Antibiogo as an innovative solution to detect antimicrobial resistance: from an operational need to a CE-marked diagnostic test available for low-income and middle-income countries

Introduction
Antimicrobial resistance (AMR) is a major threat to public health and could cause 10 million deaths per year by 2050. Access to high-quality diagnostic tests is a key intervention to tackle AMR, leading to better patient care, provision of data for global surveillance, and more rational use of antibiotics. Despite technological advances, antimicrobial susceptibility testing (AST) interpretation is complex and requires expert clinical microbiologists, which are lacking in low- and middle-income countries (LMIC). To fill the gap, The Médecins Sans Frontières (MSF) Foundation developed Antibiogo, a smartphone-based application to support laboratory technicians with AST interpretation. We aimed to assess the clinical performance of Antibiogo in intended use settings as per European regulations for in-vitro diagnostic medical devices.

Methods
Antibiogo combines image processing, machine learning, and expert system technologies for the provision of final results (S/I/R: Susceptible, Intermediate, or Resistant). In 2022, we assessed the clinical performance of Antibiogo according to European regulations in three microbiology laboratories in Jordan (MSF Reconstructive Surgery Hospital, Amman), Mali (MSF Paediatric Hospital, Koutiala), and Senegal (Pasteur Institute, Dakar). In each site, clinical AST performed for routine purposes was processed in parallel with Antibiogo. AST pictures and inhibition zone diameter values measured with Antibiogo were interpreted by an expert microbiologist who was masked to Antibiogo interpretation. We calculated S/I/R category agreement between the microbiologist and Antibiogo, as well as minor (mD), major (MD) and very major discrepancies (VMD).

Results
We included 378 fresh isolates in the study, representing 11 different pathogens. The overall category agreement was 88.8% (95% CI 87.9–89.7), ranging per pathogen from 67.1% (63.2–70.8) (for Pseudomonas aeruginosa) to 98.1% (94.4–99.6) (for Haemophilus influenzae), with 10.2% (9.4–11.1) mD, 1.6% MD (1.2–2.3), and 0.25% VMD (0.08–0.59). From these results, Antibiogo was validated for 11 WHO priority pathogens. From an operational need identified, to proof of concept and evaluation, it became the first MSF CE-marked in-vitro diagnostic (IVD) test in May 2022. As of January 2024, it has been implemented in five MSF laboratories (in Central African Republic, Democratic Republic of the Congo, Jordan, Mali, and Yemen), and in public laboratories in Mali upon request from the Ministry of Health.

Conclusion
It will take 400 years to address the shortfall of microbiologists in LMIC at the present rate of training. In the meantime, technology can help fill the gap. In parallel to deployment of Antibiogo in additional countries and regions, developments are ongoing, and an improved version of the app will be released in 2024.

Conflicts of interest
All authors declare no competing interests.