| **Criterion** | **Example of text related to this criterion** | **Rating** |
| --- | --- | --- |
| **Criterion #1**  **Intervention Characteristics:** Intervention/Program source (From CFIR, Damschroder, 2009)2  **Explanation/Example:**  Is the intervention/program externally or internally developed? An intervention/program may be internally developed as a good idea, a solution to a problem, or other grass roots effort, or may be developed by an external entity (such as a foundation or a NGO). Interventions or programs that arise internally from the populations who will be impacted are sometimes more sustainable than externally developed programs dependent on external funding. The perceived legitimacy of the source may also influence implementation. | We postulated that an intervention based on a socioculturally contextualised approach of behavior change management systematically applied to modifiable, high-risk newborn-care practices, with an emphasis on hypothermia, within a community with a high neonatal mortality rate could lead to improved care practices and reduced mortality.  (*This seems to indicate the intervention was developed by the research teams – but later, there is this text:*  Qualitative research activities provided the evidence base for investigators and community members to codevelop the intervention strategy, which underwent further refinement based on findings of trials of improved practices.  *so should this be considered internally developed?)* | Fair |
| **Criterion #2**  **Intervention Characteristics:** A description of why the intervention was hypothesized to have an impact on the outcome, according to theory. (From CReDECI, Mohler 2012; also mentioned in Michie, 2009)3,4  **Explanation/Example:**  The theoretical basis of the intervention should be clearly stated. This includes the theory on which the intervention is founded as well as, if available, empirical evidence from studies in different settings or countries. For example, "The implementation was based on Rogers’ Diffusion of Innovation theory, which posits 5 factors of innovation that influence a decision to adopt or reject an innovation: relative advantage, compatibility, complexity or simplicity, trialability, observability. A similar intervention, also based on Rogers’ Diffusion of Innovation theory, was successfully implemented in other countries." | In a study in Maharashtra, India, Bang and colleagues reported a 62–70% reduction in the neonatal mortality rate, and attributed 93% of the reduction to active management of sick newborn babies and 7% to primary prevention. Baqui and colleagues reported that an adaptation of this approach in Bangladesh in an effectiveness trial had half the effect (34% reduction) on neonatal mortality. Manandhar and co-workers3 tested a different approach in Nepal with a community-based participatory action-cycle with no prespecified intervention package, in which women’s groups identified priorities and implemented local solutions, and reported improvements in care practices, care-seeking, and a 30% reduction in neonatal mortality rate.  We postulated that an intervention based on a socioculturally contextualised approach of behavior change management systematically applied to modifiable, high-risk newborn-care practices, with an emphasis on hypothermia, within a community with a high neonatal mortality rate could lead to improved care practices and reduced mortality.  *(Identifies both a framework for why it should work and prior data)* | Good |
| **Criterion #3**  **Intervention Characteristics:**  Rationale for the aim/essential functions of the intervention/program’s components, including the evidence whether the components are appropriate for achieving this goal.  This differs from the need to articulate the theory behind the intervention in that the theory posits the general principles (such as Rogers Diffusion of Innovation) while this item is about specific components of the intervention and the effects of the component on specific targets. (From CReDECI, Mohler, 2012; also mentioned in Michie, 2009)3,4 | Our preliminary qualitative field work showed that individual behaviours were influenced by collective behaviours and social norms, and sustained by a complex, multilevel network of relationships within the community. We therefore developed a multilevel strategy targeting: community stakeholders, newborn stake holders, and households with immediate support groups. At each level, the target group consisted of individuals who were identified to have key roles as influencers, decision makers, supporters, and practitioners of newborn care and normative behaviour within the community. The support of community stake holders such as village heads, community leaders, respected members, priests, and teachers was crucial in building trust with the community and ensuring acceptance of the programme. The newborn stakeholder target group included traditional newborn-care providers and birth attendants, unqualified medical practitioners, and, to a lesser extent, health system workers, some of whom had strategic access to the newborn and mother during post-partum confinement, were perceived by the community as domain experts, and played an active part in sustaining targeted practices. Health system workers such as auxillary nurse midwives were engaged only at the community level as part of newborn stakeholder group meetings in order to keep contamination of the intervention into control clusters to a minimum. The household target group included the pregnant woman or mother, who was the primary care provider, but usually not empowered to make decisions; the mother-in-law, who was usually the key decision maker on newborn-care practices; other female members who played supportive roles; and male members, including the father-in-law and husband, who controlled access to the household, made financial and logistical arrangements, and influenced care-seeking decisions. The family’s immediate support group included neighbours and relatives who influenced family behaviours and helped with deliveries.  *(Indicates extensive field work to fit intervention components to the needs of the population)* | Good |
| **Criterion #4**  **Outer Setting:** External policies and incentives (From CFIR, Damschroder, 2009)2  **Explanation/Example:**  How does the health service, intervention, or program relate to country and global health goals? Is the program part of a larger strategy? If so how is it strategically aligned? A country's health policies may influence the implementation of a particular intervention or program. | Not explicitly mentioned | None |
| **Criterion #5**  **Intervention Characteristics:**  Detailed description of the intervention/program (From WIDER as described in Michie, 2009)4  **The detailed description should include:**  a. Characteristics of those delivering the intervention/program (such as a nurse or lay health worker)  b. Characteristics of the recipients  c. The setting  d. The mode of delivery (such as face-to-face)  e. The intensity of the intervention/program (such as the contact time with participants)  f. The duration (such as the number of sessions and their spacing interval over a given period)  g. Adherence or fidelity to delivery protocols | The primary enablers of behaviour change were paid (US$35–40 per month) community-based health workers, the Saksham Sahayak (n=26), who were recruited from the local community based on 12 years or more of education, proficient communication and reasoning skills, commitment towards community work, and references of community stakeholders.  At each level, the target group consisted of individuals who were identified to have key roles as influencers, decision makers, supporters, and practitioners of newborn care and normative behaviour within the community.  The state of Uttar Pradesh, India, accounts for a quarter of India’s neonatal deaths and for 8% of those worldwide, and shares similar sociocultural, demographic, and health system characteristics with other high-mortality Indian states and south Asian countries. The study was done in Shivgarh, a rural block in Uttar Pradesh, with a population of 104 123 divided into 39 village administrative units . Socioeconomic indicators are among the lowest in the state. The formal health-care system in Shivgarh consists of a community health centre and two primary health centres operated by trained physicians and paramedical staff supported by 18 auxiliary nurse midwives, who are outreach workers catering to a population of 6000–7000 each, and trained to deliver babies, and provide vaccinations and antenatal check-ups. Care-seeking from them, however, is low.  The intervention was delivered from January, 2004, to May, 2005. Saksham Sahayaks first engaged with community stakeholders in community meetings to seek their approval, sensitise them towards the importance of their role in newborn survival, encourage shared learning, and create a supportive environment (figure 1, webtable 2). Folk song group meetings, where messages to promote behaviour change were incorporated into folk songs, were held by Saksham Sahayaks on a monthly basis with participants from diverse target groups. They also held separate monthly meetings with newborn-care stakeholders and with community volunteers to discuss experiences, challenges, and strategies.  This process was accomplished through 3-monthly cycles of door-to-door household visits by Saksham Sahayaks, self-reporting by pregnant women, and information provided by community volunteers. An antenatal visit was planned for 60 days before the expected date of delivery and another for 30 days before the expected date of delivery to provide ample time for effective behaviour change negotiation, ensure birth preparedness, and build trust with the family to negotiate subsequent entry into the room of confinement after delivery for postnatal visits (webtable 3). Post-partum confinement was a universal practice, and coincided with the initiation of almost all the targeted practices and occurrence of most newborn deaths. As some of the new practices were skill-based,  the first postnatal visit was planned within 24 h of the delivery and the second postnatal visit was planned on day 3 (webtable 3). In case of sick neonates, no treatment was provided, but families were advised to seek care at the nearest health facility.  Coverage of household visits by *Saksham Sahayaks* was calculated as the ratio of total visitations recorded during the study period to the total number of women eligible for the visitations. For coverage on antenatal visits, all pregnancies were considered eligible and for coverage on postnatal visits, all women with at least one liveborn baby were considered eligible for the visits. Household visits by newborn-care stakeholders and community volunteers in the absence of *Saksham Sahayaks* were not recorded. The monthly coverage of group meetings was based on monitoring reports by *Saksham Sahayaks*. | Good  Good  Good  Good  Good  Good  Good |
| **Criterion #6**  **Intervention Characteristics:**  Costs of the intervention and costs associated with implementing the intervention (From CFIR, Damschroder, 2009; CReDECI, Mohler, 2012)2,3  **Explanation/Example:**  The cost of the intervention and implementation can influence the adoption and sustainability; interventions maybe more difficult to sustain if they were supported as part of a research study. | The primary enablers of behaviour change were paid (US$35–40 per month) community-based health workers.  *(Only cost data identified)* | Poor / None |
| **Criterion #7**  **Population needs**  (From CFIR, Damschroder, 2009)2  **Explanation/Example:**  The extent to which population needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritized. This could include population-based data on causes of morbidity and mortality, political or cultural barriers or facilitators, and/or more locally focused data about local needs, barriers or facilitators. | Participatory social mapping of all villages in the study area provided an  introduction to the community, initiated the process of collaborative engagement, served to identify community resources for newborn health, and facilitated the planning of home visitations and group interventions.  Qualitative research activities provided the evidence base for investigators and community members to codevelop the intervention strategy, which underwent further refinement based on findings of trials of improved practices.  Domiciliary care practices were mapped against the existing evidence base of risk factors for neonatal mortality and morbidity. Practices that were assessed to be potentially harmful, preventable, within community control, and amenable to change were selected for behavioural modification (webtable 1).  *(Field work to identify potential barriers and facilitators of implantation)* | Good |
| **Criterion #8**  **Process of implementation:** Description of facilitators or barriers which have influenced the intervention or program’s implementation (see #10) revealed by a process assessment.  In contrast to the criterion #7 above which assesses barriers and facilitators as inputs to developing the intervention strategy, this criterion assesses the actual barriers and facilitators identified during and after the implementation.  (From CReDECI, Mohler, 2012; also mentioned in Michie, 2009)3,4  **Explanation/Example:**  "The attitudes of the nursing home managers turned out to be an important factor supporting or impeding the success of the intervention's implementation. The more the managers agreed with the interventions’ aim, the better the nursing staff felt supported." | No text was found about facilitators and barriers to the actual implementation. | Poor / None |
| **Criterion #9**  **Description of materials:** Description of all materials or tools used for the implementation  (From CReDECI, Mohler, 2012)3  **Explanation/Example:**  "The primary enablers of behaviour change were paid community-based health workers, who were recruited from the local community based on 12 years or more of education,  proficient communication and reasoning skills, commitment towards community work, and references of community stakeholders. They received a combination of classroombased and apprentice ship-based field training over 7 days on knowledge, attitudes, and practices related to essential newborn care within the community, behaviour change management, and trust-building. After training, suitable candidates were closely mentored and supervised by a regional programme supervisor (n=4) responsible for 6–7 trainees, for an additional week before final selection was made." | Available in a web appendix. | Good |
| **Criterion #10**  **Process of Implementation:** Description of an assessment of the implementation process  (From CReDECI, Mohler 2012)3  **Explanation/Example:**  Process assessment is a prerequisite for determining the success of the intervention's implementation and should be an integral part of an assessment of the intervention’s effect. For example, "To gain insight into the dissemination and the delivery of the intervention and to draw conclusions about potential barriers and facilitators to implementing the intervention in other settings, data on the implementation process were collected alongside the randomized-controlled trial. Therefore, we assessed the quality of delivery of the interventional components (observed by members of the research team not involved in the delivery of the intervention) and the adherence to study protocol (number and type of deviations from the protocol, using a pilot-tested standardized form). We also analyzed barriers and facilitators for the delivery of intervention’s components (focus group interviews with intervention participants)." | No text was found describing the assessment of implementation. | Poor / None |