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DM management in HIV patients: the adoption of population health management to transform the chronic management of HIV

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Background: The success of antiretroviral therapies has made human immunodeficiency virus (HIV) a chronic disease, changing the care scenario dramatically. This study aimed to measure adherence to diabetes mellitus standards of care provided for people living with HIV (PLWH). Diabetes represents a paradigmatic case for tackling chronic care management in this target group. **Methods:** This retrospective observational study was performed on administrative health data retrieved from 2014 to 2016, with a validated algorithm to identify patients with HIV using: (i) hospital discharge records (ICD9-CM codes); (ii) drug dispensing records (with ATC codes); and (iii) disease-specific exemptions from co-payments for healthcare services. HIV-related treatments, comorbidities and health service utilization were measured, as was adherence to clinical guidelines-recommended standards of care for diabetes. **Results:** A population of 738 cases were identified in two Local Health Authorities in Italy, representing a prevalence of 0.14% of the general population, in line with the expected prevalence. Thirty-one cases of HIV patients diagnosed with diabetes were identified, a prevalence ratio of 4.2% compared to the 8% in the overall population. Adherence to diabetes standards of care tested within the same population was low, with the exception of those tests commonly administered for standard HIV follow-up care. **Conclusions:** The use of administrative data, combined with a Population Health Management approach represents a powerful tool for evaluating system capacity to manage HIV comorbidities. Study findings prove that it is time to design new care models for PLWH, affected by one or more chronic conditions, both to prevent their onset and to manage their comorbidities.

Introduction

The success of antiretroviral therapies (ART) has made human immunodeficiency virus (HIV) a chronic disease,[1] changing the care scenario dramatically; consequently, questions about how to diagnose, monitor and treat HIV and comorbid conditions[2] have emerged. By 2030, three of every four diagnosed people living with HIV (PLWH) on ART are expected to be aged 50 years and older in many countries; thus, on average, more than 80% will have at least one age-related disease and many will have at least three age-related diseases.[3] The most common comorbidities amongst PLWH include diabetes mellitus (DM), cardiovascular disease (e.g. hypertension), respiratory diseases [e.g. chronic obstructive pulmonary diseases (COPDs) and pneumonia] and hepatic diseases (hepatitis B and C).[4] It has been suggested that the prevalence of non-infectious comorbidities in HIV-infected persons mirrors patterns observed in patients roughly 10 years older in the general population.[5,6] These data support the need for understanding the burden of care associated with the chronic HIV population and for strengthening comorbidity management in HIV-infected patients in light of probable earlier onset of these conditions. A useful and innovative approach for globally addressing the present and future needs of PLWH is embodied in Population Health Management (PHM), which aims at combining population health needs assessment with effective models of care, in serving those needs, allocating the necessary resources based on risk profiles.[7] In short, the segmentation and profiling of the population based on the disease burden and risk profile represent the baseline tools that PHM can exploit in pursuing health service delivery goals regarding improving care at the individual and population levels while controlling costs, as outlined in the Berwick *et al.*[8] triple aim. PHM worldwide has been gaining momentum due to the pandemic of chronic conditions,[9] which, thanks to advances in treatment, now also includes HIV.[1]

Based on these premises, this study aimed to identify PLWH and investigate their healthcare consumption patterns using administrative databases to better understand how care is delivered in different areas of Italy. Using data retrieved from two Local Health Authorities (LHAs) for the years 2014–2016, we further sought to measure

adherence to standards of care for DM in people with HIV as a paradigmatic case for addressing today's challenges in managing a shift in HIV care from a mono-morbidity to a multi-morbidity condition. Finally, we sought to apply a PHM approach to improve service delivery for this sometimes elusive population, benchmarking with international best practices, in the hope of providing policymakers and healthcare managers with insight in managing this vulnerable group, who may be under diagnosed and underserved by the healthcare system. DM is a paradigmatic example for chronic condition management since it is a widespread condition with well-established standards of care at the international level[10–12] and also because the incidence of metabolic disorders such as pre-diabetes, diabetes, lipodystrophy and dyslipidaemia in HIV-infected patients has increased and is considered to be associated with ART.[13,14] Similar to diabetes, prediabetes can also increase the risk for developing other macrovascular complications such as cardiovascular disease and stroke.[15]

To the best of our knowledge, this study represents the first comparative test of PHM perspectives on PLWH and how administrative databases can be used as an effective tool to support today's challenges of managing HIV as a chronic condition.

Methods

Study population

This retrospective study used administrative data for the years 2014–2016, retrieved from two LHAs located in two Italian Regions: Vicenza (Veneto Region) and Trieste (Friuli Venezia Giulia Region), with a total population of 546 682 residents. The selection of the regional contexts stemmed from their focus on improving the clinical governance and management of PLWH. Indeed, the Veneto Region introduced an official integrated care pathway for HIV in 2014, focused on ART, and established dedicated HIV centres in the Region.

HIV case and comorbidities identification

A validated algorithm for identifying HIV patients was applied[16,17] using three different administrative databases: (i) hospital discharge records with diagnoses and procedures coded using the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD9-CM); (ii) drug dispensing records coded using Anatomic Therapeutic Chemical (ATC) codes for drug classification; and (iii) disease-specific exemptions from co-payment for healthcare services. Patients who requested anonymity were excluded from the database. Supplementary table S1 displays the algorithm applied to identify HIV cases. Record-linkage was performed at the patient level in each LHA using blinded, unique patient identifiers to create a project database including hospital admissions (inpatient and day hospital), outpatient services, publicly-funded medications and, where possible, emergency services, home healthcare and long-term care and psychiatric services. Patient characteristics and comorbidities were calculated using demographic codes, exemption codes, diagnostic codes in any of the datasets (e.g. hospital admissions, psychiatric services, etc.) and medication codes. Diagnostic codes and ATC codes were supplemented by fee exemption codes from the LHAs, a sort of proxy for primary care physician records since they were not available.

Health consumption from all available administrative data flows was calculated per patient for each of the 3 years of the study, 2014–2016. Two methodologies were used to calculate comorbidities for the patient cohorts: the Charlson Comorbidity Index (CCI)[18] and a methodology developed within two European Union-funded projects, EuroHOPE[19] (www.eurohope.info) and Bridge Health. Prevalence was estimated as the total number of existing cases divided by the number of residents.

Stata Version 15 was used to link, manage, convert and analyse the data.

Standards of medical care in diabetes

We defined standards for medical care in DM according to the following tests or examinations. A1C test at least two times a year; annual routine follow-up for lipid profile (in our study, we used the test for cholesterol), albuminuria test, initial dilated and comprehensive eye examination. Although a randomized observational trial demonstrated no clinical benefit to routine screening of asymptomatic patients with type 2 diabetes and a normal electrocardiogram (ECG),[12] we investigated ECG in order to measure the use of an examination with no evident benefit in DM routine follow-up. We considered as pharmacological therapy all drugs used in diabetes (ATC code A10).

Table 1 HIV prevalence and patient characteristics

	LHA A	LHA B	Total
Patients with HIV, *N*	529	209	738
Population	310 000	236 682	546 682
Prevalence (%)	0.17%	0.09%	0.14%
Male, *N* (%)	362 (68%)	143 (68%)	505 (68%)
Female, *N* (%)	167 (32%)	66 (32%)	223 (32%)
Age, mean (±SD)	48 (±9.1)	47 (±10.3)	48 (±9.3)
Age classes			
0–19 years, *N* (%)	9 (1.7%)	3 (1.4%)	12 (1.6%)
20–29 years, *N* (%)	18 (3.4%)	21 (10.0%)	39 (5.3%)
30–39 years, *N* (%)	75 (14.2%)	26 (12.4%)	101 (13.7%)
40–49 years, *N* (%)	157 (29.7%)	63 (30.1%)	220 (29.8%)
50–59 years, *N* (%)	204 (38.6%)	65 (31.1%)	269 (36.4%)
60–64 years, *N* (%)	26 (4.9%)	11 (5.3%)	37 (5.0%)
65 years and older, *N* (%)	40 (7.6%)	29 (9.6%)	60 (8.1%)

Table 2 Main comorbidities for the combined LHA population of patients with HIV, identified using the Charlson Comorbidity Index (diagnostic codes) and the EuroHOPE methodology (diagnostic codes plus medication ATC codes)

	Prevalence	95% CI
Acute myocardial infarction	1.0%	(±1%)
Hypertension	26.0%	(±3.2%)
Coronary artery diseases	1.6%	(±0.9%)
Cerebral vascular disease	1.5%	(±0.9%)
Dementia	3.0%	(±1.2%)
Chronic obstructive pulmonary disease (COPD) and asthma	14.3%	(±2.5%)
Liver diseases	1.9%	(±1%)
Diabetes mellitus (DM)	**3.0%**	**(±1.2%)**
Cancer	3.0%	(±1.2%)
Depression	13.6%	(±2.5%)
Mental disorders	26.3%	(±3.2%)

Table 3 Diabetes mellitus (DM) in patients with HIV (identified by Charlson Comorbidity Index, EuroHOPE and Bridge Health methods as well as by fee exemption status in the LHA databases)

	LHA A	LHA B	Total
Patients with HIV, *N*	529	209	738
Patients with DM, *N*	26	5	31
Prevalence (±95% CI)	4.9% (±1.2%)	2.4% (±1.3%)	4.2% (±1.2%)
Age, mean (±SD)	57 (±11.7)	65 (±17.7)	58 (±12.9)
Males, *N* (%)	22 (85%)	4 (80%)	26 (84%)
Females, *N* (%)	4 (15%)	1 (20%)	5 (16%)

Table 4 Adherence to therapy for diabetes and to standard of care for DM management

	2014	2015	2016
Patients by number of months of therapy			
0–5 (P ± 95% CI)	16 (69.6% ± 18.7%)	17 (74% ± 17.9%)	16 (69.6% ± 18.7%)
6–9 (P ± 95% CI)	5 (21.7% ± 16.9%)	3 (13% ± 13.7%)	5 (21.7% ± 16.9%)
10–12 (P ± 95% CI)	2 (8.7% ± 11.7%)	3 (13% ± 13.7%)	2 (8.7% ± 11.7%)
Total	23	23	23
Patients with at least two A1C test per year			
≤2 tests per year (P% ± 95% CI)	17 (77% ± 18%)	11 (50% ± 21%)	10 (45% ± 21%)
≥2 tests per year (P% ± 95% CI)	5 (23% ± 18%)	11 (50% ± 21%)	12 (55% ± 21%)
Total	22	22	22
Patients with at least one total cholesterol test per year			
≤1 test per year (P% ± 95% CI)	3 (14% ± 14%)	4 (18% ± 16%)	3 (14% ± 14%)
≥1 test per year (P% ± 95% CI)	19 (86% ± 14%)	18 (82% ± 16%)	19 (86% ± 14%)
Total	22	22	22
Patients with at least one albuminuria test per year			
≤1 test per year (P% ± 95% CI)	18 (82% ± 16%)	14 (64% ± 20%)	16 (73% ± 19%)
≥1 test per year (P% ± 95% CI)	4 (18% ± 16%)	8 (36% ± 20%)	6 (27% ± 19%)
Total	22	22	22
Patients with at least one serum creatinine test per year			
≤1 test per year (P% ± 95% CI)	3 (14% ± 14%)	3 (14% ± 14%)	3 (14% ± 14%)
≥1 test per year (P% ± 95% CI)	19 (86% ± 14%)	19 (86% ± 14%)	19 (86% ± 14%)
Total	22	22	22
Patients with at least one dilated fundus examinations per year			
≤1 examination per year (P% ± 95% CI)	2 (9% ± 9%)	2 (9% ± 9%)	6 (28% ± 19%)
≥1 examination per year (P% ± 95% CI)	20 (91% ± 9%)	20 (91% ± 9%)	16 (73% ± 19%)
Total	22	22	22
Patients with at least one ECG per year			
≤1 ECG per year (P% ± 95% CI)	13 (59% ± 21%)	15 (68% ± 19%)	16 (73% ± 19%)
≥1 ECG per year (P% ± 95% CI)	5 (41% ± 21%)	7 (32% ± 19%)	6 (27% ± 19%)
Total	22	22	22

Results

The prevalence and demographic characteristics of PLWH retrieved from the administrative databases are reported in table 1. Main comorbidities identified using the CCI and EuroHOPE methodologies are reported in table 2. The prevalence and characteristics of PLWH with DM are reported in table 3.

The adherence to therapy for diabetes and follow-up standards for diabetes are reported in table 4. We divided patients into three groups according to the number of months of therapy: (i) patients with <6 months of therapy; (ii) patients from 6 months to 9 months of therapy; and (iii) patients with at least 10 months of therapy. We included only patients with data available in all time periods considered.

Discussion

Major findings of the study

The present analysis used administrative databases to identify PLWH in two LHAs in Italy and analysed their use of health services and adherence to standards of care for DM. An estimated prevalence of 0.14% for the population of interest was identified, in line with HIV prevalence reported in the literature.[20] As a test of the methodology's ability to address emerging issues related to chronic conditions in ageing PLWH, patients with DM were identified through DM-specific consumption.

Prevalence estimates for DM in the HIV population investigated in our study were slightly lower than those reported in the literature (among the general population and among PLWH) and in the same Italian regions for the general population. Globally, the prevalence (age-standardized) of people living with DM in 2014 was 8.5% in the adult population,[21] while a US study found that DM prevalence among HIV-infected adults was 10.3% (95% confidence interval 9.2–11.5%).[22] At the national level, two studies identified respectively a prevalence of 5.6% in 2013 in the Veneto residents[23] and a prevalence of 6.6% in 2014 among residents of the Friuli-Venezia Giulia Region.[24]

An explanation of this lower prevalence could be attributed to the data set (over the 3 years of observation, HIV patients with diabetes may avoid using any of the major diabetes-related health services, such as medications) or to the exemption status. While DM prevalence identified exclusively through diagnostic codes and medication purchases in the study (3%) rose to 4.2% when adding in fee exemption status, it may still be the case that PLWH do not necessarily apply for fee exemption status for DM since they are already exempt for HIV. Considering the demonstrated risk factors for HIV patients with regard to DM, the low level of adherence to DM therapy found is cause for concern: the percentage of patients with at least 10 months of DM therapy in 1 year was between 8.7% and 13% (table 4). A meta-analysis has shown that the average adherence in patients with diabetes is 67.5%.[25] Also, the level of adherence to follow-up standards (table 4) was lower than what has been reported in previous studies,[26,27] with the exception of those tests also prescribed routinely in HIV follow-up, such as albuminuria and ECG. These negative results suggest that further investigation with the clinical specialists and general practitioners (GPs) managing these patients is needed to determine whether and how they are following recommended treatment for DM.

Implications of the results

This study exploits the use of administrative databases in two Italian LHAs to identify PLWH, with a focus on patients with DM; to test the ability of the analysis to examine adherence to clinical guideline-recommended standards of care for an exemplary chronic condition and, using a PHM approach,[7] assess the targeted population's health needs and improve the delivery of care for target subpopulations (e.g. mono-morbid HIV patients, multi-morbid HIV patients) to better serve this vulnerable population and improve prevention, care and outcomes.

Over the last decade, dramatic changes have occurred in health service delivery for PLWH. Steadily increasing life expectancy for

PLWH on ART has led to a rapid increase of the overall number of ageing PLWH, with a consequent increase in comorbid diseases that appear to present in HIV patients that are 10 years younger compared to the general population.[6] The British Standards for HIV clinical care (2018)[28]; indeed, recognizes the fact that HIV-infected patients are best managed within chronic disease models and makes recommendations on the level of service provision expected from centres providing HIV care and the level of professional expertise required from healthcare providers. Therefore, the management of HIV as a chronic condition and age-related condition needs new care models to integrate care and ensure effective and sustainable services. Nevertheless, reorganizing HIV management to address chronic aspects has proven challenging. Treating PLWH differs from other long-term conditions because of specialized clinical needs and the fact that sustainability matters with the chronic burden of HIV. According to the literature, there are at least five major challenges that should be addressed in any chronic care management programme for HIV.

First, from a clinical management perspective, effective delivery of HIV-related care is challenged by the 90–90–90 'treatment cascade' (90% diagnosed, 90% of diagnosed patients on ART and 90% of people on treatment have a suppressed viral load, now updated to 95–95–95 by 2030), a concept commonly applied to quantify the combination of services to provide to PLWH across the continuum of care.[29] The effectiveness of this cascade largely relies on health system capacity to manage the continuum of services: for instance, while the UK, which historically has promoted specialized services for HIV, has exceeded the targets for access to treatment and viral suppression, it has not achieved the target for diagnosis.[30] In the USA, where the health system continuum is more scattered, for every 100 patients with HIV infection, it is estimated by the Centers for Disease Control (CDC) that only 28 patients have successfully managed each of these steps.[1] The success rate is much lower in resource poor regions of the world, particularly sub-Saharan Africa, where identification of HIV status remains a huge challenge. In countries with historically high centralized and specialized services for HIV, difficulties have emerged regarding how to reorganize current HIV management. For instance, in the UK with the 2012 Health and Social Care Act, responsibilities for HIV and sexual health have been split between NHS England, the local authorities and the clinical commissioning groups.[31] In such a new landscape, the effectiveness of the treatment cascade and the vertical specialization of previous HIV centres has been deeply challenged, along with its successful results.

Second, multimorbidity in HIV infection represents an independent risk factor against comorbidities, and the number of comorbidities is higher in treated HIV-infected individuals compared with the age- and sex-matched HIV-uninfected population.[5] Third, a related problem in the ageing HIV-infected population is polypharmacy, which negatively impacts on medication adherence and increases the risk of adverse outcomes, including drug toxicities, drug interactions, hospitalization, geriatric syndromes and mortality.[32,33] Smit *et al.*[34] suggest that in 2030, 40% of patients could have complications with the currently recommended first-line regimens due to drug interactions or contraindications.

Fourth, the recognition of frailty among PLWL has become increasingly important. Most definitions of frailty describe a syndrome characterized by loss of function, strength, physiologic reserve and increased vulnerability to stressors due to age-associated declines across neuromuscular, metabolic and immune systems. Several studies have shown that frailty is more frequent in treated HIV disease than in the general population and screening of frailty is rarely performed in most HIV clinics.[35]

Finally, HIV affects a particularly diverse range of population groups and in different ways: it is associated with a unique stigma that still prevails and influences PLWH's access to services.

Therefore, recommendations for policy interventions should consider how principles that increasingly underlie services for people with long-term conditions (e.g. promoting independence and economic, social and clinical well-being; empowering people to self-manage; coordination of care) apply to PLWH and what solutions are likely to improve the management of HIV patients.

On one hand, the optimal and easiest solution to adopt would be the set-up of specialized services for HIV patients, featuring multiprofessional teams with the specialized consultant (in infectious disease) identified as the case manager for HIV patients, in charge of managing comorbidities and polypharmacy, with other health and social services professionals integrated into the care pathway. A second hypothesis could place HIV management at the primary care level, with the GP as case manager and specialized services engaged on demand. This solution is more likely to treat HIV as a chronic condition and within the mainstream of the new care models applied in this field. There is no clear gold standard. The results and the literature largely promote the first option, drawing on the idea that HIV still represents a specific condition that should be managed only under expert leadership and with dedicated services.[31]

Italian guidelines are not clear on a choice between this dichotomy, proposing both higher integration of HIV specialist services with primary care and greater GP leadership. Several arguments support the first solution as more feasible. Specialists can more easily access patients through follow-up for ART, and they can incorporate new preventative care measures to anticipate major comorbidity risk as well as manage emerging chronic conditions. Additionally, the nurse's role in case management and self-management is well-established in HIV centres administering ART, and this role could be extended to enhance patient education on comorbidities management. Conversely, PLWH are less confident with primary care services and their GP, and more comfortable with accessing specialized services. And, the social stigma still represents a major challenge in influencing decisions by PLWH on where and how to access health services.[36]

To conclude, the future model of care for HIV should be carefully evaluated within the local context, considering regulations and system capacity. Long-term HIV care is a relatively new phenomenon, and many GPs and healthcare professionals have limited knowledge and familiarity with HIV, which has historically been treated entirely within specialist clinics. Today HIV care requires new skills among the clinical workforce and a reshaping of those healthcare systems initially designed for acute care. The clinician of the future will require knowledge of ART management but will also need more expertise in preventing and managing other comorbidities typically associated with ageing to better manage the 'cascade of care'.[29]

Strengths of the study

Health administrative databases seem beneficial for planning healthcare interventions, including for HIV. They provide robust information systems subjected to regular update and data quality controls. To this extent, as largely discussed in the literature,[37] administrative databases remain the prevalent data source, reliable because of the amount of data and population coverage, especially in countries with a National Health Service System (e.g. Italy, the UK, Canada), easy to access and with no significant added maintenance costs. Administrative databases are a relevant data source in most OECD countries and can be used to improve population health and health system quality and performance, as the PHM approach largely does. Data retrieved from administrative databases can better assess the burden of disease, the uptake of therapeutics and the actual delivery system capacity with real-world implications for policy changes. Furthermore, relying on robust information systems is one of the fundamental components of clinical governance.[38] Since a main aim of clinical governance is the improvement of healthcare quality, to achieve this target reliable information from monitoring and evaluation systems should be available.[39]

The Italian experience holds interest for the international audience on two important levels. Firstly, compared to HIV treatment in other

countries, the Italian NHS has achieved a high capacity for managing and controlling HIV, with the establishment of a capillary system of specialized HIV centres dating from the 1990s. That capacity is reflected in the national HIV-AIDS plan 2017–2019, which aims to reach 95% of the HIV population on ART, and specifically addresses the development of HIV as a chronic disease, through service organization and promotion of multidisciplinary clinical and social service teams. Secondly, at the national level, the adoption of a PHM approach and the use of administrative data for profiling the population's health needs has been a requirement in Italy since 2016.[40] To the best of our knowledge, this study represents the first comparative test of PHM perspectives on the HIV population and represents an important step forward in understanding the management of chronic conditions in PLWH by adopting a PHM approach[7,9] using administrative data to assess system capacity to cope with these emerging needs, as widely applied to other long-term conditions in Italy. Further study could replicate the methodology applied here for the evaluation of DM management in HIV patients in other countries or explore prevalence and compliance in other comorbidities in HIV patients such as hypertension, COPD or mental health.

Limitation of the study

The study presents some limitations, foremost of all the inherent limitations of administrative data regarding reliable and complete coding of all diagnoses and services provided. Regarding HIV population identification and health service utilization, the population retrieved through administrative data can be underestimated due to requests by patients to remain anonymous as well as a consequence of the stigma of HIV status still evident in Italian society. This results in some patients seeking care from specialized centres outside of the LHA of residence or purchasing services out-of-pocket. In addition, in some areas, some publicly funded hospitals reported dispensing medications through global budgets, without registering patients' identification codes because of patient requests for anonymity. In fact, record linkage was not reliable for patients seeking care outside their resident LHA. Regarding DM, there is the lack of indication of type of DM (Type 1 and Type 2 DM) in administrative data.

Conclusions

The key strengths of the study rely on the application of a PHM approach to understand the comorbidity burden in HIV patient management, using one of the most common comorbidities, DM, as a paradigmatic case. The data provide insights on the current under-detection, under-treatment and poor compliance associated with comorbidities in PLWH and pave the way to reason on the future design of HIV services, with a system-diagnostic tool—administrative data analysis using a PHM approach—that can support targeted and personalized care planning and monitoring to improve prevention, care and outcomes. Whether the most efficacious model will be integrating HIV and DM management in PLWH within standard chronic care pathways or planning new HIV specialized services with increased integration with primary care in the continuum of healthcare services, is a question as yet unsolved. Different solutions tailored to different contexts and to the historical organization of HIV services will likely be required.

Ethical committee

The study received approval by the ethics committees of the organizations involved. Data collection was retrospective and concurrent for this observational study. Data were retrieved from administrative databases and anonymized at the source.

Supplementary data

Supplementary data are available at *EURPUB* online.

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Conflict of interest: None declared.

Data availability

The data underlying this article were provided by two Local Health Authorities following the approval by the ethics committees of the organizations involved. Data will be shared on request to the corresponding author with permission of the LHAs involved.

Key points

- Health administrative databases seem beneficial for planning healthcare interventions, including the human immunodeficiency virus (HIV) field and provide robust information systems subjected to regular update and data quality controls.
- The application of a Population Health Management approach to understand the comorbidity burden in HIV patient management, using one of the most common comorbidities, diabetes mellitus, as a paradigmatic case, provides insights on the current under-detection, under-treatment and poor compliance associated with comorbidities in people living with HIV (PLWH) and pave the way to reason on the future design of HIV services.
- Health policy is encouraging integration and new care models to ensure effective and sustainable services for tackling chronic care conditions. The same changes are crucial with today's challenges facing PLWH and the ageing population on antiretroviral therapies.
- The future model of care for HIV should be carefully evaluated within the local context, considering regulations and system capacity.

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