| **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. | The study was coordinated by the World Health Organization (WHO) with Principal Investigators at 5 universities in Africa. “The Kesho Bora study was a multicentre study conducted at ﬁve sites in three sub-Saharan African countries. Its multidis­ciplinary design required a large partnership of African research teams in the study sites as well as international research expertise in HIV and infectious diseases, obstetrics, paediatrics, nutrition, clinical trials implementation and anal­ysis (Fig. 2). Several sponsors supported the project ﬁnancially and technically.  Such a large network necessitated strong coordination by the WHO Department of Reproductive Health and Research.” | Good |
| **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."  | “The Kesho Bora study was conceived before the recent rapid expansion of antiretroviral treatment (ART) programmes when antenatal care services often were unable to identify women requiring ART and even less able to provide access to ART. ART was known to decrease the risk of mother to child transmission of HIV.” | Fair |
| **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 | “..the main goal of the Kesho Bora study was to optimize the use of ARVs during the antepartum, intrapartum, and postpartum periods for prevention of MTCT and for preserving maternal health.”“Because MTCT risk and risk of maternal AIDS or death are strongly associated with maternal immunologic status, different ARV regimens were prescribed based on the mother's status (Table 1). “(All regimens in the Table include references). | Fair |
| **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. | “coordinated by the WHO Department of Reproductive Health and Research” | Poor / 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 | Characteristics of those delivering the intervention/program (such as a nurse or lay health worker) “Clinicians”“During the ARV initiation visit, study clinicians reviewed with each participant the drugs she would be receiving, their dosage, expected side effects and the optimal time of day for taking the drugs.Characteristics of the recipients“Participant eligibility criteria 1. Infected with HIV-12. Pregnant, with gestational age 20–32 weeks, with the exception of women with medically documented HIV stage 4 or CD4+ cell count b 200 cells/mm3 who could be screened from gestational age 16 weeks. 3. Ability and willingness to give informed consent for screening (interview, physical examination, venipuncture for blood specimens, and estimation of gestational age) and home visits. 4. No evidence of clinically signiﬁcant conditions (obstetric, cardiac, respiratory [including active tuberculosis], hepatic, gastrointestinal, endocrine, renal, haematologic, psychiatric, neurologic, or allergic) requiring care which may interfere with the study interventions. 5. Never enrolled in an HIV-vaccine trial. 6. No previous enrolment in the Kesho Bora study (for women who became pregnant again in the course of the study). 7. Not currently taking any ARV medications. 8. Capacity and willingness to participate in all follow-up visits, all clinical examinations and agreement for venipuncture for them and their babies.  | Poor / NoneGood |
| c. The settingd. The mode of delivery (such as face-to-face) | 9. Residing and planning to continue to reside in the study site catchment area until two years after delivery. 10. Willingness to receive and no contraindication to receive ARVs, i.e.: a. Severe anaemia (haemoglobin b 7 g/dl), b. Severe neutropenia (neutrophil count b750×106 cells/l) c. Blood alanine amino transferase N 5 times upper limit of normal (ULN) d. Amylase N 2 times ULN e. Blood creatinine N 3 times ULN f. Known allergy to one of the study ARVs or to benzodiazepines; g. Treatment with anticoagulants, benzodiazepines, rifampicin, magnesium sulphate, corticosteroids for more than 7 days at the time of planned enrolment.”The setting“Site selection criteria 1. Ongoing MTCT prevention interventions (HIV counseling and testing during pregnancy, short-course ARV prophylaxis, and counseling regarding infant feeding options) through which HIV-1-infected, pregnant women could be recruited into the study; 2. Ability to enroll at least 120 eligible women per year (10 per month); 3. Capacity or potential capacity to follow enrolled women and their children adequately for 18–24 months after delivery with minimal loss of follow-up (no greater than 10% per year); 4. Signiﬁcant proportion (≥ 50%) of HIV-1-infected mothers choosing to breastfeed their infants despite counseling on infant feeding options and the availability of free or low-cost infant formula; and 5. Services for long-term HIV care, including CD4+ cell count monitoring and ART when needed (either at study initiation or with reasonable expectation that access will be available within two years after study initiation).”The mode of delivery (such as face-to-face)“face-to-face” “Follow-up visits included counseling, interviews and physical examinations.” | GoodGood |
| 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 intensity of the intervention/program (such as the contact time with participants)“Participants had scheduled study visits weekly until eight weeks after delivery, monthly until 12 months after delivery and every three months thereafter.”The duration (such as the number of sessions and their spacing interval over a given period)“Participants had scheduled study visits weekly until eight weeks after delivery, monthly until 12 months after delivery and every three months thereafter.”Adherence or fidelity to delivery protocols“Women in Part IB received a short-course ARV prophy­laxis regimen as per WHO recommendations, which consisted of 300 mg AZT taken by the mother twice daily starting from 34 to 36 weeks of pregnancy until the onset of labour, plus one 600 mg dose of AZT and one 200 mg dose of NVP at the onset of labour.”“From 2007 following a change in the WHO guidelines, ARV prophylaxis was started in both arms in Part II from 28 weeks of pregnancy, the new recommended time for starting the short-course regimen because of greater effective­ness than the previously recommended start at 34–36 weeks. In addition AZT 300 mg with 3TC 150 mg twice daily for one week postpartum was added to reduce the risk of selection for NVP resistance in the mother. All protocol versions and amendments are summarized in Table 3.”“Infant feeding counseling based on UNICEF/WHO training courses on Breastfeeding Management” | FairFairFair |
| **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. | Not reported. | 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. | “At the time of study initiation, ART programmes were only beginning to be implemented. Study sites were purposely chosen in areas where programmes to increase long-term access to ART were already established, or in development, to ensure long-term access to HIV disease monitoring and treatment for participants after study completion.” | Poor / None |
| **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." | “In Mombasa, for example, implementation within the public provincial hospital required a large and multidisciplinary team of dedicated research staff and part-time government employed health care providers. This partnership resulted in important exchange in resources, but also in logistic chal­lenges, particularly due to high turn-over of government staff. The paperwork involved in clinical trials (approximately 60 different CRFs) was very time-consuming and resulted in large logistic challenges for clinicians and the data manage­ment team.” “High mobility of many participants over the duration of the study caused difficulties in subject tracing, follow-up and retention in this rural-urban setting. Poverty of the rural participants presented an additional challenge in providing, for example, nutritional counseling to ensure adequate child growth and maternal nutrition.”“The study enrolled participants at a lower rate than expected due to several factors. First, there were ﬁnancial constraints. Funding was initially secured for only three sites (Bobo Dioulasso, Mombasa and Nairobi). It was decided to launch the project while trying to secure funds for two additional sites, with a backup plan to extend duration of recruitment in the original three sites if necessary. Funds for two planned sites in Rwanda and Tanzania were never identiﬁed, but funding for two South African sites was secured almost two years after enrolment of the ﬁrst participant. Other factors negatively affecting recruitment included a delay in initiating the RCT by more than six months following the FDA advisory regarding NVP in women with CD4+ cell counts N250 cells/mm3, and the lower than estimated prevalence of HIV-1-infected pregnant women in Bobo Dioulasso.” | Good |
| **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." | “Children's HIV-1 infection status was assessed using a quantitative HIV-1 RNA real-time PCR assay (Generic HIV-1 Charge Virale, Biocentric, Bandol, France) in all sites except Nairobi where a qualitative HIV-1 DNA PCR assay (Amplicor HIV-1 DNA v1.5 assay, Roche) was initially used and infection status of all children considered positive subsequently conﬁrmed using the quantitative real-time PCR assay.”“All infants received a single dose of NVP (0.6 ml oral suspension, approximately 2 mg/kg body weight) within 72 h of birth. From 2007, one week of AZT (4 mg/kg twice daily) was added to reduce the risk of selection for NVP resistance in infected infants (Table 3).” | Fair |
| **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)." | “In each site, study implementation was monitored by dedicated quality assurance staff as well as by the WHO Kesho Bora Site Coordinator and an independent external Good Clinical Practice (GCP) monitor.” | Fair |