Was the Hyperglycemia Due to a Bottle of Bad Insulin?

Susie T. Harris, East Carolina University  
Ray Hylock, East Carolina University

Disclaimer: This case was prepared by the author and is intended to be used as a basis for class exercise and discussion. The views presented here are those of the author based on his professional judgment and do not necessarily reflect the views of the Society for Case Research. The names of individuals and organizations are disguised to preserve anonymity. Copyright © 2017 by the Society for Case Research and the authors. No part of this work may be reproduced or used in any form or by any means without the written permission of the Society for Case Research.

Introduction

My head was splitting, recalled Shannon Smith! She peered over at the clock and saw it was midnight on January 26, 2016. Being a Type 1 diabetic since the age of 9, the 48-year-old immediately checked her blood sugar level – 510 mg/dL! She woke her husband Randy as she knew immediate action was required or her health would quickly deteriorate; potentially ending in a life-or-death encounter at the emergency room. Quickly, she pumped insulin and waited…but nothing happened.

Background

For the first fifteen years of her diagnosis, Shannon relied on a combination of NPH and Regular insulin shots 3-4 times per day. These shots mandated strict adherence to an eating regimen as the dosage included yet to be consumed meals. The shots began at 6am, requiring her to eat breakfast by 8am or her blood sugar level would drop, resulting in diabetic hypoglycemia. After her second and third (and fourth if necessary) shots of the day, she had one hour to eat to avoid the negative effects too much insulin can cause. Furthermore, everywhere she went, she kept a cooler with insulin, needles, and alcohol swabs. While frustrating for young Shannon, it was a reality shared with millions of other diabetics every day.

Around the age of 24, Shannon’s treatments took a positive turn when an insulin pump replaced her shots. The device is about the size and shape of a flip cell phone and is kept tucked into her clothing. It connects to her body via a tube inserted into the abdomen, which she periodically replaces. A major benefit of the pump is the ability to preprogram a basal rate. A basal rate is the rate at which short-acting insulin is continuously infused into the body. The rate of injection is unique to each diabetic (e.g., Shannon’s is currently set to around seventy percent of her daily requirement). Shannon was now free to eat when convenient, as the basal rate was not compensating for food/carbohydrates. Thus, as Shannon ate throughout the day, she would simply add (bolus) insulin to offset her intake. Goodbye cooler and restrictive eating schedule!

For Shannon, her pump is set to a target blood sugar level of 100, will inject 1 unit of insulin (T-insulin) for every 10 grams of carbohydrates consumed, and has a basal rate of 0.85 units per hour from 10pm to 7am and 1.0 unit per hour from 7am to 10pm.

A Problem Arises
For nearly a quarter of a century, the pump and insulin performed flawlessly in maintaining her blood sugar levels until January 26th. Something went terribly wrong. Three days and several office visits later, Shannon’s unwavering confidence in her life-sustaining medication was shattered.

After the initial reading of 510 mg/dL, Shannon pumped 8 units of insulin. Three hours later, her blood sugar levels had dropped only 100 to 410 mg/dL. If acting correctly, 8 units of T-insulin should have reduced her levels by 400 mg/dL (roughly 50 mg/dL per 1 unit of insulin). Dumbfounded, exhausted, and experiencing the effects of diabetic hyperglycemia, she pondered her three options.

Her first option was to go to the emergency room. From her years of experience managing her diabetes without any major incidents, Shannon felt she was more than capable of handling her present situation. Therefore, she decided against going to the hospital. The second option was to do nothing and allow the remaining insulin to work, if it was going to at all. Having never experienced this before, her thoughts wondered to confounding factors mitigating or delaying the effects of the insulin. However, her blood sugar levels were still dangerously high, which could lead to diabetic ketoacidosis, coma, or even death. She and her husband agreed, waiting was not a possibility. She was therefore left with her third and final option – bolus more insulin at the risk of an uncontrollable decent in blood sugar that could, amongst other things, result in death.

She added 4.5 more units at 3am, set her alarm for 6am, and anxiously tried to rest. When the alarm sounded, she hurriedly reached for her meter – 405! Fatigue, thirst, headache, and pain in her extremities from circulatory distress where quickly overtaking her senses. She bolused 5.8 more units and waited. An hour passed, her meter read 400. Something was very wrong.

Per her calculations, she had added enough T-insulin to kill herself many times over, yet her blood sugar levels were not decreasing appreciably. At this point she began to suspect a bad batch of T-insulin, but questioned her assessment as she had never heard or experienced anything of the sort. Her T-insulin did not exhibit any of the characteristic signs of spoilage such as being cloudy or having a slight hue. Regardless, something had to be done. She added 3 more units of insulin and left for work. She would pump a total of 30.4 units before 1pm – the equivalent of a 24-hour period.

The symptoms increased while at work and were joined by blurring vision. She tried to burn off the sugar through exercise by walking up and down the fire escape stairs, but it had little effect. Having eliminated all other factors that might be contributing to her hyperglycemia (e.g., excitement, stress, and carbohydrate intake), Shannon concluded her insulin must be bad. At 10am, she emailed the manufacturer to report the bad insulin (expiration date 09/2017, control# XZXZZ12). Her health deteriorating, she had no choice. Leaving work, Shannon went to a local pharmacy (which was closer than her home) and purchased syringes and a bottle of insulin (the pharmacist, Brandy, provided alcohol pads). The question now, how much insulin to inject?

Insulin is active in one’s system for up to six hours. Her blood sugar levels were dropping (or at least not rising), which indicated some of the T-insulin was functionally active. The potency of the remaining 12.1 units of insulin currently in her body, however, was purely speculation. She ascribed roughly 100 mg/dL of functionality to the existing T-insulin and decided upon 4 units of insulin to combat the remaining 200 mg/dL (current reading of 400 minus 100 existing with a
target of 100 yields an overage of 200). Drawing from the vile, she injected the 4 units of insulin while at the pharmacy, waited a few moments, then drove home and got into bed.

She was only in bed a short while when her breathing became labored, her head started to ache, and her heart began pounding in her chest. The episode was putting immense strain on her body as the signs exhibited were indicative of severe hyperglycemia, bordering on diabetic ketoacidosis which she knew was a potentially life-threatening situation.

Checking her blood pressure, she found it to be high, 153/90. She tried to calm herself in hope that it was simply emotional trauma causing the sudden rise. After two more abnormal readings over a half hour, 152/100 and 153/104, it was clear that her elevated blood sugar level was resulting in greater physiological distress. Coupled with the amount of insulin injected and bolused, and severe hyperglycemia, she feared having a stroke.

Scared, confused, and in great pain, Shannon called her husband Randy who quickly phoned Shannon’s 82-year-old mother who lived next door and asked her to take Shannon to the endocrinologist’s office. Shannon called the endocrinologist’s office while she waited for her mother to inform them of the situation and to let them know she was coming to the office– the time was 1pm.

**The First Encounter**

Upon arriving at the endocrinologist’s office, the insulin pump representative took her directly to an examination room and informed Shannon that Dr. White would not be in the office that day. Along with the nurse, they instructed Shannon to drink water as she was exhibiting signs of dehydration (E86.0) such as extreme thirst, dry skin, little urination, sunken eyes, and rapid breathing. She became nauseated and started gagging; symptoms of diabetic ketoacidosis. Sitting in front of a trash can, the near delirious Shannon sipped her water; the trauma from the event all but bringing her to tears (which dehydration prevented). Fearing diabetic ketoacidosis (E10.10) and coma (E10.11), the nurse observed Shannon, and reported back to the doctor by phone over the next few hours. Five bottles of water, 6.9 units of injected insulin, and two hours later, Shannon’s blood sugar was down to 271 with abating symptoms. By 5:30 p.m., her blood sugar level had dropped an additional 43 mg/dL to 228 mg/dL, resulting in her discharge around 6pm.

During her time at the endocrinologist’s office, Shannon replaced her insulin pump cartridge and tubing, discarding the used materials.

**Back Home**

For the remainder of the day and into the morning of the January 27th, Shannon continued pumping insulin, monitoring her blood sugar levels, and reporting back to the insulin pump representative via email. It is a difficult and delicate task to return one’s blood sugar levels to normal after such an event. Between 6am and 10am, her levels held steady at 128 mg/dL. After lunch, however, it soared to 358. She continued pumping insulin throughout the day, with very little success. The same symptoms of fatigue and headache that seemed to have dissipated returned. She was nauseated and fasted in the hope that her blood sugar level would naturally decrease. While successful in preventing a sudden spike, it made her weak and restless. By the end of the day, she was still over 200 mg/dL (twice her normal level) but it was a far cry from
the over 500 she had seen the previous day. Dull pains withstanding, Shannon began to feel that the event was finally behind her...but that was short-lived.

The next morning (January 28th), her blood sugar level was down to 141, but that was after many hours of pumping insulin and fasting. After breakfast, it returned to the 300’s, climbing into the 400’s over the next several hours. For the remainder of the day, she refrained from eating out of fear that her blood sugar levels would go beyond her ability to manage. Despite her best efforts, her levels were not staying under control. She called the endocrinologist’s office.

**The Second Encounter**

Within an hour of making the call, she was back at the endocrinologist’s office who was again, like on the first encounter, not in the office. The on-call endocrinologist for the medical practice, Dr. Jones, had Shannon accessed then ordered a pen injection of 15 units of insulin – it was 3 pm and the nurse injected the 15 units of insulin in Shannon’s leg. By 4:00 p.m., the level had actually increased to 548 mg/dL! It was at this time that Dr. Jones had instructed Jane to give a second pen injection of 25 units. The thought of 40 units of insulin coursing through her body was unnerving. It was, in effect, a massive overdose that should have resulted in her death. The event was beginning to border on the surreal.

The on-call doctor informed Shannon that in extreme situations such as this, it generally requires three times normal dosing to return one’s body to stasis (known as glucose toxicity, insulin receptors become more resistant to insulin due to prolonged, high blood sugar levels). Shocked by the statement, she came to the sobering realization that her decades of diabetes management had instilled in her a false sense of confidence in her ability to regulate her blood sugar levels in any situation. Without proper intervention, she might very well be dead or suffering permanent bodily damage such as blindness or kidney failure.

An hour later, Shannon started feeling some relief from the aches and pains plaguing her the past few days. By 5:30 p.m. and with a blood sugar reading of 371 mg/dL, she left the office under express directions to go to the local hospital’s emergency department if her levels were to rise again; however, that was not necessary because Shannon’s blood sugar level had fallen to 226 mg/dL by 6:00 p.m.

**Life Returns to Normal**

Shannon’s blood sugar levels continued to decrease the night of the January 28th, with a low of 74 around 10pm. By morning, her levels were stable and within her target range around the 100 mark. Confident yet caution, Shannon resumed her normal daily activities; realizing just how close she came to a drastically different outcome.

All totaled, Shannon had taken 119.9 units of insulin (69 via bolus, 10.9 via injection, and 40 via pen injection) over the three-day event in addition to her basal rate of 22.65 units per day. At full affect, this amount is equivalent to nearly two weeks of normal, extra-basal use.

Since this hyperglycemic episode, Shannon has been more proactive in checking her blood sugar levels and vigorously maintains them within the very narrow target range. Furthermore, she has decided that future large shifts in levels will result in immediate consultation and/or treatment from health professionals to avoid repeat occurrences and the health problems that follow.
Regarding T-insulin’s manufacturer, in a letter dated February 3rd responding to Shannon’s report on January 26th, the T-insulin manufacturer’s customer service department thanked her for her report and said that they would look into the situation. No further communications have taken place.

**Visualizing the Episode**

Shannon’s blood sugar levels and administered units of insulin for the January 26 to 29 event are displayed in Figure 1. The data was collected from Shannon’s doctor, insulin pump, and recorded blood sugar levels. The grey band from 90 to 110 denotes Shannon’s target blood sugar level in mg/dL. Clearly, her levels were erratic and extremely high. The bars refer to administered units of insulin (method delineated by color). These values represent boluses – i.e., those in addition to the basal rate. That is, Shannon’s insulin pump still maintained a continuous infusion of insulin over this range, which is not captured the chart.

![Blood Sugar Levels and Additional Units of Insulin](image)

Figure 1. Record of blood sugar levels (line) and units of insulin (bars) from January 26-29, 2016. The insulin is in addition to her standard basal rate, which is not included. The target blood sugar range is 100±10 mg/dL shown in gray.

**Definitions**

Table 1 presents a definition of the terms and abbreviations in this case.

Table 1. Definition of terms and abbreviations
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basal rate</td>
<td>The rate at which short-acting insulin is continuously infused into the body.</td>
</tr>
<tr>
<td>Bolus</td>
<td>Insulin administered in addition to the basal rate.</td>
</tr>
<tr>
<td>E86.0</td>
<td>ICD-10-CM diagnosis code: Dehydration.</td>
</tr>
<tr>
<td>E10.10</td>
<td>ICD-10-CM diagnosis code: Type 1 diabetes mellitus with ketoacidosis without coma.</td>
</tr>
<tr>
<td>E10.11</td>
<td>ICD-10-CM diagnosis code: Type 1 diabetes mellitus with ketoacidosis with coma.</td>
</tr>
<tr>
<td>Milligrams per deciliter (mg/dL)</td>
<td>In this context, mg/dL refers to the unit of measure in a blood glucose reading. Shannon’s target is 100 mg/dL.</td>
</tr>
<tr>
<td>NPH insulin</td>
<td>NPH (Neutral Protamine Hagedorn) insulin is a slow-acting insulin given to diabetics to help control blood sugar levels.</td>
</tr>
<tr>
<td>Regular insulin</td>
<td>A short-acting insulin, which includes human insulin. Used to treat high blood sugar levels in diabetics.</td>
</tr>
<tr>
<td>T-insulin</td>
<td>A fictitious name (for the case) representing a brand name of insulin.</td>
</tr>
</tbody>
</table>

APPENDIX A

Policies and Procedures

Policies

The approved policies reflect the practices carried out by the organization in its normal course of business with the legal implications associated with this concept. Noncompliance with the organization’s own policies and procedures jeopardizes legal actions and is an issue for risk management. Therefore, policy statements must be sufficiently detailed to commit the organization to specific courses of action that are clearly stated, consciously adopted, and periodically reaffirmed.

The ultimate responsibility for the development and update of policies rests with the governing body. The chief executive officer, acting on behalf of the governing body, usually delegates this responsibility to his or her functional leaders. Thus, the director of the Health Information Services Department becomes responsible for the administrative policies related to clinical data. Health information practitioners research, develop, and write policies related to clinical data practices. They also coordinate the approval and the adoption of the policies by the appropriate groups, such as the medical staff, nursing, and ancillary departments.

- Definition

Policies are general guides to thinking. They represent general, underlying principles. They are broad, permissive statements. Policies are officially expressed or
implied guidelines for behavior, decision making, and thinking within organizations. They set boundaries for permissible activity, behavior, and decision making within which managers and employees may act. They help an organization attain its objectives and thus must be consistent with them and the organization’s mission.

Policies are classified as general and operational. General policies apply to the entire organization. Operational policies apply to a specific unit or department and may be formulated by departmental managers so long as the operational policies are consistent with general policy.

The most familiar general policies are those that govern human resource management. These policies cover compensation, terms of employment, and on-the-job behavior.

Examples:
(a) We are an equal opportunity employer.
(b) Whenever possible promotion will be from within.
(c) Our organization’s compensation packages are competitive with those in the community.
(d) All patients will receive care regardless of ability to pay.
(e) Capital expenditures over $20,000 must have prior senior management approval.
(f) Life support for the terminally ill will be maintained unless the patient has an advance directive.

Operational policies that govern particular departments are subordinate to general policies and must be consistent with the general policies.

Example: As vacancies occur through attrition, nursing service will replace licensed practical nurses with registered nurses.

Good policies are not easy to develop and implement. To be effective, a policy must be clear and appropriate and must serve to guide the ways in which organizational activities are carried out.

Good policies are well-thought out. They support organizational objectives. Good policies are flexible; they apply to normal and abnormal situations. Thus, they allow managers to take atypical actions and to deviate from policy. Good policies are communicated, understood, and accepted by those they govern. Policies must be considered by organizational members to be reasonable, legitimate, and fair. Policies that display unwarranted favoritism toward certain employee groups or those that appear arbitrary and with no sound purpose will be resented and possibly even ignored. Good policies should be consistent with each other. Inconsistency among policies and in their application and enforcement is confusing and can cause disharmony, employee dissatisfaction, and frustration and will detract from accomplishing objectives.

Inconsistencies generally occur among operational policies of various departments. Finally, to serve their intended purpose, policies must be continuously re-evaluated and changed if necessary.

• Language -- specific and stylized
  a. *Shall* is used to direct activities
  b. No long paragraphs
  c. No procedural details
d. Gender neutral language (plural nouns)

- Content
  a. Definition of terms
  b. Purpose or underlying intention. *Example: The purpose of this policy is to set forth guidelines on retention of health records in accordance with the requirements of the North Carolina statute of limitations and the recommendations of the American Hospital Association and the American Health Information Management Association.*
  c. Attachments, guidelines, appendices, lists for specific, variable information
  d. Summary grid (multiple variables, such as in release of information)
  e. Cross-references to related policies or definitions of terms
  f. Consideration of constant change in professional scopes of practice, continuum of care, and technology
  g. Internal consistency
  h. Fair across groups
  i. Flexible
  j. Reasonable

- Support to planning and decision making functions of management

- Initial date (approval date), review date, revision date

- Policy author, title, reviewer, committee

- Responsibility
  a. Governing body
  b. Chief executive officer
  c. Functional leaders (department heads)
  d. Director of the Health Information Services Department
    * Administrative policies related to clinical data (research, develop, write)
    * Coordinate approval and adoption

- Advantage
  a. Documentation of operations
  b. Promote justice
  c. Conserve managerial and supervisory time

- Policy Manual
  A policy manual is one measure of compliance with state and federal regulatory requirements and with accrediting body standards. For many functions, an organization sets its own standard of practice through medical staff bylaws, rules, and regulations, patient care manuals, and administrative (policy) manuals. Licensure agencies and accrediting bodies, then, measure organization’s compliance with its own standards.

Procedures
• Definition

**Procedures are guides to specific actions.** Procedures are step-by-step instructions in chronological order for a specific task. They are the prescribed method to complete a task. Consider a procedure as a recipe. Procedures are developed for repetitive work in order to ensure uniformity of practice, to facilitate personnel training, and to permit the development of controls and checks in the work flow. Procedures are specific; they allow no room for interpretation. They address specific situations. Employee performance is evaluated against procedures; thus, procedures represent the planning, organizing, and controlling functions of management.

• Purpose

* Standing plan of work
* Means of coordinating effort
* Tool of communication
* Basis for control of performance
* Uniformity of practice
* Tool for training

• Advantage

* Force procedural decisions
* Conserve time
* Preserve experience
* Promote moral
* Provide for delegation of authority
* Provide for management by exception

• Development

* Determine the minimum number of procedural steps that are required.
* Determine best sequence of steps, grouping together similar or closely related steps.
* Review related procedures to maintain internal consistency.
* Obtain input from affected employee.
* Test the procedure prior to implementing (especially look for flaws, outliers, unusual events, test the limits).
* Proof draft copy.
* Implement.
* Evaluate procedure several weeks after implementation. Employees are good sources of information and suggestions for improvement.

• Content

a. Task to be accomplished
b. Time
c. Conditions
d. Who (job title)
Types (see examples)
  a. Narrative: series of statements with special notes or explanations in
     substatements or footnotes.
  b. Abbreviated narrative: Narrative statements organized by keys steps and key
     points
  c. Playscript: identifies worker (actor), step, and action description; used when a
     procedure involves multiple workers

Language
  a. Statements begin with action verbs, such as sends, shows, issues, obtains, records,
     provides, uses, checks, places, receives, forwards, requests, stamps, enters
  b. Brief
  c. Clear
  d. Detailed
  e. Limited scope (focused on specific task)
  f. Logical sequence

Procedure Manual
  a. Reflects current practice
  b. Easy to use
  c. Organized by functional area (Assign each functional area a code and each
     procedure a number --- Example: Release of information 003; patient review of
     record; 1 -- Procedure becomes 003-1; Response to subpoena; 2 becomes 003-2)
     (Layman, 2012).
References


