OPTIMIZING MEDICINE SAFETY FOR HIV AND TB PATIENTS

An Active Surveillance Approach

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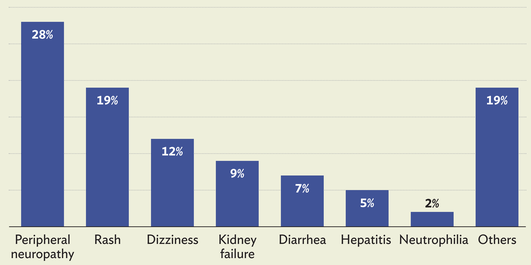
INTRODUCTION

Medicines that cause adverse events can decrease adherence and contribute to negative treatment outcomes. Swaziland has a high prevalence of both HIV and tuberculosis (TB); more than 80% of TB patients are HIV-positive. This study tested a practical approach to collect and analyze data from patients on treatment for HIV or TB to evaluate the incidence, severity, and risk factors for adverse events. The goal is to create a surveillance system that informs patient care decisions at the facility level, revisions to treatment guidelines, and regulatory decisions to promote safe treatment.

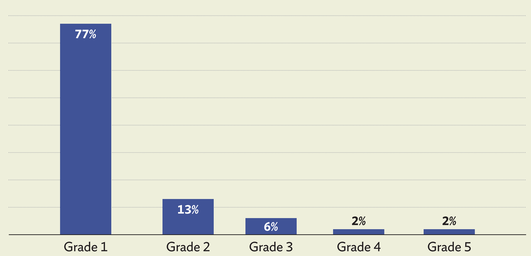
Figure 1. Percentage of adverse events by type (N = 58)



METHOD

- Two-year prospective observational study introduced at six sentinel sites in Swaziland in July 2013
- Physicians enrolled new HIV-positive patients (treatment naïve) and TB patients starting a new regimen; patients' ages varied
- Physicians collected data from patients monthly, which a data clerk entered into an electronic system and a central-level coordinator analyzed quarterly
- Target sample size was 3,360 HIV and 1,800 TB patients (representing almost 99% and 95% chances, respectively, of identifying a single adverse event with an incidence of 1:500 over the life of the study)

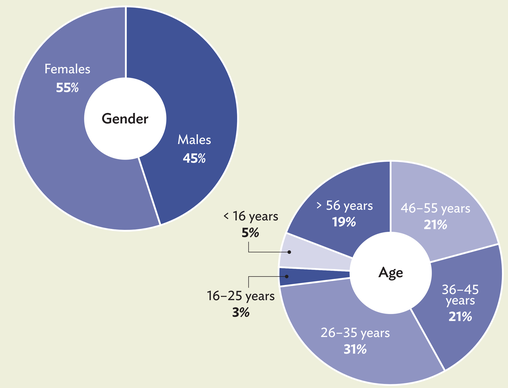
Figure 2. Percentage of adverse events by severity (N = 48)



RESULTS

- From July 2013–May 2014, 956 new cases were enrolled in the study at four sentinel sites, representing 19% of the targeted recruitment
- 58 adverse events were reported, with peripheral neuropathy the most common and kidney failure the most severe
- 55% of adverse events reported were experienced by women
- Only 5 cases out of the 956 switched regimens (0.5%) and only 2 due to medicine adverse events (0.2%)

Figure 3. Percentage of adverse events by age and gender distribution (N = 58)



CHALLENGES

- Some health facility staff show little interest in participating
- High staff turnover and staff transfers
- Few or no physicians at some facilities to enroll and monitor cases
- Inadequate data quality—incomplete reporting
- Limited capacity to enter data electronically
- Lower number of cases meeting enrollment criteria than anticipated for the planned period

LESSONS LEARNED

- Plan to routinely train new staff
- Conduct regular supportive supervisory visits
- Create a process for data validation at the health facility
- Provide feedback to facilities about findings to initiate corrective measures and generate interest

Health facility staff using the data collection tool

CONCLUSION

Active surveillance is one way to monitor the real-world effects of new treatments because clinical research is performed in select populations over short periods. However, a program requires sufficient resources, standardized processes, and regular monitoring to ensure successful outcomes.

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Acknowledgments
Ministry of Health Swaziland
PEPFAR, Swaziland
Greatjoy Mazibuko, SIAPS Namibia
Kidwell Matshotyana, SIAPS Swaziland

Presented at the 20th International AIDS Conference in Melbourne, Australia, July 2014. The SIAPS Program is funded by the US Agency for International Development under cooperative agreement AID-OAA-A-11-00021 and implemented by Management Sciences for Health.