 21, 2017.

⁵⁵ IHS, *Indian Health Service Strategic Plan FY 2019-23*, Feb. 27, 2019. Accessed at <https://www.ihs.gov/strategicplan/ihs-strategic-plan-fy-2019-2023/> on Aug. 19, 2019.

⁵⁶ Ibid.

⁵⁷ Final Management Decision to OIG for the studies *More Monitoring Needed to Ensure Quality of Care (OEI-06-14-00010)* and *Longstanding Challenges Warrant Focused Attention to Support Quality Care (OEI-06-14-00011)*, Feb. 13, 2017.

⁵⁸ Griffin, F.A. and Resar, R.K., "IHI Global Trigger Tool for Measuring Adverse Events (Second Edition)," *Institute for Healthcare Improvement, Innovation Series White Paper, 2009*.

⁵⁹ The American Academy of Family Physicians (AAFP), *Clinical Practice Guideline Manual*. Accessed at <https://www.aafp.org/patient-care/clinical-recommendations/cpg-manual.html> on Jan. 24, 2020.

⁶⁰ AAFP, *Practice Guidelines: Reducing Obstetric Hemorrhage: Recommendations from the National Partnership for Maternal Safety*. Accessed at <https://www.aafp.org/afp/2015/1001/p643.html> on Jan. 24, 2020.

⁶¹ This number reflects the number of IHS hospitals during our study period. Since then, two hospitals have transitioned from federal facilities operated by IHS to tribally operated ones.

⁶² University of California-San Francisco, *High-Risk Pregnancy*. Accessed at https://www.ucsfhealth.org/conditions/high-risk_pregnancy/ on July 10, 2019.

⁶³ CDC, *Reproductive Health: Data on Selected Pregnancy Complications in the United States*. Accessed at <https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pregnancy-complications-data.htm#post> on July 12, 2019.

⁶⁴ Callaghan, W.M., et al., "Trends in postpartum hemorrhage: United States, 1994-2006," *American Journal of Obstetrics and Gynecology*, vol. 202, issue 4, 2010.

⁶⁵ University of Rochester Medical Center, *Health Encyclopedia, Postpartum Hemorrhage*. Accessed at <https://www.urmc.rochester.edu/encyclopedia/content.aspx?ContentTypeID=90&ContentID=P02486> on Jan. 28, 2020.

⁶⁶ Martin, J.A., et al., *Births: Final Data for 2018*, National Vital Statistics Reports, vol. 68, no. 13, Nov. 2019. Accessed at https://www.cdc.gov/nchs/data/nvsr/nvsr68/nvsr68_13-508.pdf on Feb. 4, 2020.

⁶⁷ Thirteen patients only had stays in a drug dependency unit, and 2 additional patients only had stays associated with a research study.

⁶⁸ Center of Excellence for Pediatric Quality Measurement, *Global Assessment of Pediatric Patient Safety (GAPPS): A Pediatric Trigger Tool for Measuring Adverse Events, Manual of Operations*, Feb. 2016.