Author's response to reviews

Title: Initial Impact and Cost of a Nationwide Population Screening Campaign for Diabetes in Brazil: a Follow up Study

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Author's response to reviews: see over
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Andrea Bucceri PhD
Assistant Editor
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Dear Dr. Bucceri:

The authors are grateful for the comments and suggestions received from the reviewers on our manuscript, “Initial Impact and Cost of a Nationwide Population Screening Campaign for Diabetes in Brazil: a Follow up Study”.

We have considered all the comments and suggestions and we are submitting a revised manuscript. Please find below a point-by-point description of the changes made.

We believe we have considered all the reviewer's comments and suggestions and have made changes or clarifications accordingly.

Sincerely,

Cristiana Toscano, MD, DSc
Reply to specific points from Andrea Icks's review:

**Major points:**

1. As the Screening Campaign was part of a national Program to re-organize the care of diabetes and hypertension in Brazil centering diagnosis and treatment at the primary care level, the definition of the cut-off’s were based not only on their validity but also on the capacity of the health system to absorb new cases of diabetes. No pretest was done. However, as seen in Table 1, most cut offs are internationally recognized (for fasting, 5.6, 6.1, 7.0, 11.1; for non fasting, 7.8 and 11.1). Additionally, as priority for diagnosis and treatment was given to cases with more severe hyperglycemia at screening, the cut-off 15 was also set.

   Due to the nature and magnitude of the program, individual characteristic of the participating population were not sent to the central level. Characteristics of positive screenees in the follow up study are reported at the beginning of the Results section. Characteristics of the new cases of diabetes are reported at the last paragraph of page 10 of the Results section.

2. Sampling, as now described in greater detail, involved selecting municipalities, then health care units, then screening forms, all of these steps performed randomly. As the objective of this follow-up study was to characterize what happened to those who were screen positive, the sampling frame was based on individuals who were screen positive. Selection of forms of screenees and positive screenees is now described in greater detail, the technique being a consecutive selection of screening forms following a random start until 2000 total forms and 200 positive forms were obtained for each municipality. The number of positive forms was chosen to identify approximately 10,000 (200 x 50) individuals, half of whom were kept in reserve to be used in the event of inability to locate or interview members of the other half. As already described in the text, the 200 individuals were rank-ordered in each municipality. As the reserve was used only when the first 100 could not be interviewed, bias would accrue only if those interviewed were different from those not. As refusals were rare, this potential bias would accrue basically from problems in locating residences. This potential bias has already been addressed in the Discussion.
3. The calculation of the confidence intervals for each point estimate took into consideration the fact that the sample was a stratified cluster sample. This has been clarified in the text (p. 7).

4. The proportion of confirmed diabetes presented in Table 3 (and also in the text, page 10) are not really positive predictive values because not all individuals returned for diagnostic confirmation. These proportions were especially low for those in the lower categories of hyperglycemia.

5. As an oral glucose tolerance test was rarely used for the diagnosis of diabetes in the clinical setting in Brazil in 2001, many cases of diabetes by isolated 2h hyperglycemia were presumably missed by the Campaign. We have now added this phrase to the study limitations (page 16).

6. Data concerning coverage of the target population were obtained from official Ministry of Health registers which compiled the reported frequencies of screening of the 5000+ municipalities. Coverage was in fact lower than that of public health "campaigns" for vaccination previously conducted in Brazil. We believe the large participation rate resulted from concentrated training of health care workers prior to the Campaign, a well-structured primary care network with a large number of community health workers, the novelty of the glucose exam being offered to the population and widely advertised through the media, and the fact that while the target population included only those who depend exclusively on the publicly financed system (80%), anyone over 40 was received and counted as screened.

**Minor points:**

1. Confidence intervals were added to the abstract.

2. After screening forms were received and the random sample of 2000 forms and 200 positive forms selected, we excluded data pertaining to two municipalities with positivity rates > 50%, as we deduced that forms from negative screenees were lacking, resulting in their very large rates of positivity. Thus, final number of municipalities for the analysis was 48. The correct number, 48, is now mentioned on page 6, second paragraph.

3. Local costs were assessed through a questionnaire sent to a non-representative sample of municipalities. As responses regarding costs varied greatly and were not representative,
we opted to do sensitivity analyses based somewhat on this range of results. We have now clarified this in the Methods section (p. 8).

4. In the main analysis we only considered newly diagnosed individuals. However, as the screening program was part of a major plan for reorganization of healthcare services for diabetes and population awareness, the incorporation of individuals with previous diabetes into the healthcare system is an additional benefit to be considered. Thus, we have reported results separately for newly and prior diagnosed individuals in Figure 1. We have clarified our approach in the first paragraph of the Discussion (page 13).
Reply to specific points from Thomas Hoerger's review:

**Major revisions:**

1. Cost per diabetes case diagnosed was US$58, and this was calculated considering both screening and diagnostic confirmation costs. The value originally reported in the abstract (total costs were $16.4 million) included only total direct costs for the screening campaign. We have now provided the value including both screening and diagnostic costs in the revised text (abstract and Results section, page 11). We have also changed the Methods (pg 7) and Results sections (pp 11-12) to explicitly describe how confirmation and total costs were calculated.

2. Additional information on the component level costs has been added into the text (i.e., costs of reagents and glycometers = US$0.42 per target individual to be screened ($13.19 million/31.1 million population). We believe that these data (cost/target population) are the most relevant for planning and policymaking purposes.

   - Mobilization costs of $3.11 million included the following: elaboration of a media plan; media time in radio, television, newspaper and billboard announcements used to publicize screening days; and printed material used during the campaign (posters, booklets, forms etc.). This information is detailed in the text (pp 11-12).

   - Labor costs were not included in the base case, as existing personnel were used to conduct this one-time Campaign, and no additional expenses were explicitly incurred by the health system for labor. We have now explicitly stated values from the sensitivity analysis estimates (Table 2 and page 13), that, if these labor costs were included, cost per case would increase by 25-50%.

**Minor Essential Revisions**

- Page 11, last paragraph beginning "A greater fraction...": We have now (p. 12) clarified our results concerning cut points, detailing our presentation of the greater sensitivity of the fasting value and providing the numbers resulting from the study’s sensitivity analysis concerning yield and thus cost per case.

- Additional study limitations were added in this section (pg 15), as suggested.
Additional revisions

- WHO has updated its conversion rate from Reais into Int$. We have used this updated value in the text, and changed the corresponding reference.

- Several changes have been made to improve the English language quality.

- Finally, there was a typo in the text for the values of each physician visit (pg 7) in the national health care system, and confirmation cost at the private sector. The correct values were inserted in the text (US$ 1.09 for each medical visit in the public sector, and US$ 12.12 total confirmation costs in the private sector).