# Quality and Safety Problems in Chilean Hospitals

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## Priorities and root cause analysismof quality and safety problems in chilean hospitals

***Background:*** *Quality improvement is an important component of hospital operations.* ***Aim:*** *To prioritise clinical quality and safety problems in Chilean hospitals according to their severity, frequency, and detectability.* ***Material and methods:*** *The study was conducted between December 2018 and June 2019. To identify quality and safety problems, an exploratory study was conducted using an online survey aimed to those responsible for clinical quality and safety in Chilean hospitals. The survey was sent to 94 hospitals and completed by quality management personnel at 34 hospitals, yielding a total of 25 valid surveys for analysis. Based on the information gathered, a risk priority score was computed to rank the problems surveyed. Focus groups were held to find the root causes of the quality and safety problem with the highest risk priority score.* ***Results:*** *The three highest risk priorities were:* [1] *ineffective interprofessional communication,* [2] *lack of leadership for addressing frequently recurring safety issues, and* [3] *antimicrobial resistance due to inappropriate use of antibiotics. For the communication problem, the focus group found two main root causes: those due to personnel and those relating to the hospitals themselves.* ***Conclusions:*** *Hospitals can systematically use the proposed approach to categorize their main clinical quality and safety problems, analyze their causes, and then design solutions.*
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***Keywords:*** *Medical Errors; Patient Safety; Quality Improvement; Risk Management*

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## Prioridades y análisis de las causas de los problemas de calidad y seguridad en hospitales chilenos

***Antecedentes:*** *La mejora continua de la calidad es un componente importante en las actividades hospitalarias.* ***Objetivo:*** *Priorizar los problemas de calidad y seguridad en hospitales chilenos de acuerdo a su severidad, frecuencia y detectabilidad.* ***Material y métodos:*** *Se efectuó un estudio exploratorio con una encuesta en línea para detectar problemas de calidad y seguridad dirigida a quienes están a cargo de los problemas de calidad y seguridad en los hospitales. La encuesta fue enviada a 94 hospitales y respondida por los encargados de calidad y seguridad en 34 de ellos, lográndose 25 encuestas válidas para análisis. El estudio se llevó a cabo entre diciembre de 2018 y Junio de 2019. Se diseñó una escala de prioridades de riesgo para determinar la importancia relativa de los problemas detectados. Se llevaron a cabo grupos focales para*

*determinar las causas del problema más importante.* **Resultados:** *En Chile los problemas de calidad y seguridad más importantes son la falta de comunicación interprofesional, falta de liderazgo para abordar los problemas de seguridad y calidad y resistencia a antibióticos debido a su uso inapropiado. Problemas relacionados al personal y relacionados al hospital fueron las causas primarias de la falta de comunicación. Conclusiones: Los hospitales podrían utilizar este enfoque de forma sistemática para categorizar sus principales problemas de calidad y seguridad, analizar las causas y diseñar soluciones.*

**Palabras claves:** *Errores Médicos; Gestión de Riesgos; Mejoramiento de la Calidad; Seguridad del Paciente)*

## INTRODUCTION

Twenty-years after "To Err is Human", the 2001 report of the Committee on the Quality of Health Care in America, [1] medical error remains among the leading causes of death.[2,3] Preventing such events involves not only increasing resource endowments but also improving basic clinical processes.[4] The risk of a patient dying from a preventable medical accident is estimated to be 1 in 300, and in high income countries as many as 1 in 10 patients are harmed while receiving hospital care.[5] Efforts have been made to study and prevent or reduce this problem.[6,7] The rate of adverse events across 26 low-and-middle-income countries was around 8%, and 83% of them could have been prevented while 30% led to death.[5]

In Chile, an investigation found that 31 out of 500 patients at a private clinic suffered an adverse event. The most frequent were surgery or procedure complications, medication errors, and diagnostic delays.[8] A study conducted on the clinical areas of a public hospital calculated that the incidence of adverse events was 8.3% and an estimated 85% of them were potentially avoidable. [9,10] In an evaluation of medication errors, Collao et al.[11] discovered that such events resulted in the deaths of 34 to 111 people every year, with lactating babies, toddlers, adolescents, and people over 80 years being particularly at risk. Other studies have focussed on specific categories of adverse events, patients and pathologies.[12-14]

Analyses of the causes of adverse events have shown that the most frequent one is under-reporting to superiors due to fear of sanctions, lack of support from managerial staff, lack of knowledge, and work overload.[15] Adverse events impact the financial performance of health facilities, increasing their costs and expenses, and also affect hospital workload by adding days to affected patients' expected hospital stay.[16]

According to the literature, adverse events are highly avoidable and should be reduced.[17,18] Recording such events, creating a safety culture, improving the quality of professional training, and adopting preventive measures are important factors in the design of clinical quality and patient safety policies.[19,20] With this in mind, the purpose of the study reported here was to identify and gain a deeper understanding of the root causes of the main adverse event occurring in Chilean hospitals through the prioritization of a list of clinical quality and safety problems based on their severity, frequency, and detectability.

## MATERIAL AND METHODS

A descriptive study of Chilean hospitals was conducted between December 2018 and June 2019. The methodology used was an on-line cross-sectional survey of personnel responsible for clinical quality and safety at hospitals with 100 or more beds. The information collected by the survey related to the principal clinical quality and safety problems. In cases where the hospital did not have a specific service quality department, hospital management designated a person to respond to the survey. Each hospital completed a single questionnaire. In addition, focus groups were set up to gather additional information on the problem with the highest risk priority.

### Design, validation and distribution of the survey

The design of the survey instrument was adapted from a clinical quality and safety problems survey carried out in Spain to fit the Chilean reality.

[21] The list of clinical quality and safety problems included was updated on the basis of analyses of hospital quality and safety issues in recent publications by national and international organizations. A Web of Science review of clinical safety problems in hospitals was also conducted, using "clinical safety" and "hospital" as title keywords. The search covered the period 2010 to the present.

The resulting survey design consisted of three sections. The first section collected information on the characteristics of the hospital and the survey respondent; the second section solicited responses on 23 quality and safety topics to be assessed in terms of their severity, frequency, and ability to pre-detect adverse events; and the third section contained an open-ended question on how to prioritize the organization's three most important quality and safety problems. The definitive version of the survey was validated in 7 hospitals before its distribution. See appendix 1.

The survey was distributed online to the 94 hospitals nationwide that met the eligibility criterion of 100 or more beds. To obtain as many responses as possible the process included e-mail alerts and telephone reminders, achieving a response rate of 36.2% or 34 hospitals.

The survey was anonymous and a response to the questionnaire was considered to constitute consent. Frequency analyses were conducted to examine the quality and safety problems reported by the respondents. The risk priority number (RPN) was determined using the failure mode and effects analysis (FMEA) methodology,[22] an approach already used in previous studies whose steps in our implementation can be summarized as follows:[21]

- Determination of potential quality and safety problems.

- Analysis of each cause of failure according to its frequency (F), severity (S) and possibility of detection (D). Respondents were asked to assign numerical values to the three variables on a scale of 1 to 10 divided into the five following intervals: very low [1-2], low [3-4], moderate [5-6], high [7-8], and very high [9-10]. The upper limit of each interval was used to code responses.

- Calculation of the RPN as the product of the three values (F×S×D).

- Prioritization of the causes of failure according to their RPN.

Thus was obtained a prioritized list of clinical quality and safety problems at Chilean hospitals. The clinical quality and safety problem with the highest risk priority number was then analyzed in terms of its main causes in two focus groups, discussed here below. Note that the responses to Question 34 of the survey were used to screen for inattention, lack of motivation to respond seriously, or insufficient knowledge to do so. These deficiencies were assumed to be present in the case of respondents who deviated from the probable response [23] and their questionnaires were discarded, leaving a valid sample size of 26.6%, that is, 25 hospitals.[23,24] Also, a selection bias analysis was also conducted. These measures ensured a high degree of rigour in the study design.

**Focus Group**

The purpose of the focus group activities was to gain a deeper knowledge of the clinical quality and safety problem with the highest RPN. The groups were led by a moderator who explained the activities to the participants. Those invited to participate were personnel from the most representative regional hospitals. The first group brought together 7 representatives from hospitals outside of the Santiago metropolitan (i.e., national capital) region while the second group was made up of 8 representatives from Santiago. The two groups' activities took place in secure, private classrooms at the University of Bio Bio and the University of Chile, respectively.

In pursuit of their objectives, focus group participants aimed to reach a consensus concerning the main causes of the highest RPN problem. The groups followed a specific protocol consisting of the following activities, for which a total estimated time of 180 minutes was allowed:

• General brainstorming to identify the root cause of the problem. All ideas put forward were grouped and ranked.

• Description by the moderator of an adverse event representative of the problem. Each participant then selected what they considered to be the most important causes of that event. These were discussed until a consensus was arrived at.

Informed consent forms were signed by all focus group participants.

**RESULTS**

Descriptive statistics for the hospitals and the survey respondents are given in Table 1. To check

**Table1. Descriptive Statistics of Hospitals and Interviewee**

| Hospital Characteristics | | Interviewee Characteristics | |
|---|---|---|---|
| Region | Percentage | Age | Percentage |
| II | 4% | <30 | 8% |
| V | 8% | 31-40 | 12% |
| VI | 4% | 41-50 | 40% |
| VIII | 16% | 51-60 | 24% |
| Metropolitan (XIII) | 56% | >61 | 16% |
| XV | 4% | | |
| XVII | 8% | Sex | Percentage |
| | | Female | 80% |
| Number of beds | Percentage | Male | 20% |
| <100 | 12% | | |
| 101-200 | 36% | Job title | Percentage |
| 201-300 | 8% | Director/Manager/Coordinator of Quality Services | 80% |
| 301-400 | 12% | Other | 20% |
| 401-500 | 16% | | |
| 501-600 | 8% | | |
| 601-700 | 4% | | |
| 801-900 | 4% | | |
| Number of health care professionals | Percentage | | |
| <500 | 24% | | |
| 501-1000 | 36% | | |
| 1001-1500 | 16% | | |
| 2001-2500 | 8% | | |
| 2501-3000 | 16% | | |
| Accredited hospital | Percentage | | |
| Yes | 84% | | |
| No | 16% | | |

for possible selection bias between the population and the sample, the responses to questions 1, 2, 3 and 6 of the survey were analyzed. It was concluded that the sample did not present significant differences in means with respect to the entire population (see Table 2).

As noted earlier, the answers to Question 34 regarding the problem "wrong site surgery with the incorrect procedure and/or the wrong patient" were used to screen for inattention, lack of motivation to respond seriously, or insufficient knowledge to do so. The responses given to the question on the problem's severity, frequency, and detectability are shown in Figure 1. Respondents who indicated a very low severity level were excluded from the analysis. The results for the five most relevant clinical quality and safety problems would not change if the answers from the discarded surveys were included, although the ranking would change slightly.

The statistical characteristics of the valid responses for all of the quality and safety problems evaluated in the study are presented in Table 3 according to their severity (patient harm), frequency

**Table 2. Selection bias test**

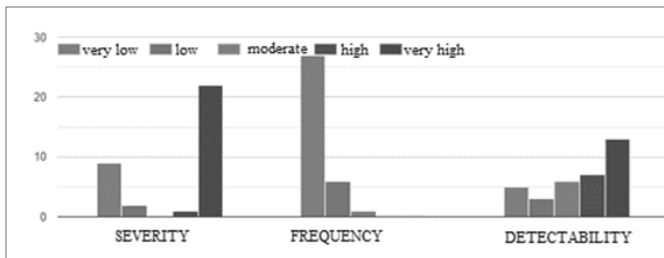| Variable | Population | | Sample | | | |
|---|---|---|---|---|---|---|
| | Mean | Std. Dev. | Mean | Std. Dev. | t-statistic | P value |
| Metropolitan Region (XIII) | 0.489 | 0.503 | 0.480 | 0.510 | 0.083 | 0.934 |
| Ownership | 1.372 | 0.639 | 1.560 | 0.768 | -1.249 | 0.214 |
| Number of beds | 3.387 | 1.848 | 3.600 | 2.082 | -0.498 | 0.620 |
| Accreditation status | 0.904 | 0.296 | 0.840 | 0.374 | 0.911 | 0.364 |



Variables of analysis

Figure 1: Severity, Frequency and Pre-detection Histogram of Clinical Quality and Safety Problem Nº34

(probability of error occurrence), and detectability (hospital's actual ability to pre-detect the event before it affects the patient). This information was the basis for computing the risk priority numbers shown in Table 4.

The problem of "ineffective interprofessional communication", that is, communication between hospital personnel, was found to be the major one and was therefore selected for an exploratory analysis in the focus groups with the aim of understanding the problem's main causes and whether they were common to the various different hospitals and regions.

In the first convergence activity of the focus groups, the question for brainstorming was "what are the root causes of an error in ineffective interprofessional communication?" Each participant was asked to note down five or so root causes they considered important, each one on a separate card. The cards were then collected and the causes indicated written on a whiteboard. Any that were not clear were clarified. Similar ones were identified by grouping them into a single category. The results are shown in Figures 2 and 3.

In the second convergence activity, two main categories of root causes were identified. Category 1 grouped the problem's causes related to interaction between personnel such as communication problems caused by poor diction or difficulty hearing instructions and lack of risk perception.

Also included in Category 1 were causes relating to performance of procedures such as non-adherence to protocols or distraction from tasks performed. Category 2 grouped the causes attributable to the hospital organization, such as the lack of protocols requiring personnel to verify instructions, problems relating to personnel numbers and competence, the absence of protocols in general, and the lack of clinical information records. The two categories may be summarized as follows:

Category 1. Personnel-related: Bad diction/difficulty hearing instructions; Lack of risk perception; Non-adherence to protocols; Distraction.

Category 2. Hospital-related: Lack of double-checking protocols to verify instructions; Lack of staff skills; Lack of personnel; Lack of protocols in general; Lack of registration.

**DISCUSSION**

Clinical quality and safety problems can lead to adverse events that are unsafe and/or dangerous actions by medical personnel that can harm patients.[2] The occurrence of such events not only affects patients and their families but also the professionals involved, giving rise to the second victim phenomenon.[25] Likewise, for health institutions, adverse events affect their reputation and image as well as imposing additional burdens in the form of legal and insurance costs.

Studies of adverse events specific to Chile are

**Table 3. Descriptive Analysis of Clinical Quality and Safety Problems. Each variable name ends with the letter s, f or d referring respectively to severity, frequency or detectability.**

| Variable | Obs | Mean | Std. Dev. | Min | Max | Q.Nº |
|---|---|---|---|---|---|---|
| hygiene_s | 25 | 8.56 | 1.583 | 6 | 10 | 13 |
| hygiene_f | 25 | 6.72 | 1.904 | 4 | 10 | 13 |
| hygiene_d | 25 | 6.56 | 1.872 | 2 | 10 | 13 |
| communication_s | 25 | 8.24 | 1.562 | 6 | 10 | 14 |
| communication_f | 25 | 6.56 | 1.474223 | 4 | 8 | 14 |
| communication_d | 25 | 7.92 | 1.579029 | 6 | 10 | 14 |
| bacteremia_s | 25 | 8.72 | 1.720465 | 4 | 10 | 15 |
| bacteremia_f | 25 | 3.84 | 1.404754 | 2 | 6 | 15 |
| bacteremia_d | 25 | 5.28 | 2.441311 | 2 | 10 | 15 |
| urinary inf_s | 25 | 7.52 | 1.446836 | 6 | 10 | 16 |
| urinary inf_f | 25 | 4.24 | 2.026491 | 2 | 8 | 16 |
| urinary inf_d | 25 | 5.12 | 2.242023 | 2 | 10 | 16 |
| surgical inf_s | 25 | 8.56 | 1.474223 | 6 | 10 | 17 |
| surgical inf_f | 25 | 4.08 | 1.579029 | 2 | 6 | 17 |
| surgical inf_d | 25 | 5.68 | 2.28619 | 2 | 10 | 17 |
| pneumonia_s | 25 | 8.96 | 1.306395 | 6 | 10 | 18 |
| pneumonia_f | 25 | 4.24 | 1.56205 | 2 | 6 | 18 |
| pneumonia_d | 25 | 6.08 | 2.413849 | 2 | 10 | 18 |
| medication err_s | 25 | 7.76 | 1.665333 | 6 | 10 | 19 |
| medication err_f | 25 | 6 | 1.527525 | 4 | 8 | 19 |
| medication err_d | 25 | 7.52 | 1.939072 | 4 | 10 | 19 |
| identification_s | 25 | 8.32 | 2.28619 | 4 | 10 | 20 |
| identification_f | 25 | 3.28 | 1.720465 | 2 | 8 | 20 |
| identification_d | 25 | 4.96 | 2.091252 | 2 | 10 | 20 |
| disclosure_s | 25 | 7.28 | 2.072036 | 4 | 10 | 21 |
| disclosure_f | 25 | 6.16 | 1.907878 | 2 | 10 | 21 |
| disclosure_d | 25 | 6.64 | 2.360791 | 2 | 10 | 21 |
| leadership_s | 25 | 8.32 | 1.6 | 4 | 10 | 22 |
| leadership_f | 25 | 6.8 | 1.632993 | 4 | 10 | 22 |
| leadership_d | 25 | 6.8 | 2.236068 | 2 | 10 | 22 |
| antibiotics_s | 25 | 8.96 | 1.30639 | 6 | 10 | 23 |
| antibiotics_f | 25 | 5.84 | 1.993322 | 2 | 10 | 23 |
| antibiotics_d | 25 | 7.28 | 2.150969 | 4 | 10 | 23 |
| compliance_s | 25 | 7.92 | 1.681269 | 4 | 10 | 24 |
| compliance_f | 25 | 6.56 | 1.87261 | 4 | 10 | 24 |
| compliance_d | 25 | 7.28 | 1.989975 | 2 | 10 | 24 |
| medication_s | 25 | 8.08 | 1.579029 | 6 | 10 | 25 |
| medication_f | 25 | 5.68 | 1.886796 | 2 | 8 | 25 |
| medication_d | 25 | 7.04 | 2.169485 | 2 | 10 | 25 |
| delay_s | 25 | 6.56 | 1.68523 | 4 | 10 | 26 |
| delay_f | 25 | 5.44 | 1.87261 | 2 | 8 | 26 |
| delay_d | 25 | 7.12 | 2.242023 | 2 | 10 | 26 |
| diagnosis_s | 25 | 8.48 | 1.758787 | 4 | 10 | 27 |
| diagnosis_f | 25 | 3.76 | 1.331666 | 2 | 6 | 27 |
| diagnosis_d | 25 | 7.84 | 1.993322 | 4 | 10 | 27 |
| participation_s | 25 | 7.04 | 1.925271 | 2 | 10 | 28 |
| participation_f | 25 | 6.24 | 2.184796 | 2 | 10 | 28 |
| participation_d | 25 | 8.08 | 1.956187 | 4 | 10 | 28 |
| unsafe_use_s | 25 | 8.72 | 1.620699 | 4 | 10 | 29 |

| Variable | Obs | Mean | Std. Dev. | Min | Max | Q.Nº |
|---|---|---|---|---|---|---|
| unsafe_use_f | 25 | 4.72 | 1.989975 | 2 | 10 | 29 |
| unsafe_use_d | 25 | 6.72 | 1.904381 | 4 | 10 | 29 |
| devices_use_s | 25 | 8.08 | 1.869046 | 4 | 10 | 30 |
| devices_use_f | 25 | 3.92 | 1.351542 | 2 | 6 | 30 |
| devices_use_d | 25 | 6.48 | 2.023199 | 2 | 10 | 30 |
| falls_s | 25 | 8 | 1.632993 | 4 | 10 | 31 |
| falls_f | 25 | 5.44 | 1.959592 | 2 | 10 | 31 |
| falls_d | 25 | 5.92 | 2.119748 | 2 | 10 | 31 |
| ulcers_s | 25 | 8 | 1.632993 | 4 | 10 | 32 |
| ulcers_f | 25 | 5.76 | 1.762574 | 4 | 10 | 32 |
| ulcers_d | 25 | 4.96 | 2.169485 | 2 | 10 | 32 |
| thrombosis_s | 25 | 8.72 | 1.720465 | 4 | 10 | 33 |
| thrombosis_f | 25 | 3.84 | 1.624808 | 2 | 8 | 33 |
| thrombosis_d | 25 | 6.72 | 2.37206 | 2 | 10 | 33 |
| incorrect_surg_s | 25 | 9.44 | 1.68523 | 4 | 10 | 34 |
| incorrect_surg_f | 25 | 2.64 | 1.113553 | 2 | 6 | 34 |
| incorrect_surg_d | 25 | 4.08 | 2.196968 | 2 | 8 | 34 |
| consent_s | 25 | 7.36 | 2.289105 | 2 | 10 | 35 |
| consent_f | 25 | 3.2 | 1.527525 | 2 | 6 | 35 |
| consent_d | 25 | 4.08 | 1.956187 | 2 | 10 | 35 |

**Table 4. Risk Priority Number of Clinical Quality and Safety Issues**

| VARIABLE | CLINICAL QUALITY AND SAFETY PROBLEMS | RPN |
|---|---|---|
| communication | Ineffective interprofessional communication | 430.4 |
| leadership | Lack of leadership in addressing frequently recurring security issues | 398.4 |
| antibiotics | Antimicrobial resistance due to inappropriate use of antibiotics | 385.6 |
| hygiene | Health professionals' inadequate hand hygiene | 383.6 |
| compliance | Poor compliance with clinical guidelines and/or protocols | 370.2 |
| participation | Patient and family involvement in safety is low | 360.9 |
| medication err | Medication errors that occur during patient´s transitions of care (admission, discharge, and interservice transitions). | 354.8 |
| medication | Adverse events caused by medications (including adverse drug reaction and medication error) in the unit | 335.3 |
| disclosure | Scarce disclosure of incidents and/or events | 315.5 |
| delay | Delay in medical care (related to appointment errors, waiting lists, etc.) | 264.3 |
| unsafe_use | Unsafe handling and use of hazardous drugs | 283.2 |
| falls | Fall related injuries in patients | 261.1 |
| diagnosis | Misdiagnosis | 253.4 |
| thrombosis | Venous thrombosis in hospitalized patients | 239.0 |
| pneumonia | Pneumonia associated with mechanical ventilation | 229.7 |
| ulcers | Pressure ulcers (bedsores) in hospitalized patients | 222.7 |
| device_use | Adverse events and injuries due to medical device use (implantable and non-implantable) | 214.0 |
| surgical_inf | Surgical site infection | 207.6 |
| bacteraemia | Catheter-related bacteraemia | 179.5 |
| urinary inf | Catheter-associated urinary tract infection | 157.4 |
| identification | Patient identification errors | 133.4 |
| consent | Lack of informed consent in diagnostic and/or therapeutic procedures | 112 |
| incorrect_surg | Wrong site surgery with the incorrect procedure and/or the wrong patient | 104.9 |
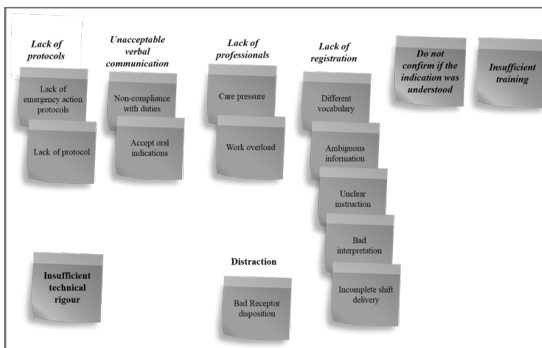
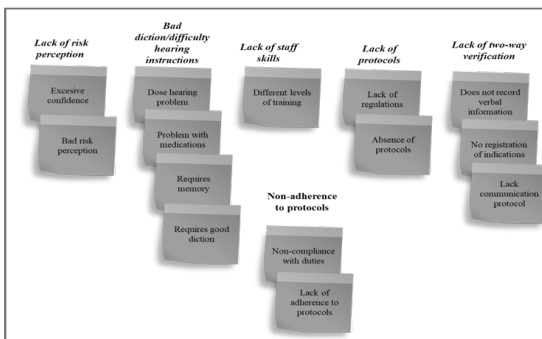Figure 2: First convergence stage result - focus group 1



Figure 3: First convergence stage result - focus group 2

required due to the country's distinct characteristics and geography that mean the results of studies conducted elsewhere are not necessarily comparable with those of the local reality. Furthermore, the prioritization of the most important clinical quality and safety problems also differs from country to country. This is demonstrated by a study paralleling the present one conducted in Spain, where the first three risk priorities were improper hand hygiene of health professionals, ineffective interprofessional communication and medication errors occurring during patient care transitions.[21]

Based on our results, the highest RPN scores in Chile were for ineffective interprofessional communication, lack of leadership in addressing frequently recurring safety issues, and antimicrobial resistance due to inappropriate use of antibiotics. It should be recognized that each hospital has its own reality that conditions its evolution and the prioritization of clinical quality and safety problems depends on processes peculiar to each one. The dispersion of the responses across the hospitals surveyed is such that prioritization tools

and root cause analysis is essential for designing solutions that will be useful for most hospitals.

Communication problems are common in all organizations and particularly those in the health care sector. Communication skills among healthcare professionals are the foundation for effective transfer of the information required to achieve superior health outcomes and patient satisfaction.[26,27] However, healthcare team members do not acknowledge all the factors that can guarantee effective communication, which makes interdisciplinary dialogue and dialogue between social actors even more difficult.[28] To reduce clinical errors at the institutional level, a change in culture must be promoted. Disciplined reflection is required to carry out a systematic investigation and analysis of the causes of adverse events and organizing preventive efforts.[29] The goal is to address communication problems between professionals before patient harm is caused. An innovative way to manage these problems is to apply the latest technologies in language processing and artificial intelligence.

In light of the similarities in the results on prioritization of the problem of inefficient interprofessional communication between the present study and the aforementioned study conducted in Spain, discussion of the root causes of the problem in our two focus groups was of particular interest. The results of the focus groups were classified into two categories, those whose causes were attributable to health professional personnel and those attributable to the hospital itself. These categories were defined to facilitate the design of interventions to prevent adverse events. For root causes of the detected clinical quality and safety problems that have personnel-related causes, the design of solutions must consider behavioural and motivational factors. Solutions that alert personnel to miscommunication problems are particularly needed. On the other hand, for root causes that have hospital-related causes, successful interventions require adequate budgets, leadership commitment and clear guidelines.

Focus group participants were also asked to point out three ways to tackle clinical quality and safety problems in their organizations they believe would help solve their issues. In addition to the solutions proposed in the groups, other possible solutions are increased training for all health professionals, improvements to organizational struc-

tures and additional hirings of health professional staff, the incorporation of monitoring systems for adverse events, and systems for monitoring protocol compliance.

Finally, we note that the approach followed in the present study for identifying root causes could be applied generally by hospitals as a means of promoting continuous improvement of the care they provide with the ultimate purpose of designing customized interventions that would gradually reduce the risk of harming patients. In this regard it should be recalled, however, that our specific implementation of the FMEA methodology used a set of five intervals rather than the usual scale of 1 to 10. Although not affecting the conclusions an individual hospital can draw from the RPN estimates, this may complicate comparisons of our results across hospitals and with other studies.

### Declaration statements

### Appendix 1

#### MAJOR QUALITY AND/OR CLINICAL SAFETY ISSUES

The purpose of this questionnaire is to identify the main Quality and/or Clinical Safety problems in Chilean hospitals.

Participating in this project is voluntary. Consent is given by accepting to answer the questionnaire. The estimated time for completion is 15 minutes.

The data obtained from the questionnaire will be codified in such a way as to guarantee the confidentiality of the information provided, and may only be disseminated as anonymous data and added in scientific reports and publications.

We believe that the results of the research can be of great use to the health organizations that participate in the research. Therefore, we encourage you to participate.

Thank you in advance.

\* Required field

**HOSPITAL INFORMATION**
**1. Geographical location (Region)** \*
**Mark only one option.**
Arica – Parinacota Region - XV
Tarapaca Region - I
Antofagasta Region - II
Atacama Region - III
Coquimbo Region - IV
Valparaiso Region - V Región
Metropolitan Region - XIII
Libertador General Bernardo O´Higgins Region - VI
Maule Region - VII
Ñuble Region - XVI
Bío-Bío Region - VIII
Araucanía Region - IX
Los Ríos Region - XIV
Los Lagos Region - X
Aysen del General Carlos Ibañez del Campo Region - XI
Magallanes y Chilean Antartic Region - XII
**2. Property** \*
Mark only one option.
National Health System
Private
Municipal
Ministry of Defence
Mutual Insurance Companies for Occupational Accidents and Diseases
Other
**3. Number of beds** \*
Mark only one option.
<100
101-200
201-300
301-400
401-500
501-600
601-700
701-800
801-900
901-1000
>1001
Other
**4. Number of outpatient visits (annually)** \*
Mark only one option.

<10.000
10.001-20.000
20.001-30.000
30.001-40.000
>40.001
I do not know

**5. It has teaching assistance agreements \***
Mark only one option.
Yes
No

**6. External certification or accreditation system for quality management \*.**
Select all that apply.
National Accreditation System
ISO
Joint Commission International
Other
The hospital does not have an external certification or accreditation system.

**7. The Hospital's Strategic Plan includes Clinical Quality and/or Safety issues \***
Mark only one option.
Yes
No
I don't know.

**8. Number of health professionals \*.**
Mark only one option.
<500
501-1000
1001-1500
1501-2000
2001-2500
2501-3000
3001-3500
3501-4000
>4001
I don't know.

**DETAILS OF SURVEYED PROFESSIONAL**
**9. Age \***
Mark only one option.
<30
31-40
41-50
51-60
>61

**10. Sex \*.**
Mark only one option.
Male
Female

**11. Experience (years worked) in Quality and/**

**or Clinical Safety \*.**
Mark only one option.
<5
6-10
11-20
21-30
>31

**12. Position you hold in the hospita**l \*
Mark only one option.
Director/Responsible/Coordinator of the Quality and Safety Service
Director/Responsible/Patient Safety Area Coordinator
Director/Responsible/Coordinator of the Quality Service
Other

**TOPICS RELATED TO CLINICAL QUALITY AND SAFETY PROBLEMS**

Below are 23 topics that, according to prestigious international Organizations and Agencies, have a substantial impact on Clinical Quality and/or Safety.

Please give us your opinion and rate each topic according to your general experience as Very low, low, moderate, high and very high according to 3 variables:

- SEVERITY (patient harm)
- FREQUENCY (probability of error occurrence)
- EVENT PRE-DETECTION (Hospital's actual ability to pre-detect the event before it affects the patient)

13. Health professionals' inadequate hand hygiene \*

14. Ineffective interprofessional communication \*

15. Catheter-related bacteraemia \*

16. Catheter-associated urinary tract infection

17. Surgical site infection \*

18. Pneumonia associated with mechanical ventilation \*

19. Medication errors that occur during patient´s transitions of care (admission, discharge, and interservice transitions). \*

20. Patient identification errors \*

21. Scarce disclosure of incidents and/or events \*

22. Lack of leadership in addressing frequently recurring security issues \*

23. Antimicrobial resistance due to inappro-

priate use of antibiotics *

24. Poor compliance with clinical guidelines and/or protocols *

25. Adverse events caused by medications (including adverse drug reaction and medication error) in the unit *

26. Delay in medical care (related to appointment errors, waiting lists, etc.) *

27. Misdiagnosis *

28. Patient and family involvement in safety is low *

29. Unsafe handling and use of hazardous drugs *

30. Adverse events and injuries due to medical device use (implantable and non-implantable) *

31. Fall related injuries in patients *

32. Pressure ulcers (bedsores) in hospitalized patients *

33. Venous thrombosis in hospitalized patients *

34. Wrong site surgery with the incorrect procedure and/or the wrong patient *

35. Lack of informed consent in diagnostic and/or therapeutic procedures *

Indicate, regarding the quality and safety of the patient and according to your criteria, the three most important topics for your organization and whether or not they are mentioned in the questionnaire (direct and brief answers on specific topics are recommended).

36. Topic 1

37. Topic 2

38. Topic 3

## References

1. Institute of Medicine (US) Committee on Quality of Health Care in America. Crossing the Quality Chasm: A New Health System for the 21st Century. National Academies Press (US); 2001. http://www.ncbi.nlm.nih.gov/books/NBK222274/

2. Makary MA, Daniel M. Medical error-The third leading cause of death in the US. BMJ. 2016;353:i2139. https://doi.org/10.1136/bmj.i2139

3. James JT. A New Evidence-based Estimate of Patient Harms Associated with Hospital Care. J Patient-Saf 2013;9(3):122-128 https://doi.org/10.1097/PTS.0b013e3182948a69

4. Wilson RM, Michel P, Olsen S, Gibberd RW, Vincent C, El-Assady R, Rasslan O, Qsous S, Macharia WM, Sahel A, Whittaker S, Abdo-Ali M, Letaief M, AhmedNA,

Abdellatif A, Larizgoitia I, for the WHO Patient Safety EMRO/AFRO Working group. Patient safety in developing countries: Retrospective estimation of scale and nature of harm to patients in hospital. BMJ2012;344(-mar13 3), e832-e832. https://doi.org/10.1136/bmj.e832

5. WHO. 10 facts on patient safety. 2019a.https://www.who.int/news-room/photo-story/photo-story-detail/10-facts-on-patient-safety

6. Robertson JJ, Long B. Suffering in Silence: Medical Error and its Impact on Health Care Providers. J.Emerg. Med 2018;54(4):402-409. https://doi.org/10.1016/j.jemermed.2017.12.001

7. Shojania KG, Dixon-Woods M. Estimating deaths due to medical error: The ongoing controversy and why it matters. BMJ Qual.Saf. 2016:006144. https://doi.org/10.1136/bmjqs-2016-006144

8. Lancis-Sepúlveda ML, Asenjo-Araya C. Estudio de incidencia de eventos adversos en una clínica privada en Chile. Revista de Calidad Asistencial 2014;29(2):78-83. https://doi.org/10.1016/j.cali.2013.10.003

9. Alarcón CG, Ortiz A. Estudio de incidencia de Eventos Adversos. Hospital P. Alberto Hurtado. Superintendencia de Salud de la República de Chile. Observatorio de Buenas Prácticas. Estudio sobre eventos adversos. 2008. Availablefrom: http://www.supersalud.gob.cl/observatorio/575/w3-article-5647.html

10. Alvarez Ortiz NJ, Carrasco Portiño M, Ramirez Donoso G. Caracterización de eventos adversos hospitalarios. Un tema pendiente. Medwave, 2019;19(S1). https://doi.org/10.5867/medwave.2019.S1

11. Collao JF, Favereau R, Miranda R, Aceitón C. Daño asociado al uso de medicamentos en hospitales chilenos: Análisis de prevalencia 2010-2017. Revista médica de Chile2019;147(4), 416-425. https://doi.org/10.4067/S0034-98872019000400416

12. Riquelme GF, Ourcilleón A. Descripción de eventos adversos en un hospital pediátrico de la ciudad de Santiago, Chile. Enfermería Global 2013;12.

13. Leiva-Caro JA, Parada NAG, Reyes MPV, Torres CMER, Martínez CL Úlceras por presión en pacientes de un hospital de alta complejidad en Chile. Benessere. Revista de Enfermería 2020;4(1). https://doi.org/10.22370/bre.41.2019.2303

14. Ortega-Lobos L, Febré N. Prevalencia de Eventos Adversos en Centros de hemodiálisis. Ciencia y enfermería 2018;24. https://doi.org/10.4067/s0717-95532018000100207

15. Luengo C, Paravic T, Valenzuela S. Causas de subnotificación de accidentes de trabajo y eventos adversos en Chile. Revista Panamericana de Salud Pública 2016;39:86-92.

16. Allué N, Chiarello P, Bernal E, Castells X, Giraldo P, Martínez N, Sarsanedas E, Cots F. Impacto económico de los eventos adversos en los hospitales españoles a partir del Conjunto Mínimo Básico de Datos. Gaceta Sanitaria2014;28(1):48-54. https://doi.org/10.1016/j.gaceta.2013.06.004´

17. Zegers M, Bruijne MC, Wagner C, Hoonhout LHF, Waaijman R, Smits M, Hout FAG, Zwaan L, Christiaans-Dingelhoff I, Timmermans DRM, Groenewegen PP, Wal G. Adverse events and potentially preventable deaths in Dutch hospitals: Results of a retrospective patient record review study. BMJ Quality & Safety 2009;18(4):297-302. https://doi.org/10.1136/qshc.2007.025924

18. Zárate-Grajales R, Olvera-Arreola S, Hernández-Cantoral A, Hernández Corral S, Sánchez-Angeles S, Valdez Labastida R, Pérez-López MT, Zapién-Vázquez MA. Factores relacionados con eventos adversos reportados por enfermería en unidades de cuidados intensivos. Proyecto multicéntrico. Enfermería Universitaria2015;12(2):63-72. https://doi.org/10.1016/j.reu.2015.03.003

19. Umpiérrez AF, Fort ZF, Tomás VC. Adverse events in health and nursing care: Patient safety from the standpoint of the professional's experience. Texto & Contexto - Enfermagem. 2015;24:310-315. https://doi.org/10.1590/0104-07072015000122014

20. Campione J,Famolaro T. Promising Practices for Improving Hospital Patient Safety Culture. The Joint Commission Journal on Quality and Patient Safety2018;44(1):23-32. https://doi.org/10.1016/j.jcjq.2017.09.001

21. Gordo C, Mateo R, Labiano J, Núñez-Córdoba JM. Ranking Quality and Patient Safety Challenges: A Nationwide Survey of Healthcare Quality Experts From General Hospitals in Spain. Journal of Patient Safety 2021a;17(8):541-547. https://doi.org/10.1097/PTS.0000000000000675

22. Sangüesa M, Mateo R, Ilzarbe L. Teoría y práctica de la calidad. Editorial Paraninfo;2006.

23. Huang JL, Bowling NA, Liu M, Li Y. Detecting Insufficient Effort Responding with an Infrequency Scale: Evaluating Validity and Participant Reactions. Journal of Business and Psychology2015;30(2):299-311. https://doi.org/10.1007/s10869-014-9357-6

24. García-Germán Vázquez, D., Sanz-Martín, J., Canillas del Rey, F., &Sanjurjo-Navarro, J. Cirugía en sitio erróneo. Revista Española de Cirugía Ortopédica y Traumatología2009;53(5):332-339. https://doi.org/10.1016/j.recot.2009.01.004

25. Nydoo P, Pillay BJ, Naicker T, Moodley J. Thesecondvictimphenomenon in healthcare: A literature review. Scandinavian Journal of Public Health2020;48(6):629-637. doi:10.1177/1403494819855506

26. Solet DJ, Norvell JM, Rutan GH, Frankel RM. Lost in Translation: Challenges and Opportunities in Physician-to-Physician Communication During Patient Handoffs. Academic Medicine 2005;80(12):1094-1099.

27. Hassan I. Avoiding Medication Errors through Effective Communication in Healthcare Environment (SSRN Scholarly Paper ID 3573437). Social Science Research Network; 2018. https://doi.org/10.2139/ssrn.3573437

28. Guillén-Fonseca M. Habilidades de comunicación en la relación médico-enfermera en la Atención Primaria de Salud. Revista Cubana de Enfermería2011;27(3):220-227.

29. Mena P. Error médico y eventos adversos. Revista chilena de pediatría 2008;79(3):319-326. https://doi.org/10.4067/S0370-41062008000300012