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

ARMEN HAYRAPETYAN, MD, PhD
DIRECTOR OF NATIONAL TB CONTROL OFFICE, ARMENIA

ANTALYA, TURKEY
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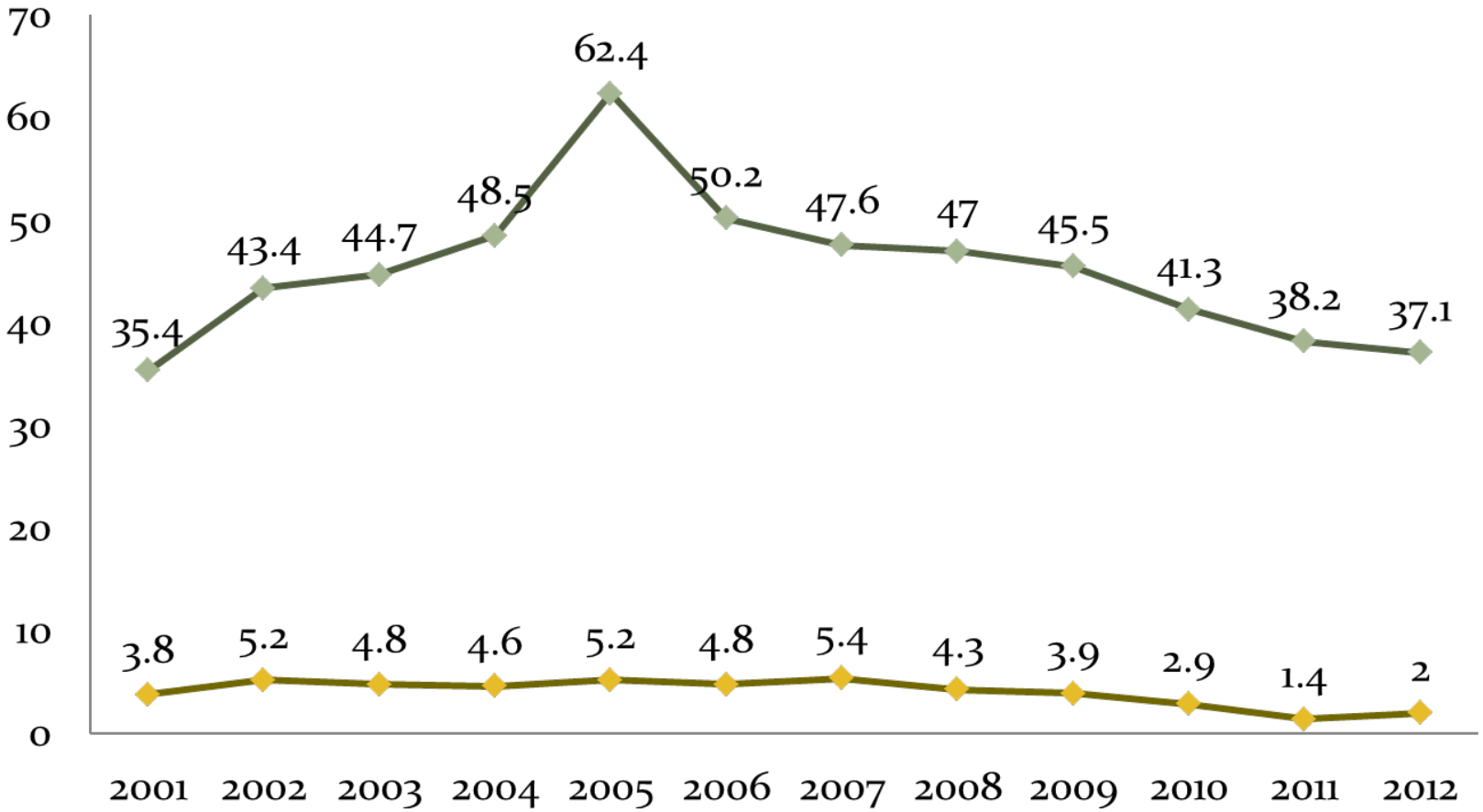
SIAPS Systems for Improved Access to Pharmaceuticals and Services

World Health Organization REGIONAL OFFICE FOR Europe

Stop TB Partnership

Tuberculosis Morbidity and Mortality in Armenia (2001–2012)



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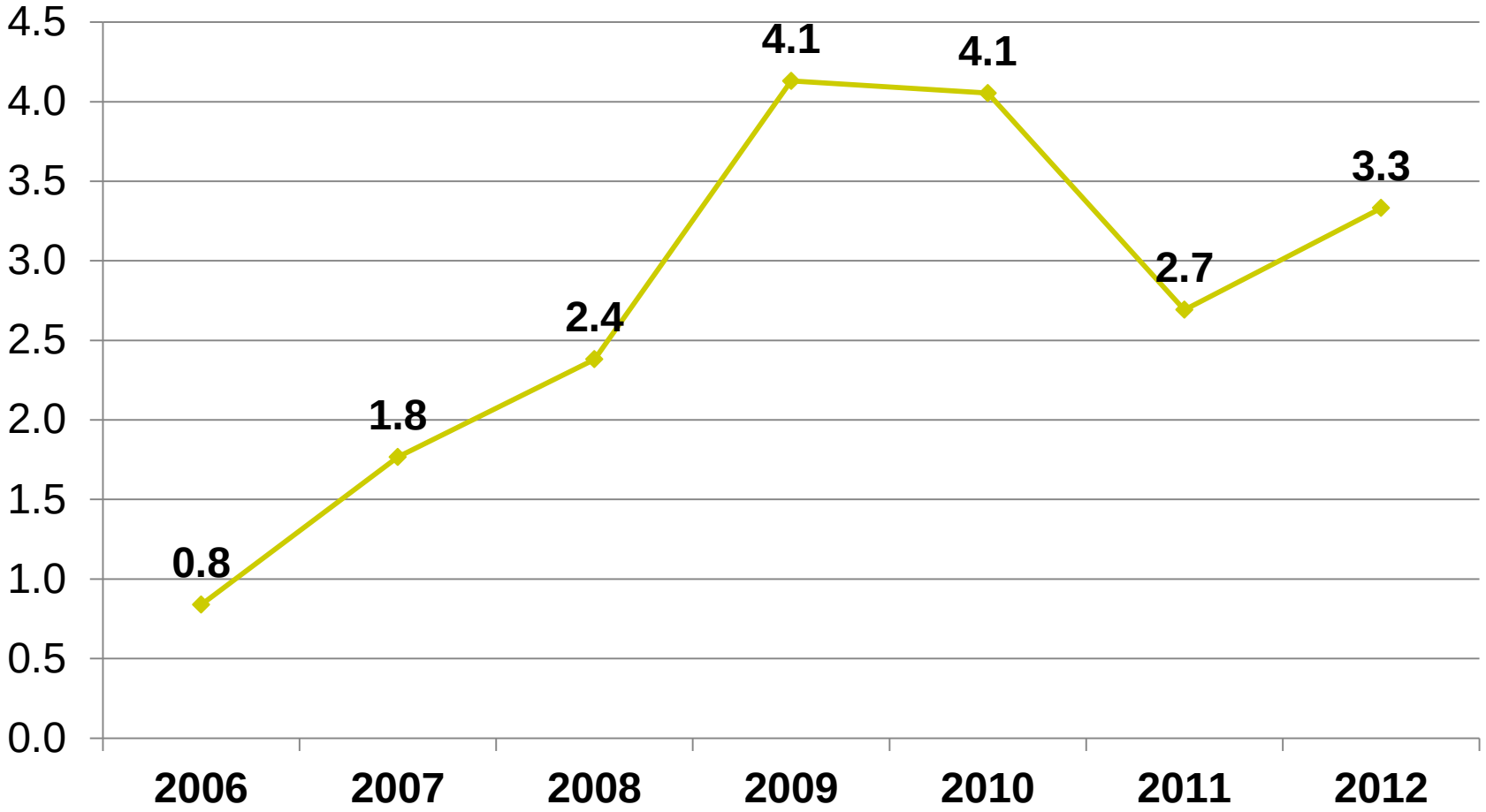
Multidrug-Resistant TB Morbidity (2006–2012)



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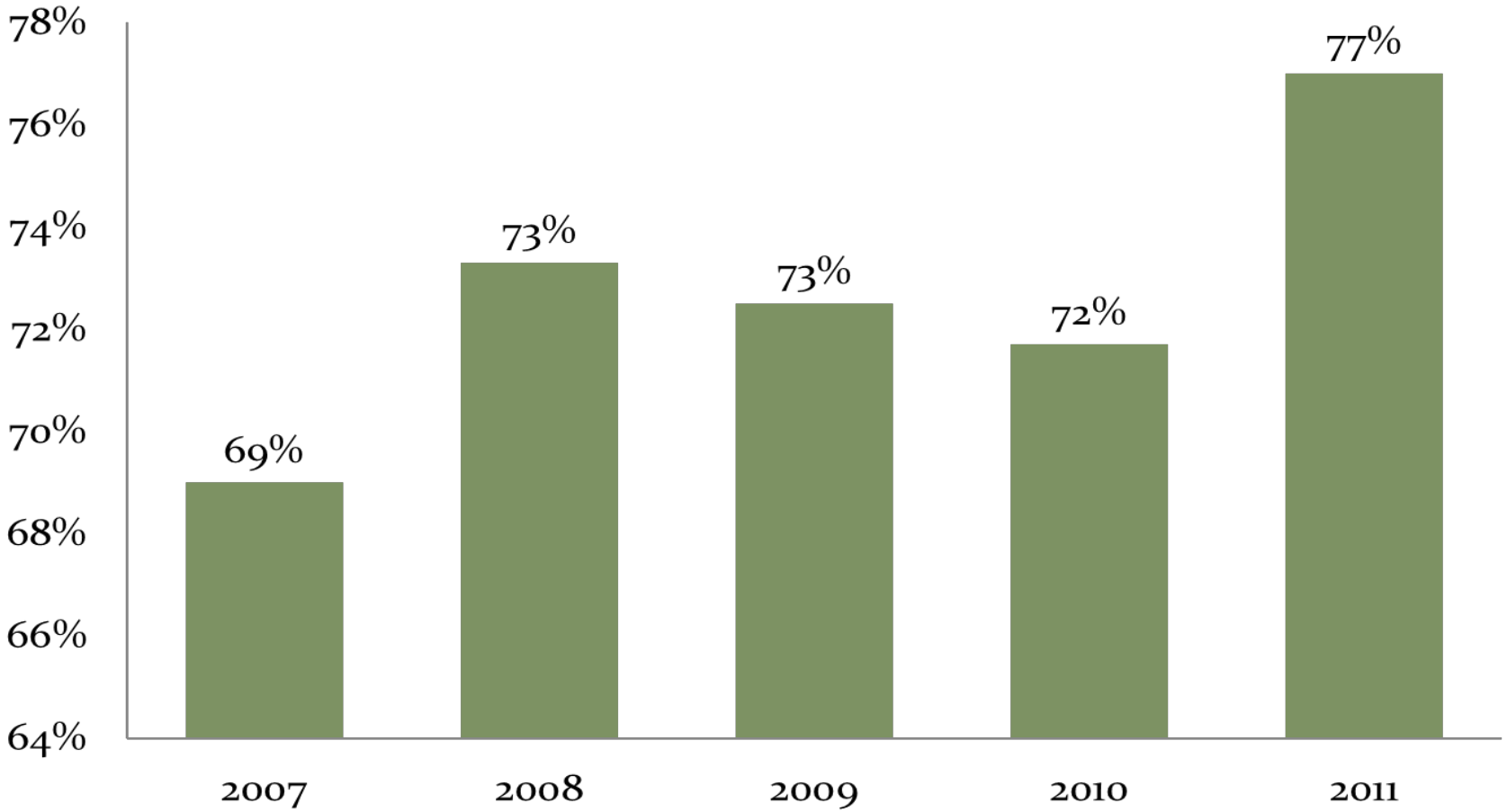
Treatment Success Rates Among New Smear (+) Patients



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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

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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

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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

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Access to Medicines

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

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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

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Status of Patients Receiving Compassionate Use Treatment in Armenia (By November 15, 2013)

PATIENTS	NUMBER
Patients approved and on treatment	24
Patients approved and refused treatment	4
Rejected by J-J or MSF	5
Died before starting treatment	3

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Treatment Results By November 15, 2013

Bacteriological Status	Patients Started Treatment	Patients Started Treatment
Smear and culture negative	3	Still same
Smear negative and culture positive	5	2 converted by culture
Smear and culture positive	16	8 converted by smear and culture 3 converted by smear but still positive by culture

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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

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