PCOS CRE mixed-methods Evaluation: Aligning with the transfer of research into policy and practice

Background and project rationale:
Polycystic Ovary Syndrome (PCOS) is the most common endocrine disorder in women and affects up to 12-18% reproductive age women [1]. The prevalence of PCOS is 3-fold greater in obese women with lifestyle modification to control weight central to management [1]. The International Obesity Task Force has highlighted the need for monitoring and evaluating all interventions relating to obesity and obesity-related diseases [2]. Evaluation of research programs is integral, as it focuses on the processes required to effectively establish, adapt and maintain evidence-based interventions under real world conditions, maximising translation of research findings into policy and practice.

The value of conducting program evaluations has been established as an integral part of the research-implementation-translation continuum. Despite this, in the setting of obesity-related conditions such as PCOS there is inconsistent use of comprehensive evaluations, limiting the translation of research into advancements in clinical practice [3]. Furthermore, knowledge gaps persist regarding the application of evaluation methods to large-scale Centre for Research Excellence (CRE) programs. The "New Knowledge Programs" of the CRE provides a unique opportunity to translate research findings into improved PCOS health outcomes. Applying robust program evaluation methods, the CRE evaluation will report on the efficacy of implementation strategies, successfulness of the individual research programs, short and long term program impacts and translational research activities. The evaluation will be conducted across the four core CRE program platforms: (1) creating knowledge, (2) evidence synthesis, (3) collaborations and (4) building the capacity of the PCOS medical research workforce (Table 1).

Methods: Comprehensive planning of the CRE evaluation has been conducted previously guided by formal evaluation methods. Evaluation levels selected: The CRE will undertake a process evaluation to document and assess implementation strategies, guided by the Medical Research Council’s framework for complex intervention [4]. The objectives of the process evaluation will be to improve our understanding of the impact of each of the CRE programs, establish program internal and external validity, generalisability, reach, fidelity and acceptability. An impact (summative evaluation) will also be undertaken to draw conclusions regarding the quality, impact, outcomes and benefits of the CRE. The evaluation approach: An action-based research and responsive evaluation approach will underlie this evaluation, centralising on stakeholder engagement and accounting for diverse stakeholder perspectives (researchers, clinicians, policy makers and consumers). Evaluation framework: The evaluation will be guided by the Centre for Disease and Control and Prevention (CDC) framework. This framework was selected as it focuses on capacity building evaluations, collaborations and stakeholder engagement, mirroring the core values of the CRE [5]. A program logic model will also guide this evaluation.

Data collection tools: A mixed-methods data collection approach will be applied with qualitative methods including semi-structured interviews with affected women, clinicians and the CRE working group. Quantitative methods will include rigorous tracking of program inputs and resources, questionnaires, checklists and research program outcome data.
Figure 1: Logic model PCOS CRE

**AIM:** To improve PCOS diagnosis, capture prevention opportunities, optimise management, and improve overall quality of life of affected women.

**IDENTIFIED NEED**
PCOS affects one in five young Australian women.

Women with PCOS have elevated rates of obesity and increased risk of reproductive, metabolic and psychological disturbances.

Salient research gaps exist such as improving diagnosis, understanding biological origins and optimising health outcomes.

The CRE will generate new knowledge to address research gaps.

**INPUTS**
- Secured NHMRC funding for the PCOS CRE.
- PCOS Alliance: bringing together a national multidisciplinary team of clinicians, medical researchers and evidence synthesis experts.
- Multiple active and engaged research and clinical collaborations.
- Strong international leadership in PCOS research (biological, pharmacological, lifestyle and translational research).

**ACTIVITIES**
- To create new knowledge (Research) to improve PCOS health outcomes.
- Evidence synthesis and translation to promote the transfer research into health policy and practice.
- To develop the PCOS health and medical research workforce.
- Facilitate collaborations & communication.

**OUTPUTS**
- Evidence that the 6 key research programs have generated knowledge.
- Minimum data set of the PCOS registry achieved.
- Engagement of an international team of experts, development of PCOS guideline and educational resources.
- Documentation of processes involved in establishing evidence-synthesis working group, collaborations, attracting high quality trainees and delivery PCOS training programs.

**OUTCOMES**
- Short-term
  - Numerous publications describing PCOS aetiology, pathology diagnosis and improving outcomes.
  - PCOS registry developed.
  - PCOS guideline developed across.
  - Educational resources.
  - National collaborations established.
  - Improved indigenous engagement.
  - Provision of funded training opportunities.
  - Delivery of CRE training program.
- Long term
  - Improved PCOS diagnosis (measures)
    - Health professional survey
    - ALSWH rates of diagnosis
    - Improved androgen assays
  - Better PCOS management and outcomes
    - Research papers
    - Qualitative interviews
  - Improved quality of life
    - Development of PCOS Qol tool

**References:**
Expected outcomes: The expected outcomes relate to the CRE desired program outcomes, informed by the program grant application. The expected outcomes are summarised in the program logic model (Figure 1) and Table 1.

<table>
<thead>
<tr>
<th>Table 1: Program timeframes</th>
<th>Feb-March</th>
<th>April-May</th>
<th>June-July</th>
<th>Aug-Sep</th>
<th>Beyond funding</th>
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<tbody>
<tr>
<td><strong>Process evaluation: data collection to monitor program implementation and outputs</strong></td>
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<td>Establishing a PCOS registry</td>
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<td>Program outputs (manuscripts, presentations, evidence based guidelines, screening tools, consumer resources)</td>
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<td>Partnerships developed (national and international)</td>
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<td>PCOS meetings organised to bring together international expertise</td>
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<td>Indigenous engagement opportunities</td>
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<td>Funding and training programs to build workforce capacity (students, researchers, clinicians)</td>
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<td><strong>Process evaluation: Qualitative interviews with the CRE working group to determine the barriers and enablers to establishing:</strong></td>
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<td>PCOS registry development</td>
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<td>Evidence synthesis working group &amp; collaborations</td>
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<td>International PCOS collaborations and partnerships</td>
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<td><strong>Summative evaluation: Focus groups with health care providers to determine the long term impacts of the CRE in relation to improving PCOS diagnosis and management</strong></td>
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<td>Value of devised PCOS screening and diagnostic tools</td>
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<td>Capacity building of the medical/allied health workforce</td>
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<td><strong>Summative evaluation: Focus group with PCOS affected women to explore long term CRE impacts</strong></td>
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<td>Acceptability of developed PCOS consumer resources</td>
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<td>Satisfaction with health care provided</td>
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Significance: This evaluation builds on CRE program, seeking to “improve, not prove” research findings, via the documentation and assessment of implementation strategies, rigorous tracking of program activities and resources (inputs), assessing program impacts (short and long term) and creating increased opportunities to share program learnings. The evaluation will promote greater CRE program reach, engaging multiple end users including: researchers, affected women, health care workers and policy makers. Ultimately, the evaluation will maximise research translation and impact PCOS policy and practice.

Translation plan: manuscript publication in peer reviewed international journals (Implementation Science), conference presentations (national and international) and development of an evaluation report for the CRE website.

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<tr>
<th>Budget:</th>
<th>Evaluation contract agreement, per Monash University Enterprise Agreement for Casual academic staff ($47.6/hour). Thus, 7 months of work (32 weeks) at 1 day per week (7.5 hours per week), 240 hours.</th>
<th>$11,420.0 +GST(1,142.0)</th>
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<td>Approximately 25 interviews to be conducted (45 minute duration). Transcribing fee at 1.85 per minute of audio.</td>
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<td>Total:</td>
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<td>$15,000</td>
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