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• 中文摘要

研究目的：醫療或用藥疏失導致再次就醫，依各國統計其負擔可高達醫療資源的 7-15%。我國健保藥價支出比例過高(25%)，腎臟疾病的發生率及盛行率又高居世界第一，隱含國人有不合理使用藥物、造病、再度浪費健保資源的可能性。但是不合理用藥產生後的藥物不良反應之通報率又遠低於先進國家，隱含國人處於用藥風險而不自知的情境。針對此社會醫療現況，國內尚缺乏用藥風險的系統性研究。本一年期研究計畫乃以健保資料探討用藥風險來源。 方法：首先結合臨床藥理及臨床藥學的實務經驗，選取最常用的、療效區間小的、不良反應通報最多的、以及已知有明顯藥物交互作用、卻可能被合用的藥品，做爲用藥風險分析標的，我國健保資料庫(Out patient Sampling Database, OSD)進行系統性篩選後，顯示 phenyltoin 爲最可能不當使用的標的藥物。進而針對 phenyltoin 進行(1)消費及給付分析；(2)可能被不當使用之態勢分析；(3)探討及評估不當使用之人爲或系統風險因子；(4)以歸人檔(Longitudinal Health Insurance Database, LHID)探討用藥後遺症(不良反應通報及後續就醫狀況之相關性分析)。研究結果將做爲政府用藥安全風險管理之建議。 結果：本研究發現(1)醫療院所各科(e. g.牙科及中醫科)普遍開立 phenytoin。各層級院所的開立該藥之習慣具有差異性，每張處方箋所開立的平均藥品數量呈現明顯的差距，層級越高的機構所開立的藥品數量越多，醫學中心的開藥量甚至是基層診所的兩倍以上，地區以上層級開立原廠藥的比率遠大於基層診所，而基層診所的原廠藥使用比率有向醫院靠攏的趨勢。各機構的疾病嚴重程度不同，是否爲造成如此差異的主要原因，可列爲後續研究進行的方向；(2)各層級醫療機構的分析顯示區域醫院開立的 phenytoin 處方箋從 86 年至 94 年之成長幅度爲 75%，地區醫院

成長幅度則高達 100%；(3)phenytoin 平均藥品價格從 86 年之 1.33 元上漲至 89 年的 1.59 元，其後雖壓低至 94 年之 1.14 元，但使用量成長幅度仍高達 22.8%，並未受藥價調整之控制；(4)以該藥整體藥費支出觀之，調整藥價使藥費下降的控制效果僅 12.3%，遠低於 28.6%的藥價調降；(5) 3 年健保前 200 大給付藥品中有 144 種爲逾專利藥，其中 81 種逾專利藥的原廠藥價高於學名藥價，健保定價使逾專利保護期的 Phenytoin 原廠藥價比學名藥平均單價高出一倍，造成高市場占有率的寡佔情況，成爲健保沉重負擔;(6) 86 年至 94 年原廠藥使用量增加 70%而學名藥使用量增加 20%;(7)在迴歸模式中各客觀因素對於 Phenytoin 費用、數量以及給藥天數的解釋力僅有 44.4%、19.7%以及 18.0%。 結論：醫療院所各科普遍開立 phenytoin，值得健保局進一步探討其適性；原廠藥與學名藥使用量消長的不均衡，值得健保局思考健保浪費以及從適法面思考行政保護造成的不公平交易是否違背公平交易法。

- 英文摘要

Purpose: Costs spent in handling consequences of medication error were reported to count, in general, for 7-15% of total healthcare expenditure. Taiwanese population was known to have high drug consumption. The population was also ranked number one among the world in the prevalence and the incidence rate of end-stage renal disease, which is believed to be partially associated with the high drug consumption. However, the reporting rate of adverse drug reaction is rather low, indicating that medication risk is an undermined problem. Identification of the risk of irrational drug use is thus the goal of this study. Target drug for study in this project was defined as the most widely used drugs with narrow therapeutic window while are most frequently reported for adverse reactions. Method: Candidate target drug for study of risk analysis was selected based on the consumption analyzed with emperical data mining from the Outpatient Database from National Health Insurance Research Database (OSD). The consumption and expenditure were calculated. Studies include (1) the analysis of distribution profile regarding to the consumption and expenditure; (2) the identification of risk factors, either individual or institutional, affecting the irrational use from the above distribution profile. Results: Phenytoin was selected as the targe drug. (1) Phenytoin was widely prescribed in all subspecialty departments of all healthcare settings; (2) The number of phenytoin prescription increased significantly with an increase of 75% and 100%, respectivey, in regional and district hospitals from year 1997 to year 2005; (3) Although the average unit price reduction of phenytoin was 28.6% (1.59 NTD vs 1.14 NTD) from year 2000 to year 2005, total phenytoin consumption increased for 22.8%; (4) the market share of the original brand-name phenytoin was about 80% to 90%, possibility due to its unit price double to the generic products. (5) National Health Insurance have 144 for exceed patent medicine, among them 81 exceed patent former factory medicine price of medicine higher than formal name medicine price while being heavy while being the first, strong in assuaring the fixed price makes the medicine price of Phenytoin former factory which exceeds protection period of patent one time higher than the average unit price of scientific name medicine. (6) The consumption of original brand phenytoin increased for 70% while that of the generic products increased for only 20%. (7) Every objective factor, to Phenytoin expenses, quantity and only there are 44.4%, 19.7% and 18.0% for the explanation strength of days of medicine in returning to the way. Conclusion: Patients potentially having irrational medication of phenytoin was identied using the Longitudinal National Health Insurance research database (LHIRD). Risk profile and risk model due to irrational medication, such as the physician’s visit for

second claim disease, the claim of adverse drug reaction and other claims of complicated indication, were established. The results will be provided to the health authority in charge of the National Health Insurance Program for implementation of pharmacovigilance, as well as for the control of drug consumption and expenditure.