Journal of Cystic Fibrosis 9 (2010) 284–287

Journal of Cystic Fibrosis

www.elsevier.com/locate/jcf

Short Communication

Opportunities for quality improvement in cystic fibrosis newborn screening ☆

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Received 21 January 2010; received in revised form 9 April 2010; accepted 19 April 2010
Available online 14 May 2010

Abstract

Background: With the rapid implementation of cystic fibrosis (CF) newborn screening (NBS), quality improvement (QI) has become essential to identify and prevent errors. Using Process Failure Modes and Effects Analysis (PFMEA), we adapted this method to determine if it could be applied to discover and rank high priority QI opportunities.
Methods: Site visits to three programmes were conducted, and PFMEA exercises were accomplished in Colorado, Massachusetts and Wisconsin with 23 experienced professionals. During each of these comprehensive sessions, participants identified and ranked potential failures based on severity, occurrence and detection to calculate risk priority number (RPN) values.
Results: A total of 96 failure modes were generated and ranked in a list of the 20 riskiest problems that show no significant discordances by site, although there were differences by profession of the rater, particularly nurses.
Conclusions: Our results illustrate that the PFMEA method applies well to CF NBS and that steps requiring communication and information transfer are perceived to be the highest risks. The number of identified failures makes and their potential impact demonstrate considerable overall risk and a need for ongoing QI.

Keywords: Cystic fibrosis; Quality improvement; Newborn screening; Communication; Risk; PFMEA

In 2004, the Centers for Disease Control and Prevention (CDC) published their pivotal recommendation [1] that regions "begin newborn screening (NBS) for cystic fibrosis (CF)." This was endorsed [2] by the U.S. Cystic Fibrosis Foundation (CFF) with subsequent guidance [3] for NBS programmes. Although only five states were then screening in the U.S., now all states and many European countries have CF NBS underway [4]. During this rapid implementation, however, many questions have arisen regarding best practices [3,5]. Until now, the most common method for providing advice between programmes has been by responding to questions and through anecdotes, usually oral and occasionally published [6]. We recognized that this verbal method of reactive quality improvement (QI) was certainly not the most effective way to communicate and that a more proactive, systematic strategy would be preferable. Also, we discovered that there was no description or assessment of the entire CF NBS process.

To address these gaps, we proceeded to study and integrate methods used in other industries. The Process Failure Modes and Effects Analysis (PFMEA) method was selected for its applicability and because its primary goal is identifying problems before they occur using a systematic method of critical analyses [7]. More specifically, PFMEA allows preemptive recognition of potential failures or errors. After being introduced in the late

☆ This project was presented by invitation from the European Cystic Fibrosis Society at the 2009 European Cystic Fibrosis Conference in Brest, France on 12 June 2009 and is published as an abstract in J Cystic Fibrosis 2009;8:S9.

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[1] Philip Farrell and Molly Groose were supported by the Robert Turrell Professorship in Medical Leadership of the University of Wisconsin.

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doi:10.1016/j.jcf.2010.04.001

1940s in the U.S. Armed Forces [7], PFMEA was applied in the aerospace industry during the 1960s, then in the automotive industry [6], and finally into healthcare as the U.S Joint Commission (JCAHO) added PFMEA use as a new requirement for hospitals to be accredited [8,9]. In fact, there are more than 500 applications to health care improvement described by the Institute for Healthcare Improvement (IHI). These range from computerized physician order entry to critical care. Although there have been applications to newborns such as an "NICU Tracer project with an aim to prevent breast milk administered to wrong babies," there is no example of application to newborn screening; see the IHI website for more data [http://www.ihi.org/ihi/workspace/tools/fmea/AllTools.aspx]. Consequently, we organized a collaborative project to apply it with members of the Colorado and Massachusetts CF NBS programmes and the CDC.

1. Methods

Our strategy was to leverage the collective knowledge of three long established and experienced CF NBS programmes (Colorado, Massachusetts and Wisconsin, which collectively have 62 years of experience with CF NBS) within the PFMEA framework. We began by reviewing the literature, obtaining advice from an automotive engineer, consulting with CDC, and then completing an online course offered by Resource Engineering, Inc. which describes the PFMEA method in detail (www.reseng.com). Then, after carefully planning site visits to each location, we conducted PFMEA exercises in 2007 and 2008, adapting the traditional ten step method (Table 1), which can be divided into two phases: 1) identification of failure modes and 2) development of an action plan; however, we chose to focus on the first phase and while doing so identified QI opportunities. A total of 23 people participated in our three PFMEA exercises, under the direction of the same team leader (RR, an industrial engineer), and included NBS laboratory directors, genetic counselors, nurses, physicians, epidemiologists, the director of the NBS Branch of CDC, and the leader of the CDC proficiency testing program.

Once the PFMEA teams at each location were established, our first priority was to introduce participants to the PFMEA process prior to the site visit. All team members were given a document briefly explaining the PFMEA process along with agendas. Each meeting began with the goal of first understanding the entire PFMEA process by reviewing the ten steps and illustrating them with a CF NBS flowchart. However, during the planning phase of the PFMEA exercises it was determined that a flowchart for CF NBS did not exist, so our team crafted one for this purpose. Specifically, prior to the first site visit the flowchart was drafted in Wisconsin; this task required as many hours of work as each PFMEA site visit. Then, it was critically reviewed/revised and finalized in Denver into a 3-component flowchart available on a website [www.research.med.wisc.edu/Farrell/]. The first section is for blood specimen collection, the second for laboratory testing *per se*, and the final component describes the steps for sweat testing and confirmation. Following the creation of the flowchart, its validity and value were confirmed independently in Boston.

At each site visit, we proceeded through to step #7, identifying potential errors and assigning severity, occurrence, and detection ratings to each failure mode in a range from 1 (lowest) to 10. The PFMEA team members were instructed carefully in how they should decide what number to assign for each category using tables and examples such as the guidelines provided in Table 2 for detection ratings. Finally, the three numbers were

Table 1
Ten steps for a PFMEA exercise[a].

Step	Action
1	Review the process and create a flowchart
2	List and critically examine potential failure modes
3	Describe potential effects of each failure mode including direct and indirect effects
4	Assign severity ratings for each failure mode individually[b]
5	Assign occurrence ratings individually[b]
6	Assign detection ratings individually[b]
7	Determine the risk priority number (RPN) for each failure mode[c]
8	Establish an action plan
9	Take action to eliminate or reduce the high-risk failure mode
10	Calculate the new RPN as failure modes are reduced

[a] Adapted from "The Basics of FMEA" by McDermott et al. [7].

[b] A severity rating is a measure of how serious a given effect would be should a failure occur, an occurrence rating is an estimate of how often failure modes occur, and detection refers the "detectability" or the probability that the failure will be detected before a problem ensues; estimates are based on the knowledge and experience of the PMFEA team members or whenever possible on data collected from the actual processes.

[c] RPN is the product of severity × occurrence × detection. Severity, occurrence, and detection ratings range from 1 to 10, with 1 representing the least troublesome and 10 representing the most problematic. To aid in the discussion of PFMEA team members regarding the meaning of each number between 1 and 10, we used guides for orientation and standardization. For example, a severity rating of 10 corresponds to "hazardous without warning: outcome likely to result in death without warning" whereas a severity rating of 1 corresponds to "none: no expected negative outcome".

Table 2
Guidelines (instructions) for assignment of detection ratings[a].

Scale for rating the probability of detecting a failure mode:
10 Almost impossible: almost never discovered (e.g., a missed baby who dies of CF, i.e., infant with a false negative NBS result followed by fatal hyponatremic/hypochloremic dehydration)
9 Very remote: unlikely to discover without extraordinary means
8 Remote: unlikely to discover without significant effort (e.g., a sick baby transferred on day 1 to a Neonatal ICU who does not have a NBS screening blood collection performed)
7 Very low: unlikely to discover without moderate effort
6 Low: difficult to discover quickly but likely to discover over longer term (e.g., false negative sweat test result, assuming that it is likely to be repeated)
5 Moderate: requires moderate detection to discover
4 Moderately high: likely to discover in a moderate time period with moderate effort (e.g., specimen is exposed to adverse conditions during transport to screening laboratory)
3 High: nearly sure to discover in a moderate time period with moderate effort
2 Very high: discovered quite easily (e.g., DNA panel is not appropriate for ethnic population being screened with IRT/DNA)
1 Almost certain to detect: discovered quickly and easily

[a] Adapted from "The Basics of FMEA" by McDermott et al. [7].

multiplied to compute the risk priority number (RPN) or risk rating which then can be used to determine the relative ranking of the failure modes [7]. A recent dramatic example from the automotive industry, the problem of "unintended-acceleration" illustrates the RPN calculation process: the risk severity (severe injury or even death) is high (9–10) but it is a relatively infrequent failure (~2000 cars out of millions sold, which might be a 1–2 rating); however, there is one easily detectable cause (a trapped floor mat which might be a 1–2 rating) and one nearly undetectable cause (mechanical failure—a rating of 9–10 on the RPN scale).

RPN values for each site were calculated by summing RPNs from each member and then dividing by the total number of members at that site. McNemar's test was used to examine the ranking concordance between each pair of the three sites by converting their original rankings into binary responses (i.e., ≤10 or >10; either ≤20 or >20**)**. The overall RPNs were calculated with each site equal weighted. A list of 20 failure modes with the highest RPNs was then generated. Effects of sites and professions on RPNs were examined by general linear models. *t* tests were used to compare RPNs between sites and between professions. Least square means, which adjust for the potential effects of sites and professions, were produced.

2. Results

After a thorough review of the CF NBS program in Wisconsin, a 3-component flowchart was drafted to include both the IRT/IRT and IRT/DNA algorithms. This was refined, finalized by consensus, and used at the first site visit in Colorado and then confirmed/used at the Massachusetts and Wisconsin site visits. During the three PFMEA exercise sessions, we identified a total of 96 potential failure modes throughout the entire CF NBS process. The three-site mean RPN values (failure mode severity × occurrence probability × detectability) for all the failure modes ranged from 15.5 to 203.0. The RPN values varied by site ($p<.0001$), possibly due to differences in screening protocols and experiences. From the same overall general linear model, there were also significant differences among professions ($p=.0013$) due to assignment of lower RPN values by the nurses who were lower than both laboratory personnel ($p=.0005$) and physicians ($p=.035$); more specifically, the nurses rated significantly lower on severity and occurrence ($p<.0001$) but not on the detection scale ($p=.89$).

On the other hand, despite the differences among sites in the magnitude of RPN ratings, the rankings were similar for the 20 items determined to be of greatest concern (Table 3). In fact, there was no statistically significant discordance between sites for the top 20 failure modes. They had RPN values over 118, which would be alarming in other industries, and occurred at many different steps in the CF NBS process. However, in what must be considered our most noteworthy finding, 14 of the 20 potential failures relate to communication and/or information transfer. Documentation of all the failure modes and the unique 3-component NBS flowchart can be downloaded at www.research.med.wisc.edu/farrell/.

Table 3
Top 20 failure modes determined by the relative ratings (RPN values) assigned by site.

Rank	Failure mode	RPN[a]
1	Parents misunderstand genetic counseling information	203.0
2	Hospital system may not screen baby if transferred immediately (i.e., to NICU, other hospital, etc)	180.1
3	Low IRT cutoff in laboratory leads to a false negative	164.9
4	Babies with similar names are confused leading to sample mix-up or reporting mix-up	159.6
5	PCP[b] who tells results to parents is not well-trained about what results truly mean	158.8
6	Clerical error (i.e., hospital or laboratory transcribes data or results incorrectly)	158.2
7	PCP[b] who tells results to parents is inconsistent in delivery of results to parents (i.e., not scripted)	157.3
8	Baby is not ever tested (i.e., baby born outside of medical system, parents refuse, etc)	153.3
9	Nurse/lab technician picks up wrong NBS card (i.e.: handling error in hospital, nursery or lab)	153.2
10	False negative outcome (i.e., baby has CF but results of IRT, DNA and/or sweat Cl indicate no CF)	148.4
11	No script for message to PCP[b] from lab about positive test result (i.e., may be misunderstood by PCP[b])	146.6
12	Multiple babies have blood drawn in assembly line process (ie: babies may be switched/confused)	139.9
13	Mother does not comprehend information provided on NBS due to language, intellect, delivery method, etc	139.5
14	Clinician assisting in delivery does not inform parents about NBS requirement	133.0
15	Specimen is exposed to adverse conditions during transport to lab	127.4
16	False negative sweat test from a baby with only one detectable mutation	125.0
17	Clinician assisting in delivery is unaware of NBS requirement	123.7
18	DNA panel is not appropriate for racial, ethnic population being screened	122.2
19	Genetic counseling is insensitive/ineffective regarding lab and sweat test results	120.7
20	All personnel involved in NBS process are not adequately trained	118.5

[a] Risk priority number (product of perceived severity × occurrence probability × detectability).
[b] Primary care provider.

3. Conclusions

These results illustrate that the PFMEA method applies well to the CF NBS process. We were able to create a system-wide CF NBS flowchart, to successfully identify 96 potential failures, as well as rank them by their relative risk, and then to determine which problems require the most immediate attention or were most worrisome. Similar results in ranking the top 20 failure modes were reached at all three locations illustrating both the successful application of the PFMEA method as well as validating the highest ranking failure modes. Upon further review of the top 20 failure modes, it becomes abundantly clear that communication and information transfer are the weak links in the CF NBS process. Well over half of the top 20 failure modes are directly related to communication between two different parties while the remaining failure modes could arguably be indirectly related to communication or information transfer. This illustrates the importance of consistency and standardization of communication when possible as well as checks to

ensure the second party received the information correctly. While communication is resounding theme, other failure modes including technical errors and sample processing errors should not be minimized.

Since our goal was to determine the applicability of PFMEA methods to NBS as well as develop a preliminary list of potential failure modes, we have not yet fully addressed PFMEA steps 8, 9, and 10 (development, implementation and follow-up of an action plan), although we discussed QI options at each site. In industries such as automobile manufacturing, the PFMEA team first identifies the failure modes with high RPN values (e.g., the "unintended- acceleration" problem recently encountered with Toyota vehicles) and then assignments are made to different QI teams to devise and study methods that will reduce or hopefully eliminate the potential failure. Accordingly, Phase II must follow in a focused fashion addressing the identified/prioritized failure modes item-by-item. However, we can briefly preview this next phase and consider corrective actions, which should involve error proofing whenever possible. For instance, the second ranked failure mode ("hospital system may not screen baby if transferred immediately") has recently been addressed by development of new policy guidelines [10] that recommend assured collection of newborn screening blood "upon admission" to the NICU and on two other occasions.

Another example involves the 16th ranked failure mode ("false negative sweat test. . ."). This is also being addressed by new procedural guidelines recently published [11] by the Clinical Laboratory Standards Institute, as well as by a concerted effort on the part of the U.S. Cystic Fibrosis Foundation. Because error proofing is not always possible, however, our study provides insight to another avenue through which the RPN values could be lowered: enhancement of detection. We believe focusing on detection is ideal because severity is unalterable and frequency can only be minimized to a limited extent. For example, to enhance detection of the first failure mode ("parents misunderstand genetic counseling information") parental understanding could be assessed routinely immediately following and several months after counseling sessions [12,13]. In addition, information transfer can be standardized [14]. In general, the aerospace, aviation, and automotive industries also place emphasis on improving detection for QI (e.g., tire pressure monitoring). In the future, CF NBS professionals should follow-up on this strategy by creating solutions and tools that address these problem areas starting with the highest ranked items and disseminating potential solutions widely.

Acknowledgements

We thank the members of the PFMEA teams who generously volunteered their efforts in this project, including Harry Hannon, Marie Earley of the CDC; Frank Accurso, Marci Sontag, Jim Beebe, Laura Taylor at the Colorado site visit; Anne Comeau, Richard Parad, Roger Eaton, Terry Spencer, Henry Dorkin, Bill Yee, Jamie Hale at the Massachusetts site visit; and Gary Hoffman, Darci Pfeil, Audrey Tluzcek, Karen Kennedy-Parker, Anita Laxova, Michael Rock, and Margaret Modaff in Wisconsin. We are also grateful to Michael So who advised us on PFMEA methods used in the automotive industry and on the interpretation of RPN values.

References

[1] Grosse SD, Boyle CA, Botkin JR, et al. Newborn screening for cystic fibrosis evaluation of benefits and risk and recommendations for state newborn screening programs. MMWR 2004;55:1–39.
[2] Campbell PW, White TB. Newborn screening for cystic fibrosis: an opportunity to improve care and outcomes. J Pediatr 2005;147:S2–5.
[3] Comeau AM, Accurso FJ, White TB, et al. Cystic Fibrosis Foundation. Guidelines for implementation of cystic fibrosis newborn screening programs: Cystic Fibrosis Foundation workshop report. Pediatr 2007;119:e495–518.
[4] National Newborn Screening and Genetics Resource Center. http://genes-r-us.uthscsa.edu/.
[5] Rock MJ, Hoffman G, Laessig RH, Kopish G, Listheim T, Farrell PM. Newborn screening for cystic fibrosis in Wisconsin: nine-year experience with routine trypsinogen/DNA testing. J Pediatr 2005;147:S73–7.
[6] Farrell PM, and the Wisconsin Cystic Fibrosis Neonatal Screening Study Group. Improving the health of patients with cystic fibrosis through newborn screening. Adv Pediatr 2000;47:79–115.
[7] McDermott RE, Mikulak RJ, Beauregard MR. The basics of FMEA. Resources Engineering, Inc; 1996.
[8] The Joint Commission. www.jointcommission.org.
[9] O'Leary DS. "Reducing medical errors: a review of innovative strategies to improve patient safety." Before the House Committee on Energy and Commerce Subcommittee on Health; May 8, 2002; 2002.
[10] Clinical Laboratory Standards Institute. Newborn screening guidelines for premature and/or sick newborns; Guideline I/LA31-P. Wayne, PA, CLSI 2009; 2009.
[11] Clinical laboratory standards institute. sweat testing: sample collection and quantitative chloride analysis; Approved Guideline-Third Edition. C34–A3 Wayne, PA, CLSI 2009.
[12] Farrell MH, Kuruvilla P. Assessment of parental understanding by pediatric residents during counseling after newborn genetic screening. Arch Pediatr Adolesc Med 2008;162:199–204.
[13] Wissow LS, Erby LH. Misunderstanding about communication. Arch Pediatr Adolesc Med 2008;162:280–1.
[14] Castellani C, Southern KW, Brownlee K, et al. European best practice guidelines for cystic fibrosis neonatal screening. J Cyst Fibros 2009;8:153–73.