Review

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Pharmaco-economic Inequalities in Access to Antifibrotic Treatment for Interstitial Lung Disease in the Asia-Pacific Region

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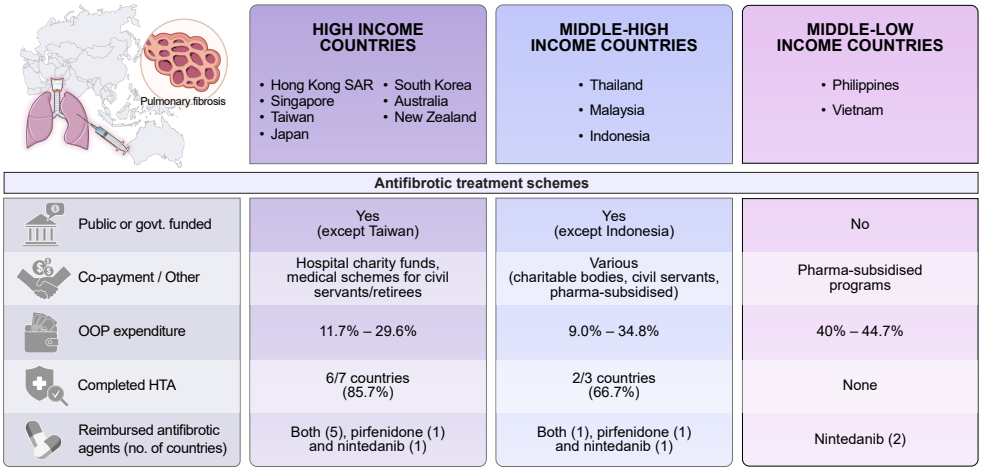

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Abstract

Antifibrotic drugs, available for the best part of the last decade in many parts of the world, have improved outcomes in patients with idiopathic pulmonary fibrosis and progressive pulmonary fibrosis. However, it is unclear whether patients suffering from these devastating conditions have timely and adequate access to antifibrotic therapy in the Asia-Pacific region (APAC). In this mixed-methods narrative review of 12 APAC countries, integration of questionnaire-based insights of 31 regional clinical experts in interstitial lung disease (ILD) with publicly available pharmaco-economic information has been used to understand how country-specific challenges impact on antifibrotic accessibility. Overall, a broad range of approaches are utilized to provide antifibrotic treatment including centrally or state-determined drug budgets, pharmaceutical industry-subsidized initiatives, charitable support and self-paying (out-of-pocket) options. Impediments to antifibrotic access commonly arise from prohibitive drug pricing in relation to income, absence of universal coverage for pharmaceutical costs, lack of

formal pharmaco-economic analysis or restrictions on the use of generic preparations. Unequal access to antifibrotic drugs is a vital unmet therapeutic need in the APAC region, one that is likely to be exacerbated by a rising fibrotic ILD burden.

Keywords: Antifibrotic Treatment; Interstitial Lung Disease; Asia-Pacific Region

Introduction

The development of pulmonary fibrosis in patients with interstitial lung disease (ILD) typically heralds severe and irreversible respiratory failure leading to premature demise[1]. The archetypal and most lethal form of ILD, termed idiopathic pulmonary fibrosis (IPF), was refractory to pharmacologic treatment until the advent of two anti-fibrotic agents, pirfenidone and nintedanib, within the last 15 years[2-5]. Both drugs have been shown to decrease the rate of decline in forced vital capacity (FVC), a major clinical hallmark of IPF progression. Similarly, positive effects of nintedanib have been demonstrated in patients with non-IPF forms of ILD collectively known as progressive pulmonary fibrosis (PPF), also termed progressive fibrosing ILD[6].

In the decade that followed the publication of the INPULSIS and ASCEND IPF trials, and 5 years after the INBUILD PPF trial, access to antifibrotic treatment remains lacking in many parts of the world including the Asia-Pacific (APAC) region[4,6,7]. Prohibitive costs keep these potentially disease-modifying drugs beyond the affordability of many individuals with pulmonary fibrosis whose treatment, for various reasons, is not funded or reimbursed.

The key unmet needs related to poor or inequitable access to antifibrotic therapy are the culmination of economic, geographic and healthcare system-specific factors. A paucity of epidemiological studies particularly in Southeast Asia also hinders ILD-related healthcare planning as its' disease burden in this region remains unknown. One detrimental result of a limited funding system is higher out-of-pocket (OOP) expenditure for the individual and their family. OOP costs unfairly and disproportionately affect people in low-income strata, increasing their risk of catastrophic financial and social impoverishment. Even where treatment subsidies are available, the self-funded component often remains unaffordable.

In this overview, we highlight inequalities that affect access to antifibrotic treatment in Southeast Asia, Japan and South Korea in East Asia, as well as Australia and New Zealand. We specifically assessed whether country-specific characteristics relating to cost or expenditure indicators, pharmaco-economic evaluation and the availability of different treatment access schemes explain the unmet demand for this vital therapy in the countries studied.

Methodology

1. Study design

The aim of the current study was to better understand unmet therapeutic access and needs related to antifibrotic treatment for fibrotic lung diseases in APAC countries. Existing treatment schemes including their limitations were contextualised principally for accessibility and population coverage using a convergent mixed-methods narrative review, integrating questionnaire responses and healthcare metrics available in the public domain.

Country-specific population and healthcare metrics were obtained from policy documents, publicly available health economic reports and peer-reviewed publications. Provider information including treatment access programmes for nintedanib (Ofev™, Boehringer Ingelheim, Ingelheim, Germany) was supplied by its manufacturer for six countries (Australia, Republic of Korea, Philippines, Thailand, Malaysia, and Vietnam). A similar request was made to Roche (pirfenidone; Esbriet™, Basel, Switzerland) but a response was not received.

A 31-item web-based questionnaire was used to collect responses from two to three expert ILD clinicians and key opinion leaders (KOLs) at different healthcare institutions in Australia, Hong Kong Special Administrative Region of China, Indonesia, Japan, Malaysia, New Zealand, Philippines, Singapore, Republic of Korea, Taiwan, Thailand, and Vietnam. Respondents were selected based on knowledge of their roles and expertise within existing regional ILD networks. APAC countries such as Bangladesh, Myanmar, and Cambodia were excluded as information on approved pathways for antifibrotic treatment or the number of patients receiving antifibrotic treatment was unavailable. Respondents were asked to include the most recent data from their

institution (or region if they provide treatment at a regional level), either published or from local sources including but not limited to clinical service reports. Collation of core information and the administration of the questionnaire was performed by Felix Chua, Larry Ellee Nyanti, Shirin Tan, Sze Shyang Kho, and Syazatul Syakirin Sirol Aflah.

2. Data sources and collection of data

A comprehensive search of articles relating to the burden of ILD, access to antifibrotic treatments and healthcare expenditure in APAC countries was undertaken. Economic indicators such as gross domestic product (GDP), gross national income (GNI) *per capita*, healthcare expenditure, OOP spending and ILD prevalence were extracted from resources including the World Bank, World Health Organization (WHO), and Organisation for Economic Co-operation and Development (OECD). Information submitted by respondents exemplifying contemporaneous antifibrotic practice in each country including treatment coverage provided simple quantitative data. Subjective explanations including unaudited proportions of patients on treatment schemes provided qualitative data.

3. Inclusion and exclusion criteria

APAC countries where antifibrotic treatment is available through reimbursement schemes or self-payment were included. Countries such as Bangladesh, Cambodia, China, India, Laos, Myanmar, Pakistan, the Pacific Islands, and Sri Lanka were excluded due to either significantly different infrastructures for antifibrotic provision, or if there was difficulty in locating data on their usage. References associated with non-peer reviewed articles were also allowed, provided the source data incorporated a publication date, author information (individual or group) and if the subject matter was relevant. The search for references and their analysis was undertaken by three authors (Felix Chua, Larry Ellee Nyanti, and Shirin Tan); where disagreement or uncertainty arose, up to two other co-authors were asked to adjudicate.

4. Data extraction and synthesis

Information on key economic indicators and related metrics such as GDP, GNI *per capita*, healthcare expenditure and percentages of health budgets allocated to high-cost drugs was extracted from public databases. Data on the prevalence of ILD including fibrotic subtypes, were gathered from the published literature and a structured survey of practising ILD experts in the 12 countries. Details on designated ILD treatment centers, public/national antifibrotic reimbursement schemes, cost-effectiveness evaluation and OOP expenditures were collected from all respondents, referenced to published literature. In this review, OOP expenditure was chosen to reflect household spending in pharmaceutical products, in order to assess any trends and associations to availability of antifibrotic access.

Data were initially extracted into an Excel sheet and analysed by the core group. Where data were inconsistent or opinion on specific items varied, a joint discussion was undertaken to establish consensus. No pharmaceutical company participated in data analysis or had access to any of the findings prior to publication.

5. Analysis

Data were analysed semi-descriptively to identify trends and gaps in antifibrotic provision with a focus on the impact of healthcare costs on treatment availability. The data were also appraised to evaluate the effectiveness of existing antifibrotic access schemes in identifying unmet treatment needs. Exploratory analyses were conducted to probe potential associations between income, specifically GNI *per capita*, and core parameters of antifibrotic access such as the number of funding schemes by country. Owing to the number of countries involved (n=12), formal statistical analysis was not undertaken.

Results

1. General characteristics of countries and respondents

Of the 31 respondents surveyed, a majority (67.7%, n=21) are employed within a university-affiliated hospital, while the remaining (32.3%, n=10) work in non-university linked hospitals. Twelve Asia-Pacific region (APAC) countries were included in this review, comprising eight in Southeast Asia, two in East Asia (Japan and Republic of Korea) and two in the south Pacific rim (Australia and New Zealand). Their population varied from <10 million (Singapore, New Zealand, and Hong Kong) to over 100 million (Philippines, Japan, and Indonesia) (Table 1). Income classification based on the World Bank Atlas method to calculate GNI *per capita* revealed two countries as low middle-income (Vietnam and Philippines), three as high middle-income (Malaysia, Thailand, and Indonesia) and seven as high income (Singapore, Hong Kong SAR, Taiwan, Japan, Korea, Australia, and New Zealand)[8].

The countries included in this study can also be grouped according to health expenditure (HE) calculated as a percentage of their GDP—in 2022, HE formed

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Table 1. Country-based pharmaco-economic parameters and approved anti-fibrotic treatment indications

Country	No. of population (million)[32]	GNI *per capita*, US$[8] (income level)*	Healthcare expenditure, % (of GDP; 2021)[9]	Healthcare expenditure *per capita*, US$	Pharmaceutical expenditure, % (of health expenditure)[33]	OOP expenditure, % (of health expenditure)	Reported/estimated prevalences of fibrotic ILD	Approved indications for antifibrotic treatment (IPF, PPF, SSc-ILD)	Antifibrotic agents approved for reimbursement (nintedanib and/or pirfenidone)
Malaysia	33.9	11,970 (Mh)	4.38	1,040.20[31]	15.7[36]	34.8[51]	12.2 ILD per 100,000 (unpublished data)	All three	Both
Singapore	5.6	70,590 (H)	5.57	2,538.00[31]	6.3[9]	22.5[37]	5–10 IPF per 100,000 (unpublished data)	All three	Both
Thailand	71.6	7,180 (Mh)	5.16	658.20[31]	21.7[38]	9.0[37]	7.36% PPF among F-ILD (unpublished data)	All three	Nintedanib
Vietnam	98.1	4,180 (Ml)	4.59	390.50[31]	33.0[44]	40.0[37]	NA	All three	Nintedanib
Philippines	115.5	4,230 (Ml)	5.10	328.90[39]	20.6[48]	44.7[49]	NA	IPF	Nintedanib
Indonesia	275.5	4,870 (Mh)	3.71	299.40[31]	24.5[40]	27.5[37]	39.78% F-ILD among total ILD (unpublished data)	All three	None
Hong Kong SAR	7.4	55,200 (H)	7.30	3,088.85[42]	7.8[45]	30.0[46]	32.6 ILD per 100,000 with IPF comprising 79.8%[52]	All three	Nintedanib
Taiwan	23.3	32,300 (H)	6.14	1,595.00[34]	18.2[41]	29.6[47]	NA	All three	Both
Japan	125.1	39,030 (H)	10.82	4,288.00[31]	18.1[35]	12.0[50]	27 IPF per 100,000[53] IPF comprises 47% all fibrotic ILD[54]	All three	Both
Korea	51.6	35,490 (H)	9.72	2,530.30[31]	17.6[32]	28.1[37]	16.9, 10.4, and 11.7 per 100,000 for IPF, F-ILD, non-progressive F-ILD[55]	All three	Pirfenidone
Australia	26.0	63,140 (H)	10.54	4,357.30[31]	12.0[32]	13.8[37]	32.6 IPF per 100,000[56]	All three	Both
New Zealand	5.1	48,610 (H)	10.05	4,018.30[31]	5.4[43]	11.7[37]	6.53 IPF per 100,000 (unpublished audit)	IPF	Both

GNI: gross national income; GDP: gross domestic product; OOP: out-of-pocket; ILD: interstitial lung disease; IPF, idiopathic pulmonary fibrosis; PPF, progressive pulmonary fibrosis; SSc-ILD, systemic sclerosis-associated interstitial lung disease; Mh: high middle-income country; H: high-income country; F-ILD: fibrosing interstitial lung disease; Ml: low middle-income country; NA: not available.

less than 10% of GDP in three-quarters of countries (range, 3.71% to 9.72%) (Table 1). The HE of Japan, Australia, and New Zealand were slightly higher at 10% to 11% of their GDP, with the Republic of Korea close behind at 9.72%[9]. Ironically, countries with the lowest healthcare expenditure *per capita*, namely Vietnam, Philippines, and Indonesia, also spent some of the highest percentages of HE as pharmaceutical expenditure (Table 1).

2. Pharmaco-economic analysis of antifibrotic therapy

Formal pharmaco-economic evaluation of antifibrotic treatment was more likely to have been done in countries with a higher income status. Two-thirds of the countries included in the analysis had utilized a health technology appraisal to assess the cost effectiveness of antifibrotic therapy (HTA-AF), of which six (Australia, Hong Kong SAR, Republic of Korea, New Zealand, Singapore, and Taiwan) came from the group of seven high-income countries and two (Malaysia and Indonesia) from the middle-income countries (Table 2). Indonesia was the most recent country to have completed HTA-AF (August 2024) but reimbursement of antifibrotic treatment is yet to be approved by the country's universal healthcare (Jaminan Kesehatan Nasional) coverage.

Countries with an HTA-AF did not have lower OOP expenditure; Singapore, Hong Kong SAR, Taiwan, and Republic of Korea all had OOP between 22% and 30% of their annual healthcare expenditure despite having evaluated the cost effectiveness of antifibrotic treatment. The proportion of OOP related to drug spending in these countries was not studied but is expected to be variable. Overall, countries that had undertaken an HTA-AF tended to have a lower pharmaceutical expenditure corresponding to 5.4%–18.2% of their annual HE (2022 data) (Table 2).

3. Out-of-pocket expenditure at the point of care/ treatment

As expected, HE *per capita* was highest in better developed countries like Japan, Republic of Korea, Australia, New Zealand, Hong Kong SAR, and Singapore. By comparison, general OOP expenditure was highest in two lower middle-income countries (Vietnam and Philippines) where it reached 40% of pharmaceutical expenditure, a figure that contrasts sharply against smaller OOP spending in countries with higher GNI such as Thailand (9.0%), Japan (12.0%), Australia (13.8%), and New Zealand (11.7%) (Table 1).

New Zealand bucks the trend with its' relatively low OOP expenditure despite a high *per capita* HE and a modest level of pharmaceutical expenditure calculated as a percentage of HE[10]. The present empiric analysis did not reveal a clear inverse relationship between general OOP and GNI *per capita*. Some higher income countries also had a sizeable OOP, for example the Re-

Table 2. Characteristics of antifibrotic funding schemes in surveyed countries

Country	Public/government-funded antifibrotic scheme (full and/or part-funding)	Co-payment or assistance/subsidy schemes offered by pharmaceutical companies	Other schemes (charitable bodies, retirees' funds, ex-service personnel)	Pharmaco-economic evaluation of antifibrotic treatment (by Health Technology Assessment)
Malaysia	Yes	Yes	Yes	Yes
Singapore	Yes	No	Yes	Yes
Thailand	Yes	Yes	Yes	No
Vietnam	No	Yes	No	No
Philippines	No	Yes	No	No
Indonesia	No	Yes	Yes	Yes
Hong Kong	Yes	No	Yes	Yes
Taiwan	No	No	No	Yes
Japan	Yes	No	Yes	No
Korea	Yes	Yes	No	Yes
Australia	Yes	No	No	Yes
New Zealand	Yes	No	No	Yes

public of Korea and Taiwan (28.1% and 29.6%, respectively).

With specific regard to antifibrotic therapy, Indonesia has the highest proportion (80% to 90%) of patients on fully self-funded antifibrotic treatment, overshadowing the 10% or lower rate in most of the other countries studied. At the time of writing, no patients in Vietnam and Japan were fully OOP for antifibrotic therapy for different reasons. Japan has a universal health insurance system, and all approved drugs are partially covered by public HEs (personal communication; Yoshizaku Inoue and Tomohiro Handa). Furthermore, Japanese patients have access to generous funding support including the Japanese Ministry of Health, Labour and Welfare's 'Nan-byo' system that covers OOP whereas the private cost of antifibrotic agents in Vietnam effectively prohibits self-funding as a sustainable ongoing treatment option (personal communication; Yoshizaku Inoue, Le Thuong Vu, and Trang Vu). Similarly, government funding of antifibrotic therapy, specifically pirfenidone, in the Republic of Korea covers approximately 90% of its' treatment cost, limiting the OOP proportion to 10% or less (personal communication; Jin Woo Song).

4. Antifibrotic treatment reimbursement based on therapeutic indication

The efficacy of antifibrotic therapy has been demonstrated in randomized controlled trials of IPF (pirfenidone and nintedanib), PPF (nintedanib), and systemic sclerosis-associated ILD (nintedanib)[4-7]. Antifibrotic therapy is approved for more than one of these indications in most of the countries studied except in the Philippines and New Zealand where it is only approved for IPF (Table 1). However, reimbursed treatment, varying in extent of assistance, is currently only available in three-quarters of these countries (Table 2). Nintedanib is the sole reimbursed antifibrotic treatment in the Philippines, Thailand, Hong Kong SAR, and Indonesia while pirfenidone is the only antifibrotic agent reimbursed for IPF in the Republic of Korea's National Health Insurance Service (NHIS). Here, the patented drug (Pirespa, Shionogi Inc., Osaka, Japan) and generic formulations respectively account for roughly 60% and 40% of total pirfenidone prescriptions (personal communication; Jin Woo Song). Differences in the usage frequency of approved antifibrotic treatment depend on local regulatory approval processes and policies.

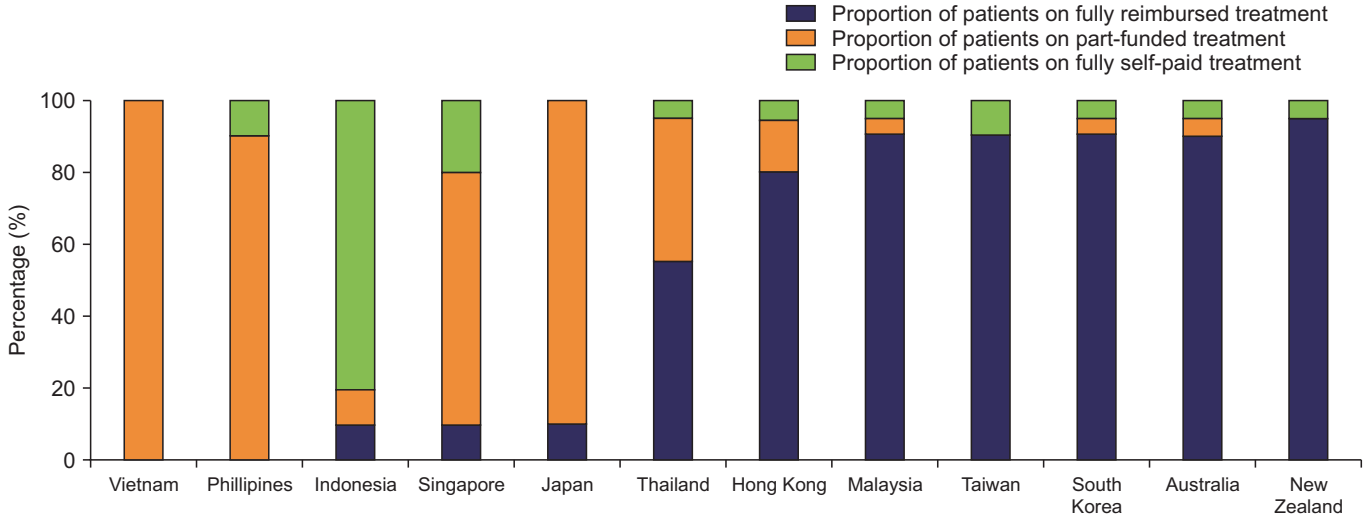
5. Overview of antifibrotic treatment schemes

Three main types of antifibrotic access schemes were identified in this review: (1) public or government-funded reimbursement schemes; (2) non-reimbursed but subsidized or assisted schemes including those offered by pharmaceutical companies; and (3) charitable schemes. Reimbursed treatment is typically dispensed at government health facilities or their nominated pharmacies, with the cost of the drug being fully or partially covered (Figure 1).

6. Reimbursed government or public-funded schemes

Most countries in this study operate a nationally reimbursed antifibrotic treatment scheme (with varying proportions and extent of support) except Indonesia,

Figure 1. Proportions of patients on different levels of funded antifibrotic treatment compared to those on fully self-paid treatment across 12 Asia-Pacific countries.



Vietnam, Taiwan, and the Philippines (Table 2). For example, although >90% of antifibrotic-treated patients in Malaysia, Australia, and New Zealand receive fully reimbursed therapy, the actual number of recipients in Malaysia is small compared to the other two countries due to population size differences and restrictions aligned to a national antifibrotic treatment quota.

In contrast, a minority of antifibrotic-eligible patients qualify for fully reimbursed therapy in Singapore, Japan, and Indonesia. The first two countries offer publicly managed assistance schemes and Japan was the first country in the world to successfully market pirfenidone as antifibrotic therapy in 2008. Substantially subsided antifibrotic treatment remains available to most patients with IPF under the Japanese Intractable Rare Disease System[11]. On the other hand, only a very small number of Indonesian IPF patients receive fully reimbursed treatment through private or company/employment-linked insurance. Since the Indonesian universal healthcare system has yet to include antifibrotic treatment, a high proportion (around 80% to 90%) of antifibrotic-treated patients are fully self-funded (personal communication; Sita Andarini, Fanny Fachrucha, and Eric Tenda).

Two-thirds (67.7%) of the countries surveyed utilize IPF and/or PPF disease severity criteria to determine eligibility for antifibrotic treatment. Qualification for treatment typically includes evidence of mild to moderate severity fibrotic ILD, practically defined by FVC between 50% and 80% of predicted. However, it is unclear how strictly the process, including prior failure of first-line treatment, is enforced.

Civil service employees in Hong Kong, Thailand, and Singapore can access fully reimbursed antifibrotic treatment. In Hong Kong SAR, this is provided by the Hong Kong Civil Service Bureau while non-civil servants are eligible for a subsidy under the Hong Kong Alliance for Rare Diseases[12,13]. In Thailand, reimbursed antifibrotic treatment via the Thai Civil Service Medical Benefit Scheme (CSMBS) extends to the dependants of civil servants whereas in Singapore, spouses of civil servants are eligible for partially reimbursed antifibrotic treatment (personal communication; Amornpun Wangkarnjana, Kamon Kawkitinarong, Su-Ying Low, and Gin Tsen Chai).

Eligibility criteria that are not contingent on employment status operate in Australia and New Zealand where public-funded antifibrotic treatment is provided through the Pharmaceutical Benefits Scheme (PBS) and the NZ Pharmaceutical Management Agency (PHARMAC), respectively[14].

Means-based assessment of the patient's household income and assets is used to assess an individual's eligibility for financially supported antifibrotic treatment in some APAC countries including Malaysia. Similarly, a Samaritan Fund operates at healthcare sites appointed by the Hong Kong Hospital Authority (HKHA) or at SafeMed HK dispensaries to enable low-income individuals to access substantially subsidized antifibrotic treatment for an initial 24 months followed by free antifibrotic medication thereafter[15].

7. Pharmaceutical or manufacturer-sponsored antifibrotic treatment

Patients with pulmonary fibrosis in half of the countries studied have access to pharmaceutical company-subsidized treatment programs with different co-payment obligations. In some places, a patient might purchase a three-month supply of medication to qualify for a similar period of free treatment. In the Philippines and Vietnam, nearly all treatment recipients rely on such schemes since antifibrotic drugs are not listed in either the Philippines National Formulary (PNF) or the Vietnamese National Reimbursement Drug List (NDRL), respectively.

At the time of writing, a pharmaceutical company-supported antifibrotic assistance scheme was not available in Australia, Hong Kong SAR, Japan, New Zealand, Singapore, or Taiwan. In Singapore, lower-income patients may receive coupons for free samples of nintedanib at the discretion of their treating physician; formal guidance on their distribution and duration of use have not been developed.

8. Charity-operated and self-paid (fully out-of-pocket) treatment

In a few countries such as Hong Kong SAR, charitable bodies contribute to co-payment schemes to widen access to antifibrotic therapy. In general, such schemes are few in number and have limited capacity. Across the countries studied, fully self-funded patients comprised no more than 10% to 20% of those on antifibrotic treatment except in Indonesia where the rate is substantially higher. Neither the absolute number of patients paying for part or the entirety of their treatment nor the proportion of patients using generic antifibrotic drugs is known.

Discussion

Across the APAC region, equitable and affordable access to antifibrotic drugs remains a significant unmet need. Lower-income countries are more sensitive to rising rates of pharmaceutical spending that outstrip healthcare expenditure, a phenomenon that can detri-

mentally affect the provision of subsidized therapies for a range of chronic diseases including ILD[16]. Vietnam, Philippines, and Indonesia have disproportionately high pharmaceutical expenditure as a fraction of their HE. The reasons for this are not entirely clear but being amongst the most populous countries in APAC, it is possible that drug expenditure across all therapeutic areas in these countries eclipses costs associated with non-drug spending such as medical services. Moreover, inadequate or unequal purchasing budgets for pharmaceuticals in the public domain inevitably lead to higher OOP costs which are difficult to quantify but are nonetheless included within the conventional calculation of pharmaceutical expenditure.

Countries with higher income levels are more likely to reimburse both antifibrotic agents, as depicted by the positive association between GNI *per capita* and an antifibrotic reimbursement score derived from the number of reimbursed agents in each country (Supplementary Table S1 and Supplementary Figure S1). Most high-income countries achieved the maximum reimbursement score of 2, in contrast to low- and lower middle-income countries that presently have limited or no reimbursement arrangements. Although economic capacity appears to be a key enabler of access to high-cost medicines, outliers to this rule such as Malaysia, may arise as a result of national healthcare priorities and policy frameworks that influence access regardless of economic tier.

The present analysis also shows that accessibility to affordable antifibrotic treatment does not automatically follow its regulatory approval. Although HTAs are often conducted to evaluate the cost-effectiveness of a new intervention, the WHO's recommendation of a cost-effectiveness threshold of one to three times a country's *per capita* GDP for low to middle-income countries is poorly supported by published evidence[17,18]. Amongst the high-income countries studied, only Japan has not undertaken a formal HTA for antifibrotic treatment (Table 2). In practice, an HTA may be waived for rare or life-threatening diseases where no alternative treatment is available, or if the effectiveness of the drug of interest has hitherto been assessed outside the framework of an HTA.

No relationship was found between GNI *per capita* and a funding support score constructed by summing the presence of three core funding mechanisms for antifibrotic agents: public/government schemes including those with HTA, co-payment including manufacturer assistance and standalone schemes such as charitable or retiree funds (Supplementary Figure S2). In effect, while national *per capita* income may influence the diversity of access-enabling treatment schemes, the complex interplay between local healthcare policies and resource prioritisation make any analysis of how antifibrotic funding strategies are shaped at the point of clinical access challenging.

What is clear is that any publicly funded antifibrotic treatment scheme that is dominated by high OOP costs will struggle to adequately provide for those who most need these therapies. Patients with fibrotic ILD in lower-income Asian countries face high OOP costs related to their medications, investigations and in some cases, hospital attendance. Transfer of the OOP burden of antifibrotic therapy to them exacerbates their financial hardship and at a societal level, risks widening socio-economic inequalities[19]. Amongst the low and middle-income countries in the present study, Thailand was an exception by having OOP expenditure that is comparable to that of higher income countries, and significantly lower than Malaysia which has a higher *per capita* GNI.

Many patients on self-funded antifibrotic treatment in Indonesia, the Philippines, and Vietnam likely come from higher earning strata of the population and represent only a relatively small proportion of patients with IPF (personal communication; Celeste May Campomanes and Le Thuong Vu). Of the high-income countries studied, the highest OOP expenditure (in Hong Kong SAR, Taiwan, and Republic of Korea) was nearly three times that in countries with the lowest OOP spending (Japan and New Zealand).

Reductions in general OOP expenditure in some countries have been achieved through the implementation of universal healthcare coverage (UHC) and risk sharing agreements (RSA). Having grown to cover 80% of the Thai population, UHC has contributed to decreasing OOP costs from around a third to just under 10% of healthcare expenditure[20,21]. At the time of writing, UHC excludes antifibrotic treatment but covers other vital medical expenses.

In the Republic of Korea, RSAs borne of collaborations between the health authority and pharmaceutical industry have improved access to some medicines and a net lowering of OOP costs[22]. However, RSAs developed specifically for a particular drug may paradoxically result in decreased treatment choice if RSA eligibility is contingent on the absence of alternative therapies[22]. In the Republic of Korea, nintedanib is currently not reimbursed for any fibrotic ILD indication due to the prior approval of pirfenidone for IPF in 2015[23].

Other strategies that could potentially help improve access to antifibrotic treatment include having a reliable assessment of disease burden to enable the size

of the target ILD population to be estimated. Such data can provide governmental leverage to achieve an optimised RSA with drug manufacturers. For antifibrotic treatments with proven clinical efficacy, governments could utilize contracts that peg reimbursement to prespecified clinical outcomes[24]. Moreover, special pricing agreements such as confidential discounts, rebates and volume purchase advantages could be employed. Lower-income countries could also develop more favourable pricing arrangements by externally referencing nations with similar or lower GDP *per capita*[25].

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement enables least developed countries to be excluded from the patent restrictions of particular drug formulations[26]. Such waivers allow generic drugs to be produced and exported to countries in need, within the terms of a compulsory licence[27,28]. Loosening the approval for generic antifibrotic compounds would likely enhance treatment access but may be subject to other issues including, crucially, supply chain inconsistencies[29].

This study has a number of limitations. Not all Southeast Asian countries were included due to missing country-specific information or where KOLs familiar with antifibrotic treatment were not available to be surveyed. The potential for confirmation or contextual bias in relation to the countries included is therefore acknowledged, since the experience of respondents is limited to their own spheres of practice. The inability to corroborate information in the grey literature also meant that some details are likely to be selective, anecdotal or not contemporaneous. The lack of accurate information on the epidemiology of ILD, the number of antifibrotic -treated patients and the proportion of pharmaceutical expenditure attributed antifibrotic treatment costs for each country represent additional knowledge gaps[30]. Information about antifibrotic scheme support and organization was available from only one antifibrotic pharmaceutical manufacturer. Detailed information on the number of individuals who were offered payment-assisted antifibrotic treatment but ultimately remained untreated due to an inability to meet co-payment obligations was not available. The lack of data granularity also applied to smaller scale funding sources such as charitable bodies, for example the Zakat scheme for Muslim patients in Malaysia.

Crucially, the size of OOP expenditure with respect to antifibrotic treatment could not be reliably estimated as such data are not routinely collected. Many of the indicators that are conventionally used to scrutinize antifibrotic treatment in Western countries lack the regional detail required for more precise cost estimations in Southeast Asia. The tax-to-GDP ratio, or tax revenue as a proportion of GDP, was similarly excluded from this study as detailed fiscal effects on pharmaceutical spending were beyond its' scope. However, it is acknowledged that the size of pharmaceutical rebates at a national level can influence a nation's purchasing power for medicines. Overall, disparities in OOP expenditure between less well-off Southeast Asia countries and higher income nations in East Asia and the Pacific are quite striking.

Future evaluations of access to antifibrotic therapy could be spearheaded by regional research networks, potentially in collaboration with regulatory or similar agencies. Healthcare providers and patient-facing stakeholders should be supported and equipped to prospectively collect data on key indicators such as the prevalence of fibrotic ILD, proportions of patients meeting criteria for and ultimately receiving antifibrotic treatment as well as the costs incurred, including crucially the self-paying component.

Conclusion

In conclusion, access to antifibrotic treatment for the management of life-limiting fibrotic lung diseases across APAC is highly variable and remains inadequate in many countries. Those with a high proportion of patients on fully reimbursed antifibrotic therapy tend to either have a small total number of treatment recipients or have well-funded reimbursement programs. Patients in lower-income countries in Asia face substantial barriers in accessing adequately subsidized treatment resulting in potentially punishing OOP costs. Across the region but specifically in Southeast Asia, such challenges are compounded by a lack of robust epidemiological data for ILD.

The current situation could paradoxically be exacerbated by the emergence of new antifibrotic drugs because increased pharmacological choice is unlikely to translate to greater treatment options due to cost. It is unclear how currently non-reimbursed first-generation antifibrotic agents will fare when the antifibrotic therapeutic field widens. At the end of the day, the positive effects of antifibrotic treatment can only be fully realised if patients with these devastating diseases can gain timely access to treatment based on clinical need, unencumbered by potentially negative economic consequences on themselves or their families.

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Authors' Contributions

Conceptualization: all authors. Methodology: Chua F, Nyanti LE, Tan S. Formal analysis: Chua F, Nyanti LE, Tan S. Data curation: Chua F, Nyanti LE, Tan S. Project administration: Nyanti LE, Tan S. Visualization: Chua F, Nyanti LE, Tan S, Syakirin Sirol Aflah S. Software: Nyanti LE, Tan S. Validation: all authors. Investigation: Chua F, Nyanti LE, Tan S, Syakirin Sirol Aflah S. Writing - original draft preparation: Chua F, Nyanti LE. Writing - review and editing: Chua F, Nyanti LE, Tan S, Syakirin Sirol Aflah S, Kho SS, Chai GT, Wangkarnjana A, Low SY. Approval of final manuscript: all authors.

Conflicts of Interest

Felix Chua has received lecture and advisory fees as well as travel support from Boehringer Ingelheim and Roche. Fanny Fachrucha has received lecture honoraria and travel support from Zuellig Pharma Therapeutics and is a member of their ILD Advisory Board. Dina Diaz has received lecture honoraria from AstraZeneca Phillipines and Boehringer Ingelheim Philippines and lecture honoraria and travel support from Glaxo-Smith-Kline Philippines. Sita Andarini has received lecture honoraria and travel support from AstraZeneca, DaryaVaria, Etana, Hetero, Johnson and Johnson, Kalbe Farma, MSD, Roche, Pfizer, Takeda, Zuellig Pharma Therapeutics. Su-Ying Low has operated educational and research grants by Boehringer Ingelheim. Valencia Lim has received lecture honoraria from Boehringer Ingelheim. Ying-Ming Tsai has received lecture honoraria from Boehringer Ingelheim. Syazatul Syakirin Sirol Aflah has received lecture honoraria from Boehringer Ingelheim. Amornpun Wangkarnjana

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Boehringer Ingelheim provided general and non-commercially sensitive information on the APAC countries included in this study which use nintedanib (OFEV); data on treatment usage or cost were not included. Use of pirfenidone across the region comprises a mix of generic and/or branded drug, without one manufacturer or distributor solely covering the region. No part of the manuscript was shared with any pharmaceutical or commercial company prior to publication.

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Supplementary Material

Supplementary material can be found in the journal homepage (http://www.e-trd.org).

Supplementary Table S1. Antifibrotics accessibility scoring.

Supplementary Figure S1. Relationship between gross national income (GNI) *per capita* and antifibrotic (AF) reimbursed score.

Supplementary Figure S2. Relationship between gross national income (GNI) *per capita* and the funding support score.

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