

憲法法庭會台字第13769號人民聲請法規範憲法審查事件

健保資料庫(二次)利用

法規範憲法審查言詞辯論結辯



中央健康保險署 署長

李伯璋

111年4月26日

完整實證資料庫全球稱羨

- 健保單一保險人制度，蒐錄完整國人醫療實證資料，2006~2021年相關研究7,177篇，涵蓋各類疾病探討，為全球醫療重要指引。
- 本人任臨床外科醫師43年，也是成大醫學院外科教授，50歲攻讀成大科法所，3年半完成84學分。深知臨床醫療照護、科學實證研究、民眾法律權益三者間衡平的重要性。

健保以實證為基礎的醫療給付

European Review for Medical and Pharmacological Sciences

2021; 25: 6548-6556

Real-world results of immune checkpoint inhibitors from the Taiwan National Health Insurance Registration System

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Following a year of data collection and analysis, the real-world ORR and PFS in Taiwan were 24.0% and 2.9 months, respectively. Experts agreed that, compared to regorafenib, payment benefits were limited while producing the same clinical status. As of March 2020, no HTA agencies in Canada, Australia, Scotland, or the United Kingdom had approved or paid for the use of nivolumab for late-stage HCC. Even Japan, nivolumab's country of origin, had not yet approved it for late-stage HCC. Furthermore, following a September 23, 2019, update, the ESMO Clinical Practice Guidelines no longer recommend using nivolumab for late-stage HCC. Other drugs, such as ramucirumab and cabozantinib, received marketing authorization.

ODAC Opposes Ongoing FDA Approval of Nivolumab for HCC in Patients Pretreated With Sorafenib

April 30, 2021

Sara Karlovitch



The FDA's Oncologic Drug Advisory Committee voted 5 to 4 against the continued accelerated approval of nivolumab for the treatment of patients with hepatocellular carcinoma who were previously treated with sorafenib.

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台灣真實世界證據(RWE)應用實證

- 109年2月台灣健保參考RWE及其他科學實證，決議暫停給付nivolumab於肝細胞癌及Penbrolizumab於胃癌之新個案用藥
- 110年4月美國FDA癌藥諮詢會議反對給予nivolumab於肝細胞癌及Penbrolizumab於胃癌之適應症

懇請給予立法/政策形成空間

- 健保資料庫二次利用非僅涉個人資料保護議題，攸關國家長遠發展及民眾健康維護。懇請庭上給予努力空間應對AI大數據時代挑戰，讓健保資料庫應用能符台灣國情及國際趨勢，以民眾隱私及公共利益最大化方向前進。
- 我將本著醫者、學者及政府機關代表立場，對國人善盡健保資料二次利用的告知說明義務，並以病患最大利益為優先考量，有效管理健保資料庫。