Reviewer's report

Title: Increasing Access to Subsidized Artemisinin-based Combination Therapy through Accredited Drug Dispensing Outlets in Tanzania

Version: 3 Date: 12 April 2011

Reviewer: Catherine Goodman

Reviewer's report:

General Comments

This paper has been improved and the authors have addressed many of my original comments.

My remaining comments are as follows:

Major Compulsory Revisions

1. There was one limitation I highlighted in my original review which you are yet to note. I said:

“Data are only available from these ADDO records on drugs dispensed by ADDOs. It is not possible to assess whether the increase in ACT dispensed is additional to baseline ACT use in the community or is substituting ACT use from other sources i.e. it is not clear whether there is a net increase in ACT coverage at the community level.”

Your response was:

“See response 3 above. Before the start of the program, other studies had documented lack or very low availability of ACTs in ADDOs. We now add this study finding that documents the first time subsidized ACTs were made available in the private sector market at the price that was deemed affordable for majority of the population living in rural areas.”

This does not address my original point, which was that you can’t tell whether increased ADDO sales are adding to total ACT use in the community or perhaps substituting for ACTs previously being obtained elsewhere eg health facilities.

You should note this point, perhaps in your discussion, to highlight that you can’t make firm conclusions about the impact on ACT uptake overall from these data.

2. You do now mention the AMFm but it is not done in a clear way:

- You introduce AMFm twice – once on page 22-23 and again on page 27-28 and the sections appear to duplicate one another. Plus the section on page 28 seems quite long and rambling and could be tightened.
- You don’t explain what AMFm is – readers may not be familiar with it at all, so it needs a few lines of introduction.
- On page 27 you call it the Affordable Facility for Malaria Medicine— it should be
• You don’t introduce the main issue clearly i.e. as currently in the private sector ACT can only be officially distributed through part 1 pharmacies and ADDOs, this will represent challenges for increasing access to ACTs in regions without ADDOs (without making this point, your subsequent arguments are difficult to follow)

Minor Essential Revisions

3. In the abstract you state that “This intervention was implemented from 2006–2008.” However, elsewhere in the text you state that distribution of subsidised ACTs began in Aug 2007 (page 8), and on page 19 you state that the program implementation period was July 07-Sep08. Dates need to be made consistent throughout or clarified.

4. Page 10 – the phrase “Generally, facilities adhere to this price and provide free access to children under five” requires a reference to back this up

5. Page 14 – it seems odd when introducing a section on safety to say “it is important to ensure that systems are in place to minimize the risk of emerging antimicrobial resistance by monitoring and promoting safety and appropriate use.” This would appear to be a separate issue?

6. Page 21 – you state “Preliminary results showed that the intervention increased access to affordable ACTs and quality dispensing services for rural and underserved populations.” I’m not sure which results are being referred to here, as you don’t give a reference and the results presented in the paper don’t relate to the quality of dispensing practices.

7. Page 24 – you say “In March 2009, after reviewing the prices of ACTs, in consultation with NMCP and TFDA, RPM Plus decided to decrease the price of all age categories of ACT from TSH 500–1,500 price range to TSH 300-1,200 (0.38–1.15 compared with 0.23–0.92 USD). This put the profit margin for ACTs in line with that of SP and may encourage more dispensers to recommend ACTs to their clients.” Please clarify whether the price referred to in the first sentence is the retail price? If yes, then I don’t get the argument as decreasing the retail price would actually decrease the markup on ACT with a given wholesale price.

8. Page 27 – I think the inserted section in yellow beginning “To prevent this...” might be meant to come after the sentence “During the pilot program, there was no known leakage of ACTs destined for the public sector to the ADDOs, which a concern raised by NMCP at the start.” Otherwise it doesn’t make sense.

9. Page 27 – you state that leaking ACT from ADDOs to DLDB would not make any business sense – I don’t follow this argument as I would have thought DLDB would be eager to stock subsidised ACT and that it would make business sense for wholesalers to sell to them.

10. Page 28 – you argue that the advantages of ADDOs make them a “worthwhile investment”. I don’t see how you can make this statement without information on their costs. I suggest cut this sentence.
11. Page 30 – I would suggest you re-insert the word “substantial” in front of “human and financial resources” as you had it in the first draft. My point then was not that this should be removed.

12. Table 2 – clarify the denominator for the last 4 columns

13. There are several sections of text that don’t make good sense in English. They need to be edited appropriately:

• Page 6 “At the time of writing of this paper, the regulations passed that all duka la dawa baridi be phased out by January 2011 (GN. No. 19 of 16th January 2009) nationwide, ADDO coverage is expected to be completed.”
• Page 16 “…the number of customers seeking antimalarial ADDOs in the 12-month period…”
• Page 16 “Owners are required to record and keep drug register (which record all dispensing transaction for list of products authorized to be sold by ADDO), ACT purchase invoices, and stock cards all of which are required” and “The location was chosen based on the proximity and easy to reach several ADDOs, most locations (primarily primary schools or ward offices or was located at peri-urban with a few in villages at ward level.” And “....since phone records for most owners was available”.
• Page 22 – “Establishing certified wholesalers is a relatively slow process; example the requirement that ADDO Restricted Wholesale be supervised by a pharmacist who are seldom available in the rural.”
• Page 27 – “To prevent this, ACTs meant for ADDOs included a special ADDO sticker (figure 2). To further prevent leakages from all levels of supply chain, ADDO owners had to present their accreditation certificate to the regional wholesaler every time they went to purchase ACTs, teams monitored sales and conducted periodic record review and stock taking at the national and regional suppliers on monthly basis and local inspectors (district and ward level) inspected the shops to see if any public ACTs was sold.”
• Page 30 – “expanding the distribution system to the district level need regulatory changes that would allow selected ADDO in remote location to act as “super-ADDOs” in the interim while they are working to meet the requirement required by TFDA to become ADDO-Restricted Wholesalers, this issue has broader regulatory implication for the entire ADDO program and is not restricted to ACT access alone”

Finally, in future revision letters it would be helpful if you could indicate sections / page numbers for all revisions made to facilitate the job of re-review.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Needs some language corrections before being published
**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests