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Global programmatic use of bedaquiline and delamanid for the treatment of multidrug-resistant tuberculosis

V. Cox,*† G. Brigden,‡ R. H. Crespo,§ E. Lessem,¶ S. Lynch,# M. L. Rich,**†† B. Waning,§ J. Furin**‡‡

*Drug-Resistant TB Scale-Up Treatment Action Team, Global Drug-Resistant Tuberculosis Initiative, Stop TB Partnership, Geneva, Switzerland; †Center for Infectious Disease Epidemiology and Research, School of Public Health and Family Medicine, University of Cape Town, Cape Town, South Africa; ‡International Union Against Tuberculosis and Lung Disease, Geneva, §Global Drug Facility, Stop TB Partnership, Geneva, Switzerland; ¶Treatment Action Group, New York, New York, #Médecins Sans Frontières Access Campaign, New York, New York, **Partners In Health, Boston, Massachusetts, ††Brigham and Women's Hospital, Boston, Massachusetts, ‡‡Harvard Medical School, Boston, Massachusetts, USA

SUMMARY

SETTING: The World Health Organization recommended two new drugs, bedaquiline (BDQ) and delamanid (DLM), for the treatment of multidrug-resistant tuberculosis (MDR-TB) in 2013 and 2014, respectively. An estimated one third of patients with MDR-TB would benefit from the inclusion of these drugs in their treatment regimens.

DESIGN: A convenience sample of 36 countries voluntarily reported monthly data on cumulative programmatic use of new drugs to the Drug-Resistant TB Scale-Up Treatment Action Team between 1 July 2015 and 31 June 2017. Programmatic use was defined as treatment for MDR-TB with newer drugs outside of clinical trials or compassionate use.

RESULTS: A total of 10 164 persons were started on BDQ and 688 started on DLM during the reporting period. Only 15.7% of the 69 213 persons estimated to need newer drugs over the study period were reported to have received them.

CONCLUSION: While there has been significant progress in some countries, uptake of the newer drugs has not kept pace with a conservative estimate of need; fewer than 20% of persons likely to benefit from either BDQ or DLM have received them. Concerted efforts are needed to ensure that the newer drugs are made available more widely for persons with MDR-TB in need of these therapeutic options.

KEY WORDS: bedaquiline; delamanid; drug-resistant TB; global use

IT HAS BEEN MORE THAN 4 YEARS since the World Health Organization (WHO)—following on from the work of the United States Food and Drug Administration—recommended the use of the novel drug bedaquiline (BDQ) for the treatment of some forms of multidrug-resistant tuberculosis (MDR-TB) in June 2013.[1] This recommendation ushered in a new era in the treatment of this global public health threat. In October 2014, the WHO recommended a second, newer anti-tuberculosis agent, delamanid (DLM), for the treatment of MDR-TB.[2]

Given the poor rates of treatment success and the high rates of toxicity seen with the existing drugs and treatment regimens used for MDR-TB,[3] there was great optimism that access to these newer therapeutic agents would revolutionize the treatment of MDR-TB.[4,5] However, the newer agents themselves are also associated with adverse events, most notably prolongation of the QTc interval.[6]

In their 2017 Global TB Report, the WHO estimated that 89 countries had started using BDQ and 54 had started using DLM.[7] These numbers, however, may not reflect broad programmatic uptake of these novel therapeutics, given that a country was defined as providing access once the first patient received the drug in the country, even if this was under compassionate use conditions. It has been estimated that each year between one third and two thirds of patients with MDR-TB, i.e., between 33 000 and 74 000 individuals, would benefit from the inclusion of BDQ or DLM in their treatment regimens.[8] This is a conservative estimate based on the fact that 110 000 persons were started on MDR-TB treatment in 2015.[9] While there has been significant progress in some countries,[10] data from 2015 showed that uptake of the new drugs was not keeping pace with estimated need.[11] Here, we present data from a 24-month period on the cumulative use of BDQ and DLM in selected TB programs between 1 July 2015 and 31 June 2017.

Correspondence to: Vivian Cox, Drug-Resistant TB Scale-Up Treatment Action Team, 511 Colville Street, Chattanooga, TN 37405, USA. e-mail: vivian.cox@me.com

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METHODS

The methodology used in the present study has been described elsewhere in detail.[12] Briefly, in April 2015, a task force of the Global Drug-Resistant TB Initiative (GDI) was formed to monitor and support the use of the newer drugs, BDQ and DLM, within national TB programs (NTPs). The task force is known as the 'Drug-Resistant TB Scale-Up Treatment Action Team' (DR-TB STAT); its mandate is based on a call to action issued by 88 civil society organizations that expressed concern about the global rate of progress in introducing the newer drugs.[13] As part of its activities, DR-TB STAT collected monthly updates on the cumulative number of patients treated with BDQ and DLM from 36 countries (Table). Data were collected via a monthly e-mail sent out by DR-TB STAT to an NTP manager or MDR-TB focal point in the country asking for the cumulative numbers of persons started on BDQ and DLM since the country began using these drugs. In some countries, data were reported by implementing or technical assistance partners instead of the NTP. The data were re-validated with the country NTP or with the NTP's designated reporting agency.

An additional source of data came from the Stop TB Partnership's Global Drug Facility (GDF).[14] The GDF monitored the number of orders placed for newer drugs and the countries ordering them and shared this information with DR-TB STAT. Most countries procure BDQ via the GDF, with the notable exceptions of South Africa and Russia, which procure BDQ directly from the companies with rights to market the drugs in those settings. For countries where the drug is not registered, DLM is almost exclusively available from the GDF.

The 36 countries participating in monthly updates were selected as part of a convenience sample. From April 2015 to 31 March 2017, the published literature, conference presentations, and meeting reports were reviewed by two authors (VC and JF) to identify countries using or planning to use BDQ and DLM; these countries were contacted by DR-TB STAT and asked to participate in ongoing reporting. In September 2015, the GDF began issuing monthly reports on BDQ and DLM orders, and DR-TB STAT contacted countries listed in the GDF database to see if they would be willing to provide routine data on use of newer drugs to DR-TB STAT. To date, of the 38 countries that have been contacted, 36 (94.7%) agreed to participate; 34 (89.5%) countries have data up to 31 June 2017; some countries reported data monthly and some only quarterly.

For the purposes of this analysis, the term 'programmatic use' is defined as any use of BDQ and DLM to treat persons with MDR-TB outside of clinical trials, compassionate use, or other early access programs; when early access programs were implemented by the NTP with partner organizations, this was counted as programmatic use. In settings where a non-governmental organization was providing the treatment as part of programmatic use, patients within these programs were also counted in the monthly cumulative totals.

Table Cumulative number of patients receiving bedaquiline and delamanid among countries reporting data to the Drug-Resistent TB Scale-Up Treatment Action Team until 31 June 2017

Country	Bedaquiline	Delamanid
Afghanistan	0	0
Armenia	115	54
Bangladesh	76	36
Belarus	389	65
China	0	0
Democratic Republic of Congo	13	0
Dominican Republic	4	3
Estonia	22	14
Ethiopia	16	12
Georgia	262	87
Haiti	20	0
India	567	51
Indonesia	73	1
Kazakhstan	196	103
Kenya	6	4
Latvia	56	45
Lesotho	47	49
Mexico	0	0
Morocco	0	0
Mozambique	20	5
Myanmar	12	6
Namibia	27	2
Niger	10	0
Nigeria	4	0
North Korea	17	0
Pakistan	124	53
Papua New Guinea	42	0
Peru	105	3
Philippines	105	1
Russia	1 444	18
South Africa	6 723	81
Swaziland	180	16
Tajikistan	35	6
Thailand	16	0
Uzbekistan	180	0
Viet Nam	99	0
Total	10 164	688

The estimated global need for new drugs was calculated for each previous year using estimates of the number of persons with MDR-TB started on treatment (as opposed to the annual number of estimated cases), as reported in the 2015 and 2016 WHO Global TB Reports for the 36 countries reporting to DR-TB STAT.[15] These numbers were then multiplied by 0.33 based on the conservative estimate that one third of MDR-TB patients would qualify to receive a new drug. Following WHO recommendations for BDQ, about 10% of patients qualify for a new drug based on resistance to fluoroquinolones, injectable agents, or both; approximately 20–25% of patients would also qualify due to intolerance to a drug(s) in the standard drug-resistant TB treatment regimen, with 23% chosen for analysis.[16] This led to conservative estimates of respective-

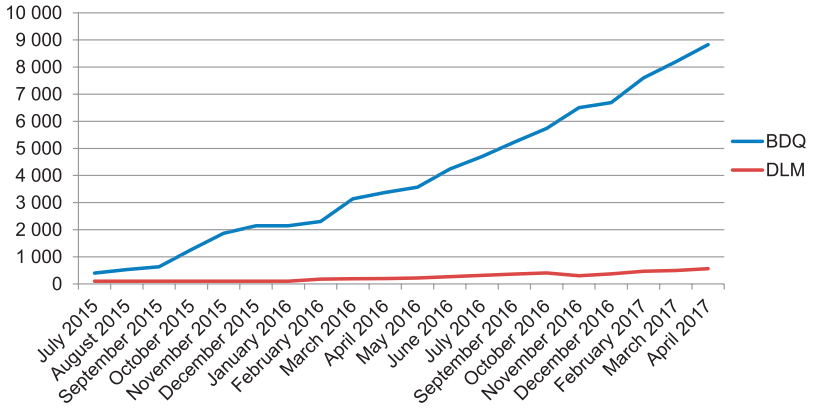

Figure 1 Monthly cumulative progress on global access to BDQ and DLM, July 2015–June 2017 (adjusted to exclude compassionate use of DLM in November 2016). BDQ = bedaquiline; DLM = delamanid. This image can be viewed online in color at http://www.ingentaconnect.com/content/iuatld/ijtld/2018/00000022/00000004/art00011

ly 29 900 and 39 313 people eligible for the newer drugs (BDQ or DLM) in 2015 and 2016. Because DR-TB STAT reports cumulative numbers for persons started on BDQ and DLM, a total of 69 213 was used to estimate the combined need for 2015 and 2016.

As the data used in this analysis were publically available, ethical approval was not required.

RESULTS

As of 31 June 2017, a cumulative global total of respectively 10 164 and 688 patients had received BDQ and DLM. The Table lists the countries providing data to DR-TB STAT and the numbers of patients who had received BDQ and DLM as of 31 June 2017.

Two countries accounted for 80% of global BDQ use: South Africa (66%) and Russia (14%). Of the 688 people who had received DLM during the study period, 542 (78.8%) had received the drug via implementing partners in the UNITAID endTB Project.[17] Figure 1 summarizes the cumulative data on BDQ and DLM by month, and Figure 2 compares the monthly cumulative totals with a conservative estimate of need. Over the 24-month reporting period, 10 852 persons received newer drugs, representing 15.7% of the estimated 69 213 persons who would have qualified for treatment using these drugs. The figures for DLM were adjusted in November 2016 to more accurately reflect programmatic, rather than compassionate, use of the drug.

DISCUSSION

The present study reports cumulative global use of the newer drugs, BDQ and DLM, for the treatment of MDR-TB under program conditions between April 2015 and June 2017 from a convenience sample of 36 countries. The results reveal that the pace of introducing these medications has not kept up with

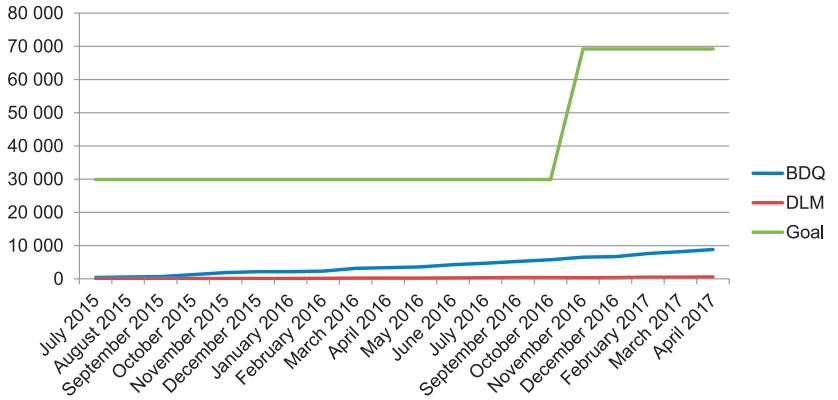

Figure 2 Cumulative progress on global access to BDQ and DLM compared with the cumulative estimate of patients in need, July 2015–June 2017 (calculation of global estimated need for new drugs adjusted to reflect cumulative number of patients started on treatment for rifampin-resistant tuberculosis in 2015 and 2016). BDQ = bedaquiline; DLM = delamanid. This image can be viewed online in color at http://www.ingentaconnect.com/content/iuatld/ijtld/2018/00000022/00000004/art00011

even a conservative estimate of need, with slightly more than 15% of the persons estimated to be in need of a newer TB agent receiving one. Most of the global use of BDQ occurred in two countries, South Africa and Russia, and almost all of the use of DLM occurred at sites supported by the endTB implementing consortium (Médecins Sans Frontières, Partners In Health, and Interactive Research and Development), suggesting global inequality in access to these novel therapeutics.

The contrast between access to BDQ and access to DLM is notable. While the WHO issued recommendations for BDQ use in 2013 and for DLM use in 2014, the time gap alone does not fully explain the wider use of BDQ compared with DLM. There may be other potential reasons for the differential use we observed during the study period.

First, BDQ had been registered in a greater number of countries than DLM, and for this reason may have been preferred by NTPs.

Second, cost differences between the two drugs may also have played a role. Over the study period, many countries were able to receive BDQ free of charge via the US Agency for International Development/Janssen Pharmaceuticals (Beerse, Belgium) donation program.[18] Countries without access to the program either negotiated their own pricing or purchased the drug from the GDF via a tiered pricing structure. For DLM, countries were only able to begin buying via the GDF in February 2016, and only if they also qualified to receive Global Fund TB grants, failing which DLM had to be purchased directly from the company. Overall concerns about the costs—and therefore sustainability—of both drugs may have been a contributing factor to the limited global uptake observed with both newer drugs.

Third, there was a clearly defined process for accessing BDQ under compassionate use conditions—with formal application and exclusion criteria available on the Internet—compared with DLM, where information had to be sought on a case-by-case basis from the drug company.[19] This may be one reason why more providers had first-hand experience using BDQ and may have been more comfortable with this drug than with DLM.

Finally, some countries may have preferred to introduce one newer drug at a time, and as most could access BDQ first, they may have been waiting to use DLM until after their BDQ programs had become more established. The notable access gap between the two drugs needs to be addressed, especially as DLM is the newer drug of choice for children aged 6–18 years,[20] can be used with most antiretroviral therapy (including efavirenz), and is recommended by the WHO for any person with MDR-TB at risk of having a poor treatment outcome.[21]

The uptake of BDQ in South Africa merits special attention. South Africa accounted for more than 60% of global BDQ use. Some of this data could be explained by the large number of MDR-TB patients in the country, as there are an estimated 30 000 MDR-TB patients each year, more than 12 000 of whom are started on treatment.[22] However, other high-burden MDR-TB countries, such as India, accounted for a limited percentage of newer drug use globally. A contributing factor to the robust uptake of BDQ in South Africa may have been the country's progressive stance toward the implementation of innovative drugs and tests, with a strong National Department of Health, researchers, and implementing partners.[23] South Africa also accounts for 60% of Xpert® MTB/RIF (Cepheid, Sunnyvale, CA, USA) cartridge use in the world,[24] and for 60% of persons who are on isoniazid for the treatment of tuberculous infection (isoniazid preventive therapy).[25,26] Taken together, these findings support the idea that South Africa is introducing multiple innovative approaches to improve the diagnosis and treatment of people with MDR-TB, suggesting that the country could be an example for other programs to follow.

The present study had three main limitations: first, data were reported voluntarily by countries and were not independently verified for accuracy. Countries may have over-estimated the number of people put on newer drugs in their settings for a host of reasons, and this could have led to over-reporting of the number of people receiving newer drugs. Second, there are several regions of the world whose countries were not represented in DR-STAT's data set. Most notable were the francophone African countries, many of which have been leaders in introducing shorter regimens for the treatment of MDR-TB;[27,28] countries from the Pan-American Health Organization region; and wealthy countries, including the United States and those in the European Union. Some countries in these regions may have been using newer drugs but were not captured in the DR-TB STAT reports, which would have led to an underestimation of the use of both BDQ and DLM under program conditions. However, given that usage data were triangulated with order data from the GDF, it is unlikely that the number of individuals with MDR-TB who had been started on these medications but not reported was significant. In addition, we used a conservative estimate of need in our calculations—some studies have suggested that as many as 67% of individuals started on treatment for MDR-TB need newer drugs—and thus the gap we report is likely underestimated. We also note that there was not complete overlap in the time periods covered by STAT data—which ran from 1 July 2015 to 31 June 2017—and the WHO data used to estimate global need. Finally, we note that there may have been substantial variations between countries in terms of operational

costs, registration barriers, and preparedness for using newer drugs in terms of meeting the criteria set forth by the WHO for optimal use. These differences are likely obscured by presenting global level data. Future studies should focus on more detailed country analyses to better understand the challenges and barriers for introduction of newer drugs.

Despite the limitations mentioned above, we report important data on global progress in introducing newer agents for the treatment of MDR-TB outside of clinical trial and compassionate use conditions. Overall, it paints a stark picture, with use of both BDQ and DLM failing to come close to reaching even conservative global estimates of need. Although there has been progress with BDQ—especially in South Africa—the lack of DLM uptake needs to be addressed. BDQ and DLM are essential to efforts to stop the transmission of MDR-TB, improve patient outcomes, and limit the toxicity seen with currently recommended strategies. More work is urgently needed, however, to ensure these therapeutic innovations reach the people who need them most.

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RÉSUMÉ

CONTEXTE : L'Organisation Mondiale de la Santé a recommandé deux nouveaux médicaments, la bédaquiline et le délamanide, pour la tuberculose multirésistante (TB-MDR) en 2013 et 2014, respectivement. On estime qu'un tiers des patients atteints de TB-MDR bénéficieraient de l'inclusion de ces médicaments dans leur protocole de traitement.

SCHÉMA : Un échantillon de commodité de 36 pays a de son plein gré rapporté des données mensuelles sur l'utilisation cumulée par le programme de nouveaux médicaments à l'équipe de Drug-Resistant TB Scale-Up Treatment Action entre le 1e juillet 2015 et le 31 juin 2017. L'utilisation par le programme a été définie comme le traitement de la TB-MDR avec des médicaments plus récents en dehors d'un essai clinique ou d'un usage compassionnel.

RÉSULTATS : Un total de 10 164 personnes ont été mises sous bédaquiline et 688 mises sous délamanide pendant la période concernée. Seulement 15,7% des 69 213 personnes estimées avoir besoin de médicaments plus récents pendant la période d'étude les ont effectivement reçus.

CONCLUSION : S'il y a eu un progrès significatif dans certains pays, la couverture des médicaments plus récents n'a pas suivi le rythme des besoins, même avec une estimation basse ; moins de 20% des personnes qui pourraient bénéficier soit de la bédaquiline soit du délamanide les ont reçus. Des efforts concertés sont requis pour s'assurer que les nouveaux médicaments sont mis plus largement à disposition des personnes vivant avec une TB-MDR et qui ont besoin de ces options de traitement.

RESUMEN

MARCO DE REFERENCIA: La Organización Mundial de la Salud recomendó dos nuevos fármacos, la bedaquilina (BDQ) y el delamanid (DLM), en el tratamiento de la tuberculosis multirresistente (TB-MDR) en el 2013 y el 2014, respectivamente. Se calcula que un tercio de los pacientes con TB-MDR se beneficiaría con la inclusión de estos fármacos en sus esquemas terapéuticos.

MÉTODO: Una muestra de conveniencia de 36 países notificó a título voluntario cada mes los datos sobre la utilización programática acumulada de nuevos fármacos, al grupo de acción sobre la ampliación de escala del tratamiento de la TB farmacorresistente del 1° de julio del 2015 al 31 de junio del 2017. La utilización programática se definió como el tratamiento de la TB-MDR con nuevos fármacos por fuera del contexto de ensayos clínicos y del uso compasivo.

RESULTADOS: En este período de notificación, iniciaron la BDQ 10 164 pacientes y 688 el DLM. Durante el período del estudio se estimó que 69 213 personas habrían necesitado nuevos fármacos, pero solo el 15,7% los recibió.

CONCLUSIÓN: Si bien se han alcanzado progresos considerables en algunos países, la utilización de los nuevos fármacos no ha evolucionado al ritmo de una estimación prudente de las necesidades; de las personas en quienes la BDQ o el DLM habrían sido útiles, menos del 20% recibió el nuevo fármaco. Se precisan iniciativas concertadas que faciliten la puesta a disposición de nuevos fármacos para las personas aquejadas de TB-MDR que necesitan estas opciones terapéuticas.