Developing a Database of Generic Specifications for Medical Equipment for Healthcare Institutions in a Developing Country

S.B. Sinha¹, A.R. Gammie² and P.J. Mellon¹

¹ Ministry of Health and Family Welfare, New Delhi, India
² Fishtail Consulting Ltd., Marshfield, UK

Abstract— With many complex items of equipment available in the market and healthcare professionals being so dependent upon them it is always a time consuming exercise to set up committees for preparing clear specifications for medical equipment. The Ministry of Health and Family Welfare of the Government of India decided to develop a database of specifications. Committees of experts were set up to frame the basic specifications. A team of consultants were entrusted with the job of providing engineering, health and safety inputs for the equipment. A dynamic web-based database has been developed which will soon be launched on the website of the Ministry and will also be linked to the new Procurement Management and Information System. The database will be made more widely available.

Keywords— Specifications, database, medical equipment.

I. INTRODUCTION

In a developing country the doctors are busy with the patient workload and cannot spare time to develop generic specifications for purchasing medical equipment. Substantial time is wasted in framing individual specifications. The cycle from making an indent to forming a committee and the vetting of the specification by experts is long.

Equipment specifications can also compromise on health and safety standards since biomedical engineers are either not available or are not involved in the process of framing specifications. This has given rise to serious problems like baby incubators catching fire since electrical safety checks were not complied with. In addition, the quality of procured equipment will be sub-standard if the specification is not thorough.

These difficulties cause the procurement cycle to be substantially delayed. Also, if the specifications are not generic there is the potential for litigation from the bidders and the bid may fail as a result. This severely affects the progress of healthcare programmes and patients will suffer.

To address this issue the Ministry of Health and Family Welfare of the Government of India decided to prepare a Compendium or Database of Medical Equipment Specifications. A committee of specialists was formed and the Ministry’s Empowered Procurement Wing was tasked to make a dynamic framework for the Compendium which can be used at the central as well as the state level.

II. MATERIALS AND METHODS

A. The committees of clinical experts

Committees of experts in 44 disciplines were formed by the Director General of Health Services (DGHS). The committees deliberated and with detailed discussions came out with a database of medical equipment specifications based on past procurement. Since the task was to list specifications for 800 plus items and involved over 200 doctors it took substantial time.

B. List of departments

The equipment was classified into 44 departments and committees of experts were formed from premium hospitals under the Director General of Health Services. These departments are AIDS, Anesthesia and OT, Biochemistry, Blood Bank, Burns and Plastic Surgery, Biotechnology, Cardiology, Cardiac Thoracic and Vascular Surgery, Dentistry and Dental Surgery, Dermatology and STD, Dietetics, Drug Lab Equipment, Emergency Services, Endocrinology, ENT, Forensic Medicine, Food Lab Equipment, Gastroenterology, General items, Gynecology and Obstetrics, Histopathology, Hematology, Hospital Wards and Sanitation, Immunology, Microbiology, Nephrology, Neurology, Neurosurgery, Office Equipment, Ophthalmology, Orthopedics, Pediatrics, Pathology, Pharmacology, Physical Medicine, Physiology, Psychiatry, Radiology, Radiotherapy, Respiratory Medicine, Surgery, Transport Equipment, Urology and Waste Management.

C. Involvement of Empowered Procurement Wing (EPW)

The Empowered Procurement Wing then substantially revised the compendium of specifications with the following terms of reference:
1. Review the specifications and make them generic.
2. Make a uniform format for the specifications and incorporate all health and safety requirements, engineering inputs, environmental issues like electromagnetic compliance, all the documentations required, power supply requirements and warranty and post warranty commitments including after sales service.
3. Involve biomedical engineers as well as teams of doctors to bring the compendium up to international standards.
4. Make this a dynamic, web-based system and involve IT Consultants to link to the Procurement Management Information System (PROMIS)
5. To incorporate UMDNS (Universal Medical Device Nomenclature System, ECRI Institute, Plymouth Meeting, USA) nomenclature and coding. To also examine the feasibility of incorporating the UNSPSC (United Nations Standard Products and Services Code, www.unspsc.org) coding system.
6. To coordinate funding from DFID for assisting with man-power and resources required.

D. Template for specifications

Biomedical engineers from EPW and Fishtail Consulting (Marshfield, UK) finalized the template to be used for every specification. It was based on a published format [1], was modified several times and finally is as given below:

**Header:** Name of the equipment.
ECRI Code and UNSPSC Code

1. Description of the function. In this block a brief function of the equipment is provided.
2. Operational Requirements. In this block a brief description of the operational requirement is given, like portability, microprocessor controlled system etc.
3. Technical Specifications. Generic technical specifications were filled up in this block. This is the major section, with all the parameters like dimensions and technical requirements.
4. System configuration and accessories. Under this block all the accessories along with the quantities required are filled up. This will enable the equipment to be supplied with all the accessories in suitable quantities so as not to miss any important items which are required to make the equipment fully functional.
5. Environmental Conditions. In this block the operating requirements as well as storage conditions with respect to temperature and humidity conditions are specified. Also the electromagnetic compliance (EMC) ratings wherever required is added.

6. Power Supply. Under this block the requirement of power source was specified, like 220V single phase supply or battery operation etc. Also specified is any requirement of voltage stabilizer and UPS or battery back up etc.
7. Standards, Safety and Training. Under this block international standards like FDA approval, CE marking or Bureau of Indian Standard markings are specified. Also specified are requirements for electrical safety and for critical devices such as ventilators as per standards of the International Electrotechnical Commission and ISO. Also specified are end user training requirements for effective usage of the equipment. Comprehensive warranty and annual maintenance contracts can also form a part of this block, although the tender documents will normally spell these out in more detail.
8. Documentation. Under this block, requirements such as inspection and calibration certificates, operating and service / maintenance manuals, spare parts list, list of available service equipment required for preventive and corrective maintenance, log book etc are specified.

E. Resources

Funding for the project, including subscriptions to the material detailed below, was provided by the Department for International Development, UK. This included a team of local consultant biomedical engineers, procurement experts and IT specialists based in the Empowered Procurement Wing of the Ministry. An external consultant biomedical engineer was also contracted. A team leader supervised the entire activity including coordination with DFID and the Ministry. All were supernumerary to the Ministry’s regular staffing level.

For technical information, a subscription was made to the ECRI Healthcare Product Comparison System (ECRI Institute, Plymouth Meeting, USA). Also consulted was the Bureau of Indian Standards (BIS), which has its catalogue available electronically. Additional coding is provided under a subscription to the UNSPSC system.

III. Present Status

The compendium is now available on the website of Ministry of Health and Family Welfare [2]. There are more than 800 items specified, listed under 44 faculties. The web based system is also in trial phase and is ready for review with guest password.