



CASE STUDY: ABACUS® ORDER ENTRY AND CALCULATION

Limits project adds margin of safety for pharmacy operations



OVERVIEW

Baxa Corporation is a customer-focused medical device company that provides innovative, solution-based technology for fluid handling and delivery products that promote patient safety. The company's systems and devices promote the safe and efficient preparation, handling, packaging and administration of fluid medications. Its ExactaMix™ and MicroMacro™ compounders automate the production of parenteral nutrition solutions for home and hospital use. Baxa compounders are the only automated systems that accurately deliver both macro and micro ingredients in a single unit with barcode ingredient verification to eliminate medication errors. These systems represent the state-of-the-art for nutritional support.

THE CHALLENGE

Total parenteral nutrition (TPN) is a specialized field that requires a high level of uncommon clinical expertise. Currently, most pharmacy and technician training programs do not provide adequate training in clinical nutrition. Most of this "knowledge" is learned on-the-job and passed down from seasoned people to new employees. As the leading provider of automated systems for nutritional support, Baxa Corporation determined the need to implement additional safety measures, without usurping healthcare provider professional and clinical judgment, to minimize the risks associated with inadvertent mistakes that can result in medication errors or patient harm.

THE DISCOVERY

Through customer audits and site visits, it came to Baxa Corporation's attention that many customers were not utilizing the built-in warning limit feature of the Abacus Software. Rather than relying on customer initiative, a team was put together to come up with a method to institute pre-determined warning limits in every customer's Abacus Database.

THE INITIAL SET OF VALUES

Clinical resources within Baxa were tasked with determining appropriate warning limits for clinical nutrition order approval in Abacus. The purpose for determining these limits was to utilize existing functionality within the Abacus Software to prevent gross dosing errors for clinically relevant nutritional ingredients. These values establish limits that are intended to assist the pharmacist in preventing order of magnitude errors in formulas that could cause patient harm. The team's initial task was to develop a set of values that would serve all patient types within all possible medical scenarios, in all practice settings, taking into account all provider practice patterns.

PROJECT CHALLENGES

The project kicked off with a review of published literature, along with an examination of established warning limits created by selected, current customers. A preliminary collection of values was gathered for evaluation. The list was peer-reviewed by several clinical practitioners both internal and external to Baxa Corporation. Comments and recommendations were evaluated and the prospective values were adjusted as necessary. Reviewers represented a diverse set of care settings, including a large primary children's hospital; an acute care hospital with a NICU and a large university hospital. This initial set of values also incorporated limits that had various units of measure (e.g., per Kg, per hour, minimum values, etc).

Early in the process, the reviews revealed a major issue with the proposed approach. A single, unchangeable value to cover multiple patient types proved to be too narrow, too complex and too conservative to implement across all practice settings while still being able to meet all customers' needs. Therefore, the Baxa team determined that two sets of warning limits should be established. One set would be baseline limits that are not intended to be altered and the second set of more clinically-based values would be provided with the intent that customers would configure them to meet their practice needs. The team also decided that these warning limits should be absolute numbers (i.e., absolute amounts per day) and not incorporate demographics such as patient weight and rate of infusion; since some institutions do not track these parameters. Warning limit types that are incomplete will not function properly if these parameters are not completed, not updated or not correct.

THE SOLUTION

There are many possible ways to classify patients. However, most of the Baxa customers classify patients by age, utilizing three patient types: neonate, pediatric and adult. Therefore, for the purposes of the project, general age groups were determined for these three types of patients. "Neonate" was classified generally as one year old or younger; "Pediatric" was classified generally as older than one year but younger than 18 years; "Adult" was classified as 18 years old or older.

During testing of the proposed limits under these criteria, another problem was identified. With the decision to provide absolute per-day values, the Baxa team had to determine an upper weight limit for each of the three patient types for those ingredients dosed on a per Kg basis. The team selected a general upper weight limit for "Neonate" to be less than or equal to 10 Kg; for "Pediatric" to be greater than 10 Kg but less than or equal to 90 Kg; and for "Adult" to be 130 Kg.

Evaluating these weight limits uncovered a third problem. Since the Pediatric group went from essentially one year old and 10 Kg up to 18 years old and 90 Kg; the breadth of the group's dosing range was too large to afford an appropriate level of protective value at the lower end of the range. Thus, to apportion risk such that all the members of a group would receive the best possible protection, the decision was made to divide the Pediatric group into two segments: 1) greater than or equal to 1 year old (and > 10 Kg) and less than or equal to 12 years old (with an upper weight limit of 40 Kg); and 2) greater than 12 years old (> 40 Kg) and less than 18 years old (with an upper weight limit of 90 Kg). These criteria were applied to the values established in our clinical market research to form the base-line, or BAXA ONLY limits, which are not intended to be manipulated.

THE REVISED SET OF VALUES

The next step was to establish starting values for the second set of limits, or institutional limits. These values were calculated from all of the parameters noted above and represent suggested absolute daily amounts of specific, clinically relevant ingredients for clinical nutrition. To further validate these values, the Baxa team reviewed 100 customer databases and extracted data on the highest value ordered for each ingredient by each customer. The team then statistically normalized the data. The data for each ingredient were further analyzed by calculating standard deviations (to four sigma) and evaluating whether the determined warning limit values were within the appropriate range. A four sigma value yields data accuracy of 99.8%.

THE RESULTS

The clinical team determined that *institutional* warning limits could be increased to allow for a broader or more specialized practice (i.e., research purposes or for medical conditions that only a few facilities have the medical resources to treat) or could be decreased to allow for greater patient safety.

PROJECT LIMITATIONS

The warning limits that were determined within the scope of this project were established for ingredients most commonly used in parenteral nutrition. Additionally, of these ingredients, values were determined only for clinically relevant nutritional therapies. In other words, dosing values for ingredients that can be utilized for therapies other than nutrition were not incorporated into these values (e.g. 3% sodium chloride therapy for head injuries or folic acid replacement therapy for certain oncology therapies). Since these non-nutritional therapies could be numerous and varied, the team decided to focus on clinical nutrition values only and allow Abacus users to customize their institutional values or create new patient types to meet these other needs.

In addition, the patient types the Baxa team chose were very broad and may not necessarily meet specific facility needs. The patient type “Neonate,” for example, can encompass other patient “types” – extremely low birth weight (ELBW), very low birth weight (VLBW), low birth weight (LBW), premies, neonates and / or infants. The terminology and classification of this “group” of patients can be clarified further by facility, region and/or IDN. However, these warning limits can easily be manipulated to accommodate specific facility needs, while not raising the limits so high that they become useless for other patients within that patient type. The patient types selected with this implementation and their associated warning limits represent a starting point from which facility customizations can be developed. New patient types and limits can be created for applications not covered in this effort. Users simply create a new patient type, copy over the most closely related group of warning limits and then customize these values to the medical needs of this new patient type.

SUMMARY

While the warning limits established through this process are not intended to replace clinical and professional judgment in the practice of medicine or pharmacy, by implementing appropriate warning limits with the Abacus TPN Order Entry and Calculation Software, Baxa customers are able to improve system efficiencies while greatly improving patient safety through a reduction in the opportunity for parenteral nutrition dosing errors.