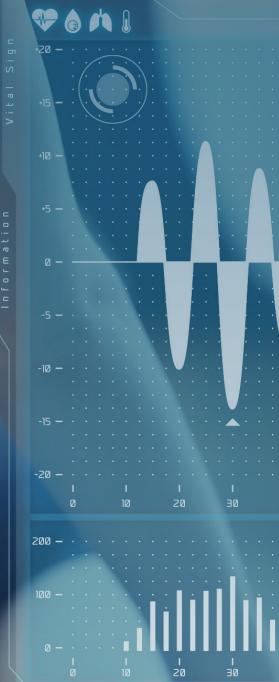
Digital tools for health and wellness in insurance





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Preface

With increasing lifespans in many OECD countries and rising medical and care costs, improving the health and wellbeing of policyholders is increasingly important for underwriting performance. Fortunately, there is growing evidence that chronic diseases can be prevented through healthier lifestyles and behaviours and by addressing key underlying behavioural risk factors, such as smoking, alcohol use, unhealthy diets and obesity, and physical inactivity.

Increasingly, digital innovations and technologies are providing tools for identifying and managing health and wellness-related risks and promoting health and wellness activities and better lifestyle choices. Wearable and mobile technologies with built-in sensors can monitor the activities of users and their physical, mental, and emotional states. Some applications provide tools for detecting disease or health risks by leveraging artificial intelligence and large user datasets. Personalised guidance and information on fitness, health, nutrition, and mindfulness are also being provided. Through the use of these tools, users are becoming better aware of their health and wellness, often leading to changes in their behaviour.

This report reviews the development of digital tools by the insurance industry to improve the health and wellness of policyholders. These tools are said to offer a win-win: better health for policyholders, and reduced claims for insurers. Many tools apply lessons from behavioural economics by seeking to influence policyholder behaviour and address short-term barriers to change; in particular, rewards and other incentives – and, in some cases, premium reductions – are provided to motivate or nudge policyholders to take actions – especially physical activity – to improve their health and wellness. The report identifies issues and challenges, such as data privacy and security, safety risks, data quality, and overall effectiveness, and relevant policy and regulatory frameworks. The report concludes with a number of observations.

This report was prepared by Timothy Bishop, under the supervision of Flore-Anne Messy and Serdar Celik, from the OECD Directorate for Financial and Enterprise Affairs. The report was developed under the programme of work of the OECD's Insurance and Private Pensions Committee and benefited from inputs provided by delegates and stakeholders through survey questionnaires. This report was approved for declassification by the Committee and was prepared for publication by the OECD Secretariat.



The OECD's Insurance and Private Pensions Committee (IPPC) has undertaken work on long-term care and health insurance in recent years. The IPPC prepared a stocktaking report in 2020 on <u>Long-term care</u> and health insurance, followed by a report on <u>Public and Private Sector Relationships in Long-term Care</u> and <u>Healthcare Insurance</u> in 2021. The 2021 report reviewed differences in the take-up of private long-term care and health insurance coverage across countries, with a view to understanding individuals' motivations for purchasing private insurance, sometimes over public healthcare, suggesting the ways in which private long-term care and health insurance serve to support health system needs.

With increasing lifespans in many OECD countries, improving the health¹ and wellbeing of policyholders by reducing the risk of disease, illness, and disability and mitigating their impacts is increasingly important for underwriting performance, especially as medical and care costs are expected to progress further alongside ageing populations. Fortunately, there is growing evidence that chronic diseases can be prevented through healthier lifestyles and behaviours, which reduce major behavioural risk factors for disease and illness such as smoking, alcohol use, unhealthy diets and obesity, and physical inactivity (see e.g. (OECD, 2019_[1]; OECD, 2021_[2]). About 27 percent of total health spending in the U.S. in 2016 could be attributed modifiable risk factors, and five risk factors in particular: obesity, high blood pressure, diabetes, dietary risks, and tobacco smoke (Bolnick et al., 2020_[3]). That said, avoiding certain habits and reducing behavioural risk factors may be a challenge for some individuals, given pre-existing conditions.

Meanwhile, digital innovations and technologies are providing tools for the prevention, detection, and management of health and wellness²-related risks ("digital health"), including through wearable and mobile devices ("mobile health" or "mHealth"). Wearable and mobile technologies are in particular suitable for monitoring individuals' physical activities (e.g. steps taken) and their physical, mental, and emotional states (e.g. heart rate, stress levels), information that may be used to identify and modify behavioural risks. These devices may collect health and related data, possess detection (or diagnostic) capabilities, and/or provide information and possible guidance on fitness, health, and mindfulness, allowing consumers to identify general health and wellness-related risks, take steps to address them, and monitor progress. These capabilities rely on, and generate, user data that enable the providers of these tools (e.g. technology companies, wellness companies, employers, insurers) to gather insights and improve their offerings.

Many insurers have seized on the fast growing digital ecosystem to launch digital tools designed to improve the health and wellness of policyholders, offering a potential win-win for policyholders (e.g. better health through prevention) and insurers (e.g. reduced claims). These tools may offer incentives to motivate or nudge users to take steps to improve their health and wellness; for instance, there may be reward plans offering discounted access to products and services linked to health and wellness (e.g. gym membership, healthy food, free mindfulness app), thus reinforcing policyholder efforts. Other insurer digital health tools may be more targeted in nature, seeking to tackle specific conditions, including through detection or health management (treatment, monitoring, and/or coordination of care).³

The OECD report on *Public and Private Sector Relationships in Long-term Care and Healthcare Insurance* already highlighted the services that insurers are offering to encourage prevention and risk mitigation, and their potential benefits. This development has extended beyond providers of health and long-term care insurance to include life insurance providers, who are seeking to increase the relevance of their products, particularly for a younger customer segment at ease with digital devices and tools.

The IPPC decided to examine the risk mitigation and prevention tools being offered by insurers to support health and long-term care and understand whether and how they are supporting policyholder wellbeing and insurer performance. In particular, the IPPC was interested in the digital means used to support these services, given the growing digitalisation of the insurance sector. There was also an interest in understanding how policy and regulatory frameworks might affect the provision of such digital tools, in order to assess the regulatory issues that may surround their integration into insurance products. Regulation and policy may play a significant role in determining if such services are provided and their scope, and this impact may convey lessons and insights regarding the appropriate policy approach.

Based on these observations and Committee directions, this report aims to understand:

- The types of digital tools being offered by insurers to promote health and wellness, as ancillary services to insurance products, and their potential benefits for policyholders and insurers; and,
- Key issues and challenges and how policy and regulatory frameworks may address them and influence the provision of such tools.

This report focusses on digital tools that are offered directly by insurers to policyholders (or indirectly by insurers to employees through employer group health insurance policies) and that are aimed at modifying policyholder behaviour through the provision of risk and wellness information as well as incentives and other mechanisms, such as personalised services. As noted, this effort at effecting behavioural change is enabled by the use of mobile health technologies that can gather data and monitor activity, and is inspired by behavioural economics, which is being applied in other areas of insurance (e.g. motor insurance and telematics). This approach means a de-emphasis on tools that simply enable interactions or transactions through digital means – such as appointment scheduling, consultations, uploading of claims documents, etc. The report also does not discuss digital health tools that insurers may be developing and promoting for use in the healthcare sector, but which are not directly linked to any insurance policies.

This report draws to a large extent from online surveys that were circulated to OECD member and nonmember regulators, as well as private health and life insurers.⁴ The regulatory survey had responses from 19 regulators, including sixteen OECD members⁵ and three non-OECD members.⁶ Eighty insurers provided responses to the industry survey and provided examples of tools that they were offering to their policyholders. The report also draws on desk-based research, which helped in identifying further examples of digital tools for health and wellness, as well as in clarifying relevant policy and regulatory frameworks.

This report is divided into three chapters. A first chapter provides background on the topic and describes a range of digital tools being offered by the insurance sector to improve prevention, detection, and management in the areas of health, wellness, and care. A second chapter outlines key issues and challenges and relevant policy and regulatory frameworks, notably for insurance, privacy and data security, and health protection and promotion. A final short chapter contains the main conclusions.

2 Promoting health and wellness through digital tools in insurance

2.1 Background

Challenges for the health, life, and long-term care insurance markets and loss drivers

Based on a survey of insurers from a number of OECD and non-OECD economies, which was undertaken for this report, one of the main challenges for health insurance and long-term care insurance was *rising costs*. For health care insurers, this might relate to the increased number of claims, rising medical costs, hospitalisations, drug costs, outpatient costs, visits and diagnostic treatments, and fraud and the provision of false information. Specific diseases are also impacting costs, such as neurodegenerative diseases, cardiovascular disease, oncological diseases, high blood pressure, and diabetes, as well as dental care. For some providers of long-term care insurance, elevated and unpredictable costs were seen as an issue.

The *pandemic* was viewed at the time as a concern for many insurers, with the situation depending on the spread of COVID-19 and the rate of immunisation. The large number of deaths associated with COVID-19 were raised by some life insurers as a concern. Mental health claims in relation to the pandemic were also noted by several insurers. Further, it was noted that the pandemic made it difficult for people to access specialist doctors and schedule routine examinations, While in-person visits declined, virtual care or digital health care access increased, including among specialists.

An *ageing society* is becoming a major factor in many OECD countries and also some non-OECD economies, and was reported as a cost driver by some insurers, for instance due to costs linked to chronic disease. Morbidity and disability were also reported as a rising trend by some insurers. *Competition* was also cited as a challenge by some health insurers in several countries.

Regulation was seen as challenging for some insurers, including limited freedom on tariff-setting for certain products, legal restrictions on the organisation and provision of medical care, difficulty in predicting changes to the public health system, lack of regulation relating to medical information, or new (EU-level) regulation for funding private health care providers. For one insurer, regulation was making the distribution of long-term care products difficult. Some insurers pointed to the need for *tax or other government incentives or subsidies* for the take-up of private health insurance and/or long-term care insurance.

The *number and quality of service providers* was seen by respondent insurers as an issue in a number of countries, including for instance insufficient long-term care facilities, insufficient number of doctors and nurses, difficulty in finding private health care providers, limited medical infrastructure, and shortages in long-term care in rural areas. For one insurer, the *lack of effective pre-contractual medical exams* was identified as a loss driver. Furthermore, while customers are willing to participate at the declaration stage, at the implementation stage only a negligible number decide to carry out preventive examinations.

The *low interest rate environment* at the time of the survey was considered to be a challenge for life insurers as pointed out by some respondent insurers. As discussed below, in some advanced markets, an *insufficient penetration of life insurance products* among the younger generation presents a challenge.

2.2 Moving beyond the core insurance function: provision of digitally enabled tools to support health and wellness

Against this backdrop, a growing number of insurance companies in the health insurance sector, and also in the life insurance sector, have been looking beyond their core functions of underwriting and claims management to include a strong focus on the health and wellness of their customers. This interest has led to the development of digital tools for policyholders aimed at reducing the risk of disease, illness, and death. These efforts reflect, in part, increased longevity, which can lead to extended health (physical and mental) and care issues for the long-lived and increase the need for health and long-term care solutions. They also reflect the prevalence of a number of chronic diseases, such as cancer, heart attacks and strokes, chronic respiratory problems, and diabetes, which are becoming more widespread in OECD countries but whose incidence could be reduced through improved behaviours and lifestyle choices.

Evidence suggests that chronic diseases can be prevented through healthy lifestyles and behaviours, and by addressing behavioural risk factors for disease and illness such as smoking, excessive alcohol use, unhealthy diets and obesity, and physical inactivity. Furthermore, dementia is strongly associated with lifestyle factors (Rizzuto D. and Fratiglioni L., 2014_[4]). Up to two thirds of all deaths in the US are substantially or primarily driven by behavioural choices, and thus can be prevented (Macarena C. García, 2016_[5]; Woon et al., 2014_[6]). OECD work shows that, in the next 30 years, obesity and excess weight will cause 220 million cases of chronic diseases in OECD countries. This will result in reducing the workforce by the equivalent of 18 million full-time workers (OECD, 2019_[1]). Poor behavioural choices can lead to impairment and disability, limiting work and social activities. By introducing tools that can address the behavioural risk factors for disease, insurers can potentially reduce the incidence and severity of claims while also bringing positive health outcomes for their policyholders, including possibly longer lives. It should be recognised however that habits or conditions such as smoking, excessive alcohol use, obesity, etc. are not always avoidable behavioural challenges. They can also be the result of diseases and are therefore not necessarily within an individual's control.

The growing adoption of innovative digital technologies and methods has provided a key enabling foundation for insurer digital initiatives in health and wellness – in particular mobile and wearable devices with sensors and software applications that can detect and monitor user conditions, track behaviour and activity, and offer information and analysis, in some instances leveraging machine learning and artificial intelligence. These technologies ease the gathering, monitoring, and analysis of health and wellness data, facilitate risk assessment and diagnosis, enhance communication on risks, support online interaction, and enable the delivery and tailoring of information, services, and tools, including possible incentive and gaming systems. Table 2.1 provides an overview of the main areas being targeted by insurer digital tools to promote health and wellness, with selected examples from the OECD industry survey and desk research.

Meanwhile, consumer acceptance and use of these innovations and technologies are increasing. Given the ease of use of mobile and wearable technologies and their monitoring abilities, consumers have become more aware of their own health and lifestyle, with an active segment seeking to modify their behaviours (e.g. by walking, standing up, meditating, following healthy recipes), prodded along by the devices and applications ("app"). Consumers are also more willing, especially among the younger generation, to interact through digital means, especially mobile phones and apps, although privacy concerns may still be a relevant consideration. Spurred by the likes of Apple Watch and Fitbit, smart wearable devices have become a mass-market product category (Montgomery, Chester and Kopp, 2018_[7]). For instance, 21 percent of US consumers regularly use a wearable device along with a mobile phone application to track their health and fitness activities, although use varies according to age, gender, socio-economic status, education, and race (Pew Research Centre, 2020_[8]).⁷ Finally, the experience with COVID-19 has also made people more conscious of their health and wellbeing and more receptive to interacting through digital means.

Health	Nutrition
 "Effective" age versus actual age Blood pressure Back pain Diabetes Pregnancy Cognitive impairment Long-term care support 	Diet planRecipesNutrition information
Activity and fitness	Wellness and leisure
Activity tracking (e.g. steps)Exercise	 Sleep Mental health Yoga Community volunteering

Table 2.1. Insurer digital tools to promote health and wellbeing: key areas with examples

Source: OECD survey

This growing consumer interest in health and wellness, facilitated by digital tools, has boosted the growth of a health and wellness industry and fostered the development of a new data-driven health ecosystem involving technology companies, health and wellness companies, corporations with employee health plans, and insurers (Calvert, 2020_[9]) There are over 350,000 health apps, although highly concentrated with 110 dominant apps (IQVIA Institue for Human Data Science, 2021_[10]). Recognising the relevance of this industry for their business, many insurers have launched digital initiatives. In order to do so, some insurers have developed their own expertise, including building new business lines (e.g. Zurich's WellCare (Zurich Insurance Group, 2020_[11])). Other insurers have partnered with selected external health and wellness providers to complement in-house services and tools. Meanwhile, some insurers have been approached by wellness companies, who have sought partnerships to access insurers' customer base.

Insurers providing health and long-term care insurance are well-placed to offer prevention tools given the potential synergies to be gained. By moving up the "health care chain" ahead of the insured event (i.e. onset of disease or illness), they can broaden health and wellness benefits to customers while potentially lowering claims (Figure 2.1). The role of private health insurance in the overall healthcare system may affect the level of interest of health insurers in offering digital health tools; where health insurers provide primary coverage, they would have a direct interest in controlling costs linked to non-communicable disease and illness and thus investing in related prevention tools for policyholders.⁸

At the same time, a number of life insurers have entered the field to provide these types of services, seeing them as a product differentiator and a means by which life insurance policies can be made more attractive to customers, particularly for a younger generation that may be less inclined to purchase such policies (Calvert, 2020[9]). For example, in the United States, for one major life insurer, such offerings represented a strategic response to growing policy attrition and provided an opportunity to engage with a younger generation that is more familiar with mobile technologies and more likely to engage directly through them.

The provision of incentives in the form of rewards, discounts, and other benefits (e.g. entries into prize draws), possibly including premium reductions (or premium rebates, increases in coverage) is often a central element in insurer digital tools aimed at promoting health and wellness (Hoad, 2020_[12]). These incentives are intended to encourage policyholders to opt into the wellness programme (typically optional and free) and change their behaviour. They aim to help users overcome potential short-term barriers and costs to behavioural change by motivating them toward attainable goals and rewarding them with goods and services offered as a gift or at a discounted cost. These rewards, such as gym membership, cash for the purchase of healthy food, or a free mindfulness app, can in turn provide health and wellbeing benefits. In some cases, premium reductions can be earned, lowering the cost of insurance for a policy, which may prove appealing for some customers who otherwise might not be able to afford the policy. In some wellness programmes, a tiered reward system may be in place to encourage sustained positive behaviour. As will be seen in Section 3.3, such reward systems tend to be found in the more comprehensive wellness programmes, with point systems and partnerships echoing the frequent flyer programmes from airlines.

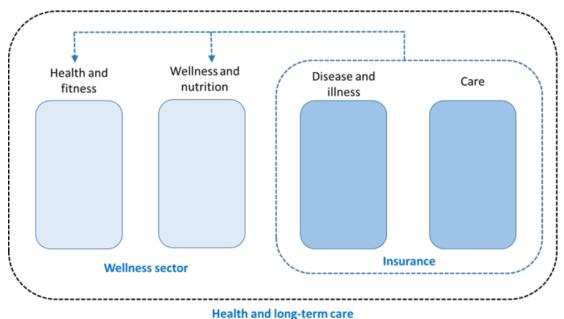


Figure 2.1. Moving beyond the insurance function toward the wellness sector

Source: OECD

This interaction between policyholder behaviour and policy benefits is seen as an example of "behavioural insurance" (Li Tan, 2020_[13]) by which insurers, through the use of monitoring tools and behavioural economics insights and data analytics (Harvard Business School, n.d._[14]), seek to modify the behaviour of policyholders for mutual benefit. This mode of insurance relies on the collection of personal data, so that behaviour can be monitored and improvements measured. In the wellness context, it seeks to encourage policyholders to develop healthier lifestyle choices by providing them with incentives and rewards as well as health insights and support so that illness can be avoided (Li Tan, 2020_[13]).

It has been argued that the provision of digital tools promoting health and wellness can bring benefits to policyholders and insurers, as well as society more generally. For policyholders, the advantages may be:

- Awareness of health, wellness, and disability risks and related preventive measures;
- Knowledge, tools, and services to help prevent the onset of medical conditions;
- Earning of potential rewards and discounts;
- Improved communications with health, wellness, and care providers and their insurer;
- The development of new insurance products, for instance by virtue of enhanced monitoring tools, enabling coverage or enhanced coverage of individuals with certain health conditions (e.g. life insurance for diabetics⁹), which would have otherwise not been possible; and, ultimately,
- Potentially improved health and wellness outcomes, and minimising time away from work.

For insurers, the benefits can include (Hoad, 2020[15]):

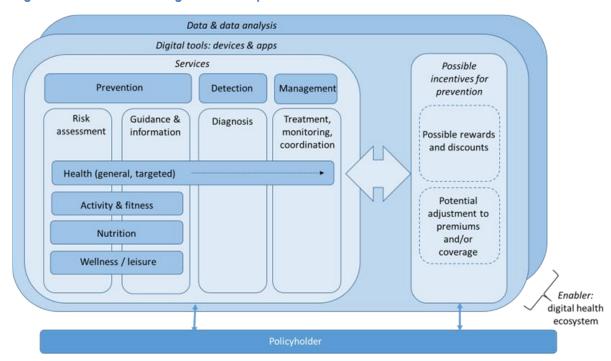
- For health and long-term care insurers, cost containment and savings through a possibly reduced claim incidence and severity;
- Enhanced data collection and analysis, leading to improved customer insights and potentially improved underwriting ability;
- Product differentiation and competitive advantage; and,
- Enhanced customer acquisition, engagement, and retention.

The anticipated improved profitability is expected to fund the provision of incentives that encourage behavioural change, creating a virtuous circle (Sumitomo Life, 2016_[16]). These mutual benefits are perceived by insurers as a "win-win" strategy for policyholders and insurers. Some insurers have also posited spillover benefits for society, for instance reduced pressure on healthcare or mental health systems and related budgets, and a healthier and more productive workforce.

Figure 2.2 on the next page provides an overview of digital tools offered by insurers to promote health and wellness – mainly in support of prevention – and the role of underlying data and data analytics in supporting healthier behaviours and offering potential incentives (possibly including premium reductions) designed to induce a behavioural response. Based on the examples collected to date (see Section 2.3), insurer digital tools are typically aimed at supporting health, activity and fitness, nutrition, and/or wellness and leisure, either on a stand-alone basis or involving some combination of these areas. There is generally a prevention component that may involve an initial risk assessment, followed by the promotion of healthy activity and lifestyle choices, coupled with the provision of general information to raise risk awareness and possible tailored guidance. For health-related areas, digital tools may also extend into disease or illness detection (or diagnosis), and/or disease or illness management (treatment, monitoring, and coordination of care), following the health continuum categories found in (Cohen et al., 2020[17]).

The successful provision of these digital tools depends critically on trust and respect for privacy, given the possible sharing of sensitive personal health data with the insurer (Hoad, $2020_{[15]}$). This data may be processed in a manner that could potentially run against the interests of policyholders, for instance through increased premiums. Moreover, there could be risks associated with the sharing of data with any third-party service provider with whom an insurer may have partnered (e.g. for diagnostic services, which may require large external datasets comprised of individual health data). In order to accept and use health and wellness-related digital tools, policyholders may expect to receive the assurance that their data will be adequately protected and not be used against them – that the use of their data will only be of benefit to them (Calvert, 2020, p. 8_[9]). While survey research in the United States suggests that the life insurance industry is better perceived in terms of health data protection than major consumer technology companies,

there is still a significant aversion to sharing this type of data with any major company, underlining the need for proper safeguards (Calvert, 2020, p. $8_{[9]}$).





Source: OECD

Whether insurers are successful in this space also depends on whether their digital offerings can credibly contribute to policyholder health and wellness objectives, in comparison with other (non-insurer) providers (Waddell, 2020_[18]). Insurance companies coming into this area need to build up the necessary expertise as well as develop analytical and AI tools, or otherwise partner with specialised third-party providers (Waddell, 2020_[18]; Hoad, 2020_[15]), For insurers, and depending on the scope of the services and tools provided, the elaboration of a suite of wellness, health, and/or care services may be a risky investment, with an uncertain outcome (Waddell, 2020_[18]), particularly given the need for policyholder acceptance.

In addition, the expected increased engagement with policyholders may raise expectations, particularly among those with whom they have successfully engaged, regarding the types of services and benefits they should be receiving, and the type of ongoing interaction – more dynamic, customised, and responsive – as they seek to adopt better lifestyles. Insurers must be aware of the new potential needs and expectations of policyholders as they embark on health and wellness strategies.

For life insurers, an added potential challenge is the network of agents and brokers, who may not be well placed to engage with policyholders on these new types of services and tools (Waddell, 2020_[18]). These agents and advisors would need to be properly informed of plans and likewise be well engaged, and be placed to understand their customers and their needs, which may not necessarily be a priority for agents and brokers (Waddell, 2020_[18]). Furthermore, the landscape may competitive, as policyholders may already be getting wellness advice from their health insurers or hospitals (Calvert, 2020, p. 12_[9]).

2.3 Insurer digital tools for health and wellness: examples

This section presents examples of insurer digital tools to promote health, wellness, and care. These examples are drawn largely from the OECD's industry survey but have also been identified based on desk research. A number of the examples have been made anonymous, to reflect the wishes of some survey respondents.

The presentation of the examples is structured in line with Figure 2.2. A clear distinction can be made between digital tools that provide a more comprehensive suite of offerings, involving some combination of services related to i) health, ii) activity and fitness, iii) nutrition, and iv) wellness, often accompanied by a reward system, and those services that are more targeted and aimed at one or perhaps two of the four main categories noted above, often without a reward system. In both cases, the services may be bundled with digital services unrelated to prevention or related incentives but which nonetheless facilitate interactions and transactions with health and insurance providers (e.g. appointments, consultations, uploading of test results, and insurance claim filings).

A. Comprehensive services and applications

Vitality programme for the life insurance industry: the examples of John Hancock (United S), a Japanese life insurer, and Discovery (South Africa)

Vitality is a wellness programme that has been offered across a number of countries, currently 40 markets and over 30 million members (Vitality, $2023_{[19]}$). A number of life insurance companies, such as AIA (Hong Kong (China)), John Hancock (US), Manulife (Canada), Generali (Italy), Ping An (China), and Sumitomo Life (Japan), have partnered with Vitality in order to offer wellness and health services to their policyholders. Vitality was created by Discovery, an insurance and financial services provider based in South Africa, which offers Vitality to its own policyholders. The Vitality wellness programme seeks to encourage healthier behaviours by addressing three areas that are expected to have a positive long-term health impact: nutrition, physical activity, and preventive screening (Vitality, 2023_[20]).

The Vitality wellness programme encourages its members to adopt healthier behaviours by providing risk information and incentives, and offering a wearable device that can be purchased at a discount. Members earn Vitality points based on their engagement with Vitality and for the carrying out of identified activities, such as reading health articles, walking, and going to the dentist (Manulife, n.d._[21]). Members reach different status levels based on accumulated points: Bronze, Silver, Gold, and Platinum. Each status level offers a suite of rewards and discounts, including premium reductions, which increase with the status level. Members receive personalised health goals and can log their activities through various digital means, including the web, mobile devices, and wearables (Sumitomo Life, 2016_[16]) (see Box 2.1 below for further details).

Box 2.1. Vitality: Risk assessment and data analytics for health

Vitality, a comprehensive, digitally based wellness programme used by a large number of insurance companies, follows a four-step approach to encourage healthier behaviour:

- 1. *Assess*: The first interaction with Vitality takes the form of a health risk assessment that involves a questionnaire on lifestyle behaviours and biometric markers, which is used to calculate the member's "Vitality Age", which shows one's effective age based on the data.
- 2. *Improve*: Based on the risk assessment, an individualised action plan is devised for the member, a "personal pathway" for a healthier life. Members are provided with knowledge, resources, and tools to enact change and stay healthy, including through a network of health and wellness partners that provide access to their services or facilities at a discount.
- 3. *Track*: Member actions are tracked through data, with data feeds integrated with network partners, such as gyms, food stores, and health screening providers. Data feeds are also secured through over 100 wearable devices, including Apple Watch.
- 4. *Reward*: Member activity is rewarded through Vitality points, which can be redeemed for incentives, including gift cards.

Source: (Eio, 2018[22])

For Vitality, key foundations for the programme are behavioural economics and clinical science, which in its view can provide a "new category of insurance", notably "shared value insurance" (Cokayne, 2016_[23]). Through the provision of risk information and incentives as well as dynamic risk pricing, policyholders can be incentivised to adopt healthier behaviours, generating benefits that can be shared by policyholders (improved health, and better product value through pricing and benefits), the insurer (better actuarial dynamics through lower claims, higher margins, positive selection, and lower lapses), and society (healthier society, improved productivity, and reduced health care burden) (Sumitomo Life, 2016_[16]).

Vitality asserts that lower claims are associated with the highly engaged Vitality members (Vitality, 2023_[19]). It points to the results of a study involving its membership base that demonstrate that Vitality incentives, combined with use of the Apple Watch, led to important and sustained improvements in activity levels, in particular an average increase of 34 percent, which for Vitality translates into an extra two years of life; within a year, further benefits were realised, such as improved blood pressure, cholesterol levels, and cardio-vascular fitness, and lower healthcare costs (Vitality, 2023_[24]; Hafner, Pollard and Van Stolk, 2018_[25]). According to Vitality, the programme has led to a 35 percent reduction in mortality among highly engaged members and a 15 percent lower policy lapse rate (McKinsey and Company, 2020_[26]).

Questions of fairness and selection bias have been raised regarding incentive-based health programmes: on fairness, whether people who are already healthy, due to genetics, benefit disproportionately from the programme; and, on selection bias, whether improved claims outcomes result more from healthier people who tend to participate in such programmes, reducing claims costs, as opposed to unhealthy sub-populations who are key cost drivers and may be less inclined to participate (Eio, 2018_[22]).

John Hancock (United States)

John Hancock, a US-based life insurance company, automatically includes Vitality as a voluntary option in every life insurance policy that it sells in the United States. The programme seeks to promote healthy living and longevity, addressing key areas of: 1) nutrition; 2) physical fitness; and 3) mental wellbeing (John

Hancock, n.d._[27]). John Hancock highlights the fact that many diseases affecting Americans are preventable through healthy lifestyle behaviours and points to the role of Vitality in incentivising behavioural change for long-term benefits. The company has stated that Vitality policyholders enjoy longer lives, between 13-21 years longer than other policyholders (BBC, 2018_[28]).

The basic version of the programme, called Vitality Go, which is free, enables, for those demonstrating healthy habits, discounts for fresh produce and healthy food items, as well discounts for wearable fitness devices. Access is also provided to recipes and nutrition experts, along with informational resources from the Friedman School of Nutrition Science & Policy at Tufts University. Furthermore, meditation and destressing exercises are provided. For a fee, policyholders can upgrade to Vitality PLUS, which unlocks access to additional rewards, including annual life insurance premium savings, a free Fitbit device or the Apple Watch at USD25 (with regular exercise), extra savings for healthy food shopping, more entertainment and shopping offers, a free subscription to HeadSpace (a meditation app), and large discounts (up to 50%) through a hotel booking site. Both the free and premium Vitality offering offer a tiered system of status levels based on accumulated Vitality Points.

John Hancock's venture with Vitality reflected an effort to change people's perceptions of life insurance, to make it more relevant for their lives and offer them the opportunity to lower their premiums as well as earn discounts and rewards. Furthermore, the combined offer of life insurance and Vitality is viewed as a dynamic, personalised insurance that rewards people for healthy living, allowing policyholders to invest in their future and their health, and not simply to secure family financial wellbeing. According to Vitality, Americans are 5 years older than they should be, based on their Vitality Age, suggesting the need for improvement in health and wellness behaviours (Philip, n.d._[29]).

Japanese life insurance company

A Japanese life insurer that participated in the OECD survey has also partnered with Vitality to provide a wellness and health offering ("Vitality Shared-Value Insurance") to their policyholders, giving them the tools, knowledge, and incentives to improve their health. The service is optional and costs a fee. However, policyholders who sign up with Vitality receive an upfront premium saving of 15 percent; this premium saving is maintained but they are subject to dynamic pricing -- insurance premiums can decrease, or increase – based on their efforts to improve or maintain their health.

Policyholders earn Vitality points, which determine their Vitality status, by doing health-promoting activities, such as participation in sports events, daily tracking of steps and heart rates with wearable devices or smart phones, and uploading of their medical exam results. The higher one's Vitality status, the higher the reward level and the larger the premium discount.

According to a survey conducted by the Japanese life insurer, 93 percent of its Vitality users have become more health conscious than before. Moreover, the average steps per day of its Vitality users increased by 17 percent.

Discovery (South Africa)

Discovery, an insurance and financial services provider based in South Africa, created the Vitality wellness programme as an innovation responding to the challenges of the South African health care system. The idea was that if policyholders could be made healthier, the insurance product could be more sustainable, conferring a competitive advantage while also benefiting policyholders and supporting the wider healthcare system (Gore, $2015_{[30]}$). It is argued that life insurance policies should not have a fixed price over one's lifetime based on an evaluation at a point in time (Gore, $2015_{[30]}$); rather, policyholders should be able to take steps to improve behaviours, change underlying risks, and obtain better pricing. Discovery Life was established in 2001 on the basis of this approach and became the leading provider of life insurance (Gore, $2015_{[30]}$). Vitality is also offered through Discovery Health, the Discovery Group's health insurer.

Discovery's Vitality Health programme provides rewards for enhanced physical activity, sound nutrition, and health checks and assessment, including through its Vitality Age diagnosis. Savings can be gained through affiliated fitness / gyms, health food stores, personal care items, fitness devices, holidays, and more. Also, Vitality Point can be earned to attain different status levels, starting from Blue then to Bronze through to Diamond (Discovery Vitality, $2023_{[31]}$). Rewards are adapted to one's stage in life and family situation. The higher the status level, the more rewards one can secure in potential premium savings and rewards. While the status level can be carried over, Vitality points are reset to zero every year, in order to sustain motivation over time.

Prudential and its Pulse health app in Asia, Africa, and the UK

Prudential, a globally active insurer based in the US, has developed a health application called Pulse that is available for free to consumers (and not just policyholders) in a large number of markets, including Asia, Africa, and the UK. Powered by artificial intelligence, the app provides functions such as a health assessment, a symptom checker, online consultation and, in the Malaysian market, a dengue alert (Fong, 2019_[32]). The app was developed through partnerships with third-party providers such as Babylon Health. The development of the app reflects a strategy on the part of Prudential to expand beyond financial protection through insurance to the prevention of illness and disease, and to develop relationships with consumers who are interested in the app and might later buy health insurance (Olson, 2018_[33]).

The app enables a health assessment through a 15-minute health survey with over 50 questions. The results lead to the generation of 3D anatomical view of your body, a "digital twin", showing the current conditions of one's organs, with information on, and the likelihood of, developing certain diseases and conditions, with a set of coloured graphs indicating the level of health risk to each organ. There is also a grade for mental health (Olson, 2018_[33]). Information on options for addressing the identified health risk is also provided. Further, the health app provides a virtual assistant to check symptoms in case there might be a need for a doctor; this AI-powered chatbot makes an assessment and determines whether a visit is necessary, and provides recommendations. This AI technology is licensed from Babylon Health, which has indicated that this function uses over 50 million data points to provide a diagnosis (Olson, 2018_[33]).

In addition, the app contains tracking and monitoring functions such as fitness, body mass, and vaccination status, as well as wellness features including on mindfulness and (in some countries) religion. There is a selfie function that can estimate your body mass index, biological age, and "skin age". The UK version of the app includes information on food and food tracking. There are subscriptions available within the app, such as Pulse Fit, which can include AI-powered health features (e.g. AI Exercise Buddy), and a Fitness Chanel for accessing fitness-related content. Other subscriptions services, like Pulse Gold in the Philippines, offer additional health and wellness features such as unlimited chat access and a one-time video consultation with a licensed dietician.

Zurich LiveWell: Brazil, Australia, and Spain

Australian LiveWell programme

Zurich Australia's LiveWell is a wellness programme that seeks to demonstrate that life insurance is about "living". LiveWell is provided to policyholders for free through an app (but they must opt in) and has three main pillars: body; mind; and community. The app encourages positive behaviour across these pillars. For health, the app enables the uploading of physical activity data from wearable devices and provides advice and personalised content on fitness, nutrition, and preventing ill-health as well as challenges and tools (Coverager, 2020_[34]; risk info, 2019_[35]; LifeInsuranceDirect, 2019_[36]). For mind, there is meditation guidance as well as mindfulness articles. For community, users are made aware of community events and volunteering opportunities, and can gain benefits from participating in them. LiveWell members have

access to a Loving Life tiered rewards programme that allows users to earn benefits from activity and have access to premium reductions and rewards from health and well-being partners across Australia.

B. Targeted services and applications

1. Health (general or targeted) and care

General: Grupo Nacional Provincial, Mexico (Cuida tu Salud)

"GNP Cuida tu Salud" is a prevention program offered at the corporate level for Medical Expenses policies, which through a series of tests called Tamizaje ("screening") allows to know the state of one's health and the risk or probability of suffering from chronic degenerative diseases, creating a culture of prevention within the client company, and providing a long-term follow-up that seeks to achieve cost containment and decrease the claims rate of the Major Medical Expenses policy.

A personalised diet plan, with a different menu each day of the week, is provided as part of the services, along with recipes and videos. Further, a full medical encyclopaedia is offered, along with daily notes, reports, and articles, with Facebook and Spotify pages available as well. The goal of the programme is to create a culture of prevention of sickness through healthy habits.

An additional cost is charged when the service is included in the corporate policy, although there is no extra cost at the level of the policyholder – only registration is required. The underwriting and pricing process are the same as for a policy without the service (the hypothesis is that the results of the program should improve the claims ratio). No data is collected. According to the insurer, consumers have not shown more propensity to buy when the service is included, although some employees have improved their health management with the information provided. The product is fully approved by the authorities.

General: Meiji Yasuda Life Insurance Company, Japan (Wellness activity report)

Policyholders can receive a "My Wellness Activity Report" that includes the possibility of their being hospitalised in the next ten years and potentially having a cognitive function impairment, as well as advice for maintaining and improving their health based on their health check-up results and medical big data of 1 million people. Policyholders can receive a refund depending on their annual health check-up results.

According to the insurer, policyholders who have seen the My Wellness Activity Report tend to have a 20 percent higher rate of becoming more health conscious than those who have not.

General: German health insurer

According to this insurer, through coaching and the use of tracking and telemedicine devices, policyholders get a better feeling about their illness and their body. Treatments can be initiated earlier and coaching targets a better lifestyle of chronic patients. Lifestyle factors like nutrition, physical activity, and mental health can be improved, leading to a better health status of chronic patients. Data is not collected due to data protection rules.

Biomechanics (back): Allianz Private Krankenversicherungs - AG, Germany

Allianz's digital service "Check my back" provides an uncomplicated online access for customers who suffer from back pain and enables a simple and clear overview of their pain. By answering six questions on medical risks, or so-called red flags, the pain is categorised into low-risk group and higher-risk group. Persons with back pain in the low-risk group receive individual recommendations and video tutorials with exercises to relieve their pain. If there are any risks, the customer receives personal advice, and a medical specialist will help to find an appropriate doctor. For this, the insurer has started a cooperation with "Berufsverband für Orthopädie und Unfallchirurgie".

At present, the service is not reflected in underwriting and pricing. although there is the hope that the service will decrease medical costs and help to stabilise insurance premium. The service does not track data due to statutory data protections. Therefore, it has not been possible to measure changes in behaviour.

The service has been implemented and is used by the insurer's customers but, due to the above, it is not possible, according to the insurer, to demonstrate any positive effect on the evolution of costs. However, the insurer has indicated that a positive effect on customer satisfaction has been found.

Blood pressure: Allianz Private Krankenversicherungs - AG, Germany

The digital service "Mein Blutdruck Coach" starts with a digital self-risk assessment to see whether there is a risk for high blood pressure. Depending on the results of the assessment, the customer will get a recommendation for action. This could be just advice to visit a general practitioner or it could be the offering of a personal coaching (by phone) by the company's partner. The customer has to measure his blood pressure regularly and track this in the app (results shared with the coach). The client learns how to manage his blood pressure and will get advice on lifestyle changes. If there are any problems with reducing blood pressure, the coach can refer the client to a specialist for a video consultation.

The programme also provides information about high blood pressure and prevention measures. Customers can listen to podcasts, read brochures, and learn how to measure their blood pressure correctly. Furthermore, they have access to a blood pressure passport, where they record their measured values every day and which provides an overview for the doctor.

Diabetes: Nan Shan Life Insurance Co., Ltd. Chinese Taipei

Nan Shan Life Insurance has developed a product that combines traditional health benefits with a blood glucose management service. This medical insurance policy is targeted exclusively to diabetic patients. With the service, policyholders can record diet activities, exercise, and blood glucose measurement results through the APP (Health2Sync). Once the blood sugar is well controlled, they can enjoy an insurance premium reduction. The app will message reminders and broadcast health education content to push customers to adjust their behaviours in real time.

This innovative "spillover" (or premium reduction) design is approved by the Financial Services Commission. Since the service is provided only after the contract is valid, it is not required to be reflected in the underwriting. In addition, this service reflects the cost and considers the possibility of a decline in the use of future health promotion benefits through pricing.

Pregnancy: German health insurer

Through the digital provision of information, videos, podcasts and checklists, a pregnant woman can inform herself in an independent way and obtain information from experts. According to this insurer, women who know more about the process of birth and the time of pregnancy have a healthier pregnancy and are less likely to have a premature birth. It is considered important to be able to offer support to pregnant women when no midwife can give classes (as was the case, for instance, during the COVID-19 pandemic).

Services are offered as an additional offer to potential customers, and are not part of the underwriting or pricing. The insurer only controls how many people use the digital service. Data protection is important; there are no plans to use the data for other uses. The insurer reports that women who have used the digital childbirth preparation course are having fewer premature births and caesarean sections.

Cognitive impairment: Meiji Yasuda Life Insurance Company, Japan

Policyholders can test cognitive functions such as ability of understanding, judgment, and logical thinking by playing mobile app games (Casual Brain Check). The possibility of cognitive function impairment is assessed together with the results of their health check-up. Policyholders are provided with an assessment in the form of a report.

Remote rehabilitation care: Polish insurer

For the duration of the insurance contract, the insurance company's Coordinated Medicine Center will arrange and cover the cost of remote or "e-rehabilitation" including: a) an initial visit (at the Coordinated Medicine Center or the policyholder's home), an assessment of the policyholder's rehabilitation needs, and the installation of the tele-rehabilitation system (control and tele-monitoring devices), with an explanation of its functioning; b) daily e-rehabilitation sessions (30 minutes duration) for 30 days under supervision of a physiotherapist; and c) a control visit and assessment of the insured's health condition and the identification of possible further rehabilitation needs.

E-rehabilitation is provided when the insured has the following conditions: 1) injuries that prevent independent movement; 2) strokes and other neurological diseases that do not allow for independent movement; 3) back pain / sciatica syndrome; and 4) heart attack. After paying a returnable deposit, the policyholder receives a tele-rehabilitation system (control and tele-monitoring equipment), which is needed for the implementation of physical and neurological rehabilitation.

Long-term care: Nan Shan Life Insurance Co., Ltd., Chinese Taipei

Through Home Angel, a matchmaking platform for hospital care and home care, long-term care insurance policyholders can look for support from professional caregivers via an app. Since the service is provided only after the contract is concluded, it is not required to be reflected in underwriting. Policyholders will use the app to look for professional caregivers; if they find one, they have to pay the caregiver.

There is no extra cost for the insurance company. Use of the service does not affect premiums. By analysing the records of whether policyholders are using the app or not during hospitalisation or during long-term care, Nan Shan Life can learn whether being taking care of by professional caregivers makes a difference. If the policyholders are taken care of by professional caregivers during hospitalisation, they may feel at ease in recovering and the number of days in hospital might be reduced. Being taken care of by professional caregivers under long-term care might reduce accidents or the incidence of complications, and lead to a lower hospitalisation rate. The service is provided through a cross-industry partnership and in accordance with regulations. No special approval was needed by the supervisory authority.

2. Activity and fitness

Chinese Taipei life insurer

A life insurer from Chinese Taipei offers a term health insurance product with an exercise "spillover mechanism". Policyholders upload activity records to the company's app through wearable devices. If the exercise reaches a certain level, policyholders can get a premium reduction. This service is reflected in underwriting and pricing. Effective exercise results have been collected during the policy period. In Chinese Taipei, products with spillover mechanism have been sold for a limited period. There is therefore not enough experience to show that policyholder behaviour has changed. No prior approval was required before selling this kind of product; however, information was submitted to the authorities for review afterward.

Chinese Taipei life insurer

A separate life insurer from Chinese Taipei launched a "Walker Health Incentive Project" in collaboration with Pokémon Go. It invited citizens to join the Project and walk 7,500 steps every day, with incentives provided; at the same time, the Walker Whole Life Insurance for Major Illness policy was developed alongside the public campaign. The policy provides services to promote the health of policyholders. If policyholders follow the contracted requirements through the app, which include walking regularly, taking physical check-ups, receiving vaccines, or screening for cancer, they can receive an extra insured amount of coverage or a premium discount as a reward. They can also receive rewards, including digital gifts and prize drawing tickets linked to weekly and monthly walking targets. Since the app also serves to manage the insurance policy, policyholders can submit certificates or relevant documents through the app.

The recording of exercise can be updated by the app through a wearable device or mobile phone. The life insurer has collected the exercise records and results of physical check-ups of policyholders. For the services related to vaccinations and cancer screening, which were launched later, data are more limited.

Since the regulatory authority encourages insurers to develop this kind of wellness product, use-and-file is allowed (as opposed to requiring prior approval). However, this service is new for insurers. The regulatory authority encourages insurers to develop such products by allowing the cost of service to be temporarily ignored and for the data to be accumulated for pricing.

German insurer

A reward programme is provided to encourage more exercise (fitness app) to prevent the long-term consequences of a lack of exercise. Policyholders have the option of downloading and registering. Points are collected for tracked sporting activities. Points can be redeemed for rewards (material rewards or discount vouchers). Only usage data (yes or no) are collected.

3. Wellness, including mental health and sleep

French insurer

For policyholders, there is the option of free access to various Novego (third-party provider) online support programmes. Novego supports people who want to prevent stress or who suffer from depression, anxiety, or burnout. Novego is an online-based support program that is tailored to the individual's situation and personal needs. The Novego programmes are accompanied by experienced psychologists, who reportedly are been tested by independent scientific institutes, and have been confirmed to be very effective. The insurer has reported that consumer wellbeing improved, reducing the costs of medical treatment.

German health insurer

The digital self-management tool treats light mental symptoms to prevent chronic mental illness and years of treatment by a psychotherapist. By offering a digital solution, the insurer can provide every policyholder quick access to medical help. In Germany, access to psychotherapists is difficult due to the high demand for psychotherapeutic treatment.

These services are not part of the underwriting and pricing process. In terms of data, only the way in which policyholders are using the self-management tool is being controlled. Data on policyholders themselves is not collected due to data protection rules.

The provider of the self-management tool offers two different versions, with one version offered only to partners. Different prices are offered.

Chinese Taipei life insurer

A life insurer from Chinese Taipei offers a term health insurance product that includes a "Healthy sleep" spillover mechanism. During a specified period, and based on activity levels uploaded to the company's app through wearable devices, policyholders can receive different premium discounts based on sleeping hours and sleep frequency. According to the insurer, medical research in Chinese Taipei suggests that adults with healthy sleep between 6 to 8 hours have better physical health than those whose sleep is too short (less than 6 hours) or too long (more than 8 hours). Given this research, this service is reflected in underwriting and pricing. Sleeping hour results have been collected during policy period. As mentioned earlier, in Chinese Taipei, products with a so-called spillover mechanism are relatively new. There is therefore not enough experience to show that policyholder behaviour has changed.

German insurer

Policyholders can use a digital self-management programme to deal with their mental health. Mental illness can be prevented or recognised through early help. Early help can be provided through a digital self-management tool or assistance to support the insured person to get an appointment quickly with a psychotherapist. At the moment, the digital service is used only as an additional offer to potential customers, and is not part of the underwriting or pricing process. The only data that is collected is the number of policyholders who are using the digital service. In terms of outcomes, the insurer reports that people who have used the self-management tool are less likely to need treatment by a psychotherapist.

2.4 Selected observations

As can be seen from the examples provided above, there is a wide range of digital tools provided by insurers, linked to their policies, that serve to support policyholders in achieving improved health and wellness outcomes. They do so by addressing, and seeking to reduce, behavioural risk factors in disease; however, they may also support risk assessment and, in some cases, enable some level of treatment and monitoring of disease and/or other types of ailments or injuries. These services are generally provided through mobile apps, which may in turn be aided by the use of wearables that provide a convenient means for measuring activity and performing other types of health-related monitoring.

From the research, it appears that many initiatives to develop health and wellness digital tools have been undertaken in the Asian region, whereas such tools seem more limited in other markets such as the EU. A number of regulator responses from the EU indicated that regulators were not aware of any health or wellness tools or services being distributed in their country as part of insurance policies, but noted that it is possible for them to not be aware of such offerings as there is no pre-approval process for insurance products or such ancillary services – they would be informed only if there is a complaint. Furthermore, for instance in the Asian region, there is some adaptation to local markets, reflecting local preferences, culture, and health and wellness risks in the population (e.g. rates of obesity). On the other hand, there is some commonality as some insurers are seeking to scale their wellness businesses globally and are often partnering with global wellness providers that offer digital health and wellness solutions to insurers.

As a general trend, insurer digital tools are often aimed at promoting general health and wellness behaviours which, by addressing behavioural risk factors, help to reduce the risk of key diseases. Some apps and tools may be more targeted at specific conditions, but will also serve as a prevention tool; for instance, a few tools serve to treat and monitor certain health or mental conditions. This overall focus on prevention may partly reflect governing regulatory frameworks for medical devices, which seek to regulate devices or software that serve to diagnose, prevent, treat, or cure specific diseases or conditions, but which may be more permissive regarding software or applications focused on general health and wellness activity (see next chapter).

While there is an overall tendency for insurer digital health and wellness tools to introduce some form of behavioural element, in the form of tracking and incentives aimed at encouraging behavioural change, it is more commonly seen in those apps that provide a fuller suite of services, from health and nutrition through to mindfulness, community, or other elements of health and wellness. From what can be seen, life insurers entering the wellness field are choosing to provide a full package of services and related rewards and benefits, perhaps due to the marketing benefit. Health insurers are offering (or are able to offer) a similar range of services for their group health insurance policies, but corporate buyers may seek a more selective and tailored approached, based on demonstrated benefits. Further research would be needed to understand insurer motivation, customer demand, and the wellness business model in these two markets.

A further observation in relation to this limited sample of examples is that, in regard to the more targeted apps provided by insurers, the fields of nutrition and long-term care are less represented as stand-alone apps. For nutrition, this absence could potentially be explained by the fact that it may be more difficult to monitor nutrition, for instance in comparison with walking steps, and to effect long-lasting changes in eating habits. Moreover, it may be more meaningful and cost-efficient to bundle the provision of nutrition information and advice with other wellness services.

COVID-19 brought greater reliance on technology in all aspects of life, which could have accelerated the general acceptance and widespread use of such medical monitoring tools. There is anecdotal evidence of app usage positively affecting behaviours, with some insurers reporting that their apps are well-received and some insurers reporting fewer claims as a result of the usage of their apps. However, there is no clear evidence based on what has been reported. Whether those changed behaviours are leading to reduced disease risk is less clear (Song and Baicker, $2019_{[37]}$; Cohen, $2021_{[38]}$) – a longer time period, with more accumulated data, may be needed to come to any meaningful conclusion.

3 Key issues and challenges and relevant policy and regulatory frameworks

The broader development of mobile health applications (mHealth), based on the use of mobile devices such as smartphones and wearables, raises a range of issues and challenges, such as data privacy and security, safety risks, data quality, and overall effectiveness. These types of issues can be expected to arise given the sheer quantity of mHealth apps that have been released, often with limited oversight and with varying quality. According to IVQIA, in 2020, over 90,000 digital apps were released, at an average of 250 per day (IQVIA Institue for Human Data Science, 2021_[10]). More specific issues may arise regarding the role of insurers as developers and distributors of these types of apps, such as insurer product approval and governance, fair competition, and underwriting.

An underlying issue is that mHealth apps tend to be consumer-centric, instead of targeting other end users, such as health care providers (see e.g. (Cohen et al., $2020_{[17]}$). This eliminates the vetting role of a third-party payor (The Geneva Association, $2020_{[39]}$), reducing the level of sophistication in the market and, by the same token, where regulation is absent, increasing the potential risk of harm – unless app developers hold themselves to a high standard of quality and opt to deliver services that are unlikely to cause harm. Yet developers may prefer innovation and speed to market, making rapid adjustments to their apps to test consumer responses and gain market traction (i.e. lean development). There is a high level of fragmentation in the market, with different evaluation frameworks to assess mHealth app quality, but none that is comprehensive (Henson et al., $2019_{[40]}$). Insurers seeking to develop digital tools and in-source the requisite expertise and tools may find it difficult to navigate the landscape. It has been argued that the insurance sector could support the developer community is critical; promoting developer guidelines and expertise (for e.g. for privacy, security) could help address some of the issues (Aljedaani and Babar, $2021_{[41]}$).

Existing policy and regulatory frameworks in many countries may, to some extent, be sufficient to address the challenges associated with digital health apps, including mHealth apps, and guide proper development. However, these frameworks may be challenged, or may be inadequate to address emerging risks related to mHealth apps. Examples include, in some countries, privacy and data protection legislation that may be incomplete or inadequate to address new risks. Meanwhile, regulatory frameworks may be evolving, for instance in the health sector, particularly in relation to regulation of software as a medical device. Policy and regulatory frameworks may affect the nature and design of digital health and wellness tools provided by the insurance sector, including the collection, processing, and possible sharing of data. This chapter seeks to identify key issues and challenges and relevant policy and regulatory frameworks that may affect the provision of digital tools, with illustrative country examples.

In order to gather information on some of the relevant policy and regulatory frameworks, a survey was circulated to delegates of the OECD's Insurance and Private Pensions Committee. There were responses from 19 regulators, including sixteen OECD members (Austria, Belgium, Chile, Colombia, Estonia,

Germany, Hungary, Japan, Latvia, Lithuania, Mexico, Poland, Portugal, Slovak Republic, Spain, United States), and three non-OECD members (Bulgaria, Chinese Taipei, Russia). It is worth noting that a number of jurisdictions indicated that insurers in their jurisdictions had not yet offered health or wellness-related services attached to their insurance products, while some other jurisdictions were not able, due to the nature of regulatory oversight, to determine whether these services were being provided or not.

3.1 Protecting policyholders

Key issues

A key – if not overriding – policy objective in the insurance sector is the protection of policyholders. The provision by insurers of digital tools for health and wellness raises a number of issues in regard to policyholder protection, in particular:

- Extent to which insurers can provide non-insurance services: There are generally financial sector
 rules governing the mixing of the provision of financial services with commercial business, which
 are intended to ensure that commercial risks do not spill over into financial activities, endangering
 an institution's prudential soundness. There are typically exceptions to allow for related or ancillary
 services to be provided, or to permit ownership of a related commercial business. Thus a key issue
 is the extent to which digital tools are supportive of the underlying insurance policies. Their role in
 promoting policyholder risk reduction can be an argument in favour of their permission.
- Consumer suitability: As a general matter, given the potentially complex nature of insurance
 products, insurers should assess whether new products and services meet customer needs, and
 ensure that customer outcomes are positive. This should in principle apply to any insurance offering
 as well as to any ancillary service or product. In this context, insurers need to carefully consider
 the design of their digital tools and ensure their suitability for the targeted consumers.
- Fair competition: The bundling of related products and services may bring synergies for consumers, but there is a risk of unfair competition if the provision of one product or service is tied to the sale of the other, or if one product or service is provided for free or sold at a below-market-price, serving as an inducement for the purchase of the other. Consideration needs to be given as whether the provision of digital health and wellness tools, if offered for free (despite the development costs), unfairly disadvantages other insurers who do not provide such offerings. There may also be a level playing field issue with other digital health apps that have no linkage with an insurance offering. For instance, the act of subscribing to an insurer app may in some cases generate a premium saving.
- Fairness and non-discrimination in underwriting: Digital tools might, for various reasons, including
 through extensive and detailed user data and related analytics, lead to underwriting decisions that
 unfairly penalise (or reward) certain classes or segments of policyholders, and which may not
 necessarily be justifiable on actuarial grounds, for instance for lack of data or evidence (or lack of
 data of sufficient quality). Such tools would also have to comply with prohibitions on certain forms
 of discrimination in underwriting.

As a general point, and in line with the <u>G20-OECD High-level Principles on Financial Consumer</u> <u>Protection</u>, insurers are expected to treat their customers equitably and fairly, provide adequate disclosure and transparency, protect consumer data and privacy, and establish adequate complaints handling, among other expectations. Many of these areas are typically addressed within the insurance policy and regulatory framework. The next section discusses the key elements of the insurance policy and regulatory framework that are relevant for insurer provision of digital tools for heath and wellness, while a later section discusses matters related to data privacy and protection, which are often addressed by other policy frameworks.

Policy and regulatory frameworks

Regulatory authority over the provision of ancillary services linked to insurance

Insurance regulatory framework may constrain the extent to which insurers can provide non-regulated services, such as digital health tools, alongside their insurance services and, if permitted, their provision may require an authorisation. Typically, in financial regulation, only services that are related to, or ancillary to, core financial services, and that support their effective delivery, are permitted to be offered by financial institutions. One reason for this constraint relates to the objective of ensuring a clear separation between financial and commercial-related activities, with financial service providers generally barred from providing or undertaking commercial services or activities, given the prudential risks that these may generate and also given the risk of confusion among consumers, who might believe that the regulatory framework and financial safety net cover these non-financial activities and/or that the services have been reviewed or vetted by regulatory authorities. Another reason is to ensure, within the financial sector, a proper segmentation of activities, in order to promote financial stability and/or prevent potential conflicts of interest.

Regulatory authorities generally have the power to circumscribe the types of ancillary services and products that might be offered with an insurance product. This power may reside in an *ex ante* review procedure of insurance products or ancillary services or *ex ante* power to impose restrictions on the linking of ancillary services to insurance. Alternatively, it may stem from an *ex post* authority to ensure the protection of consumers and policyholders once a non-insurance service or product has been made available to the market.

Table 3.1 on the next page outlines the nature of the restrictions and controls that might be imposed on the provision of ancillary services. There may be a specification, in legislation or regulation, of the types of ancillary services that can be offered by an insurer; otherwise, there may a general freedom to provide such services, subject to a few explicit limitations. An ex ante approval process may be in place and thus involve a consideration of the appropriateness of ancillary services; absent such a process, regulatory authorities may have the power, if problems arise, to conduct an *ex post* review once an insurance product – and related ancillary service – have been distributed in the market. Whatever the specifics of the regime, regulatory authorities have the mandated authority to protect policyholders and consumers and have the necessary powers to protect their interests, by imposing restrictions or prohibiting services outright.

Many jurisdictions – and notably EU jurisdictions – do not require any advance review or approval of ancillary services. This flexibility may be linked to regulatory objectives of promoting innovation and competition. However, the introduction of ancillary services, such as risk prevention services, must comply with governing legislative and regulatory frameworks, which may introduce constraints or conditions, notably to protect policyholders.

In the European Union (EU), relevant EU legislation (Solvency II, Insurance Distribution Directive (IDD)) does not require an approval process for insurance products. An insurance undertaking may engage in the classes and subclasses of insurance activities for which the insurance undertaking holds an authorisation. While there is considerable flexibility in EU regulation regarding the ability of insurers to offer ancillary services and products, Member States nonetheless have the power, under the IDD, to maintain or adopt stricter measures, or to intervene on a case-by-case basis to prohibit the sale of insurance together with an ancillary service or product, if they can demonstrate that such practices are detrimental to consumers.

		Restrictions (if any) on ancillary services that can be offered with insurance			
		Specified limitations of services that of	n the types of ancillary can be offered	Generally no specified limitations on the types of ancillary services to be provided	
		Pre-approval for provision of such services needed	No pre-approval for provision of such services required, but scope to review and ability to restrict or prohibit	but ability to restrict or prohibit	and restrictions for certain insurance contracts
Insurance product approval	Product approval process			Chinese Taipei	
process (if any)	No product approval process	Canada	Japan Mexico	Chile EU countries	Germany (for cost-of- illness insurance)

Table 3.1. Restrictions on ancillary services that can be offered by insurers

Source: OECD survey

In Germany, certain additional non-insurance services are permitted to complement cost-of-illness insurance contracts (with costs). The cost-of-illness contract of insurance may cover additional services directly linked to the coverage of medically necessary treatment due to sickness or as a result of an accident and for other agreed services, including expenses associated with pregnancy and childbirth, as well as outpatient medical check-ups for the early diagnosis of diseases in accordance with statutory programmes. The legislation specifies the additional services that can be included in the content of cost-of-illness insurance contracts, which include the provision of advice regarding those services and the providers of the services. If the conditions in Germany's *Insurance Contract Act* permitting the provision of these ancillary services as part of cost-of-illness contracts are not met, then the service would not be allowed by the supervisor. For instance, assistance services such as an initial interview to determine a need for assistance, or to enable visits to authorities or errands, would qualify and could be included.

In Chile, for some insurers, there is an explicit requirement to provide health prevention services as part of a minimum policy benefit. Under current law, private insurance companies called Instituciones de Salud Previsional (ISAPREs) are obliged to provide a series of minimum benefits, such as examination of preventive medicine (regulated by the Law on Guarantees in Health). In addition, other additional services such as prevention campaigns are offered. It is possible that other countries may impose similar requirements on insurers to provide certain benefits to policyholders that aid in health prevention.

In Spain, while there is no approval process for insurance products or ancillary services, in the process of authorisation for the conduct of health insurance, where an undertaking intends to guarantee the provision of a service, the insurer must provide indications and justifications of its capacity to organise and provide such services, with an explanatory report needing to be provided to this effect.

Other jurisdictions have indicated that they do not require any pre-approval for the provision of ancillary services, nor for insurance products. In Chile, for instance, while there is no product approval process, the Financial Market Commission (CMF) must keep a Policy Deposit available to the public that contains all

the model texts of general policy conditions and clauses that may be used by insurers when contracting insurance. The CMF has the power to ban a product or service ex post in case it is not compliant with established regulatory and legal parameters; if such a case were to arise, an insurance company could replace the rejected product with one that meets the requirements.

Mexico does not impose an approval process for ancillary services, but the scope for providing them is strictly delimited. In Mexico, insurers are strictly limited to the business of insurance and generally cannot engage in commercial activities. They are nonetheless permitted to offer a narrow scope of ancillary services, notably assistance services, which are considered to be aimed exclusively at supporting the sufficiency of resources for the fulfilment of insurance obligations. Assistance services can include: assistance in travel or transfers; home assistance; emergency medical assistance; and legal and administrative assistance. These services do not tend to use digital means as of yet. The most common examples of assistance services in Mexico are medical advisory services and assistance programmes, telephone medical guidance, emergency ambulance, nutrition guidance, and psychological care, among others. Any assistance regulator, the Comision Nacional de Seguros y Fianzas (CNSF), supervises these services to ensure that they comply with regulation and has the power to revoke a product if there is non-compliance.

In Japan, services that are attached to insurance products are not subject to the product approval foreseen in the *Insurance Business Act*, as long as they fall within the scope of permitted ancillary activities. However, given that insurers are increasingly providing new types of ancillary services, when an insurance company plans to provide a new service that is attached to a specific insurance product, the Financial Services Agency (FSA) assesses, as part of product approval, whether insurers have appropriate measures in place so as not to harm the interests of policyholders. Services that are attached to insurance products, and at the same time are subject to FSA's assessment in the product approval process, are interpreted as ancillary services if they are highly related to insurance cover and are provided together with insurance benefits before and after insured events happen.

By contrast, some jurisdictions impose an explicit approval process for the provision of ancillary services by insurers. Such an approval may be integrated with an existing approval process for new insurance products. For instance, in Chinese Taipei, insurance companies may launch a new type of insurance product only after applying for, and receiving prior approval from, the authorities. If an insurance product with services attached to that product meets the criteria of "new-type insurance product", then the insurer must apply for approval from the Financial Supervisory Commission (FSC). Ordinarily, in the product review process, insurers are required to provide empirical statistics to facilitate premium rate analysis, in order to prove that the premium product rates are adequate, reasonable, and fair. The FSC has relaxed this requirement in order to encourage the development of innovative health management insurance products with risk prevention services and a premium reward system; in particular, the FSC amended its regulations to specify that when there are no reliable statistical data regarding the measurement of costs incurred by providing an incentive mechanism (e.g. premium discount, rebate, or increase in the insured amount) within a health management insurance product, such incentive mechanism could be excluded from certain product review requirements (such as quoting data from 3 to 5 years for the rate analysis). In addition, in order to encourage insurers to properly control risks related to health management insurance products, the FSC has required insurers to have preventive measures (Financial Services Commission (Chinese Taipei), 2018[42]). The main points considered by the FSC in the product review process relating to insurance products with risk mitigation and prevention services are: (i) such services attached to the insurance product must be "positively" related to the insurance protection; and (ii) the effect of such services is "continuous", and not maintained over only a short period of time.

Alternatively, the approval process for ancillary services may follow a different route, not being connected to any product approval process. In Canada, insurers are permitted, with the consent of the Minister of Finance, to conduct specified additional activities related to financial services or insurance, including the

provision of safety and risk prevention services respecting risk management and claims adjustment, where the provision of these services is reasonably ancillary to the business of insurance carried on by the insurer, and the provision, more generally, of any other activities that are reasonably ancillary to the business of insurance carried on by the insurer.

Special case: active support for risk prevention services for health, wellness, and care

Some countries are actively encouraging the development of risk prevention services for health, wellness, and care. For instance, in Japan, the FSA has sought to support the efforts of financial institutions to assist those afflicted by dementia with innovative financial products and services that are friendly to elderly people and people suffering dementia. The goal is to improve financial inclusion among diverse groups of the population, including the elderly, and to ensure users' convenience and a sense of safety.

In Chinese Taipei, the FSC considers that, where health self-management tools and insurance products are combined, premium discounts or services can be offered as incentives for policyholders to exercise or maintain a healthy diet, thereby lowering the risk of illness and achieving prevention. For the FSC, this not only promotes the health of citizens, but also indirectly reduces the medical expenditure of society as whole and insurance claim payments, and drives the development of related industries. The FSC amended regulations in order to expand the in-kind payments that insurers could provide, to include health management tools (Financial Services Commission (Chinese Taipei), 2017_[43]). It also, as noted above, relaxed review standards for the incentive mechanism for health management insurance products, and promoted risk control measures.

Fair competition: restrictions on policy rebates and the provision of non-insurance benefits

There may be restrictions on the ability of insurers to provide, separately from the insurance contract, any benefits that could be considered to be a rebate on the policy or the provision of some other form of benefit or in-kind payment. The purpose of such restrictions is to promote insurer solvency and fair competition, and to prevent unfair discrimination among policyholders (see (Willkie Farr and Gallagher, 2021_[44]; Cooley, 2020_[45])). For instance, in the United States, the National Association of Insurance Commissioners (NAIC) <u>Model Unfair Trade Practices Act</u> (UTPA) defines as unfair trade practice the offering (or offering as an inducement), separately from the policy, of "any rebate of premiums payable on the policy, or any special favour or advantage in the dividends or other benefits thereon, or any valuable consideration or inducement".

Work within the NAIC in recent years led to the revision, in 2021, of the UTPA¹⁰ to permit the offer or provision of value-added products and services at no or reduced cost when they relate to insurance coverage and are primarily designed to satisfy specified goals, which include, among others: (i) enhancing health; (ii) incentivising behavioural changes to improve the health or reduce the risk of death or disability of a customer; (iii) monitoring or assessing risk, identifying sources of risk, or developing strategies for eliminating or reducing risk; and (iv) providing loss mitigation and loss control. At the same time, the revisions require that, in the offering of providing such products and services, the cost to the insurer for any given customer must be reasonable in relation to his or her premiums or insurance coverage for the policy class. Further, the availability of the value-added product or service must be based on documented, objective criteria and be offered in a manner that is not unfairly discriminatory. The revisions also enable insurers to offer or provide non-cash gifts, items, or services, or to conduct raffles or drawings to the extent permitted by law, as long as they are limited in value and are not offered in a manner that is unfairly discriminatory – these provisions would be relevant for insurer reward systems.

In the EU, there are cross-selling restrictions on ancillary services and products. According to the EU Insurance Distribution Directive (IDD), when an insurance product is offered together with an ancillary good or service that is not insurance or an insurance guarantee, the insurance distributor (insurance undertaking

or intermediary) must inform the client that they can purchase the different components of the package separately.

Consumer suitability: product governance and oversight

There may be requirements regarding internal procedures surrounding product governance and oversight procedures. For instance, under the <u>EU Insurance Distribution Directive</u>, insurers need to maintain, operate, and review a process for the approval of each insurance product, or significant adaptations of an existing insurance product, before it is marketed or distributed to customers. This internal approval process needs to specify an identified target market for each product, ensure that all relevant risks to the identified target market, and take reasonable steps to ensure that the insurance product is distributed to the identified target market. Such product governance and oversight requirements were cited by some EU countries as being relevant for any decision by an insurer to introduce risk prevention tools for health and wellness as part of an insurance policy.

Fairness and non-discrimination in underwriting

The use of digital tools for health and wellness, and underlying collection and processing of policyholder data, raises the prospect that insurers might use this new information for underwriting purposes, and in particular for the setting of premiums and coverage, decisions that might unfairly penalise (or reward) certain types of policyholders. Such decisions may not necessarily be justifiable on actuarial grounds, for instance for lack of data or evidence (or lack of data of sufficient quality), and may be based on flawed or biased tools. For instance, it has been recognised that the algorithms used to power artificial intelligence (AI) in health analytics ((n.a.), 2020[46]) as well as the sensors themselves (Colvonen et al., 2020[47]) may contain biases, and diagnostic tools may generate errors.

In addition, any premiums reduction benefits may accrue to young, healthy, and active individuals who adopt the digital tools, even if the long-run effectiveness of such tools remains to be proven, effectively disadvantaging those who do not participate – and who may not be in good physical condition. Furthermore, and depending on the jurisdiction, there might be a shift to dynamic, granular risk pricing in life insurance based on one's health and mental status, drawing on indicators from the wearable or app, which would involve a shifting of the risks assumed by life insurers back to policyholders, as (non-term) life premiums are generally fixed at the outset of the contract, following a physical examination.

At this stage, the lack of widespread adoption of digital tools by insurers provides a barrier to such practices, given data limitations. Further, perceptions of poor data quality in wearable devices could limit the usage of such data in underwriting decisions, and regulators may have concerns about insurers relying on data that may not be accurate. To date, practices generally suggest an asymmetric approach; that is, a premium reduction may be provided as a reward for physical activity, but penalties are typically not applied to those who have not undertaken such extra activity, or where generated data might suggest the need for an upward adjustment. That said, some insurers (including in the OECD survey) have indicated that premiums could be raised (or the premium rebate reduced).

Discrimination in underwriting may lead to financial exclusion. Accordingly, in some jurisdictions, there may be restrictions on the ability of insurers to discriminate among policyholders of the same class and facing equivalent risks. Any premium differentiation must be justified on actuarial grounds. Also, a number of jurisdictions prohibit certain forms of discrimination based on certain attributes or risks. For instance, in the EU, insurers are not permitted to take into account the policyholder's gender as an actuarial factor in determining the insurance premium. In Slovakia, insurers are required to respect and strictly follow applicable rules related to the prohibition of discrimination based on age, gender, or religion. In Japan, an insurer must take measures to ensure that it does not use information of individual customers regarding their race, creed, family origin, registered domicile, health and medical care or criminal records, or any

other special non-disclosure information that the insurer handles in the course of business for any purposes other than those deemed to be necessary for ensuring proper operation of the business in accordance with Article 53-10 of the Ordinance for Enforcement of the *Insurance Business Act*.

In Spain, discrimination due to HIV/AIDS or other health conditions is prohibited, and the denial of access to hiring, the establishment of contracting procedures different from those normally used by the insurer, or the imposition of more onerous conditions, due to having HIV / AIDS or other health conditions, are prohibited, except those that are founded on justified, proportionate, and reasonable causes, which have been previously and objectively documented.

In Belgium, the decision by a policyholder to decline the use or purchase of an Internet-connected device that collects personal data on his or her lifestyle or health cannot result in the insurance being refused, or becoming more expensive. No segmentation in terms of acceptance, pricing, and/or scope of coverage can be applied based on whether the prospective insured agrees to purchase or use an Internet-connected device that collects personal information about his lifestyle or health, or to share the information collected by such an Internet-connected device, or based on the insurer's use of such information.

In the United States, under the NAIC UTPA, insurers cannot apply or permit unfair discrimination between individuals of the same class and of equal life expectancy (in the case of life and annuity policies), or of essentially the same hazard (in the case of accident or health insurance policy). This may impact the ability of US insurers to provide premium discounts as part of a wellness rewards package.

3.2 Privacy and data security

Key issues

Due to their sensors and diagnostic and monitoring tools, health-related wearable and mobile applications generate large amounts of data and information that can be processed and analysed to assess risks, monitor behaviour, and provide specific guidance. The data and related analytics can be granular and very personal: physical, mental, and emotional states and conditions; behaviours; and location data. Such data are valuable for a wide range of parties whose interests may not be fully aligned with those of users. Stakeholders such as clinicians, employers, health insurers, data brokers, marketers, and litigators have an interest in accessing and processing this type of data (Brinson and Rutherford, 2020_[48]) For instance, marketers are keen to capture daily routine and location data from wearables (see (2018_[7])).

When shared with third parties, these data can be combined with personal information from other sources, raising the risk of discriminatory profiling and manipulative marketing, not just for the users of the mobile health apps but also for groups and society as a whole, through algorithmic decision-making and profiling (Montgomery, Chester and Kopp, 2018_[7]) Profiling could be especially damaging, potentially affecting one's employability, credit rating, or ability to access rental housing (Parker et al., 2019_[49]) As part of the monetisation strategies of some apps (not necessarily those of insurers), data are shared with digital marketing systems, such as Google Ads (2018_[7]). For instance, a review of the top 20 health and fitness apps revealed that most were sending information to more than 70 third-party companies (2020_[48]), Such sharing may be for commercial purposes unrelated to use of the app (Parker et al., 2019_[49])

The sensitive nature of health and other data collected through health-related wearable devices and mobile applications, and potentially serious repercussions should such data fall into the wrong hands or be misused, highlight the importance of privacy and data protection and security issues. Personal health data¹¹ are regarded by consumers as one of the riskiest types of information, which they are least likeliest to share (Brinson and Rutherford, 2020_[48]). Concern about privacy is the main reason why users of wearables and mobile devices are reluctant to share their health and fitness data (Brinson and Rutherford, 2020_[48]), and it has been an key obstacle to more widespread adoption of wearables. A Deloitte study from

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2021 indicated that when users subscribe to a service that provides reports on their health and fitness based on device data, their privacy concerns rise considerably, relative to simple use of fitness features (Deloitte Insights, 2021_[50]). Consumers seeking to obtain reduced insurance rates and other monetary rewards through a voluntary wellness programme would have to be willing to share data. Fortunately, compared with typical consumer apps, health-related apps, and especially medical ones, are much less likely to collect personal data; furthermore, they tend to have fewer interactions with advertising and tracking services (Tangari et al., 2021_[51])

Data generated by a user on a wearable or through an application on a mobile phone do not belong to the user but rather belongs to the device manufacturer or to the app developer, highlighting the importance of privacy policies and proper legal safeguards to protect user privacy. One study examining privacy policies in mHealth apps found that many apps in the health and fitness category had no privacy policy (roughly 36 percent), with a lower percentage for apps in the medical category (17 percent) (Tangari et al., 2021_[51]). Depending on the jurisdiction, an adequate legal framework for data privacy may or may not exist (see below). In the United States, rules surrounding the use of data collected by devices and health applications are not clear or well-defined, leaving some gaps (Brinson and Rutherford, 2020_[48])

Given the sensitivity of personal health data, data integrity, protection, and security are critical. However, mobile applications are more vulnerable to attack as data are transmitted in and out of a device over external networks (Aljedaani and Babar, $2021_{[41]}$) Studies suggest most health-related mobile applications have not adopted adequate mechanisms to protect health data. Developers may not properly implement basic security measures, such as authentication and encryption of data on the device and in data transmission (Aljedaani and Babar, $2021_{[41]}$) Table 3.1 illustrates some of the challenges facing developers in preparing secure mHealth apps:

Challenges for mHealth app developers in ensuring secur	ity
Lack of security guidelines, regulations, legal requirements or lack of compliance	;
Developers' lack of knowledge of and expertise with secure app development	
Lack of involvement of stakeholders during app development	
No or little attention by developers toward the security of apps	
Lack of financial resources	
Time constraints during app development process (e.g. "rush to market")	
Lack of security testing during app development	
Lack of motivation and ethics	
Lack of engagement with security experts during app development	

Table 3.2. Challenges with developing secure mobile health apps

Source: (Aljedaani and Babar, 2021[41])

Policy frameworks

Privacy and data security

Given the importance of privacy for personal health data, policyholders using insurer digital tools for health and wellness need to be assured that their personal health data will be collected only as necessary, and with their informed consent,¹² and used for their intended purpose, while being properly and securely protected, given the potentially damaging ramifications of health data being shared with others, or publicly released for instance through a data breach. Furthermore, user confidence depends on the assurance that the data they provide will not be used against them, for instance through future increased premiums or reduced coverage, should the data indicate a higher insurance risk. It is not known whether insurers have raised premiums or reduced coverage directly as a result of the use of an insurer's health or wellness app; however, insurers have reduced premiums or increased coverage as an incentive to participate in an app or as a reward for healthy activity – the adjustment tends be asymmetric in nature. Some insurers (including in the OECD survey) have indicated that premiums could be raised (or premium rebate reduced).

In EU countries, the process of data collection and data processing must guarantee the full application of the *General Data Protection Regulation* (GDPR). GDPR also affords a higher level of protection for private health information. It specifies that the processing of personal data concerning health is prohibited, subject to certain exceptions. Personal data concerning health include all data pertaining to the health status of a person that reveals "information relating to the past, current or future physical or mental health status of the data subject".¹³ An exception is if the data subject has given explicit consent to the processing of this personal data for specified purposes, unless EU or national law provides that the prohibition cannot be lifted for a data subject.¹⁴ This means that EU insurers seeking to collect health data via apps and other digital means must obtain the explicit consent of the policyholder for the indicated purposes or, if there is a national (or EU) prohibition, no such data collection is permitted.

In Austria, for instance, under the *Insurance Contract Act*, personal health data may only be collected by insurers for the purposes of assessing or administering an insurance contract or assessing and fulfilling contractual claims, if it is provided by the insured or damaged person itself, by third persons where the person concerned has given his or her explicit consent, by doctors, hospitals or other health facilities for the assessment and fulfilment of claims where the concerned person has given his or her explicit consent, or by using other data to which insurers have legally gained access. This information is subject to the specific confidentiality protection provided by the *Insurance Supervision Act 2016* and to sanctions in case of infringements. Data has to be deleted immediately as soon as it is no longer held for a lawful purpose (*Insurance Contract Act*).

In Estonia, the *Insurance Activities Act* sets specific data protection requirements to insurers. The processing of data concerning health is permitted when: 1) the insurer is required pursuant to law to enter into an insurance contract; and 2) it is otherwise required for determining the obligation of the insurer for the performance of the insurance contract. In addition, insurers are subject to a confidentiality obligation when data becomes known to the insurer in the course of insurance activities and relate to the personal data, economic situation, and business or professional secrets of a client. The shareholders, managers, and employees of the insurer and other persons who have access to the data must keep the confidentiality of the data for an indefinite period of time.

In Mexico, the *Insurance and Surety Institutions Law* states that the information insurers obtain from applicants must be kept strictly confidential, used for lawful purposes and the protection of public interests, but it does not specify the information that should be excluded for underwriting purposes. Meanwhile, Mexico's *Personal Data Protection Law* has a general application; it refers to the confidentiality of data owned by third parties and aims to protect personal data, regulate its treatment, and guarantee privacy and the right of individuals to control the data. Information that may reveal sensitive aspects such as racial or ethnic origin, present and future health status, genetic information, religious, philosophical and moral beliefs, union affiliation, political opinions, and sexual preference is considered to be sensitive and thus must be collected and processed in a legal manner, with the personal data to be treated in accordance with what the parties agreed to, under the consent of the owner. In the case of clinical records, secondary regulation of insurance supervision mentions that, when insurers authorised to operate health insurance provide the services with their own resources, they (or their service providers) must comply with the requirements established in the Official Mexican Standard on clinical records. When the policyholder requests it, insurers must ensure that its providers transfer a clinical summary to the institution or provider indicated by it, keep the confidentiality of the case, and comply with the minimum legal requirements.

In Chile, legislation includes the *Protection of Privacy Law*, which regulates the processing of personal data in registers or data banks by public bodies or individuals, and the *Rights and Duties of Patients Law*. Under the *Protection of Privacy Law*, which includes health data, the processor of data and provider of services cannot use sensitive data for purposes other than those specified in the contract, an obligation that does not cease with the expiry of the contract. The *Law on Rights and Duties of Patients* regulates the use of information treated by public and/or private health services. Information from clinical records and other documents where procedures and treatments are recorded can only be accessible to personnel involved in the care of patients and to other identified persons and institutions.

3.3 Health protection and promotion

Key issues

One of the main concerns that has arisen amidst the proliferation of health-related apps relates potential safety risks for consumers. While the tools and information provided by health-related apps can provide potential health benefits, they can present harm if they are inaccurate or unreliable, as consumers may rely on the information to make health-related decisions (Akbar, Coiera and Magrabi, 2020_[52]). Examples of quality problems include incorrect information, incomplete information, variation in content across apps, incorrect outputs, and inappropriate responses to consumer needs (Akbar, Coiera and Magrabi, 2020_[52]). For instance, melanoma risk assessment apps have under-diagnosed the risk of skin cancer, while blood alcohol concentration (BAC) apps have overestimated BAC levels by roughly three times. Also, there may be software problems, such as gaps in features, lack of validation of user input to prevent errors, delayed processing, and delayed response to health dangers.

While physicians may benefit from the use of health-related wearables and mobile apps, given the scope for collecting data between patient visits, there are also concerns within the medical profession about data quality. The reason for the concern is that the devices are not subject to the same oversight and standards (and legal liabilities) as normal medical devices (see discussion below); doctors may thus be sceptical and reject the data. For medical devices, clinical trials and regulatory oversight help to support data quality and validity as well as transparency and compliance (Deloitte Insights, 2021_[50]). Physicians appear to be uninterested in monitoring information obtained remotely (MedTechDrive, 2021_[53]). This perceived unreliability of data emanating from wearable devices may limit the ability or unwillingness of insurers to base underwriting decisions on such data, amongst other possible reasons.

A key issue relates to the effectiveness of health-oriented wearables and mobile apps. To date, there seems to be limited evidence of the long-term effectiveness or usage over a number years (Heidel and Hagist, $2020_{[54]}$) or of sustained changes in behaviour, particularly among higher risk groups, such as the elderly, sick, or poor (The Geneva Association, $2020_{[39]}$). Studies suggest some benefits for physical activity ((n.a.), $2019_{[55]}$), and some evidence of positive behavioural change when incentives are provided ($2020_{[39]}$). Gamification and nudges have had mixed results ($2020_{[39]}$); for instance, one study found that general messages on the importance of an activity were more impactful than specific reminders, which might have been seen as intrusive. The fact that wearable devices tend to be worn by the young and healthy, and not by the sick and elderly, introduces a self-selection bias. Those in poor health or with a chronic illness appear to lose interest in the technology when constantly reminded about their condition, and being pressured to be physically active (Heidel and Hagist, $2020_{[54]}$).

From a broader perspective, public policy interventions may be capable of generating greater impacts in addressing the risks of non-communicable diseases. For instance, the OECD conducted a return-on-investment analysis of a number of interventions to tackle obesity, examining the impact on health, healthcare expenditure, workforce productivity and, because of this, impact on GDP, while considering the costs. One of the interventions considered was upscaling mobile app-based interventions to promote a

healthier diet and an active lifestyle. While promoting an app-based intervention had a positive net impact (the cost of implementing mobile apps is about 40 percent of the benefit in terms of percentage change in GDP over 2020-50), population-wide interventions such us food labelling, menu labelling, and mass media campaigns produce the largest health gains and largest savings in health expenditure (OECD, 2019[1]).

Policy framework: regulation of medical devices

Software as a medical device (SaMD)

A key source of regulation for health risk prevention services provided digitally relates to the regulation of medical devices. The purpose of such regulation is to protect public health and patient safety. It has been recognised by regulators that software and software applications may effectively provide the same types of functions and outputs as physical medical devices, and have been regulated accordingly. This is known as "software as a medical device" (SaMD), defined by the <u>International Medical Device Regulators Forum</u> (<u>IMDRF</u>) to be "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device".¹⁵

The regulation of medical devices, including SaMD, is generally based (but not necessarily exclusively) on the *intended purpose* of the device, including in software form (Ludvigsen, Nagaraja and Daly, 2021_[56]). If the purpose of the device is to prevent, diagnose, treat, or mitigate a disease or illness, then it is generally regulated as a medical device. The <u>International Medical Device Regulators Forum (IMDRF)</u> has come up with key definitions, a framework for risk categorisation, the quality management system, and clinical evaluation of SaMD, with the goal of promoting greater convergence of approaches. Any software that is regarded as a medical device is subject to a variety of requirements, including for instance for risk management and quality management.

In the EU, software which is intended to process, analyse, create, or modify medical information may be qualified as a medical device software if the creation or modification of that information is governed by a medical intended purpose. Software that is captured by the definition is subject to regulation as a medical device (see Box 3.1 on next page).

There is a recognition in some jurisdictions (e.g. EU, United States) that apps that are focussed on general wellness or healthy lifestyle and are not seeking to diagnose, prevent, or treat any specific diseases or conditions, and that present a low risk, do not need to be regulated as medical devices, although there may still be regulatory oversight and discretionary intervention, depending on the exact nature of the application and its intended objective and usage. Although many health and wellness apps developed by insurers would appear to fall into this general wellness category, insurers should be aware of the relevant regulations, not only for compliance reasons but also given the need to manage reputational risks as they extend their services beyond the realm of pure insurance.

The United States has for instance taken measures to clarify the status of products, hardware, or software, whose intention is to support general wellness, with no clear medical intention, but which might nonetheless potentially be found to be subject to medical device regulation, with its various requirements. In particular, the Food and Drug Administration (FDA) has developed guidance regarding a provision that was introduced into the *Federal Food, Drug and Cosmetic Act* (FD&C Act) in 2016 to provide a carve-out for software that is intended "for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition" (Food and Drug Administration, 2919_[57]). Software meeting this definition is not considered to be a medical device.

Box 3.1. EU Medical Device Regulation (2017/745)

Definition of "medical device"

Definition

'Medical device' means "any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means." (from the Regulation, Article 2 ("Definitions"))

In short, any software "which is intended to process, analyse, create or modify medical information may be qualified as a medical device software if the creation or modification of that information is governed by a medical intended purpose" (EU Guidance MDCG 2019-11; see below).

General requirements

Requirements for medical devices include:

- Labelling
- Safety and performance, including a risk management system, ensuring of repeatability, reliability and performance in line with intended use (for software), and a clinical evaluation
- Quality management
- Pre-market notification and inclusion within in an EU database on medical devices (EUDAMED)
- Traceability by means of a unique device identifier
- Post-market surveillance
- Financial mechanism to ensure compensation for defective products

Examples

Excluded

 "Simple search", which refers to the retrieval of records by matching record metadata against record search criteria, or to the retrieval of information, does not qualify as medical device software (e.g. library functions).

Included

- Medical Device Software (MDSW) smartwatch app, which is intended to send alarm notifications to the user and/or health practitioner when it recognises irregular heartbeats for the purpose of detecting cardiac arrhythmia.
- MDSW intended to measure and transmit blood glucose levels, calculate insulin dose required, and drive the insulin pump to administer the calculated dosage (closed loop insulin delivery system).

Source: Regulation (EU) 2017/745 and MDCG 2019-11: Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR, New EU Rules to Ensure Safety of Medical Devices.

The FDA guidance provides further clarity to the carve-out, which applies to general wellness products. A general wellness product is defined as a product: 1) whose intended use is to encourage or maintain general health or a healthy activity; or 2) whose intended use relates to the role of a healthy lifestyle in helping to reduce the risk or impact of certain chronic diseases or conditions, and "where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition" (Food and Drug Administration, 2919, p. $2_{[57]}$) The former category refers to products that make claims regarding the improvement of functions related to a "general state of health" (e.g. weight management, physical fitness, relaxation or stress management, mental acuity, sleep management) but do not make any reference to diseases or conditions, either in terms of reducing their risk or living well with them, in which case such claims should be generally accepted, substantiated through peer-reviewed scientific literature or official statements made by professional health organisations (Food and Drug Administration, 2919, pp. $4-5_{[57]}$).

This guidance would suggest that, in the United States, there is fairly broad scope for insurers to provide health and wellness apps without being subject to the general requirements of medical device regulation. The objective of these apps must be to promote general state of health or healthy activity or, if the app points to the role of a healthy lifestyle in helping to reduce the risk of certain diseases and condition (or to live with them), this claim is well understood and accepted to be true based on peer-reviewed scientific literature or official statements from professional health organisations. Insurers seeking to develop apps in the United States with the objective of diagnosing, preventing, mitigating, or treating certain diseases or conditions (e.g. obesity, eating or anxiety disorders) will likely be subject to medical device regulation (Food and Drug Administration, 2919, pp. $3-4_{[57]}$).



This report has highlighted the interest among many insurers to complement their offering of insurance protection for life and health care risks with digital tools designed to support the health and wellness of their policyholders, with a view to providing a more comprehensive offering of wellbeing protection. Insurers have been able to tap into the fast-growing digital ecosystem to develop these tools and address some of the behavioural risk factors for disease, often involving incentives and other mechanisms designed to encourage sustained changes in behaviour.

The report has compiled a range of examples of insurer digital tools that have been developed to support healthier and more balanced lifestyles and/or to prevent or possibly address specific conditions that policyholders may face. The report benefited from industry input given the difficulty of finding specific information on these tools. Meanwhile, input from regulators helped in identifying some key elements of the regulatory framework, complemented by information gathered on the health sector.

Based on this report, a number of conclusions can be made:

- Introduction of a new dynamic into insurance: The development of digital tools to promote health and wellness introduces a new dynamic into insurance, based on new technologies and behavioural economics. Through the provision of incentives, policyholders are encouraged to take steps to improve behaviours in order to achieve improved health outcomes, a shared interest of both policyholders and insurers. This approach mirrors other insurance industry initiatives designed to modify policyholder behaviour, such as the use of telematics in automobile insurance.
- Promotion of general wellness and activity often the intended objective of applications, although uncertainty on sustained changes in behaviour: There is a wide variety of tools that can be deployed, depending on the objectives of the insurer, as well as its lines of business, expertise and resources, and the local market. That said, there is strong tendency for insurers to introduce a strong prevention component into their digital offerings, by promoting general wellness and activity. Despite their promise, the ability of digital tools to bring about sustained change in behaviour remains unclear. Further research and improved methodologies are needed, while the influence of design features on acceptance and engagement should be considered.
- Importance of privacy and data security for consumer trust and acceptance: Given the
 sensitive nature of personal health information, ensuring adequate privacy and data security is of
 paramount importance for gaining consumer trust and acceptance. Studies conducted to date of
 health-related wearables and mobile applications suggest significant data-sharing and
 weaknesses in privacy and security practices. The extent to which insurer health apps are similar
 to the broader market remains unclear, and should be investigated; however, given the resources
 at their disposal, insurers could play a role in promoting strong standards for the market.
- Insurance regulatory framework is generally permissive, with necessary safeguards nonetheless in place: The insurance regulatory framework generally does not pose a barrier to the provision of digital tools, and regulatory measures or authorities are in place to provide key safeguards for policyholders and avoid consumer detriment. Regulators have the tools to address any potential detriment to policyholders. In some jurisdictions, there have been efforts to introduce some flexibility, for instance requirements regarding the empirical evidence needed for underwriting decisions. A better understanding is needed of how (if at all) insurers are making use

of user-generated data for premium-setting decisions – at the individual policyholder level but also more broadly for other policyholders.

- Key role of health regulation in this new area of insurer activity software as a medical device: Health regulation, and in particular regulations regarding software as medical device (SaMD), is a key consideration. Such regulation may explain why a number of insurers may be taking a broad approach, focussing on improving health and wellness behaviours generally, so as to tackle well-known behavioural risk factors for disease. The marketing of digital tools needs to be carefully monitored to avoid misleading medical or health claims.
- Reputational considerations for the insurance industry: Given that the provision of health and wellness tools represent a new area of activity for insurers, creating new sets of expectations for policyholders and possibly involving outsourcing to, or partnership with external providers, reputational risks need to be carefully managed. Regulators should encourage compliance with relevant regulatory frameworks, including but not limited to data protection and privacy, and health.

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Notes

¹ While health refers, according to the World Health Organisation, to the "state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity" (World Health Organisation, n.d._[64]), and is thus a broad concept, the term can be interpreted narrowly to mean the absence of disease or illness. This report adopts this narrow definition.

² Wellness is "an active process through which people become aware of, and make choices toward, a more successful existence" ((National Wellness Institute, n.d._[58])) and involves active efforts and lifestyle choices which contribute, among other factors, to wellbeing. See ((National Wellness Institute, n.d._[58])) for the different possible dimensions of wellness, and (Physiopedia, n.d._[66]) for an explanation of the distinction between health and wellness.

³ See (Cohen et al., 2020_[17]) for a categorisation of the health continuum; the categories are prevention, detection, and management (the last containing the sub-categories of treatment, monitoring, and coordination of care).

⁴ This report does not cover social health insurers, nor bodies regulating social health insurers.

⁵ Austria, Belgium, Chile, Colombia, Estonia, Germany, Hungary, Japan, Latvia, Lithuania, Mexico, Poland, Portugal, Slovak Republic, Spain, and the United States.

⁶ Bulgaria, Chinese Taipei, and Russia.

⁷ For instance, 25 percent of those younger that 49 years old regularly use a wearable versus 17 percent of those over 50 years of age; 25 percent of women use a wearable versus 18 percent of men; 31 percent of consumers with higher incomes (USD 75,000 or more) use a wearable versus 12 percent of those with lower incomes (less than USD 30,000), gender (higher among women); those with college (27 percent) or some college education (25 percent) are more likely to use a wearable than high school or less (15 percent). The survey was based on 4,272 US adults.

⁸ Private health insurance (PHI) can play different roles in countries. In a few countries, PHI can cover primary health coverage, covering a defined core basket of benefits. In other countries, where there is a public-private cost sharing, PHI can be purchased to cover any remaining amount after the public payment (complementary). PHI may also provide supplementary benefits (e.g. prescription drugs, dental care), and/or faster access or a large choice of providers (duplicate). See (OECD, 2015_[73])

⁹ For instance, in the US, life insurer John Hancock developed a life insurance product designed specifically for Americans with diabetes, where policyholders are offered personalised services – and

possible access to a blood glucose measurement reader - and earn a premium reduction (up to 25 percent) if they adhere to a health regimen (Calvert, 2020, p. 10[9]). A behavioural approach to insurance based on digital monitoring tools may permit more customised products to be developed for risks that were previously difficult to insure. See (Calvert, 2020[9]) and see John Hancock website (https://www.johnhancock.com/life-insurance/aspire.html) product description page and (https://www.johnhancock.com/about-us/news/john-hancock-insurance/2019/10/john-hancock--verilyand-onduo-launch-john-hancock-aspire--the-first-life-insurance-solution-designed-for-americans-livingwith-diabetes.html).

¹⁰ See amendments to the model Law (underlined): <u>https://content.naic.org/sites/default/files/inline-files/MO880%20-%202020%20revisions-12042020 As Amended.pdf</u>

¹¹ "Personal health data" means any information relating to an identified or identifiable individual that concerns their health, and includes any other associated personal data (see *OECD Recommendation of the Council on Health Data Governance*, <u>OECD/LEGAL/0433</u>)

¹² The <u>OECD Recommendation on Health Data Governance</u> indicates that there may be alternatives to informed consent (see para III.5.ii).

¹³ See EU General Data Protection Regulation (EU Regulation 2016/679), Preamble (35), in the following link: <u>https://eur-lex.europa.eu/eli/reg/2016/679/oj</u>

¹⁴ See EU General Data Protection Regulation (EU Regulation 2016/679), Article 9, in the following link: <u>https://eur-lex.europa.eu/eli/reg/2016/679/oj</u>

¹⁵ See FDA webpage on Software as a Medical Device: <u>https://www.fda.gov/medical-devices/digital-health-center-excellence/software-medical-device-samd</u>

