White Paper

Shaping the Cardiovascular Disease Access Policy Landscape

Taiwan

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Executive summary

Taiwan has seen a growing population of patients with cardiovascular disease (CVD) over the past 10 years, driven by atherosclerotic CVD (ASCVD) which constitutes 79% of CVD cases.[1] Heart disease has remained the second leading cause of death over the last 10 years and ASCVD is among the top 12 leading causes of mortality and disability.[1,2] The considerable disability burden of ASCVD comes with a high price, with around 10% of annual National Health Insurance (NHI) expenditure spent on CVD management.[3] What stands out in the ASCVD population in Taiwan is that most patients are ≥65 years of age, and the proportion of people in this age group has doubled over the last 20 years.[1,4,5] As ASCVD impacts elderly patients more seriously in terms of mortality and disability, ASCVD spending is largely driven by this age group and is expected to increase substantially.[3]

There is room for improvement in the management of CVD risk factors across the patient journey in Taiwan. Although hyperlipidaemia has shown the fastest increase in prevalence of all major CVD risk factors in recent years (3.2% vs. 1.6% for hypertension, -0.9% for diabetes), it has been deprioritized in current programs, which has contributed to poor diagnosis rates of lower than 50% particularly for the younger population.[6,7] In addition, hyperlipidaemia has the lowest treatment initiation rate among all age groups compared to other risk factors.[8,9] Disease control is also sub-optimal, even among high-risk patients.[9,10] This may be attributed to poor awareness, treatment compliance and follow-up. Proactive management of hyperlipidaemia and more emphasis on secondary prevention is required.

The government and policy makers should act with urgency to tackle the growing burden of CVD in Taiwan. Several potential solutions to tackle ASCVD challenges and unmet needs have been identified, such as:

- Improvement of current screening initiatives
- Improved treatment management through incentivization programs
- Access to long-acting drugs with fewer side effects

These solutions could enhance disease management and continuity of care, ultimately improving outcomes for patients and drastically reducing the substantial burden of CVD. If no immediate steps are taken to address the challenges associated with CVD, there is a risk of a future public health crisis in Taiwan.

Government and policymakers will need to act, with urgency, as the economic and disease burden of ASCVD is increasing at high rates in Taiwan. The total cost of CVD was estimated at ~NT$169 billion in 2019. If no action is taken, the economic burden of CVD is expected to reach ~NT$277 billion by 2030, accelerated by Taiwan's ageing population.[11]

Introduction

CVD is associated with significant mortality and disability in Taiwan, with ASCVDs such as myocardial infarction and stroke contributing to most of the burden.[1] Over the last 10 years, heart disease has remained the second leading cause of death in Taiwan.[1] The disease burden of ASCVD comes with a high price: around 10% of NHI expenditure goes towards CVD management, which cost the government ~NT$63.8 billion in 2019.[3] What stands out in the ASCVD population in Taiwan is that most patients are ≥65 years of age, and this population has been growing rapidly as Taiwan is one of the fastest ageing societies in the world.[1] As ASCVD impacts elderly patients more seriously in terms of mortality and disability, ASCVD spending is largely driven by this age group and is expected to increase considerably.[1,3]

Although policy makers in Taiwan have reacted to the growing disease burden by releasing the country's first CVD roadmap,12 the burden of CVD will continue to rise as gaps still exist in government policies and plans for managing CVD risk factors. This is particularly important for hyperlipidaemia, which has shown the fastest increase in prevalence of all major risk factors in recent years.[6]

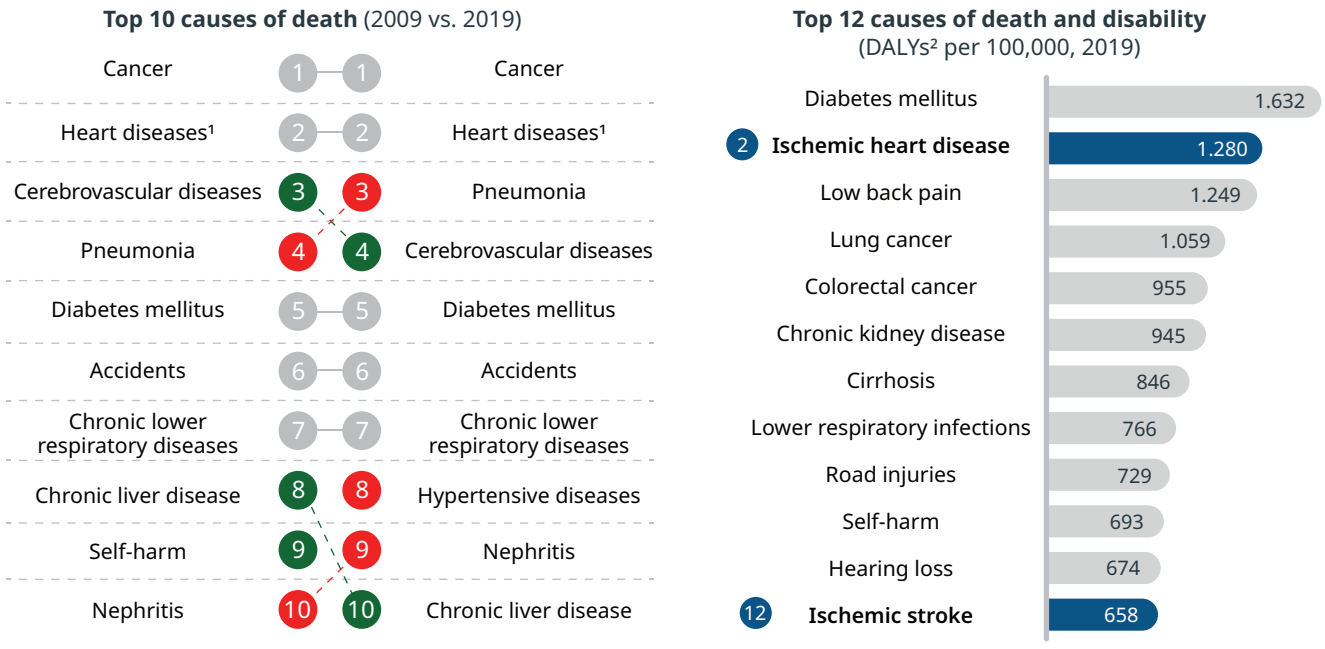
Unless urgent action is taken, the burden of CVD in Taiwan will continue to dramatically increase.[4,5] This white paper will explore the unmet needs associated with the growing burden of CVD and the potential solutions to address these challenges and avoid a future public health crisis. Potential strategies include CVD specific programs, improved treatment management and access to innovative, long-acting drugs.

What is the current state of disease?

ASCVD is increasing in prevalence and is among the leading causes of mortality and disability in Taiwan, resulting in a significant cost burden.[1-3] Spending on ASCVD is expected to increase substantially in the coming years, accelerated by the ageing population.[1,3-5]

CVD is a group of diseases that includes coronary heart disease such as ischaemic heart disease (IHD), and cerebrovascular disease such as stroke. Taiwan has seen a growing population of patients with CVD over the past

Figure 1: CVD is associated with significant mortality and disability in Taiwan



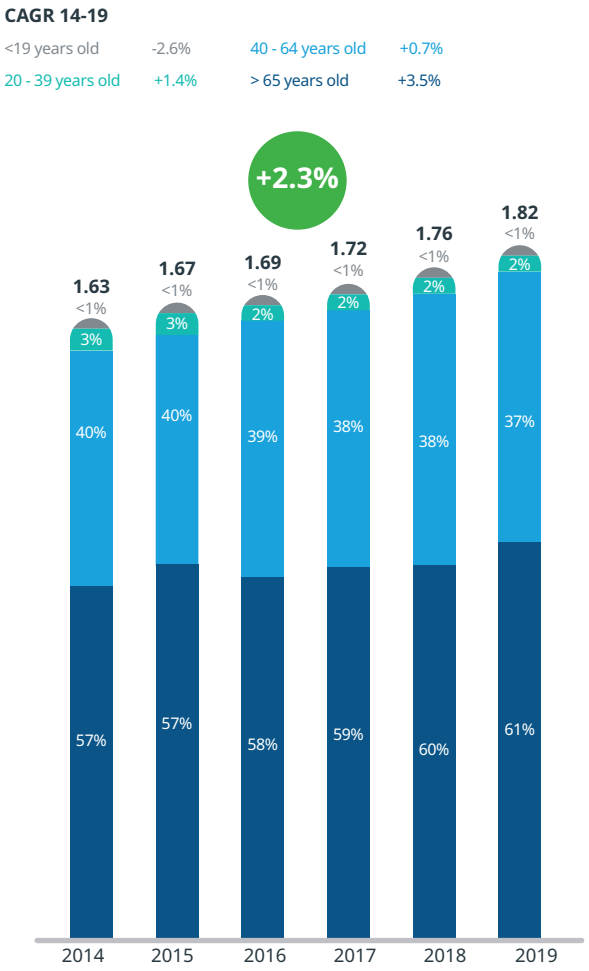
Source: Ministry of Health and Welfare Cause of Death Statistics, Global Burden of Disease

10 years, driven by ASCVD which constitutes 79% of CVD cases.[1] The prevalence of CVD is 7.7% in Taiwan, which is on par with other Asia Pacific (APAC) markets (China 7.8%, Japan 8.9%, Australia 7.6%) and mature countries such as the UK (7.1%).[1] Heart disease has remained the second leading cause of mortality over the last 10 years and ASCVD is among the top 12 leading causes of mortality and disability in Taiwan (*Figure 1*).[1,2] In 2019, IHD and ischemic stroke were the second and twelfth leading causes of death and disability, respectively (*Figure 1*).[1,2]

The considerable disability burden of ASCVD comes with a high price. The direct medical costs of CVD contribute significantly to NHI cost burden each year, with around 10% of NHI expenditure spent on CVD management, costing the government ~NT$63.8 billion in 2019.[3] Although spending is higher on other leading non-communicable diseases such as oncology (~NT$75.2 billion) and respiratory diseases (~NT$67.9 billion), the relatively faster increase in spending for ASCVD results in a substantial cost burden.[3]

What stands out in the ASCVD population in Taiwan is that most patients are ≥65 years of age (*Figure 2*), and this population has been growing faster in Taiwan than most other markets (3.5% growth in Taiwan from 2014 to 2019 versus 2.3% in Japan and 2.9% in Australia).[1] ASCVD impacts elderly patients more seriously in terms of mortality and disability. In 2019, IHD and ischemic stroke were the second and eighth leading cause of death and disability for the ≥65 years age group, accounting for 5,041 and 3,225 disability-adjusted life years (DALYs) per 100,000 individuals, respectively.[1] In contrast with the overall population in Taiwan, in which the DALYs for IHD and ischemic stroke are lower or similar to other markets (*Figure 1*), for the elderly age group, the DALYs are higher or on par with other APAC and mature markets such as the UK.

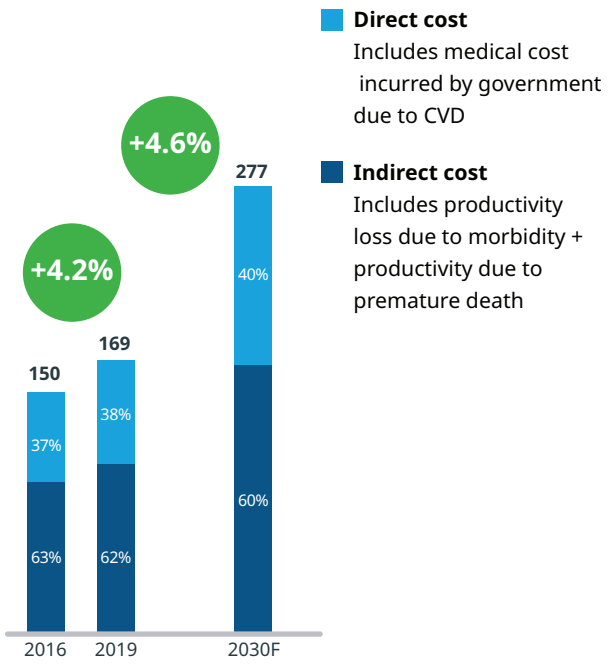
Figure 2: Estimated number of ASCVD patients in Taiwan by age group (million, 2014-2019)



CAGR, compound annual growth rate
Source: Global Burden of Disease

As a result of the significant impact on disability, ASCVD spending is largely driven by the ≥65 years age group; 59% of ASCVD spending was attributed to this group in 2019, with a growth of 6.2% from 2014.[3] Moreover, CVD is the disease area that incurs the highest spending among this age group, accounting for 15% of spending in 2019 and contributing to a significant cost burden.[3] As this is also the fastest growing age group, the substantial cost of CVD is expected to increase further. The economic burden of CVD was estimated at ~NT$169 billion in 2019, with indirect costs such as productivity loss due to morbidity and premature death constituting over 60% of the overall costs. Without action taken, the economic burden of CVD is expected to reach ~NT$277 billion by 2030, accelerated by the ageing population (*Figure 3*).[11]

Figure 3: Estimated cost of CVD including direct and indirect cost



Source: IQVIA estimation

These data highlight the significant disease burden that ASCVD poses in Taiwan, which is fuelled by an ageing population. Immediate action from the government is needed, while understanding the challenges associated with CVD in order to generate targeted solutions to tackle the growing disease burden.

The proportion of the population aged ≥65 years has doubled over the last 20 years, and Taiwan will soon enter a 'super-aged society' with 1 in 5 aged ≥65 years.[4,5] Taiwan is one of the fastest ageing societies in the world, and the burden of CVD will only increase unless immediate action is taken.

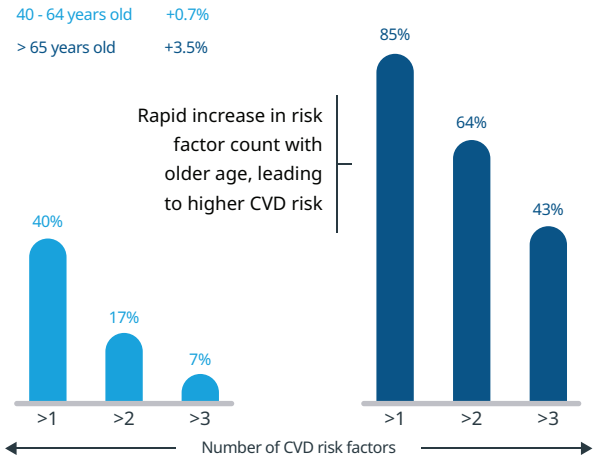
What are the key unmet needs?

Hyperlipidaemia has been deprioritized in current policies, resulting in poor awareness and treatment compliance, and loss in follow-up. This contributes to low diagnosis and treatment initiation rates, and sub-optimal disease control even among high-risk patients.[6-10]

Despite being largely preventable, CVD has been the top cause of global non-communicable disease-related mortality for decades, and is the result of many modifiable risk factors, such as hyperlipidaemia, hypertension, and diabetes mellitus.[13] All three risk factors increase with age, and hyperlipidaemia and hypertension have shown rising prevalence in Taiwan in recent years.[6] These risk factors are the primary drivers for cardiovascular (CV) events, and risk factor modification is a critical component in the reduction of CV deaths.[13] In addition to lifestyle modifications, medical interventions are required to manage these risk factors. Both primary prevention (preventing first CVD events) and secondary prevention (preventing second CVD events) are important.

The proportion of the population with risk factors for CVD rapidly increases with older age (*Figure 4*), therefore ASCVD prevention should encompass all major risk factors.[6] Strategies for prevention must also start early, as the duration of risk factor exposure is associated with CVD risk. For example, prolonged high cholesterol exposure leads to a higher risk of coronary heart disease (CHD),[14] there is an increased risk of CVD with earlier age of hypertension onset,[15] and increased duration of diabetes can lead to a higher risk of CHD and death.[16]

Figure 4: Proportion of population with risk factor by count (2017)



Source: Health Promotion Administration National Nutrition and Health Survey

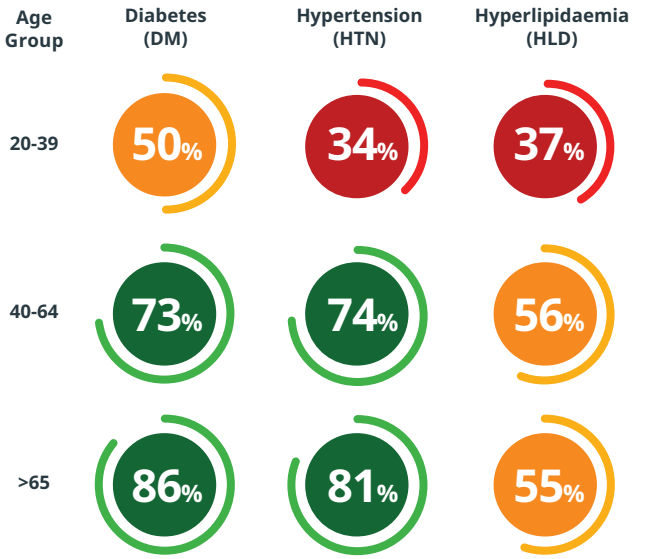
To address the increasing burden of disease in Taiwan, the first CVD roadmap (2018-2022) has been released by the Health Promotion Administration.[12] The aim of the CVD roadmap is to comprehensively prevent and treat CVD and reduce premature deaths due to CVD. The roadmap covers the major CVD risk factors and targets the higher-risk population as well as the overall population. Control rates of major risk factors (hypertension, hyperlipidaemia and hyperglycaemia) are included as key targets in the roadmap, in addition to increasing the utilization of National Health examination services and various lifestyle-related targets. However, there is room for improvement in better managing CVD risk factors across the patient journey. This is particularly important for hyperlipidaemia, which has shown the fastest increase in prevalence of all major risk factors in recent years.[6] There is currently no dedicated patient awareness initiative for hyperlipidaemia, which is instead embedded in programs for other risk factors. Furthermore, the CVD roadmap focuses only on control rates for hyperlipidaemia; in Korea, specific targets have been set for prevalence reduction, improving awareness and treatment rates. There is also less emphasis on hyperlipidaemia than other risk factors in integrated primary care and pay-for-performance programs, whereas countries such as the UK and Australia include cholesterol as a target or indicator for IHD prevention in such programs.

The key unmet needs pertaining to CVD management in Taiwan can be grouped into two categories: *awareness & diagnosis and treatment & continuity of care.*

AWARENESS AND DIAGNOSIS

There are relatively comprehensive lifestyle modification initiatives and programs to promote healthy living and awareness of CVD risk factors in Taiwan. Various programs have been introduced to improve diabetes and hypertension control through dedicated public campaigns such as “Family and Diabetes” and “Blood Pressure Measurement Month”. While these initiatives have fairly succeeded in raising awareness, there remains gaps in diagnosis of major CVD risk factors, especially among the younger age group compared to older age groups (*Figure 5*).[7]

Figure 5: Diagnosis rate of major risk factors (%)



Source: Follow-up investigation on hypertension, hyperglycaemia and hyperlipidaemia in Taiwan

Poorer diagnosis rates for the younger population could be due to a lack of awareness and urgency to screen for CVD risk factors, particularly hyperlipidaemia. Younger patients may have little awareness of disease severity and the importance of early intervention, which could be exacerbated by the fact that NHI-funded adult preventative health checks

are only provided to those ≥40 years of age. There are also limited screening programs dedicated to hyperlipidaemia compared to other risk factors such as hypertension, for which blood pressure measurement points are set up nationwide. Although the existing initiatives have achieved some success in raising awareness, the disparity between risk factors and age groups calls for a more targeted awareness program.

"Young patients perceive hyperlipidaemia and hypertension as something severe only for the elderly."

- Cardiologist, leading hospital in Taiwan

TREATMENT AND CONTINUITY OF CARE

The disparity between risk factors and age groups remains after diagnosis. Hyperlipidaemia has the lowest treatment initiation rate among all age groups versus diabetes and hypertension.[8,9] Failure to recognize 'bad' lipid levels leads to a high diagnostic threshold and healthcare professional (HCP) inertia to prescribe treatment. Furthermore, treatment may be delayed due to NHI regulations recommending ~3-6 months of lifestyle modifications prior to drug treatment. Lack of awareness of the severity of high lipid levels and the low perceived benefits of treatment among patients, especially without established CV events or symptoms, may also contribute to the low treatment rates. A 2018 hyperlipidaemia survey revealed that one-third of patients thought that hyperlipidaemia was not a serious condition, with ~70% believing that physical activity and diet control were sufficient to manage cholesterol levels.[9]

"Hyperlipidaemia is only discussed along with diabetes and hypertension, so there is relatively less public awareness."

- Ex-payer consulted as part of research

Even if patients do receive treatment, disease control rates are sub-optimal. For hyperlipidaemia, only ~50% of patients on treatment achieve optimal low-density lipoprotein-cholesterol (LDL-C) levels.[9,10] This is comparable to other risk factors such as diabetes (~42% on treatment achieve optimal HbA1c) and hypertension (~63% on treatment achieve optimal blood pressure).17,18 However, there is varying efficacy by risk group, with the lowest hyperlipidaemia control rate observed in the 'very high-risk' group (only ~22%), which comprises of patients with established ASCVD events.[10] Low control rates for hyperlipidaemia may be attributed to hesitancy to revise or increase dosage based on guideline recommendations, due to perceived side effects and poor medication compliance. A 2018 hyperlipidaemia survey found that ~30% of HCPs and patients were worried about adverse drug reactions.[9]

Another major factor contributing to poor LDL-C control is restricted access to novel, innovative treatments for the high-risk population due to strict criteria for reimbursement compared to international guidelines.[19,20] Paying out-of-pocket for treatment results in a high financial burden for patients that do not meet strict criteria.

Moreover, there is poor treatment compliance for risk factor management, caused by lack of effective patient follow-up and monitoring. Adherence and persistence are problematic, especially for hyperlipidaemia (~41% and ~57%, respectively) due to low perceived benefits of treatment and fear of side effects.[21] This leads to sub-optimal compliance even among higher-risk patients (secondary prevention), with adherence and persistence declining from 71% and 86% at 6 months to 47% and 50% at 2 years after treatment initiation, respectively.[22] This highlights the need for better CVD follow-up or access to a long-acting drug for these patients.

Case study 1: Improvement of current screening initiatives in Taiwan

A frequent health screening program encompassing all CVD risk factors and the inclusion of lipid screening in secondary check-ups for high-risk patients would be beneficial in Taiwan.

In Japan, population health screening covers all segments of the population and provides annual checks for all CVD risk factors, including blood pressure, glucose, and cholesterol. The main programs include employer-based annual core and secondary check-ups (Ippan kenshin) and annual specific health check-ups for those 40–74 years of age (Tokutei kenshin).

- Ippan kenshin: Items for core check-up cover all CVD risk factors. Free secondary health check-ups are provided for patients with high levels of CVD risk factors and doctors provide face-to-face consultations on reducing risk factors
- Tokutei kenshin: Items cover major CVD risk factors and specific health guidance is provided to higher risk patients

What are the potential solutions?

There is an urgent need for strategies and solutions to tackle ASCVD challenges and unmet needs along the patient journey, particularly for hyperlipidaemia. The solutions discussed below could enhance disease management and continuity of care, ultimately improving outcomes for patients with hyperlipidaemia.

AWARENESS AND DIAGNOSIS

To increase public urgency, interest, and awareness of CVD risk factors, current screening initiatives in Taiwan could be improved (*case study 1*) to tackle poor diagnosis of CVD risk factors. Moreover, the government can consider a more data-driven approach to identify undiagnosed or untreated patients (*case study 2*).

Case study 2: Data-driven approach to identify patients that are undiagnosed or untreated

Taiwan could improve early diagnosis and treatment by leveraging its existing patient records or screening data to proactively identify those that are undiagnosed or untreated.

Consider the National Health Service (NHS) in the UK, which has introduced CVDPREVENT as part of its long-term plan.23 This serves as a national CVD prevention audit, utilizing GP data to identify patients that are not diagnosed or not receiving optimal treatment.

Routinely held GP data covering diagnosis and management of high-risk conditions that cause CVD (including hyperlipidaemia, hypertension and diabetes) are automatically extracted to identify patients and offer optimal CVD management. The tool offers local and national reporting in real-time, allowing clinics and primary care networks to identify ways to improve patient outcomes.

Case study 3: HCP incentivization program

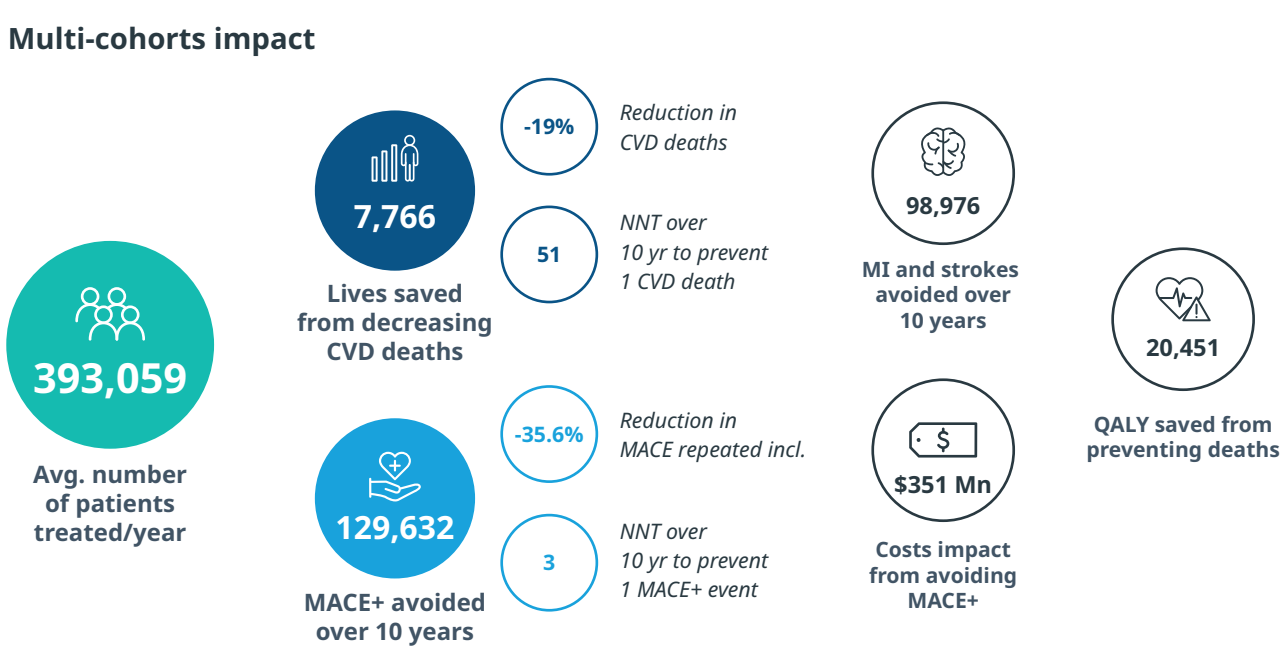
Existing HCP incentivization programs in Taiwan are disease-specific (e.g. diabetes pay-for-performance) and lack the component of integrated CVD care. To draw better outcomes, adopting targeted indicators within primary care programs could be considered. Implementing a program focused on holistic CVD prevention would also empower clinics and contribute to Taiwan's current initiatives to redirect patients to primary care facilities and avoid overcrowding at secondary and tertiary hospitals.

In the UK, the Quality of Outcomes Framework (QOF) introduced in 2004 is the best-in-class primary care pay-for-performance program, which incentivizes clinics based on assessment indicators such as primary and secondary CVD prevention.[25] Points are awarded to each practice based on their target achievements and financial incentives are paid accordingly. With a GP participation rate of ~99%, the program is highly effective in CVD prevention, resulting in an estimated saving of 11 lives per 100,000 patients with CVD per year.

TREATMENT AND CONTINUITY OF CARE

To improve treatment management and continuity for hyperlipidaemia, especially for the 'very high-risk' group, the introduction of an HCP incentivization program (*case study 3*) and availability of a long-acting drug with improved efficacy would be beneficial (*case study 4*). Modelling indicates that the introduction of a long-acting drug for effective LDL-C control could save 7,766 lives, 20,451 quality-adjusted life years (QALYs) and ~US$351 million over the next 10 years by avoiding major adverse CV events (*Figure 6*).[24]

Figure 6: Impact model output (calculated over a 10-year period)



MACE, major adverse cardiovascular event; MI, myocardial infarction; NNT, number needed to treat
Source: Impact model

Case study 4: Introduction of a long-acting drug to improve patient compliance

A long-acting drug with fewer side effects for the treatment of CVD risk factors such as hyperlipidaemia could potentially reduce treatment follow-up and monitoring frequency, as well as improve adherence.

Prolia (denosumab) is a first-in-class human monoclonal antibody indicated for the treatment of osteoporosis in post-menopausal women, which is administered by subcutaneous injection every 6 months. Amgen leveraged Prolia's longer duration of action and better side-effect profile to achieve improved adherence and persistence compared to a weekly oral bisphosphonate (alendronate). This resulted in recommendation by the Pharmaceutical Benefits Advisory Committee (PBAC) and reimbursement in Australia.[26]

Prolia was introduced to replace alendronate because it requires a lower frequency of administration, follow-up and monitoring (6-monthly), which helps to minimize hospital visits and drop-out of patients from osteoporosis treatment.

Call to action: what can be done now?

The government and policy makers will need to act with urgency to address the significant clinical and economic burden of ASCVD in Taiwan. With Taiwan's rapidly ageing population, this burden will increase considerably as long as gaps still exist in current policies for managing CVD risk factors. If no immediate steps are taken to address these challenges, there is a risk of a future public health crisis in Taiwan.

Actions that can be implemented now includes improvement of CVD policies or programs to increase awareness and diagnosis and improving treatment management to address key modifiable CVD risk factors (e.g., patient lifestyle, LDL-C control). These solutions are a mix of immediate and long-term strategies. Initiatives to raise public awareness and improve diagnosis will take more time to reap benefits, preparing the population against future disease burden. Meanwhile, innovative treatments and programs to help patients manage key clinical risk factors like LDL-C will serve as an immediate solution to tackle current challenges faced by the growing pool of ASCVD patients, while reducing the burden to the healthcare system. Potential solutions for the unmet needs associated with ASCVD must be comprehensive yet targeted, and inclusive of the general public as well as risk groups.

CVD is a costly disease, associated with significant disability and mortality. However, if government and policy makers in Taiwan are proactive in implementing CVD-specific programs and improving access to innovative treatments, the substantial burden of CVD could drastically reduce in the coming years. Modelling indicates that the introduction of a long-acting drug could save 20,451 QALYs and ~US$351 million over the next 10 years.[24]

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Appendix

Case study 1:

Population-based health check-up in Japan

Overview

- **Annual health check-ups** covering all segments of population
- **Main programs** include:
  - Employer-based annual core and secondary check-up (Ippan kenshin)
  - Annual specific health check-up for 40-74 years old (Tokutei kenshin)
- **Secondary screening for CVD risk factors** started in 2001 as part of Health Japan 21 initiative

Ippan kenshin

- Items for core health check-up cover all CVD risk factors:
  - Blood pressure
  - Blood lipid
  - Glucose
- **Free secondary health check-ups** for those identified with high levels of CVD risk factors (blood pressure, lipid, glucose and BMI)
  - In addition, doctors provide face-to-face **consultation on reducing CVD risk factors**

Tokutei kenshin

- Targeted for people aged 40-74, who are at **higher risk of developing CVD**
- Items cover major CVD risk factors including **blood pressure, lipid and glucose**
  - Specific health guidance is provided to higher risk patients

Takeaway

- Frequent health screening program **encompassing all CVD risk factors** including lipid
- **Inclusion of lipid in secondary check-up** for high-risk patients

Case study 2:

CVDPREVENT, UK [23]

NHS CVDPREVENT

Overview

- National CVD prevention audit tool to improve **early diagnosis and treatment** for those at risk of CVD
- Implemented as part of NHS Long Term Plan to **address undiagnosed or under-treated CVD population**
- Leverages Primary Care Networks (PCN) to **support primary care** in identifying number of CVD patients **potentially undiagnosed, under or over treated**

Mechanism

- **Automatically extracts routinely held GP data** covering diagnosis and management of six high-risk conditions that cause CVD:
  - Atrial fibrillation (AF)
  - High blood pressure
  - High cholesterol
  - Diabetes
  - Non-diabetic hyperglycaemia
  - Chronic kidney disease
- **Identify those undiagnosed or not optimally treated,** and offer optimal CVD management
- Offers **local and national reporting in real-time**, allowing practices and primary care networks to identify ways to improve patient outcomes

Takeaway

- Effective tool in **improving early diagnosis and treatment,** leveraging primary care data
- Taiwan can implement similar concept to **proactively identify** undiagnosed or under-treated patient population

Case study 3:

Quality of Outcomes Framework (QOF), UK [25]

NHS Quality Outcomes Framework (QOF)

Overview

- Comprehensive national **primary care** pay-for-performance and intervention scheme introduced in 2004
- Incentivizes primary care GPs for delivering interventions and achieving patient outcomes
- GP participation rate of ~99%

Objective

- **Empower primary care and improve quality of care** by remuneration
- **Efficiently manage chronic conditions** and major public health concerns through primary care
- Provide **primary and secondary preventive services** such as screening and blood pressure checks

Indicators/ Domains of QOF

- Clinical indicators cover over 20 chronic conditions including:
  - **Secondary prevention of coronary heart disease** (including cholesterol reading)
  - **Primary prevention of CVD**
  - Stroke and transient ischemic attack
  - Hypertension
  - Diabetes mellitus
- Points are awarded to each practice based on their target achievements and financial incentives paid accordingly

Outcomes

- Largest primary care empowerment program with **targeted indicators for primary and secondary prevention**
- **Highly effective in CVD prevention** with estimated saving of 11 lives per 100,000 per year

Takeaway

- Following UK, Taiwan can consider adopting targeted indicators within primary care programs to draw better outcomes

Case study 4:

Prolia (denosumab) [26]

Introduction

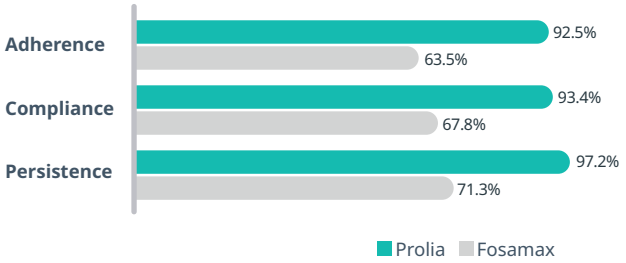
- Prolia (denosumab) is indicated for osteoporosis in postmenopausal women
- First-in-class human monoclonal antibody, administered subcutaneously every 6-month for osteoporosis

Outcomes for NHI consideration

- Proved its safety and clinical efficacy for osteoporosis
- Compared to bisphosphonates (Fosamax), Prolia has shown:
  - **Better side effect profile**
    (Fosamax commonly causes gastrointestinal discomforts)
  - **Longer duration of action**
    (Every 6-month for Prolia vs. weekly oral administration for Fosamax)
- Enhanced treatment outcomes through better patient adherence, compliance and persistence

Supporting studies

- Demonstrated benefits in treatment continuity through a **large-scale study** of 250 postmenopausal women
- This study has been included for reimbursement consideration in AU, CAN, UK as well as TW NHI



Results

- Approved reimbursement in view of **better cost-effectiveness** with its reduced side effects and **long acting nature that leads to better patient outcomes**

Takeaway

- This can be used as a case to push for replacing oral treatments associated with poor adherence and persistence with **long-acting injectable therapy**

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With thanks to the Novartis team for their contribution and collaboration in the development of this white paper.

About IQVIA Asia Pacific

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