出國報告(出國類別:開會)

應邀參加比利時佛拉蒙區政府辦理「整合式照護與社區強化:資料連結之重要性」研討會順道拜會 INAMI 及 KCE

服務機關:衛生福利部中央健康保險署

姓名職稱:龐一鳴副署長

派赴國家/地區:比利時/布魯塞爾

出國期間:113年4月30日至5月5日

報告日期:113年6月26日

摘要

衛生福利部中央健康保險署(下稱健保署)龐副署長一鳴代表衛生福利部(下稱衛福部)赴比利時,受邀至比利時佛拉蒙區政府辦理之「整合式照護與社區強化:資料連結之重要性」研討會演講,並順道拜會比利時健保機關 INAMI(法文縮寫,英文為National Institute for Health and Disability Insurance)及比利時醫療科技評估機關 KCE(法文縮寫,英文為Federal Center of Expertise for Health Care)。「整合式照護與社區強化:資料連結之重要性」研討會(以下簡稱研討會)於113年5月3日召開,健保署龐副署長代表衛福部進行演講兩場演講,並擔任閉幕討論與談人。

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壹、目的

為使歐盟層級的健康資料庫交換及取得更加便利,「歐盟衛生資料庫」 (European Health Data Space)可望於近期實施。歐盟各國對於衛生資料之取得並成立「歐盟衛生資料庫」雖持正面看法,但是對於如何與民眾溝通,如何增進醫療提供者運用數位工具,如何將資料還給個別的民眾,如何建立民眾的信任和透明的機制,亟需專家之集思廣益。

比利時佛拉蒙區為 2024 年上半年歐盟執委會輪值主席國,爰邀請衛生福利部 與會,分享台灣經驗。衛福部與比利時佛拉蒙區衛生部簽有醫衛合作備忘錄,爰由 中央健康保險署龐一鳴副署長代表衛福部與會,以官方身分交流。

另為了解比利時社會健康保險及醫療科技評估」(Health Technology Assessment, HTA), 龐副署長順道拜會 INAMI (National Institute of Sickness and Disability Insurance)及拜會 KCE (Federal Center of Expertise for Health Care),以促進全民健保國際合作之機會。

貳、 行程表

日期	地點(城 市)	拜訪對象(行程)
04/30(二)-	比利時	臺灣→奧地利→比利時
05/1(三)	布魯塞爾	(啟程、轉機至比利時)
05/2(四)	比利時 布魯塞爾	 拜會 INAMI (National Institute of Sickness and Disability Insurance) 拜會 KCE (Federal Center of Expertise for Health Care) 拜會駐歐盟駐歐盟兼比利時代表處馬公使 研討會歡迎晚會,主講人及主辦單位比利時佛拉蒙區照護部全體出席 18:30 與 Dr. Niamh Lennox-Chhugani, Chief Executive and Director of Research at the International Foundation on Integrated Care (IFIC)會談
05/3(五)	比利時 布魯塞爾	 研討會上午:主講 Digital Transformation: How Taiwan Utilizes IT to Support Health Reform 研討會上午:參與圓桌會議討論 研討會下午:主講 Digital Transformation: How Taiwan Utilizes IT to Support Health Reform 研討會下午:參與圓桌會議討論 研討會閉幕:擔任閉幕討論與談人 晚宴
05/4(六)	比利時 布魯塞爾	• 6:50 前往機場搭機返台
05/5(日)	桃園機場	● 6:35 抵達台灣

參、 過程

一、拜會 INAMI(法文縮寫,英文為 National Institute for Health and Disability Insurance,健康及失能保險署)

日期	2024年5月2日	時間	09:00am - 11:00 am					
與會人員	• 健保署龐一鳴副署長、駐歐盟兼比利時代表處沈組長茂庭陪同							
接見人員	• INAMI 副署長 Mr. Pedro F	acon, Dr	. Marc Van De Casteele					
按允八貝	• Ms. Vinciane Knappenber	g, Mr. T	hierry Delestrait					

INAMI 副署長 Mr. Pedro Facon 接見健保署龐一鳴副署長,我駐歐盟兼比利時代表處沈組長茂庭陪同。Mr. Pedro Facon 說明比利時目前的處境及面臨的挑戰,受到地緣政治的影響,比利時需要足夠的軍事費用,因此排擠健康部門的預算。現行醫療保健支出佔政府預算 16%,全部醫療保健支出中民眾自行負擔的部分約為25%,若地緣政治的間題沒有改善,民眾的負擔將愈來愈重。

Dr. Marc Van De Casteele 為負責藥品醫療科技評估的主管。介紹比利時新藥收載的制度,分三個階段,評估(Assessment)、建議(Advice)。決定(Decision)。

在評估階段,由 HTA 人員於 60 天內產出報告並提交給付委員會(Reimbursement committee),方法學稱為「快速 HTA」。依據歐盟的標準進行,資料來源需要由廠商提供,因此最後只公告開摘要報告而非完整報告。HTA 人員有專業的分工,例如專長癌藥者就專注癌藥評估。

在建議階段,由給付委員會就 HTA 的報告加上行政幕僚的報告進行意見討論, 方法學稱為「證據力的評量(Appraisal of the evidence)」,決定做成是否應該給 付的建議。建議報告會有 5 大內容:

- 1.治療價值及附加的價值:包括效果及效益、副作用、應用情境以及是否容易 使用。
- 2.價格:通常還要加上競爭產品的價格,如果有附加價值,可以再加成。如果

缺乏附加價值,按競爭者的最大成本價。

- 3.在醫療行業者及需求者的地位。
- 4.財務衝擊。
- 5.藥物經濟學的價值。

決定階段先由國家主計長(Secretary of State Budget)就政府財力決定是否進入程序,如果同意繼續,則由衛福部長(Minister of Health and Social Affairs) 決定。該國的新藥在上市前,由經濟部長決定其最高的市場價格。

以 2023 年為例,共接受 305 件申請,完成 214 件 HTA 報告。工作人員共 16 為,加上一位主管(Dr. Marc),以全職等時人員計算其實只有 9 人專職 HTA。

Ms. Vinciane Knappenberg 為負責給付的行政主管。藥品給付規定的原則有: 正面表列、是否有給付限制、供門診或醫院使用、不同病人有不同的部分負擔、 individual revision。一項藥品是否具有治療價值或附加價值、是否有學名藥,均 會影響其核價。治療價值則依據產品是否符合現行醫療需要及其對疾病問題的解決 程度來決定,由 HTA 報告負責治療價值的定義。

管理入市協議(MEA, Managed entry agreement)則由產品的製造商 (Manufacturer)與付費者(payer)或服務提供者(provider)為促進一項新醫療科技納入給付或支付項目所議定的特殊條件。此協議可以利用多種機制處理科技實際表現的不確定性,或管理科技為了最大化其使用效果的適應期,或限制對預算的衝擊。適用的對象有新世代的藥物(如孤兒藥、CAR-T治療),這些藥物要符合尚不足夠醫療需求(Unmeet Medical Need)的條件,但會提高醫療價值但是又有一定程度的臨床效果不確定性。對於成長性需求的另類治療方案,則可限制其預算衝擊但又確保病人可以及早使用。

其原則就是透過協議連結其特殊附加價值的價格與付費意願,透過合約上的條件訂定暫時性支付(Temporary Reimbursement)。目標則是為促進病人療效及早達成、促進廠商及早得到報酬、管理臨床上的不確定性、管理預算。

協議組是一個任務編組由 NIHDI 的執行長召集。諮詢階段的人員包括疾病基金、

學者專家、藥業代表及經濟部代表。決策階段則由申請者、衛福部與主計總處三者的代表決定。

MEA 的價格模式:牌告價不變但有還款成數(76.07%的合約)、每單位固定數量(7.67%的合約)、其它產品申請時折價(交叉協議)、預算上限(2.76%的合約)、價量、 論質計酬、按結果計酬,如下圖。

3. Managed entry agreements

Compensation models:

- Cost reduction, but with original list price (eg rebate percentage of turnover)
- Fixed amount per unit
- Reduction price other drugs applicant (cross deal)
- Budget cap
- Price-Volume
- Pay 4 performance scheme
- Pay by Result ('all or nothing')
- Decrease of list price in combination with one of above
- Other (e.g. combinations)

產品進入市場後則有**按年降價**的策略,直到學名藥出現則大幅調降,原廠藥亦 按學名藥訂價。 Mr. Thierry Delestrait,服務於健康照護服務處,報告總額支付的預算流程。 其 2024 年的健康照護收入及其來源如下圖。

Health Care receipts 2024 (000 €)					
Social contributions +					
Public funding +	36,675,416				
Alternative method of financing					
Retiree contributions (3,55%)	1,717,849				
Contributions turnover pharmaceutical	326,021				
compagnies (7,73%)	320,021				
Various insurances (complementary hospital	1,227,651				
insurances (10%), car, fire,)	1,227,631				
International conventions	547,353				
contract art.81/111 (innovative drugs)	1,842,235				
Other receipts	404,078				
Total receipts	42,740,603				

共約 427 億歐元,主要來自社保、公共基金及其它財源,藥廠的還款有 3.26 億歐元,佔 7.73%,其它保險(補充性商保、汽車險、火險等,有 12.27 億歐元,佔 10%。 我國正追求健保財務來源多元化的階段,比利時的方式值得借鏡。

其支出部分如下圖。

Health Care expenses 2024 (000 €)						
Health Care reimbursement	37,824,710					
International conventions	956,280					
Administrative costs Health Insurance Funds	987,221					
Administrative costs NIHDI	119,467					
Other expenses	2,852,925					
Total expenses	42,740,603					

由於比利時是全世界少數有隨物價指數調整薪資的國家,觀念簡單但實際操作 起來確不簡單。**其總額預算的公式:預算總額=前一年預算 X 真實成長率 X 通膨指** 數。真實成長率的因素有醫療保健服務消費的趨勢、新科技、新需求等,但最後還 是政治決定。歷年成長率如下圖。

Real growth rate

✓ Real growth rate:

Financial potential necessary to face the evolution of consumption of healthcare services by the general population, the evolution of new techniques/practices, new demands of care ...

✓ → Political decision

Evolution of the real growth							
rate							
1995 - 2000	1.5%						
2001 - 2003	2.5%						
2004 - 2011	4.5%						
2012 - 2013	2%						
2014	3%						
2015 - 2021	1,50%						
2022 - 2023	2,50%						
2024	2,00%						
2025	2,50%						

2023年的總額額度經公式計算則如下:

Forecasting of the global budgetary provision 2023

2023 (000 EUR)	
global budgetary provision 2022	30,638,882
real growth rate 1.50%	765,972
subtotal	31,404,854
inflation	2,322,640
subtotal	33,727,494
article 111 (art 81)	1,429,348
other - structural	19,453
global budgetary provision 2023	35,176,295

圖、5月2日拜會比利時 INAMI





二、拜會 Federal Center of Expertise for Health Care (KCE,「聯邦醫療照護專家中心」)

日期	2024 年 5 月 2 日 時間 11:00am - 12:00 am
與會人員	• 健保署龐一鳴副署長、駐歐盟兼比利時代表處沈組長茂庭陪同
與會人員	Mrs. Ann Van den Bruel

Mrs. Ann Van den Bruel 為 KCE 的局長(Director-General), 甫接任該職為 半年。KCE 的主要任務為進行醫療科技評估(HTA), 並每年出版比利時醫療品質報告。 工作人員 80 人,業務經費 80%來自 INAM, 10%來自衛生部, 10%來自社政部門。INAM 除了提供他們經費外,也提供他們健保的資料,以方便進行分析。

在政府的決策過程中,KCE 是主要的專業研究及諮詢機關,有建議權但無決策權。KCE 和 INAM 的 Dr. Marc Van De Casteele 所負責的藥品醫療科技評估的差異在於:後者是進行短評估(Short HTA)或快速 HTA,後者則進行完整的科技評估,並可以自行收集資料,耗時往往比較多。

圖、5月2日拜會比利時 KCE 與執行長 Ann Van den Bruel 合影



三、參加「Integrating Care, Strengthening Communities: The Data Connection」研討會並演講

☐ #B	2024年5月2日16:00pm - 21:30 pm
日期	2024年5月3日08:30am - 21:30 pm
	• 健保署龐一鳴副署長、駐歐盟兼比利時代表處沈組長茂庭
與會人員	· 歐洲各國和國際專家、意見領袖、從業人員、WHO One Health團
	隊人員

(一)會議摘要

比利時佛拉蒙區政府辦理之「整合式照護與社區強化:資料連結之重要性」 (「Integrating Care, Strengthening Communities: The Data Connection」)研 討會,由照護部主辦,並在比利時擔任歐盟理事會輪值主席國期間進行。本會議為 歐洲和國際專家、意見領袖以及從業人員共同探討創新策略和協作方法的平台,以 推動整合照護和社區賦能。本次會議目的,旨在著手解決資料連接的關鍵議題,以 實現全面醫療解決方案。

該會議以整合照護和社區強化為出發點,從以人為本、治療與預防並重的醫療和社會服務中展開。這個會議亦探討大數據及其解釋力在實現服務整合的重要作用,包括流行病學和社會人口學信息等「硬」數據,以及幫助我們了解個人和地方社區需求與挑戰的「軟」數據。

該會議亦就地方、區域、國家和國際的背景下,探討資料交換和知識共享的複雜性、數位工具的使用與如何有效地將這些工具整合至健康和照護領域。該會議亦就四個主題,同時辦理四個同步會議進行演講和圓桌會議討論:

- 對於使用創新數位工具,行為和文化面的探討
- 衡量重要事項:鄰里分析
- 回饋人民:人口健康與福祉管理
- 如何建立民眾對於健康照護數據的信任與透明度

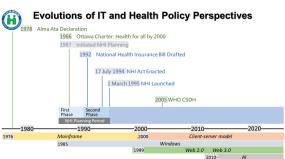
(二)龐副署長演講及參與

龐副署長受邀至此會議進行演講,講題為「Digital Transformation: How Taiwan Utilizes IT to Support Health Reform」,說明台灣在數位轉型下,如何 運用訊科技進行醫療改革。同時也就民眾及人權團體對於健保運用的訴訟及大法官 釋憲結果,與歐洲各國專家分享。同時亦參加兩場圓桌會議並擔任閉幕討論與談人。 主辦單位特別請龐副署長於閉幕討論時段,民眾對於台灣健保的信任與滿意程度。

圖、龐副署長演講簡報重點

(H)

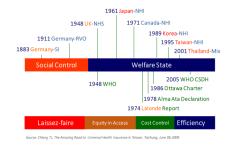


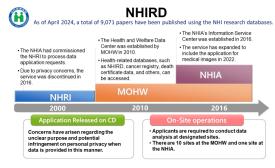


Judicial Review of NHI Data Utilization: Civic Groups' dispute on NHI Data use



World Trends in Health Care Reform





(H)

Ruling of the Constitutional Court

- The NHIA's data collection, when necessary for statistical or academic research purposes, ensures that the data is processed in a way that makes it impossible to identify specific individuals. This practice does not violate the spirit of Article 22 of the Constitution, which safeguards people's right to privacy of information.
- In terms of personal data, the lack of an independent supervisory mechanism for personal data protection necessitates action. The NHIA shall establish or amend relevant laws and regulations to create a legal framework that fully protects the right to privacy of personal information as guaranteed by Article 22 of the Constitution by August 12, 2025.
- In March 2024, the NHIA announced the draft legislation and amendments related to data protection, the right to withdraw, and supervisory mechanisms, opening them to public comments in order to complete the legal framework for the use of NHI data.

圖、龐副署長在「整合式照護與社區強化:資料連結之重要性」研討會閉幕會議說明 如何建立民眾對於台灣健保的信任與滿意度



圖、研討會會議議程

DEPARTMENT OF CARE

Integrating Care, Strengthening Communities: The Data Connection 2-3 May 2024, Leuven, Belgium

Programme Thursday 2 May 2024

16:30 - 17:30 Welcome at Leuven City Hall

Address: Grote Markt 9, 3000 Leuven (entrance via stairs)

Welcome word by Bieke Verlinden, the Alderman of the City of Leuven for care and wellbeing, community work and cemeteries, followed by a drink and tour of the Leuven City Hall.

Guided tour on the history of Leuven as a beer brewing city. This tour will take the delegates from the City Hall to venue 'De Hoom'. 17:30 - 18:30

Leuven, steeped in beer culture, offers a delightful blend of authentic and trendy beer cafes, along with accessible tours of breveriers big and small. This unique beer tour, guided by expert connoisesurs, promises an engaging experience for all. Whether you're a seasond beer lover or simply curious, Leuven's whrant scene ensures a captivating adventure for everyone.

18:30 - 19:30 Welcome reception at De Hoorn Address: Sluisstraat 79, 3000 Leuven

Live music by theme combo 'Dree's straight ahead octet'.

Students from the jazz department of LUCA School of Arts, Leuven. form a pocket big band with blazing tuttis, intimate ballads and swinging themes. Led by trombonist. Dree Peremans. Musicians are immanuel Kaljouw (trompet.) Jend Vandamme (trombone). Jasper Oosthuyse (alt sax). Wout Van Roose (tenor sax). Elly Brouckmans (bartton sax), Peter Pype (drum), Douglas Kemp (bass). Rafael Roy (piano), and Nele Uytendaele (vocals).





Programme Friday 3 May 2024

830 - 900 Welcome coffee Address: Janseniusstraat 1, 3000 Leuven

Delegates are welcome from 830 onwards at the Irish College. Join us for a welcome coffee to kick off the conference. A moment to connect and energize before we dive into the day's agenda.

9:00 - 10:30 Opening plenary session Moderation by Isabelle François, Innovation Director at MEDVIA

> Welcome by Isabelle Opening speeches

- Deputy Minister-President of the Government of Flanders and Flemish Minister for Welfare, Public Health and Family (video message)
- Karine Moykens, Secretary-General of the Department of Care, Government of Flanders
- Prof.dr. Sabine Stordeur, Director General of DG Health Care at FPS Public Health, Belgium

Setting the scene introduction to the conference themes

- Presentation on Behavioural and Cultural Insights, by Paulina Kuczynska, Senior Behavioural Science Specialist, Public Health Wales, UK
- Presentation on Population Health Management by Robby De Pauw, PhD, Scientist Health information Epidemiology and public Health, Sciensano, Belgium
- Presentation on the Caring Neighbourhoods Project by Isabelle Van Vreckem, Department of Care, Government of Flanders
- Flanders' experience in tools and data for integrated care







Parallel sessions
Delegates will be offered four sessions, from which they are invited to choose one to attend:

The role of behavioural and cultural insights in the uptake of innovative (digital) tools and solutions

Moderated by Dr Carine Boonen (MD), former coordinator of the Flanders' Care Programme at the Government of Flanders

Join our session to learn about the concept of Behavioural and Cultural Join our session to learn about the concept of behavioural and Cultural Insights (BCI and to explore the role it could play to help increase the uptake of Innovative digital look and solutions among the health and care workforce (BRCWF). We will look into ways to dose the aga between I'll developers (such as entrepreneurs, research, J. C2) enablers/facilitators (such as policy makers, health insurances, J. and 3) the HSCWF. We want to pay extra attention to the diversity between types of health and care providers as well as differences between the individual health and caregivers.

Moderated by Bettina Menne, Senior Policy Adviser, Healthy Settings, European Office for Investment for Health and Development - WHO Regional Office for Europe

Explore the integration of 'soft' contextual data and 'hard' quantitative Explore the integration of 'soft' contextual data and 'hard' quantitative methods in capturing focal voices' and measuring community concerns drawing from the Thomas More College's Support Package within the Flanders' Carnel Regishbourhood analysis, discussing the role of local actors, communication strategies and policy implications, fostering interactive discussions to formulate solutions.

3. Giving back to the people: population health & wellbeing management

Moderated by Ane Fullaondo Zabala, Scientific Director Biosistemak, (formerly Kronikgune), Institute for Health Services Research, Basque Country

Explore the synergy between hard and soft data at the micro level, discussing its implications for policy governance and integrated care Dive into topics like giving back to the people and data exchange across governance levels, with breakout table discussions focusing on mechanisms for cooperation and mitegrating wellbeing into population





tools and information needed, and explore the role of local voices in shaping effective policies and communications within communities.

3. Giving back to the people: population health & wellbeing management

Moderated by Ane Fullaondo Zabala, Scientific Director Biosistemak, (formerly Kronikgune), Institute for Health Services Research, Basque Country

Explore the synergy between hard and soft data at the micro level, discussing its implications for policy governance and integrated care Dive into topics like giving beach to the people and date exchange across governance levels, with breakout table discussions focusing on mechanisms for cooperation and integrating wellbeing into population management strategies.

How to build trust and transparency with regard to citizens' health and care data

Moderated by Michele Calabró, Director of EUREGHA, the European Regional and Local health Authorities Network

In this session we explore how to foster confidence among citizens regarding the use of health and wellbeing data, emphasizing the beauthis of data sharing in a trustworthy manner. We will delve into practical experiences and imagists, engaging various stakeholders to discuss the nuances of building trust and transparency within the health date accopystem, aiming to bridge theoretical concepts with actionable strategies.

15:00 - 15:30

Coffee break

Closing plenary: creating a legacy
Moderation by Isabelle François, innovation Director at MEDVIA

Short debrief and highlights of each session Continuing the legacy by international networks

- RHN WHO Europe

Future steps towards connecting health data: EHDS
Presentation by Maxime Morren, Attaché Health and Pharma, Perma
Representation of Belgium to the Buropean Union.





Row to build trust and transparency with regard to citizens' health and care data

Moderated by Michele Calabrd, Director of EURECIA, the European Regional and Local health Authorities Network

In this resiston we explore how to faster confidence among citizen regarding the use of health and evaluating data, explanating the benefits of data sharing in a transversibly nanowe. We will drive since produce importance and implice, regarding revious substitutions to discuss the number of building trust and transparency within the health data econystems, winting to bridge theoretical conspir with actionable strategies.

1230 - 1230 Lunch

Parallel sessions Repetition of the sessions offered before bunch Delegates are invited to choose one to actions:

The role of behavioural and cultural insights in the uptake of impossible idigital) tools and solutions

Hoderstad by Dr Carine Boonen (HDL), former coordinator of the Randers' Care Programme at the Government of Randers

Join our mession to learn about the concept of Behavioural and Calaural Inalghir BCII and to explore the role it could play to help increase the update of forcewishs (diplast tools and solutions among the health and one sendificate (BECHY). We shall book into sept to claim the gap because: 10 developers both as enterpresents, research. J. CD anables (Molitoria disch as poly makes, health hastanose. J. End CD the BECHY. We wont to pay extre abundon to the diversity between the individual health and canapters.

2. Heature what metters neighbourhood analysis

Moderated by Britina Menne, Senior Polity Advisor, Healthy Settings Bungsess Office for European for Health and Development - WWO Regional Office for Bungs

This session will explore the integration of lots' data, which provides contextual immediate, alongside hard data, facilitating better-inform policy detaines and suprovements within communios. Through interactive discussions and irrestruct stables, participant and advan-cinatinger in analyzing neighbourhood populations, consider addition.





Moderation by Dr Namh Lennox-Chlugani PhDL Chief Executive and Director of Research at the International Poundation on Integrated Care (IRC)

- Norther Moykers, Secretary-General of the Department of Care, Government of Flanders
 Dr. Hilling Penguity Director-General of the National Health Insurance Administration 0818A9 of the Ministry of Health and Welfers, 100 Chalvers
 Historia Deuble, Director general Department of Health other of the National Social Deuble, Director general Department of Health Oter of the National Social Deuble, Director general Department of Health Oter of the National Social Deuble, Director general Deuble, 100 Companion Commission.

 Public Redfield, Head of Digital Health with 100 SANTE Suropean Commission.

- Commission
 Section Merco, Senior Policy Advisor, Healthy Settings, Buropean
 Office for Investment for Health and Development WHO ional Office for Burope
- 1700 W00 Reception at Irish College with live music by Siger
 - Siger, formed by siblings Herbertn & Ward Dhoors, showcases a dynamic blend of modern and traditional Flemish music.
- Guided tour to the Paculty Club through the Groot Reginhof (UNESCO) World Heritagel. 98:00 - 1900

Depice the UNISCO-listed Grand Beguines of Leuven on a guided tour. Wander historic lanes, from beguiner homse to a vibrant university community, blending history with modernity in this unique journey.

1900 - 2130 Hetworking dinner at the Paculty Club Addres: Groot Seglishof M, 5000 Leuven





肆、 心得與建議

一、醫療費用負擔愈來越重,是國民健康的挑戰

比利時受到地緣政治的影響,軍事費用排擠健康部門的預算。現行醫療保健支出佔政府預算 16%。以目前全部醫療保健支出中,民眾負擔的部分約為 25%來看,倘若地緣政治的間題沒有改善,民眾的負擔將愈來愈重。

民眾有責任維護自我健康。健康保險的實施,便是降低民眾因健康問題,所發生的財務風險。歐洲各國所實施之健康保險,便是用社會群體力量分攤個人風險。 社會保險或公共醫療制度係以政府預算調節個人風險,如果政府預算減少,財務支出移轉到個人或雇主,甚至是使用者身上,有可能發生負擔過於沉重的問題。

二、科學性及治療價值的評估,為健保收載藥品、治療科技之基礎措施

目前各國保險收載新藥和新治療技術至保險給付時,進行醫療科技評估 (Health Technology Assessment, HTA) 的一個常態化程序。對於就現有給付項目,亦須進行醫療科技再評估(Health Technology Reassessment, HTR),以改善醫療 照護品質並維持財務穩健。

HTA 及 HTR 的目的是評估醫療技術的臨床效果、安全性、成本效益以及對公共健康的影響,從而確保醫療資源的有效分配和病人的最佳利益。由於醫療科技具有生命週期,從推出使用、改善進步、甚至過時,再於常規中淘汰的流程,爰需要 HTR 來保障醫療品質。

HTA 通常包括臨床效果、經濟評估、倫理和社會、醫療環境影響等,其結果會 影響新藥新技術納入保險給付範圍。這一過程有助於確保新技術能夠在臨床上有 效且經濟上可行,並對病人和社會產生正面影響。

三、妥善之法律架構,是資料運用之基石

妥善的法律架構,是健保資料的運用根本依據。111 年 08 月 12 日憲法法庭就 民眾蔡季勳先生等人聲請「個人資料保護法事件,認最高行政法院 106 年度判字第 54 號判決,所適用之個人資料保護法第 6 條第 1 項但書第 4 款規定等,有違憲疑

- 義,聲請解釋憲法」,做出 111 年憲判字第 13 號【健保資料庫案】判決,其中認為
- (一)健保資料欠缺個人資料保護之獨立監督機制,對個人資訊隱私權之保障不足;
- (二)健保資料庫儲存、處理、對外傳輸及對外提供利用之主體、目的、要件、範圍 及方式暨相關組織上及程序上之監督防護機制等重要事項,欠缺明確規定;
- (三)就個人健康保險資料之提供公務機關或學術研究機構於原始蒐集目的外利用, 欠缺當事人得請求停止利用之相關規定。健保署刻正就上述判決,進行法制上 的完善工作。

此次演講,亦就這項判決,說明健保署在科技創新先於法制規定的經驗,分享 給本次歐洲各國專家,尤其歐盟將在今(2024)年實施「歐盟衛生資料庫」(European Health Data Space),正好提供先完善法律架構的借鏡。

本次歐盟負責 One Health (同一健康或全健康)的團隊,亦參加本次研討會, 對於資料蒐集運用之法規完善,非常重視,參加本次研討會並對於臺灣的經驗深感 興趣。

四、公共政策是醫療數位轉型的重要驅動力量

公共政策在推動醫療數位轉型中扮演著關鍵的驅動力量,主要有幾項作法:

- (一)政策與規範的制定:政府制定政策和法規,促進數位健康技術的發展和應用,包括數據標準化、隱私保護法規、電子病歷(EHR)標準等,確保數位技術在醫療領域的有效使用和民眾資料保護。
- (二)獎勵措施:政府可以通過獎勵措施和租稅優惠等方式,促進醫療機構數位轉型 或企業進行研究。
- (三)基礎設施建設:政府可以投資於資訊基礎設施(Information Infrastructure) 建設,如高速 Internet、Cloud-computing Platform等,為數位健康的應用提供技術基礎。。
- (四)推動公共教育:政府進行宣傳和教育活動,提高醫療從業者和民眾對數位醫療技術的認識和接受度,有助於減少技術應用過程中的阻力,促進數位技術在醫療領域的廣泛應用。

- (五)推動研究與創新:政府可以經由不同的作為,鼓勵新技術的開發與應用。例如, 支持人工智慧在醫療診斷、個人化醫療等研究及應用。
- (六)跨部門合作:經由政府不同部會的合作,例如衛福部和科技部等,共同推動數位醫療技術的發展,並引進國際數位健康技術和管理經驗。

五、加強資料互通性

加強資料互通性(Interoperability)能使不同系統和機關間,順利交換、解讀並使用數據,策略上可以做到:

- (一)使用標準化協議和格式。
- (二)採用通用的數據標準。
- (三)運用 ETL(Extract, Transform, Load)工具來取得、轉換和加載數據,確保證數據在不同系統之間的一致性和可讀性。
- (四)實施數位治理策略,確保數據品質和一致性。
- (五)資料安全和隱私保護。

伍、 附錄

籌備工作文件:四大子題討論方向及各子題架構籌備人員名單

DEPARTMENT OF

Description Sessions

The role of BCI in the uptake of innovative (digital) tools and solutions

Innovative (digital) tools and solutions can play a pivotal role when it comes to better collection and exchange of data and information, and enabling better integrated care in general. However, the deployment of these technologies within the health and care sectors faces significant barriers. Despite the availability of numerous tools and solutions, integrating them into the health and social care workforce presents challenges.

We must not forget that the health and social care workforce operates under high demand, has to deal with resource limitations and increased work pressure, all within a field inherently based on personal interaction. In addition, we see that technology and innovation is confronted with preconditions such as funding, traits, developing of and alignment with estignt gregulation, etc. leaving perhaps less room to focus on determining factors of workplacel culture and user behaviour and include these as funding, trait domains a factor of innovative tools into this sector is frequently met with difficulties for these and other reasons.

In order to tackle this question, the session departs from the concept of Behavioural and Cultural Insights (BCI) and explores the role it could play to help increase the uptake of innovative (digital tools and solutions among the helath and care workforce (H8CWF). BCI can help ensure that tools and solutions respond to the needs of all actors, including the H8CWF. BCI can also help understand why some things work in one setting, but not in a different nor why acceptance and uptake of certain tools/solutions are easier with certain actors, and more difficult with others.

With this idea in mind, the session examines ways to close the gap between a trifecta of actors: fil developers fsuch as entrepreneurs, research, (2) enablers/facilitators (such as policy makers), and (3) the HBCWF. For the latter group, we want to pay extra attention to the diversity between types of health and care providers (e.g. big versus smaller hospitals, residential care centres, general practitioners, informal caregivers, etc) as well as differences between the individual health and caregivers threselves, including variety in needs, skills, workplace culture and views on innovative tools and solutions.

The session offers presentations, practical examples and break-out table discussions through which the participants will gain insight and exchange views on the use of BCI for the uptake of tools and solutions.

We thank the session working group members and contributors:

- Dr Carine Boonen, former coordinator of the Flanders' Care Programme in the Government of Flanders Belgium
- Jan Cox, Product Manager at Viduet Health BV Netherlands







- Dr Toni Dedeu, Senior Advisor on Integrated Primary Health Care, WHO European Centre for Primary Health Care, WHO European Office for Europe
- Birgit Goris, Lecturer at UC Leuven Limburg social work Flanders
- Leo Lewis, International Lead, Bevan Commission and Senior Associate, IFIC, Wales
- Dr Bettina Menne, Senior policy advisor healthy settings, Coordinator SCI & RHN
- WHO Regional Office for Europe European Office for Investment for Health and Develop Birthe Sels, Researcher at Thomas More, Expertise centre Care and Wellbeing, Belgium
- Ortwin Top, Staf employee Family Support Familiehulp vzw Flanders
- Isabelle Van Vreckem, Project Coordinator Carling Neighbourhoods Department of Care Flanders Government Section Policy Coordination Flanders
- Katrien Verschueren, Coordinator Primary Care Zone Demerland vzw Flanders

Giving back to the people: population health & wellbeing management PHSWH

Population Health Management IPHM Is often seen as a tool, a strategy used by macro policy levels, based on data. In the other parallel session on Neighbourhood Analysis we look into the potential of data at the micro level. This session native to approach the topic from a policy governance perspective, considering how these insights can inform and enhance policy-making

Data and knowledge needed for policy purposes will vary depending on the user and context. It is already a difficult exercise to exchange data between different policy areas – never mind between different tevels, different health and case accors and with Otlazen, During bits conference, we are attempting to gain an insight into how we get to integrated data and into the what does it take to connect this?

The application of FHM is not exclusive to any single governance level. Every level is looking at improving the situation of their population, and every level has ways of collecting knowledge it data. This implies that numerous collections of data and knowledge likely exist in parallel across different levels of governance. This should not be a problem in lestif if we respect flows of data and knowledge transfer amongst the different levels, the cooperation mechanisms and frameworks this require.

With this session we add a dimension to the collecting and sharing of data for population management. We take the PHM approach a step further and include the wellbeing aspects th are inherent when identifying weakness and strengths in the health and wellbeing of people.

During this session participants will be invited to partake in breakout table discussions. Each table will be based on the element of the WHO Population Health Management cycle in Primary





- Dr Toni Dedeu, Senior Advisor on Integrated Primary Health Care, WHO European Centre for Primary Health Care, WHO European Office for Europe
- Dr Tara French, Programme Lead Digital Inclusion, Digital Health and Care, Scottish Government, Scotland

How do you identify Tocal voices' and 'measure' what is important to citizens and local care actors in a local context? How do you capture contextual knowledge for policy purposes?

Contextual knowledge, 'soft' data or qualitative research methods can reveal certain issues that cannot be found or measured in hard' data or with quantitative research methods. It can also help to interpret hard data figured by providing some contextual knowledge in a combination of soft and hard data. By using knowledge obtained from 'soft' data for policy purposes, we can integrate the local level more and better.

Our approach is rooted in a neighbourhood-centric perspective, recognizing that the characteristics of neighbourhoods can vary widely across countries in Belgium, especially in Fanders, the neighbourhoods are of the perspective perspective or formed through the social interactions of residents living in close proximity to each other; though their sizes can vary.

The support because developed by the Thomas Mere College on how to conduct a neighbourhood analysis which is part of the Flanders' Carling Neighbourhoods project, will be used as a carting point during the session for how qualitable research methods and on-the ground intelligence can be used to arrive at an informed, supported neighbourhood analysis. Neighbourhood analysis asto use quantification methods and "hard" data, but the premise of this session is primarily the capture of soft data.

There are many questions to be tackled before, during and after analyses at neighbourhood level in particular, what additional resources do local actors need to analyse their populations? What other tools/information can be made available to neighbourhoods to make even better analyses based on the needs of their populations?

Dated on the measure of term proposessors.

Neighbourhood or their equivalents, possess a wealth of information. Primarily, an analysis serves as a basis for improvements within the neighbourhood itself. At the same time the findings, data and invokelegg agained at this intro-level should as much intogen or the levels of governance. The higher up the level of governance, the more ditused the knowledge of what mattern' at the ground level becomes kneembelses both hard data at macro level with soft data at micro level are invaluable for advancing the health and wellbeing of people.

During this session key aspects of a neighbourhood analysis for local-level equivalent) will be expired, including possible challenger and how to overcome them will be discusse, and what can be achieved with the results, based on concrete examples and experiences. Through breakout table topics such as how to capture sort data, the role of the local voices, the communication within the neighbourhood and other policy levels, .. will be discussed. Participants will pay an active role in the session, encouraged to propose solutions based on their own experiences and expertise.





Health Care (ref WHO-EURO-2023-7497-47264-69316-eng.pdf), where we also pay attention to the

We thank this session working group members and contributors:

- Chaloner Chute, Chief Technology Officer, Digital Health & Care Innovation Centre Scotland
- Dr Toni Dedeu, Senior Advisor on Integrated Primary Health Care, WHO European Centre for Primary Health Care, WHO European Office for Europe
- Mark Golledge, Programme Director, Project Management: Office & Integrated Care System Development One Gloucestershire ICS England
- . Prof. Dr. Oliver Gröne, Vice Chairman of the Management Board of Optimedis AG,
- . Leo Lewis, International Lead, Bevan Commission and Senior Associate, IFIC, Wales
- Annemarie Jacobi, Policy officer, team integrated care Federal Public Service Public Health Belgium
- Ane Fullaondo Zabala, Scientific Director Biosistemak, (formerly Kronikgune), Institute for Health Services Research, Basque Country
- Dr. Hanfred Zahorka, Senior Manager Integrated Care Solutions (international) at OptiMedis AG, Germany

How to build trust and transparency with regard to citizens' health and care data

In the other sessions, we thought about how to encourage the use of digital tools, and how to use data at the local level for person-centred care. In this session, we want to delive deeper into how we can reasoun chizers about the use of their health and care data. As always, it is also important to make people feel that they are part of a greater whole – the greater good. Without going overboard with this, we may look for ways to make clear to obtains and health and care providers what the added value is for themselves and for the expectations for others.

Many instruments exist, but the question still remains if this is the answer to creating trust. The European Union, along with its Member States, is making concerted efforts to address data misuse through various legislative measures and initiatives. Some, however, like GDPR, are often perceived as a burden.

. How can we reassure citizens about the use of health and care data? How do we comn to citizens the benefits of data sharing (both for primary and secondary usel in a mann fosters trust?

This session will examine how to build trust and transparency with regard to citizens' health and care data. During this session, we want to focus less on hypothetical debates and theoretical concepts and delve more into practical aspects and experience. Special focus will be on the different roles and views of actors within our society (e.g. formal and informal caregivers,





The session will kick off with an opening panel aimed at presenting the different views and use cases between actors in the health data ecosystem and spark the debate on trust and transparency by addressing several key questions.

After this, participants will be invited to actively join the discussion and share their own experiences and expertise during the breakout table discussions. Each table will have its own topic and set of questions to expiore, moderated by an expert. These topics will range from shalanding data-protection with health innovation and policy, creating legislative frameworks that are built on trust, to the essence of creating trust and adequate communication. Where possible, tangible examples and cases will be given. The session also encourages participants to reflect on experiences that did not work in the past and discuss why. This knowledge is equally valuable as good practices.

We thank this session working group members and contributors:

- Michele Calabro, Director of EUREGHA European Regions and Local health Authorities Network, Beiglum
- Dr Toni Dedeu, Senior Advisor on Integrated Primary Health Care, WHO European Centre for Primary Health Care, WHO European Office for Europe
- Erik Laes, Transition expert at VITO Flanders Institute for Technological Research, Flanders
- Leo Lewis, International Lead, Bevan Commission and Senior Associate, IFIC, Wales
- Tino Martí, Digital health facilitator, EHTEL European Health Telematics Association, Beigium
- I-Ming Parng, Deputy Director-General of the National Health Insurance Administration INHIAI of the Ministry of Health and Welfare, Talwan
- Prof. Dr. Josep Roca, Senior Researcher at Hospital Clinic Barcelona IDIBAPS, Professor of Medicine at the University of Barcelona
- Sarah Smits, Business Unit Lead Health Athumi, the Flemish Data Utility Company -Flanders
- Wannes Van Hoof, Scientific Assistant Sciensano, Public Health and Surveillance, Cancer Centre - Belgium
- Elke Wijnants, Policy Officer, Team Primary Care Department of Care from the Flanders Government - Flanders



