TB & Tobacco

TB and Tobacco

Tobacco cessation within TB programmes: A 'real world' solution for countries with dual burden of disease.

Grant Agreement no. 680995

Collaborative Project
EU H2020 Programme
Health
Medical Research and the Challenge of Ageing

Project duration: 1st November 2015 to 31st October 2019 (48 months)

Deliverable 1.1 "Intervention Materials"

Author: Helen Elsey (University of Leeds, UK)

Workpackage: 1
Workpackage Leader: Helen Elsey

Due date: 30th September 2016
Actual submission date: 30th September 2016

Dissemination Level: PU
Revision: 1.0

This project has received funding from the European Union's Horizon 2020 Research and Innovation programme, under Grant Agreement number 680995.
The European Commission is not responsible for any of the content of this document.

Contents

Abbreviations not defined in the text

COM-B	Capability, Opportunity & Motivation 'B'
DOTS	Directly Observed Therapy Short-course
FGD	Focus Group Discussion
NGO	Non-Governmental Organisation
SSI	Semi-Structured Interview
TB	Tuberculosis
WHO	World Health Organisation

TB & TOBACCO:

DELIVERABLE 1.1 INTERVENTION MATERIALS

1 INTRODUCTION

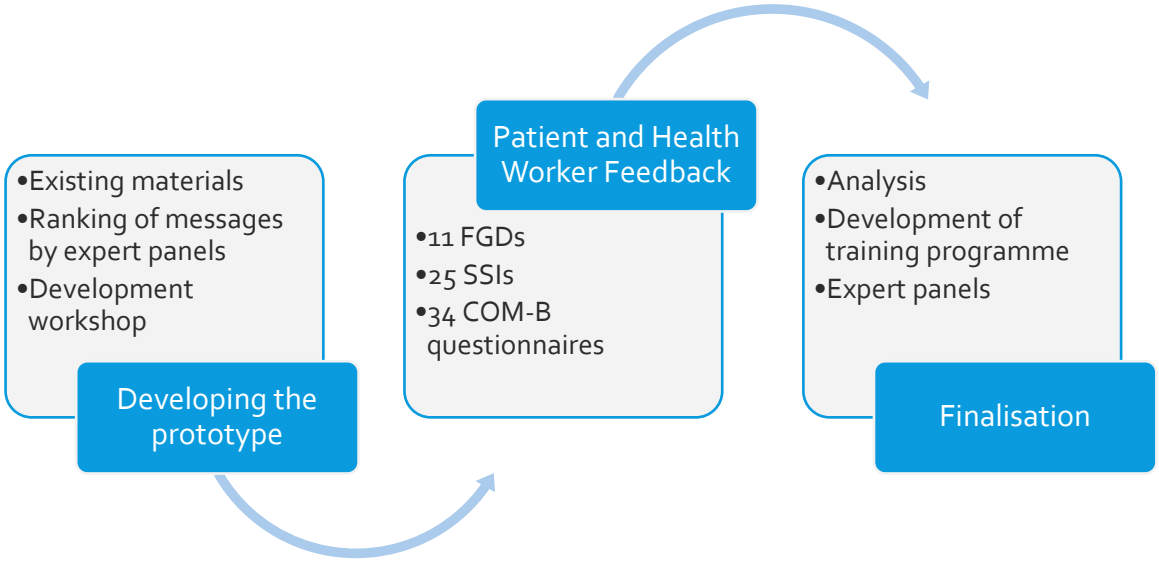
This Deliverable describes the work conducted as part of Work Package 1 (WP1), to develop the behavioural support (BS) intervention in the TB&Tobacco trial. The BS intervention will be delivered to all TB patients, in both arms of the trial, and includes general messages on TB, as well as messages on tobacco cessation. During the first year of the TB&Tobacco study, we have developed the materials and training for use by the health workers in delivering this behaviour support intervention. This fulfils the requirements of Deliverable 1.1 (Intervention Materials). The process that we have followed is outlined below and the English versions of all materials are available on our website.

2 OBJECTIVES

The objectives of Deliverable 1.1 are to develop Intervention Materials for the Behaviour Support Intervention, which forms part of the TB & Tobacco trial. The Intervention Materials must be simple, effective and appropriate to the local context in each of the three countries where the trial is taking place (Pakistan, Bangladesh and Nepal).

3 METHODS

The diagram below shows the major activities throughout year 1 of the project that have enabled us to develop the behaviour support intervention and the accompanying training programme.



3.1 DEVELOPING THE PROTOTYPE BEHAVIOUR SUPPORT MATERIALS

EXPERT PANELS: A participatory ranking exercise was conducted with an expert panel in each country. The panels included National TB Programme (NTP) managers and facility health workers. We used previous BS materials developed by our team as a starting point. The messages within these materials have been carefully phrased to include

behaviour change techniques (BCTs) which have been found effective in supporting tobacco users to quit (Bartlett et al. 2014; Michie et al. 2011).

The expert panels were given a list of all the main messages to be considered for inclusion in the BS intervention materials and were asked to rank them on the basis of:

- How **acceptable** the message is likely to be to the patient receiving the message and the Health worker/DOTS facilitator delivering the message.
- How likely it is that this message will be **effective** in helping the patient to quit tobacco use.
- How **feasible** it will be to deliver the message, given any constraints due to time and facilities.

A key decision arising from discussions with the TB&Tobacco partners and the expert panels was that the BS intervention should include TB self-management behavioural support, as well as tobacco cessation behavioural support. Inclusion of TB messages means that the package is appropriate for use amongst all those diagnosed with TB, not just tobacco users. A rapid assessment was conducted in each country, to see if there were any other simple materials to use in the initial consultation to provide basic messages to support the patient in managing their TB treatment. No such simple materials were found to be in use in any of the three countries. This highlighted the value of developing a BS intervention that covered TB and tobacco messages. Our reasoning is that this may also enhance the likelihood of routine implementation of the intervention.

The key TB messages were developed, drawing on materials found during a rapid review of publically available TB materials from both high and low/middle-income countries. Key messages from these materials focused on TB transmission, adherence to TB drugs, maintaining social support, reducing stigma and emphasising healthy behaviours to facilitate successful TB treatment.

Building on the advice of the expert panels, a workshop was held of the WP1 working group, to put together the most appropriate BS intervention materials. A member of WHO's Stop TB team was able to join our working group by Skype. Based on our previous experience of feasibility within the health facility context, we agreed to keep the BS intervention to 10 minutes only. This meant a series of 8 slides covering both the TB and the tobacco messages could be used within the intervention. Following this workshop, the materials (flip book, leaflet, poster) were sent to the country partners for testing with health workers and patients.

The components of the BS intervention include:

- **Flipbook** to guide counselling: TB messages and cessation messages on 8 slides. The time estimated to deliver this is 10 mins. The tobacco slides are then repeated, and particular concerns discussed during a 5 minute session held 5 days after the initial 10 min BS session. This time period has been agreed to fit with WP2 and the distribution of the IMP (Investigational Medicinal Product).. This second session marks the patient's 'quit day'. The flip book has male and female sections. Our previous work in both Pakistan and Nepal has highlighted the different gender norms around tobacco use. To support both men and women to quit, we believe that gender specific photographs are more likely to have resonance with patients. On the back of each slide there is the text for health workers to use during the counselling session. This text remains the same for men and women.

- **Leaflet**: Covers key messages for tobacco cessation, using the same pictures as used in the flip book, to reinforce counselling messages. The leaflet is given to those who receive the BS session, and those that decline to have the BS as they are not yet ready to quit. The leaflet has two aims: to reinforce messages given during the BS and to increase motivation among those who declined the BS.

- **Poster**: To advertise the cessation service.

The diagram below details the key messages of each page of the flip book. The photos come from each of the country contexts. The finalised BS intervention can be found on the project website. The finalised slides also present the text for the health workers.

The Initial Prototype: Key Messages for Each Page Of The Flipbook

Cover Page

- Positive image of healthy woman or man, recovered from their TB

GH1: How you got TB and how you can be cured

- Reassure patient feel comfortable by explaining TB is curable if they adhere to treatment
- Explain transmission

GH2: How to take your medicines

- When – time of day, before /after food
- Keep taking for medicines daily of six months – what to do if you take a double dose.

GH3: Adherence

- Dealing with side effects
- Attending the health centre
- Preparing for challenges - festivals

GH4: Feeling Supported

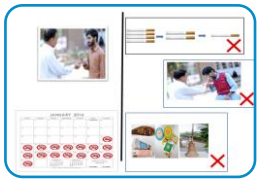
- Overcome myths of transmission
- Maintain your support networks – family and friends

GH5: Keep Healthy

- Eat well
- Rest and sleep well
- Don't drink alcohol and don't smoke

TC1: Benefits of quitting and consequences of not..

- Increase chance of recovering from TB
- Longer term risks of CVD and cancer
- Prompt client to think of other non-medical benefits



TC2: Things that help you quit and things that don't

- Pick a quit date and stick to it
- Not a puff
- Don't switch to smokeless

TC3: Withdrawal and coping

- Dealing with side effects
- Client thinks of ways to overcome these
- Given leaflet

3.2 PATIENT AND HEALTH WORKER FEEDBACK

Once the prototype had been developed, feedback was sought from people with TB and from health workers. The partners selected two of the trial sites in their country to be case study sites. These case study sites will form the setting for detailed qualitative work throughout WP1 and subsequently WP4 and WP5. The case studies were selected purposively to illustrate different key characteristics among the trial sites. In Bangladesh, the case studies were chosen to include one urban NGO-run clinic and one rural government centre supported by BRAC (NGO in Bangladesh). In Nepal, the case study sites are both urban, but one is an NGO-run national referral centre and the other is a smaller urban government-run clinic. In Pakistan, case study sites were selected as one is a large government tertiary hospital in an urban area and the other a rural government hospital. The selection of the case study sites was also influenced by the practical issues of the level of enthusiasm and support from that centre and the close location to country partner's offices.

Qualitative methods of semi-structured interviews (SSIs) and focus group discussions (FGDs) were used to understand the extent to which the messages and photos were understood by participants. Given the different gendered norms and perceptions around tobacco, we conducted separate focus groups with men and women. Participants were shown several options for each page design and asked which ones were most understandable and appropriate. Photographs were used throughout, as our previous work has highlighted how patients relate to and understand locally appropriate photos more than drawings or cartoons. Actors were used to pose in the photos. The exception to this was in Pakistan where models for both the men's and women's flipbooks were patients who were particularly keen to be photographed. Their written consent to use their photos in the Pakistani version of the flipbook was taken.

All SSIs and FGDs were audio recorded and transcribed by the country partners. As Nvivo had been identified as the data analysis tool, a method of transcription formatting was developed to allow for automatic coding of participant names in Nvivo. Transcription methods were discussed with all country partners before analysis began. Partners shared initial transcripts with the University of Leeds team for comments and feedback, after which transcription was carried out by country partners.

A tentative coding framework for materials was initially developed by UNIVLEEDS, in conjunction with country partners. In addition to coding participant responses, participants were given attributes to identify their gender, age group, and level of analysis to which their responses pertained (patient/facility, meso, macro). Initial coding attempts were shared with Leeds to each partner for comments and feedback, after which coding was carried out by country partners. Coding was conducted in two rounds. Initial coding for feedback on BS materials was conducted using transcripts of FGDs and of SSIs with health facility level and district level NTP staff. A second round of coding of FGDs and SSIs was conducted for information to inform the development of training materials.

As with coding, interpretation was conducted in two stages. Finalisation worksheets were developed for feedback on the BS materials, based on the codes for each flipbook slide, leaflet section, or poster. The finalisation worksheets provided the feedback received and linked it to the subsequent decision taken in developing the materials. In the second round of analysis, feedback from the SSIs and FGDs was summarised under a set of codes relating to different contexts of (i) the intervention, (ii) TB patient tobacco cessation, and (iii) Health Worker cessation support delivery. Summary worksheets were provided alongside framework matrices of participant responses to UNIVLEEDS for comment/feedback and discussion was undertaken between UNIVLEEDSs and partner organisations on finalisation of materials based on analysis.

3.3 DATA TO INFORM TRAINING

We re-analysed all qualitative transcripts from patients and DOTS facilitators to identify any issues to consider in designing the training.

In addition, the COM-B questionnaire was adapted from the version used by the National Centre for Smoking Cessation and Training in the UK. The questionnaire identifies the extent of health worker motivation, capability and opportunity to deliver tobacco cessation to their patients. The questionnaire was pre-tested with 3 health workers in each country. Following this, 14 questions were included. Changes made included reducing the questions on long-term follow-up (as this is not part of the planned intervention, due to feasibility constraints) and adding separate questions for building rapport with men and with women. The questionnaire is on scale of 1 to 5, where 1 is 'not confident' and 5 is 'very confident'. We planned to conduct the questionnaire in all study sites in the three countries.

4 FINDINGS

4.1 DEVELOPING THE MATERIALS

Feedback from expert panels: The expert panels included National TB Programme managers and health workers in each country. They all conducted the same ranking exercise to identify the tobacco cessation messages that they felt were most relevant and important in their country contexts. The expert panels were particularly useful in identifying which messages could be excluded. This was valuable as, from previous work, we were conscious that the BS session would have to be no more than 10 minutes in length. Thus, the number of messages to be included had to be kept to a minimum. There was much consistency across the three countries, with all finding that the messages on environmental restructuring and the messages that used a scale to assess motivation and readiness to quit were of least value. The exercise also identified challenges in wording, such as establishing a 'commitment' to quit. This word has much stronger connotations in Urdu, Bangla and Nepali. The other finding from these panels was the need for health workers to have the evidence for each of the messages clearly presented.

4.2 FEEDBACK FROM PATIENTS AND HEALTH WORKERS

Data collection and analysis were initially planned over a period of 8months (Jan-Aug), but were actually conducted over a shortened period of 3.5 months (June – Sept). The table below shows the data collected:

Qualitative Data Collected

		Bangladesh	Nepal	Pakistan
SSIs	Central Level Stake Holders	--	--	1
	Central Level NTP	1	--	1
	District Level NTP	1	2	2
	Facility In-charge (2)	2	3	2
	Facility Level NTP Staff (2)	4	3	3
	Interview – Patient	--	1	--
FGDs	Men (Patients)	1	1	2
	Women (Patients)	2	1	1
	Men and Women	--	2	1
	Facility Level Providers	1	--	--

Field-site observation was also scheduled for the two case study sites. This was carried out in a limited fashion, restricted to photographing of registers, storage facilities and documenting key characteristics of the study. More detailed observations will be conducted as part of WP4 and WP5.

Extra activities were carried out in each country to complement information collected through the scheduled data collection activities. Of the 4 NTP staff interviewed in Bangladesh, two were lab technicians who also provide DOTS, so they were interviewed in addition to the health workers. Organising separate male and female focus groups proved challenging in Pakistan due to patient availability, hence some mixed FGDs were conducted. While we tried to recruit TB patients who used tobacco, many women were not open about their tobacco use. However, once the FGD started, some of the women spoke more openly about their own or acquaintances' tobacco use. Older women were more likely to be open about their tobacco use, but had less capacity to participate in FGDs. Bangladesh also had an initial FGD with health workers to start the process of interaction in the clinic.

4.3 FEEDBACK ON MATERIALS

Feedback on the initial prototypes of the flipbook, leaflets and posters was gathered from research participants through the FGDs with patients and interviews with health workers providing DOTS. Participants in the research were asked to consider the comprehensibility of the materials as well as their acceptability for patients. A secondary objective of these activities was to collect information on patients' understanding and views on TB and tobacco, and other contextual information that would inform the development of the training plan and lay the groundwork for research to be conducted under WP4/5.

Poster: Two posters were tested in each country. One advertised the tobacco cessation service and one highlighted the health benefits of quitting tobacco, with a road to improved health. The poster advertising the service was easily understood. The second poster, depicting the road to improved health, was not understandable for many participants, particularly in Pakistan and Nepal. Given that many patients were illiterate, the winding pathway did not make sense "it is not clear what this pathway is," explained a man in Pakistan, suggesting it would be better to show steps or a mountain. A new version of the poster using steps has now been developed.

Leaflet: Feedback on the leaflet was also limited, with one criticism being that there was too much text. Health workers, however, believed the messages were necessary. Furthermore, it was suggested that friends or relatives who can read, would read out the information on the leaflet to patients. Ultimately, the text and layout were adapted in each country to cover all the points in simpler language.

Flipbook slides: In the FGDs, participants were shown prototypes of slides without titles and asked to consider what the message or theme of the slide might be. Facilitators of FGDs were trained to solicit suggestions from participants, before explaining the message of each slide. Instances in which the message was revealed to patients before soliciting suggestions were noted during transcription. After the message of a slide had been communicated, participants were asked to consider again whether the slide format and individual photographs on the slide relayed the intended message and asked for feedback. A similar process was carried out with the poster and the leaflet.

Across the three countries and between the two genders, an initial reluctance to respond was noted, as was a tendency to agree with an initial response offered by a more confident or talkative respondent. In such cases, facilitators were instructed to reiterate a point made at the beginning of each FGD that there were no right or wrong answers, but that the participants were already 'experts' on their experience of TB and that any advice or ideas they offered were useful. In this way, all participants were encouraged to speak freely and voice their opinions.

With regard to the flipbook, participants in all three countries mostly understood the messages conveyed through the pictures and slides, but did offer suggestions on how to make the pictures more appealing or accurate to speak to TB patients. There were, however, two slides in particular that were difficult to understand: GH 2 on how to take medication, and TC2 on things that do and do not help with tobacco cessation. In both cases, participants in all three countries had difficulty identifying the meaning of the picture of a calendar. A male participant in a mixed focus group indicated how "The photograph of the calendar is not clear here… [it is] not clear what should be done or what should not be done," and a middle aged female participant added that "some people are educated and some are not… non-educated people will only understand photographs not the calendars." Despite this statement, there was not an observed correlation with literacy or gender in whether participants understood the calendar or not. Based on participant feedback, the calendar was removed from GH2 and it was decided the health worker would explain that medicine should be taken for six months. The calendar was left in the slide TC2 to indicate choosing a quit date. In Pakistan some participants understood the message because of the no smoking sign; in Bangladesh the calendar was changed to a Bengali calendar; and in Nepal a picture of the TB treatment card was taken, as this is laid out by day, with the no smoking sign representing the quit date.

Another finding across the three countries was that, when given an option, participants grasped more easily slides that demonstrated a timeline with alternative positive and negative consequences. This was the case for both GH3 (adherence to medication) and TC1 (Benefits of quitting tobacco). Participants felt that presenting a timeline made messages "easy and straight forward" as a male FGD participant in Pakistan indicated, describing the clear outcomes presented. The picture of the graveyard was particularly effective in slide TC1. Some people felt the image of a graveyard might be disquieting. However, most participants felt it would be an effective deterrent. In Nepal, where the initial image used was of a funeral pyre, one female FGD participant stated that "Instead of showing smoke [sic], it is better to show a dead body in the picture. If the smoke is shown then we thought that one should not sit in front of smoke… If one dead body is shown, then we can understand many things from that."

Responses from the FGDs suggest certain myths and social norms that TB patients in all three countries might have. One issue that came out clearly was the stigma attached to TB patients. Participants in every FGD suggested that the TB patients should be wearing masks or should be segregated from family members as a Bangladeshi FGD participant indicated. In all three countries, the message that TB could not be spread through sharing food and utensils was met with some degree of scepticism or reluctance, grounded to some degree in previous information patients had received. As a male FGD participant remarked: "Earlier people used to say those who have [TB] should not eat with others…now they know it isn't true and everyone is sitting together and eating!"

In addition to TB-related stigma, participants' responses pointed to social stigma and beliefs around tobacco use. The majority of participants in all FGDs demonstrated an awareness of smokeless tobacco (SLT) and potential harm. However, in the men's FGD in Pakistan, in discussing different kinds of tobacco products, one participant indicated that "perhaps there is a link [between lung health and tobacco use]…except for naswar [a form of smokeless tobacco] I can't say anything. Perhaps there is a link with [cigarettes and hookah]." His response suggests that some degree of misunderstanding of smokeless tobacco's effect on TB exists.

There also appeared to be, across all three countries, a general stigma against tobacco use, particularly women's tobacco use. FGD participants differed in opinion on whether it is older or younger women who smoke, or urban or rural women; but it was clear that it was not seen as something socially sanctioned. As a man in Nepal related: "smoking is a bad habit and it also does not look good… There are women who smoke a lot. I have a neighbour who smokes 3 packets… she is told to refrain so many times but she won't refrain."

Despite this stigma, there were some who felt that smoking in particular is an addiction that cannot be quit. Some felt addiction can just not be overcome, like a man in Nepal who stated that: "I don't know, my soul asks for it [smoking cigarettes] so I have to smoke…I can leave drinking alcohol but there is desire to smoke… When soul asks for it [smoking], we have to have it." Others, like a female FGD participant in Bangladesh, believed that if they were to die anyway of TB then they might as well drink and smoke and be happy. However, in every country there were also several participants, patients and health workers, who believed that patients' fear of TB was an impetus to stop tobacco use. As one man in Nepal explained: "In the past, I did not have any disease, so I did not feel any need to quit smoking… [later] I thought it [referring to cigarette] will do no good, so I quit smoking."

As described above, the feedback on the materials, particularly the flipbook, not only provided guidance on developing the materials, but also on areas of further enquiry. In particular, over the course of WP4 and WP5, the study will need to attend to social attitudes and stigma toward TB patients and questions of social acceptance of tobacco use and the effect on individuals' willingness to attempt cessation.

4.4 COM-B RESULTS

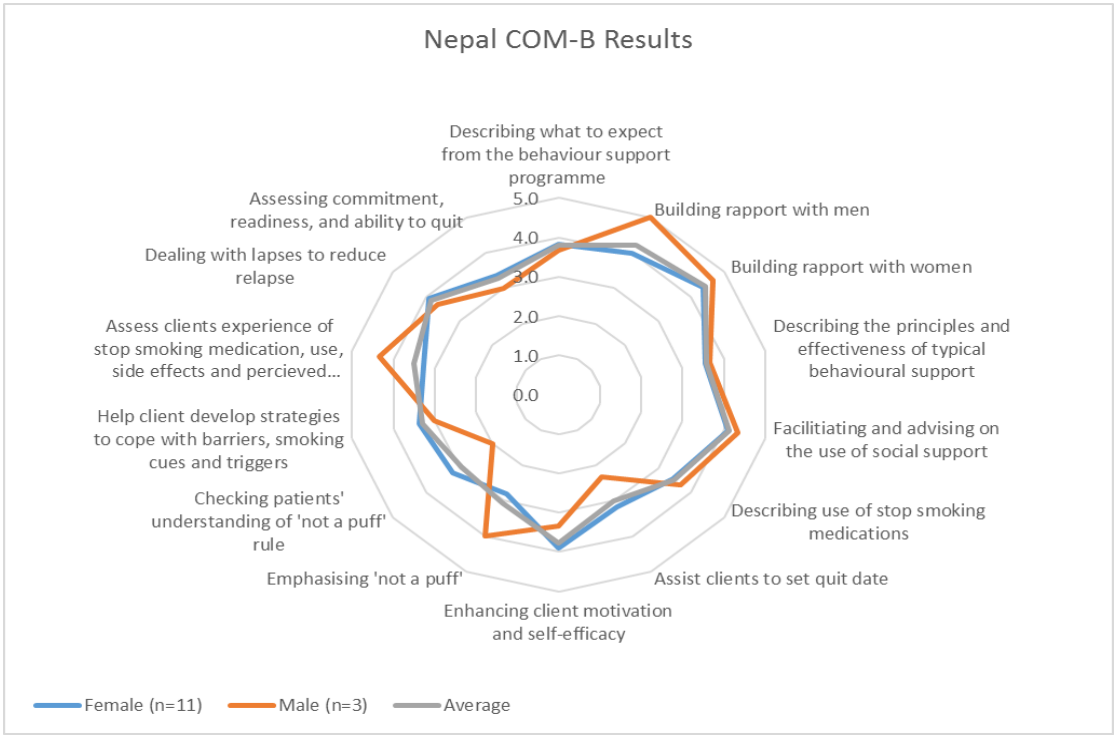
The COM-B questionnaire was pre-tested for comprehensibility in three sites in each country. The health workers interviewed understood the questions and only minor editing and simplification of the wording were needed in the

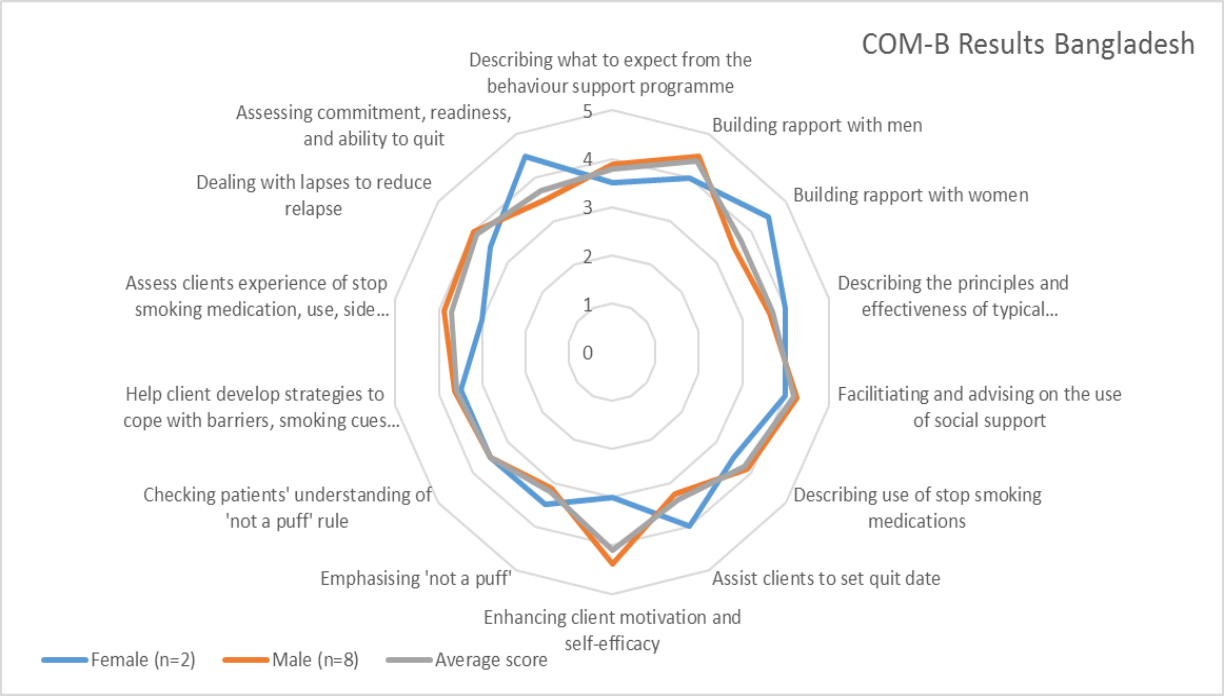
three languages. Once finalised, the researchers in each country conducted the questionnaire with health workers in all the trial sites.

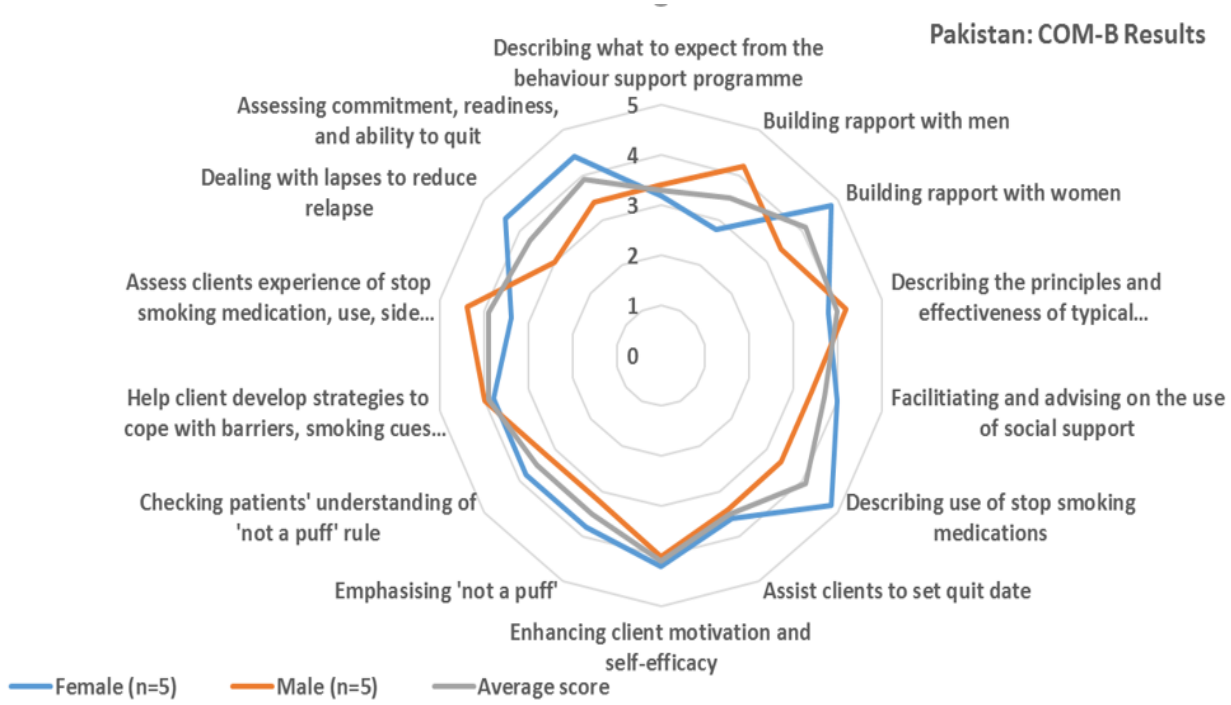
Data Collection for COM-B

	Number of sites	Number/type of health professionals	Gender breakdown
Bangladesh	9/14 sites	10 (all DOTS facilitators)	8 men and 2 women
Nepal	14/15 sites	14 (10 DOTS facilitators and 2 Dr in-charge)	3 men and 11 women
Pakistan	8 /9 sites	10 (all DOTS facilitators)	5 men and 5 women

The results of the COM-B questionnaire for the three countries are presented below:







All three countries consistently indicate that male health workers feel more confident at building rapport with male patients, and female health workers with female patients. Clearly this questionnaire was conducted before health workers had any training on implementing tobacco cessation. Across all three sites therefore, there was limited confidence in assisting clients to set a quit date, explaining and emphasising the 'not a puff' rule. Most of the health workers also had limited confidence in terms of explaining cessation medication. The exception is Pakistan where the 5 female health workers appear to be confident in this area. The questionnaire also reflects the different gender balance among health workers, with Bangladesh being predominantly male (8/10), Nepal predominantly female (11/14) and Pakistan balanced (5/10).

5 ISSUES FOR TRAINING AND IMPLEMENTATION

The second round of analysis of the qualitative interviews and focus groups also highlighted issues to be considered in the development of the training and the implementation of the intervention. In particular, these were:

Identifying smokers: Across the three countries there was evidence that patients find it difficult to open up about their tobacco use. For example, in Pakistan one health worker commented, "We don't ask about tobacco history and whenever we ask, patients find it difficult to talk" (Pakistan HW). In Nepal, health workers explained that often they would only find out whether a patient smoked from the smell on their clothes and belongings, or from a family member. A further constraint to people being open about their tobacco use was a feeling of guilt from the belief that smoking causes TB (Nepal HW). This is an issue that needs to be addressed within the training. It is also hoped that providing the first 5 flipbook slides on general TB messages to the client will enable rapport to be built before the health worker asks about tobacco use. This may help patients to open up.

Deciding who to train: Across all three countries it was common for a range of health workers to deliver DOTS, not just those designated to this task. This was seen as a way of sharing the workload within the facility. This issue presents challenges, as our training budget is sufficient for only one DOTS facilitator per site. Solutions discussed at our team partners' meeting include: using our training as a 'training of trainers' and expecting those trained to return to their facilities and train others and/or capturing the training on video and then having this available to show other health workers. This may also help to deal with challenges of staff turnover and the need to refresh health worker knowledge.

Lack of privacy: the observations in the health facilities highlighted that many settings were over-crowded, with no quiet, private room available for delivery of the flip-book session. If a room was available, it was frequently too small and would become full of other patients crowding in to hear any advice given.

Motivation for cessation: Many of the health workers felt that they were 'already over-burdened' and recommended additional staff, so that one dedicated staff member could provide the cessation service. Staff also mentioned that certificates following training and performance appraisals could help to motivate health workers.

6 CONCLUSION

The intervention developed in this work package has been shaped by the feedback from people with TB and from health workers. This has proved invaluable in ensuring that the photos and messages are understandable within the three countries. The materials have also drawn on behaviour change techniques to strengthen the impact the messages may have. Our next step is to ask several researchers external to the project to code the intervention materials for BCTs following Michie *et al*'s taxonomy. The materials will be presented to the expert panels in each country context and their advice on how to deal with the training and implementation issues will be sought. The materials will be finalised in time for the start of the trial (November 2016).

References

Michie S(1), Hyder N, Walia A, West R. Development of a taxonomy of behaviour change techniques used in individual behavioural support for smoking cessation. Addict Behav. 2011 Apr;36(4):315-9. doi: 10.1016/j.addbeh.2010.11.016. Epub 2010 . Dec 15.

Bartlett YK, Sheeran P, Hawley MS. Effective behaviour change techniques in smoking cessation interventions for people with chronic obstructive pulmonary disease: A meta-analysis. British Journal of Health Psychology. 2014;19(1):181-203. doi:10.1111/bjhp.12071.

Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, Eccles

MP, Cane J, Wood CE. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. Ann Behav Med. 2013 Aug;46(1):81-95. doi: 10.1007/s12160-013-9486-6.