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 - Four Phases of International Research and Implementation of NFP | 2018.10.21

## **INTRODUCTION**

The Nurse-Family Partnership (NFP) home visiting program has been developed over four decades of extensive research conducted by the Prevention Research Center for Family and Child Health (PRC) at the University of Colorado, Denver (UCD). This research includes three large-scale randomised clinical trials (RCTs), the most rigorous way of determining whether the program works. These RCTs (Elmira, Memphis, and Denver) have demonstrated consistent and enduring effects on maternal and child health outcomes in targeted populations of low-income, first-time mothers and their families in the United States. NFP is the first early intervention program to find reductions in maternal and child mortality, a finding from one US trial conducted with highly disadvantaged families living in highly disadvantaged neighborhoods. The PRC continues long-term follow-up research today, assessing and reporting the progress of families who participated in the original three trials. In addition, a major focus of the PRC today is to applying rigorous research to improve the underlying NFP model and its implementation.

NFP is a licensed program that comes with a set of Core Model Elements to ensure faithful reproduction of the clinical model, including the development of supportive organizational and community contexts to promote program quality. The program is grounded in a clear clinical model and includes Visit-to-Visit Guidelines; specifications for nurse competencies, nurse education, data collection systems; and quality improvement. Specially educated NFP nurses provide home visits to pregnant women starting early in pregnancy and continuing until the child's second birthday. NFP nurses use a strengths-based approach to support women in accomplishing the goals of the program: promotion of healthy pregnancies, children's health and development, and improved maternal life course – consistent with mothers' aspirations. In the United States, NFP is currently delivered in 42 states, and has served over 280,000 families.

In 2004, the PRC began responding to inquiries from researchers and/or government health agencies abroad that were interested in possibly developing the NFP program in their country. Dr. Olds (the program founder) and his team have developed a model for adapting and testing the NFP program in international contexts that is grounded in the same rigorous research standards that serve as a foundation for the U.S. program. This process is intended to balance the need for adapting the 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.* Once there is a mutual decision to proceed with implementing NFP, countries must agree to progress through the *four standard phases of Research and Implementation* designed to assess the feasibility of introducing NFP in their context and eventually the added value that the program brings for families:

## FOUR STANDARD PHASES OF RESEARCH AND IMPLEMENTATION

<u>Phase One</u> – 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 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 regarding 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 (and other PRC staff as needed) will deliver the initial NFP nurse education with the goal of countries becoming self-sufficient over time. The IC also facilitates connections with Clinical Leads in other countries implementing NFP, and access to other international NFP resources. Dr. Olds and other PRC staff will consult regarding the pilot study design, data collection tools, and evaluation procedures.

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 Dr. Olds and the IC.

<u>Phase Three</u> – 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, consideration will be given to use of other quasi-experimental designs. 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 may seek approval to continue recruitment of clients in existing pilot and/or RCT sites until analysis and reporting of the RCT data are complete. Countries are expected to continue completing annual reports during this phase.

Phase Four - Continued Refinement and Expansion. Once the evaluation of the RCT 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 the PRC.