Process evaluation of a tobacco prevention program in Indian schools—methods, results and lessons learnt

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Abstract

In India, 57% of men between 15 and 54 years and 10.8% of women between 15 and 49 years use tobacco. A wide variety of tobacco gets used and the poor and the underprivileged are the dominant victims of tobacco and its adverse consequences. Project MYTRI (Mobilizing Youth for Tobacco-Related Initiatives in India) was a tobacco prevention intervention program, a cluster-randomized trial in 32 Indian schools which aimed to decrease susceptibility to tobacco use among sixth- to ninth-grade students in urban settings in India. This culture-specific intervention, which addressed both smokeless and smoked forms of tobacco, was Indian in content and communication. We qualitatively developed indicators which would help accurately measure the dose of the intervention given, received and reached. A multi-staged process evaluation was done through both subjective and objective measures. Training the teachers critically contributed toward a rigorous implementation and also correlated with the outcomes, as did a higher proportion of students participating in the classroom discussions and better peer–leader–student communication. A sizeable proportion of subjective responses were ‘socially desirable’, making objective assessment a preferred methodology even for ‘dose received’. The peer-led health activism was successful. Teachers’ manuals need to be concise.

Introduction

Tobacco, the leading preventable cause of death, killed 100 million people in the 20th century worldwide and could kill 1 billion in the 21st century [1]. Tobacco is projected to kill 50% more people in 2015 than human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome and be responsible for 10% of all deaths globally [2]. The total economic cost of tobacco use in 2004 amounted to 1.7 billion dollars (US dollars). Of the 5.4 million tobacco attributable deaths worldwide in 2005, 700 000 were from India [3]. Although, the tobacco attributable deaths, between 2002 and 2030, in high-income countries are projected to decline by 9%, they are projected to double from 3.4 to 6.8 million in the low- and middle-income countries [2].

India is the second largest consumer of tobacco in the world, second only to China. In India, 57% of
men between 15 and 54 years and 10.8% of women between 15 and 49 years use tobacco [4]. A wide variety of tobacco gets used in India. Apart from the smoked forms which include cigarettes and bidis, a plethora of smokeless forms get used [3, 5]. Whereas 32.7% of men and 1.4% of women smoke tobacco, many more—36.5% of men and 8.4% of women—chew tobacco [4]. Aggressive marketing by tobacco companies have made the youth vulnerable to tobacco products [6]. More than 25% of the youth between 13 and 15 years have tried tobacco and 17.7% of the youth currently use tobacco [3]. In addition, an inverse correlation between tobacco use and educational/socioeconomic status, and a higher susceptibility to tobacco and its adverse health consequences among disadvantaged populations in India, makes tobacco prevention a public health priority [7–14]. Since addiction to nicotine for most people occurs prior to adulthood and nearly all first use of tobacco occurs before high school graduation, it is suggested that if adolescents can be prevented from using tobacco, most will never start using tobacco [15, 16].

Design overview of the a tobacco prevention program—MYTRI

Project MYTRI (Mobilizing Youth for Tobacco-Related Initiatives in India), a recently concluded study, aimed to decrease susceptibility to tobacco use among sixth- to ninth-grade students in urban settings in India [15]. Through a group-randomized trial design, 32 schools located in two large cities in India (n = 16 in Delhi and n = 16 in Chennai) were recruited, matched and randomly assigned to receive a 2-year tobacco preventive intervention or serve as a delayed intervention control [15]. The results of the baseline survey [17], the intermediate outcomes (after 1 year) and the final outcomes have been published. Intermediate outcomes assessed after 1 year of intervention yielded small benefits and those after 2 years of intervention yielded significant benefits [18, 19]. Project MYTRI was able to target a population of >6000 adolescents and maintain scientific standards comparable to studies conducted with much smaller samples in United States [19].

Process evaluation improves the science of randomized trials [20]. It bridges the gap between prevention science and prevention practice [20]. Process evaluation is an invaluable part of overall program evaluation as it gives us an accurate picture of program implementation [21]. Social and behavioral interventions have become increasingly complex, making it important for researchers to know the extent to which intervention components are actually implemented [22].

The scope and implementation of process evaluation have grown in complexity as their importance and utility have been more widely recognized [23]. Different results from the same or similar prevention programs raise concerns that differential implementation may account for the variability [24].

In this paper, we describe the process evaluation of this tobacco prevention program in Indian schools. We elaborate on the methodology of the process evaluation, results of the process evaluation (after Year 1 intervention) and lessons learnt. The school-based scores of (i) dose given (DG), (ii) dose received (DR) and (iii) reach, of the intervention are reported. We also correlate the school-based scores to the study’s outcome, the relative change in susceptibility to chew tobacco.

Methods

We first describe the multi-component tobacco prevention intervention (Project MYTRI) and then the participants. We then describe how we did the process evaluation. Subsequently, we outline the conceptual framework we selected for analysis and reporting of the results of the process evaluation.

Intervention

Project MYTRI intervention was entirely Indian in its content, context, communication (both textual and pictorial) and delivery. Theoretically, it was based on the social cognitive theory and the existing evidence-based smoking prevention programs, as a frame of reference [5, 19, 25, 26]. The intervention consisted of a classroom curriculum, school posters, parent postcards and training of the
The implementers of the intervention were the teachers and student peer leaders. The intervention is available in English on the website www.hriday-shan.org. Please view and download the English classroom curriculum, the teachers’ manual, the students’ manual, peer leaders’ manual, the school posters and parent postcards from the Web site. The Hindi and Tamil language versions are available on request.

**The classroom curriculum—structure**

It consisted of seven different classroom sessions. Each session was of 35–60 min each, initiated and implemented by the usual classroom teachers and peer leaders. Each classroom session had a common predefined multi-component structure consisting of the following intra-session elements: a written text of learning objectives, teacher’s script, students’ script, games, worksheets, discussion and wrap-up. Peer leaders and teachers interacted with the students to deliver the intervention, who, in turn, we hoped would actively participate and enjoy it. Student and peer leader involvement was intricately woven throughout the curriculum. Each session-specific poster provided the launch pad and complimented the content of that classroom session.

**The classroom curriculum—content**

The seven different classroom sessions, posters and parent postcards focused on imparting behavioral skills and contextual knowledge to decrease their susceptibility to taking up tobacco in the future.

In a pre-activity before the first session, Project MYTRI and the mascots Disha and Deepak were introduced and the students elected their own peer leaders in each class. ‘Classroom session 1’ entitled, ‘Guess the numbers’ put forward, in numbers, the burden of tobacco use (both smoked and smokeless). The supporting poster theme was ‘50 Lakh people die of tobacco related diseases each year in India’. The puzzle and worksheet too were on Guess the numbers. The different types of tobacco being used—zarda, beedi, khaini, gutka, hookah, panmasala, snuff, etc.—were also discussed with the students.

‘Classroom session 2’ was ‘Poison Puzzle: What is in Tobacco?’. It familiarized the children with the various harmful ingredients that are present in tobacco and which are common to poisons/harmful substances like insecticides, pesticides, naphthalene balls, nuclear weapons, etc. There were two jigsaw puzzle games—‘Grimy Gutka’ and ‘Crooked Cigarette’.

‘Classroom session 3’ was entitled ‘How does Tobacco Harm? Negative Health Consequences of Tobacco Use’. It delved into the various long- and short-term health consequences of tobacco use (smoked and smokeless forms). Students also discovered that breathing someone else’s tobacco was harmful. They appreciated the benefits of not choosing tobacco.

Classroom session 4 ‘Tobacco Trauma: It Affects Every Sphere of Life’ dealt with the harmful social effects of tobacco use and also gave more details on passive smoking. The corresponding school poster said ‘Please Stop, Your Smoke is Hurting Us’.

On similar lines, the classroom session 5 for the eighth class and session 6 for the sixth class were entitled: ‘Spin the Wheel: 10 Reasons Not To Use Tobacco’. It elaborated on the strong reasons not to use tobacco and contrasted it to the social reasons why people start using tobacco. The sessions, cumulatively, intended to develop a mindset against tobacco and decrease the susceptibility to use tobacco. It helped toward modeling social skills.

Classroom session 5 of Class 6 elaborated on creating a healthy home—a tobacco-free home. In the classroom session 6 (Class 8): ‘Pressure Pads: Learn to Resist Offer of Tobacco’, the students analyzed various social situations where tobacco is offered, learnt how to refuse it and practiced applying these skills to various social situations. It provided real-life competencies to resist tobacco.

Lastly classroom session 7, ‘Speak Out: Advocate for No Tobacco Use’ imparted advocacy skills where students learnt how to speak out against tobacco. The corresponding poster read ‘We Have the Strength to Say No to Tobacco’.

**The classroom curriculum—delivery**

The seven sessions had to be delivered on seven different days, over 4–5 months. Each classroom
teacher was free to decide their own schedule for its delivery.

**Posters**

Eight different illustrative posters were used. Each was put up in the classroom 1 day prior to the delivery of the respective classroom session. The posters reinforced the content of each classroom session.

**Parent postcards**

Six illustrative parent postcards (with six different pictorial messages, specific to the learning objectives) were given to each student after the respective classroom session, to take home to share with their parents. Parents needed to sign the postcard stubs which the student then returned to the student peer leaders, who documented its return on a tracking sheet.

**Training the program implementers**

The training conducted through lectures, group work and role playing imparted knowledge on the evils and burden of tobacco use in India and hands on skills with the intervention materials—posters, postcards, manuals, games and worksheets (conducted in September 2004).

Teachers: The teacher coordinator and the usual classroom teachers of each class, from the classes of sixth and eighth grades of the intervention schools, were invited to be trained in a whole day’s training workshop.

Peer leaders: Proportional to the number of students in each class, four to six students, in a class of 30–45, were elected by their classmates, from each section, in each class. They were designated as student peer leaders. Half a days training for the peer leaders, before the start of the intervention, was conducted at the school itself. In addition, booster training was given to them before delivery of each classroom session. These peer leaders facilitated the implementation, for example, they facilitated the small-group activities (e.g. games, brainstorming sessions) in the classrooms, as well as extracurricular activities that went on within (intra) and between (inter) schools.

**Inter-school activities**

The classroom sessions culminated with the children creating/enacting ‘drama/skits’ and ‘model making’ from each school in intra-and inter-school events. Two inter-school events, one in Delhi and the other in Chennai, conducted over half a day, were organized. The entire intervention was staggered between August 2004 and February 2005. The classroom sessions were delivered between October 2004 to February 2005 [15, 18].

**Participants**

Sixteen schools, eight each in Delhi and eight in Chennai, received the intervention. Four in each city were private and four were state-funded or government schools. The students in the private schools were from higher income backgrounds. All the students \(n = 5564; 2823 \text{ in Delhi and 2741 in Chennai}\) of the sixth and eighth grades in these schools participated in the intervention and elected their own peer leaders. The student peer leaders (781 of which, 402 were from Delhi and 379 from Chennai) and 125 teachers (67 in Delhi and 58 in Chennai) delivered the intervention. Additional characteristics of participant are available elsewhere [17].

**Process measures and indicator variables**

Systematic qualitative observations by social scientists during the piloting of the intervention enabled identification of indicator variables which would best capture the multi-component, multi-faceted tobacco prevention intervention, in its depth and breath. To develop indicators for concepts and refining their importance, qualitative observations of behaviors in their natural context should provide the lead [27, 28]. Such methods also confer greater validity [29].

A range of indicator variables were identified. Various instruments (process instruments) or process measures were developed to be administered at various stages of the intervention. These were piloted and then modified and refined after the piloting.

All the individual process measures are available from the authors and a sample is available as Supplementary material online. The various process
measures (instruments) are listed in Column 1 of Table I. Table I also lists who completed (filled) the instruments (Column 2) and when or at what stage of the intervention were they completed (Column 3), specific indicator variables in each instrument (Column 4) and how these indicator variables contributed to the process components—dose given, dose received and reach (Column 5). The scales used for each indicator variable are also given (Column 4). Variable numbers assigned in the corresponding process tables of dose given, dose received and reach are given (Column 5).

**Community coordinators**

Professionals with a master’s degree in psychology or social work or sociology or nutrition were recruited on this project and trained. They were the link between the investigators and the implementers during the actual delivery of the program in the field. They visited the schools, interacted with the teachers and the peer leaders and delivered the teachers’ manuals, the peer leaders’ manuals and the students’ manuals to the schools. They also visited the schools, to interact with the teachers and the peer leaders before each session was delivered and gave out the session-specific posters, postcards (in five of seven activities) and games (in four of seven activities). This meeting between the community coordinators and the implementers allowed for short, activity-specific booster trainings to be given.

They observed and documented the actual delivery of the classroom sessions [Objective Systematic Structured Observations (OSSOs)] on session-specific OSSO forms. The subjective feedback forms and the attendance sheets were also collected by the community coordinators. They helped in administering the outcome measure forms which the students filled. They also made school reports detailing the facilitators and barriers encountered during delivery of the tobacco prevention intervention.

**Process assessment at training**

The attendance of the teachers was recorded on the ‘teacher’s training attendance sheet’, and their feedback about the training and MYTRI program was recorded on a ‘teacher’s training feedback forms’.

Similarly, the attendance of the peer leaders was documented on the ‘peer leader’s training attendance sheet’ and their feedback of the training and MYTRI program on the ‘peer leader’s training feedback forms’.

**Process assessment done in school/classrooms and inter-school event**

Peer leaders maintained the students’ attendance, in an ‘attendance sheet’, for each classroom session, in each class. Peer leaders also gave their subjective feedbacks, at the end of the curriculum, on the peer leader’s end of curriculum feedback forms.

Teacher’s gave their feedback after each classroom session was delivered and also at the end of the entire program (seven different session-specific forms and one at the end). Attendance was also recorded at the inter-school event. OSSOs were made by the community coordinators, on session-specific OSSO forms, during actual delivery of the classroom sessions.

**Process assessment—posters and parent postcards**

On the ‘poster tracking sheets’, the peer leaders noted, before each specific classroom session, whether the specific posters were hung and its location.

On the ‘postcard stub tracking sheet’ the peer leaders noted the number of signed postcard stubs that the students returned. This documented the parental outreach of messages. Subjective feedback about the posters and postcards was sought through questions in the ‘teacher’s feedback forms’ and the peer leaders ‘end of curriculum feedback forms’. Objective assessments were made by the community coordinators on OSSOs.

**Conceptual framework for the process evaluation**

A multi-staged, multi-component process assessment was made by data collected from multiple sources: the teachers, students, peer leaders and community coordinators.

For a comprehensive assessment and rigor in evaluation, we used the process assessment framework proposed by Sauder et al. [24], which in turn has
Table I. *Instruments used for process evaluation*

<table>
<thead>
<tr>
<th>No.</th>
<th>Data collection instruments or process instruments</th>
<th>Filled by whom?</th>
<th>Implemented when?</th>
<th>Indicator variables, number denotes the classroom session (scales used for the item are given in parenthesis)</th>
<th>How did the variables contribute? Process component (variable numbers assigned in the corresponding process tables of dose given, dose received, reach)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Teacher’s training attendance sheet</td>
<td>Trained community coordinator</td>
<td>At training</td>
<td>Proportion of teachers trained</td>
<td>Dose given (Variable 5)</td>
</tr>
<tr>
<td>2</td>
<td>Peer leader’s training attendance sheet</td>
<td>Trained community coordinator</td>
<td>At training</td>
<td>Proportion of peer leader’s trained</td>
<td>Dose given (Variable 6)</td>
</tr>
<tr>
<td>3</td>
<td>Teacher’s training feedback form</td>
<td>Teachers</td>
<td>Post-training</td>
<td>Teacher’s satisfaction with the MYTRI program and materials. Four items (Likert 1–7)</td>
<td>Dose received (Variable 1)</td>
</tr>
<tr>
<td>4</td>
<td>Peer leader’s training feedback form</td>
<td>Trained peer leaders</td>
<td>Post-training</td>
<td>Peer leader’s satisfaction with the MYTRI program and materials. Four items (Likert 1–7)</td>
<td>Dose received (Variable 2)</td>
</tr>
<tr>
<td>5</td>
<td>OSSO forms activity specific (seven types, classroom session specific for each grade)</td>
<td>Trained community coordinator</td>
<td>During implementation of individual classroom sessions. Observations were made in a random subset of classroom sessions</td>
<td>Implementation of classroom session (yes/no) Implementation of intra-session elements: Posters 1–7 (yes/no, could not be conducted) Objectives 1–7 (yes/no, could not be conducted) Students’ script 1–7 (yes/no, could not be conducted) Teacher’s script 1–7 (yes/no, could not be conducted) Games (yes/no, could not be conducted) Worksheet 1–4, 5#, 6#, 7 (yes/no/could not be conducted) Wrap-up (yes/no/could not be conducted) Postcards 1, 3, 4, 5$, 6#, 7$, 7# for each activity (yes/no) Teachers were able to handle discussions well with the students? (yes/no, could not be conducted) Peer leaders able to communicate well with the students? (yes/no) General impression and suggested changes (open ended)</td>
<td>Dose given (Variable 1–Q1) Dose given (Variable 1–Q2) Dose given (Variable 7) Dose given (Variable 8) Contextual reasons</td>
</tr>
<tr>
<td>No.</td>
<td>Data collection instruments or process instruments</td>
<td>Filled by whom?</td>
<td>Implemented when?</td>
<td>Indicator variables, number denotes the classroom session (scales used for the item are given in parenthesis)</td>
<td>How did the variables contribute?</td>
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<tr>
<td>6</td>
<td>Postcard stub tracking sheet (for six different postcards)</td>
<td>Trained peer leaders</td>
<td>After the respective classroom session</td>
<td>Postcards given and proportion of signed stubs returned (yes/no)</td>
<td>Dose given (Variable 3) Reach</td>
</tr>
<tr>
<td>7</td>
<td>Poster tracking sheets (for eight different posters)</td>
<td>Trained community coordinator</td>
<td>After the respective classroom session</td>
<td>Proportion of posters hung (yes/no) and location (and open ended)</td>
<td>Dose given (Variable 2) Reach</td>
</tr>
<tr>
<td>8</td>
<td>Teacher’s classroom curriculum session-specific feedback forms and end of curriculum feedback forms (7 + end feedback)</td>
<td>Trained teachers</td>
<td>After the respective classroom session and at the end</td>
<td>Did teachers enjoy teaching lesson? 1–7 (yes/no) Students enjoyment/participation during various elements of the classroom sessions: (i) Posters (Likert 1–3 smiley faces, could not be conducted) (ii) Objectives (Likert 1–3 smiley faces, could not be conducted) (iii) Mascot script (Likert 1–3 smiley faces, could not be conducted) (iv) Teacher’s script, (Likert 1–3 smiley faces, could not be conducted) (v) Games (Likert 1–3 smiley faces, could not be conducted), (vi) Worksheet (Likert 1-3 smiley faces, could not be conducted), (vii) Discussion (Likert 1–3 smiley faces, could not be conducted) (viii) Wrap-up (Likert 1–3 smiley faces, could not be conducted) Did students find worksheets difficult? 2, 5, 6 (yes/no, could not be done) Did peer leaders communicate well with student? (yes/no) Students absorption while playing the games; 1, 2 (yes/no) Were students left out while playing the games? 2 (yes/no) Did students read and absorb the completed puzzle; 2 (yes/no) Proportion of the students in each class participating in the discussion. Session 1, 2, 3, 4, 5, 6 and 7 (%)</td>
<td>Dose received (Variables 4 and 5)</td>
</tr>
<tr>
<td>No.</td>
<td>Data collection instruments or process instruments</td>
<td>Filled by whom?</td>
<td>Implemented when?</td>
<td>Indicator variables. number denotes the classroom session (scales used for the item are given in parenthesis)</td>
<td>How did the variables contribute?</td>
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<td>Table I. continued</td>
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<tr>
<td>9</td>
<td>Peer leader’s end of curriculum feedback forms</td>
<td>Peer leaders</td>
<td>At the end of the classroom curriculum</td>
<td>General impression and suggested changes (open ended)</td>
<td>Contextual reasons</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Was the training handbook difficult? (easy to follow, little difficult can be improved, difficult to understand and can be improved, other open-ended suggestions)</td>
<td>Dose received (Variable 9)</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td>Confidence in tobacco prevention activities (very confident, not so confident, not confident at all) Commitment to tobacco prevention activities (more committed, less committed, equally committed) than their classmates General impression and suggested changes (open ended)</td>
<td>Dose received (Variables 11 and 12)</td>
</tr>
<tr>
<td>10</td>
<td>Classroom: student attendance sheet</td>
<td>Peer leaders</td>
<td>At the end of each classroom session</td>
<td>Proportion of students who attended each classroom session (yes/no)</td>
<td>Reach</td>
</tr>
<tr>
<td>11</td>
<td>Inter-school event: attendance sheet</td>
<td>Peer leaders</td>
<td>During the inter-school event</td>
<td>Proportion of students who attended the inter-school event (yes/no)</td>
<td>Reach</td>
</tr>
<tr>
<td>12</td>
<td>School reports</td>
<td>Community coordinator</td>
<td>Throughout of MYTRI implementation</td>
<td>Detailed narrations and experiences of the interactions with the students, teachers and school authorities</td>
<td>Contextual reasons</td>
</tr>
</tbody>
</table>

# For eighth grade only and $ for sixth grade only.
been adapted from other important works [23, 28, 29]. The conceptual definitions of the process components which contribute to the process assessments are as follows.

Dose given (completeness): Dose given is the quantity and the rigor of implementation, of the intended intervention units, that are actually delivered to the participants. Dose given (DG) is a function of the implementers and should be documented objectively. It was computed by each intervention school as given in Tables II and III.

Dose received (exposure): Dose received (DR) is the extent to which participants are satisfied, understand, actively engage with, interact with, are receptive to and absorb or imbibe or use material or recommended resources. Dose received

Table II. Dose given

Dose given: The composite score for the dose given, to each intervention school, was computed as the weighted average of the following eight variables.

(i) Product of the Q1 and Q2 of implementation of the classroom sessions (Q1 × Q2): Q1 was quantity and Q2 was the rigor of implementation of Q1. The quantity (Q1) was defined as the percentage of the classroom sessions actually implemented out of the seven planned sessions, and Q2 was defined as the average percentage of the implementation of the intra-session elements of the classroom session. In each classroom session, there were six intra-session elements—objectives, students’ script, teacher’s script, games, worksheets and wrap-up.

Since variable Q1 is the proportion of the seven classroom sessions delivered in each school, if all the seven classroom sessions were delivered then the score would be 100% but if only two of the seven classroom sessions were delivered then the score would be 28% (=2/7).

For variable Q2, the rigor of the implementation was a simple average of the proportion of the six intra-session elements which were implemented in classroom session 1, in classroom session 2, 3, etc., in a particular school. If 80% of the intra-session elements got conducted in classroom session 1–4 and 70% got conducted in classroom session 5–7 then the rigor of implementation of the classroom sessions was 75.7%.

(ii) Proportion of the 8 posters hung in each school: If all the eight different types of posters were hung in a school then the score assigned was 100%, but if only two types were hung then it was 25%.

(iii) Proportion of the 6 parent postcards delivered in each school: If all the six different postcards were delivered in a school then the score assigned was 100%, but if only one type of postcard was delivered then the score was 16.7%.

(iv) Did the school participate in the inter-school event? The school’s participation in the inter-school event gave a score of 100% and its absence, a score of 0%.

(v) Proportion of the teachers trained to deliver the intervention: If all the teachers who were to deliver the intervention, in a school, were trained then the score was 100%.

(vi) Proportion of the student peer leaders trained to deliver the intervention: If all student peer leaders who were to deliver the intervention, in a school, were trained then the score was 100%.

(vii) Proportion of classroom sessions in each school where the teachers handled the discussions well with the students: If, in a particular school, in one class the teachers handled the discussion well in 4/7 (57%) of the classroom sessions, and in another class, in 7/7 (100%) of the sessions, in another class in 0/7 (0%) of the classroom sessions, and if there are three classes in that school delivering the intervention, then the average score for that school would be the simple average of the three values, which is 52%.

(viii) Proportion of classroom sessions in each school where the student peer leaders communicated well with students: If there are two classes delivering the intervention in a school, and in the first class, only in 3/7 (43%) sessions the student peer leaders communicated well with the students, and in the other class the student peer leaders communicated well with the students in all the 7/7 sessions, then, the score for the school would be a simple average of two which is 72%.

The composite score for the dose given to each intervention school was computed as the weighted average of the eight variables listed above. The weights were arbitrary based on qualitative observations. During our qualitative observations during the pilot, we learnt that the observations of the actual delivery of the classroom sessions and the rigor of delivery of the classroom sessions significantly influenced the delivery of the entire intervention. We therefore gave Q1 × Q2 a weightage of 50. We also performed principal component analysis. We found that only 50–60% of the variability was explained by the first three components for the dose delivered. This helped further confirming our weightages that we had assigned.

The weights were thus measured by combining the insight gained through qualitative observational understanding and the loads given to each variable in the first three principal components. We tried changing the weights but the overall differences in the performance of the schools did not change, validating our weighing scheme.
Table III. Dose of the tobacco prevention intervention given (DG)—School scores (%)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Proportion of classroom sessions delivered (Q1) in each school</th>
<th>Proportion of intra-session elements of the classroom sessions delivered (Q2) in each school</th>
<th>Q1 × Q2</th>
<th>Proportion of eight posters hung in each school</th>
<th>Proportion of six postcards given in each school</th>
<th>Whether or not the school participated in the inter-school event</th>
<th>Proportion of teachers trained in each school</th>
<th>Proportion of peer leaders trained in each school</th>
<th>Whether or not the teachers handled the discussions well with the students? Proportion of teachers who did</th>
<th>Whether or not the peer leaders’ communicated well with students? Proportion of peer leaders who did</th>
<th>School-wise score of dose given (39–95)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>100</td>
<td>68</td>
<td>68</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>90</td>
<td>52</td>
<td>93</td>
<td>75</td>
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<tr>
<td>3ª</td>
<td>57</td>
<td>66</td>
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</table>

Dose given to each school is the weighted average of variable values in columns 1, 2, 3, 4, 5, 6, 7 and 8 for each school. Q2: Intra-session elements of the classroom curriculum are learning objectives, students’ script, teacher’s script, games, worksheets and warp-up.

ªProgram implementation indefinitely delayed after classroom session 4 (school ID 3) and 2 (school ID 7, 27).
(DR) is typically assessed by subjective behavioral indicators and was computed by each intervention school as given in Tables IV and V. Reach: It is the extent to which the intervention reached the intended target audience. It was computed by each intervention school as given in Tables VI and VII.

**Assessing the outcomes of the intervention**

Outcomes were assessed, through a student self-administered anonymous survey, administered to each student before and after the tobacco prevention intervention. Specific details about the rigorous piloting, standardization and the psychometric properties of the instrument are detailed elsewhere [6, 18, 30]. Since many more people in India chew tobacco, we use spearman’s correlation coefficient to correlate the ‘school-wise scores of change in social susceptibility to chew tobacco’ with the rigor in implementation (Fig. 1).

**Data analysis**

Dose given, dose received and reach were constructed from indicator variables extracted from the various process instruments which are listed in Table I. Dose given was based on objective documentation of the actual delivery of the intervention and dose received on subjective feedbacks.

We used Spearman’s correlation coefficient to explore the bivariate relationships between the
<table>
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<tr>
<th>Variable</th>
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<th>3</th>
<th>4</th>
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<tr>
<td>% Of class actively participating</td>
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<td>96</td>
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</table>

SS: students’ script and TS: teachers’ script.

Variable 4: due to constraints of space, this column contains six different variables and therefore has been given a weightage of 30 instead of 5. It consisted of relative enjoyments during various elements of the classroom sessions—objective, students’ script, teacher’s script, games, worksheet and wrap-up. Each of the variables was given the same weightage of ‘5’.
various variables, the composite school-based scores and the outcome.

When looking at the outcome ‘social susceptibility to chewing tobacco’, a higher score denoted a greater risk. The relative change in susceptibility to chewing tobacco was calculated as $\frac{100(\% \text{ susceptibility in 2005}}{\% \text{ susceptibility in 2004})/\% \text{ in 2004.}}$

### Results

All the classroom sessions, posters, postcards and inter-school components were fully implemented in 13 of the 16 schools with partial implementation in the remaining 3 (school IDs 3, 7, 27) schools. The average dose given was 71.3% and the average dose received was 72.5%. Though, the school-wise scores of the dose given varied widely from 39-95%, the scores of dose received showed lesser variability, they ranged from 58 to 79%.

The average reach score for the delivery of the intervention was 64.8%, (69.9% for attendance at the classroom sessions, 65.8% for inter-school event and 58.7% for the proportion of signed postcard stubs returned).

Tables III, V and VII delineate the dose of the intervention given, received and reached, respectively, to each intervention school.

### Training of the teachers and the delivery of the interventions

Proportion of teachers trained in a school correlated with better implementation of objectives ($r = 0.58$, $P < 0.02$), teacher’s script ($r = 0.57$, $P < 0.02$), student’s script ($r = 0.53$, $P < 0.05$), worksheets ($r = 0.56$, $P < 0.02$) and superior peer leaders–student communications ($r = 0.75$, $P < 0.001$) as documented by OSSOs. It was also of greater benefit in lowering the susceptibility to chewing tobacco ($r = 0.53$, $P < 0.05$).

### Subjective feedbacks versus objective assessment in the Indian setting

OSSOs revealed that the ‘learning objectives’ and ‘teacher’s script’ were relatively the least often conducted among the various components/elements, making them the differentiating variable between the well-implemented and the less well-implemented interventions. [On an average, learning objectives were conducted 51% (4–96%, standard deviation (SD) = 30), the teacher’s script 68% (17–100%, SD = 30) and games 91% (73–100%, SD = 11) of the times.] The ‘rigor of implementation’, which consisted of the percentage of these intra-session element delivered, namely learning objectives, students’ script, teacher’s script, games, worksheets and wrap-up, as documented by objective observations, therefore correlated most strongly with the implementation of the learning objectives ($r = 0.90$, $P < 0.0001$) and teacher’s script ($r = 0.95$, $P < 0.001$).

We compared the delivery of the learning objectives and teacher’s script, as recorded through OSSOs with the subjective feedbacks, in each school. On 91 occasions when the ‘learning objectives’ were not conducted, 84 times (92.3%) the teachers had reported that the objectives were ‘enjoyed and participated’ rather than reporting ‘not conducted’. Similarly, out of 64 occasions when the teacher’s script was not conducted, 63 times (98.4%) the teachers reported it as ‘enjoyed
Table VII. *Reach: extent to which the tobacco prevention intervention reached the target audience (in %)*

<table>
<thead>
<tr>
<th>Variables</th>
<th>Proportion of students attending the classroom sessions in %</th>
<th>Minimum attendance recorded across all classroom sessions in each school</th>
<th>Proportion of parent postcards returned in each school</th>
<th>Proportion of students participating in the inter-school event from each school</th>
<th>Reach score of each school 1 + 2 + 3/3</th>
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<td>Classroom session 3</td>
<td>Classroom session 4</td>
<td>Classroom session 5</td>
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<td>84</td>
<td>84</td>
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<tr>
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<td>31 (530)</td>
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</table>

Mean (including three schools where intervention was abandoned) | 69.94 | 58.7 | 65.79 | 64.75 |
Mean (excluding three schools where intervention was abandoned) | 86.08 | 72.23 | 81 | 79.69 |

*Program implementation indefinitely delayed in these schools.

*Sessions conducted but the attendance was not taken by the peer leaders.
and participated’ rather than ‘not conducted’. This clearly shows the magnitude of the ‘deference effect’ and consequently indicates the poor validity of subjective feedbacks in Indian school settings.

Correlates of outcomes
The school-wise scores of the rigor in implementation of the classroom curriculum are plotted against the school-wise outcomes, change is the susceptibility to chew tobacco, in Fig. 1. In addition, the communication between students and peer leaders ($r = 0.66, P < 0.005$) and higher proportion of students participating in the classroom discussions ($r = 0.70, P < 0.005$) correlated with better outcomes.

Discussions
Process evaluation of this culture-specific tobacco prevention intervention for urban Indian schools revealed rigor in implementation and a good reach suggesting a high potential for the intervention to impact the study outcomes. This program was Indian in content and delivery. It was well accepted by the students and teachers and implementable in both private and public schools. Some important lessons were learnt. Qualitative observations during piloting of the intervention identified variables and enabled development of a rigorous process evaluation framework for this culture-specific tobacco prevention program.

The importance of training teachers
Schools with a higher proportion of teachers trained not only had better implementation of the classroom curriculum but also better outcomes. Such schools also had better communication between the students and peer leaders. Researchers from other school-based interventions have long recognized training to be a critical contributor toward better implementation of programs [31–33]. A review, Dusenbury et al. [32], also reports that teachers who received training were more likely to implement the curriculum with fidelity than teachers who did not receive training and a more extensive training was associated with a higher quality implementation.

Teacher training manuals/handbooks
Subjectively, the teachers had reported that the training manuals are very helpful (when they examined the manuals at training). In practice, however, the community coordinators reported that teachers, more often than not, in their busy schedule, had little time to read the teacher’s manual and consequently the classroom sessions were delivered based on whatever they remembered from their
training. Although it has been extensively reported that detailed instruction manuals have the potential to enhance the delivery and fidelity of an implementation [32, 34], analysis from our study indicates that teacher-training manuals need to be most importantly concise. Resonant with our findings, a Dutch school-based obesity program also reports that although teachers perceived the detail manual as very helpful, time constraint was a commonly expressed problem [35].

Peer leaders in school-based tobacco prevention interventions

The perceptions of the peer leaders, who were elected by students themselves, would reflect and also influence the views of students. It was observed that the peer leaders were an important support to the teachers in the delivery of the tobacco prevention intervention. In fact better the ‘peer leader–student communication’, better was the rigor in the implementation. Majority of the peer leaders had found (‘7’ on a Likert scale of 1–7) the multi-component classroom sessions (75.5%), the parent postcards (74.6%) and posters (78.8%) very appropriate and also felt confident (79.2%) of leading tobacco prevention activities in the future [36].

Peer leader-led health education programs have been widely used as an effective vehicle for preventing drug abuse and tobacco prevention among adolescents [37–39]. The National Institute for Health and Clinical Excellence recommends that student nominated peer leaders should be trained by adults to deliver interventions aimed to prevent uptake of tobacco in schools [40]. The Center for Disease Control, USA, also recommends peer leaders, but recognizes that, although peer leader programs can offer an important adjunct to teacher-led instruction, such programs require additional time and effort to initiate and maintain [41]. Besides, tobacco and drug abuse, they have also been used for promoting better nutrition [42], helmet use [43] and preventing HIV [34, 44]. To go a step further, in a published review, Melanby et al. [45] critically compare peer-led and adult-led education in schools and conclude that there is evidence suggesting that peer-led health promotion may in fact be more effective than adult-led.

The importance of OSSOs as a measure for process assessment in Indian school settings

OSSOs, made by trained community coordinators, objectively documented the rigor in delivery of the curriculum; the dynamics of interaction between the teachers and students, peer leaders and students; and the classroom discussions, on pre-structured session-specific OSSO forms.

The community coordinators during observations had reported that teachers do not like to give critical feedback. This was confirmed by the large discrepancies (94–98% discordance) between the teacher feedbacks and objective observations. Although other researchers have also reported that ‘teacher reports’ may not be as valid as objective assessments [32, 46], the extent of it is alarming in the Indian school-based setting. For the same reason, dose received showed little variability across schools. This makes it imperative that (even if it means extra costs) processes need to be measured objectively in the Indian school settings.

Conceptually, similar to the OSSOs, Bouffard et al. [21] developed a structured observation technique, Systematic Social Observations, in therapeutic communities, to evaluate firsthand the social climate of correctional institutes [21]. They too reported that stakeholder interviews provided firsthand feedback, but in some cases lead to potentially biased information, therefore recommending the use of combined evaluation methodologies [21].

Objectively documenting teacher–student and peer leader–student interactions

Analytically, it was found that, better was the teachers’ and peer leaders’ communication with the students, better was the ‘rigor in implementation’. Resnicow et al. [46], for the ‘Gimme-5-school program’, developed a composite measure, in which they recorded through objective observations, the teacher–student interaction, which they called ‘rapport’. When they compared the various measures, they found that rapport and observed fidelity
Training of teachers was significantly associated with both better implementation and better outcomes. Comprehensive training of teachers needs to be a critical component of school-based interventions in India. Peer leader tobacco empowerment approaches in Indian schools are successful and should be espoused in school-based interventions.

A high proportion of socially desirable answers made OSSO a preferred assessment technique for process assessment, in schools in India. For the same reason, even dose received which theoretically should be entirely subjective needs to incorporate an objective component while assessing the processes in schools in India.

Teachers, in the Indian school settings, amidst their busy schedule do not get time to revise the curriculum before its actual delivery. So health intervention programs in Indian schools should be designed in such a way that they do not require teachers to reread or prepare before delivery of the curriculum. For the same reason, the teacher manuals need to be simple and concise rather than detailed and elaborate.

When resources limits a detailed process assessment, the following variables could be used as indicators—objective assessment of teacher’s communication and ability to handle the discussion with the students (dose given), implementation of objectives (dose given), teacher’s script (dose given), the peer leader’s communication with the students (dose received) and proportion of the class participating in the discussions (dose received).

Conclusions

The culture-specific, multi-component, tobacco prevention program which addressed both smokeless and smoked forms of tobacco was successfully implemented in both public and private schools in urban India. Qualitative observations enabled development of a rigorous process evaluation framework.

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Conflict of interest statement

None declared.

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