

# Low-cost Medical Devices for Developing Countries

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**Abstract**—Medical devices intended for developing countries have inherent differences from those intended for developed countries. Thus, many of the medical devices built for developed countries are not compatible with developing countries. In this specific case example we look to a target population: India and its respiratory epidemic as the focus for our study. The study will include different aspects of the medical device design process from development to implementation with specific examples for use in India.

## I. INTRODUCTION

According to the 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 solutions are not available in developing countries, medical practitioners commonly make decisions without essential information. A change in medical device technology could be used to fill this void as current products generally are designed for the developed world. However, special considerations should be used when designing products intended for use in developing countries. This paper considers some of these design constraints and issues with design implementation for a specific target application: the Indian respiratory epidemic.

One of the leading chronic diseases affecting more than half a billion people worldwide is asthma and chronic obstructive pulmonary disease (COPD). Long considered afflictions of developed countries, the importance of these and other chronic diseases as global health problems has risen dramatically in recent years, prompting intense epidemiological investigation, the development of clinical practice guidelines, and the launch of numerous global initiatives.

## II. MOTIVATION

Despite advances in the understanding of 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 five years of age 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 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 cases of ARI places great strain on the health care system, accounting for more than one-fourth of consultations and about one-fourth of hospital admissions.

### 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 exacerbations and respiratory 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 to doing so. Chief among them is a different overall burden of respiratory diseases, many of which have signs and symptoms that overlap with asthma, complicating the ability of providers to recognize certain typical manifestations of asthma.

Not surprisingly, epidemiological studies conducted in India and other developing countries show that a significant percentage of children with asthma are diagnosed with recurrent pneumonia or tuberculosis [6–8]

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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 epidemic of lung and respiratory diseases has prompted us to find and fully understand the needs of the region affected with these diseases and define the problem that we plan to solve. We examined the prevalence of asthma and allergy, delivery of health care and cost comparison of the some of the products available for diagnosis.

India's per capita public spending on health is about 1.1% of gross domestic product (GDP) and is much lower than that of most of the other countries with comparable per capita GDP. Private health spending far exceeds the public spending. [11]. The private sector is not highly regulated and sometimes is 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 helped us identify 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 design of a handheld device we are designing with the ability to connect to a number of different modules which would assist medical

practitioners in assessing the status of a patient. Figure 2 shows that the modules that will be included with the first version of this device will be a spirometer, pulse oximeter, and thermometer. Along with the modules a USB connection will provide increased usability for the end user if a personal computer is available.

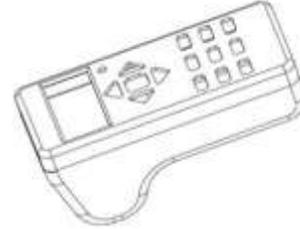


Fig. 1. The basic handheld device to interface spirometer, pulse oximeter and temperature sensor



Fig. 2. Left: spirometer sensor, Right: Pulse oximeters sensor will contain light emitting diodes and a photodiode.

#### A. Low-Cost Alternatives

As summarized in table 1, cost is still a major consideration for medical devices in India. As is the case in the developed world medical devices are overpriced leading to increases in the cost of healthcare. This overpricing can be attributed to the high spending which medical devices companies use to improve upon an already existing product. These improvements to current products add only marginal value to the end customer.

Therefore, when developing medical devices for developing countries products must be greatly simplified to minimize their cost. Therefore versatility could be a major design feature which could be added to improve the value of a medical device.

These considerations were addressed with our handheld device, which connects to different modules, thus increasing the versatility, as well as by using only "bare-bones" modules to decrease the cost of the product.

#### B. Medical education

As the medical community in India continues to progress, many medical practitioners still do not have some of the basic knowledge which is considered commonplace in developed countries. Therefore, educating medical practitioners about technology and how to use it will be one

of the most important factors for the development of medical devices.

## V. 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 three important design considerations, as they can greatly differ when compared with their developed world counterparts. Accuracy is generally not as important to the developing world as it has become in the developed world. The specific end user of the product will determine the need accuracy for the product. Reliability and durability are generally much more important to the end consumer compared with accuracy. With products which don't have reliable warranties or products which have been donated with little or no support, reliability has become a major consideration in the purchase of a product.

### **Size and weight**

Space comes at a premium in hospitals in developing countries throughout the world. Many patients are generally combined into one single room, which means that products should be as small and light as possible which leads to increased portability.

### **Materials**

If medical devices are intended for manufacture on a large scale in developing countries care must be taken to ensure that these materials will be available for distribution within the intended country.

### **Power requirements**

Any devices which will be electrical in nature, must take into account the power concerns throughout the intended country.

Medical devices which operate on battery power are especially important in emerging countries. Not only should batteries be used as a means of electrically isolating the high voltage wall outlet, but also they are required to ensure that medical devices will continue to operate since in developing countries power can be sporadic at best.

Presently only around 55% of households in India are electrified (MOSPI 2006) leaving over 20 million households without power. The supply of electricity across India currently lacks both quality and quantity with an extensive shortfall in supply, a poor record for outages, high levels of transmission and distribution (T&D) losses and an overall need for extended and improved infrastructure [15].

### **Ease of manufacture**

As many of the devices which will be designed will be ideally sold and manufactured in the same country, ease of manufacture should be taken into concern. The easier it is to manufacture a product the better.

### **Language issues**

Language issues should be addressed for many countries within the developing world as multilingual countries are far more common as compared with developed countries. Specifically in India 29 languages are spoken by more than a million native speakers, 122 by more than 10,000 [16]. Therefore products should be developed to take into account this design constraint.

### **Facilities available**

The facilities available in the intended market are very important to consider in the design of a medical device.

#### *India*

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 and nonavailability of drugs and consumables and essential equipment (WHO).

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 problem could be alleviated by using wireless and telemedicine technology in healthcare. We plan to incorporate a USB connection to allow for software updates, software to provide additional functionality for each module, interfaces to open source medical recording keeping software, and telemedicine capabilities.

### **Population dynamics**

Certain population dynamics need to be considered when developing products for developing countries. Specifically who is going to be targeted for your product.

In India the rural population is 27.8%, 57% of the population is in the 15 to 59 age group, while 8% of the population is in the 60 and above age group. 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 controls the rules, standards, and approval process for manufacturing of medical devices is the Central Drug Standard Control Organization (CDSCO). Currently in India very few medical devices need registration according to the Drugs and Cosmetics Act. These do not include pulse oximeters,

spirometers, and thermometers [20]. Therefore registration of the medical devices within India is not expected now. However, as regulations in India continue to become more stringent we do expect to have to register our devices.

### 2) Standards

Since products designed and manufactured will not obtain FDA approval, the International Organization for Standardization (ISO) will provide relevant standards for each of the medical devices to be manufactured. The pulse Oximeter is 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 occur outside of the United States, patents will not be acquired in the US. However, patents will be filed with the Indian Patent Office. Intellectual property concerns continue to be one of the concerns western companies face upon entry into India [21]. With continued perseverance from the World Trade Organization (WTO), intellectual property protection should continue to get better. Now Medecal does not feel a need to be concerned about the protection of intellectual property. Much of the technology that will be introduced presently exists.

### 4) Exporting and importing

Medical devices developed within the United States must have FDA approval in order to ship outside of the country. Medical devices fall into two categories related to the export of medical devices: 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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