Impact of Total Quality Management, Accreditation and Electronic Medical Records on the Outcomes of a Healthcare Organization

THESIS

Submitted in partial fulfilment
of the requirements for the degree of
DOCTOR OF PHILOSOPHY

by

DR. UJJWAL M. RAO

Under the Supervision of

Dr. Rajeev Boudhankar

BITS Pilani
Pilani | Dubai | Goa | Hyderabad

BIRLA INSTITUTE OF TECHNOLOGY AND SCIENCE, PILANI

2015

BIRLA INSTITUTE OF TECHNOLOGY AND SCIENCE, PILANI

CERTIFICATE

This is to certify that the thesis entitled Impact of Total Quality Management, Accreditation and Electronic Medical Records on the Outcomes of a Healthcare Organization and submitted by Dr. Ujjwal Manohar Rao ID No 2009PHXF443P for award of Ph.D. of the Institute embodies original work done by him/her under my supervision.

Signature of the Supervisor

Name in capital letters	:	DR. RAJEEV BOUDHANKAR
Designation	:	Vice President, Kohinoor Hospital
Date	:	6 November, 2015

Acknowledgements

I wish to place on record my gratitude for each and every individual who has contributed to this research study, either directly or through encouragement and inspiration.

First and foremost, I wish to express my deep adulation for Dr. Rajeev Boudhankar - my research Supervisor, who has inculcated the immaculate values of quality and excellence in me.

I'd like to express my gratitude to Prof. V. S. Rao (Acting Vice Chancellor), Prof. Bijendra Nath Jain (Former Vice Chancellor), Prof. Ashoke Sarkar (Director, BITS Pilani) and Prof. G. Raghuram (Former Director, BITS Pilani) for having provided me this research opportunity.

I am immensely grateful to the members of my Doctoral Advisory Committee, Prof. R. P. Pareek and Prof. Hemant R. Jadhav for their constant guidance and support in making this thesis more scientific.

I'd like to thank Prof. S. K. Verma (Dean, Academic Research Division) and the entire staff of ARD for their cooperation and timely help.

I would also like to thank the Departmental Research Committee members Dr. S. Murugesan, Dr. Atish T. Paul and all faculty members of the Department of Pharmacy at BITS, Pilani, for their valuable inputs.

This study would not have been possible without the support of the management and staff of Jehangir Hospital: Mr. Jehangir HC Jehangir (Chairman), Mr. George Eapen (CEO), Dr. Prasad Muglikar (Director – Medical Services), Dr. Amrita Vaidya (Asst. Medical Superintendent) and the entire Quality Systems team. I take this opportunity to thank them all. I would also like to thank Mr. Udai Kumar (Chairman, Ohum Helathcare Solutions) for having provided me the opportunity to explore the field of healthcare information technology and its implications for quality improvement.

I'd like to dedicate this work to my teachers, my family and above all, the Almighty – my primary raison d'être!

Dr. Ujjwal M. Rao
November 2015

Abstract

Background

Quality is at the core of the health systems framework. Although ubiquitous, quality is notoriously difficult to define. Since ancient times the distinction between primary and secondary quality has been made. In modern times quality is deemed to have six dimensions – Safety, Effectiveness, Efficiency, Patient-Centeredness, Equity and Timeliness. Total Quality Management (TQM) has wide applicability in healthcare. Although extensively researched, TQM in healthcare has not been validated by objective-element measures, especially in the context of quality Certification and Accreditation. There has been no published study in India quantifying the impact of National Accreditation Board of Hospitals and Healthcare Providers (NABH) accreditation through clinical quality metrics. Moreover, the expert opinion of accreditation Assessors, on whether NABH is aligned with TQM constructs and if it actually improves clinical outcomes, has never been scrutinized. The new and scantily-researched frontier of Clinical Transformation through Electronic Medical Records (EMR) presents an opportunity that is bound to significantly expand the possibilities in healthcare quality improvement.

Objectives

Deduce the impact of ISO 9001 on the quality of a healthcare organization. Implement NABH Standards in a participatory action research framework to enable translational research and experiential learning, eventually achieving the goal of NABH accreditation. Continuously monitor improvements in clinical quality indicators during the active study period to test the impact of accreditation. Test the validity of TQM constructs with NABH Assessors and cross-validate perceptions with measurable clinical, safety and satisfaction outcomes. Introduce EMR and Emergency Department Information System (EDIS) and measure the potential quality and safety outcomes.

Methods

Deductive as well as inductive approaches were adopted to study micro-environmental elements of Quality in health systems, and extrapolate inferences for macro-environmental

issues. A prospective cohort study was carried out at the study site – Jehangir Hospital, Pune, spanning the entire duration of its quality journey – from the inception of TQM, ISO 9001 implementation, NABH accreditation, and EMR adoption. Data Sources that were used included patient feedback scores maintained by Guest Relations dept of HCO; Survey questionnaire responses from NABH Assessors of India; Quality Indicator data and NABH self assessment scores maintained by the Quality Systems office of the HCO; EMR-EDIS database extracts and EMR-EDIS feedback responses maintained by the Emergency Department (ED) of the HCO. The improvements in Critical-to-Quality (CTQ) factors through ISO 9001 implementation were tested with Interrupted Time Series modelling through a univariate analysis on an Autoregressive Integrated Moving Average (ARIMA) model. Following the NABH implementation period initiated in January 2010, NABH assessment scores based on 636 objective elements of 102 NABH Standards at three stages – pre, mid and post-implementation - were tested as pairs with the Related-Samples Friedman's Two-Way Analysis of Variance by Ranks. A selected set of 15 clinical quality indicators (QIs) were monitored throughout the 56 month study period. The QIs were trended and tested with Interrupted Time Series modelling through a univariate analysis on an ARIMA model. An Expert Elicitation survey of NABH Assessors was conducted using a design based on the Checklist for Reporting Results of Internet E-Surveys (CHERRIES) to test the validity of selected TQM constructs and additional contemporary themes in healthcare quality, including the impact of NABH. The responses to the questionnaire were tested with the One-Sample Kolmogorov–Smirnov and One-Sample Chi-Square test. To study the potential quality implications of Clinical Transformation, a pilot study on EMR and EDIS was conducted in the HCO. This included a time-motion study and analysis of provider feedback. The results were analyzed using the One-Sample and Paired-Sample t-Tests. A healthcare service excellence model was finally developed through the incremental experiential learning involved in the study.

Results

ISO 9001 had a positive impact on the critical-to-quality factors' patient feedback and led to significant improvement in Admissions feedback. There were significant improvements in the NABH Assessment scores of the HCO during successive phases of NABH

implementation. NABH Assessors validated each of the proposed TQM constructs and rated NABH accredited hospitals significantly higher on TQM constructs and clinical outcomes than non-accredited hospitals. NABH implementation resulted in significant improvements in some of the clinical quality indicators – Coronary Angiography (CAG) to Coronary Artery Bypass Graft (CABG) conversion rate, Average Length of Stay (ALOS) for Renal Transplant and Infection Control metrics – Ventilator Associated Pneumonia (VAP) rate, Catheter Associated Urinary Tract Infection (CAUTI) rate and Surgical Site Infection (SSI) rate. The ALOS for Total Knee Replacement (TKR), Trans-Urethral Resection of Prostate (TURP) and for the Hospital overall increased. Paradoxically, this was statistically significant. Multiple benefits were accrued from EMR adoption – time savings, automated quality monitoring, operational reporting, medico-legal case procedures and real-time information exchange. The level of satisfaction with the EMR-EDIS system was significantly high amongst the emergency care providers.

Conclusions

ISO 9001 had a positive impact on patient feedback and can be considered a good starting point in an HCO's quality journey. NABH represents a solid reference point for any quality improvement strategy in the Indian health care domain. NABH accredited hospitals are generally rated higher on TQM constructs by Assessors, but there are certain Standards in NABH that require changes. NABH has a significant impact on some of the critical outcomes of an HCO, especially infection control. There are wide implications for EMR adoption in the HCO as well as the entire healthcare establishment in India and overseas, presenting ongoing opportunities for quality improvement. The experiential learning from the study has been consolidated by the Author in the healthcare service excellence model called SCORE (Safety, Costs, Outcomes, Research, and Experience).

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List of Abbreviations

AC	Abstract Conceptualization
ACEP	American College of Emergency Physician
ACO	Accountable Care Organization
AE	Active Experimentation
AHRQ	Agency for Healthcare Research and Quality
ALOS	Average Length of Stay
ARIMA	Autoregressive Integrated Moving Average
ARRA	American Recovery and Reinvestment Act
BCE	Before Common Era
CAG	Coronary Angiography
CABG	Coronary Artery Bypass Graft
CAUTI	Catheter Associated Urinary Tract Infection
CE	Concrete Experience
CGHS	Central Government Health Scheme
CHERRIES	Checklist for Reporting Results of Internet E-Surveys
CPG	Clinical Practice Guidelines
CPRS	Computerized Patient Record System
CQI	Continual Quality Improvement
CRBSI	Catheter Related Blood Stream Infection
CT	Clinical Transformation
CTQ	Critical to Quality
DALY	Disability-Adjusted-Life-Years
DHHS	Department of Health and Human Services
DIRFT	Doing it right for the first time
DSM	Disease State Management
EBM	Evidence-Based Medicine
ECHS	Ex-Servicemen Contributory Health Scheme
ED	Emergency Department
EDIS	Emergency Department Information System
EFQM	European Foundation for Quality Management
EHR	Electronic Health Record
ELT	Experiential learning theory
EMR	Electronic Medical Record
ETL	Extract-Transform-Load
GDP	Gross Domestic Product
H_0	Null hypothesis
H_a	Alternate hypothesis
HCO	Healthcare Organization

HIT	Health Information Technology
HITECH	Health Information Technology for Economic and Clinical Health Act
HL7	Health Level 7
ICU	Intensive Care Unit
IOM	Institute of Medicine
IP	Inpatient
ISO	International Organization for Standardization
ISQua	International Society for Quality in Healthcare
ITS	Interrupted Time Series
JCAH	Joint Commission on Accreditation of Hospitals
JCAHO	Joint Commission on the Accreditation of Healthcare Organizations
JCI	Joint Commission International
JCR	Joint Commission Resources
LBQ-T	Ljung-Box Q-Test
LIS	Laboratory Information System
M & M	Morbidity and Mortality
MBNQA	Malcolm Baldrige National Quality Award
MUMPS	Multi-User Multi-Programming System
NABH	National Accreditation Board for Hospitals and Healthcare Providers
NIH	National Institutes of Health
NSI	Needle Stick Injury
OP	Outpatient
PACS	Picture Archival and Communication System
PATH	Performance Assessment Tool for quality improvement in Hospitals
PDCA	Plan-Do-Check-Act
PDSA	Plan-Do-Study-Act
P/L	Profit and Loss
QA	Quality Assurance
QCI	Quality Council of India
QI	Quality Improvement
RAND	Research and Development Corporation
RIS	Radiology Information System
RM	Risk Management
RO	Reflective Observation
SA	Self Assessment
SCORE	Safety, Costs, Outcomes, Research and Experience
SERVPERF	Service Performance
SERVQUAL	Service Quality
SMS	Short Messaging Service
SSI	Surgical Site Infection

TKR	Total Knee Replacement
TQC	Total Quality Control
TQM	Total Quality Management
TQM-HC	Total Quality Management in Healthcare
TURP	Trans-Urethral Resection of Prostate
UK	United Kingdom
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNICEF	United Nations Children's Fund
UR	Utilization Review
US	United States (of America)
VA	Veterans Affairs
VAP	Ventilator Associated Pneumonia
VHA	Veteran Health Administration
VistA	Veterans Health Information Systems and Technology Architecture
WHO	World Health Organization

Chapter 1: Introduction

1.1 Healthcare is in crisis and needs a new paradigm

According to the World Health Organization (WHO), 100 million people world-wide are pushed into poverty annually due to healthcare costs; women in the richest 20% of the world population are up to 20 times more likely to have a birth attended by a skilled health worker than a poor woman; and, at a conservative estimate, 20-40% of health resources are being wasted globally (World Health Organization 2010).

When these inequities are considered in light of the global annual health expenditure of US$ 5.3 trillion (World Health Organization 2010), the facts are hard to reconcile.

The Director-General of WHO in the preamble to a 2007 publication had aptly described the world-health situation;

The world has never possessed such sophisticated interventions and technologies for treating disease and prolonging life. But the gaps in health outcomes keep widening. Much of the disease, death, and afflictions we see on such a large scale are easily avoidable, as “effective and affordable interventions” are available for prevention and treatment (World Health Organization 2007).

In a country like India, the burden of disease and lack of equitable care of acceptable standards is an affliction that pervades the public-private health care delivery spectrum at all levels. India accounts for 18% of the global mortality burden and 20% of the global disability-adjusted-life-years (DALYs) (World Health Organization 2009). Public healthcare spending in India is among the lowest in the world at 1.1% of GDP, which is the primary reason behind the staggering 78% private expenditure on healthcare in India (MoHFW 2009). India has less than one doctor for every 1000 patients; only 26% of children less than 5 years of age, with diarrhoea, receive oral rehydration therapy (World Health Organization 2009). As is the case with India, health outcomes are glaringly low in most of the developing world.

The overarching goals of access and equity are primal in nature, generally determined by the political-economic, socio-cultural factors and “can hardly be improved without reforming the broader system” (Bengoa, Kawar et al. 2006). But, the conundrum with quality and safety in

health systems is a more direct one, in terms of propinquity and impact. It affects the outcomes with patients that are already in the system, and unfortunately, at the mercy of its inefficiencies.

According to the IOM, more than 1 million preventable adverse events occur each year in the USA (United States of America), of which 44,000 to 98,000 are fatal (Kohn, Corrigan et al. 2000). In the USA only 50% of patients received recommended preventive care; 30% received contraindicated acute care (Schuster, McGlynn et al. 2005). Although these figures are from two decades back, they could reflect, if not worse, the current state of affairs with healthcare in most of the developing world. A recent study estimates the fatalities due to preventable medical errors in the USA at more that 400,000 (James 2013).

The big breach, it seems, lies within the health systems – in achieving acceptable outcomes with clinical interventions; ensuring base-line quality and safety; achieving overall satisfaction—patients' and providers'. The most pertinent questions to ask ourselves now, are: "Who killed healthcare" and "What is the cure" (Herzlinger 2007)?

The Institute of Medicine (IOM) report, To Err is Human (Kohn, Corrigan et al. 2000), according to Leape and Berwick (Leape and Berwick 2005), "galvanized" the quality and patient safety agenda world-wide.

IOM, in its second Report, exhorts;

As medical science and technology advances at a rapid pace, the health care delivery system has "floundered" in its ability to provide high quality care to all.

Quality issues are everywhere, affecting many patients. "Between the health care we have and the care we could have lies not just a gap, but a chasm" (Institute of Medicine 2001).

Monitoring and improving Quality of care was recognized as a cardinal requirement in the new millennium. "More information was available on the quality of airlines, restaurants, cars, and VCRs than on the quality of health care" (Schuster, McGlynn et al. 2005).

1.2 Quality at the Core of the Health Systems Framework

In the last century there have been three generations of health system reforms. The first generation saw the founding of national health care systems, mostly in the 1940s and 1950s. By the late 1960s, many of the systems were under great stress. Costs were high, poor were often not covered, and most people paid for their own health, but could get only poor quality care. There was a need for drastic change that would make systems more cost-efficient, equitable, and accessible. The second generation of reforms thus saw the promotion of primary health care as a route to achieving affordable universal coverage. By adopting primary health care as the strategy for achieving the goal of *Health for All* at the Joint WHO/UNICEF International Conference on Primary Health Care held at Alma-Ata, USSR (now Almaty, Kazakhstan) in 1978 (World Health Organization 1978), WHO reinvigorated efforts to bring basic health care to people everywhere. There was an extensive effort in many countries. In India, for example, such workers were trained and placed in over 100,000 health posts, intended to serve nearly two-thirds of the population (World Health Organization 2000). Despite these efforts, many such programmes were eventually deemed partial failures. Funding was not adequate; the workers had very little time to focus on preventive measures; their training and equipment were not commensurate with the problems they faced; and quality of care was often so poor as to be characterized as “primitive” rather than “primary”, particularly when primary care was limited to the poor and to only the simplest services (World Health Organization 2000). The primary health care approach was criticized for giving very little attention to people’s demand for health care, which is greatly influenced by perceived quality and responsiveness, and instead focusing entirely on their presumed needs. Systems fail when these two concepts are mismatched, because the supply of services offered cannot align with both. The inadequate attention to demand is reflected in the complete omission of private finance and provision of care from the *Alma-Ata Declaration* (World Health Organization 1978). Poverty is one reason why needs may not translate into demands, and that can be resolved by providing care at low cost. But there are many reasons for the mismatch between people’s needs and demands, and simply providing medical facilities and offering services may not resolve this. Both the first-generation and second-generation reforms were supply-oriented. Demand-oriented systems are more characteristic of the third generation currently taking shape, which include such reforms as

trying to make "money follow the patient" (World Health Organization 2000) and shifting away from provider budgets. There is now a gradual convergence towards what WHO calls the "new universalism" – high quality delivery of essential care, defined mostly by the criterion of cost-effectiveness, for everyone, rather than all possible care for the whole population or only the simplest and most basic care for the poor (World Health Organization 2000).

WHO for the purpose of clearly articulating what it will do to help strengthen health systems world-wide, in its health systems framework, has broken down its functions into a set of six essential 'building blocks', four mediators and four outputs (World Health Organization 2007). Figure 1 represents the *WHO health systems framework*.

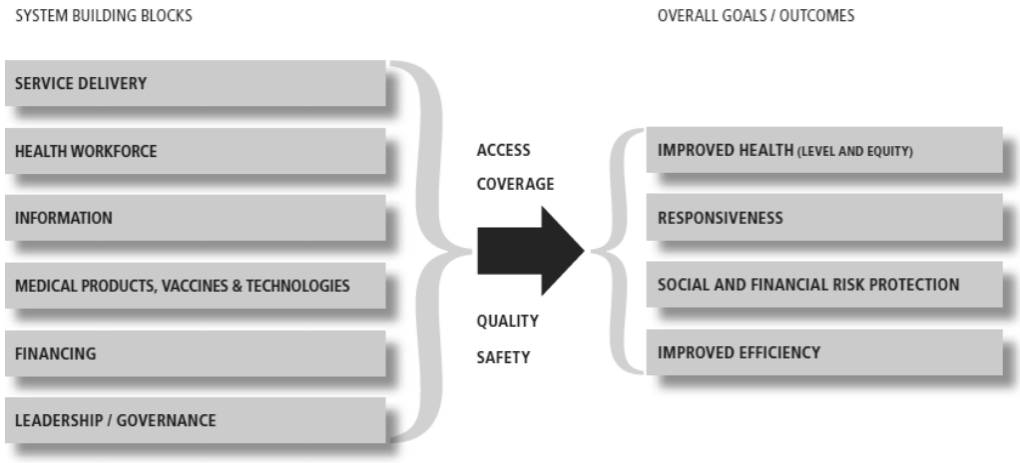


Fig 1: *The six building blocks of a Health System: Aims and desirable attributes (World Health Organization 2007).*

"Service Delivery" – health measures for the ones that require it, whenever and wherever needed, in a safe, effective and efficient manner

An optimally functioning "health workforce" is dedicated, honest and resourceful to achieve the best outcomes.

A good "health information system" is one that enables the collection, analysis, distribution and use of consistent and timely information on operations, clinical outcomes and safety.

A good health system ensures reasonable access to necessary “medical products, vaccines and technologies” of high quality, effectiveness and safety and their relevant and cost-effective use.

An effective “health financing” system manages funds for health, in order for people to receive health care and protection from financial risk due to healthcare costs.

“Leadership and governance” involves long-term planning in health policy that is coupled with effective supervision, health partnership, legal framework, incentives, systems and responsibility.

At the very core of the health systems framework are the four mediators: “Access-Coverage” and “Quality-Safety”. The latter are inextricably linked, and for the purpose of this study, will simply be called Quality, unless a separate mention is warranted.

Within overall plans for countries, there is a growing recognition that health-system strengthening should take precedence. As this trend increases, the reinforcement of quality will become a “key component” which requires reform. (Bengoa, Kawar et al. 2006).

1.3 The need for Healthcare Quality Improvement in the Developing World

Several factors are important for the process of quality improvement in developing countries. These include macro-environmental problems associated with public health policy, social science and polity and also the micro-environmental problems with health systems structures and care demand.

The role of quality improvement in the healthcare systems of developing countries, as per Leatherman (Leatherman, Ferris et al. 2010):

(1) Quality improvement (QI) is "a political and healthcare management imperative". It supports equity and yields better outcomes investments made in particular clinical areas.

(2) "QI can optimize the use of limited resources". Overt improvements in quality of care, along with better clinical outcomes, may support further investments in health systems by improving "donor, population and governmental confidence" that funds are being utilized effectively.

(3) QI in third-world countries can enable "capacity-building" efforts and achieving common goals. WHO's health system strengthening initiative's capability to achieve health outcomes may be enhanced with the "utilization of effective QI methods".

Evidence suggests that QI can augment WHO's capacity to achieve specific Millennium Development Goals such as a reduction in maternal mortality (World Health Organization 2008).

If QI is successful in improving health outcomes then these methods will be "widely adopted, catalysed" by partnerships that will percolate the advances swiftly through both "grass-roots initiatives" and the "persuasion of leaders" at all levels of healthcare systems (Leatherman, Ferris et al. 2010).

Chapter 2: Defining Quality

2.1 A Historical Perspective

Defining quality and understanding its dimensions is a necessary prerequisite to any form of research in Total Quality Management (TQM). But, finding an all-encompassing definition for Quality is a rather Herculean, and potentially Sisyphean, task.

One of the earliest mention of the concept of quality, made in the Golden Book *Tao Te Ching*, written around 6th Century BC by Chinese philosopher Lao Tzu (Thomas 1948), immediately evokes a sublime and inspired understanding:

*"*tao k'o tao, fei ch'ang tao"

The Tao that can be named is not the Absolute Tao.

"ming k'o ming, fei ch'ang ming"

The quality that can be named is not its abiding attribute.

In the Hellenic period, Plato (427-347 BC), the father of Idealism, introduced the term Quality. According to Barfield, "The more common a word is, and the simpler it's meaning, the bolder very likely is the original thought which it contains and more intense the intellectual or poetic effort which went to its making" (Barfield 1967).

The word quality is used by most educated people every day of their lives, but to have this simple word Plato had to make a tremendous effort (it is one of the most tiring which man is called on to exercise) of turning an indistinct sense into a clear idea. "He invented a new word 'poiotes,' 'what-ness,' as we might say, or 'of-what-kind-ness,' and Cicero translated it by the Latin 'qualitas,' from 'qualis' (Barfield 1967).

In Plato's dialogue Hippias Major, Socrates, asked what "the Fine" is? Cooper, the editor, translated the Greek word "kalon" as fine. This word is extensively used as term of "highly favourable evaluation, covering our 'beautiful,' 'noble,' 'admirable,' 'excellent,' and the like". What Socrates asked for, then, is a general account of what characteristic any object, action, person, or achievement of any kind has to have in order correctly to be considered as

“highly valued or worth valuing in this broad way (that is, as being fine)” (p. 898) (Barfield 1967).

Aristotle (384-322 BC), whose views strongly influenced medieval scholarship, in The Categories (Aristotle 1995), presented his canonical list of ten categories and described four kinds of quality (section titles reflect the traditional Latin title of the entire work);

Of things spoken of “without any combination”, each indicates “either substance or quantity or qualification or a relative or where or when or being-in-a-position or having or doing or being-affected” (1b25-2a4).

“By a quality I mean that in virtue of which things are said to be qualified somehow. But quality is spoken of in many ways” (8b25-8b26).

“One kind of quality let us call states and conditions”. A state is different from a condition in being steady and long-lasting (8b27-9a9).

Another kind of quality is that by which we “call people boxers or runners or healthy or sickly—anything, in short”, which they are due to an innate “capacity or incapacity” (9a14-9a28).

“A third kind of quality consists of affective qualities and affections”. Examples of such are sweetness, bitterness, sourness, hotness, coldness, paleness and darkness (9a29-9b9).

A fourth kind of quality is “shape and the external form of each thing”, like “straightness and curvedness” and their like (10a11-10a16).

“Perhaps some other manner of quality might come to light”, but we have made a pretty complete list of the most common ones (10a25-10a26) (Aristotle 1995).

So far, in our pursuit of defining quality, we have imbibed the Laotzian sublime attribute, appreciated the Platonic transcendent concept, and enlisted the Aristotelian manners of quality- state, capacity, affections and form.

In the modern era, Rene Descartes (1596-1650) propagated the idea of the quality-bearing essence and became an early exponent of what came to be known as the "primary/secondary" quality distinction.

Descartes postulated his mechanical theory principally to refute the popular Aristotelian-based Scholastic explanation of natural phenomena that employed ontology of "substantial forms" and "primary matter". In a revealing passage from The World (Descartes 1998), Descartes declares the Scholastic premise to be both an inarticulate and insufficient methodological approach to explaining natural phenomena:

If you find it odd that, in explaining these elements, "I do not use the qualities called 'heat', 'cold', 'moistness', and 'dryness', as the Philosophers do, I shall say that these qualities appear to me to be themselves in need of explanation". Not only these four qualities but all others as well, including even the forms of inanimate bodies, can be explained without the need to suppose anything in their matter other than "motion, size, shape, and arrangement of its parts" (AT XI 25–26) (Descartes 1998).

Descartes' plan was to reduce the class of metaphysically suspect properties, such as heat, weight, taste, to the empirically indisputable attributes of size, shape, and motion. In other words, Descartes' intention was to change the "mentally influenced" depiction of quality in Scholastic natural philosophy with a theory that requires only the features of extension to describe the obvious order of the natural world.

Another proponent of the primary/secondary quality distinction was John Locke (1632-1704). Locke's development of this distinction in his Essay (Locke 2013) was both careful and rational, as expressed in his three initial definitions;

"A quality of *x* is a power of *x* to create any idea in our mind" (II, viii, 8).

Primary qualities of body are those which are "utterly inseparable" from it; are such as "sense finds constantly in every perceptible particle of matter", and the mind finds indivisible from every particle (II, viii, 9).

Secondary qualities are "nothing in objects themselves but powers to produce various sensations by their primary qualities" (II, viii, 10) (Locke 2013).

David Hume (1711-1776) had a sceptical perspective and made pleasure as the standard of virtue in his moral philosophy. In his Treatise (Hume 2012), Hume restricted the human idea of quality to that which can be perceived by the senses.

If any action is "virtuous or vicious", it is only as a representation of some quality or character. It must depend upon "durable principles of the mind", which extend over the whole behaviour, and enter into the personal nature. Actions themselves, not originating from any steady principle, have no influence on love or hatred, pride or humility; and consequently are never considered in morality (Hume 2012).

Immanuel Kant (1724-1804) questioned the legitimacy of such a division, noting that both of these qualities are subjective. In his Critique (Kant, Guyer et al. 1998), Kant introduces the "schema of quality" – the creation of awareness with respect to time.

The "schema" of each category contains and makes "representable": as that for magnitude, the "generation (synthesis) of time itself" in the following apprehension of an object; the "schema for Quality", the amalgamation of "sensation (perception) with the representation of time", or the "filling of time"; for "Relation, the relationship of the perceptions among one another in all time (i.e. according to a rule of time-determination)"; finally, the "schema for Modality" and its class, time itself as the link for the determination of an object, whether and how it belongs to time (275-276; B: 184) (Kant, Guyer et al. 1998).

In turn, Georg W.F. Hegel (1770-1831) suggested that quality should be seen in its primary form as "determinateness", which takes the form of "being" in reality and may also be a limitation – a lack of quality (Hegel, 2010):

"Determinateness thus isolated by itself in the form of being is quality" — which is completely simple and instant. Determinateness as such is the "more universal term" which can equally be further extrapolated as quantity and so on. Because of this "simple character of quality" as such, there is nothing further to be described about it (196) (Hegel, 2010).

Quality, taken in the distinct character of being, is reality; as burdened with a negative it is negation in general, likewise a quality but one which counts as a deficiency, and which further on is determined as limit, limitation (197) (Hegel, 2010).

William Stanley Jevons (1835-1882) in the Principles (Jevons 1877), reflected on the indivisibility, negation and the human conception of quality. He argues that abstract terms are different from general terms by possessing only one kind of meaning; for as they denote qualities there is nothing which they can in addition imply. As in the case of colour; so far as things are merely coloured, colour is a single indivisible quality. He further enunciates that the very fact of not possessing a quality represents a new quality or condition, which can equally be the basis of conclusions. Between positive and negative there is, therefore, a perfect equilibrium and thus both positive or negative terms can be used to denote a given quality and the class of things possessing it. The conception of quality is very fundamental.

"The mind learns to regard each object as an aggregate of qualities, and acquires the power of dwelling at will upon one or other of those qualities to the exclusion of the rest". Logical construction enables the mind to become "capable of reasoning, not merely about objects which are physically complete and concrete, but about things which may be thought of separately in the mind though they exist not separately in nature" (Jevons 1877).

Friedrich Nietzsche (1844-1900) saw quality as nothing but differences in the quantity of forces that enter into relation in our "perspective truth".

"Our knowing limits itself to establishing quantities; but we cannot help feeling these differences in quantity as qualities. Quality is a perspective truth for us; not an 'in-itself'" (Nietzsche, Kaufmann et al. 1967).

The modern era's philosophical reflections on quality include the Cartesian distinction of primary-secondary quality, Locke's conceptualization of the subjective nature of quality, Hume's surmise of the virtue or vice of quality, Hegel's idea of deficient quality and Nietzsche's perspective truth of quality.

The Industrial Revolution, spurred by a revolution in technology that began in Britain, paved the way for mass manufacturing and profits, often with deleterious effects (Gimpel 1977). Increased productivity could have easily led to mass-scale deterioration in quality, were it not for the advent of Scientific Management – "Taylorism", after Frederick Taylor (1856-1915) – the exponent of the Theory that "systematically treated management and process improvement with scientific ground rules". In his Principles (Taylor 1914), Taylor argues,

that one of the dangers to be avoided when wages of workers are made in proportion to the quantity of the work done, is that in the pursuit of increasing the quantity, quality is apt to decline.

"It is necessary in almost all cases, therefore, to take definite steps to insure against any falling off in quality before moving in any way towards an increase in quantity" (Taylor 1914).

In 1924, two of the most vital events in management science transpired at the Hawthorne Works electric plant in Cicero, Illinois. In May, Walter A. Shewhart (1891-1967) put forth the first control chart and began statistical process control and modern quality improvement. In November, later that year, in the same factory, began a series of research projects that are now famously know as Hawthorne studies. This work is at the heart of the creation of social psychology in the workplace and the human relations approach to management. It is very surprising that, although these events took place in the same place and in the same year, their consequent sciences have "remarkably little cross-fertilization of ideas between them" (Best and Neuhauser 2006).

Shewhart joined the Western Electric Company in 1918 to guide their engineers in improving the quality of telephone equipment. While at Hawthorne he met and mentored W. Edwards Deming (1900-1993), the quality guru who greatly contributed to Japan's economic power, and Jospeh M. Juran (1904-2008), the well-known quality evangelist. These three are the veritable founders of the quality movement.

Two of Shewhart's creations, the control charts and the Plan-Do-Study-Act (PDSA) cycle are still very relevant in modern quality science. In his monumental work *The Economic Control of Quality of Manufactured Product* (Shewhart 1931); he introduced Part II as "A Review of the Methods for Reducing Large Numbers of Observations of Quality To a Few Simple Functions of These Data Which Contain the Essential Information". According to Shewhart, from the perspective of control of quality in manufacture, it is essential to "establish standards of quality in a quantitative manner". Thus we are required to express such standards, as far as possible, in terms of "quantitatively measurable physical properties". This does not preclude the interest in the subjective measure of quality. In fact, it is the subjective

side of quality that is more important commercially. “It is this subjective side that we have in mind when we say that the standards of living have changed” (Shewhart 1931).

Deming, who championed Shewhart’s cause, is recognized by the Japanese as being a major contributor to their rise to world economic power in the second half of the 20th Century. In fact, the most esteemed award for Quality in Japan even now is known as the Deming Prize.

Deming’s philosophy of quality is summarized in his ‘‘system of profound knowledge’’ (Deming 2000) with its four elements – “Appreciation for a system; Knowledge of variation; Theory of knowledge; Psychology”, and his ‘‘fourteen points of management” (Deming 1986).

The idea of quality was simplified, yet embellished, by Deming in *The New Economics*: “What is quality? A product or a service possesses quality if it helps somebody and enjoys a good and sustainable market. Trade depends on quality” (Deming 2000).

Juran added the “human” element to quality, effectively making it universal. The concepts of customer satisfaction, costs, income and training are predominant in Juran’s ideation. His Trilogy (Juran 1986) - planning, control and improvement, in managing for quality, has influenced every walk of managers’ lives.

In his Handbook, Juran defines quality as “features of products which meet customer needs and thereby provide customer satisfaction”. In this perspective, the meaning of quality is related to income. The goal of such higher quality is to “provide greater customer satisfaction and, one hopes, to increase income”. But delivering more and/or better quality features usually needs an investment and thus usually involves increases in costs. “Higher quality in this sense usually costs more” (Godfrey 1999).

Quality also means removal of deficiencies—“freedom from errors that require doing work over again (rework) or that result in field failures, customer dissatisfaction, customer claims, and so on”. In this perspective, the meaning of quality is related to costs, and “higher quality usually costs less” (Godfrey 1999).

Kaoru Ishikawa (1915-1989) played a key role in the Japanese quality movement, especially the scope of quality: top-to-bottom in cadres and start-to-finish in products. He contributed to

the success of quality circles and made the use of the cause-effect diagram, also called Ishikawa diagram, common-place (Ishikawa and Ishikawa 1982).

Ishikawa interpreted quality in the narrow and broad perspectives in his book *What is Total Quality Control?: the Japanese Way*: "How one interprets the term 'quality' is important. Narrowly interpreted, quality means quality of products. Broadly interpreted, quality means quality of product, service, information, processes, people, systems etc" (Ishikawa and Lu 1985).

Philp B. Crosby (1926-2001), best known for popularizing the "zero-defects" concept and the "Doing it right for the first time" (DIRFT) principle, in one of his popular books *Quality is free* argues that the first "erroneous assumption" is that quality refers to "goodness, or luxury or shininess". The word "quality" is often used to indicate the relative value of something in such phrases as "good quality", "bad quality" and "quality of life" - which means different things to different people. As follows quality must be defined as "conformance to requirements" if we need to manage it. Therefore, the non-conformance detected is the "absence of quality, quality problems become non-conformance problems, and quality becomes definable" (Crosby 1979).

Crosby tended to hold on to the definition of "conformance to requirements" and further raised the bar with the Four Absolutes in quality: "Definition - conformance to requirements (product and the customer); System – prevention; Standard - zero defects; Measurement - price of non-conformance" (Crosby 1979).

Armand V. Feigenbaum, who is widely recognized for having formulated the concept of Total Quality Control (TQC), later called Total Quality Management (TQM), also propagated the concepts of accountability and costs with regards to quality. In his book *Total Quality Control*, Feigenbaum defined TQC as an "effective system" for combining the quality development, quality maintenance, and quality improvement activities of the various groups in an organization so as to facilitate production and service at the "most economical levels which allow full customer satisfaction" (Feigenbaum 1961).

The International Organization for Standardization (ISO), an international standard setting body, was founded in 1947 to promote commercial and industrial standards. ISO 9000 series

of quality standards was first made available in 1987. ISO 9001:2008 defines quality as the "degree to which a set of inherent characteristics fulfils requirements" (ISO 2008).

The later part of the 20th century witnessed a wave of TQM initiatives, standardization and accreditation. Standards provided an easy model for organizations to adopt TQM, in their pursuit of quality improvement. In 1987 The Malcolm Baldrige National Quality Improvement Act was established by Congress for manufacturers, service businesses and small businesses. The Award was designed to increase the awareness of quality management and recognize companies in the USA that have implemented successful quality-management systems (Quality 2013). In 2010 the MBNQA was renamed the "Baldridge Performance Excellence Program" (BPEP) to emphasize the evolution of quality from the specific focus on either product, service or customers to the strategic outlook on organizational performance (National Institute of Standards and Technology 2015).

BPEP criteria for performance excellence reflect the seven facets of an organization that quality systems must address: "Leadership; Strategic Planning; Customer Focus; Measurement, Analysis, and Knowledge Management; Workforce Focus; Operations Focus; and Results" (Quality 2013).

David Garvin described five principal approaches to defining quality: "Transcendent; Product-based; User-based; Manufacturing-based; and Value-based" (Garvin 1988).

Garvin's eight dimensions of quality, "Performance; Features; Reliability; Conformance; Durability; Serviceability; Aesthetics; and Perceived Quality" (Garvin 1988) – can be seen as the culmination of the pursuit of defining quality in the modern age, starting with Shewhart.

2.2 Genesis and Evolution of Service Quality

Quality is a cardinal element of Services. The essential characteristics of services – "intangibility, heterogeneity, inseparability, and perishability" (Lovelock and Gummesson 2004), make services uniquely different from goods.

Services are intangible - they are "performances rather than objects" (Parasuraman, Zeithaml et al. 1985). Most services cannot be precisely numbered, calculated, stocked, tested and checked before delivery to ascertain quality. Due to the intangibility, the company may not be able to completely understand how customers distinguish their services and assess service quality.

Services are heterogeneous: their characteristics are usually different from provider to provider, from consumer to consumer, and from day to day. Consistent behaviour of service staff (i.e., unvarying quality) is hard to ensure every time - what the company wants to deliver may be completely different from what the customer receives.

Production and utilization of services are mostly inseparable. Consequently, quality in services is not embedded at the manufacturing plant and then distributed to the consumer, like in the case of products. In labour-intensive services quality is delivered when the service is rendered, usually in an interaction between the customer and the service provider. The service provider may also not have complete managerial control over service quality in services where customer involvement is strong, because the customer greatly influences the process. In these cases, the customer's contribution to the quality of service performance is significant.

Perishability of services means that services cannot be stocked up, accumulated, returned, or resold once rendered or once utilized. When the service has been delivered, it irreversibly disappears as it has been consumed by the consumer. The respective resources, systems and processes of a service are allocated for delivery during a defined time period.

Service quality was defined by Lewis and Booms as "A measure of how well the service level delivered matches customer expectations" (Lewis and Booms 1983). In this definition

the idea of conforming to customer expectations on a consistent basis is fundamental to service quality.

The matter of service quality became an area of focus starting in the early eighties and was addressed by many researchers (Grönroos 1984, Parasuraman, Zeithaml et al. 1985, Cronin Jr and Taylor 1994, Gummesson 1998, Lovelock and Gummesson 2004). Two models developed by Grönroos and Gummesson are important concepts in quality of services.

Grönroos developed a model in which he distinguished "technical quality" (what is received) from "functional quality" (how is it received) and surmised that the perceived quality of a service will be the result of an evaluation method, where the consumer compares his expectations with the service he perceives he has received i.e., he puts his "perceived service against the expected service" (Grönroos 1984).

In the services sector, the customer is not just concerned with "what" he gets as a result of the service delivery process, but is also concerned with the process itself. "'How' he gets the result of the technical outcome or technical quality is also important for him and his outlook towards the service received" (Grönroos 1984). This view had received empirical support. Cronin and Taylor coined the term "service performance" (SERVPERF), to highlight the process by which service is delivered (Ennew, Reed et al. 1993, Cronin Jr and Taylor 1994).

Grönroos, trying to overcome some of the limitations of his model, worked with Gummesson in the revision of the model. Gummesson had developed a comprehensive approach to quality from a large amount of empirical data from a big manufacturing company. His 4Q model stands for "design quality, manufacturing quality, supply quality and relational quality" (Gummesson and Grönroos 1987).

On the basis of an interactive approach to the provision of services, Lehtinen and Lehtinen suggested a "two-dimensional and three-dimensional approach to quality of service" (Lehtinen and Lehtinen 1991). The two-dimensional approach views service quality from the consumer's perspective, their dimensions being process quality and output quality. The concept of process quality is based on the finding that the service delivery and consumption cannot be separated, because the consumer is involved in the production process. The quality level achieved will depend on the manner of participation by the customer and provider. If

the participation is complementary, the quality of the process will be high. The three-dimensional approach describes the quality of services in terms of "physical, interactive and corporate quality" (Lehtinen and Lehtinen 1991).

Recognizing the role of employees and customer service in the provision of services, Bitner proposed an extension of the traditional marketing mix of 4P 's. Bitner's model is based on the hypothesis that there is a positive association between satisfaction with the service encounter and perceived quality (Bitner 1990).

Parasuraman proposed that consumers' expectations of services are influenced by three main factors: word-of-mouth communications, personal needs and previous experiences (Parasuraman, Zeithaml et al. 1985). While assessing the quality of services, consumers compare these expectations to the actual quality of service, and if the service does not meet expectations, there will be a "Gap". They identified five gaps that may contribute to poor quality of service perceived by customers. Their findings have been developed into the conceptual model, commonly known as SERVQUAL model, which involves a logical process that companies can use to measure and improve service quality. Focusing further on the providers' side of the model, Zeithaml, Parasuraman and Berry described the service quality gaps being between: "Customers' expectations and management perceptions; Management perceptions and service specifications; Service specifications and service delivery; Service delivery and external communication; Expected service and perceived service" (Zeithaml, Parasuraman et al. 1990).

They also described the ten criteria used by customers to evaluate the quality of services: "Credibility" - dependability, believability, honesty; "Security" – elimination of danger, threat, or uncertainty; "Access" – accessibility and ease of contact; "Communication" – informing customers in their understandable language and paying attention to them; "Understanding the customer" – endeavour to understand the customer's needs; "Tangibles" – objective evidence of the service; "Responsiveness" – keenness and inclination of employees to provide service; "Reliability" – stability of performance and dependability; "Competence" – having the required skills and knowledge to perform the service; "Courtesy" – respect, reverence, thoughtfulness and friendliness of contact personnel (Zeithaml, Parasuraman et al. 1990).

These service quality models (Grönroos 1984, Parasuraman, Zeithaml et al. 1985, Gummesson and Grönroos 1987) have widely been used across industries worldwide to help companies develop strategies to deliver quality service, to integrate customer focus across functions, and to provide the basis for service as a competitive strategy. Although, they were developed at a time when most services were delivered in person and in real time without technology in the picture, and in the following years technology has profoundly changed the nature of services, requiring strategies for closing each of the service quality gaps, the models are still relevant in this day and age (Bitner, Zeithaml et al. 2010).

2.3 Defining TQM in Healthcare: Origin and Evolution

Arguably the earliest documented attempt to define quality in medical care - King Hammurabi's Code - was an ancient Sumerian inscription on an 8-foot tall column circa 1700 BCE. Honours for successful treatment and penalties for adverse outcomes were prescribed. The latter is illustrated in the following Law:

"218: If a physician performed a major operation on a seignior with a bronze lancet and has caused the seignior's death, or he opened the eye-socket (nakkaptu) of a seignior and has destroyed the seignior's eye, they shall cut off his hand" (Majno 1991).

Throughout history, both in ancient times (Nutton 2012) and in the contemporary period, quality and safety have been key areas in medicine. Florence Nightingale (1820-1910) made some pioneering contributions to the field of quality and safety in healthcare. She managed to create the first secular nursing school in the world, in 1860, at St Thomas Hospital in London. Nightingale's greatest contributions were her efforts to reform the British military health-care system through training programs and the implementation of sound professional standards of nursing. Much of what now seems basic in modern health care can be traced back to Nightingale in the 19th century. Along with William Farr (1807-1883), who is regarded as one of the founders of medical statistics, Nightingale authored works on hygiene, sanitation, mortality and statistics all of which contributed to the body of knowledge in the science of quality (Nightingale, Farr et al. 1858, Nightingale, Farr et al. 1859, Cope 1958, Langmuir 1976, Cohen 1984).

Ignaz Semmelweis (1818-1865), the earliest known exponents of infection control, observed that women whose children were delivered by doctors and students in the first clinic at the General Hospital in Vienna, perpetually had a higher mortality than the women whose children were delivered by midwives in the Second Clinic. He noted that physicians who went directly from the autopsy suite to the obstetrics department had an unpleasant smell on their hands despite hand-washing with soap and water before entering the maternity ward. He hypothesized that puerperal fever that had affected many women in labour was caused by "cadaverous particles" transmitted from the autopsy suite to the hands of students and physicians (Semmelweis 1983). Possibly because of the deodorizing effect of chlorine

compounds, he exhorted students and doctors to wash their hands with a chlorine solution between each patient at the clinic. Maternal mortality in the first clinic had a steep decline and remained low for years. This intervention by Semmelweis represents the first evidence that the disinfection of contaminated hands with an antiseptic agent between patient contacts may reduce iatrogenic transmission of infectious diseases more effectively than hand washing with soap and water.

The last three decades of 20th Century witnessed a surge in health care quality progress. The Institute of Medicine (IOM), an American non-profit, non-governmental organization established in 1970, under the congressional charter of the National Academy of Sciences (Chassin and Galvin 1998), galvanized the cause of quality and safety in healthcare in the new millennium.

Avedis Donabedian (1919-2000), member of the Institute of Medicine, contributed a rich body of work on the conceptualization and measurement of quality. His approach to quality assessment involved three categories of information from which inferences can be drawn on the quality of care – "structure, process and outcomes" (Donabedian 1966). He suggested that quality can be assessed at multiple levels (Fig 2). At the practitioner's level there are two elements in the quality of care – technical and interpersonal.

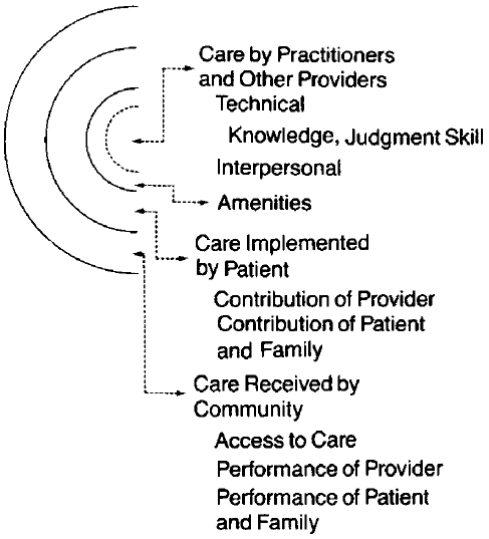


Fig 2: *Levels at which quality may be assessed (Donabedian 1997)*

In his *Introduction to Quality Assurance* Donabedian defined quality as a product of technical and interpersonal elements in healthcare, with various aspects that influence its connotation and intensity. According to him, it is possible to consider quality as the product of two factors. "One is the science and technology of health care and the second is the application of that science and technology in actual practice. The quality of care achieved in practice is the product of these two" (Donabedian 2002). That product can be regarded in terms of several elements that include "efficacy, effectiveness, efficiency, optimality, acceptability, legitimacy, and equity" and "these, taken singly or in a variety of combinations, constitute a definition of quality and, when measured in one way or another will signify its magnitude" (Donabedian 2002).

Donald M. Berwick, another pioneer in healthcare quality, co-founded the Institute for Healthcare Improvement, an organization helping to lead the improvement of health care throughout the world (Improvement 2013).

Berwick, a strong proponent of TQM principles, believed the "ultimate goal of continuous improvement is the attainment of an unprecedented level of performance" (Berwick 1989). He exhorted health care leaders to begin applying the continuous improvement model in medicine, replacing "blame and finger-pointing" with "shared goals". He insisted that organizations must invest management time, capital and technical expertise to improve quality. Respect for health professionals must be re-established, indicating that they are believed to be trying hard in good faith and not due to fear of the system.

TQM, as it was known in the manufacturing industry "evolved into continuous quality improvement as it was applied to healthcare" (Sollecito and Johnson 2011). It was well recognized that TQM / CQI (the author will use these terms interchangeably henceforth), presented a compelling case for adoption in health care (Laffel and Blumenthal 1989). At the turn of the millennium TQM became the only way for healthcare organizations to stay relevant (Kunst and Lemmink 2000), especially in the age of knowledge, consumerism and patient empowerment.

The emphasis of CQI is not on the performance of individual clinicians, but on the continuing efforts to improve the whole healthcare organization. McLaughlin and Kaluzny

presented an inter-disciplinary and integrated approach to quality in healthcare, starting with a broad definition of TQM/CQI as "A structured organizational process for involving personnel in planning and executing a continuous flow of improvements to provide quality health care that meets or exceeds expectations" (McLaughlin and Kaluzny 1990, McLaughlin 2004). This definition emphasizes the involvement of members of the staff and the need for improvement initiatives to be an unrelenting flow, primarily intended to fulfill expectations.

TQM usually exhibits these common characteristics: (1) a relationship with the key elements of the organization's strategic plan, (2) a quality committee made up of the institution's top management, (3) training programs for employees, (4) methods for selecting improvement opportunities, (5) organization of process improvement teams, (6) employee support for process analysis and redesign, and (7) employee policies that encourage staff participation in process improvement. In the course of that process analysis, rigorous techniques of the scientific method, including statistic al process control, are typically applied.

David Bluementhal deemed it necessary that physicians absorb the essence of quality, lest they lose the confidence of their patients (Blumenthal 1996). According to him, the CQI movement consists of ways to enhance quality and a "vision of leadership". The methodologies emphasize the "central role of processes in transforming inputs into outputs" in all organizations, including health care. For CQI, organizational processes are the subject matter for improvement, and their improvement is cardinal to better quality. This, in turn, is best achieved by applying scientific methods. One of CQI's important elements is its development of effective, easy techniques that are accessible to employees, who may not be aware of advanced scientific approaches, for the improvement of daily work processes (Blumenthal and Kilo 1998).

V. Kazandjian provided an interesting perspective on the definition of quality by enunciating what does not amount to quality care. According to him, the definition of quality health care is "elusive", despite the large number of publications on this subject. It is rather easy to define what quality health care is not than what it is. "It is not providing services that put patients at risk for little benefit. It is not recommending procedures and medications with high price tags and questionable results. It is not making mistakes when there are no second

chances". He further emphasizes how stories in books, newspapers and television tell in "horrific detail" what quality health care is not (Kazandjian and Sternberg 1995).

Research and Development (RAND) Corporation summarized the research done on defining and measuring quality of care into two components that are important to people. The first component is provision of high technical quality of care. High technical quality care indicates that patients receive only the interventions for which the "desired health outcomes exceed the health risks by a sufficiently wide margin"; and that each of these interventions is performed in a "technically excellent manner". The second component of quality of care is that all patients wish to be treated in a "humane and culturally appropriate manner" and be involved fully in deciding about their therapy (Brook, McGlynn et al. 2000).

It has been noticed that amongst the widely-accepted definitions of quality, there are some that are very discrete, whereas others are broad in perspective. "Discrete dimensions are sometimes subsumed in broad definitions of quality" (Leatherman 2002).

IOM defined quality as "the degree to which health services for individuals and populations increases the likelihood of desired health outcomes and are consistent with current professional knowledge" (Lohr 1990).

The widely-adopted IOM definition of Quality, in its six dimensions (Institue of Medicine 2001), is akin to WHO's working definition of Quality (Bengoa, Kawar et al. 2006). Table 1 contains the comparative definition of these dimensions.

Table 1: *Six Dimensions of Health Care Quality as per IOM (Institute of Medicine 2001) & WHO (Bengoa, Kawar et al. 2006)*

Dimension of care	Institute of Medicine (IOM)	World Health Organization (WHO)
Safe	Avoiding injuries to patients from the care that is intended to help them	Delivering health care which minimizes risks and harm to service users
Effective	Providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and overuse, respectively)	Delivering health care that is adherent to an evidence base and results in improved health outcomes for individuals and communities, based on need
Timely / Accessible	Reducing waits and sometimes harmful delays for both those who receive and those who give care	Delivering health care that is timely, geographically reasonable, and provided in a setting where skills and resources are appropriate to medical need
Patient-Centred / Acceptable	Providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions	Delivering health care which takes into account the preferences and aspirations of individual service users and the cultures of their communities
Efficient	Avoiding waste, including waste of equipment, supplies, ideas, and energy	Delivering health care in a manner which maximizes resource use and avoids waste
Equitable	Providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socio-economic status	Delivering health care which does not vary in quality because of personal characteristics such as gender, race, ethnicity, geographical location, or socio-economic status

2.4 A Quality Lexicon for Healthcare

It is difficult not to question the plenty of terms and concepts in quality and to evade thinking about the need to limit the terms, allowing it to be more "coherent and consistent". Most of the definitions of quality concepts are rather verbose and ambiguous. According the authors of the United Nations Educational, Scientific and Cultural Organization (UNESCO) publication *Quality Assurance and Accreditation: A Glossary of Basic Terms and Definitions* "Linguistic proficiency seems to be more prolific than the creative generation of practices of improvement" (Vlăsceanu, Grünberg et al. 2004). Following is a compilation of quality management terms from various sources, including original definitions from the author, and from the aforementioned UNESCO publication, extrapolated for healthcare, which intends to avoid the pitfall of leaning towards "linguistic proficiency", attempting to be more "coherent and consistent" instead.

2.4.1 Quality Culture

It refers to a set of collective, customary, and integrated patterns of quality to be found in the organizational customs and management systems of healthcare organizations. Understanding of and dedication to the quality of care, combined with a firm culture of evidence and with the proficient management of this quality are the constituents of a quality culture. As quality elements change and develop over time, so must the integrated system of quality-centric attitudes and arrangements change to facilitate new quality paradigms in health care (Vlăsceanu, Grünberg et al. 2004).

2.4.2 Quality Audit

The method of quality assessment by which an external entity assesses that (i) the organizational quality assurance procedures or (ii) the overall (internal and external) quality assurance procedures of the system are satisfactory and are actually being adhered to. Quality audit assesses the system designed for achieving intended quality and not necessarily, the quality itself. A quality audit can be performed only by persons (i.e. quality auditors) who are not directly involved in the areas being audited. Quality audits are carried out to meet internal goals (internal audit) or external goals (external audit). The outcomes of the audit must be documented (audit report) (Vlăsceanu, Grünberg et al. 2004).

2.4.3 Total Quality Management in Healthcare

The author proposes the following definition:

"A synthesis of various scientific measures to continually improve the technical and inter-personal capability of healthcare providers and organizations, to provide evidence-based care that is effective, efficient, equitable, safe, timely and patient-centred; primarily intended to promote the health and well being of individuals, communities and nations".

2.4.4 Quality Planning

It consists of the set of activities that set up the purpose and the settings of the quality of care and to the application of the established methods of the quality system. Quality planning includes health services planning, managerial and operational planning and the provision of quality improvement measures (Vlăsceanu, Grünberg et al. 2004).

2.4.5 Accreditation

The process by which a governmental, non-governmental or private body evaluates the quality of a health care organization, overall or of a specific programme, in order to formally distinguish it as having met certain pre-determined criteria or standards. The end result of this process is the awarding of a status in the form of a yes/no decision, of recognition, and usually of a license or mark to operate within a defined time-frame. The process can include initial and periodic self-assessments and assessments by external peers (Vlăsceanu, Grünberg et al. 2004).

2.4.6 Seven Basic Tools of Quality

Seven basic statistical tools integral to quality improvement efforts - Cause and Effect Diagram, Run Chart, Scatter Diagram, Flow chart, Pareto Diagram, Histogram, Control Charts (Ishikawa and Lu 1985).

2.4.7 Benchmark

A "standard, a reference point, or a criterion" against which the quality of something can be evaluated, reviewed, ascertained, and in reference with which outcomes of a specified activity can be measured. The term, benchmark, indicates a measure of "best practice performance" (Vlăsceanu, Grünberg et al. 2004).

2.4.8 Benchmarking

A standardized process for gathering and reporting important operational data in a way that allows relevant comparisons between the performances of different organizations or practices, usually to establish good practice, uncovering problems in performance, and evaluating the areas of strength. Benchmarking gives the organization external reference points and the best practices on which to base its assessment and to devise its working processes (Vlăsceanu, Grünberg et al. 2004).

2.4.9 Best Practice

An established method, involving an actual range of safe and acceptable practices resulting in improved outcomes of a particular healthcare intervention or practice, usually acknowledged by other peer organizations to be the "best". A best practice does not essentially represent an ultimate instance or pattern, whose adoption assures the improved performance of a health care organization or program; it rather identifies the best approach to a specific requirement, which has proven to be effective (Vlăsceanu, Grünberg et al. 2004).

2.4.10 Six Sigma

Six Sigma is a highly regimented process that enables a company to focus on generating and delivering near-perfect products and services. Simply put, it's an evaluation of superiority. More the Sigmas, the better it is. These days, Four Sigma is considered "mediocre". The majority of the work involved in a Six Sigma project would be in defining failures, calculating deviations and other activities which finally lead to product or service quality. Six Sigma is nowadays used more as a term for a management style, with the ultimate intention of high levels of customer satisfaction. If you are able to measure how many "defects" you encounter in a process, you can systematically understand how to eliminate them and get as close to "zero defects" as possible. For every defect you eliminate, you save money. To attain Six Sigma quality, a process must result in no more than 3.4 defects per million opportunities. This means the company needs to be near perfect in executing its key processes. The "elimination of defects makes your customer happier while you save money. That's a win-win strategy. Six Sigma makes this happen" (Harry and Schroeder 2005).

2.4.11 Lean

Lean production is the generic term used to illustrate the principles and methods of the Toyota Production System (Dyer and Nobeoka 2002). Lean production has been implemented to improve performance in multiple industries, from aerospace and aluminium refining to financial services and insurance and most recently in healthcare. Lean revolves around learning to observe waste processes from daily experience, mapping the sequence of value creation for the customer "value stream mapping - VSM" and "eliminating waste – *muda"* (Rother and Shook 2003).

2.4.12 Kaizen

Kaizen is a management philosophy which means continual improvement involving everybody, without the use of too many resources. When "Kaizen" was first described in 1986, many products from USA were of poor quality, and Japanese products were gaining market share. Since then, American companies have made significant progress in improving product quality and much of that can be attributed to their implementation of kaizen principles, which incorporate TQM (Masaaki 1986).

Chapter 3: The basis of TQM in healthcare

3.1 Characteristics of healthcare QI

Although anecdotal evidence indicates that the healthcare industry is not very different from other organisations or industry; closer scrutiny suggests that the healthcare industry is, in fact, uniquely different in the following criteria: close linkage to politics; complex organisational structures; inherent characteristics -intangibility, heterogeneity, inseparability, perishability, labour intensive, a credence product; it's objectives are continually shifting; its environment is highly influenced by concurrent government changes; and differences in the awareness, principles and work ethic of the healthcare providers (Lim and Tang 2000).

According to Margolis and Provost, the need to comprehend how to change clinical practice to integrate new knowledge increases the relevance of quality improvement (QI) methods and introducing TQM usually means motivating people in the clinical care setting to use their daily experience to recognize innovative ways to improve care, apply transformation on a small scale, collect data on the results of those changes, and assess the outcomes (Table 2). The objective is to find interventions that work well, adopt them more widely, and thereby improve clinical practice (Margolis, Provost et al. 2009).

Table 2: *Additional characteristics of QI in health care (Margolis, Provost et al. 2009)*

Characteristics of Health Care Quality Improvement
Contextual parameters (background factors or confounders in research) are a major focus
The initial changes are adapted as study progresses
Involves measuring over time (improvement is time-bound)
Includes using statistical process control methods and graphical presentation
There is involvement of local expertise in executing projects
Includes multiple iterations for quick feedback and learning
Uses multi-factorial experiments to learn from complex systems that have dynamic cause-and-effect relationships
Building reliability of the interventions can take significant effort
Sustainability is cardinal consideration, often from the initiation of the project

Margolis and Provost further define quality research as the "design, development, and evaluation of complex interventions (Table 3) to produce new general knowledge related to creating and sustaining improvement in health care delivery in real world settings" (Margolis, Provost et al. 2009). This definition highlights the need for producing generalized knowledge as a feature of QI research.

Table 3: *Features of a redesigned healthcare laboratory (Margolis, Provost et al. 2009)*

Features of a Redesigned Health Care Laboratory
Infrastructure for improvement and quality improvement research
Leadership
Use of quality improvement methods to achieve stable and reliable care delivery
Sites for developing and testing new ideas
Appropriate teams and skills
Scientific tools and resources
Health services and outcomes research capacity
Institutional review board familiarity with quality improvement methods and research
Real-time data capture during care delivery and of simultaneous analysis of data
Application of advanced quality improvement methods for experimentation
Frontline staff empowered and capable of conducting translational research
Continual development of managerial and academic leaders through training QI methods
Multidisciplinary project teams involved in translational research

3.2 What constitutes TQM: Delineating Constructs

To narrow down on what elements constitute TQM practice, early research work in the Industry by Saraph et al. (Saraph, Benson et al. 1989), was followed with numerous studies—Flynn et al. (Flynn, Schroeder et al. 1994); Black and Porter (Black and Porter 1996); Choi and Eboch (Choi and Eboch 1998); Samson and Terziovski (Samson and Terziovski 1999); and Kaynak (Kaynak 2003). These studies all addressed the core TQM elements: leadership, strategy and planning, customer focus, information and analysis, people management, and process management.

The European Foundation for Quality Management (EFQM) excellence model is a generic framework for quality management and can be construed to subsume TQM constructs. The Model (Fig 3) has nine criteria grouped as "enabler" criteria that steer the "result" criteria. The "enabler" criteria deal with how the organisation performs, how it treats its staff and resources, how it devises its strategy and how it evaluates and monitors key processes. The "enabler" criteria are: "Leadership, People, Policy and strategy, Partnerships and resources, Processes". The "results" are what the organization achieves. These include customer satisfaction, employee satisfaction, its effect on the wider community and key performance indicators. The "results" are: "People results, Customer results, Society results and Key performance results" (George, Cooper et al. 2003).

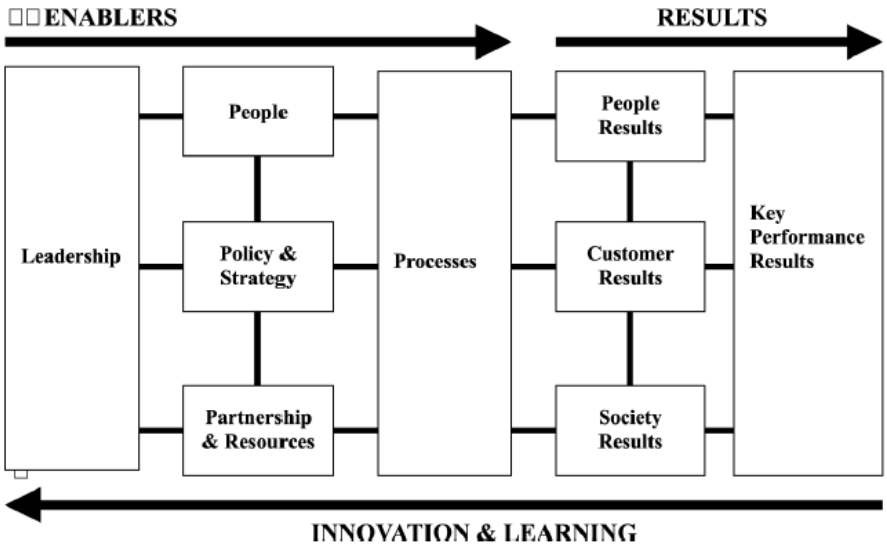


Fig 3: *The EFQM Excellence model (© EFQM) (George, Cooper et al. 2003)*

Manjunath compared the following 13 TQM constructs (Manjunath 2012), considered relevant to healthcare, with existing literature on TQM constructs (Table 4):

1. Leadership and Management Commitment
2. Strategic Planning
3. Human Resource Management and Development
4. Healthcare Service Design and Improvement
5. Process Management
6. Service Culture
7. Servicescapes
8. Administrative System
9. Measurement, Information and Analysis
10. Supplier Quality Management
11. Customer Focus and Satisfaction
12. Key Results
13. Social Responsibility

Table 4: *Comparison of 13 TQM Constructs from the Present Research to Critical Factors of TQM by Various Authors (Manjunath 2012)*

(Manjunath 2012)	(Saraph, Benson et al. 1989)	(Ahire, Golhar et al. 1996)	(Black and Porter 1996)	(Huq 1996)	(Flynn and Saladin 2001)	(Zhang, Waszink et al. 2000)	(Kunst and Lemmink 2000)	(Meyer and Collier 2001)	(Sureshchandar, Rajendran et al. 2001)	(Chow-Chua and Goh 2002)
Leadership and Management Commitment	Top Management Leadership	Top Management Commitment	Strategic Quality Management	Management Commitment Commitment to Continuous Improvement	Leadership	Leadership	Leadership	Leadership	Top Management Commitment and Visionary Leadership	Leadership and Quality Culture
Strategic Management		Benchmarking		Quality Mission Statement	Strategic Planning	Vision and Plan Statement	Policy and Strategy	Strategic Planning	Benchmarking Contiauous Improvement	Strategic Planning
Human Resource Planning, Training and Development	Employee Relations Training	Employee Training Employee Empowerment Employee Involvement	People and Customer Management	Familiarity with TQM Education and Training Performance Appraisal System Worker Empowerment	Human Resource Focus	Education and Training Employee Participation Recognition and Reward	Personnel Management	Human Resource Development and Management	Human Resource Management Union Intervention	Human Resource Development and Management
Service (or Product) Design (Patient Care Services in Healthcare)	Product Design	Design Quality Management	External Interface Management		Product Design		Patient Healthcare Design and Services	Technical System		
Process Management	Process Management		Operational Quality Planning	Causes of quality variation Problem-solving approach	Process Management	Process Control and Improvement	Process Management	Part of HRM	(Part of Technical System)	Management of Process Quality
Service Culture (or Quality Culture for Manufacturing Industry)		Corporate Quality Culture	Remove barriers for consensus Communications in Company Service Culture							
Servicescapes (Physical infrastructure)	Servicescapes									
Administrative System			Comparison of planned with	(Part included in Process		(Part included in Process				
Measurement, Information and Analysis	Quality Data Reporting Role of Quality Department	Internal Quality Information Usage SPC Usage	Quality Improvement Measurement Systems Team Work Structures Communication Improvement Information	Measures of costs of quality Statistical Evidence of Quality Quality Circles/Teams	Information and Analysis	Evaluation Quality System Improvement	Resource Management	Information and Analysis	Information and Analysis System	Use of Information and Analysis
Supplier Quality Management	Supplier Quality Management	Supplier Quality Management Supplier Performance	Supplier Partnerships	Supplier Development		Supplier Quality Management		(Part of patient care design and services)		
Customer Focus and Satisfaction		Customer Focus	Customer Satisfaction Orientation	Customer Focus Customer Feedback-Vehicles used	Customer and Market Focus	Customer Focus	Customer Satisfaction Employee Satisfaction	Focus on and satisfaction of patients and other stakeholders	Customer Focus	Customer Focus and Satisfaction
Key Results		Product Quality		Business Results		Organizational Performance Results	Employee Satisfaction	Quality Operational Results		
Social Responsibility				(Part of Leadership)		Effect on Society	(Part of Leadership)	Social Responsibility		

Jung and Wang enlisted the variable factors that constitute the four basic constructs of TQM in traditional style, but pragmatically modified based on more recent literature reviews, qualitative pre-survey interviews with TQM practitioners, and a pilot test utilizing data collected from three corporations (Jung and Wang 2006). Their TQM framework was adopted for this research study (Table 5).

Table 5: *Factor Analysis – TQM Constructs (Jung and Wang 2006)*

Constructs	**Variables**
Leadership	Top management commitment Vision and strategy Organizational quality culture Objectives for quality performance
Customer / Supplier relations	Customer relationship management Supplier partnership Customer/supplier involvement
Employee relations	Employee empowerment Human resource issues Open and transparent communication Organization-wide focus on training
Product / Process management	Availability and use of quality data Employee evaluation based on quality Use of quality improvement measurement system

3.3 Contemporary themes in Healthcare Quality

3.3.1 Tertiary Care Hospital

As per the expected functions of a tertiary care hospital, it should be located in a major city of the catchment region with a population size above one million, have a size of 500 beds or more, be affiliated with a medical school or have attached research institutions and most importantly, have service lines covering all major specialities and super-specialities of clinical care (Park and Shin 2004).

3.3.2 Evidence-Based Medicine & Clinical Practice Guidelines

In the current standardization movement in healthcare, of particular interest, is the emphasis on evidence-based medicine (EBM), or "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients" (Sackett 1997). This approach, requiring constant sources of evidence for the selected intervention, is radically different from the traditional heuristic approach to medicine. EBM "In common medical parlance, mainly denotes the use of clinical practice guidelines to disseminate proven diagnostic and therapeutic knowledge" (Timmermans and Berg 2003).

IOM defines clinical practice guidelines (CPG) as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" (Grossman, Field et al. 1990). Such guidelines offer information on which diagnostic investigations to order, when to choose conservative treatment over surgical services, how long patients should be hospitalized and other such details of clinical practice. Usually, a group of experts evaluate available scientific literature according to pre-defined clinical requirements criteria and then proposes recommendations based on the strength of the evidence, intended for the practicing clinician.

According to the fundamentals of evidence-based medicine, clinical practice guidelines should be based on scientific evidence—preferably a "meta-analysis of randomized clinical trials" presenting probability estimates of each outcome. Advocates of evidence-based medicine are careful with reasoning from basic principles, experience or heuristics; they are suspicious of claims based on expertise or "patho-physiological models". They prefer to remain distrustful as to the reason why something should or should not work—rather, they

objectively measure whether or not it works in real-life settings. Yet such evidence is not available to cover all the decision moments of a guideline. To fill in the gaps and to interpret contradictory statements that might exist in the literature, additional, less objective steps are essential to create a guideline. A preferred method is the consensus meeting, in which experts come together to discuss the disputed issues and work toward a practicable recommendation. Such meetings have been criticized for the lack of transparency in decision making and the doubt that the output of such meetings may be influenced more by group dynamics during the meeting than by the scientific literature. In response to such criticism, more systematic methods to develop clinical practice guidelines have emerged. Levels to rate the scientific quality of the evidence, which the guideline was based on, were developed, and statistical meta-analyses and systematic reviews were used to scientifically aggregate the results of multiple clinical trials. Additionally, cost-benefit data are increasingly being used in the evidence upon which the guideline is based. Relying on scientific analytic methods, guideline developers assess the benefits, harms, and costs of interventions and usually calculate estimates of the probability of each outcome. Most guideline panels include health care professionals, but also include research methodologists, health economists and even patients and consumers. Their task is to identify a focus and recipients of the guideline; retrieve, evaluate, and aggregate the evidence; recapitulate the benefits and harms; and finally decide on the appropriateness of the intervention (Timmermans and Berg 2003).

Hospitals have also emphasized the importance of process criteria in developing "critical pathways". These critical pathways define the chronology and sequence of health professionals' activities for a specific procedure or diagnosis (Coffey, Othman et al. 1995). The intention behind using critical pathways is to use resources efficiently. The emphasis in these efforts is primarily on standardizing practice of care plans for specific populations.

The implementation of EBM and CPG presents a challenge for hospitals. Availability of evidence at the point-of-care is limited, unless the Hospital uses advanced healthcare technology such as EMR / EHR. The use of CPG is usually confined to an organization and ensuring compliance across organizations is logistically difficult in fragmented healthcare delivery systems. These challenges, in part, have given rise to a new model of quality improvement called Accountable Care described later in this Chapter.

3.3.3 Standardization and Accreditation

The term ‘accreditation’ “reflects the genesis of systematic assessment of hospitals against explicit standards”. It developed in the U.S. from 1917 as a method to recognize posts in surgery. That model was the foundation of the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), which spread via Canada to Australia in the 1970s and then to Europe in the 1980s. It is most marked in Europe, including U.K., Spain, Portugal, Netherlands, Finland, Italy, France, Germany and Switzerland (Shaw 2000).

The Joint Commission on Accreditation of Hospitals (JCAH) was founded in 1951 with the primary purpose of providing voluntary accreditation. It currently certifies more than 20,000 hospitals in the U.S. alone. The Joint Commission International (JCI) was established in 1997 as a division of Joint Commission Resources, Inc. (JCR), a private, not-for-profit affiliate of The Joint Commission. Through international accreditation, consultation, publications and education programs, JCI extends The Joint Commission's mission worldwide by helping to improve the quality of patient care by assisting international health care organizations, public health agencies, health ministries and others evaluate, improve and demonstrate the quality of patient care and enhance patient safety in more than 60 countries (World Health Organization 2013). There are currently 751 JCI accredited organizations, India contributing 22 of these (Commission 2015), less than 3% of the JCI accredited hospitals world-wide.

In India the ISO 9001 quality management standard (ISO 2008) was the first to be widely accepted. An indigenous accreditation system was a growing need in the Indian healthcare industry at the turn of the millennium. It seemed, at that point of time, that India was insulated from the accreditation wave that had already settled down in the developed world. Many countries were adopting their indigenous quality standards as well and the Government of India was pursuing healthcare quality in all sectors as an important agenda. This proved to be the tipping point for Quality Council of India (QCI) to take the initiative and establish the National Accreditation Board for Hospitals and Healthcare Providers (NABH) in 2006. NABH is a constituent board of Quality Council of India (QCI), set up to start and control accreditation programmes for healthcare organisations. The board is constituted to cater to much desired needs of the consumers and to set benchmarks for advancement of health

industry. "The board while being supported by all stakeholders including industry, consumers, government, have full functional autonomy in its operation" (Providers, 2013).

Initially the overall response to the voluntary accreditation process established by QCI was tepid. Manjunath (Manjunath 2012) traced the perceived increasing need for accreditation in India from the 1980s to the post-millennial period (Table 6).

Table 6: *Changing Scenes of Establishment of Accreditation in India (Manjunath 2012)*

Time Period	Quality Management System	Need for Accreditation
1980s	Clinicians are the centre of the Hospital. QMS is applicable to the manufacturing industry	Not perceived
1990s	"A new trend. Let's see what this is all about"	Is it required in the Indian healthcare scenario?
2000s	ISO 9001 is widely accepted – NABH is slowly making inroads	A good differentiator
2010s	It's mandatory for reimbursements. Let's go beyond NABH	Established and woven into the Indian healthcare fabric

Starting in 2009, various Government health schemes started mandating entry-level pre-accreditation by NABH as a prerequisite for empanelment. This included the Central Government Health Scheme (CGHS) (News, 2013) and the Ex-Servicemen Contributory Health Scheme (ECHS) (Scheme 2011). This in more ways than one spurred a flood of applications and assessments. As of November 2015, there were 317 accredited and 490 applicant Hospitals (allopathic inpatient facility with more than 50 beds – excludes clinics, blood banks etc.) in the NABH accreditation register (Providers 2015). The number of Indian NABH accredited hospitals is ten times more than that of its JCI complement, clearly indicating the popularity of the indigenous Standard (Providers 2011). Region-wise, South India dominates the share of NABH accredited hospitals in India at approximately 40%,

followed by North India at approximately 30% (Fig 4). New Delhi is the highest in India, followed by Hyderabad, Bangalore and Mumbai (Fig 5). The influence of accreditation now seems to be percolating to third-tier cities in India, across the public-private healthcare spectrum, which inclines us towards the notion of improvement in the healthcare delivery system, but the facts are yet to be scientifically validated.

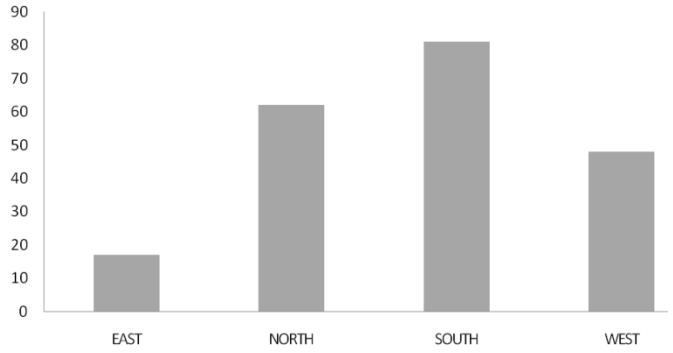


Fig 4: *Region-wise NABH Accredited Hospitals in India (Providers 2015)*

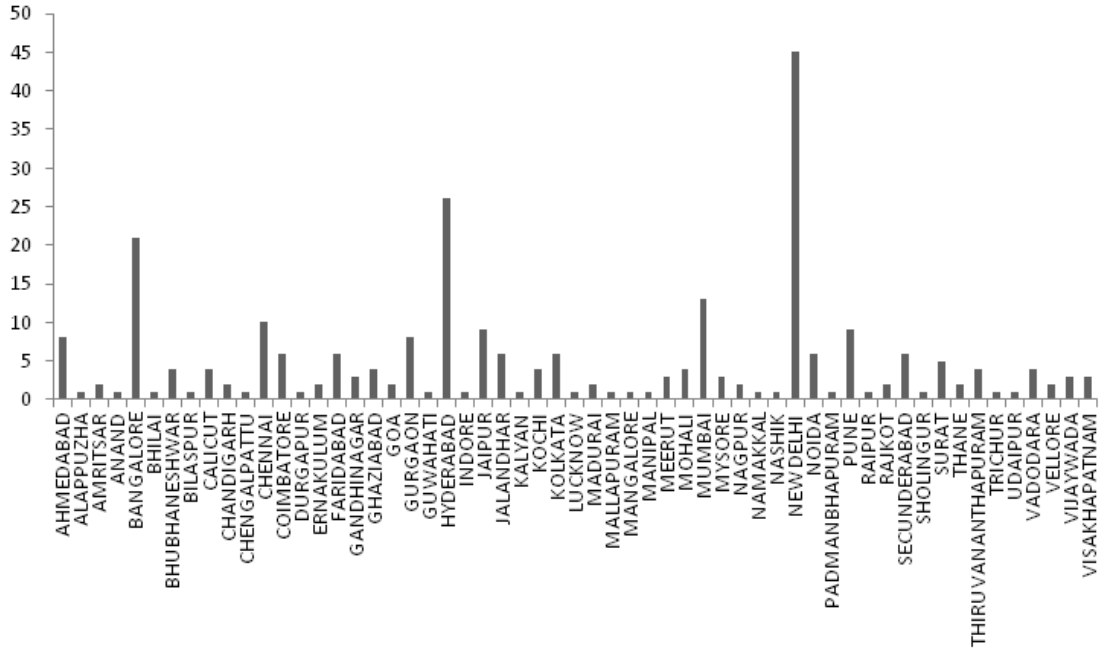


Fig 5: *City-wise NABH Accredited Hospitals in India (Providers 2015)*

International Society for Quality in Healthcare (ISQua) has accredited NABH Standards for Hospitals, 3rd Edition, November 2011, under its International Accreditation Programme for a cycle of 4 years (April 2012 to March 2016). The approval of lSQua authenticates that NABH standards are in consonance with the global benchmarks set by lSQua. The hospitals accredited by NABH have international recognition. This will provide a boost to medical tourism (Providers 2014).

NABH functions through a panel of more than 350 Assessors and experts who report to the NABH secretariat, which makes recommendations to the Accreditation Committee on accrediting hospitals that have gone through the due process of application, pre-assessment, corrective action report and final assessment (Providers 2014).

3.3.4 Experiential Learning

Experiential learning theory offers a essentially different view of the learning process from that of the behavioural theories of learning based on an "empirical epistemology" or the more established theories of learning. This theory on learning is called "experiential" for two reasons. First is to attach it clearly to its intellectual origins. The second reason is to highlight the central role that experience plays in the learning process. This distinguishes experiential learning theory from rationalist and other cognitive theories of learning that are inclined to give primary emphasis to "acquisition, manipulation, and recall of abstract symbols", and from behavioural learning theories that "deny any role for consciousness and subjective experience in the learning process" (Kolb 1984).

Experiential learning theory (ELT), according to Kolb, defines learning as the method whereby knowledge is created through the transformation of experience. Knowledge arises from the combination of grasping and transforming experience. The ELT model portrays two "dialectically related modes of grasping experience - Concrete Experience (CE) and Abstract Conceptualization (AC) - and two dialectically related modes of transforming experience -- Reflective Observation (RO) and Active Experimentation (AE)" (Kolb 1984).

According to Batalden and Davidoff, acquiring the five kinds of knowledge systems involved in healthcare quality improvement (Table 7) requires scientific and experiential learning.

Table 7: *Characteristics of five knowledge systems involved in improvement (Batalden and Davidoff 2007)*

Knowledge system	**Illustrative features**
1. Generalized scientific evidence	Controls and limits context as a variable; tests hypotheses
2. Particular context awareness	Characterises the particular physical, social and cultural identity of local care settings (e.g., their processes, habits and traditions)
3. Performance measurement	Assesses the effect of changes by using study methods that preserve time as a variable, use balanced measures (range of perspectives, dimensions), analyse for patterns
4. Plans for change	Describes the variety of methods available for connecting evidence to particular contexts
5. Execution of planned changes	Provides insight into the strategic, operational and human resource realities of particular settings (drivers) that will make changes happen

3.3.5 Translational Research

Health care researchers and their funders, including the National Institutes of Health (NIH) and the Agency for Healthcare Research and Quality (AHRQ), increasingly point to translational research as a way to effectively incorporate research findings into health care practice (Woolf 2008).

Translational research is defined as “the process of applying ideas, insights, and discoveries generated through basic scientific inquiry to the treatment or prevention of human disease” (Strokes 2010).

WHO in its 2013 World Report defines Translational Research as the "research, which moves knowledge gained from basic research to its application in the clinic and community, is often characterized as 'bench-to-bedside' and 'bedside-to-community'" (World Health Organization 2013). The translation is during any of the several stages: moving primary discovery into a prototype health application; evaluating the value of an application leading to the development of evidence-based guidelines; adopting guidelines into health practice, through release, propagation, and diffusion research; or evaluating the health outcomes of public health practice.

Translational research looks to improve health care by encouraging action and change in real-life health care settings. Although translational research promotes a deviation from the traditional researcher-initiated approach to science, ways to successfully engage clinicians and leaders of health care delivery organizations in research are still under development.

Applying the principles of community-based participatory research in line with delivery systems—including healthcare leaders, clinicians, and staff—as a focal community can augment the ability of translational research to improve health care. Applying participatory research systems, such as "engaging in collaborative partnerships, building on existing community strengths, investing in long-term relationships, and engaging in research as a cyclical, iterative process", can be an effective approach to "sustainable quality improvement at the systems level" (Schmittdiel, Grumbach et al. 2010).

3.3.6 Causal Effect

The theory of causality has many implications for TQM/CQI, especially in health care. What interventions are effective? What methodologies are actually useful in bringing about improvements? Such questions indicate the cause-effect relationship. Scientifically, causal effect has a specific implication. Hernan defined causal effect of an exposure on the outcome, as "the difference between the counterfactual risk of the outcome had everybody in the population of interest been exposed and the counterfactual risk of the outcome had everybody in the population been unexposed" (Hernan 2004).

3.3.7 Quality Monitoring

"Quality Indicators" is a very common-place term in hospitals these days. Quality assessment and monitoring is required as part of maintaining health accreditation and for continuing empanelment with third-party payment systems.

What quality indicators are the right fit for an organization is a matter for speculation and debate. JCI and NABH (International 2011, Providers 2011) require certain quality indicators to be monitored and reported. In 2003, WHO's regional office in Europe launched a project aiming to develop and disseminate a flexible and comprehensive tool for the assessment of hospital performance - the Performance Assessment Tool for quality improvement in Hospitals (PATH) (Veillard, Champagne et al. 2005). In the PATH study the criteria for quality indicator selection were set (Table 8).

Table 8: *Criteria for Quality Indicator Selection – PATH-WHO (Veillard, Champagne et al. 2005)*

Level	Criteria	Issue addressed by the criterion
Set of indicators	Face validity	Is the indicator set acceptable as such by its potential users?
	Content validity	Are all the dimensions covered properly?
	Construct validity	How do indicators relate to each other?
Indicators	Importance and relevance	Does the indicator reflect aspects of functioning that matter to users and are relevant in current healthcare context?
	Potential for use (and abuse) and sensitivity to implementation	Are hospitals able to act upon this indicator if it reveals a problem?
Measurement tools	Reliability	Is there demonstrated reliability (reproducibility) of data?
	Face validity	Is there a consensus among users and experts that this measure is related to the dimension (or subdimension) it is supposed to assess?
	Content validity	Does the measure relate to the subdimension of performance it is supposed to assess?
	Contextual validity	Is this indicator valid in different contexts?
	Construct validity	Is this indicator related to other indicators measuring the same subdimension of hospital performance?
	Burden of data collection	Are data available and easy to access?

The final PATH list contains a Core set of 17 indicators that are pertinent to all contexts and characterize a low burden of data collection and a Tailored set of 24 indicators that are either pertinent to a limited number of contexts, or, because of their high burden of data collection, are recommended if congruent with the organization or country's priorities. Following are the PATH indicators (Veillard, Champagne et al. 2005):

Core Set

C1. Caesarean Section

C2. Prophylactic Antibiotic use (planned surgery for colorectal cancer, coronary artery bypass graft, hip replacement, hysterectomy)

C3. Mortality (acute myocardial infarction, stroke, community acquired pneumonia, hip fracture, coronary artery bypass graft)

C4. Readmission (acute myocardial infarction, stroke, community acquired pneumonia, hip fracture, coronary artery bypass graft, asthma, diabetes mellitus)

C5. Day surgery for eight tracers (cataract surgery, knee arthroscopy, inguinal hernia, curettage of the uterus, tonsillectomy and/or adenoidectomy, cholecystectomy, tube ligation, varicose veins stripping and ligation)

C6. Admission after day surgery (same tracers as day surgery)

C7 Return to ICU

C8. Length of stay (acute myocardial infarction, stroke, community acquired pneumonia, hip fracture, coronary artery bypass graft)

C9. Surgical Theatre use

C10. Training expenditure

C11. Absenteeism

C12. Excessive working hours

C13. Needle injuries

C14. Staff smoking prevalence

C15. Breastfeeding at discharge

C16. Health care transitions

C17. Patient expectations

Tailored Set

T1. Door to needle time

T2. Computer tomography scan after stroke

T3. Acute myocardial infarction patients discharged on aspirin

T4. Mortality indicators (C3) with more advanced risk-adjustment

T5. Readmission indicators (C4) with more advanced risk-adjustment

T6. Pressure ulcers for stroke and fracture patients

T7. Rate of hospital-acquired infections

T8. Score on Appropriateness Evaluation Protocol

T9. Costs antibiotics/patients

T10. Length of stay indicators (C8) case-mix adjusted

T11. Cash-Flow/Debt

T12. Cost of corporate services/patient day

T13. % wages paid on time

T14. Survey on staff burnout

T15. % job descriptions with risk assessment

T16. Staff turnover

T17. Work-related injuries by type

T18. Audit of discharge preparation

T19. % discharge letters sent

T20. Score on Appropriateness Evaluation Protocol for geriatric patients

T21. Waiting time for day surgery tracers

T22. Acute myocardial infarction and coronary heart failure with lifestyle counseling

T23. Patient survey score on access to care

T24. Patient survey score on amenities of care

3.3.8 Peer Review

Peer review is an important element of clinical quality. It evaluates all aspects of clinical care provided by all physicians to all patients. Medical records are first screened to determine whether or not there are open questions about a physician's care. The criteria for medical record review are developed by physicians. Recommendations of any actions to be taken against a doctor as an outcome of the peer review are recommendations only. Departments usually do not take action against a physician. Actions are taken by Committees with higher authority, in response to continuing patterns or formal complaints, or significant events that merit actions.

3.3.9 Morbidity and Mortality Conferences

Morbidity and Mortality (M & M) conferences are one of the most effective risk management tools due to the learning that occurs when physicians discuss their own difficult or challenging cases. Cases which have recently occurred within the hospital and that have posed challenges in treatment, hold a natural appeal for discussion, making the regularly scheduled M & M conference a good opportunity for educational exchange. Clinicians may initially feel hesitant to actively criticize one another's work but this hesitation tends to dissolve in the non-punitive atmosphere that focuses on the goal of improved patient care. The basic objective of M & M conferences should always be improving the quality of care.

3.3.10 Medical Audit

An established approach to improving the quality of clinical care, a medical audit is a methodical and critical analysis of clinical care, including investigations, procedures and interventions used for diagnosis and treatment, the use of resources, and the consequent outcome and quality of life for the patient (Johnston, Crombie et al. 2000).

3.3.11 Organized Case Management

Case management is a complex phenomenon that can be defined as a clinician or clinical group that oversees a patient's plan of care "across the episode or continuum". Case management services are not required by all patients. Instead case management is used for very complex cases, cases demonstrating high cost or high volume, cases of patients admitted to acute care or with numerous unscheduled visits to ambulatory care, or for patients with many unmet socioeconomic needs. "At any given time fewer than 20% of patients cared for within a health system will require case management services" (Hill 1997). The objective of case management is to improve the management of care by anticipating high-risk patient needs, preventing or decreasing the number of acute exacerbations of the condition and monitoring the effect of the interventions continuously over time.

3.3.12 Integrated Quality Assurance, Utilization Review and Risk Management

There is a large degree of cohesion in functions, conduct and level of interest among risk management (RM), utilization review (UR), and quality assurance (QA) departments. Hospitals can take advantage of on this commonality of interest to determine if thorough integration of activities and operational improvements can be achieved. Risk managers,

quality managers and utilization review staff have a shared interest in reviewing data regarding adverse events. Each individual may have a distinctive purpose for the data but the need for data is common. Quality departments are usually replete with data on clinical outcomes, patient safety, utilization, and medication errors. Infection control programs contain useful information about nosocomial infections and other surveillance activities that may also shed light on RM and UR issues. Several databases may exist within one hospital, either alone or in combination with regional and national comparative data. These databases should be a shared resource among departments, as must the actual data needs from each area.

3.3.13 Disease State Management

Disease state management (DSM) is the practice of organizing care for a particular high-cost and/or high volume diagnosis, with an aim to improve outcomes and, when possible, lower overall costs. DSM is a multi-step process involving evidence-based clinical policies, an clear implementation strategy and a data-driven feedback mechanism to objectively measure those aspects of care the program is intended to impact. It is a synchronized systems approach to managing and improving care processes throughout the care continuum—from prevention via self-care ambulatory services, to acute hospitalization, rehabilitation and recovery.

3.3.14 Clinical Transformation

According to Bluementhal, "Information is the lifeblood of modern medicine. Health information technology (HIT) is destined to be its circulatory system. Without that system, neither individual physicians nor health care institutions can perform at their best or deliver the highest-quality care, any more than an Olympian could excel with a failing heart" (Blumenthal 2010).

Health Information Technology (HIT) has the power to transform healthcare. Electronic Health Records (EHR) could result not only in time and cost savings for both patients and physicians, but could also significantly improve outcomes (Feied, Handler et al. 2004). IOM considers some components of health IT to have significantly improved the quality of health care and reduced medical errors. According to IOM's Safety and HIT Committee Report, "continuing to use paper records can place patients at unnecessary risk for harm and

substantially constrain the country's ability to reform health care" (Institute of Medicine 2012).

The burgeoning influence of technology on healthcare is evident in the recently enacted stimulus bill in the U.S., American Recovery and Reinvestment Act of 2009 (ARRA) that promotes the adoption and use of health information technology (HIT), especially the "meaningful use" (Blumenthal 2010) of electronic health records (EHRs).

The HIT components of the unprecedented $19 billion stimulus package — collectively labelled HITECH (Health Information Technology for Economic and Clinical Health Act), reflect a shared confidence among the Obama administration, the Congress, and many health care experts that electronic information systems are vital to improving the health care. However, few U.S. doctors or hospitals — perhaps 17% and 10%, respectively — have even basic EHRs, and there are major barriers to their adoption and use: their substantial cost, the apparent lack of financial return from investing in them, the technical and logistic issues involved in installing, maintaining, and updating them, and patients' and physicians' worries about the privacy and security of electronic health information. HITECH is intended to tacke these challenges. One of HITECH's most significant features is its clarity of purpose. The U.S. Congress deems HIT — computers, software, internet connection, telemedicine — not "as an end in itself but as a means of improving the quality of health care, the health of populations, and the efficiency of health care systems" (Blumenthal 2009).

Now-a-days it is generally accepted that the wide adoption of electronic medical record (EMR) systems will result in major health care savings, curb medical errors, and improve clinical outcomes. A 2005 RAND study suggests that the adoption of interoperable EMR systems could produce efficiency and safety savings of $142–$371 billion (Hillestad, Bigelow et al. 2005).

In 1995, the Veteran Health Administration (VHA) in the Department of Veterans Affairs (VA) launched a major reengineering of its health care system with objectives that included better use of information technology, monitoring and reporting of performance, and integration of services and aligned payment policies (Kizer 1999).

Jha and Perlin compared the quality of care in the VA health care system before and after it's reengineering and established that the quality of care improved dramatically in all domains studied. These improvements were obvious within two years of its reengineering and sustained through the year 2000. When they compared similar indicators of quality in the VA and Medicare fee-for-service systems during similar time periods, we found that the VA system performed better (Jha, Perlin et al. 2003).

Clinical transformation (CT) promises to be the next "big thing" in healthcare quality. CT is the all-encompassing term for EMR and associated technologies. It is currently the "buzz-word" in the HIT industry, for which there are very few published definitions.

One published definition of CT is "clinical and non-clinical process improvement that is supported by technology. Technology must be seen as supporting and not driving the processes of care and improvement to reach the desired outcomes" (Bolton, Gassert et al. 2008).

The Author would like to define Clinical Transformation as:

"The metamorphosis of clinical and support processes through the judicious implementation and adoption of clinical technologies, especially electronic health records, to enable overt improvements in Safety, Costs, Outcomes, Research and Experience (SCORE)".

The American College of Emergency Physician (ACEP) states in one of its policies, "Health IT presents ongoing opportunities to improve the quality of emergency care, promote patient safety, reduce medical errors, and enhance the efficiency of emergency departments (EDs)" (Rothenhaus, FACEP et al. 2007). The ED can be at the forefront of quality improvements, because of its unique characteristics: a simplified environment which is "essentially a self-contained miniature health care delivery system in terms of the processes of care and categories of information that exist within its departmental walls" (Spalding, Mayer et al. 2011). The ED is deemed a potentially pioneering department when it comes to deploying and adoption clinical information systems.

According to the Emergency Care Special Interest Group – HL7 (Health Level 7), "Emergency Department Information System (EDIS) is an extended EHR system used to

manage data in support of Emergency Department patient care and operations. The functions of an EDIS may be provided by a single application or multiple applications" (Smith and Feied 1998).

EDIS has been associated with various quality and safety improvements in EDs. These include reduction in length of stay, accurate and complete patient history, patient flow automation, computerized physician order entry, automated quality-safety monitoring, and sophisticated clinical decision support systems (Feied, Handler et al. 2004, Taylor 2004).

EMR adoption world-wide has seen a steep incline in the past six years, especially in the USA, where Federal mandates and incentives have resulted in more than a five-fold increase in Hospital adoption of EMR systems. 59% hospitals in the USA have adopted at least a Basic EMR system (Charles, King et al. 2013). At least 46% of the EDs in the USA have adopted an EDIS (Landman, Bernstein et al. 2010). In India, the story of EMR adoption is still in its nascence. From the authors' knowledge of the Industry, only a handful of Private and Public hospitals have implemented and adopted systems that can be deemed to be an EMR. The Government of India has published Standards for Electronic Health Records in India (MoHFW 2013), which is definitely a sign of the ensuing surge in EMR adoption.

3.3.15 Accountable Care Organization

As part of the U.S. legislation under the Obama administration, the Affordable Care Act, the Department of Health and Human Services (DHHS) finalized the rules for establishing Accountable Care Organizations (ACO). This model of payment under the Medicare Share Savings Program is actually a quality improvement model tightly coupled with the payment model. ACOs are voluntary groups of physicians, hospitals, and other health care providers that take the responsibility for the care of a clearly defined population of Medicare beneficiaries ascribed to them on the basis of patients' utilization of primary care services. "If an ACO succeeds in both delivering high-quality care or improving care and reducing the cost of that care below what would otherwise have been expected, it will share in the savings it achieves for Medicare" (Berwick 2011). There are predefined clinical measures like Glycosylated Haemoglobin(HbA1c) level control in diabetic populations, Low Density Lipoprotein (LDL) level control in ischemic heart disease patient population, Blood Pressure control in hypertensive patient population and 30 such indicators which the ACO is required

to submit to Medicare. Based on these indicators the ACO will receive payments, incentives or penalties, in case the performance is negative. This method of reimbursement is focused on clinical outcomes and ensures the optimum care of individuals across multiple hospitals and care settings, by putting the onus of outcomes on the physicians who are part of the ACO. This innovative model of quality improvement is soon going to make inroads into the Indian healthcare domain, in the Author's opinion.

3.3.15 Big Data

The age of the EMR has now given rise to the big data revolution in healthcare. Decades of stored data that has now been made public is open of indexing, search and analysis by the healthcare sector as a whole. We now have access to promising new insights. This information is a form of "big data," due to the large volumes and complex arrays – including EMR, point-of-care devices, equipment interfaces. We now have tools and applications to analyze this enormous amount of data, that too in real-time to provide intelligence that was not available even 5 years back. This "Big Data" revolution is bound to significantly change the implications of healthcare technology on quality improvement, patient safety and research.

Chapter 4: Research Methodology

4.1 Gaps in Existing Research

Although the subject of quality in healthcare has extensively been researched in its foundation, translational research of TQM/CQI interventions' has seldom been carried out.

A test for the query "quality improvement" on the Medline database returned 6928 results in PubMed Health, 316 of these from India. There were zero results for "NABH", 96 results for EMR, only 4 of which were from India.

Research done by Manjunath (Manjunath, Metri et al. 2007) addressed validation of the MBNQA framework in a HCO, but was done at a time when Indian hospitals had started implementing NABH standards. The need for sampling NABH accredited hospitals for testing and improving quality frameworks was felt by the author then (Manjunath 2012).

Other published research on TQM/CQI from studies carried out in India (Mohanty, Santhi et al. 1996, Reddy, Arundhathy et al. 2002, Duggirala, Rajendran et al. 2008, Padma, Rajendran et al. 2010, Talib, Rahman et al. 2011), although exemplary in terms of the foundation of TQM/CQI, lacks either the statistical validation of quality improvements, or was at a time when NABH was nascent. The need for a comprehensive study that traces incremental improvements in the process of accreditation (NABH) and TQM implementation is pressing. There has been no study on the analysis of NABH Assessors' perceptions on TQM constructs aligning with NABH implementation.

A thorough review of relevant literature has made it obvious that there are not many studies in the U.S. and other developed nations which actually statistically validate the improvements in health care due to application of TQM tools and accreditation. "No country in the world requires the production of a yearly national report on the level of quality delivered in its health system, although all countries in the world produce multiple financial reports" (Brook, McGlynn et al. 2000). In India, there are no published objective studies on TQM, Standardization and Accreditation (ISO 9001, JCI, NABH) and the impact of adoption of these quality improvement methodologies in a HCO. The Government of India is strongly pursuing regulatory quality in healthcare sector through NABH accreditation requirement. A

prototype study involving development of an implementation model through translational research and experiential learning of TQM and Accreditation in a tertiary-care hospital is an urgent requirement of the Indian Healthcare Industry. Such a study based on research into the quantifiable improvements in clinical outcomes, patient satisfaction, and safety indicators, due to TQM implementation, including NABH accreditation, would definitely prove to be a valuable reference for furthering the cause of healthcare quality in India.

Although extensively researched in the U.S. and U.K., the state of HIT and clinical transformation research in India is dismal. Apart from a few nascent studies on EMR (Anantraman, Mikkelsen et al. 2002, Koppar and Sridhar 2009, Scholl, Syed-Abdul et al. 2011), there is no evidence for the impact of clinical transformation initiatives on quality and safety outcomes. A pilot study validating the potential quality improvements through EMR implementation and adoption would go a long way in setting up the EMR research agenda in India.

4.2 Research Objectives

The research is directed towards a systems-based approach for translational research of Total Quality Management constructs & tools, standardization & accreditation in a medium-sized, tertiary care hospital. This study seeks to answer the primary research question, "What difference does a TQM program make in a HCO?" The research hypothesis was that there are significant positive improvements due to TQM, NABH accreditation and EMR adoption – the alternate hypothesis (H_a); no changes occurring due to these initiatives being the null hypothesis (H_0).

The more specific objectives of the research work to be carried out are as follows:

1. Deduce critical-to-quality factors in a tertiary-care Hospital and evaluate the impact of ISO 9001:2008 on these factors.
2. Create an implementation model for Total Quality Management in an HCO through continuous experiential learning in an action research framework at study site.
3. Taking NABH compliance as base-line reference, validation of TQM initiatives by objective assessments of the HCO at various stages of the quality systems evolution.
4. Third party audit of the HCO leading to positive end-result of NABH accreditation
5. Seek empirical evidence for the causal effect of TQM initiatives and accreditation (NABH) on the HCO from specific clinical quality indicators.
6. Test NABH standards against the framework of TQM constructs through analysis of NABH Assessors' perceptions and make recommendations for improvements required in the Standard.
7. Test the potential quality improvements through implementation and adoption of EMR and suggest future research directions.
8. Develop a service-excellence model for tertiary-care HCOs and suggest a roadmap for TQM in the HCO.

Keywords:

Total Quality Management (TQM); Continuous Quality Improvement (CQI); Accreditation; Clinical Outcomes; Patient Safety; NABH; Electronic Medical Records (EMR); Experiential Learning; Translational Research

4.3 Methodology

4.3.1 Approach

The inductive as well as deductive approaches in this research were aimed primarily at the micro-environmental issues of Quality in health systems, aspiring to extrapolate inferences for macro-environmental issues. It intends to be a translational as well as a participatory action research of improvements in overall quality, tested by the accreditation of the HCO and the objective impact on measurable indicators of clinical outcomes, patient satisfaction and safety. It was designed a unicentric longitudinal observation study under experimental design to enable translational and participatory action research. The validity of the experiment was ensured operationally by detailing the implementation framework and by maintaining the same set of metrics throughout the study period.

4.3.2 Study Site

Jehangir Hospital, a 350-bedded hospital in Pune, was chosen as the study site. Established in 1946 as a nursing home, Jehangir Hospital evolved into a multi-speciality tertiary care hospital over the years. At the inception of this research study, Jehangir Hospital was initiating its formal quality journey through ISO 9001 and had plans to implement NABH Standards in the next phase. The necessary infrastructural and technical facilities needed for the longitudinal observation study and experimental design of quality research were available and accessible.

4.3.3 Research Design

A prospective cohort study was carried out at the study site spanning the entire duration of its quality journey – from the inception of TQM constructs, ISO 9001 implementation, NABH implementation and accreditation, and EMR adoption. The methodological problem of generalizing the outcomes of one study centre were resolved by converting the study into an experimental design by including benchmark measures for each of the metrics so as to deduce causality between quality indicator measures (dependent variable) and improvement methods (independent variable)

4.3.4 Sampling

Sample sizes were calculated for a 95% level of significance (LOS), based on the power of individual statistical tests and the relative standard error for each of data set. Specific details of sampling for each quality improvement method adopted are presented in Table 9.

Table 9: *Sampling Details*

QI tool	Estimation	Statistic	LOS	Sampling Frame	Sampling Method	Sample Size
ISO 9001 CTQ factors	Mean feedback scores	Ljung Box Q-test	95%	Feedback forms	Simple Random	55,306
NABH Assessments	Mean SA scores	Friedman's test	95%	Self Assessment scores	Total Population	2544
Quality Indicators	Mean rates	Ljung Box Q-test	95%	Quality Indicator measures	Total Population	840
NABH Expert Elicitation Survey	Mean response scores	Chi-Square test Kolmogorov Smirnov test	95%	NABH assessors mail-group	Stratified Random	43
EMR Time-Motion Study	Average time	Paired t-Test	95%	ED roster	Simple Random	50
EMR Feedback	Mean feedback scores	t-Test	95%	ED roster	Total Population	23

4.3.5 Research Tools

1. Paper-based questionnaires
2. Online Surveys

4.3.6 Data Analysis Tools

1. MS Excel 2007
2. SPSS v 20
3. Cloud-Hosted EMR-EDIS

4.3.7 Data Sources

1. Patient feedback scores maintained by Guest Relations department of the HCO
2. Survey questionnaire responses from NABH Assessors of India
3. Quality Indicator data maintained by the Quality Systems office of the HCO
4. NABH self assessment sheets maintained by the Quality Systems office of the HCO
5. EMR-EDIS database extracts maintained by the Emergency Department of the HCO
6. EMR-EDIS feedback responses

4.3.8 Data Analysis

Selection of the test statistic was made based on descriptive statistics of the data collected - mean, median, mode, standard deviation. Parametric tests were used for measurable quality indicators and time-motion studies, whereas non-parametric tests were used for survey responses and assessment scores.

4.3.9 Study Phases

Phase I: Extensive literature survey on existent TQM practices and healthcare accreditation. Review of literature on the impact of TQM on clinical indicators, patient satisfaction and healthcare safety.

Phase II: Current state CTQ factor analysis – ISO 9001 impact

Phase III: TQM constructs validation - survey of NABH assessors, NABH-TQM implementation – continual improvement, EMR adoption study

Phase IV: Data analysis and reporting. Healthcare service excellence model development

Phase V: Conclusions and recommendations based on above analysis with thesis writing and the thesis submission.

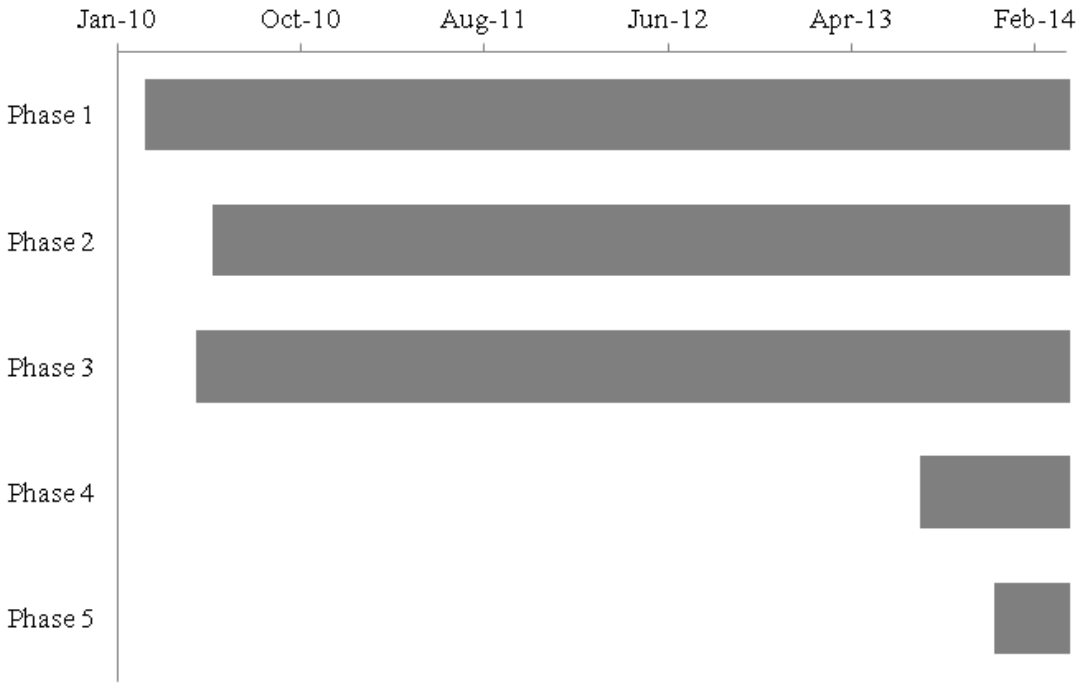


Fig 6: *Research Study Phases*

Chapter 5: Impact of Quality Improvement Methods on the HCO

5.1 ISO 9001 certification

The starting point was an objective evaluation of the critical-to-quality (CTQ) factors in the HCO. The average feedback scores (Appendix 1) for each of the CTQs from the patient feedback form, with responses on a 5-point Likert scale, were trended for a 35-month period from January 2008 until November 2010. The rationale behind the 35-month period was to specifically evaluate the isolated impact of ISO 9001 first and then the combined effect of ISO 9001 and NABH implementation which was initiated in January 2010. The 35-month patient feedback data amounted to 55306 patient feedback responses. The ISO 9001 QMS implementation was initiated in April 2008 which represented the first intervention point. ISO 9001 certification was achieved in February 2009 – the second point of interest, and November 2010 when NABH implementation was underway, the third point of interest. The improvements in CTQ factors through ISO 9001 implementation were tested with Interrupted Time Series (ITS) modelling through a univariate analysis on the Autoregressive Integrated Moving Average (ARIMA) model, with dependent variable as the average patient feedback scores before and after ISO 9001 certification. The residuals were tested with the Ljung-Box Q-Test (LBQ-test) statistic.

The average feedback scores for each of the CTQ factors – Admissions, Guest Relations, Doctors, Nursing, Housekeeping, Maintenance, Patient Care Services, Intensive Care and the Overall feedback scores were analyzed through Interrupted Time Series analysis on the *non-seasonal ARIMA (0,1,0) "random walk" model* (Model_1) for each category and residuals were tested with the Ljung-Box Q-test (LBQ-test) statistic. Following are the feedback trends and statistical inferences (Figs 7-24).

Admissions

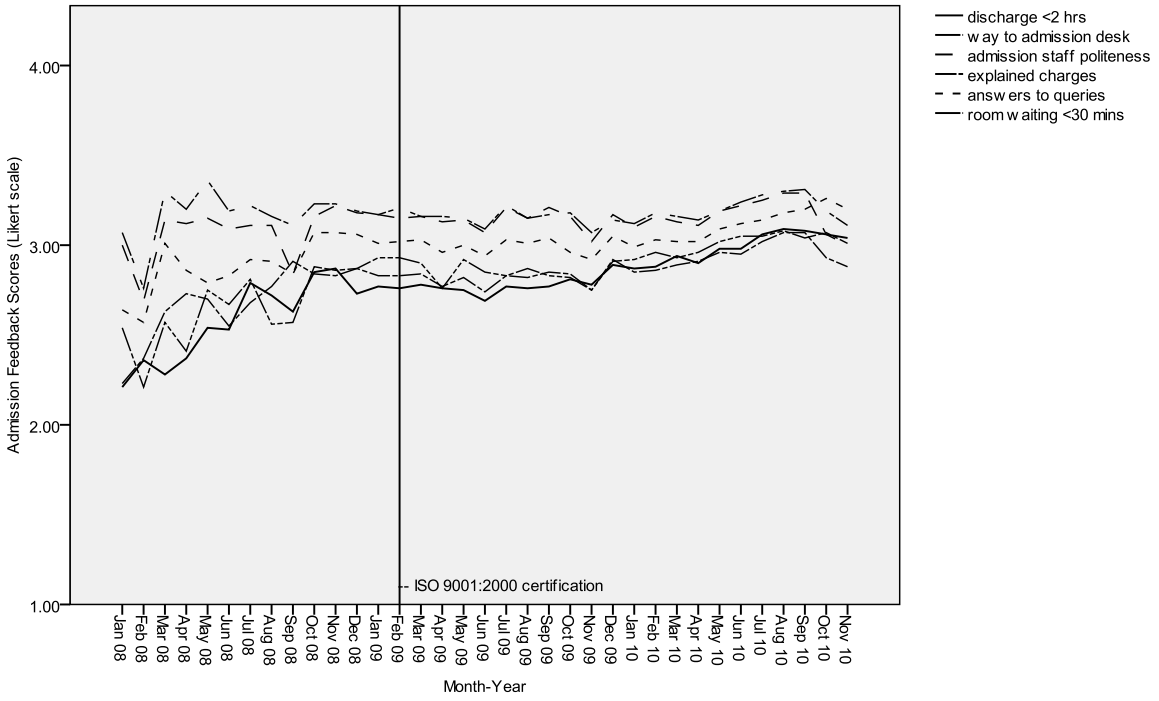
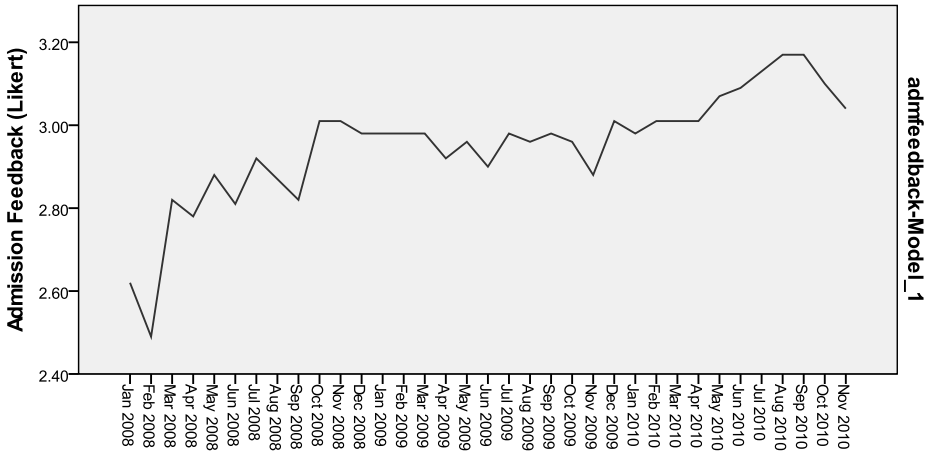


Fig 7: *Admission Feedback Trend for HCO*



Model Statistics

Model	Number of Predictors	Model Fit statistics	Ljung-Box Q(18)			Number of Outliers
		Stationary R-squared	Statistics	DF	Sig.	
Admission Feedback-Model_1	3	.062	34.865	18	.010	0

Fig. 8: *Admission Feedback ARIMA model*

The average admission feedback score improved from 2.73 to 3.00 (LBQ-test; $p < 0.05$)

Guest Relations

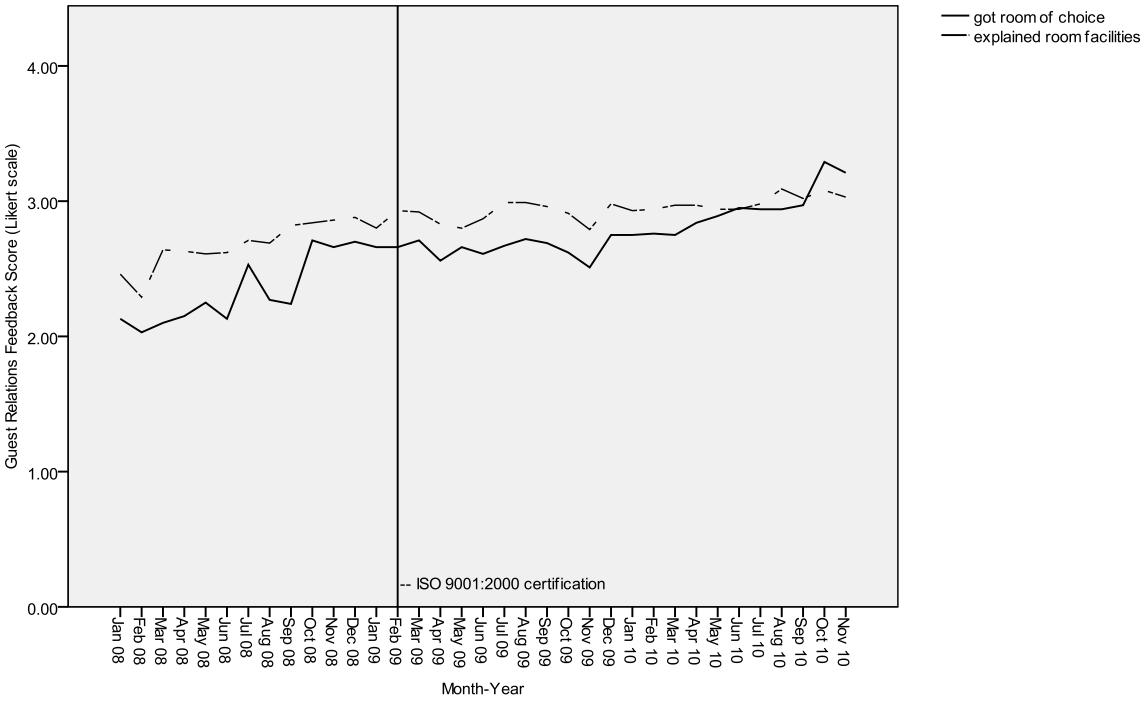
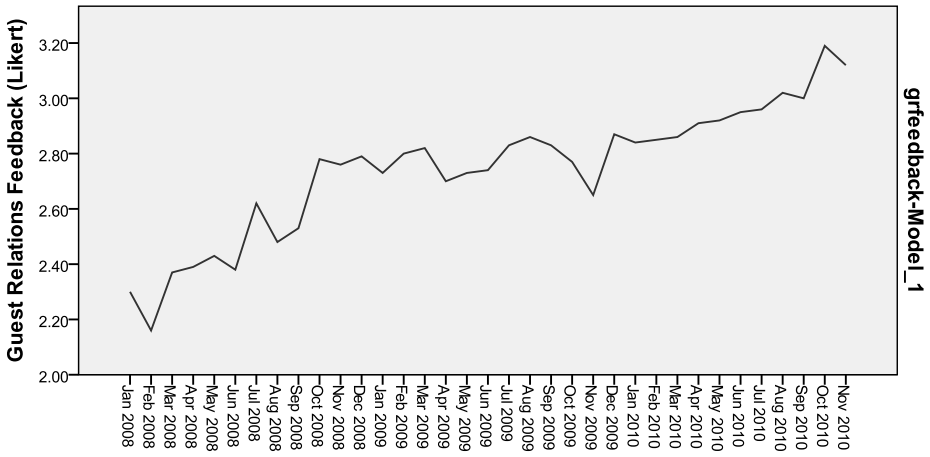


Fig 9: *Guest Relations Feedback Trend for HCO*



Model Statistics

Model	Number of Predictors	Model Fit statistics: Stationary R-squared	Ljung-Box Q(18): Statistics	Ljung-Box Q(18): DF	Ljung-Box Q(18): Sig.	Number of Outliers
Guest Relations Feedback-Model_1	3	.024	24.089	18	.152	0

Fig 10: *Guest Relations Feedback ARIMA model*

The average Guest Relations feedback score improved from 2.34 to 2.82 (LBQ-test; $p > 0.05$)

Doctors

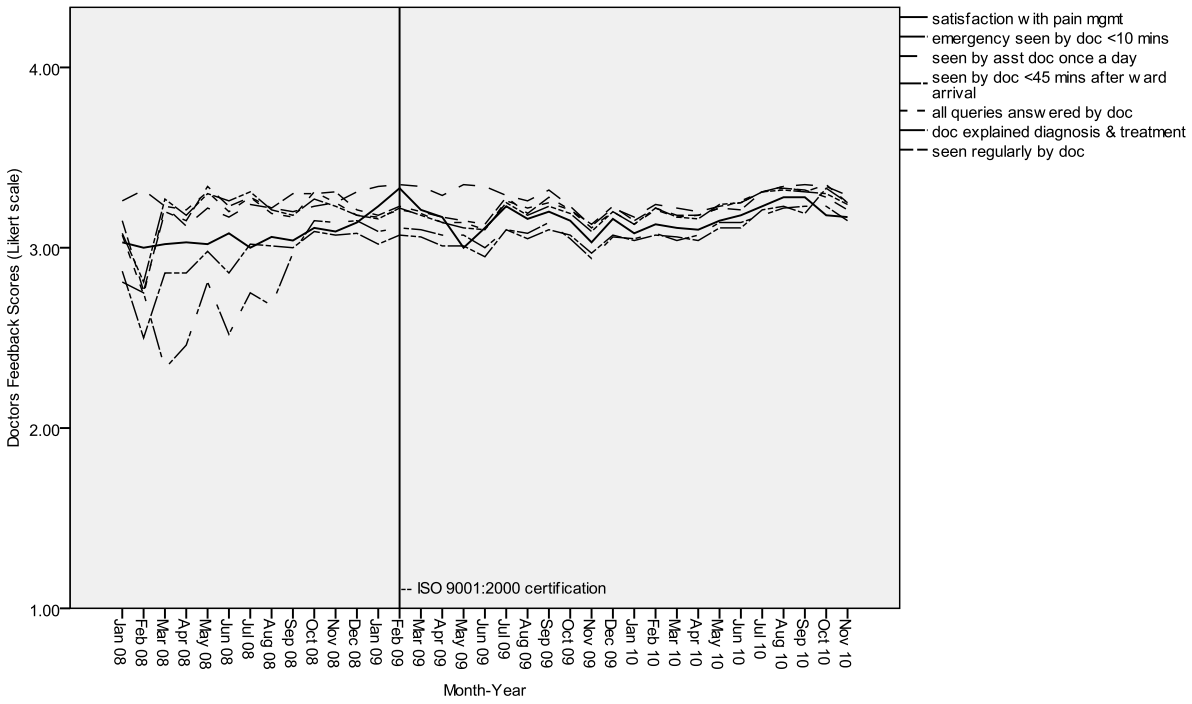
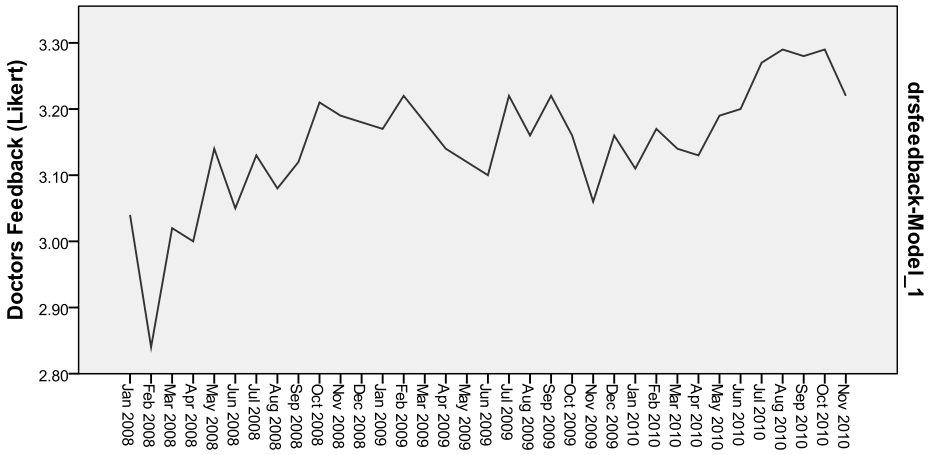


Fig 11: *Doctors Feedback Trend for HCO*



Model Statistics

Model	Number of Predictors	Model Fit statistics	Ljung-Box Q(18)			Number of Outliers
		Stationary R-squared	Statistics	DF	Sig.	
Doctors Feedback-Model_1	3	.011	26.308	18	.093	0

Fig 12: *Doctors Feedback ARIMA model*

The average Doctors feedback score improved from 3.01 to 3.18 (LBQ-test; $p > 0.05$).

Nursing

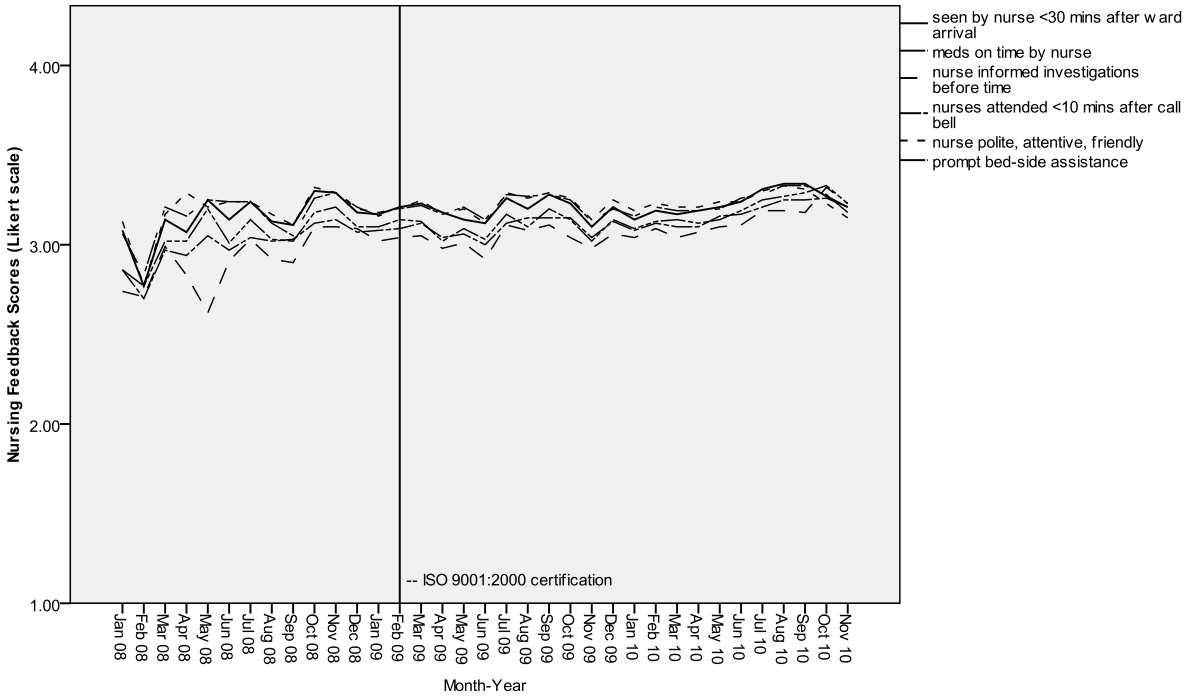
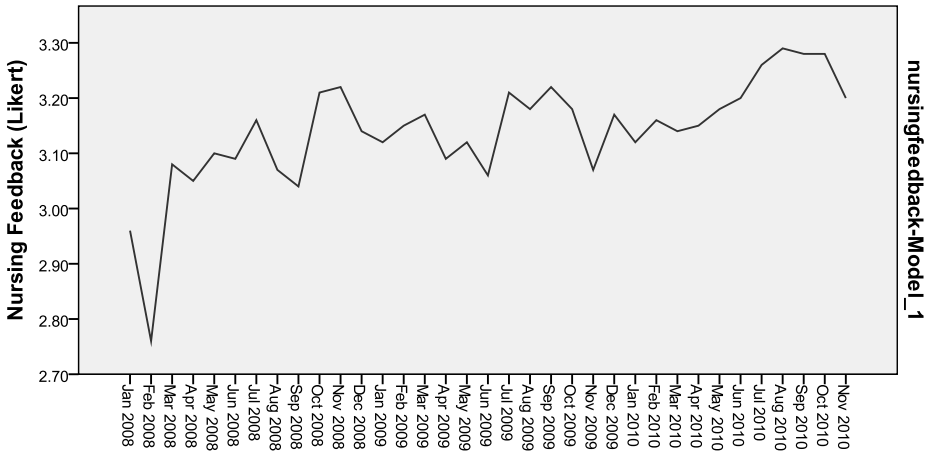


Fig 13: *Nursing Feedback Trend for HCO*



Model Statistics

Model	Number of Predictors	Model Fit statistics	Ljung-Box Q(18)			Number of Outliers
		Stationary R-squared	Statistics	DF	Sig.	
Nursing Feedback-Model_1	3	.030	24.754	18	.132	0

Fig. 14: *Nursing Feedback ARIMA model*

The average Nursing feedback score improved from 2.99 to 3.16 (LBQ-test; $p > 0.05$).

Housekeeping

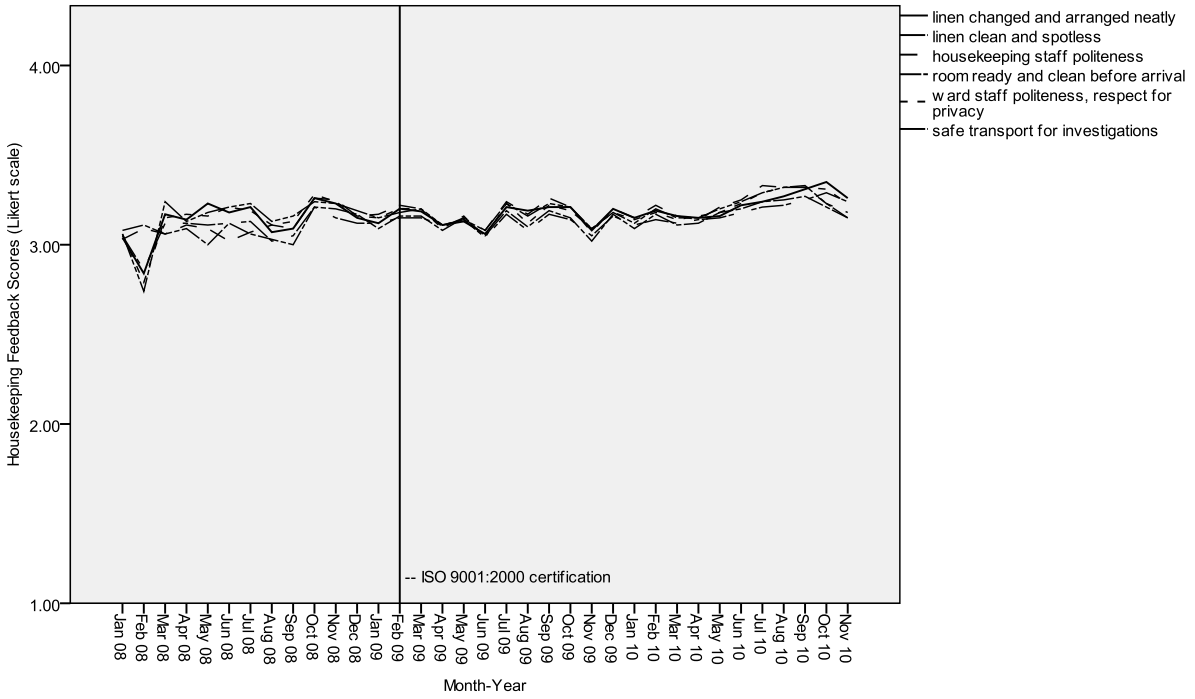
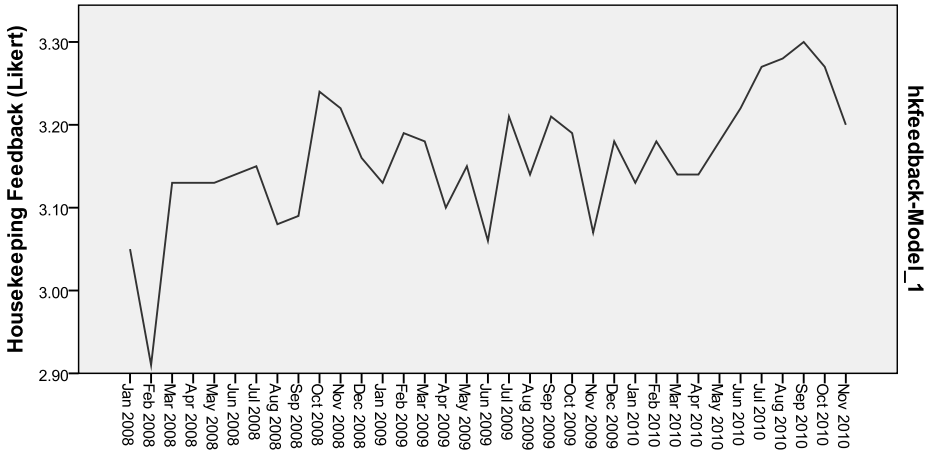


Fig 15: *Housekeeping Feedback Trend for HCO*



Model Statistics

Model	Number of Predictors	Model Fit statistics	Ljung-Box Q(18)			Number of Outliers
		Stationary R-squared	Statistics	DF	Sig.	
Housekeeping Feedback-Model_1	3	.430	12.426	18	.824	0

Fig 16: *Housekeeping Feedback ARIMA model*

The average Housekeeping feedback score improved from 3.07 to 3.17 (LBQ-test; $p > 0.05$)

Maintenance

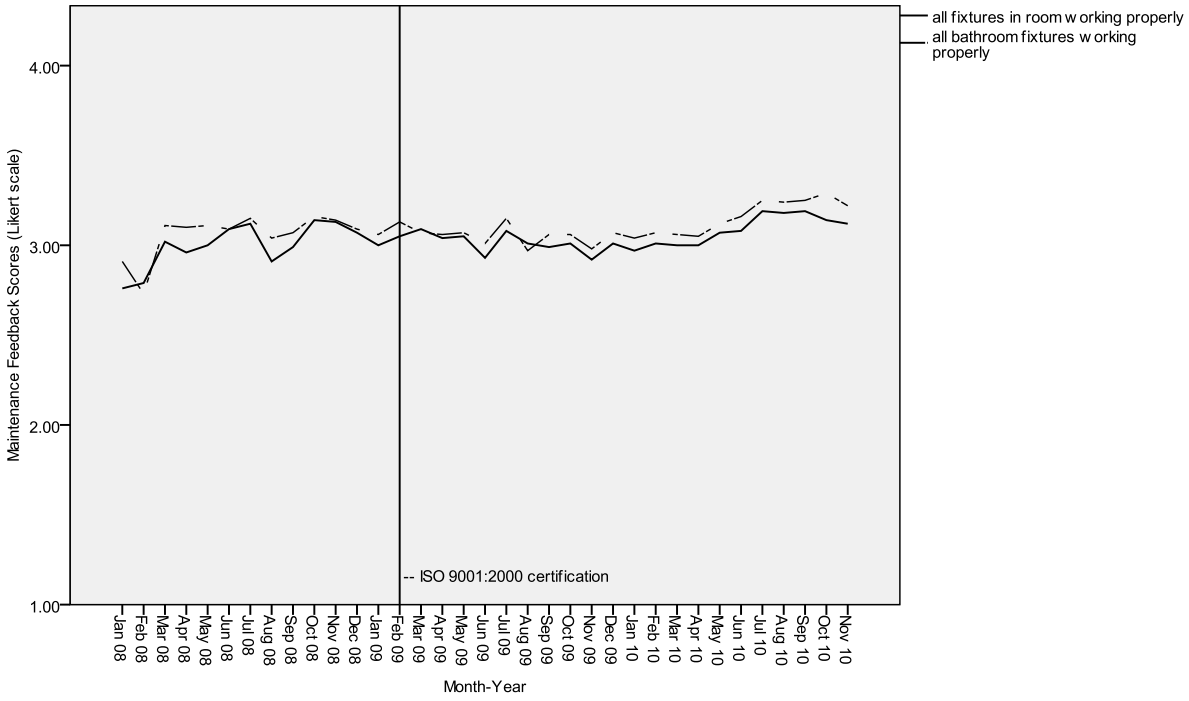
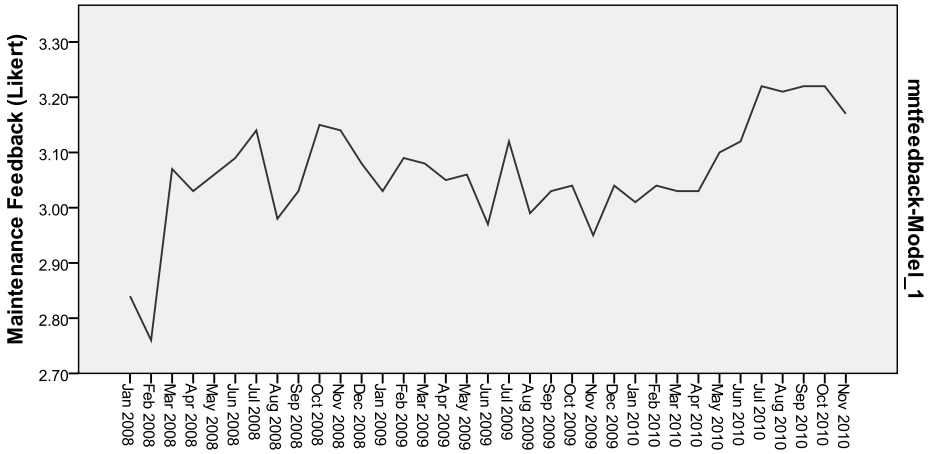


Fig 17: *Maintenance Feedback Trend for HCO*



Model Statistics

Model	Number of Predictors	Model Fit statistics	Ljung-Box Q(18)			Number of Outliers
		Stationary R-squared	Statistics	DF	Sig.	
Maintenance Feedback-Model_1	3	.068	21.936	18	.235	0

Fig 18: *Maintenance Feedback ARIMA model*

The average Maitenance feedback score improved from 2.97 to 3.08 (LBQ-test; $p > 0.05$).

Patient Care Services

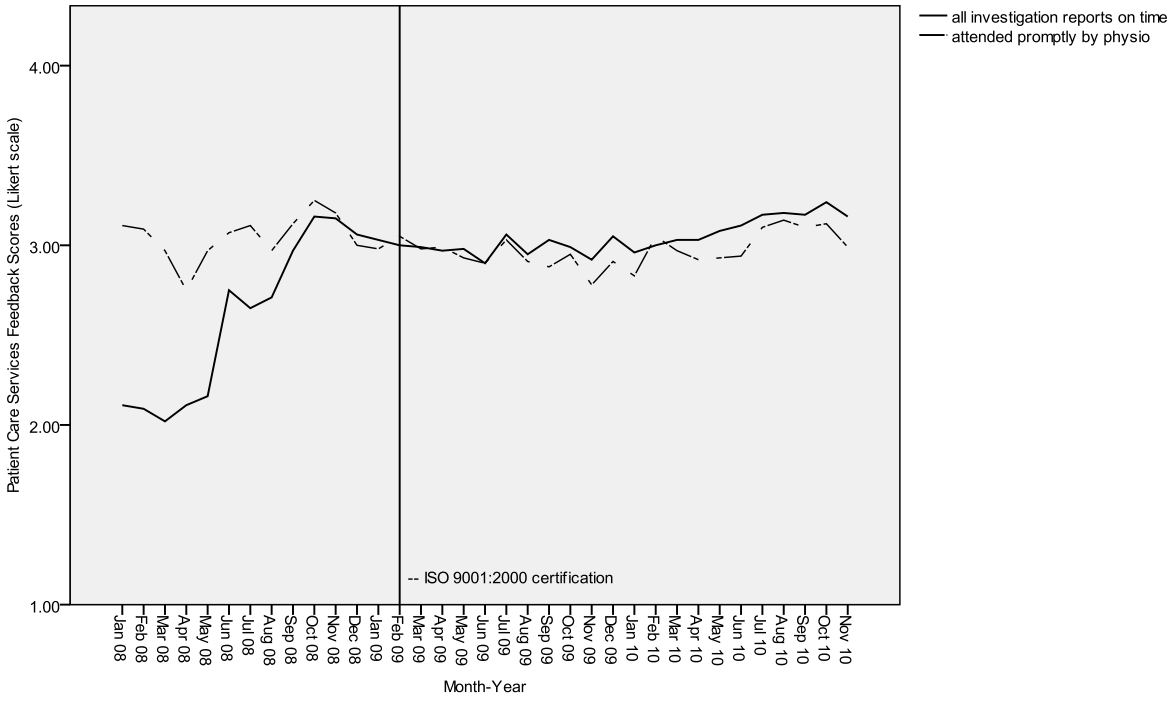
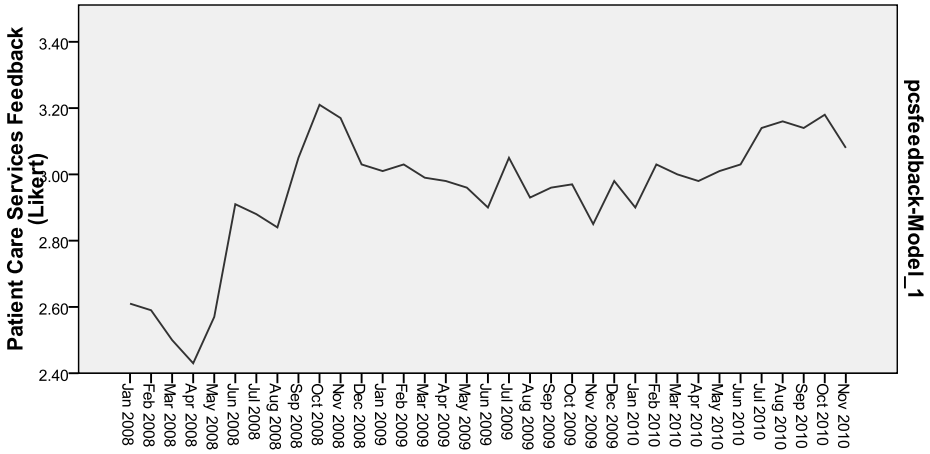


Fig 19: *Patient Care Services Feedback Trend for HCO*



Model Statistics

Model	Number of Predictors	Model Fit statistics	Ljung-Box Q(18)			Number of Outliers
		Stationary R-squared	Statistics	DF	Sig.	
Patient Care Services Feedback-Model_1	3	.023	15.339	18	.639	0

Fig 20: *Patient Care Services Feedback ARIMA model*

The average Patient-Care Services feedback improved from 2.6 to 3.01 (LBQ-test; $p > 0.05$).

Intensive Care

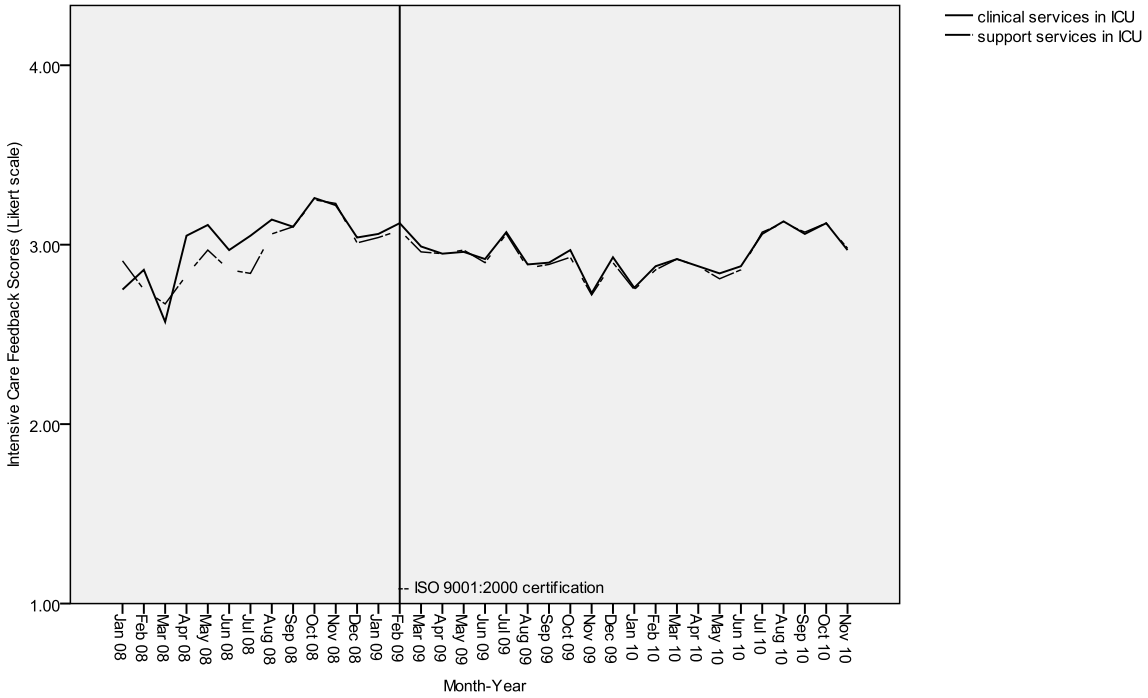
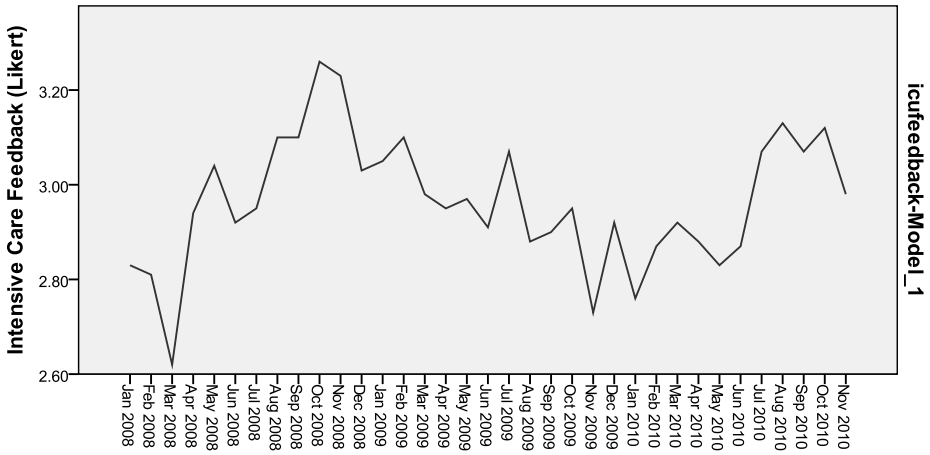


Fig 21: *Intensive Care Feedback Trend for HCO*



Model Statistics

Model	Number of Predictors	Model Fit statistics	Ljung-Box Q(18)			Number of Outliers
		Stationary R-squared	Statistics	DF	Sig.	
Intensive Care Feedback-Model_1	3	.004	14.551	18	.693	0

Fig 22: *Intensive Care Feedback ARIMA model*

The average Intensive Care feedback score improved from 2.86 to 2.98 (LBQ-test; $p > 0.05$).

Overall Feedback

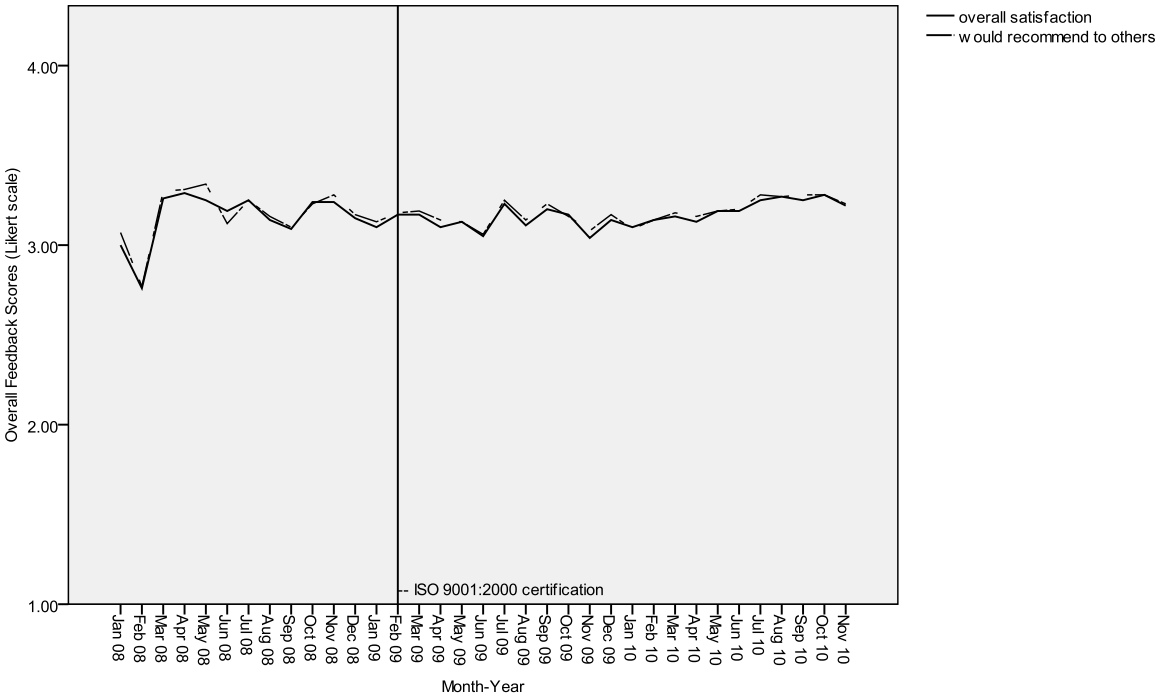


Fig 23: *Overall Feedback Trend for HCO*

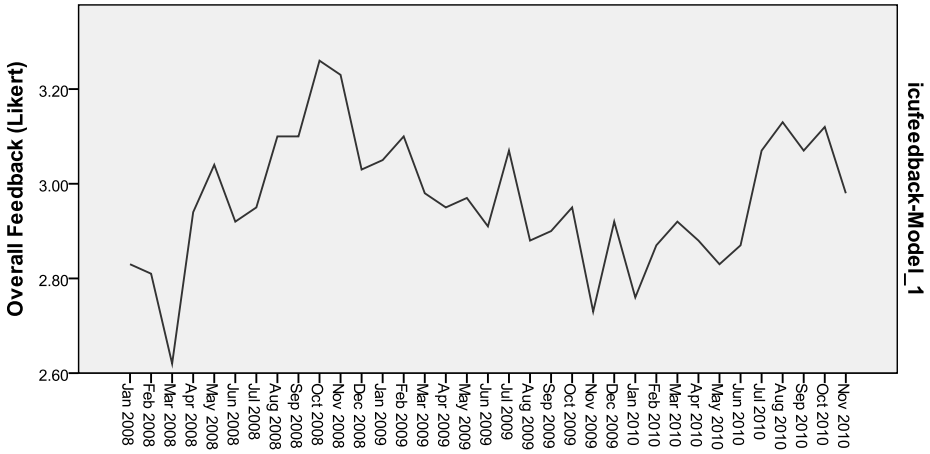


Fig 24: *Overall Feedback ARIMA model*

The average Overall feedback score improved from 3.14 to 3.18 (LBQ-test; $p > 0.05$).

5.2 Continuing NABH Assessments

The process of implementation of NABH Standards was initiated in January 2010 and completed in July 2013 with the Hospital getting accredited (Appendix 7). Implementation of NABH Standards required a multi-pronged approach and concerted efforts by all members of the HCO. Collaborative governance through "Chapter Teams", NABH Committees and Inter-Disciplinary Team were institute. Long-stay audits for patients with an average length of stay (ALOS) above 14 days were initiated. A patient-centricity Campaign "Patient First" (Appendix 4) was launched and the impact of organization-wide training and motivation were measured. The campaign was conceived with the intent of putting TQM constructs into practice and simultaneously testing the organization-wide outcomes. The activities included interactive sessions, workshops and group meetings for improving communication skills, collaboration and commitment, in order to eventually enhance the patients experience at. A number of patient-centred assignments were undertaken under this project by the elected team leaders with the help of their team members.

The campaign was also designed to reinforce NABH-related quality and safety practices. Continuing Self Assessment (SA) based on 636 objective elements of 102 NABH Standards were taken up at three stages of the NABH implementation process – pre-implementation (January 2010), mid-implementation (September 2011) and post-implementation (April 2013) . The mean SA scores in these three stages along with the Accreditation Assessment scores (June 2013) were tested as pairs with the Related-Samples Friedman's Two-Way Analysis of Variance by Ranks. A model for TQM implementation in an HCO with NABH standards as reference was then developed taking into account all the nuances of implementation that were experienced during the study period.

The chapter-wise self assessment and accreditation assessment scores for the NABH Standards (Table 10) show an increase in the mean score during successive stages of implementation (See Appendix 5 for objective-element-wise assessment scores), although the final assessment scores were slightly lower than the post-implementation SA scores. There was a statistically significant difference in the mean SA scores during the three stages of implementation – specifically between the paired scores pre-implementation and final, pre-implementation and post, mid-implementation and post (Table 11; Fig 26)

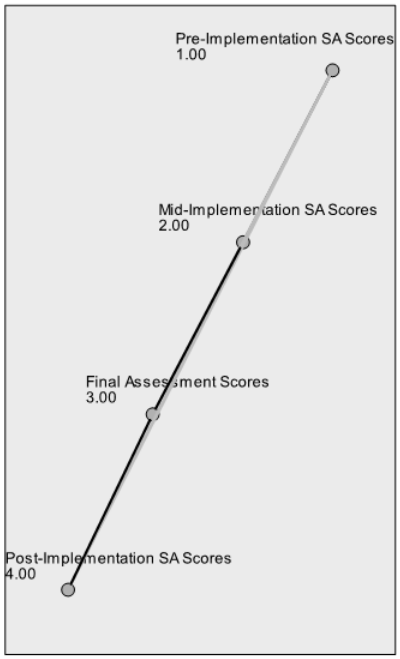
Table 10: *Chapter-Wise Mean Assessment Scores for HCO*

Chapter	Pre-Implementation Jan-2010	Mid-Implementation Sep-2011	Post-Implementation April 2013	Final Assessment Jun-2013
AAC	2.62	6.86	10.00	9.65
COP	2.79	6.29	9.89	9.12
MOM	2.88	6.64	10.00	9.04
PRE	2.17	6.41	10.00	8.91
HIC	2.94	6.86	10.00	8.24
CQI	2.02	6.32	10.00	8.20
ROM	5.13	7.50	10.00	9.61
FMS	1.76	5.46	10.00	8.15
HRM	3.37	6.92	10.00	9.33
IMS	2.33	5.35	10.00	8.60

Statistical Inferences

Table 11: *Hypothesis Test Summary for Comparative NABH Assessment Scores*

	Null Hypothesis	Test	Sig.	Decision
	The distributions of Pre-Implementation SA Scores, Mid-Implementation SA Scores, Post-Implementation SA Scores and Final Assessment Scores are the same.	Related-Samples Friedman's Two-Way Analysis of Variance by Ranks	.000	Reject the null hypothesis.
Asymptotic significances are displayed. The significance level is .05.				



Each node shows the sample average rank.

Sample1-Sample2	Test Statistic	Std. Error	Std. Test Statistic	Sig.	Adj.Sig.
Pre-Implementation SA Scores-Mid-Implementation SA Scores	-1.000	.577	-1.732	.083	.500
Pre-Implementation SA Scores-Final Assessment Scores	-2.000	.577	-3.464	.001	.003
Pre-Implementation SA Scores-Post-Implementation SA Scores	-3.000	.577	-5.196	.000	.000
Mid-Implementation SA Scores-Final Assessment Scores	-1.000	.577	-1.732	.083	.500
Mid-Implementation SA Scores-Post-Implementation SA Scores	-2.000	.577	-3.464	.001	.003
Final Assessment Scores-Post-Implementation SA Scores	1.000	.577	1.732	.083	.500

Each row tests the null hypothesis that the Sample 1 and Sample 2 distributions are the same.
Asymptotic significances (2-sided tests) are displayed. The significance level is .05.

Fig 25: *Related-Samples Friedman's Two-Way Analysis of Variance in NABH Assessment Scores by Ranks*

5.3 NABH Expert Elicitation on TQM Constructs

The research on TQM constructs was initiated through an extensive review of literature for selection of an appropriate TQM framework (Jung and Wang 2006), which was then used as reference for all further research. According to Cronbach (Cronbach and Meehl 1955) "Construct validity must be investigated whenever no criterion or universe of content is accepted as entirely adequate to define the quality to be measured" – this was addressed by conducting a survey of NABH Assessors to test the selected TQM constructs and additional contemporary themes in healthcare quality. The Questionnaire (Appendix 2) had 13 questions, including 4 questions on the four groups of 14 TQM constructs. The questionnaire was developed, first through a qualitative phase conducted to generate items and identify domains using Critical Incident Technique on reviewed literature. The second step was a quantitative validation phase designed to select items, identify dimensions, measure reliability, internal and concurrent validity. Third, a mail-back study on 2 assessors was conducted to replicate the validation. The questionnaire obtained (Appendix 2) from the qualitative phase was piloted for negatively and positively worded satisfaction items with two Assessors. The traditional approach was chosen, in which the item is structured as a statement of opinion. A five-point Likert-like balanced response scale was chosen. Out of a total of 20 pilot questions, 13 were validated. The other 7 were removed in the final questionnaire due to ambiguity and repetitiveness. The focus areas were;

1. Profile of the Assessor
2. Experiential Learning for Hospitals from NABH
3. Translational Research due to NABH implementation to improve outcomes
4. Likelihood and effectiveness of implementation of NABH Standards
5. Six dimensions of Healthcare Quality (Institute of Medicine)
6. Total Quality Management constructs
7. Evidence-Based Medicine
8. Clinical Quality Indicators
9. Overall impact of NABH

The exploratory nature of the research area prompted the need for an Expert Elicitation Survey involving the NABH Assessors of India. The rationale behind using a web-based survey of NABH experts was to generate a set of findings that can later be confirmed in a more controlled environment of a large-scale multi-centric study of NABH accredited healthcare providers. The survey design was based on the Checklist for Reporting Results of Internet E-Surveys (CHERRIES). A cloud-based survey-development tool was used to construct the questionnaire using standard controls like radio-buttons, check-boxes, and rank drop-downs. The tool generated a unique web link that could be e-mailed to all the prospective respondents.

The survey was sent to all the NABH Assessors in India, total of 271 in November 2012. Valid responses and completed questionnaires were received from 43 NABH Assessors, representing a 15.9% response rate. Out of the 43 respondents, the completion rate was 97.67%.

The survey responses were analyzed using two non-parametric tests - the One-Sample Chi-Square Test and the One-Sample Kolmogorov-Smirnov Test.

The NABH Expert Elicitation Survey results are represented graphically (Fig 27 A-D). Further, the positive hypothesis test summary results (Table 12; Fig 28A-AH) and cross-tabulation between number of assessments done and overall impression about improvements made due to NABH (Table 13) are presented.

Survey Responses

(Responses tabulated summary – Appendix 3)

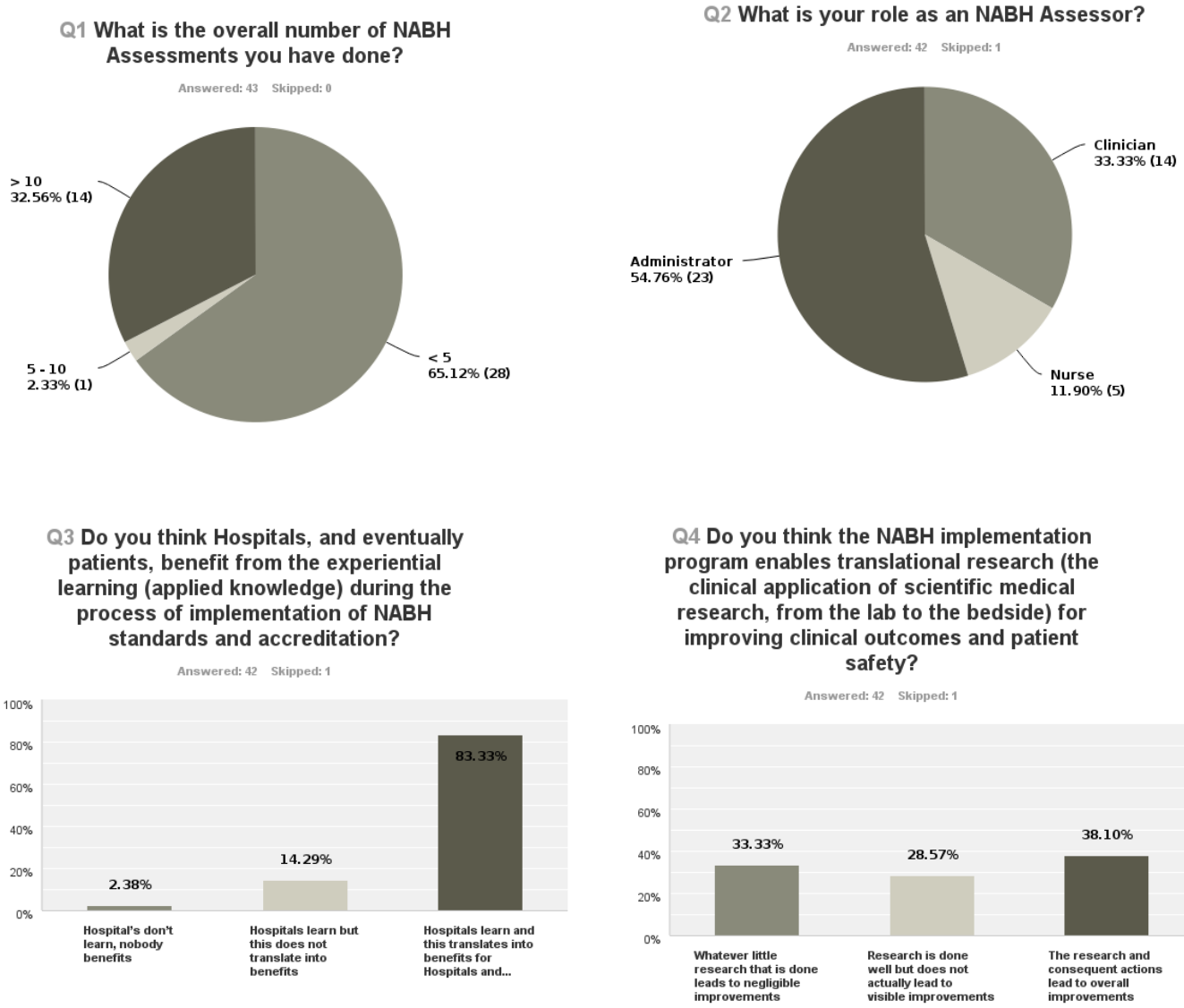
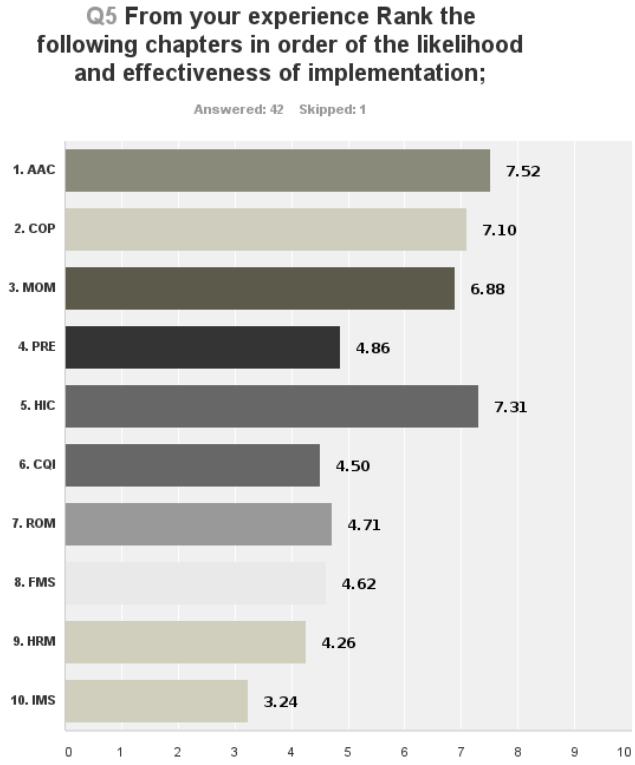
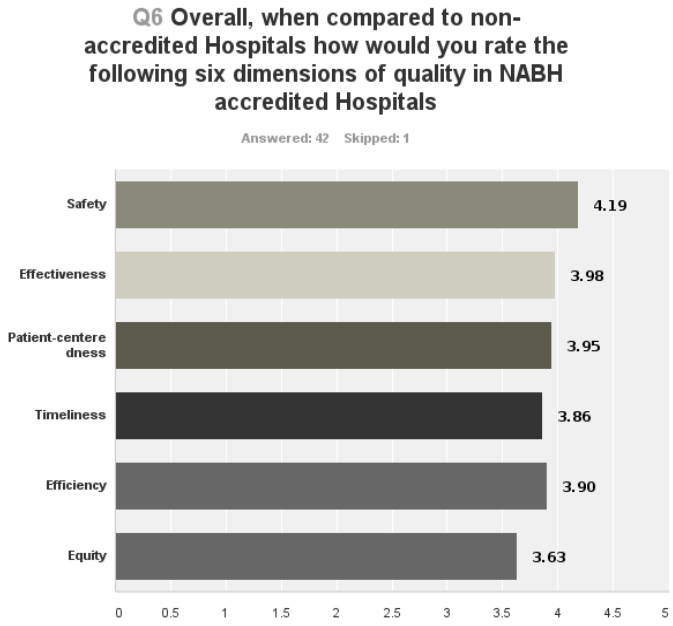
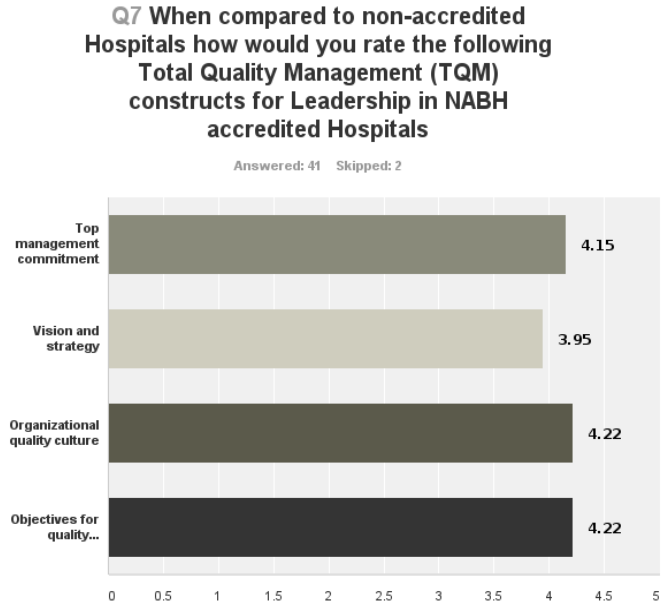


Fig 26A: *NABH Assessors' Survey Responses – Graphical Representation (Q1-4)*







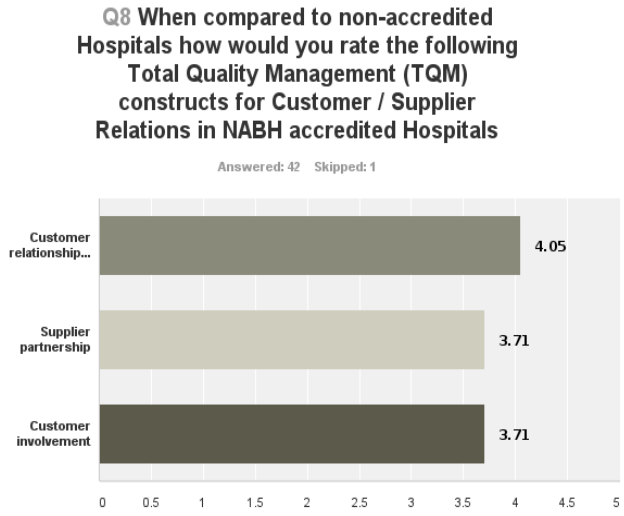


Fig 26B: *NABH Assessors' Survey Responses – Graphical Representation (Q5-8)*

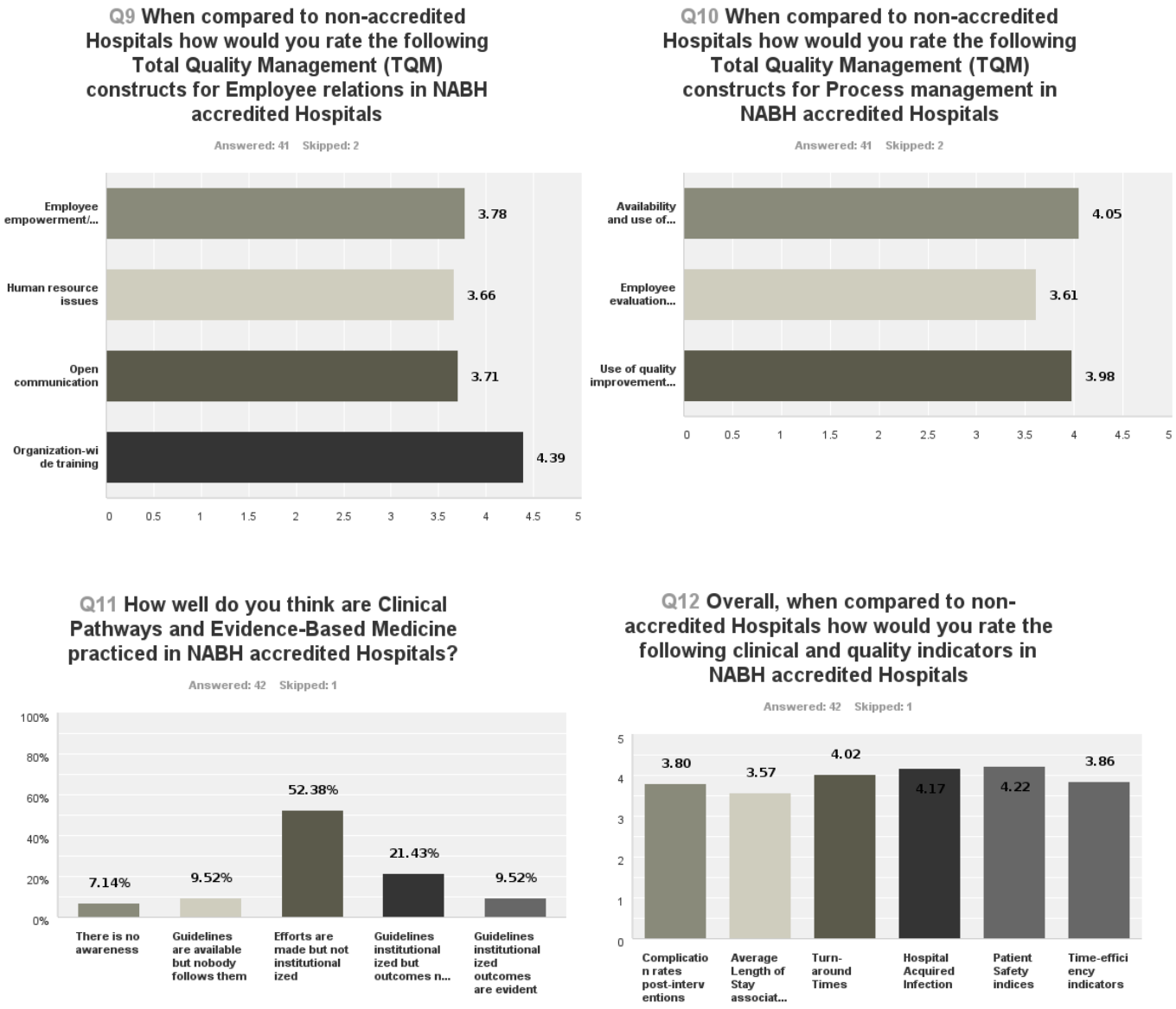


Fig 26C: *NABH Assessors' Survey Responses – Graphical Representation (Q9-12)*

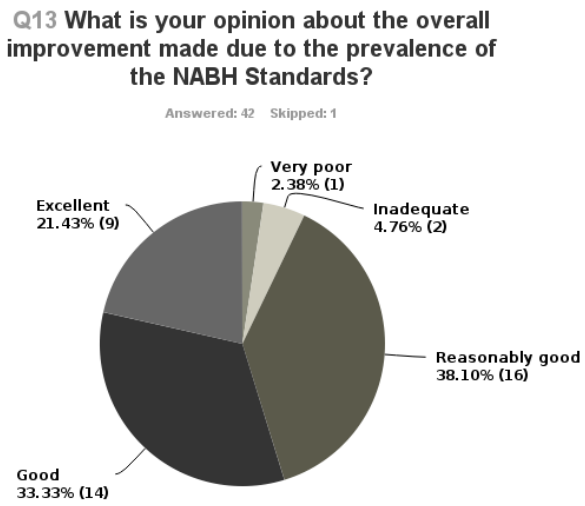
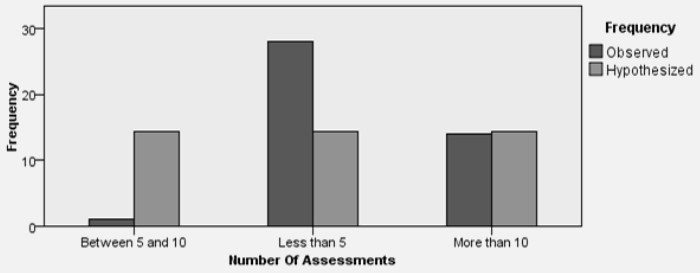


Fig 26D: *NABH Assessors' Survey Responses – Graphical Representation (Q13)*

Statistical Inferences

Table 12: *Hypothesis Test Summary for NABH Survey Responses*

	Null Hypothesis	Test	Sig.	Decision
	The categories of *Number Of Assessments* occur with equal probabilities.	One-Sample Chi-Square Test	.000	Reject the null hypothesis.

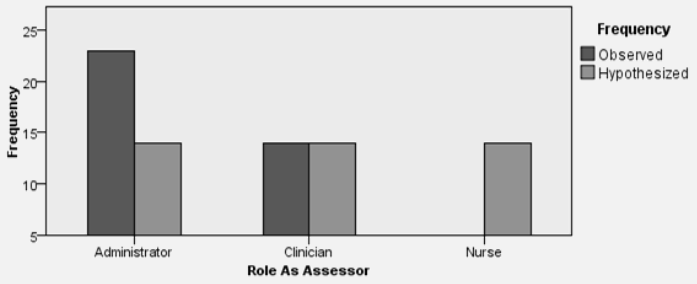


Total N	43
Test Statistic	25.442
Degrees of Freedom	2
Asymptotic Sig. (2-sided test)	.000

1. There are 0 cells (0%) with expected values less than 5. The minimum expected value is 14.333.

Fig 27A: *Hypothesis Test Summary for NABH Survey Responses*

The categories of *Role As Assessor* occur with equal probabilities.	One-Sample Chi-Square Test	.003	Reject the null hypothesis.

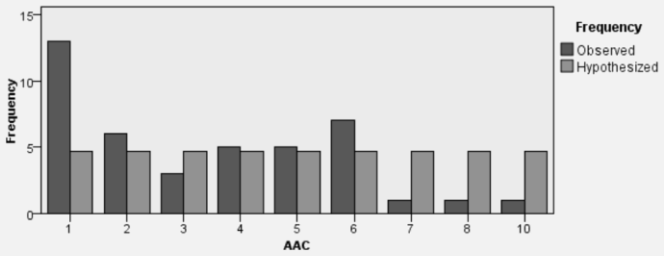


Total N	42
Test Statistic	11.571
Degrees of Freedom	2
Asymptotic Sig. (2-sided test)	.003

1. There are 0 cells (0%) with expected values less than 5. The minimum expected value is 14.

Fig 27B: *Hypothesis Test Summary for NABH Survey Responses*

	The categories of *AAC* occur with equal probabilities.	One-Sample Chi-Square Test	.001	Reject the null hypothesis.

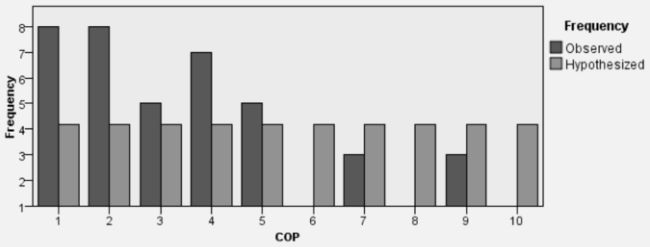


Total N	42
Test Statistic	25.714
Degrees of Freedom	8
Asymptotic Sig. (2-sided test)	.001

1. There are 9 cells (100%) with expected values less than 5. The minimum expected value is 4.667.

Fig 27C: *Hypothesis Test Summary for NABH Survey Responses*

The categories of *COP* occur with equal probabilities.	One-Sample Chi-Square Test	.048	Reject the null hypothesis.

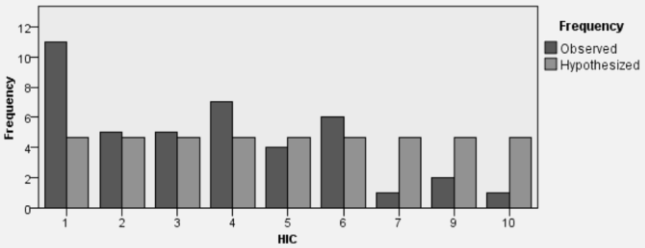


Total N	42
Test Statistic	17.048
Degrees of Freedom	9
Asymptotic Sig. (2-sided test)	.048

1. There are 10 cells (100%) with expected values less than 5. The minimum expected value is 4.200.

Fig 27D: *Hypothesis Test Summary for NABH Survey Responses*

The categories of HIC occur with equal probabilities.	One-Sample Chi-Square Test	.025	Reject the null hypothesis.

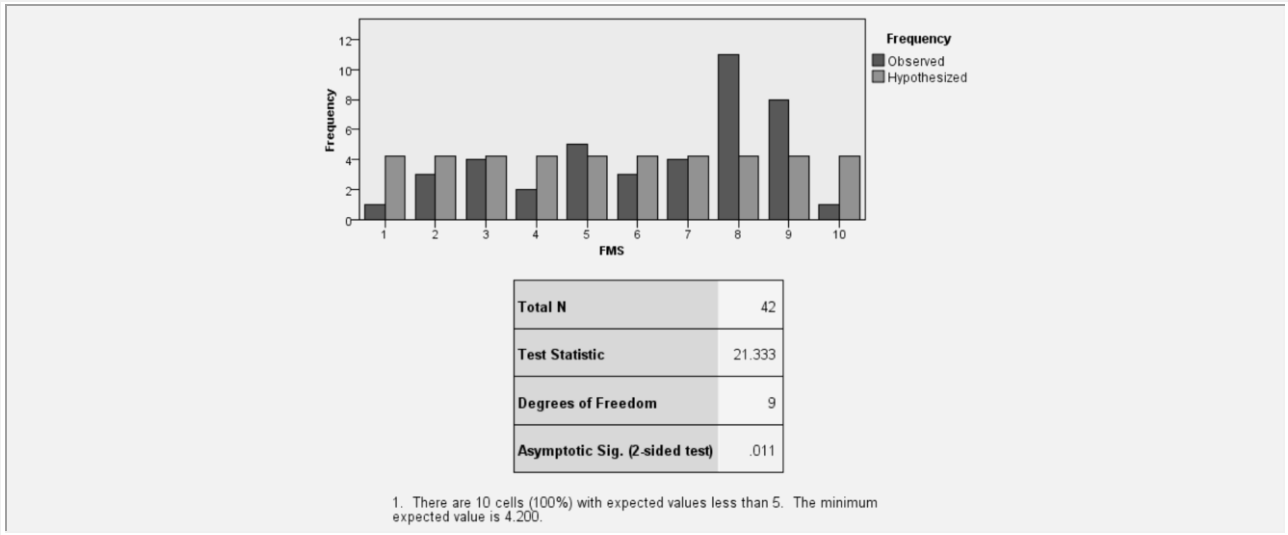


Total N	42
Test Statistic	17.571
Degrees of Freedom	8
Asymptotic Sig. (2-sided test)	.025

1. There are 9 cells (100%) with expected values less than 5. The minimum expected value is 4.667.

Fig 27E: *Hypothesis Test Summary for NABH Survey Responses*

The categories of *FMS* occur with equal probabilities.	One-Sample Chi-Square Test	.011	Reject the null hypothesis.

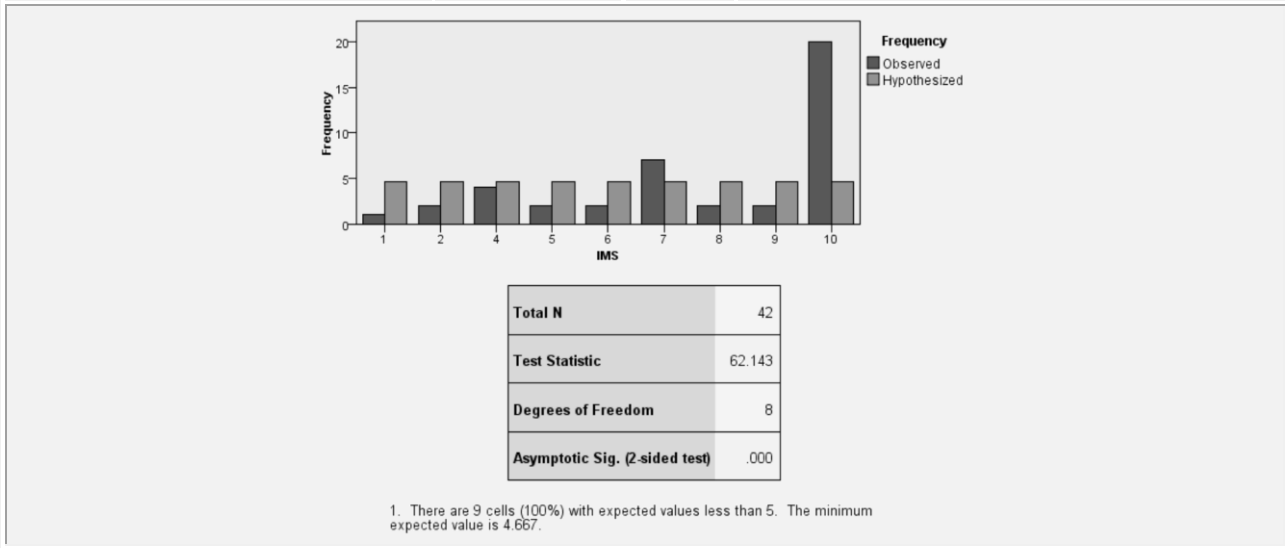


Total N	42
Test Statistic	21.333
Degrees of Freedom	9
Asymptotic Sig. (2-sided test)	.011

1. There are 10 cells (100%) with expected values less than 5. The minimum expected value is 4.200.

Fig 27F: *Hypothesis Test Summary for NABH Survey Responses*

The categories of *IMS* occur with equal probabilities.	One-Sample Chi-Square Test	.000	Reject the null hypothesis.

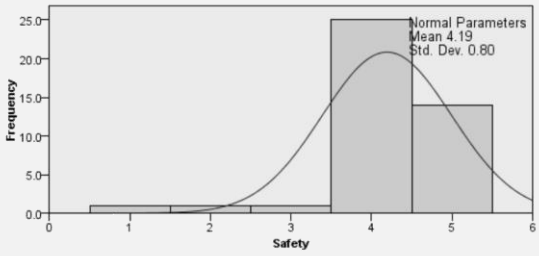


Total N	42
Test Statistic	62.143
Degrees of Freedom	8
Asymptotic Sig. (2-sided test)	.000

1. There are 9 cells (100%) with expected values less than 5. The minimum expected value is 4.667.

Fig 27G: *Hypothesis Test Summary for NABH Survey Responses*

The distribution of *Safety* is normal with mean 4.19 and standard deviation 0.80.	One-Sample Kolmogorov-Smirnov Test	.000	Reject the null hypothesis.



Total N		42
Most Extreme Differences	Absolute	.335
	Positive	.260
	Negative	-.335
Test Statistic		2.170
Asymptotic Sig. (2-sided test)		.000

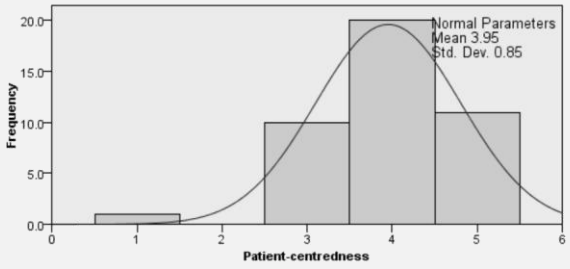
Fig 27H: *Hypothesis Test Summary for NABH Survey Responses*

The distribution of *Effectiveness* is normal with mean 3.98 and standard deviation 0.61.	One-Sample Kolmogorov-Smirnov Test	.000	Reject the null hypothesis.

Total N		41
Most Extreme Differences	Absolute	.321
	Positive	.313
	Negative	-.321
Test Statistic		2.054
Asymptotic Sig. (2-sided test)		.000

Fig 27I: *Hypothesis Test Summary for NABH Survey Responses*

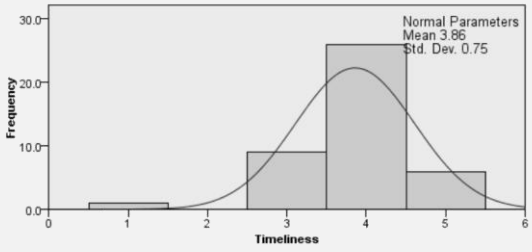
The distribution of *Patient-centredness* is normal with mean 3.95 and standard deviation 0.85.	One-Sample Kolmogorov-Smirnov Test	.007	Reject the null hypothesis.



Total N		42
Most Extreme Differences	Absolute	.260
	Positive	.216
	Negative	-.260
Test Statistic		1.687
Asymptotic Sig. (2-sided test)		.007

Fig 27J: *Hypothesis Test Summary for NABH Survey Responses*

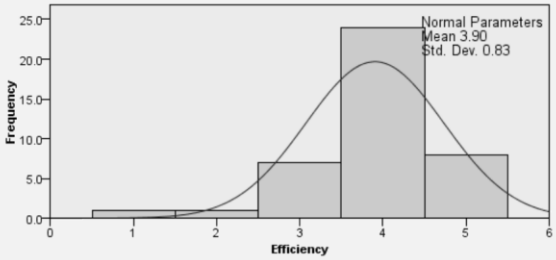
The distribution of *Timeliness* is normal with mean 3.86 and standard deviation 0.75.	One-Sample Kolmogorov-Smirnov Test	.000	Reject the null hypothesis.



Total N		42
Most Extreme Differences	Absolute	.337
	Positive	.282
	Negative	-.337
Test Statistic		2.186
Asymptotic Sig. (2-sided test)		.000

Fig 27K: *Hypothesis Test Summary for NABH Survey Responses*

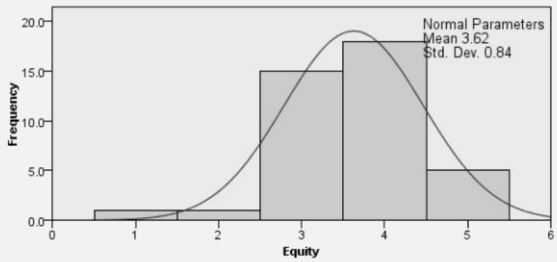
The distribution of *Efficiency* is normal with mean 3.90 and standard deviation 0.83.	One-Sample Kolmogorov-Smirnov Test	.000	Reject the null hypothesis.



Total N		41
Most Extreme Differences	Absolute	.327
	Positive	.258
	Negative	-.327
Test Statistic		2.095
Asymptotic Sig. (2-sided test)		.000

Fig 27L: *Hypothesis Test Summary for NABH Survey Responses*

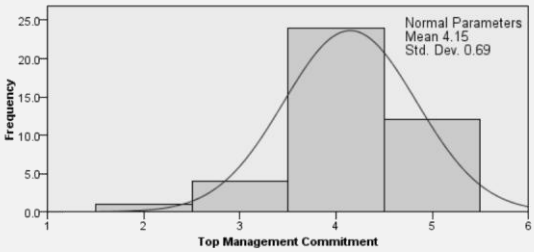
The distribution of *Equity* is normal with mean 3.62 and standard deviation 0.84.	One-Sample Kolmogorov-Smirnov Test	.015	Reject the null hypothesis.



Total N		40
Most Extreme Differences	Absolute	.248
	Positive	.202
	Negative	-.248
Test Statistic		1.567
Asymptotic Sig. (2-sided test)		.015

Fig 27M: *Hypothesis Test Summary for NABH Survey Responses*

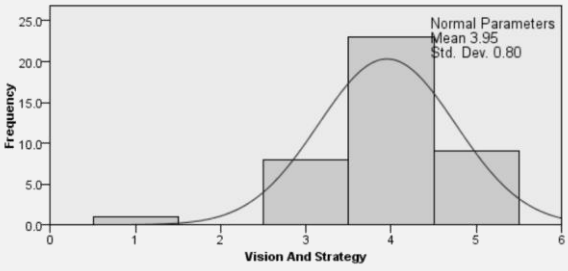
The distribution of *Top Management Commitment* is normal with mean 4.15 and standard deviation 0.69.	One-Sample Kolmogorov-Smirnov Test	.002	Reject the null hypothesis.



Total N		41
Most Extreme Differences	Absolute	.294
	Positive	.291
	Negative	-.294
Test Statistic		1.884
Asymptotic Sig. (2-sided test)		.002

Fig 27N: *Hypothesis Test Summary for NABH Survey Responses*

The distribution of *Vision And Strategy* is normal with mean 3.95 and standard deviation 0.80.	One-Sample Kolmogorov-Smirnov Test	.001	Reject the null hypothesis.



Total N		41
Most Extreme Differences	Absolute	.305
	Positive	.256
	Negative	-.305
Test Statistic		1.951
Asymptotic Sig. (2-sided test)		.001

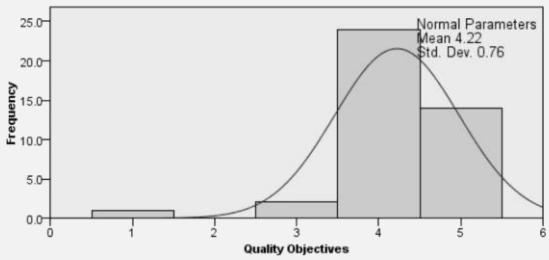
Fig 27O: *Hypothesis Test Summary for NABH Survey Responses*

The distribution of *Organizational Quality Culture* is normal with mean 4.22 and standard deviation 0.69.	One-Sample Kolmogorov-Smirnov Test	.000	Reject the null hypothesis.

Total N		41
Most Extreme Differences	Absolute	.351
	Positive	.332
	Negative	-.351
Test Statistic		2.246
Asymptotic Sig. (2-sided test)		.000

Fig 27P: *Hypothesis Test Summary for NABH Survey Responses*

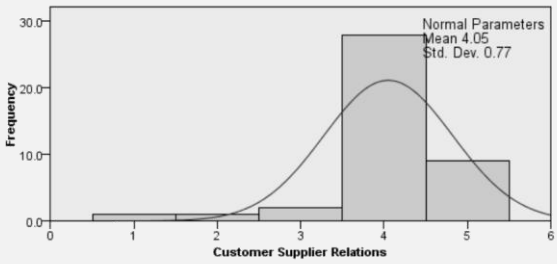
The distribution of *Quality Objectives* is normal with mean 4.22 and standard deviation 0.76.	One-Sample Kolmogorov-Smirnov Test	.001	Reject the null hypothesis.



Total N		41
Most Extreme Differences	Absolute	.313
	Positive	.272
	Negative	-.313
Test Statistic		2.004
Asymptotic Sig. (2-sided test)		.001

Fig 27Q: *Hypothesis Test Summary for NABH Survey Responses*

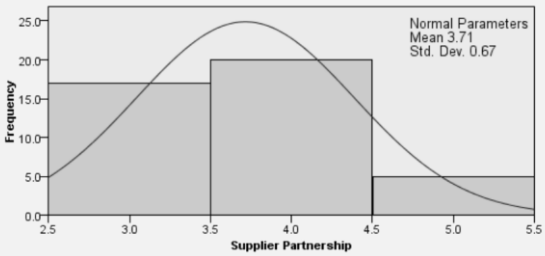
The distribution of *Customer Supplier Relations* is normal with mean 4.05 and standard deviation 0.77.	One-Sample Kolmogorov-Smirnov Test	.000	Reject the null hypothesis.



Total N		41
Most Extreme Differences	Absolute	.377
	Positive	.306
	Negative	-.377
Test Statistic		2.416
Asymptotic Sig. (2-sided test)		.000

Fig 27R: *Hypothesis Test Summary for NABH Survey Responses*

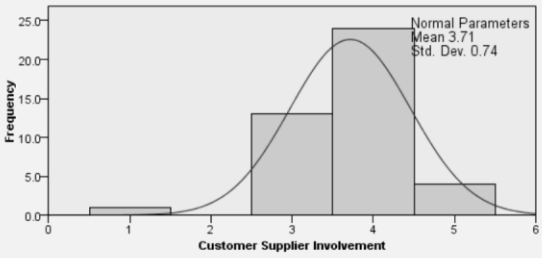
The distribution of *Supplier Partnership* is normal with mean 3.71 and standard deviation 0.67.	One-Sample Kolmogorov-Smirnov Test	.007	Reject the null hypothesis.



Total N		42
Most Extreme Differences	Absolute	.260
	Positive	.260
	Negative	-.260
Test Statistic		1.688
Asymptotic Sig. (2-sided test)		.007

Fig 27S: *Hypothesis Test Summary for NABH Survey Responses*

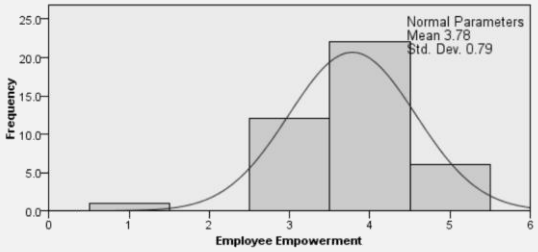
The distribution of *Customer Supplier Involvement* is normal with mean 3.71 and standard deviation 0.74.	One-Sample Kolmogorov-Smirnov Test	.000	Reject the null hypothesis.



Total N		42
Most Extreme Differences	Absolute	.317
	Positive	.255
	Negative	-.317
Test Statistic		2.052
Asymptotic Sig. (2-sided test)		.000

Fig 27T: *Hypothesis Test Summary for NABH Survey Responses*

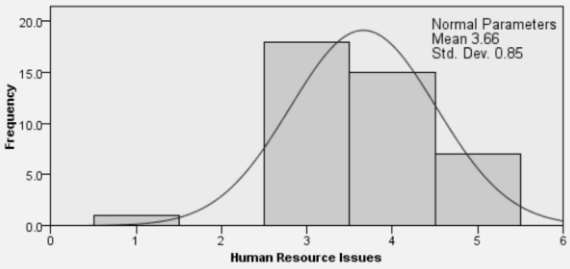
The distribution of *Employee Empowerment* is normal with mean 3.78 and standard deviation 0.79.	One-Sample Kolmogorov-Smirnov Test	.002	Reject the null hypothesis.



Total N		41
Most Extreme Differences	Absolute	.292
	Positive	.244
	Negative	-.292
Test Statistic		1.871
Asymptotic Sig. (2-sided test)		.002

Fig 27U: *Hypothesis Test Summary for NABH Survey Responses*

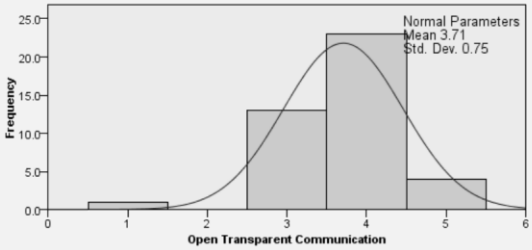
The distribution of *Human Resource Issues* is normal with mean 3.66 and standard deviation 0.85.	One-Sample Kolmogorov-Smirnov Test	.016	Reject the null hypothesis.



Total N		41
Most Extreme Differences	Absolute	.243
	Positive	.243
	Negative	-.196
Test Statistic		1.555
Asymptotic Sig. (2-sided test)		.016

Fig 27V: *Hypothesis Test Summary for NABH Survey Responses*

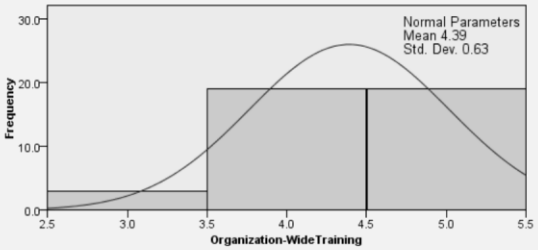
The distribution of *Open Transparent Communication* is normal with mean 3.71 and standard deviation 0.75.	One-Sample Kolmogorov-Smirnov Test	.001	Reject the null hypothesis.



Total N		41
Most Extreme Differences	Absolute	.310
	Positive	.251
	Negative	-.310
Test Statistic		1.988
Asymptotic Sig. (2-sided test)		.001

Fig 27W: *Hypothesis Test Summary for NABH Survey Responses*

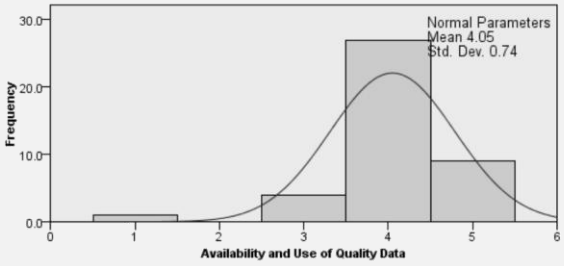
The distribution of *Organization-Wide Training* is normal with mean 4.39 and standard deviation 0.63.	One-Sample Kolmogorov-Smirnov Test	.001	Reject the null hypothesis.



Total N		41
Most Extreme Differences	Absolute	.298
	Positive	.270
	Negative	-.298
Test Statistic		1.907
Asymptotic Sig. (2-sided test)		.001

Fig 27X: *Hypothesis Test Summary for NABH Survey Responses*

The distribution of *Availability and Use of Quality Data* is normal with mean 4.05 and standard deviation 0.74.	One-Sample Kolmogorov-Smirnov Test	.000	Reject the null hypothesis.



Total N		41
Most Extreme Differences	Absolute	.352
	Positive	.307
	Negative	-.352
Test Statistic		2.252
Asymptotic Sig. (2-sided test)		.000

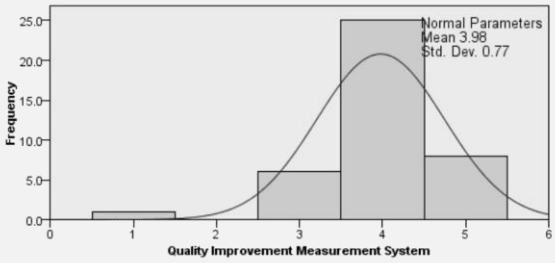
Fig 27Y: *Hypothesis Test Summary for NABH Survey Responses*

The distribution of *Employee Evaluation Based On Quality* is normal with mean 3.61 and standard deviation 0.74.	One-Sample Kolmogorov-Smirnov Test	.002	Reject the null hypothesis.

Total N		41
Most Extreme Differences	Absolute	.287
	Positive	.225
	Negative	-.287
Test Statistic		1.838
Asymptotic Sig. (2-sided test)		.002

Fig 27Z: *Hypothesis Test Summary for NABH Survey Responses*

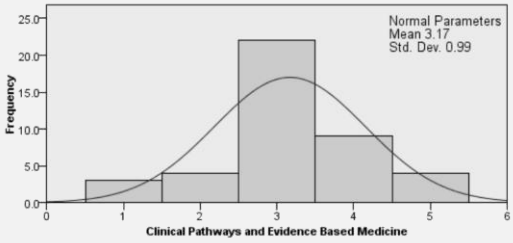
The distribution of *Quality Improvement Measurement System* is normal with mean 3.98 and standard deviation 0.77.	One-Sample Kolmogorov-Smirnov Test	.000	Reject the null hypothesis.



Total N		40
Most Extreme Differences	Absolute	.338
	Positive	.287
	Negative	-.338
Test Statistic		2.138
Asymptotic Sig. (2-sided test)		.000

Fig 27AA: *Hypothesis Test Summary for NABH Survey Responses*

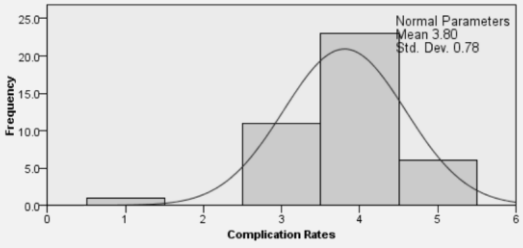
The distribution of *Clinical Pathways and Evidence Based Medicine* is normal with mean 3.17 and standard deviation 0.99.	One-Sample Kolmogorov-Smirnov Test	.005	Reject the null hypothesis.



Total N		42
Most Extreme Differences	Absolute	.266
	Positive	.258
	Negative	-.266
Test Statistic		1.725
Asymptotic Sig. (2-sided test)		.005

Fig 27AB: *Hypothesis Test Summary for NABH Survey Responses*

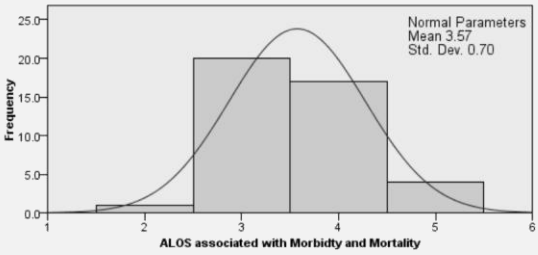
The distribution of *Complication Rates* is normal with mean 3.80 and standard deviation 0.78.	One-Sample Kolmogorov-Smirnov Test	.001	Reject the null hypothesis.



Total N		41
Most Extreme Differences	Absolute	.306
	Positive	.255
	Negative	-.306
Test Statistic		1.959
Asymptotic Sig. (2-sided test)		.001

Fig 27AC: *Hypothesis Test Summary for NABH Survey Responses*

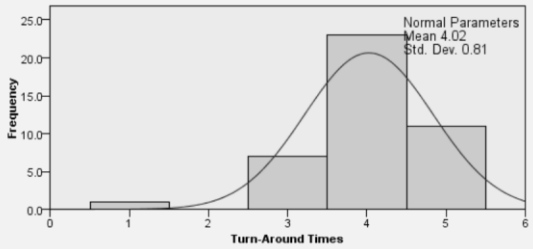
The distribution of *ALOS associated with Morbidty and Mortality* is normal with mean 3.57 and standard deviation 0.70.	One-Sample Kolmogorov-Smirnov Test	.002	Reject the null hypothesis.



Total N		42
Most Extreme Differences	Absolute	.292
	Positive	.292
	Negative	-.229
Test Statistic		1.891
Asymptotic Sig. (2-sided test)		.002

Fig 27AD: *Hypothesis Test Summary for NABH Survey Responses*

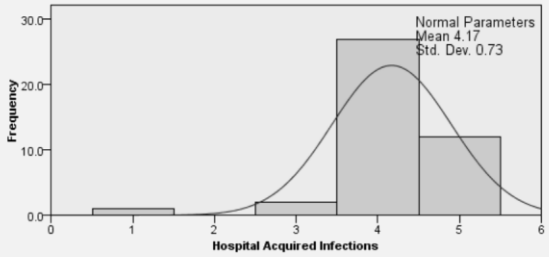
The distribution of *Turn-Around Times* is normal with mean 4.02 and standard deviation 0.81.	One-Sample Kolmogorov-Smirnov Test	.001	Reject the null hypothesis.



Total N		42
Most Extreme Differences	Absolute	.298
	Positive	.250
	Negative	-.298
Test Statistic		1.930
Asymptotic Sig. (2-sided test)		.001

Fig 27AE: *Hypothesis Test Summary for NABH Survey Responses*

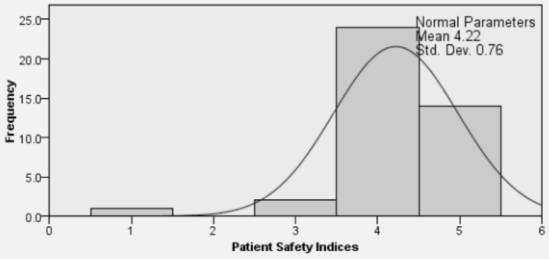
The distribution of *Hospital Acquired Infections* is normal with mean 4.17 and standard deviation 0.73.	One-Sample Kolmogorov-Smirnov Test	.000	Reject the null hypothesis.



Total N		42
Most Extreme Differences	Absolute	.338
	Positive	.305
	Negative	-.338
Test Statistic		2.192
Asymptotic Sig. (2-sided test)		.000

Fig 27AF: *Hypothesis Test Summary for NABH Survey Responses*

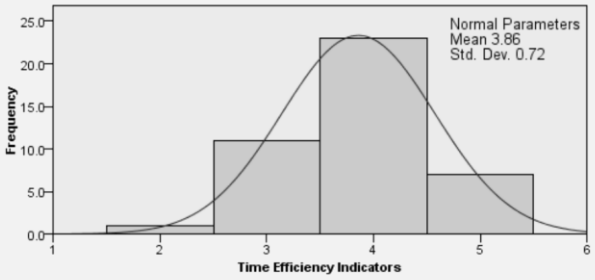
The distribution of *Patient Safety Indices* is normal with mean 4.22 and standard deviation 0.76.	One-Sample Kolmogorov-Smirnov Test	.001	Reject the null hypothesis.



Total N		41
Most Extreme Differences	Absolute	.313
	Positive	.272
	Negative	-.313
Test Statistic		2.004
Asymptotic Sig. (2-sided test)		.001

Fig 27AG: *Hypothesis Test Summary for NABH Survey Responses*

The distribution of *Time Efficiency Indicators* is normal with mean 3.86 and standard deviation 0.72.	One-Sample Kolmogorov-Smirnov Test	.001	Reject the null hypothesis.



Total N		42
Most Extreme Differences	Absolute	.293
	Positive	.254
	Negative	-.293
Test Statistic		1.900
Asymptotic Sig. (2-sided test)		.001

Fig 27AH: *Hypothesis Test Summary for NABH Survey Responses*

Table 13: *Number of Assessments vs. Overall improvement due to NABH – cross-tabulation*

			Overall Improvement due to NABH				
			Very poor	Reasonably good	Good	Excellent	Total
Number Of Assessments	Less than 5	Count	3	10	8	6	27
		% within Number Of Assessments	11.1%	37.0%	29.6%	22.2%	100.0%
	Between 5 and 10	Count	0	1	0	0	1
		% within Number Of Assessments	0.0%	100.0%	0.0%	0.0%	100.0%
	More than 10	Count	0	5	6	3	14
		% within Number Of Assessments	0.0%	35.7%	42.9%	21.4%	100.0%
Total		Count	3	16	14	9	42
		% within Number Of Assessments	7.1%	38.1%	33.3%	21.4%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	[a]	6	.711
Likelihood Ratio	4.940	6	.552
Linear-by-Linear Association	.883	1	.347
N of Valid Cases	42		

8 cells (66.7%) have expected count less than 5. The minimum expected count is .07.

5.4 Clinical and Patient Safety Outcomes

A selected set of 15 clinical quality indicators (QIs) were monitored throughout the study period. The selection of the QIs was based on the rationale of including a set of indicators and benchmarks that were specific, measurable, achievable, realistic and time-bound; covered clinical, administrative, financial, improvement parameters; and were part of the quality priorities set for the HCO. The QIs were trended and tested with Interrupted Time Series (ITS) modelling through a univariate analysis on the Autoregressive Integrated Moving Average (ARIMA) model, with dependent variable as the QI measures, for a 56 month period during the three phases of NABH implementation. This period allowed for time-series analysis with three points of intervention – initiation of NABH implementation at 10 months, pre-assessment at 31 months and final assessment at 52 months. The residuals obtained from the ARIMA model were tested with the Ljung-Box Q-Test (LBQ-test) statistic.

Measures for each of the 15 clinical quality indicators were analyzed through Interrupted Time Series analysis on the *non-seasonal ARIMA (0,1,0) "random walk" model* (Model_1) and residuals were tested with the Ljung-Box Q-test (LBQ-test) statistic. The X-axis reference line indicates the benchmark for the particular indicator. The three Y-axis reference lines at 10, 31 and 52 months represent the three points of intervention – initiation of NABH implementation at 10 months, pre-assessment at 31 months and final assessment at 52 months. Following are the quality indicator trends and statistical inferences (Fig 29 – 58).

Coronary Artery Bypass Graft (CABG) Mortality Rate

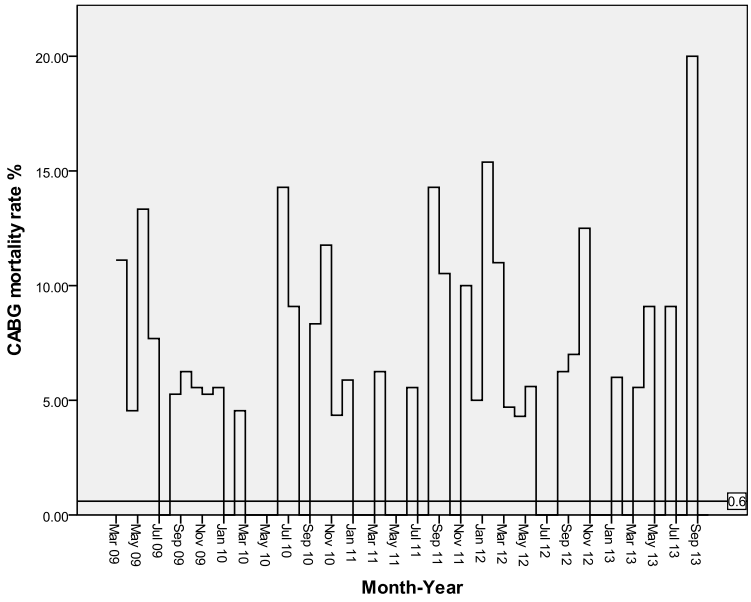
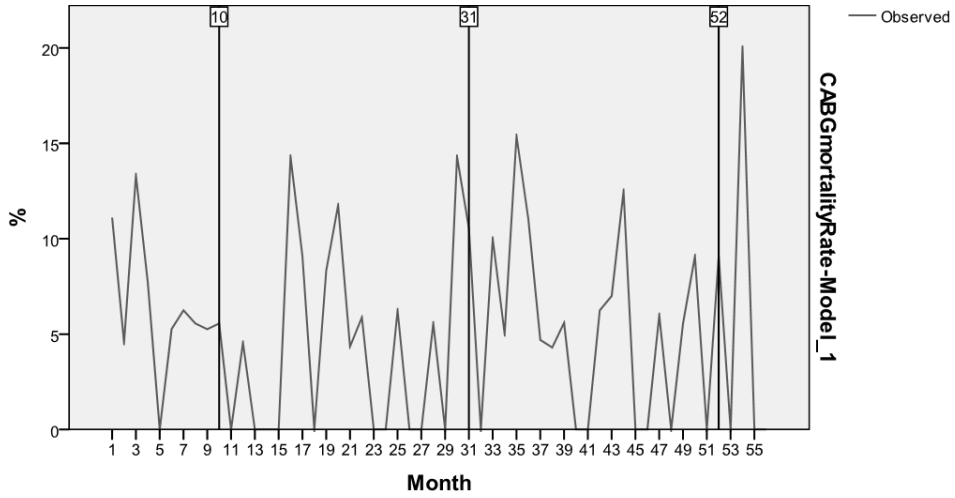


Fig 28: *CABG Mortality Rate trend*



Model Statistics

Model	Number of Predictors	Model Fit statistics	Ljung-Box Q(18)			Number of Outliers
		Stationary R-squared	Statistics	DF	Sig.	
CABGmortalityRate-Model_1	3	.006	27.897	18	.064	0

Fig 29: *CABG mortality rate ARIMA model*

The CABG mortality rate reduced from 6.46% to 4.92% (LBQ-test; $p > 0.05$).

Coronary Angiography (CAG) to Coronary Artery Bypass Graft (CABG) conversion rate

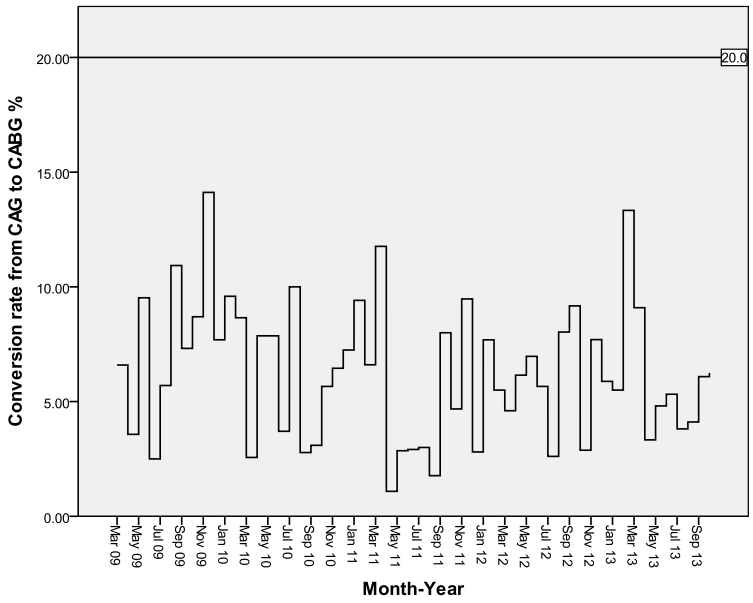
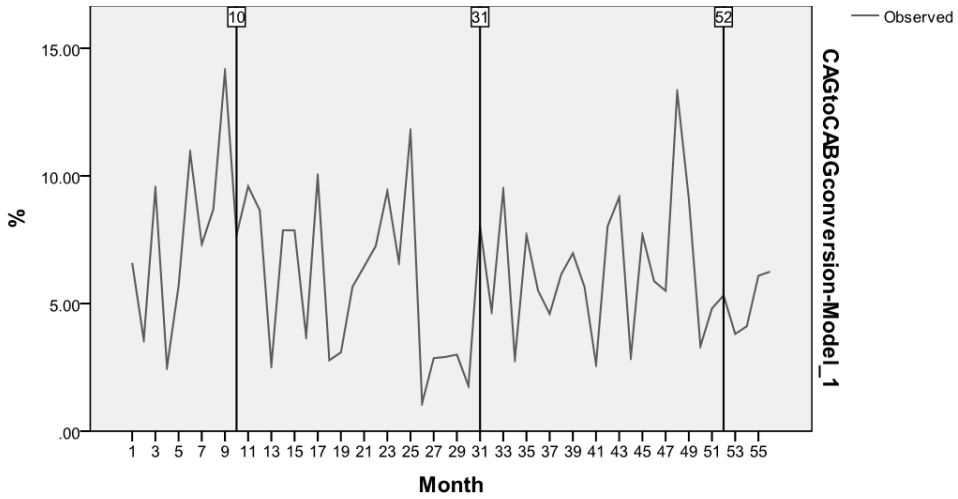


Fig 30: *CAG to CABG conversion rate trend*



Model Statistics

Model	Number of Predictors	Model Fit statistics	Ljung-Box Q(18)			Number of Outliers
		Stationary R-squared	Statistics	DF	Sig.	
CAG to CABG conversion rate-Model_1	3	.002	57.291	18	.000	0

Fig 31: *CAG to CABG conversion rate ARIMA model*

The CAG to CABG conversion rate reduced from 7.66% to 5.96% (LBQ-test; $p < 0.05$).

Average Turn-Around Rate per Dialysis Chair per Day

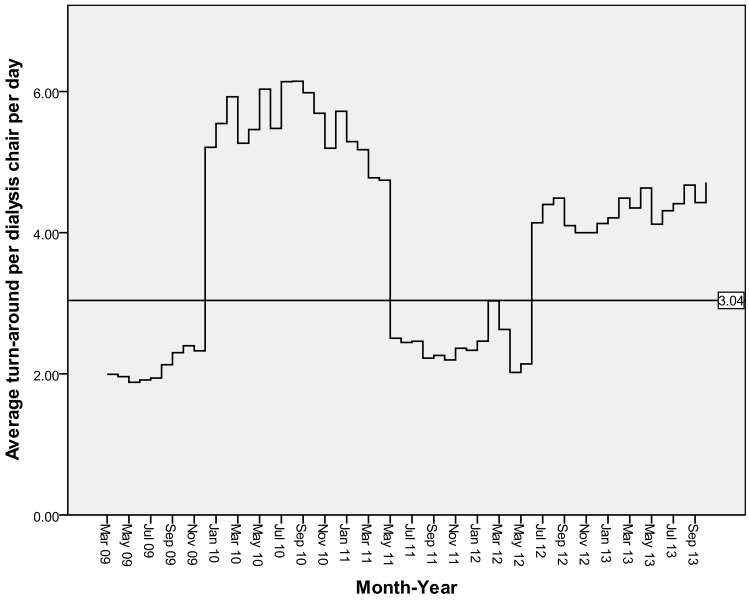
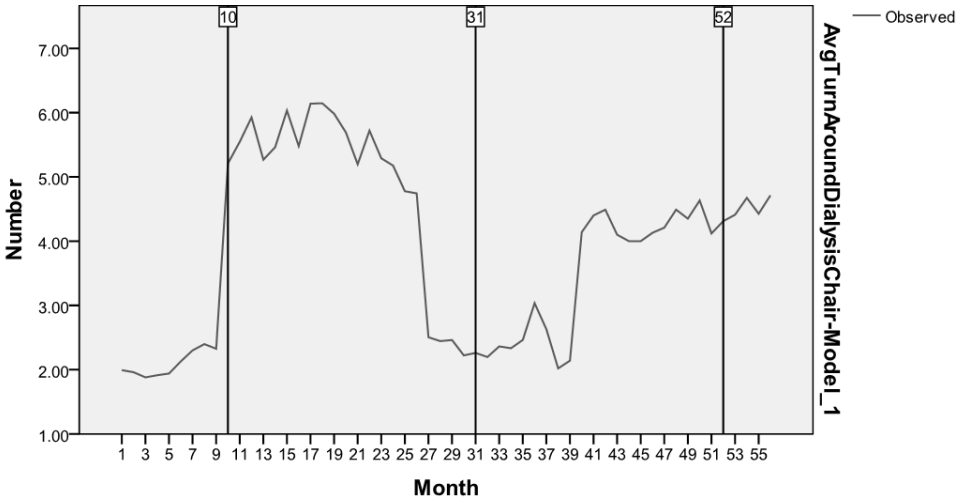


Fig 32: *Average Turn-Around Rate per Dialysis Chair per Day trend*



Model Statistics

Model	Number of Predictors	Model Fit statistics	Ljung-Box Q(18)			Number of Outliers
		Stationary R-squared	Statistics	DF	Sig.	
Average turn-around per dialysis chair per day-Model_1	3	.052	21.476	18	.256	0

Fig 33: *Average Turn-Around per Dialysis chair per day ARIMA model*

The average turn-around per dialysis chair per day improved from 2.4 to 4.2 (LBQ-test; $p > 0.05$).

Caesarian Rate

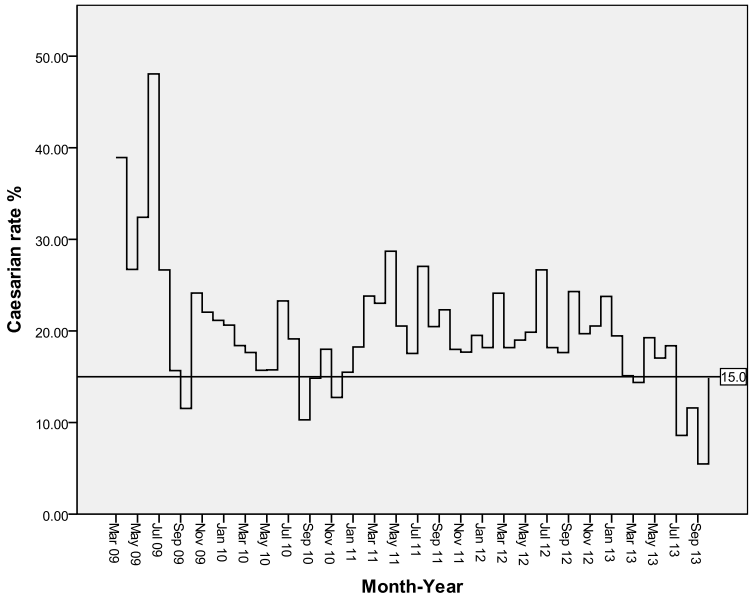
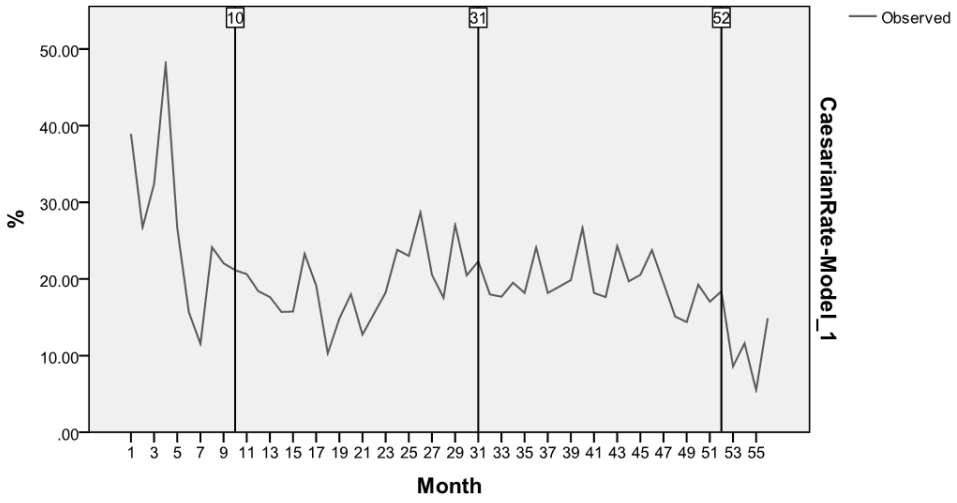


Fig 34: *Caesarian Rate trend*



Model Statistics

Model	Number of Predictors	Model Fit statistics	Ljung-Box Q(18)			Number of Outliers
		Stationary R-squared	Statistics	DF	Sig.	
Caesarian Rate-Model_1	3	.027	19.275	18	.375	0

Fig 35: *Caesarian Rate ARIMA model*

The Caesarian rate reduced from 26.18% to 18.5% (LBQ test; $p > 0.05$).

Average Length of Stay for Hospital

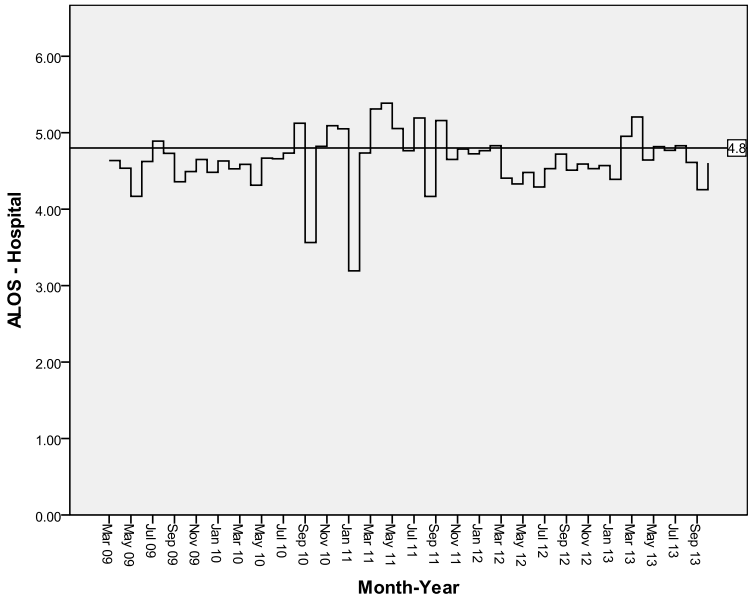
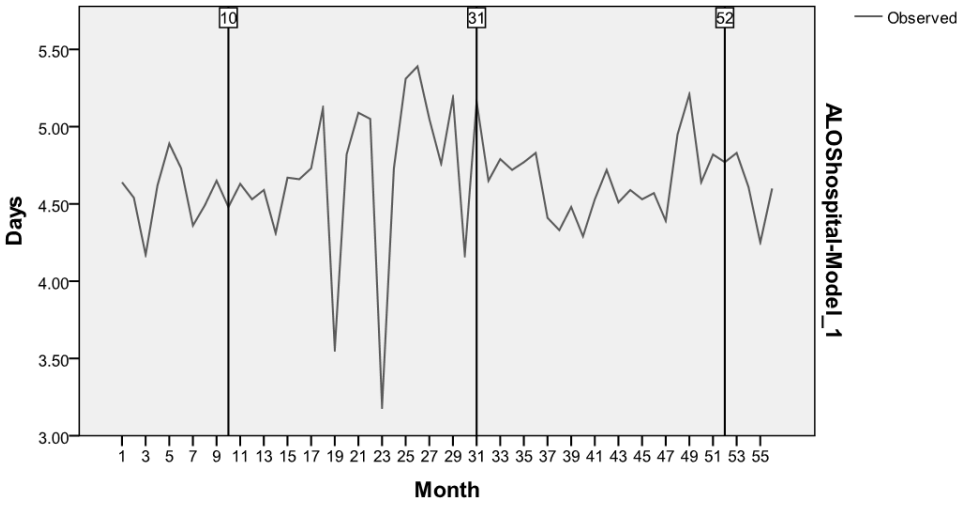


Fig 36: *ALOS for Hospital trend*



Model Statistics

Model	Number of Predictors	Model Fit statistics	Ljung-Box Q(18)			Number of Outliers
		Stationary R-squared	Statistics	DF	Sig.	
ALOS for Hospital-Model_1	3	.000	39.400	18	.003	0

Fig 37: *ALOS - Hospital ARIMA model*

The ALOS for Hospital increased from 4.56 to 4.66 (LBQ test; $p < 0.05$).

Average Length of Stay for Intensive Care Units

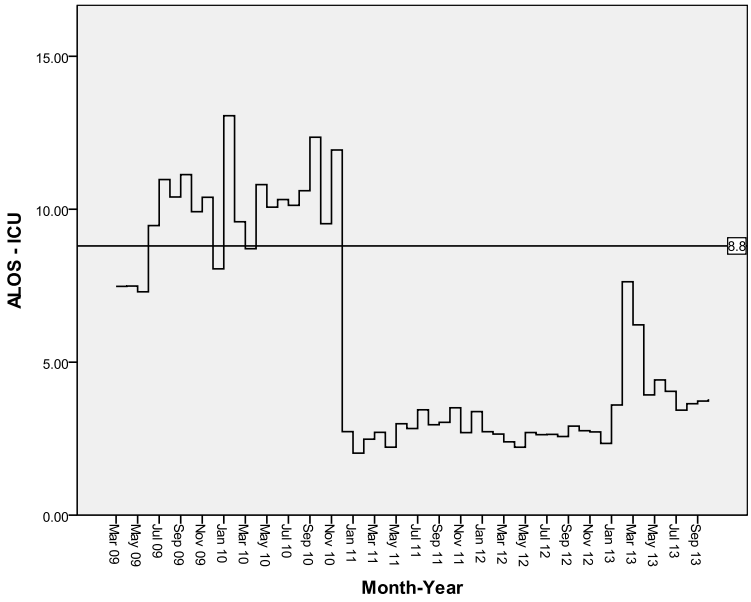
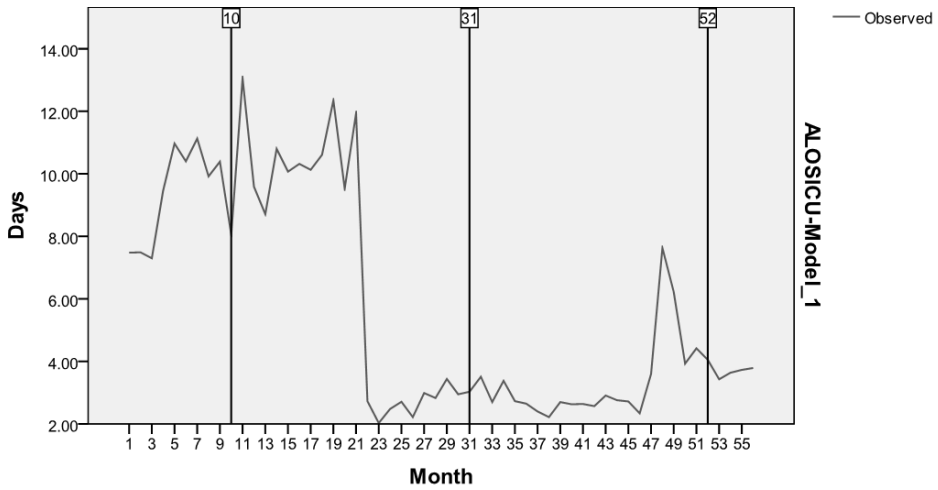


Fig 38: *ALOS for ICU trend*



Model Statistics

Model	Number of Predictors	Model Fit statistics	Ljung-Box Q(18)			Number of Outliers
		Stationary R-squared	Statistics	DF	Sig.	
ALOS for ICUs-Model_1	3	.001	20.134	18	.325	0

Fig 39: *ALOS for ICU ARIMA model*

The ALOS for ICU reduced from 9.26 days 5.00 days (LBQ test; $p > 0.05$)

Average Length of Stay for Total Knee Replacement

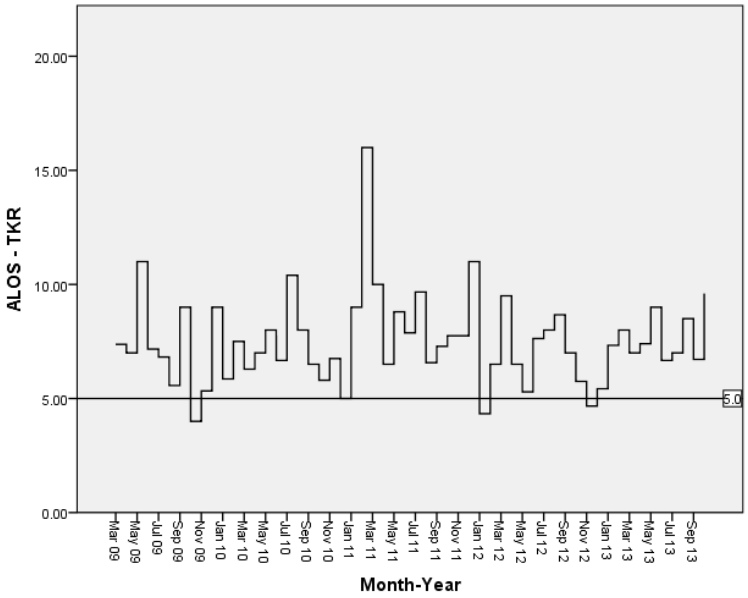
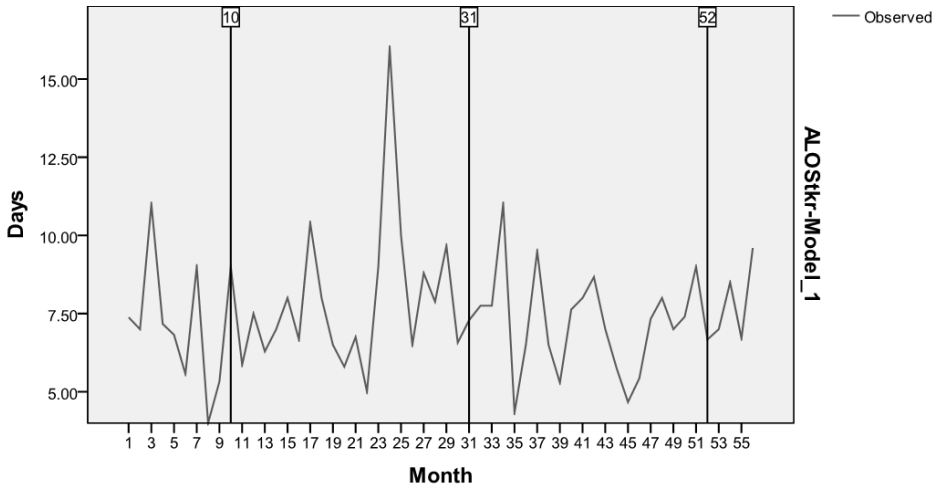


Fig 40: *ALOS for TKR trend*



Model Statistics

Model	Number of Predictors	Model Fit statistics	Ljung-Box Q(18)			Number of Outliers
		Stationary R-squared	Statistics	DF	Sig.	
ALOS for TKR-Model_1	3	.006	41.299	18	.001	0

Fig 41: *ALOS for TKR ARIMA model*

The ALOS for TKR increased from 7.23 to 7.57 (LBQ test; $p < 0.05$).

Average Length of Stay for Trans-Urethral Resection of Prostate

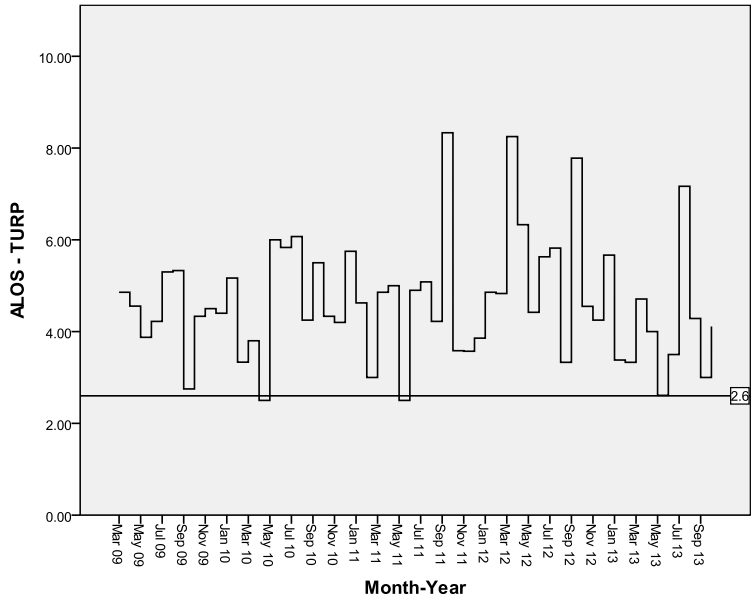
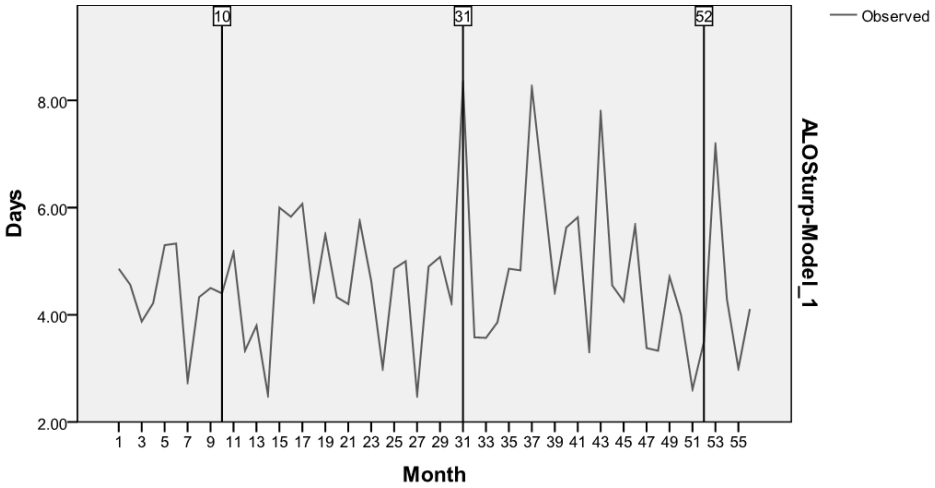


Fig 42: *ALOS for TURP trend*



Model Statistics

Model	Number of Predictors	Model Fit statistics	Ljung-Box Q(18)			Number of Outliers
		Stationary R-squared	Statistics	DF	Sig.	
ALOS for TURP-Model_1	3	.000	53.153	18	.000	0

Fig 43: *ALOS for TURP ARIMA model*

The ALOS for TURP increased from 4.41 to 4.70 (LBQ test; $p < 0.05$).

Average Length of Stay for Renal Transplant

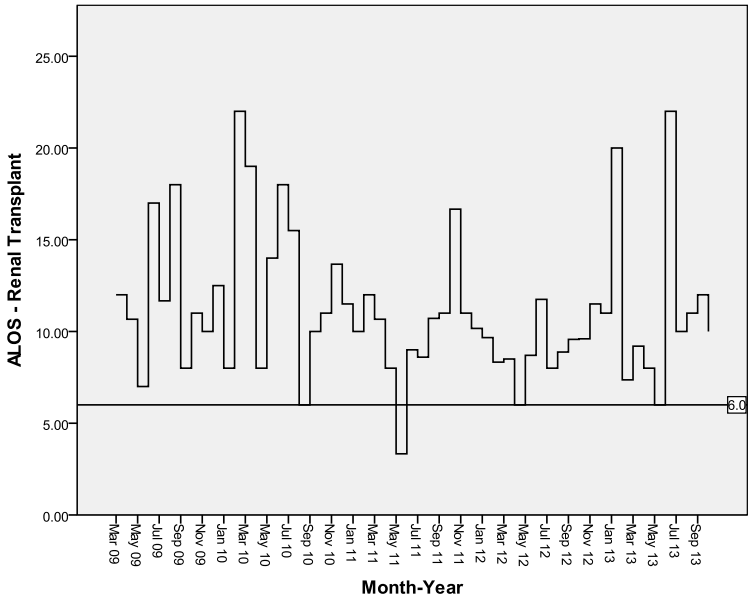
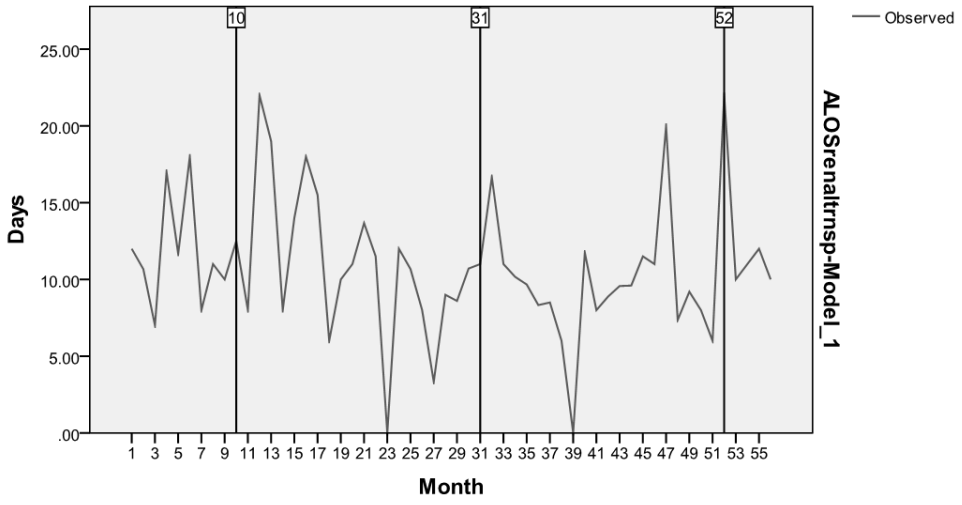


Fig 44: *ALOS for Renal Transplant trend*



Model Statistics

Model	Number of Predictors	Model Fit statistics	Ljung-Box Q(18)			Number of Outliers
		Stationary R-squared	Statistics	DF	Sig.	
ALOS for Renal Transplant-Model_1	3	.008	30.113	18	.036	0

Fig 45: *ALOS for Renal Transplant ARIMA model*

The ALOS for Renal Transplant improved from 11.78 to 10.57 (LBQ-test; $p < 0.05$).

Complication Rate post Coronary Intervention

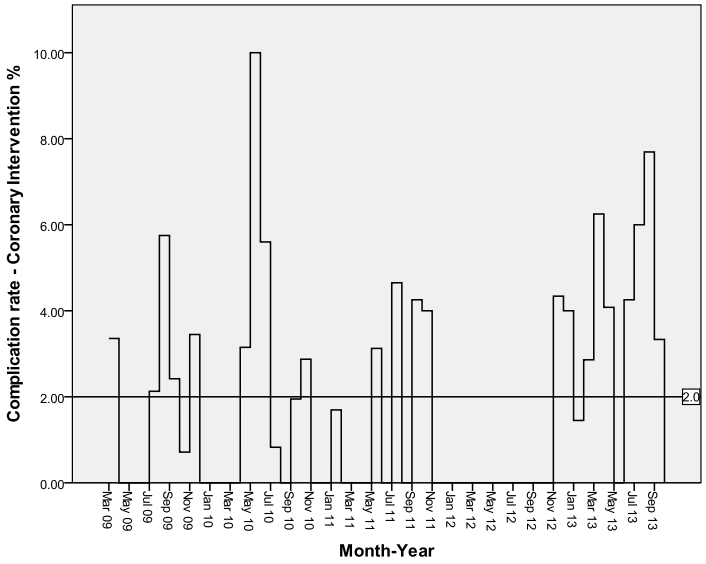
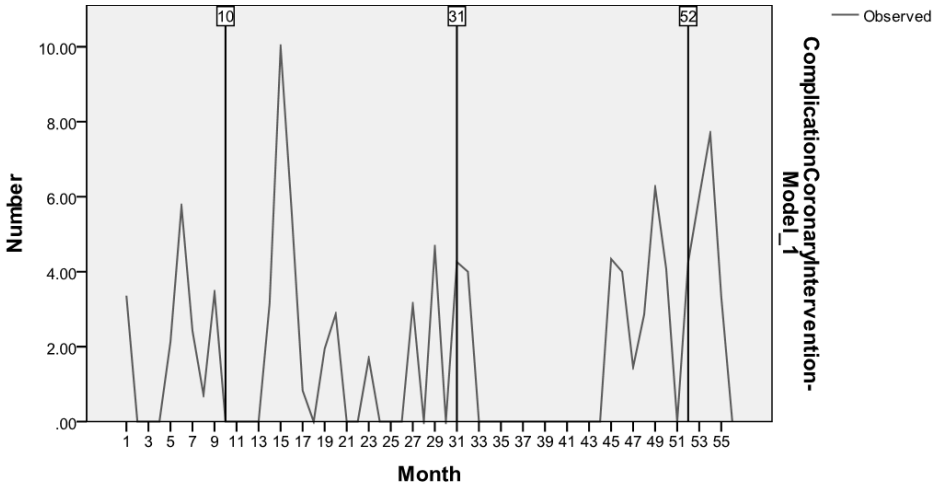


Fig 46: *Complication Rate Post Coronary Intervention trend*



Model Statistics

Model	Number of Predictors	Model Fit statistics	Ljung-Box Q(18)			Number of Outliers
		Stationary R-squared	Statistics	DF	Sig.	
Complication rate post coronary intervention-Model_1	3	.029	20.183	18	.323	0

Fig 47: *Complication Rate Post Coronary Intervention ARIMA model*

The complication rate post coronary intervention increased from 1.78% to 1.88% (LBQ-test; $p > 0.05$).

Patient Satisfaction with Pain Management

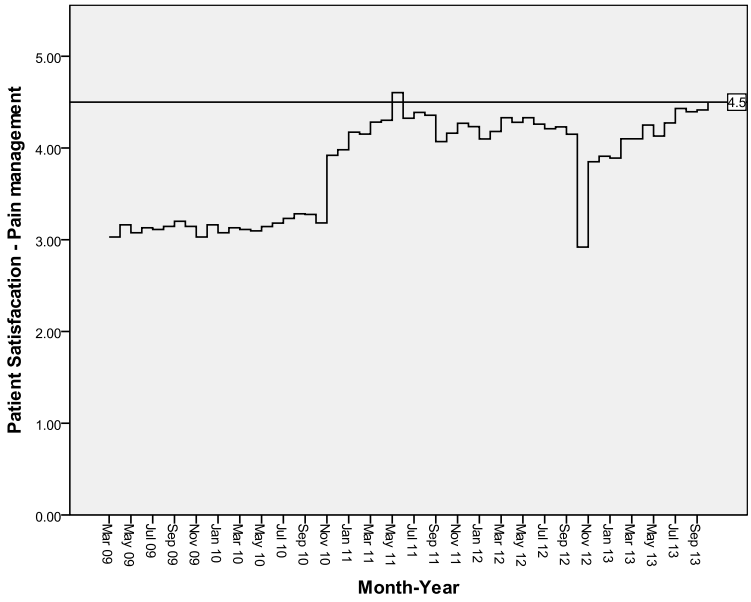
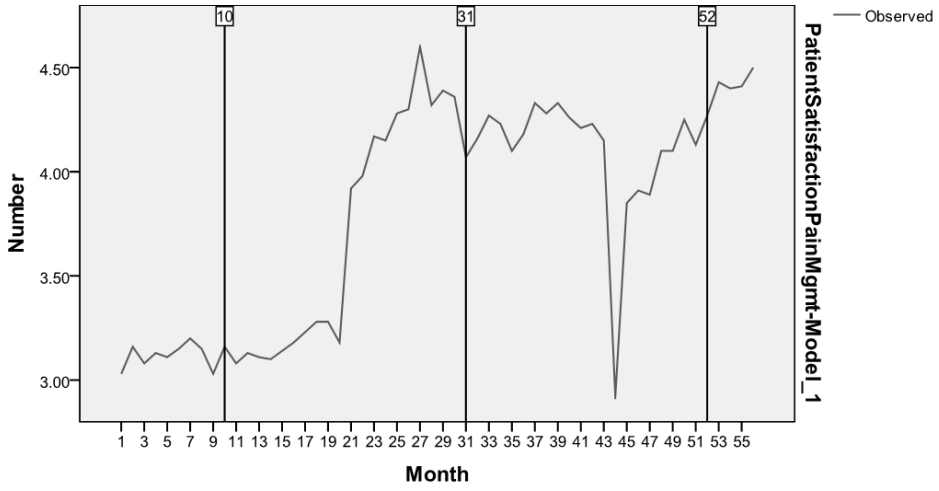


Fig 48: *Patient Satisfaction with Pain Management trend*



Model Statistics

Model	Number of Predictors	Model Fit statistics	Ljung-Box Q(18)			Number of Outliers
		Stationary R-squared	Statistics	DF	Sig.	
Patient satisfaction with pain management-Model_1	3	.002	14.050	18	.726	0

Fig 49: *Patient Satisfaction with Pain Management ARIMA model*

The patient satisfaction with pain management improved from 3.12 to 3.96 (LBQ-test; $p > 0.05$).

Catheter-Related Blood Stream Infection

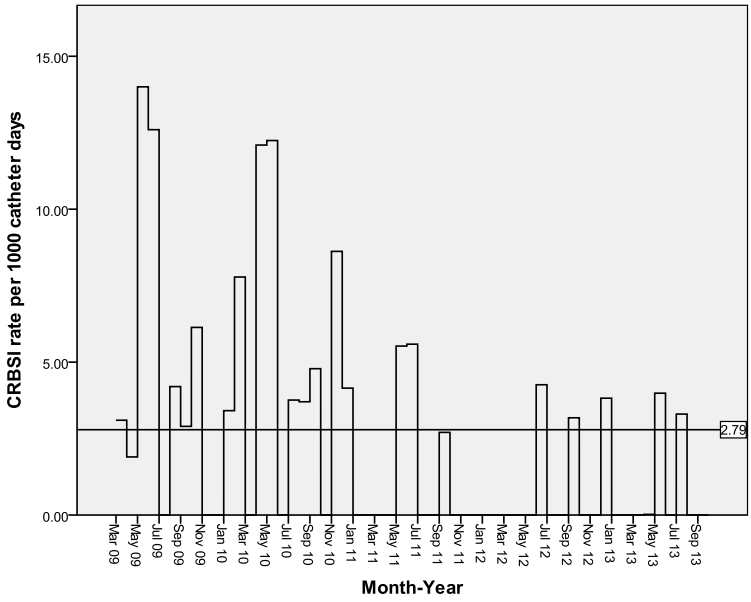
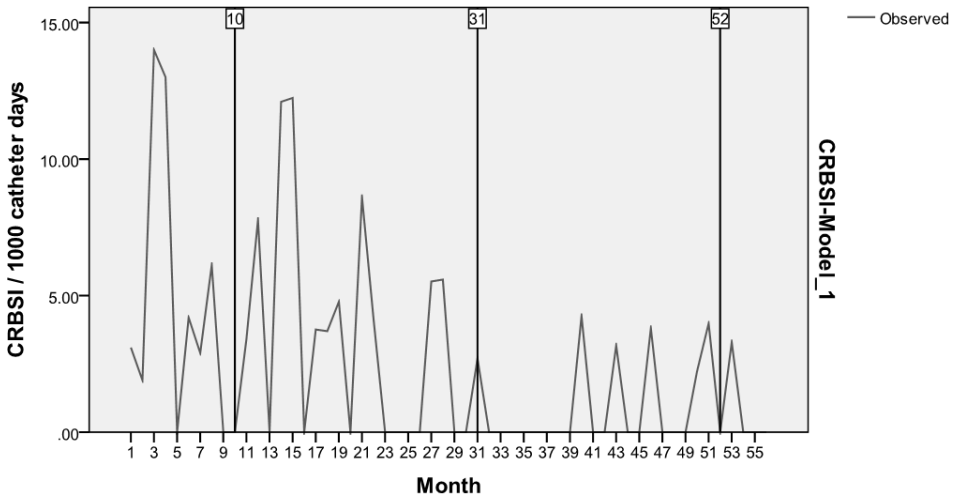


Fig 50: *CRBSI rate trend*



Model Statistics

Model	Number of Predictors	Model Fit statistics	Ljung-Box Q(18)			Number of Outliers
		Stationary R-squared	Statistics	DF	Sig.	
Catheter Related Blood Stream Infection rate-Model_1	3	.002	24.224	18	.148	0

Fig 51: *CRBSI rate ARIMA model*

The CRBSI rate improved from 4.48 to 2.07 (LBQ-test; $p > 0.05$).

Ventilator Associated Pneumonia

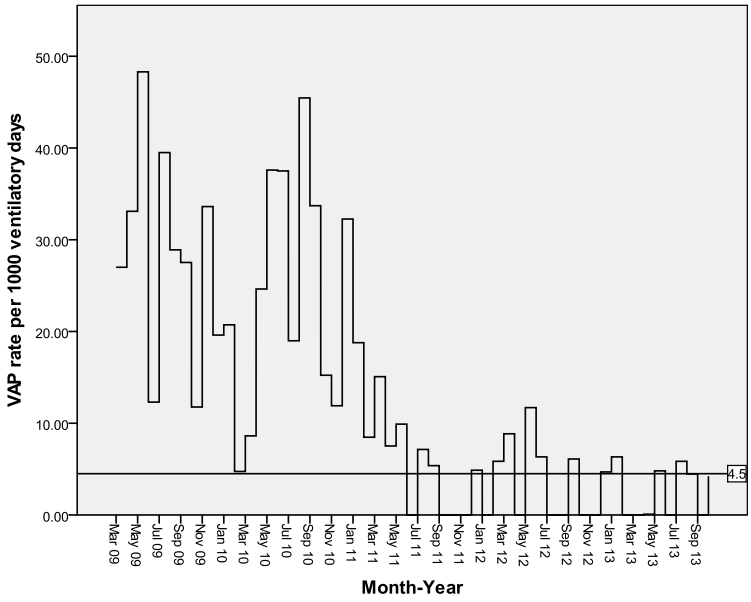
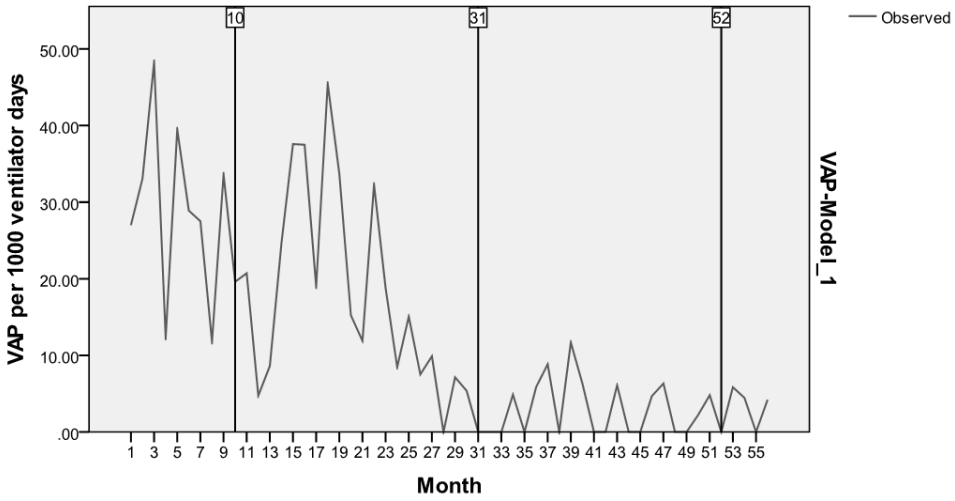


Fig 52: *VAP Rate trend*



Model Statistics

Model	Number of Predictors	Model Fit statistics	Ljung-Box Q(18)			Number of Outliers
		Stationary R-squared	Statistics	DF	Sig.	
Ventilator associated Pneumonia-Model_1	3	.001	37.561	18	.004	0

Fig 53: *VAP rate ARIMA model*

The VAP rate improved from 28.16 to 9.56 (LBQ-test; $p < 0.05$).

Catheter Associated Urinary Tract Infection

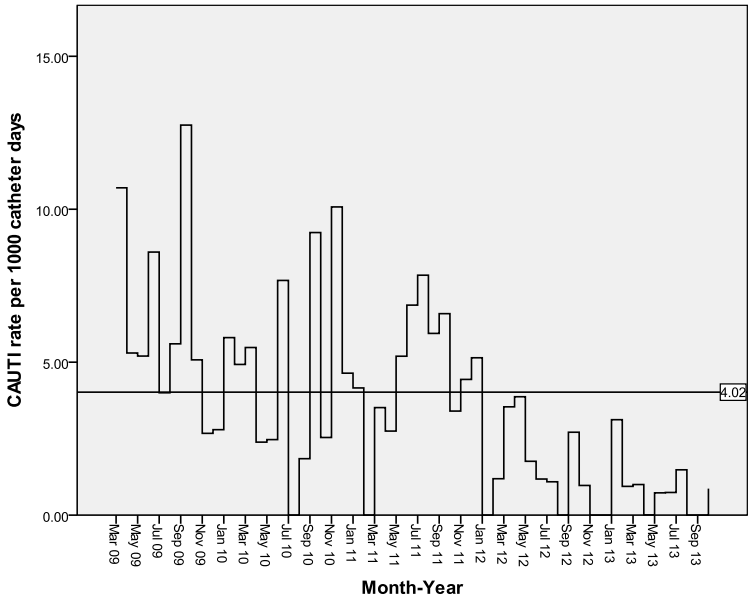
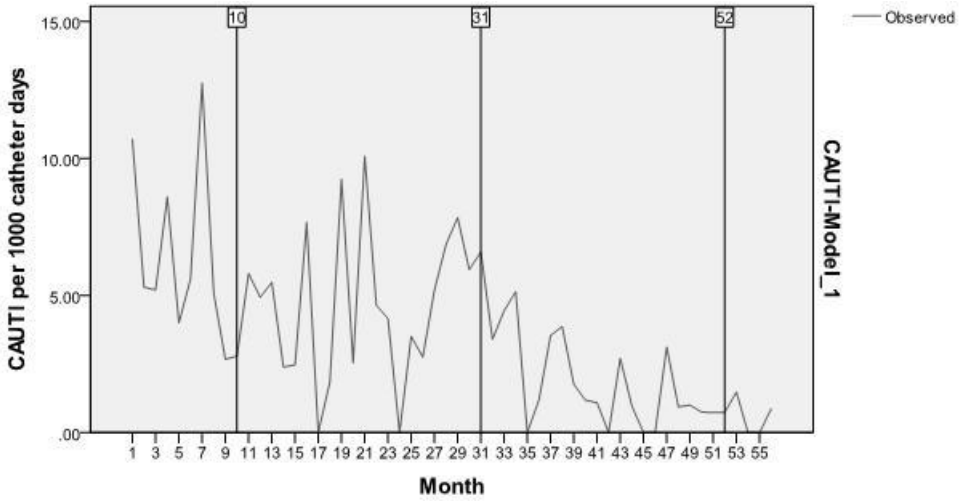


Fig 54: *CAUTI rate trend*



Model Statistics

Model	Number of Predictors	Model Fit statistics	Ljung-Box Q(18)			Number of Outliers
		Stationary R-squared	Statistics	DF	Sig.	
Catheter associated urinary tract infection-Model_1	3	.009	43.330	18	.001	0

Fig 55: *CAUTI rate ARIMA model*

The CAUTI rate improved from 6.27 to 3.02 (LBQ-test; $p < 0.05$).

Surgical Site Infection

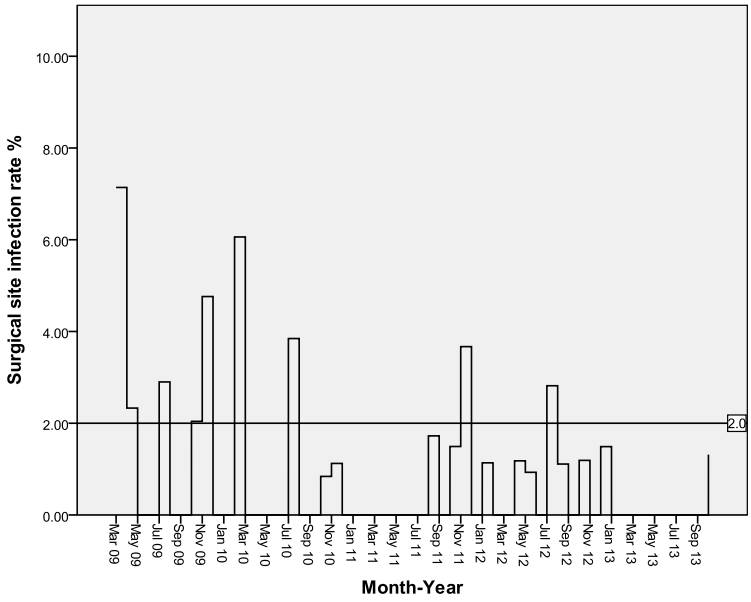
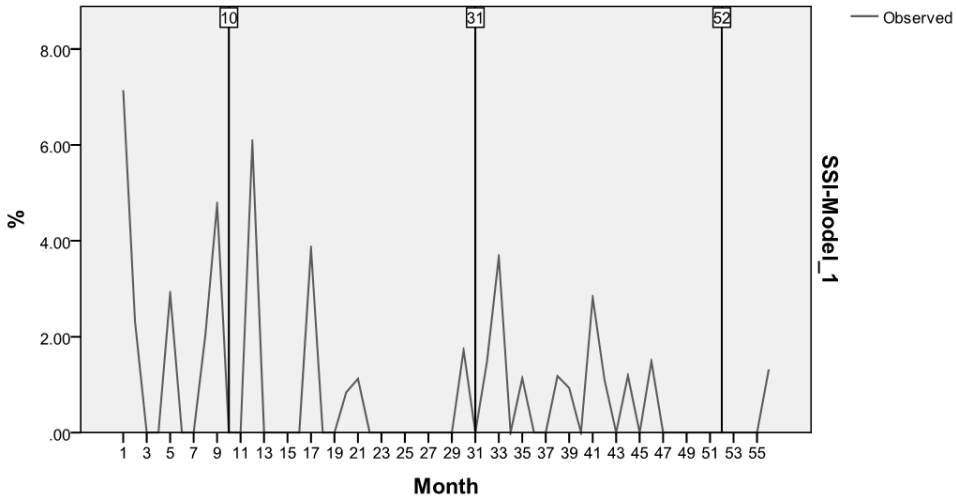


Fig 56: *SSI rate trend*



Model Statistics

Model	Number of Predictors	Model Fit statistics	Ljung-Box Q(18)			Number of Outliers
		Stationary R-squared	Statistics	DF	Sig.	
Surgical site infection-Model_1	3	.025	33.513	18	.014	0

Fig 57: *SSI rate ARIMA model*

The SSI rate improved from 1.92% to 0.65% (LBQ-test; $p < 0.05$).

5.5 Electronic Medical Records

To test the potential quality implications of the new frontier of Clinical Transformation, a comparative study on EMR and Emergency Department Information System (EDIS) was conducted in the Emergency Department of the HCO. The open-source applications available from Veterans Health Affairs (Kizer 1999) under the Freedom of Information Act were deployed and adopted. The primary objective of the study was to review and evaluate time-efficiency quality indicators in the Emergency Department, where response times are directly proportional to clinical outcomes. The secondary objective was to evaluate the use of EDIS and the feedback received from ED providers on its use – providing direction for setting up the future research agenda for EMR in India.

The EDIS solution stack deployed (Fig 6) included the following applications;

1. Electronic patient tracking system
2. Electronic Medical Record with evidence-based order sets for chest pain, head injury and poisonings
3. Reporting and intelligence system

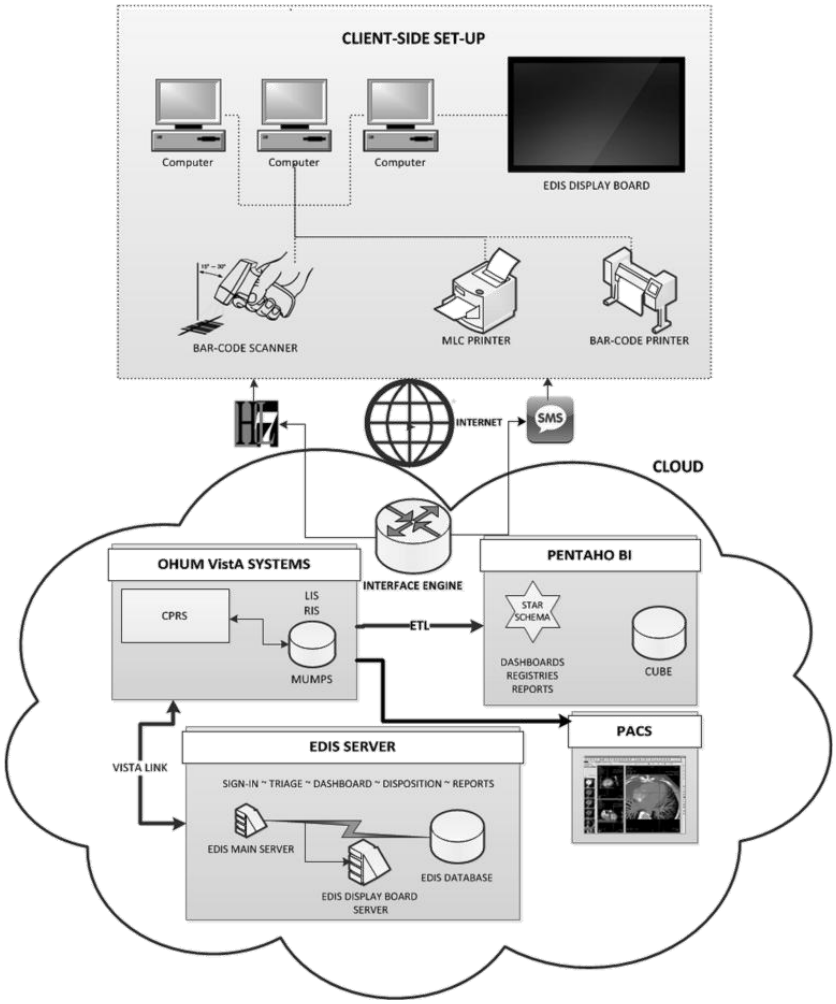


Fig 58: *EDIS Solution Architecture*

Display board, computer terminals, bar code scanners, printers, internet hosting, short messaging service (**SMS**), computerized patient record system (**CPRS**), Laboratory Information System (**LIS**), Radiology Information System (**RIS**), Picture Archival and Communication System (**PACS**), Extract-Transform Load (**ETL**), Business Intelligence (**BI**), **VistA** (Veterans Health Information Systems and Technology Architecture) and the **MUMPS** database (Multi-User Multi-Programming System)

The emergency room providers were given focused training, printed 'ready-reckoners', and were supported for using the EDIS. Primary data was captured through the EDIS patient tracking system. The VistA CPRS (Computerized Patient Record System) was used for Computerized Physician Order Entry (CPOE) and clinician documentation. Parallel legacy ED processes were compared in a time-motion study, with mean times compared with the Paired-Sample t-Test. Nine time-efficiency quality indicators were extracted and analyzed from the database. These nine quality indicators were part of the HCO's Acute Coronary Syndrome, Stroke and Sepsis quality programs that were being monitored manually and with

the EDIS could be analyzed electronically from the information captured in the database. This was followed by analysis of structured provider feedback on EDIS based on the questionnaire in Appendix 6. During the EMR adoption study period, 510 patients were tracked in the system.

Immediate Benefits

The display board enabled continuous display of patient tracking information with a color code based on the standard Canadian Triage and Acuity Scale (CTAS) (Trauma 1990). Diagnoses with International Classification of Diseases (ICD) codes, vitals, allergies and assessment notes were captured with quick electronic templates. Computerized Provider Order Entry (CPOE) was instituted with the use of quick orders and evidence-based order sets. Medico-legal case reports were also generated electronically.

ICD Groups

The ICD-9 classification of cases (Fig 59) was possible because of point-of-care coding while adding presenting complaints in the automated emergency initial assessment workflow. These were extracted from the reporting and intelligence tool and the commonest complaints could be analyzed.

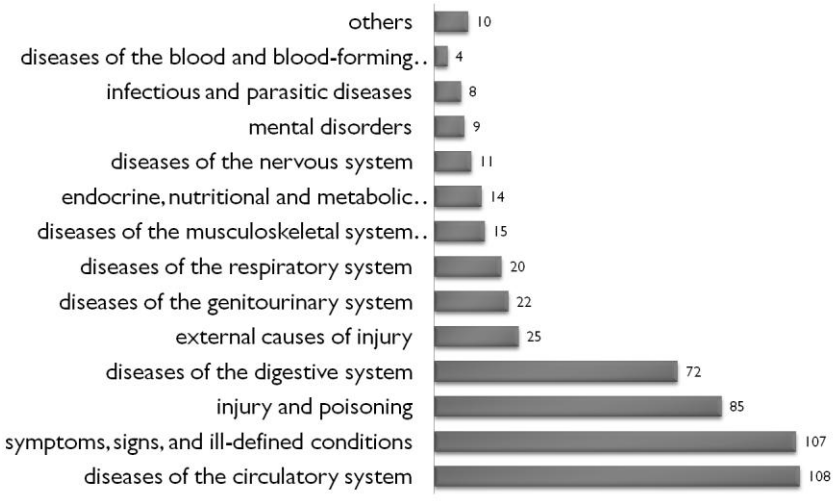


Fig 59: *ICD-9 classification of complaints presenting in ED of HCO (N=510)*

Time-efficiency Quality Indicators

Nine quality indicators (Fig 60) monitored as part of the Acute Coronary Syndrome, Stroke and Sepsis quality programs could be analyzed electronically from the information captured in EDIS. There was no manual effort required for generating these quality indicators, which otherwise required approximately a 15 man-day effort from various functionaries.

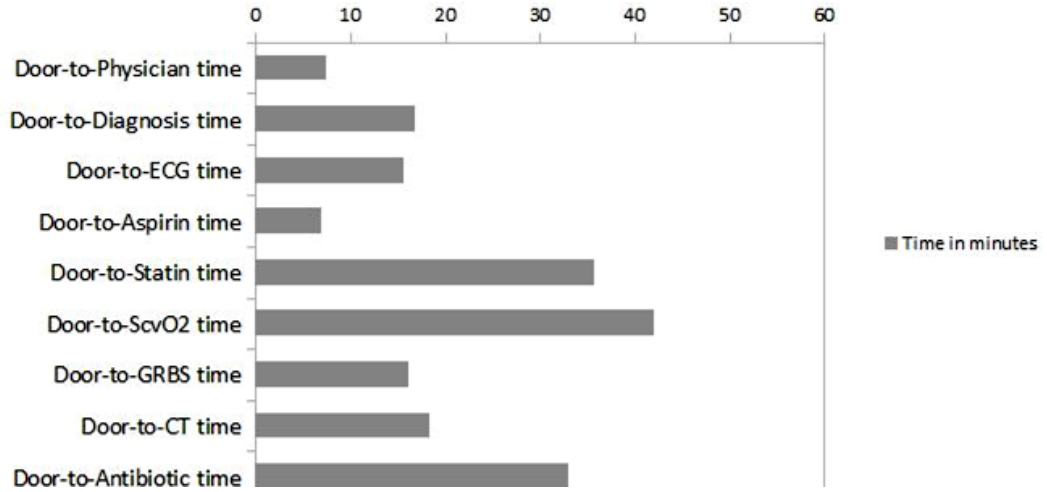


Fig 60: *Time-efficiency Quality Indicators during study period at HCO*

Time-Motion Analysis

The time-motion study (Fig 61, Table 13) conducted, revealed a statistically significant reduction in documenting history and chief complaints, from an average 97 seconds on paper to 65 seconds in EMR (Paired t-Test; $p < 0.001$). The overall assessment documentation too had a significant reduction from 6.56 minutes on paper to 4.69 minutes in EMR (Paired t-Test; $p < 0.001$). This was possible, in part, because of the auto-populating ED assessment template that had linked order sets and created the assessment notes and medico-legal case (MLC) reports simultaneously.

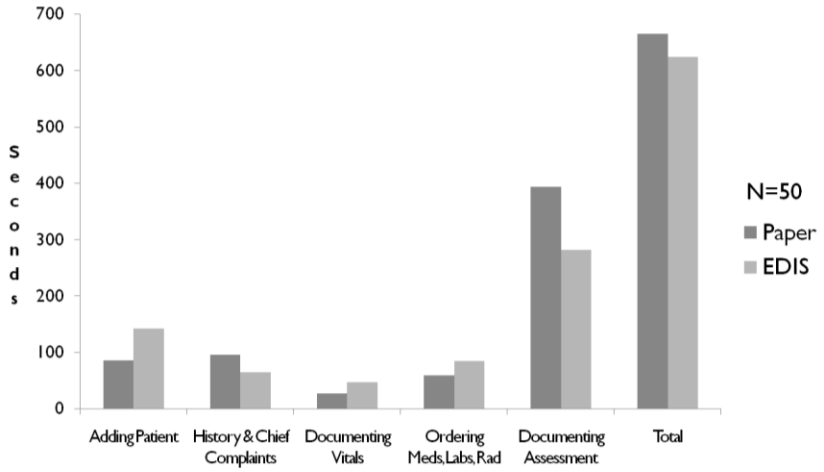


Fig 61: *Time-motion study comparing paper-based and EDIS-EMR transactions*

Table 14: *EMR vs Paper: Time-Motion Analysis*

Paired Samples Statistics

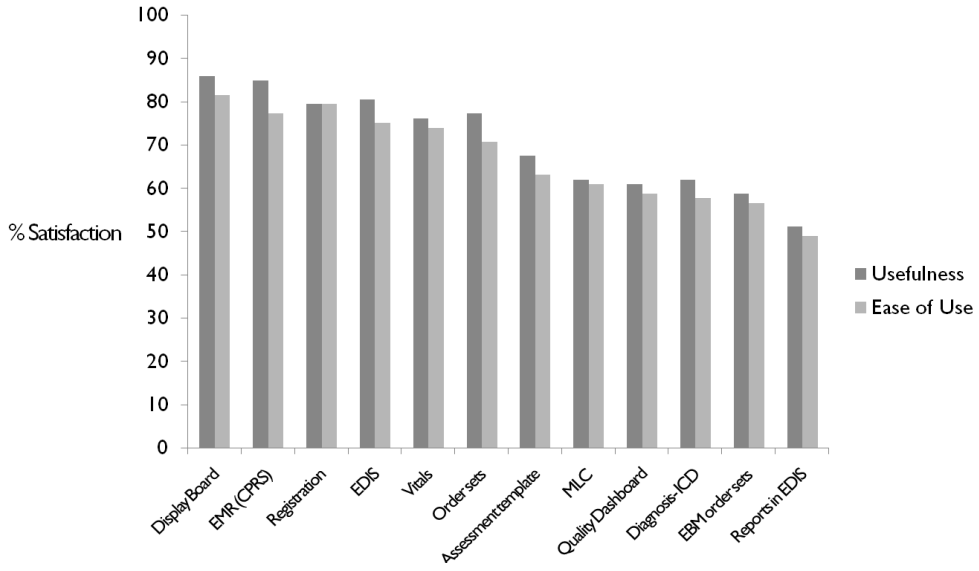
		Mean (s)	N	Std. Deviation	Std. Error Mean
Pair 1	Add Patient Paper	85.96	50	24.635	3.484
	Add Patient EMR	143.08	50	45.695	6.462
Pair 2	Record Complaints Paper	96.7000	50	51.93687	7.34498
	Record Complaints EMR	65.3200	50	16.81889	2.37855
Pair 3	Order Medication Paper	60.0200	50	28.26225	3.99689
	Order Medication EMR	85.4400	50	40.50909	5.72885
Pair 4	Record Vitals Paper	28.1600	50	14.84802	2.09983
	Record Vitals EMR	47.9800	50	20.46250	2.89383
Pair 5	Document Assessment Paper	393.4200	50	240.56253	34.02068
	Document Assessment EMR	281.5000	50	130.56709	18.46498

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	Add Patient Paper - Add Patient EMR	-57.120	42.900	6.067	-69.312	-44.928	-9.415	49	.000
Pair 2	Record Complaints Paper - Record Complaints EMR	31.38000	53.30233	7.53809	16.23165	46.52835	4.163	49	.000
Pair 3	Order Medication Paper - Order Medication EMR	-25.42000	35.16033	4.97242	-35.41245	-15.42755	-5.112	49	.000
Pair 4	Record Vitals Paper - Record Vitals EMR	-19.82000	15.06678	2.13076	-24.10193	-15.53807	-9.302	49	.000
Pair 5	Document Assessment Paper - Document Assessment EMR	111.92000	218.34188	30.87820	49.86792	173.97208	3.625	49	.001

Provider Feedback Analysis

A statistically significant proportion of providers perceived the following features of EDIS (Appendix 6) to be useful and easy to use – Display Board, CPRS, Registration, Vitals, Evidence-based Order Sets, Assessment Template, MLC, Quality Dashboard, ICD-coded Diagnosis, Reports. Overall, 80% of the respondents found EDIS useful and 75% of the respondents perceived it easy to use (One sample t-Test; $p < 0.001$) (Fig 62).

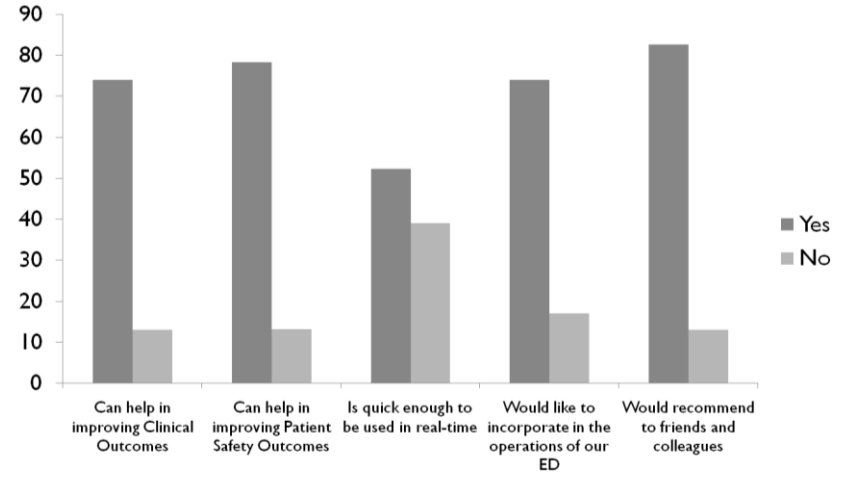


One-Sample Test

	Test Value = 0					
					95% Confidence Interval of the Difference	
	t	df	Sig. (2-tailed)	Mean Difference	Lower	Upper
Usefulness	21.283	11	.000	70.41667	63.1347	77.6987
Ease of Use	22.076	11	.000	67.08333	60.3950	73.7717

Fig 62: *Analysis of Provider feedback on EDIS functionality*

74% respondents thought EDIS can help improve clinical outcomes, whereas 78% thought EDIS can help improve safety outcomes. 83% of the respondents would recommend EDIS to colleagues (One sample t-Test; $p < 0.001$) (Fig 63).



One-Sample Test

	Test Value = 0					
	t	df	Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
Yes	13.586	4	.000	72.20000	57.4456	86.9544
No	3.755	4	.020	19.00000	4.9522	33.0478

Fig 63: *Analysis of Provider feedback EDIS Quality and Safety Improvement potential*

Chapter 6: Healthcare Excellence Model

Based on the action research and experiential learning from TQM implementation and measurement of outcomes, a standard model for NABH accreditation and TQM/CQI implementation in healthcare organizations was developed. The author would like to propose the following model for healthcare excellence (Fig 64):

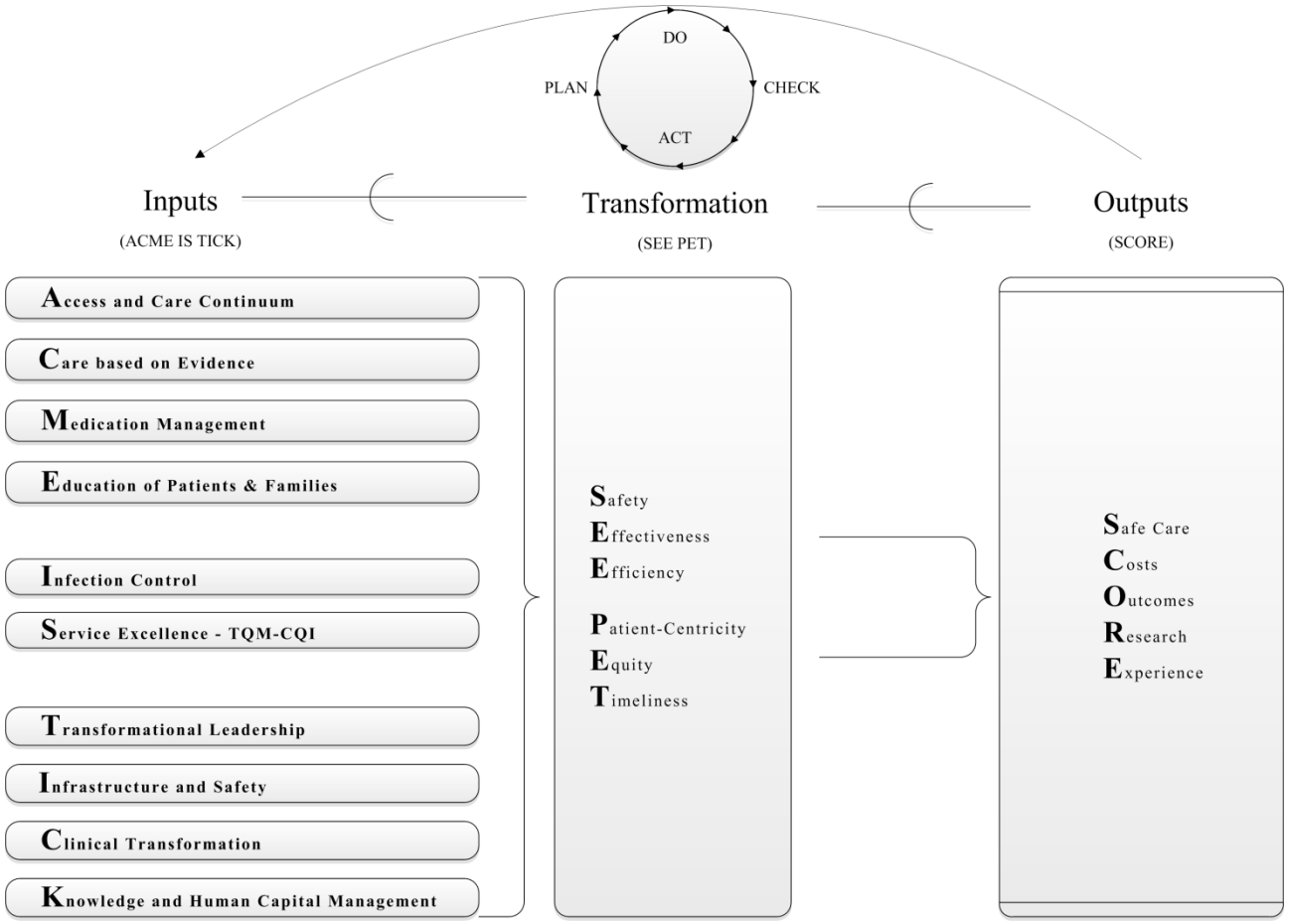


Fig 64: *Proposed Healthcare Excellence Model*

The inputs (ACME IS TICK) are based on the experiential learning from NABH implementation and is purported to address the quality and safety requirements based on established healthcare Standards (International 2011, Providers 2011). The transformation processes (SEE PET) are based on the 6 dimensions of Quality (Institute of Medicine 2001). The Outputs categorized based on SCORE. The SCORE output model is further divided into Clinical, Administrative, Financial and Improvement indicators (Table 14). These indicators are classified as vital, essential and desirable in terms of their importance and colour-coded accordingly.

Table 15: *SCORE model*

Vital / Essential / Desirable	Safety	Costs	Outcomes	Research	Experience
Clinical	Vulnerable Patient management	Medication reconciliation	Protocolized Nursing Care	Clinical Quality Indicators	EMR & Mobility
	VTE Prevention & Treatment	Formulary restrictions on medication orders	Chemotherapy management	Hospital-Based Registries	Clinical Alerts and Reminders
	High-Alert medication Safety	Credentialing & Privileging	Antibiotic Stewardship	Big Data Analytics	Real-time evidence reference
	Emergency patient tracking	Consultant Physicians' accounting	Anti-coagulation management	Criteria-based clinical audits	Outpatient consult, Prescription
	Surgical Safety	Full-timer salary accounting	Disease-specific care for common Comorbidities	Patient lists for Clinical Research	Inpatient assessment & re-assessment, Clinical note templates
Administrative	Emergency Department timeliness	Medical Cycle management	Bed turnover management	Medical Record audits	Registration & Appointment scheduling
	Early Warning Systems	Capital Asset management	Access and authorization controls	Turn-Around times	Admission, Discharge, Transfers
	Critical Call-Outs	Blood Bank management	Nutrition, dietetics and kitchen management	Waiting times	Radiology & Imaging - ordering, reporting, images & dispatch
	Shift Hand-Offs	Biomedical Equipment management	Inventory management	Services utilization	Laboratory ordering, accession, processing & dispatch
	Hazardous Materials management	Order Cancellations & Repeat tests	Hospital utilities management	Services timeliness	Outpatient and Inpatient billing
	Statutory & Regulatory Requirements	External and Internal Quality Assurance for Lab & Radiology	Recruitment and selection	Incident report analysis	Insurance & Third Party Administration
Financial	Reconciliation of accounts	OP, Diagnostics & IP collections, utilization & revenue	Financial statements – P/L, Trial Balance, Balance Sheet	Revenue mix	Enterprise Resource Planning
	Statutory financial compliance	Corporate Accounting	Discounts, subsidies and indigent fund management	Financial ratios	MIS reports & business dashboards
	Taxation management	Payroll management	Reusable consumables accounting	Activity-Based costing	Budgeting
Improvement	Infection control & improvement as per NHSN benchmarks	Improvement in utilization & collections	Reduction in complication rates & adherence to ALOS	Clinical translational research	PACS and remote image viewing
	Golden-hour compliance	Improvement in Pharmacy utilization	Patient portal and remote monitoring	Morbidity, mortality and standards-based audits	Bar-Coded Medication Administration
	Risk management – Sentinel events, Falls, Pressure Sores, NSI	Improvements in TATs - Laboratory & Radiology	Staff training and education	Patient Feedback system	Domiciliary care

Chapter 7: Conclusions

7.1 Summary of Conclusions

Critical-to-quality factors and the impact of ISO 9001:2008

From the analysis of patient feedback, the identified critical-to-quality factors in the HCO were:

1. Admissions
2. Guest Relations
3. Doctors
4. Nursing
5. Housekeeping
6. Maintenance
7. Patient Care Services
8. Intensive Care

Successful implementation of ISO 9001 Quality Management System resulted in statistically significant improvements in Admissions feedback ($p < 0.05$)

It is evident that ISO 9001 had a positive impact on patient feedback. Admissions feedback, which has more direct applicability of some of the ISO 9001 clauses, had a significant improvement due to ISO 9001 implementation.

NABH Implementation and Continuing Assessments

The average assessment scores for the HCO based on the NABH Assessment Toolkit improved from the pre-implementation score of 2.8 in January 2010 to 8.88 in the final accreditation assessment in September 2011 ($p < 0.05$). There were statistically significant increment in SA scores from pre to post-implementation ($p < 0.001$) and mid to post-implementation ($p < 0.05$).

From these scores the objective improvements due to NABH implementation are obvious. The need for documenting policies and procedures, followed by training, implementation, quality monitoring and assessments, as required by the NABH Standard puts in motion

majority of the TQM constructs. If this is amalgamated with innovative approaches like patient-centricity campaigns, collaborative governance and novel quality tools, it is bound to inculcate a quality and safety culture in the HCO.

Thus NABH represents a solid reference point for any quality improvement strategy in the health care domain.

TQM Constructs and NABH Assessors' Perceptions

Amongst the NABH chapters, the highest weighted rank of 7.52 was given to AAC ($p < 0.001$), followed by 7.31 for HIC ($p < 0.05$), 7.1 for COP ($p < 0.05$). It was evident that the top 5 ranking chapters were all patient-centred chapters, indicating the inclination that NABH Assessors have toward patient care, relegating the organization-centred standards to the last 5 ranks.

IMS got the maximum number of responses as the lowest rank with an average weighted rank of 3.24 ($p < 0.001$). This chapter primarily deals with patient related information systems, paper-based as well as electronic. In the author's opinion, NABH ought to amend the Standards in this chapter to specifically deal with Electronic Medical Records and Clinical Decision Support Systems (CDSS) – an increasingly common-place entity in modern healthcare.

Assessors scored all six dimensions of quality significantly higher in NABH accredited hospitals compared to non-accredited hospitals ($p < 0.05$). Thus it can be inferred that NABH ensures Safety, Effectiveness, Efficiency, Patient-Centricity, Equity and Timeliness.

The four leadership constructs - top management commitment, vision and strategy, organizational quality culture, objectives for quality performance are found be much better in NABH accredited hospitals ($p < 0.05$). The same was the case for customer/supplier relations, employee relations and process management constructs ($p < 0.05$).

A significant proportion of the NABH Assessors in India believe that efforts are made to follow evidence-based guidelines in NABH accredited hospitals but these are not institutionalized ($p < 0.05$). Perhaps NABH ought to consider amending the relevant COP

standard on evidence-based medicine and clinical pathways to clearly enunciate what it expects in this regard.

The Assessors rated quality indicators like Complication rates post-interventions, Average Length of Stay associated with mortality and morbidity, Turn-around Times, Hospital Acquired Infection, Patient Safety indices and Time-efficiency indicators better in NABH accredited hospitals ($p < 0.05$). Indeed the improvements in some of these clinical quality indicators were validated at the HCO during the study period (vide infra).

Impact of TQM & NABH on Quality Indicators

Although some paradoxical results on ALOS were observed in TKR, TURP and overall Hospital ($p < 0.05$), significant improvements were seen in the following quality indicators post NABH implementation; CAG to CABG conversion rate ($p < 0.05$), ALOS for Renal Transplant ($p < 0.05$), VAP ($p < 0.05$), CAUTI ($p < 0.05$), SSI ($p < 0.05$). This in turn validated the perceptions of the NABH assessors on patient safety and infection control indices being better in NABH accredited hospitals. Thus NABH presents an ongoing opportunity to make specific improvements in clinical processes of the Hospital.

EMR Adoption & Clinical Transformation

Clinical Transformation through Electronic Medical Records is healthcare quality's new-fangled way. The potential cost savings and quality-safety improvements were demonstrated in the case of the HCO's Emergency Department. From the study it was evident that EMR & EDIS have the potential to transform critical ED operations. The display board with real-time patient information, triage code and provider assignments can improve information exchange, thereby reducing care-coordination errors. Patient tracking in EDIS generates real-time quality and safety information, which can be used to institute corrective and preventive actions. This is true especially in the case of time-efficiency indicators like Door-to-ECG time, Door-to-Physician time, and Door-to-Aspirin time. The Electronic Medical Record with automated emergency assessment and medico-legal reporting procedures can significantly reduce the time taken by ER physicians for documentation, consequently improving the effective time spent on direct patient-care activities. Evidence-based order sets provide guidelines for emergency room physicians to ensure treatment interventions based on

accepted clinical practice guidelines. There seem to be many reasons to pursue a wide-scale implementation of EDIS, especially to improve efficiency, quality and safety of Emergency Departments. There was strong positive feedback for the usability and ease of use of EMR, having wide implications for EMR adoption in the HCO as well as the entire healthcare establishment in India and overseas.

Healthcare Excellence Model

The author presents his SCORE model as an amalgamation of NABH, TQM constructs, IOM dimensions of quality and the indicators of clinical, safety and patient satisfaction outcomes.

This all-encompassing reference model, developed through experiential learning and translational research, would prove useful for any quality improvement pursuit in healthcare – either in the academic or real-life setting and the Author strongly urges the healthcare quality community to adopt this improvement model.

7.2 Specific Contributions

1. ISO 9001 impact on Patient Feedback in a HCO – interrupted time series analysis – a new analytic approach for patient feedback trends.

2. NABH Assessment toolkit – assessment score improvement for a HCO – first academic submission including statistical analysis of SA scores

3. NABH Assessors Survey on TQM Constructs – first ever Expert Elicitation Survey of this specialized group using a design based on the Checklist for Reporting Results of Internet E-Surveys (CHERRIES).

4. Suggestions for improvements required in the NABH Standard in the COP chapter for EBM & CPG and in the IMS chapter for including EMR requirements

5. Clinical Quality Indicator trends - interrupted time series analysis – new analytic approach for QI trends.

6. EMR Adoption & EDIS implementation pilot study – first of its kind in India

7. New Definitions for TQM in healthcare & Clinical Transformation

8. SCORE model – Author's conception of a novel TQM model dedicated to the healthcare quality community

7.3 Limitations of the Study

1. This was a unicentric study for longitudinal observation in an experimental design to enable action research. It was not possible to have this done in a multi-centric setting due to study-centre approval and researcher constraints. The limitation of unicentric observations were partially overcome by including benchmarks for each of the quality metrics measured throughout the study period.

2. There were no control groups for any of the tests. This limitation is largely due to unavailability of a central repository of quality and safety data for all NABH accredited hospitals, where such reference measures may be available for analysis. Quality Council of India should seriously consider mandating quality indicator reporting and making this available to the public at large.

3. Only 15 QIs were maintained. Although these covered clinical, administrative, financial, improvement parameters and were part of the quality priorities set for the HCO, they did not address all 64 quality indicators recommended by NABH.

4. The scale of the EMR adoption study was limited in terms of duration, providers and locations included.

7.4 Future Scope of Work

1. Validation of new definitions of TQM in healthcare and clinical transformation
2. A multi-centric survey of NABH accredited hospitals is required to validate the quality improvement made due to NABH. A multi-centric survey is required in JCI accredited hospitals as well.
3. A head-to-head comparison of NABH and JCI accredited hospitals would bring out the essential difference in the National and International Quality Standards prevalent in India and overseas.
4. Although the EMR adoption study is indicative of the immediate benefits of EMR & EDIS and the complete transformation of the quality indicator monitoring process, a study involving a longer duration of system adoption and the aggregate benefits accruing from it, is definitely required to validate this further.
5. A larger multi-centric study of EMR adoption would uncover other unknown variables and bring in more insights into its benefits.
6. Validation and implementation of the SCORE model
7. Use of Big Data and Health Information Exchange technologies in healthcare quality

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Appendices

Appendix 1: Average Patient Feedback Scores from Jan 2008 to Nov 2010

Category	Feedback	Jan-08	Feb-08	Mar-08	Apr-08	May-08	Jun-08	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08	Dec-08	Jan-09	Feb-09	Mar-09	Apr-09	May-09	Jun-09	Jul-09	Aug-09	Sep-09	Oct-09	Nov-09	Dec-09	Jan-10	Feb-10	Mar-10	Apr-10	May-10	Jun-10	Jul-10	Aug-10	Sep-10	Oct-10	Nov-10
Admission	The discharge process was completed in 2 hours	2.21	2.36	2.28	2.37	2.54	2.53	2.79	2.72	2.63	2.85	2.87	2.73	2.77	2.76	2.78	2.76	2.75	2.69	2.77	2.76	2.77	2.81	2.78	2.89	2.87	2.88	2.94	2.9	2.98	2.98	3.06	3.09	3.08	3.06	3.04
Admission	I was able to easily find my way to the Admission Desk	3.07	2.76	3.3	3.2	3.36	3.19	3.22	3.16	3.11	3.23	3.23	3.19	3.17	3.21	3.16	3.16	3.15	3.09	3.22	3.15	3.17	3.18	3.07	3.14	3.12	3.18	3.16	3.14	3.19	3.24	3.28	3.3	3.31	3.19	3.11
Admission	Admissions Staff was polite, helpful and friendly with me	3	2.69	3.14	3.12	3.15	3.09	3.11	3.11	2.84	3.16	3.22	3.16	3.17	3.15	3.16	3.13	3.14	3.07	3.21	3.15	3.21	3.16	3.02	3.17	3.1	3.16	3.13	3.11	3.19	3.22	3.25	3.23	3.23	3.06	3
Admission	Staff clearly explained to me the room charges, estimates and billing procedures	2.23	2.37	2.63	2.73	2.7	2.55	2.68	2.77	2.91	2.84	2.83	2.87	2.83	2.83	2.84	2.77	2.82	2.74	2.83	2.82	2.85	2.84	2.75	2.92	2.85	2.86	2.89	2.91	2.96	2.95	3.02	3.07	3.07	2.93	2.88
Admission	All my queries were answered patiently by the staff at the desk	2.64	2.57	3.01	2.86	2.79	2.83	2.92	2.91	2.84	3.07	3.07	3.06	3.01	3.02	3.03	2.96	3	2.94	3.03	3.01	3.04	2.96	2.92	3.05	2.99	3.03	3.02	3.02	3.09	3.12	3.14	3.18	3.2	3.26	3.2
Admission	I had to wait for less than 30 minutes to get a room allocated	2.54	2.21	2.57	2.41	2.75	2.67	2.81	2.56	2.57	2.68	2.86	2.67	2.93	2.93	2.9	2.76	2.92	2.85	2.83	2.87	2.83	2.82	2.75	2.91	2.92	2.96	2.93	2.96	3.02	3.05	3.05	3.08	3.04	3.07	3.01
Admission	I got the room of my choice at the time of Admission	2.13	2.03	2.1	2.15	2.25	2.13	2.53	2.27	2.24	2.71	2.66	2.7	2.66	2.66	2.71	2.56	2.66	2.61	2.67	2.72	2.63	2.62	2.51	2.75	2.75	2.76	2.75	2.84	2.83	2.95	2.94	2.94	2.97	3.29	3.21
Guest Relations	I was explained about the facilities in the room by a staff member	2.46	2.29	2.64	2.63	2.61	2.62	2.71	2.69	2.82	2.84	2.86	2.88	2.8	2.93	2.92	2.83	2.8	2.87	2.99	2.99	2.96	2.91	2.79	2.96	2.93	2.94	2.97	2.97	2.94	2.94	2.98	3.09	3.02	3.08	3.03
Doctors	I was satisfied with the pain management	3.03	3	3.02	3.03	3.02	3.08	3	3.06	3.04	3.11	3.09	3.14	3.23	3.33	3.21	3.17	3	3.11	3.23	3.16	3.2	3.15	3.03	3.16	3.08	3.13	3.11	3.1	3.15	3.18	3.23	3.28	3.28	3.18	3.17
Doctors	I was attended by CMO within 10 minutes of my arrival in casualty	2.81	2.75	2.33	2.46	2.81	2.52	2.75	2.68	2.97	3.15	3.14	3.15	3.09	3.11	3.1	3.07	3.07	3	3.1	3.08	3.14	3.05	2.94	3.06	3.05	3.08	3.04	3.07	3.14	3.14	3.18	3.22	3.23	3.23	3.15
Doctors	I was seen by an assistant doctor once in a day during my stay	3.26	3.32	3.23	3.12	3.22	3.17	3.24	3.22	3.2	3.23	3.25	3.31	3.34	3.35	3.34	3.29	3.35	3.34	3.29	3.26	3.32	3.23	3.12	3.22	3.17	3.24	3.22	3.2	3.23	3.25	3.31	3.34	3.35	3.34	3.29
Doctors	I was seen by a doctor within 45 minutes of my arrival in my room	2.87	2.5	2.86	2.86	2.98	2.86	3.02	3.01	3	3.09	3.07	3.08	3.02	3.07	3.06	3.01	3.01	2.95	3.1	3.05	3.1	3.07	2.97	3.07	3.04	3.07	3.06	3.04	3.11	3.11	3.21	3.23	3.19	3.33	3.25
Doctors	All the doubts/queries were answered patiently by the Doctor	3.07	2.74	3.23	3.21	3.31	3.2	3.28	3.19	3.17	3.31	3.25	3.18	3.17	3.21	3.19	3.14	3.14	3.1	3.26	3.22	3.25	3.21	3.11	3.2	3.13	3.21	3.17	3.18	3.22	3.26	3.31	3.34	3.31	3.35	3.25
Doctors	The Doctor explained to me the detail of my procedure(s)/diagnosis	3.08	2.81	3.27	3.18	3.3	3.26	3.31	3.21	3.18	3.27	3.23	3.18	3.16	3.22	3.18	3.14	3.11	3.1	3.25	3.18	3.23	3.19	3.09	3.2	3.13	3.22	3.17	3.16	3.24	3.25	3.31	3.32	3.31	3.3	3.24
Doctors	I was seen by a Doctor regularly during my stay	3.15	2.76	3.2	3.15	3.34	3.23	3.28	3.22	3.3	3.3	3.31	3.21	3.18	3.23	3.2	3.17	3.15	3.13	3.28	3.19	3.28	3.21	3.13	3.23	3.15	3.22	3.18	3.18	3.22	3.21	3.31	3.33	3.32	3.28	3.21
Nursing	I was attended by a Nurse within 30 minutes of my arrival in the room	3.08	2.77	3.14	3.07	3.25	3.14	3.24	3.13	3.11	3.3	3.29	3.18	3.17	3.21	3.23	3.18	3.14	3.12	3.26	3.2	3.28	3.23	3.1	3.21	3.14	3.19	3.17	3.19	3.21	3.24	3.31	3.34	3.34	3.27	3.21
Nursing	I was given medicines on time by the nurse	3.06	2.83	3.21	3.16	3.25	3.24	3.24	3.12	3.05	3.26	3.29	3.21	3.16	3.2	3.22	3.17	3.21	3.14	3.28	3.27	3.28	3.25	3.13	3.2	3.16	3.21	3.19	3.19	3.2	3.26	3.28	3.33	3.33	3.28	3.18
Nursing	I was informed by the nurse about my investigation(s) ahead to time	2.74	2.71	2.99	2.83	2.62	2.91	3.03	2.92	2.9	3.1	3.1	3.09	3.02	3.04	3.05	2.98	3.01	2.92	3.11	3.08	3.11	3.04	2.98	3.06	3.04	3.09	3.04	3.07	3.1	3.11	3.19	3.19	3.18	3.32	3.23
Nursing	I was attended by a Nurse within 10 minutes of pressing the nurse call button	2.86	2.7	2.97	2.94	3.05	2.97	3.04	3.02	3.03	3.12	3.14	3.07	3.08	3.09	3.12	3.04	3.06	3	3.12	3.15	3.15	3.15	3.04	3.13	3.08	3.12	3.1	3.1	3.16	3.17	3.21	3.25	3.25	3.26	3.21
Nursing	Nurses were attentive, polite, respectful and friendly with me during my stay	3.13	2.77	3.17	3.23	3.21	3.24	3.24	3.17	3.11	3.32	3.29	3.2	3.18	3.2	3.25	3.17	3.2	3.12	3.29	3.26	3.29	3.26	3.14	3.25	3.19	3.23	3.21	3.21	3.24	3.24	3.3	3.33	3.31	3.23	3.15
Nursing	I was always provided prompt bed side assistence	2.86	2.77	3.02	3.02	3.2	3.01	3.14	3.03	3.02	3.18	3.21	3.1	3.1	3.14	3.13	3.02	3.09	3.03	3.17	3.1	3.2	3.14	3.02	3.14	3.09	3.13	3.14	3.12	3.14	3.19	3.25	3.27	3.29	3.33	3.23
Housekeeping	My linen was changed and arranged neatly everyday	3.04	2.84	3.17	3.14	3.23	3.18	3.21	3.07	3.09	3.26	3.23	3.15	3.12	3.2	3.19	3.11	3.13	3.06	3.21	3.19	3.21	3.21	3.08	3.2	3.15	3.19	3.16	3.15	3.16	3.22	3.24	3.27	3.31	3.35	3.26
Housekeeping	Linen provided to me during my stay was clean and spotless	3.05	2.86	3.12	3.12	3.11	3.12	3.13	3.02	3.05	3.21	3.15	3.12	3.12	3.15	3.15	3.11	3.14	3.04	3.17	3.08	3.17	3.14	3.05	3.16	3.11	3.14	3.12	3.14	3.15	3.18	3.21	3.22	3.25	3.29	3.24
Housekeeping	Housekeeping staff was attentive,polite and respectful with me	3.03	3.09	3.06	3.11	3.09	3.02	3.07	3.11	3.09	3.26	3.25	3.16	3.17	3.22	3.2	3.1	3.15	3.08	3.24	3.17	3.26	3.21	3.07	3.2	3.15	3.22	3.16	3.14	3.21	3.25	3.33	3.32	3.32	3.23	3.18
Housekeeping	The room was ready and clean before I entered	3.08	3.11	3.06	3.09	3	3.12	3.06	3.03	3	3.21	3.2	3.17	3.09	3.16	3.16	3.08	3.15	3.05	3.19	3.1	3.19	3.15	3.02	3.17	3.09	3.17	3.11	3.12	3.18	3.2	3.24	3.25	3.27	3.21	3.15
Housekeeping	Ward staff respected my privacy and was prompt and courteous in their behaviour	3.06	2.79	3.15	3.17	3.16	3.21	3.19	3.11	3.13	3.28	3.24	3.16	3.15	3.2	3.2	3.09	3.16	3.04	3.23	3.12	3.22	3.19	3.09	3.16	3.14	3.18	3.14	3.16	3.16	3.23	3.23	3.32	3.32	3.31	3.23
Housekeeping	I was tranported safely by the staff for all investigations/procedures	3.06	2.74	3.24	3.13	3.18	3.21	3.23	3.13	3.16	3.24	3.23	3.19	3.15	3.18	3.2	3.11	3.14	3.08	3.23	3.16	3.23	3.21	3.09	3.16	3.12	3.2	3.15	3.15	3.2	3.24	3.23	3.32	3.33	3.23	3.15
Maintenance	During my stay all light fixtures, AC and TV were in good working condition	2.76	2.79	3.02	2.96	3	3.09	3.12	2.91	2.99	3.14	3.13	3.07	3	3.05	3.09	3.04	3.05	2.93	3.08	3.01	2.99	3.01	2.92	3.01	2.97	3.01	3	3	3.07	3.08	3.19	3.18	3.19	3.14	3.12
Maintenance	All bathroom fittings were working well	2.91	2.73	3.11	3.1	3.11	3.09	3.15	3.04	3.07	3.16	3.14	3.09	3.06	3.13	3.07	3.06	3.07	3.01	3.15	2.97	3.06	3.06	2.98	3.07	3.04	3.07	3.06	3.05	3.12	3.16	3.25	3.24	3.25	3.29	3.22
Diagnositcs	I got all my investigation reports on time	2.11	2.09	2.02	2.11	2.16	2.75	2.65	2.71	2.97	3.16	3.15	3.06	3.03	3	2.99	2.97	2.98	2.9	3.06	2.95	3.03	2.99	2.92	3.05	2.96	3	3.03	3.03	3.08	3.11	3.17	3.18	3.17	3.24	3.16
Physiotherapy	I was attended promptly and regularly by physiotherapist	3.11	3.09	2.97	2.75	2.97	3.07	3.11	2.97	3.12	3.25	3.18	3	2.98	3.05	2.98	2.99	2.93	2.9	3.03	2.91	2.88	2.95	2.78	2.91	2.83	3.86	2.97	2.92	2.93	2.94	3.1	3.14	3.1	3.12	2.99
Intensive Care	I was satisfied with the clinical services received at ICU	2.75	2.86	2.57	3.05	3.11	2.97	3.05	3.14	3.1	3.26	3.22	3.04	3.06	3.12	2.99	2.95	2.96	2.92	3.07	2.89	2.9	2.97	2.73	2.93	2.76	2.88	2.92	2.88	2.84	2.88	3.06	3.13	3.06	3.12	2.97
Intensive Care	I was satisfied with the support services received at ICU	2.91	2.75	2.67	2.83	2.97	2.86	2.84	3.06	3.1	3.25	3.23	3.01	3.04	3.08	2.96	2.95	2.97	2.9	3.06	2.87	2.89	2.93	2.72	2.9	2.75	2.86	2.92	2.88	2.81	2.86	3.07	3.12	3.07	3.12	2.98
Overall	Overall, I was satisfied with the treatment received from the doctors	3	2.76	3.26	3.23	3.25	3.19	3.25	3.14	3.09	3.24	3.24	3.15	3.1	3.17	3.17	3.1	3.13	3.05	3.23	3.11	3.2	3.17	3.04	3.14	3.1	3.14	3.16	3.13	3.19	3.19	3.25	3.27	3.25	3.28	3.22
Overall	I would recommend Jehangir Hospital to others for their care	3.07	2.77	3.3	3.31	3.34	3.12	3.25	3.16	3.1	3.23	3.28	3.17	3.13	3.18	3.19	3.14	3.13	3.06	3.25	3.14	3.23	3.16	3.08	3.17	3.09	3.14	3.18	3.16	3.19	3.2	3.28	3.27	3.28	3.28	3.23

Appendix 2: Survey for NABH Assessors on TQM Constructs

1. What is the overall number of NABH Assessments you have done?

○ < 5 ◉ 5 - 10 ○ > 10

2. What is your role as an NABH Assessor?

○ Clinician

○ Nurse

○ Administrator

3. Do you think Hospitals, and eventually patients, benefit from the experiential learning (applied knowledge) during the process of implementation of NABH standards and accreditation?

○ Hospital's don't learn, nobody benefits

○ Hospitals learn but this does not translate into benefits

○ Hospitals learn and this translates into benefits for Hospitals and Patients

4. Do you think the NABH implementation program enables translational research (the clinical application of scientific medical research, from the lab to the bedside) for improving clinical outcomes and patient safety?

○ Whatever little research that is done leads to negligible improvements

○ Research is done well but does not actually lead to visible improvements

○ The research and consequent actions lead to overall improvements

5. From your experience Rank the following chapters in order of the likelihood and effectiveness of implementation;

1) Access, Assessment and Continuity of Care (AAC)
2) Care of Patients (COP)
3) Management of Medication (MOM)
4) Patient Rights and Education (PRE)
5) Hospital Infection Control (HIC)
6) Continuous Quality Improvement (CQI)
7) Responsibility of Management (ROM)
8) Facility Management and Safety (FMS)
9) Human Resource Management (HRM)
10) Information Management System (IMS)

6. Overall, when compared to non-accredited Hospitals how would you rate the following six dimensions of quality in NABH accredited Hospitals;

NABH accredited Hospitals are -

	Much worse	Worse	About the same	Better	Much Better
Safety					
Effectiveness					
Patient-centeredness					
Timeliness					
Efficiency					
Equity					

7. When compared to non-accredited Hospitals how would you rate the following Total Quality Management (TQM) constructs for Leadership in NABH accredited Hospitals;

NABH accredited Hospitals are -

	Much worse	Worse	About the same	Better	Much Better
Top management commitment					
Vision and strategy					
Organizational quality culture					
Objectives for quality performance					

8. When compared to non-accredited Hospitals how would you rate the following Total Quality Management (TQM) constructs for Customer / Supplier Relations in NABH accredited Hospitals;

NABH accredited Hospitals are -

	Much worse	Worse	About the same	Better	Much Better
Customer relationship management					
Supplier partnership					
Customer / supplier involvement					

9. When compared to non-accredited Hospitals how would you rate the following Total Quality Management (TQM) constructs for Employee relations in NABH accredited Hospitals;

NABH accredited Hospitals are -

	Much worse	Worse	About the same	Better	Much Better
Employee empowerment/involvement					
Human resource issues					
Open and transparent communication					
Existence of organization-wide training					

10. When compared to non-accredited Hospitals how would you rate the following Total Quality Management (TQM) constructs for Process management in NABH accredited Hospitals;

NABH accredited Hospitals are -

	Much worse	Worse	About the same	Better	Much Better
Availability and use of quality data	○	○	○	○	○
Employee evaluation based on quality	○	○	○	○	○
Use of quality improvement measurement system	○	○	○	○	○

11. How well do you think are Clinical Pathways and Evidence-Based Medicine practiced in NABH accredited Hospitals?

○ How well do you think are Clinical Pathways and Evidence-Based Medicine practiced in NABH accredited Hospitals? There is no awareness

○ Guidelines are available but nobody follows them

○ Efforts are made to follow guidelines but not institutionalized

○ Guidelines are institutionalized but outcomes not evident

○ Guidelines are institutionalized and outcomes are evident

12. Overall, when compared to non-accredited Hospitals how would you rate the following clinical and quality indicators in NABH accredited Hospitals;

NABH accredited Hospitals are -

	Much worse	Worse	About the same	Better	Much Better
Complication rates post-interventions	○	○	○	○	○
Average Length of Stay associated with mortality and morbidity	○	○	○	○	○
Turn-around Times	○	○	○	○	○
Hospital Acquired Infection	○	○	○	○	○
Patient Safety indices	○	○	○	○	○
Time-efficiency indicators	○	○	○	○	○

13. What is your opinion about the overall improvement made due to the prevalence of the NABH Standards?

- What is your opinion about the overall improvement made due to the prevalence of the NABH Standards? Very poor
- Inadequate
- Reasonably good
- Good
- Excellent

Appendix 3: NABH Assessors' Survey Response Summary

1. What is the overall number of NABH Assessments you have done?

Answer Options	Response Percent	Response Count
< 5	65.1%	28
5 - 10	2.3%	1
> 10	32.6%	14
answered question		43
skipped question		0

2. What is your role as an NABH Assessor?

Answer Options	Response Percent	Response Count
Clinician	33.3%	14
Nurse	11.9%	5
Administrator	54.8%	23
answered question		42
skipped question		1

3. Do you think Hospitals, and eventually patients, benefit from the experiential learning (applied knowledge) during the process of implementation of NABH standards and accreditation?

Answer Options	Response Percent	Response Count
Hospital's don't learn, nobody benefits	2.4%	1
Hospitals learn but this does not translate into benefits	14.3%	6
Hospitals learn and this translates into benefits for Hospitals and Patients	83.3%	35
answered question		42
skipped question		1

4. Do you think the NABH implementation program enables translational research (the clinical application of scientific medical research, from the lab to the bedside) for improving clinical outcomes and patient safety?

Answer Options	Response Percent	Response Count
Whatever little research that is done leads to negligible improvements	33.3%	14
Research is done well but does not actually lead to visible improvements	28.6%	12
The research and consequent actions lead to overall improvements	38.1%	16
answered question		42
skipped question		1

5. From your experience Rank the following chapters in order of the likelihood and effectiveness of implementation;

Answer Options	1	2	3	4	5	6	7	8	9	10	Rating Average	Response Count
1) Access, Assessment & Continuity of Care (AAC)	13	6	3	5	5	7	1	1	0	1	3.48	42
2) Care of Patients (COP)	8	8	5	7	5	1	3	1	3	1	3.90	42
3) Management of Medication (MOM)	2	7	10	7	5	5	5	0	1	0	4.12	42
4) Patient Rights and Education (PRE)	0	4	5	5	3	6	0	10	6	3	6.14	42
5) Hospital Infection Control (HIC)	11	5	5	7	4	6	1	0	2	1	3.69	42
6) Continuous Quality Improvement (CQI)	2	2	5	1	4	4	7	6	3	8	6.50	42
7) Responsibility of Management (ROM)	1	2	4	4	5	2	10	5	6	3	6.29	42
8) Facility Management and Safety (FMS)	1	3	4	2	5	3	4	11	8	1	6.38	42
9) Human Resource Management (HRM)	3	3	1	0	4	6	4	6	11	4	6.74	42
10) Information Management System (IMS)	1	2	0	4	2	2	7	2	2	20	7.76	42
answered question												42
skipped question												1

6. Overall, when compared to non-accredited Hospitals how would you rate the following six dimensions of quality in NABH accredited Hospitals; NABH accredited Hospitals are -

Answer Options	Much worse	Worse	About the same	Better	Much Better	Response Count
Safety	1	1	1	25	14	42
Effectiveness	0	0	8	26	7	41
Patient-centeredness	1	0	10	20	11	42
Timeliness	1	0	9	26	6	42
Efficiency	1	1	7	24	8	41
Equity	1	1	15	18	5	40
answered question						42
skipped question						1

7. When compared to non-accredited Hospitals how would you rate the following Total Quality Management (TQM) constructs for Leadership in NABH accredited Hospitals; NABH accredited Hospitals are -

Answer Options	Much worse	Worse	About the same	Better	Much Better	Response Count
Top management commitment	0	1	4	24	12	41
Vision and strategy	1	0	8	23	9	41
Organizational quality culture	1	0	0	28	12	41
Objectives for quality performance	1	0	2	24	14	41
answered question						41
skipped question						2

8. When compared to non-accredited Hospitals how would you rate the following Total Quality Management (TQM) constructs for Customer / Supplier Relations in NABH accredited Hospitals; NABH accredited Hospitals are -

Answer Options	Much worse	Worse	About the same	Better	Much Better	Response Count
Customer relationship management	1	1	2	28	9	41
Supplier partnership	0	0	17	20	5	42
Customer / supplier involvement	1	0	13	24	4	42
answered question						42
skipped question						1

9. When compared to non-accredited Hospitals how would you rate the following Total Quality Management (TQM) constructs for Employee relations in NABH accredited Hospitals; NABH accredited Hospitals are -

Answer Options	Much worse	Worse	About the same	Better	Much Better	Response Count
Employee empowerment/involvement	1	0	12	22	6	41
Human resource issues	1	0	18	15	7	41
Open and transparent communication	1	0	13	23	4	41
Existence of organization-wide training	0	0	3	19	19	41
answered question						41
skipped question						2

10. When compared to non-accredited Hospitals how would you rate the following Total Quality Management (TQM) constructs for Process management in NABH accredited Hospitals; NABH accredited Hospitals are -

Answer Options	Much worse	Worse	About the same	Better	Much Better	Response Count
Availability and use of quality data	1	0	4	27	9	41
Employee evaluation based on quality	1	0	16	21	3	41
Use of quality improvement measurement system	1	0	6	25	8	40
answered question						41
skipped question						2

11. How well do you think are Clinical Pathways and Evidence-Based Medicine practiced in NABH accredited Hospitals?

Answer Options	Response Percent	Response Count
There is no awareness	7.1%	3
Guidelines are available but nobody follows them	9.5%	4
Efforts are made to follow guidelines but not institutionalized	52.4%	22
Guidelines are institutionalized but outcomes not evident	21.4%	9
Guidelines are institutionalized and outcomes are evident	9.5%	4
answered question		42
skipped question		1

12. Overall, when compared to non-accredited Hospitals how would you rate the following clinical and quality indicators in NABH accredited Hospitals; NABH accredited Hospitals are -

Answer Options	Much worse	Worse	About the same	Better	Much Better	Response Count
Complication rates post-interventions	1	0	11	23	6	41
Average Length of Stay associated with mortality and morbidity	0	1	20	17	4	42
Turn-around Times	1	0	7	23	11	42
Hospital Acquired Infection	1	0	2	27	12	42
Patient Safety indices	1	0	2	24	14	41
Time-efficiency indicators	0	1	11	23	7	42
answered question						42
skipped question						1

13. What is your opinion about the overall improvement made due to the prevalence of the NABH Standards?

Answer Options	Response Percent	Response Count
Very poor	2.4%	1
Inadequate	4.8%	2
Reasonably good	38.1%	16
Good	33.3%	14
Excellent	21.4%	9
answered question		42
skipped question		1

Appendix 4: “Patient First” campaign theme

Appendix 5: Assessment Scores during four stages of NABH implementation

Elements			Pre-Implementation SA scores Jan-2010	Mid-Implementation SA scores Sep-2011	Post-Implementation SA scores Apr-2013	Final Assessment Scores Jun-2013
Chapter 1: ACCESS, ASSESSMENT AND CONTINUITY OF CARE (AAC)						
AAC.1: The organisation defines and displays the services that it provides.			**6.67**	**8.33**	**10**	**10**
	a	The services being provided are clearly defined and are in consonance with the needs of the community.	10	10	10	10
	b	The defined services are prominently display.	5	10	10	10
	c	The staff is oriented to these services.	5	5	10	10
AAC.2: The organisation has a well defined registration and admission process.			**0.83**	**8.33**	**10**	**10**
	a.	Documented policies and procedures are used for registering and admitting patients.	5	10	10	10
	b.	The documented procedures address out-patients, in-patients and emergency patients.	5	10	10	10
	c.	A unique identification number is generated at the end of registration.	5	10	10	10
	d.	Patients are accepted only if the organization can provide the required service.	5	10	10	10
	e.	The documented policies and procedures also address managing patients during non availability of beds.	0	5	10	10
	f.	The staff is aware of these processes.	0	5	10	10
AAC.3 There is an appropriate mechanism for transfer or referral of patients			**3**	**8**	**10**	**10**
	a.	Documented policies and procedures guide the transfer-in of patients to the organization	5	10	10	10
	b.	Documented policies and procedures guide the transfer-out/referral of unstable patients to another facility in an appropriate manner.	5	10	10	10
	c.	Documented policies and procedures guide the transfer-out/referral of stable patients to another facility in an appropriate manner.	5	10	10	10
	d.	The documented procedures identify staff responsible during transfer/referral.	0	5	10	10
	e.	The organization gives a summary of patient's condition and the treatment given.	0	5	10	10
AAC.4 Patients cared for by the organisation undergo an established initial assessment.			**1**	**7.5**	**10**	**7**

	a.	The organisation defines and documents the content of the initial assessment for the out-patients, in-patients and emergency patients.	5	10	10	10
	b.	The organisation determines who can perform the initial assessment.	0	10	10	10
	c.	The organisation defines the time frame within which the initial assessment is completed based on patient's needs.	5	10	10	10
	d.	The initial assessment for in-patients is documented within 24 hours or earlier as per the patient's condition as defined in the organization's policy.	5	10	10	10
	e.	Initial assessment of in-patients includes nursing assessment which is done at the time of admission and documented.	0	10	10	10
	f.	Initial assessment includes screening for nutritional needs.	0	10	10	10
	g.	The initial assessment results in a documented plan of care.	0	5	10	0
	h.	The plan of care also includes preventive aspects of the care where appropriate.	0	5	10	0
	i.	The plan of care is countersigned by the clinician in-charge of the patient within 24 hours.	0	5	10	0
	j.	The plan of care includes goals or desired results of the treatment, care or service.	0	0	10	10
AAC.5 Patients cared for by the organisation undergo a regular reassessment.			**3**	**7**	**10**	**10**
	a.	Patients are reassessed at appropriate intervals.	5	10	10	10
	b.	Out-patients are informed of their next follow-up, where appropriate.	0	5	10	10
	c.	For in-patients during reassessment the plan of care is monitored and modified, where found necessary.	5	5	10	10
	d.	Staff involved in direct clinical care document reassessments.	5	10	10	10
	e.	Patients are reassessed to determine their response to treatment and to plan further treatment or discharge.	0	5	10	10
AAC.6 Laboratory services are provided as per the scope of services of the organization.			**2.5**	**6.25**	**10**	**10**
	a.	Scope of the laboratory services are commensurate to the services provided by the organisation.	5	5	10	10
	b.	The infrastructure (physical and manpower) is adequate to provide for its defined scope of services.	0	5	10	10
	c.	Adequately qualified and trained personnel perform, supervise and interpret the investigations.	5	10	10	10
	d.	Documented procedures guide ordering of tests, collection, identification, handling, safe transportation, processing and disposal of specimens.	5	10	10	10
	e.	Laboratory results are available within a defined time frame.	5	5	10	10

	f.	Critical results are intimated immediately to the personnel concerned.	0	5	10	10
	g.	Results are reported in a standardized manner.	0	5	10	10
	h.	Laboratory tests not available in the organization are outsourced to organization(s) based on their quality assurance system.	0	5	10	10
AAC.7 There is an established laboratory quality assurance programme.			**2**	**5**	**10**	**10**
	a.	The laboratory quality assurance programme is documented.	5	5	10	10
	b.	The programme addresses verification and/or validation of test methods.	0	5	10	10
	c.	The programme addresses surveillance of test results.	5	5	10	10
	d.	The programme includes periodic calibration and maintenance of all equipment.	0	5	10	10
	e.	The programme includes the documentation of corrective and preventive actions.	0	5	10	10
AAC.8 There is an established laboratory-safety programme.			**1**	**6**	**10**	**10**
	a.	The laboratory safety programme is documented.	0	10	10	10
	b.	This programme is aligned with the organisation's safety programme.	0	5	10	10
	c.	Written procedures guide the handling and disposal of infectious and hazardous materials.	5	5	10	10
	d.	Laboratory personnel are appropriately trained in safe practices.	0	5	10	10
	e.	Laboratory personnel are provided with appropriate safety equipment/ devices.	0	5	10	10
AAC.9 Imaging services are provided as per the scope of services of the organization.			**2.78**	**6.67**	**10**	**10**
	a.	Imaging services comply with the legal and other requirements.	5	10	10	10
	b.	Scope of the imaging services is commensurate to the services provided by the organisation.	5	5	10	10
	c.	The infrastructure (physical and manpower) is adequate to provide for its defined scope of services.	0	5	10	10
	d.	Adequately qualified and trained personnel perform, supervise and interpret the investigations.	5	10	10	10
	e.	Documented policies and procedures guide identification and safe transportation of patients to imaging services.	5	10	10	10
	f.	Imaging results are available within a defined time frame.	5	5	10	10

	g.	Critical results are intimated immediately to the personnel concerned.	0	5	10	10
	h.	Results are reported in a standardized manner.	0	5	10	10
	i.	Imaging tests not available in the organization are outsourced to organization(s) based on their quality assurance system	0	5	10	10
AAC.10 There is an established quality assurance programme for imaging services.			**0**	**5**	**10**	**10**
	a.	The quality assurance program for imaging services is documented.	0	5	10	10
	b.	The programme addresses verification and/or validation of imaging methods.	0	5	10	10
	c.	The programme addresses surveillance of imaging results.	0	5	10	10
	d.	The programme includes periodic calibration and maintenance of all equipment.	0	5	10	10
	e.	The programme includes the documentation of corrective and preventive actions.	0	5	10	10
AAC.11 There is an established radiation safety programme.			**0.71**	**6.43**	**10**	**10**
	a.	The radiation-safety programme is documented.	0	5	10	10
	b.	This programme is aligned with the organization's safety programme.	0	5	10	10
	c.	Handling, usage and disposal of radio-active and hazardous materials are as per statutory requirements.	0	5	10	10
	d.	Imaging personnel are provided with appropriate radiation safety devices.	5	10	10	10
	e.	Radiation safety devices are periodically tested and results documented.	0	5	10	10
	f.	Imaging personnel are trained in radiation safety measures.	0	5	10	10
	g.	Imaging signage are prominently displayed in all appropriate locations.	0	10	10	10
AAC.12 Patient care is continuous and multidisciplinary in nature.			**0.71**	**5.71**	**10**	**10**
	a.	During all phases of care, there is a qualified individual identified as responsible for the patient's care.	5	10	10	10
	b.	Care of patients is coordinated in all care setting within the organisation.	0	5	10	10
	c.	Information about the patient's care and response to treatment is shared among medical, nursing and other care providers.	0	5	10	10
	d.	Information is exchanged and documented during each staffing shift, between shifts, and during transfers between units/ departments.	0	0	10	10

	e.	Transfers between departments/units are done in a safe manner.	0	10	10	10
	f.	The patient's record(s) is available to the authorized care providers to facilitate the exchange of information.	0	5	10	10
	g.	Documented procedures guide the referral of patients to other departments/ specialities.	0	5	10	10
AAC.13 The organisation has a documented discharge process.			**3.75**	**5**	**10**	**10**
	a.	The patient's discharge process is planned in consultation with the patient and/ or family.	5	5	10	10
	b.	Documented procedures exist for coordination of various departments and agencies involved in the discharge process (including medico-legal and abandoned cases)	0	5	10	10
	c.	Documented policies and procedures are in place for patients leaving against medical advice and patients being discharged on request.	5	5	10	10
	d.	A discharge summary is given to all the patients leaving the organization (including patients leaving against medical advice and on request).	5	5	10	10
AAC.14 Organisation define the content of the discharge summary.			**7.85**	**10**	**10**	**10**
	a.	Discharge summary is provided to the patients at the time of discharge.	10	10	10	10
	b.	Discharge summary contains the patient's name, unique identification number, date of admission and date of discharge.	10	10	10	10
	c.	Discharge summary contains the reasons for admission, significant findings and diagnosis and the patient's condition at the time of discharge.	10	10	10	10
	d.	Discharge summary contains information regarding investigation results, any procedure performed, medication administered and other treatment given.	10	10	10	10
	e.	Discharge summary contains follow up advice, medication and other instructions in an understandable manner.	5	10	10	10
	f.	Discharge summary incorporates instructions about when and how to obtain urgent care.	0	10	10	10
	g.	In case of death, the summary of the case also includes the cause of death.	10	10	10	10
Chapter 2: CARE OF PATIENTS (COP)						
COP.1: Uniform care of patients is provided in all settings of the organization and is guided by the applicable laws, regulations and guidelines.			**2.5**	**7.5**	**8.75**	**10**
	a	Care delivery is uniform for a given health problem when similar care is provided in more than one setting.	5	10	10	10
	b	Uniform care is guided by documented policies and procedures.	0	5	10	10
	c	These reflect applicable laws, regulations and guidelines.	5	10	10	10
	d	The organization adopts evidence-based medicine and clinical practice guidelines to guide uniform patient care.	0	5	5	10

COP.2: Emergency services are guided by documented policies, procedures and applicable laws and regulations.			**2.14**	**6.43**	**10**	**10**
	a	Policies and procedure for emergency care are documented and are in consonance with statutory requirements.	5	5	10	10
	b	This also addresses handling of medico-legal cases.	5	10	10	10
	c	The patients receive care in consonance with the policies.	5	5	10	10
	d	Documented policies and procedures guide the triage of patients for initiation of appropriate care.	0	5	10	10
	e	Staff are familiar with the policies and trained on the procedures for care of emergency patients.	0	10	10	10
	f	Admission or discharge to home or transfer to another organisation is also documented.	0	5	10	10
	g	In case of discharge to home or transfer to another organization a discharge note shall be given to patient.	0	5	10	10
COP.3: The ambulance services are commensurate with the scope of the services provided by the organisation.			**2.5**	**6.25**	**10**	**10**
	a	There is adequate access and space for the ambulance(s).	10	10	10	10
	b	The ambulance adheres to statutory requirements.	0	10	10	10
	c	Ambulance(s) is appropriately equipped.	5	5	10	10
	d	Ambulance(s) is manned by the trained personnel.	5	5	10	10
	e	Ambulance(s) is checked on a daily basis.	0	5	10	10
	f	Equipment are checked on a daily basis using a checklist.	0	5	10	10
	g	Emergency medications are checked daily and prior to dispatch using a checklist.	0	5	10	10
	h	The ambulance(s) has a proper communication system.	0	5	10	10
COP.4: Documented policies and procedures guide the care of patients requiring cardio-pulmonary resuscitation.			**2**	**6**	**9**	**6**
	a	Documented policies and procedures guide the uniform use of resuscitation throughout the organisation.	0	10	10	10
	b	Staff providing direct patient care are trained and periodically updated in cardio pulmonary resuscitation.	5	5	10	10
	c	The events during a cardio pulmonary resuscitation are recorded.	5	10	10	10
	d	A post-event analysis of all cardio-pulmonary resuscitations is done by a multidisciplinary committee.	0	0	10	0

	e	Corrective and preventive measures are taken based on the post-event analysis.	0	5	5	0
COP.5: Documented policies and procedures guide nursing care.			**3.57**	**5.71**	**10**	**7.14**
	a	There are documented policies and procedures for all activities of the nursing services.	0	5	10	0
	b	These reflect current standards of nursing services and practice, relevant regulations and purposes of the services.	0	5	10	0
	c	Assignment of patient care is done as per current good practice guidelines.	5	5	10	10
	d	Nursing care is aligned and integrated with overall patient care.	5	5	10	10
	e	Care provided by nurses is documented in the patient record.	10	10	10	10
	f	Nurses are provided with adequate equipment for providing safe and efficient nursing services.	5	5	10	10
	g	Nurses are empowered to take nursing-related decisions to ensure timely care of patients.	0	5	10	10
COP.6: Documented procedures guide the performance of various procedures.			**2.86**	**6.43**	**10**	**10**
	a	Documented procedures are used to guide the performance of various clinical procedures.	0	5	10	10
	b	Only qualified personnel order, plan, perform and assist in performing procedures.	10	10	10	10
	c	Documented procedures exist to prevent adverse events like wrong site, wrong patient and wrong procedure.	0	5	10	10
	d	Informed consent is taken by the personnel performing the procedure, where applicable.	5	5	10	10
	e	Adherence to standard precautions and asepsis is adhered to during the conduct of the procedure.	5	10	10	10
	f	Patients are appropriately monitored during and after the procedure.	0	5	10	10
	g	Procedures are documented accurately in the patient record.	0	5	10	10
COP.7: Documented policies and procedures define rational use of blood and blood products.			**1.88**	**5.63**	**10**	**10**
	a	Documented policies and procedures are used to guide rational use of blood and blood products.	0	5	10	10
	b	Documented procedures guide transfusion of blood and blood products.	0	5	10	10
	c	The transfusion services are governed by the applicable laws and regulations.	10	5	10	10
	d	Informed consent is obtained for donation and transfusion of blood and blood products.	0	5	10	10

	e	Informed consent also includes patient and family education about donation.	0	5	10	10
	f	The organization defines the process for availability and transfusion of blood/blood components for use in emergency.	5	10	10	10
	g	Post-transfusion form is collected, reactions if any identified and are analyzed for preventive and corrective actions.	0	5	10	10
	h	Staff are trained to implement the policies.	0	5	10	10
COP.8: Documented policies and procedures guide the care of patients in the Intensive Care and high dependency units.			**2.85**	**5.71**	**10**	**10**
	a	Documented policies and procedures are used to guide the care of patients in the intensive care and high dependency units.	0	5	10	10
	b	The organisation has documented admission and discharge criteria for its intensive care and high dependency units.	0	5	10	10
	c	Staff are trained to apply these criteria.	0	5	10	10
	d	Adequate staff and equipment are available.	10	10	10	10
	e	Defined procedures for situation of bed shortages are followed.	5	5	10	10
	f	Infection control practices are documented and followed.	5	5	10	10
	g	A quality assurance programme is documented and implemented.	0	5	10	10
COP.9: Documented policies and procedures guide the care of vulnerable patients (elderly, children, physically and/ or mentally challenged).			**0**	**5**	**10**	**10**
	a	Policies and procedures are documented and are in accordance with the prevailing laws and the national and international guidelines.	0	5	10	10
	b	Care is organised and delivered in accordance with the policies and procedures.	0	5	10	10
	c	The organisation provides for a safe and secure environment for this vulnerable group.	0	10	10	10
	d	A documented procedure exists for obtaining informed consent from the appropriate legal representative.	0	10	10	10
	e	Staff are trained to care for this vulnerable group.	0	0	10	10
COP.10: Documented policies and procedures guide obstetric care.			**5**	**6.43**	**10**	**10**
	a	There is a documented policy and procedure for obstetric services.	0	5	10	10
	b	The organisation defines and displays whether high-risk obstetric cases be cared for or not.	0	5	10	0
	c	Persons caring for high-risk obstetric cases are competent.	10	10	10	10

	d	Documented procedures guide provision for ante-natal services.	0	5	10	10
	e	Obstetric patient's assessment also includes maternal nutrition.	10	10	10	10
	f	Appropriate pre-natal, peri-natal and post-natal monitoring is performed and documented.	5	5	10	10
	g	The organization caring for high-risk obstetric cases has the facilities to take care of neonates of such cases.	10	5	10	10
COP.11: Documented policies and procedures guide paediatric services.			**1.25**	**6.88**	**9.38**	**8.75**
	a	There is a documented policy and procedure for paediatric services.	0	5	10	10
	b	The organisation defines and displays the scope of its paediatric services.	0	10	10	10
	c	The policy for care of neonatal patients is in consonance with the national/ international guidelines.	0	5	10	10
	d	Those who care for children have age specific competency.	5	10	10	10
	e	Provisions are made for special care of children.	5	10	10	10
	f	Patient assessment includes detailed nutritional, growth, psychosocial and immunization assessment.	0	5	10	0
	g	Documented policies and procedures prevent child/ neonate abduction and abuse.	0	5	10	10
	h	The children's family members are educated about nutrition, immunization and safe parenting and this is documented in the medical record.	0	5	5	10
COP.12: Documented policies and procedures guide the care of patients undergoing moderate sedation.			**3.75**	**6.25**	**10**	10
	a	Documented procedures guide the administration of moderate sedation.	0	5	10	10
	b	Informed consent for administration of moderate sedation is obtained.	0	5	10	10
	c	Competent and trained persons perform sedation.	10	5	10	10
	d	The person administering and monitoring sedation is different from the person performing the procedure.	0	5	10	10
	e	Intra – procedure monitoring includes at a minimum the heart rate, cardiac rhythm, respiratory rate, blood pressure, oxygen saturation and level of sedation.	5	10	10	10
	f	Patients are monitored after sedation and the same is documented.	5	5	10	10
	g	Criteria are used to determine appropriateness of discharge from the recovery area.	0	5	10	10
	h	Equipment and manpower are available to manage patients who have gone into a deeper level of sedation than that intended.	10	10	10	10

COP.13: Documented policies and procedures guide the administration of anesthesia.			**2.72**	**5.9**	**10**	**10**
	a	There is a documented policy and procedure for the administration of anesthesia.	0	5	10	10
	b	Patients for anesthesia have a pre-anesthesia assessment by a qualified anaesthesiologist.	5	5	10	10
	c	The pre-anesthesia assessment results in formulation of an anesthesia plan which is documented.	5	5	10	10
	d	An immediate preoperative re-evaluation is performed and documented.	0	5	10	10
	e	Informed consent for administration of anesthesia is obtained by the anesthesiologist.	10	10	10	10
	f	During anesthesia monitoring includes regular recording of temperature, heart rate, cardiac rhythm, respiratory rate, blood pressure, oxygen saturation and end tidal carbon dioxide.	5	10	10	10
	g	Patient's post-anesthesia status is monitored and documented.	0	5	10	10
	h	The anaesthesiologist applies defined criteria to transfer the patient from the recovery area.	0	5	10	10
	i	The type of anaesthesia and anaesthetic medications used is documented in the patient record.	0	5	10	10
	j	Procedures shall comply with infection control guidelines to prevent cross-infection between patients.	5	5	10	10
	k	Adverse anesthesia events are recorded and monitored.	0	5	10	10
COP.14: Documented policies and procedures guide the care of patients undergoing surgical procedures.			**1.36**	**5.45**	**10**	**7.27**
	a	The policies and procedures are documented.	5	5	10	10
	b	Surgical patients have a preoperative assessment and a provisional diagnosis documented prior to surgery.	5	10	10	10
	c	An informed consent is obtained by a surgeon prior to the procedure.	0	5	10	10
	d	Documented policies and procedure exist to prevent adverse events like wrong site, wrong patients and wrong surgery.	0	5	10	0
	e	Persons qualified by law are permitted to perform the procedures that they are entitled to perform.	0	5	10	10
	f	A brief operative note is documented prior to transfer out of patient from recovery area.	0	5	10	10
	g	The operating surgeons documents the post operative plan of care.	0	5	10	10
	h	Patient, personnel and material flow conforms to infection control practices.	0	5	10	0
	i	Appropriate facilities and equipment/appliances/instrumentation are available in the operating theatre.	0	5	10	10

	j	A quality assurance programme is followed for the surgical services.	0	5	10	10
	k	The quality assurance program includes surveillance of the operation theatre environment.	5	5	10	0
COP.15: Documented policies and procedures guide the care of patients under restraints (physical and/ or chemical).			**0**	**6**	**10**	**10**
	a	Documented policies and procedures guide the care of patients under restraints.	0	5	10	10
	b	These include both physical and chemical restraint measures.	0	5	10	10
	c	These include documentation of reasons for restraints.	0	5	10	10
	d	These patients are more frequently monitored.	0	10	10	10
	e	Staff receive training and periodic updating in control and restraint techniques.	0	5	10	10
COP.16: Documented policies and procedures guide appropriate pain management.			**1**	**5**	**10**	**10**
	a	Documented policies and procedures guide the management of pain.	0	5	10	10
	b	All patients are screened for pain.	5	0	10	10
	c	Patients with pain undergo detailed assessment and periodic re-assessment	0	5	10	10
	d	The organization respects and supports management of pain for such patients.	0	10	10	10
	e	Patient and family are educated on various pain management techniques, where appropriate.	0	5	10	10
COP.17: Documented policies and procedures guide appropriate rehabilitative services.			**3.33**	**5.83**	**10**	**6.67**
	a	Documented policies and procedures guide the provision of rehabilitative services.	0	5	10	10
	b	These services are commensurate with the organizational requirements.	10	10	10	10
	c	Care is guided by functional assessment and periodic re-assessment which is done and documented by qualified individual(s).	5	5	10	0
	d	Care is provided adhering to infection control and safe practices.	5	5	10	10
	e	Rehabilitative services are provided by a multidisciplinary team.	0	5	10	10
	f	There is adequate space and equipment to perform these activities.	0	5	10	0
COP.18: Documented policies and procedures guide all research activities.			**10**	**10**	**10**	**10**

	a	Documented policies and procedures guide all research activities in compliance with national and international guidelines.	10	10	10	10
	b	The organization has an ethics committee to oversee all research activities.	10	10	10	10
	c	The committee has the powers to discontinue a research trial when risks outweigh the potential benefits.	10	10	10	10
	d	Patient's informed consent is obtained before entering them in research protocols.	10	10	10	10
	e	Patients are informed of their right to withdraw from the research at any stage and also of the consequences (if any) of such withdrawal.	10	10	10	10
	f	Patients are assured that their refusal to participate or withdrawal from participation will not compromise their access to the organization's services.	10	10	10	10
COP.19: Documented policies and procedures guide nutritional therapy.			**5**	**6.67**	**10**	**8.33**
	a	Documented policies and procedures guide nutritional assessment and reassessment.	0	5	10	10
	b	Patients receive food according to their clinical needs.	10	10	10	10
	c	There is a written order for the diet.	10	10	10	10
	d	Nutritional therapy is planned and provided in a collaborative manner.	5	5	10	10
	e	When families provide food, they are educated about the patients diet limitations.	0	5	10	10
	f	Food is prepared, handled, stored and distributed in a safe manner.	5	5	10	0
COP.20: Documented policies and procedures guide the end of life care.			**2**	**7**	**10**	**10**
	a	Documented policies and procedures guide the end of life care.	0	5	10	10
	b	These policies and procedures are in consonance with the legal requirements.	0	10	10	10
	c	These also address the identification of the unique needs of such patient and family.	0	5	10	10
	d	Symptomatic treatment is provided and where appropriate measures are taken for alleviation of pain.	5	10	10	10
	e	Staff is educated and trained in end of life care.	5	5	10	10
Chapter 3: MANAGEMENT OF MEDICATION (MOM)						
MOM.1: Documented policies and procedures guide the organization of pharmacy services and usage of medication.			**5**	**7.5**	**10**	**10**
	a	There is a documented policy and procedure for pharmacy services and medication usage.	10	10	10	10

	b	These comply with the applicable laws and regulations.	10	10	10	10
	c	A multidisciplinary committee guides the formulation and implementation of these policies and procedures.	0	5	10	10
	d	There is a procedure to obtain medication when the pharmacy is closed.	0	5	10	10
MOM.2: There is a hospital formulary.			**0**	**5**	**10**	**8**
	a	A list of medications appropriate for the patients and as per the scope of the organization's clinical services is developed.	0	5	10	10
	b	The list is developed and updated collaboratively by the multidisciplinary committee.	0	5	10	0
	c	The formulary is available for clinicians to refer and adhere to.	0	5	10	10
	d	There is a defined process for acquisition of these medications.	0	5	10	10
	e	There is a process to obtain medications not listed in the formulary.	0	5	10	10
MOM.3: Documented policies and procedures guide the storage of medication.			**5**	**6.43**	**10**	**10**
	a	Documented policies and procedures exist for storage of medication.	10	10	10	10
	b	Medications are stored in a clean, safe and secure environment; and incorporating manufacturer's recommendation(s).	10	10	10	10
	c	Sound inventory control practices guide storage of the medications.	0	5	10	10
	d	Sound alike and look alike medications are identified and stored separately.	0	5	10	10
	e	The list of emergency medications is defined and is stored in a uniform manner.	0	5	10	10
	f	Emergency medications are available all the time.	10	5	10	10
	g	Emergency medications are replenished in a timely manner when used.	5	5	10	10
MOM.4: Documented policies and procedures guide the safe and rational prescription of medications.			**0.83**	**6.25**	**10**	**8.33**
	a	Documented policies and procedures exist for prescription of medications.	0	10	10	10
	b	These incorporate inclision of good practices/guidelines for rational prescription of medications.	0	10	10	10
	c	The organization determines the minimum requirements of a prescription.	0	5	10	10
	d	Known drug allegies are ascertained before prescribing.	0	5	10	10

	e	The organization determines who can write orders.	5	5	10	10
	f	Orders are written in a uniform location in the medical records.	5	10	10	0
	g	Medication orders are clear, legible, dated, timed, named and signed.	0	5	10	0
	h	Medication orders contain the name of the medicine, route of administration, dose to be administered and frequency/time of administration.	0	5	10	10
	i	Documented policy and procedure on verbal orders is implemented.	0	5	10	10
	j	The organization defines a list of high-risk medication(s).	0	5	10	10
	k	Audit of medication orders/prescription is carried out to check for the safe and rational prescription of medications.	0	5	10	10
	l	Corrective and/or preventive action(s) is taken based on the analysis, where appropriate.	0	5	10	10
MOM.5: Documented policies and procedures guide the safe dispensing of medications.			**3.33**	**7.5**	**10**	**10**
	a	Documented policies and procedures guide the safe dispensing of medications.	0	10	10	10
	b	The procedure addresses medication recall.	0	5	10	10
	c	Expiry dates are checked prior to dispensing.	0	5	10	10
	d	There is a procedure for near expiry medications.	10	10	10	10
	e	Labeling requirements are documented and implemented by the organization.	5	10	10	10
	f	High-risk medication orders are verified prior to dispensing.	5	5	10	10
MOM.6: There are documented policies and procedures for medication management.			**4.5**	**6**	**10**	**10**
	a	Medications are administered by those who are permitted by law to do so.	10	10	10	10
	b	Prepared medication is labeled prior to preparation of a second drug.	0	5	10	10
	c	Patient is identified prior to administration.	5	5	10	10
	d	Medication is verified from the order prior to administration.	5	5	10	10
	e	Dosage is verified from the order prior to administration.	5	5	10	10
	f	Route is verified from the order prior to administration.	5	5	10	10

	g	Timing is verified from the order prior to administration.	5	5	10	10
	h	Medication administration is documented.	10	10	10	10
	i	Documented polices and procedures govern patient's self administration of medications.	0	5	10	10
	j	Documented polices and procedures govern patient's medications brought from outside the organization.	0	5	10	10
MOM.7: Patients are monitored after medication administration.			**3.75**	**6.25**	**10**	**10**
	a	Documented policies and procedures guide the monitoring of patients after medication administration.	0	5	10	10
	b	The organization defined those situation where close monitoring is required.	0	5	10	10
	c	Monitoring is done in a collaborative manner.	10	10	10	10
	d	Medications are changed where appropriate based on the monitoring.	5	5	10	10
MOM.8: Near misses, medication errors and adverse drug events are reported and analyzed.			**6**	**8**	**10**	**6**
	a	Documented procedures exist to capture near miss, medication error and adverse drug event.	5	10	10	10
	b	Near miss, medication error and adverse drug events are defined.	10	10	10	10
	c	These are reported within a specified time frame.	5	5	10	10
	d	They are collected and analysed.	5	10	10	0
	e	Corrective and/or preventive action(s) are taken based on the analysis where appropriate.	5	5	10	0
MOM.9: Documented procedures guide the use of narcotic drugs and psychotropic substances.			**0**	**7.5**	**10**	**10**
	a	Documented procedures guide the use of narcotic drugs and psychotropic substances which are in consonance with local and national regulations.	0	10	10	10
	b	These drugs are stored in a secure manner.	0	5	10	10
	c	A proper record is kept of the usage, administration and disposal of these drugs.	0	10	10	10
	d	These drugs are handled by appropriate personnel in accordance with the documented procedure.	0	5	10	10
MOM.10: Documented policies and procedures guide the usage of chemotherapeutic agents.			**0**	**6.25**	**10**	**10**
	a	Documented policies and procedures guide the usage of chemotherapeutic agents.	0	10	10	10

	b	Chemotherapy is prescribed by those who have the knowledge to monitor and treat the adverse effect of chemotherapy.	0	5	10	10
	c	Chemotherapy is prepared in a proper and safe manner and administered by qualified personnel.	0	5	10	10
	d	Chemotherapy drugs are disposed off in accordance with legal requirements.	0	5	10	10
MOM.11: Documented policies and procedures govern usage of radioactive drugs.			**0**	**6.25**	**10**	**10**
	a	Documented policies and procedures govern usage of radioactive drugs.	0	10	10	10
	b	These policies and procedures are in consonance with laws and regulations.	0	5	10	10
	c	The policies and procedures include the safe storage, preparation, handling, distribution, and disposal of radioactive drugs.	0	5	10	10
	d	Staff, patients and visitors are educated on safety precautions.	0	5	10	10
MOM.12: Documented policies and procedures guide the use of implantable prosthesis and medical devices.			**2.5**	**6.25**	**10**	**7.5**
	a	Usage of implantable prosthesis and medical devices is guided by scientific criteria for each individual item and national/international recognized guidelines/approvals for such specific item(s).	0	5	10	10
	b	Documented policies and procedures govern procurement, storage/stocking, issuance and usage of implantable prosthesis and medical devices incorporating manufacturer's recommendation(s).	0	5	10	10
	c	Patient and his/her family are counselled for the usage of implantable prosthesis and medical device including precautions, if any.	0	5	10	10
	d	The batch and serial number of the implantable prosthesis and medical devices are recorded in the patient's medical record and the master logbook.	10	10	10	0
MOM.13: Documented policies and procedures guide the use of medical supplies and consumables.			**6.25**	**8.75**	**10**	**7.5**
	a	There is a defined process for acquisition of medical supplies and consumables.	10	10	10	10
	b	Medical supplies and consumables are used in a safe manner, where appropriate.	10	10	10	10
	c	Medical supplies and consumables are stored in a clean, safe and secure environment; and incorporating manufacturer's recommendation(s).	5	10	10	10
	d	Sound inventory control practices guide storage of medical supplies and consumables.	0	5	10	0
Chapter 4: PATIENT RIGHTS AND EDUCATION (PRE)						
PRE.1: The organization protects patient and family rights and informs them about their responsibilities during care.			**0**	**5**	**10**	**10**
	a	Patient and family rights and responsibilities are documented and displayed.	0	10	10	10
	b	Patients and families are informed of their rights and responsibilities in a format and language that they can understand.	0	0	10	10

	c	The organization's leaders protect patient's and family rights.	0	5	10	10
	d	Staff is aware of its responsibility in protecting patients and family rights.	0	5	10	10
	e	Violation of patient and family rights is recorded, reviewed and corrective/ preventive measures taken.	0	5	10	10
PRE.2: Patient and family rights support individual beliefs, values and involve the patient and family in decision-making processes.			**0**	**5.5**	**10**	**10**
	a	Patient and family rights include respecting any special preferences, spiritual and cultural needs.	0	10	10	10
	b	Patient and family rights include respect for personal dignity and privacy during examination, procedures and treatment.	0	5	10	10
	c	Patient and family rights include protection from physical abuse and neglect.	0	5	10	10
	d	Patient and family rights include treating patient information as confidential.	0	5	10	10
	e	Patient and family rights include refusal of treatment.	0	5	10	10
	f	Patient and family rights include informed consent before transfusion of blood and blood products, anaesthesia, surgery, initiation of any research protocol and any other invasive/ high-risk procedures/ treatment.	0	5	10	10
	g	Patient and family rights include right to complain and information on how to voice a complaint.	0	5	10	10
	h	Patient and family rights include information on the expected cost of the treatment.	0	5	10	10
	i	Patient and family rights include access to his/ her clinical records.	0	5	10	10
	j	Patient and family rights include information on plan of care, progress and information on their health care needs.	0	5	10	10
PRE.3: The patient nd/or family members are educated to make informed decisions and are involved in the care planning and delivery process.			**4.29**	**7.14**	**10**	**8.57**
	a	The patient and/or family members are explained about the proposed care includinng the risks, alternatives and benefits.	10	10	10	0
	b	The patient and/or family members are explained about the expected results.	10	10	10	10
	c	The patient and/or family members are explained about the possible complications.	10	10	10	10
	d	The care plan is prepared and modified in consultation with patient and/or family members.	0	5	10	10
	e	The care plan respects and where possible incorporates patient and/or family concerns and requests.	0	5	10	10
	f	The patient and/or family members are informed about the results of diagnostic tests and the diagnosis.	0	5	10	10
	g	The patient and/or family members are explained about any change in the patient's condition.	0	5	10	10

PRE.4: A documented procedure for obtaining patient and/ or family's consent exists for informed decision making about their care.			**1.25**	**6.25**	**10**	**5**
	a	Documented procedure incorporates the list of situations where informed consent is required and the process for taking informed consent.	0	10	10	10
	b	General consent for treatment is obtained when the patient enters the organisation.	10	10	10	10
	c	Patient and / or his family members are informed of the scope of such general consent.	0	5	10	10
	d	Informed consent includes information regarding the procedure, risks, benefits, alternatives and as to who will perform the requisite procedure in a language that they can understand.	0	5	10	0
	e	The procedure describes who can give consent when patient is incapable of independent decision making.	0	5	10	0
	f	Informed consent is taken by the person performing the procedure.	0	5	10	0
	g	Informed consent process adheres to statutory norms.	0	5	10	0
	h	Staff are aware of the informed consent procedures.	0	5	10	10
PRE.5: Patient and families have a right to information and education about their health care needs.			**1.88**	**5.63**	**10**	**10**
	a	Patient and/or family are educated about the safe and effective use of medication and the potential side effects of the medication, when appropriate.	0	5	10	10
	b	Patient and/or family are educated about food-drug interactions.	0	5	10	10
	c	Patient and/or family are educated about diet and nutrition	5	10	10	10
	d	Patient and/or family are educated about immunisations.	0	5	10	10
	e	Patient and/or family are educated about organ donation, when appropriate.	0	5	10	10
	f	Patient and/or family are educated about their specific disease process, complications and prevention strategies.	0	5	10	10
	g	Patient and/or family are educated about preventing healthcare associated infections.	0	5	10	10
	h	Patient and/or family are educated in a language and format that they can understand.	10	5	10	10
PRE.6: Patient and families have a right to information on expected costs.			**3.75**	**7.5**	**10**	**10**
	a	There is uniform pricing policy in a given setting (out-patient and ward category).	5	10	10	10
	b	The tariff list is available to patients.	10	10	10	10
	c	The patient and/or family are explained about the expected costs.	0	5	10	10

	d	Patient and/or family are informed about the financial implications when there is a change in the patient condition or treatment setting.	0	5	10	10
PRE.7: Organization has a complaint redressal procedure.			**7.5**	**10**	**10**	**10**
	a	The organization has a documented complaint redressal procured.	10	10	10	10
	b	Patient and/or family members are made aware of the procedures for lodging complaints.	10	10	10	10
	c	All complaints are analysed.	5	10	10	10
	d	Corrective and/or preventive action(s) are taken based on the analysis where appropriate.	5	10	10	10
Chapter 5: HOSPITAL INFECTION CONTROL (HIC)			0	5	10	10
HIC.1: The organization has a well-designed, comprehensive and coordinated Hospital Infection Prevention and Control (HIC) programme aimed at reducing/eliminating risks to patients, visitors and providers of care.			**4.17**	**8.33**	**10**	**10**
	a	The hospital infection prevention and control programme is documented which aims at preventing and reducing risk of healthcare associated infections.	5	10	10	10
	b	The infection prevention and control programme is a continuous process and updated at least once in a year.	0	10	10	10
	c	The hospital has a multi-disciplinary infection control committee, which coordinates all infection prevention and control activities.	10	10	10	10
	d	The hospital has an infection control team, which coordinates implementation of all infection prevention and control activities.	10	10	10	10
	e	The hospital has designated infection control officer as part of the infection control team.	0	5	10	10
	f	The hospital has designated infection control nurse(s) as part of the infection control team.	0	5	10	10
HIC.2: The organisation implements the policies and procedures laid down in the Infection Control Manual.			**2.27**	**6.36**	**10**	**7.27**
	a	The organization identifies the various high-risk areas and procedures and implements policies and/or procedures to prevent infection in these areas.	0	5	10	10
	b	The organization adheres to standard precautions at all times.	0	5	10	10
	c	The organization adheres to hand-hygiene guidelines.	10	10	10	10
	d	The organization adhere to safe injection and infusion practices.	5	10	10	10
	e	The organization adheres to transmission-based precautions at all times.	10	10	10	0
	f	The organization adheres to cleaning, disinfection and sterilisation practices.	0	5	10	10
	g	An appropriate antibiotic policy is established and implemented.	0	5	10	0

	h	The organization adheres to laundry and linen management processes.	0	5	10	10
	i	The organization adheres to kitchen sanitation and food handling issues.	0	5	10	10
	j	The organization has appropriate engineering controls to prevent infections.	0	5	10	0
	k	The organization adheres to housekeeping procedures.	0	5	10	10
HIC.3: The organization performs surveillance activities to capture and monitor infection prevention and control data.			**3.75**	**6.88**	**10**	**10**
	a	Surveillance activities are appropriately directed towards the identified high-risk areas and procedures.	5	5	10	10
	b	Collection of surveillance data is an on-going process.	10	10	10	10
	c	Verification of data is done on regular basis by the infection control team.	0	5	10	10
	d	Scope of surveillance activities incorporates tracking and analyzing of infection risks, rates and trends.	5	5	10	10
	e	Surveillance activities include monitoring the compliance with hand-hygiene guidelines.	5	10	10	10
	f	Surveillance activities include monitoring the effectiveness of housekeeping services.	0	5	10	10
	g	Appropriate feedback regarding HAI rates are provided on a regular basis to appropriate personnel.	5	10	10	10
	h	In cases of notifiable diseases, information (in relevant format) is sent to appropriate authorities.	0	5	10	10
HIC.4: The organization takes actions to prevent and control Healthcare Associated Infections (HAI) in patients.			**5**	**8.75**	**10**	**10**
	a	The organization takes action to prevent urinary tract infections.	5	10	10	10
	b	The organization takes action to prevent respiratory tract infections.	5	10	10	10
	c	The organization takes action to prevent intra-vascular device infections.	5	10	10	10
	d	The organization takes action to prevent surgical site infections.	5	5	10	10
HIC.5: The organization provides adequate and appropriate resources for prevention and control of Healthcare Associated Infections (HAI).			**2.5**	**6.25**	**10**	**7.5**
	a	Adequate and appropriate personal protective equipment, soaps and disinfectants are available and used correctly.	5	5	10	10
	b	Adequate and appropriate facilities for hand hygiene in all patient-care areas are accessible to healthcare providers.	5	5	10	10
	c	Isolation/ barrier nursing facilities are available.	0	10	10	0

	d	Appropriate pre- and post-exposure prophylaxis is provided to all staff members concerned.	0	5	10	10
HIC.6: The organisation identifies and takes appropriate action to control outbreaks of infections.			**0**	**6.25**	**10**	10
	a	Organization has a documented procedure for identifying an outbreak.	0	10	10	10
	b	The organization has a documented procedure for handling such outbreaks.	0	5	10	10
	c	This procedure is implemented during outbreaks.	0	5	10	10
	d	After the outbreak is over appropriate corrective actions are taken to prevent recurrence.	0	5	10	10
HIC.7: There are documented policies and procedures for sterilisation activities in the organisation.			**4**	**7**	**10**	**10**
	a	The organization provides adequate space and appopriate zoning for sterilization activities.	5	10	10	0
	b	Documented procedure guides the cleaning, packing, disinfection and/or sterlization, storing and issue of items.	0	5	10	0
	c	Reprocessing of instruments and equipment are covered.	5	10	10	0
	d	Regular validation tests for sterilisation are carried out and documented.	10	5	10	10
	e	There is an established recall procedure when breakdown in the sterilisation system is identified.	0	5	10	10
HIC.8: Bio-medical Waste (BMW) is handled in an appropriate and safe manner.			**4**	**5**	**10**	**6**
	a	The organization adheres to statutory provisions with regard to biomedical waste.	5	5	10	0
	b	Proper segregation and collection of Bio-medical Waste from all patient care areas of the hospital is implemented and monitored.	0	5	10	0
	c	The organization ensures that Bio-medical Waste is stored and transported to the site of treatment and disposal in proper covered vehicles within stipulated time limits in a secure manner.	5	5	10	10
	d	Bio-medical Waste treatment facility is managed as per statutory provisions (if in-house) or outsourced to authorised contractor(s).	10	5	10	10
	e	Appropriate personal protective measures are used by all categories of staff handling Bio-medical Waste.	0	5	10	10
HIC.9: The infection control programme is supported by the management and includes training of staff.			**0**	**7.5**	**10**	**10**
	a	The management makes available resources required for the infection control programme.	0	10	10	10
	b	The organization earmarks adequate funds from its annual budget in this regard.	0	5	10	10
	c	The organization conducts induction training for all staff.	0	10	10	10

	d	The organization conducts appropriate "in-service" training sessions for all staff at least once in a year.	0	5	10	10
Chapter 6: CONTINUOUS QUALITY IMPROVEMENT (CQI)						
CQI.1: There is a structured quality improvement and continuous monitoring programme in the organization.			**7.22**	**9.44**	**10**	**8.89**
	a	The quality improvement programme is developed, implemented and maintained by a multi-disciplinary committee.	5	10	10	10
	b	The quality improvement programme is documented.	10	10	10	10
	c	There is a designated individual for coordinating and implementing the quality improvement programme.	10	10	10	10
	d	The quality improvement programme is comprehensive and covers all the major elements related to quality assurance and supports innovation.	5	10	10	10
	e	The designated programme is communicated and coordinated amongst all the staff of the organization through appropriate training mechanism.	5	10	10	10
	f	The quality improvement programme identifies opportunities for improvement based on review at predefined intervals.	5	5	10	10
	g	The quality improvement programme is a continuous process and updated at least once in a year.	10	10	10	10
	h	Audits are conducted at regular intervals as a means of continuous monitoring.	10	10	10	0
	i	There is an established process in the organization to monitor and improve quality of nursing and complete patient care.	5	10	10	10
CQI.2: There is a structured patient-safety programme in the organization.			**0**	**5**	**10**	**10**
	a	The patient-safety programme is developed, implemented and maintained by a multi-disciplinary committee.	0	5	10	10
	b	The patient-safety programme is documented.	0	5	10	10
	c	The patient-safety programme is comprehensive and covers all the major elements related to patient safety and risk management.	0	5	10	10
	d	The scope of the programme is defined to include adverse events ranging from "no harm" to "sentinel events".	0	5	10	10
	e	There is a designated individual for coordinating and implementing the patient-safety programme.	0	5	10	10
	f	The designated programme is communicated and coordinated amongst all the staff of the organization through appropriate training mechanism.	0	5	10	10
	g	The patient-safety programme identifies opportunities for improvement based on review at pre-defined intervals.	0	5	10	10
	h	The patient-safety programme is a continuous process and updated at least once in a year.	0	5	10	10
	i	The organization adapts and implements national/international patient-safey goals/solutions.	0	5	10	10

	j	The organization uses at least two identifiers to identify patients across the organization.	0	5	10	10
CQI.3: The organization identifies key indicators to monitor the clinical structures, processes and outcomes which are used as tools for continual improvement.			**0**	**5**	**10**	**7.27**
	a	Monitoring includes appropriate patient assessment.	0	5	10	0
	b	Monitoring includes safety and quality control programmes of the diagnostics services.	0	5	10	10
	c	Monitoring includes medication management.	0	5	10	0
	d	Monitoring includes use of anaesthesia.	0	5	10	10
	e	Monitoring includes surgical services.	0	5	10	10
	f	Monitoring includes use of blood and blood products.	0	5	10	10
	g	Monitoring includes infection control activities.	0	5	10	10
	h	Monitoring includes review of mortality and morbidity indicators.	0	5	10	10
	i	Monitoring includes clinical research.	0	5	10	10
	j	Monitoring includes data collection to support further improvements.	0	5	10	0
	k	Monitoring includes data collection to support evaluation of these improvements.	0	5	10	10
CQI.4: The organization identifies key indicators to monitor the managerial structures, processes and outcomes which are used as tools for continual improvement.			**0**	**5**	**10**	**8.89**
	a	Monitoring includes procurement of medication essential to meet patient needs.	0	5	10	10
	b	Monitoring includes risk management.	0	5	10	10
	c	Monitoring includes utilisation of space, manpower and equipment.	0	5	10	10
	d	Monitoring includes patient satisfaction which also incorporates waiting time for services.	0	5	10	10
	e	Monitoring includes employee satisfaction.	0	5	10	10
	f	Monitoring includes adverse events and near misses.	0	5	10	10
	g	Monitoring includes availability and content of medical records.	0	5	10	10
	h	Monitoring includes data collection to support further study for improvements.	0	5	10	0

	i	Monitoring includes data collection to support evaluation of these improvements.	0	5	10	10
CQI.5: The quality improvement programme is supported by the management.			**0**	**6.67**	**10**	**7.5**
	a	The management makes available adequate resources required for quality improvement programme.	0	10	10	10
	b	Organization earmarks adequate funds from its annual budget in this regard.	0	5	10	10
	c	The management identifies organizational performance improvement targets.	0	5	10	10
	d	The management supports and implements use of appropriate quality improvement, statistical and management tools in its quality improvement programme.	0	5	10	0
CQI.6: There is an established system for clinical audit.			**0**	**6**	**10**	**6**
	a	Medical and nursing staff participates in this system.	0	10	10	10
	b	The parameters to be audited are defined by the organisation.	0	5	10	10
	c	Patient and staff anonymity is maintained.	0	5	10	0
	d	All audits are documented.	0	5	10	0
	e	Remedial measures are implemented.	0	5	10	10
CQI.7: Incidents, complaints and feedback are collected and analyzed to ensure continual improvement.			**10**	**10**	**10**	**7.5**
	a	The organization has an incident reporting system.	10	10	10	10
	b	The organization has a process to collect feedback and receive complaints.	10	10	10	10
	c	The organization has established processes for analysis of incidents, feedbacks and complaints.	10	10	10	10
	d	Corrective and preventive actions are taken based on the findings of such analysis.	10	10	10	10
	e	Feedback about care and service is communicated to staff.	10	10	10	0
CQI.8: Sentinel events are intensively analysed.			**0**	**10**	**10**	**7.5**
	a	The organisation has defined sentinel events.	0	5	10	10
	b	The organisation has established processes for intense analysis of such events.	0	5	10	10
	c	Sentinel events are intensively analysed when they occur.	0	5	10	0

	d	Corrective and preventive Actions are taken based on the findings of such analysis.	0	5	10	10
Chapter 7: RESPONSIBILITIES OF MANAGEMENT (ROM)						
ROM.1: The responsibilities of those responsible for governance are defined.			**5.56**	**7.78**	**10**	**10**
	a	Those responsible for governance lay down the organization's vission, mission and values.	10	10	10	10
	b	Those responsible for governance approve the strategic and operational plans and organization's budget.	10	10	10	10
	c	Those responsible for governance monitor and measure the performance of the organization against the stated mission.	0	5	10	10
	d	Those responsible for governance establish the organization's organogram.	0	5	10	10
	e	Those responsible for governance appoint the senior leaders in the organization.	10	10	10	10
	f	Those responsible for governance support safety initiatives and quality-improvement plans.	0	5	10	10
	g	Those responsible for governance support research activities.	10	10	10	10
	h	Those responsible for governance address the organization's social responsibility.	10	10	10	10
	i	Those responsible for governance inform the public of the quality and performance of services.	0	5	10	10
ROM.2: The organization complies with the laid-down and applicable legislations and regulations.			**6.25**	**7.5**	**10**	**10**
	a	The management is conversant with the laws and regulations and knows their applicability to the organization.	10	5	10	10
	b	The management ensures implementation of these requirements.	5	5	10	10
	c	Management regularly updates any amendments in the prevailing laws of the land.	5	10	10	10
	d	There is a mechanism to regularly update licenses/ registrations/certifications.	5	10	10	10
ROM.3: The services provided by each department are documented.			**8.75**	**10**	**10**	**10**
	a	Scope of services of each department is defined.	10	10	10	10
	b	Administrative policies and procedures for each department is maintained.	10	10	10	10
	c	Each organizational program, service, site or department has effective leadership.	10	10	10	10
	d	Departmental leaders are involved in quality improvement.	5	10	10	10

ROM.4: The organization is managed by the leaders in an ethical manner.			**5.83**	**8.33**	**10**	**10**
	a	The leaders make public the vision, mission and values of the organization.	10	10	10	10
	b	The leaders establish the organization's ethical management.	10	10	10	10
	c	The organization discloses its ownership.	10	10	10	10
	d	The organization honestly portrays the services which it can and cannot provide.	0	5	10	10
	e	The organization honestly portrays its affiliations and accreditations.	0	5	10	10
	f	The organization accurately bills for it's services based upon a standard billing tariff.	5	10	10	10
ROM.5: The organisation displays professionalism in management of affairs.			**3.63**	**6.81**	**10**	**9.55**
	a	The person heading the organization has requisite and appropriate administrative qualifications.	10	10	10	10
	b	The person heading the organization has requisite and appropriate administrative experience.	10	10	10	10
	c	The organization prepares the strategic and operational plans including long-term and short-term goals commensurate to the organization's vision, mission and values in consultation with the various stakeholders.	5	5	10	10
	d	The organization coordinates the functioning with departments and external agencies and monitors the progress in achieving the defined goals and objectives.	5	10	10	10
	e	The organization plans and budgets for its activities annually.	10	10	10	10
	f	The performance of the senior leaders is reviewed for their effectiveness.	0	5	10	10
	g	The functioning of committees is reviewed for their effectiveness.	0	5	10	5
	h	The organization documents employee rights and responsibilities.	0	5	10	10
	i	The organization documents the service standards.	0	5	10	10
	j	The organization has a formal documented agreement for all outsourced services.	0	5	10	10
	k	The organization monitors the quality of the outsourced services.	0	5	10	10
ROM.6: Management ensures that patient-safety aspects and risk-management issues are an integral part of patient care and hospital management.			**2.5**	**5**	**10**	**7.5**
	a	Management ensures proactive risk management across the organization.	0	5	10	10
	b	Management provides resources for proactive risk assessment and risk reduction activities.	5	5	10	10

	c	Management ensures implementation of systems for internal and external reporting of system and process failures.	0	5	10	10
	d	Management ensures that appropriate corrective and preventive actions are taken to address safety-related incidents.	5	5	10	0
Chapter 8: FACILITY MANAGEMENT AND SAFETY (FMS)						
FMS.1: The organisation has a system in place to provide a safe and secure environment.			**1.67**	**5.83**	**10**	**8.33**
	a	Safety committee coordinates development, implementation, and monitoring of the safety plan and policies.	0	5	10	10
	b	Patient safety devices are installed across the organization and inspected periodically.	0	5	10	0
	c	The organization is a non-smoking area.	5	10	10	10
	d	Facility inspection rounds to ensure safety are conducted at least twice in a year in patient care areas and at least once in a year in non-patient care areas.	5	5	10	10
	e	Inspection reports are documented and corrective and preventive measures are undertaken.	0	5	10	10
	f	There is a safety education programme for all staff.	0	5	10	10
FMS.2: The organization's environment and facilities operate to ensure safety of patients, their families, staff and visitors.			**3.18**	**5.9**	**10**	**6.36**
	a	Facilities are appropriate to the scope of services of the organization.	5	5	10	10
	b	Up-to-date drawings are maintained which detail the site layout, floor plans and fire escape routes.	5	5	10	10
	c	There is internal and external sign postings in the organisation in a language understood by patient, families and community.	0	5	10	0
	d	The provision of space shall be in accordance with the available literature on good practices (Indian or International Standards) and directives from government agencies.	0	5	10	0
	e	Potable water and electricity are available round the clock.	0	5	10	0
	f	Alternate sources for electricity and water are provided as backup for any failure/shortage.	0	5	10	10
	g	The organisation regularly tests the alternate sources.	0	5	10	10
	h	There are designated individuals responsible for the maintenance of all the facilities.	10	10	10	10
	i	There is a documented operational and maintenance (preventive and breakdown) plan.	0	5	10	0
	j	Maintenance staff is contactable round the clock for emergency repairs.	10	10	10	10
	k	Response times are monitored from reporting to inspection and implementation of corrective actions.	5	5	10	10

FMS.3: The organization has a program for engineering support services.			**1.11**	**5**	**10**	**8.89**
	a	The organization plans for equipment in accordance with its services and strategic plan.	5	5	10	10
	b	Equipments are selected, rented, updated or upgraded by a collaborative process.	5	5	10	10
	c	Equipments are inventoried and proper logs are maintained as required.	0	5	10	10
	d	Qualified and trained personnel operate and maintain equipment and utility systems.	0	5	10	10
	e	There is a documented operational and maintenance (preventive and breakdown) plan.	0	5	10	10
	f	There is a maintenance plan for water management.	0	5	10	0
	g	There is a maintenance plan for electrical systems.	0	5	10	10
	h	There is a maintenance plan for heating, ventilation and air-conditioning.	0	5	10	10
	i	There is a documented procedure for equipment replacement and disposal.	0	5	10	10
FMS.4: The organization has a programme for bio-medical equipment management.			**2.85**	**5.71**	**10**	**10**
	a	The organization plans for equipment in accordance with its services and strategic plan.	5	5	10	10
	b	Equipment are selected, rented, updated or upgraded by a collaborative process.	5	5	10	10
	c	Equipment are inventoried and proper logs are maintained as required.	0	5	10	10
	d	Qualified and traned personnel operate and maintain the medical equipment.	10	10	10	10
	e	Equipment are periodically inspected and calibrated for their proper functioning.	0	5	10	10
	f	There is a documented operational and maintenance (preventive and breakdown) plan.	0	5	10	10
	g	There is a documented procedure for equipment replacement and disposal.	0	5	10	10
FMS.5: The organization has a programme for medical gases, vacuum and compressed air.			**1.67**	**5.83**	**10**	**6.67**
	a	Documented procedures govern procurement, handling, storage, distribution, usage and replenishment of medical gases.	0	10	10	10
	b	Medical gases are handled, stored, distributed and used in a safe manner.	0	5	10	0
	c	The procedures for medical gases address the safety issues at all levels.	0	5	10	0

	d	Alternate sources for medical gases, vacuum and compressed air are provided for, in case of failure.	5	5	10	10
	e	The organization regularly tests these alternate sources.	5	5	10	10
	f	There is a maintenance plan for piped medical gas, compressed air and vacuum installation.	0	5	10	10
FMS.6: The organization has plans for fire and non-fire emergencies within the facilities.			**2**	**5**	**10**	**6**
	a	The organization has plans and provisions for early detection, abatement and containment of fire and non-fire emergencies.	5	5	10	0
	b	The organization has a documented safe exit plan in case of fire and non-fire emergencies.	0	5	10	0
	c	Staff is trained for its role in case of such emergencies.	5	5	10	10
	d	Mock drills are held at least twice in a year.	0	5	10	10
	e	There is a maintenance plan for fire-related equipment.	0	5	10	10
FMS.7: The organization plans for handling community emergencies, epidemics and other disasters.			**0**	**5**	**10**	**10**
	a	The organization identifies potential emergencies.	0	5	10	10
	b	The organization has a documented disaster management plan.	0	5	10	10
	c	Provision is made for availability of medical supplies, equipment and materials during such emergencies.	0	5	10	10
	d	Staff are trained in the hospital's disaster management plan.	0	5	10	10
	e	The plan is tested at least twice in a year.	0	5	10	10
FMS.8: The organization has a plan for management of hazardous materials.			**0**	**5**	**10**	**10**
	a	Hazardous materials are identified within the organization.	0	5	10	10
	b	The hospital implements processes for sorting, labelling, handling, storage, transporting and disposal of hazardous material.	0	5	10	10
	c	Requisite regulatory requirements are met in respect of radioactive materials.	0	5	10	10
	d	There is a plan for managing spills of hazardous materials.	0	5	10	10
	e	Staff are educated and trained for handling such materials.	0	5	10	10
Chapter 9: HUMAN RESOURCE MANAGEMENT (HRM)						

HRM.1: The organization has a documented system of human resource planning.			**3.75**	**6.25**	**10**	**10**
	a	Human resource planning supports the organization's current and future ability to meet the care, treatment and service needs of the patient.	0	5	10	10
	b	The organization maintains an adequate number and mix of staff to meet the care, treatment and service needs of the patient.	5	5	10	10
	c	The required job specifications and job description are well defined for each category of staff.	10	10	10	10
	d	The organization verifies the antecedents of the potential employee with regards to criminal/negligence background.	0	5	10	10
HRM.2: The organization has a documented procedure for recruiting staff and orienting them to the organization's environment.			**3.75**	**6.88**	**10**	**9.38**
	a	There is a documented procedure for recruitment.	10	10	10	10
	b	Recruitment is based on pre-defined criteria.	10	10	10	10
	c	Every staff member entering the organization is provided induction training.	5	5	10	5
	d	The induction training includes orientation to the organization's vision, mission and values.	5	10	10	10
	e	The induction training includes awareness on employee rights and responsibilities.	0	5	10	10
	f	The induction training includes awareness on patients' rights and responsibilities.	0	5	10	10
	g	The induction training includes orientation to the service standards of the organisation.	0	5	10	10
	h	Each staff member is made aware of organization wide policies and procedures as well as relevant department / unit / service / programme's policies and procedures.	0	5	10	10
HRM.3: There is an ongoing programme for professional training and development of the staff.			**5**	**7.5**	**10**	**10**
	a	A documented training and development policy exists for the staff.	10	10	10	10
	b	The organization maintains the training record.	10	10	10	10
	c	Training also occurs when job responsibilities change/ new equipment is introduced.	0	5	10	10
	d	Feedback mechanisms for assessment of training and development programme exist and the feedback is used to improve the training programme.	0	5	10	10
HRM.4: Staff are adequately trained on various safety-related aspects.			**0**	**5**	**10**	**10**
	a	Staff are trained on the risks within the organization's environment.	0	5	10	10
	b	Staff members can demonstrate and take actions to report, eliminate / minimize risks.	0	5	10	10

	c	Staff members are made aware of procedures to follow in the event of an incident.	0	5	10	10
	d	Staff are trained on occupational safety aspects.	0	5	10	10
HRM.5: An appraisal system for evaluating the performance of an employee exists as an integral part of the human resource management process.			**6**	**8**	**10**	**10**
	a	A documented performance appraisal system exists in the organization.	10	10	10	10
	b	The employees are made aware of the system of appraisal at the time of induction.	0	5	10	10
	c	Performance is evaluated based on the pre-determined criteria.	10	10	10	10
	d	The appraisal system is used as a tool for further development.	0	5	10	10
	e	Performance appraisal is carried out at pre defined intervals and is documented.	10	10	10	10
HRM.6: The organization has documented disciplinary and grievance-handling policies and procedures.			**3.57**	**6.43**	**10**	**10**
	a	Documented policies and procedures exist.	10	10	10	10
	b	The policy and procedure are known to all categories of staff of the organization.	5	5	10	10
	c	The disciplinary policy and procedure is based on the principles of natural justice.	10	10	10	10
	d	The disciplinary procedure is in consonance with the prevailing laws.	0	5	10	10
	e	There is a provision for appeals in all-disciplinary cases.	0	5	10	10
	f	The redress procedure addresses the grievance.	0	5	10	10
	g	Actions are taken to redress the grievance.	0	5	10	10
HRM.7: The organization addresses the health needs of the employees.			**5**	**10**	**10**	**10**
	a	A pre-employment medical examination is conducted on all the employees.	10	10	10	10
	b	Health problems of the employees are taken care of in accordance with the organization's policy.	10	10	10	10
	c	Regular health checks of staff dealing with direct patient care are done at-least once a year and the findings/ results are documented.	0	10	10	10
	d	Occupational health hazards are adequately addressed.	0	10	10	10
HRM.8: There is a documented personal record for each staff member.			**3.75**	**6.25**	**10**	**2.5**

	a	Personal files are maintained in respect of all employees.	10	10	10	10
	b	The personal files contain personal information regarding the employees qualification, disciplinary background and health status.	0	5	10	0
	c	All records of in-service training and education are contained in the personal files	5	5	10	0
	d	Personal files contain result of all evalutions.	0	5	10	0
HRM.9: There is a process for credentialing and privileging of medical professionals permitted to provide patient care without supervision.			**1.67**	**6.67**	**10**	**10**
	a	Medical professionals permitted by law, regulation and the organization to provide patient care without supervision is identified.	0	10	10	10
	b	The education, registration, training and experience of the identified medical professionals is documented and updated periodically.	10	10	10	10
	c	All such information pertaining to the medical professionals is appropriately verified when possible.	0	5	10	10
	d	Medical professionals are granted priviledges to admit and care for patients in consonance with their qualification, training, experience and registration.	0	5	10	10
	e	The requisite services to be provided by the medical professionals are known to them as well as the various departments/ units of the hospital.	0	5	10	10
	f	Medical professionals admit and care for patients as per their priviledging.	0	5	10	10
HRM.10: There is a process for credentializing and priviledging of nursing professionals permitted to provide patient care without supervision.			**1.67**	**6.67**	**10**	**10**
	a	Nursing staff permitted by law, regulation and the organization to provide patient care without supervision are identified.	0	10	10	10
	b	The education, registration, training and experience of nursing staff is documented and updated periodically.	10	10	10	10
	c	All such information pertaining to the nursing staff is appropriately verified when possible.	0	5	10	10
	d	Nursing staff are granted privileges in consonance with their qualification, training, experience and registration.	0	5	10	10
	e	The requisite services to be provided by the nursing staff are known to them as well as the various departments / units of the hospital.	0	5	10	10
	f	Nursing professionals care for patients as per their priviledging.	0	5	10	10
Chapter 10: INFORMATION MANAGEMENT SYSTEM (IMS)			**1.67**	**5.83**	**10**	**10**
IMS.1: Documented policies and procedures exist to meet the information needs of the care providers, management of the organization as well as other agencies that require data and information from the Organization.			0	5	10	10
	a	The information needs of the organization are identified and are appropriate to the scope of the services being provided by the organization.	0	5	10	10
	b	Documented policies and procedures to meet the information needs are documented.	0	5	10	10

	c	These policies and procedures are in compliance with the prevailing laws and regulations.	0	5	10	10
	d	All information management and technology acquisitions are in accordance with the documented policies and procedures.	0	5	10	10
	e	The organization contributes to external databases in accordance with the law and regulations.	10	10	10	10
IMS.2: The organization has processes in place for effective management of data.			**0**	**4**	**10**	**7**
	a	Formats for data collection are standardized	0	5	10	5
	b	Necessary resources are available for analyzing data.	0	0	10	10
	c	Documented procedures are laid down for timely and accurate dissemination of data.	0	5	10	10
	d	Documented procedures exist for storing and retrieving data.	0	5	10	10
	e	Appropriate clinical and managerial staff participates in selecting, integrating and using data.	0	5	10	0
IMS.3: The organization has a complete and accurate medical record for every patient.			**2.85**	**5**	**10**	**10**
	a	Every medical record has a unique identifier.	10	5	10	10
	b	Organisation policy identifies those authorized to make entries in medical record.	0	5	10	10
	c	Entry in the medical record is named, signed, dated and timed.	0	5	10	5
	d	The author of the entry can be identified.	0	5	10	5
	e	The contents of medical record are identified and documented.	5	5	10	5
	f	The record provides a complete, up-to-date and chronological account of patient care.	5	5	10	5
	g	Provision is made for 24-hour availability of the patient's record to healthcare providers to ensure continuity of care.	0	5	10	10
IMS.4: The medical record reflects continuity of care.			**3.13**	**6.25**	**10**	**10**
	a	The medical record contains information regarding reasons for admission, diagnosis and plan of care.	10	10	10	10
	b	The medical record contains the result of tests carried out and the care provided.	5	10	10	10
	c	Operative and other procedures performed are incorporated in the medical record.	5	5	10	10
	d	When patient is transferred to another hospital, the medical record contains the date of transfer, the reason for the transfer and the name of the receiving hospital.	0	5	10	10

	e	The medical record contains a copy of the discharge summary duly signed by appropriate and qualified personnel.	5	5	10	10
	f	In case of death, the medical record contains a copy of the death certificate.	0	5	10	10
	g	Whenever a clinical autopsy is carried out, the medical record contains a copy of the report of the same.	0	5	10	10
	h	Care providers have access to current and past medical record.	0	5	10	10
IMS.5: Documented policies and procedures are in place for maintaining confidentiality, integrity and security of records, data and information.			**2.5**	**5.71**	**10**	**9.29**
	a	Documented policies and procedures exist for maintaining confidentiality, security and integrity of records, data and information.	5	10	10	10
	b	Documented policies and procedures are in consonance with the applicable laws.	0	5	10	10
	c	The policies and procedures incorporate safeguarding of data/ record against loss, destruction and tampering.	0	5	10	10
	d	The organization has an effective process of monitoring compliance of the laid down policy and procedure.	0	5	10	10
	e	The organization uses developments in appropriate technology for improving confidentiality, integrity and security.	0	5	10	10
	f	Privileged health information is used for the purposes identified or as required by law and not disclosed without the patient's authorization.	10	5	10	5
	g	A documented procedure exists on how to respond to patients/ physicians and other public agencies requests for access to information in the medical record in accordance with the local and national law.	0	5	10	10
IMS.6: Documented policies and procedures exist for retention time of records, data and information.			**6.25**	**7.5**	**10**	**10**
	a	Documented policies and procedures are in place on retaining the patient's clinical records, data and information.	10	10	10	10
	b	The policies and procedures are in consonance with the local and national laws and regulations.	10	10	10	10
	c	The retention process provides expected confidentiality and security.	5	5	10	10
	d	The destruction of medical records, data and information is in accordance with the laid down policy.	0	5	10	10
IMS.7: The organization regularly carries out review of medical records.			**0.71**	**3.57**	**10**	**7.14**
	a	The medical records are reviewed periodically.	5	5	10	5
	b	The review uses a representative sample based on statistical principles.	0	0	10	5
	c	The review is conducted by identified care providers.	0	5	10	5
	d	The review focuses on the timeliness, legibility and completeness of the medical records.	0	5	10	10

	e	The review process includes records of both active and discharged patients.	0	5	10	5
	f	The review points out and documents any deficiencies in records.	0	0	10	10
	g	Appropriate corrective and preventive measures are undertaken within a defined period of time and are documented.	0	5	10	10

Feedback Form

We would appreciate it if you could take some time to fill out this form, which would enable us to get your opinion and suggestions about the EmerCare™ Emergency Department Clinical Information System currently being used at Jehangir Hospital's Emergency Department. Please tick ✓ wherever applicable.

Name: **Designation:**

Role: Doctor ◯ Nurse ◯ Support ◯

1. This is how I rate the following features in EmerCare™:	Parameter	Excellent	Good	Fair	Poor	NA
a. Display Board	Usefulness	◯	◯	◯	◯	◯
	Ease of Use	◯	◯	◯	◯	◯
b. EDIS – Sign In, Triage, Update	Usefulness	◯	◯	◯	◯	◯
	Ease of Use	◯	◯	◯	◯	◯
c. Electronic Medical Record (CPRS)	Usefulness	◯	◯	◯	◯	◯
	Ease of Use	◯	◯	◯	◯	◯
d. "Quick Ordering" order sets	Usefulness	◯	◯	◯	◯	◯
	Ease of Use	◯	◯	◯	◯	◯
e. Vitals entry with GCS & ISS	Usefulness	◯	◯	◯	◯	◯
	Ease of Use	◯	◯	◯	◯	◯
f. Patient Registration	Usefulness	◯	◯	◯	◯	◯
	Ease of Use	◯	◯	◯	◯	◯
g. Reports in EDIS	Usefulness	◯	◯	◯	◯	◯
	Ease of Use	◯	◯	◯	◯	◯
h. Evidence-Based guidelines-order sets	Usefulness	◯	◯	◯	◯	◯
	Ease of Use	◯	◯	◯	◯	◯
i. Emergency Assessment template	Usefulness	◯	◯	◯	◯	◯
	Ease of Use	◯	◯	◯	◯	◯
j. MLC Note template	Usefulness	◯	◯	◯	◯	◯
	Ease of Use	◯	◯	◯	◯	◯
k. Disposition Diagnosis- ICD-9 code	Usefulness	◯	◯	◯	◯	◯
	Ease of Use	◯	◯	◯	◯	◯
l. Quality Dashboard	Usefulness	◯	◯	◯	◯	◯
	Ease of Use	◯	◯	◯	◯	◯

2. I think EmerCare™ can help in improving Clinical Outcomes.	◯ Yes	◯ No
3. I think EmerCare™ can help in improving Patient Safety Outcomes.	◯ Yes	◯ No
4. I think EmerCare™ is quick enough to be used in real-time.	◯ Yes	◯ No
5. I would like to incorporate EmerCare™ in the day-to-day ED operations of Jehangir Hospital.	◯ Yes	◯ No
6. I would recommend EmerCare™ to my friends and colleagues in the Emergency Medicine field.	◯ Yes	◯ No

7. This is how I rate OHUM Healthcare Solutions on the following parameters	**Excellent**	**Good**	**Fair**	**Poor**	**NA**
a. Defining Solution and setting the expectations	◯	◯	◯	◯	◯
b. Understanding scope of the Project	◯	◯	◯	◯	◯
c. Team Expertise	◯	◯	◯	◯	◯
d. Timeliness, Responsiveness and Closure	◯	◯	◯	◯	◯
e. Training and Support	◯	◯	◯	◯	◯
f. Bug fixing and Enhancements	◯	◯	◯	◯	◯
g. Understanding the 'Big Picture'	◯	◯	◯	◯	◯
h. Clinical Know-how	◯	◯	◯	◯	◯
i. Technical Know-how	◯	◯	◯	◯	◯
j. Process Know-how	◯	◯	◯	◯	◯

8. For their training and support, I would like to make a special mention of some name(s) [If yes, state name(s) below]	◯ Yes	◯ No
9. I have the following additional comments / suggestions for EmerCare™.		

Appendix 7: NABH Accreditation Certificate

National Accreditation Board for Hospitals & Healthcare Providers

Scope of Accreditation

Jehangir Hospital
32, Sasson Road
Pune – 411001

Certificate No. H-2013-0192
Valid from : July 27, 2013
Valid thru : July 26, 2016

Clinical Services
- Anaesthesia
- Cardiac Anaesthesia
- Cardio Thoracic Surgery
- Cardiology
- Clinical Haematology
- Dermatology and Venereology
- Emergency Medicine
- Endocrinology
- Family Medicine
- General Medicine
- General Surgery
- Geriatrics
- Gynaecological Oncology
- Gynaecology and Obstetrics
- Hepatology
- Medical Gastroenterology
- Medical Oncology
- Nephrology
- Neuro Radiology
- Neurology
- Neurosurgery
- Ophthalmology
- Orthopaedic Surgery
- Otorhinolaryngology
- Paediatric Cardio Thoracic Vascular Surgery
- Paediatric Cardiology
- Paediatric Gastroenterology
- Paediatric Surgery
- Paediatrics and Neonatology
- Plastic Surgery and Reconstructive Surgery
- Psychiatry
- Radiology
- Respiratory Medicine
- Rheumatology
- Sports Medicine
- Surgical Gastroenterology
- Surgical Oncology
- Urology
- Vascular Surgery

Diagnostic Services
- 2D Echo
- Audiometry
- Bone Densitometry
- CT Scanning
- EEG
- EMG/EP
- Holter Monitoring
- Mammography
- MRI
- Spirometry
- Tread Mill Testing
- Ultrasound
- X-Ray

Laboratory Services & Transfusion Services
- Blood Bank
- Blood Transfusion Services
- Clinical Bio Chemistry
- Clinical Microbiology & Serology
- Clinical Pathology
- Cytopathology
- Haematology
- Histopathology

Pharmacy
- Dispensary

Professions Allied to Medicine
- Ambulance
- Dietetics
- Physiotherapy
- Speech and Language Therapy

Outsourced Services
- Occupational Therapy

Chief Executive Officer

List of Publications

Rao, U. (2015). "Impact of Emergency Department Information System on Patient Tracking and Clinical Documentation." IJHSR **5**(3): 271-277.

Rao, U. (2015). "Total Quality Management in Healthcare: A Historical Perspective for a Modern Definition." IJHSR **5**(3): 353-364.

List of Conference Presentations

Rao, U. (2012). "The e-Transformation of Emergency Care." Healthcare Leaders Forum, March 14, ASSOCHAM House, New Delhi. http://healthcareleaders.eletsonline.com/agenda/. Accessed March 26, 2015

Rao, U. (2011). "Emergency Department Information System." Cost Effective Use of Technology in Emergency Healthcare, October 27, AIIMS, New Delhi. http://www.jpnatc.com/conference/ceuteh2011/. Accessed March 26, 2015.

Brief Biography of Candidate

Name: Dr. Ujjwal Rao

Designation & Organization:

Senior Manager, Education & Clinical Solutions
Elsevier, 10-B, DLF Cybercity
Gurgaon - 122022
Tel: +91 8130808333
Email: ujjwalrao@gmail.com

Permanent Address:

D-2, 2468, Vasant Kunj, New Delhi - 110070

Date of Birth: 12 December, 1977

Education:

- M. Phil., Hospital and Health Systems Management, 2005 – 2007: Birla Institute of Technology and Science
- PGDMLE, Medical Law and Ethics, 2005 – 2006: National Law School of India University
- MDHM, Hospital Management, 2003 – 2005: Osmania University
- MBBS, Medicine, Surgery, 1995 – 2001: LTM Medical College, Sion, Mumbai

Certifications:

- NABH Assessor - QCI certified, Quality Council of India
- ISO 9001 - Lead Auditor, International Register for Certificated Auditors

Professional Career:

- Senior Manager – Education & Clinical Solutions at Elsevier
  July 2015 - Present
- Vice President – Clinical Transformation at OHUM Healthcare Solutions
  March 2011 – June 2015
- Medical Superintendent & Head-Quality Systems at Apollo Hospitals
  Dec 2007 - March 2011
- Medical Coordinator at Fortis Healthcare Ltd.
  April 2007 - November 2007
- Dy. Manager - Medical Services at Guru Nanak Hospital & Research Centre
  August 2005 - March 2007
- Hospital Administrator at SMS Hospital & Research Centre
  March 2001 - August 2003

Publications & Presentations:

- Rao U. Impact of Emergency Department Information System on Patient Tracking and Clinical Documentation. IJHSR. (2015), 5(3): 271-277.
- Rao U. Total Quality Management in Healthcare: A Historical Perspective for a Modern Definition. IJHSR. (2015), 5(3): 353-364.
- Rao, U. (2012). "The e-Transformation of Emergency Care." Healthcare Leaders Forum, March 14, ASSOCHAM House, New Delhi. http://healthcareleaders.eletsonline.com/agenda/. Accessed March 26, 2015
- Rao, U. (2011). "Emergency Department Information System." Cost Effective Use of Technology in Emergency Healthcare, October 27, AIIMS, New Delhi. http://www.jpnatc.com/conference/ceuteh2011/. Accessed March 26, 2015.

Brief Biography of Supervisor

Name: Dr. Rajeev Boudhankar

Designation & Organization:

Vice President, Kohinoor Hospital
Kirol Road, Off LBS Road, Kurla (West), Mumbai 400070
Tel: +91 9967606767
Email: rajeev.boudhankar@kohinoorhospitals.in

Permanent Address:

701, Blue Bird "C" , Opp. Rizvi College, Sherly Rajan Road, Bandra (West), Mumbai – 400 050

Date of Birth: 1 April, 1960

Education:

- M.D. – (Internal Medicine), Grant Medical College, Bombay University.
- MBBS – Grant Medical College, Bombay University.
- M.Phil in Hospital & Health Systems Management, BITS, Pilani & Tulane University, USA.
- Ph.D in Hospital & Health Systems Management, BITS, Pilani.
- MCPS – College of Physicians & Surgeons of Bombay (recognized by Medical Council).
- DHA - Diploma in Hospital Administration, Tata Institute of Social Sciences, Mumbai.
- AFIH – Associate Fellow Industrial Health, (Govt. of India – DGFASCI).
- DAHM - Diploma in Adolescent Health and Medicine.
- B.A. – Osmania University in Public Administration, Political Science and Sociology.

Professional Career:

- Ex-Consultant, Hospital Planning & Management, HOSMAC India Pvt. Ltd., Mumbai.
- Ex-Consultant, Occupational & Industrial Health.
- Ex-Consultant, Dept. for International Development, DFID (UK Govt.) sponsored RNTCP (Revised National Tuberculosis Control Program) for Govt. of A.P.
- Ex-Medical Superintendent – Medium-sized hospital in Mumbai.
- Ex-CEO & Medical Director with 143 bedded Multi-specialty Hospital, Mumbai.
- Ex-CEO & Medical Director with 122 bedded Multi-specialty Hospital, Mumbai.
- Ex-CEO & Medical Director with 150 bedded Multi-specialty Guru Nanak Hospital & Research Centre, Bandra (E), Mumbai.
- Ex-COO, 150 bedded Multi-speciality Fortis Hospital, Vashi, Navi Mumbai.
- Currently Vice President, 175 bedded Multi-speciality Kohinoor Hospital, Mumbai

Publications:

- "Insect Asthma" – Review of Bronchial Provocation Tests
- Vulnerability of Sewer Workers of BMC to Insect Asthma
- Planning a Blood Bank for a Tertiary Healthcare Corporate Hospital
- Marketing Strategy for a New Tertiary Healthcare Corporate Hospital
- Healthcare Customer's Path to Loyalty
- Expansion of a 200 bedded Private Hospital
- Security Systems for a 450 bedded Private Hospital

Guide / Faculty / Paper Setter / Examiner / Supervisor for Internship:

- Garware Institute of Career Education and Development, Vidyanagari, Santacruz (East), Mumbai – 98 affiliated with University of Mumbai for students undergoing PGDHHM i.e. 'Post-Graduate Diploma in Hospital & Healthcare Management' course.
- Symbiosis Department of Health Sciences (SDHS), { A constituent of Symbiosis International Educational Centre – Deemed University }, Pune for students undergoing PGDHHM i.e. 'Post-Graduate Diploma in Hospital & Healthcare Management' course.
- All India Institute of Local Self Government (A Govt. recognized Educational Institute), Andheri (W), Mumbai – 58 for students undergoing PGDHA i.e. 'Post-Graduate Diploma in Hospital Administration' course.

- Tata Institute of Social Sciences (A Deemed University), Deonar, Mumbai – 88 for students undergoing MHA i.e. 'Masters in Hospital Administration' and DHA i.e. 'Diploma in Hospital Administration' courses.
- AFIH i.e. 'Associate Fellow Industrial Health' course by students. MGM University, Navi Mumbai, for MBA-Healthcare Management.

Membership of professional societies:

- Member of Syllabus Committee for:
  - MBA course – Symbiosis, Pune in Hospital & Healthcare Management.
  - PDGHA – Full time course in Hospital & Healthcare Management of Mumbai University.
  - PGDHA course in Hospital & Healthcare Management of All India Institute of Local Self Govt.
  - MBA course –in Hospital & Healthcare Management, MGM University, Navi Mumbai.
- Member and Honorary Secretary of Managing Committee of The Association of Hospitals, Mumbai since 2004 and 2006.
- Life Member :
  - Indian Medical Association, Mumbai
  - Indian Hospital Association, Mumbai
  - Association of Physicians of India, Mumbai
  - TISS Alumni Association of Health Administrators' Chapter
  - Academy of Medical Specialties, India
  - Environmental Medical Association of India

Awards:

- **"**Indian Achievers' Award For Health Excellence**"** for outstanding achievements in the Healthcare Sector in India at 14th National Seminar on Corporate Achievements & Social Responsibilities awarded by Indian Achievers Forum, New Delhi on 12th September, 2006, New Delhi.