Post-analytical Error in Fatal Post-Cesarean Necrotizing Fasciitis and Sepsis: A Case Study

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ABSTRACT

This is a case study of a 28 year old morbidly obese pregnant female with severe pre-eclampsia. She delivered at 32 weeks gestation by emergency cesarean section, and was discharged at three days post-surgery. The patient developed sepsis secondary to necrotizing fasciitis. She had been released from the hospital without her final complete blood count (CBC) having been reviewed by the attending physician, although it had been available for approximately 24 hours prior to her departure. The final CBC contained persuasive data suggesting that an adverse outcome could be highly probable. Discussion as to how this ultimately lethal post-analytic error might have been avoided, and perhaps prevented in the future is undertaken.

ABBREVIATIONS: CBC - Complete Blood Count, C-section- Cesarean section, HELLP- Hemolysis Elevated Liver enzymes and Low Platelet count, NICU- Newborn Intensive Care Unit, NRBC nucleated red blood cells, Ob/Gyn - Obstetrician/Gynecologist,, TJC - The Joint Commission, WBC - White Blood Cells

INDEX TERMS: Preeclampsia, necrotizing fasciitis, sepsis, patient safety, medical errors, neutrophils, and hematology

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INTRODUCTION

A morbidly obese 28 year-old with severe pre-eclampsia had an emergency cesarean section performed at 32 weeks gestation. She was officially discharged three days post-surgery prior to the release of the results from her final complete blood cell count (CBC). Her pending results were entered into the laboratory information system less than 15 minutes after her physician signed her discharge papers at approximately 9:00 AM. She departed from the hospital at noon the following day, when the infant was discharged. This left ample opportunity for her laboratory data to have been duly noted and action taken. Her CBC exhibited a left shift (38%), six nucleated red blood cells (NRBC), and a precipitous drop in white blood cells (WBC).After departing the maternity unit with her infant, she expired approximately 34 hours later of overwhelming sepsis secondary to necrotizing fasciitis. This case presentation will track the patient's progress through three hospital admissions (hospitals A, B, C) over a course of seven days, attempt to determine why this post-analytical error occurred, and offer suggestions to avoid such errors in the future.

CASE PRESENTATION

Patient History: The patient was admitted to hospital A (day 1) with a diagnosis of pregnancy-induced hypertension and severe pre-eclampsia compounded by obesity (height, 5 feet 0 inches; weight, 198 lbs.) at 32.5 weeks gestation. She had gained 48 lbs. during pregnancy, and upon admission, her blood pressure was 164/104 mmHg with an oral temperature of 37.6°C and a dull, intermittent headache. All other physical

signs and measurements were unremarkable.

Days 1-3 (Admission and C-section): Due to severe hypertension and pre-eclampsia, labor-induction was decided upon as the best course of action. Magnesium sulfate and betamethasone were administered as a seizure preventative and as a fetal lung protectant, respectively. However, the fetus was noted to exhibit intolerance to contractions and a primary low transverse C-section was performed before distinct cervical changes or full labor had been established. Cefazolin was administered during the procedure. Since the newborn was pre-term, he was placed in the neonatal special care unit. Other staff physicians saw the patient on post-operative days 2 and 3. Her initial CBC at the time of admission yielded a slightly elevated WBC count (13.1K/mm^3), a slight eosinophilia (12.2%), all other differential values were within reference ranges and no NRBCs were observed (Table 1).

Day 4 (Post-C-section): A CBC was collected from the patient at 7:12 AM and the results were available in the hospital computer system at 9:12 AM. The patient's primary Ob/Gyn physician examined the surgical wound at approximately 9:00 AM, found it to be healing normally, and wrote the patient's discharge order. The physician did not review the laboratory report for the final CBC. The patient was not seen again or interviewed by any physician before she departed from the hospital with her infant at approximately noon on day 5 (27 hours after the discharge order was written).

Day 5 (Post-C-section): At departure on day 5, the patient was recorded as experiencing tachycardia with a pulse of 111. Her discharge prescriptions consisted only

Table 1. CBC Results Summary

Day Time	WBC (4.5 – 11.0) K/mm^3	RBC (3.90 – 5.20) M/μL	HGB (11.2 – 15.0) g/dL	HCT (32.8 – 44.7) %	PLT (125 – 400) K/mm^3	NRBC NRBC/100 (0 – 0)
Day 4 0712	5.5	3.77 L	11.3	33.5	231	6 H
Day 3 1423	19.3 H	3.79 L	11.4	33.4	297	0
Day 2 0739	23.5 H	4.20	12.9	38.0	285	0
Day 2 0011	23.3 H	4.88	15.3 H	44.8 H	232	0
Day 1 1107	13.1 H	4.80	14.6	42.9	248	0
Date Time	**SEGS % (41 – 82)**	**BANDS % (0 – 6)**	**LYMPH % (22 – 40)**	**MONO % (3 – 12)**	**EOS % (0 – 6)**	**BASO % (0 – 2)**
Day 4 0712	42*	38 H	17 L	2 L	0	0
Day 3 1423	80	0	13 L	7	0	0
Day 2 0739	80	0	14 L	6	0	0
Day 2 0011	83	6	8 L	3	0	0
Day 1 1107	52	0	31	5	12 H	0

*One metamyelocyte was observed on the differential.

of Vicodin and an over-the-counter non-steroidal anti-inflammatory medication for pain.

Day 5 (Admission to hospital B): Around 10:00 PM while at home, the patient experienced heavy vaginal bleeding, difficulty breathing, and fainted, whereupon she was transported via ambulance to the emergency room at hospital B. Upon admission, it was determined that she was suffering from abdominal pain, difficulty breathing and hypotension. Severe septicemia, metabolic acidosis, leukopenia, and possible Hemolysis Elevated Liver enzymes and Low Platelet count HELLP were suspected.

Day 6 (Admission to hospital C): Resultant from her rapidly deteriorating condition, the patient experienced respiratory failure and required intubation while at hospital B. Blood cultures were positive and the following were isolated: *Escherichia coli, Proteus mirabilis*, and *Enterococcus* species. She was placed on a regimen of 11 antibiotics. By mid-afternoon, she was transported by helicopter to hospital C, a university medical center, where it was thought she might receive a higher level of care. Despite all efforts to reverse her deteriorating status, she expired at about 10:00 PM that evening.

Day 7 (Post-Mortem): Post-mortem results revealed death caused by sepsis as a result of necrotizing fasciitis due to status post-C-section. She exhibited bilateral pleural effusions, ascites, and bilateral hemorrhagic adrenal glands.

CRITICAL LABORATORY VALUES

The thorough analysis of this case was undertaken with the belief that laboratory and other medical professionals can learn from the examination of this series of clinical events. What errors were made and what can be done, especially from the utilization of laboratory data, to ensure patient safety?

Critical laboratory values may be described as those that signifies an immediate, life-threatening situation for the patient that require immediate medical intervention.[1] Clinical laboratories are burdened with a dual challenge when they determine critical values. First, laboratories must decide which tests should have critical values assigned to them; second, they must also determine the critical thresholds for those tests. Clinical laboratory accrediting agencies such as The Joint Commission (TJC) do not include criteria for critical value specification; rather there is considerable emphasis on the process and procedure development by which critical values are reported to other health care professionals.[2] Although the ultimate responsibility for the establishment of critical values lies with the laboratory director, this individual is not always the one to set criteria for critical values.[1] In a survey of 182 clinical laboratories, respondents most commonly reported that their institution's critical values had been determined by any of the following: the medical director, published literature, the medical advisory committee, policies from another institution, textbooks and the laboratory manager.[3] In other words, there is no standardization regarding which laboratory tests should have critical value thresholds.

Since clinical laboratories do not receive direction from accrediting agencies, they must be judicious as they determine tests that will have critical values and the critical thresholds for those tests, which often will be based upon the specific patient populations for that clinical laboratory. McFarlane and colleagues reported that the most commonly noted hematology tests with critical values are the white blood cell count, hemoglobin, platelet count, absolute neutrophil count, observation of malaria and other parasites on the peripheral blood smear, presence of blast cells, sickle cells and schistocytes for red cell morphology.[3] Commonly, these tests will have variations for critical thresholds among laboratories and some laboratories may only require notification of an initial critical value.[3] Furthermore, clinical laboratories will frequently have different critical value thresholds for patients in different age ranges.[4]

The significant lab results from this case were borne from the final CBC that was ordered prior to the patient's discharge from the hospital. The CBC results, which were never reviewed by the ordering physician, included six NRBCs and marked left shift of 38%, both of which were a significant change from her initial CBC. The attending physician was not notified because the policy on critical values at hospital A did not include the presence of either NRBCs or marked increases in the segmented neutrophils. However, examples in the literature signify that it may be prudent to include NRBCs as alert values in some patient

populations.

In a study of patient records that included 200 patients with NRBCs, a multivariate analysis indicated a 25.5% mortality rate ($p < 0.001$) of patients whose CBC results included the presence of NRBCs. This particular study noted that most patients with NRBCs, "exhibited overt signs of severe disease".[5] Additionally, one patient's CBC was noted to have had NRBC's present on the day of discharge and was readmitted three days later with fulminant septic shock, and the patient expired.[5] Further data may be necessary for laboratories to determine whether NRBCs should be included as a critical value on at least the first observation, which is certainly a significant hematological finding. Clinicians, however, receive a considerable amount of laboratory data on a daily basis and adding further critical values policies may continue to burden and overwhelm them with additional data to review and initiate medical interventions.[6] Although, had the six NRBCs from the case been reported as a critical value by the laboratory or the results reviewed by a doctorate in clinical laboratory science practitioner (DCLS), this mother may not have died just days after the birth of her infant.

DISCUSSION

The final CBC was drawn at 7:12 AM (day 4) and results were released at 9:12 AM, revealing six NRBCs and 38% bands. During her hospitalization, her WBC count ranged from 13.1 K/mm^3 on day 1 to 23.3 K/mm^3 on day 2 following her surgery to 5.5 K/mm^3 on the day her discharge orders were signed. Her final examination by the physician was at approximately 9:00 AM, at which time her discharge orders were written, however she did not leave the hospital until the next day. At no time during the 27 hours before she left the hospital were the results from her final CBC examined by a physician nor was she herself examined by a physician. Arguably, however, she was waiting until her infant in the NICU was released.

In short, the patient was home for less than ten hours when she collapsed, losing consciousness following severe vaginal hemorrhaging. Ultimately, she was admitted to two additional hospitals in unsuccessful attempts to resolve necrotizing fasciitis and fulminant sepsis, which overwhelmed her on the 7th day post-C-section.

The combination of a strong left shift, a rise followed by a steep drop in WBCs, and the presence of NRBCs is a strong indicator of an unfavorable patient outcome. In a review of 2,342 patient records, Drees, Kanapathippillai, and Zubrow noted a correlation between a normal WBC count with greater than 20% bands, sepsis, and patient mortality. Data were analyzed with a multivariable logistic regression which yielded an adjusted odds ratio of 4.7 (95% confidence interval, 2.4-9.0) between patients having greater than 20% bands and inpatient mortality.[7] However, if medical laboratory professionals and other medical personnel are unresponsive to such data, catastrophic outcomes are likely to ensue. Had the physician been aware of this triad of hematological findings, then it would have drawn attention to the patient's rapidly deteriorating condition, and perhaps, she might have been readmitted or at least her discharge orders been amended to include antibiotics.

There is no question that the patient in this case was released from the hospital before her CBC results were available, however they were in the hospital's computer system approximately 12 minutes following her release. Despite the fact that she remained in her room until the next day at noon with her newborn, there is no evidence that direct care medical personnel ever sought, reacted or responded to her CBC data. Patient safety concerns arise when critical laboratory data are not available or are not reviewed by clinicians prior to patients' hospital discharge. One study reported that nearly 38% of patients discharged had at least one incomplete laboratory test or result that had not been seen by the physician before discharge. Of these results, 14% were not evaluated by physicians and were outside the reference range.[8] Failure to follow up on laboratory results contributes to unsafe patient care and outright harm, affecting between 20% and 61% of inpatient tests.[9] Nearly one-fourth of all medical errors can be attributed to poor follow-up, and are thought to represent about 25% of malpractice lawsuits associated with failures or delays in diagnosis. An evaluation of the Veterans Affairs facilities electronic health record revealed that 7% of critical laboratory results from outpatients did not receive attention from clinicians.[10] Further examples of clinicians' failure to act upon relevant laboratory data were noted in a study from which 45% of urgent tests ordered by emergency rooms were never actually viewed on the chart.[11] The lab

produces the data and has the responsibility to deliver the data in a timely manner. However, the recipients should have the requirement to verify its receipt in a timely manner in what would be called the completion of the "circle of responsibility".

TJC's Hospital National Patient Safety Goal 2 for 2015 states that written procedures will be developed for the management of critical results for tests and diagnostic procedures. Although this is not a new standard for TJC, this safety goal limits its focus to the process of reporting critical values. It mandates that those results falling significantly outside the normal range will be reported on a timely basis. It will establish by whom and to whom results will be reported. Acceptable turn-around-time for reporting critical values will also be addressed by this safety goal.[2] Hopefully, this will usher a new era of patient safety into our hospitals. In the meantime, it would behoove all medical laboratory professionals to consider patient safety to be of the utmost importance and to go that extra mile when data verging on "not quite critical values" are involved. One would also hope that mandatory failsafe systems be placed into operation that would require feedback between medical staff and laboratory professionals that require the former to verify receipt of results falling significantly outside the reference range.

CONCLUSION

This case highlights the need for team based care with an experienced medical laboratory scientist on the interdisciplinary health care team. An argument for not calling abnormal results is that "communication by telephone, especially when performed by technologists, is a costly practice in terms of the resources required to complete the phone calls and document the process".[12] Laboratory managers are under pressure to reduce costs and have implemented LEAN processes to improve turnaround time and save money. At the same time the medical laboratory professionals have become more disconnected from the patient. The culture among medical laboratory professionals should be changed to increased involvement in direct patient care. According to Barth, " . . . health-care systems have been trying to reduce their costs; it is now timely for laboratory medicine to expand its contribution to patient care and safety by taking a more active role in this area".[13] In an expanded scope of practice, the contributions that a DCLS could bring to the health care team may have a positive impact on patient safety and outcomes, which would likely lead to a reduction in the cost of the delivery of health care.

It can be argued that this death is not the laboratory's fault as blame can be placed on the nurse or the doctor for failure to follow-up on an abnormal laboratory result. However, the fact remains that if a medical laboratory scientist or DCLS had placed a phone call to the right person, this young mother's tragic death may have been averted. The patient's values did not fall into the critical value range set by that particular laboratory; however, as competent medical laboratory scientists are aware, one set of critical values does not fit all scenarios. Medical laboratory scientists should empower themselves to make judgments and not be afraid to pick-up the telephone and call the doctor or nurse in charge of the patient to report results that they know are abnormal. This is where the critical thinking skills of a medical laboratory scientist must be used.

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