University of Colorado
Anschutz Medical Campus

Department of Pediatrics
Prevention Research Center for Family and Child Health
Mail Stop 8410
13121 East 17th Avenue
Aurora, Colorado 80045

Nurse-Family Partnership® (NFP) International

Guidance Document - Phases of International Implementation and Research of NFP | July 2023

INTRODUCTION

This document outlines the phases that new countries (or Provinces where there are several licences held within one country) are expected to progress through as they test the feasibility and efficacy of NFP within their context, before progressing to expansion and sustainability of the program within their system. This process enables countries to undertake initial small scale testing of the program, adapt the model for local circumstances and evaluate the program's impact before expanding widely. This process is intended to balance the need for adapting NFP to local circumstances while preserving the integrity of the program by adhering to its Core Model Elements.

Countries interested in implementing NFP are assisted through an initial assessment process to determine their possible suitability and capacity for implementing NFP, which is outlined in the ***Guidance Document: Implementing NFP in a New Country: Assessment of Readiness.*** During this 'Pre- Implementation' phase the NFP International Team will support the country to; understand the program, its research, and the implementation requirements, agree the target population and scope of phases one and two for their country, develop funding applications and link with other implementing countries as necessary, and complete the assessment of readiness document. Once there is a mutual decision to proceed with implementing NFP, countries are provided with a license that enables them to progress through the ***Standard phases of Implementation and Research*** designed to assess the feasibility of NFP within their context and eventually the added value that the program brings for families.

STANDARD PHASES OF IMPLEMENTATION AND RESEARCH

Phase One – Adaptation.

Phase One examines the adaptations needed to deliver the NFP program in local contexts while ensuring fidelity to the NFP model. Each new country is assigned a designated international NFP International Consultant (IC) who supports the designated implementing entity in identifying: program goals; how the NFP program will be delivered in the context of the country's health and social service systems; the population to be served; potential referral pathways; and organization of community support. The IC supports the implementing entity to develop a project plan for initial implementation and feasibility and acceptability testing. Guidance is also provided regarding recruitment of a Clinical Lead, adaptation of the Visit-to-Visit Guidelines, the supervisor and nurse education curricula and materials, nursing assessment/data collection forms, and other program tools/resources. The IC also facilitates connections

with other countries implementing NFP, and access to other international NFP resources. PRC staff will be able to consult regarding the pilot study design, data collection tools, and evaluation procedures where necessary.

Phase Two – Feasibility and Acceptability through Pilot Testing and Evaluation.

Phase Two involves conducting a pilot test of the adapted NFP program with the projected number of sites and/or clients specified in the licensing agreement. The pilot includes testing the feasibility of referral pathways, data collection measures/sources, program materials, nurse recruitment, nurse education, and any other relevant measures. The pilot will determine acceptability of the program for the mothers, families, community partners, nurses, implementing agencies, and any other relevant partners. The results of this work will inform what additional adaptations may be needed to ensure the feasibility and acceptability of the NFP program within local contexts. At the end of this phase, the country develops its NFP information system or adapts its existing system to accommodate NFP data requirements. Continued recruitment of clients in existing pilot sites, or expansion to further sites for continued learning regarding required adaptations, may be approved if requested. Countries will begin submitting annual reports on their program implementation progress during this phase. These annual reports are reviewed and discussed with the leadership of a peer NFP implementing country at an Annual Review meeting.

Phase Three – Randomized Controlled Trial (RCT).

This phase is established to estimate program effects on outcomes of clear public health importance that align with the outcome domains in the original US trials and that address additional goals of that country. This work is designed to determine the added value of the program for the populations and contexts in which it is being delivered. The expected research methodology is a Randomized Clinical Trial (RCT) as this provides the strongest evidence of program impact. In some circumstances, it may not be feasible or appropriate to undertake an RCT (e.g., where the population size is too small to estimate benefits reliably or where there are serious cultural concerns). In these circumstances, use of other quasi-experimental designs will be possible. Where evidence of impact in comparable societies has already been established, this phase will not be necessary, and countries/provinces can move directly to phase four. These studies are conducted independently from the PRC. However, Dr. Olds (or his delegate) will consult on study design, sample size, recruitment and randomization methods, outcome measures, and planned data analysis as required. Selection of objective outcome measures and management of compensatory equalization within communities are critical issues involved in study planning. Countries are encouraged to conduct complementary qualitative studies, which can be helpful in understanding results of the RCT. The PRC also facilitates consultation with other international NFP researchers when requested. During this phase, the implementing entity will wish to continue recruitment of clients in existing pilot and/or RCT sites before analysis and reporting of the RCT data are complete. This will ensure that the service is maintained and available to further expand in the event of positive research outcomes. It is also possible to expand the number of sites during this phase. Countries are expected to continue completing annual reports during this phase.

Phase Four - Continued Refinement and Expansion.

Once the evaluation of the outcomes study has been completed and outcomes found to be of public health significance, the license holder and implementing agency will be in a position to further refine and expand the adapted NFP program in their country. This phase includes: building capacity and establishing sustainable systems for funding; embedding clinical leadership; selecting and developing new sites; recruiting and educating new NFP nurses and supervisors; and continuously improving program implementation, including refinement and use of the NFP information system. It is expected that countries will move to a higher level of self-sufficiency during this phase while continuing to meet licensing requirements through the annual review process, including completing an annual report. This annual process provides an assessment of program fidelity, achievement of program benchmarks, and plans for improving performance. It is expected that countries will still receive support from the IC, although the frequency of this consultation will be reduced and follow a mutually-agreed schedule. Any substantive change in the way NFP is implemented will continue to require approval of Dr Olds and the International Consultant.

Phase Five – Full-Service Integration

When the program has expanded widely within a country over a number of years, and the program has been fully established and integrated into the local health and care systems in a sustainable way, the country may progress to phase 5. In this phase, it is expected that there is Governmental support, mature national NFP leadership, and an established, data-led quality improvement process to support the program. The judgment regarding transition to phase five will be made through review of the previous five years of annual reports. Where these show consistently high adherence to the CMEs and continued indicative achievement of program outcomes, along with an established and effective leadership and QI process, a country can apply to transition to this phase. The judgement regarding transition to this phase will be made by Dr David Olds and the IC in conjunction with the country's license holder. In phase 5, countries will be expected to submit an annual report every 2 years. Annual Review meetings with Dr Olds and the IC will continue to be held annually, with the focus alternating between discussion of the annual report (in the year that this is submitted) and the country's quality improvement or adaptation projects. Consultation for the country by the IC will continue to be mutually agreed, but is expected to reflect the more autonomous implementation of NFP in Phase Five. Any substantive change in the way NFP is implemented will continue to require approval of Dr Olds and the International Consultant to preserve the integrity and reputation of the program.

