IMPLEMENTATION OF XDR-TB TREATMENT PROGRAM USING COMPASSIONATE DRUGS: ARMENIAN EXPERIENCE WITH BEDAQUILINE

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Tuberculosis Morbidity and Mortality in Armenia (2001–2012)
Treatment Success Rates Among New Smear (+) Patients

- 2007: 69%
- 2008: 73%
- 2009: 73%
- 2010: 72%
- 2011: 77%
Introducing Compassionate Use of New TB Medicines in Armenia

- Confidentiality agreement between NTP and Janssen Research and Development, LLC, in October 2012
- WHO Green Light Committee mission recommendation
- Bedaquiline importation on humanitarian grounds
- First request to Janssen—February 2013
  - 23 MDR and XDR-TB patients have been approved by Janssen
  - 16 patients were put on treatment
  - 7 patients waiting for drugs
- Guideline approved for treatment of patients with XDR-TB
Compassionate Use of Medicines
Patient Eligibility for Compassionate Use

- Life-threatening condition—XDR-TB or pre-XDR-TB
- 18 years or older
- Deteriorating clinical condition due to TB
- TB treatment options are severely limited
- Women must be on adequate contraception
Submission and Approval for Compassionate Use

1. Selection based on eligibility criteria (MOH/NTP and MSF doctors)
2. Present to the Armenian DR-TB Committee for endorsement
3. Submitting to the MSF/Partners in Health Medical Committee for endorsement and clinical advice.
   - Members: 3 from MSF, 2 from PIH, 1 expert from Argentina, and 1 from the Union
4. Two external experts are consulted in case of disagreement within the committee
5. Written consent from the patient
6. Final approval by Janssen
Access to Medicines

- Import of bedaquiline (is available free of charge) supported by MSF
- Use of bedaquiline orally
- Use with other TB medicines
Clinical Follow-Up

• For the first two weeks, perform daily clinical follow-up
• Then weekly for the first two months, do baseline clinical assessment
  • Complete blood count
  • Liver and renal function tests
  • ECG and X-ray
• Assess liver and renal functions weekly for the initial 2 months
• ECG is performed weekly for the first month, then monthly if there are no abnormal findings
• Periodically assess and evaluate all serious adverse events
### Status of Patients Receiving Compassionate Use Treatment in Armenia (By November 15, 2013)

<table>
<thead>
<tr>
<th>Patients</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients approved and on treatment</td>
<td>24</td>
</tr>
<tr>
<td>Patients approved and refused treatment</td>
<td>4</td>
</tr>
<tr>
<td>Rejected by J-J or MSF</td>
<td>5</td>
</tr>
<tr>
<td>Died before starting treatment</td>
<td>3</td>
</tr>
</tbody>
</table>
## Treatment Results By November 15, 2013

<table>
<thead>
<tr>
<th>Bacteriological Status</th>
<th>Patients Started Treatment</th>
<th>Patients Started Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smear and culture negative</td>
<td>3</td>
<td>Still same</td>
</tr>
<tr>
<td>Smear negative and culture positive</td>
<td>5</td>
<td>2 converted by culture</td>
</tr>
<tr>
<td>Smear and culture positive</td>
<td>16</td>
<td>8 converted by smear and culture, 3 converted by smear but still positive by culture</td>
</tr>
</tbody>
</table>
Conclusion

- Potentially lifesaving and new hope for patients
- Expansion of the clinical skills of doctors and nurses and the introduction of new approaches in treating TB patients
- Additional monitoring and reporting systems are required for adverse events
- Although it is too soon to draw wider conclusions, the outcomes of the initiative look promising