DMAIC Approach for the Reduction of Healthcare-Associated Infections in the Neonatal Intensive Care Unit of the University Hospital of Naples 'Federico II'

Giuseppe Cesarelli[1(✉)], Emma Montella[2], Arianna Scala[2], Eliana Raiola[3], Maria Triassi[2,4], and Giovanni Improta[2,4]

[1] Center for Advanced Biomaterials for Healthcare (CABHC), Istituto Italiano di Tecnologia, Largo Barsanti e Matteucci 53, 80125 Naples, Italy
giuseppe.cesarelli@iit.it

[2] Department of Public Health, University Hospital of Naples 'Federico II', Via Pansini 5, 80131 Naples, Italy

[3] Cardarelli Hospital – Hospital Management, Via Cardarelli 8, 80131 Naples, Italy

[4] Interdepartmental Center for Research in Healthcare Management and Innovation in Healthcare (CIRMIS), University of Naples 'Federico II', Via Pansini 5, 80131 Naples, Italy

Abstract. Improvements in the obstetrical and neonatal management have allowed children to survive. These enhancements have showed, anyway, a general increased incidence of healthcare-associated infections, one of the most influent causes of morbidity and mortality in neonatal intensive care units. The aim of this paper is to suggest corrective measures to reduce sentinel germs colonization and identify the relationships between bacteria colonization with the number of procedures and the length of hospital stay. The Lean Six Sigma methodology was used to tackle this issue using a tailored Define, Measure, Analyze, Improve, and Control problem-solving strategy. An increased number of procedures and an extended length of hospital stay demonstrated a statistically significant influence on newborns' possibility to be infected by sentinel germs. These findings could guide the clinical staff to improve the management of neonates in neonatal intensive care units reducing the number of infected patients, their length of hospital stay and the costs for the hospital.

Keywords: DMAIC · Healthcare-associated infections · Lean · Sentinel germs · Clinical management

1 Introduction

The improvement of obstetrical and neonatal management has enabled the survival of preterm infants; however, these corrective actions have inadvertently promoted an increased incidence of healthcare-associated infections (HAIs) which are contracted in

T. Jarm et al. (Eds.): EMBEC 2020, IFMBE Proceedings 80, pp. 414–423, 2021.
https://doi.org/10.1007/978-3-030-64610-3_48

the hospital setting and appear during hospitalization or soon after. Decembrino et al. argue HAIs result in prolonged hospital stays, increased hospital costs and are one of the major causes of morbidity and mortality in neonatal intensive care units (NICUs) [1]. Another Italian research has documented an incidence of these infections between 1 and 4 per 1000 live births in developed countries (7–19% in Europe, 14% in the USA), while this incidence results 6.5–38 per 1000 live births in developing countries [2]. In Italy, according to the National Institute of Health, infections occur in 5–8% of the hospitalized patients [3]. In NICUs the frequency of nosocomial infections is 7–24.5% [4] and increases up to about 40% in newborns weighing less than 1,000 grams and gestational age below 28 weeks, compared to 0.3–3% for healthy full-term babies. A previous study indicates 50% of infection cases are represented by sepsis, while 25% and 15% by respiratory and urinary tract infections, respectively [5].

Neonates result susceptible hosts when several conditions occur e.g. prematurity of organ systems, immaturity of immune system, presence of malformations, low birth weight, application of invasive devices and administration of antibiotics [6, 7]. Ghiradi [8] and Giuffré [9] have provided evidences the erroneous use of devices and antibiotics predispose neonates to colonization by the more resistant strains, especially certain Gram-negative bacteria, coagulase-negative staphylococci and yeasts. Previous studies indicate microorganisms' transmission in NICUs is promoted moreover by direct contact (e.g. with personnel's hands), other sources of infections (for instance air, water and food) and incubator's microclimate, characterized by high humidity and hot-humid air recirculation, which could even encourage growth and multiplication of these microorganisms [10].

The literature on HAIs shows a variety of multidisciplinary approaches of infection surveillance which have as purpose the control of outbreaks, suggesting possible procedures to implement [1, 8].

The University Hospital "Federico II" of Naples implements a system (which considers and involves patients, microorganisms and environment) to monitor HAIs in NICUs. This system can provide several epidemiological data extrapolated by the monitoring of invasive procedures, the environmental microbiological sampling for the identification of sentinel pathogens, the analysis of microorganisms strains resistant to antibiotics and the molecular typing of bacteria which cause infections.

Simultaneously, the Strategic Management of the University Hospital is committed in the implementation of a purely business management tool, the Lean Six Sigma (LSS), to provide an effective framework for producing systematic innovation efforts in healthcare. Controlling healthcare cost increases, improving quality and providing better healthcare are some of the benefits of this approach [11].

In healthcare, LSS allows to improve the overall performance of a process identifying and eliminating the causes of possible deviation from its ideal standards [12].

Several publications have appeared in recent years documenting LSS implementation to introduce new clinical pathways in hip [13, 14], femur [15, 16] and knee surgeries [17], evaluating pathways utility according to some clinical variables, e.g. the reduction of the length of hospital stay (LOS). Montella and co-workers have proposed this methodology to improve HAIs control aiming at reducing the number of patients affected by infections in a surgery department [18].

To the authors' knowledge, however, a study based on the implementation of the LSS methodology for the control of HAIs in a NICU is missing.

Therefore, the present work aims to identify the causes that can foster possible deviations of the neonates' care process (namely, an HAIs risk increment) from its ideal standards as well as to determine the influence of each variation and the appropriate corrective actions to be taken. The integrated application of the LSS methodology with a tailored Define, Measure, Analyze, Improve, and Control (DMAIC) strategy can improve the performance of the care process in terms of incidence reduction of patients' colonization by sentinel germs and, consequently, the risk of HAIs.

2 Methods

A tailored DMAIC strategy was adopted to study and analyze the data collected from the printed medical records and the informative system at the University Hospital "Federico II" of Naples throughout the year 2010 for 271 patients.

The tools implemented in each of the DMAIC phases are described in the next sections.

2.1 Define Phase

During this stage, a project charter and a Suppliers-Inputs-Process-Output-Customers (SIPOC) diagram were drafted. In the former, the problem to be solved was defined, the goals to achieve were clarified, the critical-to-quality (CTQ) characteristics were identified, and project time frame was fixed. In the latter, a synthetic and precise summary of suppliers, customers and process phases was drafted.

2.2 Measure Phase

During this stage, the study data were extrapolated from the hospital informative software QUANI (BIM Italia, Italy) and from the data stream for the monitoring of sentinel germs. The QUANI data provided the measurement of variables such as the number of procedures and the Diagnostic Related Group (DRG) classification; process control charts were used to preliminary check several data trends. The information extrapolated by the data stream allowed, instead, the demographic, nosological and epidemiological classification of the CTQ parameters.

CTQ was identified and represented for newborns with at least one positive biological sample per sentinel germs (as reported by the Microbiology Operative Unit) using different types of specimens such as tracheal suctions, urine, celebrospinal fluid and blood.

2.3 Analyze Phase

The analyze stage continues the diagnosis and involves an identification of possible causal relationships between the inputs and the CTQ parameters.

Firstly, the data discussed in the previous section were analyzed using control charts, histograms and statistical tests. The last ones (namely, Chi Square tests) were

Table 1. Statistical analyses on patients' data. Specifically, with the term "DRG score" it was indicated the greatest integer less than or equal to the DRG classification.

Statistical test progressive number	Input 1	Input 2
1	DRG score	Infected/non-infected patients
2	Number of procedures	Infected/non-infected patients
3	LOS (10 days blocks)	Infected/non-infected patients

carried out with Origin (OriginLab, USA) to evaluate possible correlations between variables (level of significance equal to 0.05), as summarized in Table 1.

Secondly, several histograms were generated using Microsoft Excel for Microsoft 365 (Microsoft Corporation, USA). These correlate the percentage of colonization with the DRG score, the number of procedures and the LOS, respectively.

Moreover, a 5 Whys analysis and a questionnaire to the staff were developed by the Six Sigma team. The former was performed to understand the root causes which determine the infections caused by the sentinel germs. The latter was administrated to privilege witnesses (HAIs experts belonging to Hospital Infections Committee) to analyze both structural and organizational aspects of patients' hospitalization and the professional behavior of NICU's operators (physicians and nurses). The data extrapolated from the questionnaire were considered also in the 5 Whys analysis to find possible corrective actions to reduce or potentially eliminate HAIs risk.

3 Results

3.1 Define Phase

The project charter (Table 2) summarizes the information acquired during the meetings.

Table 2. Project charter.

Project title	
LSS for the infections management of patients hospitalized in a NICU	
Problem to be solved	
Identify the relationship between bacteria colonization and the LOS and the number of procedures	
Critical to Quality	Target
Relations with the colonization of a patient	Identify corrective measures for patients tested positive to one of the "sentinel bacteria" to reduce its colonization
Deadlines	
Define	January 2012
Measure	April 2012
Analyze	July 2012

The team presented the results of the SIPOC analysis, summarized in Table 3.

Table 3. SIPOC analysis overview.

Suppliers	• University of Naples "Federico II" – Department of Public Health • University Hospital of Naples 'Federico II' – Clinical staff
Input	• Infections • Type of bacteria • Procedures of intervention
Process	• Hospitalization • Daily activities • Discharge
Output (expected)	• Reduced number of infected newborns • Improved outcome for neonates • Better management of newborns in the department
Customers	• Patients • University Hospital of Naples 'Federico II'

3.2 Measure Phase

QUANI and microbiological surveillance data have shown 20 out of 271 patients (7.38%) were infected by several sentinel germs.

The first information focused in this study was patients' LOS. Infected patients were hospitalized on average 59.85 days, while the non-infected patients 26.31 days.

Figure 1 plots LOS for both infected and non-infected patients.

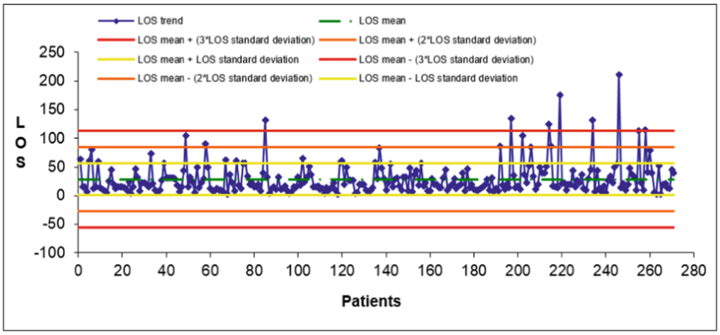

Fig. 1. Diagram illustrating the LOS for the 271 patients.

3.3 Analyze Phase

QUANI and microbiological surveillance data allowed a thorough understanding of the collected information. Firstly, the overall LOS data results (introduced in the measure phase) were summarized in the following whisker plot (Fig. 2).

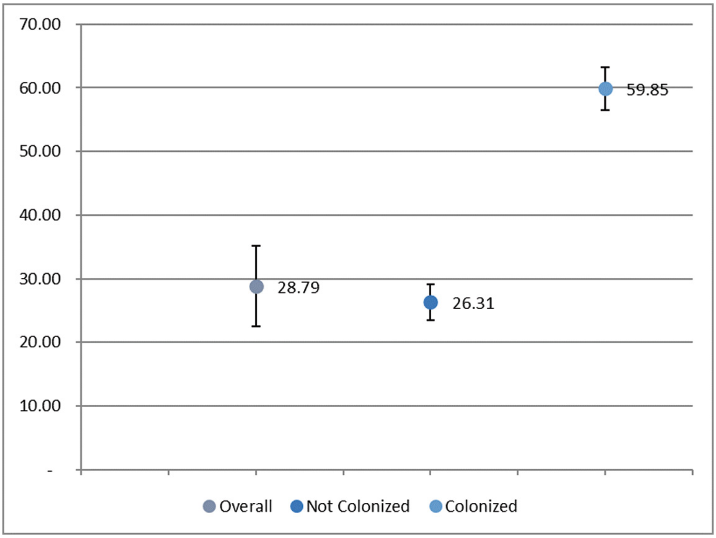

Fig. 2. Whisker plot illustrating LOS for the overall 271 patients (left), the non-infected patients (center) and the infected patient (right). Vertical bars represent the confidence interval (95%).

Secondly, samplings on infected newborns allowed the identification of the sentinel germs. Figure 3 illustrates a pie chart which summarizes the percentage amount of bacteria found in the 20 infected newborns. The main evidences of sentinel germs have been found from the tracheal aspirates of newborns (85% of the infected patients).

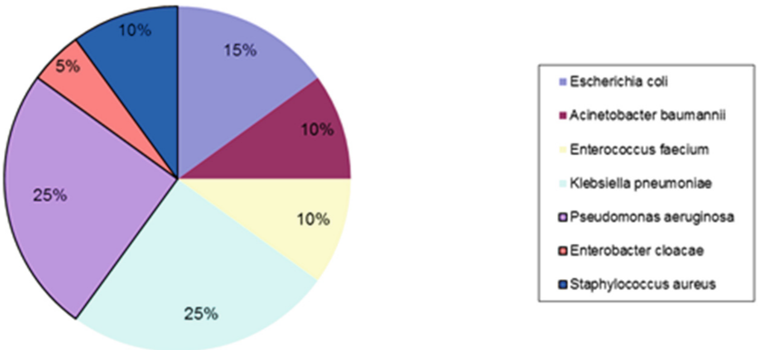

Fig. 3. Overview chart of sentinel germs found in biological samples.

The 5 Whys analysis resulted in the 5 root causes summarized in Table 4.

Table 4. 5 Whys analysis output.

1st why	The procedures lacked a standardization: there was the need of a fixed protocol to handle the processes
2nd why	Healthcare information systems need to be improved: they were old, and no updates had been performed to date
3rd why	Lack of formation and information about healthcare-related infections: not all the staff had a real knowledge of how to handle the healthcare-related infections
4th why	Lack of continuous control of the different steps of the procedures
5th why	Existent critical issues related to structural reorganization resulting from resistances of the hospital administration and management

Finally, the results of the chi square tests demonstrated the comparison between patients' DRG score and their clinical status (infected/non-infected) did not show statistically significant results (p-value = 0.223). On the other hand, tests 2 and 3 (see Table 1) demonstrated statistically significant results (p-values of 0.034 and 0.018, respectively).

Plots showing raw data of such analyses are depicted in the following Fig. 4.

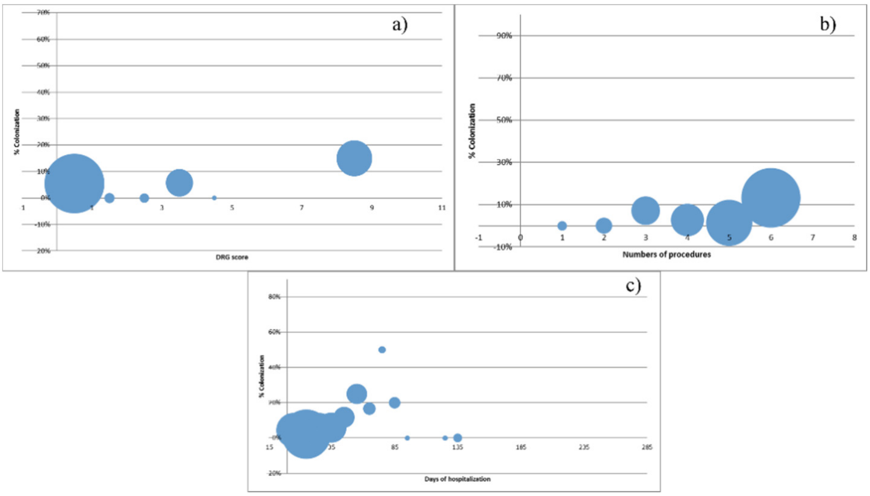

Fig. 4. Bubble plots illustrating trends of the raw data studied by the chi square statistical analyses (see Table 1). a) Test n°1. b) Test n°2; c) Test n°3.

4 Discussion and Conclusions

This paper presents a study concerning HAIs for a population of 271 neonates in a NICU considering the criterions of the LSS methodology and a tailored version of the DMAIC problem-solving strategy. This guided to firstly define the issues and the aims of the research, then to carry out an analysis of the overall process (supported by the representation of the problems data with tools of visual management). Finally, the strategy helped to perform some statistical tests to characterize the indicators to consider to potentially raise the process performance.

The presented results show as possible enhancement the reduction of the mean LOS, as shown in Fig. 2 and 4c). In fact, the latter picture reports how patients hospitalized for 2–30 days presented a low colonization percentage (around 5%), while how several patients hospitalized for longer times presented a higher predisposition of colonization (5 to 10 times the former value). Another improvement indicated by the data analysis provides evidences that the reduction of procedures number could effectively reduce the risk of HAIs. Figure 4b) shows newborns who underwent a small number of procedures had a lower risk of colonization, while the highest number of infected (16/20) was neonates who underwent a higher number of procedures, maybe because previous ones have appeared inconclusive. Another implication suggested by the results concerns LOS and procedures together; it has been observed newborns whose preoperative LOS and hospitalization/first procedure LOS was reduced had a smaller risk of colonization; nevertheless, the results of the 5 whys analysis have demonstrated potential bottlenecks to be solved to consequentially guide an improvement from this point of view.

In contrast to some reports in the literature, many sentinel germs were found analyzing tracheal suctions samplings. These results do not agree with the findings of Zingg and Kumar who report bloodstream infections as the prevalent kind of infections in children [19, 20]. The most likely explanation of these conflicting results might be motivated by a smaller newborns population respect to the other two studies (2138 and 595, respectively). Nevertheless, it is still missing an international study reporting accurate cross-national point-prevalence surveys; currently, surveys are generally developed in different countries/areas according to non-standardized procedures. This limitation is pushing scientists to organize in-depth cross-national studies which could extend the knowledge in this field with greater clarity.

This paper presents a pilot study to methodologically find the necessary enhancements to be applied in NICUs to reduce HAIs risk. To the authors' best knowledge, LSS have been used in the context of NICUs, for instance, to minimize the waste because of stocked supplies at the bedside cabinet [21] and, in combination with DMAIC, to promote the decrease of the incidence of intraventricular hemorrhage in newborns [22] and to reduce or eliminate the risk for errors in breast milk administration [23].

In conclusion, this pilot study showed the application of a tailored DMAIC approach focused on the reduction of the HAIs in a NICU. In this work, data of 271 patients were analyzed to identify possible corrective actions related to control several sentinel germs colonization. Since the HAIs are an important and sensitive theme in hospitals, further researches appear fully justified by the potential advantages for both hospitals and patients: these investigations could guide the clinical staff to improve the management of patients in NICUs reducing the number of infected newborns, their LOS and the costs for the hospital.

As an example, future developments could focus the analysis of the process considering process deviations characteristic for each single germ (and the relative improvements to bring).

Conflict of Interest. The authors declare that they have no conflict of interest.

References

1. Decembrino, L.: Surveillance of infection events in neonatal intensive care. Minerva Pediatr. **62**(3 Suppl. 1), 41–45 (2010)
2. La mortalità dei bambini ieri e oggi: l'Italia post-unitaria a confronto con i Paesi in via di sviluppo. https://www.istat.it/it/archivio/40505. Accessed 20 June 2020
3. Infezioni correlate all'assistenza. Aspetti epidemiologici. https://www.epicentro.iss.it/infezioni-correlate/epidemiologia. Accessed 20 June 2020
4. Clark, R.: Nosocomial infection in the NICU: A medical complication or unavoidable problem? J. Perinatol. **24**(6), 382–388 (2004)
5. Carey, A.J.: Hospital-acquired infections in the NICU: epidemiology for the new millennium. Clin. Perinatol. **35**(1), 223–249 (2008)
6. Couto, R.C.: Risk factors for nosocomial infection in a neonatal intensive care unit. Infect. Control Hosp. Epidemiol. **27**(6), 571–575 (2006)
7. Auriti, C.: Determinants of nosocomial infection in 6 neonatal intensive care units: an italian multicenter prospective cohort study. Infect. Control Hosp. Epidemiol. **31**(9), 926–933 (2010)
8. Ghirardi, B.: Management of outbreaks of nosocomial pathogens in neonatal intensive care unit. La Pediatria medica e chirurgica: Medical and surgical pediatrics **35**(6), 263–268 (2013)
9. Giuffre, M.: The increasing challenge of multidrug-resistant gram-negative bacilli results of a 5-year active surveillance program in a neonatal intensive care unit. Medicine **95**(10), 10 (2016)
10. Protocollo per la pulizia e disinfezione delle cullette termiche. https://www.ausl.pe.it/allegati/percorsi/professionista/RischioInfettivo/Procedure%20GOE/Protocollo%20Cullette%20termiche%20Rev_%201%20PDF(1).pdf. Accessed 20 June 2020
11. de Koning, H.: Lean six sigma in healthcare. J. Healthcare Qual. Official Publ. Natl. Assoc. Healthcare Qual. **28**(2), 4–11 (2006)
12. Van den Heuvel, J.: Lean Six Sigma in a hospital. Int. J. Six Sigma Competitive Adv. **2**(4), 377–388 (2006)
13. Improta, G.: Lean Six Sigma in healthcare: Fast track surgery for patients undergoing prosthetic hip replacement surgery. TQM J. **31**(4), 526–540 (2019)
14. Improta, G.: Lean Six Sigma: a new approach to the management of patients undergoing prosthetic hip replacement surgery. J. Eval. Clin. Pract. **21**(4), 662–672 (2015)
15. Improta, G.: The application of six sigma to reduce the pre-operative length of hospital stay at the hospital Antonio Cardarelli. Int. J. Lean Six Sigma **11**(3), 555–576 (2019)
16. Ricciardi, C.: Lean Six Sigma approach to reduce LOS through a diagnostic-therapeutic-assistance path at A.O.R.N. A. Cardarelli. TQM J. **31**(5), 657–672 (2019)
17. Improta, G.: Improving performances of the knee replacement surgery process by applying DMAIC principles. J. Eval. Clin. Pract. **23**(6), 1401–1407 (2017)

18. Montella, E.: The application of Lean Six Sigma methodology to reduce the risk of healthcare-associated infections in surgery departments. J. Eval. Clin. Pract. **23**(3), 530–539 (2017)
19. Zingg, W.: Health-care-associated infections in neonates, children, and adolescents: an analysis of paediatric data from the European Centre for Disease Prevention and Control point-prevalence survey. Lancet Infect. Dis. **17**(4), 381–389 (2017)
20. Kumar, S.: Healthcare associated infections in neonatal intensive care unit and its correlation with environmental surveillance. J. Infect. Public Health **11**(2), 275–279 (2018)
21. Verma, V.: Minimizing waste in neonatal intensive care units by effective bedside supply management: application of lean Six Sigma in neonatal intensive care unit. Neonatal Pediatr. Med. **5**(1), 5 (2019)
22. Clark, S.: Six Sigma: decreasing neonatal intraventricular hemorrhage by delayed umbilical cord clamping. Med. Dent. Res. **1**(1), 5 (2018)
23. Drenckpohl, D.: Use of the six sigma methodology to reduce incidence of breast milk administration errors in the NICU. Neonatal Netw. **26**(3), 161–166 (2007)