THE UK RANDOMISED CONTROL TRIAL – FREQUENTLY ASKED QUESTIONS

For ANFPP stakeholders, the recently released report of the RCT of the UK Family-Nurse Partnership (NFP) raises a number of interesting questions and provides some lessons and guidance for both the Australian program and the proposed Australian RCT.

1. **Q: What is the purpose of RCTs within the NFP program?**

   A: As part of the NFP's international expansion, when serving large populations it is important that an independent randomised trial takes place. By doing this, we become aware of a programme's added value within the new context which is essential for guiding policy and practice.

   This approach is consistent with the NFP's commitment to ensuring that the program continually reviews its effectiveness to shape future policies, guide further adaptation and provide ideas on improving the quality of the program.

2. **Q: The outcome of the RCT show that there was little added value detected for the NFP compared to usual care in England. Is it likely these results will have any impact on how the ANFPP is currently conducted in Australia?**

   A: It is important to conduct scientifically valid studies of programs like the NFP when they are implemented in new contexts and the numbers of participants are sufficiently large to make such studies feasible. The UK trial has limited meaning in the Australian and Aboriginal and Torres Strait Islander contexts for the following reasons: 1) the population served in England (young mothers < 20 at registration) is not uniformly at risk; NFP benefits are more pronounced for populations at heightened risk. 2) Those receiving usual care received a lot of specialized services from teen pregnancy midwives and health visitors, which may not represent the way usual care is delivered throughout the UK, much less in other parts of the world. 3) Two of the four major outcomes do not align with what the NFP claims to affect. The trial should have examined serious injury and language development as primary outcomes. The trial found that NFP-visited children had better language and cognitive development reported by mothers than did children in usual care; language development was treated as a secondary rather than primary outcome.

3. **Q: What results, or evidence, have come out of other RCTs conducted in other NFP Societies internationally?**

   A: Several randomized control trials have been conducted within various NFP programs over previous years, including the first in Elmira, New York in 1977; then in Memphis, Tennessee in 1990; and in Denver, Colorado in 1994. These have identified the following family outcomes:

   - 48% reduction in child abuse and neglect
   - 56% reduction in emergency room visits for accidents and poisonings
   - 59% reduction in arrest of children at age 15
   - 67% reduction in behavioural and intellectual problems in children at the age of six
   - 72% less convictions of mothers when children are at age 15.

4. **Q: Following the outcome of the England RCT, what direction will the UK Family Nurse Partnership (FNP) take going forward in the implementation of the program within England to address the issues that were raised?**

A: Professor Olds has highlighted four policy/practice areas that the NFP should address following the trial:

1. Supporting nurse home visitors to more effectively tackle challenging behaviours, such as pre-natal tobacco use and planning subsequent pregnancies.

2. Focus on the RCT as part of the NFP's international expansion. When serving large populations it is a prerequisite that an independent randomised trial takes place. By doing this, we become aware of a program's added value within the new context which is essential for guiding policy and practice. By doing this we are able to better identify and target those who need help most, and families living in the most adverse conditions in which the mothers have the lowest psychological resources.

3. Enabling nurse home visitors to systematically adjust the dosage of the program according to levels of risk.

4. Understanding how to align and integrate the program with wider services strategically and operationally.

5. **Q: What additional information should have been considered when reviewing the outcomes of the UK RCT?**

A: Although the RCT was not considered beneficial in identifying program effectiveness, it is worth noting that two primary outcomes of the RCT are not outcomes that the NFP claims to affect. There are no replicated prior effects on birth weight or children's accident and emergency department encounters as defined in this trial. The accident and emergency outcome in the England RCT combined all emergency encounters and hospital admissions into a 'yes' or 'no' variable. This definition does no distinguish, for example, between a parent attending the emergency department out of parental concern when GP care is unavailable (such as a concerned parent taking their child to the hospital with a possible ear infection) or a serious injury resulting from an accident or abuse (e.g. abusive head trauma).

Professor Olds noted that two child outcomes found to be consistently affected in previous NFP trials were not selected as primary outcomes in the English RCT. The first outcome is language or cognitive development which was objectively measured in earlier trials. The inclusion of this outcome measured directly (as opposed to being measured by parental report) would have strengthened the study. The second outcome not reported is serious childhood injury, which can indicate maltreatment in young children. Given NFP impact on maltreatment-related outcomes and the importance of maltreatment for children's health and development, examination of serious injury would have strengthened the trial.

6. **Q: How can we ensure that the design of the proposed Australian RCT provides an appropriate design for assessing outcomes in Australia?**
   A: Stakeholder involvement in the design of the RCT is imperative to ensure that the RCT addresses unique challenges that have emerged in Australia.

   Additional research and documentation of the nature of the participants, the service context and the implementation challenges will be undertaken so that results can be interpreted in an informed way.

7. **Q: What, if any, of the lessons learned from the UK RCT are generalizable to Australia and what lessons should the Australian stakeholders take from the UK trial?**

   A: The report shows how important it is that we undertake an RCT in Australia which pays attention to the detailed description of the client cohort, the alternative services available to women who cannot access the program, and specific challenges of implementation in Australia.

   The UK RCT adds valuable evidence to the international evidence base for the NFP. While it is not surprising that the impact of the program varies according to client characteristics and service context, it is important that this is confirmed. It is also important that a picture of where and in what circumstances the program provides best value for money is built up internationally.

   A critical aspect of the report is that it shows that it mirrors the culture of reflection and quality improvement that is built into all levels of the program.

   For the program to remain relevant and cost-effective, it must continue to be willing to examine all the evidence as it emerges. It is important that the implications of the research are considered in this light and not taken out of context to support non-evidence-based political agendas.

   The UK report reminds us that we need to undertake similar research in Australia to identify what the benefits are for our specific client group and service context. Outcomes cannot be taken for granted.

8. **Does the report provide any insights into why the program in the UK shows less improvement in outcomes for participants than RCTs in the USA?**

   A: There are four potential aspects to this question:

   - **The service context**: Issues to be considered include the UK mainstream services for mothers and babies and what support the control group was given compared to the mothers in the USA RCTs. This may be related to timing. It is likely that service providers in mainstream services did not take on board some of the evidence generated in the last 30 years.
   - **The implementation approach**: Issues to be considered include how workforce development is undertaken and what supports are provided to implementing sites.

- **The clients**: The cohort of clients in the UK is very young mothers, we need to understand if this has had an impact on the results.
- **The research design:** It is important to determine in what ways the research design mirrored or was different from the design of the RCTS in the US.