A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care

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Objectives: Based on 1984 data developed from reviews of medical records of patients treated in New York hospitals, the Institute of Medicine estimated that up to 98,000 Americans die each year from medical errors. The basis of this estimate is nearly 3 decades old; herein, an updated estimate is developed from modern studies published from 2008 to 2011.

Methods: A literature review identified 4 limited studies that used primarily the Global Trigger Tool to flag specific evidence in medical records, such as medication stop orders or abnormal laboratory results, which point to an adverse event that may have harmed a patient. Ultimately, a physician must concur on the findings of an adverse event and then classify the severity of patient harm.

Results: Using a weighted average of the 4 studies, a lower limit of 210,000 deaths per year was associated with preventable harm in hospitals. Given limitations in the search capability of the Global Trigger Tool and the incompleteness of medical records on which the Tool depends, the true number of premature deaths associated with preventable harm to patients was estimated at more than 400,000 per year. Serious harm seems to be 10- to 20-fold more common than lethal harm.

Conclusions: The epidemic of patient harm in hospitals must be taken more seriously if it is to be curtailed. Fully engaging patients and their advocates during hospital care, systematically seeking the patients' voice in identifying harms, transparent accountability for harm, and intentional correction of root causes of harm will be necessary to accomplish this goal.

Key Words: patient harm, preventable adverse events, transparency, patient-centered care, Global Trigger Tool, medical errors

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"All men make mistakes, but a good man yields when he knows his course is wrong, and repairs the evil. The only crime is pride."— Sophocles, Antigone"

Medical care in the United States is technically complex at the individual provider level, at the system level, and at the national level. The amount of new knowledge generated each year by clinical research that applies directly to patient care can easily overwhelm the individual physician trying to optimize the care of his patients.[1] Furthermore, the lack of a well-integrated and comprehensive continuing education system in the health professions is a major contributing factor to knowledge and performance deficiencies at the individual and system level.[2] Guidelines for physicians to optimize patient care are quickly out of date and can be biased by those who write the guidelines.[3–5] At the system level, hospitals struggle with staffing issues, making suitable technology available for patient care, and executing effective handoffs between shifts and also between inpatient and outpatient care.[6] Increased production demands in cost-driven institutions may increase the risk of preventable adverse events (PAEs). The United States trails behind other developed nations in implementing electronic medical records for its citizens.[7] Hence, the information a physician needs to optimize care of a patient is often unavailable.

At the national level, our country is distinguished for its patchwork of medical care subsystems that can require patients to bounce around in a complex maze of providers as they seek effective and affordable care. Because of increased production demands, providers may be expected to give care in suboptimal working conditions, with decreased staff, and a shortage of physicians, which leads to fatigue and burnout. It should be no surprise that PAEs that harm patients are frighteningly common in this highly technical, rapidly changing, and poorly integrated industry. The picture is further complicated by a lack of transparency and limited accountability for errors that harm patients.[8,9]

There are at least 3 time-based categories of PAEs recognized in patients that are or have been hospitalized. The broadest definition encompasses all unexpected and harmful experience that a patient encounters as a result of being in the care of a medical professional or system because high quality, evidence-based medical care was not delivered during hospitalization. The harmful outcomes may be realized immediately, delayed for days or months, or even delayed many years. An example of immediate harm is excess bleeding because of an overdose of an anticoagulant drug such as that which occurred to the twins born to Dennis Quaid and his wife.[10] An example of harm that is not apparent for weeks or months is infection with Hepatitis C virus as a result of contaminated chemotherapy equipment.[11] Harm that occurs years later is exemplified by a nearly lethal pneumococcal infection in a patient that had had a splenectomy many years ago, yet was never vaccinated against this infection risk as guidelines and prompts require.[12]

METHODS

The approach to the problem of identifying and enumerating PAEs was 4-fold: (1) distinguish types of PAEs that may occur in hospitals, (2) characterize preventability in the context of the Global Trigger Tool (GTT), (3) search contemporary medical literature for the prevalence and severity of PAEs that have been enumerated by credible investigators based on medical

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records assessed by the GTT, and (4) compare the studies found by the literature search.

Types of PAEs

The cause of PAEs in hospitals may be separated into these categories:

- Errors of commission,
- Errors of omission,
- Errors of communication,
- Errors of context, and
- Diagnostic errors

These distinctions are important because investigators searching for preventable harm must be aware of what they can find and what they cannot find. The easiest error to detect in medical records is an error of commission. This occurs when a mistaken action harms a patient either because it was the wrong action or it was the right action but performed improperly. For example, the patient may need his gall bladder removed, but during the surgery, the intestine is nicked, and the patient develops a serious infection, such as was alleged to be the cause leading to the death of Representative John Murtha. Errors of omission can be detected in medical records when an obvious action was necessary to heal the patient, yet it was not performed at all. For example, a patient may need a β-blocker, but because it was not prescribed, the patient died prematurely.[13] Errors of omission because of failure to follow evidence-based guidelines are much more difficult to detect, partly because there are many complex guidelines and also because adverse consequences of failure to follow guidelines may be delayed until after discharge.[14,15]

Errors of communication can occur between 2 or more providers or between providers and patient. One example of a lethal error of communication between provider and patient occurred when cardiologists failed to warn their 19-year-old patient not to run. The patient had experienced syncope while running, and 5 days of inpatient, diagnostic testing were inconclusive; however, his cardiologists knew he was not ready to return to running but failed to warn him against this risk. Having not been warned against running, he resumed running and died 3 weeks later while running.[15]

Contextual errors occur when a physician fails to take into account unique constraints in a patient's life that could bear on successful, postdischarge treatment. For example, the patient may lack the cognitive ability to comply with a medical treatment plan or may not have reasonable access to follow-up care.[16] Diagnostic errors resulting in delayed treatment, the wrong treatment, or no effective treatment may also be considered separately, although a small subset of these might be included as errors of commission or omission. For example, a diagnostic error may lead to harm from errors of commission by overtreatment or mistreatment of the patient until the mistake is discovered. The apparent eagerness of the U.S. health-care industry to over diagnose patients often leads to harmful consequences for patients.[17]

Preventability and the Global Trigger Tool

The prevailing view is that "preventability" of an adverse event links to the commission of an identifiable error that caused an adverse event. Adverse events that cannot be traced to a likely error should not be called "preventable." The portion of adverse events that are deemed preventable tends to be about 50% to 60%; however, recently, experts have postulated that virtually all adverse events they identified with the "GTT are preventable."[18] The GTT depends on systematic review of medical records by persons trained to find specific clues or triggers suggesting that an adverse event has taken place. For example, triggers might include orders to stop a medication, an abnormal lab result, or prescription of an antidote medication such as naloxone. As a final step, the examination of the record must be validated by 1 or more physicians. As will be shown shortly, the methods used to find adverse events in hospital medical records target primarily errors of commission and are much less likely to find harm from errors of omission, communication, context, or missed diagnosis.[19] There are some overlaps in these categories and cascades of harmful events can ensue from a single root cause. A "perfect storm" of unrecognized but correctable medical errors can result in serious harm or death.[15,20]

Literature Search

Our literature search included the following three terms: medical error, global trigger tool, and hospital. We searched Pub Med and "reports and publications" from the government Web site *http://oig.hhs.gov*. Those searches turned up 20 articles published between 2006 and 2012, of which, 4 were found to be suitable for the present analysis. The unsuitable studies included studies of populations outside the United States, studies confined to narrow hospital populations (e.g., intensive care unit), studies of ambulatory patients, studies involving only methodological comparisons, adverse-event issue papers, failures of incident reporting systems, and studies that did not classify the severity of the harm associated with adverse events.

Characterization of the Core Studies

The 4 key studies were reviewed for similarity and difference in methods used to find adverse events. It was found that each one employed similar methods to flag, confirm, and then classify adverse events according to level of harm. All studies used a 2-tier approach that consisted of screening of medical records by nonphysicians, usually nurses or pharmacists, to flag suspect events. In the second tier, physicians examined the suspect events to determine if a genuine adverse event had occurred and, if so, the level of seriousness of the event. In all studies, the GTT from the Institute for Healthcare Improvement was the primary screening tool;[21] however, there were variations in the supplementary tools used to detect potential adverse events.

A 2008 pilot study by the Office of Inspector General (OIG) of the Department of Health and Human Services used 5 methods in its search for adverse events—nurse reviews using the GTT, conditions that were not present on admission (POA), beneficiary interviews, hospital incidence reports, and patient safety indicators.[22] The pilot study revealed that the GTT captured the highest percentage (78%) of the events ultimately deemed to be adverse events in the second tier review by physicians. The use of POA indicator codes was second best at 61%. Together, these methods were found to identify 94% of the flags that led physicians to declare that an adverse event had taken place. A more comprehensive OIG study in 2010 employed these 2 screening methods and a third based on whether the patient had been readmitted to the hospital with 30 days of discharge from the last discharge during the October 2008 index period.[23]

A study by Classen and colleagues also employed the GTT along with Agency for Healthcare Research and Quality Patient Safety Indicators (PSIs) and hospital reports of adverse events. Of the 167 flagged events that ultimately were deemed true adverse events by physician review, the GTT detected 90% in the severity levels F through I (Table 1).[18] The longitudinal

TABLE 1. Adverse Events Classified as Serious

Level of Harm	Description
F	Required prolonged hospital stay
G	Permanent harm
H	Life sustaining intervention required
I	Contributing to death of patient

Adapted from the National Coordinating Council for Medication Errors Reporting and Prevention.

study by Landrigan and colleagues relied on the GTT and POA indicators to flag possible adverse events. Like the other studies, the ultimate determination of a genuine adverse event and the severity of the event were judged by physicians during the second-tier analysis.[24] Although there are slight variations in the approach used to discover flags in the records examined by the 4 studies, the GTT was the core method placed in the hands of trained and experienced nurses. All studies used a second tier requiring physicians to determine whether a flag signaled a genuine adverse event and, if so, then assign a severity level to that event. All studies used the National Coordinating Council for Medication Reporting and Prevention scale (Table 1).

RESULTS

Recent data from the 4 key studies provide a more comprehensive, evidence-based estimate of the number of lethal and serious medical errors than the one provided by the Institute of Medicine (IOM).[25] These data are compiled in Table 2, and the studies are described below.

A pilot study by the OIG was published in 2008 in an effort to explore the effectiveness of search methods for adverse events.[21] As noted in the methods section, this study relied on 5 search methods for flagging potential adverse events in medical records but did not specify whether such events were preventable. The 278 medical records reviewed by screeners and physicians were not randomly selected to be representative of Medicare hospitalizations; instead, they originated from hospitals in 2 unspecified counties. Of the 51 serious adverse events identified, only 3 were on the National Quality Forum's list of serious reportable events and only 11 were on Medicare's Hospital Acquired Condition (HAC) list. In 2010, the OIG estimated adverse events in hospitalized Medicare patients.[23]

Investigators looked at the medical records of 780 randomly selected patients chosen to represent the 1 million Medicare patients "discharged" from hospitals in the month of October 2008. The total number of hospital stays for the 780 patients during this period was 838 because some of the beneficiaries were hospitalized and discharged more than once during the 1-month index period. Using primarily the GTT developed by the Institute for Healthcare Improvement to find adverse events, investigators found 128 serious adverse events (level of harm F, G, H, or I) that caused harm to patients, and an adverse event contributed to the deaths of 12 of those patients. Seven of these deaths were medication related, 2 were from blood stream infections, 2 were from aspiration, and the 12th one was linked to ventilator-associated pneumonia. Only 2 of these events were on the National Quality Forum list, and none were on the Medicare HAC list. The authors of this report estimated that "events" contributed to the deaths of 1.5 % (12/780) of the 1 million Medicare patients hospitalized in October 2008. That amounts to 15,000 per month or 180,000 per year.

TABLE 2. Recent Studies of Preventable Adverse Events

Reference	Source of Medical Record Data	Time Covered by Records	No. records Reviewed	Search Tool or Method	Serious Adverse Events (Class F to I) Found (%)	% Deemed Preventable	Lethal Adverse Events (%)	Major Causes of Lethal Events
OIG (2008)	Medicare beneficiaries in 2 counties	1 wk in August 2008	278	Global trigger tool	43 (15%)	n/s	3 (1.1%)	n/s
OIG (2010)	Representative Medicare patients	October 2008	838	Global trigger tool	128 (15%)	44%	12 (1.4%)	7-medication, 2-sepsis, 2-aspiration, 1-other*
Classen et al. (2011)	3 tertiary-care hospitals	October 2004	795	Global trigger tool	167 (21%)	~100%	9 (1.1%)	4-procedure, 2-pulmonary, 1-infection, 2-not specified
Landrigan, et al. (2010)	10 hospitals in North Carolina	Jan 2002 through Dec 2007	2341	Global trigger tool	332 (14%)	63%	14 (0.6%)	7- HAI, 3-Renal/endocr. 4-other systems†

* Ventilator-associated pneumonia.

† Cardiac arrest, pulmonary embolism, hematologic event, neurological event.

Note that the percentage of deaths per hospitalization was slightly lower at 1.4% (12/838). The authors did not explicitly state the percentage of the lethal adverse events that were preventable, but given their description of the events, it seems that most were preventable. Overall, physician reviewers estimated that 44% of serious medical events were preventable.

In a somewhat similar study published in March 2011 in the journal *Health Affairs*, investigators examined the medical records of 795 patients treated in 1 of 3 tertiary hospitals in the month of October 2004.[18] These hospitals had been recognized for their efforts to improve patient safety. The investigators also used the GTT to discover adverse events. They found 167 adverse events in the categories F through I, and 9 of the adverse events contributed to the deaths of patients (category I). Thus, an adverse event contributed to death in 1.1% of these patients. The causes were as follows: procedure related (not infection)—4, nosocomial infection—1, pulmonary/venous thromboembolism—2, and unspecified other—2. Interestingly, none of the deaths were explicitly associated with medication errors, which were the primary causes of death in the Medicare patients studied by the OIG.[23] Medication-related errors caused 35% of the category-F harms in the *Health Affairs* study.[18] The average age of the patients whose records were examined was 59 years. The 10 authors of the original study did not formally assess the preventability of errors, declaring instead that it is their belief that all adverse events are preventable.

In a fourth recent study targeting changes in patient safety in 10 hospitals in North Carolina, there was a lower incidence of deaths associated with adverse events.[24] Hospitals in North Carolina were chosen because hospitals in that state had shown a "high level of engagement in efforts to improve patient safety." In that state, 96% of the hospitals had enrolled in a national campaign to improve patient safety, whereas the average in other states was only 78%. A priori, a lower rate of preventable adverse events than the national average could be expected. The investigators studied the change in incidence of adverse events using the GTT on 10 randomly selected medical records per quarter from the first quarter of 2002 to the last quarter of 2007. The tool was applied by internal and external reviewers; however, the internal reviewers had better kappa scores (a measure of agreement) when compared with experienced external reviewers, so the results of internal reviews, which were the only ones given in detail in the original paper, will be used here. Based on 2341 admissions and the finding of 14 cases where adverse events contributed to death, the percentage of lethal adverse events was 0.60%. The primary causes of death were hospital-acquired infections (HAIs) (7) and acute renal failure (2). Other causes are shown in Table 2. This study involved many more medical records than the OIG or *Health Affairs* study, but the hospitals and patients were not selected to be representative of hospitals around the country. The hospitals were selected because the investigators felt that North Carolina had made a concerted effort to improve patient safety over the study period. It is not surprising that the percentage of serious or lethal adverse events was lower than in the other studies summarized in Table 2.

All 4 studies (Table 2) have similar, 2-tier search methods to identify serious adverse events. The GTT, supplemented by other less comprehensive methods, was applied to medical records by experienced nonphysicians to identify possible adverse events, and then, physician reviewers determined which flags were associated with an adverse event. However, the study populations were quite different. One would expect the OIG studies of Medicare patients, who tend to have more comorbidity than the average hospitalized patient, to show the highest incidence of lethal PAEs. One would expect the incidence of lethal adverse events in tertiary hospitals to be above the national average for all hospitalizations because more complex illnesses are treated there with longer hospital stays. One would expect, as the original authors did, that the incidence data from North Carolina would be below the national average for lethal adverse events because of concerted efforts in that state to improve patient safety in hospitals compared with the average of other states in the United States.

It is our opinion that none of the 4 studies alone can provide a defensible estimate for hospitals across the United States; however, by combining the studies, an evidence-based estimate of the number of lethal PAEs across the country can be developed. The most favorable way to combine the 4 studies to find the lowest reasonable estimate is to weigh the studies according to how many medical records from a single hospital stay were reviewed by each team of investigators. This means that the study of patients hospitalized in North Carolina was heavily weighted compared with the other studies. Thus, there were a total of 4252 records reviewed (compiled from Table 2). Among the records reviewed, there were 38 total deaths associated with adverse events. The ratio projects to a death rate from adverse events of 0.89%. This is well below the percentages from Medicare and tertiary-care studies (1.1%–1.4%) and well above the data from the North Carolina study (0.60%). There were an estimated 34.4 million hospital discharges in 2007,[26] and the average percentage of preventable adverse events among all adverse events in the 3 studies where this was reported or postulated was 69% (averaged from Table 2). Thus, the best estimate from combining these 4 studies is $34{,}400{,}000 \times 0.69 \times 0.0089 = 210{,}000$ preventable adverse events per year that contribute to the death of hospitalized patients—based primarily on evidence in hospital medical records found by the GTT method.

DISCUSSION

There has been no lack of contention about the prevalence of PAEs, which herein will be considered synonymous with medical errors that cause harm to patients; this does not include near misses that do not harm patients.[27,28] The first estimate of medical errors that received widespread attention was declared by the IOM in its now- famous book called "To Err is Human."[25] The IOM provided 2 estimates of the number of deaths from medical errors, but careful inspection of the origin of these estimates show that they were based on data that are now quite old. The earliest estimate originated from the Harvard Medical Practice Study in which 30,000 randomly selected discharge records from 1984 in 51 New York hospitals were examined.[29] The investigators found that serious adverse events occurred in 3.7% of the hospitalizations. Of the adverse events, 58% were attributable to error (i.e., they were preventable). Of this fraction, 13.6% resulted in death. Extrapolated to 33.6 million hospitalizations nationwide in 1997, simple arithmetic yielded the following: $33{,}600{,}000 \times 0.037 \times 0.136 \times 0.58 = 98{,}000$ deaths per year. Another study of 15,000 medical records from Colorado and Utah in 1992 found lower rates of adverse events and death, from which the IOM estimated 44,000 deaths nationwide per year.[25] Although physician reviews reveal adverse events due to "negligence," which was about 28% to 29% in both studies, a later publication from the IOM suggested that the 44,000 to 98,000 deaths did not include errors of omission.[30] Because the New York study included a larger sample, the deaths-per-year figure of 98,000 attributed to the IOM is the estimate most often quoted. In fact, the IOM declared that the "number of deaths [per year] due to medical error may be as high as 98,000."

Why is the present estimate of the number of lethal PAEs so much higher than the highest estimate (98,000) from the IOM? It is likely that the bar for identification of a PAE in the New York/IOM study was much higher than in the 4 modern studies and that the GTT is better able to identify adverse events than general reviews by physicians, which was the method used in the older studies cited by the IOM.[19] It is also possible that the frequency of preventable and lethal patient harms has increased from 1984 to 2002–2008 because of the increased complexity of medical practice and technology, the increased incidence of antibiotic-resistant bacteria, overuse/misuse of medications, an aging population, and the movement of the medical industry toward higher productivity and expensive technology, which encourages rapid patient flow and overuse of risky, invasive, revenue-generating procedures.[31–33]

Several observations about the 4 varied studies described in the "Results" section are in order. Although they used varied selection criteria for the patient populations and hospitals, the results in terms of the portion of adverse events found and the portion of death-associated events are not remarkably varied. The percentage of serious adverse events (class F to I) ranged from 14% to 21%, and the percentage of death-associated adverse events (class I) varied from 0.60% to 1.4%. The result found in records from North Carolina hospitals (0.60%) is likely to be below the national average because patient safety efforts in that state have been more intense when compared with other states. The results from the other studies would be expected to be above the national average because of the age of the patients and seriousness of the illnesses. This dispersion of percentages makes sense and gives one confidence that the estimate of the average number of preventable, lethal adverse events based on hospital medical records screened by the GTT approach is representative of the nation as a whole. The portion of serious adverse events that were not lethal (class F, G, and H) were roughly 10- to 20-fold larger than the portion of lethal PAEs. This leads to a rough estimate of 2 to 4 million serious, PAEs per year that would be discoverable in medical records using the GTT approach.

There are important limitations to the 4 modern studies that must be considered. Premature deaths as a result of medical errors may occur many years after the hospital stay because the patient's care was not optimal or did not follow guidelines.[12] Furthermore, lethal PAEs can been missed by the GTT and by physician reviews. The GTT does not detect diagnostic errors or errors of omission, especially those involving failure to follow guidelines.[19] Lethal diagnostic errors have been estimated to affect 40,000 to 80,000 people per year including outpatients.[34] Physicians have been indefensibly slow to adopt guidelines that would potentially prevent premature deaths or harm.[35] One egregious example is the estimated 100,000 heart failure patients that died prematurely each year in the late 1990s because they did not receive beta-blockers.[13] The efficacy of beta-blockers was established by a study published in the *JAMA* in 1982.[36]

The 4 modern studies also rely heavily on information in medical records. One study of medical records showed that quality scores of 607 randomly selected medical records on cardiac patients treated in 219 hospitals from January 2004 to June 2005 averaged 12.5/20 points, which suggests rather poor medical record keeping.[37] The quality scores were determined based on the medical records including cardiac history, performance and cognition levels, current medications and medication allergies, differential diagnosis, and planned use of evidence-based medicine. Hospitals with low-scoring records (0–10 points) had a 40% higher in-hospital death rate than those that scored high (15–20 points). Furthermore, the larger OIG study noted that "To the extent that the study did not identify an event, it was likely because the three screening methods failed to flag the case for physicians review or because documentation in the medical records was incomplete."[23]

A few years after the seminal publication by the IOM, another IOM panel recognized the limitations of using medical records provided by medical institutions as the basis for identifying medical errors. When an adverse event is alleged and an evaluation is undertaken, the "sentinel effect can significantly alter the data that are recorded."[30] There are anecdotal accounts of data altering or omission of critical data when mistakes are alleged; however, to our knowledge, scientific studies of this phenomenon have been lacking until recently.

In a study that broke past the wall of silence about discovery of medical errors that were missing from medical records, Weissman and colleagues found that 6 to 12 months after their discharge, patients could recall 3 times as many serious, preventable adverse events as were reflected in their medical records.[14] This study involved review of 998 medical records of patients hospitalized in Massachusetts for medical or surgical treatment from April to October 2003. Record reviews by specially trained nurses and doctors identified 11 serious PAEs from the records. The method was one adapted from the Harvard Medical Practice Study, which is the method used by the core result in the report from the IOM asserting up to 98,000 deaths per year occur from medical errors.[25] However, interviews with patients identified 21 additional serious PAEs that were not documented in the medical records. Of the 21 undiscovered, serious PAEs, 12 occurred predischarge and 9 occurred postdischarge. The predischarge serious PAEs included the following: adverse drug events (3), nerve or vessel injury or wrong operation (4), deep venous thrombosis (2), hospital acquired infection (2), and postoperative respiratory distress (1). The serious PAEs postdischarge included the following: wound infection (6), deep venous thrombosis (1), operative wound dehiscence (1), and operative organ injury (1). Even in this study, the investigators found only those errors that patients were aware had happened. There certainly may be more serious errors that went undocumented and were unknown to patients. Weismann's finding that evidence of many serious adverse events is not apparent in medical records is reinforced by some older studies. For example, it has been pointed out that some medical errors are not known by clinicians and only come to light during autopsies, which have found misdiagnoses in 20% to 40% of cases.[38] "Aggressive" searches for adverse drug events and prompted self-reports from clinicians have shown a much higher rate of adverse drug events than are evident in the medical records.[39] A comparison of direct observation for medication errors with review of documentation in medical records in 36 hospitals and skilled-nursing facilities found that far more errors were found by direct observation than by inspection of medical records.[40]

A recent national survey showed that physicians often refuse to report a serious adverse event to anyone in authority.[41] In the case of cardiologists, the highest nonreporting group of the specialties studied, nearly two-thirds of the respondents admitted that they had recently refused to report at least one serious medical error, of which they had first-hand knowledge, to anyone in authority. It is reasonable to suspect that clear evidence of such unreported medical errors often did not find their way into the medical records of the patients who were harmed.

The bottom line on total, lethal PAEs as a result of care in hospitals cannot be estimated in a statistically rigorous way.

Based on our extrapolation from the 4 modern studies, there are at least 210,000 lethal PAEs detectable by the GTT approach to record reviews. To deal with other factors that should be applied to this estimate, the "weight of evidence" approach must be engaged. In addition to the core estimate of 210,000, one must consider evidence of the following:

- life-shortening errors of omission due to failure to follow medical guidelines that the GTT approach misses,[19]
- a factor for evidence of errors of commission that are not documented in medical records,[37,39]
- failure to make life-saving diagnoses.[38]

In light of the evidence above, and especially that of the Weisman study,[14] and although it is probably an underestimate, a minimum estimate of a 2-fold increase in the medical record–based estimate is reasonable to compensate for the known absence of evidence in medical records of errors of commission and the inability of the GTT to detect errors of omission even when the evidence that guidelines were not followed may be present in the medical record. Note that the Weisman study suggests a factor of 3 (32/11) for undocumented evidence of serious PAEs caused during hospitalization, but here, we settle for a factor of 2.[14] To this, one should add the undetected diagnostic errors. If we begin with the minimum estimate of 40,000 and assume that only half of these occur in hospitals, then the math looks like this: $(210{,}000 \times 2) + 20{,}000 \sim 440{,}000$ PAEs that contribute to the death of patients each year from care in hospitals. This is roughly one-sixth of all deaths that occur in the United States each year. The problem of PAEs must emerge from behind the "Wall of Silence" and be addressed for the sake of prolonging the lives of Americans.

Needed changes involve not only doctors and hospitals but increased participation by patients in their health-care decisions. Perhaps it is time for a national patient bill of rights for hospitalized patients that would empower them to be thoroughly integrated into their care so that they can take the lead in reducing their risk of serious harm and death.[15] All evidence points to the need for much more patient involvement in identifying harmful events and participating in rigorous follow-up investigations to identify root causes.[42] Even for those harms identified in the medical records of Medicare patients, only 14% become part of the hospital's incident reporting system.[9] Physician observers of our hospitals have made Congress painfully aware that the hospital peer-review system has widespread failures that permit negligent care by physicians.[43] Hospitals are simply not going to heal without attentive, systematic listening to those harmed patients or their survivors.

CONCLUSIONS

There was much debate after the IOM report about the accuracy of its estimates. In a sense, it does not matter whether the deaths of 100,000, 200,000 or 400,000 Americans each year are associated with PAEs in hospitals. Any of the estimates demands assertive action on the part of providers, legislators, and people who will one day become patients. Yet, the action and progress on patient safety is frustratingly slow; however, one must hope that the present, evidence-based estimate of 400,000+ deaths per year will foster an outcry for overdue changes and increased vigilance in medical care to address the problem of harm to patients who come to a hospital seeking only to be healed.

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ANALYSIS

Medical error—the third leading cause of death in the US

Medical error is not included on death certificates or in rankings of cause of death. **Martin Makary** and **Michael Daniel** assess its contribution to mortality and call for better reporting

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The annual list of the most common causes of death in the United States, compiled by the Centers for Disease Control and Prevention (CDC), informs public awareness and national research priorities each year. The list is created using death certificates filled out by physicians, funeral directors, medical examiners, and coroners. However, a major limitation of the death certificate is that it relies on assigning an International Classification of Disease (ICD) code to the cause of death.[1] As a result, causes of death not associated with an ICD code, such as human and system factors, are not captured. The science of safety has matured to describe how communication breakdowns, diagnostic errors, poor judgment, and inadequate skill can directly result in patient harm and death. We analyzed the scientific literature on medical error to identify its contribution to US deaths in relation to causes listed by the CDC.[2]

Death from medical care itself

Medical error has been defined as an unintended act (either of omission or commission) or one that does not achieve its intended outcome,[3] the failure of a planned action to be completed as intended (an error of execution), the use of a wrong plan to achieve an aim (an error of planning),[4] or a deviation from the process of care that may or may not cause harm to the patient.[5] Patient harm from medical error can occur at the individual or system level. The taxonomy of errors is expanding to better categorize preventable factors and events.[6] We focus on preventable lethal events to highlight the scale of potential for improvement.

The role of error can be complex. While many errors are non-consequential, an error can end the life of someone with a long life expectancy or accelerate an imminent death. The case in the box shows how error can contribute to death. Moving away from a requirement that only reasons for death with an ICD code can be used on death certificates could better inform healthcare research and awareness priorities.

How big is the problem?

The most commonly cited estimate of annual deaths from medical error in the US—a 1999 Institute of Medicine (IOM) report[7]—is limited and outdated. The report describes an incidence of 44 000-98 000 deaths annually.[7] This conclusion was not based on primary research conducted by the institute but on the 1984 Harvard Medical Practice Study and the 1992 Utah and Colorado Study.[8 9] But as early as 1993, Leape, a chief investigator in the 1984 Harvard study, published an article arguing that the study's estimate was too low, contending that 78% rather than 51% of the 180 000 iatrogenic deaths were preventable (some argue that all iatrogenic deaths are preventable).[10] This higher incidence (about 140 400 deaths due to error) has been supported by subsequent studies which suggest that the 1999 IOM report underestimates the magnitude of the problem. A 2004 report of inpatient deaths associated with the Agency for Healthcare Quality and Research Patient Safety Indicators in the Medicare population estimated that 575 000 deaths were caused by medical error between 2000 and 2002, which is about 195 000 deaths a year (table 1 ⇓).[11] Similarly, the US Department of Health and Human Services Office of the Inspector General examining the health records of hospital inpatients in 2008, reported 180 000 deaths due to medical error a year among Medicare beneficiaries alone.[12] Using similar methods, Classen et al described a rate of 1.13%.[13] If this rate is applied to all registered US hospital admissions in 2013[15] it translates to over 400 000 deaths a year, more than four times the IOM estimate.

Similarly, Landrigan et al reported that 0.6% of hospital admissions in a group of North Carolina hospitals over six years (2002-07) resulted in lethal adverse events and conservatively estimated that 63% were due to medical errors.[14] Extrapolated nationally, this would translate into 134 581 inpatient deaths a year from poor inpatient care. Of note, none of the studies captured deaths outside inpatient care—those resulting from errors in care at home or in nursing homes and in outpatient care such as ambulatory surgery centers.

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Case history: role of medical error in patient death

A young woman recovered well after a successful transplant operation. However, she was readmitted for non-specific complaints that were evaluated with extensive tests, some of which were unnecessary, including a pericardiocentesis. She was discharged but came back to the hospital days later with intra-abdominal hemorrhage and cardiopulmonary arrest. An autopsy revealed that the needle inserted during the pericardiocentesis grazed the liver causing a pseudoaneurysm that resulted in subsequent rupture and death. The death certificate listed the cause of death as cardiovascular.

A literature review by James estimated preventable adverse events using a weighted analysis and described an incidence range of 210 000-400 000 deaths a year associated with medical errors among hospital patients.[16] We calculated a mean rate of death from medical error of 251 454 a year using the studies reported since the 1999 IOM report and extrapolating to the total number of US hospital admissions in 2013. We believe this understates the true incidence of death due to medical error because the studies cited rely on errors extractable in documented health records and include only inpatient deaths. Although the assumptions made in extrapolating study data to the broader US population may limit the accuracy of our figure, the absence of national data highlights the need for systematic measurement of the problem. Comparing our estimate to CDC rankings suggests that medical error is the third most common cause of death in the US (fig 1⇓).[2]

Better data

Human error is inevitable. Although we cannot eliminate human error, we can better measure the problem to design safer systems mitigating its frequency, visibility, and consequences. Strategies to reduce death from medical care should include three steps: making errors more visible when they occur so their effects can be intercepted; having remedies at hand to rescue patients [17]; and making errors less frequent by following principles that take human limitations into account (fig 2⇓). This multitier approach necessitates guidance from reliable data.

Currently, deaths caused by errors are unmeasured and discussions about prevention occur in limited and confidential forums, such as a hospital's internal root cause analysis committee or a department's morbidity and mortality conference. These forums review only a fraction of detected adverse events and the lessons learnt are not disseminated beyond the institution or department.

There are several possible strategies to estimate accurate national statistics for death due to medical error. Instead of simply requiring cause of death, death certificates could contain an extra field asking whether a preventable complication stemming from the patient's medical care contributed to the death. An early experience asking physicians to comment on the potential preventability of inpatient deaths immediately after they occurred resulted in an 89% response rate.[18] Another strategy would be for hospitals to carry out a rapid and efficient independent investigation into deaths to determine the potential contribution of error. A root cause analysis approach would enable local learning while using medicolegal protections to maintain anonymity. Standardized data collection and reporting processes are needed to build up an accurate national picture of the problem. Measuring the consequences of medical care on patient outcomes is an important prerequisite to creating a culture of learning from our mistakes, thereby advancing the science of safety and moving us closer towards the Institute of Medicine's goal of creating learning health systems.[19]

Health priorities

We have estimated that medical error is the third biggest cause of death in the US and therefore requires greater attention. Medical error leading to patient death is under-recognized in many other countries, including the UK and Canada.[20 21] According to WHO, 117 countries code their mortality statistics using the ICD system as the primary indicator of health status.[22] The ICD-10 coding system has limited ability to capture most types of medical error. At best, there are only a few codes where the role of error can be inferred, such as the code for anticoagulation causing adverse effects and the code for overdose events. When a medical error results in death, both the physiological cause of the death and the related problem with delivery of care should be captured.

To achieve more reliable healthcare systems, the science of improving safety should benefit from sharing data nationally and internationally, in the same way as clinicians share research and innovation about coronary artery disease, melanoma, and influenza. Sound scientific methods, beginning with an assessment of the problem, are critical to approaching any health threat to patients. The problem of medical error should not be exempt from this scientific approach. More appropriate recognition of the role of medical error in patient death could heighten awareness and guide both collaborations and capital investments in research and prevention.

Contributors and sources: MM is the developer of the operating room checklist, the precursor to the WHO surgery checklist. He is a surgical oncologist at Johns Hopkins and author of *Unaccountable*, a book about transparency in healthcare. MD is the Rodda patient safety research fellow at Johns Hopkins and is focused on health services research. This article arose from discussions about the paucity of funding available to support quality and safety research relative to other causes of death.

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Summary points

Death certificates in the US, used to compile national statistics, have no facility for acknowledging medical error

If medical error was a disease, it would rank as the third leading cause of death in the US

The system for measuring national vital statistics should be revised to facilitate better understanding of deaths due to medical care

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Table

Table 1| **Studies on US death rates from medical error since the 1999 IOM report and point estimate from pooled results**

Study	Dates covered	Source of information	Patient admissions	Adverse event rate (%)	Lethal adverse event rate (%)	% of events deemed preventable	No of deaths due to preventable adverse event	% of admissions with a preventable lethal adverse event	Extrapolation to 2013 US admissions†
Health Grades[11]	2000-02	Medicare patients	37 000 000	3.1	0.7*	NR	389 576	0.71	251 454
Office of Inspector General[12]	2008	Medicare patients	838	13.5	1.4	44	12	0.62	219 579
Classen et al[13]	2004	3 tertiary care hospitals	795	33.2	1.1	100	9	1.13	400 201
Landrigan et al[14]	2002-07	10 hospitals in North Carolina	2341	18.1	0.6	63	14	0.38	134 581
Point estimate from all data	2000-08	—	—	—	—	—	—	0.71	251 454‡

NR=Not reported.

*All were considered preventable.

†Total number of US hospital admissions in 2013 was 35 416 020.[10]

‡Total number of people who died from a preventable lethal adverse event calculated as a point estimate of the death rate among hospitalized patients reported in the literature extrapolated to the reported number of patients hospitalized in 2013.

Figures

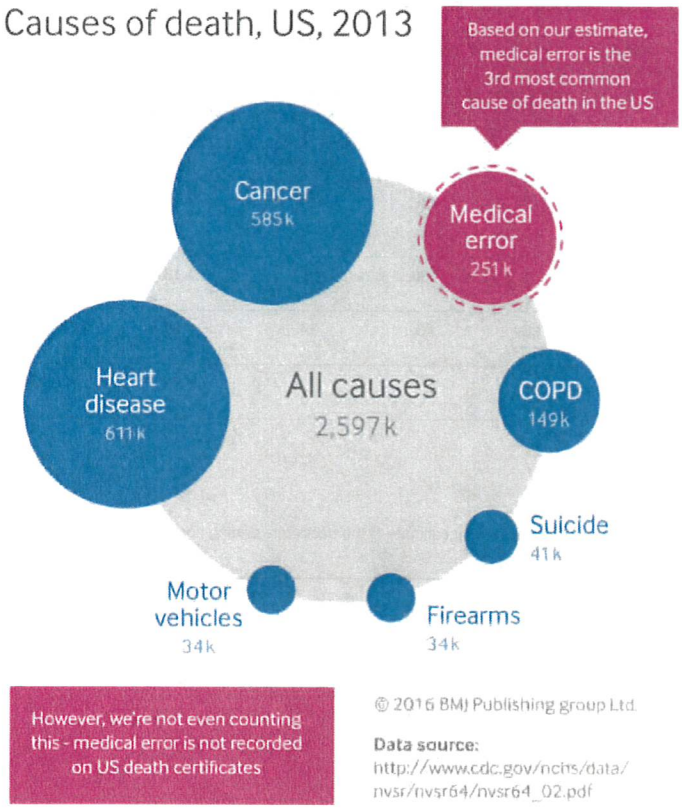

Fig 1 Most common causes of death in the United States, 2013[2]

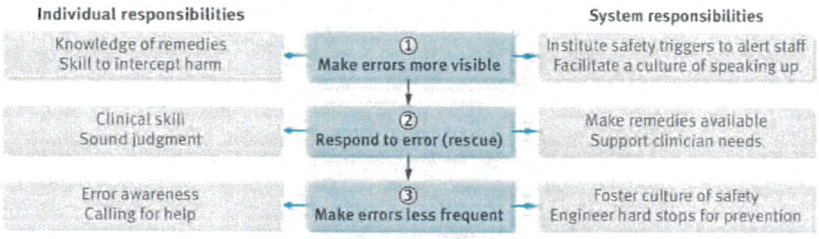

Fig 2 Model for reducing patient harm from individual and system errors in healthcare

Prevalence, severity, and nature of preventable patient harm across medical care settings: systematic review and meta-analysis

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ABSTRACT

OBJECTIVE

To systematically quantify the prevalence, severity, and nature of preventable patient harm across a range of medical settings globally.

DESIGN

Systematic review and meta-analysis.

DATA SOURCES

Medline, PubMed, PsycINFO, Cinahl and Embase, WHOLIS, Google Scholar, and SIGLE from January 2000 to January 2019. The reference lists of eligible studies and other relevant systematic reviews were also searched.

REVIEW METHODS

Observational studies reporting preventable patient harm in medical care. The core outcomes were the prevalence, severity, and types of preventable patient harm reported as percentages and their 95% confidence intervals. Data extraction and critical appraisal were undertaken by two reviewers working independently. Random effects meta-analysis was employed followed by univariable and multivariable meta regression. Heterogeneity was quantified by using the I^2 statistic, and publication bias was evaluated.

RESULTS

Of the 7313 records identified, 70 studies involving 337 025 patients were included in the meta-analysis. The pooled prevalence for preventable patient harm was 6% (95% confidence interval 5% to 7%). A pooled proportion of 12% (9% to 15%) of preventable patient harm was severe or led to death. Incidents related to drugs (25%, 95% confidence interval 16% to 34%) and other treatments (24%, 21% to 30%) accounted for the largest proportion of preventable patient harm. Compared with general hospitals (where most evidence originated), preventable patient harm was more prevalent in advanced specialties (intensive care or surgery; regression coefficient b=0.07, 95% confidence interval 0.04 to 0.10).

CONCLUSIONS

Around one in 20 patients are exposed to preventable harm in medical care. Although a focus on preventable patient harm has been encouraged by the international patient safety policy agenda, there are limited quality improvement practices specifically targeting incidents of preventable patient harm rather than overall patient harm (preventable and non-preventable). Developing and implementing evidence-based mitigation strategies specifically targeting preventable patient harm could lead to major service quality improvements in medical care which could also be more cost effective.

WHAT IS ALREADY KNOWN ON THIS TOPIC

A better understanding of the nature of preventable patient harm has the potential to impact on international healthcare policy and practice

The prevalence of overall patient harm has been established by systematic reviews but the prevalence of preventable patient harm has received less attention

WHAT THIS STUDY ADDS

A meta-analysis that quantifies the prevalence, nature, and severity of preventable patient harm in a range of medical care settings

At least one in 20 patients are affected by preventable patient harm in medical care settings

Approximately 12% of preventable patient harm causes permanent disability or patient death and is mostly related to drug incidents, therapeutic management, and invasive clinical procedures

Introduction

Patient harm during healthcare is a leading cause of morbidity and mortality internationally.[1 2] The World Health Organization defines patient harm as "an incident that results in harm to a patient such as impairment of structure or function of the body and/or any deleterious effect arising there from or associated with plans or actions taken during the provision of healthcare, rather than an underlying disease or injury, and may be physical, social or psychological (eg, disease, injury, suffering, disability and death)."[3] The health burden and patient experiencing healthcare-related patient harm has been reported to be comparable to chronic diseases such as multiple sclerosis and cervical cancer in developed countries, and tuberculosis and malaria in developing countries.[4 5] Harmful patient incidents are also a major financial burden for healthcare systems across the globe. It is estimated that 10-15% of healthcare expenditure is consumed by the direct sequelae of healthcare-related patient harm.[6 7]

Early detection and prevention of patient harm in healthcare is an international policy priority.[8] In principle, zero harm would be the ideal goal. However, this goal is not feasible because some harms cannot be avoided in clinical practice. For example, some adverse drug reactions which occur in the absence of any error in the prescription process and without the possibility

of detection are less likely to be preventable. In recent years, the recognition that a proportion of patient harm is not preventable has increased attention to the notion of preventable patient harm.[9] Most studies classify patient harm as preventable if it occurs as a result of an identifiable modifiable cause, and its future recurrence can be avoided by reasonable adaptation to a process, or adherence to guidelines, although universal consensus has not been established.[10] Key sources of preventable patient harm could include the actions of healthcare professionals (errors of omission or commission), healthcare system failures, or involve a combination of errors made by individuals, system failures, and patient characteristics.[11-14] Strengthening the focus on preventable patient harm has the potential to lead to greater tangible clinical benefits and improved translation of patient safety research findings into clinical practice. Patient safety improvement strategies underpinned by better understanding of the nature of preventable patient harm have greater prospects of efficiency (because they are more specific) and implementation (because clinicians can readily recognise their value).[10]

There are several systematic reviews on overall patient harm across different medical settings, but none of these have focused on preventable patient harm.[1 15-17] We undertook a systematic review and meta-analysis to estimate the prevalence of preventable patient harm across medical settings including hospitals, various specialties, and in primary care. We also examined the severity and most commonly occurring types of preventable patient harm.

Methods

This systematic review was conducted and reported in accordance with the Reporting Checklist for Meta-analyses of Observational Studies (MOOSE).[18] The completed MOOSE checklist is available in eTable 1.

Eligibility criteria

We included quantitative observational studies such as cohort (prospective or retrospective) and cross sectional studies in any geographical area in any medical care setting (primary, secondary, and tertiary care) published from January 2000 onwards. We selected this start date because it coincides with when the published patient safety research began to increase in volume after the publication of the landmark report *To Err is Human: Building a Safer Health System* in 1999.[1 5 19]

The primary outcome was the prevalence of preventable patient harm. Patient harm (which is synonymous with adverse events in healthcare) is defined as unanticipated, unforeseen accidents (eg, patient injuries, care complications, or death) which are a direct result of the care dispensed rather than the patient's underlying disease. Patient harm is preventable firstly, when occurring as a result of an identifiable and modifiable cause and secondly, when the prevention of future recurrence of the patient harm is possible with reasonable adaptation to a process and adherence to guidelines.[10]

The secondary outcomes were the severity and types of preventable patient harm. In accordance to the reporting format of the eligible studies, severity of preventable patient harm was classified into mild, moderate, and severe. Key types of preventable harm were drug-related, diagnostic, medical procedure-related, and healthcare-acquired infections (definitions are presented in eTable 1).

We excluded the following: studies reporting data on harm but not on preventable patient harm; studies with an exclusive focus on a specific type of harm only (only drug-related harm) or a specific severity level of harm only (incidents which only resulted in readmissions or extended length of stay) because such estimates would differ from estimates based on any type or any severity level of preventable patient harm; and studies focused on specific patient populations (eg, patients with a particular disease) because such estimates could differ from estimates in the general population.

Searches

We searched five electronic bibliographic databases from January 2000 to 27 January 2019: Medline, Cinahl, Embase, Pubmed, and PsycINFO. We supplemented these searches by screening grey literature sources including three databases (WHOLIS, Google Scholar, SIGLE), relevant reports, and conference abstracts. We also screened existing systematic reviews and checked the reference lists of eligible studies. The search strategy is available in eTable 3.

Study selection and extraction

We exported the results of the searches to Endnote X8 and removed duplicates. We completed screening in two stages. Initially, the titles and abstracts of the studies were screened for eligibility. Afterwards, the full texts of studies initially assessed as relevant for the review were retrieved and checked against our inclusion or exclusion criteria. We devised a data extraction spreadsheet, after being piloted, to extract descriptive data on key study characteristics (eg, number and age of participants, research design, data collection, assessment of preventability) and quantitative outcomes (prevalence, types, and severity of preventable patient harm). Two independent researchers (KK and MP) performed the screening and data extraction with disagreements resolved by discussion within the wider team (AA, DA, RH, RK). The inter-rater reliability was excellent (kappa=0.88 and 0.90).

Risk of bias assessment

We evaluated the risk of bias in the studies by using an adapted form of the Newcastle Ottawa scale for cross sectional and cohort studies.[20] This assessed the representativeness of the sample, sample size, response rate, ascertainment of the exposure, control of confounding variables, assessment of preventability, and appropriate statistical analysis, which provided a score ranging from 0 (lowest grade) to 9 (highest grade). A higher grade indicated a lower risk of bias.

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For our analyses, studies scoring 7 or above were considered as low risk, whereas studies scoring below 7 were considered as high risk.

Analyses

Our primary outcome was the prevalence of preventable patient harm expressed as the proportion of patients with at least one preventable patient harmful incident and stratified according to different medical services. We also calculated and reported the median prevalence of preventable patient harm and interquartile ranges across all medical care settings. Our secondary outcomes were the severity and types of preventable patient harm expressed as proportions of the total number of preventable patient harmful incidents. We pooled all data in Stata 15 by using the metaprop command.[21] To improve the meaning and interpretation of our findings in relation to the prevalence, severity, and common types of preventable patient harm, we also present data on the prevalence, severity, and common types of overall harm (preventable and non-preventable) by using the same pool of studies in all analyses.

We conducted univariable and multivariable meta regression to test the influence of study level moderators on the prevalence of preventable patient harm using the metareg command.[22] Consistent with the recommendations of Thompson and Higgins,[23] eight prespecified study level moderators were hypothesised to have an effect on the prevalence of preventable patient harm (medical setting, population, research design, assessment method of harm, assessment of preventability, sample size, risk of bias, WHO region). Moderators were selected and coded following consensus procedures and each moderator value was based on a minimum of eight studies.[23] Covariates meeting our significance criterion ($P<0.10$) were entered into a multivariable meta regression model. The $P<0.10$ threshold was conservative, to avoid prematurely discounting potentially important explanatory variables. Because proportions were often expected to be small, we used Freeman-Tukey Double Arcsine transformation to stabilise the variances and then performed a random effects meta-analysis implementing the DerSimonian-Laird method.[24 25]

Random effects models were used in all analyses because they are more conservative and have better properties in the presence of heterogeneity.[26 27] Heterogeneity was quantified by using the I^2 statistic. Conventionally, I^2 values of 25%, 50%, and 75% indicate low, moderate, and high heterogeneity, respectively.[28] We inspected the symmetry of the funnel plots and used Egger's test to examine for publication bias.[29] Funnel plots were constructed using the metafunnel command,[30] and the Egger test was computed using the metabias command.[31]

Patient and public involvement

Two patient partners, who were members of our research advisory panel, were involved in the development of our research questions and in selecting the outcome measures of this study. The two patients also provided critical feedback to the protocol of the systematic review and advised on the interpretation and dissemination of results.

Results

The searches yielded 7313 citations. After we removed duplicates and reviewed the titles and abstracts, 6522 articles were excluded. Of the remaining 307 studies, 241 were excluded after reviewing the full article. A total of 66 studies reporting 70 independent samples were included in the review.[17 32-98] Figure 1 shows the study flow for the selection process.

Descriptive characteristics

This review is based on a pooled sample of 337 025 patients, 28 150 of who experienced harmful incidents and 15 419 experienced preventable harmful incidents. A total of 47 148 harmful incidents were identified in the pooled sample, 25 977 (55%) of which were preventable. The sample sizes ranged widely across studies (median 1440 patients, range 128-96 047). Thirty three studies (47%) were conducted in the US, 27 (39%) in Europe, and 10 (14%) elsewhere. The most common study design was retrospective or cross-sectional (n=50; 71%) followed by prospective (20; 29%). Fifty three studies (76%) reviewed the medical charts of patients to detect harm, whereas 17 studies (24%) monitored patients over time or were based on self reports (eg, interviews with patients). All included studies assess the preventability of patient harm by using consensus procedures between two or more trained reviewers (physicians or teams of physicians and nurses). Fifty studies (71%) used a standardised Likert scale to facilitate the consensus decisions for the preventability of patient harm among the reviewers (harmful incidents assigned a score of four out of six and over were considered preventable).[99] The remaining 20 studies (29%) used implicit agreed criteria to reach consensus regarding the preventability of patient harm among the reviewers. Most studies were conducted in general hospitals involving patients from a range of specialties (45 studies; 64%). Twelve studies (17%) were conducted in advanced care specialties (intensive care 6 studies; surgery 6 studies), six studies (8%) in emergency department, four in obstetrics (6%), and three in primary care (4%). Except for six studies (9%), which were based on children and adolescents, and five studies on older adults (7%), the remaining 59 studies (84%) were mainly based on adults. Further details of the descriptive characteristics of the included studies are available in eTable 2.

All 70 studies reported data on the prevalence of preventable patient harm and overall patient harm. One third of the studies (20 studies, 29%) reported data on the severity of preventable patient harm. Forty three studies (60%) reported proportions of at least two of the following six types of preventable patient harm: drug management, non-drug therapeutic management, diagnosis, invasive medical procedures,

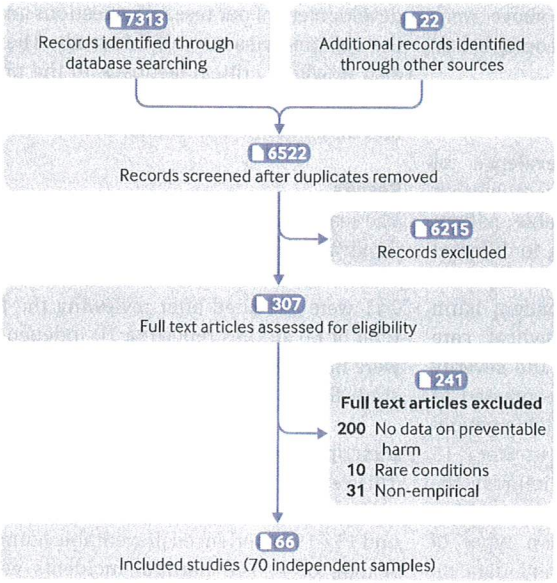

Fig 1 | Flowchart of the inclusion of studies in the review

surgical procedures, and infections acquired during healthcare.

Risk of bias results

The Newcastle Ottawa scores for the studies ranged from three to nine (maximum 9, a higher score indicating a lower risk of bias). Twenty nine studies (41%) scored eight or above and were considered to be at low risk of bias (see full assessment in eTable 3).

Meta-analysis of the prevalence of preventable patient harm stratified by medical settings

Table 1 shows that the pooled prevalence of preventable patient harm was 6% (95% confidence interval 5% to 7%, I^2=99%) and the median prevalence was 5% (interquartile range 3-9%). In comparison, the pooled prevalence of overall harm (preventable and non-preventable) was 12% (95% confidence interval 9% to 14%, I^2=99%; table 1) and the median was 10% (interquartile range 7-15%). The highest pooled prevalence estimate of preventable patient harm was reported in intensive care (18%, 95% confidence interval 12% to 26%, I^2=96%) and surgery (10%, 7% to 13%, I^2=97%) and the lowest in obstetrics (2%, 0% to 4%, I^2=95%). Figure 2 presents the forest plot of the prevalence of preventable patient harm across medical care settings.

Meta-analysis of the severity and types of preventable patient harm

Table 1 shows the pooled proportions of the severity and types of preventable patient harm. The pooled proportion of mild harm was 49% (95% confidence interval 43% to 56%, I^2=97%), moderate harm was 36% (31% to 42%, I^2=96%), and severe harm was 12% (9% to 15%, I^2=94%).

Drug management incidents (25%, 95% confidence interval 16% to 34%, I^2=98%), and other therapeutic management incidents (24%, 21% to 30%, I^2=98%), accounted for the highest proportion of preventable patient harm followed by incidents related to surgical procedures (23%, 9% to 38%, I^2=98%), healthcare infections (16%, 11% to 22%, I^2=98%), and diagnosis (16%, 11% to 21%, I^2=98%).

Meta-regressions exploring the variance in the prevalence of preventable patient harm

Table 2 shows the results of the univariable and multivariable analyses. The univariable analyses showed that the prevalence of preventable patient harm was higher across studies based in advanced

Table 1 | Proportions of types of preventable patient harm and overall patient harm

		Preventable harm			Overall harm		
Outcome	No	% (95% CI)	I^2	Median (IQR)	% (95% CI)	I^2	Median (IQR)
Prevalence							
Overall	70	6 (5 to 7)	99	5 (3-9)	12 (9 to 14)	99	10 (7-15)
Emergency department	6	3 (2 to 4)	78	3 (3-4)	5 (3 to 6)	84	5 (4-6)
Hospitals	45	5 (4 to 6)	99	5 (3-7)	10 (9 to 12)	99	10 (7-12)
Intensive care	6	18 (12 to 26)	96	14 (10-28)	34 (19 to 50)	99	29 (20-59)
Obstetrics	4	2 (0 to 4)	95	NA	4 (2 to 6)	92	NA
Primary care	3	3 (0 to 9)	0	NA	7 (3 to 10)	0	NA
Surgery	6	10 (7 to 13)	97	9 (9-10)	20 (14 to 27)	99	22 (15-30)
Severity of patient harm							
Mild	20	49 (43 to 56)	97	45 (40-55)	50 (41 to 59)	98	49 (43-58)
Moderate	20	36 (31 to 42)	96	38 (30-50)	36 (28 to 44)	98	36 (27-47)
Severe	20	12 (9 to 15)	94	10 (8-19)	12 (8 to 15)	95	13 (6-17)
Types of patient harm							
Drugs	25	25 (16 to 34)	98	20 (9-35)	26 (19 to 34)	99	21 (17-30)
Other therapeutic	17	24 (21 to 30)	98	22 (16-30)	20 (9 to 31)	98	21 (12-32)
Procedure	20	23 (13 to 33)	98	18 (6-28)	24 (17 to 31)	98	19 (14-32)
Surgical procedure	18	23 (9 to 38)	98	21 (8-36)	31 (20 to 42)	98	27 (16-41)
Diagnosis	20	16 (11 to 21)	98	12 (5-22)	9 (6 to 12)	98	10 (6-11)
Healthcare infections	14	16 (11 to 22)	98	NA	21 (15 to 28)	98	NA

The proportions for types of preventable or overall harm do not add to 100% because each figure in the table is the pooled proportion which has been calculated by combining (after assigning appropriate weights) proportions extracted from several independent studies using meta-analysis. Moreover, not all studies reported all types of preventable or overall harm and therefore it is not appropriate to assume they add up to 100%.
NA=not applicable.

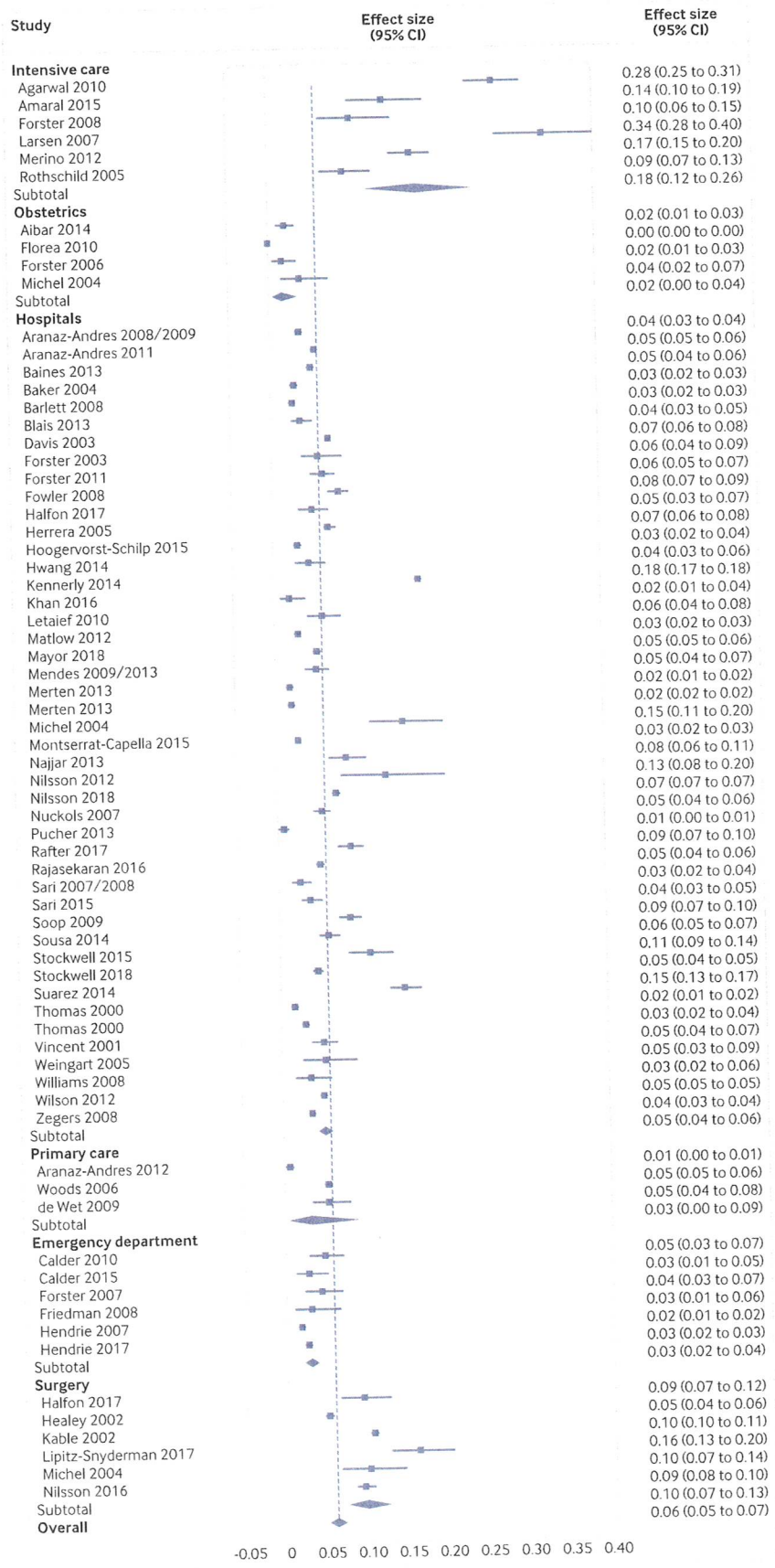

Fig 2 | Forest plot of the pooled prevalence of preventable patient harm across medical care settings

specialties such as surgery and intensive care (b=0.08, 95% confidence interval 0.05 to 0.11), in studies with relatively small sample sizes (b=0.03, 0.01 to 0.06), and in studies on children and older adults (b=0.03, −0.01 to 0.05). These three variables (medical care setting, population group, and sample size) were therefore eligible for inclusion in the multivariable regression analysis. All the other variables (research design, assessment method of harm, assessment of preventability, risk of bias, and WHO region) were ineligible for inclusion in multivariable analyses because none of them influenced the prevalence of preventable patient harm in unvariable analyses (P>0.10).

The overall multivariable model was statistically significant (χ^2 (4)=33.98, P<0.001) and reduced the I^2 statistic from 79% to 31%. Only the medical care setting (b=0.07, 95% confidence interval 0.04 to 0.10) remained a significant predictor of the prevalence of preventable patient harm in multivariable analyses suggesting that the prevalence of preventable patient harm is higher in advanced medical specialties (surgery and primary care) compared with studies in general hospitals. The population group and sample size were not significantly associated with the prevalence of preventable patient harm after controlling for the medical care setting in the multivariable analyses.

Small study bias

Figure 3 shows some evidence of publication bias as indicated by visual inspections of the funnel plots and by the Egger test for small study effects for the primary outcome (bias coefficient for the main analysis 1.20, 95% confidence interval 0.24 to 2.15, P=0.02).

Discussion

Understanding and mitigating preventable patient harm is a major public health challenge across the globe. We conducted a systematic review and meta-analysis to understand the prevalence, severity, and common types of preventable patient harm across medical care settings. We pooled data from 70 studies and we found that preventable patient harm occurs in 6% of patients across medical care settings. Considering that a pooled prevalence of 12% for overall harm was found, we conclude that half of patient harm is preventable. The proportion of severe preventable patient harm causing prolonged, permanent disability or death was 12%. The most common types of preventable patient harm were related to drugs, other therapeutic management, and invasive medical and surgical procedures. The most extensive evidence on preventable patient harm comes from hospitals (45 studies) but less evidence is available for specific medical specialties. Preventable patient harm was more prevalent in patients treated in surgical and intensive care units compared with patients treated within across general hospitals. None of the other method variations which we examined across the studies influenced the pooled prevalence of preventable patient harm (population group, research design, assessment method of harm, assessment of preventability, sample size, risk of bias, or WHO region).

Table 2 | Univariable and multivariable predictors of the prevalence of preventable patient harm (n=70)

		Univariable			Multivariable		
Variable	No	Regression coefficient (95% CI)	SE	P value	Regression coefficient (95% CI)	SE	P value
WHO region:							
US	33	1	—	—	—	—	—
Europe	27	−0.01 (−0.03 to 0.01)	0.01	0.59	NA	NA	NA
Asia or other	10	−0.01 (−0.02 to 0.04)	0.02	0.54	NA	NA	NA
Medical setting:							
General hospitals and obstetrics	49	1	—	—	1	—	—
Primary care and emergency department	9	−0.02 (−0.05 to 0.01)	0.02	0.18	−0.03 (−0.06 to 0.01)	0.02	0.12
Advanced hospital specialties	12	0.08 (0.05 to 0.11)	0.02	<0.001	0.07 (0.04 to 0.10)	0.01	<0.001
Research design:							
Retrospective or cross sectional	50	1	—	—	—	—	—
Prospective	20	0.01 (−0.01 to 0.04)	0.01	0.31	NA	NA	NA
Sample size:							
Large (n>1000)	43	1	—	—	1	—	—
Small (n<1000)	27	0.03 (0.01 to 0.06)	0.01	0.02	0.02 (−0.01 to 0.04)	0.01	0.12
Population:							
Adults	59	1	—	—	—	—	—
Children or older adults	11	0.03 (−0.01 to 0.05)	0.02	0.09	0.02 (−0.01 to 0.05)	0.01	0.09
Assessment method:							
Medical record review	53	1	—	—	—	—	—
Surveys with patients and health providers	17	−0.01 (−0.04 to 0.02)	0.01	0.58	NA	NA	NA
Preventability by consensus among reviewers using:							
Standardised Likert scale	43	1	—	—	1	—	—
Implicit criteria	27	0.01 (−0.01 to 0.04)	0.01	0.36	NA	NA	NA
Risk of bias:							
High (<7 score)	41	1	—	—	—	—	—
Low (>7 score)	29	−0.01 (−0.03 to 0.02)	0.01	0.89	NA	NA	NA

SE=standard error; NA=not applicable.

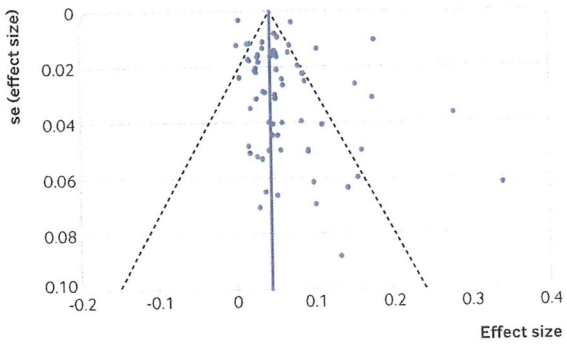

Fig 3 | Funnel plot of studies included in analysis with pseudo 95% confidence intervals (se=standard error)

Strengths and limitations of the study

Despite the unique focus on preventable patient harm and several method strengths, this review has also limitations. Firstly, the prevalence of preventable patient harm varied considerably across studies and this variation was only partly explained in meta regression analyses. Other relevant factors likely accounted for the unexplained heterogeneity. For example, variations in the timeframe used to detect harm might be important when interpreting the differences in the prevalence estimates,[1] alongside variations in the implementation of quality assurance programmes and the quality of the documentation used for detecting preventable patient harm. For example, quality assurance programmes have possibly been implemented in parallel with some of the reviewed studies which might account for some proportion of the heterogeneity that we observed in this meta-analysis.

Secondly, a critical eligibility criterion to ensure feasibility of this review was that data on preventable patient harm were available in the published reports of the studies. Studies which did not report data on preventable patient harm were excluded from the analyses. However, most studies focused primarily on overall patient harm, reported preventable patient harm as a secondary outcome, and only one third of the studies provided an analysis of severity and types of preventable patient harm.[100]

Thirdly, preventability rankings are likely to evolve over time especially after new technological advancements in healthcare. Consequently, some patient harms which are now considered non-preventable might be preventable in the future.[10] However, the studies we reviewed consistently found that about 50% of patient harm was preventable and we did not observe any different patterns over the past 19 years.

Fourthly, over half of the reviewed studies employed retrospective case record reviews to investigate the prevalence, nature, and severity of preventable patient harm. Although case record reviews are the most universally used method for assessing patient harm to date, patients and healthcare providers have repeatedly expressed concerns that data contained in case records do not capture the full range of harms that they experience during their healthcare encounters.[101 102] On the other hand, self reporting of patient harms (either by patients or healthcare providers) relies on recall and has its own limitations. Combining methods (such as prospective case record reviews with surveys with patients and healthcare providers)[103] with the parallel engagement of patients as partners in identifying medical errors and mitigating preventable patient harm are promising approaches for enhancing patient safety.[104 105]

Comparison with other studies

Our headline finding is that preventable patient harm is a highly prevalent international healthcare challenge which causes unnecessary patient suffering and can result in several avoidable deaths. As this review is specifically designed to understand patterns of preventable patient harm, comparisons with existing reviews focused on overall harm is problematic.[1 15 106-108] Although we concur that examining the nature of overall harm is important, increasing the emphasis on preventable patient harm (which is the most amenable form of patient harm) is critical in terms of designing efficient patient safety strategies.

There is also evidence that preventable patient harm is not only a public health concern but incurs a considerable opportunity cost. The excess length of hospital stays attributable to medical errors is estimated to be 2.4 million hospital days, which accounts for $9.3 billion (£7.3bn; €8.2bn) excess charges in the US.[7] Similarly, only six selected types of preventable patient harms in English hospitals result in 934 excell bed days per 100 000 population, which is equivalent to over 3500 salaried hospital nurses each year.[109] Thus, investments in developing and evaluating mitigation strategies for preventable patient harm are urgently needed and are strongly supported by our findings.

Policy implications

Our findings provide a useful agenda of priority areas for mitigating preventable patient harm. When exploring the nature of preventable patient harm, drug related and therapeutic incidents comprise the majority. This finding echoes recommendations from international patient safety policy initiatives in the past decade including the recent WHO's third global patient safety challenge "medication without harm."[106 110] Thus, it would be logical to prioritise efforts on developing and testing evidence-based mitigation strategies for these specific types of preventable patient harm. As this study establishes the scale of preventable patient harm in medical care settings, the need to gain better insight about the systemic and cultural circumstances under which preventable patient harm occurs is highlighted as a priority area. Several studies have sought to explain patient harms by reference to their sociotechnical context. For example, Vincent and colleagues proposes that patient harm occur because of contributory factors (which include "active" and "latent" failures) in the healthcare system.[111] These failures correspond to

characteristics of the system such as the tasks that are undertaken, the people, technology, and tools that are involved, and the organisational values and structures in which the system operates.[112] The studies included in our review, however, did not provide much insight into the way in which such factors might have contributed to the instances of preventable harm identified. Retrospective examination of patient harm often does not capture the myriad ways in which contributory factors could combine to produce—or avert—a preventable incident of patient harm.[113] Mixed method approaches, which connect the occurrence of patient harm to the presence of specific contributory factors and engage patients as partners in establishing these connections, have excellent prospects to achieve an in depth understanding of possible pathways to patient harm.[114-118]

A thorough understanding of the nature of preventable patient harm and its determinants could offer useful, evidence-based directions for designing efficient mitigation strategies. A combination of individual-level measures (eg, educational interventions for practitioners), system-level measures (eg, human-centred design of healthcare tasks and work environments), and organisational-level measures (eg, introducing quality monitoring and improvement processes) are likely to be a promising strategy for mitigating preventable patient harm,[119 120] but scalable evaluations of these interventions are needed to support wider implementation. Furthermore, the interventions depend on the presence of an organisational context that supports their implementation.[121 122]

Another important finding is that preventable patient harm appears to be a serious concern in advanced medical specialties including intensive care and surgical units. Patients treated in these specialties were more likely to experience preventable patient harm compared with patients treated in general hospitals. Surgical harm is a sizeable part of the overall in-hospital harm,[15 123] but our estimates are higher than anticipated. The underlying causes of these figures warrant further investigation because current safety standards could "be failing to rescue" many high risk patients treated in advanced specialties.[124] Moreover, clinicians in these specialties are often exposed to work pressures and are expected to deliver life-changing decisions quickly which might negatively impact on their personal wellbeing, a well known risk factor for preventable medical incidents.[125] On the other hand, surgery and intensive care units deal with high risk patients to whom complex medical procedures are implemented. Patient harm therefore might be more detectable in these settings because of its immediate, serious, or cumulative impact on patients' health or because better surveillance systems for detecting patient harm are implemented in these settings. Additionally, it is not always clear from the study designs that some proportion of the preventable patient harm has not occurred in the transition between general hospital care and advanced specialty care.[108]

Another major contribution of our synthesis is that it highlights key gaps in the literature on preventable patient harm. Only two studies were based in primary care, where over 80% of healthcare service is delivered internationally,[8 126] and no evidence was identified in psychiatry. Certain types of preventable harms which tend to occur in primary care and psychiatry might remain undetected or untargeted by quality and safety improvement programmes. For example, we found that diagnostic harm is a common preventable type of harm but our understanding of its nature needs to be improved. A likely explanation is that diagnostic harm is directly or indirectly linked with the provision of services in primary care where research on preventable patient harm is sparse.[127 128] Obtaining more precise estimates of the types and sources of preventable diagnostic harm occurring in primary care or in transitions from primary care to hospital care could lay the foundation for implementing efficient interventions for diagnostic harm. Systemic interventions, enhanced patient involvement in decision making for diagnoses, use of electronic tools, and emotion-cognitive interventions for boosting practitioners' confidence or certainty in making diagnoses are potentially fruitful intervention areas for reducing diagnostic harm but have not been systematically evaluated or implemented in practice.[104 127-130]

Less than a handful of studies focused on children and older adults, groups increasingly viewed as vulnerable to low quality or unsafe care. Furthermore, only a fraction of the included studies were conducted in developing countries, as many studies from developing countries failed to provide data on preventability of harm which rendered them ineligible. Thus, despite the evidence showing that the prevalence of overall harm is higher in developing countries compared with developed countries, we did not find such difference for preventable patient harm.

Commissioning research to understand the prevalence, nature, and impact of preventable patient harm in primary care and psychiatry, among vulnerable patient groups (eg, young children, older adults, or marginalised groups of the society such prison healthcare) and in developing countries has the potential to advance policy guidance and practice for mitigating preventable patient harm.

Conclusion

Our findings affirm that preventable patient harm is a serious problem across medical care settings. Priority areas are the mitigation of major sources of preventable patient harm (such as drug incidents) and greater focus on advanced medical specialties. It is equally imperative to build evidence across specialties such as primary care and psychiatry, vulnerable patient groups, and developing countries. Improving the assessment and reporting standards of preventability in future studies is critical for reducing patient harm in medical care settings.

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extraction. MP, KK, and DMA wrote the paper. All authors interpreted the findings and contributed to critical revision of the manuscript. All authors had full access to the data in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis. MP is the guarantor. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Data sharing: No additional data are available.

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Supplementary materials: Searches and eTable 1-4

MARYLAND
Department of Health
Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Robert R. Neall, Secretary

December 12, 2018

The Honorable Larry Hogan
Governor
State of Maryland
Annapolis, MD 21401-1991

The Honorable Thomas V. Mike Miller, Jr.
President of the Senate
H-107 State House
Annapolis, MD 21401-1991

The Honorable Michael E. Busch
Speaker of the House
H-101 State House
Annapolis, MD 21401-1991

RE: Health-General Article, §13-1207, Annotated Code of Maryland - 2018 Annual Report Maryland Maternal Mortality Review

Dear Governor Hogan, President Miller, and Speaker Busch:

Pursuant to Health-General Article, §13-1207 and Senate Bill 459, Chapter 74 of the Acts of 2000, the Department of Health submits this legislative report on the findings, recommendations, and program actions of the Maternal Mortality Review Program.

If you have questions concerning this report, please contact Webster Ye, Deputy Chief of Staff, Office of the Secretary, at (410) 767-6480.

Sincerely,

Robert R. Neall
Secretary

MARYLAND
Department of Health

MARYLAND MATERNAL MORTALITY REVIEW 2018 ANNUAL REPORT

Health – General Article § 13-1207

Larry Hogan
Governor

Boyd Rutherford
Lt. Governor

Robert R. Neall
Secretary of Health

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ACKNOWLEDGEMENTS

This review of maternal deaths in Maryland would not be possible without the data, expertise, and collaboration of the Maryland Department of Health's Vital Statistics Administration and the Office of the Chief Medical Examiner. The Maternal Mortality Review Program would like to also offer special thanks to the volunteer members of its Maternal Mortality Review Committee for the hours spent in discussion and the serious attention given to this important public health project. The Program is also grateful for the diligent work of the case abstractors in their careful and thorough abstraction of case materials. The Program also thanks MedChi, the Maryland State Medical Society for their collaboration in the administrative support of the Committee. Special thanks to all those who participated in this year's Committee meetings and case reviews:

Committee Member	**Hospital / Affiliation**
Cristina Aquia, RN	University of Maryland St. Joseph Medical Center
Pablo Argeles, MD	University of Maryland Baltimore Washington Medical Center
Pedro Arrabal, MD	Sinai Hospital
Robert Atlas, MD	Mercy Medical Center
Carol Ator, RN	University of Maryland St. Joseph Medical Center
Shobana Bharadwaj, MD	University of Maryland Medical System
Ann Burke, MD	Holy Cross Hospital
Diana Cheng, MD	MMR Abstractor
Andreea Creanga, MD, PhD	Johns Hopkins Bloomberg School of Public Health
Deborah Doerfer, CNM	Johns Hopkins Hospital
Jill Edwardson, MD	Johns Hopkins Bayview Medical Center, MMR Abstractor
Jen Fahey, CNM	University of Maryland Medical System
Stacy Fisher, MD	University of Maryland Medical System
Lorraine Goldstein, CNM	MMR Abstractor
Katherine Goetzinger, MD	University of Maryland Medical System
Elizabeth Greely, MD	Anne Arundel Medical Center
Asrar Green, RN	Medstar Southern Maryland Hospital
Clark Johnson, MD	Johns Hopkins Hospital, MMR Committee Chair
Jan Kriebs, CNM	MMR Abstractor
Lorraine Milio, MD	Johns Hopkins Bayview Medical Center, Center for Addiction and Pregnancy, MMR Abstractor
Judith Rossiter, MD	University of Maryland St. Joseph Medical Center
S. Lee Woods, MD, PhD	Maryland Department of Health, MMR Program Director

Staff to the Committee:

Shayna Banfield
Clara Richards

BACKGROUND

The Maryland Maternal Mortality Review Program (the Program) was established in statute in 2000. Md. Ann. Code Health-General Art., §13-1203—1207, establishes the Program in the Maryland Department of Health (the Department) and describes its scope. The purpose of the Program is to: (1) identify maternal death cases; (2) review medical records and other relevant data; (3) determine preventability of death; (4) develop recommendations for the prevention of maternal deaths; and (5) disseminate findings and recommendations to policymakers, health care providers, health care facilities, and the general public.

The Maternal Mortality Review Committee (the MMR Committee), which was established by the Program and is made up of volunteer heath care and public health professionals, conducts maternal mortality case reviews. The Department collaborates with MedChi, the Maryland State Medical Society, to provide administrative support in the maternal mortality review process by obtaining medical records, abstracting cases, and hosting meetings of the Department's MMR Committee. The MMR Committee provides an in-depth review of maternal deaths to determine pregnancy-relatedness and preventability. The MMR Committee then develops recommendations for the prevention of maternal deaths, and disseminates their findings and recommendations.

Key Definitions

- A **maternal death** is defined by the World Health Organization's (WHO's) International Classification of Diseases Ninth and Tenth Revisions (ICD-9 and ICD-10) as "the death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by pregnancy or its management but not from accidental or incidental causes."
- The **maternal mortality ratio or rate (MMR)** is the number of maternal deaths per 100,000 live births in the same time period.
- A **pregnancy-associated death** is defined by the Centers for Disease Control and Prevention (CDC) as "the death of a woman while pregnant or within one year or 365 days of pregnancy conclusion, irrespective of the duration and site of the pregnancy, regardless of the cause of death."
- The **pregnancy-associated mortality rate** is the number of pregnancy-associated deaths per 100,000 live births in the same time period.
- A **pregnancy-related death** is defined by the CDC as "the death of a woman while pregnant or within one year of conclusion of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by her pregnancy or its management, but not from accidental or incidental causes."
- The **pregnancy-related mortality rate** is the number of pregnancy-related deaths per 100,000 live births in the same time period.

The three terms "maternal death," "pregnancy-associated death," and "pregnancy-related death," create a challenge when comparing data from different sources and reports for different jurisdictional entities. The WHO monitors maternal deaths worldwide as a key indicator of population health, and of social and economic development. Maternal deaths are identified solely from information on the death certificate or similar registration of the occurrence and cause of death. Maternal deaths are limited in both the time period and causes considered.

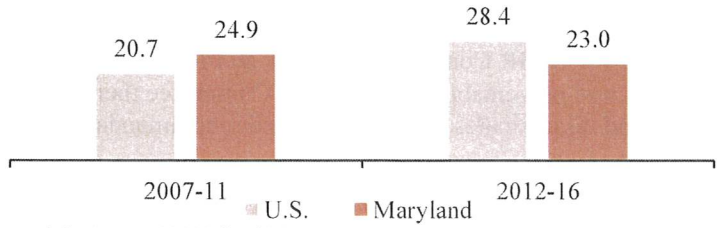
In more developed countries with improved medical care, many deaths related to pregnancy occur beyond 42 days after the end of pregnancy. In 1986, the CDC and the American College of Obstetricians and Gynecologists (ACOG) collaborated to recommend the use of expanded definitions to more accurately identify deaths among women where pregnancy was a contributing factor. This collaboration led to the definitions for pregnancy-associated and pregnancy-related deaths. Enhanced surveillance methods are necessary to determine pregnancy-associated and pregnancy-related deaths and will be discussed below.

Rising Rates of Maternal Deaths

Nationally, maternal deaths as defined above have declined dramatically since the 1930s when the MMR was 670 maternal deaths per 100,000 live births. The U.S. MMR was at its lowest level in 1987 at 6.6 maternal deaths per

100,000 live births. However, the MMR has risen since that time, and was 31.2 maternal deaths per 100,000 live births in 2016, the latest year for which national data are available. To compare Maryland's MMR with the national rate, a five-year average is used. This stabilizes the Maryland rate because maternal deaths are relatively infrequent events that may vary considerably year to year, particularly in a small state like Maryland. The Maryland MMR had consistently been higher than the national average. However, for the period from 2011 to 2015, the Maryland MMR was slightly lower than the national rate for the first time, and the most recent data (Figure 1) show that the Maryland MMR is now 19% less than the national rate. Between the two 5-year periods shown, the U.S. MMR increased by 37.2 percent and the Maryland rate decreased by 7.6 percent. Both, however, remain above the Healthy People 2020 Objective MICH-5 target of 11.4 maternal deaths per 100,000 live births.

Figure 1. Maternal Mortality Rates*, U.S. and Maryland 2007-11 and 2012-16



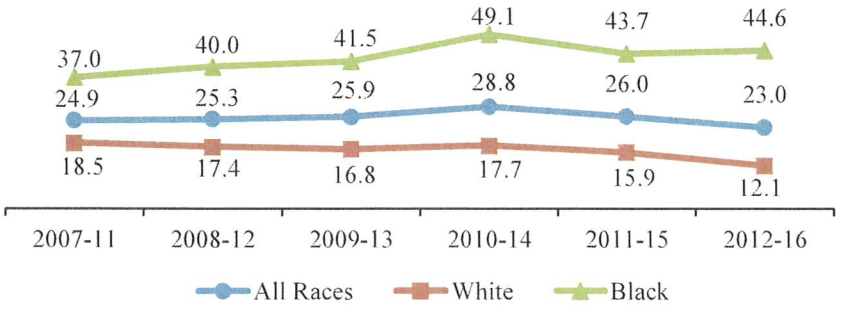
* Rate of maternal deaths per 100,000 live births
Data Source: CDC, NVSS; Maryland Department of Health (MDH), Vital Statistics Administration (VSA)

The reason for the increase in MMR since the 1980s is unclear. Many studies have shown an increase in chronic health conditions among pregnant women in the United States, including obesity, hypertension, diabetes, and heart disease.[1, 2, 3] These conditions likely put pregnant women at higher risk of adverse outcomes.

Racial Disparity

In the U.S., Black women have an MMR 2.4 times greater than White women, a disparity that has persisted since the 1940s. In Maryland, there is also a large disparity between the rates among Black and White women. Figure 2 shows the MMR by race in Maryland for six overlapping 5-year periods over the past decade. Compared to 2007-2011, the 2012-2016 White MMR in Maryland decreased 34.6 percent and the Black MMR increased 20.5 percent, increasing the racial difference. The 2012-2016 Black MMR is 3.7 times the White MMR. Given this racial disparity, it appears that the recent decrease in the Maryland MMR is a result of the decrease in the White MMR.

Figure 2. Five Year Rolling Average Maternal Mortality Rate* by Race, Maryland, 2007-2016



*Rate of maternal deaths per 100,000 live births. Data Source: MDH, VSA

[1] Kuklina EV, Ayala C, Callaghan WM. Hypertensive disorders and severe obstetric morbidity in the United States: 1998–2006.Obstet Gynecol. 2009;113(6):1299–1306.

[2] Albrecht SS, Kuklina EV, Bansil P et al. Diabetes trends among delivery hospitalizations in the United States, 1994–2004.Diabetes Care. 2010;33(4):768–773.

[3] Kuklina EV, Callaghan WM. Chronic heart disease and severe obstetric morbidity among hospitalizations for pregnancy in the USA: 1995–2006. Br J Obstet Gynaecol. 2011;118(3):345–352.

METHODOLOGY

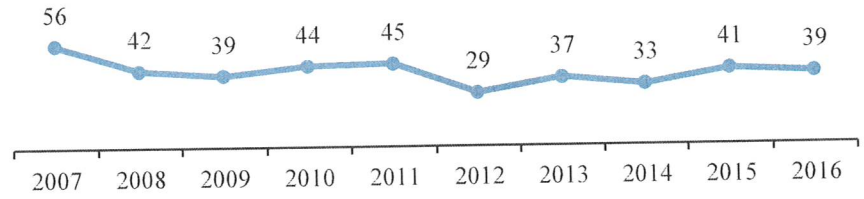
Case Identification

Cases for review are limited to women who were residents of Maryland at the time of their death. Maryland residents who died in other states are not included in the MMR case reviews. Maternal deaths are determined by cause of death and pregnancy information on the death certificates alone. The Maryland death certificate was revised in January 2001 to include questions about pregnancy status, pregnancy outcome, and date of delivery for the 12 months preceding death. This pregnancy checkbox has significantly increased identification of maternal deaths beyond those recognized by cause of death alone.[4, 5]

Pregnancy-associated deaths are identified in one of three ways in Maryland. Individual death certificates are the first method of identifying pregnancy-associated deaths through the use of checkbox questions, or because the cause of death is clearly related to pregnancy (e.g., ruptured ectopic pregnancy, postpartum hemorrhage). The second method of determining pregnancy-associated deaths comes from linking death certificates for women aged 10-50 years with birth certificates and fetal death certificates from the 365 days preceding death to identify additional cases that were not found through examination of death certificates alone. Thirdly, cases reported to the Office of the Chief Medical Examiner are reviewed to identify evidence of pregnancy in deceased women.

All deaths occurring during pregnancy or within 365 days of pregnancy conclusion are designated as pregnancy-associated and investigated further. Using the three methods above, 39 pregnancy-associated deaths were identified in 2016. These cases are reviewed in detail in this report. Figure 3 shows the numbers of pregnancy-associated deaths in Maryland from 2007 to 2016. An average of 41 pregnancy-associated deaths occurred per year during this period.

Figure 3. Number of Pregnancy-Associated Deaths*, Maryland, 2007 - 2016



*Deaths of women from any cause while pregnant or within 365 days of pregnancy. Data Source: MDH, VSA

Case Review

Pregnancy-associated deaths undergo several stages of review. Once cases are identified, medical records are obtained from the hospitals of death and delivery, when applicable. Physician and nurse-midwife abstractors review death certificates, hospital records, Medical Examiner records, and other available materials for all cases and prepare case summaries that go to the MMR Committee for review. All 2016 pregnancy-associated deaths from all causes (medical, injury, substance use, homicide, and suicide) were reviewed for cause of death, pregnancy-relatedness, and preventability.

Pregnancy-relatedness and potential preventability of the deaths are determined through Committee discussion. The MMR Committee includes obstetric, maternal fetal medicine, nurse-midwifery, nursing and social work specialties, as well as public health professionals, including representatives from the Department's Maternal and Child Health Bureau. The Committee discussions incorporate the CDC framework for case review outlined in "Strategies to

[4] Horon IL. Underreporting of maternal deaths on death certificates and the magnitude of the problem of maternal mortality. Am J Public Health. 2005; 95:478-82.
[5] Horon IL, Cheng D. Effectiveness of pregnancy check boxes on death certificates in identifying pregnancy-associated mortality. Pub Health Reports. 2011; 126:195-200.

Reduce Pregnancy-Related Deaths: From Identification and Review to Action."[6] This approach takes into account medical and non-medical factors contributing to maternal death, and examines quality and content of medical care. Cases discussed by the Committee are de-identified and all members sign confidentiality agreements.

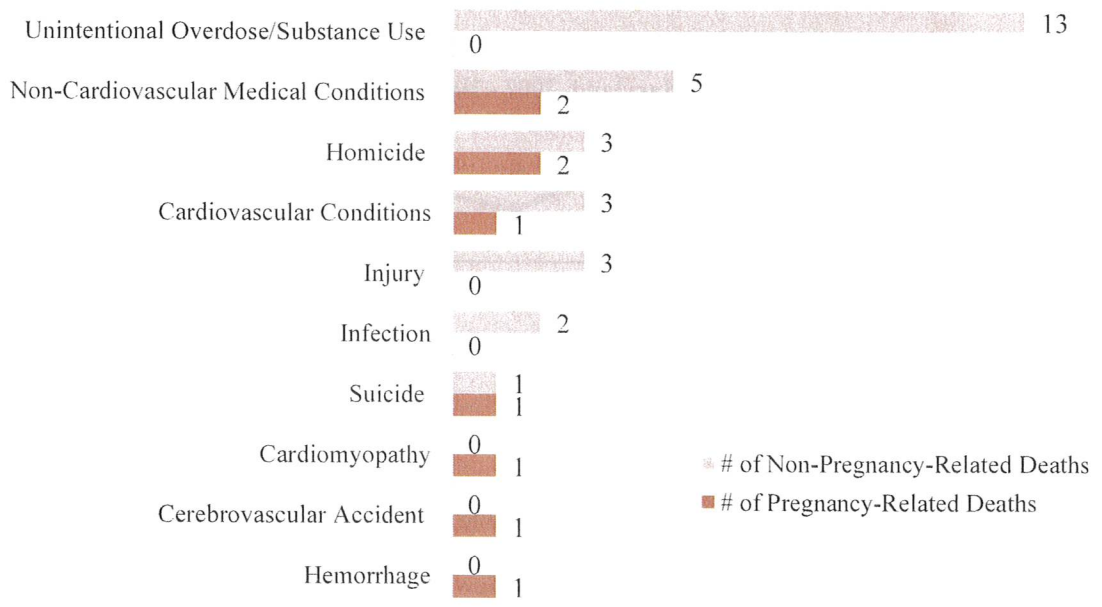
2016 CASE FINDINGS

A total of 39 pregnancy-associated deaths were identified in 2016 for a pregnancy-associated mortality rate of 53.4 deaths per 100,000 live births. For further analysis, these deaths were divided into pregnancy-related and non-pregnancy-related deaths, which represent two non-overlapping groups. Of the 39 pregnancy-associated deaths, nine were determined to be pregnancy-related, for a pregnancy-related mortality rate of 12.3 deaths per 100,000 live births. The remaining 30 deaths were determined to be non-pregnancy-related.

Cases by Cause of Death Category

Figure 4 shows pregnancy-related and non-pregnancy-related deaths by category of cause of death. The leading cause of non-pregnancy-related death was substance use with unintentional overdose, accounting for 13 deaths (43 percent of non-pregnancy-related deaths and 33 percent of all pregnancy-associated deaths in 2016). This is the highest number of overdose deaths reported in one year. Other leading causes of non-pregnancy-related death were non-cardiovascular medical conditions (predominantly cancer), followed by homicide, cardiovascular conditions, and injury (predominantly motor vehicle accidents).

Figure 4. Number of Pregnancy-Related* and Non-Pregnancy-Related Deaths by Category of Cause of Death, Maryland, 2016 (Total Deaths = 39)**



*Deaths of women while pregnant or within 365 days of pregnancy from a cause related to or aggravated by pregnancy or its management.
** Deaths of women while pregnant or within 365 days of pregnancy from any cause not related to or aggravated by pregnancy or its management.
Data Source: MDH, VSA, and Maryland Maternal Mortality Review Program

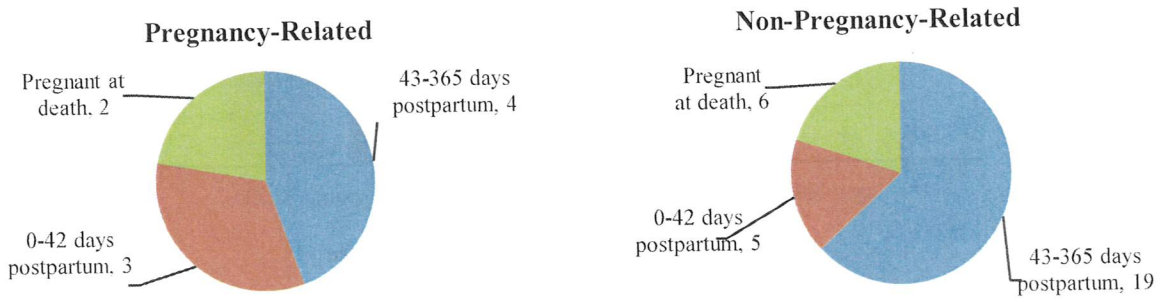
Among the nine pregnancy-related deaths in 2016, the leading causes of death were non-cardiovascular medical conditions and homicide, each accounting for two deaths. The remaining pregnancy-related deaths were single cases of cardiovascular conditions, suicide, cardiomyopathy, cerebrovascular accident, and hemorrhage.

[6] Berg C, Danel I, Atrash H, Zane S, Bartlett L (Editors). Strategies to reduce pregnancy-related deaths: from identification and review to action. Atlanta: Centers for Disease Control and Prevention; 2001 <https://stacks.cdc.gov/view/cdc/6537>.

Cases by Timing of Death in Relation to Pregnancy

Among the nine pregnancy-related deaths in 2016, four (44 percent) occurred between 43-365 days postpartum, three (33 percent) occurred within 42 days postpartum, and in two cases (22 percent) the woman was pregnant at the time of death (Figure 5). Of the 30 non-pregnancy-related deaths, 19 deaths (63 percent) occurred between 43-365 days postpartum, five (17 percent) occurred within 42 days postpartum, and six deaths (20 percent) occurred during pregnancy. Deaths in the early postpartum period, before the traditional six-week postpartum visit, were almost twice as frequent among pregnancy-related deaths compared to non-pregnancy-related deaths.

Figure 5. Number of Pregnancy-Related* and Non-Pregnancy-Related Deaths by Timing of Death, Maryland, 2016**

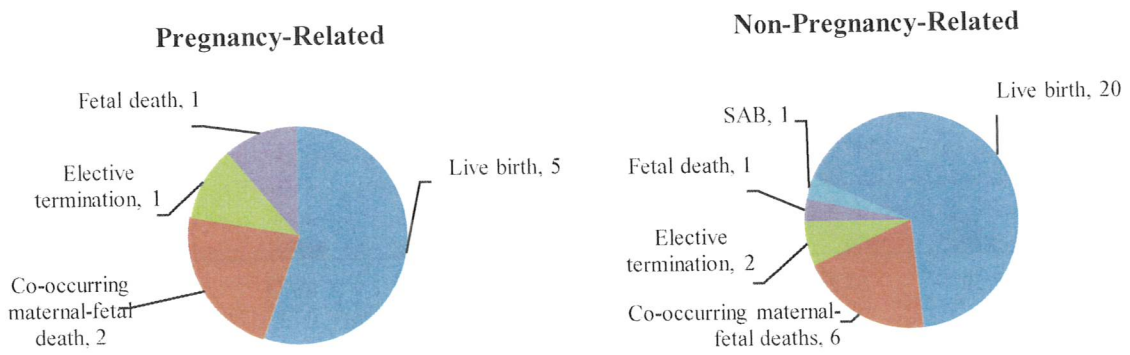


*Deaths of women while pregnant or within 365 days of pregnancy from a cause related to or aggravated by pregnancy or its management
** Deaths of women while pregnant or within 365 days of pregnancy from any cause not related to or aggravated by pregnancy or its management.
Data Source: Maryland Maternal Mortality Review Program

Cases by Outcome of Pregnancy

Among the nine pregnancy-related deaths in 2016, five cases (56 percent) had a live birth, two (22 percent) involved co-occurring maternal and fetal deaths, one had an elective termination, and one involved a fetal death prior to the mother's death (Figure 6). Among the 30 non-pregnancy-related deaths, 20 cases (67 percent) had a live birth, six (20 percent) involved co-occurring maternal and fetal deaths, two (7 percent) had elective terminations, one involved a fetal death and one involved a spontaneous abortion.

Figure 6. Number of Pregnancy-Related* and Non-Pregnancy-Related Deaths by Pregnancy Outcome, Maryland, 2016**

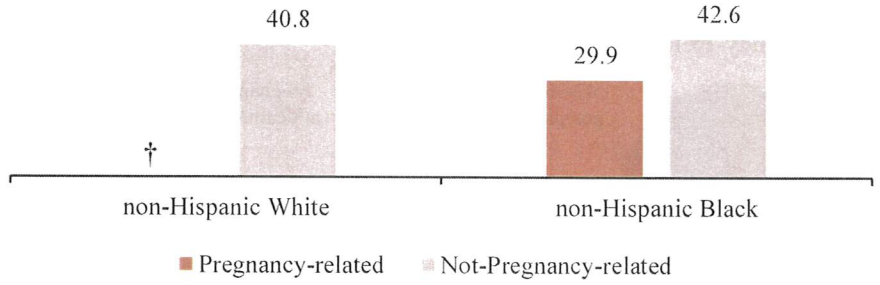


*Deaths of women while pregnant or within 365 days of pregnancy from a cause related to or aggravated by pregnancy or its management
** Deaths of women while pregnant or within 365 days of pregnancy from any cause not related to or aggravated by pregnancy or its management.
SAB: spontaneous abortion. Data Source: Maryland Maternal Mortality Review Program

Cases by Maternal Race and Ethnicity

Of the 9 pregnancy-related deaths occurring in 2016, one case involved a non-Hispanic White woman and one an Asian woman. The remaining seven pregnancy-related deaths (78 percent) were among non-Hispanic Black women. Among non-pregnancy-related deaths, 13 (43 percent) occurred among non-Hispanic White women, 10 (33 percent) among non-Hispanic Black women, six (20 percent) among Hispanic women, and one case involved a woman with race listed as other. Pregnancy-related and non-pregnancy-related mortality rates among non-Hispanic Black and non-Hispanic White women in 2016 are shown in Figure 7. A rate is not displayed if there are fewer than five deaths within a group.

Figure 7. Pregnancy-Related and Non-Pregnancy-Related Mortality Rates* by Selected Race/Ethnicities, Maryland, 2016



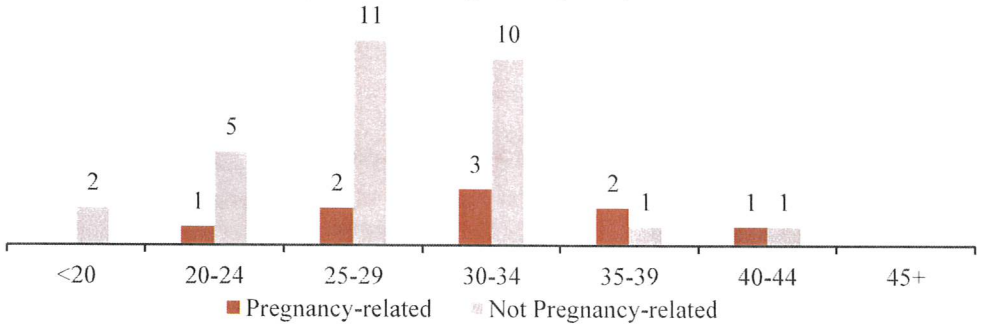
* Number of deaths per 100,000 live births. † Rate suppressed due to fewer than 5 deaths.
Data Source: Maryland Maternal Mortality Review Program

The rate of non-pregnancy-related deaths is similar between non-Hispanic White and non-Hispanic Black women. Although a rate cannot be calculated for pregnancy-related deaths among non-Hispanic White women since there was only one case, it is clear that the preponderance of pregnancy-related deaths are occurring among non-Hispanic Black women.

Cases by Maternal Age

The distribution of pregnancy-related and non-pregnancy-related deaths by maternal age group is shown in Figure 8. Rates of death by age group are not calculated because the numbers of deaths in most groups are very small. Rates involving fewer than five events are unstable and would not be reported.

Figure 8. Number of Pregnancy-Related and Non-Pregnancy-Related Deaths by Maternal Age, Maryland, 2016

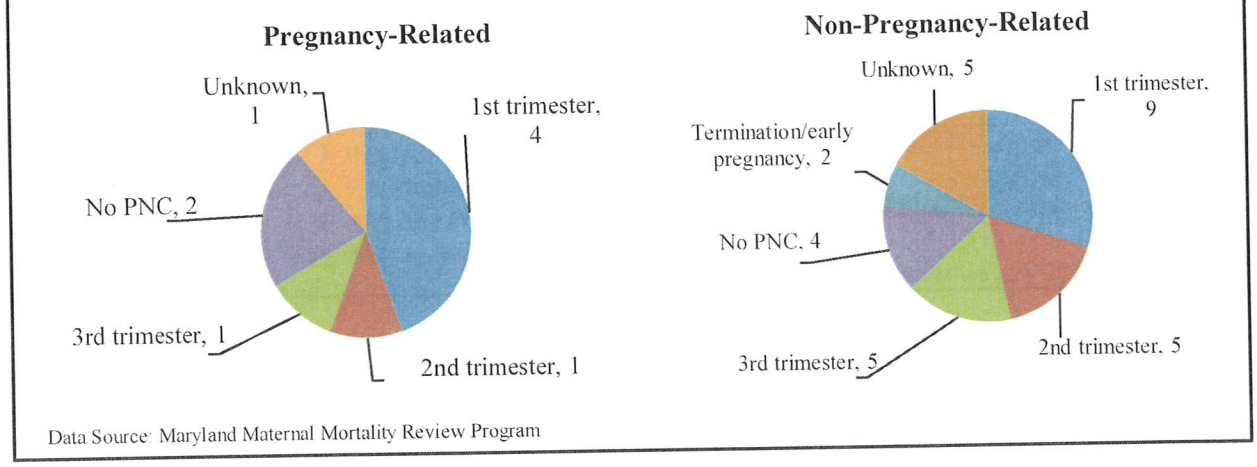


Data Source: MDH, VSA, and Maryland Maternal Mortality Review Program

Cases by Timing of Prenatal Care Initiation

Pregnancy-related and non-pregnancy-related deaths by the trimester when prenatal care was initiated are shown in Figure 9. Of the nine pregnancy-related deaths, five (56 percent) were among women who initiated care in the first or second trimester of pregnancy. Among the 30 non-pregnancy-related deaths, 14 (47 percent) of the women began prenatal care in the first or second trimester. In one pregnancy-related and five non-pregnancy-related cases, timing of prenatal care initiation was unknown.

Figure 9. Number of Pregnancy-Related and Non-Pregnancy-Related Deaths by Prenatal Care Initiation, Maryland, 2016



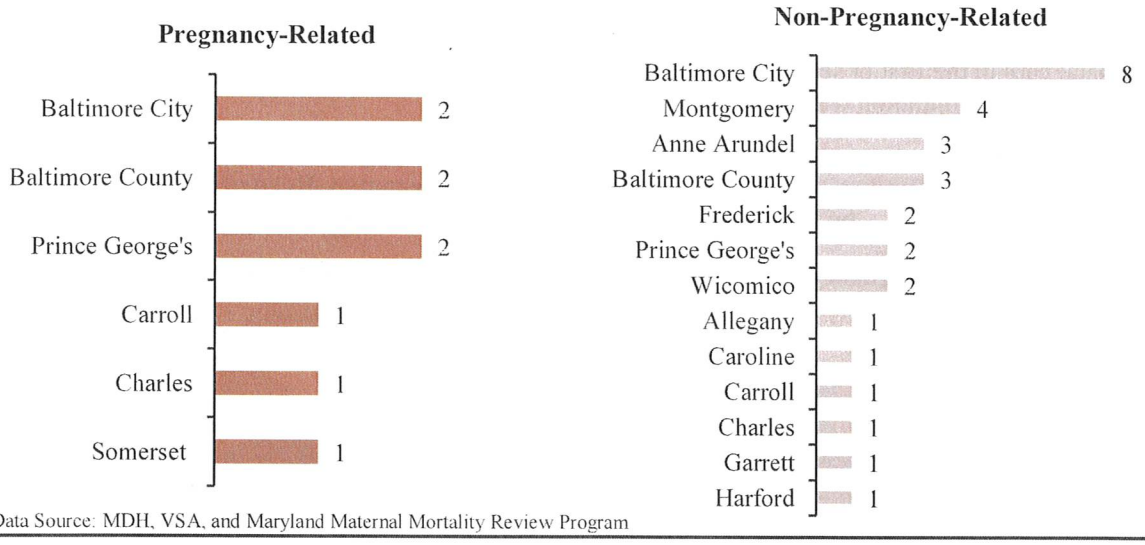
Data Source: Maryland Maternal Mortality Review Program

Cases by Jurisdiction of Residence and Occurrence

Figure 10 shows pregnancy-related and non-pregnancy-related deaths by jurisdiction of residence. Six (67 percent) of the nine pregnancy-related deaths were among residents of Baltimore City, Baltimore County and Prince George's County. There were single death cases among residents of Carroll, Charles, and Somerset Counties. Of the 30 non-pregnancy-related deaths, eight (27 percent) occurred among residents of Baltimore City and an additional ten cases (33 percent) among residents of Montgomery, Anne Arundel, and Baltimore Counties. Residents of nine other counties accounted for the remaining deaths.

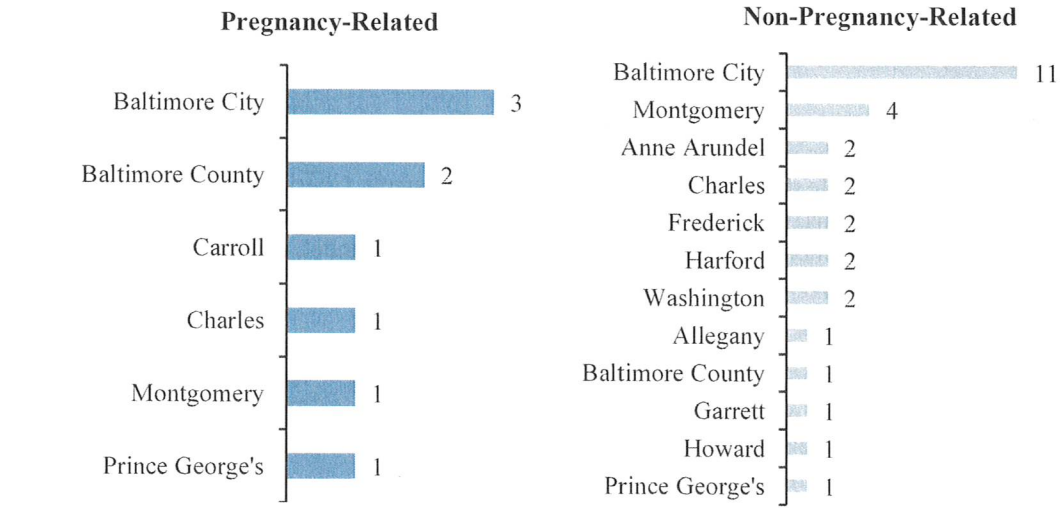
Figure 11 shows pregnancy-related and non-pregnancy-related deaths by jurisdiction in which the death occurred. Three (33 percent) of the nine pregnancy-related deaths occurred in Baltimore City and two (22 percent) in Baltimore County. Single deaths occurred in Carroll, Charles, Montgomery, and Prince George's Counties. Eleven (37 percent) of the non-pregnancy-related deaths occurred in Baltimore City and four (13 percent) in Montgomery County. The remaining deaths occurred in ten other counties.

Figure 10. Number of Pregnancy-Related and Non-Pregnancy-Related Deaths by Jurisdiction of Residence, Maryland, 2016



Data Source: MDH, VSA, and Maryland Maternal Mortality Review Program

Figure 11. Number of Pregnancy-Related and Non-Pregnancy-Related Deaths by Jurisdiction of Occurrence, Maryland, 2016



Data Source: MDH, VSA, and Maryland Maternal Mortality Review Program

Preventability of Deaths

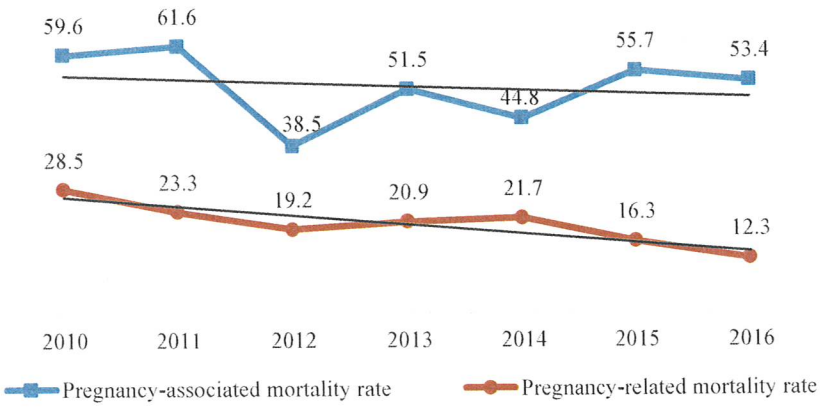
A death was considered preventable if the death "may have been averted by one or more changes in the health care system related to clinical care, facility infrastructure, public health infrastructure and/or patient factors."[7] Whether the death was clearly preventable or only potentially preventable by some intervention is a decision made by the MMR Committee. Of the 9 pregnancy-related deaths, eight (89 percent) were judged to be preventable or potentially preventable. One case was considered an unpreventable death. Among the 30 non-pregnancy-related deaths, 21 (70 percent) were judged to be preventable or potentially preventable. In three cases, preventability could not be determined, and six deaths were considered unpreventable. All of the unintentional overdose deaths were considered potentially preventable, as were the two suicide and five homicide deaths. Two of the three injury deaths were also considered potentially preventable. The seven deaths considered unpreventable involved medical causes of death (including cardiovascular conditions and cancer) and one motor vehicle accident death.

TRENDS IN PREGNANCY-ASSOCIATED AND PREGNANCY-RELATED DEATHS

Figure 2 above showed the trend and racial disparity in the Maryland maternal mortality rate (MMR). As noted, the MMR has dropped over the past ten years and is now below the national average, but the racial disparity has widened. The MMR, however, is limited in both causes of death considered and the timeframe in relation to pregnancy. The MMR includes only deaths from pregnancy-related causes that can be identified by the death certificate alone and that occurred during pregnancy or within 42 days of pregnancy conclusion. The decrease in the Maryland MMR suggests that fewer early pregnancy-related deaths are occurring, and this decrease has occurred primarily among White maternal deaths.

The cases reviewed by the Maryland Maternal Mortality Review Committee are more comprehensive and include all pregnancy-associated deaths, which include deaths from any cause that occur during pregnancy or up to 365 days after the conclusion of pregnancy. All pregnancy-associated deaths are reviewed for pregnancy-relatedness, creating a subgroup of pregnancy-related deaths. The trends in pregnancy-associated and pregnancy-related mortality rates from 2010 to 2016 are shown in Figure 12. The pregnancy-associated mortality rate shows considerable variability over the seven-year period and has dropped by 10.4 percent over that time. The pregnancy-related mortality rate, however, shows a steady decrease of 56.8 percent over the seven-year period.

Figure 12. Pregnancy-Associated and Pregnancy-Related Mortality Rates*, Maryland, 2010-2016



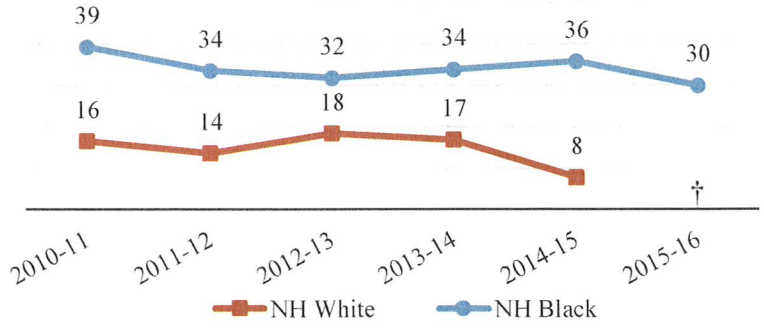
* Number of pregnancy-associated and pregnancy-related deaths per 100,000 live births.
Data Source: MDH, VSA, and Maryland Maternal Mortality Review Program

[7] Berg CJ, Harper MA, Atkinson SM, et al. Preventability of Pregnancy-Related Deaths - Results of a State-Wide Review. Obstet and Gynecol. 2005; 106:1228-1234.

Causes of pregnancy-related deaths are largely medical conditions directly related to pregnancy (such as postpartum hemorrhage, amniotic fluid embolus, or pre-eclampsia) or those exacerbated by pregnancy (such as pre-existing cardiovascular disease). There are some cases of homicide and suicide that are also determined to be pregnancy-related. The number of cases in Maryland from any individual cause is so small that determining trends for specific causes of pregnancy-related death is not possible. It does appear, however, that the number of deaths from hemorrhage and amniotic fluid embolus are decreasing.

Pregnancy-related mortality rates were calculated for non-Hispanic White and non-Hispanic Black women to see if the same trends were evident as seen for the MMR in Figure 2. Rates are shown as rolling two-year averages because of small numbers of cases when looking at deaths by race by individual year. Over the seven-year period, the non-Hispanic Black pregnancy-related mortality rate was consistently higher than the non-Hispanic White rate. Comparing rates from 2010-2011 and 2015-2016, there was a 23 percent decrease in the non-Hispanic Black rate. The non-Hispanic White rate decreased by at least 50 percent during this time period, but a rate for 2015 to 2016 could not be calculated because there were fewer than five deaths in this group during those two years.

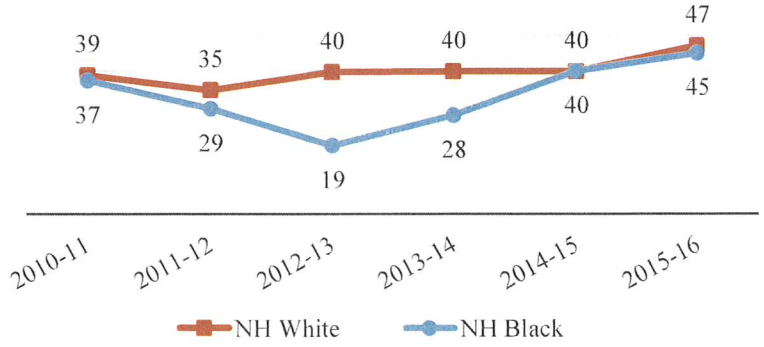
Figure 13. Pregnancy-Related Mortality Rates*



*Number of pregnancy-related deaths per 100,000 live births. † Rate suppressed due to fewer than 5 deaths. Data Source: Maryland Maternal Mortality Review Program

Non-pregnancy-related mortality rates by race were also calculated (Figure 14). Deaths from unintentional overdose have contributed increasingly to these deaths in the past several years. Overdose deaths have been predominantly among non-Hispanic White women, but the number of such deaths among other racial and ethnic groups has increased, which may be contributing to the increase in the non-pregnancy-related mortality rate among Black non-Hispanic women seen in Figure 14. Unintentional overdose deaths are reviewed in detail in the following section.

Figure 14. Non-Pregnancy-Related Mortality Rates* by Race/Ethnicity, Maryland, 2010-2016



*Number of non-pregnancy-related deaths per 100,000 live births.
Data Source: Maryland Maternal Mortality Review Program

FOCUS ON SUBSTANCE USE DISORDER AND OVERDOSE DEATHS

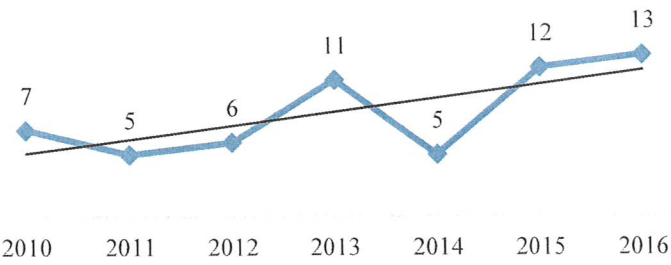
In 2016, for the fourth consecutive year, unintentional drug overdose was the leading cause of pregnancy-associated death in Maryland. Thirteen of the 39 total deaths (33 percent) resulted from substance use and unintentional overdose. All of the overdose deaths were considered to be non-pregnancy-related. The 13 overdose deaths accounted for 43 percent of the 30 non-pregnancy-related deaths. All of these deaths involved opioids. In 12 of the 13 cases (92 percent), two or more drugs were found by postmortem toxicology testing. Nine of the 12 multi-drug cases (75 percent) involved two or more different opioids. Ten of the overdose deaths (77 percent) involved the potent opioid fentanyl or one of its analogs. Alcohol was detected in three cases, cocaine in three cases, and marijuana in two cases.

The average age at death was 27.5 years (range 19 to 34 years). Six overdose deaths (46 percent) were among non-Hispanic White women, four (31 percent) among non-Hispanic Black women, two among Native American women, and one involved a Hispanic woman. Nine of the 13 women (69 percent) had delivered live born infants and the average timing of death was 193 days postpartum. Two women were pregnant at the time of death, one had a spontaneous abortion, and one had an elective termination. None of the overdose deaths occurred in the traditional postpartum period up to 42 days after the conclusion of pregnancy. All 13 of the overdose victims had a known history of substance use. In nine (69 percent) of the 13 cases, there was a history of one or more mental health diagnosis, with depression documented in eight cases, anxiety in four, and bipolar disorder in four.

Multiyear Review of Overdose Deaths

To better understand factors involved in overdose deaths, a review of all pregnancy-associated deaths in Maryland from 2010 to 2016 was undertaken. Over this seven-year period, substance use and unintentional overdose was the leading cause of death, accounting for 59 (22 percent) of 267 pregnancy-associated deaths. Figure 15 shows the number of unintentional overdose deaths by year, with the highest number of cases occurring in 2016.

Figure 15. Number of Pregnancy-Associated* Deaths From Unintentional Overdose, Maryland, 2010-2016



* Number of deaths of women from any cause while pregnant or within 365 days of pregnancy.
Data Source: MDH, VSA, and Maryland Maternal Mortality Review Program

Of the 59 overdose deaths, 57 (97 percent) involved opioids (one of the remaining two cases involved alcohol, and the other involved alcohol plus the amphetamine methylone). Table 1 shows the specific opioid(s) identified by toxicology testing at the time of death in these cases. The most frequently detected opioid was morphine, a metabolite of heroin, followed by methadone and fentanyl (including fentanyl analogs). Fentanyl was not detected in any overdose death prior to 2014. One case from 2014, three cases from 2015, and ten cases from 2016 involved fentanyl or a fentanyl analog. In 54 (92 percent) of the 59 overdose deaths, two or more drugs were detected by postmortem testing. In 20 (37 percent) of the multiple drug cases, two to four different opioids were identified. Benzodiazepines were detected in 14 (24 percent) and alcohol in 14 (24 percent) of the 59 overdose death cases. The risk of fatal overdose is substantially increased when opioids are combined with other central nervous system depressants such as benzodiazepines or alcohol.

Table 1. Opioid Identified Postmortem, Pregnancy-Associated Unintentional Overdose Deaths, Maryland, 2010-2016	
Opioid	**Number of cases (n=57)**
Morphine (heroin)	23
Methadone	15
Fentanyl / fentanyl analogs	14
Oxycodone	10
Unspecified opioid	6
Tramadol	4
Codeine	3
Oxymorphone	2
Buprenorphine	1
Hydrocodone	1
Hydromorphone	1
Meperidine	1

Data Source: Maryland Maternal Mortality Review Program
NOTE: The values in the table do not add up to the sample size of 57 because multiple drugs can be detected in a single case.

Among the 59 unintentional overdose deaths occurring from 2010 to 2016, the average age at death was 29 years. Forty-four (75 percent) of these deaths were among non-Hispanic White women and 12 (20 percent) among non-Hispanic Black women, with two cases (three percent) among non-Hispanic Native American women and one case (two percent) in a Hispanic woman. Prior to 2016, non-Hispanic White and non-Hispanic Black were the only racial or ethnic groups represented among the overdose deaths. Among overdose deaths from 2010 to 2015, 83 percent were among non-Hispanic White women and 17 percent among non-Hispanic Black women. In 2016, the distribution of unintentional overdose deaths was 46 percent non-Hispanic White, 31 percent non-Hispanic Black, 22 percent Native American, and 11 percent Hispanic, suggesting that the problem of substance use and risk of overdose is increasing among non-Hispanic Black women and women of other racial and ethnic groups.

Nine women (15 percent) among the 59 deaths were pregnant at the time of death and seven (12 percent) had had an elective termination, spontaneous abortion or fetal demise prior to death. The remaining 43 women (73 percent) delivered live born infants. Only four deaths (7 percent) occurred at 42 days or less postpartum; the remaining 46 (78 percent) occurred between 43 and 365 days postpartum. The average timing of death was 194 days postpartum. In 48 cases (81 percent), one or more mental health diagnosis was documented. Depression was diagnosed in 37 cases (63 percent), anxiety in 34 cases (58 percent), and bipolar disorder in 20 (34 percent). Fifty-five (93 percent) of the women who died of overdose had a known history of substance use and twenty-five (42 percent) had documentation of some substance use treatment.

In Table 2, the 59 overdose deaths are compared with the 208 non-overdose deaths that occurred between 2010 and 2016. Average age at death was comparable in both groups. However, the racial distribution is strikingly different, with a preponderance of non-Hispanic White women among the overdose deaths and overrepresentation of non-Hispanic Black women among the non-overdose deaths. A similar percentage of women were pregnant at the time of death in both groups, but deaths after the conclusion of pregnancy occurred on average much later among the overdose group. Pregnancy outcome was similar in both groups, with 73 percent of pregnancies among the overdose group and 68 percent among the non-overdose group resulting in a live birth. Timing of prenatal care initiation was similar, with more than half of women in both groups starting prenatal care in the first or second trimester.

Table 2: Incident Characteristics of Pregnancy-Associated Deaths, Maryland, 2010-2016 Data presented as mean ± standard deviation, or number (%)		
Characteristic	**Overdose Deaths (n=59)**	**Non-overdose Deaths (n=208)**
Demographics		
Average age at death (years)	29 ±5	31 ±7
White non-Hispanic	44 (75)	75 (36)
Black non-Hispanic	12 (20)	102 (49)
Native American non-Hispanic	2 (3)	14 (7)
Hispanic	1 (2)	17 (8)
Timing of death		
Pregnant at death	9 (15)	39 (19)
0-42 days postpartum	4 (7)	84 (41)
43-365 days postpartum	46 (78)	84 (40)
Average days postpartum	194 ±89	107 ±116
Pregnancy outcome		
Live born infant	43 (73)	141 (68)
Co-occurring maternal-fetal deaths	9 (15)	38 (18)
Spontaneous abortion / fetal death	6 (10)	18 (9)
Prenatal care initiation		
1st trimester	19 (32)	86 (41)
2nd trimester	14 (24)	23 (11)
3rd trimester	5 (9)	7 (3)
No prenatal care	6 (10)	18 (9)
Termination or death in early pregnancy	4 (7)	7 (3)
Unknown	11 (19)	67 (32)
Behavioral health / social factors		
Known history of substance use	55 (93)	42 (20)
Any history of substance use treatment (among those with known history of substance use)	25 (46)	17 (41)
Smoking	47 (80)	52 (25)
Mental health diagnosis(es)	48 (81)	44 (21)
Intimate partner violence	5 (9)	18 (9)
Preventability		
Death preventable / potentially preventable	57 (97)	115 (55)

Data Source: Maryland Maternal Mortality Review

There were large differences, however, between the two groups related to several behavioral health factors. Women who died of overdose were more than four-times as likely as women who died of other causes to have a known history of substance use (93 percent vs. 20 percent), although a similar proportion of each group with a history of

substance use had received any substance use treatment. Women who died of overdose were more than three-times as likely to smoke (80 percent vs. 25 percent) and almost four-times as likely to have one or more mental health diagnosis (81 percent vs. 21 percent). Also, 57 of 59 overdose deaths (97 percent) were considered preventable or potentially preventable, compared with 55 percent of the non-overdose deaths.

2018 MATERNAL MORTALITY REVIEW RECOMMENDATIONS

Substance use with unintentional overdose remains the leading cause of pregnancy-associated death for the fourth consecutive year in Maryland. The number and proportion of overdose deaths among deaths during pregnancy and the first year postpartum continue to increase, with overdose accounting for 33 percent of all pregnancy-associated deaths in 2016. The Committee, therefore, puts forward the following recommendations related to substance use disorder and unintentional overdose.

MMR Recommendations - Overdose Deaths	Action Items
• Promote universal screening at least once during pregnancy, at delivery, and postpartum for substance use, mental health, and intimate partner violence conditions. • Document screening tools used, referrals given, and treatment plans in perinatal records. • Reduce unintended pregnancy and encourage reproductive life planning. • Improve communication and collaboration between providers of prenatal care and other providers (mental health, substance use, primary care, oral health, etc.). • Promote interdisciplinary case management among substance use, mental health, and obstetric providers. • Improve safe opioid prescribing practices. • Encourage Prescription Drug Monitoring Program (PDMP) utilization by providers. • Encourage naloxone co-prescribing and 3rd party prescribing (prescribing for family or friends of individuals at risk of overdose). • Inform substance use treatment providers about perinatal health.	• Create and disseminate a resource list of valid screening tools for substance use, mental health, and intimate partner violence. • Create and disseminate a resource list of referral service options by Maryland jurisdiction. • Strive for a single point of contact for behavioral health services to facilitate provider access and care coordination among providers. • Promote integration of reproductive life planning and preconception counseling into health care visits by all disciplines. • Encourage use of Long Acting Reversible Contraception (LARC) for women who indicate they do not desire to become pregnant. • Promote the importance of establishing linkages and relationships to ongoing care during the perinatal and postpartum period. • Facilitate obtaining medical records from behavioral health service providers so that the obstetric chart has complete information of the patient's behavioral health care. • Provide obstetric support to behavioral health providers in the care of the pregnant patient. • Raise provider awareness about substance use during pregnancy and promote current resources and trainings. • Educate providers on the use and importance of the PDMP. • Train providers, patients, and families on naloxone use and response to opioid overdose. • Inform patients and families about the Maryland Good Samaritan law pertaining to response to an overdose emergency. • Develop consultation resources on perinatal and reproductive health issues for mental health and substance use treatment providers.

In addition, the Committee supports the Department's Perinatal Neonatal Quality Collaborative in partnership with the Maryland Patient Safety Center in its upcoming initiative related to substance use. The Collaborative is an effort among all Maryland delivery hospitals to address quality improvement in obstetric and neonatal care. In early 2019, the Collaborative will begin a quality improvement project to address care of the pregnant woman with substance use disorder.

The Committee also supports the Maryland SBIRT (Screening, Brief Intervention, and Referral to Treatment) Project in the Department's Behavioral Health Administration. SBIRT is an evidence-based approach to providing early intervention and treatment to patients with problem alcohol or drug use. Maryland SBIRT trains health care providers throughout Maryland in how to initiate conversations with patients about alcohol and drug use, and provide further assessment or referral when needed. Upcoming Maryland SBIRT efforts include SBIRT training for obstetric providers.

The Committee would also like to promote the resources made available by MedChi's Opioid Task Force. These provider resources include opioid-related educational materials and activities, information on opioid alternatives and opioid prescribing guidelines, substance use screening tools, and information and training on the Prescription Drug Monitoring Program (PDMP). MedChi has also made available an iPrescribe app which allows providers to easily access PDMP data from mobile devices.

The Committee is also continuing to develop *Provider Alerts* to disseminate information about maternal deaths in Maryland. One *Alert* will address overdose deaths to increase provider awareness of the contribution of substance use and unintentional overdose to maternal mortality in Maryland. Another will address recent guidance from ACOG and the Alliance for Innovation on Maternal Health to modernize paradigms of postpartum care, extending the postpartum period to improve maternal outcomes.

MATERNAL MORTALITY REVIEW STAKEHOLDER GROUP

House Bill 1518, enacted by the 2018 Maryland General Assembly, requires the Department to establish a Maternal Mortality Stakeholder Group to meet at least twice a year, to review the findings and recommendations in the annual Maternal Mortality Review Report. This group will include representatives of the Maryland Office of Minority Health and Health Disparities; the Maryland Patient Safety Center; the Maryland Healthy Start Program; women's health advocacy organizations; community organizations engaged in maternal health and family support issues; families that have experienced a maternal death; local health departments; and health care providers that provide maternal health services.

The Stakeholder Group is charged with examining issues resulting in disparities in maternal deaths, reviewing the status of implementation of previous recommendations, and identifying new recommendations with a focus on initiatives to address disparities in maternal deaths. House Bill 1518 requires that the Stakeholder Group meet once within 90 days of the publication this report and once 6 months after this report's annual publication. Members are currently being recruited for the Stakeholder Group, which will be convened for the first time in early 2019. The group will review the current report, and responses and recommendations from the stakeholders will be included in the 2019 Maternal Mortality Review Report.

SUMMARY

Maryland's MMR in the most recent five-year average data is 19 percent below the national rate for the first time. While the U.S. MMR continued to increase, the Maryland rate decreased by almost eight percent. Both rates, however, remain above the Healthy People 2020 goal of 11.4 deaths per 100,000 live births. While the MMR is limited in causes of death and timeframe of occurrence considered, this improvement is encouraging. However, significant racial disparities in maternal death persist.

Thirty-nine pregnancy-associated deaths were identified in 2016. Nine (23 percent) of these cases were determined

to be pregnancy-related, with the cause of death related to or aggravated by the pregnancy or its management. The remaining 30 cases were non-pregnancy-related deaths. The leading cause of non-pregnancy-related death for the fourth consecutive year was substance use and unintentional overdose. Non-cardiovascular medical conditions and homicide were the leading causes of pregnancy-related death. A majority of these deaths (70 percent of non-pregnancy-related deaths and 89 percent of pregnancy-related deaths) were considered preventable or potentially preventable.

In this report, the MMR Committee focused its recommendations on unintentional overdose deaths and improving its dissemination of maternal mortality review findings and recommendations to the provider community. The MMR Committee will continue to promote communication and collaboration among all providers caring for pregnant and postpartum women in an effort to reduce pregnancy-associated deaths in Maryland.

Hospitals know how to protect mothers. They just aren't doing it.

Alison Young, USA TODAY
Updated 6:58 p.m. EST Mar. 6, 2019

Every year, thousands of women suffer life-altering injuries or die during childbirth because hospitals and medical workers skip safety practices known to head off disaster, a USA TODAY investigation has found.

Doctors and nurses should be weighing bloody pads to track blood loss so they recognize the danger sooner. They should be giving medication within an hour of spotting dangerously high blood pressure to fend off strokes.

These are not complicated procedures requiring expensive technology. They are among basic tasks that experts have recommended for years because they can save mothers' lives.

Yet hospitals, doctors and nurses across the country continue to ignore them, USA TODAY found.

As a result, women are left to bleed until their organs shut down. Their high blood pressure goes untreated until they suffer strokes. They die of preventable blood clots and untreated infections. Survivors can be left paralyzed or unable to have more children. The vast majority of women in America give birth without incident. But each year, more than 50,000 are severely injured. About 700 mothers die. The best estimates say that half of these deaths could be prevented and half the injuries reduced or eliminated with better care.

Instead, the U.S. continues to watch other countries improve as it falls behind. Today, this is the most dangerous place in the developed world to give birth.

Maternal deaths on rise because hospitals and doctors ignore safety measures.

Identifying every hospital that doesn't provide recommended care is next to impossible. There is no national tracking system for childbirth complications. Mothers tell harrowing tales of survival, but they often have no idea whether their doctors and nurses did something wrong.

USA TODAY obtained more than a half-million pages of internal hospital quality records and examined the cases of more than 150 women whose deliveries went terribly wrong. Reporters contacted 75 birthing hospitals to track whether they follow recommended procedures.

Together, these documents and interviews reveal a stunning lack of attention to safety recommendations and widespread failure to protect new mothers.

At dozens of hospitals in New York, Pennsylvania and the Carolinas – where USA TODAY obtained records through federally funded quality programs – fewer than half of maternity patients were promptly treated for dangerous blood pressure that put them at risk of stroke. At some of those hospitals, less than 15 percent of mothers in peril got recommended treatments, the records show.

Many hospitals across the country conceded in interviews with USA TODAY that they were not taking safety steps such as quantifying women's blood loss or tracking whether moms with dangerously high blood pressure got proper medication in time.
The lack of attention happens at hospitals big and small, from tiny community delivery units to major birthing centers that tout state-of-the art technology and training. It also happens in doctors' offices when they miss or fail to act on signs of serious complications during pregnancy and after delivery.

In Ohio, Ali Lowry bled internally after giving birth in 2013, but medical staff didn't recognize and act on the warning signs for hours, according to records in a lawsuit that she has since settled. By the time she was airlifted to another hospital for lifesaving surgery, her delivery hospital had nearly run out of blood and Ali's heart had stopped.
In Texas, Beatriz Garcia nearly bled to death when doctors and nurses were slow to help her after not quantifying her blood loss, she alleged in federal and state lawsuits. Garcia's heart stopped. She needed a hysterectomy. She's now awaiting a kidney transplant.
And in South Carolina, one of the state's top hospitals sent YoLanda Mention home with her newborn despite her dangerously high blood pressure. When she returned to the emergency room with even higher blood pressure and an excruciating headache, the staff made her sit for hours in the waiting room, according to a lawsuit led by her husband. She had a stroke while waiting, and later died.

Today, YoLanda's husband, Marco, is raising their three daughters alone in rural Nesmith. He balances work as a school bus driver with all the demands of raising kids on his own – cooking the meals, cleaning and getting three girls to schools and day care.
He spends his evenings leading his church choir and reminding his girls about a mother who the youngest knows as a picture in a curio cabinet.

"The girls, they ask when she's coming home and I don't know what to tell them," Mention said, wiping tears. "It seems like a nightmare and I just need to wake up."
It doesn't have to be this way.

Countries around the world have reduced maternal deaths and injuries by aggressively monitoring care and learning from mistakes. The result has been two decades of steady or reduced maternal harms in the rest of the developed world – as U.S. rates climbed.

Divergent paths

From 1990 to 2015, the number of maternal deaths per 100,000 births in most developed nations has been flat or dropping. In the U.S., the rate has risen sharply.

One exception in the U.S.: California, where safety experts and hospitals worked together to implement practices that are now endorsed by leading medical societies as the gold standard of care. Statewide, California's maternal death rate has fallen by half, while deaths rose across most of the country.

Despite widespread recognition that the California safety measures save lives, hospitals elsewhere have been slow to use them.

"Our medicine is run by cowboys today, where everyone is riding the range doing whatever they're wanting to do," said Dr. Steven Clark, a leading childbirth safety expert and a professor at Baylor College of Medicine. While there are hospitals that follow best safety practices, change is happening slowly, he said. "It's a failure at all levels, at national organization levels and at the local hospital leadership levels as well."

In part, that's because regulators and oversight groups that could require hospitals to do more have not, USA TODAY found.
SOURCE The Global Burden of Disease 2015 Maternal Mortality study as published in The Lancet medical journal.

The lack of action by the Centers for Medicare and Medicaid Services to protect mothers stands in sharp contrast to its more aggressive approach to trying to improve care for elderly Medicare patients.

As a condition of getting Medicare payments, the federal agency requires hospitals to disclose information such as complication rates for hip and knee surgeries and whether heart attack patients got prompt care. All of that information is posted online.
That same agency helps pay for about half of the nation's nearly 4 million births each year via Medicaid, and it could set similar rules about childbirth complications.

So far, it has not.

The Joint Commission, a private accreditation group that sets safety standards for thousands of hospitals, makes hospitals track cesarean section rates.
But the commission has no requirements that hospitals report how o□en their health care providers fail to follow national guidelines for protecting moms against leading childbirth dangers. Officials said the group is still studying the safety practices, some of which have been known for at least eight years.

"For us to make it a requirement for every organization to follow something, there has to be clear national consensus that this is the standard of care," said Dr. David Baker,

executive vice president of the commission's Division of Health Care Quality Evaluation. Baker said the safety practices to protect moms from hemorrhages are "promising." But he said there are questions about whether the protocols calling for fast treatment of dangerous blood pressure are appropriate for the commission to require at the hospital level. "I suspect within the next two months, there will be a decision on whether to go forward," he said.

The American Hospital Association, the influential trade association representing nearly 5,000 hospitals and health networks, has in recent years held closed-door training sessions aimed at getting maternity hospitals to improve care.
In a series of webinars, AHA first warned anyone not invited to disconnect.
Then, trainers for the association went on to bluntly discuss how wide-ranging care failures at birthing hospitals are causing needless deaths and injuries.

"What we know about those deaths is that most of them were absolutely preventable," a trainer for the association told maternity staffs during a 2015 webinar. "They were from causes that we could have done something about. We could have prevented it if we had recognized the emergency early on."

During another closed session in 2016, a hospital association trainer said studies show that as many as 93 percent of women who bled to death during childbirth could have been saved if hospital staff had been aware of how much blood the woman lost.
The trainer said 60 percent of studied deaths from preeclampsia, a severe blood pressure disorder in pregnancy, also were preventable "because we failed to control the blood pressure or to recognize other emergencies that were happening."

"We're not talking about a Third World country, we're talking about us, here," the trainer said. "This shouldn't be happening here."

The hospital association declined to grant an interview and wouldn't answer questions about the toll of preventable harms at its member hospitals or how many of those hospitals follow best practices. In a statement, the group said U.S. hospitals are "committed to continuously working to keep all patients safe."

There is a growing recognition by hospitals that they need to adopt standardized care practices to save mothers' lives. In the past year, the number of maternity hospitals participating in a voluntary childbirth safety improvement program endorsed by leading medical societies has more than doubled.

The 985 hospitals currently enrolled in the AIM Program to reduce harms to mothers represent about 40 percent of the nation's birthing hospitals and they are in various stages of implementing care reforms, organizers say.

For more than a decade, the experts who guide medical practices in the U.S. have been

pushing doctors and hospitals to change how they treat pregnant women.
At least as far back as 2010, researchers in California began promoting "tool kits" of childbirth safety practices to reduce deaths and injuries.

Routine failures

These kits, built upon years of published research, were made up of policies, procedures and checklists that, pursued together, appeared to save mothers' lives.
Around the same time, the American College of Obstetricians and Gynecologists was lending its influence to address one of the leading childbirth killers: high blood pressure. In a 2011 bulletin to providers, the group warned that blood pressure above certain levels "if not treated expeditiously can result in maternal death." The group gave hospitals and doctors step-by-step instructions, even specifying which IV drugs to give.

Three years later, a coalition of the nation's leading medical societies created the AIM Program. The program formalized safety practices that have been shown to reduce maternal injuries into a series of "safety bundles" that detail treatment policies, safety equipment, training programs and internal reviews every maternity hospital should have. The AIM Program's "safety bundles" have been sponsored by a coalition of leading medical societies whose members include ACOG, the American College of Nurse-Midwives, the American Academy of Family Physicians and groups representing obstetric nurses and anesthesiologists.

For example, the AIM recommendations set time deadlines for taking blood pressure readings and administering medications to pregnant women and new moms experiencing dangerously high blood pressure.

Despite nearly a decade of medical studies, warnings, advice and training, hospitals continue to provide uneven care.

USA TODAY obtained internal hospital data collected from dozens of hospitals in 2015 and 2016 as part of other voluntary quality-improvement programs. Among other things, some of the federally funded programs tracked how often staff gave recommended blood pressure medicine within the called-for, one-hour deadline.
Among about 40 maternity hospitals in New York state, less than half of mothers experiencing dangerously high blood pressure got proper treatment, the records show. In Pennsylvania, the data for about a dozen hospitals show mothers being promptly treated only 49 to 67 percent of the time.

More than 65 percent of mothers didn't get proper treatment at Bon Secours St. Francis Hospital in Charleston, South Carolina.

At Carolinas Medical Center in Charlotte, North Carolina, nearly 40 percent of mothers did not receive timely blood-pressure treatments. The failure rate was 78 percent at Carolinas HealthCare System NorthEast in Concord and nearly 90 percent at Stanly Regional

Medical Center in Albemarle.

At Alamance Regional Medical Center in Burlington, North Carolina, the breakdown was almost universal. Only one of the 48 maternity patients with dangerous blood pressure readings got proper treatment.

Officials at each of these hospitals said their performance has since improved.
Women's Hospital in Greensboro is one of the biggest birthing hospitals in North Carolina, delivering about 6,000 babies a year in a metropolitan area of about 760,000 people. The hospital says on its website "...whether you seek specialized care for a high-risk pregnancy, the latest diagnostic services, or alternative birth options such as a water birth, you can count on us for world-class service that's close to home."

But the federal records obtained by USA TODAY show doctors and nurses there put scores of mothers at risk by reacting slowly to signs of dangerously high blood pressure. Women's Hospital failed to provide timely blood pressure treatment for 189 of 219 mothers, according to its own monthly tallies from October 2015 through June 2016. The treatment failures at Women's Hospital occurred even though medical staff knew their work was being tracked.

"It's unacceptable. That's really what it is," said Eleni Tsigas, who leads the Preeclampsia Foundation. She questions whether voluntary care-improvement programs alone will ever get enough hospitals to make lifesaving changes.

There is no way to know how widespread the failures like those in the Carolinas are at maternity units nationwide. The government doesn't track it and hospitals' internal numbers are usually a closely guarded secret.

Cone Health, which operates Women's Hospital and Alamance Regional Medical Center, excused its poor performance in 2015-2016 by saying it had just started training staff to quickly treat dangerous blood pressure – even though ACOG issued its treatment warning in 2011.

Cone Health defended the delayed training by saying ACOG treatment guidelines aren't mandatory and its own hospitals and doctors needed time to evaluate whether the best practices being touted by the nation's top experts were appropriate.
The numbers suggest they were. Cone Health said its two hospitals that participated in the federal quality program have significantly improved.

At Women's Hospital, 84 percent of mothers with high blood pressure got proper treatment from June 2016 to April 2017, officials said. At Alamance, it was 72 percent. And the number of mothers suffering seizures and strokes – consequences of dangerous, untreated high blood pressure – have dropped.

It was about 4 a.m. when they wheeled Ali Lowry back to Room 25 at Knox Community Hospital after delivering her baby.

'I was really scared'

As a nurse in the hospital's birthing center in Mount Vernon, Ohio, an hour northeast of Columbus, she had helped many other women deliver babies. But this was finally a baby of her own, and she was so excited to finally hold him.

As Lowry, 24, settled in and began breastfeeding her son, her vision went black.

"I was really scared, because I knew that, that I shouldn't have been feeling that way," she recalled of that morning in August 2013.

Lowry's blood pressure had plummeted. Over the next hours, nurses took her blood pressure repeatedly and found it to be low. Around 5:30 a.m., the readings were: 52/26, 57/25, 56/24, 59/27.

Blood pressures at 85/45 or below ought to be a warning sign to hospital staff that a woman is losing life-threatening amounts of blood and action is needed, according to the childbirth safety tool kit California experts made available to hospitals across the country in 2010. For women like Lowry, who deliver by C-section, the bleeding can be internal and hidden from sight.

Yet for hours, no one at the hospital took emergency action to check for internal bleeding, according to records in Lowry's lawsuit against her providers. Not the nurses on duty nor Dr. Ioanna Kanellitsas, who delivered Lowry's baby. Instead, blood continued to pool inside her body and no one knew how bad it was.

It wasn't until 7 a.m. – nearly three hours after she first began passing out – that the court records show Lowry started to get meaningful help to save her life.

A supervising nurse coming on duty saw Lowry's blood pressure history and terrible condition, and mobilized a rapid response team. Lowry was moved to intensive care and started getting blood transfusions.

A doctor coming on duty, David De Lorenzo, found Lowry no longer lucid, her skin turning blue.

Around 10 a.m., Kanellitsas took Lowry into surgery and removed six cups of blood and clots from her abdomen. But she saw no active bleeding.

"We were in the operating room for an hour and a half watching this. So, I was as certain as I could be that we had controlled the bleeding and that she wasn't having further bleeding," Kanellitsas said in a deposition in the family's lawsuit against the doctor and the hospital.

Yet Lowry kept bleeding. Unconscious and on a ventilator, blood soaked her legs and drenched her bed.

When nurses alerted Kanellitsas, the court records indicate the doctor told them it was OK. It looked like normal postpartum bleeding, she testified.

It is unclear whether the doctor and hospital staff had been quantifying Ali's cumulative blood loss since her delivery. At least during Lowry's C-section and later exploratory surgery, her blood loss – beyond what was collected in a suction machine – was being visually estimated, according to deposition testimony of the nurse anesthetist who was in the operating room for both procedures.

Multiple studies have found visual estimates underestimate blood loss, which can delay lifesaving treatments.

"She just kept getting worse and worse," Ali Lowry's husband, Shaun, said.
He had been asking for Ali to be transferred to a major medical center, but it refused to take her because she was too unstable.

By then it was clear that Lowry needed a hysterectomy to save her life – something Knox normally would have been able to handle.

But the hospital was down to its last unit of matching blood, according to court records. "We didn't even have enough blood to give her a hysterectomy," De Lorenzo said in a deposition.

De Lorenzo called Riverside Methodist Hospital in Columbus, which agreed to take Lowry. As paramedics lifted her off the gurney, she went into cardiac arrest. If Lowry had stayed at Knox, De Lorenzo said: "She surely would have died."

At Riverside, doctors found a lacerated artery, but had to remove Ali's uterus to stop the bleeding.

"I was just kind of shocked by everything," Lowry said. "I was definitely devastated by losing my uterus but at the same time I was also so thankful to be alive and that my baby was OK."

The family settled a lawsuit against Kanellitsas and the hospital, who denied the suit's allegations of wrongdoing. The terms are secret.

Knox officials declined to be interviewed. Frederick Sewards, an attorney for the hospital and Kanellitsas, said: "The resolution of that doubtful and disputed claim was subject to a confidentiality agreement, which neither I nor my clients will violate."

Across the country, USA TODAY talked with dozens of women who are among the 50,000 each year who suffer severe injuries after surviving potentially deadly deliveries.

Frustrations of the 50,000

Some praise the care they received. But many women said they felt frustrated, angry and powerless after encountering doctors and nurses they felt didn't listen or weren't prepared for emergencies.

"This was supposed to be the best time of my life and this is the worst and nobody should feel that way about the birth of their child," said Susan Goodhue of Annapolis, Maryland. Her blood pressure spiked and her liver and kidneys started to fail when she gave birth in 2012.

"The staff, by not knowing, and not listening and not taking precautions, almost killed us," she said.

Women talked about excruciating pain and fighting to survive for their children. Some say they never got good explanations for what went wrong and why.

ZaKiya Bell-Rogers of Asheville, North Carolina, said she still doesn't know what caused the blood loss that required her emergency hysterectomy in 2015. "I need to know what happened, but I don't know if mentally I can take it if there was a mistake on their end." Donielle Bell, who lives in the Atlanta suburb of Marietta, also says she never got good answers about why she hemorrhaged in 2016 – and whether it would happen again when she gave birth to her third child this spring.
"I'm facing this fear daily," she told USA TODAY earlier this year. "I'm terrified that I won't walk away from it."

In April, Bell delivered a healthy son, but she lost so much blood this time that she needed an emergency hysterectomy to save her life.

Over and over, these women said they wanted other mothers to know the importance of finding health care providers who listen to their concerns, pay attention to warning signs and are trained to deal with complications.

"Having the right hospital is life and death," said Alana Alvarez of Mililani, Hawaii, who nearly bled to death and needed a hysterectomy and other surgeries to survive a 2015 birth.

"Having the right doctors, having the right care, having the right people that know about your diagnosis, that understand your diagnosis, that know what they're doing, it's life and death," she said.

At University of Utah Hospital in Salt Lake City, maternity officials didn't want to believe

that the way they cared for mothers could be one of the reasons why 12 percent of their patients suffered hemorrhages in 2013 – triple the national rate.

Like many hospitals, they were quick to blame the women as being unusually high risk instead of scrutinizing their own care.

"We initially rationalized this," Dr. Erin Clark, the hospital's director for maternal-fetal medicine, told maternity staff from other hospitals at a 2015 training session.
But the hospital realized it had a problem when it compared its results with other university hospitals. Their peers also cared for high-risk moms, but their patients weren't hemorrhaging as often.

"We stood out in an obvious way and not a good way," she told USA TODAY.
The hospital dug into patients' records. "We diagnosed hemorrhages too late," Clark said. "And we didn't treat them fast enough or aggressively enough."

The hospital reduced its rate by one-third after it began adopting the best practices called for by California experts and the AIM Program, Clark said. That progress has been seen in other groups of hospitals following the safety practices, too.

According to a study published last year in the American Journal of Obstetrics & Gynecology, women giving birth in hospitals participating in a California quality improvement collaborative suffered 21 percent fewer severe harms related to hemorrhage from 2014 through early 2016 than those in previous years. That's fewer women suffering heart attack, kidney failure or blood-clotting disorders, and fewer women being put on ventilators or undergoing hysterectomies.

When hospitals work with well-organized state-wide quality groups – that help them train staff, track data and benchmark against peers – care can improve faster than if they're le to do it on their own, experts said. From May 2016 through June 2017, about 100 Illinois hospitals participating in an AIM Program-affiliated project increased from 42 percent to 79 percent the number of maternity patients getting treatment for dangerous blood pressure within one hour, according to data published earlier this year in the same medical journal.

For decades, hospitals and medical experts have often blamed rising maternal deaths and injuries on women for being unhealthy or overweight, or pointed to risk factors such as poverty or the age of mother.

"Just because you're older and heavier, doesn't mean you should die," said Dr. Elliott Main, medical director of the California Maternal Quality Care Collaborative, which is credited with reducing maternal injuries and deaths in the state. "That just means you should be on guard, you should bring your A game."

Blaming moms for poor health or lacking prenatal care helps mask care failures. "We cannot just blame the women," said Debra Bingham, a former vice president at Association of Women's Health, Obstetric and Neonatal Nurses, who is now at the University of Maryland School of Nursing.

Nurses and doctors believe they provide good care and don't want to harm patients, Bingham said.

"So it's very hard to accept that what I've been doing for years may not have been the best way to do it," she said.

Rachel Yencha, who nearly bled to death after giving birth in 2015, said it would have been helpful to know upfront whether hospitals follow best safety practices.

Yencha, who was young and healthy, chose a small maternity hospital near her suburban Cleveland home. But when complications arose during delivery, she had to be transferred to a bigger hospital that could save her life.

"Even if you have a normal pregnancy, you want them to be prepared for anything," she said.

Because there are no requirements that U.S. maternity hospitals follow best practices, nobody knows how many of them take all of the AIM Program's recommended actions.

"I don't have a good sense for what percentage of the hospitals. It's not huge yet, but it's gaining momentum rapidly," said Dr. Barbara Levy, vice president of health policy at ACOG.

Even if women and their loved ones knew the questions to ask, USA TODAY found that it would be nearly impossible for them to find out the safety records of maternity hospitals or whether they are following best safety practices.

USA TODAY repeatedly contacted 75 hospitals in 13 states to press for specific answers about whether they are following the AIM Program's recommended practices for hemorrhage and hypertension.

Half wouldn't answer the questions.

Those refusing to answer included Northside Hospital in Atlanta, one of the nation's largest birthing hospitals, which annually handles about 16,000 deliveries. "We are going to have to pass on this opportunity. I'm not able to get you what you need," hospital spokesperson Katherine Watson said in an email.

"We respectfully decline to participate," said Giselle Tiley, spokeswoman for Osceola

Regional Medical Center in Kissimmee, Florida.

Even hospitals that brag about their expertise in childbirth emergencies wouldn't answer questions about whether they are taking AIM's recommended safety steps.
"We will pass on this one," Johnny Smith, a spokesman for St. Agnes Hospital in Baltimore, said in an email after a reporter contacted the hospital and its parent health system, Ascension, nearly a dozen times. On its website, the hospital says: "Our innovative approach to obstetric emergencies set us apart."

The 37 maternity hospitals that answered USA TODAY's questions said they are doing many of the AIM Program's best practices to prevent women from bleeding to death. But more than 40 percent acknowledged they were not quantifying blood loss after every birth – despite it being a cornerstone safety practice.

When it came to ensuring women with dangerous blood pressure readings got proper treatment within 60 minutes, the hospitals' answers also indicated lax compliance. Of 31 hospitals that said they follow a 60-minute treatment policy, only nine said they track how often doctors and nurses actually gave treatment in time.

Experts say the slow pace of change is largely because, in this country, doctors and hospitals enjoy wide latitude in how they practice medicine. How they treat patients is often based on what providers were taught – years or decades earlier – in medical or nursing school, plus their individual experiences over time.

When researchers identify safer ways of caring for patients, there are no mandates that providers read or follow these practices. In maternity care – as well as other areas of medicine – it can take a decade or more for best practices to be widely adopted by health care providers.

The result: a system that experts say fails patients and leads to needless deaths and injuries.

In countries with publicly funded national health care systems, such as the U.K, it is easier to insist hospitals and health providers follow standard safety practices, said Dr. James Martin Jr., director of maternal-fetal medicine at the University of Mississippi Medical Center and a past president of ACOG.

Martin and other experts said that's one reason why women giving birth in Great Britain die from childbirth complications at one-third of the rate they do here.
Without a centralized system, reform will require multiple entities to insist on change: hospital administrators, insurance companies and others that pay for childbirth, and malpractice insurers who defend practitioners against lawsuits, Martin said.
"If they say, 'We expect you to do it this way,' that you've got to get on and use this safety bundle ... it can be driven from that point of view," Martin said.

Hospitals need to be accountable and the public should be able to find out each hospital's rates of childbirth complications, said Helen Haskell, president of Mothers Against Medical Error, a nonprofit patient safety group in South Carolina.
"We've put a lot of credence in the idea of voluntary improvement and it's just not enough," Haskell said. "You have to have transparency and you have to have regulation." Until that happens, women will continue to be harmed.

"So many of these are preventable," said Monica Simpson, executive director of SisterSong, an Atlanta group that is part of the Black Mamas Matter Alliance, which is pushing for national policy discussions. "I think the country should be outraged."

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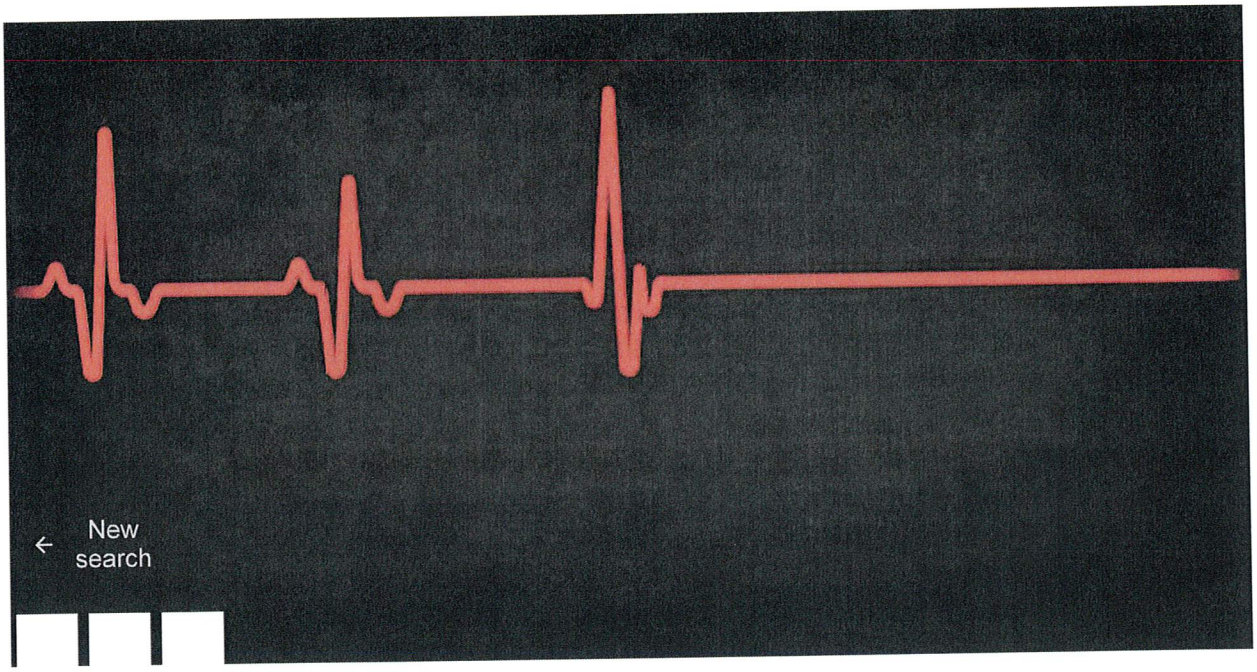
A security empire deployed guards with violent pasts across the US. Some went on to rape, assault or kill



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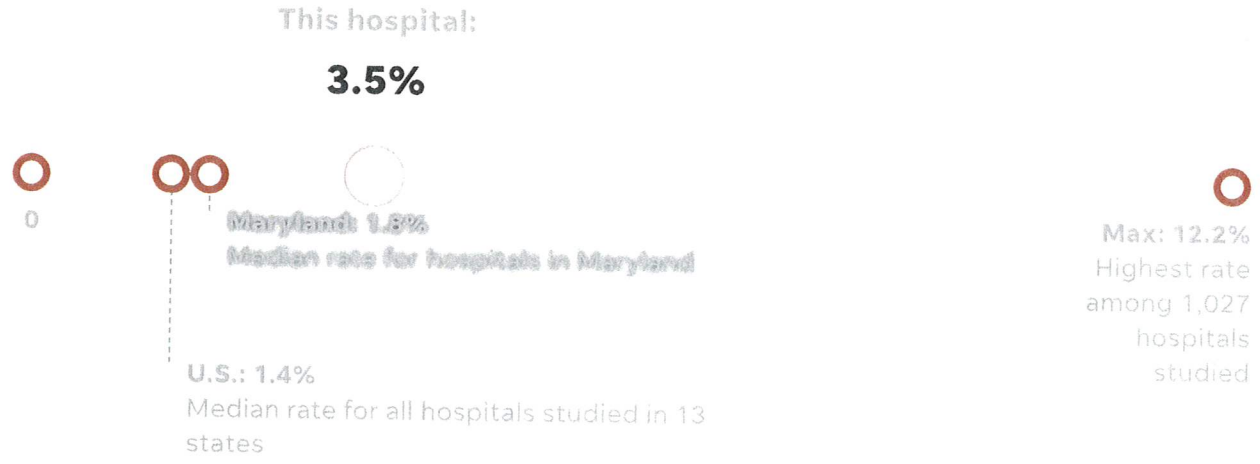
Severe maternal morbidity (SMM) rate

The SMM rate is a composite measure of things that can go wrong at the hospital before, during or after delivery – heart attacks, strokes, blood transfusions, hysterectomies and other perilous emergencies that can permanently harm or even kill a new mother. Because of national concern about disparities in harms experienced by black mothers, USA TODAY also is displaying a separate calculation for these patients.

Learn more

This hospital's severe maternal morbidity rate for births to **all mothers** is greater than the rate for Maryland

5,151 deliveries (2014-17)



This hospital's severe maternal morbidity rate for births to **black mothers** is greater than the rate for Maryland

1,101 of 5,151 deliveries

This hospital's severe maternal morbidity rate for births to **low-income mothers paid for by Medicaid** is greater than the rate for Maryland

1,727 of 5,151 deliveries

This hospital:

STORY

Hospitals blame moms when childbirth goes wrong. Secret data suggest it's not that simple.

Read the story

Other indicators

Cesarean rate

The percentage of deliveries that were the mother's first C-section. This measure excludes deliveries involving mothers who've had a previous C-section. Health safety advocates have long cautioned against unnecessary C-sections.

This hospital:

19.0%

Rate for deliveries in 13 states:

19.9%

Have questions?

What is the severe maternal morbidity (SMM) rate?

The Centers for Disease Control and Prevention created a method for calculating how often women giving birth experience severe complications by using codes in patients' billing records that show what conditions they were diagnosed as having, and what medical procedures they were given.

The resulting "severe maternal morbidity rate" is a composite index of things that can go wrong at the hospital before, during or after delivery – heart attacks, strokes, blood transfusions, hysterectomies and other perilous emergencies that can permanently harm or even kill a new mother.

The CDC developed the rate to study trends at state and national levels, but it's now widely used privately by patient safety organizations, state health departments, insurance companies and hospitals to measure hospitals' progress as they try to reduce preventable injuries and deaths.

How to use this information

Experts stress that a hospital's SMM rate should only be a starting point for asking questions about a hospital's childbirth safety practices and its experience, equipment and resources for responding to emergencies. A high rate alone doesn't mean a hospital provides bad maternity care and a low rate doesn't mean the hospital is the safest place to give birth. A major medical center with a higher SMM rate will have more expertise and resources for treating high-risk deliveries than a community hospital with a lower SMM rate and staff that delivers fewer babies and has less experience and resources when emergencies happen. The SMM rate is just one piece of information consumers should use in evaluating birthing hospitals.

What are the known weaknesses of the SMM rate?

The rate is not a definitive count of how many women suffered serious complications, but instead an indicator or estimate. The rate cannot measure, for instance, how many complications could have been prevented by better medical care or how many patients arrived with existing medical problems that put them at higher risk of a dangerous delivery. For instance, the records do not detail a patient's weight, even though obesity can contribute to complications.

Is the SMM rate published above risk-adjusted?

No. The data USA TODAY obtained does not include all of the information that is needed to adequately risk adjust for the unique factors of childbirth. In fact, there is no consensus among experts of a method for risk-adjusting the SMM rate, in part because of the vast array of contributing factors unique to childbirth.

Can the SMM rate be used to compare hospitals against one another?

Hospitals and many researchers in the field say limitations of the measurement make it difficult to use it to compare one hospital to another. The rates are most commonly used to compare a hospital to larger populations of patients or a group of hospitals. Importantly, they are recommended as a measure that a hospital should compare to its own past rate to monitor its progress in reducing complications.

What deliveries are included?

Throughout most of this database, the numbers utilized are calculations drawn from deliveries in 13 states. References to medians or national figures are aggregates of figures from across the 13 states where USA TODAY was able to get hospital data.

The deliveries in almost all cases are those from 2014-2017. In two states, there were fewer: New York's does not include the fourth quarter of 2017. Vermont's data does not include 2017. Several small Louisiana hospitals did not report hospitalization data for full quarters, but rates calculated for those hospitals from the reported quarters were consistent with rates calculated for those hospitals from previous years' data, going back to 2010.

For episiotomies, figures are a rate derived from vaginal deliveries only, and are available for eight states. The national rate is derived from those eight states. An earlier version of this graphic listed a national rate incorrectly citing all deliveries in 13 states.

Where did this data come from?

USA TODAY calculated SMM rates, following the CDC formula, from de-identified patient discharge records for every hospital in 13 states that had at least 500 births during the four-year period. USA TODAY attempted to obtain these records from all 50 states and the District of Columbia, but most denied the request, or imposed restrictions that amounted to denial or made the data useless for analysis. No patients' names or other identifying information are contained in the records USA

TODAY reviewed. Reporters followed the same strict patient privacy rules imposed on any researchers who use such data.

The records analyzed came from the following agencies: California Office of Statewide Health Planning and Development, Florida Agency for Health Care Administration, Kentucky Cabinet for Health and Family Services, Louisiana Department of Health's Bureau of Health Informatics, Maryland Department of Health and Mental Hygiene, Nevada Division of Health Care Financing and Policy, New Hampshire Bureau of Public Health Statistics and Informatics, New York State Department of Health, Pennsylvania Health Care Cost Containment Council, Rhode Island Center for Health Data and Analysis, Texas Department of State Health Services, Vermont Division of Health Care Administration, Washington State Department of Health and West Virginia Department of Health and Human Resources.

The analytical findings are USA TODAY's and not the work of the agencies that provided data and records.

Why are rates not available for some groups of mothers?

USA TODAY is not publishing rates derived from numbers of patients that are very small, in part to protect patient privacy and comply with state regulations related to the use of the hospital data behind this special report. This impacts rates for black mothers, for instance, at hundreds of hospitals.

What if I see a potential error in this database?

If you spot anything you believe is incorrect in this database, we want to hear from you. We will look into it, using available records, and get back to you. Every effort has been made to ensure hospital names, addresses and statistics reported here are accurate, according to the hospital records submitted to state agencies and obtained by USA TODAY. However, if you believe you see an error, we will review your concern and correct inaccuracies. If you spot a potential error, please let us know at jkelly@usatoday.com.

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— Ryan Marx, Michael Varano, Christopher Schnaars, Alison Young, John Kelly and Matt Wynn.

Damage Caps and Defensive Medicine, Revisited

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