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Developing Sustainable, Country-Specific Business Models for a Digital Healthy Aging Self-Management Innovation

– The ProACT Project

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Abstract: Many promising Digital Health Innovations do not make it to the market, as sustainable Business Models are difficult to find. This paper aims to show how sustainable and country-specific business models can be developed presenting several business model scenarios for an exemplary Digital Health Innovation: The ProACT service in Ireland and Belgium, a sensor platform that uses wearables to support self-management of elderly people with multiple chronic health conditions. The results of the research show that there are multiple plausible Business Model scenarios for each target country that can be classified in archetypes such as B2B, B2C or B2B2C. Each Business Model however, even when following the same basic logic, has to be embedded into a specific exploitation scenario, adapting it to the specific environment.

Keywords: Digital Health; Business Models; Integrated Care; eHealth; Value Networks; Multimorbidity.

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1 Introduction

Digital Health Innovations have great potential to improve quality of life and contribute significantly to prevention of disease and management of diseases by supporting a healthy lifestyle and making self-management easier (Heerden et al., 2012; Van Limburg et al., 2011). These benefits are especially obvious for the elderly and the chronically ill (Eysenbach, 2008). Many promising innovations in this domain however, do not make it to the market, as sustainable Business Models are difficult to find. Digital Health Business Models are heavily dependent on the healthcare environment, legislation and organization of healthcare within the target market (Van Limburg et al., 2011). The ProACT project, financed by the Horizon 2020 initiative by the European Commission (see www.proact2020.eu for more information), deals with the development of a sensor platform that uses off-the-shelf wearable sensors to help elderly people with multiple chronic health conditions to better manage themselves, stay at home longer and communicate easier with their informal and formal care providers. The resulting innovative service is targeted to be introduced in multiple European countries and beyond. In order to make such an innovative digital health service successful, there is a distinct need to prepare multiple Business Model scenarios, which are adapted to the particularities of the health systems within the target countries. This paper aims to show how economically sustainable and country-specific business models can be developed for Digital Health Innovations. For this paper we use the ProACT service as case study and selected two target countries with different health systems to show how tailored Business Models can be created: The Republic of Ireland and Belgium. The Business Modelling approach from Albert & Auwermeulen (2017) was used to construct the Business Models that were built utilising Value Network Theory (Ballon, 2007). The information regarding organization of health systems, potential willingness to pay and other country-specific information was procured through a mix of literature review, knowledge leveraged directly from members of the ProACT research consortium and complementary expert interviews.

2 The Significance of Business Modelling for Digital Health Innovations

There are several identified advantages of Digital Health Innovations, including enhanced means of communication, data sharing, quality enrichment of services and increased effectiveness of service delivery. These advantages have made Digital Health related innovations the target of numerous accelerator programs, government initiatives and private investments (Eysenbach, 2008; Popescu et al., 2016). In order to support the realization and market-application of Digital Health Innovations, Business Modelling has been identified as a tool of great importance. The unique characteristics of Digital Health Innovations are that they often rely on a large and diverse number of stakeholders to

function sustainably while at the same time demanding a flawless implementation within the targeted market (Van Limburg et al., 2011; AbuKhousa et al., 2012; Heerden et al., 2012). Digital Health Innovations need to identify the added value that drives them and generates revenue. This value creation usually involves a wide range of business-enabling stakeholders as well as significant effort around adapting go-to-market strategies to the market-specific regulations by Digital Health Innovations (Van Limburg et al., 2011).

A major flaw in current Digital Health Innovation is that Business Model construction occurs post digital innovation development, rather than integrating Business Modelling in the development process (Van Limburg et al., 2011). This is primarily due to the complexity of health care innovation and difficulty of innovating due to the complex, multi-stakeholder healthcare landscape (Herzlinger, 2006). According to Burns et al. (2012), the business of health care differs from other businesses radically on the level of value chains, or respectively Value Networks. In a traditional production model, a value chain links raw materials, manufacturers, distributors and end consumers. In the health care sector this is more complex as there are often multiple key sets of actors and several mediators to modify and redirect value flows. Key actors can be categorised according to individuals and organizations that purchase health care, provide health care and produce health care products (Burns et al., 2012). Mediators are those firms or organizations that finance health care and those who distribute healthcare. Other key difficulties related to innovation in the health care industry are the unique/differing national funding mechanisms (including the fragmentation of stakeholder groups and different reimbursement models), decoupled buyer/user decisions and the strong regulatory framework for technology deployment (Hwang & Christensen, 2008; Herzlinger, 2006).

Van Limburg et al. (2011) find that building a Business Model for Digital Health should be an iterative process, integrated in the product development phase. As such there is need for a more nuanced vision of Digital Health Business Modelling, where the above specifics of the industry are considered throughout the development process and not simply at the end. This paper sets out from this standpoint and attempts to show how business model and value network considerations can be implemented in the development process of a Digital Health Innovation taking the ProACT service and two different countries as example.

2 Framework and Methodology for Developing Business Model(s) for Digital Health Innovation

To exemplify Business Model development for a Digital Health Innovation on ProACT an approach was chosen that utilizes the concept of Value Networks that in turn inspires the development of Business Models using the same logic and visual language regardless of national context. The approach from Albert & Auwermeulen (2017) is a recent Business Modelling methodology that supports this, as it is tailored towards creating Digital Health Business Models in complex environments, involving numerous stakeholders and mapping the relationships between them. The approach is organized in a step-by-step fashion. It is tailored to work around an innovative product or service, henceforth called “innovation”. The steps are labelled as: (1) Understand, (2) Scope, (3) Environment, (4) Define Stakeholders, (5) Investigate Stakeholders and (6) Assemble.

Each step consists of a set of core-questions that have to be answered, ultimately producing a stakeholder-centric business model logic that defines the anticipated flows of goods, services, revenue and data in a Digital Health Business Model. The six steps were filled with information gathered through a number of resources, including information drawn from literature on the health systems of the targeted countries and complemented with expert knowledge from consortium partners and from expert interviews with stakeholders that were conducted within the co-creation component of the research project (see Table 1).

Table 1 Steps of the research

Step	Key-Questions	Data gathered
(1) Understand	What added value is the innovation intended to give? Who is the target-population for the innovation to be used by? Who is anticipated to gain added value from the Innovation?	ProACT project documents
(2) Scope	In which environment is the innovation intended to be deployed? In which country/countries is the innovation intended to be launched?	ProACT project documents and Grant Agreement
(3) Environment	How is health (care) organized in the target environment? How does reimbursements work? Which stakeholders in the target environment could be important for the innovation? Which regulations/policies are likely to have an impact on the deployment of the innovation?	Desk research and relevant country-specific literature
(4) Define Stakeholders	Which stakeholders will have to be interacted with in order to register the innovation or apply for eligibility for reimbursement? Which stakeholders will use/be in contact with the innovation? Which stakeholders are critical showstoppers for the innovation to be implemented? Which stakeholders' cooperation is anticipated to be needed in order for the innovation to work as intended?	Interviews and co-creation Workshops
(5) Investigate Stakeholders ¹	What is the function, revenue structure, decision-making process of the stakeholder? What situation would the stakeholder be in with and without the introduction to the innovation? What is the willingness	Interviews and co-creation workshops

¹ It is important to note that not necessarily all of the categories have to be filled out for every stakeholder, as some might not make sense. For example, when analysing a public agency that determines which services are eligible for reimbursement, it is highly unlikely that willingness to pay will play a role, if the organization is not the reimbursing actor in the respective health system.

	to pay and willingness to cooperate?	
(6) Assemble	Which stakeholders are possible revenue generators? What are the prerequisites for these stakeholders to provide revenue for the company deploying the innovation? Which stakeholders are contributing critical nonrevenue generating functions? What are the prerequisites for these stakeholders in order to perform these functions?	Input from all steps above

Source: Modified from Albert and Auwermeulen (2017).

The findings of this research are presented in two parts. The first part builds Value Networks of the two exemplary countries that are target markets for ProACT, the Digital Health Innovation. The construction of the Value Networks is inspired by Ballon (2007) and based on the results of steps 1 to 3 (Understand, Scope, Environment) of the approach from Albert and Auwermeulen (2017). The principal purpose of these Value Networks is to provide context for the formation of appropriate, country-specific Business Models that are consequently developed in the second part. Important to note here is that two Literature sources have been particularly useful while researching Ireland's and Belgium's health systems: The Health System Review of Ireland (McDaid et al. 2009) and the Health System Review of Belgium (Gerkens & Merkur, 2010), both published by the European Observatory on Health and System policies. Both Publications were the main source of information from a literature-side when constructing the value networks.

The Business Models are tailored to the targeted environment for the innovation and represents the identified revenue flows as well as their respective prerequisites. Diversification into multiple Business Model scenarios per country is possible. All Business Models are constructed to be ProACT-centric regarding the mapped value streams. This means that there will be some value streams that are existing but not mapped in the visualisation of the Business Model scenario. However, it is recognised that there are value-interactions between the health actors and the ProACT service provider, but in order to keep the visualisation readable and business focussed, these interactions were not explicitly displayed, although recognized with respect to the configuration of the Business Model. The "ProACT-player" in the centre of all Business Model configurations is representing the (business)-entity that will provide and manage the ProACT services in the respective target countries. How this "ProACT"-player could look like is not further specified in this paper to stay within its scope. For the Business Models it is sufficient to understand this player as an organisation that sells, distributes and manages the ProACT service. Steps 4 to 6 of the approach mainly informed the creation of the Business Models.

3 Value Networks

The ProACT Value Network for Belgium

The findings of the research show that the Belgian Value Network (Figure 1) is greatly influenced by the organisation of the Belgian Health System as a Social Health Insurance System (Bismarck system) with mandatory health insurance: Publicly controlled health insurance funds provide insurance to the whole population. If an individual makes use of a health service, they are either later reimbursed for the money they paid or, as is mostly the case in Belgium, they do not have to provide payment as the health service providing entity can directly file for reimbursement with the responsible public insurance.

The majority of the system is tax-financed, meaning that the population provides tax-based income to the federal government, which in turn finances the “Rijksinstituut voor ziekte- en invaliditeitsverzekering” (RIZIV), a state agency that is tasked to coordinate and govern all matters around health insurance and invalidity. The RIZIV governs which services and drugs are eligible for reimbursement by public insurance funds, thereby directing reimbursement spending in the whole country. The RIZIV also distributes the tax-based money between all public insurers via prospective budgeting. In addition to the tax-financed budgets, the public insurance funds are also provided with revenue through mandatory yearly fees, paid by every insured individual. There also exists private health insurance in Belgium, which is optional. These types of insurers offer both complementary and substitutional health insurance. Complementary insurance only incorporates non-medical advantages such as single-rooms for hospital inpatient treatment, shorter waiting times and non-medically relevant improvements to reimbursed treatments e.g. see-through braces for teeth. In case of substitutional private health insurance, the private insurer takes over all responsibilities from the public insurer and reimburses health expenses after the insured individuals paid the health service provider. It is also common that employees have private complementary insurance via their employers that only replaces the inpatient-reimbursement from the public insurance.

Reimbursement is handled on the basis of “fee-per-service”, meaning that every extra service performed by a healthcare actor can be billed towards an insurance provider as long as it falls under scope of the official regulations or a respective private contract. Primary care in Belgium is mainly provided through GPs who operate in private practices. As there is no gatekeeping mechanism in place, Belgians could also technically receive primary care at any hospital, but this is not common practice, except for emergency cases. Secondary care in Belgium is provided through specialist physicians either operating from private practices or hospitals. Specialists operating from hospitals are only very rarely salaried (only in university hospitals) and usually receive a fee-for-service compensation directly from the respective insurance and pay the hospital for the resources they use. Although Belgian hospitals have many different types of ownership, the Value Network relevant role of them does not change depending on this fact.

Nursing homes and home care are also financed through the Belgian social health insurance. Nursing homes can have a wide variety of owners both coming from public and private sources. In some cases, they are also providing home care, whereas the majority of home care providers are independent and privately organized. In the Belgian

environment, independently working home care nurses are common, which creates another important stakeholder apart from the homecare service providers. All Belgian health service providers usually charge a co-payment (except for chronically ill patients) for every visit for outpatient treatment. For inpatient treatment or longer stays there are also cases of additional payments, these are however highly individual and depend on additional services requested and the insurance situation of the service-receiving individual. As a result of building and investigating the Belgian Value Network we can derive the following conclusions that are relevant for exploitation of ProACT and that will inform the development of the business models:

1. The RIZIV is the body to be convinced when any of the public providers should be payers.
2. Private insurers have significant potential to become payers for ProACT as they are capable of freely reimbursing any health-related spending and have payment channels for all types of institutions.
3. Due to the independent nature of the provision of primary and secondary care, incentives have to be given for any extra effort surrounding private practice physicians. If any health service provider has to spend extra time with ProACT as compared to normal operations, the costs would have to be met.
4. The fee-for-service environment makes it lucrative for certain healthcare providers to incorporate Digital Health Innovations that increase their turnover with regards to billable services. This advantage can only be realized when the respective Digital Health Innovation is reimbursed.

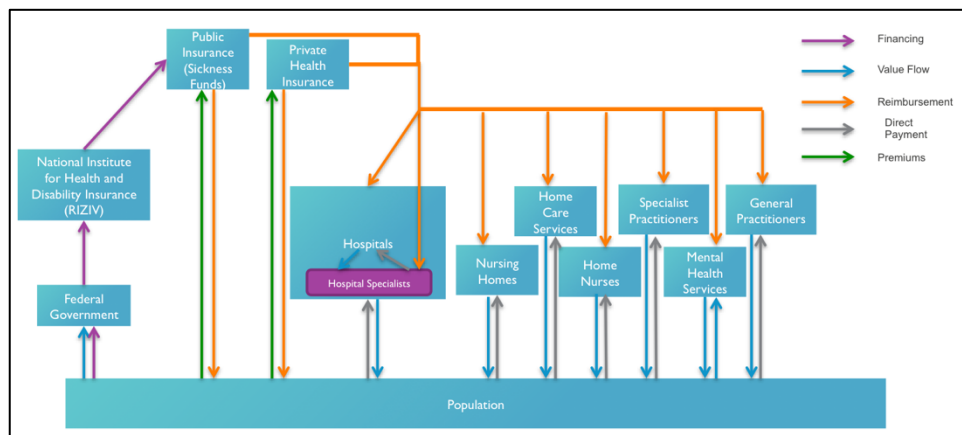


Figure 1 ProACT's Value Network of Belgium.

The ProACT Value Network for Ireland

The Irish Value Network (Figure 2) is centred on the diverse public entities that are tasked with directly financing and governing or reimbursing different health service providers. For the depiction in the Value Network, only the most important decision-makers were considered with regards to their relevance for enabling flow of revenue and reimbursement in potential exploitation scenarios. The Irish Health Care System is predominantly tax funded, although approximately half of the population is covered by

voluntary health insurance. The Department of Finance is responsible for distributing funds to the two main bodies: The HSE (Health Service Executive) and the NTPF (National Treatment Purchase Fund). The HSE is the main financing body for almost all state-budgeted health service providers such as public hospitals, special hospitals and home-care providers. It also indirectly finances General Practitioners and nursing homes through the subsidiary public agencies NHSS (Nursing Homes Support Scheme) and PCRS (Primary Care Reimbursement Service). The vast majority of healthcare institutions are funded by this scheme, although being operated either by local authorities or religious or lay boards of governors. The NTPF is a fund that can reimburse services in the whole country and even abroad in the UK in the case of excessive waiting times. It is also solely responsible for reimbursing services consumed in private hospitals, as well as providing pricing guidelines for nursing homes. Private health insurance in Ireland is mainly comprised of providing extra services that are not of medical importance such as single beds in hospitals etc. In addition, private insurance also covers any out-of-pocket spending made by its insured population. Health insurance is non-mandatory.

Any medical personnel working in the publicly financed hospitals are salaried via the hospital funding, although medical personnel, especially physicians, can supplement their income with private activity. This private activity heeds from the separation of hospital beds into private and public beds, that separates capacity planning and reserves emergency capacity for directly reimbursed patients, either through the NTPF or through private insurances. The small amount of completely private hospitals usually employs their physicians on an independent basis as per fee-for-service. Every individual receiving treatment also has to make co-payments per service received. This is true for virtually every health service provided in Ireland. Primary care is mainly provided through General Practitioners operating out of private practices that are reimbursed on a fee-per-service basis through the PCRS and source secondary revenue from out-of-pocket payments made by patients on a fee-per-service basis. Secondary care is only received via specialists in hospitals. Home Care is mainly provided by a variety of private entities. It is directly regulated by the HSE and in some cases either also directly financed or privately paid, depending on the provider. Nursing and care homes on the other hand are, although privately operated by a multitude of private, religious and semi-public groups, primarily financed via the HSE while having to comply with the pricing restrictions set by the NTPF.

As a result of building and investigating the Irish Value Network we can derive the following Business Model-relevant conclusions:

1. The most important public body to convince of ProACT's effectiveness is the HSE, as it finances and governs the majority of relevant health care service providers that would have to use ProACT. The advantage of working with such a centralised stakeholder is that it allows for mass-deployment of a solution without being required to negotiate with every health care service provider.
2. Private hospitals seem to play a minor role in the Irish health system, and while probably the most easily approachable, they would most likely only be fit to be a smaller partner to gain momentum and traction on the market.
3. Private insurers have good potential to become payers for ProACT in the short term as they are capable of freely reimbursing any health-related spending, have

payment channels for all types of institutions and have significant market impact in Ireland.

4. Other public players such as the PCRS, NHSS and NTPF are also important to communicate with in order to deploy ProACT in the public health system, although not as critical as the HSE.

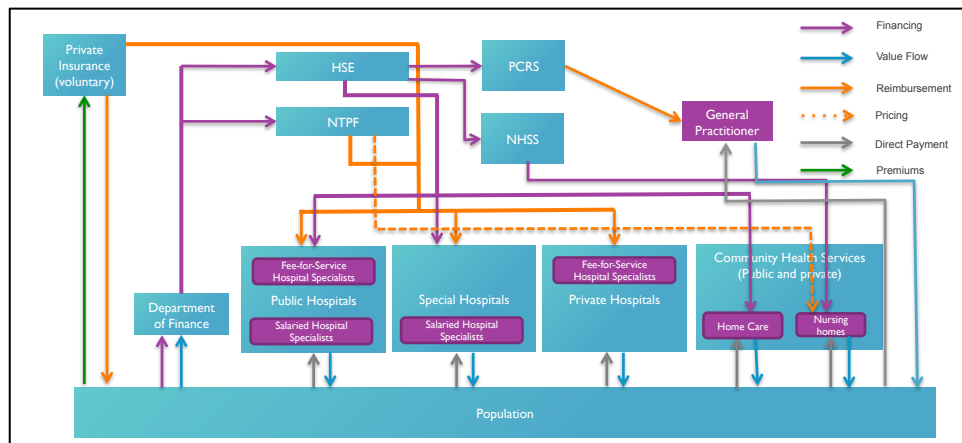


Figure 2 ProACT's Value Network of Ireland.

4 Business Model Scenario Development for Digital Health Innovation

Business-Model Scenarios for ProACT in Belgium

The first identified Business Model for the Belgian sector (Figure 3), derived from the Value Network Analysis incorporates the national social health insurance covering the cost of ProACT. There are two main monetary streams to be considered in these configurations: Reimbursement of caregivers and revenue towards ProACT. The revenue towards ProACT is most likely to be derived directly from the respective public insurer of a person with multiple chronic diseases (in the following called PwM) and to be received in a pre-defined fee-per-service solution, based on the negotiations with the RIZIV in order to accept ProACT into the catalogue of reimbursed services. In addition, there is also the potential additional cost towards the care provider that is to be covered. This additional cost incorporates all extra effort ProACT causes medical/health professionals who use it (e.g. training on system use). This will for example include extra time to review collected data and to plan interventions based on the new knowledge that ProACT is providing. While of course ProACT aims at having the lightest footprint possible with regards to extra effort from the sides of professionals, the possibility of reimbursing (mainly spent time) this effort has to be incorporated into the Business Model considerations. In the case that ProACT generates more cost-savings than extra-effort, this stream can be ignored and it can be investigated if the cost-reduction is sufficient for opening up new revenue generating opportunities. It is envisioned that while there will be an initial period of required effort to become familiar with the system and its use, over time this would be reduced and PwM's, health professionals and

associated actors would benefit from time saved in their management tasks due to quicker access to data and training around how best to manage the health and wellbeing of the PwM.

Proof of effectiveness has to be provided to three different entities: The RIZIV, the PwM and to private insurers. Proof of effectiveness in the Belgian case means different concrete things for all three affected stakeholders: The PwM has to be convinced that ProACT is worth using and brings additional value to their management and care, otherwise the individual will probably not make use of it, thereby making it impossible for ProACT to claim revenue. It can be argued that in most cases, the family and formal carer are also stakeholders to be convinced as they may influence the decision-making of the PwM. In order for the RIZIV to incorporate ProACT into its list of reimbursed services, a proof of effectiveness (including cost-effectiveness) has to be provided regarding the impact of ProACT on both individual and population health. While private health insurance will also need a similar proof of effectiveness as the RIZIV, it is expected to be more flexible with regards to individual contracting with ProACT, due to the higher amount of freedom in reimbursement of services.

ProACT is a data-driven innovation, hence the generation and distribution of data is one of the most important aspects, creating a significant part of ProACT's value proposition. The main data-generating stakeholder will be the PwM through self-assessment and measurements through the ProACT devices. This information will then be transferred to backend services for processing. The PwM will in turn receive visualized feedback regarding their data input, as well as potentially pushed information from the side of their care provider and family recognising that they linked in with the system to support the PwM. In an ideal scenario, all care providers themselves will have access to selected data, generated by the PwM, after it has been processed by ProACT system. Contextual data from the professionals themselves, such as measurements taken during appointments, could be for example fed into future iterations of ProACT, post the H2020 project phase and then redistributed to the designated recipient, which could be the PwM, another care provider and family and/or informal carer. Gathering data and making it available to a variety of stakeholders is one of the core-components of ProACT seen as valuable to most stakeholders involved. In Belgium, we also identified the desire from the side of (especially the private) insurances to receive health and lifestyle-related data from the PwM. We chose to not include this data stream in our initial Business Model as a conflict of interest between insurance and insured PwM could be foreseen. This however will be reviewed as the project progresses.

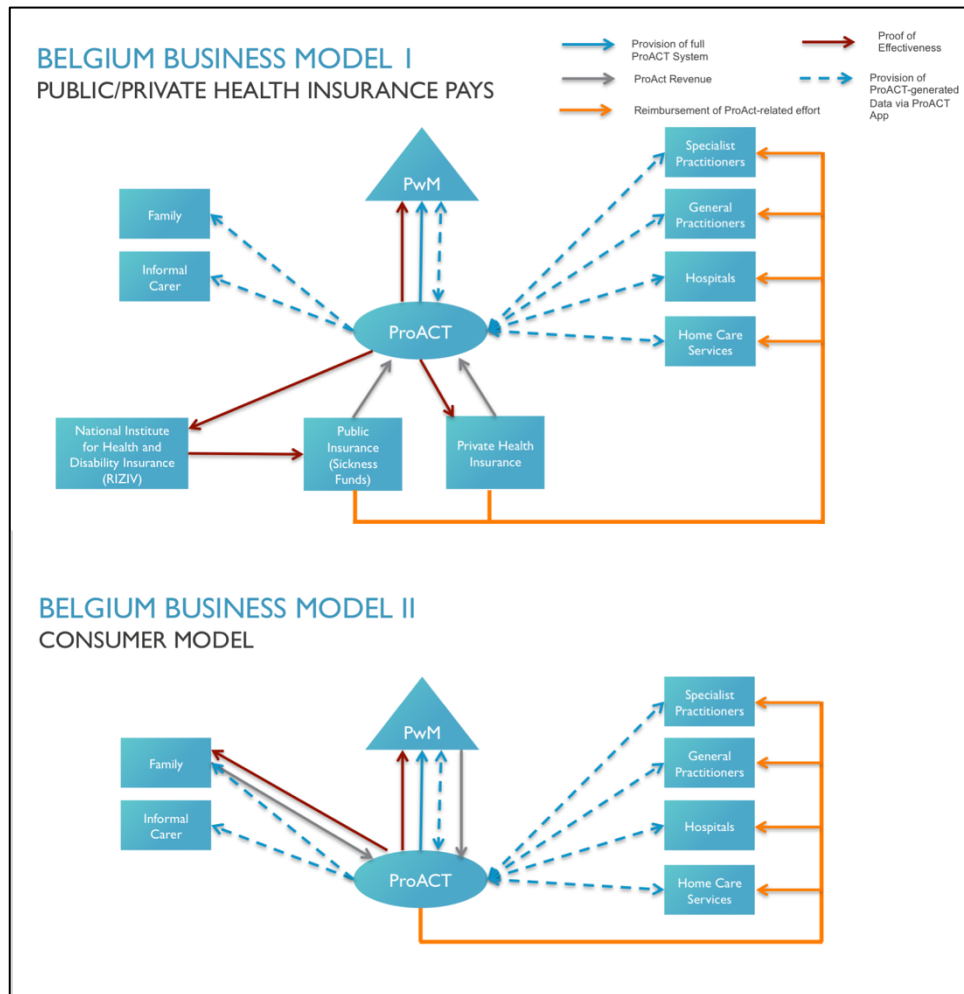


Figure 3 ProACT's Business-Model Scenarios for Belgium.

It is important in the analysis to capture a wide variety of care providers/support actors' interactions with the model due to the integrated care vision of ProACT. This is also anticipated to maximise the cost-saving potential of ProACT due to the exchange of data between a high number of caregivers, therefore increasing treatment outcome and decreasing unnecessary service utilization by the PwM. As mentioned previously, the consideration that private health insurance will be willing to pay for ProACT is incorporated in this Business Model, as it is assumed that a proof of effectiveness (including cost-effectiveness) that is sufficiently strong enough to appeal to the RIZIV will also be attractive to private insurers. An argument can be made that the overall Business Model can be split in a "public only" and "private only" variation. Due to the situation in Belgium however, with private and public insurance often being intertwined or complementary, a combined model is deemed to be most appropriate.

Business-Model Scenarios for ProACT in Ireland

The first Irish Business Model scenario (Figure 4) assumes that the Irish health authorities finance ProACT. Revenue in that case would be directly received from both the NTPF and the HSE. The NTPF is assumed to be the most important stakeholder with regards to enabling private health providers to be part of ProACT, whereas the HSE with its financing control over public providers is most likely to enable access to them. Looking at the Irish Value Network and how the health system is organized, it is most likely that revenue in this scenario will be provided by either directly budgeting ProACT in exchange for providing the ProACT service towards a set amount of people or reimbursing ProACT for every PwM it provides its services to in regular intervals (monthly, yearly fees etc.) As in the Belgian example, pricing strategies are difficult to adjust when dealing with public authorities, which are usually bound by legal constraints regarding cost of care.

Proof of effectiveness in this scenario has to be delivered to both the NTPF and the HSE in terms of public health value of ProACT. The rationale of proving effectiveness is expected to be similar to the situation with the RIZIV in Belgium. With the dual Irish system of direct financing and fee-for-service based reimbursement, it is of great importance to have both agencies convinced of the effectiveness of ProACT. Without the HSE, deployment of ProACT with directly financed care providers would likely be impossible. In addition it is to consider that only with cooperation of the NTPF, reimbursement is able to flow towards privately operated care providers, enabling them in turn to implement ProACT. Regarding proof of effectiveness towards the PwM, the same reasoning is applied as in the Belgian Business Models. Data is sourced and distributed in the same way as described in the Belgian Business Models. One difference to consider might be that, due to the common financing, HSE-governed intuitions might be better connected than completely private ones. Also in the Irish case, involvement of care providers increases the value of ProACT. Regarding compliance and reimbursement of potential additional costs caused through ProACT, there are two scenarios to take into account: The publicly financed care providers are highly likely to be just tasked by the HSE to use ProACT if the HSE deems it valuable, with or without extra financing. In parallel to this, extra reimbursement for the private providers would have to come from NTPF, which would then be added to their cost regarding ProACT. As in the Belgian scenario, cooperation of care providers is crucial. This initial Business Model configuration is the most desirable for Ireland, although probably not the easiest to achieve. Due to the split in private and public providers, the public financing system would have to accept ProACT in order to achieve maximum coverage.

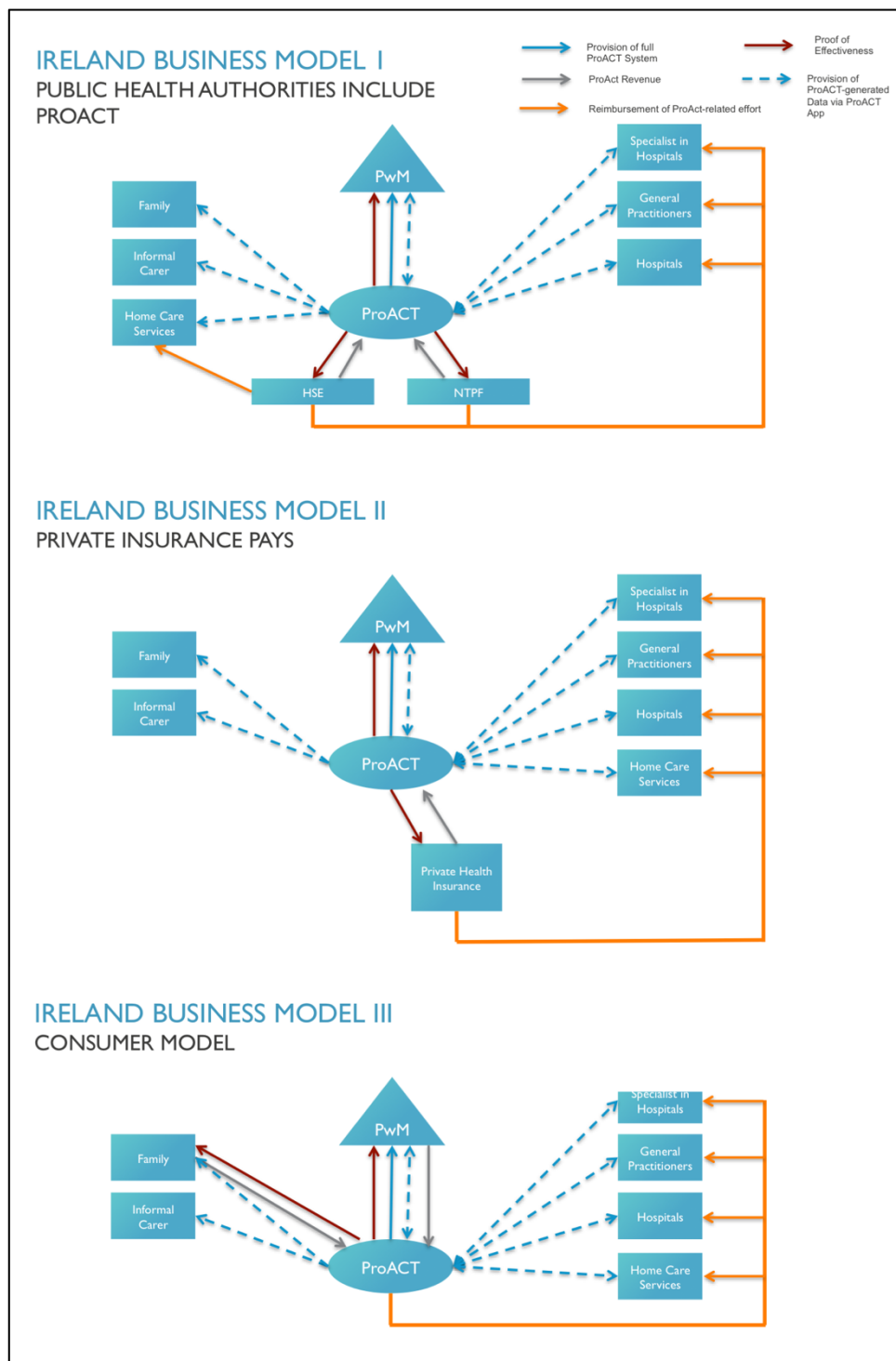


Figure 4 ProACT's Business-Model Scenarios for Ireland.

The second Irish Business Model Scenario (Figure 4) assumes that private health insurance, covering approximately 50% of the population, will reimburse the use of ProACT in Ireland including potential additional cost of ProACT towards the care providers. It is deemed most likely that the private health insurer in Ireland would reimburse ProACT per service provision per PwM. As with all other models that feature such a solution, the modalities of the reimbursement will have to be determined while further shaping the ProACT solution. Proof of effectiveness would have to be provided towards the PwM, as in every other scenario. Private health insurance is, similar to the situation in Belgium, deemed to have a lower threshold to implement innovative solutions as the insurance providers are in competition with each other and are often at times covering expenses that are not included by the public health schemes. It is important to note that in this case, integrating publicly financed care providers into the scheme might be more difficult, as there is no pressure from the HSE or NTPF to use ProACT. At the same time, the extra cost of the private health insurance regarding the reimbursement of extra initial effort caused through ProACT has to be considered when negotiating with private health insurers (this is similar to the situation for support actors (e.g. health professionals) in Belgian context). We can assume that, also similar to the Belgian context, initial effort regarding training and getting used to the system will consecutively transform into care professionals deriving added value from the use of ProACT in terms of time savings and efficiency increases. Finally, in this scenario, each private health insurance provider would have to be contracted by ProACT separately to incorporate the ProACT service; this may be an advantage regarding the initial deployment of ProACT due to the pressure of competition between providers but may also create higher go-to-market cost when aiming for maximum coverage. For data sourcing and distribution, as well as the involvement of care providers, the same concepts apply in Ireland as in the previously described scenarios for Belgium. The data will be sourced from the PwM in the same way and also distributed to care professionals, family and informal carers. The diverging organisation of care in terms of how medical professionals operate is not foreseen to have a significant impact on how data is forwarded and used.

The consumer model in Ireland (Figure 4) follows the same rationale as the consumer model in Belgium. One difference however, is that further work would need to be conducted to examine how easy and effective it could be to include care providers in ProACT that are directly salaried by the HSE or directly governed by the NTPF without the involvement of either of the two agencies. Therefore, we deem the first model the most viable potential solution for going to market at this stage, attracting early adopters to offset costs. Further information will be gathered during the trial period to understand the final proof of concept impact of ProACT to then present to the public bodies and associated stakeholders in order to refine the Business Models presented in the Irish context.

Conclusion

The results of the research show that there are multiple plausible Business Model scenarios for each target country that can be classified in archetypes such as B2B, B2C or B2B2C. Each Business Model however, even when following the same basic logic, has to

be embedded into a specific exploitation scenario, that adapts it to the specific environment. There is for example the B2C Business Model in which a public entity covers the healthcare cost for the Digital Health Innovation based on a population-health cost-benefit rationale. All identified Business Models feature different payers and different prerequisites to enable revenue to flow. These prerequisites exist mostly in the form of "proof of effectiveness", as Digital Health Innovations, similar to pharmaceuticals or medical products, have to prove their effectiveness before being able to be reimbursed or otherwise paid for by health providers, insurances or public authorities. The findings show that the type of evidence or proof required depends on the preferences and nature of the paying stakeholder and thereby varies per country although the value proposition within the Business Model stays the same.

There are multiple concrete lessons to be learned from the research: (1) Incorporating a large variety of stakeholders into the research ensures that Business Models are as realistic as possible regarding their implementation, as the circumstances for cooperation or at least non-resistance can be modelled in advance. (2) Different health care systems can demand different Business Models, especially regarding a scenario in which a public entity (e.g. insurance or health fund) is targeted. (3) Even similar Business Models have to be set up differently regarding stakeholder participation and revenue generation, when implemented in different health system environments. (4) Non-paying, non-primary-using stakeholders play a critical role, as for example care providers that are not targeted as customers and are not principal users of the innovation, as they often enable use of Digital Health Innovations. (5) Business Models generated in this way allow for an easy generation of go-to-market steps, as the Business Model comes with a stakeholder-specific list of To-Dos.

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