PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	A cash transfer scheme for people with tuberculosis treated by the National TB Program in Western India: a mixed methods study
AUTHORS	Patel, Bharatkumar; Jeyashree, Kathiresan; Chinnakali, Palanivel; Vijayageetha, Mathavaswami; Mehta, Kedar; Modi, Bhavesh; Chavda, Paragkumar; Dave, Paresh; Zala, Chintu; Shewade, Hemant; Solanki, Dipak; Kumar, Ajay

VERSION 1 – REVIEW

REVIEWER	Tom Wingfield Liverpool School of Tropical Medicine, UK
REVIEW RETURNED	18-Aug-2019

GENERAL COMMENTS	**MAJOR COMMENTS** **DBT scheme, people with MDR excluded:** why do these patients take longer to clarify their DBT receipt status given that the first payment should be made within the first two months anyway? What is this delay? This also seems important, especially given the evidence that is coming out from the TB Patient Costs Surveys of higher costs for people with MDR-TB. I feel quite strongly that if there is data available in these patients then they should be included in this analysis. **Tables 1 and 3:** can the authors also include bank account or socioeconomic status in this analysis? This is potentially important, especially with regards to examining equity of the DBT. Also, please can the authors perform a likelihood ratio test or similar interaction terms on the regression analysis to check for interactions between variables (which I think there will be for some of those they use). Please then report the findings of the interactions too. **Tables 1 and 2:** I am a little surprised that the authors didn't perform a regression analysis with the binary dependent outcome variable of treatment success (e.g. WHO defined cure or treatment completion) versus not treatment success against some of the risk factors they have identified in their other regression analyses and

	also include receipt or non-receipt of DBT (or perhaps amount received from DBT) as an independent variable. Could the authors consider this please. This would allow comparison with other papers from Brasil (Carter et al, https://gh.bmj.com/content/bmjgh/4/1/e001029.full.pdf) and Argentina (Klein et al, https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002788) that have reported just this. I understand that this issue has been reviewed in the discussion section but I disagree that this precludes showing the analysis ("warts and all" as they say), perhaps in a supplementary table. **Key informant interviews:** I cannot understand how these were 7 and 9 minutes respectively. It is unclear how they were structured and how they were formalised and consistent across participants. From previous experience, an "in-depth" interview does not last less than 10 minutes! Overall, the qualitative section is the least well described part of an otherwise well-described and reported paper. **MINOR COMMENTS** **Title**: suggest revise to "A cash transfer scheme for people with tuberculosis treated by the National TB Program in Western India: a mixed methods study". This is because for an international readership, this terminology will be most widely understood (compared to direct benefit transfer) **Abstract, Design**: suggest "Design: A mixed-methods study comprising a quantitative cohort and descriptive qualitative study." **Abstract:** it is unclear if all patients (as in introduction to abstract) or just those on first-line treatment received the cash transfer. If it is all then why did the authors just analyse coverage/enablers etc in those receiving first-line treatment **Abstract**: please include how many were asked to be recruited and how many completed recruitment (e.g. attrition rate)

	Abstract: what was the mechanism for private patients to receive the transfer (e.g. did they have to be first registered with the public NTP and then receive?) **Abstract**: please can "smooth fund flow" be rephrased to be clearer (e.g. which part of the fund flow? Identification of recipient, cash release, cash receipt…) **Introduction, Lines 118-119**: what does "primarily for nutrition support mean". Please can this be expanded on or clarified. **Introduction**: it would help greatly if the authors could give some background as to any preliminary data or findings or policy dialogue that helped to shape the direct benefit transfer scheme (e.g. how was it decided that it should be cash, how was it decided how much cash and when, how was it decided that it should be via bank transfer? On what evidence was any of this based?). Thank you. **Introduction**: please can the authors also state if this scheme was being concurrently implemented in any other regions of India other than Vadodara. Thank you. **Study design**: please clarify for the readers what a concurrent triangulation design is and justify why this was used. **General setting, Lines 139-140**: please rephrase "and was home to" to "with XXXXXX TB patients registered with the NTP in 2017." (If indeed that is what the number represents) **General setting**: Lakhs will not be a unit understood by some readers outside of the Indian subcontinent. Please clarify. Thanks. **DBT scheme, Lines 156-7**: please describe the "approval process" from field to financial office. This is quite important and might help the reader to better understand the subsequently described delays. It note that this is shown in Figure 1 later on but think this should be referred to here. Please also can the authors describe if this

	money is only for the patient and if it alters according to household size or poverty level (it appears not but would be good to clarify). **DBT scheme**: what about people who initiated treatment but were then transferred out of area or moved out of area? **Key informant vs in-depth interviews**: stakeholders had "key informant interviews" while people affected by TB had "in-depth interviews". Please describe the methods for each of these and what is the difference between these two forms of interview (if indeed they were actually different)? How can an in-depth interview be 7 minutes long? This sounds more like a closed-question rapid questionnaire interview. **Interviews**: please also include sampling technique (presumably purposive sampling) for selection of participants in these interviews. **DBT receipt**: how was this defined? Was this that the portal said they had received it or that the patient confirmed they had received it? Or both? Please can the authors also clarify what happened if a patient was lost to follow-up or died (e.g. did the household still receive DBT?) **Analysis**: suggest "factors <0.2 in [univariate] unadjusted analysis…." **Analysis, qualitative**: please explain "standard procedures" for coding and give references. **Table 1:** is treatment sector really treatment sector or just where the patient was notified from (e.g. some patients would likely have received some treatment from public and then private or vice versa) **Table 2**: explanation of the receipt of DBT for 3 months if new patient or 4 months if retreatment could do with coming in the methods section rather than just appearing here in the table.

	Table 4 is really helpful and will be useful to policy makers and implementers in future – thank you. **Enablers results**: given that the authors report that healthcare providers said that they perceived that those who received the DBT were more likely to adhere to treatment, this adds weight to my argument above to look at treatment success rates by receipt of DBT / amount of DBT received (while adjusting for confounders) **Enablers and challenges**: I think that the text results from this section could be reduced somewhat and the authors just rely on their excellent table summary. However, I understand that including some direct comments/responses from interviews is really useful. **Discussion**: can the authors comment further on a) whether they think that simply providing one lump sum at the beginning of treatment would be more beneficial than being spread throughout treatment and b) whether there were any soft conditions (or even just "expectations") placed on receipt of CBT at all (e.g. completion of treatment etc). **Discussion**: it remains unclear to me why patients treated privately had such drastically different (reduced) coverage of DBT. This is not clearly explained in the paragraph related to this area. Were private practitioners aware of DBT? Were private patients aware of DBT? Was there some hidden challenge for private patients or were they excluded? They must have been notified to India's NTP to be available for data analysis by the authors I presume so would have been registered/eligible. Please clarify.

REVIEWER	Margaret McConnell Harvard T.H. Chan School of Public Health, USA
REVIEW RETURNED	27-Sep-2019

GENERAL COMMENTS	Thank you for the opportunity to review this paper. The research addresses an important question about the implementation of a cash transfer program to support tuberculosis patients. While the research is important and the results are illuminating, key details about the methods are not provided. First, study outcomes are not clearly defined. It would be helpful to have a section of the tool that defines the key study outcomes and articulates the reasons for selection as outcomes. A better understanding of the nature of the quantitative data would also be helpful. It appears the data comes from administrative records but who completes the records? How high quality is the data?

	Second, the methods surrounding recruitment and enrollment in the qualitative study need to be provided. How were the patients recruited? This is particularly important given the very small sample of participants in the study. Finally, additional context on the intended implementation of the program would be helpful. Would failures in receipt of transfer occur both because of failures of the health system to deliver the transfers and potentially because patients did not comply with recommendations or changed address without notification? These details would be helpful. This comes out in the results but more clarity on the design of the program is needed. The discussion section would benefit from a more in depth discussion of how the findings relate to the existing literature.

VERSION 1 – AUTHOR RESPONSE

Reviewer's Comments

REVIEWER #1
Tom Wingfield
(Line numbers are with reference to the "*Revised Manuscript.docx*")

We are grateful to the reviewer for detailed review of this paper and providing positive comments and useful suggestions.

REVIEWER
General comment:
The manuscript is well-written and describes a useful, mixed-methods programmatic study evaluating the implementation of a cash transfer scheme ("direct benefit transfer") in Western India. This is an important area of study given the extensive data from diverse settings that have already shown the positive impact of cash transfers for TB-affected households including on TB treatment success. India is a country that, in my opinion, is a leader in this field and given the extensive co-burden of TB and poverty in certain parts of India, this work is vital. I congratulate the authors on their hard work.
The major limitations of the study include a lack of adjustment for socioeconomic status in their models, no model examining the impact of the cash transfer on treatment success (although I note the authors' reasons to not do this I still think this would be beneficial), the exclusion of people with drug resistant TB, and the explanation of the qualitative methods (which could be improved and include stating that an in-depth interview took, on average, less than 10 minutes).

AUTHORS RESPONSE

We thank you for appreciating our work and words of encouragement. We agreed to the comments. We have tried our best to address all these comments and provide a point-by-point response below in detailed comments section of the reviewer.

MAJOR COMMENTS

REVIEWER

DBT scheme, people with MDR excluded: why do these patients take longer to clarify their DBT receipt status given that the first payment should be made within the first two months anyway? What is this delay? This also seems important, especially given the evidence that is coming out from the TB Patient Costs Surveys of higher costs for people with MDR-TB. I feel quite strongly that if there is data available in these patients then they should be included in this analysis.

AUTHORS RESPONSE

We thank the reviewer for this comment. We do agree that patients with MDR-TB suffer higher catastrophic cost compared to drug-sensitive patients with TB and inclusion of MDR-TB patients in the study is important in context of study objectives. However, due to limitation of study period, we could not include them in the study. Nevertheless, we have now included this point as one of the limitations of the study in corresponding section. (Page number 24, line numbers 478-480)

Detailed description of this limitation:
As per the National Tuberculosis Program of India, standard duration of treatment regimens for patients with TB are- 6 months for new drug-sensitive patients with TB, 8 months for retreatment drug-sensitive patients with TB, and minimum 24 months for MDR-TB patients (Intensive phase of 6-9 months and Continuation phase of 18 months). We planned to cover first 6 months cohort of patients with TB for DBT coverage (from 1st April 2018 to 30th September 2018), after launch of DBT cash incentive scheme. We can decide receipt of even a single installment of DBT only after end of treatment period. Considering these facts and available study period, we decided censored date of 31st May 2019 to collect quantitative secondary data of patients with TB from nikshay and PFMS portal. This have covered all drug sensitive patients with TB (considering treatment period of 8 months for retreatment drug sensitive patient with TB of last date 30th September 2018) but we could not include MDR-TB patients because completion of their treatment period extended much beyond 31st May 2019. We also did not collected the data of MDR-TB patients.

REVIEWER

Tables 1 and 3: can the authors also include bank account or socioeconomic status in this analysis? This is potentially important, especially with regards to examining equity of the DBT. Also, please can the authors perform a likelihood ratio test or similar interaction terms on the regression analysis to check for interactions between variables (which I think there will be for some of those they use). Please then report the findings of the interactions too.

AUTHORS RESPONSE

We thank the reviewer for the suggestion. We also feel that the socio-economic status and having bank account could have potential interaction with respect to availing DBT. However, the details of socio-economic status was not routinely collected in the TB program and hence, not available for this analysis. We have now included this as a limitation in the study (Page number 24, line numbers 481-483). We are also planning to do future research with primary data collection to see the effect of socio-economic status on receipt of DBT, especially in private sector patients.

Availability of bank account was a prerequisite condition for beneficiary (patient with TB) to get direct benefit cash transfer. Because of this, among non-recipients of DBT, there was two groups- those having bank account and those who do not. However, among recipients of DBT all of them had bank account.

REVIEWER

Tables 1 and 2: I am a little surprised that the authors didn't perform a regression analysis with the binary dependent outcome variable of treatment success (e.g. WHO defined cure or treatment completion) versus not treatment success against some of the risk factors they have identified in their other regression analyses and also include receipt or non-receipt of DBT (or perhaps amount received from DBT) as an independent variable. Could the authors consider this please? This would allow comparison with other papers from Brasil (Carter et al, https://gh.bmj.com/content/bmjgh/4/1/e001029.full.pdf) and Argentina (Klein et al, https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002788) that have reported just this. I understand that this issue has been reviewed in the discussion section but I disagree that this precludes showing the analysis ("warts and all" as they say), perhaps in a supplementary table.

AUTHORS RESPONSE

We agree with the comment and we now included the supplementary table (as 'supplementary file 5') showing regression analysis of factors (including DBT receipt status) associated with binary treatment outcome variable (treatment success vs treatment unsuccess). We would like to thank the reviewer for

suggesting the references for the same. With the inclusion of supplementary table, we updated results section (Page number 15, line numbers 280-283) and discussion section (Page number 22, line numbers 422-433).

REVIEWER

Key informant interviews: I cannot understand how these were 7 and 9 minutes respectively. It is unclear how they were structured and how they were formalized and consistent across participants. From previous experience, an "in-depth" interview does not last less than 10 minutes! Overall, the qualitative section is the least well described part of an otherwise well-described and reported paper.

AUTHORS RESPONSE

Thanks for the comment. We would like to bring to the kind notice of reviewer that average duration of key informant interview was 12 minutes with a range of 7-21 minutes. This duration does not include introduction to participant, reading out participation information sheet, solving of any doubts, process of obtaining written informed consent for interview as well as for audio recording of interview and validation of information by participant at the end of interview. We used structured interview guide consisting of open-ended questions (Interview guide is now included as 'supplementary file 4'). Key informants were asked only about specific areas of interest, e.g. enablers and challenges for effective implementation of DBT scheme, and suggested solutions for the challenges. All interviews were conducted by principal investigator himself who is trained in qualitative methods. Considering the focused area of exploration and range of key informants from reserved to out spoken nature; the duration of interview may look shorter. However, most of the interviews have very rich information about concerned topic.

Regarding description of qualitative methods, we have provided the details in the methods section considering the word limits. However, as suggested by reviewer in general comments about this issue, we now included the statements 'less than 10 minutes' and 'less than 15 minutes' respectively for average duration of patient and key informant interviews which was 7 and 12 minutes in that order. (Page number 11, line numbers 213-214)

MINOR COMMENTS

REVIEWER

Title: suggest revise to "A cash transfer scheme for people with tuberculosis treated by the National TB Program in Western India: a mixed methods study". This is because for an international readership, this terminology will be most widely understood (compared to direct benefit transfer).

AUTHORS RESPONSE

We agree to this important suggestion and we have updated the title exactly as suggested.

REVIEWER

Abstract, Design: suggest "Design: A mixed-methods study comprising a quantitative cohort and descriptive qualitative study."

AUTHORS RESPONSE

Thank you, we have amended the study design in the abstract section as suggested. (Page number 3, line numbers 48-49)

REVIEWER

Abstract: it is unclear if all patients (as in introduction to abstract) or just those on first-line treatment received the cash transfer. If it is all then why did the authors just analyse coverage/enablers etc. in those receiving first-line treatment.

AUTHORS RESPONSE

Thanks for the comment. We would like to clarify that the DBT scheme is for all patients with TB (as in introduction to abstract); however, in the study we have included only those patients who are on first-line anti-TB treatment (as in methods to abstract). The response to the reason for exclusion of patients with drug-resistant TB already given in reviewer's major comments section.

Please note that as per the comments of other reviewer, to comply with the journal's format of abstract, we have removed background and covered methods under titles of setting, participants, and primary and secondary outcomes. (Page number 3, line numbers 50-56)

REVIEWER

Abstract: please include how many were asked to be recruited and how many completed recruitment (e.g. attrition rate)

AUTHORS RESPONSE

Thank you for the comment. All patients with TB notified on nikshay portal of city TB centre, Vadodara between 1 April 2018 and 30 September 2018; and initiated on first-line anti-TB treatment were recruited. Data of all these patients was extracted from nikshay portal. This being secondary data, the classical process of completed recruitment and attrition does not apply here.

Responsibility of the DBT for patients who were notified on nikshay portal of city TB centre, Vadodara but initiated on treatment at other district/city TB centres lies with the respective centre where treatment started. Therefore, these patients were excluded from the study, because it was not possible to obtain their DBT details. This is described in detail in methods section in main text (Page number 10, line numbers 179-183). Necessary details are also given in abstract section under 'participants'. (Page number 3, line numbers 51-54)

REVIEWER

Abstract: what was the mechanism for private patients to receive the transfer (e.g. did they have to be first registered with the public NTP and then receive?)

AUTHORS RESPONSE

Thank you for bringing this point for clarification. All patients diagnosed with TB in private sector have to be first registered with public NTP through web-enabled 'nikshay' portal by private doctor. Administrative blocks of NTP (city/district TB centres) are provided with login credentials for 'nikshay' portal to manage the data of patients in their respective areas. The program coordinator of these city/district TB centres downloads the list of notified patients in their area on regular basis and contacts them for obtaining necessary details for DBT processing. Therefore, the general process for notification and cash transfer is same for public as well as private sector patients. The process has been described in main text under methods. (Page number 9, line numbers 157-170)

Considering the word limit in abstract section, we could not provide these details in abstract.

REVIEWER

Abstract: please can "smooth fund flow" be rephrased to be clearer (e.g. which part of the fund flow? Identification of recipient, cash release, cash receipt…)

AUTHORS RESPONSE

Thank you for the comment. We have rephrased "smooth fund flow" to 'timely and sufficient fund release to TB centre' to make it clearer in the abstract section. (Page number 3, line numbers 63-64)

REVIEWER

Introduction, Lines 118-119: what does “primarily for nutrition support mean”. Please can this be expanded on or clarified.

AUTHORS RESPONSE

The official local name for DBT scheme (for patients with TB) in India is ‘Nikshay Poshan Yojana’, where the literal meaning of the word ‘Poshan’ is nutrition. As poor nutrition is one of the important factor associated with TB in India, the DBT scheme is started primarily for nutrition support. However, DBT scheme also aims to provide financial assistance for covering catastrophic cost and to encourage treatment completion.

In introduction, the phrase “primarily for nutrition support” has been expanded to clarify it. (Page number 7, line numbers 115-118)

REVIEWER

Introduction: it would help greatly if the authors could give some background as to any preliminary data or findings or policy dialogue that helped to shape the direct benefit transfer scheme (e.g. how was it decided that it should be cash, how was it decided how much cash and when, how was it decided that it should be via bank transfer? On what evidence was any of this based?). Thank you.

AUTHORS RESPONSE

Thank you for the comment. We would like to clarify this.

In line with WHO’s “End TB Strategy”, India has drafted “National strategic plan (NSP) for tuberculosis elimination 2017–2025”. In India, food insecurity and under-nutrition coexist with a large burden of tuberculosis. To address this issue, it was proposed to launch a scheme to provide a monthly cash incentive for every TB patient under NSP. The programme adopted a Direct Benefit Transfer (DBT) mechanism for transfer of monetary support to ensure that the funds reach rightful recipients in a timely manner. In addition to the nutrition support, other objectives of this support system are to increase treatment adherence and to eliminate catastrophic expenditure by TB patients.

We have now updated the corresponding paragraph in Introduction section. (Page number 7, line numbers 110-121)

REVIEWER

Introduction: please can the authors also state if this scheme was being concurrently implemented in any other regions of India other than Vadodara. Thank you.

AUTHORS RESPONSE

Thank you for the comment. The DBT scheme has been launched nationwide from 1st April 2018. This has been updated in Introduction. (Page number 7, line numbers 111)

REVIEWER

Study design: please clarify for the readers what a concurrent triangulation design is and justify why this was used.

AUTHORS RESPONSE

We agree with the comment. We have now included what is concurrent triangulation design and why it was used.

Concurrent triangulation design: it is a type of mixed methods study in which, qualitative and quantitative data are collected concurrently. The data is analyzed separately and then compared and/or combined. We have used this method to combine the findings of quantitative and qualitative study and thereby to have a holistic picture on implementation of DBT scheme. (Page number 8, line numbers 133-137)

REVIEWER

General setting, Lines 139-140: please rephrase "and was home to" to "with XXXXXX TB patients registered with the NTP in 2017." (If indeed that is what the number represents)

AUTHORS RESPONSE

Thank you for the suggestion. Accordingly, we rephrased the line in General setting. (Page number 8, line numbers 144-145)

REVIEWER

General setting: Lakhs will not be a unit understood by some readers outside of the Indian subcontinent. Please clarify. Thanks.

AUTHORS RESPONSE

Thank you for the comment. We have now replaced the term 'Lakhs' with 'million'.

REVIEWER

DBT scheme, Lines 156-7: please describe the "approval process" from field to financial office. This is quite important and might help the reader to better understand the subsequently described delays. It note that this is shown in Figure 1 later on but think this should be referred to here. Please also can the authors describe if this money is only for the patient and if it alters according to household size or poverty level, (it appears not but would be good to clarify).

AUTHORS RESPONSE

We agree with the suggestion of the reviewer. However, we would like to retain the one line of 'approval process' in methods section with supporting figure 1 (supplementary file 1). If we include detailed description of this approval process in methods section, there is a risk of substantial increase in word count of the manuscript. Hence, we leave it to the editorial office to decide if we should include the details in method section or retain the self-explanatory figure.

For the second comment, we have now included the statement mentioning that 'cash incentives are for the patient only and the amount fixed, irrespective of household size or poverty level'. (Page number 9, line numbers 161-162)

REVIEWER

DBT scheme: what about people who initiated treatment but were then transferred out of area or moved out of area?

AUTHORS RESPONSE

Thank you for the comment. People who were initiated on treatment but were then transferred /moved out of area, were not included in the study, because their DBT details were no more available with transferring facility (city TB centre, Vadodara) at the time of censoring date (31st May 2019). We have now clarified this in study population, methods section. (Page number 10, line numbers 179-183)

REVIEWER

Key informant vs in-depth interviews: stakeholders had “key informant interviews” while people affected by TB had “in-depth interviews”. Please describe the methods for each of these and what is the difference between these two forms of interview (if indeed they were actually different)? How can an in-depth interview be 7 minutes long? This sounds more like a closed-question rapid questionnaire interview.

AUTHORS RESPONSE

Thank you for the comment. Interviews for both ‘key informants’ and ‘people affected by TB’ were in-depth interviews. However, we used accepted term ‘Key informant interviews’ for in-depth interview of key informants. There was no difference in method for two forms of interview. Detailed justification for calling ‘key informant interview’ as in-depth interview has already been given in response to the major comments section on ‘Key informant interviews’. The same justification also applies to in-depth interviews of ‘people affected by TB’. The only difference is that separate interview guide was used for the people affected by TB exploring their perceptions and experiences on DBT. (‘Supplementary file 4’). The reasons for shorter period of interview in case of People affected by TB were ‘focused area of exploration’ and ‘limited response from beneficiaries, even after prompting’. As mentioned earlier, duration does not include the consent process timings.

REVIEWER

Interviews: please also include sampling technique (presumably purposive sampling) for selection of participants in these interviews.

AUTHORS RESPONSE

We agree with reviewer's comment and have included 'purposive sampling' as sampling technique. (Page number 10, line numbers 185)

REVIEWER

DBT receipt: how was this defined? Was this that the portal said they had received it or that the patient confirmed they had received it? Or both? Please can the authors also clarify what happened if a patient was lost to follow-up or died (e.g. did the household still receive DBT?)

AUTHORS RESPONSE

Thank you for the comment. DBT receipt was defined as 'Patient with TB who received minimum one installment of DBT irrespective of time of disbursement'. We have now clarified this operational definition in the newly created heading 'key study outcomes' in methods section. (Page number 12, line numbers 231-238)
DBT receipt status was ascertained as per the information extracted from the portal. It was not verified with the beneficiary.

As per the guidelines, every beneficiary (patient with TB) is eligible for installment of INR 1000 in advance for the completion of 2 months treatment. (Methods section, Page number 9, line numbers 158-161) Therefore, patient lost to follow-up or died receives DBT upto that period and not beyond that (after lost to follow-up or after death).

REVIEWER

Analysis: suggest "factors <0.2 in [univariate] unadjusted analysis…."

AUTHORS RESPONSE

We agree with the reviewer. We have modified the sentence accordingly. (Page number 12, line numbers 227-229)

REVIEWER

Analysis, qualitative: please explain "standard procedures" for coding and give references.

AUTHORS RESPONSE

"Standard procedures" for coding used in this study has been explained in detail with an appropriate reference now. Thank you. (Page number 13, line numbers 245-253)

REVIEWER

Table 1: is treatment sector really treatment sector or just where the patient was notified from (e.g. some patients would likely have received some treatment from public and then private or vice versa)

AUTHORS RESPONSE

Thank you for the comment. We would like to explain this as below.

In our study, treatment sector for the study is considered as the type of facility from where patient is notified. As per the NTP guidelines, in our study also, those patients who switched treatment facility, continued to be identified as per the original place of notification.

REVIEWER

Table 2: explanation of the receipt of DBT for 3 months if new patient or 4 months if retreatment could do with coming in the methods section rather than just appearing here in the table.

AUTHORS RESPONSE

We do agree with the reviewer's comment. We have included it in methods section as well now. (Page number 10, line numbers 176-177)

REVIEWER

Table 4 is really helpful and will be useful to policy makers and implementers in future – thank you.

AUTHORS RESPONSE

We are very happy that reviewer liked this table. We thank the reviewer for appreciating our work on qualitative part of study.

REVIEWER

Enablers results: given that the authors report that healthcare providers said that they perceived that those who received the DBT were more likely to adhere to treatment, this adds weight to my argument above to look at treatment success rates by receipt of DBT / amount of DBT received (while adjusting for confounders)

AUTHORS RESPONSE

We agree with the comment and now included the table on treatment success rates by receipt of DBT as per major comment by reviewer. (Supplementary Table has been added as 'Supplementary file 5') The relevant findings are narrated in results section (Page number 15, line numbers 280-283), and discussed in discussion section (Page number 22, line numbers 422-433).

REVIEWER

Enablers and challenges: I think that the text results from this section could be reduced somewhat and the authors just rely on their excellent table summary. However, I understand that including some direct comments/responses from interviews is really useful.

AUTHORS RESPONSE

We agree with the comment. We now reduced some text results in this section (enablers and challenges).

REVIEWER

Discussion: can the authors comment further on a) whether they think that simply providing one lump sum at the beginning of treatment would be more beneficial than being spread throughout treatment and b) whether there were any soft conditions (or even just "expectations") placed on receipt of CBT at all (e.g. completion of treatment etc).

AUTHORS RESPONSE

Thank you for the comment.

NTP prescribes conditions like 'should have bank account' and 'completion of treatment' for beneficiary to avail DBT benefit. We think that it would be more beneficial to give cash transfer spread throughout the treatment rather than giving lump sum at the beginning of treatment with a view to improve treatment adherence. Direct benefit transfer in patient's bank account is also important to ensure timely payment of cash incentive directly to the patient and thereby reducing corruption. Therefore, DBT scheme in its current form is appropriate. However, we feel that there is an urgent need to address operational challenges highlighted in this paper for better implementation of the DBT scheme. We have now added this in discussion section. (Page number 24, line numbers 470-473)

REVIEWER

Discussion: it remains unclear to me why patients treated privately had such drastically different (reduced) coverage of DBT. This is not clearly explained in the paragraph related to this area. Were private practitioners aware of DBT? Were private patients aware of DBT? Was there some hidden challenge for private patients or were they excluded? They must have been notified to India's NTP to be available for data analysis by the authors I presume so would have been registered/eligible. Please clarify.

AUTHORS RESPONSE

Thanks for the comment. We do agree that this part was not discussed in detail, so there was a difficulty for reader in interpreting it. We have now discussed it in detail and hope that we could able to clarify it. (Page number 23, line numbers 441-456)

As rightly mentioned by the reviewer, private patients have been notified to NTP and for DBT receipt also. So, our analysis already includes the data of private patients.

REVIEWER #2
Margaret McConnell
(Line numbers are with reference to the "*Revised Manuscript.docx*")

We thank the reviewer for reviewing this paper and for the detailed comments and suggestions. We have tried to revise the manuscript in line with these comments.

The specific changes and response to the different points raised include:

REVIEWER: The research addresses an important question about the implementation of a cash transfer program to support tuberculosis patients. While the research is important and the results are illuminating, key details about the methods are not provided.

Study outcomes are not clearly defined. It would be helpful to have a section of the tool that defines the key study outcomes and articulates the reasons for selection as outcomes.

AUTHORS RESPONSE

Thank you for suggesting this important point. We have now added the definitions for our outcome variables under newly added 'Key study outcomes' heading in the methodology section. (Page number 12-13, line numbers 230-242)

REVIEWER

A better understanding of the nature of the quantitative data would also be helpful. It appears the data comes from administrative records but who completes the records? How high quality is the data?

AUTHORS RESPONSE

We agree with the comment. There is a nationwide web-enabled application called 'nikshay' for the entry of records of patients with TB. Entry of records done by trained health functionaries like laboratory technician and TB health visitor, which is reviewed by supervisory cadre like Senior Tuberculosis Laboratory Supervisor (STLS) and Senior Treatment Supervisor (STS) to ensure high quality of entered data. This information has now added in methods section. (Page number 11, line numbers 197-201)

REVIEWER

The methods surrounding recruitment and enrollment in the qualitative study need to be provided. How were the patients recruited? This is particularly important given the very small sample of participants in the study.

AUTHORS RESPONSE

We thank the reviewer for drawing our attention on this matter. We now added the 'purposive sampling' as a method for recruitment in qualitative study. (Page number 10, line number 185)

REVIEWER

Additional context on the intended implementation of the program would be helpful. Would failures in receipt of transfer occur both because of failures of the health system to deliver the transfers and potentially because patients did not comply with recommendations or changed address without notification? These details would be helpful. This comes out in the results but more clarity on the design of the program is needed.

AUTHORS RESPONSE

We agree with the point raised. We have tried to give more clarity on the intended implementation of DBT program in 'background' (Page number 7, line numbers 110-121) and in 'methods' under the heading 'setting' as separate paragraph on 'DBT scheme'. (Page number 9, line numbers 156-170)

REVIEWER

The discussion section would benefit from a more in depth discussion of how the findings relate to the existing literature.

AUTHORS RESPONSE

Thanks for drawing our attention to this important point for discussion. Existing literature from other countries suggests achievement of high coverage with cash transfers. Our study also found a reasonable coverage considering the study is done during the initial period of implementation of the scheme. With regards to implementation of cash transfer schemes, there is paucity of evidence on the operational challenges. This study throws light on the operational challenges related to system, provider and patients' for a large developing country like India. Many studies have proved association between cash transfer and successful treatment outcomes. Because of certain limitations, we have restricted ourselves in a definite conclusion in this regard from our study.

All these points have been added now in the discussion section with appropriate references.

VERSION 2 – REVIEW

REVIEWER	Tom Wingfield Liverpool School of Tropical Medicine, UK
REVIEW RETURNED	30-Oct-2019

GENERAL COMMENTS	Thank you for addressing all of my original comments where possible.

REVIEWER	Margaret McConnell Harvard T.H. Chan School of Public Health
REVIEW RETURNED	14-Nov-2019

GENERAL COMMENTS	Thank you for the opportunity to review this revised manuscript. The manuscript has improved significantly. I have only a few minor remaining suggestions. - It would be helpful to clarify the key treatment outcomes -- how and at what time point are these measured? At what point is a patient considered "loss to follow-up? - I think it might be better to slightly soften the following statement: "Facilitating opening of bank accounts for patients 70 by NTP staff and better support from private providers will improve DBT coverage." to acknowledge some uncertainty, i.e. these changes "may improve DBT coverage." - It would be useful to explain what justifies this conclusion "We feel that the current policy to give cash transfer spread throughout the treatment 471 rather than giving lump sum at the beginning of treatment is appropriate." - The paper would benefit from a read through for clarity in language. For example, it would be helpful to spell out exactly what is meant by this statement "The ethical issues surrounding patient confidentiality will have to be handled though." More generally, it would be helpful to provide more discussion of the reasons and rationale for requiring a bank account and the potential limitations of moving beyond this policy.

VERSION 2 – AUTHOR RESPONSE

RESPONSE TO COMMENTS

REVIEWER #1
Tom Wingfield

REVIEWER
Thank you for addressing all of my original comments where possible.

AUTHORS RESPONSE
We are thankful to the reviewer for accepting our response. We are happy that we could revise our manuscript to the expectations of the reviewer. Constructive comments of the reviewer helped us to improve our manuscript substantially.

REVIEWER #2
Margaret McConnell

REVIEWER
The manuscript has improved significantly. I have only a few minor remaining suggestions.

AUTHORS RESPONSE
We are thankful to the reviewer for accepting our response and appreciating the revision. Positive comments from the reviewer helped us to improve our manuscript considerably. We have incorporated

the suggestions for second revision wherever possible and revised the manuscript accordingly. Point-by-point response is mentioned below.

REVIEWER
It would be helpful to clarify the key treatment outcomes -- how and at what time point are these measured? At what point is a patient considered "loss to follow-up"?

AUTHORS RESPONSE
Thank you for the comment. Treatment outcomes for the study were determined as reported in administrative records of city TB centre, Vadodara. Data on treatment outcomes were extracted from nikshay portal of city TB centre, Vadodara with censoring date of 31st May 2019 (considering last notified case in a cohort on 30th September 2018, and maximum treatment duration of 8 months in retreatment case). Staff of National Tuberculosis Program determines treatment outcome as per the operational definitions of NTP (Box 1) and enters it in nikshay portal. Treatment outcomes were categorized into two standard categories "successful" (cured, treatment completed) and "unsuccessful" (failure, loss to follow-up, died, treatment regimen changed) for key treatment outcomes. We have now updated this information in methods section (Page number 12-14, line numbers 199-200; 240-244)

As per the operational definition followed under the national program, "loss to follow up" is "A TB patient for whom treatment was interrupted for one consecutive month or more."(Box 1)

REVIEWER
I think it might be better to slightly soften the following statement: "Facilitating opening of bank accounts for patients by NTP staff and better support from private providers will improve DBT coverage." to acknowledge some uncertainty, i.e. these changes "may improve DBT coverage."

AUTHORS RESPONSE
We thank the reviewer for the suggestion. We have now updated the statement as suggested and replaced the word 'will improve' by 'may improve'. (Page number 5, line numbers 70-71)

REVIEWER
It would be useful to explain what justifies this conclusion "We feel that the current policy to give cash transfer spread throughout the treatment rather than giving lump sum at the beginning of treatment is appropriate."

AUTHORS RESPONSE
Thank you for the comment. This detailed paragraph was added in response to another reviewer's comment asking for a discussion on authors' viewpoint. As per your comment, we have now justified the statement with the reason "to improve treatment adherence" and updated the line in discussion section. (Page number 25, line numbers 472-474)

REVIEWER
The paper would benefit from a read through for clarity in language. For example, it would be helpful to spell out exactly what is meant by this statement, "The ethical issues surrounding patient confidentiality will have to be handled though."

AUTHORS RESPONSE
We thank the reviewer for this suggestion. We read through the paper for clarity in language and made required changes where necessary. For better clarity, we have now changed the previous statement, "The ethical issues surrounding patient confidentiality will have to be handled though" with following new statement, "However, this may require the physician to reveal the disease status of the patient thereby compromising physician patient confidentiality and raise ethical issues". (Page number 27, line number 520-523)

REVIEWER
More generally, it would be helpful to provide more discussion of the reasons and rationale for requiring a bank account and the potential limitations of moving beyond this policy.

AUTHORS RESPONSE

Thank you for the comment. We have now discussed more about the reasons and rationale for requiring a bank account and potential limitation of moving beyond this policy. (Page number 25-26, line number 474-490)