國立臺灣大學 104 學年度碩士班招生考試試題

※ 注意：請於試卷內之「非選擇題作答區」標明題號依序作答。

一、請詳閱下列這段敘述之後，依據其意回答所列之問題：(30%)

【摘錄自 Bolge, S.C. et al. (2015) 發表於 Patient Preference and Adherence, 9: 121-131. 文章】

Abstract

Background: To examine reasons why rheumatoid arthritis patients discontinued subcutaneous (SQ) anti-tumor necrosis factor (anti-TNF) treatment in the past 12 months, so as to help inform successful, uninterrupted therapy.

Methods: Data were collected in March and April 2011 using self-reported, internet-based questionnaires. Study inclusion criteria comprised: rheumatoid arthritis diagnosis; discontinuation of SQ anti-TNF medication (adalimumab, certolizumab, etanercept, or golimumab) within the past 12 months; aged≧18 years; United States residency; and consent to participate. Patients reported primary and other reasons for discontinuation of their most recently discontinued anti-TNF.

Results: Questionnaires from 250 patients were analyzed; 72.8% were female, 80.8% were white, and median age was 51 years. Patients had discontinued etanercept (n=109), adalimumab (n=98), certolizumab (n=24), or golimumab (n=19) within the past 12 months. When prompted about their primary reason for discontinuation, lack of effectiveness (40.8%) was cited most often, followed by injection experience (18.4%). Combining prompted primary and other reasons for discontinuation, 60.8% of patients reported lack of effectiveness, while 40.8% reported injection experience, which included: pain/burning/discomfort after injection (14.4%); pain/burning/discomfort during injection (13.2%); injection reactions such as redness/swelling after injection (12.4%); dislike of self-injection (11.6%); dislike of frequency of injection (10.4%); and fear of injection/needles (6.8%).

Conclusion: From the patient perspective, there are unmet needs with regard to the effectiveness and injection experience associated with SQ anti-TNF medications, which may lead to discontinuation. Treatment options with a better injection experience may address these needs. These results demonstrate the importance of including the patient perspective when making prescribing decisions or payer access and coverage decisions.

(1) 依據上文，此研究最有可能是哪一種類型之研究設計？試述此種研究設計的優點及缺點。(10%)

(2) 請寫出此研究之收案期間、收案數量、研究對象特性、所使用到研究工具及統計方法。(10%)

(3) 由此摘要得知此研究結果有哪些發現？您將如何應用這些研究結果於臨床護理此類患者，請寫出您可能的照護計畫及其相關立論依據。(10%)

見背面

二、請將下列這段英文敘述逐字翻譯成中文，以忠實呈現其意涵。 (20%)

【摘錄自U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research. *Guidance for Industry - E6 Good Clinical Practice: Consolidated Guidance* (April 1996 ICH). Page 1, 50.】

Good clinical practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and wellbeing of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

Essential Documents are those documents that individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor, and monitor with the standards of GCP and with all applicable regulatory requirements. Essential Documents also serve a number of other important purposes. Filing essential documents at the investigator/institution and sponsor sites in a timely manner can greatly assist in the successful management of a trial by the investigator, sponsor, and monitor. These documents are also the ones that are usually audited by the sponsor's independent audit function and inspected by the regulatory authorities as part of the process to confirm the validity of the trial conduct and the integrity of data collected.

The minimum list of essential documents that has been developed follows. The various documents are grouped in three sections according to the stage of the trial during which they will normally be generated (1) before the clinical phase of the trial commences, (2) during the clinical conduct of the trial, and (3) after completion or termination of the trial. A description is given of the purpose of each document, and whether it should be filed in either the investigator/institution or sponsor files, or both. It is acceptable to combine some of the documents, provided the individual elements are readily identifiable.

三、請依您個人對目前「臨床研究護理師（以下簡稱 CRN)」現況的瞭解或經驗，回答下列所列之問題：(25%)

(1) 說明碩士層級之護理人員於執行「進階實務護理 (advanced practice nursing)」所扮演的角色與應具備的核心能力為何? (10%)

(2) 請您從「政府政策、法規、教育、研究以及臨床實務」等多面向，提出您認為發展 CRN 專業角色，所遭遇到的瓶頸(或困境)與因應之道為何? (15%)

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四、針對此案例之研究工作情境，回答下列題目：(25%)

【案例情境】

某醫學中心有非常多的癌症臨床試驗同時在進行，院內也有好多位非常有經驗的 CRN s 都會知道院內有哪些計畫在進行。

新進蔡姓 CRN(以下簡稱「蔡 CRN」)初到執行一項末期病人最後一線藥物之研究計畫，負責的研究計畫主持人與協同主持人都非常積極地篩選病人。

某天，因為科主任有幾個病人疾病復發了，要讓此受試者轉到其他試驗計畫繼續接受治療，故資深的吳姓 CRN(以下簡稱「吳 CRN」) 請「蔡 CRN」到門診進行受試者篩選。「吳 CRN」對「蔡 CRN」說: 「這些病人參加 A 計劃治療無效，就轉到 B 計畫；B 計畫無效就轉到 C 計畫，總會有計畫讓他們參加。如果病人的 Hb 數值低，就先輸血輸到抽血檢驗結果符合收案條件，就再進案；因為廠商有成本效益考量，醫師也有競爭性收案的壓力且要有績效，我們 CRN 的責任就是協助大家，完成他們想要的，我們自己也因此而賺到錢，皆大歡喜……」。

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(1) 假設您就是蔡姓 CRN 要負責執行此臨床試驗，闡述您可能會遭遇之臨床或研究倫理議題與困境為何? (5%)

(2) 針對您可能會遭遇之臨床或研究倫理議題與困境，請說明您會如何進行此情境之倫理思辨? (10%)

(3) 你將會採取哪些行動以解決此倫理困境? (10%)

試題隨卷繳回