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Article

Article

Evaluating the impact of continuous quality improvement methods at hospitals in Tanzania: a cluster-randomized trial

YUSUKE KAMIYA[1], HISAHIRO ISHIJMA[2], AKIKO HAGIWARA[3], SHIZU TAKAHASHI[4], HENOOK A.M. NGONYANI[5], and ELEUTER SAMKY[6]

[1]Ryukoku University, Faculty of Economics, Kyoto, Japan, [2]Fujita Planning Co., Ltd., Tokyo, Japan, [3]Japan International Cooperation Agency, Tokyo, Japan, [4]International Techno Center Co., Ltd, Tokyo, Japan, [5]Ministry of Health and Social Welfare (retired), Dar Es Salaam, Tanzania, and [6]Mbeya Consultant Hospital, Ministry of Health and Social Welfare, Mbeya, Tanzania

Address reprint requests to: Yusuke Kamiya, Faculty of Economics, Ryukoku University, 67 Tsukamoto-cho, Fukakusa, Fushimi, Kyoto, Japan. Tel: +81-75-645-7894; Fax: +81-75-645-6444; E-mail: napjapan@outlook.jp

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Abstract

Objective: To evaluate the impact of implementing continuous quality improvement (CQI) methods on patient's experiences and satisfaction in Tanzania.
Design: Cluster-randomized trial, which randomly allocated district-level hospitals into treatment group and control group, was conducted.
Setting: Sixteen district-level hospitals in Kilimanjaro and Manyara regions of Tanzania.
Participants: Outpatient exit surveys targeting totally 3292 individuals, 1688 in the treatment and 1604 in the control group, from 3 time-points between September 2011 and September 2012.
Intervention: Implementation of the 5S (Sort, Set, Shine, Standardize, Sustain) approach as a CQI method at outpatient departments over 12 months.
Main outcome measures: Cleanliness, waiting time, patient's experience, patient's satisfaction.
Results:: The 5S increased cleanliness in the outpatient department, patients' subjective waiting time and overall satisfaction. However, negligible effects were confirmed for patient's experiences on hospital staff behaviours.
Conclusions: The 5S as a CQI method is effective in enhancing hospital environment and service delivery; that are subjectively assessed by outpatients even during the short intervention period. Nevertheless, continuous efforts will be needed to connect CQI practices with the further improvement in the delivery of quality health care.

Key words: continuous quality improvement, 5S, patient satisfaction, experimental research, hospital care

Introduction

Many developing countries face many difficulties in providing quality health care due to severe resource constraints such as budget, personnel, medical supplies, equipment and technologies. It is inevitable for them to improve operational efficiency in healthcare management. There is now increasing attention to continuous quality improvement (CQI or 'Kaizen' in Japanese) methods in health care to achieve maximum gains at minimum cost in resource-limited countries [1]. There are multiple sources of literature, documenting the concepts of CQI such as Lean thinking and its lessons-learnt based on actual implementation of CQI methods at healthcare facilities [2–5].

Amongst the CQI methods, the 5S approach is a work environment improvement tool that consists of a set of five actions, (i) Sort—to remove all the unneeded items from the workplace; (ii) Set—to order needed items in the correct place so that working process can be efficient; (iii) Shine—to sweep, wipe off and clean the workplace; (iv) Standardize—to maintain a proper environment after the first three S (Sort, Set and Shine); (v) Sustain—to make a habit of properly maintaining established procedures with self-discipline and commitment [6]. The 5S aims at systematically reorganizing activities especially in resource-limited settings and creating a conducive work environment that is clean, organized and efficient [7]. The 5S is now widely spread in the healthcare sector in Asian and African countries following a global movement towards outcome-oriented and client-centred health care. In particular, the 5S was officially adopted as a national strategy in the health sector in Sri Lanka and Tanzania [8, 9].

Tanzania is one of many Sub-Saharan African countries who severely suffer from limited health resources for decades. The 5S was first introduced in Tanzania for improving healthcare management system in 2007. After the 5S was successfully implemented at Mbeya Referral Hospital as a pilot case, Ministry of Health, and Social Welfare of Tanzania (MoHSW) decided to scale it up to the other regions [9]. At the time of 2011, the 5S was introduced to 37 hospitals in Tanzania.

The 5S has long been believed to improve operational efficiency in healthcare provision. A conceptual hypothesis suggests that the 5S functions as a starting point or 'ground-cleaning' tool prior to more detailed CQI processes [3, 10]. Several studies examined the effects of the 5S on managerial, clinical or patient-reported outcomes [11–13]. Nevertheless, there is almost no rigorous experimental study such as a randomized controlled trial to scrutinize the effectiveness of the 5S in the healthcare sector. Moreover, there is scarce evidence on the impact of CQI methods in developing countries. In this regard, we attempted to show the effectiveness of the 5S approach as a CQI method in improving patient-level outcomes in Tanzania.

Methods

Setting

A cluster-randomized trial was applied to examine the causal effects of the 1-year 5S intervention between September 2011 and September 2012. The trial targeted 16 district-level hospitals in Kilimanjaro and Manyara regions of Tanzania. The trial was carried out as an operational research in the Japanese aid-funded technical cooperation project, namely, 'Strengthening Development of Human Resource for Health in Tanzania'.

Kilimanjaro and Manyara regions are located in northern Tanzania with a population of ~1.6 million and 1.4 million, respectively. These two regions were selected as a study site among total 30 regions in Tanzania because there were no planned health-sector CQI projects or related studies by the other agencies during our trial period. Totally, 16 district-level hospitals, 10 in Kilimanjaro and 6 in Manyara, are located in two regions. All of these 16 hospitals were included as a study sample for the trial. Prior to the trial, we obtained ethical approval for running this trial from the ethical committee under the MoHSW through the National Institute of Medical Research of Tanzania (NIMR).

Hypothesis

A conceptual framework of the trial is shown in Fig. 1. It explains the causal mechanism of how the implementation of the 5S leads to the improvement in patient's experiences and satisfaction. Many hospitals especially in rural areas of developing countries suffer from a disorganized working environment due to the lack of budget, human resource and managerial discipline. Motivation, morale and productivity of hospital staff tend to be low and the system of service delivery does not function well. In such an environment, the health workers may treat patients badly or make a serious mistake during diagnosis or treatment. The 5S can improve the working environment by removing unnecessary items from working spaces (Sort), ordering needed items in a proper position (Set), and cleaning up rooms and facilities (Shine). Then, the 5S can make the working place more organized and efficient by reducing unnecessary workload, reorganizing working processes (Standardize) and maintaining proper environment and work procedures (Sustain). As a result, hospital staff can spend less time for searching necessary items and reduce process time to provide services. In a conducive working environment, motivation, morale and productivity of the staff will be higher, and their responsiveness to patients will be improved. Implementation of the 5S can also establish an active and highly committed team and create the foundation of hospital organization that can provide high quality of health services. In terms of patient-level outcomes, they can benefit from clean hospital environment, less waiting time, friendly staff attitude, and better diagnosis and treatment. Finally, their satisfaction level and overall rating towards the hospital will become higher.

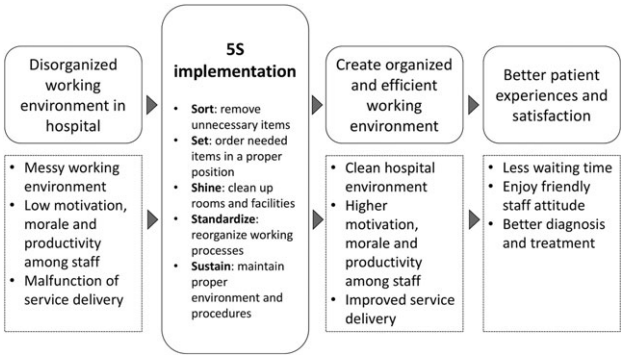

Figure 1 Conceptual framework.

Sampling

We evaluate the effects of the 5S approach at district-level hospitals using outpatient exit surveys. The sample size for outpatient exit surveys was calculated based on the following assumptions: significance level = 5%; power = 80%; effect size = 0.36; number of clusters = 16; and intra-cluster correlation coefficient = 0.05. As a primary outcome variable for the evaluation, we used a patient's satisfaction rate on healthcare services. Under these assumptions, for instance, satisfaction rate in the treatment group at 77.8% compared with control group at 60% can be detected.

Following the above assumptions, a minimum sample size was calculated as 65 individuals per cluster, i.e. 1040 in total (65 persons × 16 clusters). Based on the calculated number, we tried to sample out at least 65 outpatients per hospital for each survey period. As a result, actual sample size became 1101, 1118 and 1073 for the baseline, midline and follow-up, respectively. The survey was only conducted when a verbal consent by selected individual was given. All the surveys at baseline, midline and follow-up followed the same sampling procedure.

Randomization

The 5S intervention was randomly allocated among 16 district-level hospitals. We uses a stratified block randomization, in which we stratify Kilimanjaro and Manyara regions considering the heterogeneity of geographical characteristics that may affect outcome indicators and attempt to balance the number of hospitals from each region in both treatment and control groups. Masking of the intervention to hospital representatives was not possible because of the nature of the trial. Nevertheless, outpatients to the hospitals did not know about the trial.

Interventions

As a result of the randomization, eight hospitals were allocated into the treatment, and the other eight were in the control. After the randomization, all the hospitals belonging to treatment group received the 5S intervention for 1 year from July 2011 to July 2012. The control group hospitals did not receive any intervention until July 2012. The 5S interventions consisted of three types of activities, (i) training of trainers on the 5S, (ii) 'consultation visit' to each hospital and (iii) 'progress report meeting'. The project team carried out those activities.

First, the training of trainers was conducted in July 2011. Key personnel from treatment group hospitals were invited to participate into the 5S training for 1 week. Theoretical basics and methodologies of the 5S were taught during the training. All participants were instructed to follow each step outlined in the 5S implementation guideline, which had been issued by the MoHSW. After the training, a Quality Improvement Team (QIT) and Work Improvement Teams (WITs) that function as an implementation structure were established in each treatment group hospital. Those teams were expected to serve as a catalyst to create a positive change by introducing the 5S at the workplace [9].

Second, 'consultation visit' was made by the project team to all the hospitals in the treatment group to monitor and assess the progress of the 5S implementation during January 2012. At each visit, the project team provided technical advice on how to practice the 5S activities in a correct way.

Third, the project team organized 'progress report meetings' by inviting representatives from treatment group hospitals in May 2012. It aimed to confirm the progress of the 5S implementation at each hospital and to share knowledge and experiences among hospitals in the treatment group.

Data

In order to measure the effects of the 5S intervention, we conducted three rounds of cross-sectional outpatient exit surveys, at baseline (September 2011), at midline (February 2012) and at follow-up (August 2012). In Tanzania, 80% of patients attending health facilities visit Outpatient Department (OPD) [14]. Therefore, measuring experiences and satisfaction by patients visiting OPD will be quite relevant to assess the quality of health care in Tanzania. The surveys ask questions on patients' assessment in the area of cleanliness, waiting time, staff's behaviour and overall satisfaction. The questions regarding patient's basic characteristics, i.e. sex, age and educational attainment (no formal education, primary, secondary and college/university), were also included in the survey for the purpose of checking the balance of the sample between treatment group and control group.

Questionnaires were developed based on the extant literature review on patient's experiences and satisfaction. In principle, patient's experience or satisfaction data cannot capture the absolute level of healthcare services. Instead, we employ a wide range of indicators based on patient's direct experiences and subjective assessment to capture the quality of OPDs because quality of health care is a complex and multidimensional concept [15–18]. The questionnaires were originally made in English and then translated into Kiswahili.

Statistical analysis

Our primary interest is to assess the causal effects of the 5S implementation by randomly allocating 16 hospitals into treatment and control groups. The strategy is to compare outcome indicators by treatment status at baseline, midline and follow-up time-point within a year. All the statistical analyses were carried out using patient-level data. We employed ordered logistic regression models with clustered robust standard errors to control for hospital-level clustering effects.

Outcome variables

We applied the following outcome variables to assess hospital performance. Answer from each question was a multiple point Likert-type scale.

Cleanliness

It measures patient's subjective assessment of cleanliness at four different places at the hospital: (i) OPD totally, (ii) walls at the OPD, (iii) windows at the OPD and (iv) floors at the OPD and (v) toilet. Cleanliness variables were constructed from answers to four scaled response questions; 'Very clean' = 4, 'Fairly clean' = 3, 'Not very clean' = 2 and 'Not at all' = 1.

Waiting time

It measures patient's subjective assessment of waiting time at four different places: (i) OPD, (ii) consulting room, (iii) laboratory and (iv) pharmacy. We used answers to five scaled response questions; 'Very short' = 5, 'Short' = 4, 'Average' = 3, 'Long' = 2 and 'Very long' = 1.

Patient's experiences

It measures patient's direct experiences when receiving diagnosis or medication at the OPD by asking 10 different questions. Answers to each question are three scaled; 'Yes, definitely' = 2, 'Yes, to some extent' = 1 and 'No' = 0.

1. If the patient had enough time to discuss their health or medical problem with a health worker.
2. If the health worker explained reasons for any treatment or action in a way that they could understand.
3. If the health worker listened to what a patient had to tell.
4. If the patient received answers that they could understand if they had important question to ask the health worker.
5. If the patient had confidence and trust in the health worker examining and treating patient.
6. If the health worker explained the reasons to the patient why they needed any test in a way they could understand.
7. If the health worker explained the results of the tests to the patient in a way they could understand.
8. If the health worker explained to the patient how to take the medication.

9. If the health worker explained the purpose of medication in a way they could understand.
10. If the health worker told the patient about side effects of medication to watch for.

Patient's satisfaction

It measures patient's overall satisfaction after visiting a hospital by asking two questions. Answers to the first questions are three scaled; 'Yes, completely' = 2, 'Yes, to some extent' = 1 and 'No' = 0. Answers to the second question are six scaled, 'Excellent' = 6, 'Very good' = 5, 'Good' = 4, 'Fair' = 3, 'Poor' = 2 and 'Very poor' = 1.

1. If the main reason a patient came to the hospital was dealt with to their satisfaction.
2. How high a patient rates the care that they received at the OPD.

Results

Table 1 presents mean scores of the outcome variables as well as patient's basic characteristics by treatment status at baseline, midline and follow-up time-point. Statistical significance of the mean difference between two groups, which was obtained by bivariate ordered logistic regressions, is reported in the right-hand column as stars (*$P < 0.1$; **$P < 0.05$; ***$P < 0.01$).

Looking at the results for cleanliness, at baseline, there was no statistically significant difference in any of five variables, i.e. from (i) OPD to (v) toilets, between treatment and control groups. At midline, a mean score of window's cleanliness in treatment group became higher than control group ($P < 0.1$). Notable results were obtained at follow-up. All the cleanliness variables in the treatment group took higher scores at the <10% of significance level (except for (ii) walls), indicating that the 5S implementation had a positive effect in improving the cleanliness of target hospitals.

Regarding waiting time, at baseline, there was no statistical difference in any of the variables by treatment status. At midline and follow-up, mean scores of waiting time at the consulting room and at the pharmacy became statistically and significantly higher in treatment group than in control group. These results are consistent with the previous researches that show the reduction in lead-time at hospitals as a result of CQI practices [19]. Nevertheless, waiting time at the OPD in total and at the laboratory did not differ significantly between two groups. These results suggest that it is easier to reduce lead-time at consulting room and pharmacy by introducing the 5S approach compared to the OPD and laboratory.

Turning to patient's experiences, there were statistically and significant mean differences between treatment and control groups for the variables '(i) Enough time to discuss', '(iii) Listen' and '(vi)

Table 1 Mean scores of outcome variables by treatment status

Variables	Baseline			Midline			Follow-up		
	N	Treat	Control	*N*	Treat	Control	*N*	Treat	Control
Cleanliness									
(i) OPD	1101	2.845	2.819	1109	2.351	2.128	1061	2.314	2.047**
(ii) Walls	1101	2.819	2.802	1107	2.378	2.069	1057	2.247	2.016
(iii) Windows	1101	2.806	2.798	1093	2.347	2.028*	1044	2.290	2.004**
(iv) Floors	1101	2.823	2.787	1109	2.297	1.948	1053	2.236	1.913*
(v) Toilets	738	1.732	1.423	729	1.731	1.454	681	1.942	1.439*
Waiting time									
(i) OPD	1092	2.639	2.831	1114	3.093	3.081	1050	3.593	3.513
(ii) Consulting room	1092	2.744	2.783	1112	3.190	2.699***	1046	3.482	2.951**
(iii) Laboratory	422	2.648	2.655	491	3.373	3.117	543	3.139	2.822
(iv) Pharmacy	1072	3.505	3.317	1036	4.050	3.725*	993	4.470	4.215**
Patient's experience									
(i) Enough time to discuss	1101	1.800	1.690**	1099	1.852	1.775	1066	1.783	1.805
(ii) Reason for treatment	1092	1.540	1.515	1099	1.870	1.833	1055	1.546	1.591
(iii) Listen	1101	1.847	1.710**	1100	1.696	1.581	1065	1.777	1.838
(iv) Get answers	711	1.508	1.502	842	1.613	1.551	838	1.507	1.373
(v) Confidence and trust	1101	1.701	1.764	1100	1.859	1.788	1060	1.781	1.779
(vi) Reason for test	381	1.444	1.686*	444	1.724	1.389***	528	1.466	1.508
(vii) Result of test	374	1.524	1.643	430	1.718	1.590*	517	1.512	1.703*
(viii) How to take medication	1057	1.727	1.722	1002	1.920	1.867	993	1.799	1.880
(ix) Purpose of medication	1057	1.300	1.103	993	1.617	1.313***	986	1.472	1.173
(x) Side effect	1054	0.351	0.292	986	0.746	0.671	994	0.728	0.542
Patient's satisfaction									
(i) Satisfaction	1101	1.594	1.573	1115	1.720	1.610*	1070	1.605	1.643
(ii) Overall rating	1101	3.172	2.926	1116	3.452	3.116**	1073	3.319	2.969*
Patient's background									
Female	1101	0.655	0.644	1118	0.589	0.672**	1073	0.679	0.658
Age	1101	35.3	36.8	1118	36.6	37.8	1072	35.7	38.4
No formal education	1095	0.112	0.076	1102	0.119	0.090	1073	0.091	0.129
Primary education	1095	0.615	0.683**	1102	0.564	0.644*	1073	0.556	0.639**
Secondary education	1095	0.219	0.200	1102	0.276	0.227*	1073	0.281	0.186***
College/University	1095	0.054	0.040	1102	0.041	0.040	1073	0.072	0.046

*$P < 0.1$; **$P < 0.05$; ***$P < 0.01$ based on bivariate ordered logistics regression analysis.

Table 2 Distribution of cleanliness by treatment status

	Baseline		Midline		Follow-up	
	Treatment (%)	Control (%)	Treatment (%)	Control (%)	Treatment (%)	Control (%)
(i) OPD						
Very clean = 4	86.1	82.7	41.9	28.0	39.1	19.8
Fairly clean = 3	12.3	16.6	51.4	59.5	54.3	67.1
Not very clean = 2	1.6	0.8	6.5	9.8	5.5	11.2
Not at all = 1	0.0	0.0	0.2	2.7	1.1	1.9
(ii) Walls						
Very clean = 4	83.5	80.6	41.0	25.6	35.4	19.4
Fairly clean = 3	14.9	19.0	55.7	59.4	54.6	66.4
Not very clean = 2	1.6	0.4	3.3	11.2	9.2	10.5
Not at all = 1	0.0	0.0	0.0	3.8	0.7	3.7
(iii) Windows						
Very clean = 4	82.3	80.6	39.6	25.6	38.1	19.6
Fairly clean = 3	16.0	18.7	55.7	55.4	54.5	64.6
Not very clean = 2	1.7	0.8	4.5	15.1	5.8	12.5
Not at all = 1	0.0	0.0	0.2	3.9	1.7	3.4
(iv) Floors						
Very clean = 4	83.7	79.2	37.3	25.2	35.9	17.7
Fairly clean = 3	14.9	20.2	55.7	49.8	54.5	62.7
Not very clean = 2	1.4	0.6	6.5	19.6	7.1	12.8
Not at all = 1	0.0	0.0	0.5	5.4	2.6	6.8
(v) Toilet						
Very clean = 4	23.6	3.8	24.3	17.6	36.1	11.8
Fairly clean = 3	39.6	48.5	37.9	33.2	35.8	41.4
Not very clean = 2	23.3	33.9	24.5	26.0	14.2	25.5
Not at all = 1	13.6	13.8	13.3	23.1	13.9	21.2

Table 3 Distribution of waiting time by treatment status

	Baseline		Midline		Follow-up	
	Treatment (%)	Control (%)	Treatment (%)	Control (%)	Treatment (%)	Control (%)
(i) OPD						
Very short = 5	1.4	0.6	11.0	9.7	30.9	28.7
Short = 4	27.0	24.0	29.3	30.7	30.9	31.2
Average = 3	29.8	43.2	31.1	31.1	16.8	15.7
Long = 2	17.9	22.5	15.6	15.1	9.6	11.4
Very long = 1	24.0	9.8	13.1	13.5	11.8	13.0
(ii) Consulting room						
Very short = 5	1.6	0.8	7.9	4.7	19.9	9.0
Short = 4	29.2	20.3	34.1	24.3	38.7	29.9
Average = 3	30.5	45.3	36.4	28.5	22.2	25.9
Long = 2	19.4	23.6	12.2	21.3	8.0	17.5
Very long = 1	19.3	10.0	9.3	21.3	11.2	17.7
(iii) Laboratory						
Very short = 5	0.9	0.5	12.3	5.0	12.5	8.5
Short = 4	25.1	17.2	39.3	33.9	34.8	25.9
Average = 3	32.4	43.8	27.4	36.4	24.2	25.6
Long = 2	21.0	24.1	15.5	17.2	11.4	19.3
Very long = 1	20.5	14.3	5.6	7.5	17.2	20.7
(iv) Pharmacy						
Very short = 5	21.1	11.8	34.3	19.7	61.9	45.1
Short = 4	39.0	37.8	43.4	46.2	28.4	38.6
Average = 3	17.2	27.8	16.6	23.6	6.0	10.3
Long = 2	14.7	15.6	4.6	7.7	2.0	4.8
Very long = 1	8.0	7.1	1.2	2.7	1.6	1.2

Table 4 Distribution of patient's experiences and satisfaction by treatment status

	Baseline		Midline		Follow-up	
	Treatment (%)	Control (%)	Treatment (%)	Control (%)	Treatment (%)	Control (%)
Patient's experiences						
(i) Enough time to discuss						
Yes, definitely = 2	70.7	84.5	80.6	87.3	83.4	81.9
Yes, to some extent = 1	27.6	10.9	16.3	10.5	13.7	14.4
No = 0	1.7	4.5	3.1	2.2	2.9	3.6
(ii) Reason for treatment						
Yes, definitely = 2	56.6	70.2	85.7	87.9	70.0	66.6
Yes, to some extent = 1	38.4	13.6	11.9	11.2	19.1	21.4
No = 0	5.0	16.2	2.4	0.9	10.9	12.0
(iii) Listen						
Yes, definitely = 2	72.2	87.7	70.4	77.6	84.9	81.5
Yes, to some extent = 1	26.7	9.4	17.4	14.5	13.9	14.6
No = 0	1.1	3.0	12.2	8.0	1.2	3.8
(iv) Get answers						
Yes, definitely = 2	56.8	68.3	69.6	76.5	64.4	68.1
Yes, to some extent = 1	36.5	14.1	15.9	8.3	8.6	14.5
No = 0	6.7	17.5	14.5	15.2	27.0	17.4
(v) Confidence and trust						
Yes, definitely = 2	77.1	75.7	82.8	86.8	82.0	80.1
Yes, to some extent = 1	22.1	18.8	13.2	12.3	14.0	17.8
No = 0	0.8	5.6	4.0	0.9	4.1	2.0
(vi) Reason for test						
Yes, definitely = 2	74.6	66.8	62.5	81.6	70.6	68.8
Yes, to some extent = 1	19.5	10.7	13.9	9.2	9.5	9.0
No = 0	5.9	22.4	23.6	9.2	19.8	22.2
(vii) Reason for test						
Yes, definitely = 2	69.2	70.4	71.4	79.5	78.8	69.4
Yes, to some extent = 1	25.9	11.6	16.2	12.7	12.7	12.4
No = 0	4.9	18.0	12.4	7.7	8.5	18.2
(viii) How to take medication						
Yes, definitely = 2	73.8	78.5	89.3	92.6	90.6	85.1
Yes, to some extent = 1	24.5	15.6	8.2	6.7	6.7	9.7
No = 0	1.6	5.9	2.5	0.6	2.7	5.2
(ix) Purpose of medication						
Yes, definitely = 2	38.7	57.6	55.0	75.2	51.4	66.6
Yes, to some extent = 1	32.9	14.7	21.2	11.3	14.4	14.0
No = 0	28.4	27.7	23.8	13.5	34.2	19.4
(x) Side effect						
Yes, definitely = 2	9.9	15.7	27.7	33.7	23.6	32.0
Yes, to some extent = 1	9.3	3.7	11.7	7.3	6.9	8.7
No = 0	80.7	80.6	60.6	59.0	69.5	59.2
Patient's satisfaction						
(i) Satisfaction						
Yes = 2	66.8	61.7	77.2	67.9	68.1	70.2
Yes, to some extent = 1	25.7	33.9	17.6	25.3	24.2	23.8
No = 0	7.5	4.4	5.2	6.8	7.7	6.0
(ii) Overall rating						
Excellent = 6	12.5	5.1	17.0	13.8	17.4	5.8
Very good = 5	20.0	12.0	29.7	20.6	25.7	22.3
Good = 4	44.6	56.4	36.0	33.0	33.0	39.7
Fair = 3	18.9	23.2	15.8	29.0	20.3	27.8
Poor = 2	3.1	3.2	1.4	3.2	2.5	4.2
Very poor = 1	0.9	0.0	0.0	0.4	1.1	0.2

Reason for test' at baseline. At midline, three variables, '(vi) Reason for test', '(vii) Result of test' and '(ix) Purpose of medication', were assessed better in the treatment group than in the control group, with a statistical significance (at least $P < 0.1$). At follow-up, the mean difference in most of the patient's experience variables became statistically insignificant, and even a negative impact of 5S implementation was confirmed for '(vii) Result of test'. These results indicate that hospital personnel showed better performance in several duties at midline. Nonetheless, their better performance did not last long. As a result, the statistically significant and positive effects of the 5S on patient experiences diminished at follow-up.

Finally, as to patient's satisfaction, (i) satisfaction and (ii) overall rating did not show a significant difference between two groups at baseline. At midline, both satisfaction and overall rating score at treatment group hospitals became significantly higher compared with control group. At follow-up, overall rating score in treatment group remained significantly higher than control group ($P < 0.1$), although no positive effect was confirmed for the satisfaction variable. These results suggest the 5S consistently raised patient's overall rating throughout the 5S implementation period within 1 year. As to the statistically insignificant effect on patients' satisfaction at follow-up, one possible explanation is that patients' expectation towards hospital performance rose up among treatment group hospitals. In this study, we measured patient's satisfaction by asking 'If the main reason a patient came to the hospital was dealt with to their satisfaction.' Therefore, if patients become accustomed to better hospital environment, their required level of satisfaction will be raised up accordingly. As a result, they become less likely to be satisfied with hospital environment or services as before.

To check the robustness of the above statistical results, we conduced multivariate ordered logistic regressions by including patient's basic characteristics (female dummy, age and education level) as control variables. Then, we obtained consistent results. We also report the distribution of outcome variables by treatment status at each survey time-point in Table 2 (cleanliness), Table 3 (waiting time) and Table 4 (patient's experiences and satisfaction).

Discussion

This paper originated from a question whether or not CQI methods, which have a long history of practices in a manufacturing sector, exert a positive impact on the quality of health care provided at hospitals. We evaluated the impact of the 5S approach as a CQI method that was implemented at district-level hospitals in rural Tanzania during September 2011–September 2012. As a research design, we applied a cluster-randomized trial, whereby all the 16 hospitals in Kilimanjaro and Manyara regions were randomly allocated to either treatment group or control group.

The statistical results suggested the 5S implementation successfully improved hospital's cleanliness, waiting time and overall rating assessed by patients at the outpatient department. For instance, hospitals allocated into the treatment group had a statistically significant and higher overall rating score at both midline and follow-up than those in the control group. These results support a conceptual hypothesis that the 5S leads to the improvement in patient's overall satisfaction by improving working environment and operational efficiency in hospitals.

Nevertheless, the effect of the 5S on patient's satisfaction was not strong. One possible reason for this result is related to the nature of the intervention. In this trial, the 5S methods were introduced into hospitals in the treatment group through 'training of trainers', whereby a small number of representatives from each hospital attended an intensive 5S training course. Then, they brought back what they had learned in the training to their hospital. In this sense, it depends on motivation and ability of these 'trainers' or upper-level hospital managers how the 5S is disseminated into each hospital. If it is not successful, the effects of the 5S intervention will be minimum or null. Because we did not assess the implementation process of 5S at the hospital, further efforts will be required to assess how the 5S was introduced and disseminated at each hospital. Alternative explanation relates to relatively a short intervention time period. We assessed the impact of the 5S implementation over 12 months due to the nature of the project. Nevertheless, it seems to take a longer time for the 5S to exert more visible effects on the improvement in quality of healthcare practices. Thus, potential effects of the 5S, particularly those on better health care, might not be observed in a 1-year trial. Therefore, further studies would be required to detect the longer impact of the CQI methods by spending more time on the 5S implementation.

In conclusion, our trial will be a valuable benchmark for further research on CQI methods in health care particularly in resource-limited countries because almost no scientific evidence had been presented on the causal effects of the CQI methods. To our best knowledge, this is the first cluster-randomized trial to examine the impact of 5S approach as a CQI method in the healthcare sector in developing countries. Our results demonstrated the effectiveness of the 5S approach in improving patient-level outcomes by ameliorating work environment and operational efficiency at rural hospitals in Sub-Saharan Africa even during a short period of time. Continuous efforts will be needed to connect CQI practices with the further improvement in the delivery of quality health care.

Now that an increasing number of CQI methods is undertaken in the healthcare sector in developing countries, more strategic use of them based on scientific evidence will be favoured. In this regard, findings and lessons-learnt from this trial will be valuable to encourage frontline healthcare workers in improving hospital environment and healthcare services by CQI practices particularly in resource-poor settings.

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