

BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email info.bmjopen@bmj.com

BMJ Open

Staying Ahead of the Curve: Navigating Changes and Maintaining Gains in Patient Safety Culture—A Mixed-Methods Study

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-044116
Article Type:	Original research
Date Submitted by the Author:	25-Aug-2020
Complete List of Authors:	Titi, Maher; King Saud University Medical City, Quality Management; King Saud University Medical City, Research Chair for Evidence Based Health Care and Knowledge Translation, Baksh, Maram; King Saud University Medical City, Quality Management Zubairi, Beena; King Saud University Medical City, Quality Management Abdalla , Rawia; King Saud University Medical City, Quality Management Alsaif, Faisal ; King Saud University College of Medicine, Surgery Amer, Yasser; King Saud University, Riyadh, CPG Unit, Quality Management Department, Research Chair for Evidence-Based Health Care and Knowledge Translation; Alexandria University, Alexandria Center for Evidence-Based Clinical Practice Guidelines Jamal, Diana; American University of Beirut Faculty of Health Sciences, Health Management and Policy El-Jardali, Fadi; Department of Health Management and Policy, Faculty of Health Sciences, American University of Beirut, Beirut, Lebanon, and 2Sch,
Keywords:	Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Health & safety < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Organisational development < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

SCHOLARONE™
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Staying Ahead of the Curve: Navigating Changes and Maintaining Gains in Patient Safety Culture—A Mixed-Methods Study

Names and affiliations of contributing authors

First name	Middle name (or abbreviation)	Family name	Affiliation(s)	ORCID	Email address
Maher	Abdelraheim	Titi*	<ul style="list-style-type: none"> Quality Management Department, King Saud University Medical City, Riyadh, Saudi Arabia Research Chair for Evidence Based Health Care and Knowledge Translation, King Saud University (034), P. O. Box 7805, Riyadh 11472, Saudi Arabia 	https://orcid.org/0000-0003-1079-4118	Mahertiti1980@gmail.com mtiti@ksu.edu.sa
Maram	Mohammed	Baksh	<ul style="list-style-type: none"> Quality Management Department, King Saud University Medical City, King Saud University (034), P. O. Box 7805, Riyadh 11472, Saudi Arabia 	https://orcid.org/0000-0001-9846-2964	mbaksh@ksu.edu.sa
Beena	----	Zubairi	<ul style="list-style-type: none"> Quality Management Department, King Saud University Medical City, King Saud University (034), P. O. Box 7805, Riyadh 11472, Saudi Arabia 	http://orcid.org/0000-0002-8994-6884	bzubairi@ksu.edu.sa
Rawia	Ahmad Mustafa	Abdalla	<ul style="list-style-type: none"> Quality Management Department, King Saud University Medical City, King Saud University (034), P. O. Box 7805, Riyadh 11472, Saudi Arabia 	https://orcid.org/0000-0002-3158-0437	Rawia85@yahoo.com
Faisal	Abdullah	Alsaif	<ul style="list-style-type: none"> Department of Surgery, College of Medicine, King Saud University (034), P. O. Box 7805, Riyadh 11472, Saudi Arabia 	https://orcid.org/0000-0002-2522-1681	falsai1972@gmail.com
Yasser	Sami	Amer	<ul style="list-style-type: none"> Quality Management Department, King Saud University Medical City, Riyadh, Saudi Arabia Pediatrics Department, King Saud University Medical City, Riyadh, Saudi Arabia Research Chair for Evidence Based Health Care and Knowledge Translation, King Saud University (034), P. O. Box 7805, Riyadh 11472, Saudi Arabia 	https://orcid.org/0000-0003-4097-2317	yassersamiamer@gmail.com
Diana		Jamal	<ul style="list-style-type: none"> Department of Health Management and Policy, American University of Beirut P.O.Box 11-0236, Riad El-Solh, Beirut 1107 2020 Lebanon 	https://orcid.org/0000-0002-1852-1643	dj06@aub.edu.lb

Fadi	---	El-Jardali	<ul style="list-style-type: none"> • Faculty of Health Sciences, American University of Beirut P.O.Box 11-0236, Riad El-Solh, Beirut 1107 2020 Lebanon • Department of Health Research Methods, Evidence, and Impact, McMaster University, Hamilton, Canada 	https://orcid.org/0000-0002-4084-6524	fe08@aub.edu.lb
------	-----	------------	---	---	--

- * Corresponding Author: Maher Abdelraheim Titi,
 - email: mtiti@ksu.edu.sa, mahertiti1980@gmail.com
 - Phone: Office: +966-114691342, Mobile: +966-568310277

- Running title: Patient Safety Culture Changes
- Word count for the abstract: 251 words
- Word count for the text of the manuscript: 5036 words

- **Keywords:**

patient safety culture, patient safety, healthcare quality, Saudi Arabia

1
2
3 **Staying Ahead of the Curve: Navigating Changes and Maintaining Gains in Patient Safety**
4
5 **Culture—A Mixed-Methods Study**
6
7

8 Running title: Patient Safety Culture Changes
9

10 Word count for the abstract: 257 words
11

12 Word count for the text of the entire manuscript: 4,634 words
13
14

15
16 **ABSTRACT**
17

18
19 **Objectives:** This study examines how the results of the Hospital Survey on Patient Safety
20
21 Culture changed between 2012 and 2019 and identifies organizational factors affecting these
22
23 changes.
24

25
26 **Design:** The study combined the use of quantitative surveys of staff and qualitative interviews
27
28 with hospital leadership. Secondary data analysis was performed for previous surveys.
29

30
31 **Setting:** This study was conducted in a tertiary care teaching multi-site hospital in Riyadh, Saudi
32
33 Arabia.
34

35
36 **Participants:** One thousand hospital staff participated in the survey. Thirty-one executive board
37
38 members and directors and four focus groups of frontliners were qualitatively interviewed.
39

40
41 **Primary and Secondary Outcome Measures:** Twelve safety culture dimensions were assessed
42
43 to study the patient safety culture as perceived by the healthcare professionals. An additional
44
45 semi-structured interview was conducted to identify organizational factors, changes, and barriers
46
47 affecting the patient safety culture. Furthermore, suggestions to improve patient safety were
48
49 proposed.
50

51
52 **Results:** Comparing the results revealed a general positive trend in scores from 2012 to those
53
54 from 2019. The areas of strength included teamwork within and across units, organizational
55
56
57

1
2
3 learning, managerial support, overall perception of safety, and feedback and communication
4
5 about error. Non-punitive response to error, staffing, and communication and openness
6
7 consistently remain the lowest-scoring composites. Interview results revealed that organizational
8
9 changes may have influenced the answers of the participants on some survey composites.
10
11

12
13 **Conclusions:** Patient safety is a moving target with areas for improvement that are continuously
14
15 identified. Effective quality improvement initiatives can lead to visible changes in the patient
16
17 safety culture in a hospital, and consistent leadership commitment and support can maintain
18
19 these improvements.
20
21
22
23
24
25

26 **STRENGTHS AND LIMITATIONS OF THIS STUDY**

- 27
28
29 • This is the first study to explore the results of a survey on patient safety culture in four
30
31 consecutive rounds in Saudi Arabia.
32
- 33
34 • This study covered almost all categories of healthcare workers, including managers and
35
36 care providers.
37
- 38
39 • A mixed-methods design was used to overcome the methodological limitations of the lack
40
41 of a single tool that could capture the complexities of a safety culture.
42
- 43
44 • The lower response rate of the 2019 assessment round was observed and compared to
45
46 previous years; therefore, the results of this study should be interpreted with caution.
47
- 48
49 • To minimize the occurrence of spurious correlations due to common-method variance in
50
51 the survey instrument, we have utilized a mixed-methods design rather than simply
52
53 applying the survey method alone.
54
55
56
57
58
59
60

INTRODUCTION

Despite considerable investments in quality healthcare and patient safety over the past decades, patients continue to experience preventable harm, and the current status of patient safety around the world remains alarming.¹ Recent studies have identified adverse events as a serious global issue affecting patient safety. Therefore, identifying and preventing potential harm is a top priority of healthcare organizations, thus enhancing patient outcomes. Evidence suggests that a strong culture of patient safety in a hospital is associated with fewer adverse events and improved patient outcomes.^{2 3}

It is increasingly recognized that healthcare organizations around the world, regardless of economic status, are closely focusing on measuring and enhancing their Patient Safety Culture(PSC).⁴⁻⁶ PSC is assessed to provide information to managers and healthcare policymakers; in addition, it can help organizations understand the present state of their PSC and analyze the PSC trends over time. Measuring PSC is important for identifying areas of strength and areas needing prioritization for interventions, evaluating the impact of patient safety initiatives or programs, and tracking changes over time. Furthermore, it improves staff perceptions, develops a better understanding of patient safety, fulfills accreditation or regulatory requirements, and conducts internal and external benchmarking.^{2 7 8}

Measuring PSC is still considered relatively difficult and is well documented in the literature.^{9 10} No single tool can sufficiently assess all major components of PSC and provide leaders with clear guidance on how PSC can be effectively improved.^{11 12} To explore the complex concept of PSC in healthcare, the mixed-methods approach, by collecting and analyzing both quantitative and qualitative data, can be viewed as the most appropriate approach to increase the robustness

1
2
3 of the results and gain a deeper understanding of PSC while offsetting the intrinsic weaknesses
4 associated with each approach when used on its own.^{5 13}
5
6

7
8 Given the clear need for continuous monitoring of PSC and better understanding of how
9 organizational culture changes after multiple interventions and milestones, we used the mixed-
10 methods approach to assess PSC progressively over a period of eight years. To our knowledge,
11 assessing PSC has not yet been performed at this scale, and this study can provide us insight on
12 the key areas to improve regarding PSC in healthcare organizations and persistent challenges in
13 PSC that are difficult to change rapidly with simple interventions. This study reports on the
14 organizational survey results of 2019 and compares these results to those of three previous
15 assessments at the same multi-site facility (2012,¹⁴ 2015,⁴ and 2017).
16
17
18
19
20
21
22
23
24
25
26
27

28 **Objectives**

29
30
31 The overall objective of this study is to examine how the results of the HSOPSC survey changed
32 between 2012 and 2019 and identify organizational factors affecting these changes. Specifically,
33 this study provides an overview of the results of multiple assessments of PSC surveys at a large
34 multi-site healthcare facility in Riyadh, Kingdom of Saudi Arabia.
35
36
37
38
39

40 **METHODS**

41 **Design**

42
43
44 In this study, a mixed-methods research design was used to achieve the most comprehensive
45 understanding possible of the research problem. The study combined the use of quantitative
46 surveys and qualitative interviews with hospital staff of different levels to achieve the study
47 objectives. Additionally, we conducted a cross-validation of the results with those of the
48 previous surveys conducted at the same site in 2012¹⁴, 2015⁴, and 2017.
49
50
51
52
53
54
55
56
57

Setting

This study was conducted in a tertiary care teaching multi-site hospital having a capacity of 1,160 beds and approximately 9,000 employees. It receives referral patients from all over the country.

The hospital has three sites, varying in size and location; site A has 1,060 beds and offers free medical services with a wide range of specialties, and site B has 100 beds and offers complementary services to those of site A. Site C offers inpatient and outpatient dental services.

Quantitative component

The tool (questionnaire)

The tool used was adapted from the HSOPSC developed by the AHRQ.⁷ The survey is available in English and Arabic. The internal consistency and reliability of the original English version were tested using Cronbach's alpha that ranged between 0.62 and 0.85.^{15 16} However, the Arabic version was adapted and used in similar studies in Lebanon,¹⁷ Saudi Arabia,^{4 14} and Jordan,¹⁸ and its reliability was measured using Cronbach's coefficient that ranged between 0.45 and 0.81.¹⁷

The HSOPSC includes 42 items grouped into 12 composites. In addition to the composites, the survey includes two questions asking respondents to provide an overall grade on patient safety and to indicate the number of reported events over the past 12 months.

Data collection

Data collection for the 2017 and 2019 surveys was performed in two assessment rounds: from September to November in 2017 and from February to April in 2019. Data collection for the 2012 and 2015 surveys was described in studies by El-Jardali et al.¹⁴ and Alswat et al.⁴

1
2
3 The survey was made available in hard copies and the electronic format for all respondents. The
4
5 hard-copy surveys were provided in sealed envelopes for respondents who could not access the
6
7 electronic-format surveys. The first page of the survey included the consent form and an
8
9 explanation of the purpose of the survey. Employees were not asked to sign the consent form or
10
11 any other page of the survey; they were asked to return the hard copies of the survey in a sealed
12
13 envelope.
14
15

16 17 Data analysis

18
19 Data were analyzed using Statistical Package for the Social Sciences, version 25.0, (IBM Corp.,
20
21 Armonk, NY, USA); *p* values of > 0.05 were used to denote significance. In addition to
22
23 answering the study tool, respondents were asked to provide some background demographic
24
25 information about themselves (age, gender, marital status, profession, educational level, clinical
26
27 experience, working hours during the week, working area, and whether they were trained on
28
29 patient safety). The composite items were measured using a 5-point Likert response scale of
30
31 agreement, with the scores ranged from “strongly disagree” to “strongly agree” or frequencies
32
33 that ranged from “never” to “always.” Consequently, the HSOPSC comprised the following two
34
35 single-item measures:
36
37
38

- 39
40
41 ▪ The patient safety grade, scored with a 5-point Likert scale ranging from “excellent” to
42
43 “failing”
- 44
45 ▪ The number of adverse events reported by the respondent during the last year, ranging
46
47 from “no events” to “21 events or more.”

48
49
50 The results were presented as percentages of the average positive responses (e.g., strongly
51
52 agree/agree and most of the time/always) for each survey item; negatively worded items were
53
54 reversed when computing their percentages. The percent positives for each subscale were
55
56

1
2
3 computed as follows: [(number of positive responses/total number of responses on the item) ×
4 100%]. Missing responses were excluded when displaying the percentages of the responses to
5
6 the survey items.⁷ Composites that had at least 70% positive responses were considered areas of
7
8 strength, whereas those with less scores were considered areas for improvement. Our decision to
9
10 consider our cut-off point to be 70% for patient safety areas in need for improvement was based
11
12 on the results of our previous two PSC surveys conducted in the same facility. Composite scores
13
14 were calculated by summing the item scores and dividing the sum by the number of items within
15
16 the composite.
17
18
19
20
21

22 Descriptive statistics such as frequency and percentage were used for data summarization. Given
23
24 that the data were not normally distributed for all composites, the independent Kruskal–Wallis H
25
26 test was used to determine whether a significant difference exists between survey composites
27
28 between the 2012, 2015, 2017, and 2019 datasets. The chi-square test was used to determine
29
30 whether a significant difference exists between the 2012 and 2019 datasets for the questions
31
32 regarding the number of events and patient safety grade.
33
34
35
36

37 **Qualitative component**

38 Interview tool

39
40
41 Semi-structured interviews were conducted to probe the topic deeper, make the interviews more
42
43 conversational, and make sure all interview participants, including leaders and frontline staff, were
44
45 asked the same questions. An interview guide was adapted and modified from previous studies,¹⁹⁻²¹
46
47 and an external expert review followed (see online Supplementary 1S).
48
49
50
51
52

53 Participants

1
2
3 We used a purposive sampling technique to recruit interviewees. Thirty-one semi-structured
4 individual interviews were conducted with all executive board members in Medical City, medical
5 directors in each site, directors of the main clinical and supportive services departments, and four
6 focus groups of frontliners. Those identified to participate had received an invitation email
7 including all the information about the voluntary nature of participation and an explanation of the
8 entire study phase and a request to record the interviews, which were conducted in a private place
9 (see online supplementary table 1S).
10
11
12
13
14
15
16
17
18
19
20

21 Data collection

22 The interviews were scheduled according to the participants' availability. All interviews were
23 conducted in English. Each interview lasted 15–30 minutes and was recorded using a digital voice
24 recorder. A research assistant transcribed the recorded data as soon as each interview was
25 completed. The accuracy of the transcriptions was reviewed (and corrected if necessary) by the
26 researchers. In addition, field notes were taken, and the responses and views of the participants
27 were summarized at the end of each interview to ensure that they reflected their views.
28
29
30
31
32
33
34
35
36

37 Participation was voluntary and the interview tool did not collect any information that could be
38 used to identify the participants. Participant confidentiality was maintained at every stage of the
39 study.
40
41
42
43
44

45 Data analysis

46 Thematic analysis was conducted for the data collected through the interviews. Coding, which
47 was done by two members of the research team, was initially conducted by breaking responses
48 into similar concepts and ideas. Minimal discrepancies were found after cross-checking the work
49 between the two team members. Disagreements were discussed until a consensus was achieved.
50
51
52
53
54
55
56
57
58
59
60

1
2
3 This was followed by axial coding, which comprised the organization of the emerging concepts
4 into themes and categories.
5
6
7

8 **Patient and public involvement**

9

10
11 In this study, no patients were involved.
12
13

14 **RESULTS**

15

16 **Survey results**

17
18
19

20 **General results**

21
22

23 In total, 2,694 questionnaires from the 2017 assessment round and 1,000 from the 2019
24 assessment round were completed, giving a response rate of 59.8% and 22.2%, respectively.
25
26

27 However, the response rates in the previous two rounds were 85.7%¹⁴ and 57.6%⁴ (Table 1). The
28 discrepancy in the response rate was observed as we stopped the second data collection in 2019
29 as the organization was preparing for the final survey of dual accreditation by both national and
30 international accreditation bodies. We were concerned about the potential biases or false positive
31 responses that might arise during the deep engagement of all of the staff at all levels in these
32 accreditation activities.
33
34
35
36
37
38
39
40
41

42 Despite the low response rate in 2019, the study sample size is more than the minimum sample
43 size recommended by the AHRQ.⁷ Moreover, all three previous PSC surveys in 2012, 2015, and
44 2017 conducted at our institution showed good response rates of >50% (85.7%, 57.6%, and
45 59.8% respectively). In this study, we reflected and interpreted the four PSC surveys
46 simultaneously.
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Most respondents in all four assessment rounds were nurses (50.1%, 78.3%, 56%, and 61.7%, respectively). Most respondents were female in the four assessment rounds that could be explained by the fact that the approximate proportion of our nursing staff is approximately 27% of the total number of employees including both clinical and non-clinical staff. Moreover, our nursing staff predominantly comprised females (87%). Approximately half of the respondents were aged between 30 and 45 years (45.3%, 46.4%, 61.6%, and 65.3% in 2012, 2015, 2017, and 2019, respectively).

Among the study respondents, the majority held a Bachelor's degree (38.9%, 56.2%, 61.4%, and 59.2% in years 2012, 2015, 2017, and 2019, respectively), whereas 43.6% in 2012 and 25.4% in 2017 had diplomas. A large proportion of the respondents in the 2015 and 2017 assessment rounds had 6–10 years of experience in the hospital (32.3% and 27.5%, respectively), whereas 30.5% and 35.4% had 1–5 years of experience in the hospital in the 2012 and 2019 assessment rounds, respectively. Additionally, approximately half of the staff reported working in medical units in all assessment rounds, except in 2012, where 27.1% of the respondents were working in the hospital administration. Moreover, more than 75% of the personnel had been in direct contact with patients and working 40–60 hours a week in all four assessment surveys.

Table 1. Sociodemographic and professional characteristics of the respondents along with the number of events reported and patient safety grades.				
Sociodemographic and professional characteristics	2012^[14] N (%) Total no. 2,572	2015^[4] N (%) Total no. 2,592	2017 N (%) Total no. 2,694	2019 N (%) Total no. 1,000
Work area/unit where respondents spend most of their work time				
Many different hospital units/no specific unit	13 (0.5)	21 (0.8)	36 (1.5)	2 (0.2)
Administrative	697 (27.1)	138 (5.4)	357 (14.6)	50 (5.1)
Medical	536 (20.8)	1332 (51.9)	1193 (48.8)	517 (53.1)
Surgical	503 (19.6)	786 (30.6)	406 (16.6)	267 (27.4)
Diagnostics	277 (10.8)	99 (3.9)	399 (16.3)	101 (10.4)
Other	545 (21.2)	191 (7.4)	54 (2.2)	36 (3.7)
Missing	1	25	249	27

Respondents' positions at the hospital				
Administrator/manager/director/head	92 (3.6)	47 (1.9)	96 (3.7)	21 (2.2)
Physician	158 (6.1)	141 (5.6)	191 (7.4)	91(9.4)
Specialist	80 (3.1)	61 (2.4)	164 (6.4)	57 (5.9)
Coordinator	13 (0.5)	10 (0.4)	55 (2.1)	14 (1.4)
Assistant/aide	62 (2.4)	39 (1.6)	65 (2.5)	18 (1.9)
Pharmacist	56 (2.2)	36 (1.4)	79 (3.1)	4 (0.4)
Therapist	52 (2.0)	1 (0.0)	32 (1.2)	18 (1.9)
Registered nurse	1287 (50.1)	1969 (78.3)	1443 (56.0)	596 (61.7)
Resident/PG/intern	67 (2.6)	64 (2.5)	92 (3.6)	29 (3)
Assistant/clerk/secretary/facilitator	133 (5.2)	28 (1.1)	60 (2.3)	28 (2.9)
Technician	308 (12.0)	52 (2.1)	236 (9.2)	76 (7.9)
Other	264 (10.3)	67 (2.7)	62 (2.4)	14 (1.4)
Missing	0	77	119	34
Experience in current hospital (years)				
Less than 1 year	463 (18.6)	133 (5.3)	553 (21.8)	77 (8)
1–5 years	758 (30.5)	741 (29.6)	640 (25.2)	339 (35.4)
6–10 years	622 (25.0)	809 (32.3)	698 (27.5)	262 (27.4)
11–15 years	290 (11.7)	348 (13.9)	353 (13.9)	151(15.8)
16–20 years	136 (5.5)	222 (8.9)	154 (6.1)	73 (7.6)
21 years or more	217 (8.7)	252 (10.1)	139 (5.5)	55 (5.7)
Missing	86	87	157	43
Experience in current work area (years)				
Less than 1 year	436 (17.3)	313 (12.6)	432 (17.0)	50 (5.2)
1–5 years	986 (39.1)	520 (21.0)	404 (15.9)	233 (24.3)
6–10 years	528 (20.9)	781 (31.5)	827 (32.5)	319 (33.3)
11–15 years	245 (9.7)	358 (14.5)	411 (16.1)	165 (17.2)
16–20 years	159 (6.3)	233 (9.4)	249 (9.8)	106 (11.1)
21 years or more	168 (6.7)	272 (11)	223 (8.8)	85 (8.9)
Missing	50	115	148	42
Hours worked per week				
Less than 20 hours per week	55 (2.3)	25 (1.0)	58 (2.3)	24 (2.5)
20–39 hours per week	203 (8.3)	148 (6.0)	214 (8.6)	87 (9.2)
40–60 hours per week	2180 (89.4)	2280 (92.9)	2206 (89.0)	838 (88.3)
Missing	134	139	216	51
Job involving direct contact with patients				
Yes, I typically have direct interaction or contact with patients.	1956 (76.1)	2229 (90.9)	2045(82.2)	808 (85.7)
No, I typically do not have direct interaction or contact with patients.	615 (23.9)	224 (9.1)	443(17.8)	135 (14.3)
Missing	1	139	206	57
Gender				

Male	728 (28.6)	398 (15.9)	628 (24.6)	234 (24.6)
Female	1820 (71.4)	2103 (84.1)	1925 (75.4)	719 (75.4)
Missing	24	91	141	47
Age (years)				
Below 30 year old	854 (33.7)	925 (37.3)	558 (22.7)	175 (18.2)
Between 30 and 45 years old	1148 (45.3)	1152 (46.4)	1515 (61.6)	628 (65.3)
Between 46 and 55 years old	401(15.8)	253 (10.2)	282 (11.5)	114 (11.9)
Above 55 years old	133 (5.2)	151 (6.1)	103 (4.2)	44 (4.6)
Missing	36	111	236	39
Marital Status				
Single	752 (30.3)	851 (34.2)	807(31.5)	309 (32)
Married	1682 (67.8)	1602 (64.4)	1703 (66.4)	633 (65.6)
Divorced/Separated	25 (1.0)	16 (0.6)	33 (1.3)	13 (1.3)
Widowed	14 (0.6)	13 (0.5)	13 (0.5)	6 (0.6)
Other	8(0.3)	6 (0.2)	7(0.3)	4 (0.4)
Missing	91	104	131	35
Educational level				
Under high school level	14 (0.6)	2 (0.1)	11 (0.4)	3 (0.3)
High school level	62 (2.5)	7 (0.3)	25 (1.0)	4 (0.4)
Diploma level	1082 (43.6)	836 (33.5)	654 (25.4)	267 (27.6)
Bachelor's degree	966 (38.9)	1403 (56.2)	1579 (61.4)	574 (59.2)
Master's degree	124 (5.0)	127 (5.1)	160 (6.2)	61 (6.3)
Doctorate degree	112 (4.5)	102 (4.1)	110 (4.3)	53 (5.5)
Others	122 (4.9)	19 (0.8)	32 (1.2)	7(0.7)
Missing	90	96	123	31

PSC dimensions

PSC dimensions were examined (Table 2). The dimensions with the highest average response rates, considered areas of strength, were “organizational learning–continuous improvement” ranging from 79.6% to 83.9% between 2012 and 2019 and “teamwork within units” that scored more than 75% in all four assessments. Furthermore, the average response rates of the “hospital management support for patient safety” dimension were 70.4%, 75.3%, 73.3%, and 73.8% in 2012, 2015, 2017, and 2019, respectively.

All surveys had the same areas requiring improvement. There is a general trend toward improvement in percent positive scores from 2012 to 2019, except for the “frequency of events reported” composite. Note that “overall perception of patient safety” was found to be an area for improvement in 2012; however, it was shown to be an area of strength in 2019. The lowest reported average percentage was below 30% for “non-punitive response to error” throughout the four assessment rounds. Additionally, staffing and communication openness were the next lowest-scoring composites across the four assessment rounds (Table 2).

Patient safety culture dimensions	2012	2015	2017	2019
Teamwork within units	78.5%	84.8%	81.6%	84.5%
Supervisor/manager expectations and actions promoting patient safety	60.6%	60.8%	60.4%	64.0%
Organizational learning–continuous improvement	79.6%	86.3%	82.2%	83.9%
Management support for patient safety	70.4%	75.3%	73.3%	73.8%
Overall perceptions of patient safety	65.3%	59.5%	59.6%	61.7%
Feedback and communication about error	63.3%	71.8%	68.7%	72.0%
Communication openness	42.9%	45.0%	48.5%	49.8%
Frequency of events reported	59.4%	68.8%	64.9%	66.6%
Teamwork across units	61.6%	67.0%	64.1%	65.8%
Staffing	35.1%	33.8%	30.8%	31.9%
Handoffs and transitions	51.5%	55.8%	49.6%	52.2%
Non-punitive response to error	26.8%	24.8%	27.2%	27.2%

Comparing the results from 2012 to those of 2019

The Kruskal–Wallis test was conducted to compare the results from all four surveys (Table 3). As a result, significant differences lie across the four surveys with the exception to the “supervisor/manager expectations and actions promoting patient safety” and “non-punitive response to error” composites. A comparison of the mean scores between 2012 and 2019 showed

1
2
3 a steady increase in composite scores. The statistical significance of these differences varied
4
5 according to the survey composites; however, it is worth noting that the highest scores were
6
7 observed in 2015.
8
9

10 “Non-punitive response to error” and “staffing” remained the lowest-scoring composites in all
11
12 assessment rounds, but the difference is not statistically significant. The highest-ranking composite
13
14 for all surveys was “organizational learning—continuous improvement.”
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47

Table 3. The Kruskal–Wallis test comparing the composite scores in 2012 to those in 2019.

Patient safety culture dimensions	2012		2015		2017		2019 KAUH		Independent sample Kruskal–Wallis test	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	P-Value	Adjusted significance Bonferroni correction
Frequency of events reporting	3.64	1.16	4.04	1.54	3.83	1.1	3.82	1.14	<0.001	abce
Overall perceptions of safety	3.43	0.59	3.6	1.56	3.47	0.6	3.51	0.62	<0.001	bce
Supervisor/manager expectations and actions promoting safety	3.46	0.65	3.57	1.34	3.48	0.67	3.54	0.68	0.003	c
Organizational learning–continuous improvement	3.89	0.69	4.16	1.14	4.02	0.61	4.03	0.58	<0.001	abc
Teamwork within hospital units	3.85	0.75	4.04	0.71	4.00	0.67	4.03	0.63	<0.001	abc
Communication openness	3.25	0.85	3.45	1.08	3.43	0.82	3.43	0.89	<0.001	abcde
Feedback and communication about errors	3.73	0.95	4.11	1.1	3.95	0.87	4.04	0.8	<0.001	abcd
Non-punitive response to error	2.68	0.81	2.76	1.26	2.69	0.87	2.68	0.87	0.123	
Staffing	2.84	0.62	3.02	1.19	2.68	0.63	2.73	0.65	<0.001	bce
Hospital management support for patient safety	3.69	0.76	3.85	1.05	3.77	0.67	3.78	0.66	0.030	
Teamwork across hospital units	3.52	0.71	3.76	1.36	3.58	0.67	3.60	0.66	0.002	bc
Hospital handoffs and transitions	3.36	0.79	3.82	2.29	3.27	0.87	3.34	0.82	0.001	bc
Letter indicates a <i>p</i> -value <0.05 adjusted significance using the Bonferroni correction for multiple tests.										
a	2012–2017									
b	2012–2019									
c	2012–2015									
d	2017–2019									
e	2017–2015									
f	2019–2015									

Patient safety grade and event reporting

The percentage of the respondents who evaluated patient safety in their work area/unit as excellent/very good increased from 69.5% in 2012 to 74.1% in 2019 ($p < 0.001$) (Table 4). Moreover, Table 4 displays the percentages of the number of events reported; the analysis indicated that the percentages of the respondents who reported no events in the last 12 months decreased by almost 7.4% from 2012 to 2019 ($p < 0.001$) and the percentages of reporting more than five event reports increased from 6.4% in 2012 to 8% in 2019.

Table 4: Chi-Square test comparing patient safety grades and the number of events reported between 2012 and 2019.

Patient safety grade	2012 N (%)	2015 N (%)	2017 N (%)	2019 N (%)	Sig
Poor/failing	119 (4.8%)	57 (2.3%)	67 (2.6%)	18 (1.9%)	$p < 0.001$
Acceptable	632 (25.6%)	654 (26.6%)	614 (24.2%)	230 (24%)	
Excellent/very good	1714 (69.5)	1747 (71.1%)	1859 (73.2%)	710 (74.1%)	
Number of events reported					
No event reports	1275 (52.7%)	1364 (55.8%)	1180 (47.3%)	427 (45.3%)	$p < 0.001$
1 to 5 event reports	992 (41%)	940 (38.4%)	1092 (43.8%)	440 (46.7%)	
>5 event reports	154 (6.4%)	141 (5.8%)	223 (8.9%)	75 (8%)	

Interview results

Characteristics of the respondents

In total, 91 healthcare professionals were interviewed, among whom 10 were executive leaders (corporate level), 8 were hospital directors, and 13 were departmental chairpersons and directors.

The researcher conducted interviews with four focus groups consisting of 60 front-liner staff. Most of the staff in the focus groups comprised physicians, pharmacists, nurses, and allied health technicians. The qualitative data obtained from the interviews were thematically categorized into the following: realizing changes in PSC in the facility/departments, factors influencing the PSC in

1
2
3 healthcare, barriers to establishing PSC and how to overcome them, and suggestions to improve
4 patient safety (see online supplementary table 2S).
5
6

7 Changes in PSC in the facility

8
9
10 The interviews showed that the respondents believe that the PSC in their department has
11 changed. Some of the documented observed changes included changes in the overall culture,
12 more awareness among the staff, improved communication, increased error reporting, improved
13 understanding and following hospital policies and procedures, improved care processes within
14 the hospital, provision of guides and manuals, more awareness of the risks and how to avert
15 them, and addressing staff fears about the punitive culture.
16
17
18
19
20
21
22
23

24
25 Some factors reported by the respondents that may have contributed to these changes include the
26 multiple accreditation surveys and the introduction of an electronic event reporting system.
27
28

29
30 Despite the learning curve associated with both interventions, the respondents reported that it has
31 allowed them to streamline their operations, enabled them to provide quality care to patients, and
32 improved the process of error reporting.
33
34
35

36
37 The respondents indicated that the main changes they saw in their department was the
38 amendment of existing policies and procedures, the clarification of job descriptions and roles,
39 and making the staff less resistant to change. In addition, hospital leadership observed better
40 communication and teamwork across the hospital and better staff awareness on the topic.
41
42
43
44
45

46 Factors influencing PSC in healthcare

47
48
49 According to the hospital leaders, making patients at the core of the PSC is the first step in the
50 right direction. This requires support at the leadership and administration levels. Hospital leaders
51 reported that accreditation was one of the factors that changed the culture within their
52
53
54
55
56
57

1
2
3 organization. It has improved communication between the staff and patients and within and
4
5 across departments, staff training (including continuing education and training), and teamwork
6
7 within and across units, particularly regarding handoffs and transitions. These were all
8
9 considered factors that could support and improve event reporting and eventually lead to
10
11 performance improvement.
12
13

14
15 Some of the factors that may influence PSC reported by the respondents included leadership and
16
17 administrative support, monitoring and evaluation (including feedback) of patient safety
18
19 indicators, the number of staff available, improvement of the error reporting system, receiving
20
21 feedback on reported events, clarity and correct implementation of policies and procedures,
22
23 implementing a system for monitoring patient safety goals, and improving workflow within
24
25 specific departments. Some respondents reported that all hospital staff is responsible for
26
27 improving the PSC, whereas other respondents placed the responsibility solely on the leaders and
28
29 managers.
30
31
32

33
34 Barriers to establishing PSC and how to overcome them
35
36

37 Some of the documented barriers to establishing a PSC included poor communication within and
38
39 across departments, punitive culture, limited staff awareness, staff resistance to change, staff
40
41 shortages, language barrier, limited cooperation from physicians, and poor training of staff.
42
43

44 Other less frequently mentioned barriers included staffing, budget, and space.
45
46

47 Organizational changes since 2012
48
49

50 The slight dip in the composite scores in 2017 could be attributed to several organization-wide
51
52 factors that occurred during this transition period. Introducing new human resources regulations
53
54 and workflows during the shift from the traditional civil service to a self-operation system, a
55
56
57

1
2
3 national trend throughout the Kingdom, had a significant impact on recruitment, re-contracting,
4 and staff retention and turnover.
5
6

7
8 Another factor was the preparation for the dual accreditation (i.e., national and international) final
9 surveys that were scheduled in December 2017 had several positive and negative implications.
10
11 Overwhelming the staff with changes and escalations of improvement during a short period were
12 among the negative effects.
13
14
15
16

17
18 The outset of 2017 witnessed the separation of the administration of the university hospitals
19 (healthcare) quality from the academic (medical education) quality. Widespread expansions
20 throughout the organization occurred including the opening of a new large eastern building that
21 added to the total bed capacity of the hospital, increasing from 948 in 2014 to 1,160 in 2019.
22
23 This added bed capacity had an additional burden to all categories of healthcare providers,
24 especially physicians and nurses. The launching of new innovative healthcare services such as
25 oncology, nuclear medicine and radiotherapy, home care, and genetics and metabolic and the
26 addition of the new workflows, dynamics, and policies into the existing setting posed an
27 additional burden to specialized expert healthcare providers.
28
29
30
31
32
33
34
35
36
37
38

39 Other organizational initiatives include conducting regular “Quality Days” to share experiences
40 and recognize and reward distinguished contributions of staff and departments.
41
42
43

44 Several strategies were initiated to enhance the communication between top management and the
45 frontline staff to identify and discuss facilitators and barriers, including an “Open Day,” “Patient
46 Safety Leadership Walk-Rounds,” and “Breakfast with the Chief Executive Officer.”
47
48
49

50 An occurrence variance reporting (OVR) system was launched as a paper-based system in 2010,
51 followed by the first round of PSC survey in 2012¹⁴ that inspired the organization to gradually
52
53
54
55
56
57

1
2
3 improve the OVR system through its digitalization in 2013 with multiple functionalities such as
4
5 anonymous reporting and reporting feedback.²²
6

7 8 Suggestions to improve patient safety 9

10 The respondents believed that increasing staffing; offering rewards to staff demonstrating
11
12 excellence in performance; providing more training and education to staff, managers, and
13
14 leaders; and improving communications and teamwork within and across departments will
15
16 improve patient safety. Implementing a horizontal chain of command, more support from the
17
18 management and leadership, giving feedback on events reported so that staff can see tangible
19
20 results from their efforts, and supporting a non-punitive culture are important factors in
21
22 enhancing the PSC in the organization. Some respondents indicated that some ways that
23
24 managers can improve patient safety include using an open-door leadership approach, rewarding
25
26 and empowering staff demonstrating initiative and excellence in patient safety, and using walk-
27
28 rounds as a way to show the leaders' commitment to engaging with the staff.
29
30
31
32
33

34 In addition, the leaders proposed continuing education and training to staff in addition to regular
35
36 meetings to discuss quality and patient safety as this would encourage more reporting. Additional
37
38 ways to improve the PSC in the organization included increasing the space and number of
39
40 machines available to decrease waiting time and accommodate urgent cases.
41
42
43

44 Some suggestions proposed by the interviewees for improving patient safety included better
45
46 management of patient flow to avoid crowding and reduce waiting time, better triage and patient
47
48 assessment, better implementation of policies and procedures, and improved infrastructure. In
49
50 addition, supporting departmental initiatives relating to patient safety and disseminating the
51
52 results of those initiatives, and empowering the staff to obtain their commitment can enhance
53
54 patient safety.
55
56
57

1
2
3 Other suggestions included brainstorming sessions for the staff, initiating projects spearheaded
4 by the departments to improve patient safety, and hosting a “Quality Day” particularly targeting
5 newly recruited staff, and hosting huddles within departments to identify areas for improvement.
6
7 In addition, more suggestions included empowering the quality committee, creating ambassadors
8 in the hospital supported by the hospital leadership, and making the work and impact of these
9 ambassadors more visible.
10
11
12
13
14
15

16 **DISCUSSION AND CONCLUSIONS**

17
18
19
20 This is the first study to progressively document results of a survey on PSC in four consecutive
21 rounds, particularly in Saudi Arabia. The findings of this study can inform hospital leaders on the
22 changes in performance as a result of quality improvement plans and accreditation.
23
24
25
26

27
28 The study revealed a general positive trend in scores as we compare results from 2012 to those
29 from 2019. A spike in the scores was observed in 2015, and this was attributed to the
30 accreditation survey conducted that year and the corresponding leadership visibility and support
31 during that time. The introduction of an OVR system further reinforced the organizational shift
32 in culture toward one that was centered on creating system changes valuing patient safety.
33
34
35
36
37
38

39
40 At the regional level, many scholars have evaluated PSC in different settings. Similar to our
41 results, their findings showed that the areas of strength were “teamwork within units” and
42 “organizational learning–continuous improvement.” Alternatively, the areas for improvement
43 were “promoting non-punitive response to error,” “encouraging the openness of communication
44 among healthcare professionals,” and “facilitating hospital handoffs and transition process.”^{4 6 17}
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
18 23-25 At the international level, similar areas for improvement were identified in hospitals.²⁶⁻²⁸

1
2
3 We observed a persistent discrepancy between the results of the outcome measures “frequency of
4 events reported” and “non-punitive response to errors” throughout the four PSC surveys, despite
5 the high reported average percentage of “feedback and communication about errors.” This may
6 reflect the residual internal conflict that the hospital staff have between their desire to report
7 errors on one hand and the predominant culture of blame on the other hand.
8
9

10 A further gap was noticed as management support for patient safety had one of the highest
11 proportions of positive responses, but non-punitive response to error had one of the lowest
12 percentages of positive responses. A possible explanation for this would be that the low
13 proportion of positive non-punitive response to error was related to the fact that approximately
14 half the responses indicated that no events had been reported (Table 4). Moreover,
15 communicating about and addressing safety issues between healthcare leaders and frontliners
16 and developing training programs to help them understand their roles in the development of PSC
17 could fill this gap.²⁹
18
19

20 Accreditation in itself is a major undertaking for hospitals that subjects the hospital to a learning
21 curve for which the major benefits are gained in the first three years with decreasing perceived
22 challenges after ten years.³⁰ Hospitals can and should leverage on accreditation as a stepping
23 stone to achieve organization-wide improvement in practice and patient outcomes. As
24 demonstrated in the study results, steady improvements were observed with time, and while
25 results appeared to have stabilized, the gained benefits extended beyond the mere numbers to a
26 wider and more tangible organizational change in culture and staff perceptions.
27
28

29 Clearly, the aforementioned organizational changes led to tangible results in the overall PSC. A
30 culture assessment in itself raises staff awareness, promotes a safe patient environment, and
31 helps the hospital establish a common vocabulary and shared goals.⁸ Teamwork within and
32
33

1
2
3 across units, organizational learning, managerial support, overall perception of safety, and
4
5 feedback and communication about error consistently were areas of strength. This reflects and
6
7 reinforces hospital commitment to address areas supporting improvement of the overall culture
8
9 of safety.^{4 14}

10
11
12
13 Despite some improvements, it is of note that non-punitive response to error, staffing, and
14
15 communication and openness consistently remain the lowest-scoring composites.^{4 14} Non-
16
17 punitive response to error gives hospital staff the confidence to report without fear of punishment
18
19 and is critical for the hospital to collect data on system deficiencies.³¹ Sub-optimal staffing is
20
21 potentially the most critical challenge in ensuring patient safety as overworked staff can suffer
22
23 from lapses in performance.³²⁻³⁵ Poor communication in healthcare can lead to avoidable
24
25 outcomes compromising patient care quality.³⁶ Clearly, the hospital should address challenges on
26
27 these composites as they have an undeniable impact on patient care outcomes.³⁷

28
29
30
31
32 With this in mind, building a stronger culture requires committed and willing hospital leaders
33
34 engaged in strategies that strengthen the systems governing the organizational culture.^{38 39} Strong
35
36 leaders view adverse errors as opportunities for learning and system improvement,^{40 41} which
37
38 would ultimately build a more solid foundation for safety. A shared organizational culture
39
40 fostering safety is built around a foundation of shared decision making, leadership commitment,
41
42 mutual trust, and opportunities for learning and growth.⁴² Collectively, these comprise some
43
44 traits making an organization more adaptable and receptive to addressing emerging challenges.³⁸
45
46 Hospital leaders should collectively address challenges such poor communication, lack of visible
47
48 leadership, poor teamwork, lack of reporting systems, inadequate analysis of adverse events, and
49
50 inadequate staff knowledge about safety.²⁴

1
2
3 A consistent improvement in PSC requires maintaining the improvements achieved so far.
4
5 Patient safety is a moving target and failing to consistently address the areas for improvement at
6
7 the hospital-wide level will not allow the hospital to maintain the gains achieved to date.
8
9
10 Leadership commitment is more important than ever to consistently and visibly support PSC.
11
12 The study results confirm that quality improvement initiatives can lead to visible changes in the
13
14 hospital culture and that consistent managerial support can help the hospital in maintaining these
15
16 improvements. Hospital leaders and managers can leverage on organizational changes to make
17
18 lasting changes to the system and create a spillover effect on the entire healthcare team.
19
20
21 Navigating these changes meticulously will allow hospital leaders to sow the seeds of change
22
23 and maintain the gains of the implemented interventions (Box 1).
24
25
26

27 **Box 1. Strategies or interventions to promote improvements in patient safety.**
28
29

- | |
|--|
| <ul style="list-style-type: none">30 ▪ Leveraging on accreditation as a stepping stone to achieve organization-wide improvement in practice and patient outcomes31 ▪ Leadership engagement, support, and commitment governing the organizational culture32 ▪ Sharing and viewing adverse errors as opportunities for learning and system improvement and offering regular feedback on reported events33 ▪ Shared decision making, mutual trust, and identifying opportunities for learning and growth34 ▪ Launching and maintaining quality improvement initiatives35 ▪ Improving the human resources regulations, workflows, and staffing36 ▪ Empowering the quality management department through having direct liaison and representation in all executive boards and committees37 ▪ Investing in the infrastructure of the organization to meet patient safety standards and goals38 ▪ Conducting regular quality activities (e.g., “Quality Days”) to communicate and exchange experiences and success stories, and recognizing improvement achievements throughout the organization39 ▪ Enhancing communication between the top management and frontline staff by conducting regular activities like “Patient Safety Leadership Walk-Rounds,” “Open Day with the Executives,” and “Breakfast with the Executives”40 ▪ Digitalizing the health information system and the incident reporting system41 ▪ Providing continuous training and education42 ▪ Improving communications and teamwork within and across departments (e.g., multidisciplinary meetings, focus group discussions, and information and communication technology utilization)43 ▪ Developing a clear policy, training, and workflow involving all managerial levels to support a just culture44 ▪ Enhancing the patient flow process through establishing a unit solely working on patient flow and case management |
|--|
- 45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Strengths and limitations

The strengths of our study include using a mixed method to assess PSC progressively in four consecutive rounds in Saudi Arabia over a period of eight years. It provides us with insight on key areas for improving PSC and persistent challenges in healthcare organizations.

Conducting this study in a tertiary care teaching multi-site hospital, may not fully reflect patient safety culture in Saudi Arabia. Despite the low response rate in 2019, the study sample size is more than the minimum sample size recommended by the AHRQ. Moreover, we used the mixed-methods design to minimize the occurrence of spurious correlations due to the common-method variance that is often inherited in any survey instrument.

Implications for patient safety research

Further patient safety research is needed as there is a shortage in the literature understanding how hospital safety culture impacts patient and worker safety outcomes. Furthermore, the research is moving toward linking the results of measuring safety culture with patient, worker, and health system outcomes.

ACKNOWLEDGMENTS

We thank the department heads, healthcare providers, managers, and executives who participated in our study. In addition, we thank the quality management coordinators for their participation in the data collection, namely, Mariam Napuli and Estrelita Dela Cruz. This work was supported by the Research Chair for Evidence-Based Health Care and Knowledge Translation, Deanship of Scientific Research, King Saud University, Riyadh, Saudi Arabia.

CONTRIBUTORS

1
2
3 MT contributed to the study design, writing of the first draft of the manuscript and review. MT,
4 MB, BZ, and RA contributed to data collection and review. FA and YA critically reviewed the
5 manuscript for important intellectual content. DJ contributed to data analysis and review. FE
6 contributed to study design, data analysis, manuscript development, and review. All authors read
7 and approved the final version of the manuscript.
8
9

14 **FUNDING**

15
16
17
18 This research received no specific grant from any funding agency in the public, commercial or
19 not-for-profit sectors.
20
21

22 **COMPETING INTERESTS**

23
24
25
26 There are no conflicts of interest to declare.
27
28

29 **PATIENT CONSENT FOR PUBLICATION**

30
31
32 Patient consent for the publication of this study is not required.
33
34

35 **ETHICAL APPROVAL**

36
37
38 The study protocol and instruments were reviewed and approved (no. E19-4315) by the
39 institutional review board (IRB) of the King Saud University College of Medicine.
40
41
42
43

44 **PROVENANCE AND PEER REVIEW**

45
46
47 The study was not commissioned and externally peer-reviewed.
48
49

50 **DATA SHARING STATEMENT**

51
52
53 All relevant data were made available as tables and figures in this article and other previously
54 published articles.
55
56
57

1
2
3 **REFERENCES**
4
5

- 6 1. Kellogg KM, Hettinger Z, Shah M, et al. Our current approach to root cause analysis: is it contributing
7 to our failure to improve patient safety? *BMJ Qual Saf* 2017;26(5):381-87. doi: 10.1136/bmjqs-
8 2016-005991
- 9 2. Bates DW, Singh H. Two decades since to err is human: an assessment of progress and emerging
10 priorities in patient safety. *Health Affairs* 2018;37(11):1736-43.
- 11 3. Organization WH. Patient safety: making health care safer: World Health Organization, 2017.
- 12 4. Alswat K, Abdalla RAM, Titi MA, et al. Improving patient safety culture in Saudi Arabia (2012-2015):
13 trending, improvement and benchmarking. *BMC Health Serv Res* 2017;17(1):516. doi:
14 10.1186/s12913-017-2461-3
- 15 5. Neto AV, Silva MD, De Medeiros SG, et al. Patient Safety Culture In Health Organizations: Scoping
16 Review. *International Archives of Medicine* 2017;10 doi: doi: 10.3823/2344
- 17 6. Elmontsri M, Almashrafi A, Banarsee R, et al. Status of patient safety culture in Arab countries: a
18 systematic review. *BMJ Open* 2017;7(2):e013487. doi: 10.1136/bmjopen-2016-013487
- 19 7. Sorra J GL, Streagle S, et al. . AHRQ Hospital Survey on Patient Safety Culture: User's Guide.: (Prepared
20 by Westat, under Contract No. HHS290201300003C). AHRQ Publication No. 15-0049-EF
21 (Replaces 04-0041). Rockville, MD: Agency for Healthcare Research and Quality, 2016.
- 22 8. Nieva VF, Sorra J. Safety culture assessment: a tool for improving patient safety in healthcare
23 organizations. *Qual Saf Health Care* 2003;12 Suppl 2:ii17-23. doi: 10.1136/qhc.12.suppl_2.ii17
- 24 9. Gershon RR, Stone PW, Bakken S, et al. Measurement of organizational culture and climate in
25 healthcare. *J Nurs Adm* 2004;34(1):33-40.
- 26 10. Gutberg J, Berta W. Understanding middle managers' influence in implementing patient safety
27 culture. *BMC health services research* 2017;17(1):1-10.
- 28 11. Sine DM, Northcutt N. Interactive Qualitative Assessment of Patient Safety Culture Survey Scores.
29 *Journal of Patient Safety* 2008;4(2):78-83. doi: 10.1097/PTS.0b013e3181730322
- 30 12. Kirk S, Parker D, Claridge T, et al. Patient safety culture in primary care: developing a theoretical
31 framework for practical use. *Qual Saf Health Care* 2007;16(4):313-20. doi:
32 10.1136/qshc.2006.018366
- 33 13. Hodgen A, Ellis, L., Churruca, K., & Bierbaum, M. . Safety culture assessment in health care: a review
34 of the literature on safety culture assessment modes. Sydney: Australian Commission on Safety
35 and Quality in Health Care, 2017.
- 36 14. El-Jardali F, Sheikh F, Garcia NA, et al. Patient safety culture in a large teaching hospital in Riyadh:
37 baseline assessment, comparative analysis and opportunities for improvement. *BMC Health Serv*
38 *Res* 2014;14:122. doi: 10.1186/1472-6963-14-122
- 39 15. Sorra JS, Dyer N. Multilevel psychometric properties of the AHRQ hospital survey on patient safety
40 culture. *BMC Health Serv Res* 2010;10:199. doi: 10.1186/1472-6963-10-199
- 41 16. Alsalem G, Bowie P, Morrison J. Assessing safety climate in acute hospital settings: a systematic
42 review of the adequacy of the psychometric properties of survey measurement tools. *BMC*
43 *Health Serv Res* 2018;18(1):353. doi: 10.1186/s12913-018-3167-x
- 44 17. El-Jardali F, Jaafar M, Dimassi H, et al. The current state of patient safety culture in Lebanese
45 hospitals: a study at baseline. *Int J Qual Health Care* 2010;22(5):386-95. doi:
46 10.1093/intqhc/mzq047
- 47 18. Khater WA, Akhu-Zaheya LM, Al-Mahasneh SI, et al. Nurses' perceptions of patient safety culture in
48 Jordanian hospitals. *Int Nurs Rev* 2015;62(1):82-91. doi: 10.1111/inr.12155
- 49
50
51
52
53
54
55
56
57
58
59
60

19. Wami SD, Demssie AF, Wassie MM, et al. Patient safety culture and associated factors: A quantitative and qualitative study of healthcare workers' view in Jimma zone Hospitals, Southwest Ethiopia. *BMC Health Serv Res* 2016;16:495. doi: 10.1186/s12913-016-1757-z
20. Liu C, Liu W, Wang Y, et al. Patient safety culture in China: a case study in an outpatient setting in Beijing. *BMJ Qual Saf* 2014;23(7):556-64. doi: 10.1136/bmjqs-2013-002172
21. Listyowardojo TA, Yan X, Leyshon S, et al. A safety culture assessment by mixed methods at a public maternity and infant hospital in China. *J Multidiscip Healthc* 2017;10:253-62. doi: 10.2147/JMDH.S136943
22. Abu Alrub AM AY, Titi MA, May ACA, Shaikh F, Baksh MM, El-Jardali F. Barriers and enablers in implementing an electronic incident reporting system in a teaching hospital: a case study from Saudi Arabia. Manuscript submitted for publication, 2019.
23. Alahmadi HA. Assessment of patient safety culture in Saudi Arabian hospitals. *Qual Saf Health Care* 2010;19(5):e17. doi: 10.1136/qshc.2009.033258
24. Ammouri AA, Tailakh AK, Muliira JK, et al. Patient safety culture among nurses. *Int Nurs Rev* 2015;62(1):102-10. doi: 10.1111/inr.12159
25. Badr HE, AlFadalah, T., & El-Jardali, F. Towards promoting patient safety practices: Baseline assessment of patient safety culture in three private hospitals. *International Journal of Healthcare Management* 2017;1-8. doi: 10.1080/20479700.2017.1390958
26. Famolaro T, Yount ND, Burns W, et al. Hospital survey on patient safety culture: 2018 user comparative database report: Agency for Healthcare Research and Quality 2018.
27. Okuyama JHH, Galvao TF, Silva MT. Healthcare Professional's Perception of Patient Safety Measured by the Hospital Survey on Patient Safety Culture: A Systematic Review and Meta-Analysis. *ScientificWorldJournal* 2018;2018:9156301. doi: 10.1155/2018/9156301
28. Nie Y, Mao X, Cui H, et al. Hospital survey on patient safety culture in China. *BMC health services research* 2013;13(1):228.
29. Quenon J-L, Vacher A, Faget M, et al. Exploring the role of managers in the development of a safety culture in seven French healthcare facilities: a qualitative study. *BMC Health Services Research* 2020;20:1-11.
30. Pomey MP, Lemieux-Charles L, Champagne F, et al. Does accreditation stimulate change? A study of the impact of the accreditation process on Canadian healthcare organizations. *Implement Sci* 2010;5:31. doi: 10.1186/1748-5908-5-31 [published Online First: 2010/04/28]
31. Smits M, Wagner C, Spreeuwenberg P, et al. Measuring patient safety culture: an assessment of the clustering of responses at unit level and hospital level. *Qual Saf Health Care* 2009;18(4):292-6. doi: 10.1136/qshc.2007.025965 [published Online First: 2009/08/05]
32. Sanders J, Cook G. ABC of Patient Safety. 2007: Oxford: Blackwell.
33. Baldwin DC, Jr., Daugherty SR, Tsai R, et al. A national survey of residents' self-reported work hours: thinking beyond specialty. *Acad Med* 2003;78(11):1154-63. doi: 10.1097/00001888-200311000-00018 [published Online First: 2003/11/08]
34. Aiken LH, Sloane DM, Bruyneel L, et al. Nurse staffing and education and hospital mortality in nine European countries: a retrospective observational study. *The lancet* 2014;383(9931):1824-30.
35. Sturm H, Rieger MA, Martus P, et al. Do perceived working conditions and patient safety culture correlate with objective workload and patient outcomes: A cross-sectional explorative study from a German university hospital. *PloS one* 2019;14(1):e0209487.
36. Vermeir P, Vandijck D, Degroote S, et al. Communication in healthcare: a narrative review of the literature and practical recommendations. *Int J Clin Pract* 2015;69(11):1257-67. doi: 10.1111/ijcp.12686 [published Online First: 2015/07/07]
37. Lee SE, Scott LD, Dahinten VS, et al. Safety culture, patient safety, and quality of care outcomes: A literature review. *Western journal of nursing research* 2019;41(2):279-304.

- 1
2
3 38. Chassin MR, Loeb JM. High-reliability health care: getting there from here. *Milbank Q*
4 2013;91(3):459-90. doi: 10.1111/1468-0009.12023 [published Online First: 2013/09/14]
5 39. Smetzer J, Baker C, Byrne FD, et al. Shaping systems for better behavioral choices: lessons learned
6 from a fatal medication error. *Jt Comm J Qual Patient Saf* 2010;36(4):152-63. doi:
7 10.1016/s1553-7250(10)36027-2 [published Online First: 2010/04/21]
8 40. Clarke JR, Lerner JC, Marella W. The role for leaders of health care organizations in patient safety.
9 *Am J Med Qual* 2007;22(5):311-8. doi: 10.1177/1062860607304743
10 41. Parand A, Dopson S, Vincent C. The role of chief executive officers in a quality improvement : a
11 qualitative study. *BMJ Open* 2013;3(1) doi: 10.1136/bmjopen-2012-001731 [published Online
12 First: 2013/01/08]
13 42. Blignaut AJ, Coetzee SK, Klopper HC. Nurse qualifications and perceptions of patient safety and
14 quality of care in South Africa. *Nurs Health Sci* 2014;16(2):224-31. doi: 10.1111/nhs.12091
15 [published Online First: 2013/10/10]
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Supplementary 1S. Semi-structured interview questions for qualitative data

1. Have you realized any changes in patient safety culture in your department? Why?
2. What are your suggestions to improve patient safety in your department? Why?
3. In your opinion what are the factors that influence the patient safety culture in healthcare?

Probing question:

- a) How do you think these factors influence the patient safety culture?
 - b) Who do you think are responsible for these factors?
 - c) Do you receive feedback and action taken?
 - d) Do you feel empowered?
4. Based on the current level of patient safety culture in your hospital what do you think is an important factor to improve patient safety culture?

Followed by:

- a. Do you think these can be achieved at all hospital`s levels?
 - b. How do you think these factors could be incorporated with the hospital`s activities
5. What are the barriers and how to overcome them?
 6. Do you have any other comments?

For managerial:

7. Which managerial decisions were taken to help improving patient safety culture?
8. What are the additional areas leadership should support to enhance patient safety?

Supplementary table 1S. Interview schedule.

Position	Date and time	Location (Site A, Site B, or Both)
Chief Executive Officer	Aug-2-2019	Corporate Level
Chief Medical Officer	July-30-2019	Corporate Level
Hospital Medical Director	July-30-2019	Site C
Deputy Medical Director	July-30-2019	Site A, Site B
Nursing Corporate Director	July-25-2019	Corporate Level
Nursing Hospital Director	July-25-2019	Site A, Site B, Site C
Nursing Corporate Deputy Director	July-26-2019	Corporate Level
Chief Operation Officer	Aug-6-2019	Corporate Level
Chief Administrative and Financial Officer	Aug-13-2019	Corporate Level
Chief Academic Officer	Aug-4-2019	Corporate Level
Safety and Security Supervisor	July-21-2019	Site A, Site B
Pharmacy Services Corporate Supervisor	July-14-2019	Corporate Level
Pharmacy Services Hospital Director	July-14-2019	Site A, Site B
Human Resources, Executive director	July-2-2019	Corporate Level
Human Resources, Hospital Director	July-6-2019	Site B
Patient Affairs, Hospital Director	July-10-2019	Site A
Medical Laboratory and Pathology Director	Aug-5-2019	Corporate Level
Radiology and Medical Imaging Department Director	July-23-2019	Site A
Operating Room Department Chairman	Jun-28-2019	Site B
Emergency Medicine Department Chairman	Jun-25-2019	Site A, Site B
Medicine Department Chairman	Jun-29-2019	Site A
Surgery Department Chairman	Jun-20-2019	Site A
Nursing Service Manager	July-19-2019	Site B (2)
Health Education Center	July-19-2019	Site A
Front-liner staff – Two Focus group (15 members per group) multidisciplinary composition.	July-15-2019 July-16-2019	2 focus groups in Sites A and C and 2 in Site B

Supplementary table 2S. Summary of the main themes and subthemes identified during the interviews.

Theme	Subthemes
Changes in PSC in the facility	<ul style="list-style-type: none"> • Change in overall culture • More awareness among staff regarding patient safety • Improved communication • Increased error reporting • Improved understanding and following hospital policies and procedures • Improved care processes within the hospital • Provision of guides and manuals • More awareness of risks and how to avert them • Addressing staff fears about the punitive culture • Clearer job descriptions, roles, and responsibilities • Making staff less resistant to change • Improved teamwork across the hospital
Factors influencing the PSC in healthcare	<ul style="list-style-type: none"> • Communication between staff and patients and within and across departments • Staff continued education and training • Teamwork within and across units, particularly when it came to handoffs and transitions • Leadership and administrative support • Monitoring and evaluation including feedback on patient safety indicators • Number of staff available • Robust incident reporting system and receiving feedback on reported events • Clarity and correct implementation of policies and procedures • Implementing a system for monitoring patient safety goals • Improving workflow within specific departments
Barriers to establishing PSC and how to overcome them	<ul style="list-style-type: none"> • Poor communication within and across departments • Punitive culture • Limited staff awareness • Staff resistance to change • Staff shortage • Language barrier • Limited cooperation from physicians • Poor training of staff • Budget and space constraints
Organizational changes since 2012	<ul style="list-style-type: none"> • Changes in the human resources regulations and workflows (from the traditional civil service to a self-operation system) • Preparation for dual accreditation (i.e., national and international) • Separation of the hospitals' healthcare quality from the academic medical education quality • Infrastructure expansions throughout the organization • Launching of new healthcare services • Conducting regular "Quality Days" • Strategic initiatives to enhance communication between top management and frontline staff (e.g., "Patient Safety Leadership Walk-Rounds," "Open Day," and "Breakfast with the Chief Executive Officer") • Digitalizing the incident reporting system

Suggestions to improve patient safety	<ul style="list-style-type: none">• Increasing staffing• Offering continuous training and education• Improving communications and teamwork within and across departments• Implementing a horizontal chain of command• More support from management and leadership• Offering feedback on events reported• Supporting a non-punitive culture• Using an open-door leadership approach• Rewarding and empowering staff• Using walk-rounds• Regular meetings to discuss quality and patient safety• Increasing the space and number of machines available• Better management of patient flow• Better triage and patient assessment• Better implementation of policies and procedures and improved infrastructure• Supporting departmental patient safety initiatives• Staff empowerment to obtain their commitment• Conducting brainstorming sessions for staff and projects spearheaded by departments to improve patient safety and hosting a “Quality Day”• Empowering the quality committee and creating ambassadors in the hospital supported by hospital leadership
--	--

BMJ Open

Staying Ahead of the Curve: Navigating Changes and Maintaining Gains in Patient Safety Culture—A Mixed-Methods Study

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-044116.R1
Article Type:	Original research
Date Submitted by the Author:	05-Feb-2021
Complete List of Authors:	Titi, Maher; King Saud University Medical City, Quality Management; King Saud University Medical City, Research Chair for Evidence Based Health Care and Knowledge Translation, Baksh, Maram; King Saud University Medical City, Quality Management Zubairi, Beena; King Saud University Medical City, Quality Management Abdalla , Rawia; King Saud University Medical City, Quality Management Alsaif, Faisal ; King Saud University College of Medicine, Surgery Amer, Yasser; King Saud University Medical City, Quality Management; King Saud University Medical City, Research Chair for Evidence Based Health Care and Knowledge Translation, Jamal, Diana; American University of Beirut Faculty of Health Sciences, Health Management and Policy El-Jardali, Fadi; American University of Beirut Faculty of Health Sciences, Health Management and Policy; McMaster University, Health Research Methods, Evidence, and Impact,
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Medical management, Public health, Evidence based practice, Health policy, Qualitative research
Keywords:	Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Health & safety < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Organisational development < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Change management < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

SCHOLARONE™
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Staying Ahead of the Curve: Navigating Changes and Maintaining Gains in Patient Safety Culture—A Mixed-Methods Study

Names and affiliations of contributing authors

First name	Middle name (or abbreviation)	Family name	Affiliation(s)	ORCID	Email address
Maher	Abdelraheim	Titi*	<ul style="list-style-type: none"> Quality Management Department, King Saud University Medical City, Riyadh, Saudi Arabia Research Chair for Evidence Based Health Care and Knowledge Translation, King Saud University (034), P. O. Box 7805, Riyadh 11472, Saudi Arabia 	https://orcid.org/0000-0003-1079-4118	Mahertiti1980@gmail.com mtiti@ksu.edu.sa
Maram	Mohammed	Baksh	<ul style="list-style-type: none"> Quality Management Department, King Saud University Medical City, King Saud University (034), P. O. Box 7805, Riyadh 11472, Saudi Arabia 	https://orcid.org/0000-0001-9846-2964	mbaksh@ksu.edu.sa
Beena	----	Zubairi	<ul style="list-style-type: none"> Quality Management Department, King Saud University Medical City, King Saud University (034), P. O. Box 7805, Riyadh 11472, Saudi Arabia 	http://orcid.org/0000-0002-8994-6884	bzubairi@ksu.edu.sa
Rawia	Ahmad Mustafa	Abdalla	<ul style="list-style-type: none"> Quality Management Department, King Saud University Medical City, King Saud University (034), P. O. Box 7805, Riyadh 11472, Saudi Arabia 	https://orcid.org/0000-0002-3158-0437	Rawia85@yahoo.com
Faisal	Abdullah	Alsaif	<ul style="list-style-type: none"> Department of Surgery, College of Medicine, King Saud University (034), P. O. Box 7805, Riyadh 11472, Saudi Arabia 	https://orcid.org/0000-0002-2522-1681	falsai1972@gmail.com
Yasser	Sami	Amer	<ul style="list-style-type: none"> Quality Management Department, King Saud University Medical City, Riyadh, Saudi Arabia Pediatrics Department, King Saud University Medical City, Riyadh, Saudi Arabia Research Chair for Evidence Based Health Care and Knowledge Translation, King Saud University (034), P. O. Box 7805, Riyadh 11472, Saudi Arabia 	https://orcid.org/0000-0003-4097-2317	yassersamiamer@gmail.com
Diana		Jamal	<ul style="list-style-type: none"> Department of Health Management and Policy, American University of Beirut P.O.Box 11-0236, Riad El-Solh, Beirut 1107 2020 Lebanon 	https://orcid.org/0000-0002-1852-1643	dj06@aub.edu.lb

Fadi	---	El-Jardali	<ul style="list-style-type: none">• Faculty of Health Sciences, American University of Beirut P.O.Box 11-0236, Riad El-Solh, Beirut 1107 2020 Lebanon• Department of Health Research Methods, Evidence, and Impact, McMaster University, Hamilton, Canada	https://orcid.org/0000-0002-4084-6524	fe08@aub.edu.lb
------	-----	------------	--	---	--

- * Corresponding Author: Maher Abdelraheim Titi,
 - email: mtiti@ksu.edu.sa, mahertiti1980@gmail.com
 - Phone: Office: +966-114691342, Mobile: +966-568310277

- Running title: Patient Safety Culture Changes
- Word count for the abstract: 257 words
- Word count for the text of the manuscript: 4,683 words

- **Keywords:**

patient safety culture, patient safety, healthcare quality, Saudi Arabia

1
2
3 **Staying Ahead of the Curve: Navigating Changes and Maintaining Gains in Patient Safety**
4
5 **Culture—A Mixed-Methods Study**
6
7

8 Running title: Patient Safety Culture Changes
9

10 Word count for the abstract: 257 words
11

12 Word count for the text of the entire manuscript: 4,683 words
13
14
15

16 **ABSTRACT**
17

18
19 **Objectives:** This study examines how the results of the Hospital Survey on Patient Safety
20 Culture changed between 2012 and 2019 and identifies organizational factors affecting these
21 changes.
22
23
24

25
26 **Design:** The study combined the use of quantitative surveys of staff and qualitative interviews
27 with hospital leadership. Secondary data analysis was performed for previous surveys.
28
29

30 **Setting:** This study was conducted in a tertiary care teaching multi-site hospital in Riyadh, Saudi
31 Arabia.
32
33
34

35 **Participants:** One thousand hospital staff participated in the survey. Thirty-one executive board
36 members and directors and four focus groups of frontliners were qualitatively interviewed.
37
38

39 **Primary and Secondary Outcome Measures:** Twelve safety culture dimensions were assessed
40 to study the patient safety culture as perceived by the healthcare professionals. An additional
41 semi-structured interview was conducted to identify organizational factors, changes, and barriers
42 affecting the patient safety culture. Furthermore, suggestions to improve patient safety were
43 proposed.
44
45
46
47
48
49

50
51
52 **Results:** Comparing the results revealed a general positive trend in scores from 2012 to those
53 from 2019. The areas of strength included teamwork within and across units, organizational
54
55
56
57

1
2
3 learning, managerial support, overall perception of safety, and feedback and communication
4
5 about error. Non-punitive response to error, staffing, and communication and openness
6
7 consistently remain the lowest-scoring composites. Interview results revealed that organizational
8
9 changes may have influenced the answers of the participants on some survey composites.
10
11

12
13 **Conclusions:** Patient safety is a moving target with areas for improvement that are continuously
14
15 identified. Effective quality improvement initiatives can lead to visible changes in the patient
16
17 safety culture in a hospital, and consistent leadership commitment and support can maintain
18
19 these improvements.
20
21
22
23
24
25

26 **STRENGTHS AND LIMITATIONS OF THIS STUDY**

- 27
28
29 • This is the first study to explore the results of a survey on patient safety culture in four
30
31 consecutive rounds in Saudi Arabia.
32
- 33
34 • This study covered almost all categories of healthcare workers, including managers and
35
36 care providers.
37
- 38
39 • A mixed-methods design was used to overcome the methodological limitations of the lack
40
41 of a single tool that could capture the complexities of patient safety culture.
42
- 43
44 • A lower response rate was observed for the 2019 assessment and compared to previous
45
46 years; therefore, the results of this study should be interpreted with caution.
47
- 48
49 • To minimize the occurrence of spurious correlations due to common-method variance in
50
51 the survey instrument, we have utilized a mixed-methods design rather than simply
52
53 applying the survey method alone.
54
55
56
57
58
59
60

INTRODUCTION

Despite considerable investments in quality healthcare and patient safety over the past decades, patients continue to experience preventable harm, and the current status of patient safety around the world remains alarming.¹ Recent studies have identified adverse events as a serious global issue affecting patient safety. Therefore, identifying and preventing potential harm is a top priority of healthcare organizations, thus enhancing patient outcomes. Evidence suggests that a strong culture of patient safety in a hospital is associated with fewer adverse events and improved patient outcomes.^{2 3}

It is increasingly recognized that healthcare organizations around the world, regardless of economic status, are closely focusing on measuring and enhancing their Patient Safety Culture(PSC).⁴⁻⁶ PSC is assessed to provide information to managers and healthcare policymakers; in addition, it can help organizations understand the present state of their PSC and analyze the PSC trends over time. Measuring PSC is important for identifying areas of strength and areas needing prioritization for interventions, evaluating the impact of patient safety initiatives or programs, and tracking changes over time. Furthermore, it improves staff perceptions, develops a better understanding of patient safety, fulfills accreditation or regulatory requirements, and conducts internal and external benchmarking.^{2 7 8}

Measuring PSC is still considered relatively difficult and is well documented in the literature.^{9 10} No single tool can sufficiently assess all major components of PSC and provide leaders with clear guidance on how PSC can be effectively improved.^{11 12} To explore the complex concept of PSC in healthcare, the mixed-methods approach, by collecting and analyzing both quantitative and qualitative data, can be viewed as the most appropriate approach to increase the robustness

1
2
3 of the results and gain a deeper understanding of PSC while offsetting the intrinsic weaknesses
4 associated with each approach when used on its own.^{5 13}
5
6

7
8 Given the clear need for continuous monitoring of PSC and better understanding of how
9 organizational culture changes after multiple interventions and milestones, we used the mixed-
10 methods approach to assess PSC progressively over a period of eight years. To our knowledge,
11 assessing PSC has not yet been performed at this scale, and this study can provide us insight on
12 the key areas to improve regarding PSC in healthcare organizations and persistent challenges in
13 PSC that are difficult to change rapidly with simple interventions. This study reports on the
14 organizational survey results of 2019 and compares these results to those of three previous
15 assessments at the same multi-site facility (2012,¹⁴ 2015,⁴ and 2017).
16
17
18
19
20
21
22
23
24
25
26
27

28 **Objectives**

29
30
31 The overall objective of this study is to examine how the results of the HSOPSC survey changed
32 between 2012 and 2019 and identify organizational factors affecting these changes. Specifically,
33 this study provides an overview of the results of multiple assessments of PSC surveys at a large
34 multi-site healthcare facility in Riyadh, Kingdom of Saudi Arabia.
35
36
37
38
39

40 **METHODS**

41 **Design**

42
43
44 In this study, a mixed-methods research design was used to achieve the most comprehensive
45 understanding possible of the research problem. The study combined the use of quantitative
46 surveys and qualitative interviews with hospital staff of different levels to achieve the study
47 objectives. Additionally, we conducted a cross-validation of the results with those of the
48 previous surveys conducted at the same site in 2012¹⁴, 2015⁴, and 2017.
49
50
51
52
53
54
55
56
57

Setting

This study was conducted in a tertiary care teaching multi-site hospital having a capacity of 1,160 beds and approximately 9,000 employees. It receives referral patients from all over the country.

The hospital has three sites, varying in size and location; site A has 1,060 beds and offers free medical services with a wide range of specialties, and site B has 100 beds and offers complementary services to those of site A. Site C offers inpatient and outpatient dental services.

Quantitative component

The tool (questionnaire)

The tool used was adapted from the HSOPSC developed by the AHRQ.⁷ The survey is available in English and Arabic. The internal consistency and reliability of the original English version were tested using Cronbach's alpha that ranged between 0.62 and 0.85.^{15 16} However, the Arabic version was adapted and used in similar studies in Lebanon,¹⁷ Saudi Arabia,^{4 14} and Jordan,¹⁸ and its reliability was measured using Cronbach's coefficient that ranged between 0.45 and 0.81.¹⁷

The HSOPSC includes 42 items grouped into 12 composites. In addition to the composites, the survey includes two questions asking respondents to provide an overall grade on patient safety and to indicate the number of reported events over the past 12 months.

Participants

The survey randomly sampled staff targeting 50% (4500) of clinical and non-clinical employees similar to the previous two assessment rounds by El-Jardali et al.¹⁴ and Alswat et al.⁴

Data collection

1
2
3 Data collection for the 2017 and 2019 surveys were performed in two assessment rounds: from
4
5 September to November in 2017 and from February to April in 2019. Data collection for the
6
7 2012 and 2015 surveys was described in studies by El-Jardali et al.¹⁴ and Alswat et al.⁴
8
9

10 The survey was made available in hard copies and the electronic format for all respondents. The
11
12 hard-copy surveys were provided in sealed envelopes for respondents who could not access the
13
14 electronic-format surveys. The first page of the survey included the consent form and an
15
16 explanation of the purpose of the survey. Employees were not asked to sign the consent form or
17
18 any other page of the survey; they were asked to return the hard copies of the survey in a sealed
19
20 envelope.
21
22
23

24 25 Data analysis

26
27
28 Data were analyzed using Statistical Package for the Social Sciences, version 25.0, (IBM Corp.,
29
30 Armonk, NY, USA); *p* values of > 0.05 were used to denote significance. In addition to
31
32 answering the study tool, respondents were asked to provide some background demographic
33
34 information about themselves (age, gender, marital status, profession, educational level, clinical
35
36 experience, working hours during the week, working area, and whether they were trained on
37
38 patient safety). The composite items were measured using a 5-point Likert response scale of
39
40 agreement, with the scores ranged from “strongly disagree” to “strongly agree” or frequencies
41
42 that ranged from “never” to “always.” Consequently, the HSOPSC comprised the following two
43
44 single-item measures:
45
46
47

- 48
49 ▪ The patient safety grade, scored with a 5-point Likert scale ranging from “excellent” to
50
51 “failing”
- 52
53 ▪ The number of adverse events reported by the respondent during the last year, ranging
54
55 from “no events” to “21 events or more.”
56
57

1
2
3 The results were presented as percentages of the average positive responses (e.g., strongly
4 agree/agree and most of the time/always) for each survey item; negatively worded items were
5 reversed when computing their percentages. The percent positives for each subscale were
6 computed as follows: [(number of positive responses/total number of responses on the item) ×
7 100%]. Missing responses were excluded when displaying the percentages of the responses to
8 the survey items.⁷ Composites that had at least 70% positive responses were considered areas of
9 strength, whereas those with less scores were considered areas for improvement. Our decision to
10 consider our cut-off point to be 70% for patient safety areas in need for improvement was based
11 on the results of our previous two PSC surveys conducted in the same facility. Composite scores
12 were calculated by summing the item scores and dividing the sum by the number of items within
13 the composite.
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

29 Descriptive statistics such as frequency and percentage were used for data summarization. Given
30 that the data were not normally distributed for all composites, the independent Kruskal–Wallis H
31 test was used to determine whether a significant difference exists between survey composites
32 between the 2012, 2015, 2017, and 2019 datasets. The chi-square test was used to determine
33 whether a significant difference exists between the 2012 and 2019 datasets for the questions
34 regarding the number of events and patient safety grade.
35
36
37
38
39
40
41
42

43 **Qualitative component**

44 **Interview tool**

45
46
47 Semi-structured interviews were conducted to probe the topic deeper, make the interviews more
48 conversational, and make sure all interview participants, including leaders and frontline staff, were
49 asked the same questions. An interview guide was adapted and modified from previous studies,¹⁹⁻²¹
50 and an external expert review followed (see online Supplementary 1S).
51
52
53
54
55
56
57
58
59
60

Participants

We used a purposive sampling technique to recruit interviewees. Thirty-one semi-structured individual interviews were conducted with all executive board members in Medical City, medical directors in each site, directors of the main clinical and supportive services departments, and four focus groups of frontliners. Those identified to participate had received an invitation email including all the information about the voluntary nature of participation and an explanation of the entire study phase and a request to record the interviews, which were conducted in a private place (see online supplementary table 1S).

Data collection

The interviews were scheduled according to the participants' availability. All interviews were conducted in English. Each interview lasted 15–30 minutes and was recorded using a digital voice recorder. A research assistant transcribed the recorded data as soon as each interview was completed. The accuracy of the transcriptions was reviewed (and corrected if necessary) by the researchers. In addition, field notes were taken, and the responses and views of the participants were summarized at the end of each interview to ensure that they reflected their views.

Participation was voluntary and the interview tool did not collect any information that could be used to identify the participants. Participant confidentiality was maintained at every stage of the study.

Data analysis

Thematic analysis was conducted for the data collected through the interviews. Coding, which was done by two members of the research team, was initially conducted by breaking responses

1
2
3 into similar concepts and ideas. Minimal discrepancies were found after cross-checking the work
4
5 between the two team members. Disagreements were discussed until a consensus was achieved.
6
7 This was followed by axial coding, which comprised the organization of the emerging concepts
8
9 into themes and categories.
10
11

12 13 **Patient and public involvement**

14
15
16 No patients were involved in this study.
17

18 19 **RESULTS**

20 21 22 **Survey results**

23 24 25 **General results**

26
27
28 In total, 2,694 questionnaires from the 2017 assessment round and 1,000 from the 2019
29
30 assessment round were completed, giving a response rate of 59.8% and 22.2%, respectively.
31
32 However, the response rates in the previous two rounds were 85.7%¹⁴ and 57.6%⁴ (Table 1). The
33
34 discrepancy in the response rate was observed as we stopped the second data collection in 2019
35
36 as the organization was preparing for the final survey of dual accreditation by both national and
37
38 international accreditation bodies. We were concerned about the potential biases or false positive
39
40 responses that might arise during the deep engagement of all of the staff at all levels in these
41
42 accreditation activities.
43
44

45
46
47 Despite the low response rate in 2019, the study sample size is more than the minimum sample
48
49 size recommended by the AHRQ.⁷ Moreover, all three previous PSC surveys in 2012, 2015, and
50
51 2017 conducted at our institution showed good response rates of >50% (85.7%, 57.6%, and
52
53
54
55
56
57

59.8% respectively). In this study, we reflected and interpreted the four PSC surveys simultaneously.

Most respondents in all four assessment rounds were nurses (50.1%, 78.3%, 56%, and 61.7%, respectively). Most respondents were female in the four assessment rounds that could be explained by the fact that the approximate proportion of our nursing staff is approximately 27% of the total number of employees including both clinical and non-clinical staff. Moreover, our nursing staff predominantly comprised females (87%). Approximately half of the respondents were aged between 30 and 45 years (45.3%, 46.4%, 61.6%, and 65.3% in 2012, 2015, 2017, and 2019, respectively).

Among the study respondents, the majority held a Bachelor's degree (38.9%, 56.2%, 61.4%, and 59.2% in years 2012, 2015, 2017, and 2019, respectively), whereas 43.6% in 2012 and 25.4% in 2017 had diplomas. A large proportion of the respondents in the 2015 and 2017 assessment rounds had 6–10 years of experience in the hospital (32.3% and 27.5%, respectively), whereas 30.5% and 35.4% had 1–5 years of experience in the hospital in the 2012 and 2019 assessment rounds, respectively. Additionally, approximately half of the staff reported working in medical units in all assessment rounds, except in 2012, where 27.1% of the respondents were working in the hospital administration. Moreover, more than 75% of the personnel had been in direct contact with patients and working 40–60 hours a week in all four assessment surveys.

Table 1. Sociodemographic and professional characteristics of the respondents along with the number of events reported and patient safety grades.

Sociodemographic and professional characteristics	2012 ^[14] N (%) Total no. 2,572	2015 ^[4] N (%) Total no. 2,592	2017 N (%) Total no. 2,694	2019 N (%) Total no. 1,000
Work area/unit where respondents spend most of their work time				
Many different hospital units/no specific unit	13 (0.5)	21 (0.8)	36 (1.5)	2 (0.2)
Administrative	697 (27.1)	138 (5.4)	357 (14.6)	50 (5.1)
Medical	536 (20.8)	1332 (51.9)	1193 (48.8)	517 (53.1)

Surgical	503 (19.6)	786 (30.6)	406 (16.6)	267 (27.4)
Diagnostics	277 (10.8)	99 (3.9)	399 (16.3)	101 (10.4)
Other	545 (21.2)	191 (7.4)	54 (2.2)	36 (3.7)
Missing	1	25	249	27
Respondents' positions at the hospital				
Administrator/manager/director/head	92 (3.6)	47 (1.9)	96 (3.7)	21 (2.2)
Physician	158 (6.1)	141 (5.6)	191 (7.4)	91(9.4)
Specialist	80 (3.1)	61 (2.4)	164 (6.4)	57 (5.9)
Coordinator	13 (0.5)	10 (0.4)	55 (2.1)	14 (1.4)
Assistant/aide	62 (2.4)	39 (1.6)	65 (2.5)	18 (1.9)
Pharmacist	56 (2.2)	36 (1.4)	79 (3.1)	4 (0.4)
Therapist	52 (2.0)	1 (0.0)	32 (1.2)	18 (1.9)
Registered nurse	1287 (50.1)	1969 (78.3)	1443 (56.0)	596 (61.7)
Resident/PG/intern	67 (2.6)	64 (2.5)	92 (3.6)	29 (3)
Assistant/clerk/secretary/facilitator	133 (5.2)	28 (1.1)	60 (2.3)	28 (2.9)
Technician	308 (12.0)	52 (2.1)	236 (9.2)	76 (7.9)
Other	264 (10.3)	67 (2.7)	62 (2.4)	14 (1.4)
Missing	0	77	119	34
Experience in current hospital (years)				
Less than 1 year	463 (18.6)	133 (5.3)	553 (21.8)	77 (8)
1–5 years	758 (30.5)	741 (29.6)	640 (25.2)	339 (35.4)
6–10 years	622 (25.0)	809 (32.3)	698 (27.5)	262 (27.4)
11–15 years	290 (11.7)	348 (13.9)	353 (13.9)	151(15.8)
16–20 years	136 (5.5)	222 (8.9)	154 (6.1)	73 (7.6)
21 years or more	217 (8.7)	252 (10.1)	139 (5.5)	55 (5.7)
Missing	86	87	157	43
Experience in current work area (years)				
Less than 1 year	436 (17.3)	313 (12.6)	432 (17.0)	50 (5.2)
1–5 years	986 (39.1)	520 (21.0)	404 (15.9)	233 (24.3)
6–10 years	528 (20.9)	781 (31.5)	827 (32.5)	319 (33.3)
11–15 years	245 (9.7)	358 (14.5)	411 (16.1)	165 (17.2)
16–20 years	159 (6.3)	233 (9.4)	249 (9.8)	106 (11.1)
21 years or more	168 (6.7)	272 (11)	223 (8.8)	85 (8.9)
Missing	50	115	148	42
Hours worked per week				
Less than 20 hours per week	55 (2.3)	25 (1.0)	58 (2.3)	24 (2.5)
20–39 hours per week	203 (8.3)	148 (6.0)	214 (8.6)	87 (9.2)
40–60 hours per week	2180 (89.4)	2280 (92.9)	2206 (89.0)	838 (88.3)
Missing	134	139	216	51
Job involving direct contact with patients				
Yes, I typically have direct interaction or contact with patients.	1956 (76.1)	2229 (90.9)	2045(82.2)	808 (85.7)

No, I typically do not have direct interaction or contact with patients.	615 (23.9)	224 (9.1)	443(17.8)	135 (14.3)
Missing	1	139	206	57
Gender				
Male	728 (28.6)	398 (15.9)	628 (24.6)	234 (24.6)
Female	1820 (71.4)	2103 (84.1)	1925 (75.4)	719 (75.4)
Missing	24	91	141	47
Age (years)				
Below 30 year old	854 (33.7)	925 (37.3)	558 (22.7)	175 (18.2)
Between 30 and 45 years old	1148 (45.3)	1152 (46.4)	1515 (61.6)	628 (65.3)
Between 46 and 55 years old	401(15.8)	253 (10.2)	282 (11.5)	114 (11.9)
Above 55 years old	133 (5.2)	151 (6.1)	103 (4.2)	44 (4.6)
Missing	36	111	236	39
Marital Status				
Single	752 (30.3)	851 (34.2)	807(31.5)	309 (32)
Married	1682 (67.8)	1602 (64.4)	1703 (66.4)	633 (65.6)
Divorced/Separated	25 (1.0)	16 (0.6)	33 (1.3)	13 (1.3)
Widowed	14 (0.6)	13 (0.5)	13 (0.5)	6 (0.6)
Other	8(0.3)	6 (0.2)	7(0.3)	4 (0.4)
Missing	91	104	131	35
Educational level				
Under high school level	14 (0.6)	2 (0.1)	11 (0.4)	3 (0.3)
High school level	62 (2.5)	7 (0.3)	25 (1.0)	4 (0.4)
Diploma level	1082 (43.6)	836 (33.5)	654 (25.4)	267 (27.6)
Bachelor's degree	966 (38.9)	1403 (56.2)	1579 (61.4)	574 (59.2)
Master's degree	124 (5.0)	127 (5.1)	160 (6.2)	61 (6.3)
Doctorate degree	112 (4.5)	102 (4.1)	110 (4.3)	53 (5.5)
Others	122 (4.9)	19 (0.8)	32 (1.2)	7(0.7)
Missing	90	96	123	31

PSC dimensions

PSC dimensions were examined (Table 2). The dimensions with the highest average response rates, considered areas of strength, were “organizational learning–continuous improvement” ranging from 79.6% to 83.9% between 2012 and 2019 and “teamwork within units” that scored more than 75% in all four assessments. Furthermore, the average response rates of the “hospital

management support for patient safety” dimension were 70.4%, 75.3%, 73.3%, and 73.8% in 2012, 2015, 2017, and 2019, respectively.

All surveys had the same areas requiring improvement. There is a general trend toward improvement in percent positive scores from 2012 to 2019, except for the “frequency of events reported” composite. Note that “overall perception of patient safety” was found to be an area for improvement in 2012; however, it was shown to be an area of strength in 2019. The lowest reported average percentage was below 30% for “non-punitive response to error” throughout the four assessment rounds. Additionally, staffing and communication openness were the next lowest-scoring composites across the four assessment rounds (Table 2).

Patient safety culture dimensions	2012	2015	2017	2019
Teamwork within units	78.5%	84.8%	81.6%	84.5%
Supervisor/manager expectations and actions promoting patient safety	60.6%	60.8%	60.4%	64.0%
Organizational learning–continuous improvement	79.6%	86.3%	82.2%	83.9%
Management support for patient safety	70.4%	75.3%	73.3%	73.8%
Overall perceptions of patient safety	65.3%	59.5%	59.6%	61.7%
Feedback and communication about error	63.3%	71.8%	68.7%	72.0%
Communication openness	42.9%	45.0%	48.5%	49.8%
Frequency of events reported	59.4%	68.8%	64.9%	66.6%
Teamwork across units	61.6%	67.0%	64.1%	65.8%
Staffing	35.1%	33.8%	30.8%	31.9%
Handoffs and transitions	51.5%	55.8%	49.6%	52.2%
Non-punitive response to error	26.8%	24.8%	27.2%	27.2%

Comparing the results from 2012 to those of 2019

The Kruskal–Wallis test was conducted to compare the results from all four surveys (Table 3). As a result, significant differences lie across the four surveys with the exception to the

1
2
3 “supervisor/manager expectations and actions promoting patient safety” and “non-punitive
4 response to error” composites. A comparison of the mean scores between 2012 and 2019 showed
5 a steady increase in composite scores. The statistical significance of these differences varied
6 according to the survey composites; however, it is worth noting that the highest scores were
7 observed in 2015.
8
9

10
11 “Non-punitive response to error” and “staffing” remained the lowest-scoring composites in all
12 assessment rounds, but the difference is not statistically significant. The highest-ranking composite
13 for all surveys was “organizational learning—continuous improvement.”
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47

Table 3. The Kruskal–Wallis test comparing the composite scores in 2012 to those in 2019.

Patient safety culture dimensions	2012		2015		2017		2019 KAUH		Independent sample Kruskal–Wallis test	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	P-Value	Adjusted significance Bonferroni correction
Frequency of events reporting	3.64	1.16	4.04	1.54	3.83	1.1	3.82	1.14	<0.001	abce
Overall perceptions of safety	3.43	0.59	3.6	1.56	3.47	0.6	3.51	0.62	<0.001	bce
Supervisor/manager expectations and actions promoting safety	3.46	0.65	3.57	1.34	3.48	0.67	3.54	0.68	0.003	c
Organizational learning–continuous improvement	3.89	0.69	4.16	1.14	4.02	0.61	4.03	0.58	<0.001	abc
Teamwork within hospital units	3.85	0.75	4.04	0.71	4.00	0.67	4.03	0.63	<0.001	abc
Communication openness	3.25	0.85	3.45	1.08	3.43	0.82	3.43	0.89	<0.001	abcde
Feedback and communication about errors	3.73	0.95	4.11	1.1	3.95	0.87	4.04	0.8	<0.001	abcd
Non-punitive response to error	2.68	0.81	2.76	1.26	2.69	0.87	2.68	0.87	0.123	
Staffing	2.84	0.62	3.02	1.19	2.68	0.63	2.73	0.65	<0.001	bce
Hospital management support for patient safety	3.69	0.76	3.85	1.05	3.77	0.67	3.78	0.66	0.030	
Teamwork across hospital units	3.52	0.71	3.76	1.36	3.58	0.67	3.60	0.66	0.002	bc
Hospital handoffs and transitions	3.36	0.79	3.82	2.29	3.27	0.87	3.34	0.82	0.001	bc
Letter indicates a <i>p</i> -value <0.05 adjusted significance using the Bonferroni correction for multiple tests.										
a	2012–2017									
b	2012–2019									
c	2012–2015									
d	2017–2019									
e	2017–2015									
f	2019–2015									

Patient safety grade and event reporting

The percentage of the respondents who evaluated patient safety in their work area/unit as excellent/very good increased from 69.5% in 2012 to 74.1% in 2019 ($p < 0.001$) (Table 4). Moreover, Table 4 displays the percentages of the number of events reported; the analysis indicated that the percentages of the respondents who reported no events in the last 12 months decreased by almost 7.4% from 2012 to 2019 ($p < 0.001$) and the percentages of reporting more than five event reports increased from 6.4% in 2012 to 8% in 2019.

Table 4: Chi-Square test comparing patient safety grades and the number of events reported between 2012 and 2019.

Patient safety grade	2012 N (%)	2015 N (%)	2017 N (%)	2019 N (%)	Sig
Poor/failing	119 (4.8%)	57 (2.3%)	67 (2.6%)	18 (1.9%)	$p < 0.001$
Acceptable	632 (25.6%)	654 (26.6%)	614 (24.2%)	230 (24%)	
Excellent/very good	1714 (69.5)	1747 (71.1%)	1859 (73.2%)	710 (74.1%)	
Number of events reported					
No event reports	1275 (52.7%)	1364 (55.8%)	1180 (47.3%)	427 (45.3%)	$p < 0.001$
1 to 5 event reports	992 (41%)	940 (38.4%)	1092 (43.8%)	440 (46.7%)	
>5 event reports	154 (6.4%)	141 (5.8%)	223 (8.9%)	75 (8%)	

Interview results

Characteristics of the respondents

In total, 91 healthcare professionals were interviewed, among whom 10 were executive leaders (corporate level), 8 were hospital directors, and 13 were departmental chairpersons and directors.

The researcher conducted interviews with four focus groups consisting of 60 front-liner staff. Most of the staff in the focus groups comprised physicians, pharmacists, nurses, and allied health technicians. The qualitative data obtained from the interviews were thematically categorized into the following: realizing changes in PSC in the facility/departments, factors influencing the PSC in

1
2
3 healthcare, barriers to establishing PSC and how to overcome them, and suggestions to improve
4 patient safety (see online supplementary table 2S).
5
6

7 Changes in PSC in the facility

8
9
10 The interviews showed that the respondents believe that the PSC in their department has
11 changed. Some of the documented observed changes included changes in the overall culture,
12 more awareness among the staff, improved communication, increased error reporting, improved
13 understanding and following hospital policies and procedures, improved care processes within
14 the hospital, provision of guides and manuals, more awareness of the risks and how to avert
15 them, and addressing staff fears about the punitive culture.
16
17
18
19
20
21
22
23

24
25 Some factors reported by the respondents that may have contributed to these changes include the
26 multiple accreditation surveys and the introduction of an electronic event reporting system.
27
28

29
30 Despite the learning curve associated with both interventions, the respondents reported that it has
31 allowed them to streamline their operations, enabled them to provide quality care to patients, and
32 improved the process of error reporting.
33
34
35

36
37 The respondents indicated that the main changes they saw in their department was the
38 amendment of existing policies and procedures, the clarification of job descriptions and roles,
39 and making the staff less resistant to change. In addition, hospital leadership observed better
40 communication and teamwork across the hospital and better staff awareness on the topic.
41
42
43
44
45
46

47 Factors influencing PSC in healthcare

48
49
50 According to the hospital leaders, making patients at the core of the PSC is the first step in the
51 right direction. This requires support at the leadership and administration levels. Hospital leaders
52 reported that accreditation was one of the factors that changed the culture within their
53
54
55
56
57

1
2
3 organization. It has improved communication between the staff and patients and within and
4
5 across departments, staff training (including continuing education and training), and teamwork
6
7 within and across units, particularly regarding handoffs and transitions. These were all
8
9 considered factors that could support and improve event reporting and eventually lead to
10
11 performance improvement.
12
13

14
15 Some of the factors that may influence PSC reported by the respondents included leadership and
16
17 administrative support, monitoring and evaluation (including feedback) of patient safety
18
19 indicators, the number of staff available, improvement of the error reporting system, receiving
20
21 feedback on reported events, clarity and correct implementation of policies and procedures,
22
23 implementing a system for monitoring patient safety goals, and improving workflow within
24
25 specific departments. Some respondents reported that all hospital staff is responsible for
26
27 improving the PSC, whereas other respondents placed the responsibility solely on the leaders and
28
29 managers.
30
31
32

33
34 Barriers to establishing PSC and how to overcome them
35
36

37 Some of the documented barriers to establishing a PSC included poor communication within and
38
39 across departments, punitive culture, limited staff awareness, staff resistance to change, staff
40
41 shortages, language barrier, limited cooperation from physicians, and poor training of staff.
42
43

44 Other less frequently mentioned barriers included staffing, budget, and space.
45
46

47 Organizational changes since 2012
48
49

50 The slight dip in the composite scores in 2017 could be attributed to several organization-wide
51
52 factors that occurred during this transition period. Introducing new human resources regulations
53
54 and workflows during the shift from the traditional civil service to a self-operation system, a
55
56
57

1
2
3 national trend throughout the Kingdom, had a significant impact on recruitment, re-contracting,
4 and staff retention and turnover.
5
6

7
8 Another factor was the preparation for the dual accreditation (i.e., national and international) final
9 surveys that were scheduled in December 2017 had several positive and negative implications.
10
11 Overwhelming the staff with changes and escalations of improvement during a short period were
12 among the negative effects.
13
14
15
16

17
18 The outset of 2017 witnessed the separation of the administration of the university hospitals
19 (healthcare) quality from the academic (medical education) quality. Widespread expansions
20 throughout the organization occurred including the opening of a new large eastern building that
21 added to the total bed capacity of the hospital, increasing from 948 in 2014 to 1,160 in 2019.
22
23 This added bed capacity had an additional burden to all categories of healthcare providers,
24 especially physicians and nurses. The launching of new innovative healthcare services such as
25 oncology, nuclear medicine and radiotherapy, home care, and genetics and metabolic and the
26 addition of the new workflows, dynamics, and policies into the existing setting posed an
27 additional burden to specialized expert healthcare providers.
28
29
30
31
32
33
34
35
36
37
38

39 Other organizational initiatives include conducting regular “Quality Days” to share experiences
40 and recognize and reward distinguished contributions of staff and departments.
41
42
43

44 Several strategies were initiated to enhance the communication between top management and the
45 frontline staff to identify and discuss facilitators and barriers, including an “Open Day,” “Patient
46 Safety Leadership Walk-Rounds,” and “Breakfast with the Chief Executive Officer.”
47
48
49

50 An occurrence variance reporting (OVR) system was launched as a paper-based system in 2010,
51 followed by the first round of PSC survey in 2012¹⁴ that inspired the organization to gradually
52
53
54
55
56
57

1
2
3 improve the OVR system through its digitalization in 2013 with multiple functionalities such as
4
5 anonymous reporting and reporting feedback.²²
6

7 8 Suggestions to improve patient safety 9

10 The respondents believed that increasing staffing; offering rewards to staff demonstrating
11
12 excellence in performance; providing more training and education to staff, managers, and
13
14 leaders; and improving communications and teamwork within and across departments will
15
16 improve patient safety. Implementing a horizontal chain of command, more support from the
17
18 management and leadership, giving feedback on events reported so that staff can see tangible
19
20 results from their efforts, and supporting a non-punitive culture are important factors in
21
22 enhancing the PSC in the organization. Some respondents indicated that some ways that
23
24 managers can improve patient safety include using an open-door leadership approach, rewarding
25
26 and empowering staff demonstrating initiative and excellence in patient safety, and using walk-
27
28 rounds as a way to show the leaders' commitment to engaging with the staff.
29
30
31
32
33

34 In addition, the leaders proposed continuing education and training to staff in addition to regular
35
36 meetings to discuss quality and patient safety as this would encourage more reporting. Additional
37
38 ways to improve the PSC in the organization included increasing the space and number of
39
40 machines available to decrease waiting time and accommodate urgent cases.
41
42
43

44 Some suggestions proposed by the interviewees for improving patient safety included better
45
46 management of patient flow to avoid crowding and reduce waiting time, better triage and patient
47
48 assessment, better implementation of policies and procedures, and improved infrastructure. In
49
50 addition, supporting departmental initiatives relating to patient safety and disseminating the
51
52 results of those initiatives, and empowering the staff to obtain their commitment can enhance
53
54 patient safety.
55
56
57

1
2
3 Other suggestions included brainstorming sessions for the staff, initiating projects spearheaded
4 by the departments to improve patient safety, and hosting a “Quality Day” particularly targeting
5 newly recruited staff, and hosting huddles within departments to identify areas for improvement.
6
7 In addition, more suggestions included empowering the quality committee, creating ambassadors
8 in the hospital supported by the hospital leadership, and making the work and impact of these
9 ambassadors more visible.
10
11
12
13
14
15

16 **DISCUSSION AND CONCLUSIONS**

17
18
19
20 This is the first study to progressively document results of a survey on PSC in four consecutive
21 rounds, particularly in Saudi Arabia. The findings of this study can inform hospital leaders on the
22 changes in performance as a result of quality improvement plans and accreditation.
23
24
25
26

27
28 The study revealed a general positive trend in scores as we compare results from 2012 to those
29 from 2019. A spike in the scores was observed in 2015, and this was attributed to the
30 accreditation survey conducted that year and the corresponding leadership visibility and support
31 during that time. The introduction of an OVR system further reinforced the organizational shift
32 in culture toward one that was centered on creating system changes valuing patient safety.
33
34
35
36
37
38

39
40 At the regional level, many scholars have evaluated PSC in different settings. Similar to our
41 results, their findings showed that the areas of strength were “teamwork within units” and
42 “organizational learning–continuous improvement.” Alternatively, the areas for improvement
43 were “promoting non-punitive response to error,” “encouraging the openness of communication
44 among healthcare professionals,” and “facilitating hospital handoffs and transition process.”^{4 6 17}
45
46
47
48
49
50

51
52 ^{18 23-25} At the international level, similar areas for improvement were identified in hospitals.²⁶⁻²⁸
53
54
55
56
57
58
59
60

1
2
3 We observed a persistent discrepancy between the results of the outcome measures “frequency of
4 events reported” and “non-punitive response to errors” throughout the four PSC surveys, despite
5 the high reported average percentage of “feedback and communication about errors.” This may
6 reflect the residual internal conflict that the hospital staff have between their desire to report
7 errors on one hand and the predominant culture of blame on the other hand.
8
9

10 A further gap was noticed as management support for patient safety had one of the highest
11 proportions of positive responses, but non-punitive response to error had one of the lowest
12 percentages of positive responses. A possible explanation for this would be that the low
13 proportion of positive non-punitive response to error was related to the fact that approximately
14 half the responses indicated that no events had been reported (Table 4). Moreover,
15 communicating about and addressing safety issues between healthcare leaders and frontliners
16 and developing training programs to help them understand their roles in the development of PSC
17 could fill this gap.²⁹
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33

34 Accreditation in itself is a major undertaking for hospitals that subjects the hospital to a learning
35 curve for which the major benefits are gained in the first three years with decreasing perceived
36 challenges after ten years.³⁰ Hospitals can and should leverage on accreditation as a stepping
37 stone to achieve organization-wide improvement in practice and patient outcomes. As
38 demonstrated in the study results, steady improvements were observed with time, and while
39 results appeared to have stabilized, the gained benefits extended beyond the mere numbers to a
40 wider and more tangible organizational change in culture and staff perceptions.
41
42
43
44
45
46
47
48
49
50

51 Clearly, the aforementioned organizational changes led to tangible results in the overall PSC. A
52 culture assessment in itself raises staff awareness, promotes a safe patient environment, and
53 helps the hospital establish a common vocabulary and shared goals.⁸ Teamwork within and
54
55
56
57

1
2
3 across units, organizational learning, managerial support, overall perception of safety, and
4
5 feedback and communication about error consistently were areas of strength. This reflects and
6
7 reinforces hospital commitment to address areas supporting improvement of the overall culture
8
9 of safety.^{4 14}

10
11
12
13 Despite some improvements, it is of note that non-punitive response to error, staffing, and
14
15 communication and openness consistently remain the lowest-scoring composites.^{4 14} Non-
16
17 punitive response to error gives hospital staff the confidence to report without fear of punishment
18
19 and is critical for the hospital to collect data on system deficiencies.³¹ Sub-optimal staffing is
20
21 potentially the most critical challenge in ensuring patient safety as overworked staff can suffer
22
23 from lapses in performance.³²⁻³⁵ Poor communication in healthcare can lead to avoidable
24
25 outcomes compromising patient care quality.³⁶ Clearly, the hospital should address challenges on
26
27 these composites as they have an undeniable impact on patient care outcomes.³⁷

28
29
30
31
32 With this in mind, building a stronger culture requires committed and willing hospital leaders
33
34 engaged in strategies that strengthen the systems governing the organizational culture.^{38 39} Strong
35
36 leaders view adverse errors as opportunities for learning and system improvement,^{40 41} which
37
38 would ultimately build a more solid foundation for safety. A shared organizational culture
39
40 fostering safety is built around a foundation of shared decision making, leadership commitment,
41
42 mutual trust, and opportunities for learning and growth.⁴² Collectively, these comprise some
43
44 traits making an organization more adaptable and receptive to addressing emerging challenges.³⁸
45
46 Hospital leaders should collectively address challenges such poor communication, lack of visible
47
48 leadership, poor teamwork, lack of reporting systems, inadequate analysis of adverse events, and
49
50 inadequate staff knowledge about safety.²⁴

1
2
3 A consistent improvement in PSC requires maintaining the improvements achieved so far.
4
5 Patient safety is a moving target and failing to consistently address the areas for improvement at
6
7 the hospital-wide level will not allow the hospital to maintain the gains achieved to date.
8
9
10 Leadership commitment is more important than ever to consistently and visibly support PSC.
11
12 The study results confirm that quality improvement initiatives can lead to visible changes in the
13
14 hospital culture and that consistent managerial support can help the hospital in maintaining these
15
16 improvements. Hospital leaders and managers can leverage on organizational changes to make
17
18 lasting changes to the system and create a spillover effect on the entire healthcare team.
19
20
21 Navigating these changes meticulously will allow hospital leaders to sow the seeds of change
22
23 and maintain the gains of the implemented interventions (Box 1).
24
25
26

27 **Box 1. Strategies or interventions to promote improvements in patient safety.**
28
29

- | |
|--|
| <ul style="list-style-type: none">30 ▪ Leveraging on accreditation as a stepping stone to achieve organization-wide improvement in practice and patient outcomes31 ▪ Leadership engagement, support, and commitment governing the organizational culture32 ▪ Sharing and viewing adverse errors as opportunities for learning and system improvement and offering regular feedback on reported events33 ▪ Shared decision making, mutual trust, and identifying opportunities for learning and growth34 ▪ Launching and maintaining quality improvement initiatives35 ▪ Improving the human resources regulations, workflows, and staffing36 ▪ Empowering the quality management department through having direct liaison and representation in all executive boards and committees37 ▪ Investing in the infrastructure of the organization to meet patient safety standards and goals38 ▪ Conducting regular quality activities (e.g., “Quality Days”) to communicate and exchange experiences and success stories, and recognizing improvement achievements throughout the organization39 ▪ Enhancing communication between the top management and frontline staff by conducting regular activities like “Patient Safety Leadership Walk-Rounds,” “Open Day with the Executives,” and “Breakfast with the Executives”40 ▪ Digitalizing the health information system and the incident reporting system41 ▪ Providing continuous training and education42 ▪ Improving communications and teamwork within and across departments (e.g., multidisciplinary meetings, focus group discussions, and information and communication technology utilization)43 ▪ Developing a clear policy, training, and workflow involving all managerial levels to support a just culture44 ▪ Enhancing the patient flow process through establishing a unit solely working on patient flow and case management |
|--|
- 45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Strengths and limitations

The strengths of our study include using a mixed method to assess PSC progressively in four consecutive rounds in Saudi Arabia over a period of eight years. It provides us with insight on key areas for improving PSC and persistent challenges in healthcare organizations.

Conducting this study in a tertiary care teaching multi-site hospital, may not fully reflect patient safety culture in Saudi Arabia. Despite the low response rate in 2019, the study sample size is more than the minimum sample size recommended by the AHRQ. Moreover, we used the mixed-methods design to minimize the occurrence of spurious correlations due to the common-method variance that is often inherent in any survey instrument.

Implications for patient safety research

Further patient safety research is needed as there is a shortage in the literature understanding how hospital safety culture impacts patient and worker safety outcomes. Repeated assessments of patient safety culture can provide unparalleled insight for hospital leaders into organizational changes resulting from quality improvement initiatives. Future research should link the results of patient safety culture assessments with with patient, worker, and health system outcomes.

ACKNOWLEDGMENTS

We thank the department heads, healthcare providers, managers, and executives who participated in our study. In addition, we thank the quality management coordinators for their participation in the data collection, namely, Mariam Napuli and Estrelita Dela Cruz. This work was supported by the Research Chair for Evidence-Based Health Care and Knowledge Translation, Deanship of Scientific Research, King Saud University, Riyadh, Saudi Arabia.

CONTRIBUTORS

1
2
3 MT contributed to the study design, writing of the first draft of the manuscript, and review. MT,
4 MB, BZ, and RA contributed to data collection and review. FA and YA critically reviewed the
5 manuscript for important intellectual content. DJ contributed to data analysis and review. FE
6 contributed to study design, data analysis, manuscript development, and review. All authors read
7 and approved the final version of the manuscript.
8
9

14 **FUNDING**

15
16
17
18 This work was supported by [the Research Chair for Evidence-Based Health Care and Knowledge
19 Translation, Deanship of Scientific Research, King Saud University, Riyadh, Saudi Arabia] No.
20 [E19-4315] .
21
22
23

24 **COMPETING INTERESTS**

25
26
27
28 There are no conflicts of interest to declare.
29
30

31 **PATIENT AND PUBLIC INVOLVEMENT STATEMENT**

32
33
34 Patients were not involved in this study and as such their consent was not applicable as the sample
35 involved only hospital staff.
36
37

38 **ETHICAL APPROVAL**

39
40
41
42 The study protocol and instruments were reviewed and approved (no. E19-4315) by the
43 institutional review board (IRB) of the King Saud University College of Medicine.
44
45
46
47

48 **PROVENANCE AND PEER REVIEW**

49
50
51
52 The study was not commissioned and externally peer reviewed.
53
54

55 **DATA SHARING STATEMENT**

All relevant data were made available as tables and figures in this article and other previously published articles.

REFERENCES

1. Kellogg KM, Hettinger Z, Shah M, et al. Our current approach to root cause analysis: is it contributing to our failure to improve patient safety? *BMJ Qual Saf* 2017;26(5):381-87. doi: 10.1136/bmjqs-2016-005991
2. Bates DW, Singh H. Two decades since to err is human: an assessment of progress and emerging priorities in patient safety. *Health Affairs* 2018;37(11):1736-43.
3. Organization WH. Patient safety: making health care safer: World Health Organization, 2017.
4. Alswat K, Abdalla RAM, Titi MA, et al. Improving patient safety culture in Saudi Arabia (2012-2015): trending, improvement and benchmarking. *BMC Health Serv Res* 2017;17(1):516. doi: 10.1186/s12913-017-2461-3
5. Neto AV, Silva MD, De Medeiros SG, et al. Patient Safety Culture In Health Organizations: Scoping Review. *International Archives of Medicine* 2017;10 doi: doi: 10.3823/2344
6. Elmontsri M, Almashrafi A, Banarsee R, et al. Status of patient safety culture in Arab countries: a systematic review. *BMJ Open* 2017;7(2):e013487. doi: 10.1136/bmjopen-2016-013487
7. Sorra J GL, Streagle S, et al. . AHRQ Hospital Survey on Patient Safety Culture: User's Guide.: (Prepared by Westat, under Contract No. HHS290201300003C). AHRQ Publication No. 15-0049-EF (Replaces 04-0041). Rockville, MD: Agency for Healthcare Research and Quality, 2016.
8. Nieva VF, Sorra J. Safety culture assessment: a tool for improving patient safety in healthcare organizations. *Qual Saf Health Care* 2003;12 Suppl 2:ii17-23. doi: 10.1136/qhc.12.suppl_2.ii17
9. Gershon RR, Stone PW, Bakken S, et al. Measurement of organizational culture and climate in healthcare. *J Nurs Adm* 2004;34(1):33-40.
10. Gutberg J, Berta W. Understanding middle managers' influence in implementing patient safety culture. *BMC health services research* 2017;17(1):1-10.
11. Sine DM, Northcutt N. Interactive Qualitative Assessment of Patient Safety Culture Survey Scores. *Journal of Patient Safety* 2008;4(2):78-83. doi: 10.1097/PTS.0b013e3181730322
12. Kirk S, Parker D, Claridge T, et al. Patient safety culture in primary care: developing a theoretical framework for practical use. *Qual Saf Health Care* 2007;16(4):313-20. doi: 10.1136/qshc.2006.018366
13. Hodgen A, Ellis, L., Churruca, K., & Bierbaum, M. . Safety culture assessment in health care: a review of the literature on safety culture assessment modes. Sydney: Australian Commission on Safety and Quality in Health Care, 2017.
14. El-Jardali F, Sheikh F, Garcia NA, et al. Patient safety culture in a large teaching hospital in Riyadh: baseline assessment, comparative analysis and opportunities for improvement. *BMC Health Serv Res* 2014;14:122. doi: 10.1186/1472-6963-14-122
15. Sorra JS, Dyer N. Multilevel psychometric properties of the AHRQ hospital survey on patient safety culture. *BMC Health Serv Res* 2010;10:199. doi: 10.1186/1472-6963-10-199
16. Alsalem G, Bowie P, Morrison J. Assessing safety climate in acute hospital settings: a systematic review of the adequacy of the psychometric properties of survey measurement tools. *BMC Health Serv Res* 2018;18(1):353. doi: 10.1186/s12913-018-3167-x
17. El-Jardali F, Jaafar M, Dimassi H, et al. The current state of patient safety culture in Lebanese hospitals: a study at baseline. *Int J Qual Health Care* 2010;22(5):386-95. doi: 10.1093/intqhc/mzq047

18. Khater WA, Akhu-Zaheya LM, Al-Mahasneh SI, et al. Nurses' perceptions of patient safety culture in Jordanian hospitals. *Int Nurs Rev* 2015;62(1):82-91. doi: 10.1111/inr.12155
19. Wami SD, Demssie AF, Wassie MM, et al. Patient safety culture and associated factors: A quantitative and qualitative study of healthcare workers' view in Jimma zone Hospitals, Southwest Ethiopia. *BMC Health Serv Res* 2016;16:495. doi: 10.1186/s12913-016-1757-z
20. Liu C, Liu W, Wang Y, et al. Patient safety culture in China: a case study in an outpatient setting in Beijing. *BMJ Qual Saf* 2014;23(7):556-64. doi: 10.1136/bmjqs-2013-002172
21. Listyowardojo TA, Yan X, Leyshon S, et al. A safety culture assessment by mixed methods at a public maternity and infant hospital in China. *J Multidiscip Healthc* 2017;10:253-62. doi: 10.2147/JMDH.S136943
22. Abu Alrub AM AY, Titi MA, May ACA, Shaikh F, Baksh MM, El-Jardali F. Barriers and enablers in implementing an electronic incident reporting system in a teaching hospital: a case study from Saudi Arabia. Manuscript submitted for publication, 2019.
23. Alahmadi HA. Assessment of patient safety culture in Saudi Arabian hospitals. *Qual Saf Health Care* 2010;19(5):e17. doi: 10.1136/qshc.2009.033258
24. Ammouri AA, Tailakh AK, Muliira JK, et al. Patient safety culture among nurses. *Int Nurs Rev* 2015;62(1):102-10. doi: 10.1111/inr.12159
25. Badr HE, AlFadalah, T., & El-Jardali, F. Towards promoting patient safety practices: Baseline assessment of patient safety culture in three private hospitals. *International Journal of Healthcare Management* 2017:1-8. doi: 10.1080/20479700.2017.1390958
26. Famolaro T, Yount ND, Burns W, et al. Hospital survey on patient safety culture: 2018 user comparative database report: Agency for Healthcare Research and Quality 2018.
27. Okuyama JHH, Galvao TF, Silva MT. Healthcare Professional's Perception of Patient Safety Measured by the Hospital Survey on Patient Safety Culture: A Systematic Review and Meta-Analysis. *ScientificWorldJournal* 2018;2018:9156301. doi: 10.1155/2018/9156301
28. Nie Y, Mao X, Cui H, et al. Hospital survey on patient safety culture in China. *BMC health services research* 2013;13(1):228.
29. Quenon J-L, Vacher A, Faget M, et al. Exploring the role of managers in the development of a safety culture in seven French healthcare facilities: a qualitative study. *BMC Health Services Research* 2020;20:1-11.
30. Pomey MP, Lemieux-Charles L, Champagne F, et al. Does accreditation stimulate change? A study of the impact of the accreditation process on Canadian healthcare organizations. *Implement Sci* 2010;5:31. doi: 10.1186/1748-5908-5-31 [published Online First: 2010/04/28]
31. Smits M, Wagner C, Spreeuwenberg P, et al. Measuring patient safety culture: an assessment of the clustering of responses at unit level and hospital level. *Qual Saf Health Care* 2009;18(4):292-6. doi: 10.1136/qshc.2007.025965 [published Online First: 2009/08/05]
32. Sanders J, Cook G. ABC of Patient Safety. 2007: Oxford: Blackwell.
33. Baldwin DC, Jr., Daugherty SR, Tsai R, et al. A national survey of residents' self-reported work hours: thinking beyond specialty. *Acad Med* 2003;78(11):1154-63. doi: 10.1097/00001888-200311000-00018 [published Online First: 2003/11/08]
34. Aiken LH, Sloane DM, Bruyneel L, et al. Nurse staffing and education and hospital mortality in nine European countries: a retrospective observational study. *The lancet* 2014;383(9931):1824-30.
35. Sturm H, Rieger MA, Martus P, et al. Do perceived working conditions and patient safety culture correlate with objective workload and patient outcomes: A cross-sectional explorative study from a German university hospital. *PLoS one* 2019;14(1):e0209487.
36. Vermeir P, Vandijck D, Degroote S, et al. Communication in healthcare: a narrative review of the literature and practical recommendations. *Int J Clin Pract* 2015;69(11):1257-67. doi: 10.1111/ijcp.12686 [published Online First: 2015/07/07]

- 1
2
3 37. Lee SE, Scott LD, Dahinten VS, et al. Safety culture, patient safety, and quality of care outcomes: A
4 literature review. *Western journal of nursing research* 2019;41(2):279-304.
5
6 38. Chassin MR, Loeb JM. High-reliability health care: getting there from here. *Milbank Q*
7 2013;91(3):459-90. doi: 10.1111/1468-0009.12023 [published Online First: 2013/09/14]
8 39. Smetzer J, Baker C, Byrne FD, et al. Shaping systems for better behavioral choices: lessons learned
9 from a fatal medication error. *Jt Comm J Qual Patient Saf* 2010;36(4):152-63. doi:
10 10.1016/s1553-7250(10)36027-2 [published Online First: 2010/04/21]
11 40. Clarke JR, Lerner JC, Marella W. The role for leaders of health care organizations in patient safety.
12 *Am J Med Qual* 2007;22(5):311-8. doi: 10.1177/1062860607304743
13 41. Parand A, Dopson S, Vincent C. The role of chief executive officers in a quality improvement : a
14 qualitative study. *BMJ Open* 2013;3(1) doi: 10.1136/bmjopen-2012-001731 [published Online
15 First: 2013/01/08]
16 42. Blignaut AJ, Coetzee SK, Klopper HC. Nurse qualifications and perceptions of patient safety and
17 quality of care in South Africa. *Nurs Health Sci* 2014;16(2):224-31. doi: 10.1111/nhs.12091
18 [published Online First: 2013/10/10]
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Supplementary 1S. Semi-structured interview questions for qualitative data

1. Have you realized any changes in patient safety culture in your department? Why?
2. What are your suggestions to improve patient safety in your department? Why?
3. In your opinion what are the factors that influence the patient safety culture in healthcare?

Probing question:

- a) How do you think these factors influence the patient safety culture?
 - b) Who do you think are responsible for these factors?
 - c) Do you receive feedback and action taken?
 - d) Do you feel empowered?
4. Based on the current level of patient safety culture in your hospital what do you think is an important factor to improve patient safety culture?

Followed by:

- a. Do you think these can be achieved at all hospital`s levels?
 - b. How do you think these factors could be incorporated with the hospital`s activities
5. What are the barriers and how to overcome them?
 6. Do you have any other comments?

For managerial:

7. Which managerial decisions were taken to help improving patient safety culture?
8. What are the additional areas leadership should support to enhance patient safety?

Supplementary table 1S. Interview schedule.

Position	Date and time	Location (Site A, Site B, or Both)
Chief Executive Officer	Aug-2-2019	Corporate Level
Chief Medical Officer	July-30-2019	Corporate Level
Hospital Medical Director	July-30-2019	Site C
Deputy Medical Director	July-30-2019	Site A, Site B
Nursing Corporate Director	July-25-2019	Corporate Level
Nursing Hospital Director	July-25-2019	Site A, Site B, Site C
Nursing Corporate Deputy Director	July-26-2019	Corporate Level
Chief Operation Officer	Aug-6-2019	Corporate Level
Chief Administrative and Financial Officer	Aug-13-2019	Corporate Level
Chief Academic Officer	Aug-4-2019	Corporate Level
Safety and Security Supervisor	July-21-2019	Site A, Site B
Pharmacy Services Corporate Supervisor	July-14-2019	Corporate Level
Pharmacy Services Hospital Director	July-14-2019	Site A, Site B
Human Resources, Executive director	July-2-2019	Corporate Level
Human Resources, Hospital Director	July-6-2019	Site B
Patient Affairs, Hospital Director	July-10-2019	Site A
Medical Laboratory and Pathology Director	Aug-5-2019	Corporate Level
Radiology and Medical Imaging Department Director	July-23-2019	Site A
Operating Room Department Chairman	Jun-28-2019	Site B
Emergency Medicine Department Chairman	Jun-25-2019	Site A, Site B
Medicine Department Chairman	Jun-29-2019	Site A
Surgery Department Chairman	Jun-20-2019	Site A
Nursing Service Manager	July-19-2019	Site B (2)
Health Education Center	July-19-2019	Site A
Front-liner staff – Two Focus group (15 members per group) multidisciplinary composition.	July-15-2019 July-16-2019	2 focus groups in Sites A and C and 2 in Site B

Supplementary table 2S. Summary of the main themes and subthemes identified during the interviews.

Theme	Subthemes
Changes in PSC in the facility	<ul style="list-style-type: none"> • Change in overall culture. • More awareness among staff regarding patient safety. • Improved communication • Increased error reporting • Improved understanding and following hospital policies and procedures. • Improved care processes within the hospital • Provision of guides and manuals • More awareness of risks and how to avert them. • Addressing staff fears about the punitive culture. • Clearer job descriptions, roles, and responsibilities • Making staff less resistant to change • Improved teamwork across the hospital
Factors influencing the PSC in healthcare	<ul style="list-style-type: none"> • Communication between staff and patients and within and across departments • Staff continued education and training. • Teamwork within and across units, particularly when it came to handoffs and transitions. • Leadership and administrative support • Monitoring and evaluation including feedback on patient safety indicators • Number of staff available • Robust incident reporting system and receiving feedback on reported events. • Clarity and correct implementation of policies and procedures • Implementing a system for monitoring patient safety goals • Improving workflow within specific departments
Barriers to establishing PSC and how to overcome them	<ul style="list-style-type: none"> • Poor communication within and across departments • Punitive culture • Limited staff awareness • Staff resistance to change. • Staff shortage • Language barrier • Limited cooperation from physicians • Poor training of staff • Budget and space constraints
Organizational changes since 2012	<ul style="list-style-type: none"> • Changes in the human resources regulations and workflows (from the traditional civil service to a self-operation system) • Preparation for dual accreditation (i.e., national and international) • Separation of the hospitals' healthcare quality from the academic medical education quality • Infrastructure expansions throughout the organization • Launching of new healthcare services • Conducting regular "Quality Days" • Strategic initiatives to enhance communication between top management and frontline staff (e.g., "Patient Safety Leadership Walk-Rounds," "Open Day," and "Breakfast with the Chief Executive Officer") • Digitalizing the incident reporting system

Suggestions to improve patient safety	<ul style="list-style-type: none">• Increasing staffing• Offering continuous training and education• Improving communications and teamwork within and across departments• Implementing a horizontal chain of command• More support from management and leadership• Offering feedback on events reported• Supporting a non-punitive culture• Using an open-door leadership approach• Rewarding and empowering staff• Using walk-rounds• Regular meetings to discuss quality and patient safety.• Increasing the space and number of machines available• Better management of patient flow• Better triage and patient assessment• Better implementation of policies and procedures and improved infrastructure• Supporting departmental patient safety initiatives• Staff empowerment to obtain their commitment.• Conducting brainstorming sessions for staff and projects spearheaded by departments to improve patient safety and hosting a “Quality Day.”• Empowering the quality committee and creating ambassadors in the hospital supported by hospital leadership
--	---