



The need for a health oriented Digital Innovation Hub – the case of HealthDay.si and the Slovenian ECHAlliance Ecosystem

To retain respect for sausages and laws, one must not watch them in the making.

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Abstract

It's a known fact that most innovators never make it to market, but in health care the rate of extinction of innovative ideas on their path from the creation to the patient is even much worse. An ecosystem of support to innovators in health care requires highly specialised knowledge in regulatory processes, full adoption by the physicians and a sound business model capable of navigating the mazes of how products and services are paid for in a public health care system with a pinch of private providers.

In Slovenia HealthDay.si, an ecosystem to support the innovators was purposefully launched in 2014, without institutional support. Initially we mostly organised events, however we found out that was not enough. Besides aligning our ecosystem with international networks such as ECHAlliance and Health 2.0, we evolved the ecosystem towards a programme we call DIH.HealthDay.si, hub for digital innovation in healthcare.

Ecosystem Analysis

Slovenian health and social care system is coming under growing pressure from several factors, among which the most important we can count the lack of finance required by the constant increase in demand, demographic changes causing an increase in the numbers of chronic patients requiring care, lack of health and social care professionals with a constant drain of physicians and nurses towards higher salaried markets, outdated models of payment based on activities performed rather than on outcomes, a fragmented landscape of IT infrastructure with lacking interoperability, lack of quality control with underreporting of problems due to errors in care.

Not everything is bad though, Slovenia excels, also in comparison internationally in some areas. A prime example of this is the lowest mortality of newborns in the world, wherein we have witnessed a



constant drop in the rates of mortality over the past 30 years, to finally get lower than even traditionally best Scandinavian countries. The next excellent example is oncology, with the registry of cancer patients being put in place in 1950s is a great foundation and also legacy upon which Slovenia established three very well-developed screening programs called Zora, Dora and Svit, for cervical, breast and colon cancer respectively. These programs are internationally recognised as examples of excellence. Another area of excellence are patient associations, some of which have become very important stakeholders in the whole ecosystems. Activities of Europa Donna (breast cancer), Spominčica (Alzheimer and dementia) and Za srce (cardiovascular) are regularly recognised as some of the key educators of the public and patients, both in prevention as in therapy.

Overall, one of the overarching challenges of the Slovenian health and social care ecosystem is its resistance to change, and with-it unfriendliness to innovation. The system is very complex, with many different stakeholders involved, large overall spending of €3,5 billion annually, with interests often not being aligned around the patient but rather about one's own position.

In such an ecosystem health and social care tech innovators face many challenges. Sometimes even solutions that are recognised as excellent, providing better care to patients, and saving on costs struggle to earn enough to support the companies.

Technology park Ljubljana recognised this situation already in 2014 when it partnered with a few leading health informatics companies to start a community. The HealthDay.si was created with TPLJ being one of the initiators and the lead coordinator of the ecosystem and promotional platform for raising awareness on the healthcare-based businesses (www.healthday.si). TPLJ creates links between individual businesses and allows them to grow their potential on national and Central European stage. The main goal of the community is to assist the stakeholders in entering international markets. However, to do so, it is still needed to target main challenges in Slovenia:

- regulatory oversight,
- transparency of the process,
- intellectual property complexity,
- medical efficacy review
- related financial assessment,
- healthcare culture
- existence of a small market.

TPLJ does so also through engaging in international projects that focus on supporting digital healthcare innovations or other smart-technology based innovations through different modules; either by raising awareness to more specific, one-on-one cases where TPLJ helps the company and/or innovator in whatever capacity it can.

Slovenian ecosystem of healthcare because several characteristics one of which is a fragmentation both regionally and by specification; in the 26 hospitals and 63 Healthcare centers that according to some reports more than a hundred different IT solutions supporting the healthcare provisioning, management, care, pharmacology and other need.

Initiative For Innovation In Healthcare

In 2018 Healthday.si community, coordinated by TPLJ realized that communication activities, network nourishing, peer2peer support, international cooperation, coaching for growth and other activities existing until that point haven't addressed a need that has proven to be a serious obstacle to the development and introduction of innovative solutions and products in the field of healthcare towards the real world use by patients, physicians, caregivers and other healthcare professionals.

The problem is not unique to the Slovenian ecosystem but has been observed globally. In FastCompany magazine an article with the title "Why do digital health startups keep failing?" was published in October 2018 . It details that the main reason is neither the lack of capital, nor lack of good quality ideas, nor understanding of dynamics of growth. The reason mainly lies in the opacity and complexity of the health care system. Companies, and in our recent experience not just companies, but even the majority of other stakeholders, including healthcare professionals don't understand the whole system. Each of the stakeholders understands a single facet of this multifaceted system.

At that time our idea was not to immediately address the whole problem but wanted to create something that with the least effort would provide us with the highest result. The end goal of companies and innovators trying to become real world solutions in health care is to be reimbursed by the insurance companies.

Therefore, by intentionally not trying to solve everything that comes before you get to the finishing line, i.e. the reimbursement list with the insurance company, we asked all leading insurance companies in Slovenia if they would become a part of the Initiative for innovation in healthcare. We sent letters explaining the problem innovators are faced with and the invitation for them to participate in helping guide innovators toward the chequered flag - the reimbursement list. The invites were sent to the Slovenian health insurance fund (ZZZS), and to three main commercial insurance companies: Triglav zdravstvena zavarovalnica, AdriaticSlovenica and Vzajemna. All boards accepted us in the first meetings, and in a few weeks three of four decided to join the Initiative.

The basic idea of the Initiative is very simple. Insurance companies, in 2019 also joined by another insurance company Sava zavarovalnica, meet every 6 months and listen to presentations by 5

innovative companies. Each presentation is followed by a discussion between the company and insurances to advise the innovators on the next steps.

In this way the companies get the necessary exposure to future partners, while the insurance companies have a tap on the latest and most ready innovations, while at the same time they also get to better see and understand where there are problems in the path of innovators.

Digital Innovation Hub

With the creation of the Initiative for innovation in healthcare we realized that there's a further step that we would need to do. It simply was not enough to just search for companies with innovative solutions and ask them to present to insurances. This is already something that happens regularly, companies constantly knock on the doors of the insurance companies believing that this is the way to the health care system. In rare cases that is indeed the case, but in most companies have too many missing elements in their solutions and business plans to be ready for the insurance companies.

The Living Lab methodology proved as a good foundation to base our strategy on. As Open Days organized in the frame of the LiLab showed, stakeholders are in a dire need to cling onto something more structured and if possible, have a physical space to meet and discuss issues described above. Meetings conducted with Insurance companies only further proved this point and we focused on structuralizing our initiative through the Living Lab methodology.

We identified companies as our main stakeholders, so we first initiated our approach toward them.

We wanted companies to be preselected, prepared and ready for the presentation to the insurances, and even more, we saw the opportunity in us becoming an important accelerating partner in their way towards the real world use of their innovation.

We decided to focus not on all aspects of an innovation cycle, we intentionally ignored the usual theory and practice of how a startup or scale up needs follow the "lean methodology" to finding their problem-solution fit and the solution-market fit. It's not that it's not important that they understand how they should be developing and growing their companies, but we saw that that wasn't the missing link in what they needed to bring to the table.

Innovators in health typically lack understanding of the health care system, and especially understanding of the regulatory framework that needs to be understood and all requirements checked and accomplished if one is to be allowed to enter the market.

We already understood at that time that there are many institutions, organisations, regulators and other stakeholders that scrutinize, check, evaluate and finally allow, or disallow a solution to be brought to the patient.

We knew the following:

- To be listed on the ZZS list of reimbursed solutions they require Zdravstveni svet to approve it.
- Zdravstveni svet (Medical council, a Ministry of health appointed group of experts to evaluate new procedures and solutions) will only approve a solution, if the provider of the solution is capable of proving a significant medical advantage, safety of the new solution, and an advantage in the economics of the solution.
- Each of the requirements of Zdravstveni svet must be pre-approved, in most cases by several stakeholders for each part of the submission.
- JAZMP - Medicines and medical equipment agency registers new devices, equipment or drugs, following strict protocols of compliance, aligned with a wide scope of legislation, both Slovenian and European, medical and technical.
- Key opinion leaders in specialisation that the solution addresses who are grouped in so-called RSK ("razširjeni strokovni kolegij") - extended expert councils need to give a clear and unanimous approval of the solution.
- The submitting innovator needs to create a study of medico-economics or HTA - health technology assessment that shows the advantages of the newly proposed solutions.
- RSK will not decide without the proof in the form of a properly validated clinical trial.
- Clinical Trials can only be conducted if they are approved by the Commission of medical ethics.

We, however, knew that we needed expert knowledge. For this purpose, our first step after insurance companies agreed to participate in the Initiative for innovation in health care was to form a group of experts.

Group of Experts

The first person to join our efforts and also help us guide the process was Mrs. Mateja Urlep. Today she is the chair of our group of experts. Her professional background is pharmaceuticals. One of her biggest career achievements was her role in designing specific EMA and FDA regulations and introducing biosimilar drugs into clinical practice in the EU and the US. She was also a global manager in Sandoz. She's also known for spearheading the creation of Lek's Biopharmaceuticals production facility in Mengeš, which happened before Lek, one of two biggest Slovenia pharmaceutical producers was taken over by Novartis's generic arm Sandoz, and where the Mengeš facility today employs 600 highly qualified experts. Mrs. Urlep today's role is being an adviser to global companies in introducing innovations in health care.

Mrs. Urlep's strong record helped us in all aspects of creation of the Digital Innovation Hub. With her help we assembled the group of experts. The group is currently formed of:

- proven expert in global healthcare innovation - Mateja Urlep, TikhePharma - Chair
- experienced physician, in favour of innovation - dr. Dorjan Marusic
- expert on international practices in the field of digitization of health - Eva Turk
- medical device entrepreneur - Jakob Šušterič, Mesi
- global proton radiation therapy producer - Janko Burgar, Cosylab
- health economist and health products developer - Tina V. Vavpotič, Marand
- biomedical expert and professor - Miomir Knežević, Educell
- leading patient group leader - Tanja Španić, Europa Donna

We plan to extend the group with additional experts, in particular an innovative physician.

Goal of DIH - 5D2020

As the idea of establishing a DIH as the next logical step in the LiLab evolution proved correct, we defined the core & goals of the DIH.Healthday.si

The main goal of the DIH.HealthDay.si is to contribute to 5 digital health innovations to be reimbursed by the end of 2020.

Following up on a goal of the Initiative we also want to see that 1% of the Slovenian health care budget be used for introduction of innovative solutions into the healthcare system by 2027. Today the Slovenian budget spent on healthcare is €3.5bn, so 1% would be €35m, and is expected to grow along with GDP growth and with the expected increase of share of GDP spent for health care as the population grows older and the diseases treated become more and more chronic.

In spite of the advances of digital technology and its successful introduction into most industries, a.k.a. the digital transformation, health care is still seriously lagging behind. In Slovenia we only have one solution that is digital in nature and is a part of clinical treatment of patients, and is not just a device or a software solution for management of the hospitals, administration or support to managing the EHRs (electronic health records) to be a part of the reimbursement list of the Health insurance fund. That solution is Telekap and was developed and championed by dr. Bojana Žvan, a top Slovenian neurologist.

A few other solutions exist, such as teletransfusion and teleradiology, but none have achieved the status of a reimbursed solution, they merely replaced an existing practice and modernised it.

We aim to change that and see more solutions make our national health care system better for the patients and more efficient for all stakeholders.

Pillars of DIH

HealthDay.si ecosystem has been transformed from a community based on the communication platform, to a new level by the introduction of the DIH.HealthDay.si, hub for digital innovation in healthcare. The transformation came largely from the results and feedback we've gathered from HealthDay.si related events and meetings. For more information on these events at www.healthday.si.

There are now three pillars that form our HealthDay.si ecosystem. The pillars are:

- Programme for companies
- Dialogue with stakeholders
- Communication activities

The programme for companies is the first thing we offered to the different innovative companies that we identified in our HealthDay.si database. The programme consists of workshops, mentoring and consultancy support.

The programme was started at the end of February 2019 with the public invite to the ecosystem companies to officially register to be selected among the first generation of 5 companies with which we would work more intensely and also represent them in the dialogues with the key stakeholders of the health care system.

We received 17 registrations until the end of March. In this period, we evaluated each registered company, conducted interviews with them, the most promising ones were interviewed by our group of experts. Our group of experts and the two leaders of the programme Mojca Cvirn and Gregor Cuzak voted which companies should be the selected ones. We came to select 6 companies, but one of them decided later to not participate in the programme due to their lack of resources. So, our first generation now consists of 5 companies. They are:

- Lucis Record KLB, new proactive therapy for the chronic kidney disease
- Saving Savvy, the most mobile continuous non-invasive ECG in the world
- Smart Optometry Amblyoplay, gameplay training for the lazy eye
- Feelif, digital sight for the blind

- Bickb, EEG diagnostics of alzheimer dementia

The chosen first generation of innovative companies are each participating in the programme of workshops, each of them is receiving mentoring from our mentors and each had received their suggested plan of activities. Furthermore, they are included in our presentation to the different stakeholders and regulators. Last but not least, all of them were already a part of the Initiative and presented their solutions to the insurance companies.

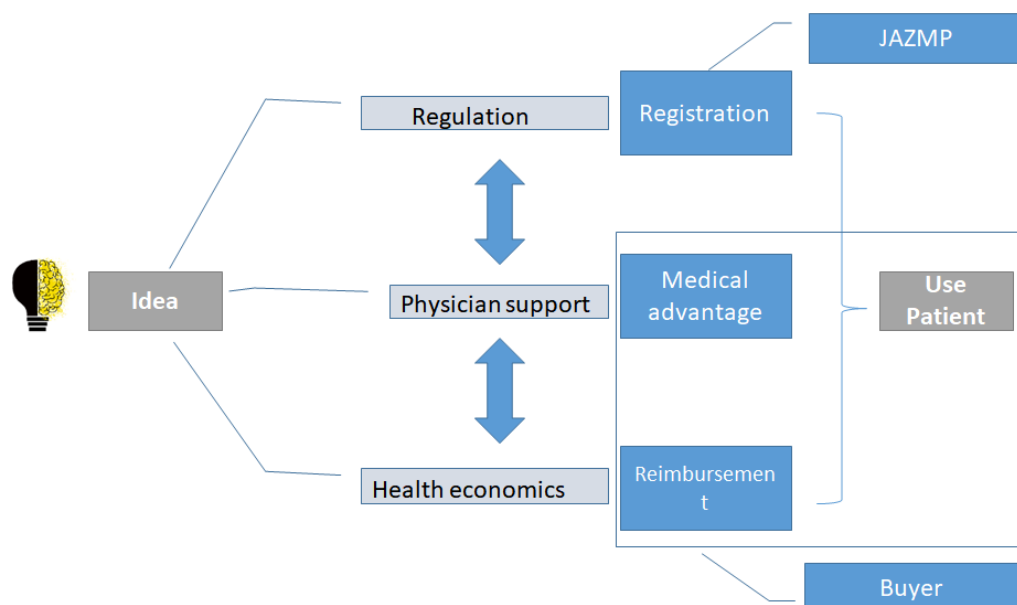
Workshops

The workshops topics and experts presenting were chosen by us with the aim to cover the whole field of what needs to be done to navigate the complexities of validation of solutions of innovators and to reach the point where they can earn something.

It was clear to us from the beginning that there are many ways in which an innovator can achieve earnings. The way by which an innovator would reach the patients would depend on the solution and on the system. The central idea of how we put the programme together was in mapping how the system looks and what the possibilities within it are and what requirements have to be met to come to reimbursement.

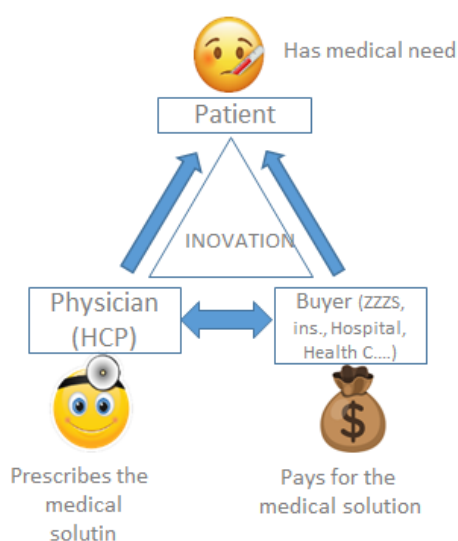
In this way the first workshop set the tone by offering a bird's eye view of the whole system. This first workshop was developed by our our chair of the group of experts Mrs. Mateja Urlep and was assisted by Mr. Janko Burgar who applied Mrs. Urlep's model to their company's plan of building a proton accelerator for proton radiation therapy in Slovenia. The result of their work the workshop about the Roadmap for innovation in healthcare, it took place on April 11, 2019.

The key idea of Mrs. Urlep's workshop is her three-branch model as it is shown in the schematic below:



A new solution's path from idea to the patients can be deconstructed into three main branches, the regulatory, the medical and the economic. Most requirements a new solution has to fulfill can fit into one of the three branches. This simplifies the process that itself is long and poorly orchestrated, with different regulatory approving bodies often behaving as if they aren't connected to other parts of the system.

Another key idea of Mrs. Urlep is that of the triple buyer:



Most of the solution, products and services that are aimed at the patient in the health care system have three distinct buyers involved, one is the patient who receives the solution, the physician decides on which solution will be applied and the payer pays it. The three-branched model and the triple-buyer are ideas that we will use in the future to bring our presenters, mentors and companies to a common understanding of the problem space.

To further develop the DIH based on the Living Lab methodology, we realized that we need to organise workshops for capacity enhancement, preferably at a pre-set location (to give the sense of a physical space) on variety of topics, chiefly aimed to enhance capacity building. The workshops' themes are:

- Application of the digital health solution to the Health Council (Zdravstveni svet)
- Medico-economics of digital health solutions
- Certification of technical compliance of digital health solutions
- Marketing in medicine
- Quality Management in the process of digital health solution development
- Financing of innovation in healthcare

Dialogue with the Stakeholders

We believe it is not enough to only advise the companies, but we need to be in dialogue with the stakeholders as well. This dialogue will make the system better understood by all and it will also enable us to find paths through the systems easier.

One important role in talking to the regulators is also building a practical understanding, which along with the legal framework will enable us to prepare a detailed roadmap for existing and future innovators.

The stakeholders that we will engage with or that we have engaged with already are:

- Health Insurance Fund - ZZZS
- Commercial insurance companies
- Ministry for Health
- Agency for medicines and medical equipment - JAZMP
- Medical chamber of Slovenia - ZZS
- National Institute for Public Health - NIJZ
- Association of Health Care Providers - ZdrZZS
- Medical Ethics Commission - KME
- and others

Mentoring

The next step, not yet a part of this project, to be followed by a similar project in the near future with a separate source of financing is mentoring. Each chosen company will be eligible to 20 hours of

mentoring. The group of mentors will experts in the fields that our programme covers, and will be identified with the commencement of the new project. The mentors will be suggested to companies based on analysis of their needs and stage of development at that time.

DIH Sustainability Plan / Strategy

2019 is the first year of the Digital Innovation Hub. We see it as a permanent activity that can help innovators as long as there are any innovators available. Our plan is to bring forward 5 new companies every half year, which is a part of the mid-term 5D2020 goal of 5 digital innovations in the reimbursement lists of insurance companies by the end of 2020 and the long term goal of 1% of the overall health care budget spent on innovative solutions each year by 2027.

We intend to focus on the regulatory and validation part of the problem space that the innovators need to solve but will also include the needs of the health care providers in the future. We believe it is better to start with the need of practitioners and also patients, that to begin with the technology.

For this reason, our programme needs to have a close connection to the medical professionals, which we intend to nourish and keep high on our list of priorities in the future.

Another area that we will tackle in the future is support for internationalization of our innovators. We believe they can only make their investments perform if they develop and market solutions not only in Slovenia, but also abroad, in most cases globally. Our current focus on Slovenia is based on our conviction that domestic companies need acceptance and validation locally first, because it provides for a solid base and reference that they will need to grow internationally.

In terms of funding DIH.HealthDay.si will need to find new sources of financing in the future. The financing should be based on different sources, partly participated by the companies, but partly also by the state as we contribute to the healthy development and progress of the ecosystem as a whole. In a wider perspective we're also important to the development of the health care system from the regional and EU perspective, so regional and EU funding is a good option for us. A special area for a later stage of development is participation in the revenue of the companies that become internationally successful.

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