

Lessons Learned from “Baby Doe”
A Case Study in Policy Development & Assurance
Mid-America Regional Public Health Leadership Institute Year 13 Fellows
“Pinkies and the Brain”
Illinois Team 4

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Abstract

This case study examines the tragic events surrounding the death of a newborn from *Enterobacter sakazakii*. This gram-negative, rod-shaped bacterium is a rare cause of fatal meningitis and/or enteritis in infants and has been linked to contaminated powdered infant formula. The situation depicts an actual case, which has been fictitiously altered to protect the confidentiality of all parties. Stakeholders demonstrate the core elements of assurance and policy development, as well as the importance of collaboration between the local public health departments, the community partners, and various levels of the State and Federal public health systems. The timeline follows the scenario from the initial report of bacterial meningitis to a local health department through a collaborative investigation, and concludes with the preventative policies put in place.

Introduction

Tuesday, June 22nd

10:34 a.m.: Baby Doe was delivered at 38 weeks gestation via c-section at County General Hospital. The pregnancy and delivery were unremarkable and Baby Doe weighed 6 pounds 7 ounces. Mother and baby were discharged 48 hours after delivery in good condition. The mother opted to formula feed and subsequently was given a complementary diaper bag containing samples of powdered formula manufactured by Noname Laboratories.

Tuesday, June 29th

11:30 a.m.: Baby Doe refused to take a bottle and was running a low-grade fever. Baby Doe was given Tylenol and taken to the family physician. The physician assessed no fever and witnessed the baby take 1 oz. of formula while in the office. Baby Doe and mother returned home.

Wednesday, June 30th

9:00 a.m.: Baby Doe demonstrated difficulty breathing and had a fever of 101.6° F. Emergency medical personnel were summoned to the residence and Baby Doe was rushed to the hospital emergency room. Sadly, all life support measures failed and Baby Doe was pronounced dead at 10:32 a.m., with laboratory testing and autopsy results pending.

1:15 p.m.: Local Health Department “A” received a call from County General Hospital with a confirmed report of bacterial meningitis and a suspected report of *Enterobacter sakazakii* (*E. sakazakii*) on Baby Doe. *E. sakazakii* is a gram-negative, rod-shaped bacterium and has been implicated as a cause of fatal meningitis and/or enteritis in infants who have consumed powdered infant formula. The formula may become contaminated through the raw materials used in production; contamination of dry ingredients after pasteurization and/or contamination of the formula as it is being prepared. The literature indicates that the highest prevalence exists in preterm infants with underlying medical conditions.

2:30 p.m.: Local Health Department “A” reported the confirmed bacterial meningitis and suspected *E. sakazakii* case to the State Health Department and Local Health Department “B”. (Local Health Department “A” received the report due to the location of the hospital, however, Baby Doe resided in an adjacent county “B”.) The State Health Department advised Local Health Department “A” to wait for confirmation of the bacteria species before reporting it to the Centers for Disease Control and Prevention (CDC). Local Health Department “A” asked if further case investigation needed to be completed and was told since it was only one case, it was “not in the realm of Public Health” unless further case details or additional cases were identified.

Case Body

Thursday, July 1st

3:17 p.m.: Local Health Department “A” receives call from County General Hospital infection control nurse confirming positive *E. sakazakii* culture from Baby Doe’s blood taken pre-mortem. The infection control nurse states that the hospital administrator is very concerned about a possible lawsuit as the family has been made aware of the link between powdered baby formula and *E. sakazakii* from the county coroner. County General Hospital immediately halts its use of powdered formula in the nursery and pulls all powdered formula samples from the complimentary diaper bags given to new moms. Local Health Department “A” asks the infection control nurse to secure the remaining samples until further instructions come from the State Health Department. The infection control nurse will contact Local Health Department “A” with any other case information that develops.

3:45 p.m.: Local Health Department “A” reports the positive culture to the State Health Department, CDC and Local Health Department “B”. The State Director of Infectious Disease suggests that Public Health Administrator “A” contact the coroner to confirm if any post-mortem cultures were positive for *E. sakazakii* and indicates that he will personally call the CDC to determine if anything further is needed from their perspective. The county coroner is contacted and informs Public Health Administrator “A” that autopsy culture results will not be ready for a few more days.

Friday, July 2nd

1:10 p.m.: The infection control nurse calls Local Health Department “A” to inform them hospital officials are contemplating a press release stating the use of powdered baby formula may not be safe. Public Health Administrator “A” confirms on the FDA website that *no recall* for powdered formula is currently in effect and encourages the hospital administrator not to release a press statement as it would cause panic in the community. The hospital administrator agrees, but feels

some type of statement should be made to the public and it should come from the Local Health Department, as it is now a public health emergency. Public Health Administrator “A” assures the hospital administrator that the current scenario is NOT a public health emergency. While the death of the infant is tragic, at this point, it is an isolated case with no causal link established. Public Health Administrator “A” also states that any statement regarding the safety of the formula should come from the FDA or the manufacturer itself.

2:03 p.m.: Public Health Administrator “A” and the hospital administrator do agree that further investigation should take place to ensure no additional cases develop, if in fact the infant formula is determined to be the cause of infection. County General Hospital plans to contact recently discharged patients who left the hospital with a standard one-day supply of powdered infant formula. The hospital will also recommend these patients discontinue the use of the powdered formula until its safety can be assured. As a further precaution, the hospital plans to contact all physicians associated with the hospital to heighten their awareness of the infection and the current investigation.

3:13 p.m.: Local Health Department “A” is now charged with leading the investigation and coordinating follow-up with Local Health Department “B”, the State Health Department, CDC, FDA and County General Hospital. Local Health Department “A” agrees to contact other local hospitals and health departments in order to initiate syndromic surveillance for symptoms and/or cases of bacterial meningitis in the area. The Health Department also recommends the parents of Baby Doe be contacted by the family physician in order to preserve any formula samples they may still have in their home. Due to the baby’s funeral being held on Saturday and the fact that it was late afternoon on the Friday before a major holiday weekend, both administrators agree that a face-to-face interview with the parents of Baby Doe be postponed until the following week. Local Health Department “A” will have local Health Department “B” conduct the face-to-face interview with the family to determine exactly what formula was used, where the formula came from, how much was used and how it was prepared.

4:15 p.m.: The State Director of Infectious Diseases calls Public Health Administrator “A” with further instruction from the CDC. Any specimen samples from Baby Doe that resulted in a positive culture for *E. sakazakii* are to be divided and sub-cultured with one half of the original specimen to remain at the lab indefinitely and the other half be sent immediately to CDC. Public Health Administrator “A” also learns the CDC has called the FDA and the FDA would like the remaining formula samples secured and the lot numbers recorded for further investigation.

4:35 p.m.: Public Health Administrator “A” contacts both the hospital laboratory and the county coroner with specimen instructions. The county coroner informs the administrator that County “C” is actually doing the autopsy and the lab work was completed at a hospital in County “C”. The coroner from County “C” is contacted and gives the contact information for the laboratory doing the autopsy testing. While this is occurring, the Doe’s family physician contacts the father to ask whether or not they have any of the formula they received at the hospital so a lot number may be obtained. The father indicates they used all the formula within the first few days and threw the containers out with the trash. The weekly garbage pick-up had already occurred on Wednesday. The father also indicated he had gone to the WIC office of Local Health Department “B” and received additional powdered formula that Monday.

Saturday, July 3rd

9:00 a.m.: The infection control nurse and the Public Health Administrator “A” meet at County General Hospital to determine lot numbers, photograph samples and determine the number of samples left for testing at the hospital. Six different lot numbers are identified and the remaining samples are divided for testing by both Noname Laboratories and the FDA. The hospital also retains at least one sample of each lot number as a back-up. The infection control nurse tells Public Health Administrator “A” that she has reported the *E. sakazakii* case to the FDA via its online MedWatch program. Local Health Department “A” begins hosting conference calls for key stakeholders involved in the case. This first Saturday afternoon call included Local Health Department “A”, Local Health Department “B” and the State Health Department.

Monday, July 5th

8:30 a.m.: A representative from the regional FDA office picks up samples for testing from County General Hospital. Test results are to be expected in 48-72 hours, but the FDA will only call if samples test positive for *E. sakazakii*. A representative from Noname Laboratories also picks up samples for testing and their test results would be available in 48 hours.

Tuesday, July 6th

8:30 a.m.: Both Public Health Administrators “A” and “B” hold staff meetings to brief key personnel on what transpired over the weekend and to address any concerns regarding their WIC programs supply of powdered formula. It is determined that both Health Departments issue WIC food instruments to clients for the same brand of formula that was given to Baby Doe, but had not *dispensed* any of this type of formula from their supply. Health Departments “A” and “B” review the proper formula preparation method with WIC staff and encourage staff to review the procedure with clients using powdered formula. Shortly after this meeting, both Health Departments receive many calls from area WIC offices inquiring about a local hospital calling mothers of new babies and asking them to return any unused formula.

12:00 p.m.: Local Health Department “A” hosts the second conference call for key stakeholders involved in the case. Participating in this call is Local Health Department “A”, Local Health Department “B”, the State Health Department, the FDA regional office and the CDC. The group is updated on events that transpired over the weekend. Both Local Health Departments express their concern over the phone calls from other WIC offices and ask for guidance on how best to respond. The State Health Department says it will issue a statement in conjunction with the State Department of Human Services with very generic details of the current case along with how to guide clients to properly prepare powdered formula.

2:30 p.m.: The mother of Baby Doe is interviewed by the WIC case manager of Local Health Department “B”. The mother thinks she received six packets (1 box) of powdered Advance formula from the hospital. Each packet made a 2 oz bottle and she has no packets left. She also received four, ready-to-feed bottles, which she has been washing and reusing. She has none of the original formula from these bottles. Other sources of formula included 6 cans of concentrate from the WIC office of Local Health Department “B”. The mother was asked how she prepared the powdered formula and indicated she followed the instructions on the box: boiled tap water, allowed to cool and mixed powder with water to 2 oz. line using the sample packets. The mother denies re-feeding or letting formula sit out for long periods of time. When the mother started to

use concentrate, she would prepare 2 bottles and feed one immediately and would refrigerate the second bottle. The remaining concentrate was placed in the refrigerator, covered with a zip-lock bag and stored no more than a day. The mother did use the microwave a few times to reheat the formula, but then changed to heating under warm tap water. The mother indicated the refrigerator was less than 1 year old, but the case manager noted it appeared to be older; yet did feel cool to the touch and working properly. No thermometer was present for an accurate reading.

The mother's recollection of the evening and morning leading up to the death of Baby Doe were as follows: *On June 29th the baby's formula intake was poor; mother kept offering formula to baby as instructed. Infant took about 1/2 ounce at 4 p.m. and at 4 a.m. took 2 ounce bottle; at 7 am took 2 ounce bottle again; by 9 am baby was having difficulty breathing- the mother called her mother for advice. At 9:30 am baby stopped breathing and ambulance was called. Baby taken to hospital- baby pronounced dead around 10:30 am.*

Wednesday, July 7th

9:00 a.m.: The public health administrator and public information officer from Health Department "A" attend a timely "Risk Communication" training with a public relations firm from Chicago. During a break, they ask for advice from the firm regarding the current events in their County. The firm advises Health Department "A" not to do a press release unless something leaks to the press. They indicate that if this story breaks, it would be national news and could cause public panic with powdered baby formula regardless of the test results. The firm is surprised the story has not already leaked.

Conclusion/Policy Development

Thursday, July 8th

9:00 a.m.: Lab results from Noname Laboratories indicate all samples (in-house library samples and samples from hospital formula) tested negative for *E. sakazakii*. Shortly after, the State Health Department issues a broadcast fax alert in conjunction with the State Department of Human Services memo to all local Health Departments.

County General Hospital implements a new policy for tracking lot numbers of sample formula given to patients. County General Hospital's expanded health system also adopts the policy throughout the Midwest region. Health Department "A" and other Health Departments throughout the state implement a new policy to track lot numbers of formula distributed to WIC clients (see attachment A).

2:00 p.m.: Although no media calls have been received from either Health Department or County General Hospital a local TV station runs a brief story on the Noon news about a "new" health alert regarding baby formula linked to *E. sakazakii*. The story contains false information and is based on out-of-date resources. Neither the hospital nor the local Health Departments verified the story since neither had spoke with the media during the case investigation. The TV station also posts a "health alert" on their website, which proves to be an old alert from two years ago about the deaths of two neonates in hospitals located in separate states. County General Hospital contacts the local TV station regarding the incorrect story and they agree to tape a live press release with hospital officials to run on the local evening news (see attachment B).

Attachment A

Local Health Department A: Procedure for Infant Formula Storage and Distribution

Introduction

The WIC program offers a supply of contract formula to each program agency. All ordering and distribution of formula is handled by the State WIC staff and a standard supply is delivered quarterly to the Health Department. The Regional WIC Representative may be contacted with any questions about formula shipment and/or specific requests for the type(s) of formula shipped. Formula supplies are available as the State WIC budget allows and no guarantee is made to clients as to the availability of formula.

Storage, Dispensing and Tracking

Upon arrival, formula shall be stored at room temperature in the appropriately labeled WIC storage cabinets. Formula is to be arranged on the shelves by brand and expiration date. Stock is to be rotated accordingly so containers with the most current expiration dates are distributed first. Expiration dates are to be checked when taking the formula from the shelf and clients are shown where the expiration date is located on the container. A formula dispensing log is maintained to facilitate tracking of any client who receives formula and the lot number/expiration date of the supply dispensed is recorded. Any outdated formula is to be promptly disposed. In the event of a formula recall, the *Health Department Policy and Procedure for Recall Notices* shall be followed (see Health Department Administration Manual).

Dispensing Guidelines

New Infant:

| | |
|---------------|--|
| Concentrate | 1 can per day until certification appointment |
| Powder | 1 can per 3 days until certification appointment |
| Ready-to-Feed | 1 can per 2 days until certification appointment. Use in special circumstances i.e. untested well water, inability to comprehend mixing instructions, etc. |

Certified Infant:

- A. Ran out of formula:
 1. Assess 24 hour formula intake and compare to age appropriate *Feeding Your Baby* handout. Counsel as appropriate.
 2. Remind client(s) that WIC is a supplemental program and they may have to purchase some formula on their own.
 3. Distribute formula per food package.

- B. Loss of Food Instruments (FIs) due to Emergency (i.e., flood, fire, motor vehicle accident):
consult with WIC Coordinator who will contact the Regional WIC Representative.
Distribute enough formula until more FIs can be issued.

Attachment B

MEDIA STATEMENT- *For immediate release by County General Hospital*

Recent media reports have raised concern about the proper use and safety of powdered baby formulas. Our pediatric units have received a number of calls from concerned parents and so, on behalf of County General Hospital, I'd like to reassure parents.

*A recent, but singular, case of sepsis linked to a pathogen called *Enterobacter sakazakii* was reported by our ER staff. "*E. sakazakii*", as it is commonly called is not rare and can be found in the gastrointestinal systems of many people and is common throughout the environment. But premature infants and newborns with weakened immune systems are more susceptible to its harmful effects. This bacteria can infect a baby in any number of ways, including transmission from mother to baby during labor or delivery.*

*However, in 2002, there was an FDA alert issued announcing the presence of *E. sakazakii* in certain varieties of powered baby formula. None of these varieties are distributed to new moms by our hospitals, but our Administration was not willing to take the matter lightly.*

Although there was no evidence of a direct link between the case of sepsis reported in our ER and the powered formula used...we felt it was prudent to explore this possibility. Therefore, we reported the incident to the FDA, the local public health agency and the manufacturer of the formula distributed by our birth centers. And, we supplied samples of our stock of powdered formula for testing.

In an effort to ensure the safety of all our patients we also contacted recently discharged mothers who left our hospitals with a standard one-day supply of powdered baby formula. We recommended they discontinue the use of the powdered formula until we had some assurance of its safety. As a further precaution, we also contacted area physicians simply to heighten their awareness.

*Noname Laboratories has now released the results of its testing. All the samples tested were clean of all pathogens, including *E. sakazakii*. These results were consistent with the extensive and routine tests Noname performs on all lots of its baby formula prior to shipment as well as the re-testing of library samples the company maintains. Based on these results, we at County General Hospital -- along with our colleagues at Local Health Departments "A" and "B"-- have no reason to suspect the safety of powdered formula provided by our hospitals or available for sale on local store shelves.*

At County General Hospital, we regard breastfeeding as the best possible choice for most newborns. But, for caregivers who must or prefer to feed their babies infant formula, we feel there is no reason why they should not choose powdered or ready-to-feed formula. When doing so, we recommend caregivers follow carefully the manufacturer's instructions on the product or the instructions of their pediatrician. If parents have any additional questions or concerns about baby formulas or feeding, they should contact their physician.

Teacher's Guide

1. How did the hospital's actions both help and/or hinder the investigation?
2. Considering that three counties were involved in the case, was Local Health Department "A" the appropriate agency to take the lead? Why or why not?
3. Did the State Health Department respond appropriately when initially contacted by Local Health Department "A"? Why or why not?
4. Where control methods implemented appropriately and in a timely manner? If not, how could things have been done differently?
5. What leadership skills did the administrators of the Local Health Departments use when coordinating the case?
6. Was the media used effectively? Why or why not?
7. Did political pressure play a role in this investigation?
8. Are you satisfied with the policy developments that resulted from this case?
9. What lessons were learned from this case?

REFERENCES

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