

Atmiyata General Evaluation Plan

I. Project Impact

Study Design & Sample Size

The study design to assess impact of the Atmiyata project is a quasi experimental, pre-post with control group design (Campbell and Stanley xxxx). The intervention site has 41 villages. Control villages from a similar geographical block to the intervention site will be selected based on distance from main town and population size. The control block will be located at a geographical distance from the intervention villages to avoid contamination. The study population includes adult women and men > 18 years.

A sample size of 823 has been calculated to detect a decrease in reported symptoms meeting the diagnosis of a CMD from 15 percent to 10 percent with 85 percent power and an alpha of 0.05 (Fleiss 2005). The sample will be stratified by women and men and will include younger and older age groups. As a result there will be 225 women (< 40 years), 225 women (40+ years) and 225 men (< 40 years) and 225 men (40+ years). As a result the total sample at baseline in the intervention group will be 900 and in the control group 900.

I. Project Outcomes

	Outcome Measure	Metric/Indicator	Tools/ Instruments	Data Source/s
1.	Access to treatment	25 percent of those detected with MI will access treatment either at the FRU or district hospital	GHQ questionnaire	Baseline and endline surveys in intervention and control groups
2.	Increase in utilization of social benefits	Percent increase in utilization of access to social benefits	A set of questions on access to social benefits by the family of a person with MI	Baseline and endline surveys in intervention and control groups Project MIS; monthly reporting on access to and utilization of social benefits
3.	Increase in quality of life	Percent increase in quality of life from baseline to endline and compared to the control area		Baseline and endline surveys in intervention and control groups
4.	Increase in capacity of Amtiyata champions	Percent knowledge & skills increased	Index of knowledge & skills	Scores on pre and post tests

II. Development of the Intervention

	Activity	Description	Outcomes/Products of Activity	Applications to Atmiyata Intervention
1.	Formative Research	10 FGDs 6 IDIs	-Local constructs of well being & mental illness - Coping patterns for MI - Treatment seeking pathways including traditional healers - Lexicon for well being & MI - Social support for MI; attitudes towards MI -Development of core criteria for Atmiyata champions.	Formative research findings will be used to develop the core structure and content of the films They will used to ensure that local context and need are prioritized in the development of the intervention
2.	Mobile phones	Several models will be tested for audio quality and screen size before finalization of the phones Usability testing will be done with Atmiyata champions prior to finalization of the model	Phones with good audio quality & screen size will be selected Functions such as Bluetooth and micro SD chip transfer will be tested with Atmiyata champions	Selection of final model of phone will be done after usability testing with Atmiyata champions; Content for technical training of Atmiyata champions will be based on usability testing
3.	Films	Field visit by film consultant Formative research findings Development of story line and concepts Preparation of photomatics Testing photomatics at the field level Finalization of films	Iterative process of generation of training and motivation films with several rounds of inputs from Atmiyata team and pretesting at the field level	Films developed that are locally relevant, technically strong, emotionally appealing and compassionate in approach.
4.	Social Benefits	Compiling details of social entitlements and establishing linkages to obtain them	List of social benefits List of documents required to obtain different social benefits List of how and where to obtain social benefits	Detailed information about social benefits Linkages to be established

III. Validation of the Atmiyata intervention (1 month) in 1 villages

	Activity	Description	Outcomes/Products of Activity	Applications to Atmiyata Intervention
1.	Undertake validation of Atmiyata intervention	<p>Orient Atmiyata champions in 1 villages</p> <p>Use photomatics if films are not ready</p> <p>Have a meeting of the Atmiyata champions with the atmiyata friends</p> <p>Have stakeholder meetings in the village</p> <p>Usability testing of mobile phones & 5 exit interviews of persons meetings</p>	<p>-Local constructs of well being & mental illness</p> <p>- Coping patterns for MI</p> <p>- Treatment seeking pathways including traditional healers</p> <p>- Lexicon for well being & MI</p> <p>- Social support for MI; stigma</p> <p>- Develop criteria for identification of Atmiyata champions</p>	<p>Formative research findings will be used to develop the core structure and content of the films</p> <p>They will used to ensure that local context and need are prioritized in the development of the intervention</p>

IV. Tracking the Atmiyata Intervention

	Activity	Indicator	Who to collect	Frequency
1.	Training of Atmiyata champions	# of champions who scored a basic 75 percent in test after training	BAIF team	Once; after champions training
2.	Tracking how many attended the 9 training meetings for Atmiyata champions	# of champions who attended 7+ meetings # of champions with core championship criteria	BAIF team	After each training meeting (a total of 9)
3.	Showing of Atmiyata films at the community level	# times films shown in each village	BAIF team/ Technical Mobile tracking	Monthly
4.	Transferring Atmiyata films at the community level	# times films downloaded in each village	Technical Mobile tracking	Monthly
5.	Detection/referred/referral utilization	# persons detected/referred/ref utilization	BAIF team	Monthly
6	Social benefits	# persons/families receiving social benefits	BAIF team	Monthly

7	Atmiyata meetings at village level	# of meetings held at village level # of persons attending Atmiyata meetings	BAIF team	Monthly
6.	Tracking the viewing, sharing and transferring of films via mobile phone	# of times films viewed/shared/transferred	Technical tracking system on the mobile phone	Monthly

ATMIYATA HEALTH-ECONOMIC EVALUATION PLAN

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We propose to take an integrated three-tiered approach to evaluating the cost-effectiveness of the ATMIYATA project. The first two stages will be conducted in the context of the current project, the third when the project is brought to scale. The stages are:

- Stage 1: A trial-based health-economic evaluation (feeding into stage 2)
- Stage 2: A health economic modelling study (to synthesise stage 1 findings)
- Stage 3: A cyclic project monitoring and management system (cycling stages 1 and 2).

Below we describe each of the stages in more detail.

STAGE 1: TRIAL-BASED HEALTH-ECONOMIC EVALUATION

Aim

A health-economic evaluation assesses if health gains (lives saved; lives improved) are obtained in an efficient way (for an acceptable and sustainable budget). Therefore we look at health gains and economic costs and combine these in a single health-economic evaluation.

Design

While we all would agree that a randomised controlled design would be ideal for evaluation, conducting a randomised community trial is logistically (and financially) too demanding. Therefore, it was a conscious choice to propose a 'next best' design and settle for a quasi-experimental study design with two parallel cohort studies, one cohort conducted in the 'control' villages and the other cohort study in the 'experimental' villages. In each cohort study a sample of the population will receive a baseline measurement and after 12 or 13 month the same people will be re-interviewed.

Not all the aims of the project can be meaningfully evaluated in the context of a health economic evaluation. To illustrate, important objectives of ATMIYATA are to provide people with access to health care, encourage them to make best use of health care and also to access government benefit schemes. As seen from a health

economic evaluation viewpoint some of these variables are 'inputs' (independent variables) and not outcomes (dependent outcomes).

In this context we need to emphasise that there is a long list of items that need to be evaluated in the ATMIYATA project, and that in this wider context the health economic evaluation is only one part of the puzzle. In the remainder of this paragraph we take the narrow perspective of the health-economic evaluation.

Central clinical endpoint

Health gains are assessed with a minimal burden to the trial participants and will be based by (1) the World Health Organization Disability Assessment Schedule (WHO-DAS) as a primary outcome) and (2) the general health questionnaire (GHQ), which measures distress (as a secondary outcome, mainly for use in the sensitivity analysis of the health-economic evaluation). Using the WHO-DAS and GHQ, a series of outcomes can be readily calculated:

1. As a continuous measure the WHO-DAS measures individual pre-post changes in disability, while GHQ measures individual pre-post changes in distress. This is relevant in its own right, because we want to evaluate to what extent the lives of the people participating in the project have improved.
2. Treatment response can be flagged up when an individual's pre-post change exceeds, say, 25% or more. This gives rise to a binary outcome and helps to evaluate if the people living in the 'experimental AMIYATA' villages have better response rates as compared to the people living in the 'control villages'.
3. The individual's standardised pre-post change, d , can be interpreted as a change in symptom level expressed in standard units, d .
4. A decrease of size d in symptom severity can be mapped on a corresponding change in utility, U , where U is one of the metrics needed to compute quality adjusted life years, QALYs. We refer to Christy Sanderson and colleagues' brilliant 2004 paper how change in symptom severity of size d can be converted into a corresponding shift in U . At individual level, QALY health gains can then be computed as the amount of time, T , being spent in a health state with utility, U .

The objective of ATMIYATA is to gain QALYs. Conceptually, gaining QALYs in a population is the same as averting years lived with disability, YLD. The YLD metric is the 'morbidity' component (non-fatal disease burden) in the disability adjusted life year, DALY. If we were to add the 'mortality' component, the years of life lost, YLL (due to premature death), then the project's impact can be expressed as $YLD + YLL = DALY$ disease burden decrements. This might be feasible if we can rely on the mortality statistics of the experimental and control villages

To summarise, WHO-DAS measures (change in) disability and the GHQ measures (change in) wellbeing / distress levels. There are a number of ways to convert WHO-DAS and GHQ scores into relevant metrics, such as

- treatment response rates (and the corresponding likelihood ratio of a better treatment response rate in the experimental group versus the control group),
- QALY health gains at individual level (and the corresponding difference in health-related quality of life increments between the experimental and control conditions), and
- YLD and perhaps even DALY disease burden decrements at population level.

This is as close as we can get measuring 'lives saved' and 'lives improved' (described as 'ultimate outcome' of GCC), while at the same time maintaining respondent burden at acceptable levels and using instruments (WHO-DAS and GHQ) that have been accepted widely across the Indian subcontinent.

Economic costs

In health-economic evaluations three types of costs are reviewed when taking the societal perspective:

1. Direct medical costs (costs of health care uptake and pharmacy use),
2. Direct non-medical costs (service user's out-of-pocket costs for making trips to and from health services, and costs of informal caregiving),
3. Indirect non-medical costs (stemming from changes in productivity due to absenteeism and lesser, or increased, efficiency while at work – also called 'presenteeism' and changes therein).

In the Netherlands, the Trimbos Institute and iMTA Costing for Psychiatry (TiC-P) questionnaire is used for collecting the relevant data and is quite similar to the Health Service Receipt Interview (HSRI) used in the UK. We propose to use the TiC-P and HSRI as models for a similar, but adapted questionnaire for use in the ATMIYATA project. The adapted questionnaire collects data on service use (e.g. number of visits to a district nurse, GP, social worker, etc.) and maps (changes in) productivity levels.

The corresponding cost calculations are straightforward:

1. The number of 'health care units' (such as GP visits) are multiplied by the pertinent health service costs (e.g. the costs of a visit at the GP's). Likewise, the costs of prescription drugs (expressed in the daily standard dose) are multiplied by the number of days that the medication is used.
2. Once data have been collected on health care uptake, it is also straightforward to compute travel costs made by health service users in the context of obtaining health care, either by asking questions about travel distances or more directly asking about travel expenses. Informal health care offered by relatives, neighbours and friends will be costed as well, as will the costs of visiting traditional healers.
3. Changes in productivity can be measured by asking the number of days too ill to work in the last 4 weeks. Presenteeism can be measured by asking about the number of days worked while not feeling well and then rating the 'lesser efficiency while at work' (on a scale of 1 to 10 ranging from totally inefficient to efficient).

Costs are always computed as 'net costs', i.e. costs minus savings. To illustrate, the additional costs of health service use may be offset by greater productivity gains, which may then imply that investing in health care can be seen as having a good return on investment when health care costs are compensated for by productivity gains. More importantly, health care is offered to increase health gains (QALY gains), or the reduce YLD and DALY disease burden (see below).

Combining costs and health gains

We hypothesise that people living in the 'experimental ATMIYATA villages' will have better access to health services and feel encouraged to make better use of these services. This is then expected to translate in a reduction of WHO-DAS disability and GHQ distress/ wellbeing, higher treatment response rates, and more QALY gains in

the experimental villages relative to the control villages. Combining QALY gains and costs gives rise to the incremental cost-effectiveness ratio (ICER):

$$\text{ICER} = (C_1 - C_0) / (E_1 - E_0),$$

where C = costs (the balance of costs and benefits), E = effects (QALY health gains), and subscripts 1 and 0 refer to the experimental and the control conditions, respectively. The ICER is the key outcome of the health-economic evaluation as it sheds light on the question if the intervention offers good value for money by quantifying the costs per QALY gained. There is a willingness to pay (WTP) for gaining a QALY. In North America, Australia and West-Europe the WTP ceiling is typically set at \$50,000 (or €50,000) per QALY gained. As a rule of the thumb, an ICER below this WTP ceiling suggests that the intervention offers good value for money and is cost-effective. That said, it should be noted that the \$50,000 threshold cannot be transferred to low and middle income countries. Instead, it has been recommended (by WHO) to set the WTP threshold at 2 ~ 3 times the mean per capita gross national income (GNI). In India this would equal 2 ~ 3 * US\$ 3,900 = US\$ 7,800 ~ US\$ 11,700 (conversion to US\$ based on purchasing power parities). This would translate to approx. 400,000 – 700,000 rupees.

Uncertainty and sensitivity analyses

The ICER is subject to stochastic uncertainty (due to sample error) and this uncertainty will be handled by conducting 2,500 non-parametric bootstraps, projecting the bootstrapped ICERs on an ICER plane, and by computing the ICER acceptability curve when additional health gains are obtained at additional costs. Sensitivity analyses, directed at uncertainty in the main cost-drivers, will be conducted to gauge the robustness of the findings. The health-economic evaluation will also be carried out with cost per treatment WHO-DAS (and apart per GHQ) responder.

The data obtained in the context of the trial-based health-economic evaluation will feed into Stage 2 Health-Economic Modelling.

STAGE 2: HEALTH-ECONOMIC MODELLING

Aim

The aim of the health economic modelling study is to move beyond the trial-based (i.e. sample-based) cost-effectiveness analysis and to place ourselves in a much better position to assess, monitor, forecast and evaluate ATMIYATAs health economic impact at the macro level (population level).

Health-economic simulation model

At Trimbos Institute (Netherlands Institute of Mental Health and Addiction, and WHO Collaborating Centre for Mental Health) a series of general-purpose health-economic simulation models have been built. These models make use of the same computational strategies that are also being used in the Assessing Cost Effectiveness (ACE) models that have been used in Australia for ACE Heart Disease, ACE Cancer, ACE Mental Health and more recently ACE Prevention. The Trimbos models also benefitted from WHO's choosing interventions that are cost effective

(CHOICE) models. The Trimbos models were commissioned by WHO and the Netherlands Ministry of Health and were funded by the Netherlands Organisation for Health and Care Research. Currently the Trimbos models are being used for the development of clinical guidelines in collaboration with the National Institute of Clinical Excellence (NICE) in the UK. Trimbos Institute is an independent not-for-profit organisation and is happy to provide the models free of charge to the ATMIYATA project. The model runs using Excel 2007 (or later versions).

Input parameters

The Trimbos models have been designed for easy use and require only a few input parameters:

1. the size of the intervention's target population, N ;
2. the coverage rate, CR , which is the percentage of the population exposed to the intervention;
3. the adherence rate, AR , which is the percentage of the health service users compliant with the intervention;
4. the interventions effectiveness, expressed as a standardised effect size, d ;
5. the sample size, n , on which d was based (for assessing the distribution of d);
6. the per-patient costs of offering the intervention (in the relevant currency).

The model can handle multiple target groups and for each target group multiple interventions. In other words, the model can help to evaluate a single intervention, but with room for modelling and comparing health care *systems*. This is done for both a 'base-case scenario' (usual care as seen in the control villages) and an 'alternative scenario' (the experimental villages where ATMIYATA has been implemented).

It is worth noting that parameters 1 and 2 help to assess the impact of scaling up and exposing a larger number of people to the intervention (or package of interventions). Combining parms 1 and 2 with parm 3 helps to assess how many people are effectively exposed. The effect size d (parm 4) is automatically converted into a utility shift such that health gains can be expressed in QALYs (or YLD averted). Since d typically is an estimate based on a trial with sample size n , we also need to know this n to compute the variance and distribution of d . The per-patient intervention costs are assumed to follow a gamma distribution, which helps to capture stochastic uncertainty in this parameter. The model parameters can be assessed from the Stage 1 trial-based cost-effectiveness analysis, or extracted from an on-going monitoring system.

Throughput

The model's throughput can be described as follows. The costs and QALY health gains are computed for both the base-case scenario and the alternative scenario, and then combined into the ICER. This computation is not carried out once, but, say, in 1,000 iterations, each time drawing effect sizes d and costs from their respective distributions and then computing the ICER. All simulated ICERs are stored in the model's internal memory. This helps to capture and to quantify stochastic uncertainty in the simulated ICERs.

Output

The model's output page is dubbed the 'cockpit', because there is a range of graphs and statistics. To name but a few: there are the mean costs and mean QALY health

gains in the base-case and alternative scenarios, each placed within its own uncertainty interval; there is the mean ICER; and all the simulated ICERs have been plotted on the ICER plane (with costs on the vertical axis and effects on the horizontal). Taking into account low, middle and high WTP ceilings for gaining one QALY, a cost-benefit analysis can be conducted, which allows the calculation of the cost-to-benefit (C/B) ratio and the return-on-investment (ROI) of the intervention at population level. It may also be interesting to conduct budget impact analyses to see how, at the macro level of the population, the health care budget is changed under the intervention.

Limitations

The model has some limitations that need to be described here. First, the model typically takes only the health care perspective and not the broader societal perspective (although we do have models that also factor in cost offsets owing to greater productivity – provided that such data are available and can be fed into the model). Second, the model describes costs and outcomes under a ‘steady state’ situation (equilibrium) after full implementation of the intervention. In other words, the model ignores initial investments that are required to implement the transformation from the base-case to the alternative scenario. Third, the model has a time horizon of one year, because most effects and costs have been assessed in trials (and meta-analyses thereof) with similar follow-up times and we do not dare to extrapolate to longer-term follow-ups. Finally, we always make the disclaimer that the model cannot be used as an autopilot for policy-making and is no substitute for good business judgement. These limitations are particularly relevant for Stage 3.

STAGE 3: CYCLIC MONITORING AND PROJECT MANAGEMENT SYSTEM (Transition-to-scale)

Once the Stage 2 model has been populated with the data obtained at Stage 1, then the model is ready to conduct ‘what-if’ analyses to inform project management and stakeholders about the consequences of managerial decisions and thus act as a forecasting and decision-support tool.

More specifically, when the ATMIYATA project is scaled up to include adjacent districts and being run over longer time horizons, then it might be worthwhile to set up a cyclic Monitoring & Modelling system. During its start-up phase, the expanded project could benefit from the Trimbos simulation model to conduct ‘what if’ analyses (informed by Stages 1 and 2). This would help to address questions such as:

- How would the project impact on the number of YLD averted (or QALYs gained) when the project is scaled up to include another population of XX thousand people?
- How does a modified health care package impact on population health and health care budgets?
- Is it perhaps more cost-effective to invest in improving coverage (or compliance) rates or is it better to change the health care package?

Thus at the project’s start-up phase, the model may be used as a decision support and planning system for setting targets and making choices in the health care package.

After implementation, the data from the monitoring system may help to empirically update the model's parameters, which helps to evaluate if the project is still running according to plan or going off track. This cycle of collecting monitoring data and modelling helps as a project evaluation, monitoring, feedback and forecasting system to support decision-making for adapting implementation strategies and for reformulating project aims 'on the run'.

Setting up a cyclic Monitoring & Modelling (M&M) system, requires that the input parameters for the simulation model (see above) are periodically reassessed and updated and then fed back into the simulation model. This would allow for a series of ante-hoc forecasts and once embedded in a monitoring cycle could also assist in making empirically supported 'before and after' comparisons to monitor if the project is unfolding and delivering as expected or in need of managerial intervention. This would not only be a way to monitor progress, but also a way to keep project management and stakeholders up to date and motivated about the way the project is delivering.