

# Medical Devices for Developing Countries: Design Constraints and Approaches

Amit J. Nimunkar, Jonathan Baran, David Van Sickle, Naresh Kumar Pagidimarry and John G. Webster

**Abstract**—Medical devices intended for use in developing countries have certain differences compared to those used in developed countries. Thus, many of the medical devices built for developed countries may not be compatible with the environment in developing countries. In this specific case study we consider the respiratory problems in India and elucidate design constraints and approaches for the development of medical devices to diagnose them.

## I. INTRODUCTION

According to the World Health Organization (WHO), currently 86% of the world's population spends \$6 per capita on medical equipment as compared to the \$290 per capita spent by developed countries. Because low – cost medical devices are not available in developing countries, medical practitioners commonly diagnose a patient without essential clinical information. Thus, there is a need to design low – cost medical devices to perform accurate diagnosis and make healthcare affordable to general population. However, special considerations should be made during the design of medical devices for developing countries. This paper highlights some of the design constraints and approaches that need to be considered for diagnosis of respiratory diseases in India.

One of the leading chronic diseases affecting more than half a billion people worldwide is asthma and chronic obstructive pulmonary disease (COPD). These diseases are not prevalent in developed countries but are still a huge global health problem. The dramatic rise of these problems in recent years have resulted in intense epidemiological investigation, development of clinical practice guidelines, and the launch of numerous global initiatives.

## II. MOTIVATION

Despite advances in understanding the pathogenesis of asthma and the development of more effective medications, morbidity and mortality from asthma has continued to increase. Worldwide, one in every 250 deaths is attributed to asthma (estimated at 255,000 in 2005) with over 80% of

these deaths occurring in low – and middle – income countries [1]. The economic burden of asthma is considerable in terms of both direct medical expenditures (such as hospital admissions and medications) and indirect costs (such as absences from work and premature death).

### A. Acute Respiratory Infection

Acute respiratory infection (ARI) is the most common cause of death in children under age of five in developing countries. Acute lower respiratory infections (ALRIs)—which, in contrast to upper respiratory infections, rapidly become life threatening—account for 13% of all deaths in India and an estimated 25% of all mortality cases in children under five. At any given time, approximately 15 to 20% of children under age five in India have some type of ARI. The large number of ARI cases impose great strain on the health care system, accounting for more than one – fourth of consultations and about one – fourth of hospital admissions [1].

### B. Factors responsible

A number of common environmental exposures in low – and middle – income countries either increase the risk for the onset of asthma and COPD or cause exacerbations of existing disease. For example, exposure to outdoor air pollutants—the levels of which in Indian cities are among the highest in the world—is a major cause of asthma aggravations, respiratory illnesses and, all – cause mortality [1 – 3]. Indoor air pollution—resulting from the widespread use of biomass fuels for cooking and heating, often in unventilated situations—and a high rate of tobacco smoking also represent major public health problems and important risk factors for a variety of respiratory disease [1]. In addition, high rates of occupational asthma (and other lung disease) occur in a range of common industries in these countries because of inadequate workplace protections [1, 4 – 5].

### C. Prevention and other measures

A primary goal of global asthma activities is to encourage practitioners to recognize and diagnose asthma; yet practitioners in India face a number of practical hurdles in doing so. Chief among them is a different overall burden of respiratory diseases, many of which have signs and symptoms that overlap with asthma. This proves cumbersome to medical practitioners to recognize certain typical manifestations of asthma.

The epidemiological studies conducted in India and other developing countries show that a significant percentage of

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Amit J. Nimunkar, Jonathan M. Baran and John G. Webster are with the Biomedical Engineering Department at the University of Wisconsin, Madison, WI 53706 USA (corresponding author phone: 608-263-1574, fax: 608-265-9239; email: webster@engr.wisc.edu, ajnimunkar@wisc.edu, baran@wisc.edu), David Van Sickle is with the Department at Population Sciences at the University of Wisconsin, Madison, WI 53706 USA (email: vansickle@wisc.edu) and Naresh Kumar Pagidimarry is with the Academic Center for Regulatory Affairs and Services at the St. Cloud State University, St. Cloud, MN, 56301 USA (email: agidimarry.nk@gmail.com)

children with asthma are diagnosed with recurrent pneumonia or tuberculosis [6 – 8]

In India, acute respiratory infections account for 40% of all childhood illnesses and approximately 30% of deaths among children, and each year, 2.2 million new cases of tuberculosis are diagnosed across the country [9]. Global efforts to improve asthma care through guidelines have assumed that a primary determinant of the diagnosis and management of asthma is the level of knowledge of physicians.

### III. EXAMINATION OF NEED

The prevalence of lung and respiratory diseases has directed the focus of the project to understand the needs of the affected region. As such, the incidence of asthma and allergy, delivery of health care and cost comparison of some of the products available for diagnosis were examined.

India’s per capita public spending on health is approximately 1.1% of gross domestic product (GDP) and is substantially lower than most other countries with comparable per capita GDP. Private health spending far exceeds the public spending [11]. The private sector is not highly regulated and is sometimes expensive for the patient. This coupled with the high cost of medical devices has deprived lower and middle – income people of access to proper health care facilities. Table 1 shows some of the pulse oximeters and spirometers sold in India and their costs.

TABLE I  
RESPIRATORY DIAGNOSIS DEVICES

System	Technology Used	Cost (Rs/\$)
<b>Pulse Oximeter</b>		
Mediaid (Opto Circuits) M340	Handheld Pulse Oximeter	23000/454
Mediaid (Opto Circuits) M900	Desktop Pulse Oximeter	28000/553
<b>Spirometer</b>		
Recorders and Medical Systems LTD. India Helios 701	Desktop Spirometer	88200/1760
Recorders and Medical Systems LTD. India Helios 401	Spirometer with data accessibility through USB	65000/1300

### IV. LOW-COST SPIROMETER AND PULSE OXIMETER

This examination of needs has identified that (a) reduction in cost of the medical device and (b) educating the patient on the usage of the device, are two ways to approach this problem. The reduction in cost will help make healthcare affordable to a larger population, primarily consisting of lower and middle – income groups afflicted with respiratory and lung diseases. Figure 1 shows the concept model of a handheld device being designed with the ability to be connected to a number of different modules which would

assist medical practitioners in diagnosing a patient. Figure 2 shows the spirometer and pulse oximeter sensors to be interfaced with the handheld device. In addition a temperature sensor will also be included. Along with these modules a Universal Serial Bus (USB) connection will provide increased usability for the end user if a personal computer is available.

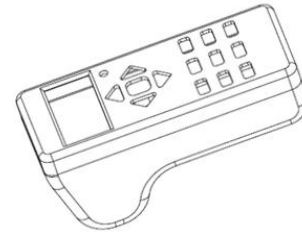


Fig. 1. The basic handheld device to interface spirometer, pulse oximeter and temperature sensor

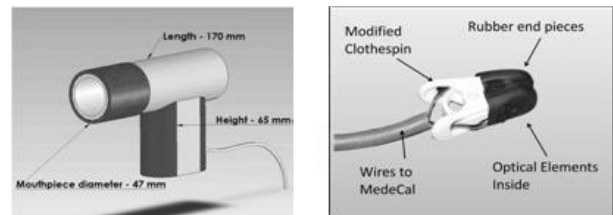


Fig. 2. The spirometer and pulse oximeter sensors to be interfaced with the handheld device.

#### A. Low-Cost Alternatives

As summarized in table 1, cost is still a major consideration for medical devices in India. As the medical device companies in developed countries spend hugely on improvement of their existing products, it increases the cost of healthcare. These improvements to current medical products may not necessarily correlate to increased functionality. Thus, in the design of medical devices for developing countries like India, the design specifications have to be framed such that it reduces the cost of the end product. These considerations are taken into account with the proposed handheld device.

#### Collaborative Efforts

The project is initiated as a Biomedical Engineering student design project at the University of Wisconsin (UW), Madison. Three teams, each of four students worked on the preliminary design of various aspects of the project. They were supported by faculty members, physicians at UW and an interdisciplinary group of graduate and undergraduate students. Their work was taken further by a group of summer interns from different parts of US and other developing countries. Physicians from developing countries extended their collaborative support for the project. On a whole the project is being carried out in an in – house collaborative environment which is a crucial factor in developing the product at low – cost.

## B. Medical education

Some of the medical practitioners in developing countries like India might not have proper expertise otherwise considered commonplace in developed countries. Therefore, educating medical personnel about technology and its usage will be an important factor for the development of medical technology in underprivileged communities. This can be accomplished by incorporating video tutorials in the device to train the physicians and technicians on proper usage and safety measures. Similarly, video tutorials will be provided for the patients to direct them about the maneuver they need to perform effectively.

## V. DEVICE DESIGN CONSIDERATIONS

The two approaches mentioned above have led to further design considerations for the basic handheld device, as described below:

### Accuracy, Reliability and Durability

Accuracy, reliability, and durability are parameters that are determined with respect to the desired market cost. Cost must be minimized to ensure the target population's access to the technology. However, harsh environmental conditions associated with rural medicinal practice, insist the medical device to be more durable, with respectable accuracy and reliability.

### Size and weight

The medical devices should be less in weight and portable due to the lack of space in most of the hospitals in developing countries. The portability of the medical device enables the devices to be easily carried from one unit to the other in a hospital.

### Materials

If medical devices are intended for large-scale manufacturing in developing countries, unit materials must be locally available for distribution to the manufacturers to minimize production costs.

### Power requirements

Any electrical device, must account for the power availability. Medical devices which operate on battery power are especially important in emerging countries. Batteries are used as a means of electrically isolating the high voltage wall outlet, and, they also ensure that the device works in power fluctuations, as power layoffs are prevalent in most of the developing countries.

Presently only around 55% of households in India are electrified [14] leaving over 20 million households without power. The supply of electricity across India currently lacks both quality and quantity, and has a poor record for outages with high levels of transmission and distribution (T&D) losses, and hence needs an extended and improved infrastructure [15].

### Ease of manufacture

As many of the devices which will be designed, manufactured and sold in the same country, problems in manufacturing should not be a concern. The easier it is to manufacture the better the product.

### Language Barriers

Since most of the countries in the developing world are multilingual compared to the developed countries, language issues should be addressed. Specifically, in India 29 languages are spoken by more than a million native people [16]. Therefore, this constraint should be taken into account during the design of the product.

### Facilities available

The facilities available in developing countries like India are very important in the design of a medical device.

In India, there are approximately seven physicians, and eight nurses per 10,000 people. The existing public health infrastructure is not evenly distributed across the states. Many institutions are not functional due to staff shortage, unavailability of drugs, consumables and essential equipment [16].

Although, India may lack some facilities that developed countries may have there is a surprisingly high portion of technology penetration within the Indian market for wireless/cellular technology. However, the computer and internet penetration in India is only 0.58 and 0.68 per 100 people respectively [17]. But the cellular market has a penetration of over 11 per 100 people with growth still booming with a customer base of over 93 million subscribers [18]. Thus some of the problems could be alleviated by using wireless and telemedicine technology in healthcare. A USB connection can be included in the device (depending on the feasibility). This will allow software updates, software to provide additional functionality for each module, interfaces to open source medical record keeping software, and telemedicine capabilities.

### Population dynamics

Certain population dynamics need to be considered when designing medical devices for developing countries, such as the target population. In India, for example the rural population is 27.8%, 57% of the population is in the age group of 15 to 59 while 8% of the population is in the age group of 60 and above. However, the overall literacy rate within the country is 64.8% [16].

### Implementation in the Target Country

Considerations such as medical device registration, product standards, intellectual property, and import/export policies must be taken into account with the design of the product. As this can vary dramatically from country to country, the specific target case of India will be further analyzed.

#### 1) Medical Device Registration

The regulatory agency in India that governs the rules, standards, and approval process for manufacturing of medical devices is the Central Drug Standard Control

Organization (CDSCO). Currently, very few medical devices need registration according to the Drugs and Cosmetics Act. These do not include pulse oximeters, spirometers, and thermometers [20]. However, as regulations in India continue to become stringent, more devices would be required to be registered.

### 2) Standards

Since products designed and manufactured in India do not require FDA approval, the International Organization for Standardization (ISO) will provide relevant standards for each of the medical devices to be manufactured. The pulse oximeter will be designed in accordance with ISO 9919:2005, digital thermometer in accordance with EN 12470-3, and the spirometer in accordance with ISO 26782. All devices will be designed with IEC 60601-1, which describes electrical safety protocols for medical devices.

### 3) Intellectual Property

Since manufacture and sales will be outside of the United States, patents need not be acquired in the US. However, patents will be filed with the Indian Patent Office. Intellectual property continues to be one of the concerns western companies face upon entry into India [21]. With continued perseverance from the World Trade Organization (WTO), there will be increased intellectual property protection in the future.

### 4) Exporting and importing

If manufacturing facilities are not well established in India at the time of production, manufacturing can be initiated in the US, pending FDA approval. Medical devices subject to export fall into two categories, namely, legally marketed and unapproved devices. Legally marketed devices are intended for distribution within the United States and unapproved devices are intended for distribution outside the country.

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