Report on the NABH Workshop for the MBA – HHM Students

SIHS PUNE

30th November – 4th December 2015

The NABH workshops on various topics and modules at the FOHBS Auditorium and Vishwabhavan Auditorium at Symbiosis Institute of Health Science, S B Road, Pune.

Day 1 – 30th November 2015

Session 1

Speaker – Dr. B. Krishnamurthy

Topic – Hospitals

Dr(Brig) Pandit, welcomed the Guest Speaker and gave a brief outline of the NABH workshop. He also emphasised on the importance of knowing about Grading, Rating, Accreditation, Certification & Evaluation of Hospitals & Healthcare Delivery systems. He advised us, to be more interactive with the speakers and learn about Quality Improvement & Patient Safety.

The workshop began with a session on the introduction to the healthcare sector regarding the key issues and possible solutions which was delivered by Dr.B.Krishnamurthy, Director of Acute Patient Care Services, Kaveri Hospital, Chennai as well as Principal Accessor & Technical Advisor NABH.

His talk began with the emphasis on the "Four Wheels" of a successful hospital i.e doctors,

nurses, technical staff and administrator.

He stressed on the necessity of teamwork and leadership in a hospital and also spoke of how important "value of money" in healthcare industry is, so that patient care attains a satisfactory level.

He gave an overview of the U.S health records and statistics which showed the difference between the state of awareness with respect to India and explained how these records are essential to know the medical errors and the state of health in a country. The prevalence of lifestyle diseases due to contamination and also the concern of delivering the right: drug, dose, route, time, patient and documentation was discussed.

"High Reliability Organisations" was the next point of discussion where he gave the examples of submarines, nuclear industry and aviation industry which focus on "crew resource training" and are more reliable than the accreditation and standards.
The patient point of view was spoken of next where we were asked to think of what we as a patient would want in a hospital. Various views from students were expressed and each of the points were discussed elaborately which helped us understand what our priorities should be when we look at running a successful hospital.

The four basic criteria for NABH towards a hospital were spoken of i.e quality, safety, ethics and legal perspectives; and the other qualities like affordability, efficiency, effectiveness were also emphasised.

The factors on which quality depends i.e., structure, process and outcome were discussed.
The standard "P's" which form a part of any system were introduced to us which are: process, plan, procedure, protocol, program and policy.

The talk was concluded with a brief Q&A session. It was indeed a great start to the workshop and inculcated a sense of importance of accreditation.

Session 2

Speaker – Dr. S. K. M. Rao

Topic – Hospitals

The workshop was conducted by Dr S.K.M Rao, GM, Columbia Asia hospital, Kharadi, Pune who is also one of the Principal Accessor, NABH on its accreditation board.

The lecture in the afternoon session was conducted by Dr S.K,M. Rao. He introduced us to the concept of NABH and how it’s a part of Quality council of India. He explained how NABH standards for hospitals.

He distributed the class in various groups and assigned topics such as

1) Access, Assessment and Continuity of care (AAC)

2) Care of patient (COP)

3) Management of Medications (MOM)

4) Hospital infection control (HIC)

5) Continuous quality improvement (CQI)

and asked groups about their understanding of NABH standards.

This hands on exercise helped us understand the internal structure and the elements of each module much better.

Day 2 – 1st December 2015

Session 1

Speaker – Dr B Krishnamurthy

Topic – Hospitals

Dr B Krishnamurthy is presently directing the London Hospital's Trust in Chennai, He is a principal assessor and Trainer, NABH and Honorary Adviser to AHPI and is an MD in anaesthesiology and an adult intensivist.

Dr Krishnamurthy has conducted workshop on CONTINUAL QUALITY IMPROVEMENT, which has 64 indicators. He has mentioned some of KEY PERFORMANCE INDICATORS like clinical indicators, managerial indicators and other indicators basis on safety, quality, structure, process, outcome etc. He gave insight about UHID, International patient safety goal and quality improving programmes.

According to him in NABH there are 3 ways to express statistical indicators and that are number/month, percentage and rate. He also mentioned some sentinel events which might occur due to compromised quality indicators.

He also acknowledged us with the various discoveries of techniques such as hand washing, asepsis, sterilization etc.

He shared his work life experiences, enlightening us with various issues and problems related to quality control in a hospital; further describing in detail the solutions and implication of improvement in quality control measures

As an overall delineation of his session, he briefed us thoroughly about all the standards, regulations of CONTINUAL QUALITY IMPROVEMENT thereby having a consistent interactive interaction with students throughout.

Session 2

Speaker – Dr. S. K. M. Rao

Topic – Hospitals

Shortage of human resources in the healthcare industry is India's worst kept secret, stated Dr S K M Rao, General Manager of Columbia Asia, Pune, during the session on NABH directed Human Resource and Information Management Service Guidelines. The session provided an insight into the Indian healthcare industry and a rare chance to glimpse the healthcare system from inside.

While Human Resource Management is a crucial aspect of every field of work. The healthcare industry is among the few which relies almost exclusively on the human resources. For the same reason, Dr Rao reasoned human resource planning, verification and sourcing is fundamental to healthcare institutions. Technology today, is advancing at a mind numbingly rapid pace so much so, that manual labour is quickly being eased. However no amount of technology could replace the cognitive effort mandatory for the functioning of a healthcare institution, which is why human resource management will continue to be a central part of healthcare.

Budgeting is a central part of every financially conscious organisation. In a world, with constantly expanding markets, changing inflation rates and vast economic uncertainty, planning is key to survival. NABH directs intensive planning and documentation of human resources, which includes guidelines for recruitment, HR policies and authentication professional qualification. No length is too far when human life is at stake, suggested Dr Rao. He went on to delve into the increasingly worrying shortage of qualified healthcare professionals.

Orientation is generally part of the standard practises of an organisation's HR. NABH extends orientation to acquainting employees with hand hygiene, hospital infection control methods, BLS, and so on. Orientation to measurable service standards is also suggested. Having being classified in the red category of hazardous areas, safety training is important in hospitals. Occupational safety practises such as using protective gear, handling Hepatitis B vaccines, blood and other body fluids that can transmit infections etc. should also be a part of training. In addition, Dr Rao suggested that professional development and feedback mechanisms can be used to improve training. Areas of human resource management such as performance appraisal, grievance redressal, disciplinary procedures, and health needs of the employees, personal files, and credentialing, privileging medical and nursing professional were also briefly discussed.

The second half of the session dealt with Information Management Service guidelines with emphasis on the importance of data privacy and information needs. Policies and procedures have to be in conformance with prevailing laws and documentation of even simple procedures such as daily census reports is mandatory. The PCPNDT Act and MTP Act with regard to privacy was also delved into.

The Indian Government has made it compulsory for all hospitals to have a standardised discharge summary in accordance with the IRDA. Internationally movements to standardize EMR has also been initiated and is in its conception stage. Effective data management requires

standardised formats a concept which is still gaining hesitant acceptance in India. Though it is the way ahead, with a large majority of doctors being hesitant India still has a long way to go. The advantages of a complete, up-to-date, and chronological account of patient care, the 24hr availability are yet to be experienced in the Indian healthcare industry. On a more positive note Dr Rao suggested that the Indian industry's data management pivots around the maintenance of confidentiality, integrity and security of data, record and information for paper record. Medical records are regularly reviewed, with focus on timeliness, legibility, and completeness and both the live and discharged records are reviewed by hospitals and appropriate corrective action is taken for the errors found.

The session ended with the platform being opened for questions. The students were able to clear their doubts regarding the governing body of NABH, the implications and credibility of an accreditation status, the difference between suspension and black listing and the challenges of standardizing a subjective concept quality.

The session left us with the status quo of the Indian healthcare industry. Dr Rao not only cleared doubts and answered questions but also introduced the class to aspects of the healthcare industry previously overlooked and raised new questions. The session acquainted the class with the NABH, its functions and its guidelines in the areas of human resource management and data management.

Day 3 – 2nd December

Session 1

Speaker – Dr. Naveen Chug

Topic – Dental

The speaker for the training session was Dr. Naveen Chugh from Bangalore, General Manager, Head of Quality, Healthcare Global Enterprises Ltd, NABH Qualified and Empanelled Assessor and Faculty, Member Appeals Committee NABH 2014-2016. He is also an Orthodontist and the Legal advisor. Obtained M.Phil. in Hospital and Healthcare Management from BITS Pilani.

The session was started by Brig (Dr).Anil Pandit (Retd.), who welcomed the guest speaker Dr. Naveen Chugh and gave an introduction on him to the audience.

The speaker gave us the knowledge about NABH Accreditation Standards for Dental Healthcare Service Provider (DHSP). He started with briefing on the various chapters, standards and its objective elements. In total there are 10 Chapters, 85 Standards and 403 Objectives elements recognized by NABH. He spoke on standards for setting up the Dental facilities.

He started to teach us about each and every chapter and its various standards in detail and also in addition about various acts and compliances like Indian Contract Act, Indian Dentist Act, Cosmetics Act, NACO Guidelines on blood transfusion and donation, CDC Guidelines Atlanta for infection control, WHO Guidelines, etc.

He also briefed on how the NABH Standards on the Dental facilities is different from the other NABH standards on hospitals, MIS, blood bank, etc. like there is the provision for the prisoner in the dental standards and the Day Care facilities.

During the whole session Brig (Dr).Anil Pandit (Retd.), Mr.Abdus Farooqui, Ms. Sarika Deshmukh were present along with the students of MBA-HHM 2015-17 batch.

In the end Dr. Zuwaina Kadri, Member, Academic Committee, SIHS gives the vote of thanks and felicitate Dr. Naveen Chugh for giving their time and dedication to acknowledge the audience.

<u>Session 2</u>

Speaker – Dr. Atul Kulkarni

Topic – Blood Bank

NABH for Blood Bank was taken none other than Dr. Atul Kulkarni Director Incharge-Janakalyan Blood Bank. He is Principal Assess NABH for blood bank. He has done U.G and P.G from B.J.Medical College, Pune. He is Member State Blood transfusion Council.

Blood is essential component of human body. The main technical functions of Blood bank are Blood collection, blood testing, component separation, blood storage and issuing. The social function includes Donor motivation, donor and patient counselling, setting camps. The lecture was very informative included various guidelines needed for setting up blood bank such as rules and regulations, license and eleven clauses.

Clause 1. Legality, management, policies and procedures.

Clause 2. Accommodation and Environment.

For camps also various guidelines such as personal, equipment, adequate lighting, environmental control such as biological, chemical and radioactive safety.

Clause 3. Record keeping and Personal requirement according to qualifications and training.

Clause 4. Equipment requirement, selection validation, use and its maintenance is explained.

Clause 5. External Services and Supplies procurement of Material.

Clause 6. Process Control is the important part. It includes donor selection, process of collection, donor reaction management and handling of blood samples.

Clause 7. Identification of deviation and adverse events.

Clause 8. Performance improvement.

Clause 10. Quality and technical records.

Clause 11. Internal audit and management review.

There are various quality indicators such as TTI%, adverse transfusion rate%, Wastage rate, component of QC failure, adverse donor reaction rate.

The various doubts and queries of enthusiastic students were solved by the speaker.

Session 3

Speaker – Dr. Uday Patil

Topic – MIS

Dr.Uday Patil sir is MD also a Radiologist. He is on the technical committee of NABH which drafts, modifies and implement all the standards.
He furthered explained how NABH works-

NABH is an institutional member of international society of Quality Assurance.

Accreditation-motive of NABH

Achievement of accreditation standards by a healthcare organization, demonstrated through an intendent external assessment of the organizational level of performance in the relation to the standards.

Quality: Appropriate for the purpose.

Sir, explained about difference between Regulation and Accreditation.

Regulation: it is mandatory

Accreditation: it is voluntary, promoted by way of incentives and market forces, in order to achieve best of the worlds regulating in time to come can simply rely on accreditation and to provide appropriate care at proper time leads to automatic dividend.

- Purpose of accreditation:
- Improve yourself
- Force to actually what you are doing
- It benefits to staff

PROCESS:

1. Conventional radiation based diagnostic radiology

2. Ultrasound scans and Doppler studies

3. Bone densitometry

4. CT,MRI,PET-CT,SPE CT, Radionuclide imaging and therapy

5. Interventional procedures

Sir, explains how to prepare for NABH accreditation procedure.

- -purpose of documentation
- -transparent open process
- -legal and statutory requirement must.

Sir explains about MIS in 6 chapters. Every chapter gives standards about how it works.

Chapter 1:

Controls of services – The intent here is to work collaboratively with colleagues to agree and deliver appropriate service pathways to ensure diagnosis. Service delivery is patient focused and respectful. Provision of appropriate information. Actively promote patient privacy.

*PROTOCOLS: Who, What When and How to control patient information, identification, activity and Consent.

*SEDATION: Is it required, What type, who?

CHAPTER 2-

Intent here is agreed protocol, competent staff

*control of imaging processes

*Implementation and monitoring

*error assessment

*amendment to report

Diagnostic and therapeutic interventional procedures, government HIV and testing policy and proper management of drugs, isotopes, contrast media and radio pharmaceuticals and most importantly inventory control

CHAPTER 3-

Control of personnel - Individual documentation records, benefits, grievances.

CHAPER 4-

Control of equipment – services, safe and to prevent obsolescence and inappropriate use, Equipment inventory, ultrasound, check and calibration, maintenance and repair, correction and preventive action, downtime

STANDARDS-

CE1-procrurment and instalment

CE2-operation and working

CE3-maintainance and repair

CE4-replacement and new equipment procurement

CHAPTER 5:

CONTROL OF DOCUMENTS AND RECORDS

Intent here is Essential documentation, Ethics manual, Apex manual, Cross reference of all documents

CHAPTER 6:

Protective measures, minimise the risks, risk control and safety:

Day 4 – 3rd December 2015

Session 1

Speaker – Dr. Sanjeev Gupta

Topic – CQI

Dr(Brig) Pandit, welcomed the guest speaker and spoke in brief about the changing dynamics of "Quality" and how to keep upgrading the levels of standards. He made a note that CQI is a 24X7 and year long process, aligning self with the changing environment & technology.

Day 4, Thursday morning session of the NABH workshop was taken up by Dr. Sanjeev. Gupta sir. He is currently working as Additional General Manager at Jaypee Hospital, Noida. At the same time managing two of the group hospitals in HP (at Palampur) & MP (at Raghogarh, Guna) as a project head, responsible for BD, P & L, Consultants Management & Operations.

He started with what does quality means to us? Followed by the pioneers in quality like, Walter Shewhart who was a statistician, Edward Deming and Joseph M. Juran who gave us the total quality management. He also talked about the fish bone diagram which is also called the cause and effect diagram given by Kaoru Ishikawa. This was followed by history of medicine, where he talked about Hippocrates and Florence Nightingale who introduced prevention of infection control during the Crimean war. Sir asked various questions to the audience and gave away flowers to the people who answered them correct, this encouraged us and brought interest to his lecture. Sir also talked about Kaizen used in CQI, which is the technology which involves every employee. He informed us about some pioneers in this namely, ASQ, ISO, NABH, and ISQua.

Sir also spoke about the quality tools namely the flow chart, cause and effect diagram, Pareto chart, check sheet. He also mentioned about other tools like the control chart, the histogram, the scatter diagram, affinity diagram, interrelationship diagram, tree diagram, etc. Sir talked briefly on PDCA, which was created in the 1950's to be rebuilt by the Japanese economy ravaged by World War 2 and its purpose was to use PDCA with a continuous improvement process. It is a 4 step process which includes plan, do, check and act. He further went on to talk about the problem solving tools and non-productive time in O.T. this was followed by the

FMEA i.e. Failure Modes and Effect Analysis. This consisted the 6 steps of FMEA, namely, Define topic, form a committed team, develop a process map, conduct a risk or hazard analysis for each sub process, develop and implement an action plan and redesign process and lastly, monitor(sustain share and re-evaluate the improvement) this is the most difficult step. He went on to talk about the challenges of FMEA and then talked about Root cause analysis. He ended his talk with Lean 6 sigma which was developed by Motorola in the 1980's. Lean is decrease in waste by streaming process and six sigma is decrease defects by effectively solving problems.

Session 2

Speaker – Dr. Sanjeev Gupta

Topic – Clinical Audit

The post lunch session was an interactive session on clinical audit by Dr. Sanjeev Gupta in SIHS Auditorium. He is currently now working as Additional General Manager at Jaypee Hospital, Noida. He was a part of the start up team in commissioning of this green field hospital, actively involved in Strategy Planning, Budgeting, Operations, Consultant acquisitions, Quality & Accreditation and at the same time managing two of the group hospitals in HP (at Palampur) & MP (at Raghogarh, Guna) as a project head, responsible for BD, P & L, Consultants Management & Operations.

He commenced his talk with a brief, concise and very understandable definition of clinical audit as “a quality improvement process that seeks to improve patient care and outcome through systematic review of care against explicit criteria at the implementation of change”. Clinical audit cannot be accomplished unless and until we have preset standards. It was followed by the types of audits: standard based audits, adverse/ critical incident, peer reviews, patient surveys.

He gave flowers to the students who answered his questions. Later he briefly discussed about the process of clinical audit which is a continuous cycle and it includes 5 stages i.e identifying the problem, selecting criteria or standards, observe practice/ data collection, making improvements and finally sustaining improvements.

He initiated the discussion by asking the audience which stage of the clinical audit would be difficult and easy? Although many of them voted for sustaining improvements as the most difficult stage and selecting criteria and standards as the easiest stage compared to all, he said that at the end of this brainstorming session we will get to know what would be the answer and yes as he said at the end of the session we were able to understand all the basics of clinical audit just like what is the difference between clinical research, clinical audit , medical audit and medical records audits, pre-requisites of clinical audit, criteria required for clinical audit and also benefits of clinical audit to hospitals, healthcare providers and also to patients.

He even conducted a quiz type exercise on whether the situation or topic that can be audited is structure, process or outcome. He motivated each and everyone in the lecture to participate in the exercise.

He even said that in today’s competitive generation, skill sets are required compared to education levels and these skills can be acquired only if we have the hunger to acquire. He threw some light on words like top line, bottom line, standard, criterion, target, clinical performance indicators etc. and explained why it is essential to pick a topic for clinical audit that would be relevant to the organisation. He finally discussed about the barriers to successful audit.

He concluded the session with the difference in views of U.K and U.S on Clinical audit. His knowledge of clinical audit aroused a feeling of becoming a part of the audit team during our tenure of administration.

Day 5 – 4th December 2015

Session 1

Speaker – Dr. S.K.M Rao

Topic – Medical Device Safety.

Dr(Brig) Pandit, once again welcomed the speaker and spoke briefly on safety of medical equipment & medication errors.

The points discussed in the lecture are as below:
"Medical device" means any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury
- investigation, replacement, modification, or support of the anatomy or

  of a physiological process
- supporting or sustaining life
- control of conception
- disinfection of medical devices
- providing information for medical purposes

Safety can only be considered in relative terms. All devices carry a certain degree of risk and could cause problems in specific circumstances. Many medical device problems cannot be detected until extensive market experience is gained. For example, an implantable device may fail in a manner that was not predictable at the time of implantation; the failure may reflect conditions unique to certain patients.

Global Medical Device Nomenclature (GMDN) is a system of internationally agreed generic descriptors used to identify all medical device products. Such products include those used in the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury in humans

STANDARDS

- ISO: The international quality system standards for medical devices by ISO is 13485:2003 and includes all the elements of ISO9001:1994 plus a set of minimum supplementary requirements for medical devices.
- FDA
- CE

CLASSES OF MEDICAL DEVICE

Classification	Level of Risk
• Class I	Low
• class II a	Low – medium (supplied unsterile)
• Class II b	Medium - high (supplied sterile)
• Class III	High - Active implantable medical devices (AIMD)

HEALTH TECHNOLOGY ASSESMENT (HTA)

- Safety
- Legal and human rights perspective
- Clinical effectiveness- methods and ways
- Cost effectiveness- its not just the MRP
- Impact assessment – efficacy measurement

COST EFFECTIVENESS

- Cost Effectiveness (natural units)
- Cost Utility (DALY/QALY)
- Cost Benefit (Rs. or $)

WHO –CHOICE : The CHOICE (CHOosing Interventions that are Cost-Effective) project is a WHO initiative developed in 1998 with the objective of providing policy makers with the evidence for deciding on the interventions and programme which maximize health for the available resources.

HEALTH TECHNOLOGY MANAGEMENT

- Needs assessment
- Procurement (special procurements/donations)
- Installation
- Maintenance
- Disposal

PERFORMANCE AUDIT

- Utility of performance audits
- Components of performance audits

Calculating indices of medical devices maintenance

- - Downtime Index = Downtime hours x 100
  - Service Hours
- -Breakdown maintenance = Total hours spent on breakdown x 100
  - Total man hours available
- - Maintenance cost Index = Maintenance cost x 100
  - Capital cost

INPUTS FOR PLANNING

- UN procurement manual
- DG S&D procurement manual
- MOHFW procurement manual

EQUIPMENT MANAGEMENT

The following aspects are covered in Equipment Management.

- New **equipment acquisition**, replacement of old technology, new services introduction based on strategic plan which covers new construction or renovation. (FMS 4a,4g)
- Control & monitor **equipment performance** (FMS 4e,f)
- Monitoring **maintenance cost**
- **Training program** for users & Biomedical **Engineers**(HRM 3a,c)
- **Quality assurance program** (AAC 7d,AAC 10d)
- **Risk Management** related to technology.(ROM 6a,FMS 1a,CQI 8a)

MEDICAL DEVICES: LEGAL ISSUES IN INDIA

- No regulations existed for medical devices in India till 2005.
- After 2005 medical devices were bought under the ambit of the Drugs and Cosmetics Act and subsequent rules.

The Central Licensing Approval Authority (CLAA)……. In INDIA

- The CLAA, is a branch of the CDSCO.

Serves as the main regulatory body for medical devices in India.

- For **Class A** devices

Manufacturers may perform their own conformity assessment procedures.

- For **Class B, C and D** devices.

The CLAA, in consultation with the BIS, will publish a list of notified bodies authorized to perform conformity assessment.

Medical device manufacturers must submit an application for assessment to one of these notified bodies.

The necessary application materials will include technical documentation, corrective and preventative action procedures, as well as information about the organization and goals of the business.

- In the case of **Class C and D** devices.

  Further information and clinical investigation may be required.

Legal documents with regards to medical devices in India

- Drugs and Cosmetics Act and Rules
- Specific Guidance Documents Clarification on Import and Manufacture of Medical Devices
- General Guidance Documents
- Guidance Document on common submission format for registration of medical devices in India
- Cosmetics Regulation in India
- List of Notified Medical Devices (List of Devices in the Gazette)

Session 2

Speaker – Dr. S. K. M. Rao

Topic – MOM

4th dec,2015 marked the last day of the NABH workshop. It was held at Symbiosis Vishwabhawan auditorium. It ended with the session on management of medication(MOM) which was delivered post lunch by Mr.S.K.M.Rao.

Under the session the following points were covered:

.Medication error

.Patient safety a global issue

.Focus on medication errors with respect to incidents and errors like sentinel events and near misses

.Reasons for medication errors with respect to swiss cheese model"

.Root causes of sentinel events

.Occurence of errors with respect to errors during ordering and administering

.Polypharmacy as the largest risk factor

.Type of medical errors: human and system

.Critical steps to meaningful improvement in patient safety: need for root cause analysis and its characteristics

.Phonological errors and surgery related errors

.Disclosing errors

.Formulary

.Inventory control mechanism

Narcotics administration

After explaining these the MOM objective elements were discussed.

It was a very educative session and a session which would help us to deal with all such situations in practical life when we enter into these domains.

It was an immense pleasure for everyone to be a part of this workshop. It was also followed by a question and answer session which further helped to clarify everyone's doubt and generate an interest in everyone to work for these domains in near future.

At the end of this session, the students of MBA-HHM 2015-17 has knowledge on how the NABH accreditation, its various parameters, standards, checklist and other criterion on the dental facilities work in In-patient, Out-patient and private clinic set-ups. Students are also thankful for giving an extra views on the various acts and guidelines necessary to be checked before running the set-ups.

Outcomes of the Training Workshop-

At the end of these sessions, the students of MBA-HHM 2015-17 have expanded their knowledge on how the NABH accreditation, its various parameters, standards, checklist and other criterion related to various facilities work in In-patient, Out-patient and private clinic set-ups. Students are also thankful for giving an extra views on the various acts and guidelines necessary to be checked before running the set-ups.