

Guidance Document

Biomedical Equipment Maintenance & Oxygen Supply Systems

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This guidance document is intended for health facility administrators, clinical decision-makers, and procurement officers, planning officers, biomedical engineers, infrastructure engineers and policy-makers. It describes how to plan oxygen supply systems as per your demand, biomedical equipment maintenance management system, and guidance on developing a rationale for availability of medical equipment throughout various levels of health care facilities, treating patients with respiratory disease including Covid-19.

Five national best practices (**Aga Khan University Hospital Karachi, Indus Hospital Karachi, Shaukat Khanum Memorial Hospital and Research Centre Lahore, Fatima Memorial Hospital Lahore, Hayatabad Medical Complex Peshawar and Biomedical Equipment Resource Centre, Punjab**) are highlighted in terms of oxygen supply systems and its availability and their biomedical maintenance management systems. Comparison is drawn between the ideal system and national best practices and recommendations are put forward in terms of Oxygen Systems and Biomedical Maintenance Management System. Comparison between the rationale for medical equipment availability of national best practices and international publications (Zambia, Kenya and India) is drawn and recommendations are given for developing a standard and working towards an Equipment Policy.

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Background

The daily medical oxygen for COVID-19 as of November 17, 2020 for all low and middle income countries (LMICs) was 9,073,385m³ as reported by path.org is shown in Figure 1. On 4th April 2020, Data from China suggested that although the majority of people with COVID-19 have mild illness (40%) or moderate illness (40%); about 15 % of them have severe illness requiring oxygen therapy, and 5% will be critically ill requiring intensive care unit treatment. In addition, most critically ill COVID-19 patients will require mechanical ventilation. For these reasons, COVID-19 treatment health-care facilities should be equipped with pulse oximeters, functioning oxygen systems including single-use oxygen delivery interfaces.¹



Figure 1: Daily medical oxygen for COVID-19 as of November 17, 2020 for LMICs

The ability to properly detect and diagnose hypoxemia, and having a reliable supply of oxygen to treat hypoxemia, have always been a crucial elements of ending preventable deaths among adults and children globally. Oxygen systems can improve clinical outcomes for patients suffering from severe

¹ Oxygen sources and distribution for COVID-19 treatment centres – Interim Report 4th April 2020

² <https://www.path.org/programs/market-dynamics/covid-19-oxygen-needs-tracker/>

pneumonia and other respiratory diseases. It was found through a study in Papua New Guinea, improved oxygen systems reduced the risk of death by 35%. In Malawi, the introduction of oxygen concentrators in all district hospitals resulted in a decline in pneumonia case fatality rates from 18.6% to 8.4% among total admitted pneumonia patients. Several international initiatives involving national governments, implementing partners and researchers are increasing the availability and use of pulse oximetry, growing the evidence-base for this technology.

Medical oxygen is required across many levels of the health system, for various medical units and services ranging from primary health care, general wards and emergency transport, to delivery rooms, operating theatres, intensive care units (ICUs) and specialized hospital and outpatient units. The oxygen systems required to meet needs at these different levels of the health system are varied. Achieving this requires a holistic and integrated system of technologies that includes everything from the oxygen source (either produced locally at a health facility or delivered and stored) and devices for flow regulation and conditioning, to consumables for oxygen delivery to the patient as show in Figure 2

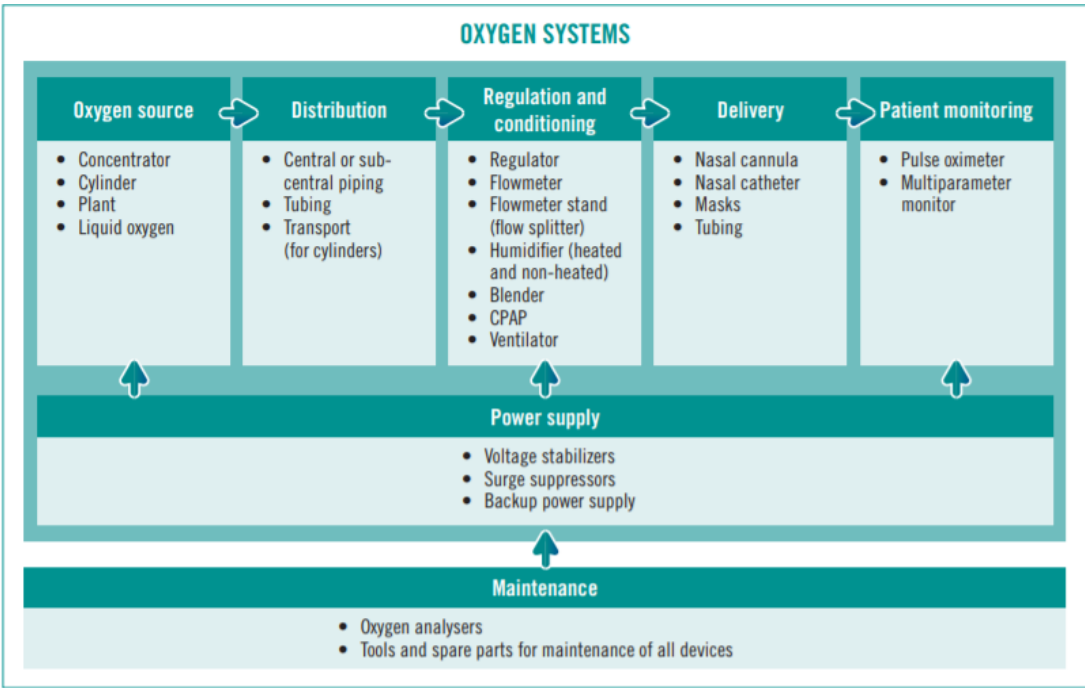


Figure 2: Oxygen System Components

First and foremost, oxygen systems must consist of an oxygen source, i.e. equipment for oxygen production or oxygen storage. Common sources of oxygen are compressed gas cylinders, oxygen concentrators, oxygen generating plants and liquid oxygen in bulk storage tanks. The appropriate choice of oxygen source is multifactorial; it is important to take into consideration the amount of oxygen needed at the health facility, available infrastructure, cost, capacity and supply chain for local production of medicinal gases, reliability of electricity, access to maintenance services and spare parts, etc.

Although there are commercially available oxygen technologies that can be used at most levels of the health system, there are inherent complexities in the selection, procurement, distribution and safe utilization of appropriate oxygen systems that make providing reliable oxygen supply a challenge. The market for oxygen therapy products is diverse in terms of cost and quality, leading to a high degree of demand-side confusion when selecting and procuring devices. Sometimes, even if oxygen is available, supplies are often unreliable, equipment is poorly maintained, and users and technicians do not have adequate training to use and maintain the equipment effectively. Due to these challenges, life-saving oxygen therapy remains inaccessible or unreliable for many severely ill patients admitted to hospitals in low-resource settings (LRS).

In addition to the oxygen source, many other oxygen system components are required to get oxygen to patients who need it. This includes mechanisms for oxygen distribution, apparatuses to control pressure, flow, humidity and concentration, and devices for delivering oxygen to patients. Pulse oximetry is used to detect hypoxemia and monitor oxygen saturation (SpO₂) during oxygen therapy for respiratory diseases, anesthesia, emergency obstetric care, surgery, trauma or any other cause of respiratory difficulty. Finally, for electrically powered devices, devices for continuity of power and power quality are required. Devices for monitoring oxygen concentration are also a requirement. Underpinning all of this is the need for maintenance, which, in addition to available expertise, requires tools to test the functionality of the oxygen therapy equipment as well spare parts for equipment maintenance. All of these are essential components of effective oxygen systems.³

The global impact of COVID-19 not only emphasized on the importance of oxygen systems but also on the importance improve access to safe and appropriate medical equipment that adequately addresses global public health needs. Medical equipment are the most important and necessary components of all healthcare systems. They are introduced and utilized for patient diagnosis and treatment whether it's in the emergency room, surgical department or outpatient clinic. These tools, when operating at peak functionality, allow healthcare professionals to better monitor the health of their patients and perform a wide variety of functions. Doctors, nurses and healthcare professionals of all types require properly functioning medical equipment to provide the best possible care to their patients. If a piece of equipment fails, then the quality of that patient care could suddenly decrease, and even pose a risk to patient safety. Medical devices must be kept in safe condition in order to prevent injuries in patients and staff.⁴ It is highly important that these medical devices are properly managed and maintained for safe and appropriate use. The different components of the equipment life cycle management are shown in Figure 3.

³ <https://apps.who.int/iris/bitstream/handle/10665/329874/9789241516914-eng.pdf?ua=1>

⁴ https://www.researchgate.net/publication/324924732_Affecting_Medical_Equipment_Maintenance_Management_A_Systematic_Review

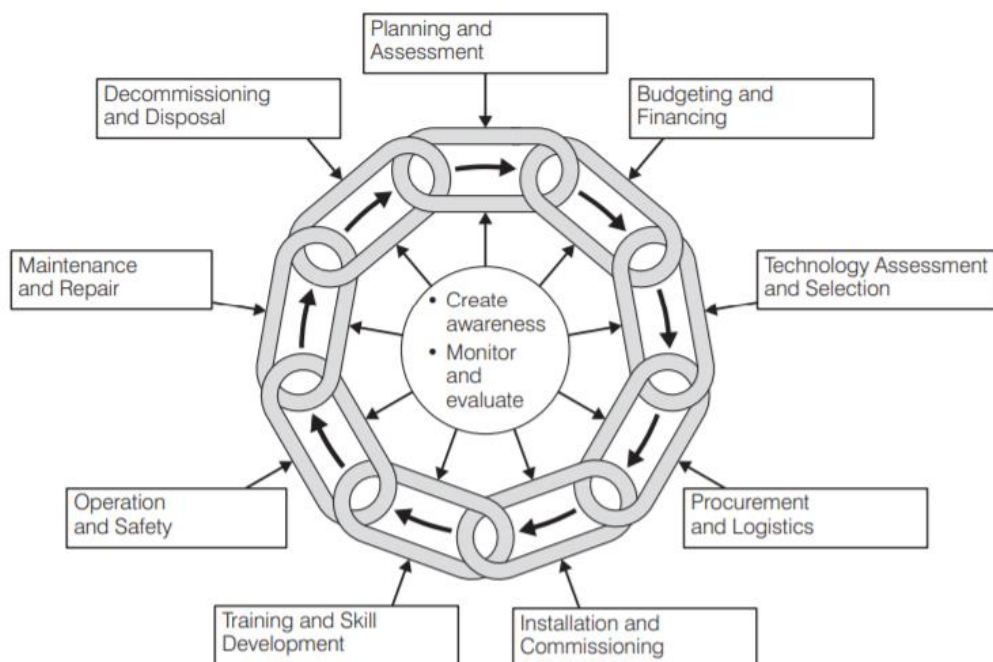


Figure 3: Life Cycle Management of Medical Equipment

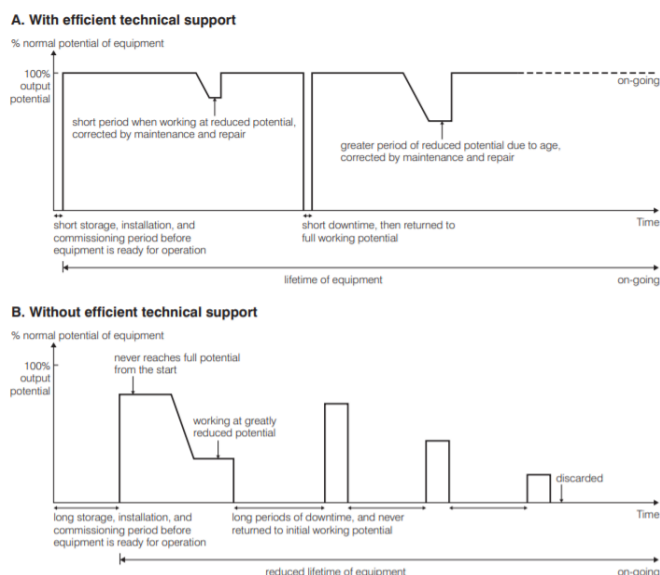
Health technology management should be carried out on all levels of health care and ideally should be coordinated by a designated health technology management unit within the ministry of health that dictates policies on planning of medical equipment allocation, development of technical specifications for procurement purposes, application/ user training or other related elements. It should relate to other government agencies like the regulatory agency or the health technology assessment or similar units in the ministry of health. Governmental units for health technology management, or clinical engineering, can be located at the national, regional or local (hospital) level. In some countries, the national health technology management team is part of a national centre or governmental institution that issues national standards and guidelines for best practice in all areas of health technology management, as stated in WHA 60.29: “The World Health Assembly urges Member States “to establish where necessary national institutions for health technologies[...].” Decision-makers can consult national centres for health technology for information on a host of issues including: medical equipment per facility, technical specifications, procurement best practices, maintenance procedures, content of user training courses, and steps required for certificate of need authorization. Health technology management teams on all facility and administrative levels need to work together to ensure coordination and supervision across the entire system. It is also advisable to encourage continuous information exchange with the health technology assessment agency and regulatory authorities as well. Effective and efficient technical management of medical devices remains a concern in most low-income countries and middle-income

⁵ http://resources.healthpartners-int.co.uk/wp-content/uploads/2015/04/Guide1_How-to-Organize-a-System-of-Healthcare-Technology-Management.pdf

countries despite the existence of dedicated responsible units at the national level⁶. The advantages of having this are that:

- Health facilities can deliver a full service, unimpeded by non-functioning healthcare technology.
- Equipment is properly utilized, maintained, and safeguarded.
- Staff makes maximum use of equipment, by following written procedures and good practice.
- Health service providers are given comprehensive, timely, and reliable information on:
 - the functional status of the equipment
 - the performance of the maintenance services
 - the operational skills and practice of equipment-user departments
 - the skills and practice of staff responsible for various equipment
 - related activities in a range of departments are including finance, purchasing, stores, and human resources.
- Staff controls the huge financial investment in equipment, and this can lead to a more effective and efficient healthcare service.

In healthcare, preventing failures is more efficient than concentrating on correcting them. Repairs are always expensive as they require highly specialized personnel and often costly spare parts. By inspecting and servicing regularly, using service manuals and checklists, the impact of maintenance is maximized and the costs are minimized. Thus it is important to introduce a planned preventive maintenance (PPM) system. This is highlighted in Figure 4 by comparing the potential life of equipment with and without maintenance.



Adapted from: Mallouppas A, 1986, 'Background document for the WHO programme on maintenance and repair of hospital and medical equipment', WHO, Geneva, Switzerland, WHO/SHS/86.5

⁶ https://www.who.int/medical_devices/management_use/3_4.pdf

Figure 4: Potential Life of Equipment with or Without Maintenance

In addition to all these, healthcare facilities can benefit from regular maintenance for medical equipment by:

- **Safety:** You should always be striving to provide your patients with the safest possible healthcare experience. Medical equipment that undergoes regular, proper maintenance is significantly safer for patients and medical staff alike. If these devices get inspected and maintained, you can root out potential issues long before they ever become problematic, which can prevent the device from either malfunctioning or completely failing to work. Our team provides full-service maintenance appointments for a wide variety of medical devices so you can make sure your equipment is constantly performing at peak functionality.
- **More efficient operation:** For some medical devices, failure might not lead to safety concerns, but it could make your job significantly harder due to inefficiency. Being proactive with repairing and maintaining your medical equipment allows you to have plans in place for what happens if one of your devices will be temporarily out of service. You can thereby schedule your regular equipment maintenance without having to compromise on the quality of care you provide to your patients, which is an extremely important ability.
- **Financial savings:** Preventative maintenance for your medical equipment can save you a lot of money in the long run. Completely replacing medical devices or equipment or having to make emergency repairs to those devices is typically much more expensive than having routine maintenance performed. So while it might seem like throwing money away to schedule maintenance appointments if there seems to be nothing wrong, think of it as insurance for your equipment. You don't want to avoid spending money until something is really wrong, because then you're going to have to spend a lot.
- **Professionalism:** While this consideration is not quite as important as the other three, it's still something to keep in mind. If you are constantly having problems with medical equipment or devices because you are not making maintenance a priority, you are going to come across as very unprofessional to patients who have to deal with the inefficiencies or substandard care that result from those equipment failures. These patients will in turn be more likely to tell friends and family members to avoid your practice. You can avoid this damage to your reputation by getting your maintenance checks done, and regularly.⁷

⁷ <https://stat-biomed.com/2017/01/the-importance-of-preventative-maintenance-for-medical-equipment-in-lubbock-tx/>

Introduction

Biomedical Equipment Maintenance Setups-Pakistan Perspective

The data analyzed from health facilities across 5 provinces of Pakistan give a substantial evidence of equipment shortages across health facility. Disparity in equipment can be seen between the same level of facilities in one province and across 5 provinces as well.

Punjab

Punjab has been divided into two health secretariats, hence the finding are separately incorporated in the document.

Primary & Secondary Health Department

As per the data analysis of the sample facilities, equipment is evenly distributed among all healthcare facilities. The majority non-functional equipment is Suction Machines, Semi-Automatic Chemistry Analyzers and Dialysis Machines. There are quite a few nonfunctional X-ray machines; it is more likely that these are old machines which should be discarded soon.

The Overall equipment non-Functionality is 6.3%. The Primary and Secondary (P&S) department has good number of technical staff as compared to other provinces. The have technical staff in the HCFs and have a parallel system known as the Biomedical Equipment Resource Centre (BERC) which manages the equipment in all P&S HCFs. The reasons for non-functionality are evenly distributed it can be inferred from the data that induction of new staff and training of existing staff can further increase the overall functionality of Equipment in the province. The distribution of Engineers can be seen in **Error! Reference source not found.**

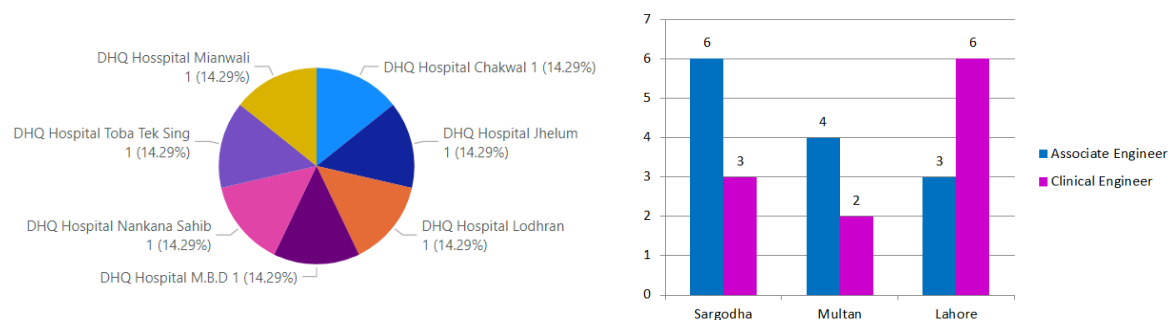


Figure 5 : Distribution of Maintenance Staff across districts and biomedical equipment workshops

Specialized Health & Medical Education Department

As per the data analysis of the sample facilities, equipment is evenly distributed among all healthcare facilities. The equipment with highest percentage non-functional equipment is Suction Machines, OT

Tables, CT scanners and Dialysis Machines. There are quite a few nonfunctional X-ray machines; it is more likely that these are old machines which should be discarded soon.

The Overall equipment non-Functionality is 5%. This number is expected to be higher for a larger sample plus the fact that big hospital like **Lahore General Hospital (LGH)** did not provide data for non-functional equipment has to be taken into consideration. The distribution of Engineers can be seen in Figure 6. The Children's Hospital has the highest number of maintenance Staff while no data was provided for LGH. The reasons for non-functionality are evenly distributed it can be inferred from the data that induction of new staff, availability of spares and training of existing staff can increase the overall functionality of equipment in the province. Services Hospital has also highlighted they do not have a proper workshop facility, further investigation on this reason highlighted that 4 out of 5 hospitals lacked proper maintenance tools even if the workshops are available. Planned periodic maintenance is to the minimal and biomedical inventory and maintenance management system is not up to date for most of the hospitals.

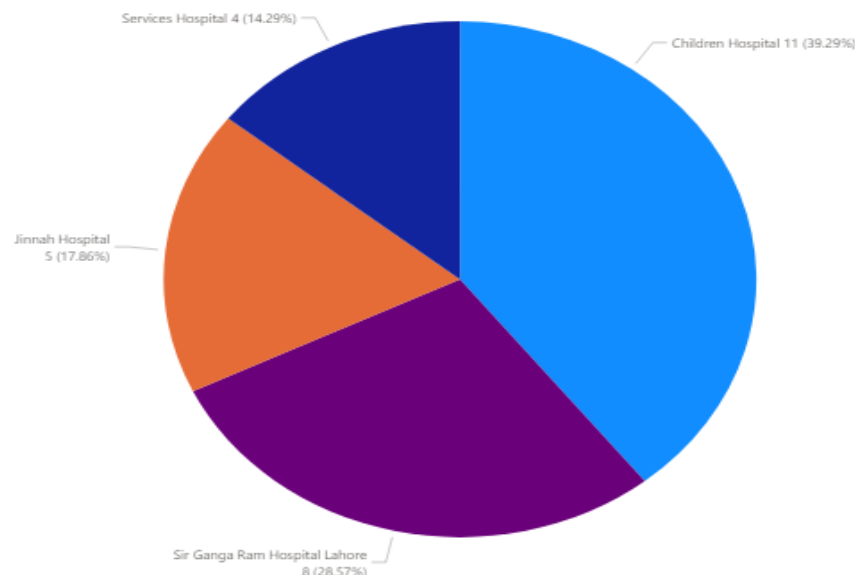


Figure 6: Distribution of Maintenance Staff across sample hospitals for SH&ME Punjab

Sindh

As per the data analysis of the sample facilities, the overall equipment non-Functionality is 10%. In reality this number might be higher than this since a lot of HCFs did not give details about the non-functional equipment. Although the reasons for non-functionality were not filled properly in the survey column but it can be inferred from the data and through interviews with healthcare managers that the main reasons are unavailability of technical staff, shortage of funds, shortage of spare parts and almost no maintenance contracts. No onsite repair facility or workshop is available in most of the hospital. There is no designated maintenance budget and most of the high tech and critical equipment is not under service contracts and the concept of planned periodic maintenance is almost absent. Figure 7 shows distribution of maintenance staff across samples facilities in Sindh.

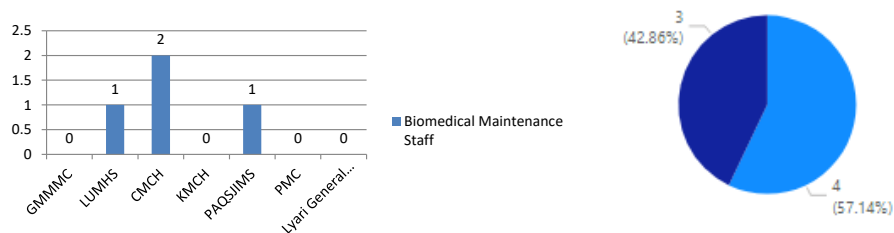


Figure 7: Distribution of Maintenance Staff across sample hospitals in Sindh

Balochistan

As per the data analysis of the sample facilities, secondary hospitals are severely short on Pulse Oximeters and Ventilators (All type and Bipap/Cpap). **DHQ Naseerabad** has no Chemistry Analyzers while **DHQ Chaman** has 4 out of which 3 are not functional. The Overall equipment Functionality is non-7.6%. In reality this number might be higher that this since a lot of HCFs did not give details about the non-functional equipment. Although the reasons for non-functionality were not filled in it can be inferred from the data that it is mostly due to unavailability of technical staff. No planned periodic maintenance is carried out and usually nonfunctional equipment in the province is discarded. Figure 8 shows distribution of maintenance staff across samples facilities in Balochistan.

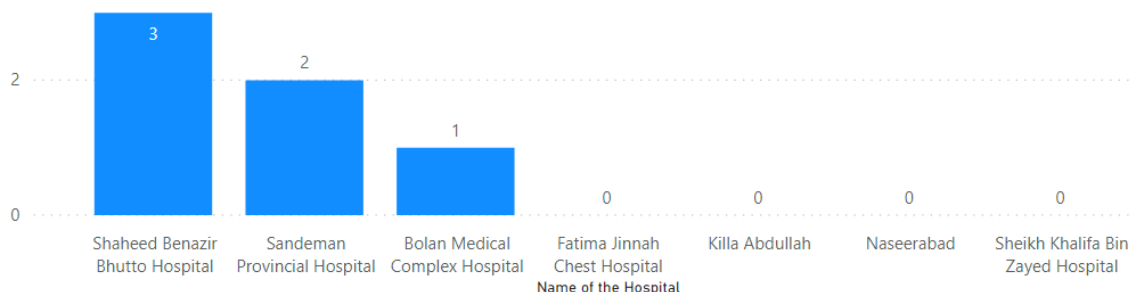


Figure 8. Distribution of Maintenance Staff across sample hospitals in Balochistan

AJK & GB

As per the data analysis of the sample facilities, the Overall equipment non-Functionality is 14.5% . The number is quite high but in reality it might be higher that this since a lot of HCFs did not give details about the non-functional equipment. The main reasons for non-functionality are unavailability of technical staff. No planned periodic maintenance is carried out and usually corrective maintenance of nonfunctional equipment is delayed. Figure 9 shows distribution of maintenance staff across samples facilities in AJK & GB.

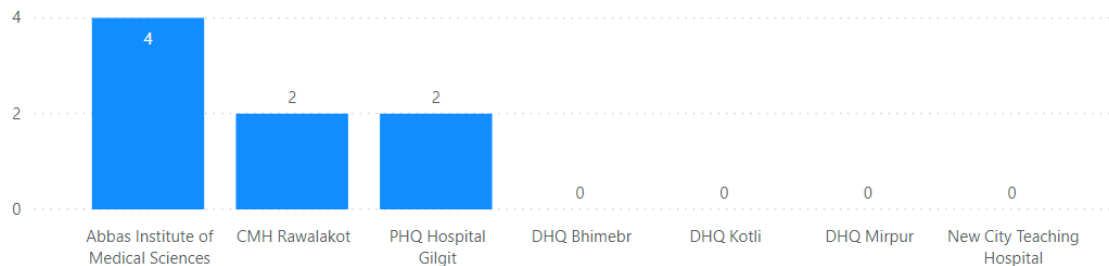
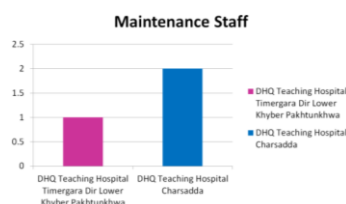


Figure 9: Distribution of Maintenance Staff across sample hospitals in AJK & GB

KPK

As per the data analysis of the sample facilities, most Hospitals are short on pulse oximeters, ventilator and vital signs monitor while there is good number of PCR, biochemistry and immunology labs. Most of the hospitals are equipped with at least 2 X-rays, 1 CT scanner, 3 Ultrasounds and 1 MRI. The Overall equipment Functionality cannot be stated since exact numbers for non-functional equipment was not provided. While talking to existing engineering staff, it was also highlighted that's due to unavailability of a centralized repositories or inventory management system, a lot of new equipment in the province is still uninstalled and warranty period for these equipment has expired. Although the reasons for non-functionality were not filled in it can be deduced from the validation process done through engineering staff that it is mostly due to unavailability of technical staff, shortage of fund and spares and no maintenance contracts. No planned periodic maintenance is carried out and usually corrective maintenance of nonfunctional equipment is delayed. Figure 10 shows distribution of maintenance staff across samples facilities in KPK.



Biomedical Maintenance staff available in only 2 of the HCFs included in the sample size. Nawaz Sharif Kidney hospital has two sanctioned positions but they have not been filled

Maintenance Staff in Workshops And DG Office

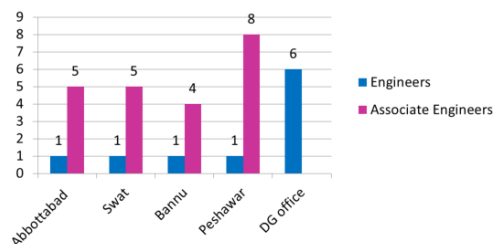

















Figure 10: Distribution of Maintenance Staff across sample hospitals in KPK

For the majority of hospitals and health service providers, no one has clear responsibility for managing medical equipment and its costs. Responsibility is dispersed across health service staff, biomedical engineers, hospital operations managers, heads of clinical service areas and central health department staff. This reduces accountability and efficiency.

According to the Asian Development Bank's Report in Pakistan hospital managers are mostly physicians who spend some of their time, or take a leave from their physician duties, to supervise the facility. They are not trained in or familiarized with management objectives, principles, or tools. Furthermore, given the systematic underfunding and lack of agreed process or management guidelines, they spend most of their time attending to "issues" requiring their immediate attention rather than planning and managing organized processes to manage equipment. There are no monitoring, feedback, or review mechanisms for key performance and quality indicators that can aid in better management of the Equipment. Hence there is no assurance that the hospitals are achieving value for money from their management of medical equipment.

Equipment failures occur due to various causes which include the following; improper storage and transportation, Initial failure, inappropriate handling, inadequate maintenance, Environmental stress, Random failure, Inappropriate repair technique and Wear-out failure. Province wise status of biomedical Equipment can be seen Figure 11.

Province	Identifiers	Assessment	Key Findings
Punjab	MGPL&/PSA		• MGPL installed in DHQs and Tertiary Centres
	Maintenance System		• DHQs and THQS have a centralized maintenance management system. Most Tertiary Centers <u>donot</u> have a system in place
	Equipment availability		• Some centres are very well equipped while others are not
Sindh	MGPL&/PSA		• MGPL not installed most DHQs and Tertiary Centres
	Maintenance System		• No proper maintenance Setup
	Equipment availability		• Some centres are very well equipped while others are not
Balochistan	MGPL&/PSA		• PSA installed across few facilities
	Maintenance System		• No proper maintenance Setup
	Equipment availability		• Most DHQs are not equipped with basic diagnostic equipment such as pulse oximeters
AJK&GB	MGPL&/PSA		• MGPL&/PSA not installed in most centres
	Maintenance System		• No proper maintenance Setup
	Equipment availability		• Some centres are very well equipped while others are not
KPK	MGPL&/PSA		• MGPL not installed most DHQs and Tertiary Centres
	Maintenance System		• Some sort of equipment maintenance management is in place through workshops but a lot needs to be done
	Equipment availability		• Some centres are very well equipped while others are not






 Donot Exist
  Minimal
  Partially
  Mostly
  Fully Exist

Figure 11: Province wise status of Biomedical Equipment

All of this calls for a National Equipment Policy and setting up standards for equipment availability in various levels of healthcare facilities. Computerized Inventory Management systems should be in place. Protocols for maintenance management of equipment should be defined and the motto should focus on preventing failure rather than correcting them. HR plays a vital role in all of this, existing staff should be trained while, induction of new staff is essential for an effective system.

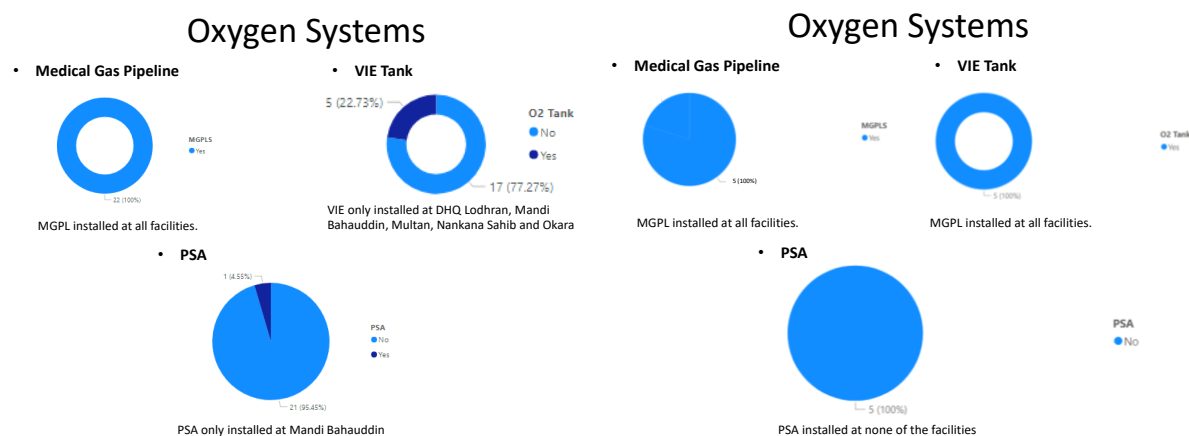
A risk and evidence based approach should be adopted and planned periodic maintenance should be carried out throughout all facilities.

Oxygen Supply System-Pakistan Perspective

Access to Oxygen is very critical for hospitals in the provinces especially secondary level hospitals; they are usually the first point of admission for the general population especially during a pandemic such as COVID-19. Despite usefulness of Oxygen therapy, the baseline survey conducted WHO Pakistan; found that District hospitals of most of the provinces had poor oxygen supply system. The Survey revealed that in all provinces, except Punjab, the centralized medical gas pipeline distribution system was only installed in Tertiary care Hospitals. Very few hospitals had VIE Tanks, generator plants or oxygen concentrators in their critical care facilities.

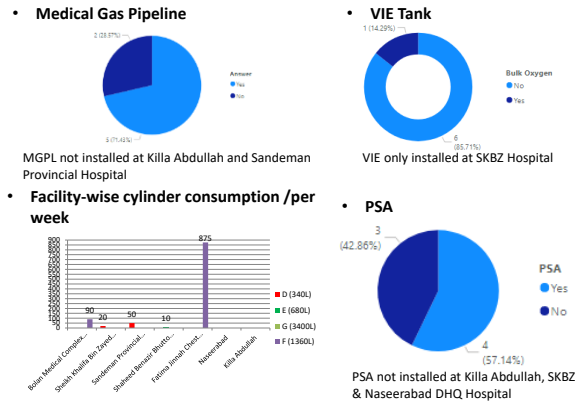
Based on interviews with key stakeholders and the data analysis, it was most oxygen is currently delivered using cylinders, and availability varies depending on the province, type of facility, and whether the facility is part of the Primary, secondary or tertiary healthcare facility. In general, oxygen is less available primary health care facilities and in more remote areas. This is because these facilities are often more remote, do not have reliable electricity⁸, and have limited financial and human resources as compared to larger facilities. Oxygen concentrators are in use in most of the provinces in Pakistan. However, they are mainly found in higher-level facilities and are less common than cylinders..

Figure 12 shows the status of oxygen supply system in Punjab (P&SHD and SH&ME), Sindh, Balochistan, AJK & GB and KPK for the sample size. While Table 1 shows the province wise data for oxygen concentrators and functional and non-functional oxygen cylinders for the sample data.

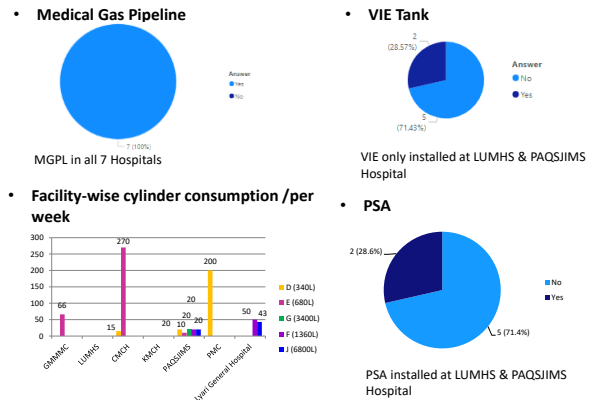


⁸ Reliable electricity is defined as not only the presence of continuous electricity but also the absence of significant sags and spikes that can be detrimental to electromedical equipment

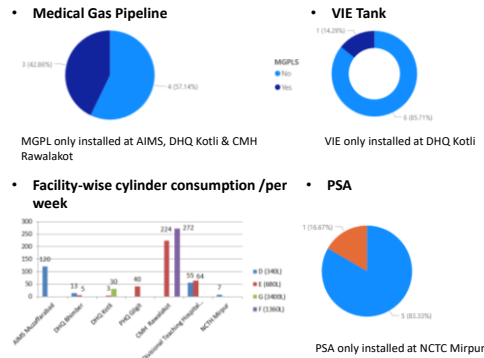
Oxygen Systems



Oxygen Systems



Oxygen Systems



Oxygen Systems

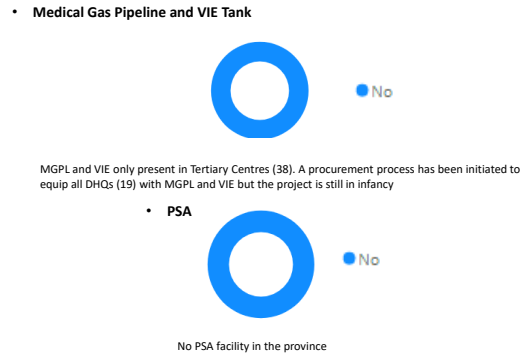


Figure 12: Status of oxygen supply system in Punjab (P&SHD and SH&ME), Sindh, Balochistan, AJK&GB and KPK

Province	Total Number of Facilities for which oxygen conc. data is available	Total No. of functional oxygen cylinder	Total No. of non-functional oxygen cylinder
Punjab	31	184	7
Sindh	7	5	2
Balochistan	7	9	0
KPK	7	29	2
AJK & GB	8	74	11

Table 1: Province wise availability of oxygen cylinder and oxygen concentrators

In Pakistan, the oxygen production sector can be divided into two basic regions: north-west and south region. Major players in the North West region included Linde, GGL, and Sharif Oxygen (Pvt.) Limited, while the southern region is dominated by Linde, Ghani Gases and Agha Steel.⁹ All facilities are privately owned and there are no government owned setups.

There are many potential reasons for a lack of oxygen in any facility. All these factors are becoming more and more crucial due to the CoVID-19 pandemic. Figure 13 shows the daily oxygen consumption for Pakistan as of December, 1, 2020. It has increased from 30,000m³ on November, 1, 2020 to 129,598 m³ on December, 1, 2020. It is very important we identify these reasons and overcome them to plan oxygen supply system in various levels of health care facilities.

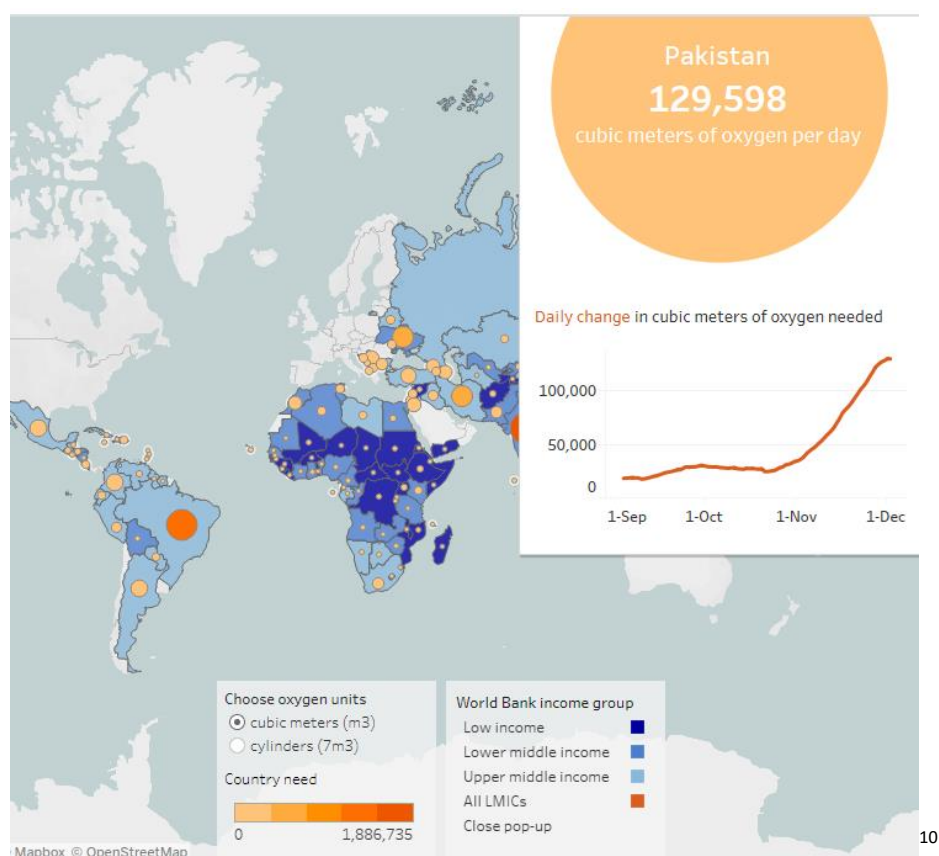


Figure 13: Daily oxygen consumption in m³ for Pakistan as of December, 1, 2020

⁹ <https://fp.brecorder.com/2018/03/20180308349916/>

¹⁰ <https://www.path.org/programs/market-dynamics/covid-19-oxygen-needs-tracker/>

The main reasons are:

- Shortage of funds relating to setting up medical Gas pipeline System with manifold, VIE and/ Oxygen generation system.
- Logistical/supply chain challenges associated with availability and refilling cylinders and replacement parts for oxygen-generation devices. There are no government owned large oxygen generation plant in each province to make transport of liquid oxygen easier.
- Expenses associated with refilling cylinders and/or maintenance/repair of oxygen-generation devices. Issues resulting from lack of payment and potentially from improperly trained staff. Disruptions due to lack of payment are not uncommon. Oxygen consumption requires routine monitoring and advanced supply planning all while choices are made to prioritize use of limited resources for many public health interventions.
- Lack of Trained Personnel to install and maintain the system
- Assumptions around the presence of a cylinder equating to oxygen availability.

All of these have to be dealt with and procedures should be made efficient for an effective oxygen supply system in all facilities in Pakistan. This is important to meet the needs of the current pandemic and to avoid shortage of this basic utility for any respiratory related pandemic or epidemic in the future.

National Best Practices

For the purpose of this guidance document we have identified five national best practices (**Aga Khan University Hospital Karachi, Indus Hospital Karachi, Shaukat Khanum Memorial Hospital and Research Centre Lahore, Fatima Memorial Hospital Lahore, Hayatabad Medical Complex Peshawar and Biomedical Equipment Resource Centre, Punjab**). All facilities were asked to complete the data survey and interviews with their staff were held separately to understand the procedures and protocols in place. Oxygen supply systems and its availability and their biomedical maintenance management systems are discussed in detail to show what has worked for these hospitals and setups in Pakistan. We can take these as examples and plan systems accordingly, for oxygen and biomedical maintenance management, as per the facilities or provinces.

Aga Khan University Hospital, Karachi (Sindh)

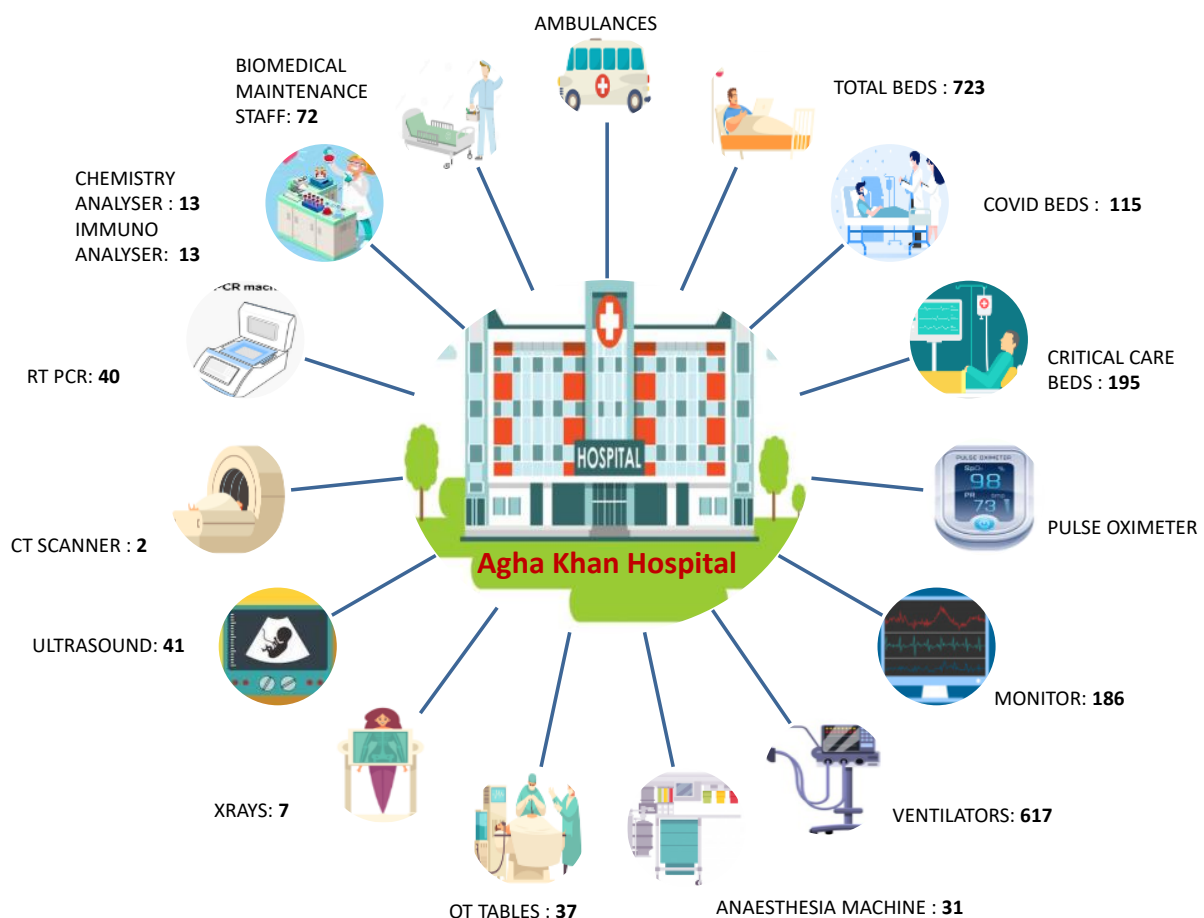


Figure 14: Medical Equipment and Maintenance Staff in Aga Khan University Hospital

Aga Khan University Hospitals in Karachi, Pakistan and Nairobi, Kenya are private, not-for-profit institutions providing high quality health care. The Main Hospitals serve as the principal sites for clinical training for the University's Medical Colleges and Schools of Nursing and Midwifery in Pakistan and East Africa

Established in 1985 as the primary teaching site of the Aga Khan University's Faculty of Health Sciences, Aga Khan University Hospital in Karachi Pakistan is committed to providing diagnosis of disease and team management of patient care. These services are backed up by the highest doctor-to-patient and nurse-to-patient ratios and support services. The University Hospital's multidisciplinary approach to diagnosis and care ensures a continuum of safe and high quality care for patients - with all services under one roof.

A broad range of secondary and tertiary care is available in the 750-bed University Hospital to all patients in need. It has a total of 195 critical care beds and 115 Covid beds. Those who are unable to pay for treatment receive generous assistance through a variety of subsidies and the Hospital Patient Welfare Programme.

In 2000, AKUH became the first teaching hospital in Pakistan to be completely ISO 9002 certified. It has since received ISO 9001 certification. The AKUH quality assurance programme serves as a model for other health institutions in the private and public sectors and in the Aga Khan Development Network. It is Joint Commission International accredited (JCIA) facility, one of the only three in Pakistan.

The Aga Khan Hospitals are part of an international referral network providing primary, secondary and tertiary level care. It is a paperless hospital where doctors need not be affiliated to the Aga Khan Hospitals to refer patients to its comprehensive healthcare network.¹¹ . It is a paperless hospital and has now become a symbol of hope for the most vulnerable members of the society. As shown in Figure 14. Aga Khan Hospital is a well equipment facility with a total of 72 Biomedical Engineering staff to maintain medical equipment. The oxygen Data is summarized in Table 2.

Facility Name	Number of Oxygenated Bed	Type of Flow Meter	Number of Functional Flow Meter	Type of Cylinder	Number of Cylinder	Number of Cylinder in Oxygen Manifold	Capacity of VIE	Number of times it is refilled per Week
Aga Khan Hospital	800	15L/min	800	6800L(J)		20	22000L	3

Table 2: Oxygen Supply System in Aga Khan University Hospital

Aga Khan Hospital has worked as a front line Hospital during the Covid-19 pandemic and has provided quality care, not only to the people of Pakistan. It is one of the best hospitals in Pakistan and can be considered as a best practice. Hence, we would discuss its maintenance management structure in detail to design a best suited model for maintenance management of medical equipment for hospitals across Pakistan.

¹¹ <https://www.agakhanhospitals.org/AKUH>

Biomedical Department

Objectives:

To Ensure that all equipment medical or non-medical are:

- Reliable, accurate and safe for clinical or operational use.
- Available in best working condition for high quality patient care.
- Equipment life is prolonged without any compromising on quality and safety
- Equipment is cost effective and capable to maintain

Hierarchy

The Biomedical Engineering department consists of a team of 72 Engineers and Technician, including the Senior Manager biomedical. The team is divided into three teams; Imaging and off campus work, Lab & Critical and Electronics. Each Team has a group leader and two team leaders working under them. Each team leader has specialist engineers, trainee engineers and technicians working under them. They have a well-equipped workshop with all of the testing, calibration and repair tools. Testing and Calibration Tools are re calibrated every year through a 3rd party using master calibrators. The Biomedical workshop keeps commonly used consumables and for spare parts of the critical equipment in stock and replenishes other required parts. The departmental organogram is summarized in Figure 15.

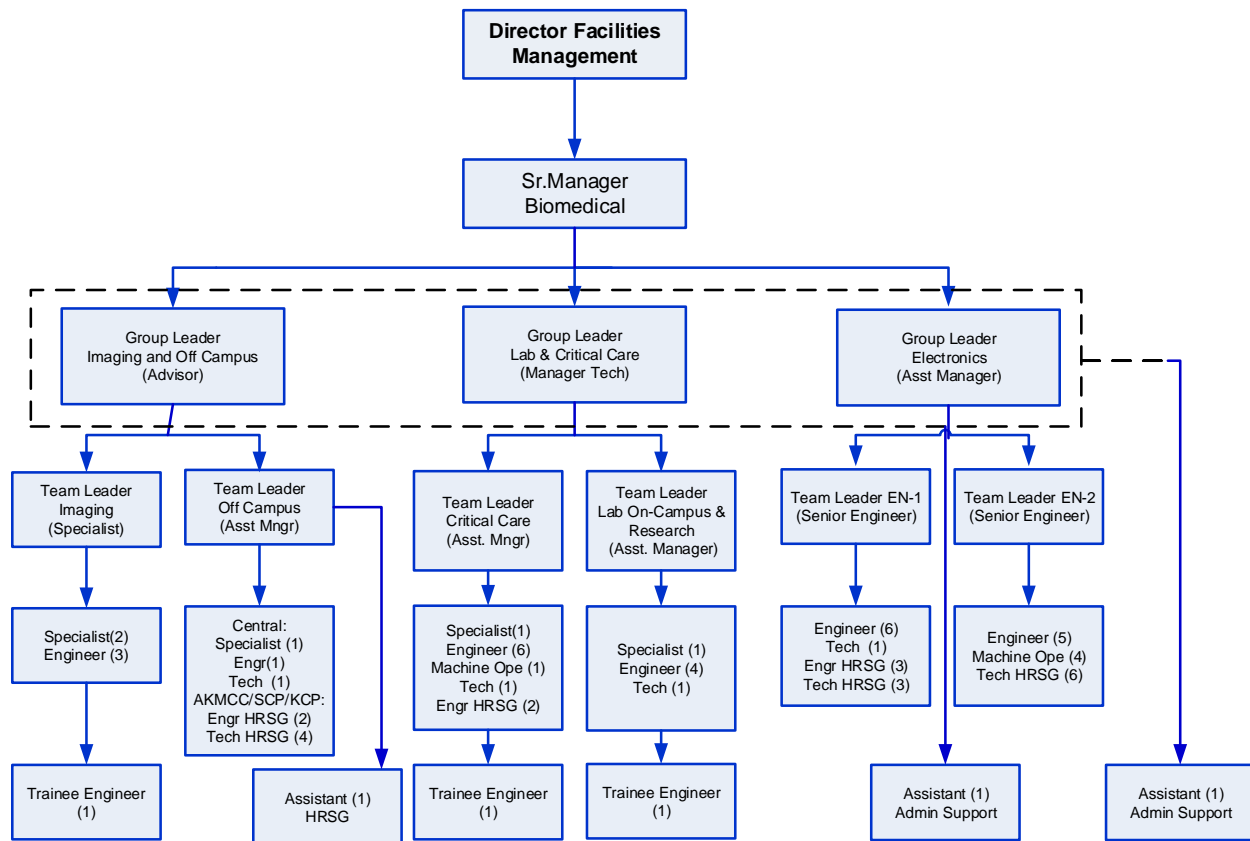


Figure 15: Organogram Biomedical Department in Aga Khan University Hospital

Scope of Work

The following equipment is not covered under the Biomedical Department. The key equipment managed by the biomedical department is summarized in the Table 3.

- Autoclaves/ sterilizers
- Fume hoods/ Safety cabinet
- Gross-lab (Histopathology)
- Ultralow freezers
- All fridges/ freezers
- Printers
- UPS connected with PCs
- Generators
- Air compressors
- Gas cylinders and regulators
- Digital Thermometers (Freezers/Fridge)

Imaging/ Radiotherapy	Critical Care	Lab
PET/CT & Cyclotron 64 and 640 Slice CT	Anesthesia/Ventilators	Biochemistry Lab Automation
1.5 and 3Tesla MRI	Low and High end simulations	Hematology lab Automation
Angiography Systems Physiotherapy systems	25 Bed Telemetry System	Microbiology Automation (in process)
LINAC	Central Monitoring	Atomic Absorptions
Gamma Camera	Baby Incubators	Gas Chromatography – Mass Spectrometer
General /Cardiac Ultrasound	Infusion Pumps	Amino Acid Analyzer
Bone Densitometry	Dialysis/RO	Microscopes (Basic + Advanced)
Radio/ Fluoro X-Ray & OPG	Endoscopy	Flow cytometers
EEG/EMG/ETT	Dental Equipment	Point of Care Testing (POCT)
Mammography	Defib/ECG	Histology equipment

Table 3: Key Equipment under the biomedical department

Key operational functions

The biomedical department manages the life cycle of the equipment from pre-purchase planning, maintenance and operations to disposal and replacement. The following are the key operational functions.

1. Pre-purchase Technical Appraisals
2. Equipment installation and commissioning
3. Equipment Acceptance
4. Equipment Inventory
5. Operator Training
6. Technical Trainings
7. Planned Preventive Maintenance
8. Equipment Inspections, testing and calibrations
9. Breakdown Maintenance
10. Equipment Incidents Investigation & Recalls

11. Monitoring of Vendors Performance
12. Equipment Replacement
13. Equipment Disposal

The biomedical department ensures quality through various interventions such as:

- Incident Reports
- Internal non-conformance checks
- Internal and external audit inspections
- Implementing standards (ECRI, AAMI, JCIA and CAP)

Maintenance Management

The biomedical department manages almost 7575 equipment through computerized equipment maintenance system which is part of the hospital management information system. Corrective Maintenance (CM) and Planned Preventive Maintenance (PPM) are carried out through work order in the CMMS and a US based system infoM® is used to access all logs and history related to maintenance for up to 10 years. A few of the equipment from Imaging, Lab, and Radiology are managed by the OEM's designated Service companies. The inventory is divided into critical and non-critical items using Fenning & Koh Method.

Planned preventive maintenance (PPM) is usually carried out as per the manufacturer's guidelines but other rigorous standards such as AAMI, JCIA and CAP are also implemented. Frequency of PPM is usual tweak according to environment, experience or equipment condition. Detailed inspections are carried out on monthly basis to identify potential failures.

For CM, a work instruction manual is present for all common problem and engineers are trained internally and through OEM's distributor. End user feedback is given high importance and history based root-cause analysis strategies are implemented to avoid recurring faults.

A quality representative (QR) from the department liaises with the quality assurance department of the hospital and ensures compliance as per standards (JCIA, ISO). Incident Investigation and recalls are also in place including adverse effect reporting. Usually it is the manufacturer and the service provider's responsibility to inform the hospital about alerts and recall, but the hospital has additionally assigned this task to the QR. The QR checks for alerts with ECRI and regulatory bodies such as FDA, MHRA etc and inform the hospital on a weekly basis.

Indus Hospitals Karachi (Sindh)

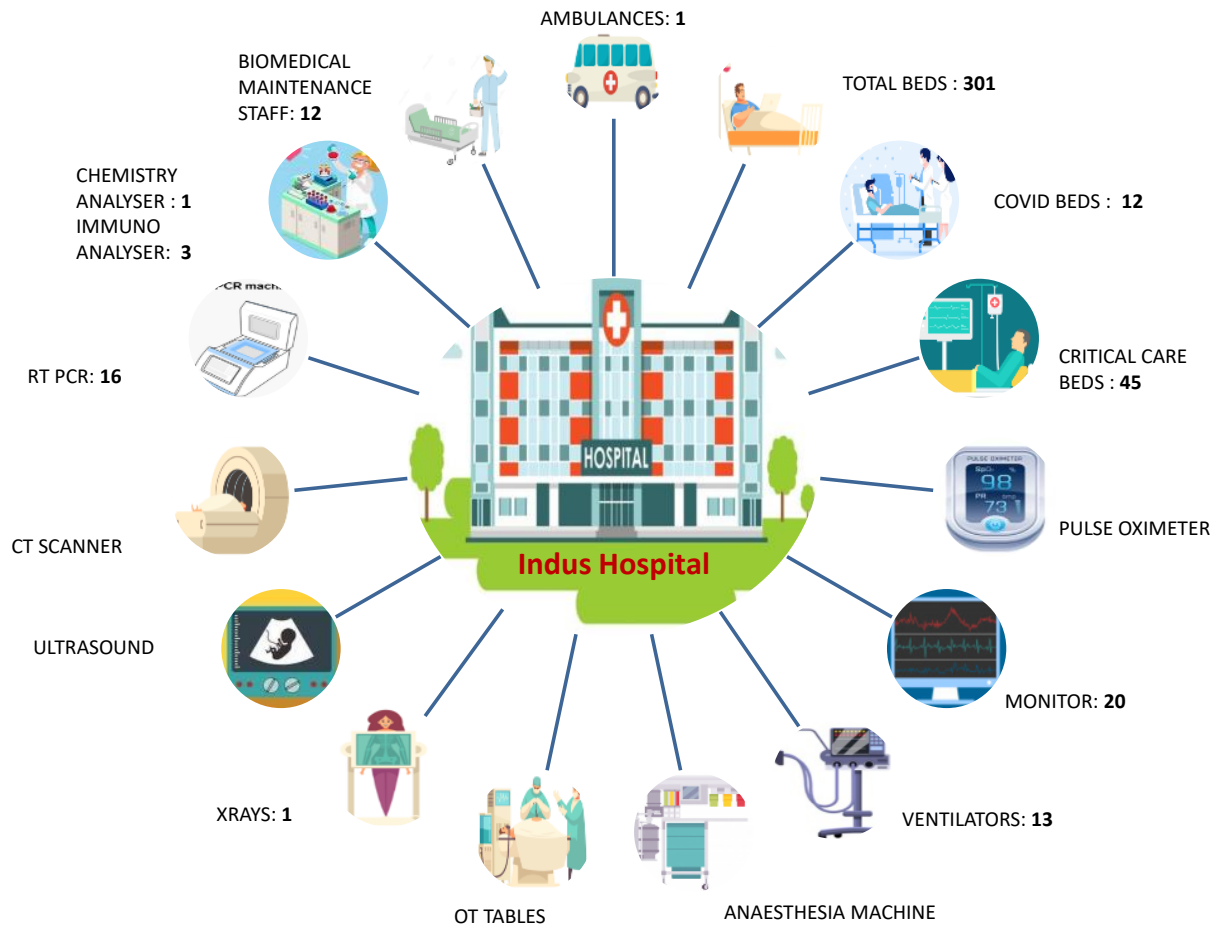


Figure 16: Medical Equipment and Maintenance Staff in Indus Hospital Karachi

The Indus Hospital Network (IHN) is a prestigious institution, with multidisciplinary hospitals not only in Karachi, but in Sindh and now all over Pakistan. IHN man multiple tertiary and secondary care Hospitals, Physical Rehabilitation Centers, Regional Blood Centers, Community Health Centers, and a Public Health Program spread across 52 districts of Pakistan. IHN is a not-for-profit healthcare system that solely relies on public donations.

In Karachi, built in 2007, it is a 300-bed tertiary care multidisciplinary hospital with 21 ICUs, 24 HDUs and 12 designated Covid beds providing premium healthcare in an impressive, state-of-the-art facility **completely free** to everyone. It is a paperless hospital and has now become a symbol of hope for the most vulnerable members of the society. The Indus Hospital provides essential healthcare services to almost 400,000 underserved patients per month across Pakistan. As shown in Figure 16. Indus Hospital is a well equipment facility with a total of 12 Biomedical Engineering staff to maintain medical equipment. The oxygen Data is summarized in Table 4.

Facility Name	Number of Oxygenated	Type of Flow	Number of	Type of Cylinder	Number of	Number of	Capacity of VIE	Number of times
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	Bed	Meter	Functional Flow Meter		Cylinder	Cylinder in Oxygen Manifold		it is refilled per Week
Indus Hospital Karachi	290	15L/min	290	6800L(J)	80	38	5250L	4-5

Table 4: Oxygen Supply System in Indus Hospital

Indus hospital has worked as a front line Hospital during the Covid-19 pandemic and has provided quality care, not only to the people of Karachi but to whole of Pakistan. It is one of the best hospitals in Pakistan and can be considered as a best practice. Hence, we would discuss its maintenance management structure in detail to design a best suited model for maintenance management of medical equipment for hospitals across Pakistan.

Biomedical Department

The Biomedical Engineering department consists of a team of 12 Engineers, including the manager biomedical. There are 5 Senior Engineers and 6 graduate Engineers. Most of the Engineers in the team are a Master's Degree Holder. The team is divided into four teams; Radiology, Critical area and Inpatient Department, Laboratory Services and CSSD Department. They have a well-equipped workshop with all of the testing, calibration and repair tools. Testing and Calibration Tool are re calibrated every year through a 3rd party using master calibrators. The Biomedical workshop keeps commonly used consumables and for spare parts of the critical equipment in stock and replenishes other required parts through close consultation with the supply chain department. Equipment such as CT and MRI are under service contracts and are managed by OEM's designated service providers. Medical gas pipeline and Oxygen Plant are not managed by the biomedical department.

The Biomedical Team is responsible for the Life cycle management of medical equipment from procurement to disposable. All of these activities are managed by Indus Hospital's In-house developed CMMS system.

Procurement:

Since the biomedical department is responsible for disposal of the equipment, so they are the ones who do the needs assessment of the medical equipment. They suggest whether an equipment replacement is required based on the useful life of the equipment considering the maintenance budget spends each year for repair or new equipment is based on the clinical requirement.

Every Budget cycle, goals are presented by the clinical department based on the recommendation by biomedical department and by means of extensive discussion with the board, needs are incorporated in the budget and signed off by the stake holders.

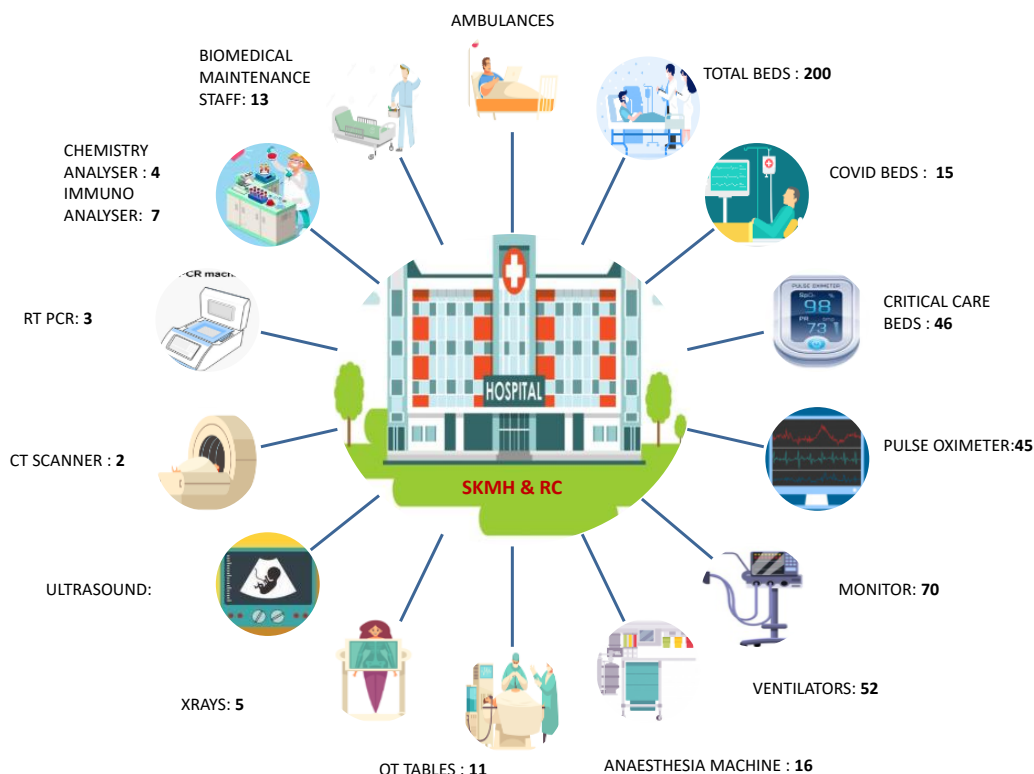
An RFP is generated by the Supply Chain Department based on these recommendations; Technical Evaluation is done by the biomedical department and end user is facilitated with demo for the equipment if requested. Once the equipment is technically approved, the board makes the financial decision keeping in view the technical evaluation and the service provider feedback given by the biomedical department.

Planned Periodic Maintenance (PPM) and Corrective Maintenance (CM)

The total complaints received per month are around 300-350. A work order is generated in the CMMS for both CM and PPM. CM is initiated by the end user while PPM is generated each month as per the yearly schedule. Respective Engineer from the concerned tem is informed about the work order and a user feedback is given by the end user once the work order is completed.

Preventive Maintenance is usually done as per manufacturer's guidance but in some cases, the frequency is cut down by increasing the frequency of Inspection through validation and checking. Corrective maintenance is carried out as per end user's request through a work order. A risk management policy is in place which ensures that adverse events due to faulty equipment are minimized. Investigations are carried out for recurring faults and unbudgeted replacement may be advised according to the condition of the equipment and reoccurrence of faults.

Shaukat Khanum Memorial Hospital and Research Centre, Lahore (Punjab)



20
Figure 17: Medical Equipment and Maintenance Staff in SKMH & RC

Shaukat Khanum Memorial Cancer Hospital and Research Centre (SKMCH&RC) is a state-of-the-art cancer centre located in Lahore, Pakistan. It is a project of the Shaukat Khanum Memorial Trust, which is a charitable organization established under the Societies Registration Act XXI of 1860 of Pakistan. Today, the Shaukat Khanum Memorial Trust has a presence in over fifty Pakistani cities in the form of hospitals, diagnostic centres, walk-in-clinics (cancer screening centres) and collection centres. The Trust aims to build a series of hospitals in various cities of Pakistan to bring cancer care closer to patients.

In Lahore, built in 1994, it is a 200-bed cancer care hospital with 35 ICUs, 11 Isolation beds, 8 Triage and 15 designated Covid beds providing premium healthcare **completely free** to 75% of the patient. SKMH & RC is a **Joint Commission International accredited (JCIA)** facility, one of the only three in Pakistan. It is a paperless hospital and has helped millions of patient with a total of Rs. 46 Billion¹² in philanthropic spending. The Shaukat Khanum Memorial Hospital & Research Centre has an annual budget of Rs. 17 Billion and over 3136 Staff. As shown in **Figure 17**. Shaukat Khanum Memorial Hospital & Research Centre (SKMH&RC) is a well equipment facility with a total of 13 Biomedical Engineering staff to maintain medical equipment. The oxygen Data is summarized in **Table 5**.

Facility Name	Number of Oxygenated Bed	Type of Flow Meter	Number of Functional Flow Meter	Type of Cylinder	Number of Cylinder	Capacity of VIE(L)
Shaukat Khanum Memorial Hospital	195	15L/min	195	680(E)	14	259200
				3400(G)	63	
				6800 (J)	48	

Table 5: Oxygen Supply System in SKMH & RC

SKMH & RC, although being a super-specialty hospital worked as a front line Hospital during the Covid-19 pandemic and has provided quality care, to the people of Pakistan through hospitals and diagnostic centres. During the peak, the SKMH & RC was receiving 200 patients per day with almost 40 percent with COVID-19 symptoms. It is one of the best hospitals in Pakistan and can be considered as a best practice. Hence, we would discuss its maintenance management structure in detail to design a best suited model for maintenance management of medical equipment for hospitals across Pakistan.

Biomedical Department

Life Cycle Management

The Biomedical department of Shaukat Khanum Memorial Hospital & Research Centre comes under the Facility Management Department (FMD). They have a total biomedical inventory of 3500 and receive

¹² <https://shaukatkhanum.org.pk/about-us/facts-and-statistics/>

around 115 complaints on monthly basis. Medical Gas Pipeline, Manifold and VIE tank are managed by the FMD while all the supply system (flow meters and cylinder) are managed by the biomedical department. The Biomedical Team is responsible for the Life cycle management of medical equipment from procurement to disposable. All of these activities are managed by SKMH & RC's in-house developed CMMS system.

Health Technology Assessment

The process is initiated on the request of the end-user, and then various stake holders get involved, starting with information gathering and finishing with procurement of the medical equipment/technology. Given below are the steps involved in the health technology assessment.

- Materials Management department (MMD) contacts all the relevant companies for the required medical technology/equipment, and then subsequently shares all the brochures to the relevant end-user department and Biomedical Engineering department (BMED).
- BMED gives its feedback on the
 - Technical specifications;
 - Past experience with the manufacturer;
 - Services of the local distributor;
 - Approvals from relevant certifying body(ies)
 - Previous recalls or hazard notices.
 - Any documentation and training requirements, and
 - Overall recommendations

This is done through the equipment selection form developed for this purpose.

Departmental Hierarchy

We have a total of thirteen staff members in Biomedical Engineering department. Out of these, there are twelve engineers, including the head of department, and one Help Line coordinator

The hospital departments are categorized as either clinical or diagnostic (referred to as divisions) based on their functionality, and all equipment in these departments are, therefore, categorized as clinical or diagnostic respectively. Engineers as a result have also been grouped to look after equipment in these two divisions. Every engineer is assigned a buddy, a colleague from the other division, to assist him as much as possible.

However, the primary responsibility of the equipment lies with the main member of the pair. This is done to manage and distribute engineer's workload, as well as to have every member of the department trained on as many equipment as possible.

Health Technology Management

Our maintenance management system of health technology is an online module integrated with the Hospital Information System (HIS). In this module we are maintaining the life cycle of the medical equipment from the installation to its disposal. The following services related to the medical technology are logged in this module.

- Installation (To make a newly received equipment functional as early as possible after its inspection)
- Corrective Maintenance (To identify and fix the equipment breakdowns, and give feedback to the end user.)
- Preventive Maintenance (Yearly generated schedule based on OEM's recommendations, through experience and age of the equipment).
- Calibration/ Testing (Yearly generated schedule based on OEM's recommendations)
- Inspection (This is done for a newly received equipment; for critical equipment; and where required).

Break down of Medical Equipment

- Protocols and procedures are in place to ensure uninterrupted services to the patients. This is based on the following steps:
- End-user department enters the complaint work-order in the online module for a faulty equipment.
- Biomedical help line assigns the work-order to the relevant engineer, and assigns a 'priority' to that complaint.
- Complaints priority is set as HIGH if the work-order is for a critical equipment.
- Engineer has to respond to that complaint within 15 minutes, and then 'acknowledges' the work-order in the system.
- If the work-order is for critical equipment, then the complaint has to be attended within 10 minutes.
- Based on the assessment, the engineer also enters the expected time to complete the assigned work. The expected time to complete the work order depends on the nature of complaint, diagnosis time and the availability of spare parts.
- Critical equipment is attended to and fixed on priority, and BMED ensures that relevant spare parts are in stock.
- Once the equipment has been fixed and normal operations are resumed, then the engineer completes the service report, which automatically sends an alert to the end-user so that he can verify the work done.
- In addition, the end-user gives their feedback and performance rating against each work-order by scoring response time, service quality and staff attitude.

Inventory Management System

When new equipment is received, it is inspected and then it is added into the online module of inventory list in the Computerized Maintenance Management System with complete details, i.e. model, serial number, date of installation and warranty period. This is done before the installation takes place, and the installation is done against the online work order. Inventory list is also verified before the end of the year to confirm the active equipment, and to remove equipment from the list that are no more in use. This is also required to finalize the yearly maintenance schedule of the active equipment.

Risk-Based Assessment Strategy

Every engineer is encouraged to conduct analysis of the equipment in their area with the aim to find out if there are unusual and unexpected breakdowns or repetitive issues occurring in the departments assigned to them. This allows them to focus on the root causes of those issues and then fix them appropriately. So, for example, if there are repeated complaints that, after analysis, point towards lack of training of the staff handling that equipment, then the engineer discusses this with his colleagues and senior engineers and devises an appropriate training for the staff. Or if the analysis highlight that it's the age of the equipment that is causing these repeated issues, then BMED recommends budgeting for that equipment for the next year, or its immediate purchase – whichever is appropriate in the given scenario.

As an oversight for this, the department meets every morning for 30 minutes in which every engineer goes over his schedule for the day and gives an update on the outstanding issues amongst other things. This allows for others to give their feedback on these issues as well and it often leads into further analysis of repeated issues.

Availability of spare parts and consumables

Biomedical Engineering department maintains stock of the most commonly used consumables and for spare parts of the critical equipment, where possible. However this is not an exhaustive list, and therefore BMED works closely with the hospital's Materials Management Department (MMD) and local companies /distributors for ensuring timely availability of the required spare parts.

Equipment Disposal/ Discard

Equipment is recommended for discard, or replacement based on the following factors:

- Company's recommendation
- Unavailability of spare parts
- Obsolete Model
- Repeated number of complaints
- Equipment that is not repairable
- Unsafe for patient.
- Cost of repair makes no economic sense.

Fatima Memorial Hospital, Lahore (Punjab)

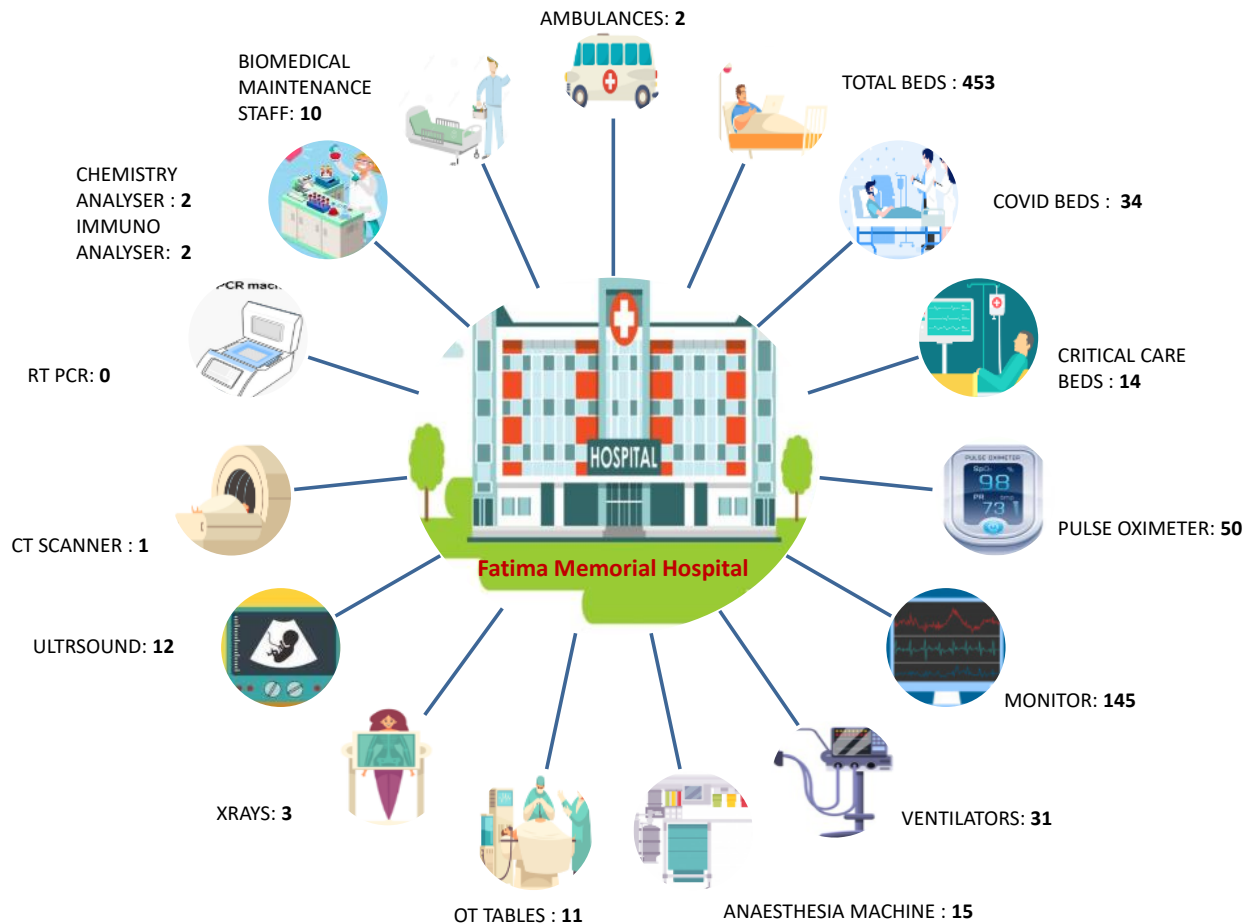


Figure 18: Medical Equipment and Maintenance Staff in Fatima Memorial Hospital

Fatima Memorial Hospital (FMH) was born out of a tragic history of personal bereavement. Maulvi Feroz-ud-din, a prominent scholar, lost his young wife, Kaneez Fatima, during childbirth in 1917, due to a severe lack of adequate medical facilities.

In 1944, he founded the Ferozsons Trust with an initial cash endowment along with all the proceeds from his books. The aims of this Trust were to provide quality medical care to the under-privileged of society on a non-profit, self-sustaining basis and to promote the education and social development of the community. The fulfillment of this vision began in 1971, when his son and daughter-in-law, Dr. Abdul Waheed and Begum Saida Waheed donated their assets towards the construction of a hospital for women and children.

In 1977, it started as a 200 bed community hospital for women and children care. By the Grace of God Almighty in the year 2000, Fatima Memorial Hospital transformed into a 470 bed multi-specialty tertiary care teaching hospital. FHM has a total of 10 ICU bed, 4 HDU Beds and 34 designated Covid Beds. Fatima Memorial Hospital believes in service excellence and quality health care to the ailing humanity. Core

philosophy of functioning of Fatima Memorial Hospital is cross subsidization where funds generated from affording patients are utilized for the benefit of underprivileged and indigents. As shown in Figure 18. FMH is a well equipment facility with a total of 12 Biomedical Engineering staff to maintain medical equipment.

Biomedical and Clinical Staff are responsible for meeting statutory requirements related to medical gases and ensuring their safe usage. The oxygen Data is summarized in Table 6.

Facility Name	Number of Oxygenated Bed	Type of Flow Meter	Number of Functional Flow Meter	Type of Cylinder	Number of Cylinder	Capacity of VIE	Number of times it is refilled per Week
Fatima Memorial Hospital Lahore	225	15L/min	203	6800L(J)	9	5490L	1
				340L (D)	4		
				1360 (F)	52		
				680L (E)	21		

Table 6: Oxygen Supply System in Fatima Memorial Hospital

Safety Feature of the Medical Gas System

All gas pipes are color coded according to C& U Central Uni. Co. Japan standards. That is

- Black for Vacuum
- Yellow for air
- Green for oxygen
- Blue for nitrous oxide

The outlet knobs (with different number of pins and various angles) are design differently for each gas to prevent mixing of gases. Adequate gas cut off valves are installed to shut off a gas supply in case of leakage in an emergency or when repair and maintenance is required. Procedure for safe use and transport of medical cylinders are also in place.

Today FMH stands committed to provide quality health care services to all categories of patients regardless of their ability to pay. The hospital serves not only as a hub for patients, but also as the teaching base of all human health resource which includes the FMH College of Medicine and Dentistry and for FCPS, MCPS, MD & MRCPG training of postgraduate trainees. FMH Continues to be a practice base for nurses trained at the Saida Waheed FMH College of Nursing. The hospital also continues to act as a referral center for patients treated by the mobile health service.¹³

It is one of the best private care facilities in Lahore and can be considered as a best practice. Hence, we would discuss its maintenance management structure in detail to design a best suited model for maintenance management of medical equipment for hospitals across Pakistan.

¹³ <https://www.fatimamemorial.org.pk/history-of-fmh-3/>

Biomedical Department

A systematic approach is taken for inspection, repair, maintenance and technical vetting of medical equipment for Fatima Memorial System (FMS) which includes Fatima Memorial Hospital, Fatima Memorial Dental Hospital, FMH college of Medicine & Dentistry, Saida Waheed College of Nursing, and Institute of Allied Health Sciences.

The mission of Biomedical Services Department is to facilitate and support the delivery of quality health care by ensuring efficient functioning of all medical equipment in the hospital. The Biomedical department consists of a team 10 maintenance staff with a manager, deputy manager, 1 biomedical engineer, 1 associate engineer, 1 senior technician and 5 biomedical technician.

Role

- Carries out inspection, repair, maintenance, commissioning & decommissioning of biomedical equipment.
- Reduces cost on spares, consumables and accessories through planned preventive maintenance. Provides guidance and technical assistance to all relevant departments.
- Installs, maintains, and repair biomedical equipment.
- Evaluates, negotiates and manages biomedical equipment related service and maintenance contracts.
- Performs other duties within the technical scope of the Biomedical Services Department.

Responsibilities

Fatima Memorial Hospital (FMH) operates this policy through Medical Superintendent and manages through the Head of the Department (HoD) Biomedical Services. HoD Biomedical Services has executive responsibility for issues relating to biomedical equipment. HoD Biomedical services reports to Medical Superintendent for financial aspects of maintenance of biomedical equipment. HoD Biomedical is responsible for arranging, managing and controlling all activities related to technical vetting for installation, inspection, repairs, maintenance and condemnation of all biomedical equipment. They are also responsible for the training of all biomedical staff through on-the-job training and training programs. HoD Biomedical ensures that all biomedical staff is familiar with this standard procedure and to monitor compliance. The Biomedical staff works around the clock in three shifts. All staff has been assigned different tasks/ hospital departments for repair and maintenance of assigned equipment.

Complaint Management

Complaints from the end users are received through the Biomedical Module of complaint Management system (cMS). A unique ticket number is generated by the Biomedical Module of cMS for each complaint. The cMS provides the following details for each complaint: ticket number, time, date, complaint originator, from user, and description. The area designated staff print out a hard copy of the complaint and visits the site to address the complaint.

The designated staff attends the complaint and enquires the user about the nature of the fault. They usually carry out visual inspection of the equipment first to locate the fault in the equipment. Biomedical staff checks the presence / continuity of electrical power supply and correctness of required voltage. If spare part is present in the biomedical store inventory, then they will be issued from the inventory (part of the cMS) and CM is done either on site or in the workshop depending on the nature of the equipment. If spare parts are not available then concerned staff will raise the demand to the materials management department and repair the equipment once the part is made available. If problem is unresolvable e.g. rewinding of motors, casting of plastic parts etc. in the biomedical lab, then biomedical staff will call to the supplier/ manufacturer/third party or the machine/ part of machine can be sent to the local market for economical repair. Once the complaint has been answered and repair has been done then a signed form from the complainant is uploaded on the cMS and kept for record.

Planned Preventive Maintenance

There are two types of maintenance procedures, namely:

- Preventive Maintenance by Biomedical Staff
- Preventive Maintenance by the distributor/vendor of the equipment through annual maintenance contract.

Biomedical Staff prepares a schedule of periodic maintenance to be performed on quarterly basis.

Generally, this maintenance includes the following tasks:

1. Visual inspection of the equipment, connectors and tubing for damage, stains, and cracks.
2. Checking for and correcting any gaseous and liquid leakages.
3. Checking for leaks and corrosion of battery terminals.
4. Inspection of AC power plugs and power cords for cracks and deterioration of insulation.
5. Removal of dust/dirt with a dry or damp cloth.
6. Checking of screws, connectors and parts for their tight fitting.
7. Removal of any rust from metallic parts and electrical connections.
8. Functional check of the equipment.
9. Calibration of the equipment if required.
10. After completion of PPM a sticker has been pasted on the equipment.
11. The PPM Performa has also been filled which gives the information of all checked parameters.

For the following equipment preventive maintenance and calibrations are performed by their distributors or any other company through annual maintenance contracts which are renewed on a yearly basis e.g.

- a) Ultrasound Machines
- b) X-ray Machines
- c) Dialysis Machines
- d) Laboratory Equipment

e) CT Scanner

f) Reverse Osmosis plant etc

Distributors send their engineers/ technicians who carry out maintenance in the presence FMH designated biomedical staff and get the PPM Performa signed by the end user as well as Manager Biomedical. In case of any malfunctioning of the equipment other than routine PPM occurs then the concerned company is informed to send their engineers/ technicians for repair.

Disposal

When the Biomedical equipment has reached the end of its useful life and is no longer repairable or further repair is considered to be financially unviable, it is prudent to discard / condemn the equipment according to the Asset Management Policy, MM-SI7. Under these conditions the user department will be advised to request a condemnation of the equipment by using the "CONDEMNATION PERFORMA", available with the Material Management Department (generally known as Store). Condemnation of biomedical equipment can only be authorized after approval has been granted by HoD Biomedical Services.

Records

The Biomedical services Department Keeps the following records:

- a) CMS Complaint Record
- b) CMS Complaint Resolved Record
- c) Telephonic Call Record (Evening & Night Shift)
- d) Biomedical Log Book Equipment sheet Softcopy/ Hardcopy
- e) Periodic Preventive Maintenance Schedule for Biomedical Equipment
- f) Periodic preventive Maintenance Record
- g) PPM Tag Record, pasted on equipment accordingly to the schedule
- h) Periodic Preventive Maintenance / Corrective Service Reports from Contractors
- i) Record of Calibration of Calibrators
- j) Record of Biomedical Staff Trainings
- k) Record of End User Training
- l) Equipment condemnation Record

BERC (P&SHD Punjab)

A Biomedical Equipment Resource Centre (BERC), a first of its kind in part of the Secondary healthcare facilities in Punjab, to efficiently manage biomedical equipment in the province. BERC manages the maintenance system through a networked computerized maintenance management system (CMMS) and Customer Centre to ensure an uptime of 95% of all medical equipment in District Head Quarter Hospitals (DHQs) and Tehsil Head Quarters (THQs). The three main components of BERC (as shown in Figure 19: Three main components of BERC) are:

- RFID tagging and Line Listing (Inventory Management, through ECRI's software)
- Computerized maintenance management System and Call Centre
- Three District Level Workshops and nine associated mobile workshops.

BERC Inventory Management System

Text for printing Max 30 characters

Equipment

id: 70429

Equipment: Anesthesia

Type: THQ

Location:

City: Lahore

District: Lahore

Division: Lahore

Zone: Zone 1

Category: Anesthesia Machine

Sub-Category: Anesthesia Machine

Equipment Type: Medical

Make: Drager

Model: DS-2000

Origin: Japan

Year Build: 1999

Product Details

Supplier: Anesthesia Machine

Purchase Date: 08-Jan-2000

Purchase Price: Rs. 450,000

Purchased By: Govt of Punjab

Notes:

Delivery Date: 24-Feb-2000

Installation Date: 02-March-2000

Serial#: 786876877697

Parts with Serial #:

Warranty Expiry: 08-Jan-2005

SLA: Yes

SLA Vendor:

Start Date: 08-Jan-2015

End Date: 08-Jan-2025

Status

Equipment Status: Active

Status Details:

Repairable: Yes

Non-Repairable Description:

QR Code: LHR_DHQ_70429

Physical Components:

- Anesthesia Machine (80-2A) with a digital display showing '8888' and a QR code.
- E.C.G Machine (003344) with a QR code and a label indicating 'Primary & Secondary Healthcare Department' and 'CALIBRATION'.
- Calibration Tag (1.25" x 2.00") with fields for TAG, DATE, and ENG/L.

Figure 19: Three main components of BERC

BERC is an organization which ensures the equipment life cycle management. Everything is managed through a centralized dashboard as shown in Figure 20

- Planning future procurements.
- Evaluating current contracts.
- Maintaining equipment (PPM and Calibration)
- Identifying and Building capacity of the HR through additional resources and trainings (service and operational).
- Planning Maintenance budgets

- Reporting various Key Performance Indicators (KPIs) for the maintenance system such as disposal, support to PHC and other certifications.

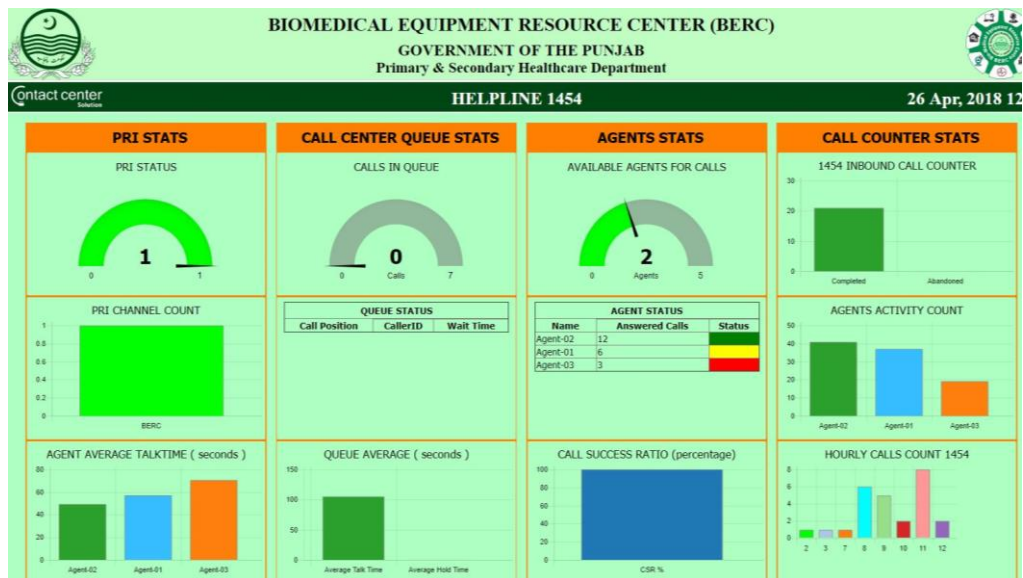
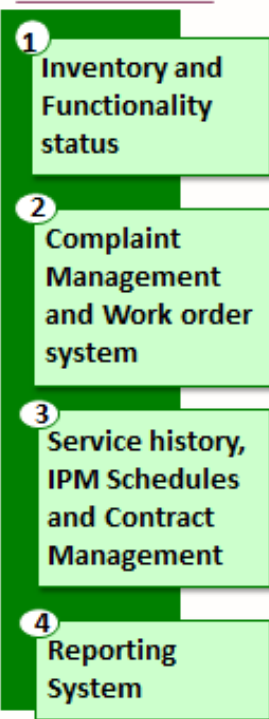


Figure 20: Dashboard for BERC

BERC also acts as a liaison between the procurement department, health facilities and the maintenance mechanism as show in Figure 21.

Components



Details

Will have Equipment Information and will be updated through

- Third Party Audit (RFID)
 - New Equipment Update through Procurement Data
 - In-house Tagging and Verification Team
-
- Complaint log through customer care and the process from work-order generation, execution through existing workshop or external service providers, to completion
-
- Inspection, preventive maintenance and corrective maintenance schedules updated into the system
 - Equipment repair history updated after work order completion
 - Managing existing Service Contracts
-
- Reports various Key Performance Indicators (KPIs) for the maintenance system (downtime, delays, repetitive breakdown etc, disposals and need for new procurement)

Figure 21: Main Responsibilities of BERC

CMMS¹⁴

The CMMS is a networked software package for medical equipment inventory and complaint management and will include inventory, functionality and utilization status, complaint management and work order system, service history, inspection and periodic maintenance schedules, equipment and service performance indicators such as down time, repetitive breakdowns and timely maintenance. The CMMS is implemented with the existing inventory management system to monitor the maintenance and procurement operations for biomedical equipment in all DHQs and THQs through Biomedical Equipment Resource Centre (BERC). CMSS will ensure uptime of 95% of all medical Equipment in DHQs and THQs by aiming that at no given point in time, a single breakdown there are more than 7 days from the date and time of registration of the problem to return to service.

Architecture

CMMS is used to:

¹⁴ BERC-RFP

- Standardize and harmonize information by importing and updating info into the inventory database and exporting utilities
- Assist in the monitoring of planned inspection and planned periodic and corrective maintenance, and schedule and track periodic maintenance and repairs;
- Raise Status flags indicating current status of the equipment (e.g operational, out of order, under installation, awaiting spares, due for replacement)
- Monitor equipment performance indicators such as mean time between failures, downtime and maintenance costs for individual or equipment groups of the same model, type or manufacturer;
- Monitor maintenance providers performance indicators such as repeated repairs for the same problem, average down time associated with individuals, and productive work time for individuals or groups;
- Generate reports that can be used to plan procurement activities, user training programs and to qualify and evaluate supplier and maintenance based on equipment failure trends in certain departments or health facilities;
- Host libraries of training and safety information;
- Generate reports to assist in the monitoring and improvement of the productivity, effectiveness and performance of HTM.

System Features

The CMMS (ECRI®) is a comprehensive, robust user friendly, intuitive system. The system is a 100% Internet –based application requiring no installation on the client’s Machine and is deployed over the Internet. It is an Open architecture with a scalable connection (design and architecture to be used regardless of whether application has 10 or 10 000 concurrent users) allowing integration to other applications on similar or different platforms built using Web technologies and includes mechanism to prevent simultaneous or erroneous updating. All of this is backed up by an excellent 24/7 customer care and support services provided by skilled team of software developers, business and project managers, and administrators who are all experienced in working on such a system.

The system provides backup services. Any removable media device can be used to back up the data. Additionally the system also has an in-built backup routine. The system allows networking facility and all the system data should be stored on just one machine. This is a server.

Key Features include

- Quick search feature for easy access to records
- Extensive complaint records including personal information and contact details
- Multiple issues can be stored against one complaint
- Investigator record including caseload details/allocations
- Quick and easy logging of a complaint
- Capable of storing details of both direct and third party complainants
- Automatic production of acknowledgement email or sms

- Records and tracks key events, deadlines and outcomes
- Highlights overdue actions in progress screen
- Measures time between key milestones and events
- Creates record cards including progress at the click of a button
- Space to record unlimited case notes
- Tailored drop down lists for consistent and simple data entry
- Comprehensive Diary, automatically alerts and generates reminders for all key events
- In-built reports
- Custom reports feature for creation of ad-hoc statistics
- Built-in audit trail recording user data changes
- Multi-tiered, user-level access allows administrators to allocate user permissions and security level

The Software consists of 4 main key areas; Complaint/ Maintenance Module, Resource/Inventory, Contract Management and Reports.

1. Complaint/Maintenance Module

The maintenance module assists the user of the CMMS programme to effectively manage their maintenance schedule. The CMMS can be used for both planned preventive maintenance and corrective maintenance. Planned preventive maintenance with the appropriate inputs, the computerized system can calculate when a piece of equipment will require maintenance and advise which parts might need to be ordered and when. The package can also monitor the maintenance process and log when it has been completed. Fields required for this module may include:

- Equipment-specific acceptance testing, inspection and preventive maintenance procedures;
- Equipment-specific acceptance testing, inspection and preventive maintenance schedule;
- Frequency of equipment fault;
- Estimated equipment running hours.

Corrective maintenance/Complaints

When an equipment user reports a problem with a piece of equipment, the clinical engineering department can log the fault in the CMMS system. The programme will automatically generate a work order and allow the manager of the system to assign a service to the job. The CMMS programme can provide information regarding in-house or outsourced maintenance to assist with this decision. If an initial evaluation of the fault identifies that a specific part is required to complete the job, the computerized system can record this and provide the appropriate ordering information about the part. Once a complaint is logged CMS can produce an acknowledgement, tailored according to the type of complaint, and will set the clock ticking towards the first milestone. Every date in the process can be recorded and reminders automatically generated in accordance with your own procedures.

Correspondence and communication should be tracked. When the job is complete the status of the equipment can be logged in the system and work order can be closed instantly after user satisfaction remarks have been fed in. Whether preventive or corrective, priority levels for the maintenance to be done can be assigned with reference to the equipment risk, the strategic value to the health facility, and the availability of back-up equipment. In addition, maintenance work order forms can be generated in electronic format to include the relevant maintenance procedures required to complete the work order

- Work order manager
- Scheduling
- Priority
- Service charges (e.g. labor time, spares)
- Integrated fields
- Customized fields

Within the complaint record one should be able to store specific details of the complaint (who, what, when, where etc.). Any number of separate complaints for one case can be stored and repeat complaints can also be tracked. Multisite asset tracking and work orders should be allowed

2. Resource/Inventory

Within the resource record one is able to store a range of Equipment details and contact details, correspondence reference and business type of the service provider. Once is able to view all complaints listed including current progress. Additional information and documentation is also recorded here. The Resource module manages the inventory system and imports data from the existing inventory software with QAR codes. It updates it according to the service and maintenance history. Provision for Spare parts management module is also present with

- Inventory control
- Minimum stock order
- Spares order
- Costing
- Parts exchange

This module is an extension of the inventory module that tracks the spare parts related to equipment and helps to maintain stock levels. Stocked parts include those that are common to a number of different pieces of equipment such as fuses, wires, batteries and basic electronic components, and those parts that are more specific to a particular model such as circuit boards, power supplies, X-ray tubes and ultrasound probes. Fields in the spare parts inventory include:

- Part description (name);
- Stock (inventory) number;
- Manufacturer's name, serial and part number;
- Link to equipment model;

- Minimum stock level;
- Current stock level;
- Part storage location;
- Price and date purchased.

The data is used to generate windows that:

- Alert the user to minimum stock levels for particular parts;
- Create reports regarding the frequency of part replacement, which can help with predicting maintenance schedules and future stock levels;
- List all the parts required for certain pieces of equipment;
- Report on the consumption of reused parts.

3. Investigator /Contact management Module

The contract management module tracks all externally provided maintenance services. The main factors to monitor are cost and performance of both vendor and equipment. If the medical equipment is under contract, either through warranty, comprehensive service contracts or partial support service contracts, the vendor is required to provide technical support to the equipment over an agreed period. The CMMS program automatically generates alerts addressed to vendors when a piece of equipment is logged as faulty or is scheduled for inspection and preventive maintenance. The terms and related costs of any contract are stored in the system for reference.

Within this record one can store personal and contact details, view caseload allocations and progress, and store additional information and documents.

4. Reports

This module runs quick, comprehensive, standard, technical and managerial reports. A range of in-built reports should be available here ready for use covering all aspects of recorded information for efficient running of the following departments

- Contract Management Unit (DG office)
- Maintenance Department (Workshops)
- Monitoring and Evaluation (New DG)
- Procurement Cell
- District EDO Health Office

Custom reports features are also be present allowing creation of your own ad-hoc statistics. Some mandatory reports may include:

- Number of Break Down per Equipment in a certain period
- Functional / Non Functional per Equipment type/ Hospital
- Equipment Under Warranty
- Delays in PPM
- Call Centre Response Time
- Engineering Service Response Time
- Incomplete corrective maintenance per company and per equipment type
- Uninstalled equipment
- Downtime
- Equipment Failure Causes, feedback for user training and evaluate Maintenance Services
- User Satisfaction (Quality, Timely Response)

Dashboard summary reports to give an overview of the health technology management program, maintenance activity per health facility. The Work order module is shown in Figure 22

Figure 22: Work- order module for BERC

Hierarchy

The hierarchy of the biomedical workshop associated with BERC is shown in Table 7

Bio-Medical Equipment Repair Workshops

	Name of Post	Total No. of Sanctioned Positions	Lahore	Multan	Sargodha	Total
Contractual	Zonal Head	3	1	0	1	2

Staff	Divisional Engineer	9	3	2		5
	District Clinical Engineer	27	5	2	4	11
	Associate Engineer	27	4	5	6	15
	Network Administrator	3	1	0	1	2
	Total	69	14	9	12	35
Permanent Staff	Total	59	8	11	11	30

Table 7: Total Staff in biomedical workshops

Asset Management and Maintenance

The project was partially implemented and was piloted in Nov 2017. Since then 95 % of the Equipment has been inventoried and tagged. An in-house Call Centre has been established with a hotline. All infrastructure equipment is in place and HR recruited. Training Centre has been established with all IPM equipment and DEMO equipment.

Till April 2018, 3700 complaints have been completed (including installation requests) since the launch in November 2017. Mobile workshops are fully equipped and are handling all complaints since the three main workshops (Lahore, Sargodha and Multan) are under renovations.

Follow up and monitoring was started in April 2018 but was affected by the change in government and still hasn't been fully implemented. The overall impact of the initiative has been tremendous. Punjab has risen from an overall functionality of Equipment in DHQs, BHUs and RHCs of 64% in 2012 to 93% in April 2018.

BERC still faces a lot of challenges in terms of budget and autonomy. But still a lot of progress has been made. BERC was a major reason that facilitated in collection of data for biomedical Equipment in Punjab and made it easier for the decision makers to make informed decision about the availability of essential functioning equipment during the COVID- 19 pandemic. The BERC staff facilitated not only in repair and maintenance of existing equipment but in planning and installation of new equipment.

Hayatabad Medical Complex, Peshawar (KPK)

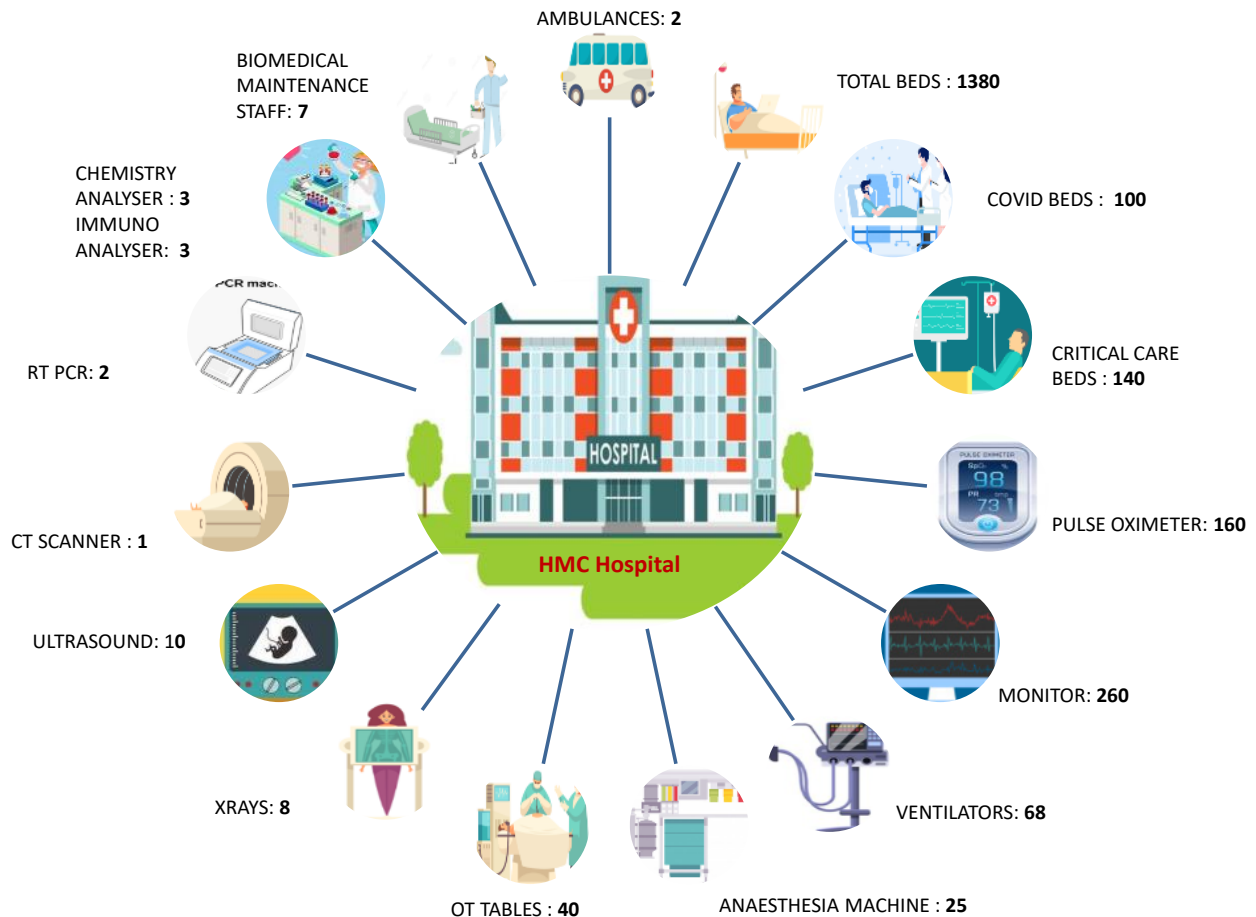


Figure 23: Medical Equipment and Maintenance Staff in HMC

The Hayatabad Medical Complex, a public facility, is a large medical complex and hospital located in the Hayatabad suburb of Peshawar in Khyber Pakhtunkhwa, Pakistan. It is the second largest hospital in the city, it is a medical postgraduate training centre. Hayatabad Medical Complex provides a comprehensive range of preventive, curative, rehabilitative, emergency and educational health services with compassion to the people in KPK, through its healthcare facilities and services with a view to raising the long-term health status of community.

It is a network of hospital, including the Child and Mother Centre, Eye Centre, Kidney Centre and the Burn Centre. HMC is a 1380-bed facility with 40 ICUs, 100 HDUs and 100 designated Covid beds. Since 2017, 3234380 patients have been treated, 90000 surgeries have been performed and 176071 cardiology procedures have been done. As shown in Figure 23. HMC is a well equipment public sector tertiary healthcare facility with a total of 7 Biomedical Engineering staff to maintain medical equipment. There is 1 technician per Centre as well. The oxygen Data is summarized in Table 8.

Facility Name	Number of Oxygenated Bed	Type of Flow Meter	Number of Functional Flow Meter	Type of Cylinder	Number of Cylinder	Number of Cylinder in Oxygen Manifold	Capacity of VIE	Number of times it is refilled per Week
Hayatabad Medical Complex	400	15L/min	400	6800L(J)	12	40	900000L	1

Table 8: Oxygen Supply System in HMC

HMC is a front line Hospital during the Covid-19 pandemic and has provided quality care, not only to the people of KPK but to whole of Pakistan. It is one of the best public hospitals in the province and can be considered as a best practice. Hence, we would discuss its maintenance management structure in detail to design a best suited model for maintenance management of medical equipment for hospitals across Pakistan.

Biomedical Department

The Biomedical Engineering department consists of a team of 7 trained Engineers, including the manager biomedical. There are 2 Senior Engineers and 2 graduate Engineers and 2 diploma Holders. The two Senior Engineers are Modality Specialists. The team is divided into two teams; one team looks after Radiology, Laboratory Services and CSSD Department while the other team is responsible Critical area, OT and Inpatient Department. They have a well-equipped workshop with all of the testing, calibration and repair tools.

Life Cycle Management

The biomedical department is responsible for the life Cycle management of the equipment. The key responsibilities are highlighted below:

1. Purchase and Procurement of biomedical equipment
2. Pre-shipment inspection and post-shipment inspections
3. Pre-requisite for medical equipment including infrastructure, electrification, plumbing etc if required
4. Installation of medical equipment
5. Demonstration of medical equipment
6. Periodic preventive maintenance (PPM)
7. Break down or casual maintenance (BDM or CM)
8. Inventory Management
9. End to end disposable

Purchase and Procurement of biomedical equipment:

The Biomedical engineering department is involved in all sort of purchase in the hospital. Since it is a government hospital, provincial government's procurement rules and regulations are followed. The defined procurement criterion for goods and services as well like mainly as follows;

- Single stage, single envelope
- Single stage, two envelopes
- Two stage, two envelopes

All the technical specifications are prepared and complied by Biomedical Engineering. Technical evaluation then carries out in the presence of all the participating bidders. To get quality medical equipment, 80% weightage is given to technical and 20% to financial. Once the technical evaluation is completed, the lowest bidder is awarded the contract. Biomedical department plays a vital role in this procurement process to avoid any audit objection and get quality and most appropriate and advance medical equipment for the hospital.

Pre-shipment and post-shipment inspection:

After finalizing heavy medical equipment and machinery, pre-shipment inspection at site of manufacturing is performed to ensure authenticity and accuracy of the equipment. The inspector usually marks the equipment with a permanent marker and verifies at the time of delivery at port and in the hospital.

Pre-requisite for medical equipment including infra structure, electrification, plumbing etc if required:

Pre-requisite are the most important especially for sensitive and heavy medical equipment. The biomedical team checks the site before installation and ensures that the space is according to the standards. Electrical cabling and grounding are most important because electrical noise is an issue which is always present there. If there is no proper grounding then most of the equipment will lack accuracy. Dimensions of site are verified and standardized. Room temperature, proper ventilation and humidity are the key checks for pre-requisite planning. Power/load calculation and UPS and backup requirements are all verified from biomedical engineering department.

Installation of medical equipment:

All the installation of medical equipment is carried out in the presence of biomedical engineer to avoid any mishandling equipment and reduce errors at this stage. Onsite trainings are also done at this time. For offsite training, the hospital's protocol has to be followed and can take up to 2-3 months. The department is well equipped with all the biomedical tools using during installation and for repair of the equipment. Proper SOP's and safety protocols are adopted during installation including use of PPE's.

Demonstration of medical equipment:

After successful installation, the biomedical engineer checks the machine, properly calibrates it at site so it is ready to be used. User training is given to the end users (doctors, technicians and nurses) including safety protocols and day to day maintenance.

Planned Periodic Maintenance (PPM):

PPM is done on quarterly and for some sensitive and critical care equipment, PPM might be carried out on monthly basis. All equipment is tagged with specialty wise PPM tags. These include PPM date, next due date, performed by under special code and date is written. During PPM all the parameters are checked, various sensors and consumables may be changed if necessary and the equipment is calibrated.

Break down or corrective maintenance (BDM or CM):

HMC has a comprehensive complaint management system through which all types of complaint received from different areas of the hospital. In the complaint form (Job Form), the complainant name, nature of fault, date, complaint receiver name, time and date, engineer assigned for its trouble shooting, parts required or not, job date etc, is written. All the IC programmers and various components and spare parts are present in the inventory. The department has some general and some specialized tool necessary for the repair of medical equipment. To avoid any sort of misuse of the biomedical equipment by end users, a specialized tagging system (Alert tags) is used of different color (12 different colors) coding based on months of the year. The tags are placed on the equipment according to the month it is repaired on. If 3 tags of the same color are found on the equipment then an investigation is done to do a root cause analysis on the faulty equipment. It can either be due to mishandling by the operator, faulty repairs by the engineer and a need for the equipment to be replaced.

Inventory Management:

HMC has complete inventory of all the fixed assets of the hospital including, biomedical equipment, electrical items, etc. All the equipment is tagged at the time of installation and the serial no's, make, model, country of origin, manufacturing date, date of installation, supplier firm/company, standard warranty period, extended warranty period etc are logged in the CMMS.

Disposal:

Biomedical Engineering department is also involved in the disposal of the equipment after its expiry or EOL (End of Life). All the expired products or equipment which has completed its useful life and repair is not feasible or economical is presented for auction. Items which are considered as waste are properly segregated and are sent for incineration. An open auction is advertised in the newspaper and government auctioneers are called upon to auction all non-useful equipment.

Ideal Biomedical maintenance Department

Biomedical Equipment is an essential part of the healthcare system and an effective biomedical maintenance management system is the key to safe, efficient and economically viable patient outcomes. As we have seen above, all of these national best practices have an effective maintenance management system to ensure 98% for all medical equipment. The maintenance management plays a vital role in the overall life cycle management of the equipment or else health facilities might end with redundant technologies. Ignoring these PPM and validation procedure, CM, electrical safety and functionality testing, proper handling and storage, adverse events and recall can directly impact the clinical efficacy of the equipment and may alter the overall life expectancy of the equipment. To plan an Ideal Maintenance Management, ***“Medical Equipment Maintenance Program Overview, part of WHO Technical Series”, “How to Organize a System of Healthcare Technology Management, Guide 1, How to Manage Series”*** and ***“How to Organize the Maintenance of Your Healthcare Technology, Guide 5, How to Manage Series”*** should be referred to.

Human Resource

Medical device management requires the involvement of staff from all disciplines whether technical, clinical, financial, or administrative, etc. It is not just the job of managers; it is the responsibility of all members of staff who deal with healthcare technology. This may include the departments of Clinical/ Biomedical Engineering, information technology, Nursing, Medical, Finance, Projects, General maintenance, Asset management.

Developing the human resources necessary to operate an effective maintenance program is a slow and steady process. Firstly one needs to identify the number and type of staff required in a facility or a group of facility. Level of facility is also very relevant in this case. For example, a small health-care facility with relevantly small inventory and simpler equipment can do with a single technician (as in the case of associated facilities which HMC). On the other hand, a large tertiary care or specialized hospital will need a complex clinical engineering department with large number of technical and management personnel, including specialists in particular technologies, with multiple levels of supervision (as in the case of AKU). In general, however, there are two categories of clinical engineering personnel: technical and management. The skills found in the local marketplace, and the financial capacity of the organization is also a driving factor in identifying the correct blend of engineers and technicians. Almost all maintenance programs will find it necessary to complement the internal staff with external service providers (either the vendor/ manufacturer’s service representatives or third-party service representatives). The service providers, operate under the supervision of the in house biomedical department’s staff, provide the IPM and CM for equipment that is under warranty and for highly sophisticated equipment that require trained specialists. Figure 24 Classifies and highlights the technical personnel working in/for the biomedical maintenance Department.

Personnel	Title	Role
Engineer	Biomedical engineer or clinical engineer	Management, specialized maintenance, supervision of external service provider, needs assessment, planning, and user training.
	Other related fields (e.g. electrical engineer, mechanical engineer)	Require a training course and certificates to work in the medical device field. Primary focus is on the maintenance of medical equipment and sometimes managerial positions.
Technician	Biomedical equipment technicians	Primary focus on specialized medical equipment repair and maintenance.
	Other related fields (e.g. electrical or medical technologist, polyvalent technician)	Preventive maintenance and repair of less complex equipment. It is important that they receive specialized training for high-risk medical devices.
Service provider	Engineer or technician	Provide maintenance that cannot be performed in house. They are product-oriented and specialized in a certain field.

Figure 24: Classification of technical personnel and their Role

Life Cycle Management

The biomedical departments are usually involved in

- Planning
- Procurement
- Installation and Commissioning
- Inventory and Asset Management
- Training
- Operations, Audit and Maintenance Management
- Workshop Maintenance
- Decommissioning

Planning

Planning can be divided into four major sub-phases:

- Healthcare needs assessment in terms of clinical needs, budget and HR
- Design in terms of level of care

- Infrastructure requirements (Civil, MEP and IT)
- Occupancy (Installation and Commissioning and space planning)

Procurement

The goal of the procurement activity is quality, service and value for money. Usually the biomedical department is involved in the technical activities such as specification design and prequalification of vendor for service quality. Technical specifications are designed as per the need of the organization. Technical evaluation is done by the biomedical department and procurement process is done in a two stage basis where it is mandatory for the product and service qualify technically and then only they can move towards the financial evaluation. The procurement process should have a standardized structure and should be transparent, auditable, effective and fair

Once the financial evaluation is completed and the contract is awarded, the biomedical department liaison with the service provider for contract administration till delivery, installation, commissioning and after sales service

Installation and Commissioning

It is the responsibility of the biomedical/clinical engineering department to ensure all pre-installation checks are complete and facilitate in the civil and MEP works related to the equipment before its delivery.

When a new equipment is received in the hospital, the asset management department should initiate a work order for the biomedical/clinical engineering department. The biomedical/clinical engineering department ensures that the new equipment is inspected for:

- Presence of all accessories required for proper operation.
- Presence of operators' manuals and technical service manuals, and schematics.
- Proper operation of the equipment. For this purpose performance specifications in the manufacturer's service literature should be used.
- Clinical alarm functionality and audibility
- Passage of electrical safety requirements.

The equipment should also check for compliance on labeling of equipment, to ensure that the equipment has been evaluated for safety and suitability for intended use by a nationally or internationally recognized testing laboratory.

Involvement of HTM and End-user departments during the installation and acceptance process is a must. The entire process should be coordinated by the clinical / biomedical department, which should liaise with other groups as required. Reports should be signed from the responsible clinical/biomedical

engineer and end user explaining that the medical device is installed, in good condition and fully functional. Confirmation should be given that all documentation has been delivered including local configurations, as-built drawings, and IT information for connected devices.

If equipment passes all required inspections and installation is completed, then it should be tagged (Identification number and inspection Sticker) and included in the inventory and maintenance program. The clinical engineering technician who performs the inspection is responsible for ensuring the completion of the initial inspection documentation. If the technician determines that an in-service orientation/training would be beneficial, the technician will make a recommendation to the hospital education department or the department manager. Should a manufacturer in-service demonstration be required, the technician will assist in coordinating this effort with the hospital education department.

In case the delivered medical device failed to comply with healthcare facility's identified requirements in the tender, the supply chain Department shall be responsible for liaising with the medical equipment supplier in the event of damaged or inappropriately delivered or irreparable medical equipment.

Inventory and Asset Management

The record for each medical equipment should be included in the the computerized inventory system should identifying data such as:

- Asset Number
- Asset Description
- Facility/Location
- Department
- Room (if applicable)
- Manufacturer
- Model or Product Number
- Spare parts/consumables
- Serial Number
- Biomed / Clinical Engineering Tag Number

It is helpful to also include data regarding the time and expense of providing scheduled and unscheduled maintenance services for the device. These data are typically contained in work order records that provide documentation of every maintenance task performed on the device. As a result, the inventory database will contain the entire technical and financial history for every equipment in the inventory.

This will apply a asset tag to each item inventoried and capture all descriptive data pertaining to each asset.

Training

For the safety of the patient and the user, proper training is critical for both the user and the technical staff. Biomedical engineering departments could usefully be more involved in training for safe medical equipment use. It is observed that Training of users by maintenance Staff can improve the overall management of the equipment. Training of technical staff and operation training can be carried out in a number of ways as listed below:

- Self-study; reading the equipment service and training manuals and materials provided by the manufacturer or the third party.
- One-to-one training (technical or user) provided by a more experienced staff from inside the organization.
- The biomedical equipment technician taking part in an education class for nurses or other clinical users to learn about the operation of the equipment
- Technical and user training by a third party, service provider or the manufacturer.
- Third-party, service provider's or manufacturer 's external training programs for end user and technical Staff

Operations, Audit and Maintenance Management

Contract management 3rd party

Prioritization of Equipment

Based on the complexity of the Equipment maintenance can be organized in a VEN systems

Vital – items that are crucial for providing basic health services and should be kept functioning at all times (for example, electrical generator, operating theatre light, suction pump in the theatre, mortuary refrigerator)

Essential – items that are important but are not absolutely crucial for providing basic health services and a period when they are out of operation can be tolerated (for example, suction pump in a ward, dental compressor, physiotherapy ultrasound)

Not so essential/ – items that are not absolutely crucial for providing basic health services. In other words, it is possible to adapt and plan around their absence if they are out of operation (for example, ECG recorder, lift, a back-up X-ray machine).

Prioritization can also be done through various other strategies such as

- Risk based prioritization (criticality of Equipment)
- Maintenance based prioritization (Maintenance requirement)
- Resource based prioritization
- Mission based prioritization (Certain speciality)

Additionally, as stated in the WHO guide, a cut-off value for Equipment Management (EM) Number can also be used. It is calculated using the following equation. Detailed table for all numbers are given in the guidebook.

EM Number= Function Number + Application Number + Maintenance Number + Incident History¹⁵

Maintenance protocol

It is invaluable to have thorough documentation of all service events which have taken place over the life of the equipment. Being able to keep this in a CMMS for electronic retrieval is ideal, but simply having the information available in a paper format is still useful. The maintenance programme must strive for accurate records of both the total list of equipment requiring maintenance as well as an accurate accounting of the specific work completed. Using an organized CMMS system to print appropriate procedures for each scheduled activity, and a good system of annotations and coding to record the results of the IPM (for quality control and productivity analysis purposes), are good methods to keep records.

A CMMS system may provide the following capabilities essential maintenance operations:

- Keep an inventory of each device in the facility, including the ability to easily add or change the equipment information.
- Keep track of past service events (e.g. IPM, CM, recalls, software updates etc.) and retrieve or print them if needed.
- Store IPM procedures and related information.
- Schedule IPM procedures and protocols (related to functionality and performance), change the schedule of IPM procedures and print a summary list of what has been scheduled.
- Print individual IPM forms with the appropriate procedure, the past few service events (for reference), and the expected IPM completion date/ time.

¹⁵ ***Medical Equipment Maintenance Program Overview, part of WHO Technical Series***

- Record and store the results of the IPM inspection procedures – including tasks that passed or failed, the measurements taken and the acceptable range of measured values.

- Record the CM activity including the problem with the device, time spent in the repair process, a description of the work done and the list of parts used.

- Produce summary reports of:

- IPM completion rates;

- IPM that failed and required repair work;

- IPM actual versus expected completion times;

- Inventory lists of equipment by location, owner or device type;

- Repairs completed in a certain time period;

- List of parts used to repair equipment over a certain time period

Particularly for repairs and corrective maintenance it is essential that a Good Practice Checklist, and basic trouble shooting, maintenance and safety protocols are identified as per the manufacturer's guidelines. Safety Protocol has to be strictly implemented for Personnel and medical Equipment. These should include Electrical safety and infection control.

Separate Labels should be introduced for Installation, IPM and calibration and Corrective Maintenance. Continual Performance monitoring and Performance improvement strategies are essential for smooth management of the department and should also be in place to ensure safe and function medical equipment.

Risk management and Adverse effect reporting

The risks associated with equipment and medical devices are entered onto the risk register for ongoing monitoring and review. If the majority of these incidents are no or minor harm, the ratio of risks to incidents is appropriate and reasonable. A sample incident summary reporting template is shown in Table 9. Incidents marked as 'Red' area areas of concern that need to be brought to the Hospital Boards or regulating bodies' attention. While 'Amber' areas have to be identified and action plans should be in place to ensure that controls are implemented, reviewed & reported on into the organization, specifically to the Medical Devices Committee and the Resuscitation Committee of the organization.

Type of Incident	Number of Incident
Patient care Equipment	
Medical Device	

Total
Severity of incidents
Green(no injury or harm)
Green(minor injury or harm)
Amber(major harm, Injury including permanent
Red (death, Multiple death, catastrophic)
Total
Risks
Open Risk

Table 9: Sample Incident Summary reporting template

Workshop Management

- Sufficient secure workshop facilities (or maintenance rooms) equipped with suitable tools and test equipment should be present
- Adequate supplies of maintenance materials and spare parts stocked in suitably located stores
- Office space including adequate filing facilities and space for record-keeping
- Adequate supplies of stationery for record-keeping
- Adequate technical reference material and access to information-Library of manuals should be maintained
- Adequate access to transport to maintenance staff should be available so that they can carry out their tasks.

Decommissioning

The reasons for decommissioning of equipment can be divided into three

- Factors intrinsic to the device include:
 - single-use designation,
 - inadequate disinfection or sterilization,
 - unresolved performance issues,
 - unresolved safety issues,
 - continuous unreliability or history of serious failure,
 - high cost of repair making the device cost effective or financially unviable, and

- end of life.
- Factors related to the infrastructure (decision to be made by local health care workers) are:
 - reorganization, closure or relocation of the health care facility;
 - shortage of local technical support, spare parts, accessories or consumables; infrastructure incompatibility (e.g. the device must be connected to a network in order to provide electronic health records or for another purpose, but this is not technically or financially feasible);
 - serious concern about unreliable cyber security (for networked devices); and
 - a catastrophic event (such as an accident, emergency or disaster) that may compromise the functioning of the device.
- Factors related to administrative or policy-level decisions are:
 - high maintenance costs,
 - regulatory withdrawal of a medical device from the market,
 - availability of new, more expensive or clinically effective technology,
 - standardization (limiting the number of models of a particular device) and
 - clinical or technical obsolescence.¹⁶

Whatever the reasons a pathway must be chosen; disposal, donation, sale, refurbishing or reprocessing, trade-in or internal reassignment. Firstly, this is based on their, risk and cost associated to the equipment in relation to the personnel and infrastructure available. The next step is to ensure that the device is safe for handling and treatment or removal, by cleaning and decontaminating it, removing patient data, disposing of consumable parts and (if relevant) withdrawing or removing its listing from the paper-based or computerized inventory. In a final step, the preceding stages and the end status of the device should be documented in a report for future reference. A “decommissioning document” may be required in order to remove the device from the asset registry

¹⁶ Decommissioning of Medical Devices, WHO Technical Series

Rationale and Equipment Norms

National

We have compared data from the five hospital facilities taken as the national best practices and tabulated then in Table 10 to infer what has worked for these facilities. Aga Khan University Hospital and Shaukat Khanum Memorial Hospital are also two of the three JCIA accredited institutions in the country.

Hospital Name		AKU	SKM	INH	FMH	HMC
Rationale for Equipment	Number of Beds in a Hospital	723	200	301	453	1380
	Critical Care Beds	195	46	45	14	140
	Pulse Oximeter				50	160
	Vital Signs Monitoring Device	186	70	20	145	260
	Patient Ventilator	617	52	13	31	68
	Anaesthesia Machine	31	16		15	25
	Xrays	7	5		3	8
	CT	2	2		12	1
	Ultrasounds	41			1	10
	OT Table	37	11	1	11	40
	Chemistry Analyzer	13	4	1	2	3
	Immuno Analyzer	13	7	3	2	3
	Ambulances			1	2	2
	PCR	40	3	16		2

Table 10: Equipment Availability in National Best Practices

International

We have compared data from three Low Middle Income Countries; **India, Zambia and Kenya** and have created a comparison table. We have used “Medical equipment standard list for 3rd level hospital, published by ministry of Zambia”, “Medical device by facility, provincial Hospitals, Kenya” and “Guidelines for District Hospitals (101-500 Beds), published by Indian Public Health Standards”. Table 11 shows quantities of equipment, identified in the survey, available in similar type of health facilities for these three countries. India has developed a very comprehensive facility planning guidelines for each type of hospitals. This includes department-wise medical equipment rationale as well. Mexico has a very comprehensive guide “The resource model for planning of medical units, published by the ministry of health”. This guide covers everything from infrastructure, office furniture, ambulances to medical equipment for various types of health facilities (10 bedded Health Centre to a 300 bedded Hospital). The only problem is that this guide is only available in Spanish and is known as :**Modelos de Recursos Para Le Planeacion de Unidades Medicas de La Secreteria de Salud**”. During the Covid Pandemic ECRI® has also

published a list of equipment with quantities for an emergency treatment room and an ICU treatment Room. This resource is also freely available on their website.

Country		Kenya	Zambia	India
Equipment	Type of Hospital	County referral or Provincial Hospital	Level 3 >500 Beds Hospials	300-500 Bedded hospital
	Pulse Oximeter	3	60	21
	Vital Signs Monitoring Device	12	56	31
	Bipap and Cpap			1
	Suction Machine	21	25	18
	Laryngoscope	7	20	15
	Patient Ventilator	2	20	11
	Xray	6	17	6
	CT		1	1
	Ultrasound	1	14	6
	Anaesthesia Machine	4	10	4
	OT Table	4	5	9
	Heart Lung Machine		1	
	Infusion Pump	8	80	10
	Defibrillator	5	11	9
	Dialysis		4	3
	Chemistry Analyzer		2	2
	Immuno Analyzer		2	1
	PCR		2	1

Table 11: Equipment Norms for India, Kenya and Zambia

Discussions

We can take examples from these guidebooks and hospitals considered as national best practices and develop our own benchmark for minimum number of biomedical equipment according to the type of healthcare facility. A medical equipment guidebook relating clinical requirements to the type of facility (Primary Secondary Tertiary or Specialized care) is the need of the hour.

Moreover we also worked on a rationale for Ventilators, Pulse Oximeters, and Anesthesia Machines and Patient Monitoring devices considering these national best practices. This is shown in Table 12 with rounded off ratios to the nearest 0.5 value. A recommended ratio In addition to these in also proposed. Some of these hospitals also have backup for ICU Monitors, ventilators and Anesthesia Machines which have not been made part of the ratios.

Ratios	AKU	SKM	INH	FMH	HMC	Recommended
Critical Bed to Ventilator	1:3	1:1	3.5:1	1:2	2:1	1:1
OT Table to Anaesthesia Machine	1:1	1:1.5		1:1.5	1.5:1	1:1
Total Beds to Monitor	4:1	3:1	15:1	3:1	5:1	4:1
Total Bed to Pulse Oximeter				9:1	8.5:1	9:1

Table 12: Recommended ratios for Ventilators, Pulse Oximeters, Monitors & Anesthesia Machines

Recommendations

Oxygen Systems

Oxygen consumption requires routine monitoring and advanced supply planning while choices are made to prioritize use of limited resources for many public health interventions. Simultaneously, payment delays limit suppliers' working capital and impacts their business viability. These unique dynamics associated with oxygen supply, medical oxygen should only be considered as a therapeutic entity but also an essential utility. This will help in identifying more efficient procedures for the budgeting and payment of oxygen. The patient load and complexities of care required at District Head quarter and Tertiary care hospitals require medical oxygen to be supplied through centralized pipeline system. It should be supplemented by compressed oxygen gas cylinders, which also acts as reserve supply. During COVID- 19 WHO has published various guidelines to plan the oxygen needs. About 75% of the COVID-19 patients requiring hospitalization will be classified as "severe", and 25% as "critical". Thus, the total supply of medical oxygen required can be estimated based on the recommended flow rates for each patient severity category (shown in the Table 13 below).

Hypothetical 100 bed COVID-19 treatment facility				
Disease severity	Avg. O ₂ flow rate		Size of solutions of scale*	
	per patient	Total	PSA Plant	Bulk liquid
Severe 75 patients	10 L/min	75 * 10 * 60 = 45,000 L/hr	= 45 m ³ /hr	= 1.25 m ³ /day
Critical 25 patients	30 L/min	25 x 30 x 60 = 45,000 L/hr	= 45 m ³ /hr	= 1.25 m ³ /day

Table 13: Oxygen supply calculation for a 100- Bed Facility

Centralized pipeline system in health care facilities should be planned according to HTM 02:01 and 02:02 guidelines or the ISO 7396-1:2007. It comprises of a main source of supply (generally with a secondary and tertiary source to ensure continuity of service) connected via a permanent fixed pipeline system to appropriate terminal unit outlets in relevant locations across the site. Plant and system status is monitored continuously by a series of alarms which sound at designated locations to indicate faults or low pressure.

Oxygen Generator Plants can be installed at least at Divisional level. Operations and maintenance can be outsourced for these purposes. The cost of setting up these plants can be made viable by providing oxygen to all districts within the region and by selling oxygen to all private healthcare facilities in the

division. Liquid oxygen tank may be installed at all hospital with 300 bedded capacity or higher. Jumbo sized cylinders should be commonly used in manifold room, which are capable of holding 6800 litres of oxygen. In manifold room cylinders should be arranged into three groups a primary group, secondary group and a reserve tank. Normally, the oxygen gas is used up from the primary group, with gas being expended equally from all cylinders, as they are connected in parallel through a common outlet. Once the levels in the cylinders are sufficiently low, a pressure transducer switches to the secondary manifold; allowing the primary manifold to be replenished.

The Authorities assess the Oxygen requirements of their hospital on routine basis and monitor its consumption. In addition to the covid-19 calculated suggested by WHO there are other simple methods to estimate oxygen uses in District level hospitals. Formula used to calculate the oxygen requirements at the facility level. Typically, one Type B cylinders are used for 3 major surgeries each lasting for an average duration of 2 hours. This information can be used to estimate the Oxygen requirements of a district hospital. Detailed and accurate information can be obtained by analyzing data about Oxygen consumption and different types of surgeries (major /minor) performed by a hospital during a defined time period. Another method to measure the Oxygen requirement is given below.

(No. of beds x 1.25 + ICU and OT x 1.25 + delivery beds x 1.25) x 0.06 = is Oxygen required per hours

Oxygen management not only requires a fool-proof system of delivery and supply of the gas, but also proper procedures in place to ensure that hospitals order appropriate amounts and well in time. It also requires standard apparatus and procedure for maintenance of the medical gas supply system. Medical oxygen is mainly supplied in following ways:

a) Oxygen Cylinders Oxygen gas can be stored in a portable tank. These are called compressed gas systems. They require continuous refills and are thus most useful where central refilling and transportation infrastructure are reliable and affordable.

b) Oxygen Concentrators (Bed side and portable) Oxygen concentrators is a device that takes oxygen from the room, concentrates it for therapeutic use, and removes other naturally occurring gases. It is less portable than oxygen cylinder. The benefits of concentrators are that they are less expensive and don't require filling like tanks. However, they require a consistent supply of electricity and routine maintenance.

c) Central Source (Liquid tank & Oxygen generator) A central oxygen or pipeline, system uses pipes to provide oxygen to various locations within a health facility/hospital. These systems are typically economical in large hospitals that require a high volume of oxygen and can support the costs of the centralized pipeline infrastructure. Liquid oxygen can be stored in a portable tank and connected to central pipeline. Liquid oxygen is highly concentrated, so more oxygen can be stored in a smaller tank. This is useful in large district hospitals because it will evaporate if it isn't used in a timely manner then it will be wastage. Hospitals with higher Oxygen consumptions may use Oxygen generator to produce Oxygen inside the hospitals itself. Such a system may have lower per unit cost of Oxygen but would

require uninterrupted power supply and highly skilled manpower. Comparative of the three supply system is given in Figure 25.¹⁷

Model	Cylinders	Concentrators (Bedside & Portable)	Central Source (Liquid tank & O2 generator)
Description	High pressure gas is supplied via portable canisters (typically 7,500L) and delivered to health facilities, which must exchange the empty cylinders	Oxygen enriched gas is supplied by entraining air from the environment and separating the nitrogen via pressure swing absorption (PSA)	Oxygen is provided via a large central source on-site, most often in addition to a manifold or network of copper pipes
Use case(s)	<ul style="list-style-type: none"> Facilities without a reliable power source or in close proximity of a plant Deliver medium-high output flow; well-suited for all 3 application areas 	<ul style="list-style-type: none"> Facilities with a reliable power source (or backup) Deliver low output flow (~ 5L/min); well-suited for disease management but too low for emergencies 	<ul style="list-style-type: none"> Large facilities with reliable infrastructure and skilled technicians Deliver high output flow and pressure; well-suited for all 3 application areas
Main advantages	<ul style="list-style-type: none"> No need for electricity or highly skilled technicians Low capital investment cost 	<ul style="list-style-type: none"> Can ensure continuous supply at low running cost One concentrator can serve up to 4 beds 	<ul style="list-style-type: none"> Can ensure continuous supply at high pressure Most cost effective system for larger facilities
Main disadvantages	<ul style="list-style-type: none"> Supply is highly dependent on supplier availability Cost of transport can lead to budget constraints System is highly sensitive to leakage Canisters are potentially hazardous (explosion risk) Only one bed per cylinder 	<ul style="list-style-type: none"> Requires access to uninterrupted power Service and supply of spare parts should be foreseen Relatively low output often insufficient for emergency care (ICU) 	<ul style="list-style-type: none"> High capital investment Requires access to reliable and sufficient power source Need for skilled technicians and adequate infrastructure System is potentially hazardous
Peripheral equipment necessary	<ul style="list-style-type: none"> Manometer (Regulator, gauge, flowmeter) Humidifier Nasal prongs/catheter Cylinder Key 	<ul style="list-style-type: none"> Humidifier Nasal prongs/catheter 	<ul style="list-style-type: none"> Cylinders incl. peripheral equipment

Figure 25: Comparative of three Supply Systems

Based on medical oxygen requirements at district level hospitals and considering the best industry practices, following key measures must be taken on national and provincial levels.

Production of Oxygen on Provincial and Divisional Level: Oxygen is an essential drug; still it is produced by only produced by a few vendors in Pakistan. This may result in cost escalations and irrational supply of Oxygen. The government should encourage investment by engaging private sectors through long term agreements in this sector. Vendors may setup Oxygen units in various provinces and divisions depending on the oxygen requirements.

Assessment of Oxygen gas Supply system: Most of district level hospitals do not have piped medical gas system. Also despite heavy consumption of medical oxygen, many district hospitals in bigger cities have single manifolds. Therefore, there is a need to do assessment of Oxygen supply system so that uninterrupted Oxygen supply may be ensured in all district level hospitals. Such assessment should be done at least every five years or at an interval as decided by health department, so that change in demand and technology can be addressed.

¹⁷ Oxygen Guideline and Guidebook, Uttar Pradesh India

Provision of appropriate and adequate technology: All district level hospitals must be provided with sufficient medical gas and air points, as per need of different patient care areas. District hospitals should be provided with potentially life-saving equipment such as Oxygen flow meters (in order to achieve the target saturation range), pulse oximeters, humidifiers and Oxygen concentrators.

Establishment of Medical Gases Committee: Each hospital should have a medical gas committee. This committee should be responsible to ensure that risks from medical gases are minimized and it provides support for handling, storage and maintenance of Oxygen gas in their hospital. In addition the committee will endeavour to improve efficiency and compliance with the set standards.

Oxygen conservation: Pakistan has high incidences and prevalence of child and maternal disease conditions requiring Oxygen therapy for several days. Therefore, to ensure the access of uninterrupted Oxygen supply within limited resources; District level hospitals should focus on Oxygen conservation through routine titration and other suitable methods.

Establishing Oxygen demand analysis and procurement system: Each district hospital should have a system of assessing/forecasting requirements of Oxygen gas. Such assessment should include monthly or seasonal variations in oxygen consumption. Review should also include the performance of medical gas supplier and such information should be used by the District hospital for procurement of medical gas.

Oxygen monitoring system: Most of District hospitals are ill equipped to monitor uninterrupted oxygen supply in hospital, this results in unwanted casualties in critical care areas. Therefore, there is a need to have effective alarm system based monitoring system to supervise the oxygen supply in different areas of hospital especially in critical care areas so that shortage of oxygen supply can be managed in time. Use of dedicated Oxygen monitoring dashboard may also be used for monitoring Oxygen gas supply in District hospitals. Monitoring system should include daily checking and recording of oxygen pressure level in standby cylinders kept in different patient care areas. Similarly, oxygen saturation and delivery system (including flow rate) should be recorded on the patient's monitoring chart.

Maintenance system for Oxygen gas supply system: Maintenance of Oxygen manifold, central pipelines, oxygen cylinder and pressures levels is a specialized job therefore, all District level hospital should have a dedicated trained manpower to maintain the oxygen gas supply systems. Team should have a routine oxygen pressure level and leakage monitoring schedule based on which problem in gas pipelines may be identified and problems are fixed on time to time. Figure 26 Shows activities and troubleshooting required for oxygen cylinders and associated activities

Schedule period	Activities	Check
Daily	Cleaning	<ul style="list-style-type: none"> ✓ Ensure delivery tubes and masks are decontaminated. ✓ If humidifier bottle is used, disinfect and refill with clean water.
	Visual checks	<ul style="list-style-type: none"> ✓ Check cylinder is correct type and correctly labelled. ✓ Check all parts are fitted tightly and correctly.
	Function	<ul style="list-style-type: none"> ✓ Before use, ensure cylinder has sufficient pressure. ✓ Ensure flow is sufficient for intended use. ✓ Close cylinder valve after each use.
Weekly	Cleaning	<ul style="list-style-type: none"> ✓ Clean cylinder, valve and flowmeter with damp cloth.
	Visual checks	<ul style="list-style-type: none"> ✓ Check for leakage: hissing sound or reduction in pressure.
	Function	<ul style="list-style-type: none"> ✓ Remove valve dust with brief, fast oxygen flow checks. ✓ Check flow can be varied using flow control.

Problem or fault	Possible cause	Solution
No oxygen is flowing	<ul style="list-style-type: none"> • Empty cylinder. 	<ul style="list-style-type: none"> • Replace cylinder.
	<ul style="list-style-type: none"> • Flowmeter knob or cylinder flow valve is closed. 	<ul style="list-style-type: none"> • Open valves, and then check meter registers flow.
	<ul style="list-style-type: none"> • Faulty regulator. 	<ul style="list-style-type: none"> • Close all valves and replace regulator.
Leakage from cylinder or flowmeter	<ul style="list-style-type: none"> • Cylinder is not connected to pressure regulator properly. 	<ul style="list-style-type: none"> • Tighten all fittings.
	<ul style="list-style-type: none"> • Faulty or missing washer between regulator and cylinder. 	<ul style="list-style-type: none"> • Replace washer.
	<ul style="list-style-type: none"> • Flowmeter seal damaged or loose. 	<ul style="list-style-type: none"> • Replace sealing washer and realign flowmeter.
	<ul style="list-style-type: none"> • Cylinder faulty. 	<ul style="list-style-type: none"> • Label faulty and take appropriate action.
Leakage cannot be located	<ul style="list-style-type: none"> • Leakage too small to be heard. 	<ul style="list-style-type: none"> • Apply detergent solution (NOT oily soap) to joints. Bubbles will show at leak point. • Clean/replace washer and tighten at that joint.
Flowmeter ball not moving, yet oxygen is flowing	<ul style="list-style-type: none"> • Faulty flowmeter. 	<ul style="list-style-type: none"> • Close all valves, disconnect flowmeter and clean inside. Reconnect and test. • If problem persists, replace flowmeter.
Pressure gauge does not show pressure, yet oxygen is flowing	<ul style="list-style-type: none"> • Faulty pressure gauge. 	<ul style="list-style-type: none"> • Replace pressure gauge.

Figure 26: Activities and Troubleshooting required for oxygen cylinders and associated activities

Operational guidelines for clinical staff of the hospitals: Staff providing oxygen gas should be given an operational manual or guide book devised on national and provincial level as per the type of facility. Such guidebook should describe oxygen management in different conditions of patient so that they can effectively handle oxygen gas administration. Staff should also be trained in the use of a range of different oxygen delivery devices.

Training of staff handling medical gas: Staff responsible for supply and maintenance of medical oxygen should be trained about basic equipment care.¹⁸ Following staff should be involved in the Oxygen supply

¹⁸ Oxygen System Operational Guidebook, Uttar Pradesh, India

and management in the hospital. Facility Management Department/ Biomedical Department should be responsible for the overall use & procurement of medical gases in the hospital. A Medical gas operator should be placed on 24X7 basis and S/he should be designated with following:

- Order medical gases in the hospital.
- Maintenance of manifold, Medical Gas Pipelines and Dispensing Outlet
- Checking the Quality of Oxygen Gas
- Storage of the gas cylinders
- Shifting/moving of cylinders within the hospital
- Replacement of cylinders

Biomedical Maintenance Management System

Maintenance of Biomedical equipment is a collective responsibility of Health Managers at all levels, Health Technology (HT) Managers, Maintenance Staff, User Departmental heads, End User, HT Teams, Finance and Supply Chain Department. It is essential that all these people work collectively together to manage the life cycle of the equipment as shown in Figure 3. The aim should be to provide comprehensive maintenance and management to improve the functionality and life of equipment, simultaneously improving healthcare services in public health facilities- reducing cost of care and improving the quality of care.

There should be a referral network of workshops where maintenance staffs with technical skills are based. However, equipment management should also take place in health care facility under the Biomedical Equipment Department headed by the Health Technology Manager. At every level, there should also be a committee which regularly considers all equipment-related matters, and ensures decisions are made that are appropriate to the health system as a whole. The term HTM Working Group (HTMWG) can be used for this committee, which will advise the Health Management Teams on all equipment issues.

It is advised that system like BERC should be introduced in all provinces and maintenance of all primary and secondary levels facilities should be done through them. As in the case of Punjab, network of workshop in the province should come under the preview of BERC. All Tertiary level health facility should have dedicated in house workshops and a team of at least 8-10 engineers for 300-400 bed facility to evenly distribute the work. To plan an Ideal Maintenance Management, ***“Medical Equipment Maintenance Program Overview, part of WHO Technical Series”, “How to Organize a System of Healthcare Technology Management, Guide 1, How to Manage Series”*** and ***“How to Organize the Maintenance of Your Healthcare Technology, Guide 5, How to Manage Series”*** should be referred to. The workshops should include store for spare parts and consumable for medical equipment.

All planned periodic maintenance (IPM and Calibration) and corrective maintenance activities should be carried out as per the standard guidelines by WHO. A library of manuals should be available to the technical staff and technical training should be carried out on regular basis.

Policy and Guidelines

Additionally, it is advised that on national and provincial level unified best practices in medical equipment management should be devised within healthcare facilities. These include

- Develop guidelines for health technology assessment as a continuous tool for effective planning and management of health technologies.
- Develop guidelines for health technology management to enhance the effectiveness and improve the management of medical equipment, their operation and their rational use within healthcare facilities.
- Increase the life-time and reduce the overall cost of health technology within healthcare facilities
- Mitigate the risks associated with the usage, transportation and storage of medical devices within the healthcare facilities.
- Ensure the medical devices within the healthcare facility are
 - Serve a clear predetermined purpose
 - Utilized appropriately and effectively
 - Suitable for its intended purpose
 - Maintained in a safe and reliable condition
 - Operated in accordance with the manufacturer's instruction by users and professionals who have obtained and maintained the correct level of knowledge and competency necessary, and disposed of appropriately at the end of its useful life.
- Periodically monitor medical equipment that related to the following:
 - Its performance and safety inspection;
 - Calibration;
 - Reporting the related adverse events.
- Perform surveillance tasks to monitor compliance of healthcare facilities with international standards of safety performance for medical equipment”.

- Perform continuous assessment of devices is performed to measure (impact on health, utilization cost, patient experience, performance, comparison with alternative methods, spare parts, down time, service cost, etc).

Way Forward

It is essential that the following steps are implemented Health System Strengthening and to ensure safe, appropriate and reliable biomedical equipment in Pakistan

- National Biomedical Equipment (covering oxygen systems) policy should be introduced.
- All level of facilities should have similar equipment to Bed/critical ratios.
- There is need to involve regulatory bodies such as DRAP in the maintenance management of equipment and compliance to medical equipment standards (IEC, ASNZ, ISO) for patient safety.
- There is a need for a focal person in WHO to coordinate the efforts for best practices, norms and standards with Health Ministry and department of Health related to maintenance and regulation biomedical equipment and medical devices.
- Keeping Covid in perspective, WHO should provide technical support for Emergency Use Equipment in terms of regulation, maintenance and Callbacks.
- Health Ministry Provincial & Department of health should be advised on setting up training workshops and institutes of biomedical engineers.
- QMS (SOPs) should be designed for each level of facilities on how to maintain and manage medical equipment through provincial level workshops and in the health care facility.
- Basic trouble shooting and most common maintenance problems for all equipment should be identified and a national repository should be devised.
- Designate dedicated maintenance staff and dedicate a maintenance budget on national and provincial levels or Maintenance firm for repair of critical equipment
- Health Ministry Provincial Department of health should be advised to create a network of master trainers on equipment maintenance (All equipment included) by engaging engineering from AKU, SKM and other national best practices and service engineering firms, and repeated training should be provided on a national and provincial to ensure better management of equipment
- Create an facility wise essential medical equipment list keeping in view WHO's published Document and national and international best practices (India, Mexico)
- National Advisory Boards should be created to estimate Risk and Adverse effects caused by medical equipment.