Chapter

1

Procurement, Use and Maintenance of Neonatal Equipment: Practical Considerations

Optimum care of sick and small neonates necessitates the use of biomedical equipment. These gadgets range from simple thermometers to microprocessor-based incubators and ventilators. Some equipment is manufactured in the country, while other needs to be imported. However, all of them entail quite a cost for a poor country like ours. Pediatricians endeavoring to establish neonatal units, often with limited resources and in the face of competing priorities, find it difficult to decide the right category and make of equipment. Once acquired, the equipment may remain idle or in disrepair for ages due to trivial reasons or lack of effort on the part of the supplier or the user or both. Indeed, equipment maintenance is a nightmare for any physician.

We would now be able to take up some important questions regarding neonatal equipment.

What equipment do I need to acquire?

This is the most important question. The equipment you choose should be priority-based, rational and affordable.

The scope and stage of the neonatal care services one proposes to develop determines the package of equipment you require. For instance, resuscitation equipment (suction machine, resuscitation bag, oxygen and laryngoscope), thermometer, oxygen hoods and a weighing scale are usually the first bunch of equipment required to start a newborn service. At this stage, one will also require plenty of disposable items such as feeding tubes, syringes, katori–spoons, intravenous cannulae and small volume infusion sets. One may then supplement them with radiant warming system(s) or incubators. The next logical equipment to buy are perhaps a phototherapy unit and a pulse-oximeter. The latter is an excellent monitoring device that provides not only oxygen saturation in the blood but also the heart rate. It gives a warning in the event of hypoxia, bradycardia and tachycardia.

The issue of rationality in deciding the equipment needs elaboration. It is irrational to think of buying a ventilator before ensuring provision of pulse oximetry and arterial blood gas (ABG) estimation. In addition, there must be sufficient staff round the clock to manage the ventilated neonates. Likewise, it is irrational to have pulse oximeter but no oxygen hood to deliver oxygen.

Which indigenous equipment is of acceptable quality?

In recent years, good quality indigenous equipment of certain categories has become available. These include resuscitation bags, weighing scales (up to 1–10 gm sensitivity), oxygen head boxes and radiant warming (open care) systems. On the other hand, locally made phototherapy units, incorporating white tubelights do not provide adequate irradiance but recently blue light sleek light emitting

diode or compact fluorescent lights which are lightweight portable are available in the market. Those using halogen bulbs, although effective, are bulky, tend to overheat the baby, and their bulbs have a short life. Incubators and CPAP machines made in the country are also not of satisfactory quality as yet. Currently even infusion pumps and pulse oximeters are being assembled in the country but they need to improve the quality of the products.

Is it better to buy indigenous or imported equipment?

For obvious reasons, this choice is unavailable for equipment like non-invasive blood pressure monitors, ventilators, blood gas analyzers and bilirubin analyzers which are not manufactured in India. For that equipment which is manufactured in India and is of reasonable quality, it is better to buy an Indian product. The cost is usually much lower than the imported versions, although, often they do not have impressive looks and are not as sturdy. For the cost of one imported open care system, you can acquire 3 to 4 indigenous ones which is a good deal in practical terms.

Do you think there should be accreditation for medical equipment in India?

Yes, accreditation and standardization are extremely necessary to monitor the quality of the mushrooming of small time equipment manufacturers in India. Today, anybody can start manufacturing equipment, like any other small business, without any permission or license. By the same norm, the quality of equipment sold by the MNCs needs to be filtered. Also India should not become a dumping ground for other countries. In the US, Japan and China, one needs to have FDA, PMDA and SDA approvals respectively, to sell medical equipment. Similarly, no medical equipment can be installed in the European Union countries, unless it carries the CE mark.

Are the domestic manufacturers losing out to the MNCs? Is there a clash of clientele?

No, there is no clash. The MNCs target the corporate hospitals and super-specialty hospitals, mainly institutes, where price is less of a concern for buying equipment. Only 0.5 percent of the population, i.e. the high income group can afford the treatment offered by corporate and super-specialty hospitals. The indigenous industry has customers mainly in nursing homes, clinics as well as private and government hospitals.

What is the scope of the growth of the medical equipment market?

As of today, the 5000 crore diagnostic and imaging equipment industry, to a large extent dominated by MNCs, like GE, Philips Medical Systems, Siemens, etc. is growing at a rapid pace of 15–20% annually. In the health care, medical equipment market segment is one of the top growth markets in India. It is estimated to be $922 million in 2010 and is forecast to reach $1,693 million by 2014. The market is highly dependent on imports, with more than 50% of the demand fulfilled by imports.

What protocol recipient needs to follow while accepting equipment from donor?

Following checklist will help

1. Prepare an equipment checklist and check whether the equipment to be received conforms to the set checklist. This checklist should be made considering factors such as name/brand of the equipment, country of origin, company track record, installations if any around, import legalities involved, *octroi,* sales tax if any applicable, technical specifications, such as humidity, temperature, voltage, frequency, current required, size, weight, etc.
2. Whether equipment is provided with the required accessories and reasonable quantity of spares and consumables

essential for the basic operation of the equipment. This should take into account the "lead period" (i.e. period between placing an order and receipt of spare parts).

3. Whether equipment can be fully supported with spares/accessories in the recipient's country/area.
4. Whether equipment is provided with a complete manual of operations and technical manual, for its use by the end user and the technical team for maintenance.
5. Ensure availability of the required trained staff (clinical and technical) for the installation, operation and maintenance of the equipment.
6. Keep maintenance costs, import costs, taxes if any, in mind, etc.
7. All new equipment must be accompanied by documents of warranty/guarantee.
8. Availability of required space for the equipment, keeping in mind factors such as accessibility, environmental conditions (temperature, humidity, etc.), utilities such as required power supply, gas supply, type of water if required, etc.
9. Availability of the support services required for the optimal functioning of the equipment.
10. Involve technical departments and the end user for the type of equipment required, its use, application, etc.

Enumerate Obligations of Genuine Donor for Humanitarian Cause

Following stated guidelines if implemented and ensured are sure to assist an effective donation of the medical equipment thereby complying with its basic reason of donation: "Optimal use of functional ability of the equipment".

1. Ensure that the equipment supplied is clinically, technologically, ergonomically and economically appropriate for the recipient.
2. Request for the equipment checklist set by the recipient and verify whether the equipment to be supplied conforms to the same. Both the donor and the recipient should reach an agreement on all conditions before the shipping of the equipment.
3. A basic list of all components must be provided and the "life expectancy" of the equipment should be clearly stated.
4. Ensure that the equipment supplied is fully equipped with the required accessories, spares, manuals and other related documents.
5. Supply an initial requirement of essential spares and consumables as agreed upon.
6. Provide the manufacturer's contact details to ensure easy accessibility by the recipient in case of any queries, requirements (of spares/consumables), etc.
7. Provide the contact details of the authorized distributor/local dealer if any.
8. Ensure proper packaging and provide the complete packaging list to the recipient.
9. Packaging should be strong and sturdy to avoid damage during transportation.
10. Ensure immediate delivery of all the shipping documents to the recipient to avoid delay in receiving the equipment, due to unavailability of essential shipping documents required at the recipient end.
11. Understand the import regulations/liabilities like taxes, import duties, etc. and the regulations for donated equipment if any of the recipients' country. Ensure the ability of the recipient to conform to such liabilities/regulations.

How should one select a particular brand of equipment?

This choice should depend on a careful scrutiny of all the available brands.

1. Make sure that the given equipment is technically capable of providing the required care, has reasonable precision of controls, provides the required alarms, is

sturdy and sleek, runs on 220 volts, has good wheels, and so on. Go for equipment holding certification of standards (ISI, ISO, FDA, PMDA, etc.).

2. Check about the functioning of the equipment from friends and colleagues who have used the same equipment. Also confirm the track record of the company from the users. A company having a headquarter or an agent near one's town may be in a better position to provide satisfactory service.
3. Bargain for the price because affordability needs to be taken into consideration in selecting one brand versus the other.
4. For indigenous products especially the life-saving machines be very sure to buy safe and reliable machines. Unfortunately in India we do not have strict laws which can have check on marketing of these products.

While buying equipment, what other practical points should be kept in mind?

1. Ask for sufficient warranty period (say, 2 years with spares, plus 3 years without spares) in writing, specifying the frequency of preventive maintenance checks during that period.
2. Ask for reusable and not disposable parts/ accessories for items such as incubator probes or BP cuffs. Include additional accessories to last 2 to 5 years. For instance, extra tubelights for phototherapy units, extra temperature probes for the incubator, extra cuffs for BP monitors or probes of pulse oximeters should be procured. These should be included in the initial order.
3. Take commitment from the supplier to install the equipment by a specific date and to train one's staff in the use of the equipment through a specified number of training sessions. Also, insist on providing users' manuals.
4. Take commitment from the supplier to provide service for at least 7 years (which is the usual life of electromedical equipment) in writing, specifying the "uptime" (time for which the equipment shall be functional, usually taken as 90%) and "response time" (time taken to examine the equipment upon receiving a complaint, usually less than 24 hours).
5. For imported equipment, make sure that the local supplier possesses an authorization from the parent company. For highly expensive equipment, a counter-guarantee of service should also be taken from the foreign principals.
6. Check with the supplier if any preinstallation facilities (such as wall-mounts) are required.
7. It is advisable to run all equipment on stabilized voltage to guard against damage due to fluctuation in voltage which is so common in our country.

How does one maximize the use of available equipment?

Here are some suggestions for getting the best out of your equipment:

1. Train all concerned staff in proper handling and use of the given equipment. Reinforce this by simple placards explaining the steps of correct use as well as how to switch it off and keep it properly when not in use.
2. Provide a copy of users' manual in the unit and display simple trouble-shooting tips.
3. Include the demonstration of use and trouble-shooting of the equipment as a part of the postgraduate assessment and examination. This will help the residents to master their correct use and care.
4. Insist on regular disinfection after use of the equipment on a baby.
5. Encourage at least one person in one's team to master the care of the equipment. He/ she can help solve the day to day problems in their use.

How does one ensure good maintenance and service of equipment?

One has to be obsessed with ensuring full functioning of the equipment; only then can one ensure that most of the equipment under

one's charge remains in working order. Hardly any suppliers, whether of the indigenous or the imported equipment, will ever come up to expectations in providing satisfactory service. Be prepared to be after them to get one's work done.

Insist on preventive maintenance visits. Formulate annual or biannual maintenance contracts and earmark funds for spares and accessories. It is advisable to maintain an equipment register in which the events pertaining to the equipment (from acquisition, installation, cost, to breakdowns) is recorded. Keep record of when the complaint was lodged. Do send a written complaint if verbal/telephonic complaint is not responded to in a reasonable time. Do not hesitate to write to the parent company if there is unacceptable delay in repairs. Documentation is a deterrent to the companies and can be used in due course to inform the principals or seek redressal at the consumer courts. Tell one's friends about the companies with callous attitude so that they do not become their victims. Raise these issues at annual meetings of the professional organizations such as National Neonatology Forum. One can write to equipment committee of NNF. For details visit website www.nnfequipment.org Do not give up till your equipment is repaired and made fully functional! We do that for our personal vehicle!