

## Supplementary material

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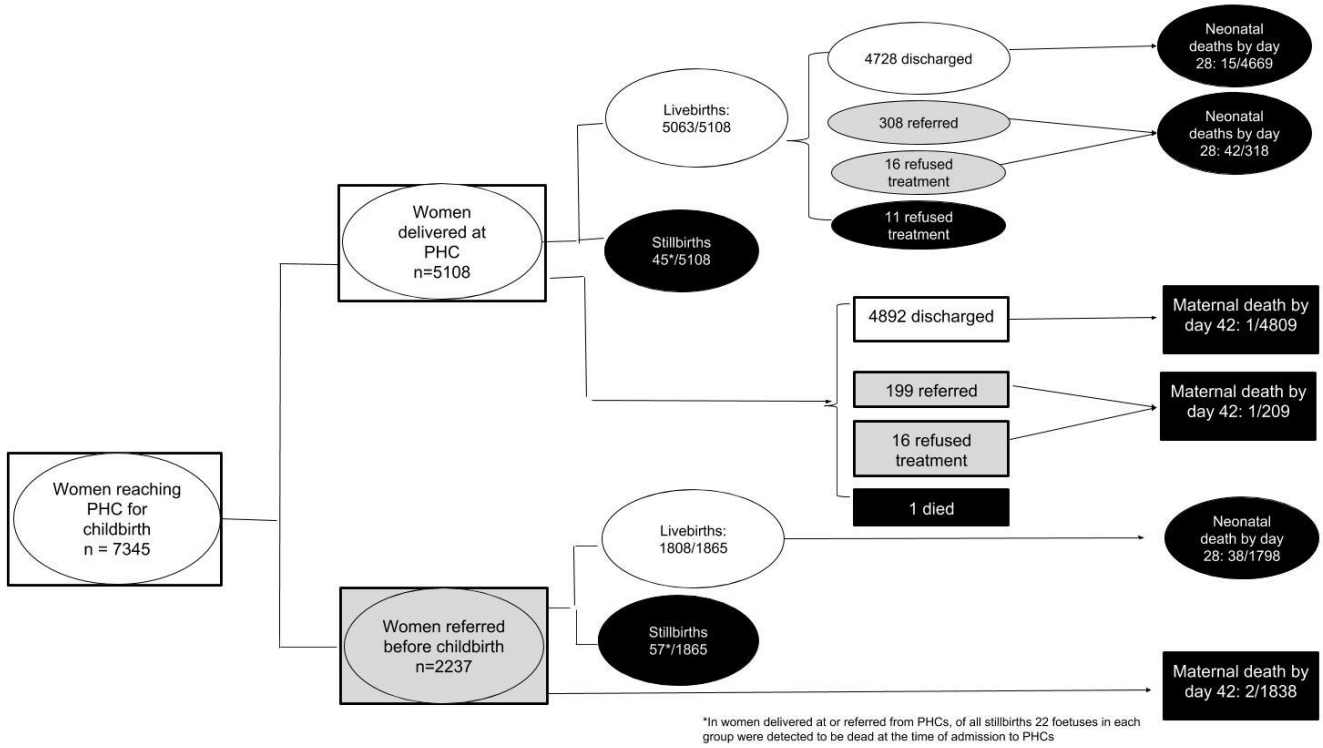
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<b>Table S1</b> Demographic and health profile of Haryana and two study districts			
	<b>Haryana</b>	<b>Ambala</b>	<b>Yamuna Nagar</b>
Total population, million (Census 2011)	25.4	1.1	1.2
Density of population, no of persons per square kilometre (Census 2011)	573	717	687
Rural population (Census 2011)	65.2%	55.6%	61.1%
SC population (Census 2011)	19.3%	26.2%	25.3%
Access to electricity (DHS 2012)	90.5%	99.2%	98.6%
Per capita income, Indian Rupees (2011 white paper Govt. Haryana)	106 000	116 000	82 232
Population below poverty line (Ministry of Social Justice)	14% (2005)	Data not available	Data not available
Female literacy (Census 2011)	65.9%	75.5%	71.4%
Community Health Centres	109	4 (156,792)	6 (129,136)
Primary Health centres	461	18 (47,742)	18 (40,046)
Sub health centres	2569	104 (7208)	113 (7312)
Institutional delivery (NFHS-4)	80.5	91.0%	75.7%

	Period 1	Period 2	Period 3	Period 4	Period 5	Period 6	Period 7
Cluster 1	258	339	419	364	275	277	336
Cluster 2	185	200	262	258	224	217	181
Cluster 3	133	140	207	187	161	136	181
Cluster 4	115	162	198	181	132	150	151
Cluster 5	92	172	257	248	171	192	184

Control period	n=3831
Intervention period	n=3514

**Figure S1:** Stepped Wedge design of the trial. The columns and rows represent period of three months and clusters of three PHCs each, respectively. The control period is marked as white and intervention period as grey. The numbers represent women approaching PHC for delivery in respective period



**Figure S2** Study participant flow. Rectangles represent women and ovals represent foetuses or neonates. Grey shading represents referral or refused treatment and black shading represents death.

**Table S2** List of learning resource material shared with PHC staff and the study assessment tools

**Learning resource materials**

1. Standard operating procedures for maternal and neonatal care at PHC
  - a. Care during childbirth
  - b. Care after childbirth
  - c. Recognition of conditions requiring referral and referral and transport

**Sources:**

1. Operation Guidelines for Maternal and Newborn Health. National Rural Health Mission. Available at: [http://nhsrindia.org/index.php?option=com\\_content&view=article&id=150&Itemid=700#](http://nhsrindia.org/index.php?option=com_content&view=article&id=150&Itemid=700#)
2. Maternal and Newborn Health Toolkit. Department of Family Welfare Ministry of Health and Family Welfare, Government of India, 2013. Available at: [http://nhsrindia.org/index.php?option=com\\_content&view=article&id=150&Itemid=700#](http://nhsrindia.org/index.php?option=com_content&view=article&id=150&Itemid=700#)
3. Guidelines for Pregnancy Care and Management of Common Obstetric Complications by Medical Officers. Department of Family Welfare Ministry of Health and Family Welfare, Government of India, 2005.
4. Guidelines for Antenatal care and Skilled attendance at birth by ANMs/LHV/SNs. Department of Family Welfare Ministry of Health and Family Welfare, Government of India, 2010.
5. Infection Management And Environment Plan Guidelines For Healthcare Workers For Waste Management And Infection Control In Primary Health Centres. Ministry of Health and Family Welfare, Government of India, 2007. Available at: [http://nhsrindia.org/index.php?option=com\\_content&view=article&id=171&Itemid=647](http://nhsrindia.org/index.php?option=com_content&view=article&id=171&Itemid=647) .
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8. WHO Integrated Management of Pregnancy and Childbirth (IMPAC). Available at: [http://www.who.int/maternal\\_child\\_adolescent/topics/maternal/impac/en/](http://www.who.int/maternal_child_adolescent/topics/maternal/impac/en/)
9. Indian Public Health Standards (IPHS) Guidelines for Primary Health Centres Revised 2012. Available at: <http://health.bih.nic.in/Docs/Guidelines/Guidelines-PHC-2012.pdf>

2. Job aids to assist the staff at PHC in quality assured service delivery:
  - a. Mother postnatal observation chart
  - b. Newborn postnatal observation chart guidelines

3. Learning resource materials for skills improvement on:
  - a) Videos on: process of labour & delivery, positioning of the baby, use of partograph, per-vaginal examination during labour, three stages of labour, active management of 3rd stage of labour, examining the placenta, post-natal care, immediate care after birth, newborn physical examination, danger signs in newborn, hand washing

**Sources:** Global Health Media Project. <https://globalhealthmedia.org/>; WHO collaboration centre for Training and Research in Newborn AIIMS, New Delhi. <http://newbornwhocc.org/>

- b) Weekly digest (one pager pamphlet on a topic from SoP): hand hygiene, assessment of temperature, assessment of pulse, measuring blood pressure, assessment of respiration rate, measuring newborn weight, examination for clinical anaemia, monitoring of bleeding, breastfeeding practices, kangaroo mother care (KMC), postnatal care of mother and newborn, use and assessment of partograph, PPH management, clinical shock assessment and care, eclampsia management, resuscitation of newborn

4. Training workshop to build obstetric skills of the nurses

Practice of key obstetric skills including partograph, control of postpartum bleeding, life-saving newborn care using MamaNatalie Birthing Simulator and Neonatalie Simulator (Laerdal Medical)

**Study tools**

1. Standard operating procedures for
  - a. Internal Quality Review Process
  - b. External Quality Review Process
2. Quality Audit Tools for external review:
  1. Tools for assessing the skills of PHC staff
  2. Clinical Case Sheet Review
  3. Direct case observation
  4. Checklist for the assessment of facility including human resource
  5. Dashboard review checklist
  6. Patient satisfaction checklist
  7. Report Card for PHC

**Table S3** Primary outcomes and sample size assumptions

<b>Primary Outcomes</b>	<b>Prevalence before the intervention (p1)</b>	<b>Expected prevalence after intervention (p2)</b>	<b>Assumed ICC</b>	<b>Measurements per cluster per 3-month period</b>	<b>Power</b>
<ul style="list-style-type: none"> <li>Proportion of all births (estimate per PHC area= 600 per year) that occur in the PHC</li> </ul>	20%	30%	0.1	150	>95%
<ul style="list-style-type: none"> <li>Hand washing before per-vaginal examination, delivery and handling newborn.</li> <li>Use of sterile gloves</li> </ul>	35%	50%	0.1	12	85%
<ul style="list-style-type: none"> <li>Foetal heart sound (FHS) recording</li> <li>Use of partogram</li> </ul>	15%	30%	0.1	12	>95%
<ul style="list-style-type: none"> <li>Oxytocin/misoprostol or other agents for augmentation of delivery (harmful practice)</li> </ul>	75%	60%	0.1	12	91%
<ul style="list-style-type: none"> <li>Oxytocin/ misoprostol tablet (uterotonic) after delivery</li> </ul>	55%	70%	0.1	12	82%
<ul style="list-style-type: none"> <li>Skin to skin contact within one hour of birth</li> </ul>	10%	20%	0.1	12	89%
<ul style="list-style-type: none"> <li>Initiation of breastfeeding within 1 hour of birth</li> </ul>	35%	50%	0.1	12	85%
<ul style="list-style-type: none"> <li>Drying of the baby thoroughly within 1 minute of birth</li> </ul>	45%	60%	0.1	12	82%
<ul style="list-style-type: none"> <li>Measurement of birth weight within 2 hours of birth</li> </ul>	45%	60%	0.1	12	82%
<ul style="list-style-type: none"> <li>Discharge from PHC at least after 24 hours of birth</li> </ul>	10%	20%	0.1	12	89%
<ul style="list-style-type: none"> <li>Correct assessment of preparedness at discharge (at least breastfeeding and danger signs in the mother including excessive vaginal bleeding and the baby assessed)</li> </ul>	10%	20%	0.1	12	89%

<b>Table S4</b> Details of quality improvement activities: coverage, participation and activities undertaken			
	<b>Quality improvement meetings</b>		
	<b>Weekly</b>	<b>Monthly</b>	<b>Quarterly</b>
<b>Quality improvement meetings</b>			
Meeting scheduled	600	165	60
Meeting conducted (n, % of the meeting scheduled)	371 (62%)	131 (79%)	44 (73%)
<b>Participants in meetings</b>			
<b>PHC Medical officers</b>			
Posted at the time of meeting	2 (1 to 2)	1 (0 to 1)	2 (1 to 2)
Proportion attended (%)	50 (0 to 100)	50 (0 to 50)	100 (50 to 100)
<b>PHC Nurses</b>			
Posted at the time of meeting	4 (3 to 5)	4 (3 to 4)	4 (3 to 4)
Proportion attended (%)	80 (60 to 100)	75 (60 to 100)	100 (100 to 100)
Quality coach (SWACH team member)	NA	131 (100%)	44 (100%)
NHM officials	NA	2 (1.2%)	19 (43.2%)
DH officials	NA	1 (0.8%)	4 (9.1%)
<b>External experts</b>			
Subject expert (Obstetrics, Paediatrics or Nursing)	NA	NA	44 (100%)
Health management expert	NA	NA	27 (61.4%)
At least 2 experts	NA	NA	44 (100%)
<b>Activities undertaken</b>			
Case audit	82 (22%)	94 (72%)	NA
Discussion of a topic from SOPs	350 (94%)	122 (93%)	NA
Practice of a skill	203 (55%)	117 (89%)	NA
Review of actionable information system	357 (96%)	127 (97%)	44 (100%)
Review of selected dashboard indicators	325 (88%)	120 (92%)	44 (100%)
Administration of facility checklist to ascertain gaps in physical resources	NA	85 (65%)	44 (100%)
Skill assessment of nurses	NA	NA	44 (100%)
Assessment of families' experience of care	NA	NA	44 (100%)
Actual observation of clinical care	NA	NA	24 (55%)
Review of activities undertaken during WMs & MMs	NA	NA	44 (100%)
Values expressed as median (IQR) or n (%)			
DH=district health; MMs=monthly quality review meeting; NA=not applicable; NHM= National Health Mission; PHC=primary health centre; SOPs=standard operating procedures; SWACH=Survival for Women and Children Foundation ; WMs=weekly quality review meetings			



**Table S5 Meetings held with NHM and District Health Administration to facilitate closure of quality gaps**

<b>Meeting</b>	<b>Purpose</b>	<b>Participants</b>	<b>Decisions taken/action points</b>	<b>Follow up/gap closure</b>
Jan 2015	To discuss problems and gaps existing for the quality improvement	Officials of NHM, District immunization and program officers, investigators from SWACH, medical officers and nurses of 9 PHCs	1. Strengthen referral transport	Partly done emphasis of pre- referral care and during transport
			2. Supply staff and equipment shortage (4 GNMs per PHC), generator for power back up	Circular issued to districts; partially successful
			3. Review of adverse outcome of cases	Sample tool for root cause analysis developed and rolled out
			4. Uniformity of records in all the PHCs and add postnatal monitoring forms	Postnatal monitoring forms for mothers and newborn infants finalized
Jan 2015	To review the progress of QI and support PHCs to overcome the problems identified	MD and staff from NHM, external quality team, SWACH	1. NHM would visit 4 PHCs for oversight of QI process	Could not visit
			2. Identify a nodal person from NHM to coordinate QI activities	Identified
			3. Supplementary budget allocation for each PHC based on needs identification	Could not be done (PHCs submitted demands)
			4. Improve cleanliness through improved supplies and outsourcing of services	Could not be done
			5. To provide 24*7 electricity by establishing hotline by the state electricity board and/or use of solar energy	Could not be done
			6. Post 4 GNMs per PHC. District CMO to ensure the stability of the GNMs to be posted	Partially done could not be sustained

			7. Engage district training unit to enhance the skills of GNMs	Could not be done
			8. Supply of warm food for mothers during the postnatal period	Partially done; implemented in 3 PHCs
			9. Ensure the uniformity of record keeping (Case sheet, labour room referral register and postnatal monitoring forms)	Implemented
			10. Discontinue key harmful practices e.g. uterotonic prior to childbirth, antibiotic and analgesic after childbirth, frequent per-vaginal examination, routine early cord clamping and routine episiotomy through NHM directive	Partially done
			11. Explore the application of cross learning through inter PHC meetings.	Could not be done
			12. Promote the audit of adverse outcomes and near misses by PHC staff for quality improvement.	Partially done
February 2015	Overview of QI project progress	NHM Additional commissioner and all staff from NHM SWACH and other knowledge partners of NHM Haryana	1. Briefing of NHM officials about the progress in QI project 2. Lessons learned for action, gap identification and closure	-
April 2015	To discuss and resolve the quality gaps existing for improving QoC in the PHCs	Focal person NHM, Haryana, other NHM official, investigators and external experts	1. Participation of NHM staff in upcoming EQR	Could not be done due to staff shortage
			2. Roll out uniform records	Records printed and rolled out
			3. Organize district level review meetings one in each district	Could not be done due to staff shortage

			4. Incorporate key quality indicators in HMIS	Could not be done
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**Table S6** Demographic variables and characteristics at admission of women in whom childbirth was observed

Characteristics	Intervention period (n=1623)	Control period (n=1720)
<b>Demographic</b>		
Age (years)	24.4±3.2	24.5±3.2
Formal education less than ten years	1151 (70.9)	1177 (68.4)
Homemaker	1565 (96.4)	1650 (95.9)
Husband being a daily wager	959 (59.1)	1254 (72.9)
Underprivileged social classes (scheduled caste or scheduled tribe)	630 (38.8)	834 (48.5)
Below poverty line	758 (46.7)	729 (42.4)
<b>At-admission</b>		
First pregnancy	514 (31.7)	538 (31.3)
Grand multipara (had four or more prior pregnancies)	57 (3.5)	66 (3.8)
History of previous stillbirth or neonatal death	91 (5.6)	141 (8.2)
Twin gestation	5 (0.3)	6 (0.4)
Hypertension	57 (3.5)	165 (9.6)
Pre-eclampsia	17 (1.0)	37 (2.2)
At least three antenatal visits	1141 (70.3)	1283 (74.6)
Received any TT injection	1594 (98.2)	1664 (96.7)
Had consumed at least 90 IFA tablets	341 (21.0)	452 (26.3)
Haemoglobin measured anytime during pregnancy	1561 (96.2)	1607 (93.4)
Urine examination done anytime during pregnancy	1388 (85.5)	994 (57.8)
Reached PHC by a government ambulance	1029 (63.4)	1260 (73.3)
Values expressed as mean±SD and n (%) IFA= iron folic acid; PHC= primary health centre; TT= tetanus toxoid.		

<b>Table S7 Secondary outcomes</b>			
	<b>Intervention period</b>	<b>Control period</b>	<b>Adjusted OR (95% CI)*</b>
<b>For all women approaching PHCs for childbirth</b>			
Stillbirths, per 1000 deliveries (In women with alive foetus at admission to PHC)	32/3489 (9.2)	26/3810 (6.8)	2.07 (0.99 to 4.35)
Early neonatal deaths up to 7 days	44/3257 (13.5)	47/3564 (13.2)	0.77 (0.44 to 1.34)
Neonatal deaths (up to 28 days)	52/3257 (16.0)	54/3564 (15.2)	0.79 (0.46 to 1.36)
Maternal deaths (up to 42 days after delivery)	3	2	-
Referral to higher health facilities, n per PHC-month Women Newborns	8.4 (1127/135) 1.2 (157/135)	7.3 (1306/180) 0.8 (151/180)	1.15 (1.06 to 1.25) 1.39 (1.10 to 1.74)
<b>For women delivered at PHCs</b>			
Client satisfaction score	7.1±2.0	6.1±3.0	0.3 (0.1 to 0.5)
Women recommending PHC to their relatives and friends for childbirth	1231/1233 (99.8%)	1280/1291 (99.2%)	-
*adjusted for secular trend and cluster Data expressed as no (%) or mean SD. PHC= primary health centres			