

## Study Protocol

### **Study Protocol for Process Evaluation of Health and Wellness Center Programme in Bhandara district of Maharashtra**

#### **Abstract:**

**Background :** Ayushman Bharat programme, which was started by Government of India in 2018-19 ,which has two component. First component is up gradation of existing primary health centres and sub centres in to Health and Wellness centers(HWCs) , which will deliver comprehensive primary health care services at government facility level in rural area within no more than 30 minutes . Non-Communicable disease services is the integral part of comprehensive primary care . This study aims to assess availability and readiness of Health and Wellness centres at sub centres for provision of Non communicable disease Services in rural area of Bhandara district and to assess utilization of Non communicable disease Services in rural area of Bhandara district .

**Methodology:** This implementation research will be conducted in Health and Wellness Sub centers from rural areas of Bhandara district. It will include the facility assessment of Sub centers. Household survey will be conducted by a stratified multi-stage sampling design using Digital questionnaire Standardized and validated Facility survey Tool , Service delivery Tool and Household survey Tools. Data will be analyzed using STATA-14 software.

**Expected Results:** Increase in coverage and utilization of Non communicable disease Services in Health and Wellness Centre Subcenters in rural area and reduction in out of pocket expenditure of villagers is expected.

**Conclusion:** The proposed component of NCD services matches well with health and wellness programme targets in district and is helpful in delivery of non-communicable disease services in rural areas.

**Keywords :** Comprehensive, Primary Health Care, Health and Wellness Center , Non communicable Disease , Ayushman Bharat Programme.

#### **Background:**

Ayushman Bharat programme was started by Government of India in 2018-19 ,which has two component. First component is up gradation of existing primary health centres and sub centres in to Health and Wellness centers(HWCs) , which will deliver comprehensive primary health care services at government facility level in rural area within no more than 30 minutes . HWCs in rural area will be act as first point of contact to government health facility to deliver expanded set of health-care services. Second component is Pradhan Mantri Jan Arogya Yojana to provide financial help to population for hospitalization required

to access secondary and tertiary health care services. Previously government primary health care facility are providing services mainly related to Reproductive and child health services and communicable diseases which are nearly 20% health care need of population . Services for Non communicable diseases and other chronic diseases are major unmet need of population in rural area. HWCs is providing 12 services as a part of expanded range of services at SC and PHC level. Out of these services screening, prevention, control and management of non-communicable services is an need of majority of population. The major inputs at HWC SC level to deliver expanded range of services include a team of three service provider , one is Mid Level health provider , one female and one male health worker with support with ASHA per 1000 thousand population in SC area. HWC SC has adequate availability of medicine and diagnostics. HWC team had Tablet for digitalization of data keeping, and reporting like population enumeration , report of service delivery and keep a record of every individual for NCD screening, confirmation and follow up for treatment. Tele consultation facility is available at HWC SC level for seeking expert opinion , advice for some complicated cases. Performance based incentives are given to Health provider at SC level as per there achievements in various health programme indicators. (1)

Non-communicable diseases (NCDs), are chronic diseases of long duration and result of a multifactorial causation which include genetic, physiological, environmental and behaviours factors. As per the estimation of WHO NCDs are responsible for 41 million deaths in each year, which are 71% of all deaths globally. In the age group of 30 to 69 years 15 million people die from a NCD in every year. (2) Around 85% of premature deaths due to NCDs are occurred in low and middle income countries. The major 4 NCDs i.e. Cardiovascular diseases , Cancer, respiratory diseases and diabetes contributes around 80% of deaths out of total premature NCD deaths.

According to National family Health Survey 5 ( NFHS-5) which was conducted in 2019-20 burden of major NCD in age group of 15 year and above showed that In Maharashtra, 12.4% of women and 13.6% of men had high blood sugar level and taking medicine . wherever 24.4% of men and 23.1% of women had elevated blood pressure or taking medicine. (3) In Bhandara district 10.5% of women and 10.1% of men had blood sugar level high or taking medicine wherever 21.8% of women and 14.3% of men had elevated blood pressure or taking medicine (4)

In India due to increasing cases of NCDs Government of India launched National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) in 2010 with the objectives of life style modification through BCC to prevent NCDs and early diagnosis by screening , treatment and follow up of diagnosed cases to control NCDs and prevent premature deaths.(5)

In India 11.5% households in rural areas and about only 4% in urban areas are availing OPD care services ant PHC or SC level other than RCH services indicating low utilization of the

public health facilities for other common health problems. 75<sup>th</sup> National Sample Survey for the period July 2017 to June 2018 showed that 30.1% of population treated by Government hospitals, 65.8% of population taken treatment from Private hospitals or clinic. (6).

Process evaluation of any programme is an operational research conducted with the aim of improvement in coverage & effectiveness of programme through identify gaps and mitigate them.

### **Rationale:**

Bhandara district is one of the few districts in Maharashtra in which Health and Wellness programme was launched in 2019-20. In Bhandara out of total government health facility 28 PHC and 152 sub center was proposed for HWC in 2019-20 out of which 28 PHC and 46 sub center is operational in April 2019. However district health system are at varying stages of readiness to deliver this care universally to all populations in need. For successful implementation of HWC Programme Process evaluation is important in early phase of implementation of Programme and this type of evaluation of Health and Wellness Center Programme at Sub center level on coverage and utilization of Non communicable disease services in real field setting has been conducted so far in India.

### **Aim & Objectives:**

**AIM:** Process evaluation of Health and Wellness centre programme for provision of Non communicable disease services in rural area and to assess impact on coverage, utilization and out of pocket expenditure for NCD services in rural area of Bhandara district in Maharashtra.

#### **Objectives:**

- To assess availability and readiness of Health and Wellness centre sub centre for provision of Non communicable disease Services in rural area of Bhandara district.
- To assess coverage and utilization of Non communicable disease Services in rural area of Bhandara district.
- To assess impact on out of pocket expenditure (OOPE) for Non communicable disease Service in rural area of Bhandara district.

### **Hypotheses**

Increase in coverage and utilization of Non communicable disease services in rural area of Bhandara district at Sub center level on where Health and Wellness Center Programme implemented.

### **Methods:**

**Study Design:** Implementation research.

**Study setting:** The study will be carried out in rural area Bhandara district in Maharashtra.

**Study Population:** All population in the Health and Wellness sub center area in rural area of Bhandara district.

**Inclusion and Exclusion Criteria:**

All Health and Wellness Sub center which are operational till April 2019 will be included in study and individual who are residing in HWC SC area and above 30 yr of age at the time of data collection will be included in study

**Sampling Method and sample Size:**

**Facility Assessment:** In Bhandara District of Maharashtra 28 PHC and 75 sub centers was proposed for Health and Wellness programme in 2018-19 out of Which 28 PHC and 46 sub centre is operational till April 2019, these all 46 sub centre selected for assessment.

**Community Assessment:**

A stratified multi-stage sampling design will be used for household survey which method was adopted for the 75th round National Sample Survey by GOI. The first stage units (FSU) were the census villages in the rural area. The ultimate stage units (USU) will be households. In case of large FSUs, one intermediate stage of sampling will be the selection of two hamlet-groups (hg's) from each FSU.

Selection of households: From each SSS, the 10 households will be selected by simple random sampling without replacement (SRSWOR). Total 1750 household will be surveyed.

**Data collection Tool:** .

1. Facility survey Tool
2. Service delivery Tool
3. Household survey Tool

**Methods of Data Collection:**

Data collection for Household survey will be conducted by personal visit to randomly selected family and take permission from head of the family for data collection and then with the help of digital questionnaire data will be collected through interview with individual who are above 30 yr of age at the time of data collection will be included in study.

For facility assessment first take permission from District Health Officer for data collection in HWC facility in district and visit to selected HWC facility personally. In facility seek written permission from head of facility and digital questionnaire will be used for data collection through survey, key informant interviews, observation and verification of records for monthly reports.

**Data Management and Analysis:**

- Service availability indicators (Health infrastructure, Health workforce , Service Utilization) & Indices (Health infrastructure, Health workforce , Service Utilization and Service availability ) will be calculated.
- Access to health facility for NCD services will be calculated

- Out of Pocket Expenses (OOPE) for NCD services will be calculated.

**Table 1 : Indicator wise Purpose , tool and source of data collection**

Indicator	Purpose	Tool	Source
1. Physical Infrastructure	availability and readiness assessment	Facility assessment Checklist	Observation
2. Human Resource	availability and readiness assessment	Facility assessment Checklist	Observation
3. Equipments/ consumables	availability and readiness assessment	Facility assessment Checklist	Observation
4. Functional IT Equipment	availability and readiness assessment	Facility assessment Checklist	Observation
5. Drugs/ Medicine	availability and readiness assessment	Facility assessment Checklist	Observation
6. Diagnostic services	availability and readiness assessment	Facility assessment Checklist	Observation
1. NCD Service delivery at SC - Screening	Utilization of Facility	Service delivery Checklist	HMIS Data/ NCD Software/HWC software Data
2. NCD Service delivery at SC - Treatment	Utilization of Facility	Service delivery Checklist	HMIS Data/ NCD Software/HWC software Data
3. NCD Service delivery at SC - Follow up	Utilization of Facility	Service delivery Checklist	HMIS Data/ NCD Software/HWC software Data
4. NCD Service delivery at SC - Referral	Utilization of Facility	Service delivery Checklist	HMIS Data/ NCD Software/HWC software Data
5. Access to health facility by individual for NCD services	Coverage by Facility	Household survey	Interview with Participant
6. Sociodemographic profile of individual accessing HWC SC	Coverage by Facility	Household survey	Interview with Participant
7. Geographical profile of individual accessing HWC SC	Coverage by Facility	Household survey	Interview with Participant
8. Determinants for not accessing NCD services for HWC SC	Coverage by Facility	Household survey	Interview with Participant
9. No. of Individual above 30 yrscreened for NCD	Coverage by Facility	Household survey	Interview with Participant
10. No. of Individual above 30 yr Diagnosed for NCD	Coverage by Facility	Household survey	Interview with Participant
11. No. of Individual above 30 yr on treatment who are diagnosed NCD	Coverage by Facility	Household survey	Interview with Participant
12. No. of Individual above 30 yr on follow up who are diagnosed NCD	Coverage by Facility	Household survey	Interview with Participant
13. No. of Individual above 30 yr on referred who are diagnosed NCD	Coverage by Facility	Household survey	Interview with Participant
1. Facility wise out of out of pocket expenditure (OOPE) for Non communicable disease Services	Impact on OOPE	Household survey	Interview with Participant
2. Average out of out of pocket expenditure (OOPE) for Non communicable disease Services from HWC SC health facility	Impact on OOPE	Household survey	Interview with Participant

3. Facility wise out of out of pocket expenditure (OOPE) for Non communicable disease Services on Medical and Non medical expenses for health facility	Impact on OOPE	Household survey	Interview with Participant
--	----------------	------------------	----------------------------

**Study Duration :** Dec 2020 to Dec2021

**Ethical Consideration:**

- Institutional Ethics Committee of Datta Meghe institute of Medical Sciences given approval to carry out the study.
- Written permission from District Health Authority i.e. District Health Officer, Health department Bhandara taken to conduct facility survey in HWC SC in district.
- Informed written consent will be taken from MLHP/ANM/MPW for facility survey of their SC
- Informed written consent will be taken from participant for survey of their interview

**Expected Outcomes/Results:**

Increase in coverage and utilization of Non communicable disease Services in HWC SC public health facility in rural area and Decrease in out of pocket expenditure (OOPE) for Non communicable disease Services in rural area where Health and Wellness Center Programme implemented.

**Discussion:**

Key Results : HWC programme will create Population data base which include population enumeration and empanelment of every individual. HWC will provide access to NCDs related health services at periphery sub centre level which will reduced out of pocket expenditure on NCDs. Increase in utilization of sub center facility will decongestion of secondary and tertiary health facilities.

Universal health coverage pilot project in Tamilnadu was launched in 2017 in 3 block with expectation that over a period of time Health sub centre will cater larger and significant portion of outpatient care which will divert patient taking care from higher level government facility or private hospitals or clinic . It will also reduce average out of pocket expenditure for health care needs of population. Study conducted on project collected data through Household survey & Facility survey with primary survey of progress of UHC pilot project . The result showed remarkable change in improvement access to primary care at sub center level . It was also seen that taking care from private hospitals and clinic was fall down significantly and fall in per capita public expenditure per outpatient visit due to patient diverted from PHC/CHC/DH to health centers. In our study we are expecting the

same result for NCD health care services when provided at sub center level through Health and Wellness programme which is near to community. (7)

After launching of HWC programme at Sub center level we are expecting adequate availability of medicines and diagnostic services with additional trained manpower i.e. Mid level health provider with existing health worker to provide NCD services where in study conducted on preparedness for delivering NCD services in district of south India found that sufficient medicine was not available at Primary health facility due to which 76% individuals obtained medicines from private sector, shortage of availability of human resources like doctors and health worker and infrastructure for NCD service delivery. (8)

Quality of care is an important factor for utilization of health facility in HWC SC quality care will be provided through equipped with infrastructure , manpower , availability of digital and IT support which will increase utilization of sub center facility where study conducted to find out reasons for low utilization of public health facilities among household with hypertension in India find out that technical quality i.e. poor quality care , doctor not available, drugs not available and inadequate infrastructure are most common reason for non-utilization of government health facility. (9)

Equitable access to essential health services is key component of universal health coverage , as HWC SC are located in rural area we are expecting better access from all group of population in community through HWC SC for there NCD health care needs. In Study conducted in Kenya on Equity in access to non-communicable diseases medicine shown that poor population are less likely to have medicine at home for their NCDs , poor household are facing barrier to access NCD services from government facility due to which they are purchasing medicines from private which is financial burden for them.(10)

As in HWC SC health worker will get additional monetary incentives for NCD health services they will proactively worked for that digitalization of HWC by providing Tablet and Tele consultation facility will provide better NCD health care services while Operational research conducted in Ballabgarh project in India to identify the define and validate package for NCD services in primary health care system shown that opportunistic screening was more cost effective than domiciliary screening , health workers resisted for doing NCD work as it considered as additional work for them. Result was shown that with sufficient strengthening by provision of basic technologies and medicines primary health care system can deliver better NCD services. (11-12)

**Limitations :** This study is proposed to conduct only in one district which may not be represent whole country or state.

**Conclusion:** This study will help to give insight to what extent and how well HSC covers the scope of the proposed component of NCD services in HWC of the GoI. It will also help to monitor the implementation of health and wellness programme in district for health system

and study will help to find out the strengths and weaknesses in delivery of Non communicable disease services at Health and Wellness sub centre.

### References:

1. Operational Guidelines For Comprehensive Primary Health Care through Health and Wellness Centers.pdf [Internet]. [cited 2020 Dec 20]. Available from: <http://nhsrcindia.org/sites/default/files/Operational%20Guidelines%20For%20Comprehensive%20Primary%20Health%20Care%20through%20Health%20and%20Wellness%20Centers.pdf>
2. Riley L, Cowan M, World Health Organization. Noncommunicable diseases progress monitor, 2015 [Internet]. 2015 [cited 2020 Dec 20]. Available from: [http://apps.who.int/iris/bitstream/10665/184688/1/9789241509459\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/184688/1/9789241509459_eng.pdf)
3. FactSheet\_MH.pdf [Internet]. [cited 2020 Dec 22]. Available from: [http://rchiips.org/nfhs/NFHS-5\\_FCTS/FactSheet\\_MH.pdf](http://rchiips.org/nfhs/NFHS-5_FCTS/FactSheet_MH.pdf)
4. Bhandara.pdf [Internet]. [cited 2020 Dec 22]. Available from: [http://rchiips.org/nfhs/NFHS-5\\_FCTS/MH/Bhandara.pdf](http://rchiips.org/nfhs/NFHS-5_FCTS/MH/Bhandara.pdf)
5. Operational Guidelines of NPCDCS (Revised - 2013-17)\_1.pdf [Internet]. [cited 2020 Dec 22]. Available from: [https://main.mohfw.gov.in/sites/default/files/Operational%20Guidelines%20of%20NPCDCS%20%28Revised%20-%202013-17%29\\_1.pdf](https://main.mohfw.gov.in/sites/default/files/Operational%20Guidelines%20of%20NPCDCS%20%28Revised%20-%202013-17%29_1.pdf)
6. KI\_Health\_75th\_Final.pdf [Internet]. [cited 2020 Dec 22]. Available from: [http://mospi.nic.in/sites/default/files/publication\\_reports/KI\\_Health\\_75th\\_Final.pdf](http://mospi.nic.in/sites/default/files/publication_reports/KI_Health_75th_Final.pdf)
7. Muraleedharan V, Dash U, Vaishnavi S, Meena R, Meghraj R. Universal Health Coverage - Pilot in Tamil Nadu: Has it delivered what was expected? 2018.
8. Elias MA, Pati MK, Aivalli P, Srinath B, Munegowda C, Shroff ZC, et al. Preparedness for delivering non-communicable disease services in primary care: access to medicines for diabetes and hypertension in a district in south India. *BMJ Glob Health*. 2018 Jan;2(Suppl 3):e000519.
9. Kujawski SA, Leslie HH, Prabhakaran D, Singh K, Kruk ME. Reasons for low utilisation of public facilities among households with hypertension: analysis of a population-based survey in India. *BMJ Glob Health*. 2018 Dec;3(6):e001002.
10. Rockers PC, Laing RO, Wirtz VJ. Equity in access to non-communicable disease medicines: a cross-sectional study in Kenya. *BMJ Glob Health*. 2018 Jun;3(3):e000828.
11. FAUTH. Lessons for addressing noncommunicable diseases within a primary health-care system from the Ballabgarh project, India. [DATE] [cited 2020 Dec 23]; Available from:

<http://www.who-seajph.org/printarticle.asp?issn=2224-3151;year=2015;volume=4;issue=2;spage=130;epage=138;aulast=Amarchand>

12. Khatib N, Gaidhane S, Gaidhane AM, Khatib M, Simkhada P, Gode D, Zahiruddin QS. Ghrelin: ghrelin as a regulatory Peptide in growth hormone secretion. Journal of clinical and diagnostic research: JCDR. 2014 Aug;8(8):MC13.

UNDER PEER REVIEW