Reviewer's report

Title: Acceptability and implications of the rapid hepatitis C screening test among high-risk young people who inject drugs

Version: 2 Date: 24 March 2014

Reviewer: Ann Drobnik

Reviewer's report:

Major compulsory revisions

• The last paragraph of the background section needs to more clearly communicate your objective. In the statistical analysis paragraph you state that your main outcome of interest was which test participants chose, however, the background section and your title seem to indicate that your main interest was in the acceptability of the rapid test. From this paragraph and the results section, it seems like you were looking at test choice only to assess whether or not persons who chose the rapid test were different from those who chose the blood draw.

• In general in the background section you need to make a stronger case for why and how young PWID may be different from other PWID and therefore worth studying. This could also be strengthened in the discussion.

• It’s not clear what data was collected from the outcomes questionnaires of persons who chose phlebotomy testing. There are some data presented for the first time in the 1st paragraph of the discussion that are not in the tables or presented in the results and seem to indicate that you collected additional data from this group that wasn’t shown previously.

• The second to last paragraph of the paper you note that the study is limited by the fact that participants were already engaged in a study of HCV transmission and risk, but based on your sampling method paragraph, I understood that participants had also agreed to be periodically tested. This is the real limitation because the advantage of the rapid test is that it may encourage persons who wouldn’t test otherwise to get tested. This should be discussed if my understanding of the agreement to test is correct.

Minor essential revisions

• In paragraph 1, last line, you state that young PWID and young injectors are at especially great risk. A sentence or two explaining why the risk of HCV acquisition is especially high in this group as compared to other age groups, and information on trends over time in this group would make a stronger case for why this is an important demographic group to focus on for HCV testing.

• In paragraph 2 you state that identifying acute HCV is important, however, the rapid test cannot necessarily detect acute HCV so this statement seems out of place in the background section. It may be better as a point of discussion at the
end in pointing out the limitations of the rapid test where you bring up the need for RNA testing.

• On page 5 in the first paragraph of the methods section, specify that the HCV rapid test is a finger stick.

• On p. 5 in the first paragraph of the methods section, please explain what a rapid test disclosure is.

• On p. 5 in the first paragraph of the methods section, were participants all recruited from baseline of the UFO study, or were they approached at follow-up visits as well? The second sentence made me think the former, but then a couple of sentences later data collection at baseline and follow-up visits is mentioned.

• On p. 5 in the first paragraph of the methods section, you indicate that subjects must self-report negative HCV RNA – you need more explanation for how this was asked/ascertained. Were persons with unknown HCV status eligible? Were persons with a previous negative antibody test eligible? Were persons with a previous positive antibody but negative RNA eligible?

• The last sentence of the first methods paragraph – the word choice of “perfunctory” is a little confusing. Does this mean that participants got a blood draw at each visit as per the standard protocol for the UFO study whether or not the individual chose to participate in the rapid test portion of the study?

• In the second paragraph of the methods section (measures) there are several measures listed which do not appear in your tables (age of first injection, incarceration history, some service utilization measures). You should either exclude them from the methods, or present them in your table and comment on the findings in the results section.

• In the statistical analysis paragraph, you don’t need to repeat the measures that you looked at unless you did distinct analysis on particular variables. These should be listed only in the measures paragraph.

• As in the measures section, in the statistical analysis section you need a separate paragraph devoted to the methods that generated table 2. As is, it reads as though you used chi square to look at the survey outcomes measures, but since these questions were restricted only to those who chose the rapid test, the analysis for these data need to be explained separately. It’s also confusing that you’re referring to the table 2 findings as the “survey outcomes”, when these aren’t the stated outcomes of interest of the study.

• Fishers exact test may be more appropriate for comparing differences between the two testing groups as you have a very small sample size of persons who chose the blood draw.

• Table 1 – why not break down the non-white category?

• Table 1 – It’s counter intuitive to have the first column of the total sample adding to 100% going down the rows, while the second column of rapid test takers adds
to 100% going across and adding that column to the missing phlebotomy column. Suggest structuring it so that by adding the rows going down rather than across you arrive at 100%, showing the phlebotomy column to make the numbers much more meaningful, and adding p-values

• Table 2 – suggest being consistent with table 1 and showing both N and %, with just 1 decimal place.

• In the results section, paragraph 2, you state that there were no significant differences in participant characteristics between those who chose the rapid test and those who chose the phlebotomy. First, table 1 doesn’t show the data for the phlebotomy participants so readers aren’t able to look at these results, and second, it’s not clear whether or not there were differences on the other measures (service utilization or risk behaviors). Because you list participant characteristics as separate from service utilization and risk behaviors in the methods it’s important to explicitly state any differences or the lack thereof, particularly if the data are not shown in your table.

• You do a nice job in the measures paragraph to label the 3 types of measures you collected as a-c, making it very easy to follow. Be consistent when you refer to these three groups of measures in the results and in the discussion (first paragraph). As stated above, some of the measures are left out of the results section, and in the discussion the language isn’t consistent.

• In the results, it would be helpful to say a bit more about who the young PWID population in your sample is and in the discussion to contrast them with the literature about PWID generally. For example, a large majority of your sample was homeless in the previous 3 months. Are most PWID homeless, and if this is something that is more common among young injectors, might this be a reason given the instability and transitory nature of homelessness to offer a testing method that doesn’t require the patient to come back for results?

• In the discussion, paragraph 2, please explain why RNA testing is necessary and emphasize that for sites that don’t have phlebotomists on staff or cannot cover the cost, referrals must be provided to persons testing antibody positive.

Discretionary revisions

• On p. 5 in the first paragraph of the methods section, state what CLIA is, why its required for rapid testing

• On page 5 in the first paragraph of the methods section, “participapnts participating” (line 3) doesn’t flow well. Suggest rephrasing to avoid using these two words together.

• On p. 5 in the first paragraph of the methods section, be consistent with the use of report and self-report (injected in the last 30 days, negative HCV RNA)

• On page 5 in the first paragraph of the methods section: specify that the pre- and post-test risk reduction counseling is specific to HCV risk. It follows a
sentence about phlebotomists having HIV rapid test counseling experience, but not HCV so it’s not clear that the counselors are trained in HCV risk reduction specifically.

• The last sentence of the measures paragraph in the methods section explaining why these measures were collected should come before the explanation of the measures themselves.

• First sentence of the 3rd paragraph under discussion, change to “this test offers a critical opportunity to increase HCV testing AMONG high risk young PWID”

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

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I wrote a paper that was published in 2011 in AJPH on the OraSure rapid HCV test. The project was funded by OraSure, however, my salary was not paid from these funds, nor was OraSure involved in the design, data collection, data analysis or results interpretation of the project.