

Development and Validation of a Measuring Tool for Medical Equipment Management System

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ABSTRACT: The study consisted of designing of a measuring tool and its validation process for measuring the performance of Medical Equipment Management System (MEMS) in the hospital. This involved an in-depth literature review and the opinion of the experts in the relevant field for proposing a set of 30 Key Performance Indicators (KPIs). Percentage agreement amongst the respondents for five attributes of each proposed KPI was found out. Craunbach's alpha and Guttman Split-half coefficients were calculated to find the reliability of each proposed KPI. The content validity and statistical significance of all five attributes to each corresponding KPI was subjected to the hypothesis testing by Kolmogorov Smirnov Single Sample testing method. Finally, the development and selection process produced a final set of 28 numbers of KPIs and the study concluded that the KPIs can be used for measuring the performance of Medical Equipment Management System in the hospital.

KEYWORDS: Key performance indicator, reliability, validity, Guttman Split-half coefficient, Cronbach's alpha coefficient, Kolmogorov Smirnov single sample test

I. INTRODUCTION

Health care is one of the most important and fast emerging industries in the world. Medical technology plays an important role in patient care delivery system. The present day hospital equipment has become a necessity in all the areas of investigative and testing procedures, so in the monitoring and therapeutic procedures as well. The use of medical technology has risen rapidly particularly during the last few decades due to rapid technological progresses. The technology also plays its role in enhancing the quality of patient services in the hospitals, reduction in the cost, and increased access to services offered by the healthcare system. Over the past few decades, the use of the medical devices for the delivery of healthcare services has tremendously grown. [1]

1.1 Key Performance Indicators (KPIs): Key Performance Indicators are the metrics or other source of information which indicate how outcomes can be measured or recognized. As per Armstrong, performance indicator is "a statistic or other unit of information which reflects, directly or indirectly, the performance of a health or welfare intervention, facility, service or system in maintaining or increasing the well-being of its target population". [2]

Once the targets for the organization are decided, it is possible to practice and maintain a record of quality of care with the help of KPIs over a period of time. KPIs also facilitate benchmarking within and outside an organization and also facilitates for improvements in quality and safety over time. These benchmark processes help to identify various opportunities for improvement and monitor the changes once the improvements have already occurred. [3]

1.2 KPI as Performance Measurement Tool: Goal-setting is an important part of any organizational strategic management. The set goals guide the organization's efforts, decide the distribution of resources and help to keep a focus on the organization's success. Goal setting is one of the first steps an organization should complete at an early stage. There are many benefits of setting goals as they help to ensure what type of jobs and activities to be performed,

International Journal of Innovative Research in Science, Engineering and Technology

(An ISO 3297: 2007 Certified Organization)

Vol. 5, Issue 6, June 2016

when it needs to be done, what type of people will perform it and within what allocated resources the activities will be made available. [4]

A Key Performance Indicator (KPI) helps to measure the performance of an organization against the decided goals and objectives. KPIs link the organizational vision with the individual action. To ensure that the activities and the decided targets run parallel in an organization, there is a need to review these activities periodically. This can be obtained through performance management, setting the desired targets and then measuring those activities. Measuring the performance of any management system is an attempt to achieve the long term goals and objectives of any organization. These efforts in turn can be translated in terms of organizational success.[5]

1.3 Attributes of Key Performance Indicators: The SMART criteria of deciding KPI was developed under Peter Drucker's management by objectives concept. It is essential that these KPIs must be characterized by following five essential attributes:

1. **Specific (attribute 1)** – KPI has to be specific to an area so that they can be applied to the particular intervention/program;
2. **Measurable (attribute 2)**– it must include quantifiable units or targets;
3. **Achievable (attribute 3)**– the resources must be made available to measure the selected KPI;
4. **Relevant (attribute 4)**– the measurement process must establish a direct link to the program's objective; &
5. **Timely (attribute 5)**- include specific timeframes for completion of the task.[6]

1.4 Why KPIs for Medical Equipment Management System: The importance of an effective and efficient medical equipment management system was also considered in the Alma-Ata declaration in 1978. [7]

The need to have a proper system in place for the management of Medical Devices/ Equipment is realized due to:

1. Now-a-days the medical equipment is generally more sophisticated but also complicated.
2. The medical equipment need to be safe, effective and efficient.
3. The hospital management must ensure that these are managed throughout its life cycle and must serve the intended purposes.
4. 'Value for money' must be realized throughout the life cycle of the equipment.
5. To establish a systematic and dynamic performance management approach to measure, monitor, track, and continuously improve the different aspects of hospital performances based on medical devices.
6. To ensure the safety, accuracy, effectiveness and overall reliability of the medical equipment.
7. To enhance the interest and confidence of the healthcare workers while handling the medical equipment.

These problems are best addressed by having policies and procedures in place and an organization wide approach for the management of medical equipment. These policies and procedures are best monitored and reviewed with the aid of agreed KPIs. [8]

II. RELATED WORK

2.1 Role of KPI in healthcare: Key performance indicators can be developed both for the financial and nonfinancial measures that can be used to define and evaluate the success of an organization. KPIs have been incorporated into many healthcare management systems. As per the studies of Abujudeh et al., a list of 67 radiology-specific KPIs and 125 measurement parameters were prepared and got validated by an expert group. These KPIs were developed keeping in mind the institutional vision, strategies, and goals and hence it was recommended that these radiology-specific KPIs may help provide a framework for measuring performance in radiology practice in the future.[9]

According to Barrett et al., guidance for managing drug therapy in children is seriously desirable. For managing pediatric drug therapy, doctors need to be more meticulous and must monitor the expected pediatric response. Their objectives were to construct key performance indicators for pediatric pharmacotherapy guidance to identify and use drugs to make it the most beneficial. [10]

The literature study shows that the instrument and scale based on KPIs have been used as an effective tool to monitor the quality improvement programs in the health care organizations by the expert group of WHO. Key to successful implementation was the embedding of PATH (Performance Assessment tool for Quality Improvement in Hospital) in existing performance measurement initiatives while acknowledging the core objective of the project as a self-improvement tool. Moreover, the process of evaluating PATH also resulted in interesting learning points for other existing and newly emerging quality indicator projects. [11]

International Journal of Innovative Research in Science, Engineering and Technology

(An ISO 3297: 2007 Certified Organization)

Vol. 5, Issue 6, June 2016

As per the guidelines of Medicine and Healthcare Products Regulatory Agency, UK, the application of Key quality indicators can show the improvements in medical devices management. These indicators give an early warning of risk, which can be managed at an appropriate stage of medical device life cycle. The policy also stressed that these KPIs must be reviewed regularly and the healthcare organizations should consider benchmarking their management of medical devices with those of others. This can help sharing of best practices. [12]

2.2 Need of Quality Indicators to measure the Performance of MEMS: Literature reviews show that the performance measurement techniques have not been explored much in the Indian hospitals especially in the public sector. Moreover, literature study of the developed countries also highlights that the applications of KPIs have been done in various fields of healthcare but their application has not been explored in measuring the performance of Medical Equipment Management System in the hospital. [13]

The present study has been undertaken to develop a reliable and valid performance measurement tool which can be used to measure the performance of MEMS of any healthcare organization involved in patient care. We have proposed 30 numbers of KPIs to manage the costly medical equipment after their installation/commissioning in the hospital.

2.3 Aim & Objective: To develop a reliable and valid measuring instrument for the performance measurement of MEMS. For this, following two objectives were kept as under:

1. To define and propose KPIs for MEMS.
2. To find the validity and reliability of each KPI as a measuring tool.

Hypothesis: To find the content validity and statistical significance of keeping five attributes (specific, measurable, achievable, relevant and timely) of each KPI, the following hypothesis was proposed:

H₀ The different attributes of the proposed KPI are not statistically significant.

H₁ The different attributes of the proposed KPI are statistically significant.

III. DATA COLLECTION

- Best practices related to the MEMS (inventory & record keeping, utilization pattern, preventive & corrective maintenance, quality control and safety practices) were reviewed by undergoing the systematic review of guidelines recommended by WHO, Ministry of Health & Family Welfare (Govt. of India), and Medical Equipment Management Program of many developed countries. [14-22]
- Using the available literature worldwide, operable and feasible KPIs were enlisted for the Indian scenario.
- The 'SMART' criteria were adopted while proposing KPIs.
- The templates for a set of 30 KPIs along with the scoring matrix were prepared. These KPIs were also defined as per the four perspectives of any effective and efficient management system [3] viz. service user perspective, internal management perspective, continuous improvement perspective and the financial perspective. (Table 1)
- The suggestions and advice from a panel of 18 experts from multidisciplinary fields related to MEMS were invited. All participants received the information sheet for the introduction of study topic and gave their informed consent before initiating the process of scoring of the proposed KPIs.
- Their suggestions and opinions for the face and content validity of the set of 30 proposed KPIs/measuring tools were also taken.
- For the evaluation of 'SMART' criteria, the experts were asked to give their opinions on the scoring matrix of each proposed KPI template.
- The responses of the experts were evaluated on the basis of 5-point Likert's scale.
- Hypothesis was tested using Kolmogorov Smirnov Single Sample Test. [23]
- Disagreement and the ambiguities found were resolved and the KPIs not fulfilling the agreement criteria were excluded from the final list of selected KPIs.
- The study proposal was also approved under the research and ethical committee of the institute.

IV. ANALYSIS AND RESULTS

4.1 Analysis and Results of Objective 1: A list of 30 KPIs was proposed under following 3 steps:

1. **Defining KPIs:** A systematic review of literature of MEMS related to the policy & procedures, inventory & record keeping, preventive maintenance, corrective maintenance, availability of spares & consumables, safety practices,

International Journal of Innovative Research in Science, Engineering and Technology

(An ISO 3297: 2007 Certified Organization)

Vol. 5, Issue 6, June 2016

functional status of the medical equipment, reporting of adverse events and the utilization pattern was studied and proposed for the development of KPIs. The items of the proposed KPIs were built and categorized after an in-depth study of official documents of MEMS of the developed countries and quality management practices. The opinions and expectations of the health care administrators, users (clinicians, dentists, nurses and the senior technical personnel), and the academicians were also taken into account.

2. **Describing KPIs:** after thorough study of academic literature, a rationale for each KPI was described. The template also mentioned about the nature of KPI (qualitative/quantitative), method of data collection & analysis, source of data collection and the review period was kept for the period of one year. (Table 2)
3. **Proposing and Enlisting KPIs:** To achieve a balance in measurement, care was taken to consider all perspectives of quality care/system in mind. 11KPIs for service user perspective, 11 for internal management perspective, 5 for continuous improvement perspective and 3 KPIs for the financial perspective were kept. [3] The panel of 18 experts consisted of senior hospital administrators (experts in the field of hospital services and academics both), clinical &

Table 1: List of Proposed KPIs

KPI No.	Proposed KPI	Under the Perspective
1.	Policy and Guidelines for MEMS	Internal management
2.	Accountability framework	Internal management
3.	Patient-centric approach	Service user
4.	Human resources	Internal management
5.	Biomedical engineering services	Service user
6.	Infrastructure and facilities	Internal management
7.	Funds/grants allocation for MEMS	Financial
8.	Risk management	Continuous improvement
9.	Record keeping and documentation	Continuous improvement
10.	Preventive maintenance	Continuous improvement
11.	Safety practices	Service user
12.	Accuracy and Quality control	Continuous improvement
13.	Training and development	Continuous improvement
14.	Corrective maintenance	Internal management
15.	Cost-benefit analysis	Financial
16.	SOP & instruction manuals	Internal management
17.	Utilization pattern	Service user
18.	Reliability of medical equipment	Internal management
19.	Patient safety	Service user
20.	Employee safety	Service user
21.	Cost of service ratio	Financial
22.	User's satisfaction	Service user
23.	Proper updated inventory	Internal management
24.	Utilization coefficient (percentage)	Service user
25.	Uptime Index	Internal management
26.	Percentage completion of PPM	Internal management
27.	TAT of medical equipment repair	Service user
28.	Percentage of completed repairs	Service user
29.	Percentage functional medical equipment	Service user
30.	Percentage medical equipment under maintenance program	Internal management
MEMS- Medical Equipment Management System		SOP- Standard Operating Procedures
PPM- Planned Preventive Maintenance		TAT- Turn Around Time

dental experts, quality management experts like NABH and ISO quality management assessors, technical expert, biomedical engineers and a statistician. Their opinions were taken on the scoring matrix for all proposed KPIs as shown in the table 3. However, the proposed KPIs were finally enlisted and selected only after fulfilling the agreement criterion. The agreement criterion was kept at 70% agreement (combining 'agree' or 'strongly agree' on the Likert's scale). [24]

International Journal of Innovative Research in Science, Engineering and Technology

(An ISO 3297: 2007 Certified Organization)

Vol. 5, Issue 6, June 2016

Table 2: Defining and Describing KPI: First Part of KPI Template

KPI Title [Proposed]	
KPI Rationale/Description	
Type of KPI	
Minimum Data Sets/Metric Parameters[Proposed]	
KPI calculation/Analysis	
KPI Target [Expected performance as per best practices]	
Data Source[s]&collection method	
KPI Reporting/Review Period	
Additional Information/Expert's views	

Fig. 1 shows the comprehensive percentage agreement expressed by the experts for KPI based measurement tool. A comprehensive percentage agreement of the whole scale was summarized in table 4. The percentage agreement of all five attributes were 91% (Specific), 85.2% (Measurable), 85.6% (Achievable), 93% (Relevant) and 87.1% (Timely) respectively and hence all the attributes show agreement above 70% which was the minimum limit to show the agreement amongst the experts.

Table 3: Scoring Matrix: Second Part of KPI Template

kindly give your opinion that the proposed KPI is:	(To be evaluated on 'SMART' criteria based on Likert's-5-point Scale)				
	Kindly tick the appropriate box				
	Strongly Disagree (1)	Disagree (2)	Can't say (3)	Agree (4)	Strongly Agree (5)
Specific (can be attributed to the MEMS)					
Measurable (can be quantifiable)					
Achievable (resources can be made available)					
Relevant (direct link to the program objective)					
Timely (completed within the time frame)					

4.2 Analysis and Results of objective 2: Face and content validity of the proposed instrument was confirmed by subjective judgement of the experts. The experts were also asked to comment upon the relevant perspectives and domains under which the proposed KPIs were categorized.

Table 4: Percentage Agreement amongst Experts

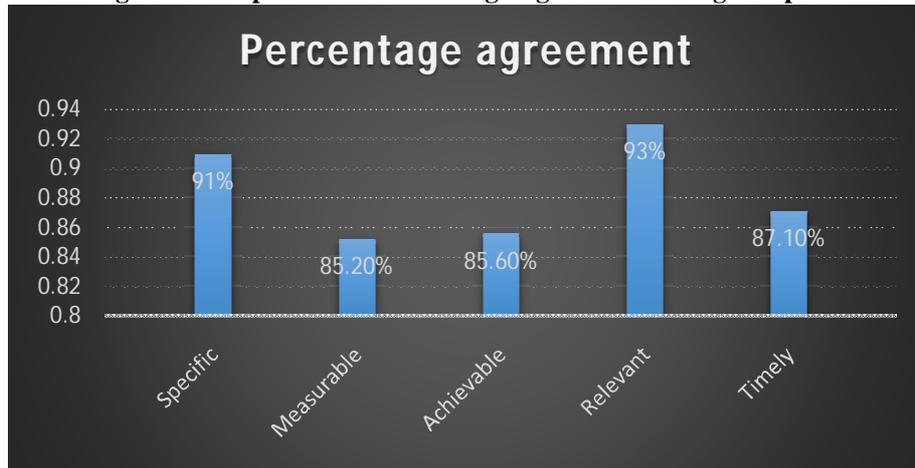
Attribute	Strongly Disagree	Disagree	Can't say	Agree	Strongly Agree	Percentage agreement
Specific	0.0	2.1	6.9	42.9	48.1	91%
Measurable	0.0	2.5	12.3	46.9	38.3	85.2%
Achievable	0.0	1.7	12.7	46.0	39.6	85.6%
Relevant	0.0	1.5	5.6	41.7	51.3	93%
Timely	0.0	1.9	11.0	52.3	34.8	87.1%

International Journal of Innovative Research in Science, Engineering and Technology

(An ISO 3297: 2007 Certified Organization)

Vol. 5, Issue 6, June 2016

Fig. 1: A Comprehensive Percentage Agreement amongst Experts



The Guttman Split-half reliability and Cronbach’s alpha coefficient of each KPI were examined by using statistical software of SPSS version 23. Besides an assessment of individual KPI, the reliability of the comprehensive instrument (the aggregate of all KPIs) was also assessed. For calculating Guttman split-half reliability, the dataset was divided into two parts. The part 1 consists of attribute 1 (specific), 2 (measurable) and 3 (achievable). Similarly, part 2 also consists of three attributes i.e., attribute 3, 4 (relevant) and 5 (timely). The criterion for acceptable split-half reliability and Cronbach’s alpha coefficient was kept for the value of 0.70 at least. [25]

The results of reliability testing and hypothesis testing by single sample Kolmogorov Smirnov test for each KPI is summarized in the table 5.

The Guttman split-half reliabilities of all the agreed KPIs ranged from 0.78 to 0.95 and Cronbach’s alpha coefficients were in the range of 0.77 to 0.98. The same values of the overall scale were 0.87 and 0.85 respectively and hence it was found satisfactory for all agreed KPIs. The results of one sample Kolmogorov Smirnov for hypothesis testing showed that the ‘p’ value was less than 0.05 and hence the null hypothesis was rejected (Fig. 2). The statistical significance of keeping all five different attributes i.e., specific, measurable, achievable, relevant and timely as the components of all selected KPIs was hence proved.

Two KPIs no. 15 (Cost-benefit analysis) and KPI no. 17 (Utilization Pattern) were excluded from the final set of KPIs since the minimum criteria of reliability and hypothesis testing were not fulfilled as shown in table 5.

Fig. 2: Hypothesis testing by Single Sample Kolmogorov Smirnov Test

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of attribute 1 normal with mean 4.37 and standard deviation 0.705.	One-Sample Kolmogorov-Smirnov Test	.000 ¹	Reject the null hypothesis.
2	The distribution of attribute 2 normal with mean 4.21 and standard deviation 0.750.	One-Sample Kolmogorov-Smirnov Test	.000 ¹	Reject the null hypothesis.
3	The distribution of attribute 3 normal with mean 4.24 and standard deviation 0.732.	One-Sample Kolmogorov-Smirnov Test	.000 ¹	Reject the null hypothesis.
4	The distribution of attribute 4 normal with mean 4.43 and standard deviation 0.668.	One-Sample Kolmogorov-Smirnov Test	.000 ¹	Reject the null hypothesis.
5	The distribution of attribute 5 normal with mean 4.20 and standard deviation 0.703.	One-Sample Kolmogorov-Smirnov Test	.000 ¹	Reject the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

¹Lilliefors Corrected

International Journal of Innovative Research in Science, Engineering and Technology

(An ISO 3297: 2007 Certified Organization)

Vol. 5, Issue 6, June 2016

V. DISCUSSION & CONCLUSION

The systematic literature review did not identify that KPI could be used as a measuring tool to assess the performance of medical equipment management system in the hospital. A list of 30 numbers of KPIs were identified, defined and described related to the best practices of MEMS. These were proposed keeping in mind the scenario of public hospitals especially. A panel of 18 experts from all dimensions of MEMS were invited for expressing their choices on 5-point Likert's scale. The data were analyzed for the validity and reliability for each proposed KPI. The overall percentage agreement, reliability and significance of all attributes were tested statistically and were found satisfactory. Finally, out of 30 proposed KPIs, a set of 28 KPIs were agreed upon based upon the fulfilling criteria of statistical tests.

Establishment of various KPIs will help to measure the performance of MEMS and also help to justify investment and maximize asset utilization in the hospital and similar type of organizations involved in patient care based upon the utility of costly medical devices. At the same time, it will also help to provide relevant real-time data which will facilitate the detection of deviations at an initial stage and hence unnecessary costs in the future can be avoided.

Table 5: Results of Reliability Testing and Hypothesis Testing for Each KPI

KPI NO. [Proposed]	Craunbach's alpha	Guttman Split-half Coefficient	Null hypothesis Accepted/Rejected					KPI selected
			S	M	A	R	T	
1.	0.77	0.78	R	R	R	R	R	√
2.	0.81	0.82	R	R	R	R	R	√
3.	0.85	0.86	R	R	R	R	R	√
4.	0.83	0.87	R	R	R	R	R	√
5.	0.85	0.84	R	R	R	R	R	√
6.	0.85	0.84	R	R	R	R	R	√
7.	0.92	0.81	R	R	R	R	R	√
8.	0.83	0.83	R	R	R	R	R	√
9.	0.86	0.94	R	R	R	R	R	√
10.	0.90	0.82	R	R	R	R	R	√
11.	0.93	0.89	R	R	R	R	R	√
12.	0.87	0.79	R	R	R	R	R	√
13.	0.79	0.86	R	R	R	R	R	√
14.	0.88	0.78	R	R	R	R	R	√
15.	0.63	0.67	R	A	R	A	A	X
16.	0.80	0.79	R	R	R	R	R	√
17.	0.68	0.62	A	R	R	A	A	X
18.	0.90	0.83	R	R	R	R	R	√
19.	0.78	0.81	R	R	R	R	R	√
20.	0.79	0.85	R	R	R	R	R	√
21.	0.90	0.83	R	R	R	R	R	√
22.	0.96	0.92	R	R	R	R	R	√
23.	0.77	0.82	R	R	R	R	R	√
24.	0.93	0.90	R	R	R	R	R	√
25.	0.96	0.89	R	R	R	R	R	√
26.	0.96	0.88	R	R	R	R	R	√
27.	0.86	0.78	R	R	R	R	R	√
28.	0.98	0.95	R	R	R	R	R	√
29.	0.92	0.95	R	R	R	R	R	√
30.	0.90	0.88	R	R	R	R	R	√
	0.87	0.85	R	R	R	R	R	Comprehensive Score
Kolmogorov Smirnov single sample test for hypothesis testing [Significance level set at 0.05] H₀ accepted [p value more than 0.05] R- H₀ rejected [p value less than 0.05] S- Specific, M- Measurable, A-Achievable, R-Relevant, T- Timely								

International Journal of Innovative Research in Science, Engineering and Technology

(An ISO 3297: 2007 Certified Organization)

Vol. 5, Issue 6, June 2016

Acknowledgements

The authors would like to express their sincere gratitude to Prof. Shakti K Gupta, Medical Superintendent, Dr. R. P. Centre for Ophthalmic Sciences, AIIMS, New Delhi, Brig. Dr. Sunil Kant, Deputy Director, Medical Services-Plans & Projects, Delhi and Dr. Sanjeev Sood, Hospital & Health Systems Administrator cum NABH Empaneled Assessor, Gurgaon for their valuable suggestions and unconditional support while developing the key performance indicators. Finally, we would like to express our gratitude to all experts who participated in the KPI validation process.

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