Guidance for Syphilis Elimination Effort Evidence-based Action Planning

Syphilis Elimination (SE) activities are more likely to be successful when they are carefully planned, managed, and monitored. An Evidence-based Action Plan (EBAP) is a strategy to assist the planning and management of syphilis prevention and control programs. The epidemiology of syphilis is always changing. SE programs must respond to changes in the epidemiology by directing efforts toward emerging at-risk populations. Furthermore, awareness of the costs and benefits of different interventions will help programs choose the most efficient intervention activities.

An EBAP guides the collection of information on target populations, interventions provided, resources allocated, and outcomes in order to facilitate program assessment, improve effectiveness, and inform decisions about future program development.[1] [2] An EBAP gives credibility to the organization, ensures that all components of a local intervention are considered, grounds interventions in reality, and improves efficiency and accountability.

A number of state and local STD programs are moving toward a more evidence-based approach to syphilis prevention and control interventions. The purpose of this document is to provide guidance for the development of an SE EBAP for interventions that will facilitate gathering information and tracking resources, and provide a framework for ongoing evaluation.

All HMAs will create an annual EBAP

The *Comprehensive STD Prevention Systems* (CSPS) grant guidance requires that SE applications include a Syphilis Elimination Monitoring Plan (i.e. EBAP) that monitors the activities and progress toward meeting the objectives developed for each SE strategy. SE programs are also required by *The National Plan to Eliminate Syphilis from the United States* to use an EBAP.[3] SE grantees are required to prepare an EBAP for their SE interventions, using the guidance provided below. Activities included should be those conducted by the state or local health departments and those conducted by community-based organizations (CBOs) that receive funding from the health department.

In addition to a Monitoring Plan in the CSPS grant application, CSPS also requires annual (by March 31 of each year) and six-month performance reports (by September 30 of each year) to be submitted to CDC by grantees. SE grant applicants/grantees are required to submit an EBAP for each intervention with each CSPS grant application, annual report, and six-month progress report. For ongoing interventions, the program must provide data on the objective of the intervention, the target population, the intervention, resources used, performance indicators, outcomes, and an evaluation of data to re-consider the intervention. For interventions that are new to the program, the program must provide data for objective of the intervention, the target population, the intervention, resources used, performance indicators, and outcomes.

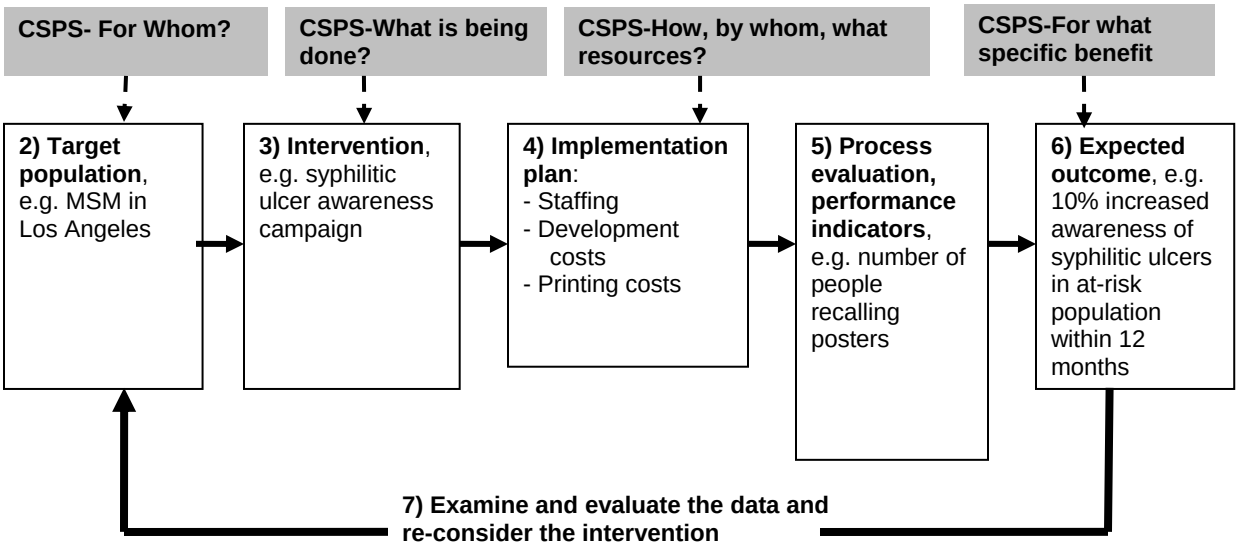
Grant applications and progress reports will be reviewed by the CDC program consultant and the CDC Syphilis Elimination Effort Implementation Monitoring Group (SEE IMG) for compliance with the requirements of individual monitoring plans.

All EBAP submitted to the CDC must be formatted as described in this guidance.

The Syphilis Elimination EBAP framework[4]

Note- An action plan is needed for each SE intervention.

1) Objective



Understanding the elements of the Action Plan

In general, individual syphilis prevention and control activities are parts of a whole STD control effort or local public health program. Therefore it is important to understand and appreciate the influence of relationships among the components of an STD program and the elements of the SE action plan.

For ongoing interventions, the seven elements described below and in the above framework will be required in grant applications and six-month progress reports; only elements 1–6 are required for a new intervention.

1) Objective

The program should describe the overall objective and purpose of the intervention and should explicitly state whether the intervention is ongoing or new.

2) Target population

The program should describe the target population for the intervention and provide justification for selecting the target population. Demographic and epidemiologic data should support the choice of the population as a target of the intervention. For example, an intervention may target white men who have sex with men (MSM) between the ages of 25 and 45 years, because 60% of the state's total cases are in this population.

3) Intervention

In this section, the program should describe the intervention in detail, including all staff, steps, and activities needed to complete the intervention. The intervention may be traditional, (e.g., screening and treatment, partner services, outreach, or community collaboration) or it may be a novel intervention (e.g. a

provider-focused intervention). Separate monitoring plans may be helpful if the same intervention is used in two different populations (partner notification in the MSM population and partner notification in the heterosexual population) or in two different venues (screening in a mobile van and screening in a jail).

4) Implementation plan

The SE grantee should list and describe the amount, type, and cost of all of the resources required to implement the intervention. This list should include the cost of staff hours, travel, vehicle, print materials, screening supplies, laboratory services, and any other resources needed to implement the intervention.

5) Process evaluation and performance indicators

The action plan should include performance indicators or measures that will demonstrate how the program will reach the intervention's expected outcome. Examples of performance indicators include the number of syphilis tests conducted per month, the number of provider visits per month, the number of partners elicited per month, and the number of people who recall seeing a poster.

6) Expected outcomes

The ideal long term outcome is decreased incidence of P&S syphilis; however, it may be difficult to attribute a decrease in syphilis morbidity to a single intervention. Therefore this section should also include short-term or intermediate outcomes of the intervention. For example, a short term outcomes may be increased awareness of a syphilis campaign in the community; an intermediate outcomes may be a measured behavior change in the at-risk population or a measured practice changes among private healthcare providers.

7) Examine and evaluate the data and re-consider the intervention

All interventions defined as ongoing must include this section. Data collected should be reviewed to determine the effectiveness of an intervention in achieving objectives stated in element 1. SE programs should use these data to analyze the success of interventions during the current year and to inform the development of subsequent interventions. If an intervention is determined to be ineffective in achieving the determined short, intermediate, or long term outcome, then the program must provide a description of planned changes in the intervention or reallocation of SE resources to achieve the stated outcome in the application or six-month progress report. Alternatively, the program may provide justification for continuation of the intervention without change.

Action Planning Examples

To illustrate how the guidance may be applied, below is a series of examples using commonly implemented intervention activities – screening, partner notification, community collaboration, and provider-focused interventions. The EBAP examples provided are from 2008 CSPS grant applications written by various state and local SE program representatives; they are being shared with the permission of each program. Please note that these are only examples and are not intended to include all intervention possibilities or to set standards for intervention effectiveness. **Also note that these examples do not include objectives, as they are from 2008 when objectives were not included in EBAPs.**

Example A – Screening

2) Target population

Of the 29 primary and secondary (P&S) syphilis cases reported in Oregon during 2006 all were male and 28 of the 29 were MSM. The majority (83%) of the reported P&S cases lived in the Portland tri-county area: Multnomah, Washington and Clackamas Counties. The intervention is targeted to MSM, because they represent the highest case counts in the tri-county area.

3) Intervention

During 2008, syphilis screening for MSM will be offered once per month at two different venues (bathhouse, MSM oriented club, or sex club) and twice per month at one venue (The Men's Wellness Center). Screening sessions will be 4 hours at MWC and 3 hours at other venues. Screening sessions will be staffed by one Outside In staff member and one outreach worker from CAP. Some sessions may also include a volunteer. Advertisements will appear at the Men's Wellness Center, a gay newspaper, and flyers placed at clubs, the health department, and other sites in the community.

4) Implementation plan

Each screening session will beis estimated at five hours (MWC) and four hours (other venues), to includeinlcuding travel to and from the screening site and handling of blood specimens prior to sending to the lab. It is expected that 8 individuals will be screened at each session.

Costs of labor for one phlebotomist will average $16 per hour and the cost of one outreach worker will average $10 per hour:
$16 X 18 (hours/month) X12 (months) = $16 X 18 X 12 = $3,456
$10 X 18 (hours/month) X12 (months) = $10 X 18 X 12 = $2,160; $3,456 +$2,160 = $5,616.

Travel costs will include an average of 20 miles for month (all screening venues are in close proximity to Outside In and CAP) at $0.485 per mile = $9.70. Either the CAP outreach worker or the Outside In staff member will drive a privately owned vehicle (POV).

Expendable screening supplies, needles, vacutainers, band-aids, and antiseptic pads are estimated at $1.25 per blood specimen: $1.25 X 32 (specimens/month) X 12 = $480.
Blood specimens will be evaluated by RPR in the Multnomah County Health Department Lab at no cost to Outside In. However, we would like to capture all costs associated with this activity, cost of an RPR is estimated at $4: 32 (specimens per month) X $4 X 12 = $1,536. Any reactive RPR tests will be forwarded to the Oregon State Public Health Lab (OSPHL) for a confirmatory FTA test at a cost of $12 per test. We estimate one reactive RPR test needing confirmation per month: $12 X 1 X 12 = $144.
Total lab = $1,536 + $144 = $1,680

Advertisement costs in two special focus newspapers is estimated at $60 per month per paper:
$60/month X 2 (papers) X 12 (months) = $1,440

Labor costs per year $5,616
Travel costs per year $9.70
Supply costs per year $480
Lab costs per year $1,680
Advertisements per year $1,440
Total costs per year = $9,225.70

5) Process evaluation and Performance indicators
During 2006 two early syphilis cases were identified from about 384 individuals tested at various venues. Finding 2 early syphilis cases per year by testing 384 individuals per year at a cost of $9,226 is $4,613 per case identified by screening.

6) Expected outcomes
We expect prevalence of syphilis among MSM in the Portland area to decrease to some extent by identifying and treating possible infectious cases. Screening for syphilis is always accompanied by STI prevention information and possibly a client centered discussion on reducing risks of syphilis and other STI's.

7) Examine and evaluate the data and re-consider the intervention.
Of the two cases identified by outreach screening during 2006 both were tested as the Men's Wellness center. One of these cases was in the secondary stage at testing, so identification and treatment may have prevented spread infections. The contractor has mentioned that more men are tested for syphilis at the Men's Wellness Center than other venues, e.g., an MSM club. Because of higher volume testing at this site, for 2008, screening hours per session at the Men's wellness center will be extended from 3 hours to 4 hours. Increasing screening hours at MWC may result in additional individuals tested for syphilis.

During 2008, screening MSM and others for syphilis will continue at tri-county area health departments and the Outside In medical clinic.

Example B – Partner notification

2) Target Population
In 2006, the P&S Syphilis rate in the Metro Atlanta area (consisting of the counties of Fulton, Dekalb, Gwinnett, Cobb and Clayton) was 14.1/100,000. Most of the cases in men were diagnosed among MSM. The intervention is targeted to all individuals that test positive for Syphilis.

3) Intervention
Throughout the metropolitan Atlanta area, 30 Communicable Disease Specialist (CDS) staff members interviewed newly diagnosed Syphilis patients to solicit sexual partners' names and locating information. Each CDS staff member works 20 hours each week to contact named partners. Contact and communication with the named partners is attempted by locating them at home, by telephone, and by standard mail.

4) Implementation plan
In the Metro Atlanta area, 30 CDS staff members work at least four hours per day, 5 days per week on partner notification.
The input of labor hours each year:
30,000 hours/year x $15/hour = $450,000/year for labor costs

5) Process evaluation and performance indicators

In a one year period, 593 index Syphilis cases were reported to health departments in the Metro Atlanta area, and each of these index cases named less than 1 partner with locating information. CDS investigations initiated 309 partners. Twenty-six partners were infected and treated for syphilis, and 77 partners were provided epi-treatment. Twenty-five suspects and associates were tested and resulted in the identification of four new syphilis cases.

6) Expected outcomes

Surveillance data for 2007 will be monitored for a decrease in P&S syphilis.

7) Examine and evaluate the data and re-consider the intervention

Data from the past year (2006):

Individuals located and treated, and epi-treated individuals:

26 people + 77 people = 103 people treated

The input of labor hours per individuals treated:

30,000 hours/year ÷ 103 people treated/year = 291 hours/person treated

The cost per person treated

(291 hours/person treated x $15/hour) + (103 persons treated) = $4468/person

Although only a small number of infected partners are located, the intervention resulted in the epi-treatment of several individuals. The program will continue this intervention for one more year and then will re-evaluate it.

Example C – Partner notification

2) Target Population

Any individual diagnosed with primary, secondary, and early latent syphilis in Tennessee.

3) Intervention

This interview will attempt to conduct a timely original interview of all persons from the target population to elicit the name, description, exposure and locating information of their sexual partners and others (cluster suspects) determined to be at increased risk of infection. These sexual partners and cluster suspects will then be located and referred for testing and treatment, as appropriate. These partners and cluster suspects will also be selectively interviewed to elicit cluster suspects and associates to the original patient; and these cluster suspects and associates will also be located and referred for testing and treatment, as appropriate. Re-interviews of the original patient will be conducted, when appropriate.

Case management will include systematically documenting all case information, and analyzing this information to develop action plans aimed at identifying and locating other individuals at risk of infection or exposure to syphilis. Case management will also be used to determine the source of and spreads from the original patient, and when the case should be closed.

4) Implementation Plan

The *type* of resources

Disease Intervention Specialists and Disease Intervention Specialist Supervisors will be involved in this intervention to interview patients, locate and refer patients, document case information and analyze case information. It also includes the clinical costs associated with the examination and/or treatment of sexual partners and cluster associates. These estimated costs are based upon data from the first six months of 2007:

The *amount* of resources

In excess of 40 Disease Intervention Specialists working in Tennessee's ninety-five (95) counties.
Nurses in Public Health Department clinics operating in Tennessee's ninety-five (95) counties.

1,800 RPR tests and 90 TPPA tests.
3,600 miles involved in disease intervention services

The cost of these resources = $ 112,600

Disease Intervention Specialists @ $17 average hourly rate

2 hours original interview
1 hour case documentation
1 hour reinterview x 2 reinterviews
.5 hours cluster interview x 2 cluster interviews
1 hour partner and cluster referral
Total 5.5 hours per case
600 cases x 5.5 hours per case x $17 per hour = $56,100

Fringe Benefits @ 31% = $17,400

Nurse @ $22 average hourly rate

.25 hours per examination x 3 examinations (2 partners and 1 cluster) per case x 600 cases x $22 = $9,900 per year

Fringe Benefits @ 31% = $3,100

Laboratory Costs (materials and personnel)

600 cases x 3 RPR's per case x $5.00 per test = $9,000 per year
30 TPPA's x $15 per test = $500 per year

Mileage: 60 miles per case x 600 cases x .46 = $16,600 per year

5) Process Evaluaion

The percentage of early syphilis cases interviewed.
The partner examination index (mean number of partners examined per case)
The cluster examination index (mean number of partners examined per case)
The percentage of early syphilis cases with disease intervention (cases with at least one partner/cluster brought to treatment or epidemiologically treated)
The percentage of partners/clusters examined within 7 and 14 days of initiation.

6) Expected Outcomes

Decreased incidence of early syphilis in Tennessee and each of the two previous HMA's – Davidson County and Shelby County.

7) Examination and Evaluation of Data

During first six months of 2007, there were 301 cases of early syphilis assigned for interview and 294 (97.7%) cases were interviewed. During this same time period there were 343 partners initiated with 244 partners examined for an examination index of .83, or less than one partner examined per case interviewed. The cluster examination index was (25/294) 0.1. The percentage of cases with disease intervention is 40% for the first six months of 2007. There were 189 partners and 19 clusters that were newly examined totally 208 new examinations during the first four months of 2007. There were 160 (77%) partners/clustered that were examined within seven (7) days, and 186 (88%) partners/clusters that were examined within 14 days.

Example D – Community collaboration

2) Target population

The intervention is targeted to MSM, because this target population accounts for the majority of new P&S syphilis in NYS. In 2006, 90% of early syphilis cases in NYS were among men. Of men interviewed who identified partners, 81% noted male partners (76% only had sex with males, and 5% identified both male and female partners). MSM in the cities of Rochester, Albany and Syracuse have been targeted because of

elevated rates, and the presence of an operating bathhouse/club where a relatively large number of MSM congregate.

3) Intervention

The required evidence-based action plan for syphilis elimination will focus specifically on partnering with local CBOS funded to do HIV prevention with MSM communities, to integrate STD testing, including syphilis, into bathhouses operating in Rochester, Albany, and Syracuse, New York. In these three communities, CBOs already funded under NYSDOH HIV Prevention contracts will offer integrated STD and HIV testing in targeted bathhouses/health clubs two nights per month, for 4 hours each session. Integration of enhanced STD screening (especially syphilis) into existing HIV testing in bathhouse/sex venues was identified as a priority activity by the NYSDOH AIDS Institute, which has given increased attention to the role of STDs in enhanced risk for HIV transmission and disease progression.
Clients are offered HIV (oral), gonorrhea/Chlamydia (urine) and syphilis screening (phlebotomy). In a prior pilot, sites found that the addition of Gc/Ct screening tests significantly increased the proportion of clients who accepted syphilis testing thereby substantiating its importance as a component of comprehensive STD screening and an incentive for increased participation in syphilis testing. Collected syphilis and Gc/Ct specimens are transported according to specified lab procedures, and a protocol is in place for notification of test results and clinical and epidemiologic follow-up of partners.

4) Implementation plan

<u>The input of labor hours each year:</u>
2 employees/site x 3 sites x 2 testing nights/month x 4 hours/night x 12 months=576 hours. Other labor is primarily in-kind (e.g., venipuncture, CBO staff primarily funded on HIV prevention contracts, BSTDC and AI /Syphilis Elimination Workgroup for monitoring and data summarization, and coordination of state lab contract testing). Expected costs:
Partial salary of CBO peer outreach staff (576 hours x yr × $10/hour = 5,760)
Labor costs per year $ 5,760
<u>Other associated costs:</u>
Cost of 540 syphilis tests @$5.00 (test kit and supplies) = $ 2,700
Cost of 540 urine Gc/Ct tests @ 11.95 (test kit and supplies) = $ 6,453
Publicity and advertising in 3 localities $ 4,500
Total direct cost $19,413

5) Process evaluation and performance indicators:

The programs expect to screen an average of 15 people per site per month, 12 months a year. The process measure is the number of people screened in the sites each year: 540 individuals.

6) Expected outcomes

There are three outcomes expected from the program: 1) Identification of a limited number of new early syphilis cases in the MSM population. Based on a meta-analysis of
syphilis screening in non-medical settings, the proportion of new cases identified by syphilis screening in sex venues, including bathhouses, was 1.2%. Using that figure, an estimate of new cases from the proposed screening would be 540 x 1.2%=6 new cases. However, in the same article it concluded that "the secondary benefits, such as increasing awareness of syphilis and prompting earlier treatment due to symptom recognition, may be substantial". It is these ancillary outcomes that provide significant additional benefit to the project. Additional expected outcomes (which are more difficult to measure) include: 2) enhanced awareness of the risk of syphilis and the importance of frequent STD testing by venue patrons and 3) strengthened relationships between staff of three CBOs and Bureau of STD Control, including coordination of partner notification.

7) Examine and evaluate the data and re-consider the intervention
The program will collect quantitative data on outcome 1 above and compute a cost per case of early syphilis diagnosed. For outcomes 2 and 3, assessment will be made through more qualitative approaches including assessing perceptions of CBO staff, as well as regional STD staff counterparts for the projects.

Example E – Provider-focused

2) Target Population
The primary and secondary syphilis rate in San Francisco in 2006 among men was 57.9/100,000. Local analyses indicate that MSM account for 95% of P&S cases in men in San Francisco. This intervention is targeted to MSM between the ages of 25 – 55 because they have the highest P&S syphilis rate in the City.

3) Intervention
The STD Section will enroll health providers that target the largest numbers of G/MSM in San Francisco in an MSM Syphilis Screening Program and provide them with free lab testing, courier service and Bicillin G-LA in exchange for their agreeing to test all of their sexually active MSM for syphilis every three months. They will obtain a detailed medical and sexual history and current demographic information from the patient, perform phlebotomy to obtain a syphilis specimen and then arrange to have the syphilis specimen transported to the DPH Microbiology Lab the following day by the STD Section Courier for processing.

4) Implementation Plan
Staffing the screening program requires three employees to spend two hours per day, five days per week working 50 weeks per year.

- The input of labor hours each year:
  1500 hours/year x $28/hour = $42,000/year for labor costs

  * There is no cost for the microbiologist who processes the specimens since the salary for the position is included in the Laboratory's General Fund budget.
- Cost to operate STD delivery van each year
  * There is no cost since this is a city vehicle and the City pays for maintenance, gas and insurance)

  Specimen collection materials (phlebotomy equipment, vacutainers, lab costs)
  $10/test x 5,000 tests/year = $50,000/year for testing supplies and lab costs

5) Process Evaluation and Performance Indicators
Over a one-year period, The MSM Screening Program screens an average of 20 people each day, five days each week, 50 weeks per year. The process measure is the number of people tested through the MSM Screening Program each year: 5,000 individuals

6) Expected Outcomes
During a one-year period, 5,000 G/MSM were screened and 170 early syphilis cases were diagnosed. Ideally, the long-term outcome will be decreased incidence of P&S syphilis and we plan to monitor surveillance data to compare rates this year with those in the following year.

7) Examine and Evaluate the Data and Re-Consider the Intervention

- The input of labor hours each year:
  1500 hours/year divided by 170 cases = 9 hours/early syphilis case
- The cost per case of early syphilis diagnoses (a staff salary of $28/hour, testing supplies and lab charges of $50,000).

(9 hours/case x $28/hour = $252) + ($50,000 divided by 170 cases = $294) Total = $546/early syphilis case

Screening G/MSM through its MSM Syphilis Screening Program appears to be a good value because it identifies 170 new cases of early syphilis per year with a reasonable input of staff effort. While the percentage of new infectious syphilis cases identified through this intervention was not substantial (only 3% of those tested were infected), data indicate that the secondary benefits of this type of intervention, such as increasing awareness of syphilis and prompting earlier treatment due to symptom recognition may be substantial. This type of intervention also it increases the syphilis knowledge and diagnostic expertise of private providers targeting the individuals at the highest risk for syphilis which should not be taken for granted. For all of the above reasons, we will continue to utilize this intervention.

Example F - Other

2) Target population
The primary and secondary (P&S) syphilis rate in San Diego in 2006 among men was 14.5/100,000 and among women 0.8/100,000. MSM account for 91 percent of P&S syphilis cases in men reported in San Diego, of whom 60 percent are co-infected with HIV. The intervention is targeted to MSM, because they have the highest P&S syphilis rate in the city.

3) Intervention
The proposed intervention is to improve the GUD diagnostic capacity for primary syphilis in the private sector by making available the multi-plex PCR thorough our state reference laboratory.

4) Implementation plan
The specific implementation plan and costs will be developed with San Diego. Providers serving MSM will be notified of the availability of the test and collection tubes will be provided by the state reference lab. The DIS visitation program may also deliver collection tubes during site visits to high volume providers. This test can also be incorporated into STD-Prevent. Until validations studies are complete the results with be epidemiologic and patients can be epidemiologically treated.

5) Process evaluation and performance indicators
The number of collection tubes requested and the number returned will be monitored. The number of primary syphilis cases in MSM identified along with the number of HSV cases will be monitored. DIS case management data will be monitored for number of missed primary syphilis in the private sector. Cost of case detected will be calculated.

6) Expected outcomes
The expected outcome is an increase the number of primary syphilis detected and treated and a decrease in the percentage of primary cases reported that were not initially missed in the private sector.

7) Examine and evaluate the data and re-consider the intervention
The cost effectiveness of the intervention will be crudely calculated one year after Implementation.

References

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