P-194 Exploring the scope, value and contribution of the clinical research nurse to trial design, conduct and overall trial performance [Abstract only]

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ABSTRACT - Principal Research Question

This qualitative study aims to explore the scope, value & contribution of the Clinical Research Nurse and Midwife (CRN/M) to trial design, conduct and overall trial performance when included and funded as a co-applicant and member of the Trial Management Group (TMG).

Background: The Clinical Research Nurse and Midwife (CRN/M) make significant contributions to the clinical research process, quality of research outcomes and most importantly the safe expert care of research participants. However, there is limited evidence in relation to the scope, value & contribution of the CRN/M to trial design, conduct and overall trial performance when included and funded as a co-applicant and member of the Trial Management Group (TMG).

Aim: This study examines the role of the CRN/M performing an extended role during the performance of three case studies with the aim of discovering the CRN/M's value, scope, and contribution in the context of this specific research nursing delivery role.

Methods: A qualitative instrumental case study design was selected to describe, compare, and evaluate the perspectives of the TMG members interviewed. Eight semi-structured qualitative interviews were performed with participants from the three case studies. This provided an opportunity to explore their perspectives and experiences of working with a CRN/M in this specific extended research delivery role. Method of recruitment used was purposeful and individual interviews were audio recorded and transcribed verbatim. Interview transcripts were analysed, and common themes identified.

Results: Inductive thematic analysis of the data identified four key themes and eleven sub-themes using Braun and Clarke (2006) six-phase method. Key themes identified that influenced trial design and performance in this context were – Specialist operational and organisational knowledge & experience; organisational and operational practical perspective; advocacy and attributes. All members unanimously recognised the value of the CRN/Ms in this extended role describing the positive influence the role has.

Implications to practice and conclusions: A significant outcome from this qualitative evaluation is the need for trial membership to include the right multidisciplinary team members with the most appropriate skills, knowledge, and experience from the conception of a trial question by embedding representation from a wide team of clinical and academic colleagues including the CRN/M workforce. To the author's best knowledge, this is the first qualitative evaluation study that assessed the effectiveness of CRN/Ms in this extended role providing an important contribution to the lack of literature on the topic.