Although mandatory newborn screening throughout the United States for cystic fibrosis (CF) has resulted in increased sweat chloride testing for infants, obtaining an adequate volume of sweat to perform this test has remained a challenge. Currently, the standard as established by the National Clinical and Laboratory Standards Institute (NCCLS) for patients older than 3 months is to achieve a less than 5% quantity not sufficient (QNS) rate; the suggested goal for patients aged 3 months or younger is a less than 10% QNS rate. St. Alexius Medical Center (SAMC) began performing sweat chloride testing in 2008. After an initial period of testing, a quality improvement (QI) program for sweat testing was instituted to improve QNS rates.

Methods: Quantity not sufficient rates were evaluated before and after implementation for patients aged 3 months or younger and those older than 3 months. The QNS rates for each technician performing the tests were also evaluated.

Results: Improvement was observed in QNS rates after implementation of the QI initiative regardless of patient age. After QI was implemented, QNS rates improved for most technicians.

Conclusion: This study demonstrates how a QI improvement initiative can significantly improve QNS rates in sweat testing of infants, especially under 3 months of age.

Keywords: cystic fibrosis, sweat testing, sweat chloride, quality not sufficient rate, quality improvement

Abbreviations

CF, cystic fibrosis; QNS, quantity not sufficient; CFCC, Cystic Fibrosis Center of Chicago; SAMC, St. Alexius Medical Center; QI, quality improvement; CAP, College of American Pathologists; CLSI, Clinical and Laboratory Standards Institute

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through December 2010 were included in this analysis. In 2009, a working group was formed to address CF-related QI initiatives at SAMC. The group, including the CFCC director, laboratory director, and sweat testing coordinator met monthly and produced a comprehensive program addressing important aspects of sweat testing (Figure 1). Each component was reviewed and reevaluated monthly. Although the QI program is still being developed, the main elements were in place by December 2009. Thus, data are compared before this point (ie, March 2008–December 2009) and after implementation (January 2010–December 2010).

The QNS rates were evaluated before and after implementation for patients aged 3 months or younger and for those older than 3 months. Also, the QNS rates for each technician who performed the tests were evaluated before and after QI implementation. Fisher exact tests, \( \chi^2 \) testing, and logistic regression were performed for the QNS data. \( P < .05 \) indicated significance.

**Results**

Between March 5, 2008 and December 31, 2010, a total of 291 specimens were categorized as QNS. A total of 264 patients provided those specimens; 243 patients had a specimen analyzed once, 15 patients had specimens analyzed at 2 different time points, and 6 patients had specimens analyzed at 3 different time points.

The age of patients varied from 10 days to 17 years, with one outlier aged 48 years. The mean (SD) age of patients at the time of specimen collection was 3.3 (5.0) years; the median age was 1.4 years. Approximately 30% (n = 86) of the specimens were collected when the patient was 3 months old or younger.

The proportion of specimens designated QNS before implementation of the QI program was 15.6% for the sample (n = 179). After QI was implemented, the proportion of QNS specimens was 2.7% (n = 112). Results of \( \chi^2 \) analysis indicate that the frequencies of QNS collections before and after the QI implementation differ significantly: \( X^2 (1; n = 291) = 12.16; P < .001 \). Due to the presence of a cell with less than 10 specimens the Fisher exact test was performed; substantially similar results were obtained \( (P = .0003) \) (Table 1). Implementation of QI was associated with an 85.5% reduction in the rate of QNS specimens \( (z = -3.10, P = .002, \text{OR} = .145) \). Logistic regression analysis indicated that QI implementation was associated with a reduction in the QNS status of specimens regardless of age; however, patients aged 3 months or younger had 5.1-fold greater odds of yielding a QNS specimen \( (z = 3.98, P < .001) \). No significant association was observed between the age of the patient and the odds of yielding a QNS result. Specifically, the proportion of QNS specimens among patients aged 3 months or younger was 31.0% before QI and 7.1% after, compared with 8.3% before and 1.2% after QI for patients older than 3 months (Table 1).

Wide variability was observed in the QNS rates when evaluated by a technician, with ranges from 0% to 75% (Table 2). After the initiation of the QI program, QNS rates for all ages improved for 2 technicians, remained at 0% for 1, and were unchanged for 1, who was subsequently reassigned within the laboratory (Table 2).

**Discussion**

This study demonstrates the use of a QI program designed to reduce QNS rates in sweat testing in all age groups. Because newborn screening will result in an increased need for sweat testing in infants, the challenge of obtaining an adequate specimen from this population must be met.
The study was limited because multiple variables, which may affect results (including hydration status, family instructions, time of day, and ambient temperature), were not included in the analysis. Also, details about the patient such as race, weight, and disease status were not always available.

Although standards for performing sweat tests have been published by the CLSI, a wide variability in success rates is clear, as seen in the literature. Multiple factors can account for this variability, including time of testing, age at testing, prematurity, and birth weight; these factors may interfere with achieving desired QNS rates. Competency testing of technicians has been suggested; however, no agreement has been found on ways to accomplish this goal. Studies examining neonatal QNS rates at CF Foundation (CFF) accredited and nonaccredited centers show significant variability and the need for a formal comprehensive QI program. Combined, the results of these studies and the current study suggest widely variable results despite the ready availability of CLSI documents that provide guidance for sweat-testing procedures. The success of an individual program such as that undertaken at SAMC appears to depend on experience with sweat testing and commitment to the implementation of a QI program.

**Conclusion**

Achieving acceptable QNS rates for sweat testing of patients aged 3 months or younger and patients older than 3 months requires vigilance and ongoing attention to factors that may affect those rates. This study has demonstrated the success of a QI program and should encourage other programs that are having difficulty obtaining targeted QNS rates to develop such a program.

**Acknowledgments:** Luna O’Kada, MS, CGC, assisted in the development of the newborn screening program at St. Alexius Medical Center; Lucille Kulik, MT(ASCP), oversaw laboratory processes and the implementation of new standards; and all the sweat-testing technicians and laboratory support staff displayed dedication and provided support.