Outpatient Care and New Medications

Location of care

Because the new and repurposed medications have only been given to a limited number of patients, many experts and programs feel more comfortable hospitalizing patients for a certain period of time. Many of the concerns center around possible electrocardiogram (ECG) abnormalities that have been associated with the new medications and some of the repurposed medicines (i.e., clofazimine [CFZ]). However, it is important to note that bedaquiline (BDQ), delamanid (DLM), and CFZ—all of which have been associated with QTc prolongation—take several weeks to reach their steady-state concentrations and, therefore, the QTc prolongation risk may not be apparent early in the course of therapy. If hospitalization is to occur for reasons of cardiac safety, there should be access to a defibrillator (a simple automated one will suffice) should a fatal arrhythmia develop. Details about QTc management are discussed in the section on adverse event management.

If there is sufficient adherence support, patients can be treated with new and repurposed medications in the community setting, provided that they can access appropriate care after hours if need be. Hospitalization of patients receiving new and repurposed medicines may contribute to nosocomial transmission and may be associated with higher costs and increased stigmatization for patients and the program. For these reasons, unless there is a clear medical need for hospitalization, patients receiving BDQ, DLM, linezolid (LZD), or CFZ can be started on treatment in an outpatient setting, provided that there is close community monitoring and follow up. This is in keeping with important programmatic management of drug-resistant tuberculosis (PMDT) achievements in decentralized care settings over the past decade.

Outpatient care should follow standard protocols for PMDT in the country. If possible, monitoring of adverse events can and should occur in settings that are convenient for the patients. If there are no 12-lead ECG machines or travel to sites with these machines is complicated, patients should be given transportation support. Alternatively, handheld screening devices can be used and only those patients with QTc prolongation should be sent for screening. Patients will need to be seen on a monthly basis while on BDQ or DLM.

HOSPITALIZATION WHILE ON BDQ OR DLM IS NOT REQUIRED AND PATIENTS CAN BE TREATED IN THE COMMUNITY SETTING PROVIDEDTHAT THERE IS ADHERENCE AND TRANSPORTATION SUPPORT.