Quality of medicines for life-threatening pregnancy complications in low- and middle-income countries: A systematic review

An estimated 295,000 women die every year due to complications of pregnancy and childbirth. Most of these deaths occur in low- and middle-income countries (LMIC).

The main causes of maternal death are:
- Postpartum haemorrhage (PPH): 27%
- Pre-eclampsia/eclampsia (PE/E): 14%
- Sepsis due to direct maternal infections: 11%

It is estimated that 1 in 10 medicines in LMIC are substandard and falsified medicines.

Adequate and timely use of good quality, safe, effective, and affordable medicines is essential to... reduce maternal mortality and to achieve universal health coverage.

Objective: to identify, critically appraise and synthesize findings of studies on quality of selected medicines (uterotonics, tranexamic acid, magnesium sulfate, and injectable antibiotics) available in LMIC.
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Included studies looked at the quality of medicines at different points in the health supply chain.

Flow chart of the process of study selection:
- 9,918 records identified through database searching
- 9,699 total unique records screened
- 122 selected for full-text reading
- 234 full-text articles assessed for eligibility
- 34 studies conducted in 40 countries
- 12 studies in Asia
- 14 studies in Africa
- 4 studies in Latin America
- 3 studies conducted in more than one region
- Nearly half of the studies assessed samples collected since 2011, indicating that the quality of these medicines is a current global concern.

Study country income category:
- >1 income level: 6 studies
- Upper-middle: 4 studies
- Lower-middle: 18 studies
- Low: 6 studies

Quality of study:
- High: 12 studies
- Low: 22 studies

Publication date of studies:
- 2000: 7 studies
- 2001-2011: 12 studies
- 2012-20: 15 studies

Included studies looked at the quality of medicines at different points in the health supply chain:
- National providers
- Wholesaler
- International providers
- Central/Regional Medical Store, District Health Office
- Health Center
- Community Health Worker
- Drug Shop / Pharmacy
- Clinic
- Drug Shop / Pharmacy
- Women

Central level: Warehouses, major distributors or central medical stores

Peripheral level: Clinics, hospitals, local medical stores, pharmacies, or markets that sell directly to customers.
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Prevalence of samples that failed quality tests

<table>
<thead>
<tr>
<th>Medication</th>
<th>% Fail</th>
<th>Samples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ergometrine</td>
<td>75.4%</td>
<td>500</td>
</tr>
<tr>
<td>Oxytocin</td>
<td>39.7%</td>
<td>979</td>
</tr>
<tr>
<td>Misoprostol</td>
<td>16%</td>
<td>411</td>
</tr>
<tr>
<td>Cefazolin</td>
<td>13.6%</td>
<td>449</td>
</tr>
<tr>
<td>Penicillin G</td>
<td>13.5%</td>
<td>118</td>
</tr>
<tr>
<td>Ampicillin</td>
<td>9.4%</td>
<td>266</td>
</tr>
<tr>
<td>Gentamycin</td>
<td>3.4%</td>
<td>223</td>
</tr>
<tr>
<td>Magnesium sulphate</td>
<td>2.9%</td>
<td>179</td>
</tr>
<tr>
<td>Metronidazole</td>
<td>3%</td>
<td>34</td>
</tr>
</tbody>
</table>

*Several studies assessed >1 uterotonic or >1 antibiotic. There were no studies on carbetocin, TXA and clindamycin.
Conclusion:

There is a widespread problem with the quality of medicines used in LMIC to manage postpartum haemorrhage, pre-eclampsia/eclampsia and infections. This could be a contributing factor to the persistence of severe maternal morbidity and mortality in these settings despite affordable and effective treatments.