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Section-C

BIODATA OF THE INVESTIGATORS(S)

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1. Title of the Research Project :

Official Title : Community-based Management of Adult Diseases for Reducing Mortality in Economically Productive age-group: Cluster Randomized Control Trial in India: 2004 -2022.

Brief title : Mortality Control Program for Economically Productive Age Group in Tribal Area of Melghat. (Acronym : MCPEPAG)

Unique Protocol ID: MAHAN MCPEPAG 2004/2

2. Name , Designation & Email of

Principal Investigator

Dr. Ashish Rambhau Satav (M.B.B.S., M.D. –Internal Medicine)

Project Director & President of MAHAN trust,
Professor, MGIMS, Sevagram, Coordinator, THRPM,
drsataav@rediffmail.com

Co-Investigator(s)

Dr. Avinash Saoji (M.B.B.S., -Expert for life style modification.)

Director, PRAYAS, ati_aksaoji@sancharnet.in

Dr. Rajnish Joshi (M.B.B.S., M.D. –Internal Medicine, M.P.H.) (Physician and Epidemiologist) Associate Professor, MGIMS, Sevagram, rjoshimgims@gmail.com

Dr. Kavita Ashish Satav, (M.B.B.S., M.S.)

Consultant Ophthalmologist drsataav@rediffmail.com

Dr. Vrinda Sahasrabhojaney (M.B.B.S, M.D.)

Professor of Medicine, Govt. Medical College, Nagpur/Mumbai

Dr. Vibhavari Dani (M.B.B.S, M.D.)

(Ex Dean, GMC, Nagpur)

Head , Research, MAHAN trust.

2.Objectives:

- 1 To reduce the age specific mortality rate in the age group of **16-60 years** from existing 413.8 (reduction by more than 30%) in usual residents population of 13755 (from 16 villages in tribal area of Melghat) over a period of 12 years.
- 2 To reduce the age specific mortality rate in the age group of **16-60 years due to tuberculosis** (reduction by more than 10%) in above setting.
- 3 To reduce the age specific mortality rate in the age group of **16-60 years due to cardiovascular diseases (IHD, CVE, HT, etc.)** (reduction by 10%) in above setting.
- 4 To reduce the age specific mortality rate in the age group of **16-60 years due to COAD** (reduction by more than 10%) in above setting.
- 5 To reduce the age specific mortality rate in the age group of **16-60 years due to diarrheal diseases** (Reduction by 10%) in above setting.
- 6 To reduce the age specific mortality rate in the age group of **16-60 years due to Pneumonia** (reduction by more than 25%) in above setting.

- 7 To reduce the age specific mortality rate in the age group of **16-60 years due to clinical Malaria/fever** (Reduction by more than 10%) in above setting.
- 8 A. To reduce the prevalence of untreated hypertension in the age group of 16 to 60 years from existing 10% to 7% (reduction by 30%) in above setting.
B. To reduce the prevalence of complications of hypertension in the age group of 16 to 60 years by 10 % in above setting.
C. The secondary aim of this study is absolute reduction of 5mm Hg in mean systolic blood pressure in the intervention arm.

3. Background: Melghat is a hilly forest tribal area with grossly inadequate medical facilities. In Melghat, age specific death rate (16-60 years) is very high (more than 400 per 100000 population in age group of 16-60 years). Premature death in this age group has major impact on the whole families, communities & nation.

3.1)The major causes of deaths are (2004 study)

	Cause	%
1	Cardiovascular diseases –IHD+CVE	13.7
2	CNS Infection(?Cerebral malaria??meningitis???encephalitis)	12.1
3	Tuberculosis	10.6
4	Jaundice	10.1
5	Pneumonia/ LRTI	8.8
6	COAD	7.5
7	a. Dysentery.	5.7
	b. Chronic diarrhea	5.2
	c. Acute diarrhea	2.6
8	Suicide	5.3
9	Cancer	2.8
10	Tetanus ??	2.8
9	AIDS	2.6
10	Anemia	1.3
11	Other	9.0
	Total	100.0

3.2) Prevalence of hypertension is 10% (age group >=16-60years) in Melghat (16 villages).

3.3) Our research experience : (in Melghat)

A) During last 7 years, we have conducted the home based child care program in 17 villages of Melghat and we could reduce the prevalence of severe malnutrition and child mortality by more than 50% . This project was selected as Best Tribal Research Project Award by Indian council of Medical Research and was presented in 9 international medical conferences.

B) During last 7 years, we have conducted the home based care program in 17 villages of Melghat and we could reduce the mortality in the age group of 16-60 years by more than 25% .

C) Due to our public private partnership endeavor counselor program , there was statistically significant reduction in mortality due to severe malnutrition in hospitalized children.

3.4) Due to our indoor services for critically ill patients , we could save more than 800 serious patients over a period of 13 years in Melghat.

4. Overall aims and importance of the research:

To reduce the mortality in the age group of 16-60 years of Melghat by more than 30% over a period of 12 years. **The results obtained in this area will be applicable & can be replicated for reducing mortality in above age group in other rural and tribal areas of world.**

5. Methodology :

5.1 Setting: Randomized Control Trial -Home based care for people from economically productive (16 to 60 years) age group by trained VHWs in Dharni and Chikhaldara tribal block of Melghat, Amaravati, India.

Due to overt nature of the interventions and the impact i.e. mortality, blinding is not possible and not needed also.

5.2. Sample size: Considering 20% reduction in mortality (ASMR) in treatment arm (i.e. 5.6%) as compared to the existing mortality in control arm (i.e. 7%), a sample size of 6470 subjects per group was found sufficient with 90% power and 95% Confidence Interval. Further, assuming 20% attrition due to losses to follow up and non-response, the sample size was adjusted to 7000 per group. Total 7744 eligible subjects from 16 clusters were selected in IA and 8952 subjects from 18 clusters were selected from CA.

5.3 Duration of Research Project :

Proposed commencement date: 01/01/2004.

Last date of intervention : 31/12/2015

Data analysis, third party evaluation and dissemination of results : 01/01/2016 to 31/12/2016.

3. Amount of grant-in-aid asked for (details are to be furnished in Section B)

	<u>1st year (Rs.)</u>	<u>2nd year (Rs.)</u>	<u>3rd year (Rs.)</u>	<u>Total (Rs.)</u>
i. Staff	24,03,315	26,41,606	29,03,727	79,48,648
ii. Contingencies				
a.	61,92,472	67,86,757	74,40,470	2,04,19,699
Recurring				
b1. Non-recurring	26,07,558			26,07,558
b2.equipment)	10,74,958			10,74,958
c. Travel :	188496	207346	228081	623923
iii. Overhead charges (Audit & Administration)	3,39,338	3,72,024	4,08,080	11,19,442
Total	71,26,095	78,12,494	85,69,675	2,35,08,264

4. Institution responsible for the research project

Name : MAHAN

Postal address :

Dr. Ashish Satav,
Mahatma Gandhi Tribal Hospital, Karmagram, Utavali,
Tah: Dharni. Dist: Amaravati. Maharashtra, Pin :444 702

Telephone : 09423118877, 07226-202291, 202793

e-mail : drsataav@rediffmail.com

Fax No. : Not available.

5. Institutional ethical clearance and Project approval

(Necessary documents indicating institutional ethical clearance must be enclosed for research involving human subjects as also animal experiments).

Yes___Attached.

7. Is radio tagged material proposed to be used in the project either for clinical trials or experimental purposes? If so, clearance from Nuclear Medicine Committee, Bhabha Atomic Research Centre, Mumbai, indicating should be attached.
No.
8. Projects involving recombinant DNA/Genetic engineering work should be examined and certificate by the Institutional Biosafety Committee (IBSC) to be enclosed. Guidelines for constitution of IBSC can be obtained from Secretary, Department of Biotechnology, CGO Complex, Lodhi Road, New Delhi-110003.
Not applicable.
9. Approval of the institutional ethics committee(IEC) should be enclosed. Guidelines for IEC for animal experiments should follow CPCSEA requirements and for human studies should follow ICMR guidelines. : Attached.
10. The Institution where the study is being done should ensure that there is no financial conflict of interest by the investigators. : There is no financial conflict of interest by the investigators.

DECLARATION AND ATTESTATION

- i. I/We have read the terms and conditions for Research Grant. All necessary Institutional facilities will be provided if the research project is approved for financial assistance.
- ii. I/We agree to submit within one month from the date of termination of the project the final report and a list of articles, both expendable and non-expendable, left on the closure of the project.
- iii. I/We agree to submit audited statement of accounts duly audited by the auditors as stipulated by the laws of India.
- iv. It is certified that the equipment(s) is/are not available in the Institute/Department or these are available but cannot be spared for the project

- v. It is further certified that the equipment(s) required for the project have not been purchased from the funds provided by funding agencies for another project(s) in the Institute.

If any equipment already exists with the Department/Institute, the investigator should justify purchase of the another equipment.

Signature of the:

a) Principal Investigator _____

b) Co-Investigator(s) _____

c) Head of the Department _____

Signature of the Head of the Institution with seal

Date:

Certificate:

It is to certify that none of the investigators in the project has financial conflict of interest in the project.

Dr. Ashish R. Satav (M.B.B.S., M.D.)

Principal Investigator.

Signature:

Signature of Head of the institute.

Role of the funding source

This is to certify that the funding source had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Dr. Ashish R. Satav (M.B.B.S., M.D.)

Principal Investigator.

Signature of Head of the institute.

Clinical Trials Registry – India (CTRI) Since this study started in the year 2004, it was registered with only regional Institutional Ethics Committee of MAHAN trust (Maharashtra) as there was no CTRI in India in 2004.

Section - B
DETAILS OF THE RESEARCH PROJECT

Adequate information must be furnished in a brief but self-contained manner to enable the Council to assess the project.

1. Title of the project.

MCPEPAG-Mortality Control Program for economically productive Age Group. Or

Home Based people care for reduction of mortality in *economically* productive age group (16-60 years) in Melghat.

2. Objectives
 3. Summary of the proposed research (up to 150 words) indicating overall aims of the research and importance of the research proposal. Application of the work in the context of national priorities of medical research, if any, may also be mentioned.
 4. Present knowledge and relevant bibliography including full titles of articles relating to the project.
 5. Preliminary work already done by the Investigator on this problem, e.g. selection of subjects, standardisation of methods, with results, if any.
 6. Links with other ICMR projects (ad-hoc, task force or collaborative).
 7. List of important publications of last 5 years of the all the investigators in the relevant fields (enclose reprints, if available)
 8. Detailed research plan. (give here the design of study, indicating the total number of cases/samples/animals to be studied, the mode of selection of subjects specially in experiments involving human beings, equipments and other materials to be used, methodology/techniques to be employed for evaluating the results including statistical methods any potential to obtain patents etc.)
 9. Facilities in terms of equipment, etc, available at the sponsoring institution for the proposed investigation.
 10. Budget requirements (with detailed break-up and full justification):
 - (i) Staff
 - (ii) Contingencies
 - Recurring
 - Non-recurring (equipment)
 - Travel
 - (iii) Overhead charges
-

Section - B

DETAILS OF THE RESEARCH PROJECT

Adequate information must be furnished in a brief but self-contained manner to enable the Council to assess the project.

1. Title of the project. :

MCPEPAG-Mortality Control Program for economically productive Age Group (16-60 years). Or
Home Based people care for reduction of mortality in economically productive age group (16-60 years) in Melghat.

2. Objectives:

- 1** To reduce the age specific mortality rate in the age group of **16-60 years** from existing 412 (reduction by more than 30%) in usual residents population of 13755 (from 16 villages in tribal area of Melghat) over a period of 12 years.
- 2** To reduce the age specific mortality rate in the age group of **16-60 years due to tuberculosis** (reduction by more than 10%) in above setting.
- 3** To reduce the age specific mortality rate in the age group of **16-60 years due to cardiovascular diseases (IHD, CVE, HT, etc.)** (reduction by 10%) in above setting.
- 4** To reduce the age specific mortality rate in the age group of **16-60 years due to COAD** (reduction by more than 10%) in above setting.
- 5** To reduce the age specific mortality rate in the age group of **16-60 years due to diarrheal diseases** (Reduction by 10%) in above setting.
- 6** To reduce the age specific mortality rate in the age group of **16-60 years due to Pneumonia** (reduction by more than 25%) in above setting.
- 7** To reduce the age specific mortality rate in the age group of **16-60 years due to clinical Malaria/fever** (Reduction by more than 10%) in above setting.
- 8** A. To reduce the prevalence of untreated hypertension in the age group of 16 to 60 years from existing 10% to 7% (reduction by 30%) in above setting.
D. To reduce the prevalence of complications of hypertension in the age group of 16 to 60 years by 10% in above setting.
E. The secondary aim of this study is absolute reduction of 5mm Hg in mean systolic blood pressure in the intervention arm.

3. Summary of the proposed research (up to 150 words) indicating overall aims of the research and importance of the research proposal. Application of the work in the context of national priorities of medical research, if any, may also be mentioned.

Background: Melghat is a hilly forest tribal area with **worst medical facilities.**

Need:

In Melghat, age specific mortality rate (16-60 years) is high. It made the whole family orphan and many of these deaths occurred prematurely, affecting families, communities.

The major causes of deaths are Tuberculosis, Diarrheal diseases, CNS Infections, Pneumonia, Cardiovascular diseases, Jaundice, Suicide, COAD, CVE, Cancer, etc. Prevalence of hypertension is 10% (age group ≥ 20 years).

Overall aims and importance of the research:

To reduce the mortality in the age group of 16-60 years of Melghat by 30% over a period of 12 years. The results obtained in this area will be applicable for reducing mortality in above age group in other difficult to access areas of world.

Methodology: Cluster Randomized Control Trial -Community based care for economically productive age group by trained VHWs .

Setting: Tribal areas of Melghat, Amaravati district. (34 villages), target population of 7767.

4. Present knowledge and relevant bibliography including full titles of articles relating to the project.

Melghat is known for high death rate in Maharashtra.

Background: Melghat is a hilly forest tribal area. **Medical facilities are grossly inadequate in Melghat, (no chest physician, tuberculosis expert, cardiologist, gynecologist, anesthetist, pathologist, cesarean surgery, cancer experts, etc).**

Need of project :

There is high crude death rate and age specific death rates in the age group of 16-60 years in Melghat . It made the whole family orphan and many of these deaths occurred prematurely, affecting families, communities and countries.

Case stories:

- 1.** Nine years before , one ~20 years old lady was brought to our hospital in comatose condition with brain stem damage. History and clinical examination was suggestive of Puerperal sepsis with encephalopathy. I was depressed to see her 8 days old newborn baby in a bag. The lady could not be saved as she was in terminal stage. I thought, if she could have come to hospital 7 days back , we could save a precious life of a young mother for a help less newborn baby.
- 2.** Few years back, one 14 years old orphan boy came to me for treatment of tuberculosis. When I investigated, I came to know that his father died before the age of 35 years and mother married to another person living him orphan. He could not afford to treat himself.
- 3.** Recently one 40 years old man died of extensive pulmonary tuberculosis, one 23 years young lady died of AIDS with TB and one 38 years old man died of Acute Myocardial infarction. In all above cases the dependent family became orphan.
- 4.** One man died of oral cancer due to tobacco chewing at the age of 30 years leaving young wife and 3 children helpless .

All these deaths disturbed me a lot . Such incidences made me to search a new pathway in the form of village based health care to save such precious lives in the economically productive age group in backward poor tribal area of Melghat which will bring light to millions of people living in poor underdeveloped areas of world.

The causes of deaths (age group of 16-60 years) as per our study (verbal autopsy) in the 36 villages of Melghat in 2004.

Baseline casues of deaths 16-60 years		
Sr. Number	Cause of Death	CSMF
		%
1	TB	13.5
2	Miscellaneous	22.2
3	Diarrheal diseases	9.6
4	CNS Infection	8.7
5	Pneumonia	7
6	IHD	6.7
7	Jaundice	6

8	Suicide	5.8
9	COAD	4.1
10	CVE	3.8
11	Cancer	3.4
12	Homicide	2.4
13	Alcohol Toxication	1.7
14	AIDS	1.4
15	Tetanus	1.4
16	Drowning	1
17	Snake Bite	0.7
18	RF	0.5
19	RTA	0.3
20	ALD	0
	Total	100

The underlying causes are poor hygiene, infections, addiction(tobacco, bidi smoking & alcohol) ,poor nutrition, lack of early detection and treatment, lack of health education, etc.

The prevalence of hypertension in Melghat is 8-11% in the age group of 20years and above -as per our pilot study of population of 10000. (2004)

Mortality in 15-59 years age group is very important priority of global health. Though causes of adult deaths are important part of MDG, adult mortality has been neglected by policy makers, funding agencies and monitoring agencies. Intensifying the reduction in adult mortality will be needed to achieve many targets of healthy world.

Rationale and significance

The low-income countries need cost-efficient solutions for prevention of deaths in age group of 16-60 years. This calls for screening for high risk individuals, and approaching them with effective low cost interventions. The success of low-cost and effective VHW centered interventions can be extended to death prevention models. The feasibility and efficacy of this model however needs to be demonstrated. Adherence to preventive life-style and pharmacological interventions in the intermediate term is essential to achieve a long term reduction in adult morbidity. We have aimed this intervention for rural communities, as most India resides in villages, which have larger gaps in access to health care. There is an opportunity for VHW based health care model for adult diseases to be integrated with the National rural health mission.

Village health workers (VHWs) are central to the primary health care approach towards health care utilization in India. The personnel at the village level from the local community trained by our organization can be classified as village health workers (VHWs). They are typically selected from the areas they work in, have four to twelve years of educational qualification, and receive a short training (ranging from one to twelve months) before they start working. Currently none of the VHWs are involved in any aspect of adult disease management, but have a potential to be trained for this activity. They are trained for treatment for under 5 children illness.

The healthcare resources in developing countries like India are limited; there is an opportunity as well as a need to identify feasible, effective, and low cost interventions which can then be readily integrated in the existing public health delivery system. Such interventions needs to be tested in rigorously designed, intermediate duration studies using tangible surrogate outcomes to establish a definite health benefit. The current program focuses on individual level efforts to determine the paradigms of grass-root level adult disease care management for rural India, and to find ways of how to integrate this strategy with existing health care delivery system. The aim of this proposal is to evaluate feasibility and impact of village health worker led strategy to achieve adherence to preventive

therapies and reduction in mortality in the economically productive age group & aggregate chronic disease mortality in rural India. Thrust of the proposal is to promote treatment adherence to prevent chronic disease & infectious diseases.

Review of literature:

Authentic adult mortality data is needed for evidence-based health policy and achievement of UNSDGs.⁽¹⁾ The adult mortality rate (15-59 years) was 416.9 in 2000,⁽²⁾ 970 in males and 860 in females per 100,000 population in Uganda (2000-2001) (LMIC),⁽³⁾ 204 to 307 per 100000 population in USA (2002).⁽⁴⁾ Adult is defined as person in age group of 15-60 years. Age-specific mortality rate (ASMR) is calculated by dividing the number of deaths registered in a particular age group in a calendar year by the mid-year population estimated for that age group, multiplied by 100000. Adult mortality is the death of people in age group 15-59 years. The crude death rates in total population were lower than 1640 per 100,000 reported by Central Bureau of Health Intelligence for Indian rural population during the period (1961 to 1968).

The mortality data used were from 2003-4 surveillance system covered 45 villages in the Godavari region (total population 180,162) and recorded 1354 deaths for which verbal autopsies were completed in 98%. The crude death rate was 7.5/1000 population and diseases of the circulatory system were the leading cause of mortality(32%).

According to WHO, the 10 leading causes of death in 2002 were

- 1. 12.6% IHD.
- 2. 9.7% CVE.
- 3. 6.8% Lower respiratory infections.
- 4. 4.9% HIV/AIDS.
- 5. 4.8% COAD.
- 6. 3.2% Diarrhoeal diseases.
- 7. 2.7% Tuberculosis.
- 8. 2.2% Malaria.
- 9. 2.2% Trachea/bronchus/lung cancers.
- 10. 2.1% Road traffic accidents.

The age specific death rate (per 100000) in Banglore district :

Year of survey	Age group(15 to 34 years)	Age group(35 to 54 years)
first 1.5 years	610.4	992.2
second 1.5 years	493.1	933.9
third 2 years	556.5	1046.7

The annual death rates due to tuberculosis in 100,000 population between I and II surveys were 10.00 in 5-14 years, 79.0 in 15-34 years, 146.0 in 35-54 years, 394.0 in 55 and over years and 95 in combined age group . Annual all causes death rate of 893 for 100,000 among both sexes in 5 years and over age group, in this study.

Annual all causes death rate of 1211.3 per 100,000 calculated from Frimodt Moller’s study material (236 deaths in 4138 persons in 4.7 years).

McDougal in 1949⁷ quoted the cause specific mortality rate due to tuberculosis in India as 250 per 100,000.

Frimodt Moller⁸ estimated the cause specific mortality rate due to tuberculosis in Madanapalle town to be 253 per 100,000 in 1949; and 64 to 21.2 per 100,000 between repeat surveys in urban and rural Madanapalle areas. In these surveys deaths among all persons diagnosed as having active tuberculosis were regarded as deaths due to tuberculosis.

Compared to the above, the cause specific mortality rate due to

tuberculosis reported in Banglore study (84/100,000) per year aged 5 years & over could be taken as indicative of a declining trend.

Proportional mortality rate from tuberculosis i.e., ratio of cause specific death rate due to tuberculosis to the total death rate.

	in 5 years & over age group(?5-14 years)	in age group 35-54 years
first interval (I-II survey)	11%	15%
Second interval(II-III survey)	8 to 9 %	15%
Third interval (III-IV surveys)	8 to 9 %	10%

Though tuberculosis mortality rates increased with age and the highest was in 55 years and over age, yet, the contribution made by tuberculous deaths to the total deaths did not show an increasing trend with age.

5. Preliminary work already done by the Investigator on this problem, e.g. selection of subjects, standardization of methods, with results, if any.

We have already started the work on this issue from 2004. We have selected the villages randomly and selected the village health workers through gram sabha(village meetings) and oral and theory examination. They are working with us since 2004 as VHW for child hood illnesses. We have collected the deaths **in the age group of 16-60 years and studied their causes of death with the help of verbal autopsies.** We have measured blood pressure of 3000 similar tribal population of the same area but from different villages in the age group of 16 years and above and we found the prevalence of hypertension be around >10%.We have selected the study area, subjects, standardized the methods .

We provided referral facilities to ill patients in intervention area and also conducted health awareness campaign on health, hygiene, importance of hospital care, malaria, diarrhea, pneumonia, nutrition, antenatal and postnatal care, BCC for pregnant ladies, etc.

Most of the deaths in both areas were home deaths. Hospital deaths were 8.3%.

We did similar study “Effect of home based child care on child mortality in a tribal population: results of a field trial.

6. Links with other ICMR projects (ad-hoc, task force or collaborative).
No.

7. List of important publications of last 5 years of the all the investigators in the relevant fields (enclose reprints, if available

Not yet published in any journal . But the study of Home based child care was presented in the National symposium on tribal health at Jabalpur (organized by RMRCT , ICMR). The abstract was published in abstract books of International Symposium on Tribal Health at Jabalpur organized by ICMR, International symposium by European society of pediatric research in Germany and international symposium in Netherlands, medical school of UK, etc .

8. Detailed research plan. (give here the design of study, indicating the total number of cases/samples/animals to be studied, the mode of selection of subjects specially in experiments involving human beings, equipments and other materials to be used, methodology/techniques to be employed for evaluating the results including statistical methods any potential to obtain patents etc.)

A. Materials & Methods:

Methodology:

Randomized (Cluster) Control Trial - i.

- Home based care for people in economically productive age group care (HBRC) by trained village health workers for diseases like Hypertension, T.B., Maternal illness, addiction, life style modification, Diarrhea, Malaria , Pneumonia, Asthma, cardiovascular diseases, anemia, in 16/18 villages.
- ii. Strengthening of existing government health system.

Methods:

- i. Design and setting.
- ii. Study sample: Inclusion criteria. Study sample: Exclusion criteria.
- iii. Availability of participants.
- iv. Data collection procedures.
- v. Outcomes:
- vi. Intervention/ controls (if applicable).
- vii. Data analysis or sample size calculations.
- viii. SWOT analysis.
- ix. Tentative timetable.

Design	Open labeled, single-centre, household level cluster-randomized control trial with 1:1 allocation to intervention and non-intervention arms.
Setting	The study would be performed in the tribal areas of Melghat, (Dharni & Chikhaldara tahsil of Amaravati district of Maharashtra, India. (40 villages)
Recruitment and consent	Written informed consent would be sought in the local language, from the village gramsabha(peoples meeting/ panchayat)and individuals comprising the study base. The consent would be sought for all study related procedures, before the baseline survey is done to identify those at risk.
Availability of participants.	Availability of participants have been ensured by discussion with people in gramsabha (village meetings).
Target population	People aged 16 to 60 years identified as high risk from 36 villages.
Study scheme	See figure1 below

Study procedures	Identification and training of community health workers (CHWs), identified from within the community of their work. They would receive a 9 initial training sessions (30 days total)& later on refresher training every two monthly for 72 days and field training for five years. Training procedure would be detailed in manual of operations for the project. <u>Training of VHW-Time table.: Pg.46</u> Training of staff:
Protocol Approval Date : 01.03.2004,	Last updated.: 1.1.2016
Data collection procedures.	
Intervention by VHW.	1. Baseline survey would be done to identify target population and at risk households. The baseline survey would be done using standardized pilot tested questionnaire, which would specifically ask about tobacco or alcohol consumption, past & present history of hypertension, diabetes mellitus, manifest coronary artery or a cerebrovascular disease, tuberculosis, Malaria, Diarrhea, HIV, physical activity levels, dietary salt, fruit and vegetable consumption, and psychosocial profile, premarital or extramarital sex, high risk pregnancies, anemia . The following measurements would be performed – height and weight, waist and hip circumference, and blood pressure, respiratory rate, temperature, chest wall shape and movements, genital lesions for high risk group, pallor, conjunctival examination for icterus, etc. INTERHEART risk score would be determined at baseline. The data on mortality will be collected prospectively by village health workers(regularly) and confirmed by vital statistic supervisor from the parents, head of village panchayat-sarpanch and police patil once in every 15 days. The data will be collected retrospectively by independent set of workers every 6 monthly again confirmed by vital statistics supervisors. We will also collect data from govt. health department and patwari or talathi(grass root worker of revenue department). <i>The village health workers (VHW) will treat the patients suffering from Hypertension, tuberculosis, addiction, COAD, malaria, diarrhea, anemia, pneumonia, minor dental ailments, etc.</i> 1. Intervention households will have once weekly visits from a trained village health worker over 12 months. VHW would counsel at-risk individuals in risk factor modification, check their medical therapy and will continue the therapy for high risk group and diseased people, screen patients with suspected illness. VHWs will also provide treatment to them in the village itself if people are not ready to go to hospital, but after informed written consent. VHW will run clinics for patients in their house dispensary. 2. The VHW will be monitored regularly once in every 15 days by doctor/medical supervisors who will cross check the treated cases, guide the VHW and monitor their activities, mobilize people for disease prevention and treatment. 3. A study clinic would be arranged in base hospital at Karmagram. so that all at-risk individuals are prescribed evidence based preventive therapies. All at-risk individuals would be provided access to care, and appointment dates for follow up visits, to see the doctor who would be available at the hospital.
Outcomes	Outcomes would be evaluated at six month intervals (6, 12, 18 , 24, 30, 36, 42, 48,54 and 60 months and then yearly) after the onset of the intervention. The first two evaluations are aimed at

	the early impact during the intervention, while the evaluation at next four years is aimed to determine the sustained impact of the interventions. We will extend the study for long term and in new villages to test long term sustainable impact in different areas, if needed. The key outcome measures are mortality in the age group of 16-60 years, prevalence of hypertension, cause specific death rates due to hypertension, CAD, tuberculosis, Diarrhea, Malaria, HIV , COAD, Maternal mortality, Jaundice and Suicide, anemia, tetanus, prevalence of tobacco /alcohol addiction. Improved adherence to pharmacological therapy, reduction in INTERHEART risk score, reduction in systolic blood pressure so that an optimal control is achieved (systolic BP of 140mm Hg or less).
Sample size	Considering 20% reduction in mortality (ASMR) in treatment arm (i.e. 5.6%) as compared to the existing mortality in control arm (i.e. 7%), a sample size of 6470 subjects per group was found sufficient with 90% power and 95% Confidence Interval. Further, assuming 20% attrition due to losses to follow up and non-response, the sample size is adjusted to 7000 per group. Total 7767 eligible subjects from 16 clusters were selected in IA and 8952 subjects from 18 clusters were selected from CA.
Study sample: i. Inclusion criteria. ii. Exclusion criteria.	All the people in the age group of 16-60 years who are residence from the study area will be included in the study. All the deaths in the village or hospital, in above age groups will be included in study. Those individuals who will give consent and mentally fit will only be included. All the people below the age of 16 years or above the age of -60 years and people from outside the study area will be excluded from the study.

Adherence to drug therapy would be determined by using a self and spouse reported Morisky medication scale (MMS)(14) and inspecting proof of purchase records/ from government or our hospital record. Adherence to non-drug treatments would be measured by using improvement in risk factor levels (among individuals receiving intervention visits compared to those not receiving visits) as a surrogate. Using the INTERHEART data, we have developed models to estimate risk score for acute myocardial infarction. The risk for tuberculosis, COAD, HIV, Maternal mortality , etc. will be determined.

Section B: Program interventions:

Intervention/ controls

B.1 Study design : Open labeled, single -centre, household level cluster-randomized trial with 1:1 allocation to intervention and non-intervention arms .

B.2 Setting & Study area:

The study would be performed in the tribal areas of Melghat, (Dharni & Chikhaldara tahsil of Amaravati district of Maharashtra, India. (34 villages) . The Melghat area especially Dharni block was divided into 5 clusters(4 peripheral and 1 central) . 7/8 villages were randomly selected from each cluster by lottery method. The study area has 16 villages for intervention and 18villages for control area, with 13755 and 16151 population respectively. The villages are as follows.

Particulars	Intervention area	Control area.
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1. Name of villages.	Ambadi, Baspani, Berdaballa, Bothra, Chitri , Dabiyakheda , Didamda, Ghota, Hirabambai, Jampani, Keli, Kot, Kokmar, Mansudhawadi, Pohara & Tarubanda.	Bhiroja , Dharakot, Dharanmahu, Dhodhara, Gadgamalur, Kara, Kasaikheda, Khamda, Kinhikheda, Katkumbh, Kavalaziri, Lawada , Mogharda, Nanduri, Padidam, Rabang, Tatara & Zilangpati,
2.Population	13755	16151

All people in the age group of 16-60 years who are ill will be screened and some cases will be treated by trained VHW if they refused hospitalization after informed written consent & Other cases will be referred to hospital in intervention area . While data collection (vital statistics) will be conducted in both areas.

Approximately 55.94% the population in this population would be of age 16 to 60 years (eligible target population), all of whom be approached for screening and subsequent study procedures. The eligible individuals would be enumerated, and a written informed consent would be sought from all individuals prior to screening.

To evaluate multiple risk factor strategies for primary prevention & treatment of tuberculosis , pneumonia, hypertension, cardiovascular diseases, COAD, diarrhea, Malaria, anemia, addiction, Jaundice, & maternal illness.

Primary prevention strategies at the community level to promote treatment adherence to prevent cardiovascular disease, hypertension, tuberculosis, AIDS, Malaria, Diarrhea, Pneumonia, Anemia, Jaundice, Suicides, etc.

Since the awareness level about the chronic diseases and their risk factors is still limited in the low and middle income countries, it is expected that the health education based primary prevention interventions could be as successful as the first generation COPC models.

Study period: 1st January , 2004 to 31st December , 2015.

B.3 Identification and training of Village health workers (VHWs)

VHWs have been identified from within the community of their work, and would receive a short but intensive training in management of diseases (of people in the age group of 16-60 years) which are leading causes of deaths in that age group with special stress on infectious disease and HT management. Their qualifications, learning objectives, and materials would be detailed in the manual of operations for the project.

B.4 Baseline survey and data collection:

A baseline survey would be done by the study team (including VHWs) in all people above the age of 16 years (especially 16 to 60 years age group) to identify at risk households. An *at-risk household* would be defined as the household which has one or more at-risk individual. An *at-risk individual* would be defined as the one who is in moderate or high risk category for future cardiovascular risk, based on the low information (NHANES) score (defined as 10% risk of developing an adverse cardiovascular outcome in next 5 years, and a person with treatable hypertension), tuberculosis, COAD, pneumonia, HIV-AIDS, Suicides, Jaundice, diarrhea, anemia, addiction, cerebral malaria, meningitis, cancer of oral cavity ,etc.

The baseline survey will include the pattern of diseases in the target age group.

A Questionnaire administered at the household which would ask about age, gender, socio-economic status, tobacco or alcohol consumption, past history of hypertension, diabetes mellitus, manifest coronary artery or a cerebrovascular disease, respiratory tract infections, COAD, Tuberculosis, diarrhea, jaundice, HIV-AIDS, anemia, physical activity levels,

dietary salt, fruit and vegetable consumption, and psychosocial profile. The questionnaire would also capture information if individuals in the household were ever prescribed life style interventions, or medications and what components of these prescriptions they might be adhering to. The following measurements would be performed – height and weight (to calculate body mass index, height to be measured by measuring tape, and weight by standardized portable spring balance/ digital scales), waist and hip circumference (to calculate the waist hip ratio, measured by standardized tape measures), and blood pressure (three measurements, 5 minutes apart, using a standardized digital sphygmomanometer), respiratory rate, temperature, pallor, conjunctival examination for icterus, skin turgor, tongue moistness, oral cavity for cancer, chest wall shape and movements, genital lesions for high risk group, etc. The information about gender, history of diabetes and smoking, systolic blood pressure measurement (average of three measurements) and body mass index would be used to compute the risk category at baseline. VHWs would use this information at the time of the interview, and determine the risk categories using color coded risk charts (See Appendix 5). Individuals at moderate to high risk would be specially selected for inclusion in the study. Non-Lab based components of INTERHEART risk score (The score includes smoking, alcohol use, fruits and vegetable consumption, hypertension, diabetes waist to hip ratio and psychosocial factor) would be calculated for all the at-risk individuals so identified.

The vital statistics data(deaths in the age group of 16-60 years, their verbal autopsy)

will be collected prospectively by VHW, confirmed by vital statistics supervisors, parent/spouse/son/ daughter-police patil, Sarpanch, etc. Data will also be collected retrospectively by independent set of surveyors (house-to-house survey every six months)and will be confirmed by above team. We will also collect data from govt. health department and patwari or talathi. T. B. A. s will also assist in the vital statistics data collection.

B.5 Randomization to intervention and non-intervention arms of the study

Any household, where one or more at-risk individual resides, would be defined as an at-risk household. Since the intervention is planned at the household level, and the risk factors among individuals who are residing in same household are likely to be clustered, we have plan a cluster randomized study. The randomization process was done by lottery method. The villages were divided into two groups, intervention area and control area .

B.6 Procedures in all at-risk individuals

B.6.1 Procedures in the intervention households

Immediately after the results of the baseline survey are available, a regular village clinic would be arranged in each village after the risk stratification is completed. This clinic would be operated by a village health worker (VHW) who would provide the initial drug prescription. The prescriptions would be based on evidence based guidelines (seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7),⁽¹⁶⁾ and National Cholesterol education program (NCEP) and standard text book of Medine and WHO.⁽¹⁷⁾ The prescriptions would have a low pill count, and preferably once-daily therapies. The VHW would advise about key life-style interventions a) smoking /tobacco /alcohol cessation (prescribed if individual smokes/abuse tobacco), b) consuming fewer salt containing foods(prescribed if the individual had a blood pressure of 140 systolic or higher at baseline or on anti-hypertensive drugs) c) Consuming more of fruits, vegetables, pulses, and less of

fried foods. d) avoid unprotected sex and multiple sex partners , e) Avoid unsafe food and drinking water, f) Avoid unnecessary injections especially by quacks and not with proper sterilization. g) Avoid close contact with cases of active tuberculosis- refer them for early drug treatment, provide proper ventilation in houses, precautions to prevent transfer to normal cases, h) proper hand washing before feeding and after defecation, i) go for low cost sustainable organic farming for nutrition production, j) meditation & yoga, k) early referral to hospitals, etc. VHW will counsel at-risk individuals in risk factor modification, check their preventative medical therapy, and advise them to make an appointment to see the doctor if required.

The VHW will use flip charts, audiovisual media, gram sabha- villagers meeting, lectures, group discussions, posters, self help groups, nutrition demonstration, counseling , etc. for behavior change communication. A non-fasting blood glucose determination , ECG, blood urea and creatinine, rapid antigen test for malaria, sputum for AFB, chest x ray, HIV rapid antibody test, HB, typing of anemia, Sr. Albumin, Sr. Bilirubin, Sr. Cholesterol, dental examination by specialist, etc. would also be arranged for all the moderate and high risk individuals whenever indicated. One medical supervisor / doctor will visit every village at least twice a month.

It would be ensured that all at-risk individuals obtain at least one physician consultation during the study. The at risk individuals identified by the health worker would be referred to the doctor for consultation & prescription. After the initial baseline survey , the physician would be available at the hospital for expert opinion and follow up visits. The medical supervisor will cross check all the people referred and 10% of the population that the health worker did not refer. All at-risk individuals would be advised to have at least one visit every three months at the clinic. This model is likely to be replicable & has potential for integration into the existing health care delivery system of India, through the ASHA worker, ANM and physician medical officer available at the primary health centers.

In addition all at-risk individuals would be provided with an envelope where they would be asked to preserve the empty blister packs of the medication consumed by them. These envelopes would be collected every six months by a medical supervisor and used in determining adherence. All at-risk individuals would also be administered a baseline knowledge questionnaire, which would be re-administered at the end of the study.

Those patients who are confirmed or suspected cases of tuberculosis, HIV, IHD, Jaundice, CNS infections , etc. will be referred of to base hospital for treatment initiation. The follow up and treatment continuation will be done by the village health workers and medical supervisors.

A VHW would visit the households, randomized to intervention arm, once every two months. Each visit would be about 30 to 45 minutes long, and during each visit VHW would perform the following activities: 1)Prescribe drugs to all possible cases. Ascertain the adherence to prescribed therapies (a) Questionnaire administered by self / significant other (spouse), (b) Inspection of proof of purchase records; 2) Reinforce treatment adherence by (a) providing and explaining pictorial patient education material, which would have clear short goal directed messages (b) advising how preventive therapies could be integrated with activities of daily living, and simple reminders be implemented (c) involve spouse or another care-giver in the household for promoting treatment adherence; (3) Measure blood pressure, weight and waist circumference, and provide goals for the next visit; (4) Advise simple dose adjustments in anti-hypertensive drugs, if required (in consultation with a study physician, using proxy prescriptions). The proxy prescriptions will be used for dose adjustments and not for initiating a new medication. These adjustments would be based on a algorithm which would be provided to the VHW. If required a referral to a physician would be advised. In addition the first visit and additional six month, and twelve month visits would involve collection of additional information which would include a)Food-frequency questionnaire, b) Physical activity questionnaire, c)Psychosocial stress questionnaire. The information collected in these visits would be used to determine INTERHEART risk score.

We estimate that each VHW would need to visit 160 households in each two month period (A total of sixty households and two VHWs per region). We estimate that the household visits would amount to a maximum full-time equivalent (FTE) of 0.1 for each

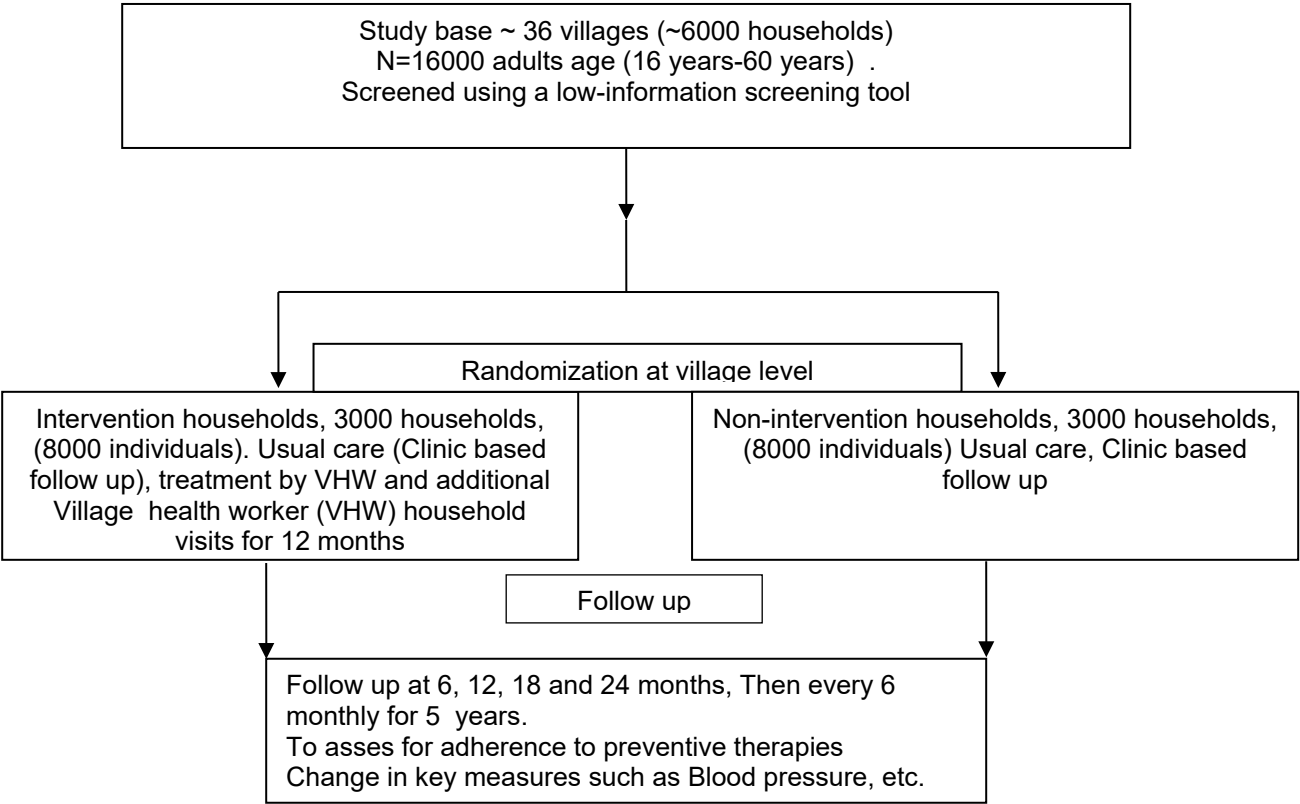
CHW. We estimate that this amount of work load can be integrated into the existing health care delivery system.

Each VHW will treat the patients in village who will come to their clinic in village if they refused to go to hospital after informed consent.

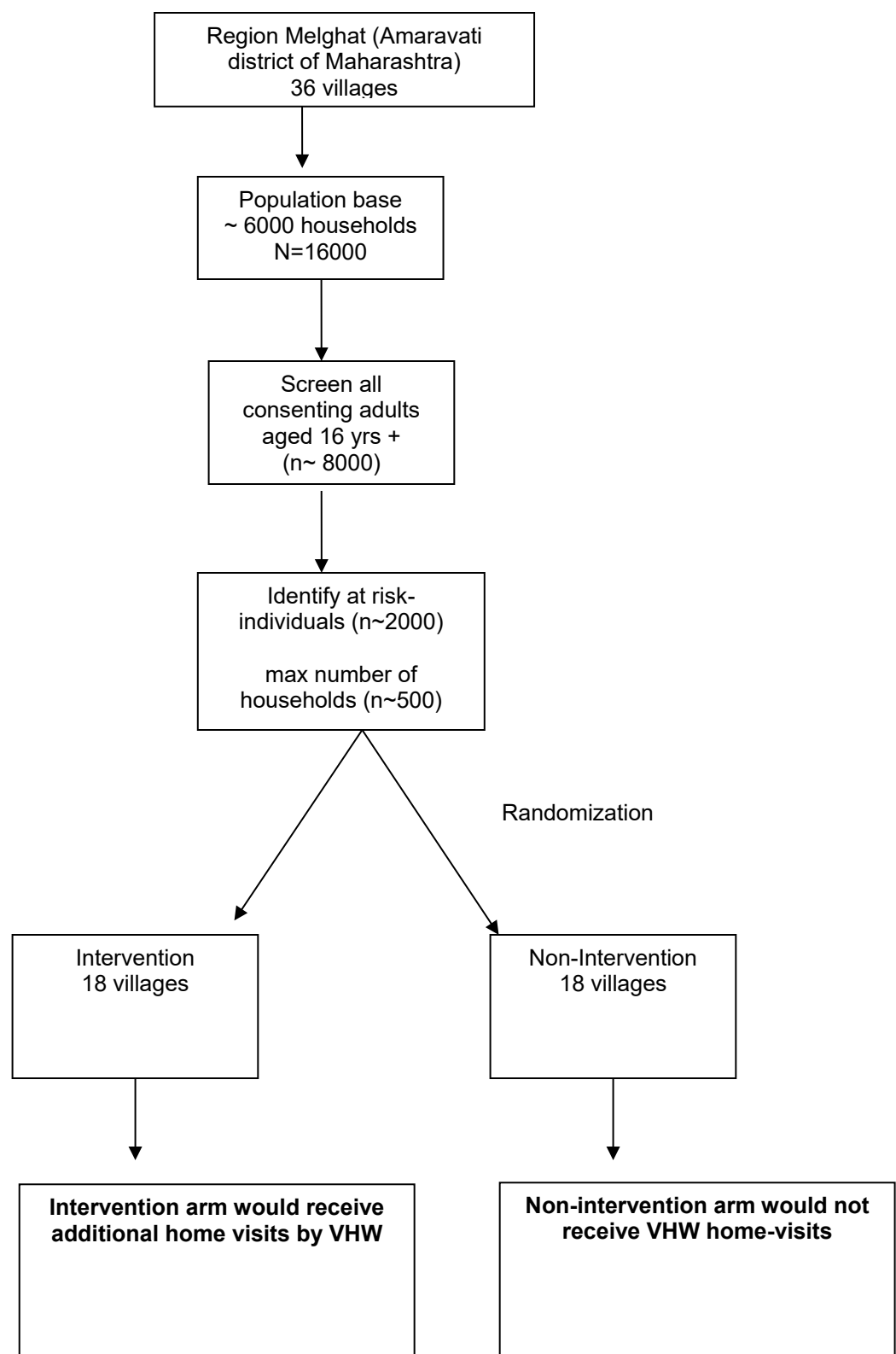
The village health workers will train the villagers especially high risk individuals for addiction, Hypertension and IHD for yoga and meditation .

B.6.2 Procedures in the non intervention households

The VHW will collect the data of mortality from the control villages also. They will also record the BP in the age group of 16 to 60 years and above. They will provide paracetamol as symptomatic treatment to the villagers.



Study Design (e.g. for cardiovascular diseases)



B 7. Who needs referral to a specialist facility ?

Referral is required if there are clinical features suggestive of:

- acute cardiovascular events such as: heart attack, angina, heart failure, arrhythmias, stroke, transient ischemic attack
- secondary hypertension (table 2), malignant hypertension, (table 3)
- diabetes mellitus (newly diagnosed or uncontrolled)
- established cardiovascular disease (newly diagnosed or if not assessed in a specialist facility).
- Tuberculosis (newly diagnosed)for confirmation and drugs from govt. hospitals.
- COAD with acute exacerbations.
- Diarrhea with severe dehydration.
- Severe anemia.
- Jaundice with encephalopathy.
- Cerebral malaria , meningitis.
- Brain hemorrhage.
- HT –accelerated or malignant.
- Cancer of oral cavity.

- Full blown AIDS.
 - Any serious patients in the age group of 16 to 60 years.
- Once the condition of the above categories of people is assessed and stabilized, they can be followed up by VHW on the recommendations provided in these guidelines. They will need periodic reassessments in specialty care.

Section C: Timelines of MCPEPAG Study

C.1. (GANTT chart)

Quarters→	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Activities/ Projects ↓	Year-1				Year-2				Year-3				Year-4				Year-5			
Manual of operations, Preparation of micro plan, Intervention villages identification	X	X	X	X																
Retrospective survey for deaths during last 6 years			X																	
KAP Studies	X	X	X																	
Preparation and finalization of contract with Funding agency		X	X	X	X															
Appointment of project manager, trainer- supervisor & VHW.			X																	
Orientation of project manager/ NGO head			X																	
Community consent & contact & seeking cooperation from TBA, SHG, other key stakeholders.			X																	
Gram Sabha - quarterly village meeting)			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Ethical committee approval			X																	
Training (Induction & Refresher)			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Baseline survey			X	X	X	X														
Identify at risk					X	X	X	X												
Third party evaluation					X															
Intervention				X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Full implementation											X	X	X	X	X	X	X	X	X	X
Measurement of adherence								X		X		X		X		X		X		X
Follow-up surveys (Retrospective) MIS –its third party evaluation.			X		X		X		X		X		X		X		X		X	X

Follow-up surveys (Regular) Data Collection Vital Statistics								X	X	X	X	X	X	X	X	X	X	X	X	X
Year -6 to 12 Quarters→																	21	22	23	24
Data cleaning and analysis																	X	X		
Third party evaluation																		X		
Reporting and publication																			X	X

C.2. Time table of activities by the NGO under the project for implementation of MCPEPAG

Treatment of people in the age group of 16-60 years , yoga therapy, counseling, de-addiction program, BP record, vital statistics data collection by Village health workers, referral of critical patients itself will be a regular activity throughout the 4 years of full intervention . Intervention in the form of treatment and behavior change communication will start from Jan 2005 in phases. It will be a regular activity till end.

Data collection by VHW in both intervention and control areas will be a regular activity throughout the study period. Retrospective survey of 6 months.-Intervention & control area and data analysis will be conducted in Jan-Feb &July-Aug of every year. It will be followed by third party evaluation for statistical verification.

Meeting of VHW from control area will be organized on 1st day of every month. Meeting and training for VHW from intervention area will be organized from 2nd to 4th of every even month for first year and then every alternate month for rest of the study period.

Community participation will be a regular phenomenon.

Period	Year 1	Year 2	Year 3	Year 4	Year 5
January	i)Gramsabha & Community consent & contact & seeking cooperation from TBA, SHG, other key stakeholders. <i>Program manager village visit .</i> <i>ii)Launch</i> <i>iii)Contact with SHG in village.</i> <i>iv) Manual of operations, Preparation of micro plan,</i> <i>v) Intervention villages identification</i> <i>vi)Retrospective survey for deaths during last 6 years.</i> <i>vii) Preparation and finalization of contract with Funding agency</i>	i) Gramsabha <i>BCC- community or group health education (Group BCC)</i>	i) Gramsabha <i>Group BCC</i> <i>ii)Phase wise treatment of diseases in community.</i>	i)Gramsabha <i>Group BCC</i> <i>ii)Phase wise treatment of diseases in community.</i>	i) Gramsabha <i>Group BCC</i> <i>ii)treatment of diseases in community.</i>

	viii) Appointment of project manager, trainer-supervisor & VHW. ix) Ethical committee approval.				
Period – Year Month	Year 1	Year 2	Year 3	Year 4	Year 5
February	<i>i) Gramsabha & Launch</i> Community consent & contact & seeking cooperation from TBA, SHG, other key stakeholders. <i>ii) Retrospective survey for deaths during last 6 years</i> <i>iii)VHW induction training &meeting Intervention area.</i> iv). KAP Studies v)Preparation and finalization of contract with Funding agency vi) Ethical committee approval. vi) Orientation of project manager/ NGO head viii)Baseline survey	i)VHW revision training & meeting Intervention area.	<i>i) VHW revision training & meeting Intervention area.</i> ii)Phase wise treatment of diseases in community.	i) VHW revision training & meeting- Intervention area . ii)Phase wise treatment of diseases in community.	VHW revision training & meeting- Intervention area . ii)treatment of diseases in community.
March	<i>i)VHW induction training &meeting Intervention area</i> ii. KAP Studies <i>ii) Preparation and finalization of contract with Funding agency</i> <i>iii) Baseline survey</i>		ii)Phase wise treatment of diseases in community.	i)Phase wise treatment of diseases in community.	i)treatment of diseases in community.
April	i))VHW induction training &meeting Intervention area ii) Preparation and finalization of contract with Funding agency ii) Gramsabha & Group BCC. iii) Baseline survey	i) VHW revision training & meeting Intervention area. i) Gramsabha , Group BCC	i.VHW revision training & meeting Intervention area. ii. Gramsabha Group BCC ii)Phase wise treatment of diseases in community.	i)VHW revision training & meeting- Intervention area . ii)Gramsabha Group BCC ii)Phase wise treatment of diseases in community.	i)VHW revision training & meeting- Intervention area . ii.Gramsabha Group BCC iii)treatment of

					diseases in community.
May	i))VHW induction training &meeting Intervention area. ii) Preparation and finalization of contract with Funding agency. iii. Beginning of Treatment of patients iv. Behaviour change communication. iv)Baseline survey		ii)Phase wise treatment of diseases in community.	i)Phase wise treatment of diseases in community.	i)treatment of diseases in community.
June	i)VHW induction training &meeting Intervention area. ii)Preparation and finalization of contract with Funding agency. iii) Baseline survey	i) VHW revision training & meeting- Intervention area.	i.VHW revision training & meeting- Intervention area.(IA) ii)Phase wise treatment of diseases in community.	i.VHW revision training & meeting- Intervention area . ii)Phase wise treatment of diseases in community.	i.VHW revision training & meeting-IA ii)treatment of diseases in community.
Period – Year Month	Year 1	Year 2	Year 3	Year 4	Year 5
July	i)Preparation and finalization of contract with Funding agency ii) Gramsabha ,Group BCC. iii) Baseline survey. iv)Base line Third party evaluation	ii) Gramsabha iii) Group BCC Special efforts from July to October.	i)Gramsabha ii)Phase wise treatment of diseases in community. iii)Group BCC Special efforts from July to October.	i) Gramsabha Group BCC ii)Phase wise treatment of diseases in community.	i) Gramsabha ii) Group BCC iii)treatment of diseases in community.

August	i)VHW revision training & meeting-Intervention area. ii).Preparation and finalization of contract with Funding agency iii) Baseline survey iv) Base line Third party evaluation	i) VHW revision training & meeting-Intervention area.	i) VHW – intervention area – revision training & Meeting. ii)Phase wise treatment of diseases in community.	i)VHW revision training & meeting-Intervention area . ii)Phase wise treatment of diseases in community.	i)VHW revision training & meeting-Intervention area ii)treatment of diseases in community.
September	i. Preparation and finalization of contract with Funding agency ii. Baseline survey iii. Base line Third party evaluation			i)Phase wise treatment of diseases in community.	i)treatment of diseases in community.
October	i) Gramsabha ii) . iii)VHW revision training & meeting-Intervention area iv) Baseline survey	i) Gramsabha Group BCC. ii) VHW revision training & meeting-Intervention area. ii)	i) VHW revision training & meeting-Intervention area. ii) Gramsabha Group BCC iii)Phase wise treatment of diseases in community.	i)VHW revision training & meeting-Intervention area . ii) Gramsabha Group BCC iii)Phase wise treatment of diseases in community.	i)VHW revision training & meeting-Intervention area ii.Gramsabha Group BCC iii)treatment of diseases in community.
November	i. Baseline survey		i)Phase wise treatment of diseases in community.	i)Phase wise treatment of diseases in community.	i)treatment of diseases in community.
December	i)VHW revision training & meeting-Intervention area. ii) Baseline survey	i) VHW revision training & meeting-Intervention area.	i. VHW revision training & meeting-Intervention area . ii)Phase wise treatment of diseases in community.	i)VHW revision training & meeting-Intervention area . ii)Phase wise treatment of diseases in community.	i)VHW revision training & meeting-IA . ii)treatment of diseases in community.

Data cleaning and analysis: Jan to June, 2016

Final Third party evaluation : April to June, 2016.

Reporting and publication: July to December , 2016.

C.3. Phases :

Four distinct phases of work of VHW under MCPEPAG can be identified.

- 1) The first year of MCPEPAG :Observation, baseline data collection and recording – January 2004 to December 2004.
- 2) Intermediate phase (May 2005 to January 2010): VHW (in the intervention villages for home based child care program) were also treating minor ailments of adult patients and were referring needy patients to base hospital since 2005. There was also nonspecific health awareness generation .
- 3) Training phase and gradual provision of MCPEPAG treatment services (February 2006 to December 2010)
- 4) Full implementation of MCPEPAG : January 2011 to December 2015).
(Interventions will be implemented in the specified time periods and were continued subsequently.)
- 5) Data analysis & publication of results :from January 2016 to December 2016.
- 6) Replication of the program in new 40 villages (2017 to 2022)

Section D:

D. 1. Contents of the home based health Package for the age group of 16-60 years: Annexures

A) Treatment of patients by VHW:

(those patients who will not go to hospital).

- i. Treatment of hypertension.
- ii. Treatment of diarrhea.
- iv. Treatment of malaria.
- v. Treatment of anemia.
- vi. Treatment of COAD and Asthma.
- vii. Treatment of Pneumonia.
- viii. Treatment of tobacco and alcohol addiction.
- ix. Vaginal discharge-purulent/white

This approach comprises provision of home-based health care to people in the age group of 16-60 years and pregnant women/mothers through a trained semiliterate female village health worker (VHW) resident of the same village under medical supervision by trained medical supervisor.

B) Continuation and/ follow up of treatment by VHW: Improving adherence to treatments: (for those patients whose treatment will be started in hospital).

The simple inexpensive methods of improving adherence to treatments, which we would use in the current study are 1) Providing clear instructions (using pictorial patient education material), 2) Home based counseling and positive re-enforcement provided by VHWs, 3) Using reminders or cues, and using them to integrate preventive therapies to activities of daily living, 4) Involving families and significant others (spouse) in treatment adherence , 5)Provision of drugs in the village itself at low cost or free of cost.

1. Tuberculosis.
2. IHD.
3. CVE.
4. Jaundice.
5. CNS infection.
6. Maternal complications.
7. AIDS.
8. Dental infections, caries teeth.
9. Other diseases (A: i. to vii) treated in hospital.

C) Yoga and meditation by VHW :

- i. Tobacco and alcohol addiction.
- i. Multiple sexual contact & healthy sexual behaviour.
- ii. Hypertension and IHD.
- iii. COAD.
- iv. Suicide.

D) Behaviour change communication (by VHW & Supervisors):

1. Tobacco and alcohol addiction.
2. Multiple sexual contact & AIDS.
3. Hypertension and IHD.
4. COAD.
5. Suicide.
6. Jaundice.
7. Tuberculosis.
8. Diarrhea.
9. Malaria.
10. Anemia,
11. Good oral hygiene.

E) De-addiction program for the villages by trained team.

1.

Treatment Camps.

2. Rehabilitation programs.

3. Gramsabha/village meetings. Village bandi for addicts.

F) Government system mobilization (by Project manager, supervisor, VHW):

1. Provision of treatment for Tuberculosis.
2. Provision of treatment for IHD, etc.
3. Provision of treatment for HIV –AIDS.
4. Provision of treatment for critical patients of COAD.
5. Provision of treatment for cancer.
6. Provision of treatment for addiction.

G) Dental camps for good oral hygiene, treatment of caries teeth and infections and to prevent tobacco addiction by reducing toothache.

H) Eye care . especially for cataract induced blindness & other causes of blindness.

I) Referral of serious cases to base hospital.

D.2. Management or Treatment modality :

1. Treatment of Hypertension:

- a. Tablet Enalapril 5 mg. 1 OD.
- b. Tablet Amlodipine 5 mg. **(One out of two)**
- d. Tablet Aspirin 75 mg OD.
- e. Salt restricted diet (< 5 gm i.e. 2 tea spoon full per day), low fat diet , high fiber diet,
- f. No tobacco / no alcohol.
- g. Yoga & meditation.

2. Treatment of IHD:

- a. Tablet Aspirin 75 mg OD.
- b. Tablet Sorbitrate 10 mg 8 hourly.
- c. Tab. Statins –Atorvastatin 10 mg OD for selected cases who will purchase.
- d. Salt restricted diet (< 5 gm i.e. 2 tea spoon full per day), low fat diet , high fiber diet,
- e. No tobacco / no alcohol.
- f. Yoga & meditation.

3. Treatment of Tuberculosis: (from government hospitals).

- a. Tablet 2 EHRZ +4 HR-
- b. Tablet Pyridoxine 10 mg OD or 40 mg biweekly.

- c. Tablet Iron +multivitamins
- d. High calories, protein & vitamin diet,
- e. Well-ventilated house, precautions for other/mask..
- f. No tobacco / no alcohol.
- g. Strict follow up for treatment adherence and completion.
- h. Mobilization of government health department for confirmation of diagnosis and treatment .
4. Treatment of COAD:
 - a. Asthalin rotacaps 2 puffs 2 to 8 hourly .
 - b. Seroflow rotacaps 2 puffs BD.
 - c. Tablet Derriphylline R (300 mg) BD.
 - d. Tab. Doxycycline 200 mg OD day 1 , 100 mg OD for next 4 days-if indicated.
 - e. Acute exacerbations to be referred or to be managed by Asthalin Nebulization in village.
 - f. Well-ventilated house, .
 - g. No smoking. Tobacco de-addiction
 - h. Smokeless chulhas
5. Treatment of Pneumonia:
 - a. Cap. Amoxycillin 500 mg tds or tab. Azithromycin 500mg OD * 5-7 days.
 - b. Tab. Paracetamol 500 mg tds –as per need.
 - c. Well-ventilated house/ precautions for other/mask.
 - d. No smoking.
6. Treatment of Diarrhea:
 - a. ORS.
 - b. Tab. Furoxone 100 mg tds * 3- 5 days. Or Tab. Norfloxacin 400 mg bd for 3 days for patients with blood in stool, severe dehydration, serious, high grade fever, no response to ORS after 48 hours .
 - c. Tab. Metronidazole 400mg TDS for blood or mucus in stool.
 - d. Tab. Domperidone 10 mg –as per need.
 - e. Safe water and food.
7. Treatment of Malaria :
 - a. Tab. Chloroquine (250 mg i.e. 150 mg base – 10 tablets over 48/72 hours.
 - b. Tab. Paracetamol 500 mg –as per need.
 - c. Tab. Artesunate 100mg (2 OD day 1, 1 OD for 6 days) for indicated cases only-those who are positive for falciparum malaria.
 - d. Tepid water sponging.
 - e. Hygienic house and village for mosquito prevention.
 - f. Mosquito nets.
8. Treatment of Tobacco addiction:
 - a. Counselling & health education.
 - a. Yoga & meditation.
 - b. Tablet Bupropion 150 mg BD for 6 months.
 - c. Nicotin replacement therapy : Nicotin gum, Nicotin spray/inhaler (Nicotin patch in base hospital)
 - d. Gaon bandi for tobacco.
9. Treatment of alcohol addiction:
 - a. Counselling & health education.
 - b. Yoga & meditation.
 - c. Tablet Librium 25 mg tds for 3 day, 10 mg BD * 4 days.
 - d. Tablet Naltrexone, 50–150 mg/d, / once-per-month injection of this drug (380 mg).

or + Acamprosate tab. (2 gm /day)tablet .
 - e. Tablet Neurobion 1 tds for 15 days.
 - f. Injection Lorazepam , Thiamine IM as per need.
 - g. De addiction camps.
 - h. Gaon bandi for alcohol.

10. Treatment of Anemia :
 - a. Tab. Ferrous sulphate 200 mg tds for 3 months.
 - b. Tab. Folic acid 5 mg OD for 3 months.
 - c. High iron diet. Iron pans for cooking.
 - d. Tab. Albendazole.
11. Eye care: Treatment of eye infections & screening for eye disorders:
 - a. Chloromycetin eye applicaps.
 - b. Screening for cataract, refractive errors, vitamin A deficiency, eye injuries, glaucoma, etc.
12. Dental care: Treatment of minor dental infections and maintenance of good oral hygiene.

We would use the NHANES risk score for screening of eligible individuals in our study (Appendix 3) We have derived INTERHEART risk score based on the largest global case-control study of risk factors of acute myocardial infarction (Appendix 4). We would use non-lab based components of INTERHEART risk score to evaluate the impact of intervention in our study.

D.3. Interaction with government health system .

- i. Motivation of government health system to supply drugs for tuberculosis, hypertension, IHD, HIV-AIDS, oral cancers, etc.
- ii. Motivation of government ICDS to supply properly supplementary nutrition to the common tribal pregnant mothers.
- iii. Vaccination for jaundice.

D.4. KAP studies . To know the prevalent knowledge and attitudes of the community. regarding health of people in the reproductive age group (16 to 50 years) ,so as to formulate the management package.

Section E: Monitoring & Evaluation of MCPEPAG Study

❖ Monitoring indicators for the objective:

1. Age specific Death /mortality rate (16-60 years)=

Total no. of deaths (in the age group of 16-60 years) in one year.

$$\frac{\text{Total no. of deaths (in the age group of 16-60 years) in one year.}}{\text{Total population in the age group of 16-60 years in the same year}} \times 100,000$$

(Age specific death rate
 = $\frac{\text{Total deaths in the specified age group(16-60 years)}}{\text{Total population in the Same specified Age group (16-60 years)}} \times 1,00,000$
 (Ref: Mortality rate –Wikipedia , the free encyclopedia)

2. Crude death rate =

Total no. of deaths in one year.

X 1000

Total No. of population in the same year

3.Cause-Specific Death Rate/ Disease specific mortality rates in the age group of 16-60 years:

Total no. of deaths (in the age group of 16-60 years) in one year due to one particular disease.

X 100000

Total No. of people in the age group of 16-60 years in that population in the same year

4. Prevalence of untreated hypertension=

No. of people (in the age group of 16-60 years)with untreated hypertension in one year.

X 100

Total no. of people (in the age group of 16-60 years) in that year .

5. Prevalence of untreated tuberculosis=

No. of people (in the age group of 16-60 years)with untreated tuberculosis in one year.

X 100

Total no. of people (in the age group of 16-60 years) in that year .

6. Prevalence of untreated COAD=

No. of people (in the age group of 16-60 years)with untreated COAD in one year.

X 100

Total no. of people (in the age group of 16-60 years) in that year .

7. Prevalence of addiction=

No. of people (in the age group of 16-60 years)who are tobacco /alcohol addict in one year.

X 100

Total no. of people (in the age group of 16-60 years) in that year .

Monitor monthly

- E. g. No. of pregnant ladies ;
- No. of expected ladies .
- No. of deliveries.
- How service indicators are behaving.
- % of VHW attendance during deliveries.
- Vital Statistics - conclusion : various death rates as above.
- Prevalence of diseases.
- No. of patients treated.
- Number of deaths.

- ❖ The purpose of evaluation and monitoring processes is to determine the progress of the study, and assessment of non-health outcomes. We would evaluate the MCPEPAG study under the following heads:

1) Curative & Prevention activities (numbers, reach, operational evaluation)

Mechanism: Self and cross-audits. Self-audit refers to the centres themselves providing a structured report about the operational indicators, and cross-audit to the process whereby investigators from outside will evaluate.

Evaluation heads: The key heads under which evaluation would be performed would include a) Community health worker training and competency, b) Population surveyed, households reached, and at-risk households identified, c) Number of intervention visits, d) Qualitative and quantitative verification of patient treatment , e) Qualitative verification of BCC, f) Cross verification of non-referrals, g) Outcome assessment.

Frequency: Self audit at every month interval, and cross audit every six months. The details of this evaluation mechanism would be indicated in the manual of operations.

1. Community participation (participation, perceptions of personnel, and key stakeholders)

Mechanism: Periodic qualitative studies, using triangulation technique to assess the outcomes. This would be performed as a sub-study, not involving any of the study personnel. Briefly, three sources of information would be used a) focus group discussions would be conducted among the MCPEPAG team (which would be attended by an evaluator. These discussions would be video-graphed and transcribed), b) semi-structured interviews of the study personnel and key stakeholders (members of the village panchayat, school teacher, anganwadi worker, sub-centre ANM etc) to assess their perceptions about utility of the program. c) Qualitative assessment from a subsample of the at-risk households in each region, about participant perceptions and felt needs.

Frequency: This is planned to be performed at six, and twelve months into the study. This would be designed as a sub-study, and implemented independently.

2. Economic evaluation (cost-benefit analysis)

Mechanism: A cost-benefit evaluation, performed as a prospective sub-study of MCPEPAG. Briefly, the sources of direct and indirect expenditure incurred would be identified, quantified, and their costs would be valued. In addition a valuation technique would be evolved for the key outcomes. The details of this sub-study would be finalized in consultation with the subject experts.

Frequency: beginning six months into the project, to be completed by year1.

- d. Outcome evaluation - i) Vital statistics. Age specific death rates, Proportional mortality rates, Cause specific death rates, Crude death rate, Prevalence of chronic diseases , etc.

- 4. **Process evaluation** at the end of the project.
- 5. **Human Resource Evaluation** : V. H. W s. and supervisors at the end of training & after 5 years.

❖ **Probable Agencies for evaluation of project: (Baseline and Final)**

By Government medical college, Nagpur, / Government medical college, Mumbai/**SEARCH, Gadchiroli** / Govt. Medical College, Aurangabad (P.S.M. Department)/ International medical college/Nagpur university/ Other.

❖ Microsoft Excel and fox pro will be utilized for data analysis.

Section F: Outcomes

The outcomes would be evaluated at six month intervals (6, 12, 18 and 24 months) after the onset of the intervention. The first two evaluations are aimed at the early impact during the intervention, while the evaluation at 18 and 24 months is aimed to determine the sustained impact of the interventions.

The key outcome measures are as follows:

Primary outcomes

- a) Reduction in age specific death rate (16-60 years) by 10-40% .

Secondary outcomes

- a) Reduction in cause specific death rates and proportional mortality rate due to Tuberculosis, Cardiovascular diseases, COAD, Malaria, Diarrhea, Anemia, Pneumonia, maternal mortality, etc.
- b) To assess the effectivity of community-based program implemented by VHWs for reducing adult mortality in rural-tribal area.
- c) Reduction in systolic blood pressure so that an optimal control is achieved (systolic BP of 140mm Hg or less)

The adherence measures would be done by a medical social worker, who is not involved in the CHW based home visits. This person will be blinded to the intervention and non-intervention status of the households, and would ascertain adherence by a) Person (and spouse, if available) administered questionnaire using MMS scale, b) Pill count using empty blister packs, or c) Proof of purchase kept by the patient from pharmacy records. A composite assessment using these methods would be done as a measure of adherence.

Table showing the frequency of measurement of outcome measures

Outcome Measure	6 months	12 months	18 months	24 months
Age specific death rate	X	X	X	X
Cause specific death rates and proportional mortality rate	X	X	X	X
Adherence measurements	X	X	X	X

BP		X		X
INTERHEART risk Score		X		X
Addiction		X		X

9. Facilities in terms of equipment, etc, available at the sponsoring institution for the proposed investigation.

Rest of the Facilities in terms of equipment, etc. available at the Mahatma Gandhi Tribal Hospital for the proposed study will be utilized and it will be also a referral hospital along with existing govt. hospitals.

Two full time post graduate doctors(internal medicine specialist and eye surgeon) are available who have experience of Melghat since last 6 years. Human resources in the form of trained village health workers (17), medical supervisors and project manager are available with the institute. Facilities for hospitalization and training of village health workers are available with the institute.

Trainings will be provided by team of MAHAN trust, external expert & THRPM.

Most of the equipments for management of patients like endo-tracheal intubation, oxygen concentrator, Nebulizer, Ventilator, ECG Machine, Multi-parameter, ECG monitor, operating microscope , etc. are available in our hospital.

10. Budget requirements (with detailed break-up and full justification attached as excel sheet):

- (i) Staff
- (ii) Contingencies
 - Recurring
 - Non-recurring (equipment)
 - Travel
- (iii) Overhead charges

	<u>1st year (Rs.)</u>	<u>2nd year (Rs.)</u>	<u>3rd year (Rs.)</u>	<u>Total (Rs.)</u>	
i. Staff	24,03,315	26,41,606	29,03,727	79,48,648	8
ii. Contingencies					
b. Recurring	61,92,472	67,86,757	74,40,470	2,04,19,699	
b1. Non-recurring	26,07,558			26,07,558	8
b2.equipment)	10,74,958			10,74,958	8

d. Travel :	188496	207346	228081	623923	3
iii. Overhead charges (Audit & Administration)	3,39,338	3,72,024	4,08,080	11,19,442	
Total	71,26,095	78,12,494	85,69,675	2,35,08,264	

11. Annexures:

Annexure A: The team of workers under the program are as follows:

- i) The trained Village Health Worker (VHW) (17)
 - ii) Two medical supervisors, who are trainer and guide of the VHWs .
 - iii) One counselors cum supervisors who are trainer and guide of VHW for life style modification.
 - iv) One yoga therapist cum de-addiction instructor.
 - v) Two vital statistic supervisor who are trainer and guide of VHWs for collection of vital statistics in intervention and control areas.
 - vi) Data entry team supervisor / data collection team supervisor / Statistician-1
 - vii) Computer operator-2.
 - viii) One statistician (M. Sc . or B.Sc.-statistics)
 - ix) One accountant cum clerk.
 - x) One stockiest cum purchaser.
 - xi) One laboratory technician.
 - xii) A project manager is required to implement the MCPEPAG through these workers and to supervise and evaluate the outcome of the MCPEPAG approach.
 - xiii) One doctor will guide and train and evaluate the program when needed. He will also routinely examine critical patients when necessary and pregnant ladies.
- Experts cum consultants:**
- xiv) Project director cum Physician (internal medicine expert). Dr. Ashish Satav (M.B.B.S., M.D.)
 - xv) Eye surgeon. Dr. Kavita Satav (M.B.B.S., M.S.)
 - xvi) Kitchen garden consultant. (Mr. Manohar Khake, M.Sc.)
 - xvii) Nutrition expert. (Mrs. Pendharkar) (M.Sc., Dip, Dietetics.)
 - xviii) Life style modification expert. (Dr. Avinash Saoji) (M.B.B.S.)
 - xix) Psychiatrist/ Psychologist. (
 - xx) Dentist.
 - xxi) Epidemiologist & chief guide. (Dr. S.P. Kalantri.) (M.B.B.S., M.D. –Internal Medicine, M.P.H.- Physician and Epidemiologist)

Annexure B :Clear definitions of roles and responsibilities of categories of workers.

1. The traditional birth attendant (TBA)

- a) Reinforce the health education messages given by V. H. Ws. to pregnant mothers and her relatives such as mother and mother in laws.
- b) Encourage mother to access Antenatal Care (ANC) care from the regular government health services.

- c) Conduct hygienic and safe delivery.
- d) Recognize danger signals in mother (delivery, post-partum) and refer.
- e) Insist that family calls VHW to assist her during delivery e.g. cleaning of blades with spirit , application of G.V. paint to umbilical cord, guidance on hygiene or (if VHW not present)within few hours after delivery.
- f) Work in collaboration with VHW.

2. The village health worker (VHW)

The Village health worker is the direct provider of components of the **MCPEPAG..** Preparation of list of women in the reproductive age group who can become pregnant and preparation of list of pregnant women; provision of maternal health care, health care of people (male and female) in the age group of 16-60 years as specified in the **MCPEPAG** package are the main responsibilities of the VHW. Record keeping is also an essential component of her responsibility. These records include: record of history of the pregnant woman, condition of the pregnant woman, record of delivery, diagnosis and the treatment of people in the age group of 16-60 years, death record, survey of health of people in the age group of 16-60 years.

Job description of VHW under MCPEPAG..

1. Work in smooth collaboration with TBA & other stakeholders in village.

Periodically visit every house in her village and collect information on all married women of child bearing age-every 2 months.

Make a list of women eligible to become pregnant, every 6 months

Identify pregnant women and register them (Pregnant Mothers Form)- every 2 months. And collect information on their previous deliveries and present condition.

Refer pregnant women to ANM for iron and folic acid & for tetanus toxoid injection.

Organize and assist supervisors in conducting group health education for pregnant women every 4 months in the village and evaluate effect of health education.

Make two antenatal visits to pregnant women in the village as follows:

At 7 month of pregnancy

- i)Conduct health screening (pregnant Mothers Form)
- ii) Provide health education (using counseling cards appropriately) on
 - Nutrition during pregnancy.
 - Danger signs in pregnancy and appropriate action
 - Provide health information sheet to expectant mothers
- iii) Advise on taking iron and folic acid and tetanus toxoid from ANM

b) At 9 months of pregnancy

- i)Conduct health screening (Pregnant Mothers Form)
- ii) Provide health education (using Counseling cards appropriately) on
 - Danger signs in pregnancy and labor & action to be taken
 - Planning for delivery
 - Breast feeding

Attend delivery and observe baby

- a) Record information on delivery and birth (Delivery Form)
- b) Give emotional support to mother and family
- c) Encourage/assist cleanliness, hand washing, use of new blade
- d) Assist TBA in referral when necessary
- e) Observe the newborn baby at 30 seconds after birth for cry, respiration and movement of limbs

4. Observe mother for 42 days after delivery for complications like post partum hemorrhage, puerperal sepsis, anemia, convulsions, etc. Health education of mother after delivery.

5. Home visits for examination of people (male and female) in the age group of 16-60 years.

Initiate treatment for diseases described below:

HT, COAD, Pneumonia, Anemia, diarrheal diseases, addiction, malaria, etc.

Screen people for following diseases and refer them to hospital for treatment and follow up and continue treatment in village:

TB, IHD, CVE, CNS Infection, cerebral malaria, meningitis, maternal diseases like post-partum hemorrhage, puerperal sepsis, anemia, convulsions, HIV-AIDS, Jaundice, Suicide, cancer of oral cavity, etc.)

6. Self-evaluate the care, identify success, deficiencies

7. Provide treatment to people (male and female) in the age group of 16-60 years.

for

a. Pneumonia

- Repeat 3 home visits to patients receiving ARI treatment.
- Complete pneumonia form.

b. Diarrhea and dysentery.

- Repeat one home visit to patients receiving treatment for diarrhea.
- Complete diarrhea form.

c. Malaria.

- Repeat two home visit to patients receiving treatment for malaria.
- Complete malaria form.

d. Management of HT.

- Blood pressure record once a months and as per indication for patients receiving treatment for HT.

- Nutrition education.
- Continuation of treatment of associated diseases e.g. DM, IHD, addiction, hyperlipidemia, etc.
- yoga & exercise.
- Complete HT form.

e. COAD:

- Repeat 3 home visits to patients receiving COAD treatment.
- Complete COAD form.
- Continuation of treatment for tobacco(smoking) addiction, etc.
- yoga & exercise.
- Visit to asymptomatic patients during winter season once a month.

f. Addiction:

- Repeat 7 home visits to patients of alcohol addiction during first 7 days after discontinuation of alcohol(once a day). Then one visit per week for one month and then monthly visits for one year and quarterly visit for 5 years.

- complete alcohol treatment form.

- Repeat 3 home visits to patients of tobacco addiction during first 7 days after discontinuation of tobacco. Then one visit per week for one month and then monthly visits for one year and quarterly visit for 5 years.

6. Provide treatment to villagers for

- i) Basic wound care
- ii) Basic treatment for fever, head ache, body ache.
- iii) Management of reproductive tract infection.

7. Behavior change communication on following topics:

Tobacco and alcohol addiction, Multiple sexual contact & AIDS.
Hypertension and IHD, COAD, Suicide, Jaundice, Tuberculosis.
Diarrhea, Malaria & Anemia.

8. Maintain all registers and records.

9. Maintain VHW kit and seek timely replacement/repair.

10. Maintain medicine stock and seek timely replenishment.

11. Work with the supervisor on the day of her visit.

12. Cooperation with health care system or other health providers.

13. Education and motivation of married people for use of temporary and permanent methods of contraception.

14. Basic eye care-& screening of patients for cataract, eye injuries, refractive errors, glaucoma, eye infections, vitamin A deficiency, etc.

15. Basic Dental care .

3) The trainer cum medical supervisor of the V. H. Ws.

Eligibility : Ideally BAMS or BHMS. If not then at least GNM or ANM.

The supervisor of the V. H. Ws. is responsible for training of the V. H. Ws., providing support and guidance to the V. H. Ws. in their work in the field and for execution of the MCPEPAG through the V. H. Ws. The responsibility as trainer includes training of the V. H. Ws. in classrooms and ongoing training in the field during supervisory visits. Supervision of activities of village health workers.

Job Description of Medical Supervisor of VHW under MCPEPAG..

- 1) Make a time table of village (area) visits of Supervisor and give V. H. Ws. the timetable 15 days prior to the visit.
- 2) See that the material provided to the V. H. Ws. for work is in good condition.
- 3) Check medicine book and stock book
- 4) Check list of pregnant women & high risk people/ patients in the age group of 16 to 60 years.
- 5) Visit each high risk patient once a month.
- 6) Check treatment forms of patients treated by VHWs.
- 7) Supply medicines to VHW.
- 8) Visit all T. B. As. to record all deliveries and see whether VHW has missed any post pregnant ladies who are high risk.
- 9) In addition all at-risk individuals would be provided with an envelope where they would be asked to preserve the empty blister packs of the medication consumed by them. These envelopes would be collected every six months by a medical supervisor and used in determining adherence.
- 10) Examination of resistant patients / cases for disease confirmation and proper management and referral to base hospital for treatment.
- 11) Monitoring of drugs distribution to VHW and to patients via government health department.
- 12) Read on subjects of health.
- 13) Conduct meeting of pregnant women and high risk patients with chronic diseases thrice in a year for Health Education.
- 14) Meet Sarpanch, chief of Self Help Groups, Nurse, ASHA worker at regular intervals and exchange the information.
- 15) Write daily report.
- 16) Arrange camp for refresher course of VHW once in a month for initial few months and later on one in two months.
- 17) Prepare monthly report and discuss it with project manager.
- 18) Deposit treatment forms of patients and all forms with the project manager within 7 days.
- 19) Anticipate requirement of stock 4 months prior to requirement and note demand. Put up requirement of necessary medicine and other necessary material to project manager at least 1 month before the stock is exhausted.
- 20) Take care of own vehicle.
- 21) Record briefly different type of cases and experiences.
- 22) Motivation for hospital seeking behavior for indicated cases.
- 23) Visit to patients treated by VHW for verification of diagnosis and treatment given.
- 24) Random B.P. record of few high risk cases-(10-25%).
- 25) Monitoring immunization status of pregnant women .
- 26) Attend gramsabha/village meeting once in 3-4 months.

4. One counselor cum BCC supervisor who is trainer and guide of VHW for life style modification.

Eligibility: M.S.W. or B.S.W., M.A. Psychology or graduate with experience of counseling.

- i. Selection and enrollment of high risk patients for life style modification.
- ii. Meeting of beneficiaries who are high risk patients.
- iii. Group Counseling & motivation of high risk patients for life style modification.
- iv. Mass health awareness program in villages once in 3 months for life style modification.
 - v. Consolidate the records.
 - vi. Healthy person competition – 6 monthly.
 - vii. VHW training on nutrition, life style modification, addiction, high risk sexual behaviour, etc. Give advice & guidance to VHW on preparation of teaching aids & demonstrations of health education program.
 - viii. Arrange workshops for V.H.W. on life style modification.
 - ix. Prepare time table of village visit of supervisor & give the VHW the time table 15 days prior to the visit. Also give that time table to project manager and Dr. Satav. Conduct at least one village visits per month to each village for monitoring and supervision of VHW activities related to life style modification.
 - x. Responsible for training equipment & teaching aids.
 - xi. Stock checking.
 - xii. Write daily report.
 - xiii. Read on subject of life style modification.
 - xiv. Care of own vehicle.
 - xv. Arrange experts visit to high risk cases who are not responding to life style modification.
 - xvi. Record briefly different types of cases & experiences.
 - xvii. Participation in meeting of local women.
 - xviii. Sponsor good public relationship.
 - xix. Survey of traditional high risk practices (KAP) responsible for chronic diseases and deaths in reproductive age group.
 - xx. Managing media visits as a matter of public relations for the project. This includes print and electronic media.
 - xxi. Arrangement of gram sabha.
 - xxii. Conduct monthly meetings of village health committee.
 - xxiii. Co-ordination with small saving groups in villages.

5. One yoga therapist cum de-addiction instructor.

Eligibility : i.

Diploma or degree in yoga , meditation or regular yoga practitioner.

2. Experience of conducting de-addiction program.
3. Should have inner burning desire for de addiction of people and yoga and meditation. This is the most important criteria amongst the three.

Job description :

- i. Selection and enrollment of addicts for treatment.
- ii. Meeting of addicts and family members for de addiction.
- iii. Group Counseling & motivation of addicts for de-addiction.
- iv. Mass health awareness program in villages once in 3 months for de-addiction.
 - i. Organize de-addiction camps in the villages.
 - ii. Organize yoga camps in the villages.
 - iii. Yoga classes for high risk group people in villages.
 - iv. Training of VHW for yoga and de-addiction.
 - v. Consolidate the records.
 - vi. Healthy people competition – 6 monthly.
 - vii. Give advice & guidance to VHW on preparation of teaching aids & demonstrations of health education program.
 - viii. Arrange workshops for V.H.W. on de addiction and yoga.
 - ix. Prepare time table of village visit of supervisor & give the VHW the time table 15 days prior to the visit. Also give that time table to project manager and Dr. Satav.

Conduct at least one village visits per month to each village for monitoring and supervision of VHW activities related to yoga and de addiction.

- x. Responsible for training equipment & teaching aids.
- xi. Stock checking.
- xii. Write daily report.
- xiii. Read on subject of life style modification.
- xiv. Care of own vehicle.
- xv. Arrange experts (psychiatrist or yoga consultant) visit to high risk cases who are not responding to VHW activities.
- xvi. Record briefly different types of cases & experiences.
- xvii. Participation in meeting of local people.
- xviii. Sponsor good public relationship.
- xix. Survey of traditional high risk practices (KAP) responsible for addiction in reproductive age group.
- xx. Managing media visits as a matter of public relations for the project. This includes print and electronic media.
- xxi. Arrangement of gram sabha.
- xxii. Conduct monthly meetings of village health committee.
- xxiii. Co-ordination with small saving groups in villages.

6. Two vital statistic supervisor who are trainer and guide of VHWs for collection of vital statistics in intervention and control areas.

Eligibility criteria:

1. At least 12th class pass.
2. Able to drive two wheeler.
3. Well versed with local language.
4. Able to communicate properly with people.

Job responsibility:

1. VHW will record weight, abdomen girth, waist-hip measurement of all high risk people and supervisor will cross check 25% of all the measurements.
2. Check the efficiency of weighing machine, tape & other materials/equipments (monthly).
3. Consolidate the weight, waist hip ratios, etc. & other records.
5. Confirmation of all births & deaths especially in the age group of 16-60 years.
6. Supervision of retrospective survey for vital statistics data & demographic data collection once in 6 months.
7. VHW & surveyor training on vital statistics data collection & demographic surveys.
8. Arrange training workshops for V.H.W. & surveyor.
9. Prepare time table of village visit of supervisor & give the VHW the time table 15 days prior to the visit. Also give that time table to project manager and Dr. Satav. Conduct at least two village visits per month to each village for monitoring and supervision of VHW activities.
10. Write daily report.
11. Read on subject of population surveys, vital statistics and verbal autopsy.
12. Care of own vehicle.
13. Conduct verbal autopsies.
14. Record briefly different types of cases & experiences.
15. Support to MCPEPAG training of VHW.
16. Participation in meeting of local village stakeholders.
17. Sponsor good public relationship.
18. Help in KAP studies.
19. Supply cards to high risk cases.

7. The Project Manager:

Eligibility criteria.: 1. M.H.A. 2. M.B.A. 3. M.S.W. 4. Any postgraduate with experience of management. 5. Must be able to communicate in English and Hindi. 6. Computer literate.

The project manager has to shoulder the responsibility of ensuring that the **MCPEPAG** is provided in the chosen area through the chosen workers mentioned above and that the desired outcome of reduction in mortality rates has to be achieved. (Besides planning, resource management, overseeing execution, monitoring and evaluation of the implementation of the **MCPEPAG** approach from time to time, specifically he has to undertake following responsibilities.)

- Maintaining rapport with the community
- Making available existing infrastructure and goodwill.
- Recruitment and deployment of V. H. Ws., supervisor, trainer.
- Organizing training of supervisors and trainers of V. H. Ws. and TBAs.
- Implementing the MCPEPAG model as per guidelines.
- Gathering data and its analysis through a competent organization or person.
- Maintaining the implementation schedule.
- Maintaining liaison with government at the district level.
- Documenting case studies of the replication exercise.
- Problem solving, as and when required, network management etc.
- Ensuring availability of material including medicines, kits for the workers and record formats
- Financial & human resource monitoring,
- Preparing reports.
- T.B.A. Motivation.
- Self-training and reading.
- Weekly checking of motor log book of supervisors.

8. Data entry team supervisor/ data collection team supervisor/Statistician

Eligibility criteria:

- i. B.Sc. statistics or M.Sc. statistics.
- ii. Able to handle all needed program of computer.
- iii. Capable of training people in office and field.
- iv. Able to supervise & train the staff.

Job responsibility : The core tasks of a data collection team supervisor & data entry supervisor are provided in the checklist below.

General roles are as follows:

Tasks	Description
1	Train data collection team staff & data entry staff.
2	Obtain lists of the selected sample and maps for each area.
3	Set up a tracking system for data collection & data entry teams and participants.
4	Provide data analysts with summary sheets showing, for each cluster and stratum, details of interviews completed, non-response, etc.
5	Make travel arrangements for data collection teams.
6	Arrange and maintain computers for data entry team.
7	Contact local authorities.
8	Obtain and distribute forms and supplies to interviewers.
9	Supervise data collection & data entry.
10	Supervise human resources.
11	Provide progress updates to the STEPS site coordinator/ project manager and director and /or the STEPS coordination committee.

- 12 Provide feedback.
- 13 Analysis of the data.
- 14 Provide statistical information to project director and manager.
- 15 Statistical calculation of the data collected by team.
- 16 Keeping the data secrecy

1. Train staff

A. Train the data collection team staff in:

- i. Interview technique
- ii. Approaching households.
- iii. Conducting interviews for Step 1
- iv. Taking measurements for Step 2
- v. Completing the Instruments.
- vi. Using the forms and available tools.

B. Train the data entry team staff in:

- v. Entry of the data on computers.
- vi. Computerized Analysis of the data.

2. Manage Human Resources

- i. Manage and support the data collection & data entry team to ensure :
- ii. • Good quality interviews are conducted and Instruments are complete
- iii. • Interview timeframes are adhered to
- iv. • Interviewers are supported if participant issues arise
- v. • Performance issues are dealt with appropriately
- vi. • Confidentiality of all STEPS surveillance material is respected at all times
- vii. • Feedback is provided to data collection staff
- viii. • Sick leave and annual leave is appropriately covered.
- ix. Data entry done in proper fashion. (qualitative and quantitative data entry).
- x. Data entry completed within allotted time limit.

9. Computer operator-2.

Eligibility: i. should be at least 12th pass. ii. Should be able to handle computer properly.
 iii. Capable of operating MS Office, fox pro, tally and other account software, internet ,
 power point presentations, etc.
 vii. Able to type in Hindi, Marathi and English with good speed(40-60).

The roles and responsibilities of these workers are described below:

- i. Computerization of the data of community health activities.
- ii. Computerization of data of hospital.
- iii. Data analysis.
- iv. Maintenance of data secrecy.
- v. Coding of data to be entered.

10. One accountant cum clerk.

Eligibility: i. B.com or B.C.C.A.

- ii. Able to handle computerized accounts like Tally.
- iii. Should be able to use computer properly .

Job responsibility:

- i. Maintain daily accounts of the project.
- ii. Daily computerization of accounts.
- viii. Handle all daily financial transactions(cash and bank etc.)
- iv. Should complete yearly audit of the project with the help of chartered accountant within stipulated period.
- ix. Maintain all records of the project.
- x. Handle all clerical job including postal correspondence, etc.

11. One stockiest cum purchaser.

Eligibility: i. Graduate.

- ii. Should be able to use computer properly .

- iii. Basic mathematical skills are needed.
- iv. Should be honest.

Job responsibility:

- i. Maintain daily stock record of the material.
- ii. Daily computerization of stocks.
- iii. Handle all daily material transactions.
- v. Maintain inward outward registers of material.
- vi. Proper maintenance of all material.
- vii. Make all necessary material available on time.
- viii. Do not waste the material and prevent its damage.
- ix. Purchase of all the materials needed for the project at reasonable rate and quality.

12. One laboratory technician / Technician:

- Eligibility :** i. D.M.L.T. ,
ii. X-ray training done.

Job responsibility: testing of following investigations.

- i. Anemia testing & typing- e.g. HB, P.S., etc.
- ii. HIV testing- Tridot or other rapid antibody test.
- iii. Blood sugar,
- iv. Lipid profile,
- v. K.F.T.
- vi. Malaria testing. P.S, Rapid antigen test.
- vii. SGOT, SGPT, Sr. Bilirubin, Sr. Alkaline phosphatase, Sr. Albumin.
- viii. Sr. CPK-MB, Troponin T or Troponin I,
- ix. Sputum for AFB, Gram staining.
- x. Stool examination-microscopy, ova –cyst, occult blood.
- xi. Urine –micro, albumin, sugar, ketones, etc.
- xii. C.S.F. Microscopy.
- xiii. Mantoux test.
- xiv. Peak flow meter,
- xv. Chest X ray,
- xvi. E.C.G.

13. Doctor :

Eligibility criteria: i. Ideally M.B.B.S. or ii. if not possible at-least B.A.M.S. or B.H.M.S. with specialized training in community health.

Job responsibility : i. Guide and train the staff.

- ii. Routinely examine critical patients when necessary and pregnant ladies.
- iii. Critically monitor the daily medical part of the project.
- iv. Cross check randomly some patients treated by VHW.
- V. Evaluate the program when needed.

Experts cum consultants: (Honorary for guidance when needed.)

14. Project director cum Physician (internal medicine expert). Dr. Ashish Satav (M.B.B.S., M.D.)
15. Epidemiologist & chief guide. (Dr. S.P. Kalantri.) (M.B.B.S., M.D., M.P.H.)
16. Life style modification expert. (Dr. Avinash Saoji) (M.B.B.S.)
17. Eye surgeon. Dr. Kavita Satav (M.B.B.S., M.S.)
18. Kitchen garden consultant. (Mr. Manohar Khake, M.Sc.)
19. Nutrition expert. (Mrs. Pendharkar) (M.Sc., Dip, Dietetics.)
20. Psychiatrist/ Psychologist.
21. Dentist.
22. Yoga consultant/trainer.

Annexure c :

a. Checklist for medical supervisor Activities

1. Testing of medical supervisor for morbidity diagnosis of diseases in the age group of 16-60 years and MCPEPAG. (Weekly examination and no. of topics read.)
2. No. of villages visited as per time table.
3. No. of forms (e.g. Hypertension, Tuberculosis, IHD, Diarrhea, Malaria , etc) checked properly & signed.

(All above forms must be deposited within 15 days with project manager.)

4. No. of field classes conducted for VHW.
5. No. of mistakes of VHW picked up.
6. No. of group health educations conducted for pregnant ladies & high risk group people.
7. Corrections suggested for village health registers, pregnancy registers , drug delivery registers, etc.
8. Improvement in skills of VHW .
9. No. of pregnant ladies who received complete vaccination.
10. No. of critically ill patients visited.
11. No. of patients visited who were treated by VHW.
12. No. of TBA attending training program & Co-operating VHW for delivery attendance.
13. Availability of drugs & material with VHW.
14. Daily report.
15. VHW trainings- Quantity and quality of attendance.

16. No. of pregnant ladies whose BP were recorded.
17. No. of patients coming to base hospital for treatment from intervention area.
18. Condition of vehicle , fuel & maintenance expenses.

b. Checklist for other supervisor Activities

1. No. of villages visited as per time table.
 2. No. of village health Committee meetings conducted & attendance of members.
 3. No. of Gramsabha conducted & attendance of villagers.
 4. No. of group health education programs conducted.
 5. VHW trainings- Quantity and quality of attendance.
 6. Daily report.
 7. Condition of vehicle, fuel & maintenance expenses.
 8. No. of small saving groups formed and meetings conducted.
 9. Condition of weight machine of VHW.
 10. Percentage of allotted work done.
-

c. Checklist for VHW Activities

1. No. of eligible female in list. (Random 10% cross checking).
2. No. of pregnant female in list (A form conducted). (Random 10% cross checking).
3. No. of health education sessions conducted – Group & Individual.
4. No. of deliveries attended.
5. No. of deaths recorded
6. No. of patients treated-e.g. HT , TB, Diarrhea, Malaria, pneumonia, addiction, etc.
7. Presence during community functions such as launches.
8. Presence during community health education program.
9. No. of training workshops attended.
10. Presence during supervisor visit.
11. Proper maintenance of Registers (village health + pregnant lady + medicine stock).
12. Cross checking of eligible couple & pregnant lady list by medical supervisor – random 10% cross check.

Annexure D: Training of staff:

Training is mainly required for four categories of workers:

- 1) Training of trainer cum supervisors & project manager of VHW.
- 2) Training of V. H. Ws.
- 3) Training of T.B. As
- 4) Data entry and data collection staff.
- 5) Some soft skill training for all workers.

1. The training of trainer cum supervisor

MCPEPAG is a new concept for the trainer cum supervisors themselves.

For Medical supervisors and doctors, the total duration of training may be of about 30 days, to be imparted in a number of training workshops spaced by suitable time interval (of about one months). The actual number, which has been found most effective, is total 9 workshops over a period of 9 months- like VHW. The refresher trainings will also be like for VHW.

Every year from Jan 2007 to Dec. 2015 – There will be 3 days refresher trainings on alternate months-even months(6 training session every year). So total training days will be 192 days for initial and refresher trainings.

Training of Yoga therapist cum de-addiction supervisors and counselor cum life style modification supervisors will be of 15-30 days for first month and then for 5 days every 6 months.

2. Training of the Village Health Workers (V. H. Ws.)

Training of the V. H. Ws. should be carried out using the training material developed by TRIBAL HEALTH RESEARCH PROJECT, MELGHAT (MAHAN TRUST).

The training will be conducted by trainers approved by above organizations.

A. Topics:

- i. Baseline survey: registration of people in the age group of 16-60 years, prevalence of diseases in above age group[e.g. TB, IHD, COAD, CNS Infection{?Cerebral malaria??meningitis???encephalitis}, CVE, Hypertension, Suicidal attempts/thoughts, Jaundice, Dysentery. Chronic diarrhea, Acute diarrhea, Pneumonia/ LRTI, Cancer, AIDS, Anemia, addiction], death recording in above age group, diet history, tobacco or alcohol consumption, past & present history of hypertension, diabetes mellitus, manifest coronary artery or a cerebrovascular disease, tuberculosis, HIV, physical activity levels, dietary salt, fruit and vegetable consumption, and psychosocial profile, premarital or extramarital sex, high risk pregnancies, anemia.
- ii. Patient-disease identification: history taking(e.g.: cough, fever, weight loss, hemoptysis, anorexia, breathlessness, lymph node enlargement, chest pain-angina, abnormal perspiration, headache, vomiting, abnormal consciousness, weakness in half part of body, convulsions, loose-motions, blood and mucus in stool, yellow urine, vertigo, easy fatigability, abnormal lump or ulcer, inability to open mouth, stiffness, hyperextension of back, tobacco, alcohol, cannabis addiction, depression or abnormal mental condition, genital ulcer or discharge, symptoms of high risk pregnancy etc.) physical examination e.g.(built, height, weight, waist hip ratio, blood pressure measurement, pulse rate, respiratory rate, temperature, lymph node examination, pallor, icterus, cyanosis, edema feet, clubbing, wheeze, crackles, neck stiffness, abnormal consciousness,

- irrelevant talk, unsteady gait, hemiplegia, plantar reflex, gibbus, paraplegia, signs of dehydration, abnormal lump/ulcer specially in oral cavity, trismus, bow like back, convulsions, facial weakness, genital ulcer, smell of tobacco, alcohol, signs of high risk pregnancy, etc.)
- iii. *Treatment history and addiction and sexual history.*
 - iv. Early screening of diseases.
 - v. Treatment of diseases in village itself: hypertension, diarrhea, dysentery, anemia, Pneumonia, malaria, addiction, angina, COAD, continuation of therapy and its follow up(once started in hospital) for TB, IHD, CVE, hypertension, etc.
 - vi. Early timely referral of cases to hospital(serious cases).
 - vii. Govt. system mobilization for tuberculosis treatment.
 - viii. Testing of HB, malaria rapid test, blood sugar, urine sugar, urine albumin, urine for pregnancy test.
 - ix. Counseling for de-addiction, extra marital sex and multiple sex partners, tetanus immunization, etc.
 - x. Health education. Diet, early disease identification-angina, TB and diarrhea prevention, addiction, HIV-AIDS, Malaria, pneumonia, dental care, tetanus, anemia, hypertension and IHD prevention.
 - xi. Yoga and meditation .
 - xii. Primary oral hygiene and dental care.

B. Training of VHW-Time table.:

S.NO.	Topic	Time/Period-
1	Baseline data collection	1 st to 3 rd , of January .
2	Management of cardiovascular diseases.	1 st to 3 rd , February
	Yoga & Meditation (For general well being,)	4 th and 5 th February
3	Life style modification Management of Diarrhea, Malaria, Pneumonia, Revision of cardiovascular diseases and data collection.	5 th to 9 th March.
4	Management of Anemia, Tuberculosis & COAD ,tobacco and alcohol addiction. Life style modification. Revision of OLD.	2 nd to 5 th April.
5	Screening of people for Jaundice, HIV-AIDS, CNS infections, maternal complications-high risk pregnancies, oral malignancies,	2 nd to 5 th May

	& referral to hospital for treatment and follow up of treatment . Revision of old.	
6	Primary eye care. Dental care, Revision of old..	2 nd to 6 th June.
7	Refresher training.	2 nd to 4 th August
8	Refresher training.	2 nd to 4 th October
9	Refresher training.	2 nd to 4 th December

First year: 30 Days training. (9 training sessions)
Every year from Jan 2007 to Dec. 2015 – There will be 3 days refresher trainings on alternate months-even months(6 training session every year). So total training days will be 192 days for initial and refresher trainings.

3. Training of T. B. A. s

The T. B. A. s are trained in three workshops each of two-day duration. Experience sharing and providing helpful inputs to foster close collaboration between the V. H. Ws. and the TBAs is an essential feature of the TBA training.

4. Orientation of the project manager

Since the project manager is the person who is responsible for implementation of the MCPEPAG, it is most essential that he understands fully, each aspect of the implementation of MCPEPAG and hence an orientation workshop for the project manager is considered very important.

Annexure E: The Physical Inputs:

1. List of items in the VHW Kit and Medicine Stock

(The prevalence of Hypertension is 10% . Hence in the target population of 8000 in intervention area, 800 patients will be hypertensive . Hence on an average one village has 50 hypertensive patients.) (80% people are anemic-i.e. 6400 people in intervention area)
(10% of people will have at least 2 episodes of diarrhea or dysentery-presumption)
(20 tobacco addict and 10 alcohol addict will require drug treatment per village as per our survey and assumptions)

Sr. No.	Item	Make	Quantity per VHW
A.	Non -Recurring items		
1	Wrist Watch	Standard company	1
2	Digital Thermometer	Becton & Dickinson B-D or Hicks soft Flexible digital thermometer	1

3	Weighing Scale	Adult weighing scale (Digital / Spring)-company	1
4	Height scale – with stand. (Stadiometer)		1
5	Tape -6 feet		1
6	Ambu bag	-Phoenix, Chennai	1
7	Digital BP Apparatus(electronic)	Omron	1
8	Stethoscope,		
9	Peak flow meter		1
10	Health education booklet/flipchart	To be prepared	1
11	Photo album with photograph		1 album
12	Solar Torch	Can be purchased/ ordered locally	1
13	Trunk for storage of kit, records etc, size 22” x 12” x 10”	Can be purchased/ ordered locally	3
14	Bag for carrying kit/ material during home visits.	Can be purchased/ordered locally	1
Sr. No.	Item	Make	Quantity per VHW
B.	Recurring items		
1	Slides, spirit swabs, Needle		10 sets
2	Surgical cotton	Can be purchased/ ordered locally	1 bundle per month
3	Malaria Rapid Antigen test kits	Aspen lab	1 sets
4	Sputum collection cup	Collect from Govt. health department	30
5	HIV antibody rapid test kit	Tridot	100
6	Haemoglobin test - Hemoglobinometer		6400
7	Tab Paracetamol 500 mg	Locost -Can be purchased/ ordered locally	200 per month.
8	Tab Acetylsalicylic Acid 150 mg (Aspirin) (for adults)	Can be purchased/ ordered locally	3000 tablets per month
9	Tab antihypertensives (Enalapril/Amlodipine).	Can be purchased/ ordered locally	3000 tablets per month
10	Tablets Statins.	Patients will purchase	
11	Tablets sorbitrate (10 mg)	Can be purchased/ ordered locally.	3000 tablets per month
12	Spirit	Can be purchased/ ordered locally.	100 ml per month
13	Insulin Syringe (for injecting insulin actrapid/Mixtard)	Can be purchased/ ordered locally	10 per month
14			
15	Disposable syringe 2 ml.	Can be purchased/ ordered locally Dispovan	50
16	Tab Salbutamol- 4mg	Can be purchased/ ordered locally	20 per month
17	Injection Derriphylline	Can be purchased/ ordered locally	20
18	Tab. Derriphylline-Retard 300 mg	Can be purchased/ ordered locally	600 per month
19	Ipratropium bromide/ Tiotropium rotacaps,	Patients will purchase	
20	Salbutamol rotacaps		10 pack per month
21	Seroflow rotacaps		10 packs per month

22	Rota halers		20 per year
23	Influenza vaccine	Patients will purchase	12 per year
24	Cap. Amoxycillin 500 mg.	LOCOST / Can be purchased/ ordered locally	50 per month
25	Tab ferrous Sulphate + Folic acid 5 mg	LOCOST / Can be purchased/ ordered locally	40000 tablets per year
26	Tab folic acid (for elevated ApoB100/Apo A-I ratio)	Patients will purchase	
27	Eye ointment Chloromycetin eye applicap.	Can be purchased/ ordered locally	(100 per year)
28	Oral Rehydration packets.	Prepared in base hospital	400 packets per year
29	Tab. Albendazole	LOCOST /Can be purchased/ ordered locally	20 Per month
30	Tab. Chloroquine (150 mg)	LOCOST /Can be purchased/ ordered locally	50 per month
31	Tab. Artesunate (100 mg)or artesunate suppository	LOCOST /Can be purchased/ ordered locally	6 per month
32	Tab. Furoxone 100 mg	LOCOST /Can be purchased/ ordered locally	1500 tab. Per year
33	Tablet Metronidazole (400 mg)	LOCOST /Can be purchased/ ordered locally	2100 per year
34	Tablet Bupropion 150 mg. (1 BD for 6 months for 20 tobacco addict per village)	Can be purchased/ ordered locally	7000 per year
35	Nicotine replacement therapy spray /inhaler/gum.	Patients will purchase	10 per year
36	Tab. Naltrexone, 50–150 mg/or	Can be purchased/ patient will purchase	For 10 patients
Sr. No.	Item	Make	Quantity per VHW
37	injection Naltrexone (380 mg).	Can be purchased/ patient will purchase	For 10 patients
38	Acamprosate tab. (2 gm)	Can be purchased/ patient will purchase	For 10 patients
39	Librium 25 mg.	Can be purchased/ ordered locally	200 per year
40	Tab. Stemetil/Perinorm 5 mg.	Can be purchased/ ordered locally	15 per month.
	Injection Thiamine 100 mg	Can be purchased/ ordered locally	5 per month
41	Tab. Alerid 10 mg	Can be purchased/ ordered locally	10 tab. Per month.
42	Disposable plastic Mucus extractor	Ramsons (Can be purchased/ordered locally)	12 per year
43	Endotracheal tube		1
44	Antiseptic powder (10gram)	Can be purchased/ ordered locally	2-3 packs per month.
45	Adhesive plaster	Can be purchased/ ordered locally	1 pack per month

1. Medicine for dental care after consultation with dentist.

2. Ask about PAP smear to gynecologist.

(We may provide drugs free of cost or motivate patients to purchase it from us –at cost or LOW COST depot / outside shops, depending upon the situation).

2. Materials for study area patients which will be kept in base hospital and may be circulated to field area as per need.

Item	Quantity
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A. Recurring Items	
1. Injection streptokinase	12 per year
2. Glucostrix with lancet	8000
3. ECG -	1600 patients
4. CPKMB	25 patients.
5. Lipid profile	1600 patients
6. Liver function tests	100 patients
7. Peripheral smear	6000 patients
B. Non-recurring items	
1. Nebulizers	2
2. Glucometer (Accoutred alpha)	4
3. Oxygen cylinders	10
4. Spirometer	1

Annexure F : Ethical committee members:

- 1. Dr. Ulhas Jajoo (M.B.B.S, M.D.-Internal Medicine).
- 2. Dr. Vikas Bisne (M.B.B.S, M.D, D.M. & D.N.B.-Cardiology)
- 3. Respiratory physician.-Dr. Ajay Lanjewar. (M.B.B.S., D.T.C.D., D.N.B.)
- 4. Dentist.: Dr. Hazare (B.D.S., M.D.S.)
- 5. Psychiatrist.- Dr. _____ Saoji.
- 6. Gynecologist : Dr. Mrs. Kuthe. (M.B.B.S., DGO)
- 7. Ethicist.
- 8. Local community member- Ghota Sarpanch.
- 9. Community physician/member secretary- Dr. Devendra Khandait.
- 10. Social worker/ NGO-Sunil Deshpande/KHOJ

Annexure G: Data Safety Monitoring Board:

- 1. Epidemiologist.
- 2. Community physician-Dr. Dixit.
- 3. Statistician.
- 4. Local community member.

Annexure H :

Community Participation including awareness, consent and acceptance.

Local panchayats (Village Councils), women’s micro-credit groups (small saving groups) and Gramsabhas are some structures, which could be used for ensuring community participation.

Community participation may be sought at the following stages:

- a. Key person visits.
- b. Village meetings(Gram sabha).
- c. The village should be invited to recommend potential candidates for the work of V. H. Ws..
- d. Launch meetings.
- e. Periodic interactions with the village to give feedback and encourage suggestions.
- f. Small saving groups.
- g. Village health committee.
- h. Local panchayats (Village Councils),

Annexure I:

Plan for next 30 years after the trial:

- 1. To decrease LBW and premature babies and later complications in life as per Barkers Hypothesis:

Plan trial in Melghat : for next 40 years

- Education of pregnant mother- proper diet, rest, rest, no heavy work, no tobacco/alcohol, iodine rich salt, no extramarital sex to reduce LBW & SGA babies to prevent future generation with cardiovascular diseases.
- Iodine for mother
- 2. Replication of the model through govt. and other voluntary organizations in other backward area of world.
- 3. Lobbying for de addiction.

Instructions

- 1. Collect consent from community , participant –written**
- 2. data & safety monitoring committee/ Board (DSMB)?**
- 3. Checklist for attached documents:** PI ethical committee

Project proposal – 20 Copies	☐
Curriculum Vitae of Investigators	☐
Brief description of proposal	☐
Patient information sheet	☐
Informed Consent form	☐
Investigator’s brochure for recruiting subjects	☐
Copy of advertisements/Information brochures	☐
Copy of clinical trial protocol and/or questionnaire	☐
Institutional Ethics Committee clearance	☐
Institutional Animal Ethics Committee clearance	☐
CPCSEA clearance, if any	☐
HMSC/DCGI/DBT/BARC clearance if obtained	☐

- 4. High risk mother care : Saved many lives?**
(Suggestion from Ann.- consider female below 16 years who become pregnant).

- 5. . For Individuals**
☐All individuals concerned about biomedical ethics should be encouraged to form

National Forum. These fora should review the changing pattern of ethical issues and give appropriate suggestions to legislative authorities. They should also actively build up capacity in biomedical ethics.

☐ All interested individuals in the Region should become members of FERCAP (Forum For Ethical Review Committees in Asia and Western Pacific)

VI. Implementation of MCPEPAG

MCPEPAG is a community-based project concerning health and following are the main components of the implementation strategy:

A. Micro plan preparation.

This may be an early activity in the implementation and on the quality of the micro plan may depend success of the MCPEPAG approach.

The micro plan includes following:

- i) Objectives, activities and methods to be followed in the implementation of MCPEPAG. For Activities see Annexure 1.
- ii) Area profile including socio-economic profile of the villages. Annex 3.
- iii) Profile of the TRIBAL HEALTH RESEARCH PROJECT, MELGHAT (MAHAN TRUST) trust implementing the MCPEPAG. Annex 4.
- iv) Map of the area with topographic features. Annex 5.
- v) Distribution and allocation of villages to VHW : Each VHW have been allotted one villages considering accessibility .
- vi) Clear definitions of roles and responsibilities of categories of workers. Annex 6.
- vii) GANTT chart - Annex 2.
- viii) Description of basis for emoluments. At our project, it is found that on an average a VHW earns Rs.1000 to 1500/- per month and she has to put on an average only about three hours work per day. This emolument or earning in the scheme is as per her performance based calculation of payment due to her. (Budget , point 15)
- ix) Checklist for supervisor activities. Annex 7.
- x) Checklist for VHW activities. Annex 8.
- xi) Community involvement . Annex 9.
- xii) Financial requirements based on quantity of input. (Budget) Annex 10.
- xiii) Prior knowledge and practices (KP) of traditional care during pregnancy, & patient treatment.
- xiv) Involvement of the T. B. As.
- xv) Placement of the supervisor

Two full time medical supervisor will supervise the work of 17 V. H. Ws..

Section-C

BIODATA OF THE INVESTIGATOR(S)

1. Name (Dr./Kum./Smt./Shri)

First name(s)

Surname
2. Designation:
3. Complete Postal Address, Telephone Number, Fax, e-mail etc.
4. Date of Birth:
5. Educational Qualification : Degrees obtained (Begin with Bachelor's Degree)

Degree	Institution	Field(s)	Year
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Duration	Institution	Particulars of work done
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7. Research specialization (Major scientific fields of interest)
8. Important recent publications (last 5 years, with titles and References), including papers In press
9. *Financial support received
 1. From ICMR-no
Past
*Present
*Pending
 2. From other sources
Past
*Present
*Pending

* This information must be given, otherwise the application will be returned. In case no financial assistance has been received, nil should be stated. Indicate titles of the projects and reference number, if available, for ICMR grants.

To compare with WHO Standards: economically productive age group is 15 to 64 years.

1. Rao C, Gupta A, Gupta M, Yadav AK. Premature adult mortality in India: what is the size of the matter? *BMJ Glob Health*. 2021;6(6).
2. Gakidou E, Hogan M, Lopez AD. Adult mortality: time for a reappraisal. *International journal of epidemiology*. 2004;33(4):710-7.
3. DHS U. ADULT MORTALITY. ICF, 530 Gaither Road, Suite 500, Rockville, MD 20850, USA, Program DaHSD; 2002.
4. CDC. Measures of Risk. In: database] W-bISQaRSWo, editor. Atlanta; USA: Centers for Disease Control and Prevention; 2003.
5. Nabukalu D, Calazans JA, Marston M, Calvert C, Nakawooya H, Nansereko B, et al. Estimation of cause-specific mortality in Rakai, Uganda, using verbal autopsy 1999-2019. *Global health action*. 2024;17(1):2338635.
6. Schumacher AE, Kyu HH, Aali A, Abbafati C, Abbas J, Abbasgholizadeh R, et al. Global age-sex-specific mortality, life expectancy, and population estimates in 204 countries and territories and 811 subnational locations, 1950–2021, and the impact of the COVID-19 pandemic: a comprehensive demographic analysis for the Global Burden of Disease Study 2021. *The Lancet*. 2024;403(10440):1989-2056.
7. Gasiorowski A. ScotPHO Deprivation Profiles Technical Report v1.1. In: National Services S, editor. Scotland: National Services, Scotland; 2016. p. 21.
8. Bloom DE, Cafiero-Fonseca E.T., Candeias V, Adashi E., , Bloom L. GL, Jané-Llopis E., Lubet, A., Mitgang E, Carroll O'Brien J, , A S. Economics of Non-Communicable Diseases in India. In: Department of Global Health and Population HSoPH, editor. Geneva Switzerland: World Economic Forum and Harvard School of Public Health; 2014. p. 68.
9. Harris KM MM, Becker T., High and Rising Mortality Rates Among Working-Age Adults. Harris KM, Majmundar MK, Becker T, editors. Washington, DC: The National Academies Press; 2021. 596 p.
10. WHO. Adult mortality rate (probability of dying between 15 and 60 years per 1000 population). In: OBSERVATORY TGH, editor. Geneva Switzerland: WHO; 2023.
11. Rajaratnam JK, Marcus JR, Levin-Rector A, Chalupka AN, Wang H, Dwyer L, et al. Worldwide mortality in men and women aged 15–59 years from 1970 to 2010: a systematic analysis. *The Lancet*. 2010;375(9727):1704-20.
12. Masquelier B, Hug L, Sharrow D, You D, Mathers C, Gerland P, et al. Global, regional, and national mortality trends in youth aged 15-24 years between 1990 and 2019: a systematic analysis. *The Lancet Global health*. 2021;9(4):e409-e17.
13. Huffman MD, Ojji D, Lloyd-Jones DM. Improving Blood Pressure Control and Health Systems With Community Health Workers. *Jama*. 2017;318(11):1009-11.
14. Morisky DE, Green LW, Levine DM. Concurrent and Predictive Validity of a Self-Reported Measure of Medication Adherence. *Medical Care*. 1986;24(1):67-74.
15. Gaziano TA, Young CR, Fitzmaurice G, Atwood S, Gaziano JM. Laboratory-based versus non-laboratory-based method for assessment of cardiovascular disease risk: the NHANES I Follow-up Study cohort. *Lancet*. 2008;371(923-31).
16. National Heart Lung Blood Institute. Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7). Bethesda: NHLBI; 2003. Report No.: 03-5233.
17. National Heart Lung Blood Institute. Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (ATP III). Bethesda: NHLBI; 2002. Report No.: 02-5215.