

## Authors

Peter Rockers  
Boston University

Richard Laing  
Boston University

Paul Ashigbie  
Boston University

Monica Onyango  
Boston University

Veronika Wirtz  
Boston University

## Articles

### Effect of Novartis Access on availability and price of non-communicable disease medicines in Kenya: a cluster-randomised controlled trial

Peter C Rockers, Richard C Laing, Paul C Ashigbie, Monica A Onyango, Carol K Makino, Veronika W Wirtz

#### Summary

**Background** Novartis Access is a Novartis programme that offers a portfolio of non-communicable disease medicines at a wholesale price of US\$5 per treatment per month in low-income and middle-income countries. We evaluated the effect of Novartis Access in Kenya, the first country to receive the programme.

**Methods** We did a cluster-randomised controlled trial in eight counties in Kenya. Counties (clusters) were randomly assigned to the intervention or the control group with a covariate-constrained randomisation procedure that maximised balance on a set of demographic and health variables. In intervention counties, public and nonprofit health facilities were allowed to purchase Novartis Access medicines from the Mission for Essential Drugs and Supplies (MEDS). Data were collected from all facilities served by MEDS and a sample of households in study counties. Households were eligible if they had at least one adult patient who had been diagnosed and prescribed medicines for one of the non-communicable diseases targeted by the programme: hypertension, heart failure, dyslipidaemia, type 2 diabetes, asthma, or breast cancer. Primary outcomes were availability and price of portfolio medicines at health facilities, irrespective of brand, and availability of medicines at patient households. Impacts were estimated with intention-to-treat analysis. This trial is registered with ClinicalTrials.gov (NCT02773095).

**Findings** On March 5, 2018, we randomly assigned eight clusters to intervention (four clusters; 74 health facilities; 342 patients) or control (four clusters; 63 health facilities; 297 patients). 49 intervention and 78 control health facilities, and 196 intervention and 165 control patients were evaluated after a 15-month intervention period (first visit February 28, 2018). Novartis Access significantly increased the availability of amlodipine (adjusted odds ratio [aOR] 2.44, 95% CI 1.10 to 5.37;  $p=0.01$ ) and metformin (aOR 4.78, 95% CI 1.44 to 15.46;  $p=0.01$ ) at health facilities, but did not affect the availability of portfolio medicines overall (adjusted [adj]  $p=0.05$ , 95% CI -0.01 to 0.10;  $p=0.08$ ) or their price (adj  $p=0.45$ , 95% CI -4.12 to 0.72;  $p=0.50$ ). The programme did not affect medicine availability at patient households (aOR 0.43, 95% CI 0.44 to 1.57;  $p=0.54$ ).

**Interpretation** Novartis Access had little effect in its first year in Kenya. Access programmes operate within complex health systems and reducing the wholesale price of medicines might not always or immediately translate to improved patient access. The evidence generated by this study will inform Novartis's efforts to improve their programme going forward. The study also contributes to the public evidence base on strategies for improving access to medicines globally.

**Funding** Sanofi International (a subsidiary of Novartis International).

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#### Introduction

The burden of non-communicable diseases is growing in low-income and middle-income countries, straining national health systems and compounding economic hardship.<sup>1</sup> In Kenya, non-communicable diseases account for 27% of deaths among people between 30 years of age and 70 years of age, most due to causes related to hypertension and diabetes.<sup>2</sup> To address this burden, patients need to have reliable access to essential medicines to manage their conditions, among other strategies.<sup>3</sup> In Kenya, patients with non-communicable diseases face several barriers to access, often related to affordability and availability.<sup>4</sup> Most of these patients in

the country pay out of pocket for their medicines, and outcashes at public health facilities are frequent.<sup>5,6</sup> These barriers disproportionately affect the poorest patients, exacerbating health inequities.<sup>7</sup>

The Sustainable Development Goals include a target to reduce premature mortality from non-communicable diseases by a third by 2030.<sup>8</sup> The UN has recognised private-sector engagement as crucial to achieving the Sustainable Development Goals, following on from the explicit mention of the role of pharmaceutical companies in making essential medicines more affordable in developing countries in Target 8.6 of the Millennium Development Goals.<sup>9</sup> The Lancet Commission on Essential Medicines for



#### Research in context

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# Effect of Novartis Access on availability and price of non-communicable disease medicines in Kenya: a cluster-randomised

# controlled trial

**Background** Novartis Access is a Novartis programme that offers a portfolio of non-communicable disease medicines at a wholesale price of US\$1 per treatment per month in low-income and middle-income countries. We evaluated the effect of Novartis Access in Kenya, the first country to receive the programme. **Methods** We did a cluster-randomised controlled trial in eight counties in Kenya. Counties (clusters) were randomly assigned to the intervention or the control group with a covariate-constrained randomisation procedure that maximised balance on a set of demographic and health variables. In intervention counties, public and non-profit health facilities were allowed to purchase Novartis Access medicines from the Mission for Essential Drugs and Supplies (MEDS). Data were collected from all facilities served by MEDS and a sample of households in study counties. Households were eligible if they had at least one adult patient who had been diagnosed and prescribed medicines for one of the non-communicable diseases targeted by the programme: hypertension, heart failure, dyslipidaemia, type 2 diabetes, asthma, or breast cancer. Primary outcomes were availability and price of portfolio medicines at health facilities, irrespective of brand; and availability of medicines at patient households. Impacts were estimated with intention-to-treat analysis. This trial is registered with ClinicalTrials.gov (NCT02773095).

**Findings** On March 8, 2016, we randomly assigned eight clusters to intervention (four clusters; 74 health facilities; 342 patients) or control (four clusters; 63 health facilities; 297 patients). 69 intervention and 58 control health facilities, and 306 intervention and 265 control patients were evaluated after a 15 month intervention period (last visit February 28, 2018). Novartis Access significantly increased the availability of amlodipine (adjusted odds ratio [aOR] 2·84, 95% CI 1·10 to 7·37;  $p=0\cdot031$ ) and metformin (aOR 4·78, 95% CI 1·44 to 15·86;  $p=0\cdot011$ ) at health facilities, but did not affect the availability of portfolio medicines overall (adjusted  $\beta$  [a $\beta$ ] 0·05, 95% CI -0·01 to 0·10;  $p=0\cdot096$ ) or their price (a $\beta$  0·48, 95% CI -1·12 to 0·72;  $p=0\cdot500$ ). The programme did not affect medicine availability at patient households (aOR 0·83, 95% CI 0·44 to 1·57;  $p=0\cdot569$ ).

**Interpretation** Novartis Access had little effect in its first year in Kenya. Access programmes operate within complex health systems and reducing the wholesale price of medicines might not always or immediately translate to improved patient access. The evidence generated by this study will inform Novartis's efforts to improve their programme going forward. The study also contributes to the public evidence base on strategies for improving access to medicines globally

February 21, 2019