Reviewer’s report

Title: Nurse led, primary care based antiretroviral treatment versus hospital care: a controlled prospective study in Swaziland

Version: 3 Date: 26 March 2010

Reviewer: Benjamin Chi

Reviewer’s report:

This is a timely study, investigating an important operational issue for HIV programs in sub-Saharan Africa. Although the approach of “stepped down” referrals to primary care centers has been previously described, few have sought to evaluate its effectiveness. This study is unique in that regard and will provide important new information for program managers and policymakers. Despite this general enthusiasm, I did have several concerns about the manuscript itself, which I describe below:

MAJOR REVISIONS

The authors should include more detail regarding the outcomes. For the primary outcome measure of clinic attendance, for example, was each visit in the follow-up period counted equally and – perhaps this is for later in the Results – how many did patients have on average? It is possible that individuals who remained at the hospital were scheduled for more visits, were sicker, had more complaints, etc., (i.e., had more opportunity to attend), all of which could result in differences in the denominators for the comparison. Also, it seems there should be a “window” of sorts for patients to make it to the clinic (or did the authors require attendance on the exact day for it to not count as a failure)? Either way, this should be clearly specified.

I found the clinical outcomes (what the authors term health-related outcomes) very interesting, but again, the timing is not explicit. Was it CD4 response and weight change over a standard period (e.g., 3 months, 6 months)? This is important to note because of the differential follow-up time between the groups and the low portion of patients with follow-up CD4 counts.

I am interested in knowing more about the care provided at the clinical site. There is discussion of a “hand-over” of services from a centrally based team to the clinic staff. How long did it take for this transition to be completed? What systems were in place for the referral of complicated patients? These program characteristics are important for others looking to replicate these findings.

I’m a bit confused about the sample size calculation. In my reading, the primary outcome measure seems to be a description of the facility (i.e. the proportion of patients with missed visits) and not the individual. Although the effect size is big (30% vs. 15%), the precision of these estimates seems low with an average of 15
patients per site. If I’ve misinterpreted the primary outcome and it is indeed at the level of the individual (e.g., that a patient comes to 15% or 30% of his/her clinical visits), then the issue of differential follow-up time is very critical, since patients who have been in care longer will “penalized” in smaller increments than one with far fewer visits. Regardless – and as mentioned before – it seems a better explanation of the primary outcome is needed.

I have a major concern about the authors’ interpretation of the results about patient experience. Patients who were properly referred seemed to have good experiences. One-quarter of patients presumably would not have liked primary center-based care; after all, they refused to be referred in the first place. The authors do well to acknowledge the importance of offering such choices to patients in the Discussion, given the myriad of reasons why people might not want to receive care in their own community. However, I think that the conclusions about patient experience (end of first paragraph, Discussion) should further be tempered since this was a self-selected group of patients predisposed to favoring the care at the primary care clinic.

The investigators demonstrate favorable clinical outcomes. However, I would urge some discussion about the importance of properly triaging patients for primary care referral and for referral back to hospitals. The authors did not evaluate the quality of care for more complex issues – for example, drug toxicities, opportunistic infections, or first-line treatment failure. While I agree that the preliminary data are encouraging, these results need to be placed in their proper context – with perhaps stronger recommendations for linking these primary care clinics to more specialized care.

MINOR ESSENTIAL REVISIONS

The tables reference per protocol analyses and modified intent-to-treat. Please include a description of these analyses in the Methods.

DISCRETIONARY REVISIONS

Figure 2 is a bit hard to follow. I would suggest putting those excluded between each step with an arrow straight out to the side (like with “11 inadequate information”). This should be the case with “109 not eligible” and further down “108 refused intervention.” This will make it easier to quickly delineate the primary comparison groups.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.
Declaration of competing interests:

I declare no competing interests.