2.2 An estimation of the pulse oximetry gap

No study has ever quantified the extent to which pulse oximetry devices are available to operating room personnel in low and middle-income countries. Even basic information such as the number of operating rooms and the types of monitoring devices is lacking. Anecdotal evidence suggests the presence of an enormous and pervasive “pulse oximetry gap,” defined as the number of pulse oximeters needed to achieve 100% penetrance in a given setting. To estimate this “gap,” other data sources must be examined.

We must first estimate the total number of operating rooms in resource-constrained settings. This will give us a sense of the “operating room market.” Once this market is estimated, the gap in pulse oximeter availability can be evaluated. Given the universal use of pulse oximetry in high-income countries, the gap is assumed to be present predominantly in low and middle-income countries. Using 2007 Gross National Income per capita data, The World Bank has defined these types of countries as follows:11

- low income country: $935 or less
- lower middle income country: $936 - $3,705
- upper middle income country: $3,706 - $11,455

Since an accurate estimate of the total number of operating rooms in poor and middle-income countries does not exist, and a time-consuming survey is impractical given our timeline, we identified two principle ways to estimate this:

1) Hospital bed-based calculation: WHO collects data on the number of hospital beds within a country, and the number of operating rooms can be derived from an assumed relationship between hospital beds and operating rooms within a hospital. Anecdotal evidence suggests that there are approximately two operating rooms for every 100 beds in the poorest of settings. This gives us a minimum estimated figure of approximately 208,200 operating rooms in low and middle-income countries.

2) Operative volume-based calculation: We have recently published an estimate of the number of major operations performed annually around the world.4 The number of operating rooms can be derived from an assumed relationship between it and the number of operations performed in a country. If each operating room performs 3 cases a day and runs 5 days a week, or 260 days a year, there are approximately 124,780 operating rooms in low and middle-income countries.

In order to determine the immediate “operating room market” for pulse oximetry, we need to estimate the penetrance of these devices in operating rooms throughout a country, or conversely the “pulse oximetry gap.” Limited survey data suggest that pulse oximetry is present and functioning in 5% of the operating rooms in low income countries, 20% of the operating rooms in lower middle income countries, and 50% of the
operating rooms in upper middle income countries. Using hospital bed and operative volume-based calculations of the total number of operating rooms, the immediate market for pulse oximetry is likely between **90,000** and **150,000** devices as shown in Table 1.

For comparison, we have also included in Table 1 an estimation of the potential pulse oximeter market based on population figures. If we wish to make a public health argument for pulse oximetry as an essential item for use in hospitals, we need to consider not only the hospitals that currently exist, but also those that should exist if a country were meeting the true needs of its population. By this estimate, if we assume that a country should provide one pulse oximeter for every 5000 people (a rough estimate of what is currently provided in developed settings), the total market for pulse oximetry in low and middle income countries is likely more than 1 million devices.

**Table 1. Pulse oximetry market estimates based on total number of operating rooms (from hospital bed and surgical volume extrapolations) and a population-based market assessment**

<table>
<thead>
<tr>
<th></th>
<th>Operating room market estimate based on number of hospital beds</th>
<th>Operating room market estimate based on operative volume</th>
<th>Population based market assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td># of operating rooms</td>
<td>Pulse oximeter penetrance</td>
<td>Pulse oximeter market</td>
</tr>
<tr>
<td>Low Income</td>
<td>24,974</td>
<td>5%</td>
<td>23,725</td>
</tr>
<tr>
<td>Lower Middle Income</td>
<td>112,151</td>
<td>20%</td>
<td>89,721</td>
</tr>
<tr>
<td>Upper Middle Income</td>
<td>71,083</td>
<td>50%</td>
<td>35,542</td>
</tr>
<tr>
<td>Totals</td>
<td>208,208</td>
<td><strong>148,988</strong></td>
<td>124,784</td>
</tr>
</tbody>
</table>

As demonstrated by the population-based estimate in table 1, which exceeds 1 million pulse oximetry devices, the hospital bed and operative volume approaches probably both underestimate the true pulse oximetry market. They do not take into account labor rooms, post anaesthesia recovery rooms, emergency rooms, intensive care units, and other areas where pulse oximetry clearly has a place in clinical evaluation and monitoring. They also do not account for the future market as surgical services increase in the developing world. There is a vast distance between what is currently provided and what is actually needed in terms of surgical services in much of the developing world. As countries address the shortfall of surgical services, the need for and use of pulse oximetry for safe anaesthesia monitoring will need to increase in parallel.
Figure 1 illustrates the pulse oximetry gap in the 25 countries where the gap is believed to be greater than 1,000 devices (note the change in units on the y-axis for those countries with a market less than 10,000 and those with a market greater than 10,000).

Figure 1. Immediate market estimate for pulse oximetry (blue line) and the total number of operating rooms based on number of hospital beds (orange bar). NB: there is a change in scale of the Y-axis at 10,000 devices.

To calculate the pulse oximeter market, we have used the operating room as the initial goal for distribution. Each operating room has been targeted for introduction of a standing pulse oximeter, thus making the item an essential monitoring technology. There is also the potential to target health personnel as a purchaser of individual, portable pulse oximeters. This would make the item an essential personal diagnostic tool similar to a stethoscope. Clinicians from specific specialties (such as anaesthesia, critical care, emergency wards, neonatal wards, and pulmonology) would find such an item of
particular utility. However, for the purposes of this project, we have focused only on devices suitable for use in the operating room.