

BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email info.bmjopen@bmj.com

BMJ Open

Integrated multisectoral strategy to improve girls' and women's nutrition before conception, during pregnancy and after birth in India (Swabhimaan): a prospective, non-randomized controlled evaluation

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-031632
Article Type:	Protocol
Date Submitted by the Author:	13-May-2019
Complete List of Authors:	Sethi, Vani ; UNICEF India Bhanot, Arti; Independent consultant, ; Bhattacharjee, Sourav Gope, Rajkumar ; Ekjut Sarangi, Debjeet Nath, Vikash Nair, Nirmala; Ekjut, Singh, Usha Daniel, Abner Parhi, Rabi Sinha, Sonali Loomba, Avinash S, Somya Purty, Apollo Ali, Naushad Mohapatra, Babita Agarwal, Neeraj; All India Institute of Medical Sciences (AIIMS), Patna Bhatia, Vikas Ruikar, Manisha Sahu, Bharati RS, Reshmi Pedgaonkar, Sarang Dwivedi, Laxmi Kant; International Insititute of Population Sciences, Saiyed, Farhat Prajapati, Mahendra Mishra, Preetu Prost, Audrey ; London School of Hygiene and Tropical Medicine, Global Health and Development Kejrewal, Nita Wagt, Arjan Sachdev, Harshpal; Sitaram Bhartia Institute of Science and Research, Department of Paediatrics Unisa, Sayeed; International Institute for Population Sciences, Mathematical Demography and Statistics
Keywords:	Adolescent girls, Nutrition < TROPICAL MEDICINE, Agriculture, Mutli-sector, Women collectives, India

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60



SCHOLARONE™
Manuscripts

1 STUDY PROTOCOL

2 Title

3 Integrated multisectoral strategy to improve girls' and women's nutrition before conception, during
4 pregnancy and after birth in India (Swabhimaan): a prospective, non-randomized controlled
5 evaluation

7 Authors

8 Vani Sethi¹ vsethi@unicef.org, Arti Bhanot² arti.bhanot@gmail.com, Sourav Bhattacharjee³
9 sbhattacharjee@unicef.org, Rajkumar Gope⁴ rajkumar.ekjut@gmail.com, Debjeet Sarangi⁵
10 livingfarms@gmail.com, Vikash Nath⁴ vikash.ekjut@gmail.com, Nirmala Nair⁴
11 nirmala.ekjut@gmail.com, Usha Singh⁶ usha_pusa@yahoo.co.in, Abner Daniel¹ adaniel@unicef.org,
12 Rabi N Parhi⁷ rparhi@unicef.org, Sonali Sinha³ ssonali.sss@gmail.com, Avinash Loomba⁸
13 avinash.lumba@gmail.com, Somya S⁹ somya@brlp.in, Apollo Purty⁹ apollo@brlp.in, Naushad Ali²
14 nsz2004@gmail.com, Babita Mohapatra¹⁰ apdpro.tripti@gmail.com, Neeraj
15 Agrawal¹¹ neeraj502@rediffmail.com, Vikas Bhatia¹² bhatiaaiims@gmail.com, Manisha
16 Ruikar¹³ manisharuikar@rediffmail.com, Bharti Sahu¹⁴ sahubharati2@gmail.com, Reshmi
17 RS¹⁴ reshmi@iips.net, Sarang Pedgaonkar¹⁴ drsarangpedgaonkar@gmail.com, Laxmi Kant Dwivedi¹⁴
18 laxmikant@iips.net, Farhat Saiyed⁸ fsaiyed@unicef.org, Mahendra Prajapati⁴
19 maprajapati@unicef.org, Preetu Mishra⁸ pmishra@unicef.org, Audrey Prost¹⁵
20 Audrey.Prost@lshtm.ac.uk, Nita Kejrewal¹⁶ n.kejrewal@nic.in, Arjan De Wagt¹ adewagt@unicef.org,
21 H.P.S. Sachdev¹⁷ hpssachdev@gmail.com, Sayeed Unisa¹⁴ unisa@iips.net.

22
23 ¹ Nutrition Section, UNICEF India, Country Office, New Delhi, India

24 ² Independent consultant

25 ³ UNICEF India, Field Office Odisha, Bhubaneswar, India

26 ⁴ Ekjut, Jharkhand, India

27 ⁵ Living Farms, Odisha, India

28 ⁶ Dr. Rajendra Prasad Central Agriculture University, Bihar, India

- 1
2
3 29 ⁷ UNICEF India, Field Office Bihar, Patna, India
4
5 30 ⁸ UNICEF India, Field Office Chhattisgarh, Raipur, India
6
7 31 ⁹ Bihar Rural Livelihoods Promotion Society, Bihar, India
8
9 32 ¹⁰ Odisha Livelihoods Mission, Odisha, India
10
11 33 ¹¹ All India Institute of Medical Sciences (AIIMS), Patna India
12
13 34 ¹² All India Institute of Medical Sciences (AIIMS), Bhubaneswar, India
14
15 35 ¹³ All India Institute of Medical Sciences (AIIMS), Raipur, India
16
17 36 ¹⁴ International Institute for Population Sciences, Mumbai, India
18
19 37 ¹⁵ Institute for Global Health, University College London, United Kingdom
20
21 38 ¹⁶ Deendayal Antyodaya Yojana, National Rural Livelihoods Mission, India
22
23 39 ¹⁷ Sitaram Bhartia Institute of Science and Research, New Delhi, India
24
25
26
27
28

29 41 **Corresponding author**

30 42 Vani Sethi vsethi@unicef.org
31
32
33
34

35 44 **ABSTRACT**

36 45 **Introduction**

37 46 Swabhimaan is community-based programme to improve adolescent girls' and women's nutrition in
38 47 rural areas of three Indian states- Bihar, Chhattisgarh and Odisha with high prevalence of
39 48 undernutrition among women, high fertility and high proportion of young mothers.

40 49 **Methods and analysis**

41 50 Swabhimaan has a nested prospective, non-randomized controlled evaluation. Five intervention sites
42 51 receive community-led interventions through national government's livelihood mission supported
43 52 women's self-help group federations (or Village Organisations) since 2017 and five control sites will
44 53 initiate these activities 36 months later, in 2020. The evaluation includes baseline (2016-17), midline
45 54 (2018-19) and endline (2020-21) surveys. Baseline survey covered 6352 adolescent girls, 2573
46 55 pregnant women and 8755 mothers of children under two. The final impact analysis will be by
47 56 intention-to-treat, comparing primary and secondary outcomes in five intervention areas and five

1
2
3 57 control areas. This analysis will be carried out at an individual level, adjusting for clustering at the
4
5 58 level of the village and Village Organisation, using linear and logistic random effects models in
6
7 59 STATA 14. The expected outcomes are: (1) a 15% reduction in the proportion of adolescent girls
8
9 60 with a Body Mass Index (BMI) <18.5; (2) a 15% reduction in the proportion of mothers of children
10
11 61 under two with a BMI<18.5; (3) and a 0.4cm improvement in mean mid-upper arm circumference
12
13 62 among pregnant women; and (4) improvements of between 5% and 20% in the coverage of key
14
15 63 nutrition interventions over three years.

17 64 **Ethics**

18
19
20 65 All procedures involving human subjects were approved by the Institutional Ethics Committee of the
21
22 66 All India Institute of Medical Sciences (AIIMS), Bihar, Chhattisgarh and Odisha and in compliance
23
24 67 with guidelines laid down in the Declaration of Helsinki.

25 26 68 **Evaluation registration**

27
28 69 The evaluation is registered with the Registry for International Development Impact Evaluation
29
30 70 (RIDIE-STUDY-ID-58261b2f46876) and the Indian Council of Medical Research, National Clinical
31
32 71 Trials Registry of India (CTRI/2016/11/007482)

33 34 72 **Key words**

35
36 73 Adolescent girls, nutrition, agriculture, multi-sector, women collectives, India
37
38 74

39 40 41 75 **STRENGTHS AND LIMITATIONS OF THIS STUDY**

- 42
43 76 ■ The study will provide evidence on effectiveness of a community-led model in delivering a
44
45 77 comprehensive package of 18 nutrition services, on improving nutrition status of adolescent girls,
46
47 78 pregnant women and mothers of children under two in resource-poor settings.
- 48
49 79 ■ The model is based on sustainable government resources with only one of the three states
50
51 80 receiving additional non-government funding to test the model.
- 52
53 81 ■ The pace of implementation will vary considerably across three states due to variable governance,
54
55 82 availability of resources, maturity of self-help groups and intensity of non-government
56
57 83 engagement which is likely to impact the study outcomes.
- 58
59
60

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

- 84 ▪ While the design includes a comparator site, introduction of new government schemes that can
- 85 have variable influence in intervention and control sites are not ruled out.
- 86 ▪ The evaluation is led by an independent third party with no role in implementation of the model.

For peer review only

89 INTRODUCTION

90 There is compelling evidence on the importance of women's nutrition prior to and during pregnancy,
91 to ensure optimal foetal growth and development and for the health and wellbeing of the mother [1].
92 Globally, over 800,000 neonatal deaths and 20% of stunting in children less than five years of age is
93 attributable to poor nutrition in utero, including protein-energy and micronutrient deficiencies [2].
94 Nearly 4.5 million Indian women become pregnant in adolescence, 58% have anaemia and 23% are
95 thin. It is unsurprising that over 50 million children under-five (38%) are stunted [3,4]. India has both
96 policies and programs in place to deliver and monitor globally-recommended preconception and
97 antenatal nutrition interventions. Most recently, India's National Nutrition Mission or Poshan
98 Abhiyaan (2018-22) aims to reduce the proportion of children born with low birthweight from 19% to
99 11% and under-five children stunted from 38% to 13% respectively, by 2022. It also aims to reduce
100 anaemia among adolescent girls and pregnant women, which is over 50%, by 3% per annum. This is
101 to be achieved through coordinated efforts across 11 different ministries that together can make all
102 essential nutrition services available to women and children through integration of their ongoing
103 vertical programmes and schemes [5]. Despite these policies and programmes, in 2015-16 the
104 coverage of at least four antenatal care visits was just over 50%, only a third of pregnant women
105 consumed Iron Folic Acid (IFA) tablets for at least 100 days during pregnancy, and less than 40%
106 used the maternity benefit scheme [3]. Challenge lies in lack of effective operational models to deliver
107 a comprehensive package of essential nutrition interventions for adolescent girls and women, models
108 that can overcome both systemic challenges and those around user service uptake.

109
110 Evidence from randomized controlled trials within and outside India suggests that working with
111 women's groups as a platform for promoting health interventions and increasing service uptake is a
112 feasible approach in low-resource settings [6,7,8,9,10]. This is provided the necessary requisites, such
113 as high-quality facilitators for establishing and maintaining the group, high coverage of intervention,
114 sufficient time for implementation of the intervention, concomitant supply strengthening interventions
115 and appropriate safeguards against harm such as conflict with service providers and domestic

1
2
3 116 violence, are met. However, none of these trials investigated nutrition outcomes for adolescent girls or
4
5 117 women.

6
7 118

8
9 119 In view of the undisputed role of income poverty in the aetiology of undernutrition, there is a need to
10
11 120 integrate women-centric poverty alleviation in nutrition programs and vice-versa. Notable global
12
13 121 examples where women's collectives have been engaged with to deliver services and promote health
14
15 122 and nutrition behaviours in underserved communities, along with economic empowerment include a
16
17 123 community conditional cash transfer programme in Indonesia, as well as livelihood and food security
18
19 124 programmes in Bangladesh (Shouhardo, Jibaon-o-Jibika) and Nepal (Suaahara) [11,12]. Indian
20
21 125 experiences include Kudumbashree (Kerala), the Society for Elimination of Rural Poverty Project
22
23 126 (Andhra Pradesh and Telangana), Self Employed Women's Association (rural areas of several states),
24
25 127 Community Health Care Management Initiative (West Bengal), Jamkhed (Maharashtra), and urban
26
27 128 health models by the Urban Health Resource Centre and Mahila Abhivrudhi Society, Andhra Pradesh.
28
29 129 Women's groups are trained on promotion of the health and nutrition interventions, the scope and
30
31 130 duration of training varying with the type of programme. The promoting agency, which is mostly a
32
33 131 non-government organisation or federated structure, provides capacity building and supervisory
34
35 132 support. Most programmes strengthen the health services delivery system in addition to intervening
36
37 133 with community groups [13,14].
38
39
40

41 134

42
43 135 Women's SHGs and their federations supported by the Deendayal Antyodaya Yojana -National Rural
44
45 136 Livelihoods Mission (DAY-NRLM)'s Government of India's flagship poverty alleviation program,
46
47 137 remain an untapped platform for improving reach and use of essential nutrition interventions,
48
49 138 particularly for women residing in income-constrained settings [15]. A 2016 scoping study from
50
51 139 UNICEF India suggested that DAY-NRLM village organisations have the potential to manage grants
52
53 140 for improving last mile delivery of essential nutrition services for women, provided they are enabled,
54
55 141 supervised and incentivised [16]. DAY-NRLM is also one of the nodal agencies for implementation
56
57 142 of the Poshan Abhiyaan. Capitalising on this, the Swabhimaan programme is a four-year initiative
58
59 143 launched in 2016 to improve adolescent girls' and women's nutrition.
60

1
2
3 144 Swabhimaan is a package of community-led interventions delivered by DAY-NRLM-supported
4
5 145 federations of women self-help groups (SHGs) comprising Village Organizations (VOs) and the
6
7 146 higher order Cluster-Level Federations (CLFs), to improve the nutrition status of adolescent girls and
8
9 147 women in three Indian states: Bihar, Chhattisgarh and Odisha. The objectives of the program are:

- 11 148 1. To improve the food and nutrient intake of adolescent girls and women
12
13 149 2. To prevent micronutrient deficiencies and nutritional anaemia
14
15 150 3. To increase access to services during fixed day, Village Health Sanitation and Nutrition Days
16
17 151 (VHSNDs) and provide special care to nutritionally 'at risk' women, defined as those with mid-
18
19 152 upper arm circumference (MUAC) <23 cm or Body Mass Index (BMI)<18.5 kg/m²
20
21 153 4. To increase access to education about water, sanitation and hygiene (WASH) and access to
22
23 154 WASH commodities
24
25 155 To prevent early, poorly spaced and repeated pregnancies
26
27 156

30 157 **METHODS AND ANALYSIS**

32 158 This protocol describes the intervention and evaluation methods for the Swabhimaan program, which
33
34 159 aims to improve the nutrition status of adolescent girls and women in three Indian states: Bihar,
35
36 160 Chhattisgarh and Odisha.

39 161 **Intervention target groups**

41 162 The primary target groups for the program are adolescent girls, newlywed women and couples,
42
43 163 pregnant women, and mothers of children under two years of age. Swabhimaan also reaches out to
44
45 164 husbands, mothers-in-law and farmer producer groups.

47 165 **Intervention processes**

49 166 Swabhimaan's technical package of 18 nutrition-specific and nutrition-sensitive interventions includes
50
51 167 interventions to improve the adequacy of food consumed in terms of both quantity and quality, the
52
53 168 prevention of micronutrient deficiencies including anaemia, access to basic health services, and
54
55 169 special care of nutritionally "at risk" women, identified as those with MUAC <23 cm or Body Mass
56
57 170 Index (BMI)<18.5 kg/m², where latter is available, improving hygiene and access to water and
58
59 171 sanitation services and preventing early, too many and too soon pregnancies (Table 1).
60

172 **Table 1 Nutrition-specific and nutrition-sensitive interventions package, Swabhimaan**

	Relevant target group		
	Preconception	Pregnancy	Lactation
Improve food and nutrient intake			
1. Access to generalized household ration through Public Distribution System (PDS), a food subsidy scheme	*	*	*
2. Balanced energy protein supplementation through access to supplementary rations	*	*	*
3. Access to knowledge and choices about how to increase maternal dietary diversity	*	*	*
4. Access to knowledge and support for nutrition-sensitive agriculture at home (kitchen garden) and community based food insecurity coping strategies.	*	*	*
Prevent micronutrient deficiencies and anaemia			
5. IFA supplementation	*	*	*
6. Universal use of iodized salt	*	*	*
7. Calcium supplementation and deworming	X	*	*
8. Access to information and commodities like insecticide treated bed-nets for malaria prevention	*	*	*
9. Access to information on preventing tobacco and alcohol use in pregnancy	X	*	*
Increase access to health services and special care to nutritionally “at risk” women			
10. Early registration in outreach services	*	*	X
11. Recording and monitoring of nutritional status and special community-based at-nutritional risk package	X	*	X

12. Quality reproductive health, antenatal and postnatal care	*	*	*
13. Access to knowledge and entitlements for promotion of institutional deliveries and maternity benefits	X	*	*

Increase access to education and commodities for

WASH

14. Sanitation and hygiene (including menstrual hygiene) education	*	*	*
15. Access to safe drinking water and sanitation commodities	*	*	*

Prevent early, poorly spaced or unwanted pregnancies

16. Promotion of secondary education and education for delaying the age at marriage to legal age	*	X	X
17. Access to information and family planning commodities for delaying age at first pregnancy and prevention of repeated pregnancies	*	*	*
18. Women's collective voice and empowerment for decision-making to prevent child marriage, violence against women, child spacing and other gender-related issues	*	*	*

173

174 In intervention sites, these interventions are delivered through a combination of community- and
 175 systems-led efforts, while control sites receive only systems strengthening. Community-led
 176 interventions are delivered through trained community cadre who are members of VOs, namely
 177 Poshan Sakhis (lit. 'Nutrition sister/friend') or Community Resource Persons (CRPs) and Krishi
 178 Mitras (lit. farmer friends) or Village Resource Persons (VRPs). The community cadre are part of the
 179 DAY-NRLM and SRLM implementation structure. In Bihar, a separate cadre of Kishori Sakhis (lit.
 180 'Adolescent sister/friend') for reaching out and serving adolescent girls has been created (Table 2).

181 **Table 2 Geographic scope and service providers for community-led interventions under**
 182 **Swabhimaan**

	Bihar	Chhattisgarh	Odisha	Total
Revenue villages	77	111	168	356
CLF and related (Tier -3)	5	4	12	21
VOs (Tier 2)	72	80	79	231
Poshan Sakhis or CRPs of Tier 2	72	100	79	251
Kishori Sakhis of Tier 2	72	-	-	72
SHGs (Tier-1)	1985	1488	702	4175
VRPs/Krishi mitras	115	80	39	234

183

184 Poshan Sakhis and Kishori Sakhis undergo three days of pre-service training on integrated nutrition
 185 microplanning, which includes a theoretical orientation and practical on consultative identification
 186 and prioritization of nutrition and related problems among target groups in their village/s, developing
 187 an annual plan of activities including a budget to address these problems, the use of MUAC tapes,
 188 recording and using MUAC measurements for screening nutritionally “at risk” adolescent girls and
 189 women. As no standard MUAC cut-offs are available for screening adolescent girls at risk of
 190 undernutrition and <21 cm as well as <22 cm have been reported in research, a stricter cut-off of <19
 191 cm is being used to identify those, most at risk [17,18,19]. In addition, clinical examination for signs
 192 of anaemia is also done. Post-training, they co-facilitate the development of the integrated nutrition
 193 microplan with the block coordinator/ supervisor through a 12-day process, which can spread over
 194 almost two months. The process entails microplanning at VO level, its validation by reaching out to
 195 the most vulnerable communities and village clusters, then consolidation of all VO plans at CLF and
 196 block levels. Poshan Sakhis and Kishori Sakhis are then trained over three days on use of
 197 participatory learning and action (PLA) to facilitate monthly women’s group and adolescent girls’
 198 group meetings. Poshan Sakhis and Kishori Sakhis lead activities in their village/s as per decided

199 activities in the microplan. More cost-intensive and complex grant management activities are led by
 200 CLFs (Table 3).

201 **Table 3 Community led interventions under Swabhimaan**

Responsible agency / Service provider	Intervention	Frequency
VO		
Social action committee	Selection of Poshan Sakhi (1 per VO)	One time
Poshan sakhi/CRP	Integrated nutrition microplanning (12 days over 2 months)	Once, followed by annual review
	Maitri bethak (lit. friendly meeting) of women open to non-group members using Participatory Learning and Action	Monthly
	One additional monthly home visit/group meeting of nutritionally “at risk” women	Monthly
Krishi mitra/ VRP	Maitri kishan bethak (lit. friendly farmers meeting) on nutrition-sensitive agriculture Participatory Learning and Action	Monthly
	Home-based Poshan beds/backyard poultry	Monthly
CLF		
Social action committee	Families with women and children at risk of undernutrition linked to agri-poultry linkage and social protection schemes	Monthly
	Loans for secondary education	Monthly
	Creating farmer training school sites	Monthly
	Training for Poshan sakhi and Krishi mitras	Quarterly
	Newly wed couples meetings	Biannual
	Entitlement camps and health checkups for SHG	Biannual

members

Review of integrated nutrition plan

Annual

202

203 The CRPs receive INR 450 (USD 7) for developing the poshan microplan and thereafter a similar
 204 incentive every month for completed activities. CLFs also receive grants including: INR 500 (~USD
 205 7) for meetings with newlywed couples; INR 500 for each 'welcome kit' given to newlywed couples
 206 with essential items like IFA, contraceptives, sanitary napkins; INR 1500 (~USD 22) for review of
 207 each VO's integrated nutrition microplan; and INR 5000 (~USD 77) for developing farmer training
 208 school sites which are model nutri-farms for training farmer producer group members interested in
 209 nutri-sensitive agriculture.

210 The system strengthening activities include five components:

211 1) strengthening VHSNDs to improve access to antenatal care, family planning and micronutrient
 212 supplementation through quarterly trainings of health service providers, monthly review of nutrition
 213 indicators, and the identification of women at risk of undernutrition (MUAC <23cm) for special
 214 supplementary food and counselling;

215 2) Strengthening adolescent health days to improve access to adolescent health and nutrition services
 216 via quarterly trainings of health service providers;

217 3) an extended VHSND once every six months for newlyweds and women, including individual
 218 counselling and information about entitlement camps;

219 4) annual training and follow-up meetings with service providers from food security, Integrated Child
 220 Development Services (ICDS), water and sanitation departments to help them improve the delivery of
 221 entitlements and services;

222 5) ensuring regular review meetings with representation across government departments involved in
 223 service delivery (Table 4).

224 **Table 4 Service providers engaged in system strengthening interventions under Swabhimaan**

	Bihar	Chhattisgarh	Odisha	Total
ASHA	252	471	212	935

AWW	261	358	304	923
ANMs	49	58	33	140
Lady Supervisors	9	7	12	28
Fair Price Shop owners	109	78	46	233

225 * Auxiliary Nurse Midwife (ANM), Accredited Social Health Activist (ASHA) and Anganwadi
226 Worker (AWW)

227

228 Thus, in addition to DAY-NRLM, system strengthening activities engage four other government
229 departments: Department of Woman and Child Development for increasing ICDS reach and quality,
230 Department of Health and Family Welfare for VHSND strengthening, Department of Water and
231 Sanitation for improving water quality and achieving open defecation free villages and districts, and
232 finally Department of Civil and Food Supply for increasing coverage of food subsidy schemes.

233

234 **Study design**

235 The Swabhimaan evaluation is a prospective, non-randomized controlled study with baseline, midline
236 and endline cross-sectional surveys. Across Bihar, Chhattisgarh and Odisha, five areas (intervention
237 arm) have been purposively allocated to community-led interventions delivered through VOs and
238 CLFs since 2017, and five remaining areas (control arm) will initiate these activities 36 months later,
239 in 2020. Both intervention and control sites are located in the poorest areas (also referred to as
240 resource blocks) identified by DAY-NRLM in four districts: Purnea in Bihar, Bastar in Chhattisgarh,
241 and Angul and Koraput in Odisha. In Bihar, within Kasba and Jalalgarh blocks located in Purnea
242 district, we allocated two clusters of villages to the intervention and one to act as control. In
243 Chhattisgarh, we allocated Bastar block in Bastar district to intervention and Bakawand block to
244 control. In Odisha, 12 gram panchayats (an administrative structure comprising around five villages)
245 within Koraput block in the district of Koraput and Pallahara block in the district of Angul both serve
246 as intervention areas, and 14 remaining gram panchayats serve as control. The unit of assignment to
247 intervention and control is an area comprising a defined number of villages. There are a total of five
248 intervention and five control areas across three states, as follows:

- 249 - Bihar: two intervention areas (42 villages across two blocks); two control area (31 villages
 250 across two blocks)
- 251 - Chhattisgarh: one intervention area (40 villages); one control area (40 villages)
- 252 - Odisha: two intervention areas (80 villages across two blocks); two control areas (80 villages
 253 across two blocks)

254

255 **Study hypotheses and outcomes**

256 We hypothesize that, over an intervention period of three years, Swabhimaan's community-led
 257 interventions will lead to:

- 258 (a) a 15% reduction in the proportion of adolescent girls with a BMI<18.5
- 259 (b) a 15% reduction in the proportion of mothers of children under two with a BMI<18.5
- 260 (c) a 0.4cm improvement in mean MUAC among pregnant women

261 These three indicators are considered the evaluation's primary outcomes.

262 We also hypothesize an improvement of between 5% and 20% in the coverage of 18 key nutrition-
 263 specific and -sensitive interventions over three years (Table 5). These constitute the evaluation's
 264 secondary outcomes. The International Institute of Population Sciences, Mumbai is Swabhimaan's
 265 independent impact evaluation partner.

266 **Table 5 Primary and secondary outcomes for Swabhimaan**

PRIMARY OUTCOMES	
1.	% adolescent girls with BMI <18.5 kg/m ²
2.	mean MUAC among pregnant women
3.	% mothers of children under 2 with <18.5 kg/m ²
SECONDARY OUTCOMES	
ADOLESCENT GIRLS (Girls aged 10-19) – unmarried, not pregnant and not the mother of a child under two	
1.	Mean dietary diversity score
2.	% receiving minimum dietary diversity score (MDD) (5

of 10 food groups)

3. % consuming four or more IFA tablets in the month

preceding the survey

4. % living in a household with iodized salt

5. % living in food secure households

6. % living in households with a kitchen garden

7. % living in households with a toilet or covered pit latrine

8. % using safe pads or sanitary pads

9. % accessing adolescent health services (Kishori Divas) in

six months preceding the survey

10. % who attended at least three Kishori meetings in six

months

11. % who attended at least three Kishori meetings in in six

months

PREGNANT WOMEN (if she is pregnant, a girl or woman will

join this category whether she is an adolescent, newlywed or the

mother of any child under two)

1. % of pregnant women in the 2nd and 3rd trimester

consuming at least 25 IFA tablets in the month preceding the

survey

2. Mean dietary diversity score

3. % receiving minimum dietary diversity (5 out of 10 food

groups)

4. % living in a household with iodized salt

5. % living in food secure households

6. % living in households with a kitchen garden

7. % living in households with a toilet or covered pit latrine

1
2
3 8. % receiving ICDS entitlement for supplementary food in
4
5 month preceding the survey

6
7 9. % who had one antenatal check-up in the first trimester

8
9 10. % weighed at least once in first trimester

10
11 11. % who received one dose of albendazole in second
12
13 trimester

14
15 12. % who took two calcium tablets in 2nd trimester

16
17 13. % below the age of eighteen

18
19 14. % who attended at least three Maitri Bethak meetings in
20
21 six months

22
23 15. % who attended at least three Maitri Bethak meetings in
24
25 six months

26
27 16. % who attended at least three VHSNDs in six months

28
29 17. % who attended at least three VHSNDs in six months

30
31 18. % using a modern family planning method (in previous
32
33 delivery); before the current pregnancy

34
35 19. % who are members of women's Ag-producer groups and
36
37 have adopted at least 1 mix micronutrient-rich cropping methods,
38
39 against previous practice

40
41 20. % who are members of women's Ag-producer groups and
42
43 have adopted at least 1 pesticide-free agri-methods, against
44
45 previous practice

46
47
48
49 **MOTHERS OF CHILDREN AGED UNDER TWO YEARS**

50
51 1. Mean dietary diversity score

52
53 2. % receiving minimum dietary diversity (5 out of 10 food
54
55 groups)

56
57 3. % living in a household with iodized salt

4. % living in food secure households
5. % living in households with a kitchen garden
6. % living in households with a toilet or covered pit latrine
7. % receiving their minimum PDS entitlement in month preceding survey
8. % receiving ICDS entitlement for supplementary food in month preceding survey
9. % who received at least four ANC overall in last pregnancy
10. % consuming 100 or more IFA tablets during last pregnancy
11. % weighed at least four times in last pregnancy
12. % using a modern family planning method
13. % who accessed at least one of three social protection schemes (JSY, Adarsh Dampati Yojana)
14. % who delivered in a health facility in last pregnancy
15. % who attended at least three Maitri Bethak meetings and three VHSNDs in last year
16. % who attended at least three Maitri Bethak meetings and three VHSNDs in last year
17. % who are members of women's Ag-producer groups and have adopted at least 1 mix micronutrient-rich cropping methods, against previous practice
18. % who are members of women's Ag-producer groups and have adopted at least 1 pesticide-free agri-methods, against previous practice

267

268 The theory of change for Swabhimaan is presented in Figure 1.

269 **Figure 1 Theory of change for Swabhimaan: Bihar, Chhattisgarh and Odisha (2016 -2021)**

270

271 **Inclusion and exclusion criteria for cross-sectional surveys**

272 The three evaluation cross-sectional surveys will include all adolescent girls aged 10-19 years,
273 pregnant women, and mothers of children under two residing in the study areas and who agreed to
274 participate.

275

276 **Sample size calculation**

277 We conducted State-specific sample size calculations to determine the appropriate number of
278 adolescent girls, pregnant women and mothers of children under two to be interviewed in each state to
279 be able to detect differences of 15% in the proportion of adolescent girls with a BMI<18.5, a 15%
280 reduction in the proportion of mothers of children under two with a BMI<18.5, and a 0.4cm
281 improvement in mean MUAC among pregnant women between intervention and control areas at
282 endline, accounting for 5% refusal to participate (Table 6). Overall, we estimated that baseline and
283 endline surveys should include a total of 6638 adolescent girls, 10,160 mothers of children under two
284 and 2992 pregnant women across the three States.

285 **Table 6 State wise estimated total sample in intervention and control areas by target groups**

	Bihar	Chhattisgarh	Odisha	Total
Adolescent girls	1750	3294	1594	6638
Pregnant women	748	1122	1122	2992
Lactating mothers	2846	3294	4020	10160
Total	5345	7710	6736	19790

286

287

288 **Data collection**

289 We conducted the baseline survey for the evaluation in 2016. In Bihar, a full household listing was
290 conducted to identify adolescent girls aged 10-19 years, pregnant women and mothers of children
291 under two in all programme areas. Simple random sampling using a sample interval was then used to

1
2
3 292 select respondents in each of these three groups. In Chhattisgarh, 224 villages in two blocks
4
5 293 (administrative areas of around 100,000 population) were paired on the basis of population size and
6
7 294 whether they had held a monthly Village Health and Nutrition Day for the last three months. Forty
8
9 295 such pairs (a total of 80 villages) were then randomly selected for data collection, and all eligible
10
11 296 respondents in each of the three target groups in these 80 villages were approached for interview. In
12
13 297 Odisha, a set of 12 Gram Panchayats (administrative units of around 5000 population in two blocks
14
15 298 have been purposively identified as the intervention areas, and all remaining Gram Panchayats in the
16
17 299 two blocks serves as control areas. All eligible respondents in each of the three target groups are to be
18
19 300 approached for interview.
20
21
22 301

23 301

24 302 **Blinding**

25
26 303 It is not possible to blind participants to allocation, but data collection teams and analysts are blind to
27
28 304 allocation.
29

30 305

31 306 **Data analysis**

32
33 307 In each state, we will assess the comparability of intervention and control areas at baseline by
34
35 308 examining area-level and individual level characteristics, including: the number of self-help groups
36
37 309 and village organisations in each area, the socio-demographic profile of respondents and their
38
39 310 households (caste, literacy and assets) and key evaluation outcomes at baseline.

40
41 311 The final impact analysis will be by intention-to-treat, comparing primary and secondary outcomes in
42
43 312 five intervention areas and five control areas. This analysis will be carried out at an individual level,
44
45 313 adjusting for clustering at the level of the village and Village Organisation, using linear and logistic
46
47 314 random effects models in STATA 14. We will use the difference-in-difference method to compare
48
49 315 primary and secondary outcomes between intervention and control areas at endline, adjusting for their
50
51 316 baseline values and for other characteristics that differed significantly between the two areas at
52
53 317 baseline. We will present analyses both a State level, and conducted a pooled analysis with data from
54
55 318 all States.
56
57
58
59

60 319 **Process monitoring and progress review**

1
2
3 320 In addition to the impact evaluation described above, we are conducting process monitoring. The
4
5 321 process monitoring system is based on the reporting structures within the SRLM (Figure 2).
6

7 **322 Figure 2 SRLM organization structure and its adaptation in Swabhimaan, Bihar**
8

9 323
10
11 324 SRLM's have a project management units at State, district and block levels (SPMU,DPMU, BPMU).
12

13 325 The block Management Information System (MIS) coordinator is the reporting link between the CRPs
14
15 326 and their supervisors and the BPMU. In Bihar, a supervisor position has been embedded in the
16
17 327 organization structure while in Chhattisgarh and Odisha, supervisory staff is a representative from the
18
19 328 SRLM's organogram.
20

21 329
22
23
24 330 CRPs/ Poshan sakhis collect data and report coverage of community-led interventions on monthly
25
26 331 monitoring formats which are available in both web-based and paper formats. Key performance
27
28 332 indicators include:
29

- 30 333 ▪ Target women who attended the VHSND (%)
31
32 334 ▪ Target women who attended the maitri bethak (%)
33
34 335 ▪ At-risk women visited fortnightly in their home visits (%)
35
36 336 ▪ At-risk women attended fortnightly food demonstration and counselling session (%)
37
38 337 ▪ Target newly-wed who attended the couple meeting (reported quarterly)
39
40 338 ▪ Target groups who attended the women only camps (reported biannually)
41
42

43 339
44
45 340 All CRP reports are collated monthly at the block level. A CLF level review of the progress on
46
47 341 performance indicators and the planned activities as per the poshan microplan is planned for every
48
49 342 quarter, however, Swabhimaan has mixed experience in achieving this with Chhattisgarh undertaking
50
51 343 monthly reviews while other states undertaking annual reviews. DAY-NRLM hosts annual reviews
52
53 344 with the respective SRLMs for stock taking and approval for next annual cycle.
54

55 345

56
57
58 **346 Timeline**
59
60

1
2
3 347 Baseline was completed in 2016. The first phase of implementation is between 2017 and 2020.
4
5 348 Midline and endline for first phase will be completed in 2019 and 2021 respectively.
6

7 349
8

9 350 **ETHICS**

11 351 The baseline survey was conducted according to the guidelines laid down in the Declaration of
12
13 352 Helsinki and all procedures involving human subjects were approved by the Institutional Ethics
14
15 353 Committee of the All India Institute of Medical Sciences (AIIMS), Bihar, Chhattisgarh and AIIMS,
16
17 354 Odisha in July 2016 (Supplementary files 1,2 and 3). Written informed consent was obtained from all
18
19 355 subjects. The impact evaluation has been registered with the Registry for International Development
20
21 356 Impact Evaluations (RIDIE-STUDY-ID-58261b2f46876) [20] and Indian Council of Medical
22
23 357 Research National Clinical Trials Registry of India (CTRI/2016/11/007482).
24
25

26 358
27

28 359 **CONCLUSION AND IMPLICATIONS**

30 360 Swabhimaan operates in complete alignment with DAY-NRLM's mandate under the joint convergent
31
32 361 action plan for Poshan Abhiyaan. In coordination with departments of Woman and Child
33
34 362 Development and Health, DAY-NRLM shares responsibility for (1) SHG members mobilizing
35
36 363 communities for utilizing entitled services through Department of Health, (2) SHG members
37
38 364 participating in Behaviour Change and Communication activities, promoting recommended health,
39
40 365 nutrition and WASH behaviours, (3) common use of infrastructure by the three departments such as
41
42 366 use of Panchayat halls for SHG and VO meetings and (4) promoting nutri-based livelihoods for
43
44 367 women's collectives. These activities are integrated in VO's poshan microplans and system
45
46 368 strengthening activities under Swabhimaan.
47
48

49 369
50

51 370 Swabhimaan operates as three different models in Bihar, Chhattisgarh and Odisha. Bihar is the
52
53 371 demonstration and learning site, with financial support for human resources and activities through
54
55 372 UNICEF India. In Chhattisgarh and Odisha, the initiative is almost completely led by the respective
56
57 373 SRLMs with UNICEF to SRLM cost ratio at 1:5. UNICEF India supports some human resource at
58
59 374 state and block levels, but none at the VO level in these two states. By 2020, it is planned to advocate
60

1
2
3 375 for increased number of positions at SRLMs to support implementation of the convergent action plan
4
5 376 and create a system of CRPs graduating to block level positions in the three states. UNICEF India's
6
7 377 support on human resource will gradually lessen. DAY-NRLM has recognized the Chhattisgarh
8
9 378 model of Swabhimaan as a best practice for integrating health, nutrition and WASH on the SHG
10
11 379 platform and has planned to take elements from the initiative for horizontal expansion to poorest
12
13 380 resource blocks in other states. Findings from the Swabhimaan midline survey will inform scale-up
14
15 381 plans in other states.
16
17

18 382

19 383 **DECLARATIONS**

20 384 **Abbreviations**

21
22
23
24 385 AIIMS All India Institute of Medical Sciences, ANM Auxiliary Nurse Midwife , ASHA Accredited
25
26 386 Social Health Activist, AWW Anganwadi Worker, BMI Body Mass Index, BPMU Block Project
27
28 387 Management Unit, CLF Cluster Level Federation, CRP Community Resource Person, DAY-NRLM
29
30 388 Deendayal Antyodaya Yojana- National Rural Livelihoods Mission, DPMU District Project
31
32 389 Management Unit, ICDS Integrated Child Development Services, IFA Iron Folic Acid, MIS
33
34 390 Management Information System, MUAC Mid-upper Arm Circumference, PLA Participatory
35
36 391 Learning Action, PDS Public Distribution System, RIDIE Registry for International Development
37
38 392 Impact Evaluation , SHG Self-help group, SPMU State Project Management Unit, SRLM State Rural
39
40 393 Livelihoods Mission, VHSND Village Health Sanitation and Nutrition Day, VRP Village Resource
41
42 394 Person, VO Village Organization, WASH Water Sanitation and Hygiene
43
44

45 395 **Ethics approval and consent to participate**

46
47 396 The baseline survey was conducted according to the guidelines laid down in the Declaration of
48
49 397 Helsinki and all procedures involving human subjects were approved by the Institutional Ethics
50
51 398 Committee of the All India Institute of Medical Sciences (AIIMS), Bihar, Chhattisgarh and AIIMS,
52
53 399 Odisha in July 2016. Written informed consent was obtained from all subjects. The impact evaluation
54
55 400 has been registered with the Registry for International Development Impact Evaluations (RIDIE-
56
57 401 STUDY-ID-58261b2f46876) and Indian Council of Medical Research National Clinical Trials
58
59 402 Registry of India (CTRI/2016/11/007482).
60

1
2
3 **403 Patient and Public Involvement**

4
5 404 This research did not have any patients. The public (community) was involved in the design and
6
7 405 implementation of the intervention package at the village level but not in the evaluation. Public were
8
9 406 not invited to contribute to the writing or editing of this document for readability or accuracy.

10
11 **407 Competing interests**

12
13
14 408 None of the authors have any competing interests.

15
16 **409 Funding**

17
18 410 This research is funded by UNICEF India.

19
20 **411 Authors' contributions**

21
22 412 VS and ADW provide technical oversight and VS is the national focal point of the initiative. NK is
23
24 413 key contact in NRLM and advises on effective utilization of NRLM platforms. VS, AB, SB, NN,
25
26 414 AD,RNP, SS, AL and NK were involved in designing Swabhimaan initiative at national and state
27
28 415 level. RG, VN and NN contributed to the Participatory Learning Action component of the initiative.
29
30 416 DS and US contributed to the agriculture component. SB, RNP, SS, AL, NA, FS, MP, PM are
31
32 417 involved in the implementation of the initiative in Bihar, Chhattisgarh and Odisha. BM, SS and AP
33
34 418 are government counterparts; BM provides management support in Odisha and Somya and AP in
35
36 419 Bihar. AP, HPSS and SU advise on evaluation of the initiative and AP drafted the registered protocol.
37
38 420 NA, VB, MR, BS, RRS, SP, LKD were part of evaluation team; NA, VB and MR led baseline
39
40 421 evaluation in Bihar, Odisha and Chhattisgarh, respectively. VS, AB and AP drafted the manuscript.
41
42 422 All authors reviewed the manuscript.

43
44
45 **423 Acknowledgements**

46
47 424 Shivani Dar (UNICEF Bihar) and Anoop Jha (Independent consultant) supported stakeholder
48
49 425 coordination in Bihar. Anoop Jha was part of implementation team in Bihar. Shibanand Rath (Ekjut)
50
51 426 participated in the designing workshop and made significant contribution to the participatory learning
52
53 427 action component of the initiative. CM Singh (AIIMS, Patna, Bihar) managed evaluation teams in
54
55 428 Bihar. Aparajita Chattopadhyay, Preeti Dhillon, Prakash H. Fulpagare and Konsam Dinachandra
56
57 429 Singh (IIPS) supported quality control in baseline survey and are part of the evaluation team. Sarita
58
59 430 Anand (Roshni, Lady Irwin College, New Delhi) leads process documentation of the initiative.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

431 Rachna Sharma (UNICEF India) and Dhruv Sengupta (DAY-NRLM) offer technical advice on
432 specific components related to communication and government coordination, respectively.
433

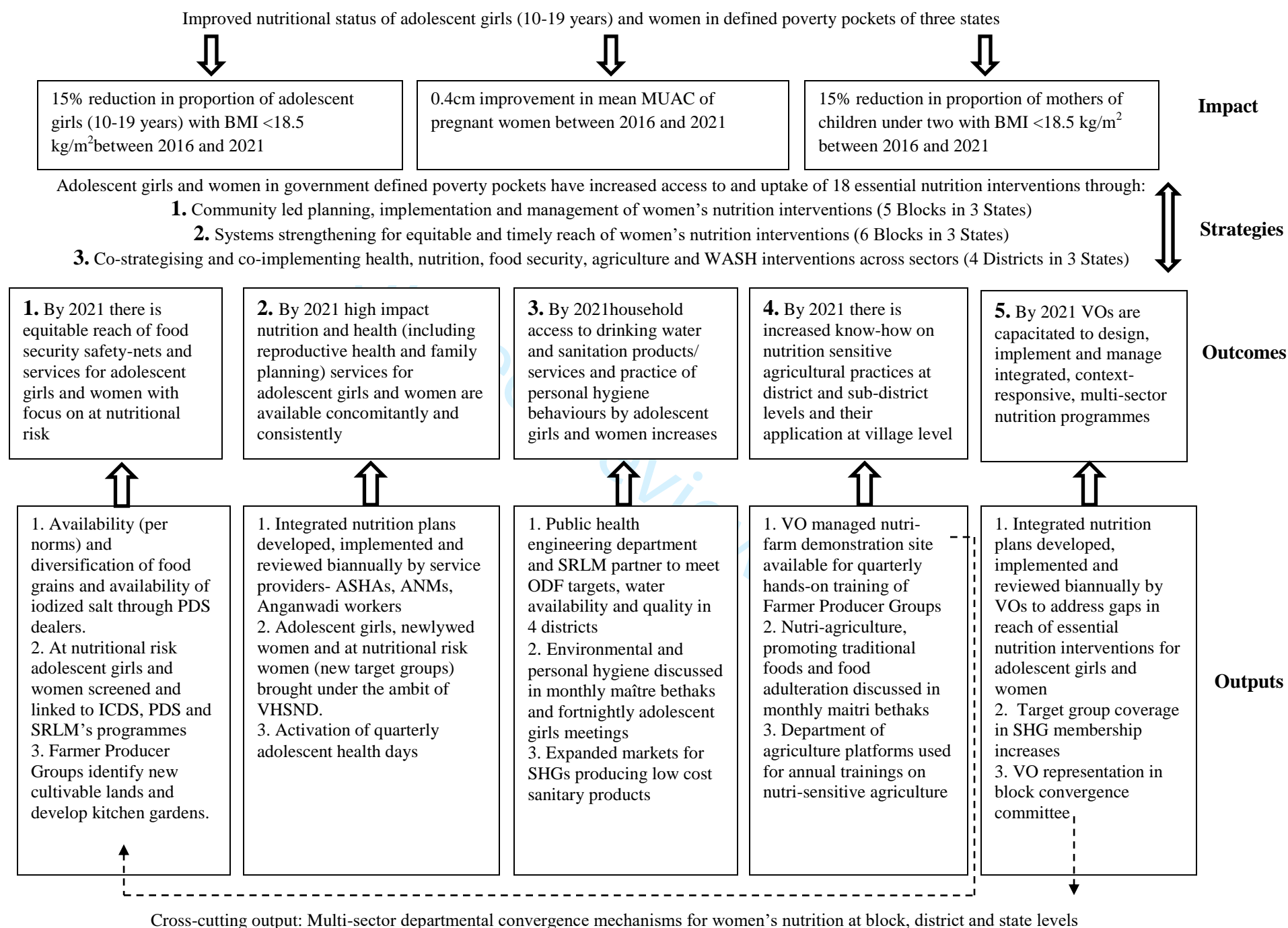
For peer review only

434 **REFERENCES**

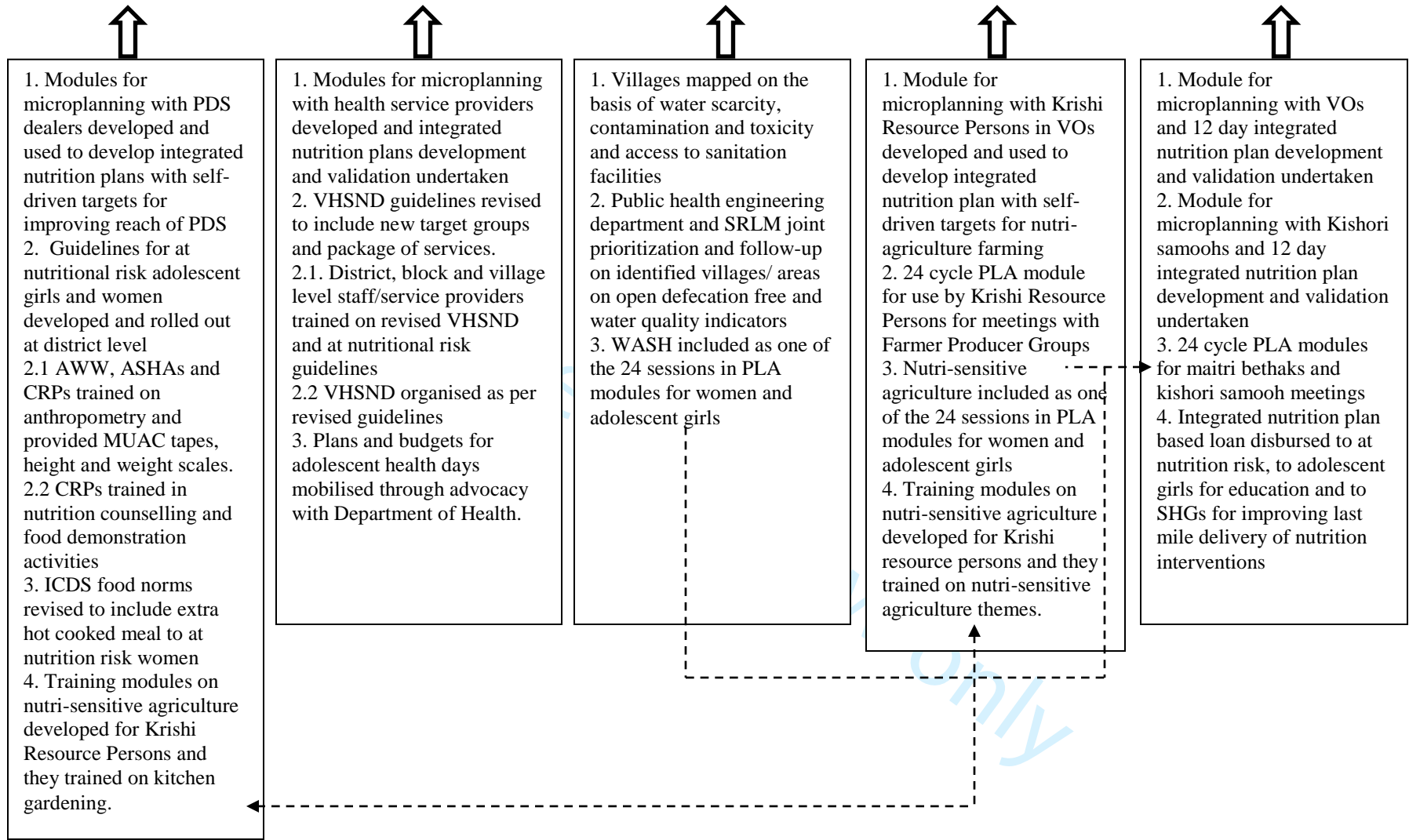
- 435 1. Black RE, Victora CG, Walker SP, Bhutta ZA, Christian P, de Onis M, Ezzati M, et al. Maternal
436 and child undernutrition and overweight in low-income and middle-income countries. *Lancet*.
437 2013; 382:427-451.
- 438 2. Bhutta ZA, Das JK, Rizvi A, Gaffey MF, Walker N, Horton S, et al. Evidence based interventions
439 for improvement of maternal and child nutrition: What can be done and at what cost? *Lancet*.
440 2013; 382:452-477.
- 441 3. International Institute for Population Sciences (IIPS) and Macro International. 2015-16. National
442 Family Health Survey (NFHS-4), 2015–16: India Factsheet.
- 443 4. Ministry of Home Affairs. Office of the Registrar General and Census Commissioner, India.
444 Population enumeration data 2011.
- 445 5. <https://www.icds-wcd.nic.in/nnm/home.htm#>
- 446 6. Prost A, Colbourn T, Seward N, Azad K, Coomarasamy A, Copas A, et al. Women’s groups
447 practising participatory learning and action to improve maternal and newborn health in low-
448 resource settings: a systematic review and meta-analysis. *Lancet*. 2013; 381(9879):1736–46.
- 449 7. Fottrell E, Azad K, Kuddus A, Younes L, Shaha S, Nahar T, et al. The effect of increased
450 coverage of participatory women’s groups on neonatal mortality in Bangladesh: a cluster
451 randomized trial. *JAMA Pediatr*. 2013; 167(9):816–25.
- 452 8. Colbourn T, Nambiar B, Bondo A, Makwenda C, Tsetekani E, Makonda-Ridley A, et al. Effects
453 of quality improvement in health facilities and community mobilization through women’s groups
454 on maternal, neonatal and perinatal mortality in three districts of Malawi: MaiKhanda, a cluster
455 randomized controlled effectiveness trial. *Int Health*. 2013; 5(3):180-95.
- 456 9. More NS, Bapat U, Das S, Alcock G, Patil S, Porel M, et al. Community mobilization in Mumbai
457 slums to improve perinatal care and outcomes: a cluster randomized controlled trial. *PLoS Med*.
458 2012; 9(7):e1001257.
- 459 10. Tripathy P, Nair N, Barnett S, Mahapatra R, Borghi J, Rath S, et al. Effect of a participatory
460 intervention with women’s groups on birth outcomes and maternal depression in Jharkhand and
461 Orissa, India: a cluster-randomised controlled trial. *Lancet*. 2010; 375(9721):1182–92.

- 1
2
3 462 11. The World Bank. Indonesia's PNPM Generasi Programme. Final impact evaluation. 2011.
4
5 463 12. TANGO International Inc.. SHOUHARDO a Title II program of USAID. Final evaluation report.
6
7 464 2009.
8
9 465 13. Saha S, Annear PL, Pathak Sather effect of Self-Help Groups on access to maternal health
10
11 466 services: evidence from rural India. *International Journal of Equity in Health*. 2013; 12:36.
12
13 467 14. VOICES. A report on success and failure of SHGs in India- impediments and paradigms of
14
15 468 success. 2008. Report submitted to Planning Commission, Government of India.
16
17 469 15. National Rural Livelihoods Mission, Ministry of Rural Development, Government of India.
18
19 470 Briefing book. 2012
20
21 471 16. Sethi V, Bhanot A, Bhalla S, Bhattacharjee S, Daniel A, Sharma DM, et al: Partnering with
22
23 472 women collectives for delivering essential women's nutrition interventions in tribal areas of
24
25 473 eastern India: a scoping study. *J Health Popul Nutr*. 2017; 36 (20).
26
27 474 17. Bulliyya, G, Mallik G, Sethy GS, Kar SK. Haemoglobin Status of Non-School Going Adolescent
28
29 475 Girls in Three Districts of Orissa, India. *International Journal of Adolescent Medicine & Health*.
30
31 476 2007.19; (4):395–406.
32
33 477 18. Mramba L, Ngari M, Mwangome M, Muchai L, Bauni E, Walker SA, Gibb DM, Fegan G,
34
35 478 Berkley JA. A growth reference for mid upper arm circumference for age among school age
36
37 479 children and adolescents, and validation for mortality: growth curve construction and longitudinal
38
39 480 cohort study. *BMJ*, 2017;358:j3423.
40
41 481 19. Tang AM, Dong K, Deitchler M, Chun M, Maalouf-Manasseh Z, Tumilowicz A, Wanke C. Use
42
43 482 of Cutoffs for Mid-Upper Arm Circumference (MUAC) as an Indicator or Predictor of Nutritional
44
45 483 and Health Related Outcomes in Adolescents and Adults: A Systematic Review. 2013.
46
47 484 Washington, DC: FHI 360/FANTA
48
49 485 20. Integrated multisectoral strategy to improve girls' and women's nutrition before conception,
50
51 486 during pregnancy and after birth in India (Swabhimaan): prospective, non-randomised controlled
52
53 487 evaluation. Principal investigator: Sethi V. Co-Principal investigator: Unisa S.
54
55 488 <http://ridie.3ieimpact.org/index.php?r=search/detailView&id=485>
56
57 489
58
59
60

Figure 1 Theory of change for Swabhimaan: Bihar, Chhattisgarh and Odisha (2016 -2021)



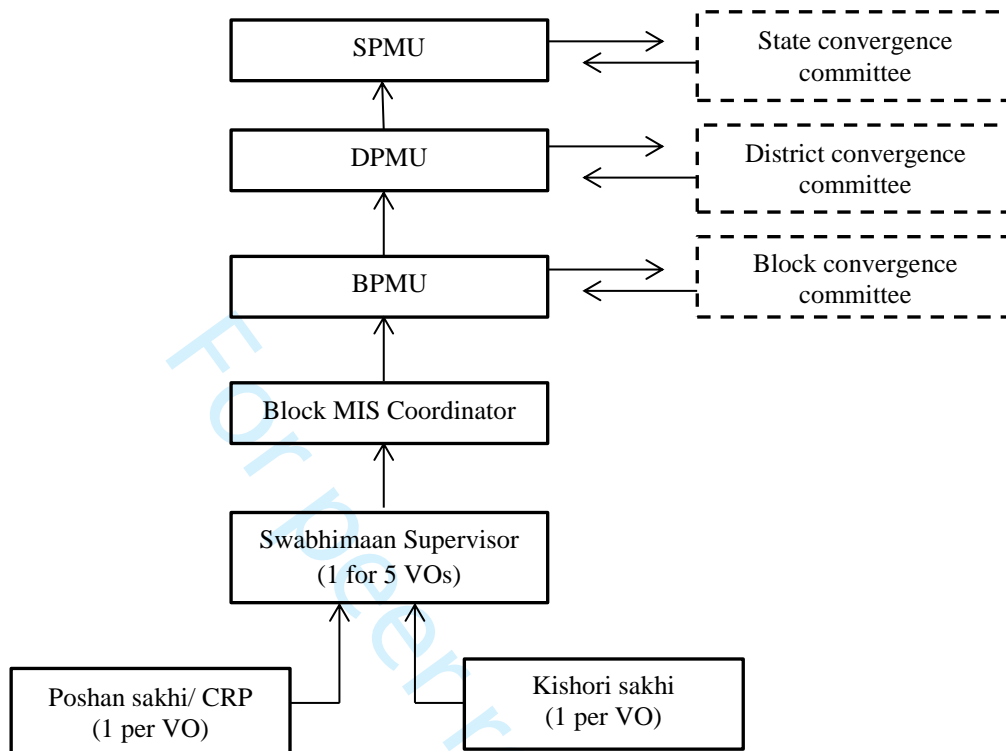
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47



Inputs and processes

Cross-cutting input: Annual planning and review of selected nutrition indicators by a multi-sector nutrition committee at block, district and state levels

Figure 2 SRLM organization structure and its adaptation in Swabhimaan, Bihar





All India Institute of Medical Sciences, Patna

Ethics committee approval letter

Date: 23/01/2016

Dr. Neeraj Agarwal
 Prof. & Head
 Department of Community & Family Medicine
 AIIMS, Patna

Dear Dr. Neeraj Agarwal

Ref: IEC/AIIMS/PAT/52/2016

The Institutional Ethics Committee, All India Institute of Medical Sciences, Patna reviewed & discussed your study documents entitled "**Prospective, controlled, non-randomized evaluation of a programme to improve the nutritional status of women before conception, during pregnancy and after birth in Bihar**". (The Swabhimaan Programme) dated: 19.01.2016 study code: IEC/AIIMS/PAT/52/2016 on 19.01.2016.

The following members of ethics committee were present at the meeting held on 19.01.2016 at 2:00 P.M. at Department of Community and Family Medicine, All India Institute of Medical Sciences, Patna.

S. No.	Name and address of the EC members	Designation
1.	Dr. R.N. Singh, Consultant Orthopaedic Surgeon	Chairman
2.	Dr. P.P. Gupta, HOD, Pharmacology, AIIMS, Patna	Member: Pharmacologist
3.	Dr. Sadhana Sharma, Professor, Biochemistry, AIIMS, Patna	Member: Basic Sciences
4.	Dr. Ramji Singh, Addl. Prof. & Head, Physiology, AIIMS, Patna	Member: Pre- Clinical
5.	Dr. Ravi Kirti, Asst. Prof., General Medicine, AIIMS, Patna	Member: Physician
6.	Dr. Subhash Kumar, Assit. Prof., Radio Diagnosis, AIIMS, Patna	Member: Clinician
7.	Mr. Binay Kumar Pandey, Advocate, Patna High Court	Member: Legal Expert
8.	Mr. Ajit Kumar Chaudhary, Social Worker	Member: Social Worker
9.	Ms. Shahina Khan, Director of Raza International Group of Schools	Member: Philosopher
10.	Dr. C.M. Singh, Addl. Prof., Dept. of C&FM, AIIMS, Patna	Member Secretary

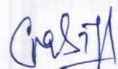
Address: All India Institute of Medical Sciences, District - Patna, State - Bihar, Pin Code – 801507,
 E-mail – iecaiimspatna@gmail.com

The IEC approves the study to be conducted in its presented form.

Principal Investigator is responsible for fulfilling the following requirements:

- All Co-investigator must be kept informed of the status of the project.
- Any, amendment(s) to the protocol or the consent form(s), must be informed and submitted to the IEC for review and approval prior to the activation of the same. The IEC number assigned to the project should be cited in any correspondence.
- Serious Adverse Events (SAE), if any, should be reported to the IEC immediately. New information that becomes available which could change the risk-benefit ratio must be submitted promptly for IEC review.
- Records of documents related to signed consent (by subjects/witnesses) should be maintained properly for the audit by IEC.
- Approved study needs to be reviewed by IEC AIIMS Patna periodically at least once in a year as appropriate.
- After completion of the permitted tenure of the study, submission of the study report to the IEC AIIMS Patna is mandatory.
- A continuing review application must be submitted to the IEC in order to continue the study beyond the approved period. Failure to submit the same will result in the termination of the study.
- IEC AIIMS Patna will maintain the confidentiality of all the approved studies and will share the information with authentic bodies only on justification of the request.

Yours sincerely



Member Secretary
IEC, AIIMS, Patna

**MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
AIIMS, PATNA**

Address: All India Institute of Medical Sciences, District - Patna, State - Bihar, Pin Code – 801507,
E-mail – iecaiimspatna@gmail.com



आरोग्यम् सुखं सम्यदा

Institute Ethics Committee

अखिल भारतीय आयुर्विज्ञान संस्थान, रायपुर (छत्तीसगढ़)

All India Institute of Medical Sciences, Raipur (Chhattisgarh)

Department of Pharmacology

2nd Floor, South Wing

Medical College Complex, Gate No. 5

Tatibandh, GE Road,

Raipur-492 099 (CG)

www.aiimsraipur.edu.in

Ethics Committee Registration No.: ECR/714/Inst/CT/2015

Letter No.: 114/IEC-AIIMSRPR/2016

Date: 02.09.2016

CERTIFICATE OF APPROVAL

To : Dr. Manisha Ruikar (Principal Investigator)
Professor & Head, Department of Community & Family Medicine,
AIIMS Raipur (CG)

Review Date : 06.08.2016

Reference : IEC Proposal No: **AIIMSRPR/IEC/2016/042**

Title : Baseline Survey for Swabhimaan Project, Bastar Block and Bakavand
Block, Bastar District (Developed in consultation with UNICEF)

The Institute Ethics Committee, All India Institute of Medical Sciences, Raipur (Chhattisgarh) reviewed and discussed your above referenced research proposal in the meeting held on 06.08.2016.

The following documents were reviewed.

1. Covering Letter
2. Research Project Proposal (Version 2.0)
3. Case Record Form (Version 1.0)
4. Participant information sheet for participants more than 18 years of age (English & Hindi) (Version 1.0)
5. Participant information sheet for participants less than 18 years of age - English & Hindi (Version 1.0)
6. Consent Form for participant more than 18 year of age (English & Hindi) (Version 1.0)
7. Assent Form - English & Hindi (Version 1.0)
8. Undertaking regarding GCP guidelines and reporting of SAE
9. Other documents

Certificate of Approval: Proposal No. AIIMSRPR/IEC/2016/042
Ref: 114/IEC-AIIMSRPR/2016 dated 02.09.2016

a. Duly signed compliance sheet submitted to IEC by PI alongwith following documents :

- i. E-comunication by Dr Abner Daniel, Nurition Specialist, Child Development and Nutrition, UNICEF to the Principal Investigator
- ii. Letter by Director, National Rural Livelihood Promotion Society to Mision Director, Chhattisgarh Gramin Ajjevika Samvardaan Samiti
- iii. Letter by Mission Director, SRLM, Chhattisgarh to the Chief, Field Office , UNICEF

The following members of Institute Ethics Committee were present at the meeting held on 06.08.2016 at 11:00 AM at Department of Pharmacology, AIIMS Raipur.

Sr. No.	Name of IEC Member	Designation
1	Dr. Arun T. Dabke Ex. Vice-chancellor Ayush and Health Science University Raipur (CG)	Chairman
2	Dr. S. R. Gupta M.D. (Med.), M.D. Pharmacology Retired Professor & Head Department of Medicine Pt. J. N. M. Medical College, Raipur	Basic Medical Scientist
3	Dr. P. K. Neema Professor and Head Department of Anaesthesiology AIIMS Raipur	Clinician
4	Dr. Sarita Agrawal Professor and Head Department of Obstetrics and Gynaecology AIIMS Raipur	Clinician
5	Mrs. Kamla Janswami Ex-president Lion's Club, Raipur	Lay Person from Community
6	Ms. Pushpy Michael Principal Bharatmata Higher Secondary School GE Road, Tatibandh, Raipur Chhattisgarh	Social Scientist
7	Dr. Nitin Gaikwad Associate Professor Department of Pharmacology AIIMS Raipur	Member Secretary
Outside Legal Expert		
8	Advocate Shekhar Amin	Legal Expert

Certificate of Approval: Proposal No. AIIMSRPR/IEC/2016/042
Ref: 114/IEC-AIIMSRPR/2016 dated 02.09.2016

Clear statement of decision reached:

At Institute Ethics Committee meeting held on 06.08.2016, the committee reviewed the research project and study related documents and discussed the ethical issues involved.

A letter to this effect was sent to you seeking certain clarifications / modifications vide letter no. 104/IEC-AIIMSRPR/2016, dated 19.08.2016. In response to this, you have submitted required clarifications / modifications vide letter no. CFM/MR/Project/348/2016 dated 24.08.2016 (IEC inward letter no. 2016/84 dated 25.08.2016). Therefore, the research project and study related documents are approved with respect to ethical issues.

Hence, at the convened meeting of IEC-AIIMS Raipur on 02.09.2016, IEC decided to **approve** the above referenced research project.

As Principal Investigator, you are responsible for fulfilling the following requirements of approval:

1. This approval is valid for entire duration of the study (i.e. Six months). The review application must be submitted to the IEC-AIIMS Raipur in order to continue the study beyond the approved period.
2. All the co-investigators must be kept informed of the status of the project.
3. Changes, amendments, and addendum to the protocol or the consent form, must be submitted to the IEC-AIIMS Raipur for re-review and approval prior to the activation of the changes.
4. Any change of study site, change of investigator/s, termination of study (with reason to do so) should also be informed to IEC-AIIMS Raipur.
5. The IEC proposal number assigned to the project should be cited in any correspondence.
6. Any Serious Adverse Event (SAE) occurring during the course of the study should be reported to the IEC-AIIMS Raipur.
7. New information that becomes available which could change the risk: benefit ratio must be submitted promptly for IEC review.
8. Only approved consent forms are to be used in the enrolment of participants. All consent forms signed by subjects and/or witnesses should be retained on file. The

Certificate of Approval: Proposal No. AIIMSRPR/IEC/2016/042
Ref: 114/IEC-AIIMSRPR/2016 dated 02.09.2016

IEC may conduct audits of all study records, and consent documentation may be part of such audits.

9. The study progress report should be made available for the IEC review on every 6 month.
10. The final report of the study must be submitted to IEC-AIIMS Raipur after the completion of the study.

It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.

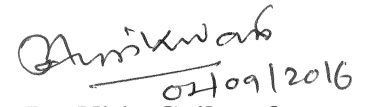
Sincerely,



Dr. Arun T. Dabke
Chairman

Institute Ethics Committee
All India Institute of Medical Sciences
Raipur 492 099 (C.G.)

2/9/16



Dr. Nitin Gaikwad

Member Secretary
Institute Ethics Committee
All India Institute of Medical Sciences
Raipur 492 099 (C.G.)



INSTITUTIONAL ETHICS COMMITTEE
(ECR/534/Inst/OD/2014)

All India Institute of Medical Sciences Bhubaneswar,
Village Sijua, Patrapada, PO Dumduma, Bhubaneswar
751019, Odisha
Email: iec.aiimsbbsr@gmail.com
Phone:

SA ①

To: Dr. Vikas Bhatia (Principal Investigator)

Date: 10.05.16

Re: IEC Proposal: T/EM -F/CMFM/16/02

Title: **Swabhiman- a nutritional intervention program in Odisha. Pre-implementation status assessment.**

Chairperson of IEC-AIIMS BBSR

Dr Suresh Chandra Dash
(Clinician)

Members of IEC AIIMS BBSR

Prof Debasis Hota
(Pharmacologist)

Dr K C Misra
(Scholar & Academician)

Dr Manaswini Mangaraj
(Basic Scientist)

Mr. Surendra Kumar Patri
(Lawyer)

Dr Amit Ghosh
(Basic Scientist)

Dr Ashish Patnaik
(Clinician)

Dr Swagatha Tripathy
(Clinician)

Ms. Swarna Misra
(Social Scientist)

Ms Pranita Acharya
(General community
representative)

Member- Secretary

Dr Somnath Mukherjee

I am pleased to inform you that at the convened meeting of 07.05.2016, the IEC voted to approve an amendment and to re-approve (renewal approval of the protocol and the consent form(s) is for 12 months) the above referenced protocol. As Principal Investigator, you are responsible for fulfilling the following requirements of approval:

1. All co-investigators must be kept informed of the status of the project.
 2. Changes, amendments, and addenda to the protocol or the consent form must be submitted to the IEC for re-review and approval prior to the activation of the changes. The IEC number assigned to the project should be cited in any correspondence.
 3. Adverse events should be reported to the IRB. New information that becomes available which could change the risk: benefit ratio must be submitted promptly for IEC review. The IEC and outside agencies must review the information to determine if the protocol should be modified, discontinued, or continued as originally approved.
 4. Only approved consent forms are to be used in the enrolment of participants. All consent forms signed by subjects and/or witnesses should be retained on file. The IEC may conduct audits of all study records, and consent documentation may be part of such audits.
 5. IEC AIIMS needs review of an approved study not less than once per 12-month period. **Therefore, a continuing review application must be submitted to the IEC in order to continue the study beyond the approved period.** Failure to submit a continuing review application in a timely fashion will result in termination of the study, at which point new participants may not be enrolled and currently enrolled participants must be taken off the study.
 6. Principal investigator should initiate the project only after obtaining administrative permission from Director/Dean, AIIMS, Bhubaneswar.
- Sincerely,

Chairman, IEC

Chairman

Members of the IEC who voted in Favour of the Proposal

Dr. Debasis Hota, Dr. Manaswini Mangaraj, Dr Amit Ghosh, Dr. Swagatha Tripathy, Dr. K C Mishra, Dr. Somnath Mukherjee.

अखिल भारतीय आयुर्विज्ञान संस्थान, भुवनेश्वर - ७५१ ०१९

RESEARCH CELL

All India Institute of Medical Sciences, Bhubaneswar-751 019



AIIMS-BBSR/RC/EM-F/02/2016/05

Dt: 13/05/2016

Dr. Vikas Bhatia

Professor & Head

Department of Community Medicine & Family Medicine

Subject: Regarding initiation of extramural research project.

Dear Prof. Bhatia,

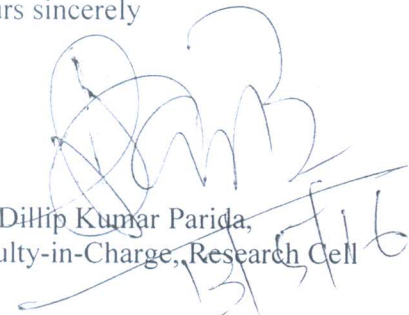
The research cell is pleased to inform you that your extramural funded project entitled “**Swabhimana nutritional intervention program in Odisha, Pre-implementation status assessment**” (bearing provisional project code T/EM-F/CMFM/16/02 and IEC approval letter No T/EM-F/CMFM/16/02 dated 10.05.2016) has been examined and approved by the competent authority.

Kindly note that following the approval, you have been assigned permanent project code: P/EM-F/CMFM/16/02 and the study may be initiated in the institute.

You are requested to provide 6 monthly progress reports (in case study duration is longer than 6 months) and a consolidated summary report within 1 month of end of study to the research cell.

Thanking You

Yours sincerely


Dr. Dillip Kumar Parida,
Faculty-in-Charge, Research Cell

Project file

13/05/16

BMJ Open

Integrated multisectoral strategy to improve girls' and women's nutrition before conception, during pregnancy and after birth in India (Swabhimaan): protocol for a prospective, non-randomized controlled evaluation

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-031632.R1
Article Type:	Protocol
Date Submitted by the Author:	29-Aug-2019
Complete List of Authors:	Sethi, Vani ; UNICEF India, Child Development and Nutrition Bhanot, Arti; Independent consultant; Bhattacharjee, Sourav; UNICEF Odisha, Nutrition Gope, Rajkumar ; Ekjut Sarangi, Debjeet; Living Farms Nath, Vikash; Ekjut Nair, Nirmala; Ekjut, Singh, Usha; Dr Rajendra Prasad Central Agricultural University Daniel, Abner; UNICEF India, Child Development and Nutrition Parhi, Rabi; UNICEF Bihar, Nutrition Sinha, Sonali; UNICEF Odisha Loomba, Avinash; UNICEF Chhattisgarh S, Somya; Bihar Rural Livelihoods Promotion Society Purty, Apollo; Bihar Rural Livelihoods Promotion Society Ali, Naushad; Independent consultant Mohapatra, Babita; Odisha Livelihoods Mission Agarwal, Neeraj; All India Institute of Medical Sciences (AIIMS), Patna Bhatia, Vikas; All India Institute of Medical Sciences Bhubaneswar Ruikar, Manisha; All India Institute of Medical Sciences - Raipur Sahu, Bharati; Independent consultant RS, Reshmi; International Institute for Population Sciences Pedgaonkar, Sarang; International Institute for Population Sciences Dwivedi, Laxmi Kant; International Institute of Population Sciences, Saiyed, Farhat; UNICEF Chhattisgarh Prajapati, Mahendra; UNICEF Bihar Mishra, Preetu; UNICEF Chhattisgarh Prost, Audrey ; London School of Hygiene and Tropical Medicine, Global Health and Development Kejrewal, Nita; Deendayal Antyodaya Yojana, National Rural Livelihoods Mission Wagt, Arjan; UNICEF India, Child Development and Nutrition Sachdev, Harshpal; Sitaram Bhatia Institute of Science and Research, Department of Paediatrics Unisa, Sayeed; International Institute for Population Sciences, Mathematical Demography and Statistics
Primary Subject Heading:	Public health

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Secondary Subject Heading:	Nutrition and metabolism
Keywords:	Adolescent girls, Nutrition < TROPICAL MEDICINE, Agriculture, Mutli-sector, Women collectives, India



1 STUDY PROTOCOL

2 Title

3 Integrated multisectoral strategy to improve girls' and women's nutrition before conception, during
4 pregnancy and after birth in India (Swabhimaan): protocol for a prospective, non-randomized
5 controlled evaluation

7 Authors

8 Vani Sethi¹ vsethi@unicef.org, Arti Bhanot² arti.bhanot@gmail.com, Sourav Bhattacharjee³
9 sbhattacharjee@unicef.org, Rajkumar Gope⁴ rajkumar.ekjut@gmail.com, Debjeet Sarangi⁵
10 livingfarms@gmail.com, Vikash Nath⁴ vikash.ekjut@gmail.com, Nirmala Nair⁴
11 nirmala.ekjut@gmail.com, Usha Singh⁶ usha_pusa@yahoo.co.in, Abner Daniel¹ adaniel@unicef.org,
12 Rabi N Parhi⁷ rparhi@unicef.org, Sonali Sinha³ ssonali.sss@gmail.com, Avinash Loomba⁸
13 avinash.lumba@gmail.com, Somya S⁹ somya@brlp.in, Apollo Purty⁹ apollo@brlp.in, Naushad Ali²
14 nsz2004@gmail.com, Babita Mohapatra¹⁰ apdpro.tripti@gmail.com, Neeraj
15 Agarwal¹¹ neeraj502@rediffmail.com, Vikas Bhatia¹² bhatiaaiims@gmail.com, Manisha
16 Ruikar¹³ manisharuikar@rediffmail.com, Bharati Sahu¹⁴ sahubharati2@gmail.com, Reshmi
17 RS¹⁴ reshmi@iips.net, Sarang Pedgaonkar¹⁴ drsarangpedgaonkar@gmail.com, Laxmi Kant Dwivedi¹⁴
18 laxmikant@iips.net, Farhat Saiyed⁸ fsaiyed@unicef.org, Mahendra Prajapati⁴
19 maprajapati@unicef.org, Preetu Mishra⁸ pmishra@unicef.org, Audrey Prost¹⁵
20 Audrey.Prost@lshtm.ac.uk, Nita Kejrewal¹⁶ n.kejrewal@nic.in, Arjan De Wagt¹ adewagt@unicef.org,
21 Harshpal Sachdev¹⁷ hpssachdev@gmail.com, Sayeed Unisa¹⁴ unisa@iips.net.

22
23 ¹ Nutrition Section, UNICEF India, Country Office, New Delhi, India

24 ² Independent consultant, New Delhi, India

25 ³ UNICEF India, Field Office Odisha, Bhubaneswar, India

26 ⁴ Ekjut, Jharkhand, India

27 ⁵ Living Farms, Odisha, India

28 ⁶ Dr. Rajendra Prasad Central Agriculture University, Bihar, India

- 1
2
3 29 ⁷ UNICEF India, Field Office Bihar, Patna, India
4
5 30 ⁸ UNICEF India, Field Office Chhattisgarh, Raipur, India
6
7 31 ⁹ Bihar Rural Livelihoods Promotion Society, Bihar, India
8
9 32 ¹⁰ Odisha Livelihoods Mission, Odisha, India
10
11 33 ¹¹ All India Institute of Medical Sciences (AIIMS), Patna India
12
13 34 ¹² All India Institute of Medical Sciences (AIIMS), Bhubaneswar, India
14
15 35 ¹³ All India Institute of Medical Sciences (AIIMS), Raipur, India
16
17 36 ¹⁴ International Institute for Population Sciences, Mumbai, India
18
19 37 ¹⁵ Institute for Global Health, University College London, United Kingdom
20
21 38 ¹⁶ Deendayal Antyodaya Yojana, National Rural Livelihoods Mission, India
22
23 39 ¹⁷ Sitaram Bhartia Institute of Science and Research, New Delhi, India
24
25
26
27
28

29 41 **Corresponding author**

30 42 Vani Sethi vsethi@unicef.org
31
32
33
34

35 44 **ABSTRACT**

36 45 **Introduction**

37 46 Swabhimaan is community-based programme to improve adolescent girls' and women's nutrition in
38 47 rural areas of three Indian states- Bihar, Chhattisgarh and Odisha with high prevalence of
39 48 undernutrition. .
40
41
42
43
44

45 49 **Methods and analysis**

46 50 Swabhimaan has a nested prospective, non-randomized controlled evaluation. Since 2017, five
47 51 intervention sites receive community-led interventions through national government's livelihood
48 52 mission supported women's self-help group federations and five control sites will initiate these
49 53 activities 36 months later, in 2020. Community-led activities aim to improve coverage of 18
50 54 interventions including adequacy of food consumed, prevention of micronutrient deficiencies, access
51 55 to basic health services, and special care of nutritionally at risk girls and women, improving hygiene
52 56 and access to water and sanitation services and access to family planning services. The evaluation
53
54
55
56

1
2
3 57 includes baseline (2016-17), midline (2018-19) and endline (2020-21) surveys covering 6352
4
5 58 adolescent girls, 2573 pregnant women and 8755 mothers of children under two. The final impact
6
7 59 analysis will be by intention-to-treat, comparing primary and secondary outcomes in five intervention
8
9 60 areas and five control areas. The primary outcomes are: (1) a 15% reduction in the proportion of
10
11 61 adolescent girls with a Body Mass Index (BMI) <18.5 kg/m²; (2) a 15% reduction in the proportion of
12
13 62 mothers of children under two with a BMI<18.5 kg/m² and (3) and a 0.4cm improvement in mean
14
15 63 mid-upper arm circumference among pregnant women

17 64 **Ethics and dissemination**

18
19
20 65 All procedures involving human subjects were approved by the Institutional Ethics Committee of the
21
22 66 All India Institute of Medical Sciences (AIIMS), Bihar, Chhattisgarh and Odisha and in compliance
23
24 67 with guidelines laid down in the Declaration of Helsinki. Evidence will inform maternal and
25
26 68 preconception nutrition policy at national and state level.

27 69 **Evaluation registration**

28
29
30 70 The evaluation is registered with the Registry for International Development Impact Evaluation
31
32 71 (RIDIE-STUDY-ID-58261b2f46876) and the Indian Council of Medical Research, National Clinical
33
34 72 Trials Registry of India (CTRI/2016/11/007482)

35 73 **Key words**

36
37 74 Adolescent girls, nutrition, agriculture, multi-sector, women collectives, India
38
39
40
41
42

43 76 **STRENGTHS AND LIMITATIONS OF THIS STUDY**

- 44
45 77 ▪ The study will provide evidence on effectiveness of a community-led model in delivering a
46
47 78 comprehensive package of 18 nutrition services, on improving nutrition status of adolescent girls,
48
49 79 pregnant women and mothers of children under two in resource-poor settings.
50
51 80 ▪ The model is based on sustainable government resources with only one of the three states
52
53 81 receiving additional non-government funding to test the model.
54
55 82 ▪ The pace of implementation will vary considerably across three states due to variable governance,
56
57 83 availability of resources, maturity of self-help groups and intensity of non-government
58
59 84 engagement which is likely to impact the study outcomes.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

- 85 ▪ While the design includes a comparator site, introduction of new government schemes that can
- 86 have variable influence in intervention and control sites are not ruled out.
- 87 ▪ The evaluation is led by an independent third party with no role in implementation of the model.

For peer review only

90 INTRODUCTION

91 There is compelling evidence on the importance of women's nutrition prior to and during pregnancy,
92 to ensure optimal foetal growth and development and for the health and wellbeing of the mother [1].
93 Globally, over 800,000 neonatal deaths and 20% of stunting in children less than five years of age is
94 attributable to poor nutrition in utero, including protein-energy and micronutrient deficiencies [2].
95 Nearly 4.5 million Indian women become pregnant in adolescence, 58% have anaemia and 23% are
96 thin. It is unsurprising that over 50 million children under-five (38%) are stunted [3,4]. India has both
97 policies and programmes in place to deliver and monitor globally-recommended preconception and
98 antenatal nutrition interventions. Most recently, India's National Nutrition Mission or Poshan
99 Abhiyaan (2018-22) aims to reduce the proportion of children born with low birthweight from 19% to
100 11% and under-five children stunted from 38% to 13% respectively, by 2022. It also aims to reduce
101 anaemia among adolescent girls and pregnant women, which is over 50%, by 3% per annum. This is
102 to be achieved through coordinated efforts across 11 different ministries that together can make all
103 essential nutrition services available to women and children through integration of their ongoing
104 vertical programmes and schemes [5]. Despite these policies and programmes, in 2015-16 the
105 coverage of at least four antenatal care visits was just over 50%, only a third of pregnant women
106 consumed Iron Folic Acid (IFA) tablets for at least 100 days during pregnancy, and less than 40%
107 used the maternity benefit scheme [3]. Challenge lies in lack of effective operational models to deliver
108 a comprehensive package of essential nutrition interventions for adolescent girls and women, models
109 that can overcome both systemic challenges and those around user service uptake.

110
111 Evidence from randomized controlled trials within and outside India suggests that working with
112 women's groups as a platform for promoting health interventions and increasing service uptake is a
113 feasible approach in low-resource settings [6,7,8,9,10]. This is provided the necessary requisites, such
114 as high-quality facilitators for establishing and maintaining the group, high coverage of intervention,
115 sufficient time for implementation of the intervention, concomitant supply strengthening interventions
116 and appropriate safeguards against harm such as conflict with service providers and domestic

1
2
3 117 violence, are met. However, none of these trials investigated nutrition outcomes for adolescent girls or
4
5 118 women.

6
7 119

8
9 120 In view of the undisputed role of income poverty in the aetiology of undernutrition, there is a need to
10
11 121 integrate women-centric poverty alleviation in nutrition programmes and vice-versa. Notable global
12
13 122 examples where women's collectives have been engaged with to deliver services and promote health
14
15 123 and nutrition behaviours in underserved communities, along with economic empowerment include a
16
17 124 community conditional cash transfer programme in Indonesia, as well as livelihood and food security
18
19 125 programmes in Bangladesh (Shouhardo, Jibaon-o-Jibika) and Nepal (Suaahara) [11,12]. Indian
20
21 126 experiences include Kudumbashree (Kerala), the Society for Elimination of Rural Poverty Project
22
23 127 (Andhra Pradesh and Telangana), Self Employed Women's Association (rural areas of several states),
24
25 128 Community Health Care Management Initiative (West Bengal), Jamkhed (Maharashtra), and urban
26
27 129 health models by the Urban Health Resource Centre and Mahila Abhivrudhi Society, Andhra Pradesh.
28
29 130 Women's groups are trained on promotion of the health and nutrition interventions, the scope and
30
31 131 duration of training varying with the type of programme. The promoting agency, which is mostly a
32
33 132 non-government organisation or federated structure of community based groups, provides capacity
34
35 133 building and supervisory support. Most programmes strengthen the health services delivery system in
36
37 134 addition to intervening with community groups [13,14].
38
39
40

41 135

42
43 136 Women's SHGs and their federations supported by the Deendayal Antyodaya Yojana -National Rural
44
45 137 Livelihoods Mission (DAY-NRLM)'s Government of India's flagship poverty alleviation programme,
46
47 138 remain an untapped platform for improving reach and use of essential nutrition interventions,
48
49 139 particularly for women residing in income-constrained settings [15]. A 2016 scoping study from
50
51 140 UNICEF India suggested that DAY-NRLM village organisations have the potential to manage grants
52
53 141 for improving last mile delivery of essential nutrition services for women, provided they are enabled,
54
55 142 supervised and incentivised [16]. DAY-NRLM is also one of the nodal agencies for implementation
56
57 143 of the Poshan Abhiyaan. Capitalising on this, the Swabhimaan programme is a four-year initiative
58
59 144 launched in 2016 to improve adolescent girls' and women's nutrition.

1
2
3 145 Swabhimaan is a package of community-led interventions delivered by DAY-NRLM-supported
4
5 146 federations of women self-help groups (SHGs) comprising Village Organizations (VOs) and the
6
7 147 higher order Cluster-Level Federations (CLFs), to improve the nutrition status of adolescent girls and
8
9 148 women in three Indian states: Bihar, Chhattisgarh and Odisha. The objectives of the programme are:
10
11 149 1. To improve the food and nutrient intake of adolescent girls and women
12
13 150 2. To prevent micronutrient deficiencies and nutritional anaemia
14
15 151 3. To increase access to services during fixed day, Village Health Sanitation and Nutrition Days
16
17 152 (VHSNDs) and provide special care to nutritionally 'at risk' women, defined as those with mid-
18
19 153 upper arm circumference (MUAC) <23 cm or Body Mass Index (BMI) <18.5 kg/m²
20
21 154 4. To increase access to education about water, sanitation and hygiene (WASH) and access to
22
23 155 WASH commodities
24
25 156 5. To prevent early, poorly spaced and repeated pregnancies
26
27
28
29

30 158 **METHODS AND ANALYSIS**

31
32 159 This protocol describes the intervention and evaluation methods for the Swabhimaan programme,
33
34 160 which aims to improve the nutrition status of adolescent girls and women in three Indian states:
35
36 161 Bihar, Chhattisgarh and Odisha.

37 162 **Target groups**

38
39 163 The primary target groups for the programme are adolescent girls, newlywed women and couples,
40
41 164 pregnant women, and mothers of children under two years of age. Swabhimaan also reaches out to
42
43 165 husbands, mothers-in-law and farmer producer groups.
44
45
46

47 166 **Evaluation design**

48
49 167 The Swabhimaan evaluation is a prospective, non-randomized controlled study with baseline, midline
50
51 168 and endline cross-sectional surveys. Across Bihar, Chhattisgarh and Odisha, five sites covering 162
52
53 169 villages (intervention arm) have been purposively allocated to community-led interventions delivered
54
55 170 through VOs and CLFs since 2017, and five sites covering 151 villages (control arm) will initiate
56
57 171 these activities 36 months later, in 2020. Both intervention and control sites are located in the poorest
58
59 172 areas (also referred to as resource blocks) identified by DAY-NRLM in four districts: Purnea in Bihar,
60

173 Bastar in Chhattisgarh, and Angul and Koraput in Odisha. In Bihar, within Kasba and Jalalgarh blocks
 174 located in Purnea district, we allocated 42 villages to the intervention and 31 villages to control arm. In
 175 Chhattisgarh, we allocated 40 villages in Bastar block in Bastar district to intervention and 40 villages
 176 in Bakawand block to control. In Odisha, 80 villages within Koraput block in the district of Koraput
 177 and Pallahara block in the district of Angul both serve as intervention areas, and 80 more serve as
 178 control. The unit of assignment to intervention and control was a cluster of villages in Bihar and
 179 Chhattisgarh and a gram panchayat (administrative units of around 5000 population) in Odisha which
 180 was in alignment with NRLM identified administrative boundaries for managing the livelihoods
 181 programme in these states (Figure 1).

182 **Figure 1. Evaluation design**

183 **Study hypotheses and outcomes**

184 We hypothesize that, over an intervention period of three years, Swabhimaan's community-led
 185 interventions will lead to:

- 186 (a) a 15% reduction in the proportion of adolescent girls with a BMI < 18.5
- 187 (b) a 15% reduction in the proportion of mothers of children under two with a BMI < 18.5
- 188 (c) a 0.4cm improvement in mean MUAC among pregnant women

189 These three indicators are considered the evaluation's primary outcomes. The targets for reduction in
 190 proportion of adolescent girls and pregnant women with BMI < 18.5 kg/m² was based on population
 191 based survey data for the selected districts while that for MUAC in pregnancy was based on a rapid
 192 assessment undertaken in the intervention sites and the reductions noted in previous research on
 193 women's nutritional status [17,18]. We also hypothesize an improvement of between 5% and 20% in
 194 the coverage of 18 key nutrition-specific and -sensitive interventions over three years (Table 1). These
 195 constitute the evaluation's secondary outcomes.

196 **Table 1 Primary and secondary outcomes for Swabhimaan**

PRIMARY OUTCOMES
1. % adolescent girls with BMI < 18.5 kg/m ²
2. mean MUAC among pregnant women

1
2
3 3. % mothers of children under 2 with <18.5 kg/m²
4

5 **SECONDARY OUTCOMES**
6

7 **ADOLESCENT GIRLS** (Girls aged 10-19) – unmarried, not pregnant and not the mother of a child
8
9 under two
10

- 11
12 1. Mean dietary diversity score
13
14 2. % receiving minimum dietary diversity score (MDD) (5 of 10 food groups)
15
16 3. % consuming four or more IFA tablets in the month preceding the survey
17
18 4. % living in a household with iodized salt
19
20 5. % living in food secure households
21
22 6. % living in households with a kitchen garden
23
24 7. % living in households with a toilet or covered pit latrine
25
26 8. % using safe pads or sanitary pads
27
28 9. % accessing adolescent health services (Kishori Divas) in six months preceding the survey
29
30 10. % who attended at least three Kishori meetings in six months
31
32 11. % who attended at least three Kishori meetings in in six months
33
34

35 **PREGNANT WOMEN** (if she is pregnant, a girl or woman will join this category whether she is an
36 adolescent, newlywed or the mother of any child under two)
37
38

- 39 1. % of pregnant women in the 2nd and 3rd trimester consuming at least 25 IFA tablets in the
40 month preceding the survey
41
42 2. Mean dietary diversity score
43
44 3. % receiving minimum dietary diversity (5 out of 10 food groups)
45
46 4. % living in a household with iodized salt
47
48 5. % living in food secure households
49
50 6. % living in households with a kitchen garden
51
52 7. % living in households with a toilet or covered pit latrine
53
54 8. % receiving ICDS entitlement for supplementary food in month preceding the survey
55
56 9. % who had one antenatal check-up in the first trimester
57
58
59
60

10. % weighed at least once in first trimester
11. % who received one dose of albendazole in second trimester
12. % who took two calcium tablets in 2nd trimester
13. % below the age of eighteen
14. % who attended at least three Maitri Bethak meetings in six months
15. % who attended at least three Maitri Bethak meetings in six months
16. % who attended at least three VHSNDs in six months
17. % who attended at least three VHSNDs in six months
18. % using a modern family planning method (in previous delivery); before the current pregnancy
19. % who are members of women's Ag-producer groups and have adopted at least 1 mix micronutrient-rich cropping methods, against previous practice
20. % who are members of women's Ag-producer groups and have adopted at least 1 pesticide-free agri-methods, against previous practice

MOTHERS OF CHILDREN AGED UNDER TWO YEARS

1. Mean dietary diversity score
2. % receiving minimum dietary diversity (5 out of 10 food groups)
3. % living in a household with iodized salt
4. % living in food secure households
5. % living in households with a kitchen garden
6. % living in households with a toilet or covered pit latrine
7. % receiving their minimum PDS entitlement in month preceding survey
8. % receiving ICDS entitlement for supplementary food in month preceding survey
9. % who received at least four ANC overall in last pregnancy
10. % consuming 100 or more IFA tablets during last pregnancy
11. % weighed at least four times in last pregnancy
12. % using a modern family planning method

13. % who accessed at least one of three social protection schemes (JSY, Adarsh Dampati Yojana)
14. % who delivered in a health facility in last pregnancy
15. % who attended at least three Maitri Bethak meetings and three VHSNDs in last year
16. % who attended at least three Maitri Bethak meetings and three VHSNDs in last year
17. % who are members of women's Ag-producer groups and have adopted at least 1 mix micronutrient-rich cropping methods, against previous practice
18. % who are members of women's Ag-producer groups and have adopted at least 1 pesticide-free agri-methods, against previous practice

197

198 **Sample size calculation**

199 We conducted State-specific sample size calculations to determine the appropriate number of
 200 adolescent girls, pregnant women and mothers of children under two to be surveyed to be able to
 201 detect achievement of hypothesised targets for primary outcomes (Table 2). Sample size accounted
 202 for 5% refusal rate and design effect of 1.5. Overall, we estimated that baseline and endline surveys
 203 should include a total of 6638 adolescent girls, 10,160 mothers of children under two and 2992
 204 pregnant women across the three States.

205 **Table 2 State wise estimated total sample in intervention and control areas by target groups**

	Bihar	Chhattisgarh	Odisha	Total
Adolescent girls	1750	3294	1594	6638
Pregnant women	748	1122	1122	2992
Lactating mothers	2846	3294	4020	10160
Total	5345	7710	6736	19790

206

207

208 **Sample selection**

209 We conducted the baseline survey for the evaluation in 2016-17. In Bihar, a census was undertaken
 210 and full household listing was conducted to identify adolescent girls aged 10-19 years, pregnant

211 women and mothers of children under two in all programme areas. Respondents for each of the three
 212 target groups were then selected by simple random sampling. In Chhattisgarh, all villages in
 213 designated programme site were paired on the basis of population size and whether they had held a
 214 monthly VHSND for the last three months. Forty such pairs were then randomly selected for data
 215 collection, and all eligible respondents in each of the three target groups in these 80 villages were
 216 surveyed. In Odisha, all eligible target groups in 26 purposively identified Gram Panchayats- 12
 217 intervention and 14 control were surveyed.

218 **Tools**

219 Bilingual questionnaire (Bihar: English and Hindi, Chhattisgarh: English and Hindi and Odisha:
 220 English and Odia) for all target groups were developed, field tested and standardized for all states. In
 221 baseline, information obtained included but was not limited to socio-demographic and household
 222 characteristics, educational attainment, diet diversity, household food security, access to services.
 223 Anthropometric measurements (weight, height and MUAC) were conducted using standard
 224 techniques [19]. Weight to the nearest 0.1 kg was recorded using a SECA electronic weighing scale
 225 with minimal clothing. Height was taken barefoot to the nearest 0.1 cm using a stadiometer. MUAC
 226 was measured to the nearest 0.1 cm with a non-stretchable measuring tape.

227 **Sample coverage in baseline survey**

228 Sample coverage for both interviews and anthropometric measurements was universal in all states
 229 except among mothers of children under two in Bihar where 85% of those sampled could be
 230 interviewed and coverage for all anthropometric measurements was 83%.

231 **Intervention**

232 Swabhimaan covers 18 nutrition-specific and nutrition-sensitive interventions (Table 3).

233 **Table 3 Nutrition-specific and nutrition-sensitive interventions package, Swabhimaan**

	Relevant target group		
	Preconception	Pregnancy	Lactation
Improve food and nutrient intake			
1. Access to generalized household ration through	*	*	*

1				
2				
3		Public Distribution System (PDS), a food subsidy		
4		scheme		
5				
6				
7	2.	Balanced energy protein supplementation through	*	*
8		access to supplementary rations		*
9				
10				
11	3.	Access to knowledge and choices about how to	*	*
12		increase maternal dietary diversity		*
13				
14				
15	4.	Access to knowledge and support for nutrition-		
16		sensitive agriculture at home (kitchen garden) and	*	*
17		community based food insecurity coping strategies.		*
18				
19				
20				
21				

Prevent micronutrient deficiencies and anaemia

22				
23				
24	5.	IFA supplementation	*	*
25				*
26	6.	Universal use of iodized salt	*	*
27				*
28	7.	Calcium supplementation and deworming	X	*
29				*
30	8.	Access to information and commodities like	*	*
31		insecticide treated bed-nets for malaria prevention		*
32				
33				
34	9.	Access to information on preventing tobacco and		
35		alcohol use in pregnancy	X	*
36				*
37				
38				

Increase access to health services and special care to nutritionally “at risk” women (MUAC <23 cm)

39				
40				
41				
42				
43	10.	Early registration in outreach services	*	*
44				X
45	11.	Recording and monitoring of nutritional status and		
46		special community-based at-nutritional risk package	X	*
47				X
48				
49	12.	Quality reproductive health, antenatal and postnatal		
50		care	*	*
51				*
52				
53	13.	Access to knowledge and entitlements for promotion		
54		of institutional deliveries and maternity benefits	X	*
55				*
56				
57				

Increase access to education and commodities for

WASH

14. Sanitation and hygiene (including menstrual hygiene) education	*	*	*
15. Access to safe drinking water and sanitation commodities	*	*	*
Prevent early, poorly spaced or unwanted pregnancies			
16. Promotion of secondary education and education for delaying the age at marriage to legal age	*	X	X
17. Access to information and family planning commodities for delaying age at first pregnancy and prevention of repeated pregnancies	*	*	*
18. Women's collective voice and empowerment for decision-making to prevent child marriage, violence against women, child spacing and other gender-related issues	*	*	*

234

235 In intervention sites, these interventions are delivered through a combination of community- and
 236 systems-led efforts, while control sites receive only systems strengthening. Community-led
 237 interventions are delivered through trained community cadre who are members of VOs, namely
 238 Poshan Sakhis (lit. 'Nutrition sister/friend') or Community Resource Persons (CRPs) and Krishi
 239 Mitras (lit. farmer friends) or Village Resource Persons (VRPs). The community cadre are part of the
 240 DAY-NRLM and SRLM implementation structure. In Bihar, a separate cadre of Kishori Sakhis (lit.
 241 'Adolescent sister/friend') for reaching out and serving adolescent girls has been created (Table 4).

242 **Table 4 Geographic scope and service providers for community-led interventions under**
 243 **Swabhimaan**

	Bihar	Chhattisgarh	Odisha	Total
Revenue villages	77	111	168	356

CLF and related (Tier -3)	5	4	12	21
VOs (Tier 2)	72	80	79	231
Poshan Sakhis or CRPs of Tier 2	72	100	79	251
Kishori Sakhis of Tier 2	72	-	-	72
SHGs (Tier-1)	1985	1488	702	4175
VRPs/Krishi mitras	115	80	39	234

244

245 Poshan Sakhis and Kishori Sakhis undergo three days of pre-service training on integrated nutrition
 246 microplanning, which includes a theoretical orientation and practical on consultative identification
 247 and prioritization of nutrition and related problems among target groups in their village/s, developing
 248 an annual plan of activities including a budget to address these problems, the use of MUAC tapes,
 249 recording and using MUAC measurements for screening nutritionally “at risk” adolescent girls and
 250 women. As no standard MUAC cut-offs are available for screening adolescent girls at risk of
 251 undernutrition and <21 cm as well as <22 cm have been reported in research, a stricter cut-off of <19
 252 cm is being used to identify those, most at risk [20,21,22]. In addition, clinical examination for signs
 253 of anaemia is also done followed by a diagnostic test for blood haemoglobin level by a health service
 254 provider at VHSND. Post-training, they co-facilitate the development of the integrated nutrition
 255 microplan with the block coordinator/ supervisor through a 12-day process, which can spread over
 256 almost two months. The process entails microplanning at VO level, its validation by reaching out to
 257 the most vulnerable communities and village clusters, then consolidation of all VO plans at CLF and
 258 block levels. Poshan Sakhis and Kishori Sakhis are then trained over three days on use of
 259 participatory learning and action (PLA) to facilitate monthly women’s group and adolescent girls’
 260 group meetings. Poshan Sakhis and Kishori Sakhis lead activities in their village/s as per decided
 261 activities in the microplan. More cost-intensive and complex grant management activities are led by
 262 CLFs (Table 5).

263 **Table 5 Community led interventions under Swabhimaan**

Responsible agency /	Intervention	Frequency
----------------------	--------------	-----------

Service provider

VO

Social action committee	Selection of Poshan Sakhi (1 per VO)	One time
Poshan sakhi/CRP	Integrated nutrition microplanning (12 days over 2 months)	Once, followed by annual review
	Maitri bethak (lit. friendly meeting) of women open to non-group members using Participatory Learning and Action	Monthly
	One additional monthly home visit/group meeting of nutritionally “at risk” women	Monthly
Krishi mitra/ VRP	Maitri kishan bethak (lit. friendly farmers meeting) on nutrition-sensitive agriculture Participatory Learning and Action	Monthly
	Home-based Poshan beds/backyard poultry	Monthly

CLF

Social action committee	Families with women and children at risk of undernutrition linked to agri-poultry linkage and social protection schemes	Monthly
	Loans for secondary education	Monthly
	Creating farmer training school sites	Monthly
	Training for Poshan sakhi and Krishi mitras	Quarterly
	Newly wed couples meetings	Biannual
	Entitlement camps and health checkups for SHG members	Biannual
	Review of integrated nutrition plan	Annual

264

265 The CRPs receive INR 450 (USD 7) for developing the poshan microplan and thereafter a similar
 266 incentive every month for completed activities. CLFs also receive grants including: INR 500 (~USD

1
2
3 267 7) for meetings with newlywed couples; INR 500 for each 'welcome kit' given to newlywed couples
4
5 268 with essential items like IFA, contraceptives, sanitary napkins; INR 1500 (~USD 22) for review of
6
7 269 each VO's integrated nutrition microplan; and INR 5000 (~USD 77) for developing farmer training
8
9 270 school sites which are model nutri-farms for training farmer producer group members interested in
10
11 271 nutri-sensitive agriculture.

12
13
14 272 The system strengthening activities include five components:

- 15
16 273 1) strengthening VHSNDs to improve access to antenatal care, family planning and micronutrient
17
18 274 supplementation through quarterly trainings of health service providers, monthly review of nutrition
19
20 275 indicators, and the identification of women at risk of undernutrition (MUAC <23cm) for special
21
22 276 supplementary food and counselling;
- 23
24 277 2) Strengthening adolescent health days to improve access to adolescent health and nutrition services
25
26 278 via quarterly trainings of health service providers;
- 27
28 279 3) an extended VHSND once every six months for newlyweds and women, including individual
29
30 280 counselling and information about entitlement camps;
- 31
32 281 4) annual training and follow-up meetings with service providers from food security, Integrated Child
33
34 282 Development Services (ICDS), water and sanitation departments to help them improve the delivery of
35
36 283 entitlements and services;
- 37
38 284 5) ensuring regular review meetings with representation across government departments involved in
39
40 285 service delivery

41
42
43 286 Thus, in addition to DAY-NRLM, system strengthening activities engage four other government
44
45 287 departments: Department of Woman and Child Development for increasing ICDS reach and quality,
46
47 288 Department of Health and Family Welfare for VHSND strengthening, Department of Water and
48
49 289 Sanitation for improving water quality and achieving open defecation free villages and districts, and
50
51 290 finally Department of Civil and Food Supply for increasing coverage of food subsidy schemes.

52
53 291 The theory of change for Swabhimaan is presented in Supplementary File 1.

54
55 292

56
57 293

58
59 294

295 **Blinding**

296 It is not possible to blind participants to allocation, but data collection teams and analysts are blind to
297 allocation.

298

299 **Data analysis**

300 In each state, we will assess the comparability of intervention and control areas at baseline by
301 examining area-level and individual level characteristics, including: the number of self-help groups
302 and village organisations in each area, the socio-demographic profile of respondents and their
303 households (caste, literacy and assets) and key evaluation outcomes at baseline.

304 The final impact analysis will be by intention-to-treat, comparing primary and secondary outcomes in
305 five intervention areas and five control areas. This analysis will be carried out at an individual level,
306 adjusting for clustering at the level of the village and VO, using linear and logistic random effects
307 models in STATA 14. We will use the difference-in-difference method to compare primary and
308 secondary outcomes between intervention and control areas at endline, adjusting for their baseline
309 values and for other characteristics that differed significantly between the two areas at baseline. We
310 will present analyses both a State level, and conducted a pooled analysis with data from all States.

311 **Patient and Public Involvement**

312 This research did not have any patients. The public (community) was involved in the design and
313 implementation of the intervention package at the village level but not in the evaluation. Public were
314 not invited to contribute to the writing or editing of this document for readability or accuracy.

315 **Process monitoring and progress review**

316 In addition to the impact evaluation described above, we are conducting process monitoring. The
317 process monitoring system is based on the reporting structures within the SRLM (Figure 2).

318 **Figure 2 SRLM organization structure and its adaptation in Swabhimaan, Bihar**

319

320 SRLM's have a project management units at State, district and block levels (SPMU, DPMU, BPMU).

321 The block Management Information System (MIS) coordinator is the reporting link between the CRPs
322 and their supervisors and the BPMU. In Bihar, a supervisor position has been embedded in the

1
2
3 323 organization structure while in Chhattisgarh and Odisha, supervisory staff is a representative from the
4
5 324 SRLM's organogram.

6
7 325
8

9 326 CRPs/ Poshan sakhis collect data and report coverage of community-led interventions on monthly
10
11 327 monitoring formats which are available in both web-based and paper formats. Key performance
12
13 328 indicators include:

- 15
16 329 ▪ Target women who attended the VHSND (%)
17
18 330 ▪ Target women who attended the maitri bethak (%)
19
20 331 ▪ At-risk women visited fortnightly in their home visits (%)
21
22 332 ▪ At-risk women attended fortnightly food demonstration and counselling session (%)
23
24 333 ▪ Target newly-wed who attended the couple meeting (reported quarterly)
25
26 334 ▪ Target groups who attended the women only camps (reported biannually)
27

28 335
29

30 336 All CRP reports are collated monthly at the block level. A CLF level review of the progress on
31
32 337 performance indicators and the planned activities as per the poshan microplan is planned for every
33
34 338 quarter, however, Swabhimaan has mixed experience in achieving this with Chhattisgarh undertaking
35
36 339 monthly reviews while other states undertaking annual reviews. DAY-NRLM hosts annual reviews
37
38 340 with the respective SRLMs for stock taking and approval for next annual cycle.
39

40 341
41

42 342 **Timeline**

43
44 343 Baseline was completed in 2017. The first phase of implementation is between 2017 and 2020.
45
46 344 Midline and endline for first phase will be completed in 2019 and 2021 respectively.
47

48 345
49

50 346 **ETHICS AND DISSEMINATION**

51
52 347 The baseline survey was conducted according to the guidelines laid down in the Declaration of
53
54 348 Helsinki and all procedures involving human subjects were approved by the Institutional Ethics
55
56 349 Committee of the All India Institute of Medical Sciences (AIIMS), Bihar, Chhattisgarh and AIIMS,
57
58 350 Odisha in July 2016 (Supplementary files 2,3 and 4). Written informed consent was obtained from all
59
60

1
2
3 351 subjects. The impact evaluation has been registered with the Registry for International Development
4
5 352 Impact Evaluations (RIDIE-STUDY-ID-58261b2f46876) [23] and Indian Council of Medical
6
7 353 Research National Clinical Trials Registry of India (CTRI/2016/11/007482).

8
9 354 Government of India is committed to reviewing its antenatal care guidelines with focus on nutrition in
10
11 355 addition to other components of antenatal care in line with new recommendations of the World Health
12
13 356 Organization, 2016 [24]. Evidence from the evaluation will inform maternal nutrition policy as well
14
15 357 as incorporation of nutrition interventions for adolescent girls and newly-wed women in existing and
16
17 358 new policies.

19 359 **CONCLUSION AND IMPLICATIONS**

20
21
22 360 Being a controlled evaluation, Swabhimaan will measure impact of community-led interventions over
23
24 361 standard practice of public health and nutrition services for adolescent girls, pregnant women and
25
26 362 lactating mothers. A third party evaluator, International Institute for Population Sciences, India, with
27
28 363 no role in implementation, further bolsters the evaluation design. Swabhimaan operates in complete
29
30 364 alignment with DAY-NRLM's mandate under the joint convergent action plan for Poshan Abhiyaan.
31
32 365 In coordination with departments of Woman and Child Development and Health, DAY-NRLM shares
33
34 366 responsibility for (1) SHG members mobilizing communities for utilizing entitled services through
35
36 367 Department of Health, (2) SHG members participating in Behaviour Change and Communication
37
38 368 activities, promoting recommended health, nutrition and WASH behaviours, (3) common use of
39
40 369 infrastructure by the three departments such as use of Panchayat halls for SHG and VO meetings and
41
42 370 (4) promoting nutri-based livelihoods for women's collectives. These activities are integrated in VO's
43
44 371 poshan microplans and system strengthening activities under Swabhimaan.

45
46 372
47
48
49 373 Swabhimaan operates as three different models in Bihar, Chhattisgarh and Odisha. Bihar is the
50
51 374 demonstration and learning site, with financial support for human resources and activities through
52
53 375 UNICEF India. In Chhattisgarh and Odisha, the initiative is almost completely led by the respective
54
55 376 SRLMs with UNICEF to SRLM cost ratio at 1:5. UNICEF India supports some human resource at
56
57 377 state and block levels, but none at the VO level in these two states. By 2020, it is planned to advocate
58
59 378 for increased number of positions at SRLMs to support implementation of the convergent action plan

1
2
3 379 and create a system of CRPs graduating to block level positions in the three states. UNICEF India's
4
5 380 support on human resource will gradually lessen. DAY-NRLM has recognized the Chhattisgarh
6
7 381 model of Swabhimaan as a best practice for integrating health, nutrition and WASH on the SHG
8
9 382 platform and has planned to take elements from the initiative for horizontal expansion to poorest
10
11 383 resource blocks in other states. Findings from the Swabhimaan midline survey will inform scale-up
12
13 384 plans in other states.
14
15
16 385

17 386 **DECLARATIONS**

18 387 **Abbreviations**

19
20
21 388 AIIMS All India Institute of Medical Sciences, ANM Auxiliary Nurse Midwife , ASHA Accredited
22
23 389 Social Health Activist, AWW Anganwadi Worker, BMI Body Mass Index, BPMU Block Project
24
25 390 Management Unit, CLF Cluster Level Federation, CRP Community Resource Person, DAY-NRLM
26
27 391 Deendayal Antyodaya Yojana- National Rural Livelihoods Mission, DPMU District Project
28
29 392 Management Unit, ICDS Integrated Child Development Services, IFA Iron Folic Acid, MIS
30
31 393 Management Information System, MUAC Mid-upper Arm Circumference, PLA Participatory
32
33 394 Learning Action, PDS Public Distribution System, RIDIE Registry for International Development
34
35 395 Impact Evaluation , SHG Self-help group, SPMU State Project Management Unit, SRLM State Rural
36
37 396 Livelihoods Mission, VHSND Village Health Sanitation and Nutrition Day, VRP Village Resource
38
39 397 Person, VO Village Organization, WASH Water Sanitation and Hygiene
40
41
42

43 398 **Ethics approval and consent to participate**

44
45 399 The baseline survey was conducted according to the guidelines laid down in the Declaration of
46
47 400 Helsinki and all procedures involving human subjects were approved by the Institutional Ethics
48
49 401 Committee of the All India Institute of Medical Sciences (AIIMS), Bihar, Chhattisgarh and AIIMS,
50
51 402 Odisha in July 2016. Written informed consent was obtained from all subjects. The impact evaluation
52
53 403 has been registered with the Registry for International Development Impact Evaluations (RIDIE-
54
55 404 STUDY-ID-58261b2f46876) and Indian Council of Medical Research National Clinical Trials
56
57 405 Registry of India (CTRI/2016/11/007482).
58
59

60 406 **Data sharing**

1
2
3 407 **Funding**
4

5 408 This research received no specific grant from any funding agency in public, commercial or not-for-
6
7 409 profit sectors.
8

9 410

10
11 411 **Competing interests**
12

13 412 None of the authors have any competing interests.
14
15

16 413

17
18 414 **Authors' contributions**
19

20 415 VS and ADW provide technical oversight and VS is the national focal point of the initiative. NK is
21
22 416 key contact in NRLM and advises on effective utilization of NRLM platforms. VS, AB, SB, NN,
23
24 417 AD,RNP, SS, AL and NK were involved in designing Swabhimaan initiative at national and state
25
26 418 level. RG, VN and NN contributed to the Participatory Learning Action component of the initiative.
27
28 419 DS and US contributed to the agriculture component. SB, RNP, SS (Sonali Sinha), AL, NA (Naushad
29
30 420 Ali), FS, MP, PM are involved in the implementation of the initiative in Bihar, Chhattisgarh and
31
32 421 Odisha. BM, SS and AP (Apollo Purty) are government counterparts; BM provides management
33
34 422 support in Odisha and SS (Somya S) and AP (Apollo Purty) in Bihar. AP (Audrey Prost), HPS and
35
36 423 SU advise on evaluation of the initiative and AP (Audrey Prost) drafted the registered protocol. NA
37
38 424 (Neeraj Agarwal), VB, MR, BS, RRS, SP, LKD were part of evaluation team; NA (Neeraj Agarwal),
39
40 425 VB and MR led baseline evaluation in Bihar, Odisha and Chhattisgarh, respectively. VS, AB and AP
41
42 426 (Audrey Prost) drafted the manuscript. All authors reviewed the manuscript.
43
44

45 427

46
47 428 **Acknowledgements**
48

49 429 Shivani Dar (UNICEF Bihar) and Anoop Jha (Independent consultant) supported stakeholder
50
51 430 coordination in Bihar. Anoop Jha was part of implementation team in Bihar. Shibanand Rath (Ekjut)
52
53 431 participated in the designing workshop and made significant contribution to the participatory learning
54
55 432 action component of the initiative. CM Singh (AIIMS, Patna, Bihar) managed evaluation teams in
56
57 433 Bihar. Aparajita Chattopadhyay, Preeti Dhillon, Prakash H. Fulpagare and Konsam Dinachandra
58
59 434 Singh (IIPS) supported quality control in baseline survey and are part of the evaluation team. Sarita

1
2
3 435 Anand (Roshni, Lady Irwin College, New Delhi) leads process documentation of the initiative.
4

5 436 Rachna Sharma (UNICEF India) and Dhruv Sengupta (DAY-NRLM) offer technical advice on
6

7 437 specific components related to communication and government coordination, respectively.
8

9 438
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

439 **REFERENCES**

- 440 1. Black RE, Victora CG, Walker SP, Bhutta ZA, Christian P, de Onis M, Ezzati M, et al. Maternal
441 and child undernutrition and overweight in low-income and middle-income countries. *Lancet*.
442 2013; 382:427-451.
- 443 2. Bhutta ZA, Das JK, Rizvi A, Gaffey MF, Walker N, Horton S, et al. Evidence based interventions
444 for improvement of maternal and child nutrition: What can be done and at what cost? *Lancet*.
445 2013; 382:452-477.
- 446 3. International Institute for Population Sciences (IIPS) and Macro International. 2015-16. National
447 Family Health Survey (NFHS-4), 2015–16: India Factsheet.
- 448 4. Ministry of Home Affairs. Office of the Registrar General and Census Commissioner, India.
449 Population enumeration data 2011.
- 450 5. <https://www.icds-wcd.nic.in/nnm/home.htm#>
- 451 6. Prost A, Colbourn T, Seward N, Azad K, Coomarasamy A, Copas A, et al. Women’s groups
452 practising participatory learning and action to improve maternal and newborn health in low-
453 resource settings: a systematic review and meta-analysis. *Lancet*. 2013; 381(9879):1736–46.
- 454 7. Fottrell E, Azad K, Kuddus A, Younes L, Shaha S, Nahar T, et al. The effect of increased
455 coverage of participatory women’s groups on neonatal mortality in Bangladesh: a cluster
456 randomized trial. *JAMA Pediatr*. 2013; 167(9):816–25.
- 457 8. Colbourn T, Nambiar B, Bondo A, Makwenda C, Tsetekani E, Makonda-Ridley A, et al. Effects
458 of quality improvement in health facilities and community mobilization through women’s groups
459 on maternal, neonatal and perinatal mortality in three districts of Malawi: MaiKhanda, a cluster
460 randomized controlled effectiveness trial. *Int Health*. 2013; 5(3):180-95.
- 461 9. More NS, Bapat U, Das S, Alcock G, Patil S, Porel M, et al. Community mobilization in Mumbai
462 slums to improve perinatal care and outcomes: a cluster randomized controlled trial. *PLoS Med*.
463 2012; 9(7):e1001257.
- 464 10. Tripathy P, Nair N, Barnett S, Mahapatra R, Borghi J, Rath S, et al. Effect of a participatory
465 intervention with women’s groups on birth outcomes and maternal depression in Jharkhand and
466 Orissa, India: a cluster-randomised controlled trial. *Lancet*. 2010; 375(9721):1182–92.

- 1
2
3 467 11. The World Bank. Indonesia's PNPM Generasi Programme. Final impact evaluation. 2011.
- 4
5 468 12. TANGO International Inc.. SHOUHARDO a Title II programme of USAID. Final evaluation
6
7 469 report. 2009.
- 8
9 470 13. Saha S, Annear PL, Pathak S. The effect of Self-Help Groups on access to maternal health
10
11 471 services: evidence from rural India. *International Journal of Equity in Health*. 2013; 12:36.
- 12
13 472 14. VOICES. A report on success and failure of SHGs in India- impediments and paradigms of
14
15 473 success. 2008. Report submitted to Planning Commission, Government of India.
- 16
17 474 15. National Rural Livelihoods Mission, Ministry of Rural Development, Government of India.
18
19 475 Briefing book. 2012
- 20
21 476 16. Sethi V, Bhanot A, Bhalla S, Bhattacharjee S, Daniel A, Sharma DM, et al. Partnering with
22
23 477 women collectives for delivering essential women's nutrition interventions in tribal areas of
24
25 478 eastern India: a scoping study. *J Health Popul Nutr*. 2017; 36 (20).
- 26
27 479 17. Office of the Registrar General and Census Commissioner, India. Annual Health Survey. Clinical,
28
29 480 Anthropometry and Biochemical Survey, Purnea, Bihar. 2012.
- 30
31 481 18. Kumar P, Sareen N, Agrawal S, Kathuria N, Yadav S, Sethi V. Screening maternal acute
32
33 482 malnutrition using adult mid-upper arm circumference in resource-poor settings. *Indian Journal of*
34
35 483 *Community Medicine*. 2018; 43:132–134.
- 36
37 484 19. World Health Organization (WHO). Physical status: the use and interpretation of anthropometry.
38
39 485 Report of a WHO Expert Committee. World Health Organ Technical Report Series. Geneva:
40
41 486 WHO, 1995.
- 42
43 487 20. Bulliyya, G, Mallik G, Sethy GS, Kar SK. Haemoglobin Status of Non-School Going Adolescent
44
45 488 Girls in Three Districts of Orissa, India. *International Journal of Adolescent Medicine & Health*.
46
47 489 2007.19; (4):395–406.
- 48
49 490 21. Mramba L, Ngari M, Mwangome M, Muchai L, Bauni E, Walker SA, Gibb DM, Fegan G,
50
51 491 Berkley JA. A growth reference for mid upper arm circumference for age among school age
52
53 492 children and adolescents, and validation for mortality: growth curve construction and longitudinal
54
55 493 cohort study. *BMJ*, 2017;358:j3423.
- 56
57
58
59
60

- 1
2
3 494 22. Tang AM, Dong K, Deitchler M, Chun M, Maalouf-Manasseh Z, Tumilowicz A, Wanke C. Use
4
5 495 of Cutoffs for Mid-Upper Arm Circumference (MUAC) as an Indicator or Predictor of Nutritional
6
7 496 and Health Related Outcomes in Adolescents and Adults: A Systematic Review. 2013.
8
9 497 Washington, DC: FHI 360/FANTA
10
11 498 23. Integrated multisectoral strategy to improve girls' and women's nutrition before conception,
12
13 499 during pregnancy and after birth in India (Swabhimaan): prospective, non-randomised controlled
14
15 500 evaluation. Principal investigator: Sethi V. Co-Principal investigator: Unisa S.
16
17 501 <http://ridie.3ieimpact.org/index.php?r=search/detailView&id=485>
18
19 502 24. World Health Organization. WHO recommendations on antenatal care for a positive pregnancy
20
21 503 experience [Internet]. WHO 2016. Available from:
22
23 504 <http://apps.who.int/iris/bitstream/10665/250796/1/9789241549912-eng.pdf>.
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Figure 1 Evaluation design

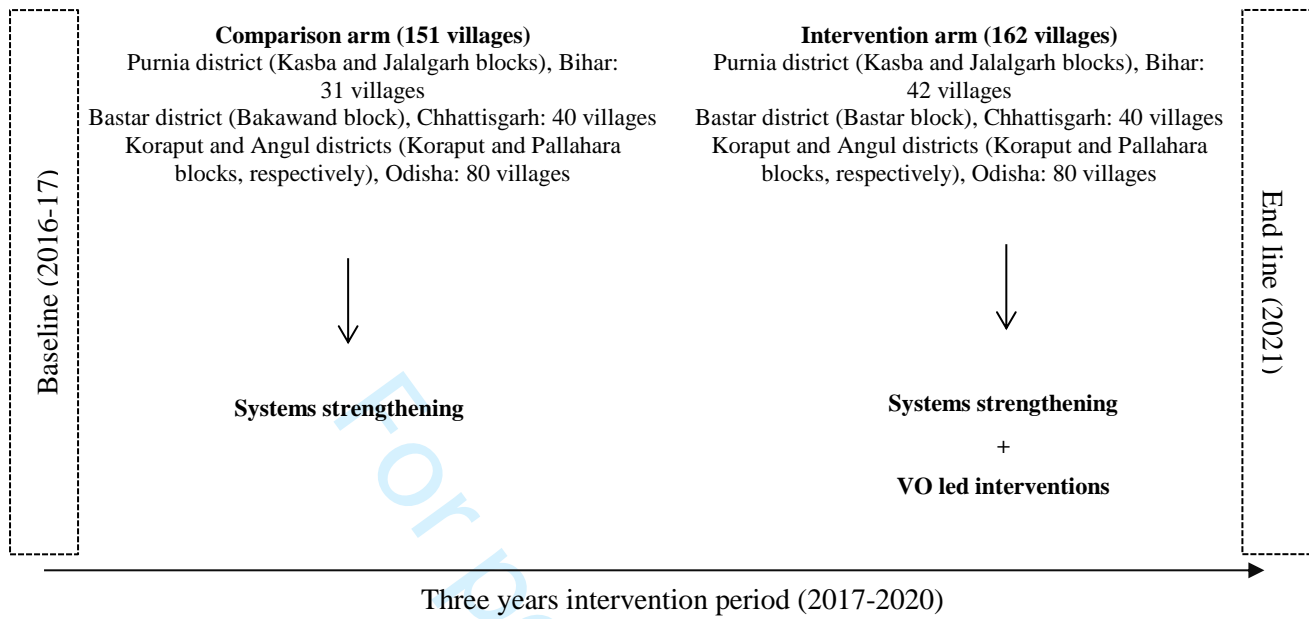
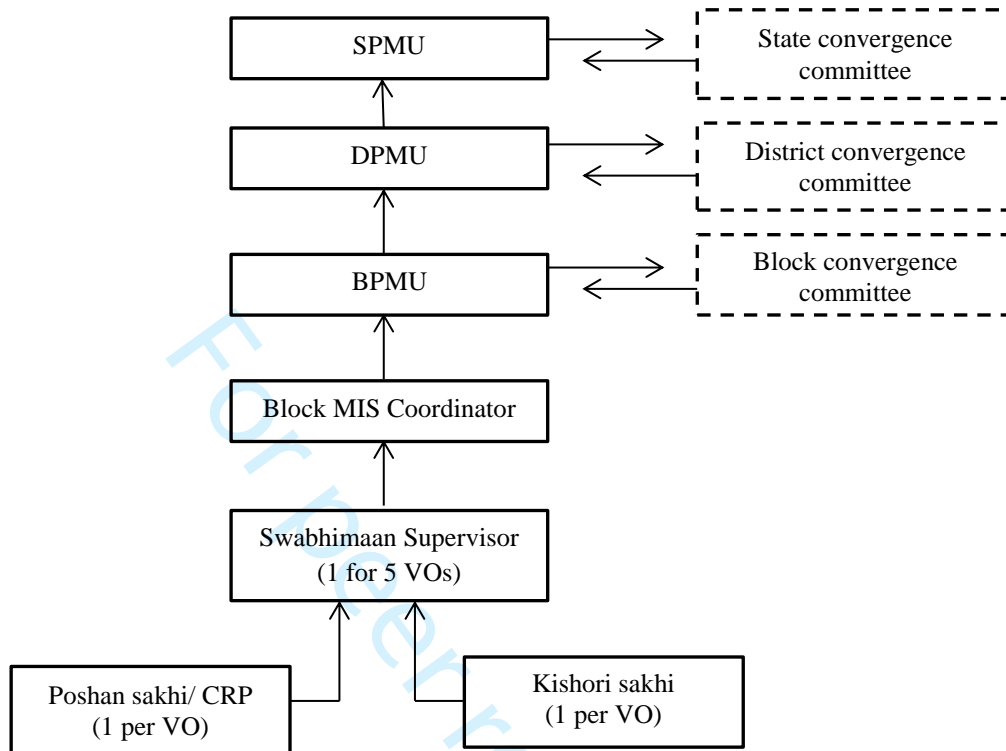


Figure 2 SRLM organization structure and its adaptation in Swabhimaan, Bihar



Theory of change for Swabhimaan: Bihar, Chhattisgarh and Odisha (2016 -2021)

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47

Improved nutritional status of adolescent girls (10-19 years) and women in defined poverty pockets of three states



15% reduction in proportion of adolescent girls (10-19 years) with BMI <18.5 kg/m ² between 2016 and 2021	0.4cm improvement in mean MUAC of pregnant women between 2016 and 2021	15% reduction in proportion of mothers of children under two with BMI <18.5 kg/m ² between 2016 and 2021
--	--	---

Impact

Adolescent girls and women in government defined poverty pockets have increased access to and uptake of 18 essential nutrition interventions through:

1. Community led planning, implementation and management of women’s nutrition interventions (5 Blocks in 3 States)

2. Systems strengthening for equitable and timely reach of women’s nutrition interventions (6 Blocks in 3 States)

3. Co-strategising and co-implementing health, nutrition, food security, agriculture and WASH interventions across sectors (4 Districts in 3 States)

Strategies



1. By 2021 there is equitable reach of food security safety-nets and services for adolescent girls and women with focus on at nutritional risk	2. By 2021 high impact nutrition and health (including reproductive health and family planning) services for adolescent girls and women are available concomitantly and consistently	3. By 2021 household access to drinking water and sanitation products/ services and practice of personal hygiene behaviours by adolescent girls and women increases	4. By 2021 there is increased know-how on nutrition sensitive agricultural practices at district and sub-district levels and their application at village level	5. By 2021 VOs are capacitated to design, implement and manage integrated, context-responsive, multi-sector nutrition programmes
---	---	--	--	---

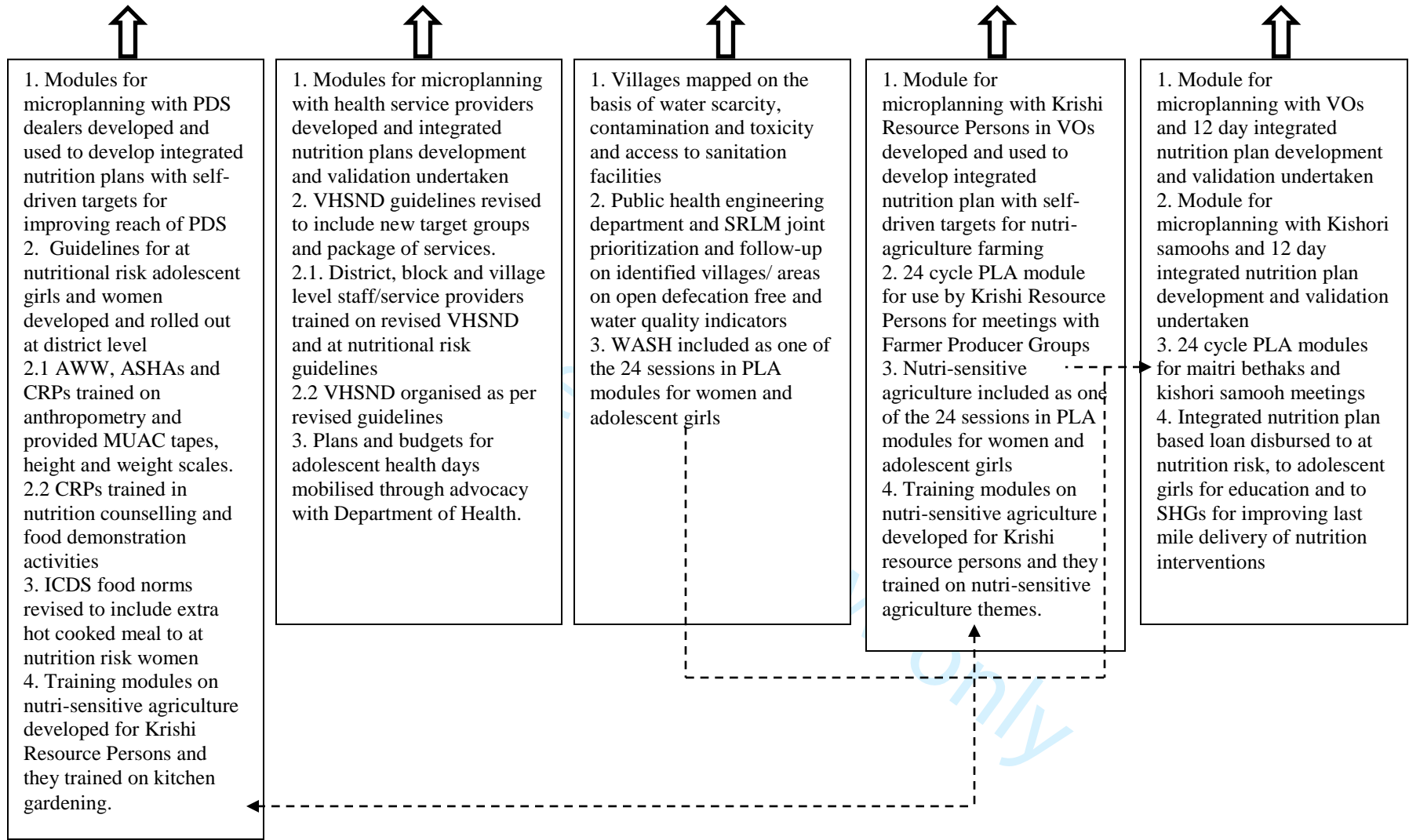
Outcomes

<p>1. Availability (per norms) and diversification of food grains and availability of iodized salt through PDS dealers.</p> <p>2. At nutritional risk adolescent girls and women screened and linked to ICDS, PDS and SRLM’s programmes</p> <p>3. Farmer Producer Groups identify new cultivable lands and develop kitchen gardens.</p>	<p>1. Integrated nutrition plans developed, implemented and reviewed biannually by service providers- ASHAs, ANMs, Anganwadi workers</p> <p>2. Adolescent girls, newlywed women and at nutritional risk women (new target groups) brought under the ambit of VHSND.</p> <p>3. Activation of quarterly adolescent health days</p>	<p>1. Public health engineering department and SRLM partner to meet ODF targets, water availability and quality in 4 districts</p> <p>2. Environmental and personal hygiene discussed in monthly maitre bethaks and fortnightly adolescent girls meetings</p> <p>3. Expanded markets for SHGs producing low cost sanitary products</p>	<p>1. VO managed nutri-farm demonstration site available for quarterly hands-on training of Farmer Producer Groups</p> <p>2. Nutri-agriculture, promoting traditional foods and food adulteration discussed in monthly maitri bethaks</p> <p>3. Department of agriculture platforms used for annual trainings on nutri-sensitive agriculture</p>	<p>1. Integrated nutrition plans developed, implemented and reviewed biannually by VOs to address gaps in reach of essential nutrition interventions for adolescent girls and women</p> <p>2. Target group coverage in SHG membership increases</p> <p>3. VO representation in block convergence committee</p>
--	---	---	---	---

Outputs

Cross-cutting output: Multi-sector departmental convergence mechanisms for women’s nutrition at block, district and state levels

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47



Inputs and processes

Cross-cutting input: Annual planning and review of selected nutrition indicators by a multi-sector nutrition committee at block, district and state levels



All India Institute of Medical Sciences, Patna

Ethics committee approval letter

Date: 23/01/2016

Dr. Neeraj Agarwal
 Prof. & Head
 Department of Community & Family Medicine
 AIIMS, Patna

Dear Dr. Neeraj Agarwal

Ref: IEC/AIIMS/PAT/52/2016

The Institutional Ethics Committee, All India Institute of Medical Sciences, Patna reviewed & discussed your study documents entitled "**Prospective, controlled, non-randomized evaluation of a programme to improve the nutritional status of women before conception, during pregnancy and after birth in Bihar**". (The Swabhimaan Programme) dated: 19.01.2016 study code: IEC/AIIMS/PAT/52/2016 on 19.01.2016.

The following members of ethics committee were present at the meeting held on 19.01.2016 at 2:00 P.M. at Department of Community and Family Medicine, All India Institute of Medical Sciences, Patna.

S. No.	Name and address of the EC members	Designation
1.	Dr. R.N. Singh, Consultant Orthopaedic Surgeon	Chairman
2.	Dr. P.P. Gupta, HOD, Pharmacology, AIIMS, Patna	Member: Pharmacologist
3.	Dr. Sadhana Sharma, Professor, Biochemistry, AIIMS, Patna	Member: Basic Sciences
4.	Dr. Ramji Singh, Addl. Prof. & Head, Physiology, AIIMS, Patna	Member: Pre- Clinical
5.	Dr. Ravi Kirti, Asst. Prof., General Medicine, AIIMS, Patna	Member: Physician
6.	Dr. Subhash Kumar, Assit. Prof., Radio Diagnosis, AIIMS, Patna	Member: Clinician
7.	Mr. Binay Kumar Pandey, Advocate, Patna High Court	Member: Legal Expert
8.	Mr. Ajit Kumar Chaudhary, Social Worker	Member: Social Worker
9.	Ms. Shahina Khan, Director of Raza International Group of Schools	Member: Philosopher
10.	Dr. C.M. Singh, Addl. Prof., Dept. of C&FM, AIIMS, Patna	Member Secretary

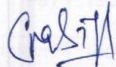
Address: All India Institute of Medical Sciences, District - Patna, State - Bihar, Pin Code – 801507,
 E-mail – iecaiimspatna@gmail.com

The IEC approves the study to be conducted in its presented form.

Principal Investigator is responsible for fulfilling the following requirements:

- All Co-investigator must be kept informed of the status of the project.
- Any, amendment(s) to the protocol or the consent form(s), must be informed and submitted to the IEC for review and approval prior to the activation of the same. The IEC number assigned to the project should be cited in any correspondence.
- Serious Adverse Events (SAE), if any, should be reported to the IEC immediately. New information that becomes available which could change the risk-benefit ratio must be submitted promptly for IEC review.
- Records of documents related to signed consent (by subjects/witnesses) should be maintained properly for the audit by IEC.
- Approved study needs to be reviewed by IEC AIIMS Patna periodically at least once in a year as appropriate.
- After completion of the permitted tenure of the study, submission of the study report to the IEC AIIMS Patna is mandatory.
- A continuing review application must be submitted to the IEC in order to continue the study beyond the approved period. Failure to submit the same will result in the termination of the study.
- IEC AIIMS Patna will maintain the confidentiality of all the approved studies and will share the information with authentic bodies only on justification of the request.

Yours sincerely



Member Secretary
IEC, AIIMS, Patna

**MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
AIIMS, PATNA**

Address: All India Institute of Medical Sciences, District - Patna, State - Bihar, Pin Code – 801507,
E-mail – iecaiimspatna@gmail.com



आरोग्यम् सुखं सम्यदा

Institute Ethics Committee

अखिल भारतीय आयुर्विज्ञान संस्थान, रायपुर (छत्तीसगढ़)

All India Institute of Medical Sciences, Raipur (Chhattisgarh)

Department of Pharmacology

2nd Floor, South Wing

Medical College Complex, Gate No. 5

Tatibandh, GE Road,

Raipur-492 099 (CG)

www.aiimsraipur.edu.in

Ethics Committee Registration No.: ECR/714/Inst/CT/2015

Letter No.: 114/IEC-AIIMSRPR/2016

Date: 02.09.2016

CERTIFICATE OF APPROVAL

To : Dr. Manisha Ruikar (Principal Investigator)
Professor & Head, Department of Community & Family Medicine,
AIIMS Raipur (CG)

Review Date : 06.08.2016

Reference : IEC Proposal No: **AIIMSRPR/IEC/2016/042**

Title : Baseline Survey for Swabhimaan Project, Bastar Block and Bakavand
Block, Bastar District (Developed in consultation with UNICEF)

The Institute Ethics Committee, All India Institute of Medical Sciences, Raipur (Chhattisgarh) reviewed and discussed your above referenced research proposal in the meeting held on 06.08.2016.

The following documents were reviewed.

1. Covering Letter
2. Research Project Proposal (Version 2.0)
3. Case Record Form (Version 1.0)
4. Participant information sheet for participants more than 18 years of age (English & Hindi) (Version 1.0)
5. Participant information sheet for participants less than 18 years of age - English & Hindi (Version 1.0)
6. Consent Form for participant more than 18 year of age (English & Hindi) (Version 1.0)
7. Assent Form - English & Hindi (Version 1.0)
8. Undertaking regarding GCP guidelines and reporting of SAE
9. Other documents

Certificate of Approval: Proposal No. AIIMSRPR/IEC/2016/042
Ref: 114/IEC-AIIMSRPR/2016 dated 02.09.2016

a. Duly signed compliance sheet submitted to IEC by PI alongwith following documents :

- i. E-communication by Dr Abner Daniel, Nurition Specialist, Child Development and Nutrition, UNICEF to the Principal Investigator
- ii. Letter by Director, National Rural Livelihood Promotion Society to Mision Director, Chhattisgarh Gramin Ajjevika Samvardaan Samiti
- iii. Letter by Mission Director, SRLM, Chhattisgarh to the Chief, Field Office , UNICEF

The following members of Institute Ethics Committee were present at the meeting held on 06.08.2016 at 11:00 AM at Department of Pharmacology, AIIMS Raipur.

Sr. No.	Name of IEC Member	Designation
1	Dr. Arun T. Dabke Ex. Vice-chancellor Ayush and Health Science University Raipur (CG)	Chairman
2	Dr. S. R. Gupta M.D. (Med.), M.D. Pharmacology Retired Professor & Head Department of Medicine Pt. J. N. M. Medical College, Raipur	Basic Medical Scientist
3	Dr. P. K. Neema Professor and Head Department of Anaesthesiology AIIMS Raipur	Clinician
4	Dr. Sarita Agrawal Professor and Head Department of Obstetrics and Gynaecology AIIMS Raipur	Clinician
5	Mrs. Kamla Janswami Ex-president Lion's Club, Raipur	Lay Person from Community
6	Ms. Pushpy Michael Principal Bharatmata Higher Secondary School GE Road, Tatibandh, Raipur Chhattisgarh	Social Scientist
7	Dr. Nitin Gaikwad Associate Professor Department of Pharmacology AIIMS Raipur	Member Secretary
Outside Legal Expert		
8	Advocate Shekhar Amin	Legal Expert

Certificate of Approval: Proposal No. AIIMSRPR/IEC/2016/042
Ref: 114/IEC-AIIMSRPR/2016 dated 02.09.2016

Clear statement of decision reached:

At Institute Ethics Committee meeting held on 06.08.2016, the committee reviewed the research project and study related documents and discussed the ethical issues involved.

A letter to this effect was sent to you seeking certain clarifications / modifications vide letter no. 104/IEC-AIIMSRPR/2016, dated 19.08.2016. In response to this, you have submitted required clarifications / modifications vide letter no. CFM/MR/Project/348/2016 dated 24.08.2016 (IEC inward letter no. 2016/84 dated 25.08.2016). Therefore, the research project and study related documents are approved with respect to ethical issues.

Hence, at the convened meeting of IEC-AIIMS Raipur on 02.09.2016, IEC decided to **approve** the above referenced research project.

As Principal Investigator, you are responsible for fulfilling the following requirements of approval:

1. This approval is valid for entire duration of the study (i.e. Six months). The review application must be submitted to the IEC-AIIMS Raipur in order to continue the study beyond the approved period.
2. All the co-investigators must be kept informed of the status of the project.
3. Changes, amendments, and addendum to the protocol or the consent form, must be submitted to the IEC-AIIMS Raipur for re-review and approval prior to the activation of the changes.
4. Any change of study site, change of investigator/s, termination of study (with reason to do so) should also be informed to IEC-AIIMS Raipur.
5. The IEC proposal number assigned to the project should be cited in any correspondence.
6. Any Serious Adverse Event (SAE) occurring during the course of the study should be reported to the IEC-AIIMS Raipur.
7. New information that becomes available which could change the risk: benefit ratio must be submitted promptly for IEC review.
8. Only approved consent forms are to be used in the enrolment of participants. All consent forms signed by subjects and/or witnesses should be retained on file. The


Certificate of Approval: Proposal No. AIIMSRPR/IEC/2016/042
Ref: 114/IEC-AIIMSRPR/2016 dated 02.09.2016

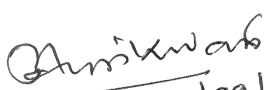
IEC may conduct audits of all study records, and consent documentation may be part of such audits.

9. The study progress report should be made available for the IEC review on every 6 month.
10. The final report of the study must be submitted to IEC-AIIMS Raipur after the completion of the study.

It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.

Sincerely,


Dr. Arun T. Dabke
Chairman
Institute Ethics Committee
All India Institute of Medical Sciences
Raipur 492 099 (C.G.)
2/9/16


Dr. Nitin Gaikwad
Member Secretary
Institute Ethics Committee
All India Institute of Medical Sciences
Raipur 492 099 (C.G.)
02/09/2016



INSTITUTIONAL ETHICS COMMITTEE
(ECR/534/Inst/OD/2014)

All India Institute of Medical Sciences Bhubaneswar,
Village Sijua, Patrapada, PO Dumduma, Bhubaneswar
751019, Odisha
Email: iec.aiimsbbsr@gmail.com
Phone:

SA ①

To: Dr. Vikas Bhatia (Principal Investigator)

Date: 10.05.16

Re: IEC Proposal: T/EM -F/CMFM/16/02

Title: **Swabhiman- a nutritional intervention program in Odisha. Pre-implementation status assessment.**

Chairperson of IEC-AIIMS BBSR

Dr Suresh Chandra Dash
(Clinician)

Members of IEC AIIMS BBSR

Prof Debasis Hota
(Pharmacologist)

Dr K C Misra
(Scholar & Academician)

Dr Manaswini Mangaraj
(Basic Scientist)

Mr. Surendra Kumar Patri
(Lawyer)

Dr Amit Ghosh
(Basic Scientist)

Dr Ashish Patnaik
(Clinician)

Dr Swagatha Tripathy
(Clinician)

Ms. Swarna Misra
(Social Scientist)

Ms Pranita Acharya
(General community
representative)

Member- Secretary

Dr Somnath Mukherjee

I am pleased to inform you that at the convened meeting of 07.05.2016, the IEC voted to approve an amendment and to re-approve (renewal approval of the protocol and the consent form(s) is for 12 months) the above referenced protocol. As Principal Investigator, you are responsible for fulfilling the following requirements of approval:

1. All co-investigators must be kept informed of the status of the project.
 2. Changes, amendments, and addenda to the protocol or the consent form must be submitted to the IEC for re-review and approval prior to the activation of the changes. The IEC number assigned to the project should be cited in any correspondence.
 3. Adverse events should be reported to the IRB. New information that becomes available which could change the risk: benefit ratio must be submitted promptly for IEC review. The IEC and outside agencies must review the information to determine if the protocol should be modified, discontinued, or continued as originally approved.
 4. Only approved consent forms are to be used in the enrolment of participants. All consent forms signed by subjects and/or witnesses should be retained on file. The IEC may conduct audits of all study records, and consent documentation may be part of such audits.
 5. IEC AIIMS needs review of an approved study not less than once per 12-month period. **Therefore, a continuing review application must be submitted to the IEC in order to continue the study beyond the approved period.** Failure to submit a continuing review application in a timely fashion will result in termination of the study, at which point new participants may not be enrolled and currently enrolled participants must be taken off the study.
 6. Principal investigator should initiate the project only after obtaining administrative permission from Director/Dean, AIIMS, Bhubaneswar.
- Sincerely,

Chairman, IEC

Chairman

Members of the IEC who voted in Favour of the Proposal

Dr. Debasis Hota, Dr. Manaswini Mangaraj, Dr Amit Ghosh, Dr. Swagatha Tripathy, Dr. K C Mishra, Dr. Somnath Mukherjee.

अखिल भारतीय आयुर्विज्ञान संस्थान, भुवनेश्वर - ७५१ ०१९

RESEARCH CELL

All India Institute of Medical Sciences, Bhubaneswar-751 019



AIIMS-BBSR/RC/EM-F/02/2016/05

Dt: 13/05/2016

Dr. Vikas Bhatia

Professor & Head

Department of Community Medicine & Family Medicine

Subject: Regarding initiation of extramural research project.

Dear Prof. Bhatia,

The research cell is pleased to inform you that your extramural funded project entitled “**Swabhimana nutritional intervention program in Odisha, Pre-implementation status assessment**” (bearing provisional project code T/EM-F/CMFM/16/02 and IEC approval letter No T/EM-F/CMFM/16/02 dated 10.05.2016) has been examined and approved by the competent authority.

Kindly note that following the approval, you have been assigned permanent project code: P/EM-F/CMFM/16/02 and the study may be initiated in the institute.

You are requested to provide 6 monthly progress reports (in case study duration is longer than 6 months) and a consolidated summary report within 1 month of end of study to the research cell.

Thanking You

Yours sincerely

Dr. Dillip Kumar Parida,
Faculty-in-Charge, Research Cell

[Handwritten signature of Dr. Dillip Kumar Parida]
13/5/16

[Handwritten signature]
13/05/16
Project file