多中心臨床試驗研究護理師之工作困境-以臺灣癌症臨床研究合作組織爲例

The Obstacles of Site Research Nurse on Conducting Multi-center Clinical Trial-A Case Study on Taiwan Cooperative Oncology Group

中文摘要

爲配合組織發展及提昇研究護理師進案績效，本研究探討 TCOG 研究護理師執行多中心臨床試驗之現況及其面臨之困境。就機構面、流程面與人員管理面分別提出改善建議，希望有效協助研究護理師達成工作目標，而主管也可據以作爲人力調整與未來規劃之參考。

本研究採用質性研究方法，以 TCOG 派駐各院的 11 位研究護理師爲研究對象進行深度訪談，訪談大綱包括對派駐醫院臨床試驗政策與管理的因應，與醫院醫護人員、病患、TCOG 執行中心互動的現況，及生涯發展等。以紮根理論嚴謹的分析方式探索訪談資料中研究護理師對組織、工作與個人的認知與期望。

TCOG 研究護理師執行臨床試驗時，需要極大耐心配合各院繁複的行政系統，運用人際關係協助工作進行，發揮專長提供醫護人員所需資訊；維護病患權益，給予希望與信心以鼓勵他們度過人生的最後階段；完成行政系統中大量的書面作業，以確保臨床試驗的品質；專業規劃受阻的同時，還主動關心 TCOG 的未來發展，對於如何將研究護理師的角色做得更好也提出寶貴的建議，更希望有機會了解最新的研究與治療趨勢，以利專業提升。

本研究由機構、流程與人員管理等三個構面進行討論並提出建議。機構面在討論政府與醫院的臨床試驗政策，法規環境雖有長足之進步，但執行體系仍有待加強。TCOG 將由架構扁平化開始重整，例如以計畫工作群取代疾病委員會避免疊床架屋，視醫院專業與配合度以合作醫院取代會員醫院，以及新增計畫審查委員會加速審查過程。

流程面則討論 TCOG 計畫資料品質的維護，需建立病患失聯之標準處理方式，同時檢討病患追蹤作業之執行方式、成效或是重新設定追蹤期限，並新增監測作業。而建立各計畫工作流程與時間表以確實分析研究護理師工作量更是當務之急。爲確保病患資料表格與計畫的相關性與合理性，研究護理師於計劃發展期間即參與病患資料表格的設計。

人員管理面討論執行中心爲提供有效率的支援與協助，也應建立各計畫工作流程與時間表以了解人力需求與後續作業方向。改變護士會議型態是能立即進行而又能有效協助研究護理師加強其參與感的行動方案，而團隊會議的彈性運用不僅能讓協調人員了解各院實際狀況，也可讓主管和研究護理師雙方有機會交換意見，研究護理師也可藉此模式討論研究專題以展現其醫療專業。TCOG 也應鼓勵及補助研究護理師參加研討會、投稿或海報，創造一個既能吸引又能激勵研究護理師

投入的工作環境，以及永續的職涯發展機會。
研究護理師是臨床試驗中不可或缺的靈魂人物，關鍵在於他們連結各項資源並有效運用的能力。TCOG 如何在資源有限的環境中，以適當的規劃與管理導引研究護理師充分發揮核心價值，提升臨床試驗品質與執行效率，是 TCOG 主管面臨的最大考驗。
受限於研究者的經驗，未來研究希望對計劃主持人與中心協調人員等進行訪談，以便從更多元的角度探討 TCOG 的組織發展與研究護理師的角色。也希望未來能有更多探討研究護理師的研究，讓有意願跨入臨床試驗領域的醫療專業人員有更深入的了解。

英文摘要

This study mainly discusses the obstacles that research nurses of TCOG face when execute multi-center clinical trials, and in the end to give away suggestions to advance organizational development and performance of the nurses from the perspective of organization, process, and human resource management.
We utilize qualitative research methodology. Firstly, we set interview guidelines, including how nurses perceive the way hospital and staff interacts with them, the operation obstacles, and their career planning. Secondly, we interview 11 research nurses and transcribe the content to transcripts. Thirdly, we analyze the content through grounded theory to explore the code and construct on the issues.
In order to successfully complete their jobs, research nurses of TCOG consume their energy and patience on hospital’s complex administrative system, exercise their interpersonal impact to finish jobs, supply available information to medical staff, advocate patient’s right to support their terminal lives, complete mass paper work to assure the quality of trial, give concern and suggestion to TCOG and roles of nurses, and continuous learning to assure their competency.
This study focuses on three perspectives of organization, process and human resource management. Organization perspective includes the policy of government and hospital, and how nurses evaluate the strategies now hospital utilizing. And the restructuring of TCOG on replaced diseases committees by study working groups, replaced member hospitals by collaborate hospitals, create Protocol Review Committee to improve review procedure.
Process perspective includes the quality maintenance of case data. It needs to build standard operation procedure on patient out of reach, review and improve the operation of case follow up, and create monitor operation to guarantee the requirement of data quality assurance. Due to analyze work lording of research nurses, the most important task is to build their job description by protocols and sites. To ensure case report forms are designed to be as relevant and reasonable as possible, it

is necessary to have research nurses' involved in the planning of protocol.

Human resource perspective includes the effective support and assistance from TCOG, human resource management and on-job-training program. In order to achieve effective support to research nurses, it also needs to build coordinator's job description by protocols and evaluate manpower demanding accordingly. An activity can be feasible immediately to heighten the interest and involvement of research nurses is to change the pattern of nurse meeting. The application of group meeting assists coordinators getting better understanding the practice of certain hospital, promotes the communication between TCOG executive and research nurses, provides research nurses a space to discuss the research topics basis on their professional on oncology nursing. To approach an attractive work environment and long-term career opportunities, TCOG should provide funds for the research nurses to attend a major meeting of oncology nursing and when they are involved with an abstract or poster being presented.

Research nurses play an important role of clinical trial because they are the one to connect and fully utilize resources. Executive of TCOG faces the biggest challenge how to plan and motivate these nurses, and ultimately improve the quality and efficiency of clinical trial under restricted resources.