

Review of Antiretroviral Therapy Guidelines in Select Countries of Africa and the Caribbean: A Challenge for Optimizing Treatment and Product Supply

Background

Standard treatment guidelines (STGs) may contribute to the quality of HIV/AIDS treatment programs and facilitate antiretroviral (ARV) product supply. The World Health Organization (WHO) has identified 19 antiretroviral therapy (ART) regimens for adult patients in resource-limited settings and has prequalified ARV products to facilitate country program procurement.

Objective

Management Sciences for Health's Rational Pharmaceutical Management Plus (RPM Plus) Program, funded by the U.S. Agency for International Development, compared ART recommendations for 13 countries supported by the U.S. President's Emergency Plan for AIDS Relief to (1) determine the extent of (a) agreement among the guidelines and (b) consistency with current WHO ART guidelines; (2) identify the most commonly listed ARVs; and (3) determine potential for supply with internationally prequalified products.

Method and Information Sources

Draft or published guidelines were collected for Botswana, Côte d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Namibia, Mozambique, Rwanda, South Africa, Tanzania, Uganda, and Zambia. Guidelines for Nigeria and Vietnam were not obtained. Adult ART recommendations were compared among countries and with WHO's revised *Scaling Up Antiretroviral Therapy in Resource-Limited Settings* (2004). Potential supply with WHO-prequalified products was determined from the list in WHO's *Pilot Procurement, Quality and Sourcing Project: Access to HIV/AIDS Drugs of Acceptable Quality*. ARV prices were obtained from Médecins Sans Frontières' *Untangling the Web of Price Reductions: A Pricing Guide for Developing Countries* (sixth edition).

Results

Common Recommended Treatment Combinations

- No treatment recommendation was common to all 13 countries.
- The 13 countries recommended up to 95 different first- and second-line treatment combinations for adults, ranging from 3 to 78 in any given country. Of the 95, 19 combinations were consistent with WHO recommendations.
- All but one country (Guyana) listed treatment recommendations not included in the WHO guidelines; 22–100% of individual country recommendations were consistent with WHO guidelines (average, 53%).
- Forty of the recommended treatment combinations were listed in only one country and were not consistent with current WHO recommendations.
- The four most commonly recommended treatment combinations included five antiretroviral agents—
 - Zidovudine (ZDV)
 - Stavudine (d4T)
 - Lamivudine (3TC)
 - Nevirapine (NVP)
 - Efavirenz (EFV)

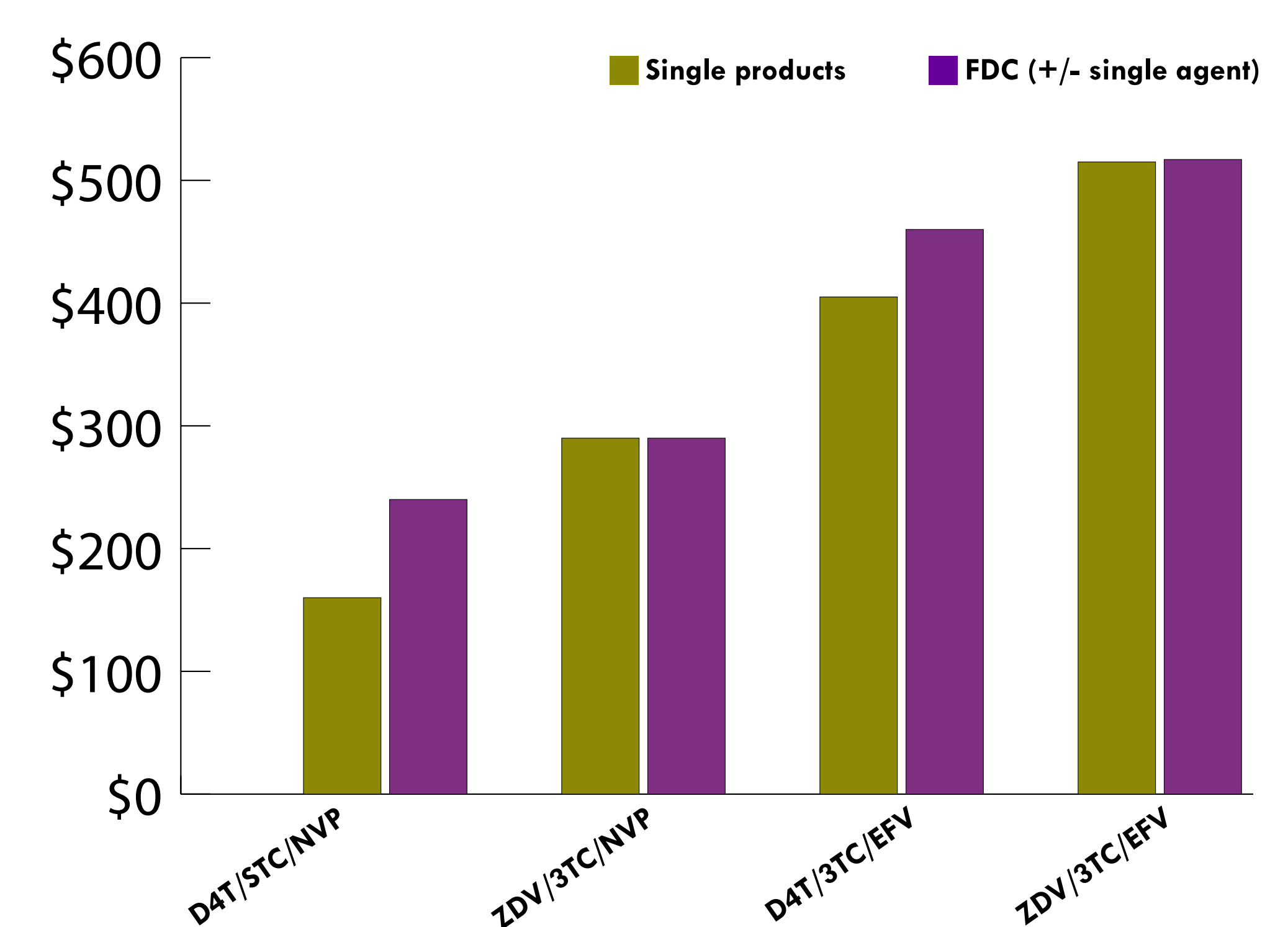
Potential Supply by WHO-Prequalified Sources

- Recommended by 11 countries (by 8 as first-line treatment and by 3 as second-line treatment), the zidovudine/lamivudine/nevirapine combination can be fully supplied with WHO-prequalified products.
- Recommended by 11 countries as first-line treatment, the stavudine/lamivudine/efavirenz combination can be supplied with a WHO-prequalified fixed-dose combination product of stavudine/lamivudine and a single-agent product of efavirenz.
- Recommended by 10 countries (by 9 as first-line treatment and by 1 country as second-line treatment), the zidovudine/lamivudine/efavirenz combination can be supplied with a WHO-prequalified fixed-dose combination of zidovudine/lamivudine and a single-agent product of efavirenz.
- Recommended by 9 countries (by 8 as first-line treatment and by 1 as second-line treatment), the stavudine/lamivudine/nevirapine combination can be supplied with a WHO-prequalified fixed-dose combination product.
- Two WHO-recommended combinations, 1 listed by 7 countries and 1 listed by 9 countries, may be supplied with prequalified fixed-dose products that contain all agents.

Cost Implications (Four Most Common Treatment Combinations, at Currently Available Low Prices)

- The least costly treatment combination is stavudine/lamivudine/nevirapine, with single-agent products.
- The most costly treatment combination is zidovudine/lamivudine/efavirenz, as single-agent products or as a fixed-dose combination with single-agent products.
- Treatment combinations with efavirenz are the most costly, as efavirenz alone is twice the cost of the least costly treatment combination.

Comparative Costs (per Person per Year) for the Most Commonly Recommended ART Combinations



Discussion

- The findings in this comparative analysis can be used to assess and guide multi-country and national planning for ARV supply procurement and supply chain management, including product quality assurance; they can also be used to guide development and implementation of appropriate clinical and supply management training programs.
- Operations research is needed to assess the extent to which product availability, prescribing, and use are consistent with national ART guidelines, and to determine what actions will be needed to scale up existing programs.

